Innovative Medical Devices
For the Health of Women and Children in Low-Resource Settings

A report by:
The IWG Task Force on Medical Devices
Every Woman Every Child Initiative

The Every Woman Every Child (EWEC) initiative was launched by the United Nations Secretary-General Ban Ki-moon at the United Nations Millennium Development Goals Summit in September 2010. The initiative aims to save the lives of 16 million women and children in the world’s 49 poorest countries by 2015 and accelerate the achievement of the Millennium Development Goals.

EWEC works to mobilize and intensify international and national action. To address the major health challenges facing the world’s women and children, it works with governments, multilaterals, the private sector and civil society.

The initiative follows the Global Strategy for Women’s and Children’s Health, which presents a roadmap to help women and children in the world’s poorest nations. This roadmap details ways of enhancing finance, strengthening policy and improving delivery of health services and products. For more information on the Every Woman Every Child effort, please visit [www.everywomaneverychild.org](http://www.everywomaneverychild.org).

The Innovation Working Group (IWG)

The Innovation Working Group (IWG) was convened by the United Nations Secretary General (UNSG) in 2010 to use cost-effective innovation to accelerate progress on the health Millennium Development Goals (MDGs). Supporting the Global Strategy for Women’s and Children’s Health, the IWG is the global hub for innovation in the UNSG’s Every Woman Every Child initiative.

The IWG supports the initiation and scaling-up of innovations – whether they are technological, social, financial, policy or business-related. The IWG also supports and leads collaborative efforts among stakeholders in mHealth (mobile health, or health services supported by mobile communications technology).

The IWG consists of a broad network of interested parties with a small secretariat, working through partner organizations. It comprises members of governmental, inter-governmental and non-governmental organizations, as well as the private sector (both for-profit and not-for-profit), with everyone on an equal footing.

The IWG is co-chaired by Tore Godal, Special Adviser to the Prime Minister of Norway on Global Health, and Scott Ratzan, Vice President of Global Health, Government Affairs and Policy at Johnson & Johnson. Project management is provided by the Norwegian Agency for Development Cooperation (NORAD), and the Secretariat is housed at the Partnership for Maternal Newborn & Child Health (PMNCH).

Four IWG task forces have been convened to develop innovations for improving maternal and child health: Sustainable Business Models, Checklists, Medical Devices and Innovative Finance. For more information on IWG, please visit [www.everywomaneverychild.org/resources/innovation-working-group](http://www.everywomaneverychild.org/resources/innovation-working-group).

Authors

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Despite the significant improvements in maternal and child health achieved by many countries over the past few decades, progress in reducing mortality rates has remained uneven in many low-resource settings. The Millennium Development Goals (MDGs) call for child mortality rates to be cut by two thirds and the maternal mortality rate to be reduced by at least three quarters by 2015 (as compared with 1990 rates). Yet mortality rates among under-five-year-olds remain high across sub-Saharan Africa, and 99% of maternal deaths occur in developing countries. In order to reach the MDG targets, the international community must focus its attention and intensify its efforts to improve health outcomes for women and children. Innovative medical devices, affordable and appropriate, are needed to improve the quality and delivery of care for women and children around the world.

Medical devices are critical health technologies that support health workers in providing effective preventive, diagnostic, therapeutic, and rehabilitative services. The technologies are diverse – devices are used to monitor maternal blood pressure, to resuscitate newborns, or, like female condoms, to provide family planning. They offer affordable and effective interventions for improving maternal and child health outcomes. Yet, despite their potential, in many low-resource settings there are barriers hindering the development, introduction, and scaling-up of these technological solutions. This limits health systems’ capacity to provide adequate care that is accessible to all those in need.

Creating or adapting medical devices for low-resource settings requires sustained funding, rational selection and safe use. These things are not yet in place for all maternal, newborn, and child health (MNCH) products. Unfortunately, market forces alone will not produce sufficient, affordable, and appropriate new devices because the private sector often sees these markets as being unlikely to provide sufficient return on investment. As a result, few manufacturers are willing to fund technologies targeting low-resource settings. To overcome this market failure, the public and commercial sectors must share the risks and costs involved in developing, manufacturing, and introducing medical devices that might not otherwise have come into being.

The public sector plays a critical role in ensuring the safety and efficacy of medical devices. National regulatory authorities protect the public’s health by monitoring the development, manufacture, and use of health technologies. However, some low-income countries still have insufficient regulatory processes in place for medical devices. In many countries these regulatory processes can be complex and often result in increased costs and delays, which can derail the most promising products. A trend towards harmonization has begun, but regulatory requirements still vary among countries, making it difficult to test and deliver new devices efficiently. To strengthen local regulatory oversight of devices – both current and new – common processes must be established and resources must be invested in building capacity.

To bring innovative devices to scale, the requirements are rational selection, technical support, supply-chain management and normative guidance. These will increase delivery and help healthcare workers to understand which devices to use, how to use them, and under what circumstances.
Without these systems in place, promising technologies can languish in pilot programmes and never become part of the standard of care. Creating demand for new medical devices is critical to achieving scale, and should begin early in the development process. From the start of the product-development process through to the adoption of a new technology, everyone involved – developer, funder, producer, and procurer – must consider a range of factors including the public health need, technical feasibility, the needs of the end user, the economic rationale, market sustainability, and the policy environment.

Methodology

The medical devices highlighted in these case studies were selected by the members of the Medical Devices Task Force of the Every Woman Every Child Innovation Working Group (IWG). They are maternal, newborn, and reproductive health technologies that, used appropriately, have the potential to improve MNCH outcomes. The Medical Devices Task Force’s objective was to make recommendations to the IWG, its members, and other relevant stakeholders on ways to facilitate the introduction and integration of medical devices that can significantly improve MNCH.

The recommendations are based on common strengths and barriers to scaling-up that were identified in the case studies by members of the task force. These strengths and barriers concern the ways in which innovative devices can be introduced and scaled up for national or global adoption. The recommendations address policies that support the adoption and integration of new technologies at the global and national levels. These include normative guidance that tells people about the evidence for innovative medical devices, as well as about demand-creation and market development for new tools. Other important messages concern strengthening regulatory processes and capacity, and implementing sustainable financing mechanisms to encourage innovation.

The medical devices presented in the report’s case studies are examples of innovative technologies that are ready to be introduced and brought to scale. This does not mean that these devices, rather than others, should necessarily be the focus of our efforts. Each case study includes an explanation of the problem being addressed and the proposed intervention, as well as the product’s characteristics. The cases were selected to represent different types of devices including preventive (female condoms and injectable contraceptives), diagnostic (blood pressure measurement devices and portable ultrasounds), therapeutic (resuscitation devices) and educational (resuscitation training mannequins). They were also selected to represent different price ranges (from injectable contraceptives to portable ultrasounds). These cases are not meant to be comprehensive but illustrative of common barriers and potential solutions.
2. Recommendations

In the course of assembling the product and market profiles that follow, the Medical Devices Task Force identified a number of factors affecting innovation and uptake. While the factors identified are by no means comprehensive, they provide significant opportunities to improve the uptake of devices appropriate for MNCH. In order to achieve best outcomes, it is important to mention the alignment between these recommendation of the task group of medical devices of the Innovations Working Group along with the recommendations of the UN Commission for Life-Saving Commodities (LSC) for Women and Children. Specifically the recommendation number 10 addresses innovation research and development, in line with the objectives of the Innovation Working Group. The specific next recommendations of the medical devices task force is related to a recommendation of this UN commission of LSC and will be addressed as follows:

- The World Health Organization (WHO) and other normative bodies to update clinical guidelines and Interagency List of Essential Medical Devices for reproductive, maternal, new born and child care. International normative guidance can provide a platform for introducing and scaling up new devices. This may be achieved by prioritizing certain technologies in guidelines, checking the decision-making algorithms that are used to guide implementation, and using prequalification processes to certify new devices and manufacturers. Many new and emerging technologies are being constantly developed, so it is important for WHO and for national regulatory agencies to have staff or agreements with other specialized agencies to do horizon scanning for new and emerging technologies and be able to review appropriateness, cost effectiveness and clinical effectiveness. It is also important that regulatory authorities and WHO improve coordination, in order to streamline processes and harmonize nomenclature and technical specifications to facilitate the uptake of new medical devices. This is aligned to the recommendation 4 and 5 of the UN Commission on LSC on regulatory efficiency.

