HUMANITARIAN INNOVATION FUND
Final Report

Organisation Name	Massachusetts General Hospital, Division of Global Health & Human Rights, Department of Emergency Medicine

Project Title	**Ultra-Low Cost Uterine Balloon Tamponade Package for Management of Postpartum Haemorrhage in Post-Conflict Informal Settlements**
Problem Addressed / Thematic Focus	Avoidable maternal mortality due to PPH | Optimize, deploy, and evaluate a best-evidence postpartum haemorrhage package with an integrated low-cost uterine balloon tamponade (UBT) for maternal health workers across informal, resource-limited settlements in Sierra Leone
Location	Freetown-Western Area catchment, Sierra Leone
Start Date	July 2014
Duration	26 months
Total Funding Requested	£149,986

Partner(s)	Ministry of Health and Sanitation of Sierra Leone, Massachusetts General Hospital, University of Sierra Leone, World Vision
Total Funding	£149,986 from HIF

Innovation Stage	Implementation
Type of Innovation	Product Innovation
Project Impact Summary	ESM-UBT implementation across informal settlements in Sierra Leone can reduce maternal morbidity and mortality related to postpartum haemorrhage, which in turn can lead to improved outcomes for the post-conflict community as a whole.

Reporting Period	July 14th, 2014 – September 10th, 2016
Total Spent *	£149,986+

**Due to brexit and fluctuations in USD/GBP exchange rate, we are currently overspent on the grant if we use the exchange rate as of grant completion (pending adjustments to make up for this deficit). See attached financial reports.*

PROJECT ACTIVITIES AND OUTPUTS

What have been the key achievements of the project?

Background

Postpartum hemorrhage (PPH) is the most common cause of maternal morbidity and mortality in developing countries. More than 30% of all maternal deaths are attributable to PPH, accounting for approximately 130,000 deaths each year, with an additional 2.8 million suffering from PPH-related disability.[i,ii] Currently, there is a lack of accessible and effective options in resource-limited settings to treat PPH when bleeding is uncontrolled by initial interventions, such as removal of the placenta, uterine massage and compression, uterotonics, and repair of perineal tears.[iii] Options for managing uncontrolled PPH in well-resourced settings also balloon tamponade using an expensive Bakri balloon, arterial embolization, and surgical treatments such as bilateral uterine artery ligation, B-Lynch sutures, and emergency hysterectomy.[iv,v] However, these options are rarely available in resource-limited settings, and even when available in some hospitals, still the majority of women deliver outside of these surgically equipped facilities and may die during transfer to a hospital.

In these low-resource settings, efforts are underway to find new effective treatments that can be applied in lower-level, non-surgical facilities where the great majority of births take place. Uterotonics, where available, can often be applied but may fail. Surgical interventions, although they can be effective, are risky, only accessible at higher levels of care, and are generally not available to haemorrhaging women in time to prevent death or injury. Additional options for managing PPH are urgently needed, particularly in resource-limited settings where immediate access to surgical interventions is severely limited.

The Every Second Matters for Mothers and Babies - Uterine balloon tamponade (ESM-UBT) device was designed in an effort fill this critical need by providing a very simple, rapid, *affordable*, and effective point-of-care method to manage PPH.[vi] Using the principals of the more expensive Bakri balloon, ESM-UBT is comprised of a condom, tied to the end of a foley catheter which is then placed within the uterine cavity and inflated with water to achieve tamponade against the bleeding uterine wall and thereby arrest bleeding. In most cases, UBT can stop the bleeding rapidly and no further intervention is required. In cases of intractable PPH, it reduces bleeding while further intervention is sought, thereby reducing risk of death.

Uterine balloon tamponade (UBT) is recognized by the WHO, International Federation of Gynecology and Obstetrics, American College of Obstetricians and Gynecologists, Royal College of Obstetricians and Gynecologists, and International Confederation of Midwives as a method that may significantly impact management of PPH.[vii,viii,ix,x] While UBT devices such as the Bakri balloon have been used for emergency obstetrics in high-income countries since the 1980s and have received FDA clearance,[xi] the single-use proprietary uterine balloons used in these countries are prohibitively expensive for resource-limited settings, costing up to $400 per device. Thus the need for an affordable, easy-to-use uterine balloon device as this method can be applied in facilities without surgical capabilities and can provide an effective option for treatment of refractory PPH.

The intervention

The ESM-UBT project in Sierra Leone was designed to evaluate the effectiveness and safety of an ultra–low cost UBT package for facility-based management of uncontrolled postpartum haemorrhage. At Massachusetts General Hospital (MGH), we developed this condom-catheter UBT (less than US $5) that can be built from components readily available in developing countries. Our ESM-UBT device consists of a condom tied to a Foley catheter and inflated with clean water through a syringe and one-way stopcock. The ESM-UBT package involves skills-based training in PPH management including UBT use, checklists, reference materials and the ESM-UBT kits deployed in a facility-based package.

In collaboration with the Ministry of Health and Sanitation (MOHS) of Sierra Leone and World Vision, MGH implemented ESM-UBT in 105 health care facilities in the catchment area of Freetown in western Sierra Leone. Throughout the project, a total of 542 health care workers received training on the management of postpartum haemorrhage/ESM-UBT (training started in December 2013 supported by our SLAB UBT grant).

Impact

Fifty-two UBT uses were reported during the intervention despite the Ebola outbreak which began in late 2014 and essentially halted UBT use for several months. These 52 women had failed conventional PPH treatment short of surgery, 28 (54.9%) were in late stages of haemorrhagic shock by blood pressure and mental status changes including 2 who were unconscious and moribund. 23 (82.1%) of these women in advanced haemorrhagic shock survived with use of the UBT - a survival rate much higher than would be expected with on-going, severe haemorrhagic shock.[xii] Of the 52 recorded cases of UBT use, 45 women survived for an overall survival rate of 87%. Among the seven deaths, two patients were moribund before UBT placement, three patients were in a confused mental state due to advanced haemorrhagic shock, one had malaria and another had a bleeding diathesis at the time of kit placement. No deaths or complication related directly to the ESM-UBT use was identified.

Scholarly outputs

The results of UBT uses in Sierra Leone were combined with data from Kenya, Nepal, and Senegal in a case series of 201 UBT uses and an overall survival rate of 95% from uncontrolled PPH, which was published in 2015 in the *British Journal of Obstetrics and Gynaecology*.[xiii] During the duration of the HIF UBT project, using data from Sierra Leone combined with that from Kenya and other implementation sites, 13 papers were published in peer reviewed journals and 18 posters and oral presentations were delivered at international conferences including FIGO, Global Maternal and Newborn Health Conference, then Kenyan Obstetrics and Gynecological Society Meeting and Yale University's Global Health Innovation Conference.

UBT film

Medical Aid Films and Massachusetts General Hospital have collaborated to produce a short animated film to demonstrate the UBT technique to treat uterine haemorrhage in resource-poor settings. This film will be used to support training of health workers in how to assemble the UBT and improvise in the absence of a kit. We plan to widely distribute this in Sierra Leone, Kenya, Tanzania, Zambia and the US (to rural midwives).

What were the major activities and outputs of the project (this may include a description of the activities conducted and how they related to the work plan)?

The major activities we had planned for this project were: 1) to roll out a best-evidence package of training, commodities, and checklists for treatment of postpartum haemorrhage in Sierra Leone; and 2) monitoring and evaluation of UBT introduction and impact.

