

The Barriers to the Integration of the Uterine Balloon Tamponade into South
Africa and Ghana's Health Systems for the Management of Postpartum Hemorrhage

by

Adityavarman Mehta

Duke Global Health Institute
Duke University

Date: _____

Approved:

Dr. Melissa Watt, Supervisor

Dr. John Schmitt

Dr. Joy Noel Baumgartner

Thesis submitted in partial fulfillment of
the requirements for the degree of
Master of Science in the Duke Global Health Institute
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ABSTRACT

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Abstract

Background

Postpartum hemorrhage is the most significant contributor to maternal mortality globally, claiming 150,000 lives annually. Postpartum hemorrhage is a leading cause of maternal death in South Africa, with the literature indicating that 80 percent of the postpartum hemorrhage deaths in South Africa are avoidable. Ghana, as of 2010, witnesses 2700 maternal deaths annually, primarily because of poor quality of care in health facilities and services being difficult to access. As per WHO recommendations, uterotonics are integral to treating postpartum hemorrhage as soon as it is diagnosed. In case of persistent bleeding or limited availability of uterotonics, the uterine balloon tamponade (UBT) can be used as a second line of defense. If both these measures are unable to counter the bleeding, providers must perform surgical interventions. Literature on the UBT, as one tool in the protocol to address postpartum hemorrhage, has shown it to have success rates ranging from 60 to 100 percent. Despite the potential to lower the number of postpartum hemorrhage deaths in South Africa and Ghana, the UBT has not been incorporated widely in South Africa and Ghana. The aim of this study is to describe the barriers involved with integrating the UBT into South Africa and Ghana's health systems to address postpartum hemorrhage.

Methods

The study took place in multiple sites in South Africa (Cape Town, Johannesburg, Durban and Mpumalanga) and in Accra, Ghana. South Africa and Ghana were selected because postpartum hemorrhage contributes greatly to their maternal mortality numbers and there is potential in both countries to lower those rates through greater use of the UBT. A total of 25 participants were interviewed through purposive sampling, snowball sampling and participant referrals, and included various categories of stakeholders integral to the integration process of a medical device. Individual in-depth interviews were used for data collection, with interview questions being tailored to each stakeholder category. The focus of the interviews was on the protocol used to counter postpartum hemorrhage, the frequency with which the UBT is used as part of the protocol, and the process of integrating it into the South Africa and Ghana's health systems. The data collected were coded using NVivo and analyzed using content analysis.

Results

The barriers to integration of the uterine balloon tamponade to address postpartum hemorrhage in South Africa and Ghana were evident on the political, economic and health delivery levels. The results indicated that the barriers to integration in South Africa included the low recognition of postpartum hemorrhage as a problem, the lack of clarity surrounding the role of the Medicines Control Council as a regulatory body for medical devices, and low awareness of the UBT as an intervention to control postpartum hemorrhage. The barriers in Ghana were the cash constraints experienced by the Ghana Health Services to fund medical devices, a heavy reliance on donors for funding, and the lack of consistent knowledge on processes involving clinical trials for new medical devices in Ghana.

Conclusion

Existing literature on methods to counter postpartum hemorrhage to reduce maternal mortality has focused on and emphasized the efficacy of the UBT. Despite overwhelming evidence supporting the use of the UBT, many health systems across the world, particularly low-income countries, do not have access to the device owing to numerous barriers in integrating the device into obstetric care. This study illustrates the need to focus on incorporating the UBT into health systems for greater availability to health workers and its use as standard of care. Ultimately, this study can be used as a stepping-stone for more research on this subject, providing evidence to influence policymakers to integrate the UBT into their protocols for postpartum hemorrhage response.

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1. Introduction

Globally, 14 million cases of postpartum hemorrhage occur annually (Rath W. H. 2011). It is estimated that 18% of all childbirth deliveries globally are affected by postpartum hemorrhage, and that severe hemorrhage affects 1-5% percent of all deliveries (Devine 2009, Ganguli et al. 2011). Postpartum hemorrhage claims approximately 150,000 lives every year (Oyelese et al. 2007, Devine 2009). Approximately 88% of these deaths occur within 4 hours of delivery, highlighting the need for timely management during delivery and in the immediate aftermath (Devine 2009, Prata et al. 2014). Treatment delays and substandard care are often reported to be factors contributing to the high incidence of postpartum hemorrhage and subsequent mortality (Woiski et al. 2015).

Postpartum hemorrhage is a response to an abnormality of one of four processes that may occur individually or simultaneously (Devine 2009). They include: abnormalities of tone, referring to the failure of the uterus to contract after delivery of the placenta; retained placental tissue or blood clots; genital tract lacerations or coagulopathy (Devine 2009, Su 2012). The ability of a patient to effectively tolerate blood loss during postpartum hemorrhage depends on numerous factors, the most important being her health pre-delivery (Devine, 2009). Maternal blood volume increases by 40 to 50 percent during pregnancy because of an elevated plasma volume and red blood cell mass, which protects women from the effects of hemorrhage before and after delivery (Oyelese et al. 2007). A healthy woman can potentially lose 10 to 15 percent of blood volume without experiencing a drop in blood pressure (Oyelese et al. 2007, Su 2012). Pre-existing anemia or hypovolemia that may occur with pre-eclampsia, which is a volume-contracting condition, impairs the woman's ability to tolerate excessive blood loss (Oyelese et al. 2007, Devine 2009, Soltan et al. 2011). It is crucial for the health provider to be able to recognize excessive bleeding in a timely manner and respond accordingly (Ganguli et al. 2011).

1.1 Definition of Postpartum Hemorrhage

Postpartum Hemorrhage is defined as blood loss of 500 ml or more within 24 hours after birth, and severe postpartum hemorrhage is a blood loss of 1000 ml or more in the 24-hour period (World Health Organization 2012, Khan et al. 2006, Mercier et al. 2008, Kong et al. 2013, Hancock et al. 2015). Postpartum hemorrhage is classified as primary when it occurs within 24 hours of delivery and secondary if it occurs between 24 hours and 6-12 weeks postpartum (Rath W. H. 2011, Hancock et al. 2015). Primary postpartum hemorrhage occurs in 4 to 6 percent of deliveries and is normally the result of uterine

atony (Devine 2009, James et al. 2012, Rathore et al. 2012, Hancock et al. 2015). Untreated postpartum hemorrhage can result in shock and death in a span of hours because of vasoconstriction, ultimately leading to key organs in the body being deprived of oxygen (Maine et al. 1991, Tsu et al. 2004). Postpartum hemorrhage is the leading cause of maternal mortality worldwide and the main factor contributing to maternal complications in Western countries (Ganguli et al. 2011, Driessen et al. 2011, Prata et al. 2012, Hancock et al. 2015).

1.2 Risk factors for Postpartum Hemorrhage

The lack of access to antenatal care, essential for recognizing risk factors early, contributes to the risk of postpartum hemorrhage cases because long distances to health facilities in rural areas of developing countries is a deterrent for women seeking antenatal care (Tsegay et al. 2013). Educational qualifications of the woman and her partner, poverty, low quality of health care, and public infrastructure are key determinants of antenatal care utilization (Nketiah-Amponsah et al. 2013) (Tsegay et al. 2013). Women's education, in particular, improves their status in society and equips them to identify danger signs, leading them to seek the best health care available (Tsegay et al. 2013).

A significant number of deliveries in the developing world take place without the presence of a skilled birth attendant (Miller et al. 2004). 53 million women deliver children at home or in the presence of an unskilled birth attendant, presenting tremendous challenges for prevention and treatment of postpartum hemorrhage (Geller et al. 2006, Sibley et al. 2004). This leads to a failure in timely identification of the symptoms of postpartum hemorrhage such as uterine atony, rupture and genital lacerations, ultimately resulting in women experiencing shock and death (Miller et al. 2004). These challenges are exacerbated by transportation in rural areas (Krasovec et al. 2004, Geller et al. 2006).