- National governments must ensure that the introduction of new medical devices is supported by comprehensive plans to ensure that they are used appropriately and integrated speedily into standards of care for women and children. Programmatic funding – in combining with effective products and comprehensive implementation plans – has been shown to support broad uptake and appropriate use of medical devices. International donors and national governments should agree rollout plans for new devices. These plans should cover support activities for healthcare providers, including training and retraining, as well as covering ways of generating demand among healthcare providers and the community. The plans should also cover policy changes on regulation and service delivery, as well as incorporating maintenance, where required. This work can be linked to the UN Commission for Life-Saving Commodities for Women and Children. One of the Commission’s recommendations (recommendation 9) is to ensure that healthcare providers are knowledgeable and incentivized to adhere to national guidelines. This should include both in regards to the use of appropriate medicines and medical devices.

- The launch of new MNCH medical devices must be accompanied by activities that will increase demand. The uptake of medical devices requires strategies for both the demand and the supply side. To increase demand, evidence of efficacy is required to convince national and international policy-makers to invest in new products. Demand generation among users and beneficiaries is also required. On the supply side, improved market analysis is needed to determine the size of the market and the number of products it can support. Supplier-engagement strategies could be used more effectively to encourage improved pricing and supply terms, particularly if coordinated across stakeholders. A clear link to the Commodity Commission’s work appears here as well. The Commission’s recommendation 7 focuses on improving the demand of commodities amongst users, caregivers and healthcare providers.

- Donors must invest in strengthening regulatory oversight of medical devices by funding efforts to clarify regulatory pathways, strengthen national capacity, and harmonize requirements and processes. National regulatory processes can be a significant barrier to market entry. New products often face a multiplicity of national clinical trials, non-standard dossier submissions and trade barriers. At a minimum, if countries harmonized regulation of medical devices and combination products (such as Depo-subQ provera 104® in Uniject™) it would clarify requirements for approval and use of products, and identify gaps in post-marketing surveillance. In addition, new medical devices could enter markets more quickly and cheaply if there were coordinated capacity-building within national regulatory agencies, focusing on maternal, newborn, child, and reproductive health. This could be further augmented by regional or global harmonization of regulatory processes and requirements, such as the East African Medicines Regulatory Harmonization Project and the African Vaccine Regulatory Forum. This approach would also improve regulatory oversight of scaling-up activities. This too has clear links to the Commodities Commission’s recommendations, where recommendation 5 will promote regulatory harmonization. It is vital that the IWG work with the conveners of this recommendation to ensure that medical device regulatory approval are also harmonized, including products which are considered both a device and a medicine (i.e., pre-filled syringes).
Donors should establish financing mechanisms that create demand at the national level and reduce manufacturers’ uncertainty about new MNCH medical devices. Large-scale uptake of medical devices typically takes many years, leading manufacturers to produce at low volumes for an extended period, unable to recover their development costs. The anticipation of low volumes can lead manufacturers to price high when they enter a market. Governments and donors experience “sticker shock” at these prices, which slows uptake and prolongs the imbalance between supply and demand. Two answers are creative financing schemes and actions to help markets achieve economies of scale earlier. This would bring prices down more quickly, stabilize suppliers’ commitment, and signal to developers that innovation is rewarded. To reduce barriers to entry and speed the uptake of new devices, donors could invest in advanced market commitments, or there could be UNITAID-style investments in maternal, newborn, child, and reproductive health. Other innovative financing mechanisms could also be useful. The Commodity Commission’s recommendation 3 will focus on innovative financing mechanisms to rapidly increase access to essential commodities. It is imperative that the devices included in the Commission’s mandate (i.e., resuscitation devices, female condoms, micro-patches for injectable antibiotics, pre-filled syringes of oxytocin, and more) receive guidance from the IWG on streamlining market entry of these devices to encourage the greatest appropriate uptake.
3. Product Profile - Blood Pressure Measurement Devices

Problem and proposed intervention: Pre-eclampsia and eclampsia

Pre-eclampsia (PE) is a life-threatening disorder that only occurs during pregnancy, childbirth, and the postpartum period and is characterized by high blood pressure (BP) and protein in the urine (proteinuria). Convulsions (fits) with signs of PE indicate eclampsia, although convulsions occasionally occur in the absence of hypertension with proteinuria. PE and eclampsia (PE/E) are among the leading causes of maternal death and disability worldwide. WHO estimates that PE/E accounts for at least 16% of maternal deaths in low-resource settings that lack the skilled providers and facilities required for prevention, identification, and management of PE/E.¹

In most countries, PE/E ranks second only to haemorrhage as a direct cause of maternal death. The risk of PE/E varies greatly depending on where a woman lives: a woman in a low-resource country is approximately 300 times more likely to die of PE/E than a woman in a high-resource country.² Reductions in maternal mortality and serious morbidity result mainly from early identification of women with PE, followed by close clinical and laboratory monitoring to prevent, recognize, and manage the progression of the disease. Positive maternal and perinatal outcomes for women with PE/E depend on how soon the condition is identified and how quickly the woman has access to treatment. Treatment packages may include inpatient monitoring, anticonvulsive and antihypertensive therapy, optimal timing of childbirth, and skilled attendance at birth. Table 1 shows estimated maternal lives saved per year for a blood-pressure PE/E suite of technologies.

Table 1. Estimated maternal lives saved per year for a blood-pressure pre-eclampsia and eclampsia suite of technologies⁰

<table>
<thead>
<tr>
<th>Region</th>
<th>Annual PE/E maternal Deaths</th>
<th>Annual maternal lives saved</th>
<th>% Reduction in maternal mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>12,000</td>
<td>800</td>
<td>7%</td>
</tr>
<tr>
<td>Sub-Saharan Africa</td>
<td>17,000</td>
<td>1,100</td>
<td>7%</td>
</tr>
</tbody>
</table>

PATH collaborated with the Research Triangle Institute (RTI) to estimate the annual number of PE/E maternal lives saved for a novel BP measurement device in India and sub-Saharan Africa. The Maternal and Neonatal Directed Assessment of Technology (known as MANDATE) model was used for the analysis; it revealed that, on its own, a novel, improved BP measurement device has little impact on preventing maternal deaths due to PE/E. However, the model found that a substantial portion of maternal deaths from PE/E can be prevented when an improved BP measurement device is combined with the following technologies: improved proteinuria testing, magnesium sulphate, transfer capabilities, and rapid delivery of pregnancies with severe disease. Furthermore, using BP measurement to diagnose hypertension is an important vital sign for assessing basic body functions, and thus may have a broader impact. Launching a novel, improved BP measurement device thus has the potential to save lives from numerous hypertension-related diseases beyond PE/E.

Secondary prevention of PE/E has focused on antenatal screening for high BP and proteinuria as part of focused antenatal care (ANC).⁴ While obtaining BP during routine ANC and postpartum care would seem relatively simple, current Demographic Health Survey data on women between the ages of 15 and 49 who received ANC for their most recent birth suggests that BP is not routinely collected during ANC visits. (BP was checked in 80.4% of cases in Zambia,³ 52.5% in Uganda,⁵ and 63.8% in India.)⁶ The major impediments to the routine measurement of BP in ANC are the absence of BP-measurement devices (BPMDs) in many resource-limited and infrastructure-poor settings, coupled with the complexity and poor durability of the available devices.

