End to End Development of an Innovative regulated Affordable Uterine Balloon Tamponade for the Management of Post-partum Hemorrhage
Addressing a critical gap in maternal health in low-resource settings.

WHO 3rd Global Forum on Medical Devices - Geneva
May 10, 2017
Elizabeth Abu-Haydar, PATH
eabuhaydar@path.org
Chris de Villiers, Sinapi biomedical
chrisd@sinapibiomedical.com
May 10, 2017 workshop agenda
10:00-10:45 AM

- Introductions.
- Key objective of the workshop.
- Describe our process, approach, and tools for developing an innovative and affordable uterine balloon tamponade (UBT) for the management of postpartum hemorrhage (PPH).
- Demonstrations and hands-on with the medical devices.
- Input from participants.
- Summary and questions.
Goal and objectives

Goal of the project
To ensure greater access to and availability of a safe and affordable UBT for maternal health programs in countries where PPH claims thousands of lives a year.

Objective of the workshop
To describe our process of development of the Ellavi UBT from initial research all the way to planning for introduction and scale-up.
Technology evaluation criteria

**Public Health Problem**
Are we solving the most critical health problems?

**Technical Feasibility**
Does the technology have overwhelming advantages and the possibility of meeting target specs?

**Economic Rationale**
Does the technology have value for money?

**Market Sustainability**
Does a market exist in both the public sector as well as the private sector?

**Policy Environment**
Is the technology likely to be supported by policymakers?
The problem: Postpartum hemorrhage is the leading cause of maternal death and disability

PPH contributes to more than 115,000 maternal deaths a year.

- PPH can happen to any pregnant woman. It can kill a woman in less than 2 hours.
- Each year, more than 10 million women with uncontrolled bleeding from PPH are at risk of death and severe morbidities.
- Women who survive a severe PPH suffer long-term effects.

The majority of these deaths are preventable if adequate and timely emergency obstetric care is provided.

In Ghana, Vivian Badu lost her sister to excessive bleeding after childbirth. Pictured is her sister’s son, for whom she now is responsible, along with her own six children.
The management and treatment of PPH: Identifying the need

- The majority of cases of PPH occur due to uterine atony—failure of the uterus to contract and retract following delivery of the baby.

- Severe PPH requires immediate management. Obstetric surgical capabilities are often lacking and emergency transportation is expensive and limited in low-resource settings.

A gap in management options exists

UBT is a safe, effective, and conservative intervention to control bleeding before surgery takes place.
Global guidelines

• The WHO Guideline Development Group acknowledges: balloon tamponade is a lifesaving device that is recommended for the treatment of PPH due to uterine atony.

• It should be used if women do not respond to treatment using uterotonic drugs, or if uterotonics are unavailable.
UBT: An effective tool for managing severe PPH

The Ebb balloon

- Balloon filled with water inserted into the uterus.
- Exerts pressure on the uterine cavity.
- Causes tamponade.
- Stops bleeding within 5 to 15 minutes of insertion.

The Bakri balloon

Condom catheters
The glove balloon

A Monograph of the Management of Postpartum Haemorrhage

Photo: Professor Gerhard Theron
Filling the need for a low-cost, safe, and effective regulated medical device

Key considerations
- Safety.
- Ease-of-use.
- Alignment with recognized guidelines.
- Potential marketability.
- Cost.
- Clarity of a regulatory or clinical pathway.
- Country readiness and policy.
- Distribution systems.

**Photos:** PATH/ Erica Jacoby and Patrick McKern
Developing the Target Product Profile: Triggers to think about when defining design, needs, wants, and use cases

<table>
<thead>
<tr>
<th>Who</th>
<th>Target user? Stakeholders?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What</strong></td>
<td>Pain points? Price?</td>
</tr>
<tr>
<td></td>
<td>Function? Features?</td>
</tr>
<tr>
<td><strong>When</strong></td>
<td>Timing of use? Process?</td>
</tr>
<tr>
<td><strong>Where</strong></td>
<td>Place? Health post? Tertiary hospital?</td>
</tr>
<tr>
<td><strong>How</strong></td>
<td>How is it used? Resources?</td>
</tr>
<tr>
<td><strong>Why</strong></td>
<td>Rationale? Personal experience?</td>
</tr>
<tr>
<td></td>
<td>Safety? Easier to use?</td>
</tr>
</tbody>
</table>
The development process

- Input on needs was obtained by PATH, Sinapi biomedical, and the Global Health Innovation Accelerator – from experts, providers, and key stakeholders worldwide.
- Product specification workshops were held and included midwives from Kenya, obstetricians and gynecologists, policymakers, and engineers (Like- Wish- Wonder).
- Shortcomings and future requirements were discussed.
- Detailed Target Product Profile was determined.
Designing the solution

• Balloon must be simple and intuitive.
• Safety to patient and health care worker is essential.
• Cost needs to be low considering the low-resource settings for which it is designed.
• Training needs and disruption should be minimal.
• Ability to manufacture in volumes with correct quality requirements.
The UBT design

- Single balloon gravity fed (large diameter tubing with shut-off valve).
- Single balloon constant pressure reservoir system.
- Double balloon gravity fed (large diameter tubing with shut-off valve).
- Double balloon constant pressure reservoir system.
The UBT design

- External reservoir pre-connected to the balloon.
- Latex free, DEHP free, BPA free.
- Balloon mounted on soft catheter.
- Reservoir is filled and lifted higher than the patient to provide constant pressure.
- Change pressure by changing the height.
- Tap fitted to close and maintain constant pressure during patient transport.
UBT – Prototypes

- Reservoir Bag
- Stopcock valve
- 1.8m tube
- Balloon
Building evidence to support decisions

**Clinical evidence**
- UBT – Case series presently conducted.
- A central hospital and 3 district hospitals:
  - Enrolled 10 women.
  - 9 successes (6 profuse hemorrhages immediately arrested).
  - 1 failure (a commercial device also failed); bleeding arrested with compression suture.

