Developing an affordable balloon tamponade for postpartum hemorrhage treatment and management

DIV Progress report #1

Overall project objective
The objective of the project is to assess the design, manufacturing, and programmatic feasibility of developing an affordable, high-quality balloon tamponade by conducting the first phase of product development activities.

First milestone
For the period extending from mid-October, 2011 to mid-January, 2012, the project milestone is to define the functional product requirements and technical specification of a uterine balloon device.

Progress to date and work completed
- PATH conducted an evaluation and mechanical testing of three commercially available uterine balloon tamponade devices (the ebb™ balloon, the Cook® Bakri balloon, and the BT-Cath® balloon) and two balloons used in developing countries (the condom catheter balloon and the glove balloon). We looked at device features and benefits of each model, compared the five technologies, collected cost information, and assessed the benefits of each device.
- We took photographs and videos to document the properties of the devices (weight, length, diameter, balloon material) and mechanical performance (durability, material expansion capability, fill rates, failure modes).
- We procured or, in the case of the glove balloon and condom catheter, assembled. Destructive testing was completed and an analysis of the differences in functionality among the various devices was done. Appendix A summarizes the mechanical safety factors of the devices that were tested, and Images 1, 2, and 3 provide an example of a filled and burst balloon.
- We generated a list of pertinent questions (see Appendix B) and sought expert opinions to answer these questions. One set of issues related to materials and design features and the second set related to function and program requirements. For example, a question about the dimensions of a postpartum uterus was raised, as well as a question about the appropriate latex cure process. In both cases, the questions served to define and refine the functional product requirements and technical specifications. Expert opinions were collected from obstetricians and gynecologists who use the Bakri balloon and the condom catheter in both developing- and developed-country settings. This type of feedback from stakeholders and experts will be collected throughout the design and development process in an iterative fashion.
- A potential design for a low-cost molded uterine balloon tamponade was completed, including balloon, mandrels, and tooling. This could be the basis for a preliminary prototype as well as for a first round of cost analysis. Drawings of the preliminary balloon model are attached to this report (see Images 4, 5, and 6).
- We are in the process of conducting a preliminary cost analysis of various materials to get a better idea of the best material candidate for a low-cost device.
Work planned for the next quarter
The key activities in the next phase of the project are an evaluation of manufacturing and retail costs for several design options. Specifically, we will:

- Assess various balloon materials based on clearly defined functional and cost requirements. At present, there is no clear, preferred candidate material for a low-cost balloon device. However, latex (natural or synthetic) and silicone are the two primary categories for consideration. During the next quarter, we will develop a better understanding of the materials and their appropriateness.
- Compile a bill of materials that captures the information collected so far from the performance testing in the laboratory, discussions with materials experts, as well as feedback from experts on required necessary design features. Desired features will be added in and factored into cost-analysis modeling for comparison purposes.
- Gain a clearer understanding of the manufacturing process and supply chain, and document this information to determine a more accurate estimate of the manufactured device/product.
- Conduct another round of expert consultations that will get us closer to the development of the product requirements specification document.

Issues, challenges, and changes
We did not experience any major issues or challenges during this first phase of the project. One minor issue we faced that impacted our initial timeline was that procuring/purchasing the various balloon devices for testing and evaluation proved to be a bit more complicated than we anticipated. Sale of devices is limited to practicing physicians. However, our clinical partners were able to assist.

At this time, we do not anticipate any changes to the proposed dates or milestones.
Appendix A

Balloon tamponade device testing—mechanical safety factors

<table>
<thead>
<tr>
<th>Test Subject</th>
<th>Material</th>
<th>Operation Volume (max mL)</th>
<th>Burst Volume (mL)</th>
<th>Safety Factor</th>
<th>Failure Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bakri</td>
<td>Silicone</td>
<td>500</td>
<td>2310</td>
<td>3.6</td>
<td>Longitudinal failure in balloon parent material</td>
</tr>
<tr>
<td>Ebb uterine balloon</td>
<td>Polyurethane</td>
<td>750</td>
<td>9800</td>
<td>12.1</td>
<td>Longitudinal failure in balloon parent material</td>
</tr>
<tr>
<td>Ebb vaginal balloon</td>
<td>Polyurethane</td>
<td>300</td>
<td>10450</td>
<td>33.8</td>
<td>Longitudinal failure in balloon parent material</td>
</tr>
<tr>
<td>Nitrile glove</td>
<td>Synthetic latex</td>
<td>500</td>
<td>20200</td>
<td>39.4</td>
<td>Knot failure where the “wrist” is tied to form balloon</td>
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<td>Condom (full length)</td>
<td>Latex</td>
<td>500</td>
<td>15500</td>
<td>30.0</td>
<td>Longitudinal failure in balloon parent material</td>
</tr>
<tr>
<td>Condom (tied to 3.5&quot;)</td>
<td>Latex</td>
<td>500</td>
<td>8900</td>
<td>16.8</td>
<td>Longitudinal failure in balloon parent material</td>
</tr>
</tbody>
</table>
Appendix B

Balloon tamponade—expert opinion questionnaire

1. How important is the blood drainage feature on uterine balloon tamponades?

2. How long does the drainage feature typically function during a postpartum hemorrhage episode?

3. For developing-country applications: is a catheter required or can tubing, a stopcock, and a condom be used alone? (lowest-cost option)

4. Why is there a 500-mL fill limit on these medical devices?

5. What is the mechanism of action (pressure, irritation that induces contractions, temperature differential, other)?

6. Are there issues with latex that we need to be aware of?

7. Is shape of the balloon important? How about the shape of the uterus?

8. What are the dimensions of a postpartum uterus? Are they different for an atonic uterus?

9. How important is placement of the balloon in the uterus? Is there “proper” placement?
Developing an Affordable Balloon Tamponade for Postpartum Hemorrhage Treatment and Management

Development Innovation Ventures Progress Report # 4

Overall project objective
The objective of the project is to assess the design, manufacturing, and programmatic feasibility of developing an affordable, high-quality, uterine balloon tamponade (UBT) by conducting the first phase of product development activities.