Product characteristics: Blood-pressure measurement devices

There are currently two BPMDs designed to conform to most or all of WHO’s recommended specifications for BPMDs (http://www.who.int/medical_devices/innovation/blood_pressure_monitor.pdf) in low-resource settings: the Microlife BP3AS1-2, developed by the Microlife Corporation (Taipei, Taiwan), and the Omron HEM-SOLAR, developed by the Omron Corporation (Kyoto, Japan). These devices are semiautomatic, oscillometric, and easy to use. Both devices are expected to be validated in pregnant populations soon (clinical evidence for the Omron device is expected by the end of 2012, and Microlife claims already to have evidence). The Microlife device runs on batteries, while the Omron device includes a solar recharging circuit, a feature strongly recommended by WHO.
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### Proposed indication
Detection of elevated blood pressure is a requirement for diagnosing pre-eclampsia.

### Specifications
A group of WHO experts\(^1\) made the following general recommendations for a BPMD for low-resource settings:

1. The BPMD should be accurate, simple to use, affordable, and easily available worldwide.
2. Given the serious inherent inaccuracy of the auscultatory technique, validated and affordable electronic devices that have the option to select manual readings are the preferred option.
3. Because of mercury’s toxicity, it is recommended that mercury BPMDs be gradually phased out in favour of affordable, validated, professional electronic devices as these become available. However, where it is difficult to replace mercury devices, they should be serviced and calibrated at regular intervals.
4. In circumstances where aneroid devices are already being used, their continued use is appropriate provided they have been shown to be accurate not only at the time of manufacture but also after a period of time in use, and they are calibrated at regular intervals (e.g. every six months).
5. Regardless of the type of BPMD, appropriate cuff sizes should be available.
6. If the BPMD uses the auscultatory technique, users should receive appropriate training and be assessed periodically for accuracy.

### Approximate cost
The Microlife device is inexpensive – available for US$15 in Hong Kong – while the Omron device has a list price of US$100.

### Strengths and barriers
These strengths and the barriers to scaling-up the device are based on a literature review and informal discussions with key stakeholders.

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Barriers</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Policy and regulation</strong></td>
<td></td>
</tr>
<tr>
<td>Both Omron and Microlife devices are CE marked.</td>
<td>None</td>
</tr>
<tr>
<td>No additional regulatory activities are required.</td>
<td></td>
</tr>
<tr>
<td>It is unlikely that validating the device in a subpopulation will require an additional regulatory review.</td>
<td></td>
</tr>
<tr>
<td><strong>Global</strong></td>
<td></td>
</tr>
<tr>
<td>Blood-pressure measurement is already included in global guidelines for management of PE/E.(^2)</td>
<td>Guidelines do not specify caution about using inaccurate devices.</td>
</tr>
<tr>
<td>BPMDs are included in the WHO Interagency List of Essential Medical Devices for Reproductive Health.</td>
<td>The auscultatory technique, considered to be the gold standard, is difficult to perform even for well-trained healthcare professionals.</td>
</tr>
<tr>
<td>BPMDs are included in the WHO Essential Emergency Equipment List.</td>
<td></td>
</tr>
<tr>
<td><strong>National and regional</strong></td>
<td></td>
</tr>
<tr>
<td>BPMDs are suitable for use in the general population.</td>
<td>Many countries do not have a national standard or recommended list for medical devices.</td>
</tr>
<tr>
<td>Blood pressure is a health indicator needed by all clinicians and healthcare providers for routine examinations and other disease diagnosis.</td>
<td>BPMD equipment is often not regulated by the national medical supplies and equipment regulatory board.</td>
</tr>
<tr>
<td>If a country does have a national standard or recommended medical device list, BPMDs are likely to be on it. (<a href="http://gamapserver.who.int/gho/interactive_charts/health_techologies/lists/atlas.html">http://gamapserver.who.int/gho/interactive_charts/health_techologies/lists/atlas.html</a>)</td>
<td>BPMD and PE/E management are not prioritized at national and regional levels.</td>
</tr>
<tr>
<td><strong>Product specifications and characteristics</strong></td>
<td></td>
</tr>
<tr>
<td>International standards exist – European Norm (EN) standards EN1060, Non-Invasive Sphygmomanometers, and EN60601, Medical Electrical Equipment: General Requirements for Basic Safety and Essential Performance.</td>
<td>Product selection can be complicated, given the vast array of product types, product costs, and product quality. The selection of products should be influenced by the patient loads and the settings in which they will be used.</td>
</tr>
<tr>
<td>WHO specifications are included in Parati et al, 2005.(^3)</td>
<td>To ensure accurate detection of hypertension and PE during pregnancy, labour, and postpartum, BP measurement must be determined using a device that is accurate (validated), simple to use, affordable, and robust. Although BPMDs are available from many manufacturers, appearing to be functional, and offered at competitive prices, very few manufacturers offer a BPMD that is validated for use with pregnant women and with demonstrated conformity to WHO recommendations and international standards.</td>
</tr>
<tr>
<td>Both devices are expected to be validated in pregnant populations soon (clinical evidence for the Omron device is expected by the end of 2012, and Microlife claims already to have evidence of accurate blood-pressure measurement in this population).</td>
<td></td>
</tr>
<tr>
<td><strong>Strengths</strong></td>
<td><strong>Barriers</strong></td>
</tr>
<tr>
<td>-------------</td>
<td>-------------</td>
</tr>
<tr>
<td><strong>Financing, procurement, and supply</strong></td>
<td>There is a large supplier base supporting this category of medical devices in developed and developing countries, although most products do not meet WHO’s recommended specifications for low-resource settings. Two options for appropriate, high-quality devices have recently become available. Complicated supply-chain problems, such as expiry dates and cold chain, do not apply to these products.</td>
</tr>
<tr>
<td><strong>Service provision (rational use)</strong></td>
<td>Many health-service providers understand the value of BP screening in antenatal care but are prevented or discouraged from providing it by absent, unsuitable, or unusable equipment.</td>
</tr>
<tr>
<td><strong>Demand</strong></td>
<td>A strong health system will have multiple BPMDs at all levels of care, including community use.</td>
</tr>
</tbody>
</table>
4. Product Profile – Newborn Resuscitation Devices

(From: http://www.everywomaneverychild.org/component/content/article/1-about/309-newborn-resuscitation-devices--product-profile-)

**Problem and proposed intervention: Asphyxia**

Almost half of all newborn deaths occur within 24 hours of birth, the majority resulting from birth asphyxia. This condition, which manifests itself as a failure of the newborn to establish breathing after birth, kills 814,000 newborns every year, accounting for almost a quarter of newborn deaths.\(^{13}\) Additionally, there are an estimated 1.02 million intrapartum stillbirths every year. An unknown number of these may be liveborn but misclassified as fresh stillbirths when no resuscitation was provided.\(^{14}\)

Many of these deaths could easily be prevented with basic neonatal resuscitation. This requires tactile stimulation, a neonatal bag and mask and a suction device. With this basic equipment – and effective pre- and in-service training using a resuscitation-training mannequin – successful newborn resuscitation can be accomplished in about 30% of cases that would otherwise end in death among full-term babies, and 5-10% among preterm births.\(^{15}\)

For many babies born in low-resource settings, however, this basic intervention is not available. Ensuring universal access to newborn resuscitation is essential to the effort to reduce neonatal mortality. At the national level, more attention is being paid to newborn health, and donor-supported initiatives are programming essential newborn care. As a result, for countries needing to reduce neonatal deaths from birth asphyxia, the best strategic investments are bag-and-mask resuscitators, suction devices, mannequins and the associated training programmes.

