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CLINICAL ARTICLE 1

Provider experience of uterine balloon tamponade for the management of postpartum hemorrhage in Sierra Leone 3

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ABSTRACT

Objective: To understand healthcare providers' experience of incorporating uterine balloon tamponade (UBT) 16 into the national postpartum hemorrhage (PPH) clinical pathway after UBT training. Methods: In a qualitative 17 study, semi-structured interviews were undertaken with healthcare providers from 50 centers in Freetown, 18 Sierra Leone, between May and June 2014. All eligible healthcare providers (undergone UBT training, actively 19 conducted deliveries, and treated cases of PPH since UBT training) on duty at the time of center visit 20 were interviewed. Results: Sixty-one providers at 47 facilities were interviewed. Bleeding was controlled in 28 21 (93%) of 30 cases of UBT device placement. Participants reported that UBT devices were easy to insert with only 22 minor challenges, and enabled providers to manage most cases of uncontrolled PPH at their own facility and to 23 refer others in a stable condition. Reported barriers to optimal UBT use included insufficient training and practical 24 experience, and a scarcity of preassembled UBT devices. Facilitators of UBT use included widespread acceptance 25 of UBT, comprehensive and enthusiastic training, and ready availability of UBT devices. Conclusion: UBT-used either 26 as a primary endpoint or en route to obtaining advanced care-has been well accepted and integrated into the 27 national PPH pathway by providers in health facilities in Freetown. 28

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1. Introduction 41

Postpartum hemorrhage (PPH) is the leading cause of maternal 42mortality and morbidity worldwide, with the vast majority of PPH-43 related deaths occurring in low- and middle-income countries [1–4]. 44 45 Even before the Ebola crisis. Sierra Leone's maternal mortality statistics were among the worst in the world, with an estimated 860 maternal 46deaths per 100 000 live births [2,5]. 47

In peripheral facilities, second-line treatments for uncontrolled 4849 PPH-e.g. bilateral uterine artery ligation or embolization, B-Lynch sutures, and emergency hysterectomy-are often unavailable because 50they have to be managed by highly skilled professionals and are 5152expensive [6]. Uterine balloon tamponade (UBT) has recently gained considerable attention as a promising intervention for uncontrolled 53 PPH, and has been both endorsed by the International Federation of 5455Gynecology and Obstetrics, and recommended by WHO as a second-56line intervention for severe uncontrolled PPH [7–11].

57Through partnership with the Sierra Leone Ministry of Health and 58Sanitation, Massachusetts General Hospital has been implementing and evaluating a PPH package with UBT called "Every Second Matters 59 for Mothers and Babies-UBT" (ESM-UBT) [12]. Although there are 60 preliminary quantitative data on the use of UBT, little is known 61 about provider experience or strategies for optimal implementation of 62 ESM-UBT in Sierra Leone.

The aim of the present study was to understand the experiences 64 of health providers who have been managing PPH subsequent to 65 implementation of the ESM-UBT package. The specific goals were to 66 etermine the feasibility of incorporating ESM-UBT into the existing 67 PPH management protocol, providers' experiences with the use of 68 ESM-UBT during uncontrolled PPH, and barriers to and facilitators of 69 optimal PPH management. 70

2. Materials and methods

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In a qualitative study in Freetown, Sierra Leone, information was 72 collected from healthcare providers managing cases of PPH and who 73 had received UBT training by means of semi-structured interviews 74 between May 1 and June 30, 2014. Approval for the study was obtained 75 from the Partners Healthcare Human Research Committee, Boston, MA, 76 USA, and the Sierra Leone Ministry of Health and Sanitation. Informed 77 verbal consent was obtained from all participants. 78

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79 In December 2013 and January 2014, Massachusetts General 80 Hospital, in conjunction with the Sierra Leone Ministry of Health and Sanitation, conducted eight 3-hour workshops on PPH in-service 81 82 training (ESM-UBT). The training components of ESM-UBT included active management of the third stage of labor (AMTSL), basic PPH 83 management, and the use of a condom-catheter ESM-UBT device as a 84 second-line treatment for uncontrolled PPH [13]. Two representatives 85 86 from each of 50 health facilities-usually a facility head and an 87 experienced midwife-were asked to attend a session and subsequently 88 disseminate the knowledge to all members of the facility who are 89 involved in conducting deliveries. The 50 health facilities had been selected by the Ministry of Health and Sanitation predominantly on 90 the basis of need. Each facility was provided with two PPH instruction 9192manuals, a pictorial wall chart, and several ESM-UBT devices. By March 2014, all the original facility representatives reported that all 93 members of their facility had been trained. 94

Approximately 6 months after the initial training session, qualitative 95 96 data were collected from providers at the trained facilities via semistructured interviews. Purposive sampling within the facilities was 97 used to capture both providers who had experience using the UBT and 98 providers from facilities that had managed cases of PPH. At each health 99 facility, a facility leader was asked to identify all health providers on 100 101 duty who had been trained in ESM-UBT, actively conducted deliveries, and had treated cases of PPH since the ESM-UBT training. All health 102 providers on duty at the time of visit who met these criteria were invited 103 to participate in the study. 104