Fourth project milestone
The first and second project milestones completed in January 2012 and March 2012, respectively, focused on defining the functional requirements and technical specifications of a low-cost UBT device, developing the product requirements document, and conducting an initial cost analysis for low-cost manufacturing processes. The third project milestone, completed in May 2012, provided prototypes ready for input on device design, product features, and functionality from maternal health experts. This fourth milestone focused on gathering user input on the device design, perceived functionality, suitability, and acceptability.

Progress to date and work completed since May 2012
The plans for the user assessment in Ghana were finalized in late May in collaboration with colleagues in the PATH office in Ghana. Approvals were secured from the Ghana Health Services (GHS), and a list of stakeholders and key users was compiled.

PATH/USAID Ghana mission meeting: A meeting took place between the PATH team and Ms. Salamatu Futa at the USAID mission in Ghana. The PATH team briefed Ms. Futa on the project objectives and progress to date and the planned expert opinion interviews.

Expert opinion interviews: Eight experts representing various professional organizations and institutions were contacted. Interviews originally scheduled with the United Nations Children’s Fund, the United Nations Population Fund, and Dr. Kwaikuame at the International Federation of Gynecology and Obstetrics were cancelled. Dr. Gloria Asare, Director of Family Health Division of GHS, was on leave and will provide input at a later date. Interviews were conducted with the following stakeholders:

- Dr. Sylvia Deganus, Obstetrician and Gynecologist in charge, Tema General Hospital.
- Joyce Jetuah, President of the Ghana Registered Midwives Association.
- Dr. Paul Cooper, Head Medical Officer, St. Martin de Porres Hospital.
- Dr. Charles Fleischer-Djoleto, Representative of the World Health Organization’s (WHO) Regional Office for Africa.
- Dr. S. A. Obed, Korle Bu Teaching Hospital.

See Appendix 1 for the interview guide.
Key findings:

Overall design

- All stakeholders liked the integrated unit design of the device (no assembly required, as is the case with the condom catheter tamponade).
- A pre-packaged system is a big advantage and makes it very convenient (see Appendix 2, image 1 for currently used kits).
- All experts agreed that the device seemed simple, straightforward, and easy to use.
- Several stakeholders noted that the balloon would be better if shaped like a pear (more in line with the shape of the uterus).
- Generally, the grip on both the balloon and the tube felt secure and firm.
- The thickness of the balloon was seen as an advantage over the thin condom and might help reduce slippage out of the uterus, making it easier to insert and use.
- Several experts suggested using an infusion bag instead of the syringe. Several physicians stated that this would free them up to tend to the woman’s other needs and not have to worry about the filling.
- A mechanism that allows filling with both syringe and infusion would be most desirable in case facilities lack one or the other.
- Most experts found the mechanism for securing the syringe with a one-way valve was a big advantage that would make it easier to use and may prevent leakage.
- Everyone thought the device appeared to be high quality, but a couple of experts had concerns about the balloon "melting" or the walls of the balloon sticking together, especially during storage in the heat, leading to possible tearing of the balloon when inflated and inserted.

Cost

- On average, stakeholders thought approximately 10 cedis (US$5.20) per device would be a fair cost, but 5 cedis (US$2.50) would be ideal.
- Most experts stressed that it would be very important that the device be accepted by insurance and that it would be great to include in the Standard Treatment Guidelines issued by the Ministry of Health (MOH).
- An affordable and easy to use UBT would reduce long-term costs incurred by the GHS and families if hysterectomies or other surgical procedures were to be used.
- It is likely that the MOH and GHS would purchase UBTs once they are approved by WHO.

Acceptability

- A UBT can be easily and safely used by physicians and midwives, but would/could not be used by trained birth attendants.
- Acceptability and widespread use of the device would be achieved if a group of physicians was trained and encouraged its use. Training would require use of an appropriate simulation model (see Appendix 2, image 2 for example).
• Introduction of the device would not add a huge burden on the system in terms of training and monitoring.

**Next Steps**

The findings from the expert interviews will be summarized and incorporated into the design requirements to the extent possible. Additional bench testing on shape variations, balloon thickness, and tubing length may be carried out if necessary. A final round of expert opinions from global experts will be sought.
Appendix 1

Uterine Balloon Tamponade Interview Guide

1. Overall impressions of the design:
   - Is it an improvement over the condom tamponade?
   - What do they like or dislike about this design?

2. Are there any features they would change? Which ones? How?

3. Probe on the following:
   - Filling mechanism.
   - Tubing stiffness.
   - Materials in general: latex, silicone, etc.
   - Thickness of balloon.
   - Other.