**Product characteristics: Newborn resuscitation devices**

<table>
<thead>
<tr>
<th>Product</th>
<th>Self-inflating Bag and Mask Devices</th>
<th>Suction Devices</th>
<th>Training Mannequin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proposed indication</td>
<td>Positive pressure ventilation support.</td>
<td>Used to clear the airway of the newborn to help facilitate breathing.</td>
<td>Allows competency-based training of health workers, plus follow-up practice and supervision.</td>
</tr>
<tr>
<td>Specifications</td>
<td><strong>Resuscitator Bag:</strong> 240 ml or 500 ml volume, specifically designed. <strong>Mask:</strong> two sizes to fit low- and normal-birth-weight babies with pressure-relief valve designed to limit the pressure.</td>
<td>Use of bulb suction device as a mechanical source of negative pressure.</td>
<td>Model of the baby permitting visualization of selected features of effective ventilation such as chest rise.</td>
</tr>
<tr>
<td>Approximate cost</td>
<td>$8-$100 US$</td>
<td>$2-$10 US$</td>
<td>$50-$1,500 US$</td>
</tr>
</tbody>
</table>

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Innovative Medical Devices For the Health of Women and Children in Low-Resource Settings
## Strengths and barriers

The strengths and barriers outlined below are the initial findings from working paper analysing each product’s current global situation. The findings are presented below for further consideration in order to finalize a list of issues and recommendations. The full text of the working paper is forthcoming.

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Barriers</th>
</tr>
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<tbody>
<tr>
<td><strong>Global policy and regulation</strong></td>
<td></td>
</tr>
<tr>
<td>The Helping Babies Breathe (HBB) Global Development Alliance is working to increase coverage of a high-quality resuscitation programme and has begun to increase demand for the product.</td>
<td>The WHO-updated <em>Guidelines for Basic Newborn Resuscitation</em> is still a draft. It needs to be published urgently.</td>
</tr>
<tr>
<td>The WHO-approved update to <em>Grades of Recommendation, Assessment, Development, and Evaluation approach to newborn resuscitation</em> was drafted in December 2011.</td>
<td>WHO draft <em>Essential Medical Devices List</em> for priority interventions for MNCH is still in draft form. It needs to be published as a reference and include resuscitation-training mannequins.</td>
</tr>
<tr>
<td>The key commodities listed in the Essential Interventions, Commodities and Guidelines for Reproductive Maternal, New Born and Child Health includes neonatal resuscitators (bag and mask) and suction devices, but not resuscitation training mannequins.</td>
<td></td>
</tr>
<tr>
<td>The self-inflating bag-and-mask device is specified by international policy guidelines as the standard, evidence-based technology for use.</td>
<td></td>
</tr>
<tr>
<td>An updated international purchasing guide on sources and prices for high-quality, affordable resuscitation products is available to international and national purchasing agents.</td>
<td></td>
</tr>
<tr>
<td><strong>National and regional policy and regulation</strong></td>
<td></td>
</tr>
<tr>
<td>Newborn survival and development is often a national priority. With support from the Helping Babies Breathe Global Development Alliance, national newborn resuscitation programmes are being scaled up. This has increased the coverage of high-quality resuscitation programmes and the demand for newborn resuscitation devices in some countries.</td>
<td>Resuscitation equipment is not systematically included in national essential device lists.</td>
</tr>
<tr>
<td>Resuscitation equipment is not regulated by national medical supplies and equipment regulatory boards.</td>
<td>Newborn resuscitation equipment is often not regulated by national medical supplies and equipment regulatory boards.</td>
</tr>
<tr>
<td><strong>Product specification and characteristics</strong></td>
<td></td>
</tr>
<tr>
<td>There is a high safety profile for bag-and-mask devices. Innovation in the product category focuses on simplification of device design and parts so that infrequent users at peripheral health centres will be better able to use the technology. Options exist for disposable and/or reusable devices. Recently, there has been further development of high-quality, hand-operated resuscitators. Alternative options are now available: affordable, multiple cleaning and disinfecting bulb syringe suction products with excellent durability.</td>
<td>No industry reference standards are available for newborn bulb suction devices. There is no standardization in mask size, specifications, nor in the nomenclature used to describe them. Failures due to quality issues occur relatively frequently, most commonly due to inferior materials used during manufacture, mechanical failure during operation (mostly of the valves), substandard finishing lacking precision (valves and fittings leak), or dust particles inside the device. Product selection can be complicated, given the vast array of product types, costs and quality. The selection of products should be influenced by patient loads and the settings in which they will be used. It is common to reuse the single-use bulb syringe suction, which makes it likely to increase the risk of infection. Only recently have affordable, multiple cleaning and disinfecting options become available.</td>
</tr>
</tbody>
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### Strengths

<table>
<thead>
<tr>
<th>Financing, procurement, and supply</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is a large supplier base supporting this category of medical device in developed and developing countries.</td>
</tr>
<tr>
<td>More options for affordable, high-quality devices have recently become available.</td>
</tr>
<tr>
<td>Tube-and-mask devices, which require the user to blow into the tube, were developed as a low-cost alternative to bag-and-mask devices and may be useful in environments where self-inflating bags are not available, affordable, or functional.15</td>
</tr>
<tr>
<td>There is evidence that increased demand in 2010-11 has led to increased product branding and availability.</td>
</tr>
<tr>
<td>Resuscitators are manufactured in multiple locations worldwide with regional concentrations. Most manufacturers state that they have worldwide distribution capabilities.</td>
</tr>
<tr>
<td>Laerdal Global Health has committed to continue providing the innovative and affordable NeoNatalie equipment – which includes a mannequin, bag and mask and suction bulb – to all 68 MDG countries on a not-for-profit basis throughout 2015.</td>
</tr>
<tr>
<td>Complicated supply-chain problems, such as expiry dates and cold chain, do not apply to these products.</td>
</tr>
<tr>
<td>UNICEF country offices often act as a distribution channel by providing support for the supply of devices at the country level.</td>
</tr>
</tbody>
</table>

### Barriers

<table>
<thead>
<tr>
<th>Financing, procurement, and supply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Countries often do not prioritize newborn resuscitation equipment.</td>
</tr>
<tr>
<td>Buyers have difficulty in procuring high-quality, affordable resuscitation equipment.</td>
</tr>
<tr>
<td>Resuscitation equipment is more likely to be available in tertiary and district hospitals than lower-level health facilities and is almost non-existent in home deliveries.</td>
</tr>
<tr>
<td>A self-inflating bag-and-mask device is often too costly for low-resource settings. Only recently have affordable high-quality devices become available.</td>
</tr>
<tr>
<td>Manufacturing of tube-and-mask devices is severely limited, making them a less feasible option for low-resource settings.</td>
</tr>
<tr>
<td>Even when equipment is available, it may not be readily accessible in the delivery room.</td>
</tr>
<tr>
<td>With countries relying on international and regional procurement, delays in delivery, custom clearance and additional tariffs and customs costs pose a challenge.</td>
</tr>
<tr>
<td>Price variations among seemingly similar products are enormous. While sourcing cheap products may seem attractive, attention to quality is imperative.</td>
</tr>
<tr>
<td>In-country manufacturing is limited and most procurement is international or regional, increasing lead times and the potential for delays in delivery.</td>
</tr>
<tr>
<td>Low-resource settings face a lack of appropriate companies, agents, and distributors to supply the necessary commodities, repairs, replace spare parts, or obtain new equipment.</td>
</tr>
<tr>
<td>Major barriers delay distribution: inadequate logistics coordination, planning, and budgeting.</td>
</tr>
</tbody>
</table>