Activity 1a) ***Establish implementation design for UBT introduction at scale in Sierra Leone with the ministry of health and local stakeholders.***
Output: The planning/roll out of this project began prior to the start of the HIF grant through initial funding by the Ujenzi Charitable Trust and Saving Lives at Birth grant. Through the addition of HIF funds, the training of 105 facilities was designed and implemented on schedule, including the assembly and distribution of ESM-UBT kits and training materials. Direct leadership and involvement of the Ministry of Health – Dr. SAS Karbo, head of Reproductive Health at the time and members of his MOH team including Piti Kanu and Mohammed **Santigie Conteh – proved to be invaluable to early adoption and uptake in the facilities in Freetown. Due to direct ministry leadership and their decision to make ESM-UBT training a priority to reduce maternal mortality, facility staff responded quickly and enthusiastically in the adoption of UBT prior to the Ebola outbreak.**

World Vision was a key implementing partner in the continued training, facility surveillance and UBT data collection beginning in July 2014. Their role became increasingly important in the project after the Ebola outbreak since the outbreak required the full attention of MOH staff.

Activity 1b) ***UBT training and device provision among providers in Sierra Leone***
Output: MGH faculty/staff provided the initial ToT trainings in Sierra Leone beginning in December of 2013, and attended and supported the subsequent trainings and facility visits led by the Ministry of Health UBT champions. In total, 105 health care facilities were trained and brought online; the large majority of which are at the community level in Freetown. ("Online" is defined as the state in which at least 85% of the healthcare providers at the facility are trained on ESM-UBT use, and the facility has ESM-UBT kits available 24 hours a day with wall charts in labor rooms and training materials on site for reference.) Training also included the Princess Christian Maternity Hospital (PCMH) which serves as the referral center for these community facilities. Dr. Koroma, an obstetrician/gynecologist and the Medical Director of PCMH, also played a strong supportive role of the ESM-UBT project in partnership with the Ministry. Among the 105 facilities, we trained 109 master trainers and 433 health providers in Sierra Leone on the ESM-UBT package. The MOH champions and in-country World Vision staff distributed the ESM-UBT kits to these facilities; the UBT kits were procured from MGH during the project period.

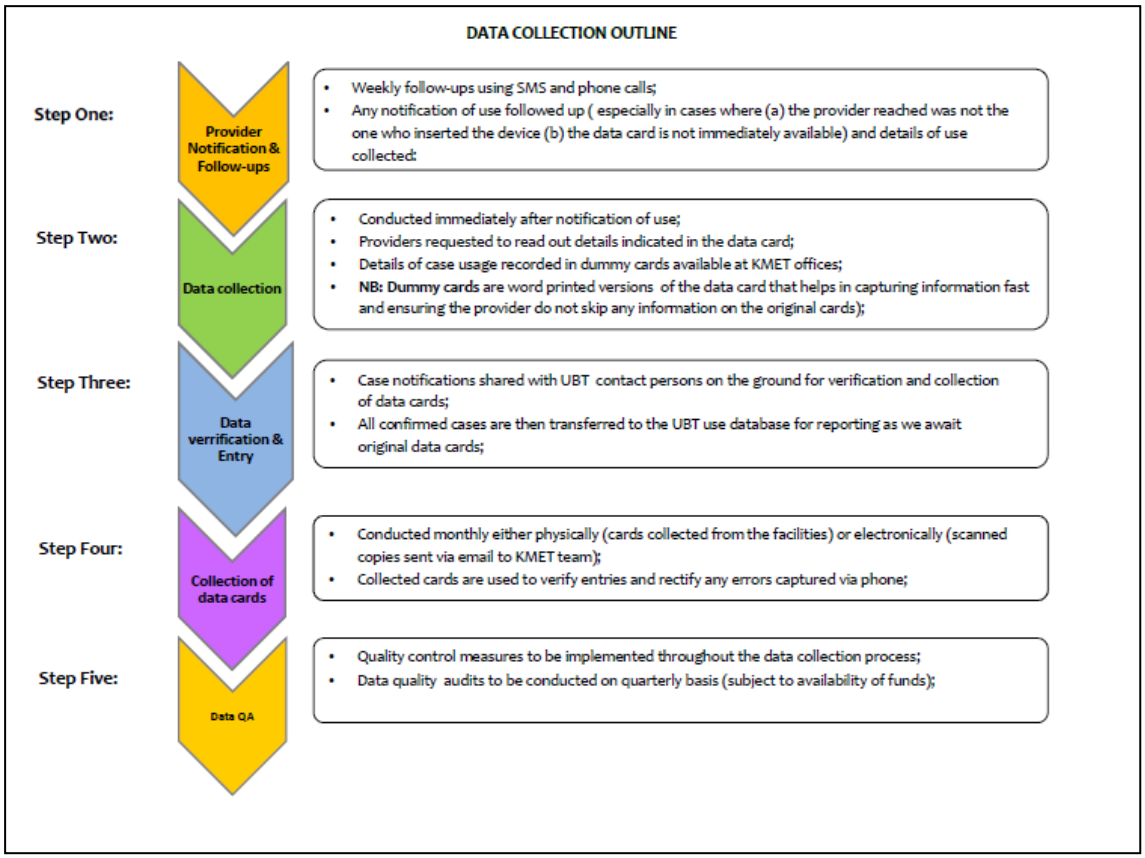
Due to the Ebola crisis, our project was put on hold after December 2014; no additional facilities were bought online and no additional formal TOT trainings were performed. Due to the contact with blood, hands-on management of PPH was a high-risk activity for maternal health providers and without training or adequate supplies of personal protective equipment (PPE), UBT uses virtually stopped. Our Ministry of Health master trainers/champions were pulled from the UBT project to work on Ebola containment. World Vision, our in-country partner, however, continued site visits for data collection and provided technical support and on-site training intermittently. We were quite fortunate to have completed our initial ESM-UBT trainings in Sierra Leone prior to the outbreak, which gave us a tremendous head start on the project. As noted, initial acceptance and uptake of ESM-UBT was excellent.

When the Ebola crisis passed, MGH in collaboration with World Vision and the MOH conducted refresher trainings for old and new providers from the original 105 facilities. A great deal of turnover had occurred during Ebola so retraining was done systematically over a week in March 2016 by MGH, World Vision and MOH trainers. Subsequently, World Vision again conducted facility visits and surveillance completing training of staff, and assuring ESM-UBT materials and kits were available at these sites. The final number of facilities that were brought back online shortly after the refresher trainings was 103.

Activity 2) ***Monitoring and evaluation of UBT introduction and impact***
Output: We implemented a robust monitoring and evaluation system for this innovation project. We focused on research questions that assess the impact of ESM-UBT introduction on patient outcomes, facilitators and barriers to implementing UBT at scale, and safety and effectiveness of UBT use among facility-based providers. Our mixed-methods evaluation methodology included data collection on each use of UBT, plus semi-structured interviews and focus

group discussions with providers trained in ESM-UBT. Case data on each UBT use was collected from the target sites. UBT data collection cards were included in the UBT kits. These cards were completed by the health provider responsible for UBT placement and were completed immediately after the patient was stabilized and PPH had been arrested. Because PPH is not a common (i.e., daily) occurrence for a particular health provider, the potential time burden on the provider for completing the data cards was reasonable (15-30 minutes per UBT case). We did not incentivize data completion by the provider given ethical considerations and IRB guidelines. (In Sierra Leone, we had 2 World Vision FTEs funded by HIF, plus 2 from the MOH who assisted with UBT work. However, due to Ebola we had to cut back to 1 FTE and no MOH staff.)