Incorrect assessments of blood loss are a central factor in the delayed treatment for postpartum hemorrhage (Le Bas et al. 2014). The standard practice to assess blood loss begins with visual estimate, typically with a health care provider observing blood loss during delivery and making a quantitative estimate (Patel et al. 2006). This method has been proven to be inaccurate for decades, with many studies showing that estimates are 50 percent less than the actual amount of blood lost (Patel et al. 2006, Geller et al. 2006, Chua et al. 1998). In certain areas, birth attendants use rags and clothes to estimate blood loss (Geller et al. 2006, Duthie et al. 1991). Often, concealed blood loss results in underestimation of true blood loss (Mercier et al. 2008, Ganguli et al. 2011, Hancock et al. 2015). The inaccurate visual estimation of blood results in major delays in diagnosing and treating postpartum hemorrhage, contributing to greater risk of maternal morbidity and mortality (Le Bas et al. 2014).

Postpartum hemorrhage has various classifications. Immediate postpartum hemorrhage, the bleeding following childbirth, is most common and can occur due to a number of clinical abnormalities (Driessen et al. 2011, Tsu et al. 2004). These include uterine atony, ruptured uterus, retained placenta, or cervical, vaginal or perineal lacerations (Tsu et al. 2004, Gronvall et al. 2013, Rathore et al. 2012, Su 2012). Of these causes, uterine atony is responsible for most cases of postpartum hemorrhage, which can occur in the first hour of birth and escalate quickly (Tsu et al. 2004, Cunningham et al. 2001, Breathnatch et al. 2009, Driessen et al. 2011, Su 2012, Hancock et al. 2015). Uterine atony occurs when the uterus does not contract adequately after delivery because of a loss of tone in uterine muscles (Breathnatch et al. 2009). It appears as painless continuous bleeding that increases gradually and is often detected late because blood can be hidden in the uterus until external compression is performed (Mercier et al. 2008). Uterine atony creates complications in 1 out of 20 births and is responsible for approximately 80 percent of postpartum hemorrhage cases (Su 2012). Interventions for uterine atony include medical uterotonic therapies such as oxytocin, ergometrine, and methergonovine (Breathnatch et al. 2009). The lack of access to these interventions in the developing world points to the disparity in the treatment of postpartum hemorrhage in the developed world and low-resource settings (Breathnatch et al. 2009). The inclusion of treatment measures for uterine atony in the third stage of labor in international guidelines have not made a significant impact either, as developed countries, despite greater access to uterotonics, show a rise in the rate of postpartum hemorrhage (Driessen et al. 2011).

Placental abruption is also a common cause of postpartum hemorrhage. Placental abruption refers to the detachment of the placental bed from the decidua before the fetus is delivered, with key aftereffects being vaginal blood loss, uterine tenderness, and increased uterine activity (Mercier et al. 2008, Mayer et al. 2004). In addition, the retained placenta is a significant contributor to postpartum hemorrhage. The retained placenta is seen in 1 in 100 deliveries but is responsible for approximately 20-30 percent of PPH cases (Mercier et al. 2008). It refers to the failure of the placenta to deliver within 30 minutes of birth (Su 2012). When the placenta has not delivered, it prevents the uterus from contracting adequately and therefore, it must be removed manually to ensure that the uterus is empty (Mercier et al. 2008, Su 2012).

Lacerations of the vagina and cervix are also responsible for a high number of postpartum hemorrhage cases. These lacerations often happen when forceps deliveries are misjudged or women push before the cervix has fully dilated (Miller et al. 2004). . They are likely to occur after instrumental extraction, fetal macrosomia, or quick labor and delivery before full cervical dilation (Mercier et al. 2008). A diagnosis for lacerations should also be performed when the retained placenta and uterine atony

are no longer present. This diagnosis, Mercier et al. believe, is made too late because the bleeding can be concealed in the vaginal wall or pelvis.

Cesarean section births also contribute to a higher number of postpartum hemorrhage cases because of a greater loss in blood during delivery (Xu et al. 2012). During labor in cesarean section births, fibrinogen and fibrin degrade quickly and the fibrinolytic system activates for as long as 6-10 hours postpartum, thereby resulting in more blood loss (Xu et al. 2012).

Mercier et al. argue that there are multiple risk factors for postpartum hemorrhage before and during labor, but statistics indicate that the odds ratio and sensitivity/specificity of these factors are too low to formulate a strategy to prevent postpartum hemorrhage. All patients should be considered at risk of postpartum hemorrhage, regardless of initial presentation, and every maternity unit must be prepared to deal swiftly and efficiently to emergent cases of postpartum hemorrhage because many patients have no visible risk factors (Mercier et al. 2008, Devine 2009).

1.3 Prevention of Postpartum Hemorrhage

Prevention of uterine atony and subsequently, postpartum hemorrhage, depends on the active management of the third stage of labor (Mercier et al. 2008, Sanghvi et al. 2010). Common prevention measures include emptying the bladder and administering oxytocin. If bleeding persists, health providers must search for cervical/vaginal lacerations (Mercier et al. 2008). Active Management of the Third Stage of Labor (AMTSL) has been known to reduce the incidence of blood loss of 1 liter and more, lowers the need for transfusion and more uterotonics (Sanghvi et al. 2010). Active management of the third stage of labor is effective at preventing postpartum hemorrhage in facility-based deliveries and is known to reduce severe postpartum hemorrhage by 60 to 70 percent (Stanton et al. 2009) (Gülmezoglu et al. 2009). While it is managed differently across the world, the central aim of active management is to combat postpartum blood loss (Gülmezoglu et al. 2009). It comprises three components including the administration of uterotonics immediately after delivery, controlled cord traction, and uterine massage after delivering the placenta (Gülmezoglu et al. 2009, Miller S. et al. 2004, Devine 2009).

The standard of care in basic Emergency Obstetric Care facilities to prevent postpartum hemorrhage involves the administration of intravenous uterotonic drugs and manual removal of the placenta or any retained products during delivery (Lalonde 2013). The WHO recommendations for the prevention of postpartum hemorrhage include the use of uterotonics during the third stage of labor. Uterotonics are drugs that result in adequate uterine contraction and can be used for prophylactic therapy

or treatment (Munoz et al. 2012). Oxytocin, given at 10 International Units (IU), is suggested as the primary uterotonic and is also recommended to prevent PPH during the course of cesarean section births as well (World Health Organization 2012). In settings that do not have easy access to oxytocin, injectable uterotonics such as ergometrine and methylergometrine, as well as misoprostol can be used as alternatives (World Health Organization 2012). The WHO supports the administration of misoprostol by health workers with limited experience, if skilled birth attendants are not available. Finally, the WHO also recommends the monitoring of the uterine tonus through abdominal palpation for the early detection of uterine atony.

Identifying excessive bleeding after delivery is key to preventing postpartum hemorrhage (Geller S.E. et al. 2006, Su 2012). Equally important is the presence of a skilled birth attendant during delivery. 60 to 80 percent of postpartum hemorrhage cases can be prevented in the care of a skilled birth attendant (Sanghvi et al. 2010). Studies show that family and unskilled birth attendants are likely to identify excessive bleeding after delivery only 11 percent of the time (Geller et al. 2006, Sibley et al. 2005). By the time the patient arrives at a hospital, given potential delays, the patient may have already lost significant amounts of blood (Geller et al. 2006). Although a blood pressure drop may not be evident despite losing 10 to 15 percent of blood volume, a significant drop will mean that the patient has lost almost 30 percent of her blood volume (Su 2012). It is difficult to predict postpartum hemorrhage based on risk since two-thirds of women with postpartum hemorrhage have no risk factors (Gronvall, 2013). Primary prevention methods will help lower mean postpartum blood loss, reducing the incidence of postpartum hemorrhage (Raghavan et al. 2015). Primary prevention methods include the active management of the third stage of labor, the administration of oxytocin and misoprostol, a non-inflatable antishock garment to address shock in postpartum hemorrhage, and the hydrostatic condom balloon catheter to control postpartum hemorrhage subsequent to uterine atony (Miller S. et al. 2004, Devine 2009).