4. What would they estimate to be a fair price for the device? Who would pay, the health system or patient? Issues around training:
   - Concerns?
   - How would they envision training on use?
   - How often?
   - Management vs. treatment?
   - How do you get a new intervention into the national training curriculums?

5. Who would/could use it? What do they see as the barriers or challenges for each group to adopt it?
   - Physicians.
   - Midwives.
   - Trained birth attendants.

6. Which key stakeholders buy-in do you feel is important for country adoption?

7. What do you see as the advantages and disadvantages of the uterine balloon tamponade when compared to the non-pneumatic antishock garment? Do you think one is more appropriate for certain conditions than the other?

8. Other?
Appendix 2

Image 1. Postpartum hemorrhage kit in Ghana.

Image 2. Improvised uterus for training.
Designing an Affordable Uterine Balloon Tamponade for the Management and Treatment of Postpartum Hemorrhage

Final Report
Development Innovation Ventures
USAID
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Designing an Affordable Uterine Balloon Tamponade for the Management and Treatment of Postpartum Hemorrhage

Summary

The uterine balloon tamponade (UBT) is a minimally invasive, easy-to-use, and effective intervention for treating and managing severe postpartum bleeding when medical management and bimanual compression fail and when surgical options are unavailable. It works rapidly and effectively, reducing the need for risky surgical interventions and blood transfusions. It also serves a critical role in reducing or stopping blood loss until the woman can be transported to a facility that can provide surgical management and other treatment options. Current and commercially available devices are prohibitively expensive for developing-country maternal health programs. A low-cost UBT that can be used in developing-country tertiary settings as well as in lower-level facilities would equip health care providers with an effective and safe option for the management and treatment of postpartum hemorrhage (PPH) when standard care procedures have failed to arrest bleeding. By expanding access to a lifesaving intervention, an affordable UBT would have an impact on the rate of maternal mortality directly and indirectly attributed to PPH.

With USAID Development Innovation Venture (DIV) Stage I funding, PATH undertook a series of activities that led to the development of a preliminary low-cost UBT design that demonstrated proof of concept and a reference document that will support further development efforts and future commercialization plans. The project set out to (1) identify critical functional and design characteristics that would ensure safety, acceptability, and ease of use; (2) determine optimal and feasible manufacturing approaches; and (3) consult with experts, stakeholders, and health care providers in developing countries to support design and development decisions. A packet of information was assembled composed of a preliminary design concept including guides to product requirements, prototype development and assembly, cost estimates, manufacturing requirements, packaging concepts, and input from experts and stakeholders. A determination of the final design, packaging, and manufacture of an affordable and sustainable UBT will be driven by considerations of user needs, costs, and manufacturer’s capabilities and resources.

Background

PPH continues to be the single most common cause of maternal morbidity and mortality in developing countries. PPH is responsible for around 25 percent of maternal mortality worldwide, and severe PPH occurs in approximately 11 percent of live births. PPH can cause severe morbidity, and approximately 12 percent of women who survive PPH will have long-term debilitating health conditions including severe anemia. Women who have severe PPH and survive are significantly more likely to die in the year following the PPH. The incidence of PPH is especially high in developing countries, where women do not have access to a skilled attendant at delivery, where active management of the third stage of labor may not be routine, and where emergency obstetric care is insufficient. The consequences of PPH are devastating to families and costly to health systems. Current options for managing PPH include medical
treatment with uterotonics, uterine massage, or bimanual compression followed by invasive surgical
treatments. When uterotonics fail or are unavailable, health providers have few options. Options are
urgently needed, particularly in resource-limited settings. A UBT can fill a critical need by providing a
simple, rapid, and effective method to manage PPH. A low-cost, fast-acting UBT device that can be used
in the public and private sectors would offer another lifesaving tool to health care providers. While UBT
introduction in tertiary facilities can potentially reduce the need for surgery, and in turn decrease costs
and negative health outcomes, the UBT may have the greatest impact on lives saved at peripheral health
facilities that are not equipped for surgery or transfusions.

The UBT is a minimally invasive obstetric intervention that can effectively control severe postpartum
bleeding. When inserted into the uterus and filled with water or saline, a uterine balloon exerts pressure in
the uterine cavity, creating a tamponade, and stops the hemorrhage within 5 to 15 minutes of insertion.
The balloon tamponade is unique among a group of comparative treatments in that it is a nonsurgical,
relatively easy and quick approach for the management and treatment of massive bleeding. In most
instances it can stop the bleeding and be an end-point intervention. In cases of intractable PPH, it reduces
bleeding while further intervention is sought, thereby reducing risk of death. The success rates for the
control and management of PPH with a UBT are high and range between 70 percent and 100 percent.6,7
A more recent systematic review on the effectiveness of the UBT found it to be an effective and safe
intervention. A case study (submitted manuscript unpublished) of low-cost condom catheter UBT in
South Sudan showed that the UBT was effectively used by community health care workers in 12 of the 13
cases studied. In an economic assessment that studied the cost-effectiveness and cost-benefit of PPH
interventions, the balloon tamponade was highest ranked among eight other interventions.9

Balloon tamponade devices have received United States Food and Drug Administration regulatory
clearance and are currently used for emergency obstetrics in high-income countries. UBT is recognized
by the World Health Organization (WHO), the International Federation of Gynecology and Obstetrics, the
American Conference of Obstetricians and Gynecologists, the Royal College of Obstetricians and
Gynaecologists, and the International Confederation of Midwives as a method that could significantly
impact the management of intractable PPH, especially when surgical interventions can be avoided or are
not an option.