**Cost-effectiveness analysis**
- Conducted in Kenya in 2015.
- Shown to be highly cost-effective if priced at less than US$15.

**Modeling impact**
- Looking at penetration, utilization, and efficacy.
- Modeled for the year 2018 in sub-Saharan Africa – 6,547 mothers can be saved; 11% reduction in mortality; 11,000 hysterectomies averted.
The way forward

- 50 prototypes delivered before end of the year.
- CE Mark registration by end of 2017.
- Marketing materials developed and will be widely used and disseminated.
- Hope to receive funding for additional clinical demonstration studies to expand understanding of use case scenarios.
- Professor Theron and team are ready to start the next study – outlay already done.
- Funding is being sought to commercialize in 2018:
  - Molds.
  - Assembly equipment.
  - Marketing material/media.
  - Marketing plan including trade shows, travel, samples, etc.
Technology evaluation tools

<table>
<thead>
<tr>
<th>Technology Evaluation Tools</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gap</strong></td>
<td>Gap-filling potential for health</td>
</tr>
<tr>
<td><strong>Technology Performance</strong></td>
<td>Clinical evidence (efficacy/effectiveness)</td>
</tr>
<tr>
<td></td>
<td>Safety (patient/health care worker)</td>
</tr>
<tr>
<td></td>
<td>Ease of use</td>
</tr>
<tr>
<td></td>
<td>Usage requirements (e.g., durability, shelf life, electricity, storage temperature)</td>
</tr>
<tr>
<td><strong>Enabling Factors</strong></td>
<td>Alignment with internationally recognized guidelines (e.g., WHO, FIGO, and ICM)</td>
</tr>
<tr>
<td></td>
<td>Donor financial support (product development or implementation)</td>
</tr>
<tr>
<td></td>
<td>Other non-financial support</td>
</tr>
<tr>
<td></td>
<td>Acceptability profile</td>
</tr>
<tr>
<td></td>
<td>Merck/PATH capabilities</td>
</tr>
<tr>
<td><strong>Market Analysis</strong></td>
<td>Manufacturing costs</td>
</tr>
<tr>
<td></td>
<td>Distribution system requirements (warehouse, cold chain, transportation factors)</td>
</tr>
<tr>
<td></td>
<td>Manufacturing plan established</td>
</tr>
<tr>
<td></td>
<td>Target setting (community, primary health care, hospital)</td>
</tr>
<tr>
<td></td>
<td>Target provider/administrator</td>
</tr>
<tr>
<td></td>
<td>Potential multiple markets (additional value to the health care system)</td>
</tr>
<tr>
<td></td>
<td>Technology readiness level (clinical/regulatory development)</td>
</tr>
<tr>
<td></td>
<td>Cost of clinical development</td>
</tr>
<tr>
<td></td>
<td>Clarity of regulatory/clinical pathways</td>
</tr>
<tr>
<td><strong>Unique Considerations</strong></td>
<td>System requirements (disruption)</td>
</tr>
<tr>
<td></td>
<td>Product bundling</td>
</tr>
<tr>
<td></td>
<td>Other</td>
</tr>
</tbody>
</table>
## A closer look

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Gap</td>
<td>Gap Filling Potential for Health PPH</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Technology Performance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Safety</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ease of Use</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Usage Requirements</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enabling Factors</td>
<td>Alignment with Internationally Recognized Guidelines</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Donor Financial Support ( Millions)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acceptability Profile</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Merck / PATH Capabilities</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacturing Costs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distribution System Requirements</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target Provider / Administrator</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potential Multiple Markets</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Technology Readiness Level</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost of Clinical Development ( Millions)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clarity of Regulatory / Clinical Pathway</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Market Analysis</td>
<td>System Requirements (Disruption)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unique</td>
<td>Product Bundling</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Legend:**
- HIGH
- MED
- LOW
The PATH/Sinapi partnership

- Good example of a successful private-public partnership.
- Greatly benefits both parties.
- Exposure to see in how much detail PATH approaches projects.
- Able to make use of international network of the PATH team and South African expertise in biomedical design.
- Clear understanding of and respect for the value proposition to each party.
- We have access to a local office/contact person to work with/call when needed.
Participant input

Challenges to introduction and scale-up of the UBT.

Opportunities for introduction and scale-up of UBT.
Save one mother’s life and you have made an impact on generations

Thank you!

The UBT has received support from United States Agency for International Development, The Health Innovation Portfolio, private foundations, and individual donors. PATH has no conflict of interests; we have no financial stake, nor will we have any financial gain from this project.

Visit us in Exhibit Hall at NW9

Photo: PATH/Gabe Bienczycki