The data collection cards documented kit tracking number, facility name, delivery date and time, steps in the PPH protocol taken before UBT placement, patient's mental status and blood pressure at time of UBT placement, steps taken after UBT placement, as well as outcomes including fever, need for maternal resuscitation or transfusion, surgery, and death. Additional space was provided for provider free-response comments. The UBT kits were numbered with a corresponding number on the data card that was in that kit. A central phone number was also printed on each kit, and the provider was instructed to call the number to notify the national nursing line in Sierra Leone of the UBT use and to coordinate collection of the data card. (This was later changed when the central number was overwhelmed by calls related to the ebola crisis.) The schema below shows our MGH team's data collection procedures. We have found that consistent follow up by our research team – via phone calls, weekly SMS texts, and direct site visits – is crucial to ensuring that accurate data are collected. All facilities were called or visited regularly (generally weekly) by World Vision staff to check for unreported UBT uses, encourage refresher trainings and training of new staff and replenish supplies.



We set up in country reporting systems and surveillance for each UBT use and weekly data reporting from the field teams in Sierra Leone to the MGH Research Team in Boston each Friday. A World Vision staff member entered information into the UBT database on a weekly basis after the in-country team confirmed the information on the data cards were complete and accurate. Weekly reporting to MGH included the number of UBT uses, number of facilities online, maternal survival outcomes, data on trainings (who/when/how many) and the updated, de-identified UBT registry. MGH held frequent phone calls and audits with the in-country team to ensure quality control in terms of the ESM-UBT data. This allowed the MGH team to build a case series database of ESM-UBT use, and ultimately document lives saved by our package.

Furthermore, we implemented an additional tool for safety surveillance. This was in response to the remarkably low complication rates that first year (none) and a concern that we could possibly be missing complications (such as infection) which may become evident after the patient left the facility, particularly if she did not return to the same facility for treatment of complications. A follow up tool was developed in which patients are contacted at 2 and 6 weeks postpartum and asked questions about fever, pain, return of bleeding and additional treatments they may have required in that postpartum period. Patients in our initial database were also contacted and questions were asked retrospectively to assure that, as much as possible, all complications or concerns would be recorded after ESM-UBT use. (See UBT safety manuscript attached.)[xiv]

Qualitative Studies

In Kenya and Sierra Leone, we conducted semi-structured interviews and focus group discussions with providers that have been trained in ESM-UBT, regarding the package's strengths, barriers to uptake, recommendations for improvement, etc. We interviewed providers from a wide array of trained facilities – stratified by geography, type of facility, delivery volume, and other important factors.

In Sierra Leone, we assessed the impact of the PPH/ESM-UBT training on adherence to the national PPH protocol and the use of uterotonics. One hundred and ninety-five interviews of providers at 86 peripheral health facilities were conducted in Sierra Leone. In Kenya, research focused on averted emergency hysterectomies, provider perceptions and experiences with ESM-UBT, and the use of improvised condom-based UBTs. (Please see manuscripts attached for more details.)

Below we summarize three of six UBT manuscripts (out of 18 total) that incorporated quantitative/qualitative data from Sierra Leone:

1) Between June 2014 and July 2014, we conducted a qualitative study entitled **Provider Experience of Uterine Balloon Tamponade for the Management of Postpartum Hemorrhage**. May 2014 – June 2014 qualitative semi-structured interviews were conducted of 61 providers in 47 of the original 50 facilities trained in the ESM-UBT program in Sierra Leone. (17 midwives, 19 maternal and child health aides (MCHA), 9 state-enrolled child health nurses (SECHN), 14 clinical health officers and 2 medical doctors). Themes from this qualitative study included: (1) Providers who inserted a UBT device found it to be a valuable tool to manage uncontrolled PPH. (2) The UBT device was easy to insert by providers at all levels of training. (3) The UBT device allowed providers to manage most cases of uncontrolled PPH at their own facilities and refer others in stable condition. (4) Reported barriers to optimal UBT use included insufficient training and practical experience and a scarcity of pre-assembled UBT devices. (5) Reported facilitators included widespread acceptance of ESM-UBT, comprehensive and enthusiastic trainings and ready availability of ESM-UBT devices.

   Published 2015 in the International Journal of Gynaecology and Obstetrics.

2) During the summer of 2014, the MGH study team conducted a complementary research study focused on understanding the **impact of the ESM-UBT training on use of uterotonics during the third stage of labor**. One hundred and thirty four providers were surveyed at 39 peripheral health facilities. Provider use of uterotonics was not adversely affected by ESM-UBT training, with higher rates of use among those who attended the training verse those who did not. Facility protocols, widespread availability and provider perception of the utility of uterotonics facilitated their use.

Published 2016 in BMC Pregnancy and Childbirth.

3) In 2016, we conducted a study to **evaluate the safety of the ESM-UBT for facility-based management of uncontrolled PPH** in Kenya and Sierra Leone. Data were collected on complications/adverse events in all women who had an ESM-UBT device placed among facilities in Sierra Leone and Kenya, between September 2012 and December 2015, as part of a multi-country study. Three expert maternal health investigator physicians analyzed each complication/adverse event independently and developed consensus on whether there was a potential causal relationship associated with use of the ESM-UBT device. Of the 201 women treated with an ESM-UBT device in Kenya and Sierra Leone, 189 (94.0%) survived. Six-week or longer follow-up was obtained in 156 of the 189 (82.5%). The study concluded that the ESM-UBT device appears safe for use in women with uncontrolled PPH.

   Manuscript submitted for review to British Journal of Obstetrics and Gynaecology

In addition to publications, we had several opportunities for presentations in national and international conferences and academic and professional society forums. Beginning on page 18, we list the academic presentation of abstracts and posters related to the UBT project in Sierra Leone since the start of the HIF grant. These include presentations at the Consortium for Universities for Global Health conference (CUGH), Massachusetts General Hospital Research symposium, International Federation of Gynaecology and Obstetrics (FIGO), and Yale University's Global Health Innovation Conference. We also delivered several presentations and hosted a plenary session on UBT (including findings from Sierra Leone) during the Kenya Obstetrics and Gynecology Society annual meeting in Kisumu in February 2016.

What adjustments and adaptations were made through the course of the project? Why were these needed and how were these made?
Please explain any budget various greater than 15% of the original budget headlines

This project had to make significant adjustments due to the Ebola crisis affecting plans for facility supervision and support for UBT use, hiring of in-country staff and continued refresher trainings. Project activities were extremely limited during the height of the outbreak because project staff could not consistently visit facilities after December 2014 until restrictions began to be lifted in June 2015. During this period, facility visits were extremely limited and research staff had to collect data and monitor the utilization of UBT kits at the health facilities over the phone. Throughout the Ebola outbreak, most health facilities would not use the kits because of fear of contracting Ebola and patient usage of health facilities services was extremely low. The Ebola crisis also negatively impacted health facility staffing due to health workers being moved to cover other needs, some facilities being converted to Ebola treatment centres, staff leaving healthcare jobs

and even loss of life of healthcare workers. As a result, few facilities were able to remain online with ESM-UBT.

The outbreak also caused challenges in local leadership/HR for the ESM-UBT project. MOH staff previously intimately involved with promoting the project, data collection and refresher trainings now had to focus entirely on Ebola. World Vision took over the majority of these tasks but experienced significant delays in hiring in-country staff members for the UBT project.

Additionally, planned surveillance had included use of the nursing hotline for UBT reporting. This hotline became entirely devoted to Ebola and UBT was no longer reported using this method. World Vision staff relied primarily on direct calls to/from facility champions for UBT reporting. However, few UBT uses were recorded during the outbreak as noted above due to fear of Ebola transmission.