Despite significant evidence of improved health outcomes and appropriateness for low-resource settings,
uptake of the balloon tamponade in impoverished countries has been minimal for several reasons
including lack of affordably priced options in low- and middle-income countries, limited knowledge of
the UBT as an available and effective intervention, and lack of protocols and national guidelines.
Effectively reducing mortality and morbidity resulting from PPH will require a combination of
approaches involving expanded access to an intervention such as UBTs. PATH conducted a landscape
analysis of second-line PPH interventions, investigating current approaches and novel technologies and
looking specifically at the UBT, its role in the PPH care pathway, and its potential impact on maternal
health outcomes. UBT may have the greatest impact on lives saved at peripheral health facilities and can
fill a critical gap if made available at low cost to providers. PATH proposes to advance an innovative,
affordable UBT product design for use in the management and treatment of PPH and initiated the first stage of design and development with Stage I DIV support.

Project Goal

The goal of the project was to advance the development of a lower-cost balloon tamponade to be used to manage and treat PPH with a focus on increasing access to a proven impactful intervention, especially in peripheral health care facilities in developing countries.

Project Objective

The objective of the project was to assess the design and manufacturing feasibility of developing an affordable, high-quality balloon tamponade by conducting the first phase of product development.

Project Activities

To reach the objective, five key activities were conducted to complete the Phase 1 primary contextualization and feasibility assessment of a low-cost uterine balloon. Two of the activities focused on technical analysis, design, and development, and three activities focused on collecting input from the users and experts on UBT design and related programmatic issues. The next section describes the project activities and summarizes key findings.

Technical activities

- Produce a clear and verifiable list of the product requirement specifications for a safe and effective UBT.
- Conduct a manufacturing analysis to establish the viability of the proposed design and manufacturing methods.

Project activities took place over an 11-month period. PATH worked closely with a consultant with expertise in low-cost manufacturing processes and balloon bladder technologies; this work resulted in a comprehensive technical plan for taking the product requirement specifications and the product engineering plan to the next stage of prototype development and scale-up, including rigorous bench testing and field evaluations.

Summary of work conducted

The technical work conducted for this project consisted of five parts.

1. An overview and evaluation of UBT devices.
2. A preliminary design concept for a low-cost UBT.
3. A prototype balloon.
4. Prototype assembly fabrication.
5. Packaging concepts.
1. Overview and evaluation of UBT devices. Our initial landscape identified four commercially available standard medical balloon devices and two uterine balloons made of components available at the point of care. We obtained multiple samples of the medical devices, assembled glove and condom balloons, and conducted an evaluation and mechanical testing of each of these devices.

The following medical devices were evaluated:

- Cook Medical’s Bakri Postpartum Balloon.
- Utah Medical’s BTC-100.
- Bardia Foley Catheter.
- Ebb™ Uterine and Vaginal Balloon.

The following low-cost devices that are assembled at point of care were evaluated:

- Condom catheter.
- Glove catheter.

The bench testing was conducted by a team of engineers who compared the five devices, assessing device features, potential design advantages for each model, and materials costs. Specifically, the testing included an assessment of the following characteristics and product features:

- Mechanical design, including shape and thickness.
- Functionality and ease of use (insertion, inflation, retention, and removal).
- Material selection and related costs.
- Durability and integrity through inflation testing, burst tests, and mechanical safety.

Three samples of each of the devices were procured or in the case of the glove balloon and condom catheter were assembled. Destructive testing of the devices was completed, and an analysis of the differences in functionality between the various devices was completed. The shapes of all devices were recorded at inflation with 500 mL and at burst. Illustrations of the burst tests are found in Appendix A.

The results showed that all devices with the exception of the glove (see Appendix A) have a very similar shape at 500 mL, and all devices at 500 mL are very pliable and conformable. Mechanical testing also proved that the functionality of a well-executed condom catheter uterine balloon tamponade was equivalent or even surpassed medical-grade solutions.

The team took photographic and video documentation of device properties including weight, length, diameter, balloon material and mechanical performance such as durability, material expansion capability, fill rates, and failure modes. A matrix summarizing the mechanical safety factors of each device was developed, see Table 1 below.
Table 1. A comparison of UBTs showing mechanical safety testing factors.

<table>
<thead>
<tr>
<th>Test Subject</th>
<th>Material</th>
<th>Operation Volume (max. mL)</th>
<th>Burst Volume (mL)</th>
<th>Safety Factor</th>
<th>Failure Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bakri</td>
<td>Silicone</td>
<td>500</td>
<td>2,310</td>
<td>3.6</td>
<td>Longitudinal failure in balloon parent material.</td>
</tr>
<tr>
<td>Ebb uterine balloon</td>
<td>Polyurethane</td>
<td>750</td>
<td>9,800</td>
<td>12.1</td>
<td>Longitudinal failure in balloon parent material.</td>
</tr>
<tr>
<td>Ebb vaginal balloon</td>
<td>Polyurethane</td>
<td>300</td>
<td>10,450</td>
<td>33.8</td>
<td>Longitudinal failure in balloon parent material.</td>
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<td>Nitrile glove</td>
<td>Synthetic latex</td>
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<td>30.0</td>
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<tr>
<td>Condom (tied to 3.5&quot;)</td>
<td>Latex</td>
<td>500</td>
<td>8,900</td>
<td>16.8</td>
<td>Longitudinal failure in balloon parent material.</td>
</tr>
</tbody>
</table>