1.4 Treatment of Postpartum Hemorrhage

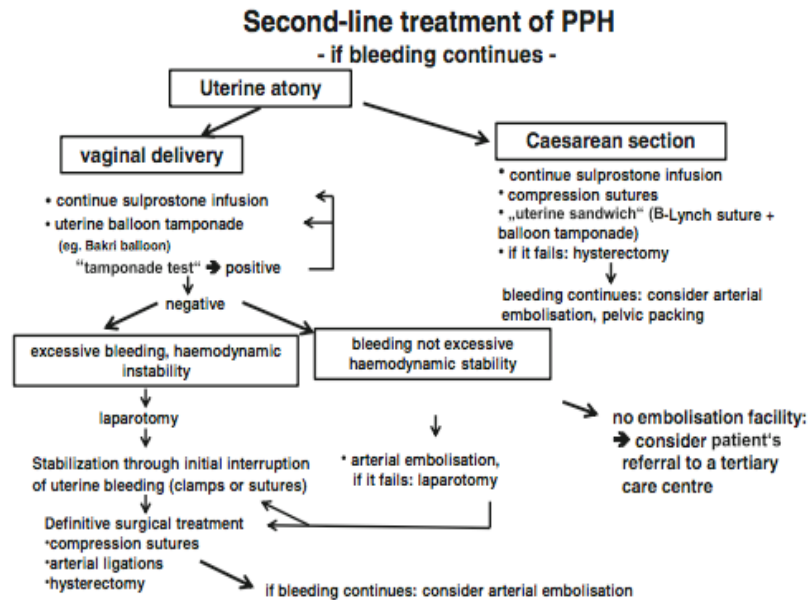


Figure 1: Second-line treatment of postpartum hemorrhage (Rath et al. 2012)

According to The American College of Obstetricians and Gynecologists (ACOG), these surgical techniques include bilateral uterine ligation to stop uterine bleeding, the B-Lynch technique to control excessive bleeding caused by uterine atony, and hemostatic multiple square suturing to address uterine atony and placenta praevia (Rath et al. 2012).

The WHO, in its clinical guidelines to address postpartum hemorrhage, advocates for the use of oxytocin and control cord traction to manage the retained placenta if the third stage of labor lasts over 30 minutes. However, if the placenta is retained and bleeding continues, health workers must attempt to remove the placenta manually (World Health Organization 2012). When health workers make the diagnosis for postpartum hemorrhage, the WHO recommends a uterine massage and initial fluid resuscitation with isotonic crystalloids. If the uterine massage and initial fluid resuscitation fail to stop bleeding, tranexamic acid should also be considered. In addition, the intrauterine balloon tamponade can be used to counter refractory bleeding if the health worker does not have access to uterotonics (World Health Organization 2012). In the period before quality care is available, bimanual uterine compression, external aortic compression and anti-shock garments can be used. Uterine artery embolization should be used to counter persistent bleeding. If bleeding continues, despite the use of all of the above interventions, surgical alternatives must be administered (World Health Organization 2012).

Oxytocin is uterotonic agent of choice recommended to address postpartum hemorrhage. Grotegut et al., however, indicate that excessive oxytocin can be detrimental to a patient suffering from postpartum hemorrhage. Oxytocin is a peptide that acts through the oxytocin receptor (OXTR) (Grotegut et al. 2011). The OXTR belongs to the family of G protein-couple receptors. At the onset of persistent agonist stimulation, OXTR undergoes rapid internalization, ultimately limiting oxytocin's physiological actions (Grotegut et al. 2011). When a patient is administered prolonged oxytocin treatment, it results in OXTR desensitization, further limiting oxytocin contraction responses (Grotegut et al. 2011). Protocols that reduce the amount of oxytocin that patients receive may decrease the incidence of postpartum hemorrhage secondary to uterine atony (Grotegut et al. 2011). Mercier et al. list a number of invasive treatment options to counter postpartum hemorrhage when the first line of defense is unable to control bleeding. These include the uterine balloon tamponade, arterial embolization, uterine compression sutures and internal iliac artery ligation (Mercier et al. 2008). A study by Doumouchstis and colleagues presented data that showed that uterine embolization and B-Lynch sutures proved successful in 91 percent cases, while the uterine balloon tamponade and iliac artery ligation were successful in 84 percent cases (Doumouchstis 2007).

Uterine arterial embolization is also a successfully tested method to treat postpartum hemorrhage. It is a therapeutic approach that avoids the morbidity linked with peripartum hysterectomy and helps the patient preserve her fertility (Mercier et al. 2008). The success rate of this treatment is over 90 percent and most patients have been able to return to regular menstruation (Mercier et al. 2008). Currently, health providers place arterial catheters and the occlusion balloons before delivery whenever they suspect major hemorrhage. These balloons reduce blood loss while the patient prepares to undergo embolization.

The uterine balloon tamponade has been a favored form of treatment to manage PPH in recent times, especially in low-resource settings that may not have easy access to blood transfusion and surgical facilities (Mercier et al. 2008, Rath W. H., 2012). When uterotonics are unable to stop the bleeding, the UBT is a preferred second option to operative therapies such as hysterectomy because of the morbidity of surgical procedures and to preserve the patient's fertility (Dabelea et al. 2007). Since the UBT is at the center of this study, the section below will provide detailed information on how the UBT works, its benefits and its efficacy, which will be illustrated through studies performed on the UBT.

1.5 The Uterine Balloon Tamponade

The UBT procedure involves the insertion of a balloon into the uterine cavity followed by inflation to achieve a tamponade effect (Tindell et al. 2013). The balloon is inflated using 250-500 ml saline and typically stopped if there is resistance to additional saline or the bleeding stopped (Tindell et al. 2013). Various types of balloons have been used such as a condom, Sengstaken-Blakemore tube, Foley, Rusch and Bakri balloons (Rathore, et al. 2012, Gronvall et al. 2013). In high-resource settings, the Sengstaken-Blakemore tube and Rusch balloon have been used to control hemorrhage by creating pressure in the uterus to stop bleeding (Miller et al. 2004). Both devices, however, are expensive and not easily accessible in low-resource settings, as opposed to an under- \$5 condom tamponade that is equally effective (Miller et al. 2004). There is little reliable literature on the high cost of the Bakri balloons, Sengstaken-Blakemore tube and Rusch balloon, but speculations suggest that the production of these devices in Western countries and their multiple functions such as drainage from the uterus contribute to their high cost. The Sengstaken-Blakemore tube has a tip that is finely cut to allow a comfortable fit between the balloon and the uterine fundus and facilitates drainage of the uterine cavity (Georgiou 2009). While some health providers argue that the Sengstaken-Blakemore tube is designed to conform to the shape of the uterine cavity, other providers suggest that the Rusch balloon and condom catheter adapt to the shape of the uterus more (Georgiou 2009).

Alternatives to the Sengstaken-Blakemore tube, Foley, Rusch and Bakri balloons such as the condom balloon can be cost-effective and it is easy to detect if it has successfully controlled hemorrhage (Dabelea et al. 2007, Doumouchtsis et al. 2008, Rath W. H., 2012). The UBT can also be used to stabilize the patient's condition while preparing her for laparotomy, arterial embolization or transferring her to a higher-level facility (Rath W. H. 2012, Rathore et al. 2012). The UBT can be administered by inexperienced personnel and requires little or no anesthesia (Mercier et al. 2008, Rath W. H., 2012).