In Sierra Leone, as the Ebola crisis continued, opportunity for refresher trainings was exceedingly limited. World Vision staff did provide technical support and some facility-based refresher trainings as able, but UBT was understandably not an MOH priority during this time (Dec 2014 – early 2016) despite consistent efforts to re-engage by the MGH team. After Sierra Leone was declared Ebola free in March 2016, refresher trainings were conducted in Freetown to retrain old and new providers at the original facilities to bring them back online.

Furthermore, we requested a 6-month no-cost extension given the ESM-UBT project was put on hold by the Ministry of Health for more than a year. Given our limited ability to conduct project activities during the Ebola outbreak, we were underspent and HIF approved the no-cost extension to complete the following activities after Sierra Leone was declared Ebola free in March of 2016:

1) Conduct refresher trainings and facility supervision/data collection post Ebola
2) Host a national stakeholders meeting in Freetown
3) Work with Medical Aid Films (based in UK) to develop a short animated training film to demonstrate the UBT technique to treat PPH in resource-poor/post-crisis settings

During the first week of March 2016, we trained/retrained 168 providers from 97 facilities in Freetown. These trainees were instructed to train fellow colleagues at their facilities. World Vision staff monitored the facilities and provided regular supervision. They also ensured all 97 facilities represented during the refresher trainings were brought back online and equipped with UBT kits, wall charts and user manuals.

The MOHS Director of Reproductive Health, Dr. Santigie Sesay, in collaboration with World Vision and MGH, hosted the national stakeholders meeting in Freetown March 3, 2016. The meeting was attended by MOHS officials, maternal health providers, various NGO reps (John Snow Inc, PSI, International Medical Corps, etc), World Vision and MGH staff. MGH presented the UBT data and findings to date from Sierra Leone, Kenya, Tanzania and other countries. After discussion, there was unanimous interest in national scale-up of UBT.

Discussions are currently ongoing with the MOH and USAID Mission regarding next steps.

Given the positive support we received in Sierra Leone and other countries for UBT expansion, we thought it would be an opportune time to use our project savings and collaborate with Medical Aid Films to develop a short UBT training film that demonstrates the UBT technique to treat PPH in resource-poor/post-crisis settings and reach those we are unable to with in-person trainings. This film will be used to support education of health providers in how to assemble and use the UBT and improvise in the absence of a UBT kit. This film has been completed and will be widely distributed in Sierra Leone, Kenya, Tanzania, Zambia and US (to rural mid-wives).

The UBT training film can be accessed using the below link:
http://www.medicalaidfilms.org/film/uterine-balloon-tamponade/
(password: ubt2016)

Note, due to Brexit and fluctuations in GBP/USD rate, we are overspent on the grant if we use exchange rate as of Nov 2016. We are making adjustments to make up for any deficit.

INNOVATION AND LEARNING

What were the outcomes of the project (positive or negative) and how did these follow from activities and outputs described above?
Outcomes of the project were mixed due to Ebola, but generally positive. We were able to replicate the success of our program in other countries, and our calculated survival rate of 87% was acceptably similar to other programs (the women who did not survive presented at advanced stages of shock or were comorbid; deaths were unrelated to UBT use). We would certainly have preferred more opportunities for UBT use in Sierra Leone, but due to Ebola this was not possible. Nevertheless, based on our multicounty UBT case series data (including Sierra Leone), we have been able to demonstrate the following. **If a mother is uncontrollably hemorrhaging:**

- The ESM-UBT device will arrest the hemorrhage nearly 100% of the time.
- All levels of providers are able to place an ESM-UBT device.
- She has a 100% survival if the ESM-UBT device is placed before she succumbs to advanced shock. And, shock progression halts.
- She has a 97% chance of survival if the ESM-UBT device is placed while in stage 3 hemorrhagic shock.
- She has an 86% chance of survival if the ESM-UBT device is placed while in stage 4 hemorrhagic shock.
- She has an 84% overall survival if the UBT that is placed is improvised.
- The ESM-UBT device definitely averts hysterectomy. (Kenya/Senegal data only)
- The ESM-UBT device is safe at two and six week follow-up.

Through our qualitative research, we learned introduction of the ESM-UBT did not have a negative impact on quality PPH care using advanced management of the third stage of labor (AMTSL) and appropriate uterotonic treatments where available. Based on provider surveys, we found that the UBT device was a valuable, well accepted, and easy-to-use tool that can be incorporated into the existing PPH management protocol by providers of all levels of training. Overall, most providers who used UBT devices reported that it was useful in minimizing blood loss, served as an endpoint to bleeding, and reduced the number of referrals to higher-level facilities.

Some discomfort and dislike of having the UBT in place for several hours was reported in 16 patients, but all were able to tolerate keeping the UBT in place until it was no longer needed and bleeding had stopped. In 3 cases, the UBT became dislodged and fell out of the uterus. In one case, unfortunately, that occurred in transport to the hospital and the patient died shortly after arrival. In another, the bleeding had stopped and UBT did not need to be replaced. This issue of UBT dislodgement has lead to a current research project we are conducting in Tanzania looking at the use of a holder for the catheter attached to the thigh area of the woman with UBT placed to see if it will decrease the risk of dislodgement.

Safety data were collected in 80% of UBT patients in Kenya and Sierra Leone out to 6 weeks post partum and revealed no complications, adverse events or death after discharge from the hospital. There was no incidence of post-partum endometritis in the Sierra Leone follow up data and only one in Kenya out of 156 total patients followed out to 6 weeks.[xv]

The experience in Sierra Leone, in addition to revealing remarkably positive health outcomes for women with PPH, also highlighted the positive impact true Ministry of Health involvement and support can have on a project. Initial uptake was rapid and acceptability high among providers and facilities. UBT facility champions felt directly accountable to their own ministry, not to foreign researchers and this created a great environment for positive change.

However, reengagement after Ebola has been slow and fewer cases have been reported for reasons reviewed below.

Has the project demonstrated the success of the innovation? If yes, what evidence is there for the performance of the innovation?

The project demonstrated success of the innovation in several ways. First, the rapid uptake of the training program from its inception, provider buy-in and acceptability and the continued professed support from the MOH for further roll out post-Ebola are evidence of the acceptability of this innovation in Sierra Leone. (See provider perceptions manuscript) Further, there was a remarkably high survival rate in the sickest of patients who received the UBT when all else short of surgery had failed. (Most women deliver in health centres without the option of surgery.) As mentioned before, of the 52 women who had UBT placed,

28 (54.9%) were in late stages of haemorrhagic shock by blood pressure and mental status changes including 2 who were unconscious. 23 (82.1%) of these women in late haemorrhagic stage shock survived with use of the UBT, a survival rate much higher than one might expect from on-going haemorrhage in late-stage shock.
Additionally, the ESM-UBT has been shown to be safe. Safety data were collected in 80% of UBT patients in Kenya and Sierra Leone out to 6 weeks post partum and revealed no complications, adverse events or death after discharge from the hospital. There was no incidence of post-partum endometritis in the Sierra Leone follow up data and only one in Kenya out of 156 total patients followed out to 6 weeks.[xvi]

Do the outcomes support the initial rationale for the innovation?

Even with the major disruption of the Ebola epidemic, the outcomes of the project support that the ESM-UBT package is safe, effective, and appropriate for post-conflict settings with limited resources. It clearly strengthens the capacity of health providers to respond to postpartum haemorrhage during childbirth and is life-saving even in advanced stages of shock. It can be deployed at the bedside and does not require transfer to a higher-level facility in most cases.