2. Preliminary design concept for a low-cost UBT. The priorities for the UBT preliminary design concepts developed during the project were around simplicity, reduced part count, and cost reduction. For example, while mechanical testing proved that functionality of a well-executed condom catheter was equivalent or even surpassed the medical-grade devices such as the Bakri, the condom catheter’s main drawback was the complexity of assembly in the hands of a less-experienced provider in an emergency situation.

In addition to the mechanical and functionality tests, we conducted an analysis of the various candidate materials for the UBT. The focus was narrowed to look more closely at custom-dipped latex balloons interfacing with latex tubing. The advantage of this material and processing is a balloon that is more robust and has less potential for leakage. Additionally, the cost of manufacturing a dipped latex balloon is much less expensive than closed molding of silicone or welding of thermoplastic urethane.

The manufacturing strategy for mass production and deployment of the dipped latex balloon would be to work with a condom manufacturer(s) that is International Organization for Standardization certified. To capture all the elements that are part of the critical pathway, a decision matrix was developed to help arrive at critical decisions related to key product features (see Figure 1).
Based upon the survey of the commercial devices, the lower-cost condom and glove balloons, and the analysis of the data, the following key design criteria were selected:

- Low cost—must be under US$10.00.
- Minimized part count.
- Incorporating as many off-the-shelf components as possible.
- Ease of use with developing-country settings in mind.
- Preassembled.
- Safe for transport while in situ.
- Single use.
- Focusing on custom latex balloon development.

3. **Prototype balloon development.** PATH completed a design concept for a low-cost molded UBT. This served as the basis for a preliminary prototype (see Figures 2 and 3 below) as well as for a first round of cost analysis. A bill of materials was compiled to capture the goal of lowest cost including volume discounts and simplest functionality to ensure ease of use and acceptability (see Appendix B). We assembled proof-of-concept prototypes for the first round of user assessments.
Figure 2. Low-cost UBT design concept components: Luer lock valve, latex tube, attachment, and dipped latex balloon.

Figure 3. Low-cost UBT design concept assembled (not inflated).

At least four candidate materials were considered and evaluated. The cost of materials drove the PATH balloon to be manufactured using latex. The Table 2 below outlines the cost of materials for the balloon component.
Table 2. Cost of balloon components.

<table>
<thead>
<tr>
<th>MATERIALS</th>
<th>COST (US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Latex</td>
<td>$2.00</td>
</tr>
<tr>
<td>Nitrile</td>
<td>$4.00</td>
</tr>
<tr>
<td>Thermoplastic polyurethane</td>
<td>$10.00</td>
</tr>
<tr>
<td>Silicone</td>
<td>$40.00</td>
</tr>
</tbody>
</table>

Once the decision was made to proceed with a latex balloon, four aluminum dipping mandrels (see Appendix C) in the shape of the balloon were made and shipped to California. A California-based company that specializes in short-run production for gloves and industrial applications was commissioned to produce 40 dipped balloons. The dipped balloons were tested for wall thickness, performance, and material integrity (deformation) following various levels of inflation (see Figure 4 below). After being tested, the dipped balloons were assembled and prepared for further testing and for user input.

*Figure 4. Dipped balloons after inflation testing and wall thickness testing.*

4. Prototype assembly fabrication. Ease of use of the UBT assembly was one of the primary design criteria for this project. A properly assembled condom catheter works effectively, however the thin wall of the condom creates problems with durability. Additionally, tying the condom to the latex tubing can be difficult and cause leakage if not properly accomplished. The goal for the PATH UBT is to have a fully assembled device that is ready for use immediately upon removal from its packaging. Figure 5 shows a fully assembled UBT.
5. Packaging concepts. Packaging is an essential part of the design concept, affecting cost as well as durability and shelf life, but usually comes at later stages of the technical development plan. Our team however, did spend some time thinking about the potential packaging options, tried to identify optimal concepts, and collected very preliminary cost estimates. One packaging option is envisioned as a simple vacuum thermoformed tray. The tray could have two compartments, one for the preassembled UBT device and the second compartment for the 60 mL inflation syringe (see Figure 6). Instructions for proper and safe use would be attached to the tray cover and would be very visible to the providers once the box was opened. Additionally, to accommodate and preserve the integrity of the latex portions of the device, especially to meet the requirements for hot climates, the packaging will need to maintain an impermeable barrier to prevent material degradation. User feedback will be a critical part of determining packaging and may be driven by several factors such as size and shape of packaging, durability, cost, and usability.

Figure 6. Package/container for the fully integrated UBT and filling syringe.
In-country user assessment and stakeholder consultation activities

These activities included the following:

- Gathered expert opinions from providers, specifically obstetricians and gynecologists with knowledge of the concept of using a tamponade for the management of PPH and familiar with use of uterine balloons for tamponade. This activity guided the first stages of conceptualization and primary contextualization as the key design features and product requirements were selected.
- Gathered user input in Ghana to collect their views on optimal design and cost for developing-country applications. User feedback on the most effective approaches to balloon tamponade scale-up, adoption, introduction, and integration into existing health systems was also sought.
- Convened a gathering of key expert stakeholders for discussions on the critical steps necessary to ensure that an affordable balloon tamponade advances toward commercialization and large-scale impact.