### Service provision (rational use)

<table>
<thead>
<tr>
<th>Service provision (rational use)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In 2010, the American Academy of Pediatrics launched Helping Babies Breathe (HBB), a simplified, evidence-based, resuscitation-training programme designed to address the lack of neonatal resuscitation skills in resource-limited areas.</td>
</tr>
<tr>
<td>A Global Development Alliance has been established to introduce the HBB curriculum.</td>
</tr>
<tr>
<td>The studies so far have indicated that HBB training results in significant improvement in resuscitation knowledge and skills. However, the studies also showed that developing competency in newborn resuscitation with bag and mask is complex and requires adequate time for instruction and possible mentoring.17</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Service provision (rational use)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor resuscitation skills are common among healthcare workers at all levels of delivery in low-resource settings.</td>
</tr>
<tr>
<td>Even when equipment is available, many healthcare workers are unable to use it effectively.18</td>
</tr>
<tr>
<td>Most pre-service institutions lack the necessary resuscitation equipment for hands-on training by the students. There is limited or no time dedicated to practising or refreshing skills, and no post-training system to maintain skills.</td>
</tr>
<tr>
<td>There is low exposure to asphyxia cases and inadequate use and retention of resuscitation skills by healthcare workers in peripheral centres.</td>
</tr>
<tr>
<td>There is a lack of provider procurement awareness about suitable sizes for the self-inflating bags and masks and about negative pressures required with the use of suction machines.</td>
</tr>
<tr>
<td>Providers are sometimes unwilling to maintain a good quality of care, such as the appropriate maintenance of resuscitation commodities.</td>
</tr>
</tbody>
</table>
5. Product Profile: Injectable Contraceptives

Depo-subQ provera 104® in the Uniject™ injection system

Problem and proposed intervention

Over 35 million women worldwide use injectable contraceptives. In sub-Saharan Africa, more than a third of contraceptive users choose injectables, making it the leading modern method in that region. The most widely used injectable contraceptive formula and presentation is the progestin-only depo-medroxyprogesterone acetate (DMPA) 150 mg formula, delivered via deep intramuscular (IM) injection, which is WHO approved. The brand of DMPA-IM most widely used in developing countries, Pfizer’s Depo-Provera®, was approved by the United States Food and Drug Administration (USFDA) for contraceptive use in 1992.

Several factors inhibit greater access to and use of injectables. These include intolerance of side effects, DMPA’s return-to-fertility timeframe, and the fact that injectable contraceptives are most often delivered by a healthcare worker, such as a physician, nurse, nursing aide, or medical assistant, working from a static facility and thus requiring users to return for reinjection. Currently available injectables are effective for between one and three months (depending on the formulation), requiring women to return to their provider between four and twelve times per year. With regard to improving injectable contraceptive access and convenience, a Cochrane review noted that the key to improving their acceptability and use is to provide “injections in settings more convenient than clinical sites [and] methods for women to administer their own injections.” Global policy guidelines support the deployment of lower-level providers to expand access to injectable contraceptives.

A new formulation and presentation of Pfizer’s Depo-Provera® offers the potential to improve access to injectable contraceptives. Depo-subQ provera 104® in the Uniject™ injection system (hereafter referred to as Depo-subQ in Uniject) contains 104 mg of DMPA. Its safety and efficacy are equivalent to the widely accepted DMPA-IM 150 mg benchmark product, and it comes in the single-use, pre-filled Uniject injection system. The objective of introducing Depo-subQ in Uniject is to reach new users of injectable contraceptives and to improve women’s ability to obtain repeat injections by accelerating their access through channels other than clinics. Because Depo-subQ in Uniject is uniquely suited to self-injection, it may also help pave the way for home- and self-administration of injectable contraceptives.

Three-Month Progestin-Only Injectable Contraceptive Product Formulations and Presentations

Depo-subQ in Uniject is administered via subcutaneous injection. The Uniject injection system (Figure 1) is a small, auto-disable injection device that is prefilled with the precise dosage of DMPA required for three months of contraceptive protection.
Table 2 below compares the currently available DMPA IM product (the benchmark) and Depo-subQ provera 104 in the Unject injection system.

Table 2. Depo-subQ in Unject compared to the benchmark

<table>
<thead>
<tr>
<th></th>
<th>Benchmark</th>
<th>New technology</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product</strong></td>
<td>DMPA-IM 150</td>
<td>Depo-subQ provera 104® Unject™</td>
</tr>
<tr>
<td><strong>Contraceptive efficacy</strong></td>
<td>99% contraceptive efficacy</td>
<td>Equivalent contraceptive efficacy</td>
</tr>
<tr>
<td><strong>Safety</strong></td>
<td>Equivalent safety profile</td>
<td></td>
</tr>
<tr>
<td><strong>Side effects</strong></td>
<td>Equivalent side effects:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>intermittent bleeding,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>nausea, weight gain,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>amenorrhea,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>9-10 months return-to-fertility after last injection.</td>
<td></td>
</tr>
<tr>
<td><strong>Frequency of administration</strong></td>
<td>Delivered every three</td>
<td></td>
</tr>
<tr>
<td></td>
<td>months</td>
<td></td>
</tr>
<tr>
<td><strong>Other method benefits</strong></td>
<td>Freedom from fear of</td>
<td>Ability to conceal contraceptive use from partner.</td>
</tr>
<tr>
<td></td>
<td>forgetting to use</td>
<td></td>
</tr>
<tr>
<td></td>
<td>protection.</td>
<td></td>
</tr>
<tr>
<td><strong>Presentation</strong></td>
<td>Glass vial with syringe</td>
<td>Prefilled in Unject</td>
</tr>
<tr>
<td><strong>Formulation</strong></td>
<td>150 mg DMPA</td>
<td>104 mg DMPA</td>
</tr>
<tr>
<td><strong>Type of injection</strong></td>
<td>Intramuscular injection</td>
<td>Subcutaneous injection</td>
</tr>
<tr>
<td><strong>Needle length</strong></td>
<td>1 inch needle</td>
<td>3/8 inch needle</td>
</tr>
<tr>
<td><strong>Injection sites</strong></td>
<td>Deep muscle tissue of</td>
<td>Subcutaneous fat of abdomen, anterior</td>
</tr>
<tr>
<td></td>
<td>gluteals, deltoid.</td>
<td>thigh, back of the upper arm⁵⁵</td>
</tr>
<tr>
<td><strong>Who can administer</strong></td>
<td>Nurse, nursing assistant,</td>
<td>Any provider, including community worker.</td>
</tr>
<tr>
<td></td>
<td>medical officer,</td>
<td>Suitable for self-administration.</td>
</tr>
<tr>
<td></td>
<td>and in some locations,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>community workers</td>
<td></td>
</tr>
<tr>
<td><strong>Price</strong></td>
<td>US$0.78 per unit with</td>
<td>Offered to current global health</td>
</tr>
<tr>
<td></td>
<td>auto-disable needle and</td>
<td>procurers at US$1.55 per unit for 12</td>
</tr>
<tr>
<td></td>
<td>syringe for 40 million</td>
<td>million units. Higher volume could lead</td>
</tr>
<tr>
<td></td>
<td>units (United States</td>
<td>to lower prices. (September 2011)</td>
</tr>
<tr>
<td></td>
<td>Agency for International</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Development [USAID])</td>
<td></td>
</tr>
<tr>
<td><strong>Brands, suppliers</strong></td>
<td>Most widely used brand:</td>
<td>Pfizer product: patent until 2020. Produced at Pfizer</td>
</tr>
<tr>
<td></td>
<td>Depo-Provera® (Pfizer).</td>
<td>plant in Puurs, Belgium.</td>
</tr>
<tr>
<td></td>
<td>Generic versions of DMPA-IM 150 mg are produced by manufacturers in India, Indonesia, Pakistan, South Africa, Thailand, and the United States.</td>
<td></td>
</tr>
</tbody>
</table>