How has your understanding of the innovation changed through the project period?

Through the project period, we learned that even in the face of a major barrier such as the Ebola epidemic, providers largely retained knowledge of the ESM-UBT package. Providers of all cadre are able to place the UBT successfully and UBT can be used in all levels of health facilities were maternity services are rendered.

Facility level	Reported cases
Maternal Child Health Post	7
Community Health Post	3
Community Health Center	29
Level 1 or 2 hospital	5
Tertiary	7
Unknown	1

Provider Cadre	Reported Cases
Nurse	12
Maternal and Child Health Aide	19
Community Health Officer	4
Midwife	12
Doctor	4
Unknown	1

Our provider experience research revealed despite instructions to transfer patients to higher-level facilities once UBT is placed, in most circumstances,

providers and patients elected not to transfer and patients did well. Providers noted the ability to successfully take care of more severe PPH without the dangers of transporting the patient was a distinct advantage of UBT. When patients were transferred, providers felt they were more often in stable condition during transfer. [xvii]

Providers also noted the large majority of the time the UBT was easy to insert. Occasionally placement involved minor challenges including difficulty finding the cervix or the UBT slipping out of position while it was filled. This was noted particularly in patients where were combative or more severe. In some cases, providers used a speculum and forceps to place the UBT with good results. However, most often these additional tools were not necessary.

Did the innovation lead to any unexpected outcomes or results? How were these identified and managed?

Conversations with providers highlighted their impression that UBT not only saved lives, but also saved women from having to undergo a hysterectomy. The harm of a hysterectomy includes the surgical risk and trauma and the resulting infertility, but across Africa, loss of the uterus has an important social impact such that women and their communities may feel a woman has lost her femininity, her identity and even her worth when she loses their uterus. Consequently, protection from hysterectomy is of great benefit.

As a result of these conversations, our team pursued qualitative research in Kenya and Senegal on the impact of UBT use on decisions to proceed with haemorrhage for PPH. All of the providers interviewed responded that UBT devices immediately controlled haemorrhage and prevented women from being taken to emergency hysterectomy.[xviii]

What are the key lessons learnt relating to the innovation (this should related to the innovation itself, rather than project implementation)?

Key lessons have been discussed in some detail above. All levels of providers who provide maternity care in Sierra Leone were able to assemble and successfully use the ESM-UBT. This could be done at all levels of the health system. The ESM-UBT can often be used as the final step in treating PPH and patients may not require transfer to another facility and may avoid surgical intervention. Success rate for use of the UBT was very high and no major adverse effects were noted. The UBT is inexpensive, effective, safe and acceptable to providers and patients.

Further, more than any other country, the experience in Sierra Leone highlights the impact direct involvement of the Ministry of Health can have on rapid uptake and acceptance of a new technology. Their involvement was absolutely essential to the early and rapid success of the innovation. After the Ebola crisis, the Ministry of Health continued to have to focus a rebuilding the health system and without their leadership, challenges in revitalizing UBT utilization remained.

METHODOLOGY

Was the methodology successful in producing credible evidence on the performance of the innovation?

The initial methodology of creating a database of all UBT uses throughout the study period was the same as programs that have been implemented in other countries. Despite the limitations presented during this period, the data from Sierra Leone was easily combined with other UBT uses in our database resulting in a robust series of UBT uses. As we began to learn from these cases, we began to ask additional questions regarding acceptability and impact that lead to multiple qualitative and mixed-methods studies. Further, the need for additional safety data out to 6 weeks post partum resulted in an effort to obtain additional follow-up data via survey to confirm the safety of the intervention. Each of these monitoring and evaluation methods have been described in detail above. These methods combined to successfully produce credible evidence regarding UBT effectiveness, acceptability and safety. Quantitative data allowed us to calculate survivorship, safety and efficiency, while qualitative data illustrated a comprehensive portrayal of the landscape and helped identify limitations and barriers to uptake and use. The quality of the data does not match that of a clinical trial, but we are proud of the quality of information we were able to obtain with careful scientific inquiry.

What adjustments were made to the methodology during the course of the project? Why were these needed and how were they made?

In the fall of Year One, we continued to collect careful data on each use of the ESM-UBT as well as any uses of improvised condom-based UBT kits that we discovered. We recognize that training and dissemination of information on the use of our condom-based ESM-UBT would have ripple effects leading to improvised kits, so we felt it was important to capture data for the registry from each of those cases as well. Only two such cases were reported in Sierra Leone and both patients survived. Further research was later conducted into similar cases of improvised kits in Kenya.

In October 2014, as noted previously, we implemented increased surveillance for complications or adverse outcomes with ESM-UBT out to 6 weeks postpartum since there were no complications found previously in any UBT patients on the initial data collection tools from the delivery facilities. To avoid missing any issues once patients were discharged from the hospital, patients were contacted at 2 and 6 weeks postpartum and asked questions about fever, pain, return of bleeding and additional treatments they may have required in that postpartum period. Patients in our initial database up to the time of implementation of this new monitoring tool, were also contacted and asked questions retrospectively to assure that, as much as possible, all complications or concerns were recorded after ESM-UBT use. No significant adverse events including infections such as

post partum endometritis, hospitalizations or deaths were uncovered with this additional surveillance.

PARTNERSHIPS AND COLLABORATION

Describe the partnership arrangements and how these may have changed during the course of the project.

This specific project was implemented in collaboration with the Ministry of Health and Sanitation of Sierra Leone and their Reproductive, Newborn, and Child Health Department. World Vision served as our in-country partner helping with data collection, facility surveillance and continued training. Due to the Ebola epidemic, collaboration with other organizations and at times the Ministry of Health was very limited.

World Vision provided regular monitoring of the facilities that Massachusetts General Hospital (MGH) previously trained and provided with UBT kits. They conducted on the job trainings on how to assemble and use the kits and restocked the supply of UBT kits as needed. World Vision collected data on UBT kit usage as well as any complications that took place in an excel database. Due to the Ebola crisis, from July 2014 to November 2015, facilities could only be visited when absolutely necessary because the country was in a state of emergency, movement was extremely limited, and some of the online facilities became Ebola treatment centers. Additionally, many facilities were afraid to see patients because fear of contracting Ebola. During the Ebola crisis, facilities were monitored through phone calls.

After Sierra Leone was declared Ebola free in March 2016, World Vision worked with us to conduct a comprehensive refresher training program with 97 online facilities. The project was extended for an additional 6 months (no cost extension) starting in March and during this time kit distribution, on the job refresher trainings and facility monitoring continued at 97 health facilities. Six additional facilities were trained during the refresher training bringing the total number of trained facilities to 103. However, there were several challenges encountered during this period reported by World Vision and they are as follow:

- Some facilities were unable to re-adjust after the Ebola outbreak. These facilities decided that it was too risky to accept PPH patients, so they started referring all patients that presented with signs of PPH to the main referral hospital.
- Some of the facilities kept their kits locked up, so that the kits could only be utilized when the person in charge of the key was in the facility. This caused major challenges when a PPH patient came into the facility when the kits were inaccessible.
- Some mothers stopped going to the health facility to deliver their babies. They preferred traditional birth attendants to do their deliveries at home instead of going to the hospital.

The MOHS Director of Reproductive Health, Dr. Santigie Sesay, in collaboration with World Vision and MGH, hosted a national stakeholders meeting in Freetown on March 3, 2016. The meeting was attended by MOHS officials, maternal health providers, various NGO reps (John Snow Inc, PSI, International Medical Corps, etc.), World Vision and MGH staff. MGH presented the UBT data and findings to date from Sierra Leone, Kenya, Tanzania and other countries. After discussion, there was unanimous interest in national scale-up of UBT. Discussions are currently ongoing with the MOH and USAID Mission regarding next steps.