The UBT, while easy for health providers to use, is also proven to be effective in arresting postpartum hemorrhage. Studies have reported success rates between 60 and 100 percent when using the balloon tamponade to address PPH (Doumouchtsis 2008). A study performed by Martin et al. in France showed that the introduction of the balloon tamponade stopped bleeding in 32 of the 49 respondents recruited for the study, which is a success rate of 65 percent (Martin et al. 2015). It must be noted, however, that the UBT was introduced in these patients 50 minutes after the onset of postpartum hemorrhage and a mean blood loss of 1284 ml, which would qualify as severe postpartum hemorrhage (Martin et al. 2015). Martin et al. attribute the lower overall success rate to administering the UBT 50

minutes after postpartum hemorrhage had begun.

Rathore et al. conducted a study in a New Delhi hospital from October 2009 to March 2011, recruiting 18 patients on the basis of uterotonics failing to control bleeding. All patients recruited had primary postpartum hemorrhage and 67 percent of participants were hemorrhaging because of uterine atony. The condom catheter balloon used for this study was made by tying a condom to a foley catheter using silk (Rathore et al. 2012). The condom catheter balloon was connected to a saline bottle through IV infusion and filled with saline till the balloon contained the bleeding and was visible in the cervical canal (Rathore et al. 2012). The authors defined failure of the balloon as continued bleeding after 15 minutes of the balloon being inserted. If the bleeding did stop, however, the balloon remained in the cervical cavity from 8 to 48 hours. The results of the study showed that the balloon was successful in 17 of the 18 patients, which is a 94 percent success rate, and the mean time to control bleeding was 6 minutes.

Doumouchtsis et al. (2007) performed a systematic review of 46 studies to assess the success rates of various methods used to address postpartum hemorrhage. The systematic review indicated that the cumulative outcomes from the studies analyzed showed a success rate of 84 percent for the UBT. However, Doumouchtsis and colleagues argue that the review did not yield results that favored a particular method to manage severe postpartum hemorrhage over alternative treatments. This is, in part, because of the number of different clinical scenarios in which postpartum hemorrhage can occur. While postpartum hemorrhage during cesarean section may be best managed by compression sutures, the balloon tamponade might be most effective after a vaginal birth (Doumouchtsis et al. 2007). The authors also argue that the lack of evidence, at present, means that health workers should adopt the least invasive, easiest and quickest approach, which they believe is the UBT. They advocate for the UBT to be used as the first step in the protocol to treat intractable postpartum hemorrhage, when the patient does not respond to medical treatment in the form of uterotonics. It is important, however, to recognize that the studies analyzed in this systematic review were conducted in high-resource tertiary settings and may not apply easily to low-resource settings (Tindell et al. 2013). The effectiveness of the UBT may be significantly different in high-resource and low-resource settings owing to the availability of uterotonics, trained personnel, and operating theatres (Tindell et al. 2013).

Rathore et al. (2012) argue that the ideal scenario for the treatment of postpartum hemorrhage would require a combination of skilled health workers and the availability of technology. Since skilled health workers and technology are not easily available in low-resource settings, the UBT in the form of the condom catheter balloon can be an effective and inexpensive intervention (Rathore et al. 2012, Mercier et al. 2008, Rath W. H., 2012). Rathore et al.'s study was conducted in India, where hospitals

received condoms free of charge from the Indian government, making the condom catheter balloon a feasible option to address postpartum hemorrhage.



Figure 2: The UBT in the form of a condom tamponade (Tindell et al. 2013)

1.6 Postpartum Hemorrhage In South Africa

Obstetric hemorrhage is the third most common cause of maternal death in South Africa. Maternal mortality caused by obstetric hemorrhage has been on the rise with the rate rising from 13.6 per 100,000 live births in 1999 to 18.8 from 2005 to 2007 (Fawcus et al. 2011). The major conditions responsible for obstetric hemorrhage included abruption placentae, which accounted for 9.8 percent of hemorrhage cases; retained placenta, responsible for 17.9 percent of cases; uterine atony, resulting in 13.6 percent of cases; uterine rupture, causing 16.3 percent of hemorrhage cases; and uterine trauma, primarily bleeding during and after cesarean section accounting for 28.5 percent cases (Fawcus et al. 2011).

Postpartum hemorrhage tests the efficiency of the South African health system and skills of the workers in the system because the onset of hemorrhage is unpredictable and patients deteriorate quickly (National Department of Health South Africa 2010). Patients suffering from postpartum hemorrhage may not survive referral to another health care center, emphasizing the importance of having postpartum hemorrhage management systems at all levels of care (National Department of Health South Africa 2010). In South Africa, more than 75 percent of hemorrhage deaths occur at Level 1 (district) and Level 2 (regional) hospitals, with 43 percent of these deaths occurring at Level 1 facilities (National Department of Health South Africa 2010). The National Department of Health found that many women arrived at health facilities in a critical condition or died in transit. In many parts of South Africa, women deliver at home, which not only creates barriers for emergency obstetric care, but may also result in maternal deaths going unreported (National Department of Health South Africa 2010). It is possible that mortality is

higher in provinces where the number of home deliveries is higher (National Department of Health South Africa 2010).

Fawcus and Moodley state that 80 percent of the postpartum hemorrhage deaths in South Africa that occurred were identified as “clearly avoidable.” Substandard care was a major problem, which contributed to over 40 percent of deaths for every level of care. The parameters of substandard care included the failure to perform essential steps of prescribed protocols and serious delays in doing so (Fawcus et al. 2011). Resuscitation of patients was also not performed adequately (Fawcus et al. 2011).

1.7 Postpartum Hemorrhage In Ghana

Ghana’s maternal mortality ratio is estimated to be 350 per 100,000 births, representing 2700 maternal deaths annually (WHO, UNFPA, World Bank, 2010). Lee et al. suggest in their study that delays in accessing emergency obstetric care is a contributing factor to preventable maternal deaths (Lee et al. 2012). District hospitals lack the resources and expertise to address obstetric emergencies. 43.4 percent of maternal deaths at KATH, the hospital at which Lee et al. conducted their review, were referrals from district hospitals. A study conducted in Berekum, Ghana compared active and expectant management at the Holy Family Hospital. 5,088 birth records from 1992 and 1995 when expectant management was followed compared to 3,840 records from women who delivered from 1996 and 1998, when active management was the standard of care (Geelhoed et al. 2002). The results of the study indicated that postpartum hemorrhage was less frequent in the patients that received active management (Geelhoed et al. 2002).

11 percent of deliveries in Ghana are C-Section births and only doctors are permitted to perform them, therefore, they attend to approximately 2 percent of vaginal deliveries (Maya et al. 2015). When postpartum hemorrhage occurs during cesarean section births, surgical management is available if the patient does not respond to first line treatment (Maya et al. 2015). However, there is a time lapse between the failure of medical treatment and the administration of surgical management (Maya et al. 2015). The time in between is when the condom tamponade should be instituted (Maya et al. 2015). Condoms are easily available in health facilities across Ghana at a reasonable price (Maya et al. 2015). Midwives and nurses perform 54 percent of deliveries in Ghana, doctors do 13 percent and traditional birth attends, friends and relatives account for the rest (Maya et al. 2015).

1.8 Statement Of The Study

South Africa and Ghana are grappling with maternal deaths caused by postpartum hemorrhage. There is evidence that low-cost measures like the UBT can help lower the number of deaths resulting from postpartum hemorrhage. Previous literature on maternal mortality and the UBT has described the efficacy of the device and its contribution to reducing the number of maternal deaths. Therefore, a qualitative study that illustrated these barriers in South Africa and Ghana was necessary. This study aims to describe the barriers involved with integrating the UBT into South Africa and Ghana's health systems to address postpartum hemorrhage.