The contraceptive efficacy of Depo-subQ provera 104 is equivalent to that of DMPA-IM 150mg with 30% less active ingredient. However, clinical studies on Depo-subQ provera 104 indicate that the product’s side effects and return-to-fertility profiles are similar to those of the benchmark product.²⁶

Depo-subQ in Unject is administered as a subcutaneous (SC) injection rather than the traditional IM injection. SC injections offer benefits over IM injections, especially when training lower-level providers and users for self-injection.²⁶ These benefits include the following:

- There is a greater area for target injection sites.
- Fewer landmarks are required for targeting injection sites.
- Shorter needles can be used (3/8 inch to 5/8 inch for SC vs. 1 inch for IM).
- It is readily self-administered.
- Muscle mass is not an issue.
### Strengths and barriers

<table>
<thead>
<tr>
<th>Policy and regulation</th>
<th><strong>Strengths</strong></th>
<th><strong>Barriers</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Eligibility criteria and contraindications are identical to those of DMPA-IM.</td>
<td>There is a need to determine what country-level service delivery guideline revisions may be required for Depo-subQ in Uniject.</td>
</tr>
<tr>
<td></td>
<td>A June 2009 technical consultation held at the World Health Organization concluded that evidence supports the introduction, continuation, and scale-up of community-based provision of progestin-only injectable contraceptives. Depo-subQ provera 104 is approved by the USFDA and the Medicines and Healthcare Products Regulatory Agency (MHRA). Final approval of Depo-subQ provera 104 in Uniject by the MHRA is pending (expected Q4 2012). A key element of WHO’s recommended plan for safe and appropriate use of injections is immunization and family-planning services, making auto-disable injection equipment and safety boxes available with vaccine and injectable contraceptives.</td>
<td>With some exceptions (e.g. Ethiopia, Bangladesh, Pakistan) formal nonclinical distribution and delivery systems for injectable contraceptives are not widely or consistently established, even where they are supported by local service-delivery policies. Most country policies are silent on or prohibit self-administration. There are varying timeframes for receiving country-level registrations.</td>
</tr>
<tr>
<td></td>
<td>WHO guidelines provide detailed information concerning the provision of three-month progestin-only injectable contraceptives. Depo-Provera (Pfizer) is prequalified by WHO.</td>
<td>WHO guidelines do not specifically address Depo-subQ provera 104. Depo-subQ provera 104 has been reviewed but is not yet prequalified by WHO.</td>
</tr>
<tr>
<td></td>
<td>The method category is widely used and known; DMPA-IM is provided by public-sector family-planning programmes and through social marketing in many developing countries.</td>
<td>India is a notable exception in that the government’s family-planning programme explicitly prohibits the use of injectable contraceptives.</td>
</tr>
<tr>
<td>Product specifications and characteristics</td>
<td>WHO guidelines specify DMPA-IM and NET-EN (two existing injectable contraceptives).</td>
<td>WHO and country Essential Medicines Lists normally do not yet recognize Depo-subQ provera 104.</td>
</tr>
<tr>
<td>Financing, procurement, and supply</td>
<td>USAID and the United Nations Population Fund (UNFPA) routinely procure injectable contraceptives based on national interest and requirements. It is offered to donors at US$1.55 per unit for 12 million units (September 2011)</td>
<td>USAID procurement requires USAID mission financing. UNFPA procurement requires UNFPA country office demand. The price is considered high compared with that of the benchmark product. The benchmark product is available for US$0.78 per unit with auto-disable needle and syringe for 40 million units (USAID). Generic suppliers of DMPA-IM will soon be eligible to sell to USAID and are likely to offer comparable or lower prices.</td>
</tr>
<tr>
<td>Service provision (rational use)</td>
<td>Injectable contraceptives are widely used by most service providers. In many countries, small but growing cadres of community-health workers, community-based distributors, and other lower-level, non-clinic providers are trained to deliver injectable contraceptives, thereby expanding coverage and increasing convenience for women. Other recent reports indicate that retail sellers such as pharmacies and drug shops sometimes sell injectable contraceptives over the counter directly to users, who are then injected on site or elsewhere.</td>
<td>The policy environment for non-clinic provision of injectable contraceptives is uncertain and varies by country.</td>
</tr>
<tr>
<td>Demand</td>
<td>Unmet demand for injectables remains high in many sub-Saharan African and South Asian countries.</td>
<td>Because the product will only become available for routine use in the next year or two, there is currently limited evidence to support the added value of Depo-subQ in Uniject, given the likely higher cost compared with the benchmark product.</td>
</tr>
</tbody>
</table>
6. Product Profile: Female Condoms

Problem and proposed intervention

Women account for more than half the cases of HIV infection globally and nearly 60% of all cases in sub-Saharan Africa. Women desperately need a way of protecting themselves from pregnancy and sexually transmitted infections while engaging in sexual intercourse. The female condom was developed in 1984 as a potential solution. However, uptake has been disappointing for several reasons.

Like all new products, the female condom requires a certain level of programming in order to ensure successful uptake. Women need to be alerted to its existence, and they need to be trained to use it correctly. If a country were to make this investment in programming, it would want to ensure that the product is readily available. At present, however, female condoms are predominantly purchased by international agencies such as UNFPA and USAID. Only two manufacturers – Cupid Ltd and the Female Health Company – have been prequalified. This monopoly situation, as well as the cost of materials for female condoms, has kept the price high (almost 20 times that of a male condom). Since these agencies have limited budgets, they are unable to purchase enough products to make them widely accessible. This uncertainty regarding accessibility, combined with the higher price, reduces countries’ incentive to make the necessary investment in programming.

PATH has designed a new female condom, called the Woman’s Condom (Figure 2), and in 2008 it licensed production of the product to Dahua Medical Apparatus Company in Shanghai, China. If it is prequalified, this product may incentivize more countries to invest in programming as well as potentially encouraging manufacturers to invest in additional marketing.