User and expert feedback was collected during the last six months of the project. Input from experts helped guide refinements to the design concept and identified some of the outstanding technical and programmatic issues that will affect wider adoption and inclusions into national guidelines. Ghana was chosen for the field and user assessment because UBTs are being used in health facilities, Ghana has several stakeholders that are championing the use of UBTs, and Ghana Health Services is very supportive of and interested in this technology. The Ghana Ministry of Health (MOH) has conducted several training workshops aimed at midwives and physicians on use of UBT as a second-line intervention.

Summary of work conducted

In-country user assessment and stakeholder consultation resulted in the following three components:

1. Initial design feedback and technical consultations with obstetricians and gynecologists.
2. Field input on design concept from providers in Ghana and Uganda.
3. Discussion and consultation with maternal health experts and stakeholders to elicit targeted feedback on design as well as on programmatic issues.

1. Initial expert consultation for design feedback. A list of pertinent questions was compiled for the first round of expert consultations. The interviews were conducted after the evaluations of all the devices had been completed, and some outstanding issues remained unanswered (see Appendix D). The questions and answers served to define and refine the functional product requirements and technical specifications. The key findings from the first set of interviews are as follows.

- The underlying mechanism of action of UBT is not very well understood. How the tamponade effect is achieved is still unclear. While it could work by compression action, the device might also cause some irritability in the uterus that causes it to contract. The question of whether this was important to know was also discussed, and in most cases experts agreed that while it might be good to know it is also not clear whether it affects the efficacy of the intervention; so far the evidence indicates it might not. More research could be used around this topic.
A drainage tube was not seen as necessary by the majority of respondents. In fact in more instances than not, the drainage channel gets blocked and could result in the false notion that the bleeding has stopped.

There is no predefined volume or pressure needed to achieve tamponade—each uterus is different and each case will require a different volume. The only way to determine the right amount of volume to fill in the balloon is by using a clinical test that involves a visual inspection and observation of the bleeding from the opening of the cervix. While most uterine balloons are designed to be filled to 500 mL, most cases report use of anywhere from 250 mL to 350 mL with successful tamponade.

The methods of fill varied depending on the environment and the availability of syringes and or infusion sets. The silicone balloons are stiffer and thicker and would be harder to use with a gravity fill mechanism.

Ease of insertion during a severe PPH can be facilitated by a device that has a slighter stiffer tube.

Contact with the walls of the uterus is assumed to be important to the effectiveness of the device. A balloon shape that approximates the shape of a uterus would be beneficial.

2. Field input on design concept from providers in Ghana and Uganda. PATH conducted a series of interviews in Ghana and Uganda. The interviews were preceded with a short description and demonstration of how the low-cost prototype works. The demonstration was followed by an interview for which a discussion guide was developed (see Appendix E). The demonstrations and discussions with clinicians were very productive. Overall, providers and stakeholders in both countries stated that the design concept we showed them seemed simple and easy to understand and use. Many expressed the need for such a device and the desire to participate in future pilot demonstrations. The interviews provided some key input that resulted in a few more design changes.

Eight experts representing various professional organizations and institutions were contacted in Ghana. A list of participants is included in Appendix F. Four interviews were conducted with stakeholders in Ghana and a meeting was held with Ms. Salamatu Futa at the USAID mission in Ghana. In Uganda, a PATH team conducting interviews with maternal health providers and experts on a different topic opportunistically collected some information about the low-cost UBT for this project. Six people were interviewed. In both countries special care was given to identify experts in maternal health care and representatives of key professional organizations such as the national organization of obstetricians and gynecologists and the midwifery organizations.

Below are key findings from the interviews.

Overall design

- All stakeholders liked the integrated unit design of the device (no assembly required, as is the case with the condom catheter tamponade).
- A prepackaged system is a big advantage and is perceived as very convenient.
- All experts agreed that the device seemed simple, straightforward, and easy to use.
- Several stakeholders noted that the balloon would be better if shaped like a pear (more in line with the shape of the uterus).
Generally, the grip on both the balloon and the tube felt secure and firm.
The thickness of the balloon was seen as an advantage over the thin condom and might help reduce slippage out of the uterus, making it easier to insert and keep in place.
Several experts suggested using an infusion bag instead of the syringe. Several physicians stated that this would free them up to tend to the woman’s other needs and not have to worry about filling.
A mechanism that allows for filling with either syringe or infusion would be most desirable in case facilities lack one or the other.
Most experts found the mechanism for securing the syringe with a one-way valve was a big advantage that would make it easier to use and may prevent leakage.
Everyone thought the device appeared to be high quality, but two of the experts had concerns about the balloon melting or the walls of the balloon sticking together—especially during storage in the heat—leading to the balloon tearing when inflated and inserted.