2. Methods

This is a qualitative study, which used in-depth interviews to gather data. Participants were selected through snowball and purposive sampling, and referrals from PATH, an American non-profit organization. Through PATH's head office in Seattle and assistance from PATH's country offices in Johannesburg and Accra, I contacted health providers, experts, policy makers, donors and manufacturers to capture diverse perspectives on what they believed were barriers to the integration of the uterine balloon tamponade in South Africa and Ghana's health systems.

2.1 Setting

This study took place in South Africa and Ghana. South Africa and Ghana were selected because they have high rates of maternal mortality due to postpartum hemorrhage and there is potential in both countries to lower those rates. In addition, PATH had connections with the stakeholders interviewed for this study and has been working to introduce low-cost measures to alleviate the burden of postpartum hemorrhage in South Africa and Ghana.

In South Africa, data collection took place in Cape Town, Johannesburg, Durban and Mpumalanga. The multiple sites in South Africa provided access to university-based academics and UBT manufacturing plant in Cape Town, policy makers and administrators in Pretoria and Johannesburg. In addition, a number of policymakers and experts who participated in this interview were based in Mpumalanga and Durban. In Ghana, the interviews took place in the capital city of Accra, where access was available to access the Ghana Health Services, Food and Drug Authority, and key regional and district hospitals.

2.2 Ethical Considerations

This study was reviewed by Duke IRB and deemed exempt because there was no potential harm to any respondents from their participation in this study. Prior to the interview, participants were read an oral consent, which stated the purpose of the study and their participation in it, and promised anonymity.

2.3 Participants

This study aimed to include participants who were stakeholders in the process of integrating medical devices in South Africa and Ghana. They included health providers, experts, policymakers, donors and manufacturers. The approach to recruit participants for this study included purposive sampling, snowball sampling, and participant referrals. In total 25 participants were interviewed for this study. A list of stakeholders was made before the interview process began to ensure that a broad spectrum of stakeholders that contribute to the integration process of a medical device was reached. Once this list was constructed, PATH's connections in South Africa and Ghana helped set up the interviews with policy makers and experts on maternal health. With respect to health providers, they were contacted via telephone, after which interview times were set up. At the end of each interview, recommendations were solicited for other stakeholders who might be contacted for an interview.

2.4 Procedures

All interviews took place in English and in private spaces convenient for the participants. The interviews typically took 30 to 45 minutes each. I conducted the interview based on an interview guide that was tailored specifically for each stakeholder type (Table 1). The guide included probes and follow-up questions for clarification. The interviews were not recorded, but extensive notes were taken throughout the interviews.

Table 1: Categories of questions posed to each stakeholder type

Policymaker
<ul style="list-style-type: none"> • Procedure to introduce a medical device nationally. • Regulating medical devices. • Evidence required to introduce a medical device as standard of care. • Endorsements. • Rollout nationally.
Health provider
<ul style="list-style-type: none"> • Number of patients with PPH per month. • Standard protocol to treat patients with PPH. • If and when they use the condom tamponade. • Anything they dislike about the condom tamponade.
Academics/Experts
<ul style="list-style-type: none"> • Consensus among experts. • Building guidelines. • Integrating the UBT as a standard of care. • The process that hospitals and clinics need to do to access the UBT. • Use of the UBT among community health workers. • Important stakeholders in the process.
Donors
<ul style="list-style-type: none"> • Items supplied to the Ghana Health Service. • Quantities of these items and the yearly budget. • Procedure to supply to GHS. • Donor catalogue items.
Manufacturer
<ul style="list-style-type: none"> • Modifications to the UBT. • Plan for selling the UBT. • Process of integrating the UBT into the health system. • Process of incorporating it into policy. • Other considerations.

2.5 Data Analysis

Since all interviews took place in English, they did not require translation. The data was collected through written notes. The theoretical approach used for analysis was content analysis. Content analysis intends to arrive at a broad description of the phenomenon, resulting in categories and themes describing the phenomenon of interest (Elo et al. 2008). Within content analysis, the approach that this study took was inductive content analysis. Inductive content analysis was used because there is a limited amount of data on the UBT and its use in South Africa and Ghana. Inductive content analysis demands the creation of categories to help describe the phenomenon being studied and to increase knowledge (Elo et al. 2008). The researcher is responsible for organizing data that belong to the same categories once the categories have been created. Given my topic, the categories were created along the line of questioning used for the various stakeholder groups. Once the categories were created, it was necessary to find recurring themes. Pattern coding was used, using Nvivo, to establish these themes. The process of pattern coding identifies emergent themes and groups large amounts of data into recurring themes (Miles et al. 1984).

The codes included key words from the categories I created and the research question, such as ‘awareness of the UBT’ and ‘postpartum hemorrhage as a problem.’ Based on these codes, key themes were identified. Key themes were typically issues that were brought up by a significant majority of the respondents interviewed or helped answer the research question in any way, still being mentioned by a large number of respondents. In order to illustrate these themes, quotes from at least two respondents were used. Within these themes, if respondents presented contrasting opinions, a minimum of two contrasting views were quoted.

3. Results

Description of Sample

A total of 25 participants were interviewed, representing stakeholders important to the integration of medical devices in South Africa and Ghana (Table 2). Their perspectives provided an understanding of their perception of the integration process and their roles in the process.

Table 2: A description of the respondents

South Africa	Description of Respondent
Academic 1	OBGYN professor at a teaching university in the Western Cape
Academic 2	OBGYN professor in Gauteng
Manufacturer 1	Medical device manufacturer in the Western Cape
Expert 1	Maternal health and policy expert in Mpumalanga
Expert 2	Consultant at a health care technology firm
Expert 3	Part of a medical device association
Expert 4	Technical project manager
DoH 1	Ministry official in Pretoria
DoH 2	Ministry official in Mpumalanga
DoH 3	Ministry official in KwaZulu Natal
Provider 1	Works at a community health center in the Bishop Lavis township, Cape Town
Provider 2	Works at a community health center in the Delft township, Cape Town
Provider 3	Works at a government hospital in Johannesburg

Ghana	Description of Respondent
DoH 1	Policy expert at Ghana Health Services
DoH 2	Works for the FDA
DoH 3	Works for GHS procurement department
Expert 1	Policy expert at a non-profit
Expert 2	Pharmacist
Donor 1	Works for UNFPA

Donor 2	Works for USAID Deliver
Provider 1	Gynecologist
Provider 2	Nurse at a regional facility
Provider 3	Midwife at a district facility
Provider 4	Midwife at a regional facility
Provider 5	Midwife, regional facility

The key categories related to barriers in the integration of the UBT across interviews in the two countries were: acknowledging postpartum hemorrhage as a problem and number of cases, protocol to treat postpartum hemorrhage, and the process of integration of the UBT in South Africa and Ghana’s health systems. Using these categories, the rest of this section will delineate themes that emerged from the interviews.

3.1 Acknowledging Postpartum Hemorrhage as a Problem and Number of Cases

South Africa

In South Africa, there was little consistency in acknowledging postpartum hemorrhage as a problem. DoH 2, Expert 2 and Provider 3 stated that the number of PPH cases were high. DoH 2 from Mpumalanga said, “...it is definitely a huge problem.” Expert 1 also said, “...it is frequent.” Provider 3 in Johannesburg confirmed their view saying, “...we have a high number of patients coming in with various post-birth complications.” In contrast, two providers in health facilities in Cape Town said PPH was not a problem. Provider 2 said, “We don’t get too many cases of postpartum hemorrhage; it is rare here because of good management.” This was a surprising revelation, given that the data on postpartum hemorrhage and maternal mortality indicate that South Africa has a high maternal mortality rate and postpartum hemorrhage is a key contributor to maternal mortality.

Ghana

Overall, respondents in Ghana felt that postpartum hemorrhage cases had reduced in the last few years but remained a major problem. DoH 1 stated, “postpartum hemorrhage is a major problem in Ghana,” but “the frequency has decreased over the years.” This view was corroborated by Expert 1, who said, “postpartum hemorrhage is a huge issue. Maybe not as much as it was a few years ago but it affects a lot of women, even in a city like Accra.” Two of the health providers also confirmed this view explicitly. Provider 1 claimed, “100 (cases of PPH) is still a high number but much less than before.”