Product characteristics: PATH’s Woman’s Condom

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pouch</td>
<td>0.03 mm thin polyurethane film provides good sensation and comfort during sex for both women and men. Loose fit allows good heat transfer offering greater pleasure.</td>
</tr>
<tr>
<td>Ring</td>
<td>Soft, flexible polyurethane ring keeps the condom in place and gently hugs the body, providing comfortable coverage of external genitals.</td>
</tr>
<tr>
<td>Foam shapes</td>
<td>Four small, thin shapes of soft, hydrophilic polyurethane foam (same material used in wound-dressing applications) cling lightly to vaginal wall, ensuring stability. The foam is safe and comfortable when in contact with sensitive vaginal tissue.</td>
</tr>
<tr>
<td>Dissolving capsule</td>
<td>Rounded insertion capsule made of polyvinyl alcohol (same material used in contraceptive film) contains the condom pouch and aids insertion. When the capsule dissolves, the pouch expands into the vagina. Inserting a finger or the penis expands the pouch fully. The dissolved capsule leaves the woman’s body naturally in her vaginal secretions after use.</td>
</tr>
<tr>
<td>Lubricant</td>
<td>The condom is unlubricated and supplied with water-based lubricant to be applied at point of use. This allows couples to use the amount of lubricant that is right for them. The condom is recommended for use only with the lubricant that comes packaged with the product.</td>
</tr>
<tr>
<td>Packaging</td>
<td>Aluminum foil laminate to keep the condom fresh.</td>
</tr>
<tr>
<td><strong>Strengths</strong></td>
<td><strong>Barriers</strong></td>
</tr>
<tr>
<td>------------</td>
<td>-------------</td>
</tr>
<tr>
<td><strong>Global policy and regulation</strong></td>
<td></td>
</tr>
<tr>
<td>Donors ensure that they only fund the purchasing of high-quality products by insisting upon manufacturer prequalification from WHO or another stringent regulatory authority.</td>
<td>WHO prequalification is expensive and time-consuming, with only two female condom manufacturers approved to date.</td>
</tr>
<tr>
<td><strong>National and regional policy and regulation</strong></td>
<td></td>
</tr>
<tr>
<td>Some countries have distributed female condoms to female sex workers to help them avoid STIs.</td>
<td>The association with female sex workers has stigmatized the female condom in some markets, so that it is not perceived as a mainstream contraceptive choice.</td>
</tr>
<tr>
<td><strong>Product specification and characteristics</strong></td>
<td></td>
</tr>
<tr>
<td>Today the female condom is the only available technology for prevention of STIs and pregnancy that a woman can initiate herself. In Zimbabwe, the female condom is said to be more comfortable for both partners and less prone to breakage than male condoms.</td>
<td>It requires training for correct insertion and use. The failure of the product may result in pregnancy or the transmission of an STI.</td>
</tr>
<tr>
<td><strong>Financing, procurement, and supply</strong></td>
<td></td>
</tr>
<tr>
<td>Additional manufacturers are entering the market. There are six to date. Most recently PATH developed the Woman’s Condom, which has been designed to be more acceptable for both partners. The Female Health Company is currently scaling their manufacturing up to 100 million condoms annually.</td>
<td>Only 0.28% of all condoms produced are female condoms. However, manufacturers are not managing to sell their entire stocks at current manufacturing levels.</td>
</tr>
<tr>
<td></td>
<td>The female condom is considered expensive at about $0.55 per condom. Additionally, the programming that is needed for successful uptake is also expensive.</td>
</tr>
<tr>
<td></td>
<td>Some advocate the reuse of the female condom, which lowers the price per use. However, WHO does not recommend reuse, and the Woman’s Condom is not designed for reuse.</td>
</tr>
<tr>
<td><strong>Service provision (rational use)</strong></td>
<td></td>
</tr>
<tr>
<td>UNFPA and USAID purchase the bulk of female condoms and distribute them to developing countries at a subsidized price.</td>
<td>The number of WHO-prequalified or USFDA-approved manufacturers is growing and it remains to be seen how this will affect product pricing. In the past, the relative expense of the female condom limited the quantity that the agencies were able to purchase. However, the market size has steadily increased over the last 10 years and is expected to continue to grow, offering hope for greater competition and reduced prices.</td>
</tr>
<tr>
<td><strong>Demand</strong></td>
<td></td>
</tr>
<tr>
<td>Implementation in Zimbabwe has demonstrated that demand can be dramatically increased by active programming, such as education and making female condoms available in communities – e.g. through barbers and hairdressers.</td>
<td>The female condom is not widely used in most countries (developed and developing). Most women are simply unaware of the product.</td>
</tr>
<tr>
<td></td>
<td>Women in typically male-dominated societies find it difficult to ask their partners to wear a male condom or initiate the use of a female condom.</td>
</tr>
</tbody>
</table>
Innovative Medical Devices For the Health of Women and Children in Low-Resource Settings

7. Product Profile: Portable Ultrasound Device

GE Healthcare initiated a study entitled “Enhancing Training and Appropriate Technologies for Mothers and Babies in Africa.” It is currently being conducted by Ifakara Health Institute and the Tanzanian Ministry of Health.

Problem and proposed intervention

Maternal health has been at the top of the global health agenda for several decades. In most developing countries, improvements in women’s health have been slower than their economic and technological advances would suggest. In Tanzania, for example, while the maternal mortality ratio has decreased in the last decade, the current figure of 454 per 100,000 live births remains higher than it should be if we are to achieve Millennium Development Goal 5, which requires a global figure of 133 by 2015.

Common causes of maternal death in developing countries include haemorrhage, obstructed labour, hypertensive disorders, sepsis, and unsafe abortion. Although some of these maternal complications are unpredictable, many can be prevented at various stages of pregnancy, during delivery and soon after. Unfortunately, most African health systems are not well equipped with sufficient skilled staff, equipment, tools, and technologies that could be used to save lives. Portable ultrasound devices, combined with proper skills, knowledge, and quality-assurance, have the potential to change this scenario – provided they are acceptable, feasible, cost-effective, and scalable. They can contribute toward efforts to reduce maternal mortality and newborn deaths, and hasten the attainment of MDGs 4 and 5.

Product characteristics: Vscan

The GE Vscan ultrasound device is shown in Figure 3.

<table>
<thead>
<tr>
<th>Proposed usages</th>
<th>Pocket-sized visualization tool with ultrasound technology. Provides black-and-white anatomic and color-coded blood-flow images in real time.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specifications</td>
<td>Dimensions and weight:</td>
</tr>
<tr>
<td></td>
<td>• Display unit: 135 x 73 x 28 mm</td>
</tr>
<tr>
<td></td>
<td>• Probe: 120 x 33 x 26 mm</td>
</tr>
<tr>
<td></td>
<td>• Weight (unit and probe): 390 g</td>
</tr>
<tr>
<td></td>
<td>• Display: 3.5 inch, 240 x 320 pixels resolution</td>
</tr>
<tr>
<td></td>
<td>Clinical applications:</td>
</tr>
<tr>
<td></td>
<td>• Cardiac</td>
</tr>
<tr>
<td></td>
<td>• Abdominal</td>
</tr>
<tr>
<td></td>
<td>• Urology</td>
</tr>
<tr>
<td></td>
<td>• Foetal/Obstetrics</td>
</tr>
<tr>
<td></td>
<td>• Paediatric</td>
</tr>
<tr>
<td></td>
<td>• Selected peripheral vessels</td>
</tr>
<tr>
<td></td>
<td>• Thoracic/pleural motion and fluid detection</td>
</tr>
<tr>
<td>Approximate cost</td>
<td>US$6,000-8,000</td>
</tr>
</tbody>
</table>
**Strengths and barriers**

*Note: GE provided the devices used for the research study that began in April 2012 and which is being carried out by Ifakara and the Tanzanian MOH. The strengths and barriers outlined below are based on the study in Tanzania and also on some of the initial findings of similar studies in which GE is involved outside Africa. Further findings will be tracked as part of the larger ongoing study that is scheduled to conclude in 2013.*