Cost

On average, stakeholders thought approximately 10 cedis (US$5.20) per device would be a fair cost, but 5 cedis (US$2.50) would be ideal.
Most experts stressed that it would be very important that the device be accepted by insurance and that it would be great to include in the Standard Treatment Guidelines issued by the MOH.
An affordable and easy to use UBT would reduce long-term costs incurred by governments and families if hysterectomies or other surgical procedures were to be reduced.
It is likely that the MOH and Ghana Health Services would purchase UBTs once they are approved by WHO.

Acceptability

A UBT can be easily and safely used by physicians and midwives, but would/could not be used by trained birth attendants.
Acceptability and widespread use of the device would be achieved if a group of physicians was trained and encouraged its use. Training would require use of an appropriate simulation model.
Introduction of the device would not add a huge burden on the system in terms of training and monitoring. Training needs to be hands on, and in-service refresher training would be needed.
For in-service, it could be easy to leverage trainers, and trainers would need to work with the country Private Midwives Organization and the Association of Obstetricians and Gynaecologists.
Buy-in by the government as well as professional organizations and the private sector is key to adoption and acceptance.

Adoption

Present at the Maternal and Child Health cluster meetings at the MOH.
Need the MOH to put the products in the essential package of medicines, suppliers, and devices that are sent to each health facility that has deliveries.
Also need to work with the private, not-for-profit health facilities that have a fair amount of influence.

3. Discussion and consultation with maternal health experts and stakeholders to elicit targeted feedback on design as well as on programmatic issues. This was the final round of consultations that was meant to bring together some key experts that have championed use of the UBT, who currently use the UBT in their practice, and who are very familiar with the challenges and requirements of developing-country settings. Two consultations took place; one with maternal health experts from around the world and another with USAID team leaders. Each discussion was one hour long. The discussions centered around three main topics: (1) technical design and specifications of a low-cost UBT, (2) levels of evidence needed to promote use globally and approaches to collecting clinical evidence, and (3) other potential activities that would support wider adoption and introduction.

The following key issues were discussed:

- Characteristics of the balloon: the size of the balloon was seen as important; larger balloons or size 9 gloves have the capacity to expand and fill the entire uterine cavity. The thickness of the balloon is somewhat related in that a soft balloon is more easily filled—especially if gravity fill is being used. In addition a soft balloon does not need to be stretched, and the thinner walls of soft balloons allow it to confirm more easily to the walls of the uterus. Both condoms and gloves work well and can be used as a good reference when determining materials. A balloon that is shaped more like a uterus (pear shape) may offer an added advantage.

- Volume and pressure requirements: general consensus was to conduct the “tamponade test” which involves incrementally adding fluid into the balloon until the bleeding is arrested. This can be further ascertained by visual inspection of the cervix.

- Pressure could be an important factor to consider, and some experts believed it is more critical than volume. Their approach is to suspend an infusion bag about 1 meter above the woman to maintain intrauterine pressure at about 75 mm Hg. An animal study of pressure levels could help answer this question.

- An outlet draining valve is not necessary and may lead to a premature assessment of stoppage of blood if the drain gets obstructed, which is quite common.

- Mechanism of action, while still not clear, should be understood and may warrant some animal tests to help clarify.

- A device that you can pull out of a pack and use immediately in an emergency PPH would be the preference of most providers. However, several experts pointed out that components such as gloves and condoms are readily available in most places in developing-countries for tamponade.

- Keeping the balloon in place was briefly mentioned. Vaginal packing is still practiced in some cases to prevent the balloon from migrating out. Other approaches to prevent this are cerclage of the cervix. The group did not discuss possible design modifications that might prevent this from happening, and this may be a question to pursue during the next round of consultations and design refinements.
• In principle, the panel was in agreement that clinical evidence is lacking and is needed but also acknowledged the difficulty in conducting randomized control trials. There will always be a certain amount of doubt and skepticism until there is more definitive clinical data to support use of UBT as a second-line intervention. Different study designs should be investigated that might be more feasible and may be more acceptable from an ethical standpoint.

• Target end-users: who are they and who should they be? For the intervention to be most impactful it must be used where the need is greatest, at the more peripheral facilities where the majority of women in developing countries seek care and where options are more limited. Concerns about use by providers at lower levels of the health system and ensuring adequate level of training and support must be addressed.

• A registry to gather data on a large cohort and build a large case series may be worthwhile in the interim. This could be set up relatively rapidly. Funding for such an effort would be needed but not expected to be prohibitive.

• The International Federation of Gynecology and Obstetrics (FIGO) will be forming a committee during the FIGO General Meeting in Rome in October 2012 to develop and issue a technical bulletin on UBT use.

Conclusions

The project achieved the goals it had laid out within the 12 months allocated for the scope of work. A design concept for a low-cost UBT was completed, and a preliminary list of product specifications was developed. In addition, PATH conducted a preliminary analysis of manufacturing approaches and related costs. The design was modified over the course of the project to incorporate feedback from maternal health experts from around the world. We have created a detailed technical plan and a comprehensive packet of materials that will be critical to moving to the next stage of development and validation. In addition, through the consultations and interactions with providers, PATH has developed contacts with key professionals and experts globally who have expressed a strong interest in collaborating on building evidence around UBT use. Moving this project forward to the next level would involve working with technical partners and users to refine and finalize the design, identifying commercialization partners, and conducting implementation studies. Funding for randomized clinical trials will also be explored. It is expected that a technology transfer activity will occur in India in the next two years, supported by market studies in India and Africa.