Since the stakeholders meeting, World Vision has had a series of meetings with the MOH and USAID Mission to explore possible partnerships for the scaling up of the intervention. No formal commitments have been made, but USAID voiced excitement about the ESM-UBT work that has been done so far and interest to explore ways they can provide additional support to the MOH to expand ESM-UBT coverage in Sierra Leone.

DISSEMINATION

Indicate the steps taken to disseminate the outcomes of the project.

What dissemination activities have or will be conducted (whether or not included in the budget)?

As mentioned, in March 2016, coincident with the refresher training for birth providers on the use of the UBT kit, the current MOH Director of Reproductive Health, Dr. Santigie Sesay, hosted an ESM-UBT stakeholder meeting in collaboration with MGH and World Vision. During the meeting MGH and World Vision discussed the findings from the ESM-UBT project, review challenges including the impact of the Ebola crisis and ways to move forward on the potential for possible ESM-UBT scale up.

Beyond the in country dissemination of findings, numerous invited lectures, stakeholder meetings, keynote addresses, conference presentations, and an animated film have been made for dissemination of the ESM-UBT projects' findings and the potential for saving lives through ESM-UBT. Invitations to review the findings of our work in Sierra Leone and Kenya and to provide technical support for UBT implementation continue. (Please see p.18-21 for a full list of our publications/manuscripts and presentations.)

We have also worked to help refine and improve our approach and to pave the way for policy change for sustainability. For example on July 24, 2014, we co-hosted a one-day forum of experts (from WHO, USAID, Gynuity, MGH) in New York City called Consultation on Uterine Balloon Tamponade Research. The goal of the forum was to bring together thought leaders and craft a research agenda for UBT, based on the latest scientific evidence. The forum was led by MGH Division Chief Dr. Thomas Burke and Gynuity's President Dr. Beverly Winikoff. As a result, international stakeholders were informed about the ESM-UBT work, our follow up tools were further developed and strengthened and Gynuity is

planning additional research on UBT with MGH as technical advisors which will expand UBT use to Egypt and Uganda.

Our 18 manuscripts to date have been globally disseminated to donors (USAID, UKAID, Gates Foundation, etc.), WHO, FIGO, professional societies, numerous maternal health conferences/meetings, government health leaders, and others over the years. ESM-UBT has been introduced in nine developing countries to date. Given the overwhelming global evidence, we have received requests for UBT implementation from an additional 11 countries including Malawi, Ivory Coast, Uganda, Peru and India over the past few months. We are working closely with our in-country partners, Villgro and the Boston Consulting Group to develop our ESM-UBT business plan for East Africa and global strategy.

What publications have resulted from the project, or are forthcoming (i.e. research and policy reports, journal articles, case studies, evaluations etc.)?

The following academic presentations were made related to UBT use in Sierra Leone and other project countries since the start of HIF:

1. Natarajan R, Chavez J, Ahn R, Nelson BD, Eckardt MJ, Burke TF. Uterine balloon tamponade as a second-line treatment for uncontrolled postpartum hemorrhage: A qualitative study exploring provider perceptions of effectiveness, feasibility, and acceptability in lower-level health facilities in Kenya. Poster presentation. Consortium of Universities for Global Health conference. Boston, MA. March 26-28, 2015.
2. Pendleton AA, Natarajan A, Nelson BD, Ahn R, Eckardt M, Ramanathan A, Burke TF. Uterine balloon tamponade as a treatment to avert surgical intervention in uncontrolled postpartum hemorrhage: a multinational qualitative assessment of doctor practices and perceptions. Poster presentation. Massachusetts General Hospital Clinical Research Day. Boston, MA. October 8, 2015.
3. Natarajan A, Pendleton AA, Nelson BD, Ahn R, Oguttu M, Eckardt M, Burke TF. Use of uterine balloon tamponade for uncontrolled postpartum hemorrhage: a qualitative study of provider experiences and perceptions in Kenya. Poster presentation. Massachusetts General Hospital Clinical Research Day. Boston, MA. October 8, 2015.
4. Burke TF, Ramanathan A, Ahn R, Nelson BD, Hines R, Kamara J, Oguttu M, Natarajan A, Maua J, Kargbo SAS, Altawil Z, Tester K, de Redon E, Niang M, Eckardt M. A postpartum hemorrhage package with uterine balloon tamponade: a prospective multi-center case series in Kenya, Sierra Leone, Senegal, and Nepal. Poster presentation. Massachusetts General Hospital Clinical Research Day. Boston, MA. October 8, 2015.
5. Natarajan A, Pendleton AA, Nelson BD, Ahn R, Oguttu M, Eckardt M, Burke TF. Improvised uterine balloon tamponade for uncontrolled postpartum hemorrhage: a qualitative assessment of provider experiences in Kenya. Poster presentation. Massachusetts General Hospital Clinical Research Day. Boston, MA. October 8, 2015.
6. Pendleton AA, Natarajan A, Ahn R, Nelson BD, Eckardt MJ, Burke TF. Uterine balloon tamponade as a treatment to avert surgical intervention in uncontrolled postpartum hemorrhage: a multinational qualitative assessment of doctor practices and perceptions. Oral presentation. International Federation of Gynecology and Obstetrics (FIGO) World Congress. Vancouver, Canada. October 4-9, 2015.
7. Natarajan A, Ahn R, Nelson BD, Eckardt M, Burke TF. Use of uterine balloon tamponade for uncontrolled postpartum hemorrhage: a qualitative study of provider experiences and

perceptions in Kenya. Oral presentation. International Federation of Gynecology and Obstetrics (FIGO) World Congress. Vancouver, Canada. October 4-9, 2015.