Responses to questions from this category indicated that regional facilities got more postpartum hemorrhage cases primarily because of the number of referrals from smaller facilities. This implies that smaller facilities do not have the resources to address postpartum hemorrhage. Patients who have lost a lot of blood may end up being in greater danger if they seek care in a district facility and the facility is unable to treat them. Three out of the five providers mentioned this in their responses, probably because they worked at regional hospitals. Provider 1 explained, “...100-150 (of PPH) cases every month. This is a big hospital and most of the staff is trained to treat PPH, that is why we get more cases. This is a referral facility.”

3.2 Postpartum Hemorrhage Protocol

South Africa

Responses to questions on postpartum hemorrhage protocol in South Africa indicated that the UBT (condom catheter) was used as a second line of defense. Expert 1 described the procedure: “*The current procedure in general terms is to resuscitate, institute correct measures, monitor and rehabilitate. We try to stop bleeding by direct compression of the iota, uterus, oxytocin combined with misoprostol... If oxytocin does not work, we use the condom catheter.*” Similarly, Provider 3 stated, “*We prefer using oxytocin and massaging the uterus but we use the condom catheter too. It is normally used before we consider a surgical intervention like a hysterectomy.*” Both academics also provided similar information on postpartum hemorrhage protocol. Academic 1 said, “*Normally, the first line of treatment works i.e. oxytocin, uterus massaging. For the rare cases that don’t respond to this treatment, UBT is needed... UBT is not meant for immediate use.*” The views expressed by the providers and academics are in sync with recommendations that the UBT should be used as a second line of defense.

Responses to this category of questions also showed that there is less widespread knowledge of the UBT in South Africa than there is in Ghana, especially among providers, although the number of providers interviewed in South Africa was a limitation. Provider 1 said, “*I don’t know very much about the UBT. We don’t use a balloon-type device to manage PPH here.*” Along similar lines, Provider 2 said, “*we do not use the UBT or any other ballooning devices to treat PPH.*”

Similar to Ghana, one of the academics brought up the assembly of the condom tamponade as a disadvantage of using it. Academic 2 said, “*At the moment, the condom catheter and glove catheter are used quite a lot. However, they need to be constructed. The possibility of a mistake during construction is high. A one-piece model that requires no assembly would be welcome.*” These concerns might have been raised by other respondents if there had been more awareness of the condom tamponade.

Ghana

From responses to questions on postpartum hemorrhage protocol, it appeared that there was knowledge of the protocol to counter postpartum hemorrhage among experts. Expert 1 said, “...*oxytocin, massage, and condom tamponade are used. It also depends on individual patients and the amount of blood they have lost.*” Provider responses varied to a certain degree, but all verified the experts’ responses. They all talked about using uterotonic drugs and the condom tamponade, followed by hysterectomy if prior intervention failed. Provider 1 explained, “*we use oxytocin, ergometrine, IV drip first. If it doesn’t work, then we use the condom tamponade. If it does not work, we go with surgery.*” Similarly, provider 4 said, “*we use oxytocin, cytotec, transamic acid, bimanual compression...condom tamponade.*”

Respondents indicated that the UBT was used as a second line of defense. Both of the experts interviewed first mentioned uterotonics and then the condom tamponade. Responses from all five providers also followed a similar pattern. Provider 5 confirmed this view, “*First we call for help, then bimanual compression, IV, ergometrine, cytotec and oxytocin. When all this does not work, we use the condom tamponade.*”

The success rate of the condom tamponade is an important factor in its frequent use as part of postpartum hemorrhage protocol. Three out of the five providers interviewed explicitly mentioned that the condom tamponade had a high success rate when they used it. Provider 3 said, “*It works when we use it. We have not yet encountered any difficulty with the tamponade. So I think it has a high success rate.*” Other providers, not necessarily critical of the condom tamponade, offered alternative perspectives. For instance, provider 1 explained, “*It works most of the time. There are times when we have to go into surgery after the condom tamponade. It is difficult to tell if the condom tamponade failed or there was too much blood from the beginning.*” The highly favorable view of the condom tamponade is an indication of the enthusiasm of the provider population to use it when confronted with cases of postpartum hemorrhage.

Four out of five providers, however, found assembling the condom tamponade to be a cumbersome process, especially when the patient was bleeding profusely and needed immediate treatment to stem the flow of blood. Provider 5 gave a detailed explanation of this challenge. “*Tying the condom tamponade is a pain. I do night shifts, when I have to make the tamponade at 4 am, it is irritating. And I trust myself that I will put the patient’s needs first and do it correctly. If midwives who are more tired than I have to do it, they can make mistakes. And when the patient is bleeding, every second is important.*” Provider 5 made a similar argument: “*...I think putting the tamponade together is very*

annoying. Especially if we have an urgent case.” The providers are under pressure to save their patients and claimed to prefer an assembled version of the UBT in order to expedite the process of using it.

3.3 Process of Integration of the UBT in the Health System

South Africa

There was a lack of consistency in responses within various categories of stakeholders interviewed on the process of integration into the health system as standard of care. DoH 2 said, *“Any device will have to be approved by the MCC. It is imperative.”* On the other hand, DoH 3 refuted, *“The MCC is not in the picture. Their consent is not required. They have no role to play in this. The SABS is important, as are the CSAR and the MRC.”* The MCC refers to the Medicines Control Council, a regulatory authority entrusted with approving drugs to be sold in South Africa. The SABS stands for the South African Bureau of Standards, which is responsible for providing standards development and quality assurances services. The MRC refers to South Africa’s Medical Research Council, aiming to improve health outcomes through research and health systems strengthening. All the organizations mentioned above have a role to play in ensuring that a medical device is used as a standard of care throughout the country. However, the respondents appeared to be unsure of the exact role of these organizations in the integration process.

A similar pattern was observed in the responses of experts. The experts on policy interviewed for this study conveyed a different perception of the role of regulatory organizations and the overall process of integration in South Africa. Expert 2 argued, *“MCC approval is not necessary at the provincial level, it is necessary at the national level...Clinicians have the freedom of judgment to use what they want to.”* Expert 3, however, said, *“There are no regulations for medical devices in South Africa...Central DoH has been trying to centralize and decentralize for years. It’s an on and off process.”*

The academics’ responses to questions on the integration process were not consistent with those of the policymakers and experts. Academic 1 said, *“MCC approval is imperative...which is very difficult because they are swamped and struggling to review all applications.”* In contrast, Academic 2 said, *“Medical devices are easier to get on the market than medicines...I don’t know what is going on with the MCC and SAHPRA. I believe the MCC regulates medical devices but there was talk of SAHPRA taking over from them.”* SAHPRA is the South African Health Products Regulatory Authority expected to take over responsibilities pertaining to the regulation of medical devices from the MCC.