Appendices

Appendix A—Uterine Balloon Tamponade Mechanical Testing

Appendix B—Medical-Grade Assembly Components Selected for Connecting the Balloon to the Syringe

Appendix C—Dipping Mandrels

Appendix E—Uterine Balloon Tamponade Interview Guide—Ghana and Uganda

Appendix F—List of Experts and Stakeholders

References


Appendix A

Uterine Balloon Tamponade Mechanical Testing

Figure 1. Bakri balloon burst test—inflated with 2,300 mL water.

Figure 2. Glove balloon—inflated to 500 mL.
Figure 3. Condom catheter filled with 500 mL.
Appendix B

Medical-Grade Assembly Components Selected for Connecting the Balloon to the Syringe

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<th>Number</th>
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<th>Description</th>
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<td>Piercan</td>
<td>PATH/TCE custom-dipped balloon</td>
<td>1-way Hi-Flow Stopcock; female Luer lock to male Luer spin lock</td>
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Total: $14.576 $7.116 $3.869
Appendix C

Dipping Mandrels

Figure 1. Aluminum dipping mandrels.

Figure 2. Tooling for mandrels.
Appendix D


1. How important is the blood drainage feature on UBTs?

2. How long does the drainage feature typically function during a PPH episode?

3. For developing-country applications, is a catheter required, or can tubing, a stopcock, and a condom be used alone? (lowest-cost option)

4. Why is there a 500 mL fill limit on the medical devices?

5. What is the mechanism of action (pressure, irritation that induces contractions, temperature differential, other?)

6. Are there issues with latex that we need to be aware of?

7. Is shape of the balloon important? How about the shape of the uterus?

8. What are the dimensions of a postpartum uterus? Are they different for a atonic uterus?

9. How important is placement of the balloon in the uterus? Is there “proper” placement?
Appendix E

Uterine Balloon Tamponade Interview Guide—Ghana and Uganda

1. Overall impressions of design:
   - Is it an improvement over condom balloons?
   - What do they like or dislike about this design?

2. Are there any features they would change? Which ones? How?

3. Probe on the following:
   - Filling mechanism
   - Tubing—stiffness
   - Materials in general—latex, silicone
   - Thickness of balloon
   - Other

4. What would they estimate to be a fair price for the device? Who would pay? The health system or patient? Issues around training:
   - Concerns?
   - How would they envision training on use?
   - How often?
   - Management vs. treatment?
   - How do you get a new intervention into the national training curriculum?

5. Who would/could use it?

6. What do they see as the barriers or challenges to adoption for each group?
   - Physicians
   - Midwives
   - Trained birth attendants

7. Which key stakeholders buy-in do you feel is important for country adoption?

8. What do you see as the advantages and disadvantages of the uterine balloon tamponade when compared to the non-pneumatic antishock garment? Do you think one is more appropriate for certain conditions than the other?

9. Other?
Appendix F

List of Experts and Stakeholders

One-on-one interviews with providers and stakeholders in Ghana and Uganda

- Dr. Paul Cooper, Head Medical Officer, St. Martin de Porres Hospital, Accra, Ghana
- Dr. Sylvia Degnus, Obstetrician and Gynecologist in Charge, Tema General Hospital, Accra, Ghana
- Dr. Charles Fleischer-Djoleto, Representative of the World Health Organization’s (WHO’s) Regional Office for Africa.
- Joyce Jetuah, President of the Ghana Registered Midwives Association of Ghana
- Dr. Frank Kahuruza, Association of Obstetricians and Gynecologists of Uganda
- Dr. Osinde Michael, Hospital Director, Jinja Regional Referral Hospital, Uganda
- Sarah Namyalo, Reproductive Health Trainer, Uganda Private Midwives Organization and Registered Nurse Officer in Charge, Kikajjo Maternity Home, Uganda
- Dr. Miriam Ssentongo, Senior Medical Officer, Ministry of Health, Reproductive Health, Uganda
- Dr. Jennifer Wanyana, Principal Medical Officer, Ministry of Health Reproductive Health, Uganda

Interviews with key experts

- Dr. Susan Briggs, trauma specialist, Harvard Medical School, Boston, MA
- Dr. Melody Eckhardt, Obstetrician and Gynecologist, Massachusetts General Hospital (MGH), Boston, MA
- Dr. C. Gerorgiou Medical School University of Wollongong, New South Wales Australia

Conference call with panel of experts

Attended

- Jill Boezwinkle, USAID
- Adam Clark, JPHIEGO
- Dr. Melody Eckhardt, MGH
- Dr. Justus Hofmyer, University of the Witwatersrand, South Africa
- Dr. Andre Lalonde, the International Federation of Gynecology and Obstetrics (FIGO)
- Dr. Matthews Mathai, WHO
- Nathaniel Moller, JPHIEGO
- Joe Wilson, USAID
- Dr. John Ye, USAID

Invited but unable to attend

- Deb Armbruster, USAID
- Dr. Sabaratnam Arulkumaran, UK/FIGO
- Neal Brandes, USAID
- Dr. Sylvia Degnus, Ghana, Tema Hospital
- Unja Hayes, USAID
- Marissa Leffler, USAID
• Dr. David Milestone, USAID
• Ahmed Mohib, USAID
• Dr. Harshad Sanghvi, JPHIEGO
• Mary Ellen Stanton, USAID