Researchers conducted semi-structured interviews regarding pro-105106 vider management of PPH since the training. All interviews were conducted at the facility and ranged from 15 to 60 minutes. Interviews 107were documented using a standard interview guide. All interviews 108 were voice-recorded and transcribed. Interviewers began by collecting 109110 general statistics about the facility and provider. Participants were 111 then asked to describe the specifics of both managing PPH and using the UBT device since their training to understand whether PPH manage-112 ment was done in accordance with training and whether UBT was used 113 appropriately within the training algorithm. Providers were asked 114 about their experience managing PPH, challenges to managing PPH, 115116 perception of the UBT device, and recommendations for improving the implementation of ESM-UBT training. 117

The transcribed data were analyzed using standard qualitative 118 methods [14]. Two researchers (A.N. and A.M.W.) independently 119 120 analyzed the data via NVivo version 10 (OSR International, Doncaster, VIC, Australia). After first-pass independent analysis, a code book was 121 created. Major codes pertinent to the research question were agreed 122 123by the researchers. Coding of the data was iterative, and provider 124responses were triangulated with data cards completed and verified 125after each use of a UBT. Transcripts were recoded and any discrepancies were resolved. After review of the interview data, provider comments 126were organized into three main domains-experiences with UBT use, 127barriers to UBT use, and facilitators of UBT use-and the major themes 128that emerged were reported. 129

130 **3. Results**

In all 50 ESM-UBT facilities, more than 85% of healthcare providers had been trained in the use of a UBT. Providers at 47 (94%) of the 50 facilities were interviewed. Three (6%) facilities were not visited because of difficult terrain. All health providers on duty who met the study criteria were interviewed. No providers refused to participate in the study.

137 It was known from the multicountry study database that 30 women
had UBT devices placed over the prior 5 months (mean age 26.7 years
[range 16–37]). Fifteen (50%) of these women were either confused or
unconscious and had recorded systolic blood pressures of less than
90 mm Hg at the time that their UBT devices were placed, consistent
with severe blood loss and advanced shock.

Of the 61 health providers interviewed, 17 (28%) were midwives, 19 143 (31%) were maternal and child health aides, 9 (15%) were state-enrolled 144 child health nurses, 14 (23%) were clinical health officers or assistants, 145 and 2 (3%) were medical doctors. The mean years of experience and 146 number of deliveries conducted per month were 9.3 (range 0.5–35) 147 and 32.0 (range 1–200), respectively. Twenty-four (39%) of the 61 148 providers had participated in at least one of the 30 cases of UBT device 149 use. UBT devices had been used at peripheral health centers and 150 hospitals by all levels of the interviewed providers, and state-enrolled 152 child health nurses (Table 1).

Major themes emerging from the interviews are summarized in 154 Supplementary Material S1. Interviewed providers reported the use of 155 UBT appropriately as a last resort and within the national PPH management algorithm. For 28 (93%) of the 30 women who underwent UBT 157 device placement for uncontrolled PPH, providers inserted the UBT 158 device only after administering both prophylactic and treatment doses 159 of uterotonic drugs. Other treatable causes of PPH, in addition to an 160 atonic uterus, were sought in each of the 30 cases of UBT device use before device placement. 162

The 61 interviewed providers described 31 cases of PPH for which UBT 163 devices were not used. In 29 (94%) of these cases, providers were able to 164 arrest the hemorrhage with the use of uterotonic agents or cause-specific 165 management (e.g. repairing a tear or expelling retained products). Most 166 providers who had managed less serious PPH cases stated that they 167 would have used the uterine balloon had the bleeding continued. 168

The interviewed providers reported that PPH was successfully controlled for 28 (93%) of the 30 women in whom UBT devices were placed 170 for severe uncontrolled PPH. The two women who died despite initial 171 UBT device placement had been promptly referred to the nearest referral hospital from the health center where they delivered. One of deaths 173 was attributed to disseminated intravascular coagulation subsequent to fetal demise (severely macerated stillbirth). In the second case, the profusely despite appropriate care. A UBT device was placed after she was already confused and in advanced shock, and the uterine balloon 178 was displaced when the patient became severely agitated and restless 179 during transfer to a referral facility. Unfortunately, the uterine balloon 180 was not replaced and the women continued to hemorrhage and died. 181

Twelve (40%) of the 30 women who underwent UBT were 182 transported to a referral facility, and displacement of the UBT device 183 occurred in 2 (17%) of these 12 women during transport. Of these, one 184 woman had a new uterine balloon placed, received a transfusion and 185 survived; the other woman died, as previously described. Providers 186 universally responded that use of a UBT device was not a barrier to 187 accessing higher levels of care when referral was needed. 188

All interviewed providers who inserted a UBT device found it to be a 189 valuable additional tool to manage uncontrolled PPH. Providers com- 190 monly described the uterine balloon as critical for arresting bleeding 191 when other measures failed, particularly in situations when resources 192 were limited (e.g. uterotonic drugs). Two providers who inserted UBT 193

Fable 1 Uterine balloon tamponade use by type of facility and provider.	
Facility or provider	No. (%)
Facility (n=30)	
Maternal and child health post	2(7)
Community health post	1 (3)
Community health center	20 (67)
Hospital	7 (23)
Provider $(n=24)$	
Midwife	5 (21)
Maternal and child health aide	10 (42)
State-enrolled child health nurse	4 (17)
Clinical health officer/assistant	2 (8)
Medical doctor	3 (13)

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