Ghana

Answers emerging from questions on the process for the integration of a medical device showed that there was a lack of consistency in outlining the process. For instance, DoH 1 explained that a new document listing medical devices that should be used for various health conditions was being created for the first time in Ghana. This list, upon completion, would be discussed with stakeholders and experts on insurance and policy, as well as clinicians and representatives from the WHO. When these individuals analyze a product, there must be substantial evidence to prove its efficacy and it is imperative that the product must address health problems that Ghanaians are currently facing. DoH 1 said, *“When the list is ready, it is opened for discussion to stakeholders...data from these discussions is given to a committee with experts on insurance, policy, clinicians, WHO. A subgroup with these experts will review the evidence and then make a recommendation.”* For integration into the health system, *“there needs to be substantial evidence to prove the efficacy of the product...needs to be collected in Ghana itself...device is relevant to Ghana and will be good for the Ghanaian people.”*

On the other hand, DoH 3 tried to explain the process through the lens of other departments involved in the process of integrating a medical device in Ghana. Depending on the function of the device, the evidence is studied carefully by the relevant department. Given that the Ghanaian health ministry is currently experiencing a cash deficit, it is not in a position to fund medical devices. Therefore, it is important to have funding mechanisms in place before incorporating a new device as standard of care. DoH 3 said, *“It depends on the function of the device and the department it is relevant to. Whatever it is, the funding for the device to be a part of the GHS must be in place...the ministry has financial constraints, it is not able to fund medical devices.”* Furthermore, she explained, *“A committee that looks into maternal and child health devices will send a letter to the procurement department...coordinate multiple donors.”*

The interviews also reflected on a lack of clarity on the requirements for clinical trials to be held in Ghana. Respondents provided conflicting answers on whether clinical trials for devices new to the Ghana Health Services needed to be performed in Ghana. For a new medical device to be integrated in Ghana, the Ghana Health Services will examine evidence produced through clinical trials. However, there is a degree of confusion surrounding where this evidence is collected. While some respondents suggested that clinical trials must be performed in Ghana in order to prove its safety and applications to the Ghanaian people, other participants claimed that evidence collected from another country can be applied to Ghana. Expert 1, for instance, stated, *“...clinical trials need to be performed in Ghana to prove that the UBT is safe and effective to treat patients from PPH.”* On the other hand, DoH 2 who worked for the

Ghana Food and Drug Authority claimed, “...*clinical studies will not be needed if all the documentation is adequately provided. The evidence for efficacy, even if it is shown for another country, can be applied to Ghana...*” These contrasting answers reflect that respondents working in different departments of the health system have a varying understanding of the procedure linked to clinical trials of new devices.

4. Discussion

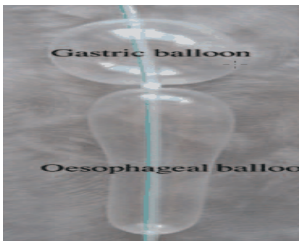
The literature on postpartum hemorrhage and the efficacy of the UBT in arresting it has shown it to have potential in alleviating the burden of postpartum hemorrhage in low-resource settings (Doumouchsis et al. 2007, Tindell et al. 2013). The evidence from these studies indicates that the UBT has a high success rate as a second line of defense and can be useful in low-resource settings, given its low cost and potential to be used effectively by inexperienced health workers. This study investigated the barriers to the integration of the UBT into South Africa and Ghana's health systems through in-depth interviews with stakeholders who are integral to the process of integration of medical devices in the two countries.

Twenty-five respondents were interviewed for this study. The challenges confronting South Africa and Ghana, as the respondents put it, appeared to be different. In South Africa, the lack of acknowledgement of postpartum hemorrhage as a problem is a significant barrier. There was also lesser awareness of the UBT as a device that controls postpartum hemorrhage. Responses indicated that the understanding of the integration process for a medical device into the South African health system differed significantly among policymakers, experts and academics. In Ghana, all stakeholders admitted to postpartum hemorrhage being a matter of concern in the country, despite recent strides in addressing it. The Ghana Health Services, according to policymakers, is experiencing cash constraints, impeding its ability to purchase medical devices. Like South Africa, there is a varied understanding on procedures associated with performing clinical trials for new medical devices in Ghana. Finally, health providers in Ghana used the UBT in the form of the condom tamponade significantly more than South African health providers.

The UBT, in iterations like the condom tamponade, is a cost-effective intervention to control bleeding from postpartum hemorrhage, compared to other balloon technologies such as the Rusch balloon and Sengstaken-Blakemore tube, therefore making it a viable option to scale-up in the management for postpartum hemorrhage in low-resource settings. Researchers at the Massachusetts General Hospital designed the Every Second Matters for Mothers and Babies kit that includes the UBT (ESM-UBT), which costs less than \$5 and consists of a kit containing a condom tied to a Foley catheter and inflated with clean water through a syringe and one-way valve. The UBT is used as standard of care in hospitals in the United States, but balloons manufactured used in these settings are single-use and cost over \$400 dollars (Massachusetts General Hospital 2016). Below are the various balloons that are used to address postpartum hemorrhage, along with their costs (Georgiou 2009):



The Bakri Balloon, \$250 per device



The Sengstaken-Blakemore Tube, \$220



BT- Cath, \$200



The Rusch Hydrostatic Balloon, \$77

The costs and lack of availability make the above devices inaccessible to health workers in low-resource settings, in contrast to an under- \$5 UBT in the form of a condom tamponade that is known to be just as effective. In fact, findings from recent studies, such as one conducted by Burke et al., suggest that women that have had the UBT placed were not transferred to higher-level facilities for surgical interventions. This is corroborated by Natarajan et al's work on provider experience with the UBT in Kenya, which also stated that most providers interviewed found the UBT to arrest bleeding effectively enough to reduce the need for a referral, therefore proving its efficacy as an endpoint intervention for postpartum hemorrhage.

While the data on the efficacy of the UBT is encouraging, it must be noted that there is still little robust data that has proven the UBT's efficacy in low-resource settings (Tindell et al. 2013). Assessments of the feasibility of using the UBT in peripheral facilities with lower-level health workers have not been investigated (Natarajan et al. 2015). In particular, questions on the use of the UBT in the postpartum hemorrhage protocol in these settings, the provider's skill and ability to be able to insert the balloon well, and challenges to implementing the UBT on a wider scale have not yet been addressed (Natarajan et al. 2015).

4.1 Implications for policy and practice

Literature on the effectiveness of the uterine balloon tamponade has shown it to be a life-saving intervention for women suffering from postpartum hemorrhage, after uterotonics fail to stem the flow of blood. Success rates in studies conducted using the UBT have ranged from 60 to 100 percent (Kinugasa et al. 2015, Tindell et al. 2013, Doumouchstis, 2007). Dabalea et al. have shown the UBT to have a success rate of 90 percent in controlling postpartum hemorrhage. The UBT has been successful in all cases of

hemorrhage caused by uterine atony and 80 percent success when a retained placenta has been responsible for postpartum hemorrhage (Dabelea et al. 2007). Given the frequency at which health providers, experts and policymakers mentioned the condom tamponade as part of Ghana's protocol to treat postpartum hemorrhage, an assembled version of the UBT may be easier for health providers to administer. The health providers in Ghana corroborated this view and confirmed that an assembled version of the UBT would save them time. However, there are concerns that it may not be able to fit inside a postpartum cervix and runs the risk of slipping out if the volume of saline is low (Albayrak et al. 2011). Potential problems noted during UBT administration raise the question of health providers receiving adequate training to effectively use it on a patient. A study by Natarajan et al. (2015), gauging provider experiences of the UBT in Kenya, indicated that the UBT was incorporated in peripheral facilities in Kenya through half-day standardized training with practical skills development to informal training carried out by providers who attended the initial training. In addition, word-of-mouth and on-the-job training were also used, but a significant challenge with consistent use of the UBT is high staff turnover and the need to repeatedly train staff to use the UBT (Natarajan et al. 2015). The authors of the study argue that introducing the UBT into training curricula and combining pre-service training, refresher training and making it a part of facility protocols will ensure that providers will have the skills necessary to use it regularly. The approach recommended by Natarajan et al. can be applicable to facilities in South Africa and Ghana as well.

While the degree of awareness of the UBT was lower in South Africa compared to Ghana, the providers and academics that were well versed with its functions advocated for its integration in the South African health system. The low recognition of postpartum hemorrhage as a problem in certain South African facilities is in contrast from the data on postpartum hemorrhage and maternal mortality in South Africa. The maternal mortality ratio in 2007 was 625 per 100,000 live births compared to 369 per 100,000 live births in 2001 (UNDP 2010).