<table>
<thead>
<tr>
<th>Global policy and regulation</th>
<th><strong>Strengths</strong></th>
<th><strong>Barriers</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Standardized classroom and practical training for the task-shifting workers who use ultrasound technology in sub-Saharan Africa. A proper device in the hands of the end user supports their ability to provide care.</td>
<td>Portable ultrasound products are new to rural health care, so the lack of awareness – in-country and globally – prevents immediate acceptance. Proof of concept in the Tanzania research study offers the evidence required to position the products for use in rural settings.</td>
</tr>
<tr>
<td></td>
<td>Ultrasound services are being made available to pregnant women in rural Africa.</td>
<td>There are no published details on innovations such as Vscan for rural health care.</td>
</tr>
<tr>
<td></td>
<td>Portable ultrasound can help healthcare workers to supply health care in low-resource settings, addressing delays in seeking care, delays in reaching care, and delays in care delivery.</td>
<td>Product awareness is critical to successful acceptance and usage. Promoting this using a partnered maternal and neonatal health-campaign strategy will be key to sustainability and scalability.</td>
</tr>
<tr>
<td></td>
<td>Ultrasound technology is being used across the world and is considered a useful and convenient imaging device.</td>
<td>High per-unit initial cost could be a barrier to early acceptance.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>National and regional policy and regulation</th>
<th><strong>Strengths</strong></th>
<th><strong>Barriers</strong></th>
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<tbody>
<tr>
<td></td>
<td>The use of handheld portable ultrasound devices can contribute to governments’ efforts to reduce maternal mortality and newborn deaths, accelerating attainment of MDGs 4 and 5.</td>
<td>The learning curve for ultrasound and continued oversight could affect its acceptance and sustained use.</td>
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<td></td>
<td>In sub-Saharan Africa there is increasing government support for task-shifting to new key end-users.</td>
<td>Limited electrification in developing countries affects the chances of increased use of ultrasound scans.</td>
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<td></td>
<td>The limited availability of physicians shifts the focus of healthcare delivery to the nurses and clinical officers who work with the physicians. These end-users are licensed to deliver ultrasound scans. However, lack of resources affects the ability to support rural settings, where over 80% of women continue to give birth in unassisted environments. Providing portable, intuitive ultrasound technology has an immediate impact on care delivery, thus reducing maternal and neonatal mortality.</td>
<td>Myths and misconceptions about the use of ultrasound can lead to initial resistance to its use.</td>
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<td></td>
<td>Due to portability and ease of use, Vscan may be used in ways for which it was not intended or for inappropriate activities in certain regions (e.g. to identify the gender of a baby).</td>
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<table>
<thead>
<tr>
<th>Product specification and characteristics</th>
<th><strong>Strengths</strong></th>
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<tr>
<td></td>
<td>The device meets the guidelines for rural products: portable, intuitive to use, rechargeable.</td>
<td>Limited battery life; requires on-going charging.</td>
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<td></td>
<td>Technological innovation in the Vscan has simplified the device’s design and parts so that limited setup is needed to use the technology.</td>
<td>The product is portable and therefore liable to be stolen.</td>
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<td></td>
<td>The Vscan product design allows for use outside the foetal/obstetric field if desired. The device includes three use pre-sets (OB, abdominal, and cardiac).</td>
<td>The product has no telemedicine or wireless functionality.</td>
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<td></td>
<td>It is possible to upload images and share or request guidance on findings by using the Vscan gateway or the micro SD card.</td>
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<td></td>
<td>Charging the device with solar power is being tested in Tanzania. This has not been tested or evaluated by GE. If found successful, it would open up a plethora of opportunities for integration in rural Africa.</td>
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</tr>
<tr>
<td><strong>Financing, procurement, and supply</strong></td>
<td><strong>Strengths</strong></td>
<td><strong>Barriers</strong></td>
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<td>There is a funding request and need for this category of medical devices in developed and developing countries.</td>
<td>The current model is exclusive to Tanzania. Potential expansion is based on having the capacity to host similar studies in other countries.</td>
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<td></td>
<td>There is an opportunity to create an entrepreneurial business model in the public and private sectors throughout sub-Saharan Africa.</td>
<td>The difficulty of securing a funding partner for purchase.</td>
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<td></td>
<td>The research study model currently available for use in sub-Saharan Africa is based on the scaling of best practices gained from similar research studies in Asia.</td>
<td>The cost of Vscan is much higher than other low-resource products. However, relative to overall ultrasound costs, it is very inexpensive and bulk prices can be negotiated. The device’s long life also ensures that the per-person cost of scanning falls over time.</td>
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<tr>
<td></td>
<td>The GE Capital Markets team is committed to identifying local partners to structure business models for procurement.</td>
<td>The procurement and delivery model is challenged by customs and specific in-country challenges.</td>
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<thead>
<tr>
<th><strong>Service provision (rational use)</strong></th>
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<tr>
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<td>Vscan requires minimal servicing and replaceable consumables, which makes the device’s initial cost the most significant expense for potential procurers to consider.</td>
<td>Intermittent service requirements could pose challenges.</td>
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<td></td>
<td>The initial one-time cost of Vscan is high. However, the usage of the device is long term (a minimum of five years) and this could bring the per-person scan cost to acceptable levels.</td>
<td>There are limited activities that the user can perform to service Vscan if needed. The device may need to be shipped to a repair facility for days.</td>
</tr>
<tr>
<td></td>
<td>Vscan in Africa is a new model of healthcare delivery and is yet to be tested for scalability.</td>
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<th><strong>Demand</strong></th>
<th><strong>Strengths</strong></th>
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<tr>
<td></td>
<td>There is high demand for ultrasound devices among health providers and health facilities. However, there is almost no awareness of handheld portable ultrasound devices and their capabilities in Africa or in the global healthcare community. Expanded branding and awareness could stimulate demand.</td>
<td>Awareness-raising could create demand for the product despite the challenges of funding it and using it in a rural environment.</td>
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<td></td>
<td>The initial focus of the project was on OB scanning and its impact on MDGs 4 and 5. This has shown good acceptance among communities in Bangladesh, Indonesia and Tanzania. In low-resource settings, one of the major problems of managing pregnancy is calculating the expected delivery date, as most women forget the exact date of their last menstrual period. This makes it difficult to make a proper birth plan for women. If the expected delivery date can be calculated with the help of technical devices, the birth plan can be made more easily and many complications can be prevented.</td>
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Notes


3. The source is the MANDATE model (baseline year 2007), assuming improved blood-pressure measurement, proteinuria detection, MgSO₄ delivery, and patient transfer. Foetal and newborn lives saved were excluded from the analysis.

4. Focused ANC is evidence-based, goal-directed care that is tailored to the gestational age of pregnancy and the individual needs of each woman. It emphasizes the quality of visits over their quantity and is conducted by a skilled health care provider. Goals of focused ANC include early detection and treatment of complications, prevention of problems, birth preparedness/complication readiness, and promotion of healthy practices to help ensure a positive health outcome for the woman and her baby. Focused ANC provides a woman-centered approach that values the dignity and worth of each woman and her family.


10. The UNICEF Supply Catalogue, which depends upon requests from countries, currently includes one adult aneroid sphygmomanometer (US$10.68; product #S0683200) and one child aneroid sphygmomanometer (US$11.42; product #S0683300).


24. Uncject is a trademark of BD.

25. DMPA-IM cannot readily be self administered because of the skill required to draw up the drug into a needle and syringe from a vial, and the injection sites (gluteals, deltoid muscle) cannot be easily reached.

26. Pfizer’s product labelling does not include the back of the upper arm as an injection site.


31. PATH. Woman’s Condom Features: Comfortable and confident protection for women and men [web site]. Available at: http://sites.path.org/rhtech/womans-condom/features/.


35. RHInterchange Shipment Summary – Global Summary of Shipments [web site]. Available at: http://rhi.rhsupplies.org/rhi/shipmentssummary. Do Date of access: June 12, 2012.


37. Enhancing Training and Appropriate Technologies for Mothers and Babies in Africa. *Clinical study agreement between GE Healthcare and Ifakara Health Institute, with the Tanzania MOH*.


42. Trademark of General Electric Company.

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**Acronyms**

- **ANC**: antenatal care
- **BP**: blood pressure
- **BPMD**: blood-pressure measurement device
- **DMPA**: depo-medroxyprogesterone acetate
- **HBB**: Helping Babies Breathe
- **IM**: intramuscular
- **IWG**: Innovation Working Group
- **MDG**: Millennium Development Goal
- **MHRA**: Medicines and Healthcare Products Regulatory Agency
- **MNCH**: maternal, newborn and child health
- **PE/E**: pre-eclampsia/eclampsia
- **SC**: subcutaneous
- **STIs**: sexually transmitted infections
- **UNFPA**: United Nations Population Fund
- **USAID**: United States Agency for International Development
- **USFDA**: United States Food and Drug Administration
- **WHO**: World Health Organization