8. Burke TF, Ahn R, Nelson BD, Hines R, Kamara J, Oguttu M, Natarajan A, Maua J, Kargbo S.A.S., Altawil Z, Tester K, de Redon E, Niang M, Eckardt MJ. A postpartum hemorrhage package with uterine balloon tamponade: a prospective multi-center case series in Kenya, Sierra Leone, Senegal, and Nepal. Poster presentation. International Federation of Gynecology and Obstetrics (FIGO) World Congress. Vancouver, Canada. October 4-9, 2015.
9. Natarajan A, Pendleton AA, Nelson BD, Ahn R, Oguttu M, Dulo L, Eckardt M, Burke TF. A qualitative study exploring Kenyan healthcare provider experiences with improvising condom-catheter uterine balloon for the management of uncontrolled postpartum hemorrhage. Oral presentation. Kenya Obstetrical and Gynaecological Society (KOGS) Conference. Nairobi, Kenya. February 18-19, 2016.
10. Burke TF, Nelson BD, Oguttu M, Dulo L, Achieng E, Achieng B, Altawil Z, Abdalla K, Eckardt M. A postpartum hemorrhage package with uterine balloon tamponade: A prospective multi-center case series in Kenya, Sierra Leone, Senegal, and Nepal. Oral presentation. Kenya Obstetrical and Gynaecological Society (KOGS) Conference. Nairobi, Kenya. February 18-19, 2016.
11. Pendleton AA, Natarajan A, Oguttu M, Nelson BD, Eckardt M, Burke TF. Uterine balloon tamponade averts emergency surgical interventions in uncontrolled postpartum hemorrhage. Oral presentation. Kenya Obstetrical and Gynaecological Society (KOGS) Conference. Nairobi, Kenya. February 18-19, 2016.
12. Natarajan A, Pendleton AA, Nelson BD, Ahn R, Oguttu M, Dulo L, Eckardt M, Burke TF. Use of uterine balloon tamponade for uncontrolled postpartum hemorrhage: A qualitative assessment of provider experiences and perceptions in Kenya. Oral presentation. Kenya Obstetrical and Gynaecological Society (KOGS) Conference. Nairobi, Kenya. February 18-19, 2016.
13. Guha, M. Burke TF, Ahn R, Nelson BD, Hines R, Kamara J, Oguttu M, Natarajan A, Maua J, Kargbo S.A.S., Altawil Z, Tester K, de Redon E, Niang M, Eckardt MJ. A postpartum hemorrhage package with uterine balloon tamponade: a prospective multi-center case series in Kenya, Sierra Leone, Senegal, and Nepal. Oral Presentation. Yale University Global Health and Innovations Conference. New Haven, CT. April 17, 2016.
14. Burke TF, Ahn R, Nelson BD, Hines R, Kamara J, Oguttu M, Natarajan A, Maua J, Kargbo S.A.S., Altawil Z, Tester K, de Redon E, Niang M, Eckardt MJ. A postpartum hemorrhage package with uterine balloon tamponade: a prospective multi-center case series in Kenya, Sierra Leone, Senegal, and Nepal. Poster presentation. MIT Rethinking Global Health Conference. Cambridge, MA. May 9, 2016
15. Steer J, Ramanathan A, Eckardt M, Nelson BD, Guha M, Oguttu M, Altawi Zl, Burke TF. Safety of a condom uterine balloon tamponade (ESM-UBT) device for use in uncontrolled postpartum hemorrhage. Poster presentation. Massachusetts General Hospital Clinical Research Day. Boston, MA. October 6, 2016.
16. Danso-Bamfo S, Herrick T, Guha M, Lightbourne A, Nelson BD, Oguttu M, Eckardt M, Mvundura M, Abu-Haydar E, Burke TF. Low-cost uterine balloon tamponade for management of postpartum hemorrhage: modeling the potential impact on maternal mortality and morbidity in sub-Saharan Africa. Poster presentation. Massachusetts General Hospital Clinical Research Day. Boston, MA. October 6, 2016.
17. Burke TF, Cappetta A, Lall K, Guha M, Lightbourne A, Danso-Bamfo S, Nelson BD, Oguttu M, Kargbo S, Niang M, Tarimo V, Eckardt M. A condom uterine balloon tamponade package is highly effective in treating women in advanced shock from uncontrolled postpartum hemorrhage originating from an atonic uterus. Poster presentation. Massachusetts General Hospital Clinical Research Day. Boston, MA. October 6, 2016.

18. Carlson L, Mvundura M, Kokonya D, Abu-Haydar E, Oguttu M, Burke TF. Cost-effectiveness of condom uterine balloon tamponade for control of severe postpartum hemorrhage in Kenya. Poster presentation. Massachusetts General Hospital Clinical Research Day. Boston, MA. October 6, 2016.

ESM-UBT case data and qualitative interviews in Sierra Leone were combined with that of Kenya and other countries with ESM-UBT implementation and resulted in a number of published studies in peer-reviewed journals over the course of the project. In addition, our combined efforts in these countries helped us ask additional research questions resulting in further submissions and publications. The following is our list of publications on UBT since the start of the program in Sierra Leone. Those in bold include specific data from Sierra Leone, but experience obtained in Sierra Leone contributed to our thinking for all these publications.

Publications/manuscripts:

1. **Burke TF, Ahn R, Nelson B, et al A postpartum hemorrhage package with condom uterine balloon tamponade: A prospective multi-center case series in Kenya, Sierra Leone, Senegal, and Nepal. BJOG; 2015: DOI: 10.1111/1471-0528.13545.**
2. Natarajan A , Achieng E, Chavez J, Oguttu M, Ahn R, Tester K, Nelson BD, Burke TF, Eckardt M. Provider experiences with uterine balloon tamponade for uncontrolled postpartum hemorrhage in health facilities in Kenya. Int J Gynecol Obstet. 2015. Nov;131(2):201-4.
3. Pendleton, AA. Natarajan, A. Ahn, R. Nelson, BD. Eckardt, MJ. Burke, TF. Emergency hysterectomy for uncontrolled postpartum hemorrhage may be averted through uterine balloon tamponade in Kenya and Senegal. Int J Gynecol Obstet . 2015 Dec 11. pii: S0020-7292(15)00717-1.
4. Pendleton, AA. Natarajan, A. Ahn, R. Nelson, BD. Eckardt, MJ. Burke, TF. A qualitative assessment of the impact of a uterine balloon tamponade package on decisions regarding the role of emergency hysterectomy in women with uncontrolled postpartum hemorrhage in Kenya and Senegal. BMJ Open 2016;6:e010083 doi:10.1136/bmjopen-2015-010083
5. Pendleton, AA. Natarajan, A. Ahn, R. Nelson, BD. Eckardt, MJ. Burke, TF. Emergency hysterectomy for uncontrolled postpartum hemorrhage may be averted through uterine balloon tamponade in Kenya and Senegal. Int J Gynecol Obstet . 2015 Dec 11. pii: S0020-7292(15)00717-1.
6. **Natarajan A, Ahn R, Nelson BD, Eckardt MJ, Kamara J, Kargbo SA, Kanu P, Burke TF. Use of prophylactic uterotonics during the third stage of labor: A survey of provider practices in community health facilities in Sierra Leone. BMC Pregnancy and Childbirth. 2016;16:23.**
7. **Natarajan A, Kamara J, Ahn R, Nelson BD, Eckardt M, Williams AM, Kargbo SA, Burke TF. Provider experience of uterine balloon tamponade for the management of postpartum hemorrhage in Sierra Leone. International Journal of Gynecology and Obstetrics. 2016. Jul;134(1):83-6. doi: 10.1016/j.ijgo.2015.10.026.**
8. Natarajan A, Pendleton A, Nelson BD, Ahn R, Oguttu M, Dulo L, Eckardt MJ, Burke TF. Qualitative study of improvised condom-catheter uterine balloon tamponade for the management of uncontrolled postpartum hemorrhage in Kenya. Int J Gynecol Obstet. 2016. 2015 Nov;131(2):201-4. doi: 10.1016/j.ijgo.2015.05.020
9. **Natarajan A, Ahn R, Nelson BD, Eckardt MJ, Kamara J, Kargbo SA, Kanu P, Burke TF. Use of prophylactic uterotonics during the third stage of labor: A survey of provider practices in community health facilities in Sierra Leone. BMC Pregnancy and Childbirth. 2016;16:23.**

10. **Ramanathan A, Eckardt M, Nelson BD, Guha M, Oguttu M, Altawil Z, Burke TF. Safety of a condom uterine balloon tamponade (ESM-UBT) device for use in uncontrolled postpartum hemorrhage. Submitted to IJGO.**
11. Altawil Z, de Redon E, Dinh H, Eckardt M, Nelson BD, Burke TF. Uterine Balloon Tamponade awareness in United States. Submitted to J Midwifery and Women's Health.
12. Herrick T, Abu-Haydar E, Burke TF. Impact modelling of a low cost uterine balloon tamponade package. Submitted to IJGO.
13. **Burke TF, Nelson BD, Guha M, Eckardt M, Oguttu M, Eckardt M. Condom uterine balloon for women with uncontrolled postpartum hemorrhage in advanced shock. Submitted to BJOG.**
14. Mvundura M, Abu-Haydar E, Okoth E, Mukabi J, Herrick T, Oguttu M, Carlson L, Burke TF. Cost effectiveness of the uterine balloon tamponade to control severe post-partum hemorrhage in Kenya ESM-UBT. Submitted to IJGO.