In South Africa, the lack of clarity surrounding the process of integration from a policy standpoint is one of the biggest barriers to incorporating the uterine balloon tamponade in standard practice to address postpartum hemorrhage. The Medicines Control Council is a regulatory body appointed by the Minister of Health, with the primary responsibility to ensure that medicines, medical devices and in vitro diagnostics being sold and used in South Africa meet high standards of quality (Medicines Control Council 2016). Applications seeking approval must submit proof of safety, quality and performance (Medicines Control Council 2016). While the MCC has provided this information, the respondents interviewed for this study have expressed uncertainty over the process. This is evident in responses

received from the two Department of Health officials quoted in the results section. Similarly, the experts and academics mentioned have also given contrasting answers. Respondents in Ghana provided a more streamlined process for integration, albeit they worked for different departments of the Ghana Health Services. However, there were contrasting views on clinical trials for new medical products being held in Ghana. The Ghana Health Services rely strongly on donors for funding the procurement of medical devices in Ghana. This can be a major barrier if the manufacturer of the medical device in need does not have a WHO certification, as one of the donors interviewed pointed out.

If the obstacles discussed above are, in fact, overcome, the process to implement the UBT can be beneficial in equipping health workers with the tools to use the UBT confidently. Preparing a postpartum hemorrhage-training curriculum that use the UBT in the context of the national postpartum hemorrhage protocol, in collaboration with ministries of health and other important partners (Burke et al. 2015). The curriculum must have guidelines incorporated by the WHO and FIGO (International Federation of Gynecology and Obstetrics) for postpartum hemorrhage care. The implementation program suggested by Burke et al. including a PPH-UBT checklist, a wall poster postpartum hemorrhage clinical pathway, a trainer's flipchart and a learner's booklet can be of use in training providers to use the UBT. These materials can also be useful when giving refresher courses to providers or training new providers. A training-of-trainers model that gives providers hands-on exposure to postpartum hemorrhage scenarios, with models depicting the uterine cavity will give providers more confidence when using the UBT (Burke et al. 2015).

4.2 Implications for further research

There is substantial evidence to prove the efficacy of the UBT in controlling postpartum hemorrhage when uterotonics fail and it is used in low resource settings, as can be seen in Ghana. However, there is limited literature on the efficacy of the UBT in sub-Saharan Africa. It is imperative to produce this literature because a number of proven and affordable interventions used in well-resourced settings are often difficult to implement in developing countries because of limited resources and poor infrastructure (Geller et al. 2006). A useful analogy that illustrates this is that there is literature to prove that AMTSL is efficacious in controlling bleeding after delivery, but the importance of the various components that make up AMTSL is unknown (Geller et al. 2006). More research is also needed to determine if AMTSL training can be adapted for traditional birth attendants and lesser skilled personnel (Geller et al. 2006). Similarly, it is essential perform studies in sub-Saharan Africa to get a better idea of the efficacy of the UBT in controlling postpartum hemorrhage and the resources available to administer

the UBT in these settings. By extension, investigating processes that would facilitate the integration of the UBT into a country's health system, making it easier for health workers to gain access to the intervention.

Specifically on the barriers of integration of the UBT into the health system, it would be useful to study larger sample sizes, including the main stakeholder categories that contribute to the process of integration of medical devices in countries with high maternal mortality. While this was a qualitative study, a mixed methods approach would also yield interesting results. A survey can be administered to health providers and midwives across the country to assess the frequency with which the UBT is being used. Qualitative methods such as in-depth interviews with policymakers or focus groups with policy experts can help illustrate gaps in the understanding of integrating a medical device into the health system. In addition, retrospective record reviews and prospective observational studies can be of value in obtaining accurate data on postpartum hemorrhage incidence and UBT use to arrest postpartum hemorrhage. Given Ghanaian health providers' preferences for an assembled UBT, a study comparing outcomes between an assembled UBT versus the condom tamponade will help policymakers arrive at an informed decision on the iteration of the UBT the country should pool its resources for.

4.3 Study strengths and limitations

Interviewing stakeholders who contribute to the integration process of medical devices into the health system is a strength of this study. Being able to conduct this study in two countries- South Africa and Ghana- provided additional perspective and a more comprehensive comparison of how the UBT is used in the two countries. However, the small sample sizes in South Africa and Ghana are a limiting factor, not ideal for arriving at firm conclusions. While this study incorporated the perspectives of various stakeholder categories, interviewing more individuals in each of these categories would have provided greater insight into the barriers to the integration of the UBT. In addition, the desired level of detail could not be achieved in the interviews conducted because of limited knowledge of postpartum hemorrhage and interventions used to control it among all stakeholder categories except health providers and academics. Finally, questions implicitly highlighting some of the inadequacies of South Africa and Ghana's health systems with respect to their protocols for managing postpartum hemorrhage may have contributed to bias among certain stakeholder groups, especially policymakers.

5. Conclusion

Based on the findings of this study, the South African and Ghanaian health systems have various challenges that prevent them from successfully incorporating the device as a standard of care, as part of a larger protocol, to address postpartum hemorrhage. In South Africa, recognition of postpartum hemorrhage as a problem may be a barrier to the UBT's integration into the health system. Given the perceived low prevalence of postpartum hemorrhage, as stated by the health providers interviewed, there is little awareness of the UBT as a second line of defense to treat postpartum hemorrhage. Interviewee responses also suggested a lack of clarity on the responsibility of the Medicines Control Council as a regulatory body and its role in the integration process. One of the biggest challenges that Ghana faces in integrating the UBT is that the Ghana Health Services do not have the funding to pay for the procurement of medical devices, instead relying heavily on donors, who might not want to prioritize the procurement of medical devices for the Ghana Health Services. Similar to South Africa, respondents displayed inconsistencies in describing integration procedures, with some respondents claiming that clinical trials for new devices must be carried out in Ghana and others stating that clinical trials in Ghana are not necessary.

Previous literature on postpartum hemorrhage and the UBT highlight the device's efficacy in alleviating it. This study, in addition to highlighting the UBT's benefits, emphasizes the barriers in two African countries that prevent it from being accessible to providers, which exist on the political, economic, and health delivery level. The elimination of these barriers will help health providers receive access to a life-saving intervention that can control hemorrhaging and ultimately save lives that would otherwise be claimed by postpartum hemorrhage. More attention can be garnered to this subject if future studies include a larger sample size and involve more respondents from all categories of stakeholders integral to the integration of the UBT. This study attempted to incorporate perspectives of a diverse range of stakeholders key to integrating medical devices in South Africa and Ghana and hopes to be the stepping-stone for more research on this subject to ensure that medical devices such as the UBT, proven to be effective, can be accessed by health workers in low-resource settings, ultimately reducing deaths caused by postpartum hemorrhage.

According to Goal 5 of the Millennium Development Goals, countries should have aimed to reduce their maternal mortality ratio by three-quarters between 1990 and 2015. South Africa had a maternal mortality ratio of 108 in 1990, which increased to 138 in 2015 (World Bank 2016). Ghana, in 1990, had a maternal mortality ratio of 634 and managed to reduce the number of deaths to 319 by 2015 (World Bank 2016). Both countries were unable to achieve the targets set by the Millennium Development Goals. Goal 3 of the Sustainable Development Goals targets a Maternal Mortality Ratio of

70 per 100,000 by 2030. Countries across the world face different challenges in meeting targets set by the Millennium Development Goals and Sustainable Development Goals. However, the literature reviewed for this study and some of the results presented indicate that consistent use of the UBT can save the lives of women hemorrhaging after delivery, particularly in peripheral facilities that may not have the means to perform surgical interventions or transfer patients to higher-level facilities in time. While there is limited data on the efficacy of the UBT in low and middle-income countries, there is evidence to suggest that the high success rate and cost-effectiveness of the UBT can make it a useful tool in the protocol to address postpartum hemorrhage, ultimately saving the lives of women who would, otherwise, succumb to this largely preventable condition.

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