Has the project received any third party coverage during the project (from news media, third party blogs, researchers or academic etc.)?

ESM-UBT has had coverage on UNICEF news media – they did a piece on UBT in Kenya. Our research has been cited by multiple articles in the literature. On July 13, 2015, the ESM-UBT was announced at the 3rd annual United Nations Finance Development meeting to be the intervention (out of more than 500) likely to make the most impact in the lives of women between now and 2030. In September 2015, PATH also featured MGH's ESM-UBT as one of the most important innovations for the poor on the countdown to 2030. The WHO has incorporated UBT in the PPH management protocol.

TRANSFERABILITY

Please indicate if there is any potential to replicate the project and how.

There is tremendous potential to replicate this project in resource-limited settings, especially in the face of complex humanitarian emergencies, but more importantly there is an astounding need. Postpartum haemorrhage remains one of the leading causes of death in women, and a main contributor is a lack of timely access to facilities with treatment options (generally surgical) for women with PPH when uterotonic medications fail. These surgical options, which include hysterectomy, also increase morbidity for women. This is a world-wide concern in LMICs and even rural areas in higher income countries.

The ESM-UBT package provides needed access to a safe, easy-to-administer, inexpensive, life-saving bedside treatment option when uterotonics fail. The ESM-UBT package can be easily replicated without significant alterations both within the African continent and throughout the world. The Division of Global Health and Human Rights has seen significant expansion of interest in implementation of UBT since the start of this project. The ESM-UBT is currently introduced in 7 counties including Sierra Leone, Kenya, Senegal, Nepal, Ghana, Tanzania and Zambia with a training recently held for UBT use in Egypt, Uganda

and additional hospitals in Senegal and with plans for training in the next two months in Peru and Panama. Conversations and planning are underway in several additional countries including Coates D'Ivoire and India.

What are the plans for scale-up beyond the pilot?

There is a strong interest from the Ministry of Health in Sierra Leone to own and scale the ESM-UBT package across their more than 1700 facilities that provide maternal health care. As noted above, in March of 2016, the MOH held a meeting with MGH, World Vision, international NGOs, and key stakeholders to disseminate the findings of the initial work supported by HIF and to discuss the future of ESM-UBT in Sierra Leone. Given the compelling global evidence to date, the meeting generated substantial interest in scaling up ESM-UBT. World Vision's Health Advisor also presented the results of the project to the country's Reproductive, Maternal Newborn and Child Health technical committee, who also strongly supported partnering with other organizations to scale up this intervention. However, finding sufficient funds to support scale-up remains a challenge. MGH/World Vision are also currently in dialogue with the USAID Mission.

In partnership with the Kenya Medical and Education Trust (KMET), MGH has established a social enterprise to commercialize the ESM-UBT package in order to locally sustain ESM-UBT supply/distribution, accelerate uptake utilizing a market-based approach and avoid continued reliance on donor funding. Business plans for Kenya and East Africa are being finalized. The ESM-UBT package is currently being assembled and distributed in Kenya at the Center for Maternal Health Innovations (CMHI) – we hope this will become the center for supply to all of East Africa. This business development has been seeded by additional grants leveraged by the work done in Sierra Leone, Kenya, Senegal, Tanzania and beyond. This social enterprise in Kenya will serve as the initial business development site with potential for further development of local companies across regions where low-cost UBTs are in great need. If there is interest from the right stakeholders, we could set up a social enterprise in Sierra Leone for local, sustainable supply of the ESM-UBT to West Africa.

Are any other organisations planning to use or adapt the innovation?

In close collaboration with the Kisumu Medical and Education Trust (KMET) and national/county Ministries of Health, we are currently in the process of scaling up ESM-UBT nationally in Kenya. We have introduced/are in the process of rolling-out ESM-UBT in 9 additional countries to include Tanzania, India, Sierra Leone, Senegal, Ghana, Nepal, South Sudan, Uganda and Zambia. In these countries, we have worked with various organizations including Jhpiego, PATH, World Vision, One Heart, Gynuity, CIDRZ and ministries of health. Discussions are underway with the Inter-American Development Bank for UBT implementation in Honduras, Nicaragua, and Guatemala.

The health advisor and the program effectiveness director at World Vision Sierra Leone were able to arrange a meeting with USAID Mission on September 6,

2016. The USAID representative at the meeting was impressed with the innovation/project and expressed interest in providing further support, but no formal commitment has been given at this time. The Health Advisor will continue to follow up.

What steps have been taken to ensure the transfer of the innovation and the learning from the project?

The Health Advisor at World Vision, MGH team and the MOHS are exploring funding options and ways to encourage health facilities to continue using this innovation. There are about 400 UBT kits, 62 wall charts, 12 user manuals and 13 training flipcharts available at the World Vision National Office in Freetown to replenish supplies and for future training.

The six publications containing data/results from Sierra Leone have been widely disseminated in international/national conferences and meetings and shared with various stakeholders. Learning from the project will also be incorporated in our global strategy for UBT as we expand to multiple countries.

Furthermore, HIF funded the completion of an ESM-UBT training film in collaboration with Medical Aid Films (UK). The 7-minute training video is designed to provide culturally competent education to providers on steps to treat PPH and how to use the ESM-UBT when uterotonics fail. This film will be widely disseminated to train providers on UBT use in Sierra Leone, Kenya, Tanzania and beyond. It will be accessible online and specifically useful to educate providers in hard-to-reach/post-conflict areas and settings of instability/unrest where in-person training may not be possible.

The ESM-UBT training film can be accessed using the below link:
http://www.medicalaidfilms.org/film/uterine-balloon-tamponade/
(password: ubt2016)

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xiii Burke TF, Ahn R, Nelson B, et al A postpartum hemorrhage package with condom uterine balloon tamponade: A prospective multi-center case series in Kenya, Sierra Leone, Senegal, and Nepal. *British Journal of Obstetrics and Gynaecology*; 2015: DOI: 10.1111/1471-0528.13545.

xiv Ramanathan A, Eckardt MJ, Nelson BD, Guha M, Oguttu M, Altawil Z, Burke TF. Safety of a condom uterine balloon tamponade (ESM-UBT) device for use in uncontrolled postpartum haemorrhage. *Submitted to International Journal of Gyncology and Obstetrics 2016.*

xv Ramanathan A, Eckardt MJ, Nelson BD, Guha M, Oguttu M, Altawil Z, Burke

TF. Safety of a condom uterine balloon tamponade (ESM-UBT) device for use in uncontrolled postpartum haemorrhage. *Submitted to International Journal of Gyncology and Obstetrics 2016.*

[xvi] Ramanathan A, Eckardt MJ, Nelson BD, Guha M, Oguttu M, Altawil Z, Burke
TF. Safety of a condom uterine balloon tamponade (ESM-UBT) device for use in uncontrolled postpartum haemorrhage. *Submitted to International Journal of Gyncology and Obstetrics 2016.*

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[xviii] Pendleton AA, Natarajan A, Ahn R, Nelson BD, Eckardt MJ, Burke TF. A qualitative assessment of the ipact of al uterine balloon tamponade package on decisions regarding the role of emergency hyeterectomy in women with uncontrolled postpartum hemorrhage in Kenya and Senegal. *BMJ Open* 2016.