OB/GYN Resident Global Health Education Module



Association des académiciens professionne en obstétrique-gynécologie UNIVERSITY OF TORONTO





DALHOUSIE UNIVERSITY Inspiring Minds Faculty of Medicine

Case 7: Innovative Approaches to Improving Global Women's Health



Non-pneumatic Anti Shock Garment (NASG)

A neoprene compression device to help with post-partum hemorrhage in low-resource settings. Entails the global burden and morbidity of unsafe abortion, as well as the traditional methods by which these were performed.Also discusses the legal environment of abortion and costs of unsafe abortion.

Resources:

Compendium of new and emerging technologies that address global health concerns 2011: Nonpneumatic Anti Shock Garment, WHO (2011)

Comorbidities and lack of blood transfusion may negatively affect maternal outcomes of women with obstetric hemorrhage treated with NASG, *PLoS One* (2013)



The Odon Device

A device created to assist in difficult deliveries; it achieves similar outcomes to a vaccum extractor. Cost and training required for this device are limited, making it effective in low-resource or community settings.

Resources:

Odon device: A promising tool to faciltate delivery and increase access to emergency care, *Reproductive Health* (2013)



Mobile Health (mHealth)

The use of mobile devices has diversified to encompass health services; particularly, providing remote point-of-care, epidemiological information, and health monitoring.

Resources:

Improvement of maternal health services through the use of mobile phones, *TMIH* (2011) Special delivery: An analysis of mHealth in maternal and newborn health programs and their outcomes around the world, *Matern Child Health J* (2012)

Non-pneumatic Anti Shock Garment (NASG)



http://www.who.int/medical_devices/in novation/new_emerging_tech_30.pdf

The non-pneumatic anti shock garment (NASG) is a device designed to help mitigate the risks of post-partum hemorrhage. The garment consists of five neoprene segments which wrap along the lower extremities, pelvis, and abdomen; a foam compression ball in the abdominal segment provides consistent uterine pressure. The goal of this device is to limit blood loss and shunt blood to vital organs, such as the heart, lungs, and brain.

A series of NASG pilot projects have shown a reduction in blood loss as much as 50%, and extreme adverse outcomes by 68% (Turan et al., 2011). Additionally, with it's low cost, reusability (up to 50 times), and avoidance of adverse effects of traditional anti-shock garments (i.e. compartment syndrome), the NASG is an appropriate option in low-resource settings (Turan et al., 2011). While this stabilization method is not a replacement for treatment, and there is still some concern over sterility and reusability, the NASG is effective in enabling hemorrhaging patients to survive the often lengthy transfer to urban centers to receive definitive treatment (Ayadi et al., 2013).

Non-pneumatic anti-shock garment

Country of origin | United States of America

Health problem addressed

Postpartum hemorrhage (PPH) in developing countries continues to be the single most common cause of maternal morbidity and mortality, accounting for approximately 25 percent of maternal deaths globally. Over 90 percent of these deaths occur in developing countries.

Product description _

For women suffering from uncontrollable PPH, a method to control the bleeding, reverse the shock, and stabilize the patient for safe transport to a comprehensive obstetric care facility could be lifesaving. One method to manage PPH is the use of a non-pneumatic anti-shock garment (NASG).

Product functionality _

The NASG is a lightweight neoprene garment that is made up of five segments that close tightly with Velcro. The NASG applies pressure to the lower body and

abdomen, thereby stabilizing vital signs and resolving hypovolemic shock. When fitted correctly, the reusable NASG forces blood to the essential organs - heart, lungs, and brain.

Developer's claims of product benefits

This garment provides an improvement over existing products in that is a validated, low-cost, high-quality garment. This is achieved by providing direct access to qualified manufacturers who can supply the garment at the price of US\$54 (purchaser is responsible for freight forward from China and import regulations, minimum order is 1,000 units).

Operating steps _

1. Place NASG under woman; 2. close segments 1 tightly around the ankles; 3. close segments 2 tightly around each calf; 3. close segments 3 tightly around each thigh, leave knees free; 4. close segment 4 around pelvis; close segment 5 with pressure ball over the umbilicus; 6. Finish closing the NASG using segment 6. Segments 1, 2, 3 can be applied by two persons simultaneously, segments 4, 5, 6 should only be applied by one.

Development stage _

Clinical trials led by Suellen Miller at the University of California, San Francisco are on-going. Currently, the large-size device is cleared by the US Food and Drug Administration and has been tested in low-income settings. The device is ready for manufacturing and sale in China.

Future work and challenges.

NASG Sizes: The NASG is not a one-size-fits-all PPH tool. Three sizes (small, medium, and large) of NASG have been developed to accommodate the significant population-dependent anthropomorphic variations around the world. In interviews in Nigeria, the company also learned that an extra-large-size NASG was desired to accommodate larger women in that region. Only the large-size NASG has been qualified with manufacturers.

Cleaning of the NASG: Cleaning is another challenge. There is no established method of accurately tracking the number of uses and cleanings, thus it is difficult to identify when sufficient degradation has occurred to retire the NASG and replace it with a new one.

Use and maintenance _____

User: Familiy member, nurse, midwife, physician, technician

Training: Pathfinder International has developed course curriculum and training materials which vary in length depending on target audience, and whether the intended user is applying or removing the garment.

Maintenance: Hospital orderlies are generally responsible for cleaning.

Product specifications _

List price (USD): 53.76

Other features: Portable and reusable

Currently sold in: United States of America

Environment of use _____

Setting: At home and in health care facilities in rural or

Requirements: Water and bleach for cleaning.

urban settings.

Life time: Approx. 40 uses



Maternal health

Commercialized

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Comorbidities and Lack of Blood Transfusion May Negatively Affect Maternal Outcomes of Women with Obstetric Hemorrhage Treated with NASG

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Abstract

The Non-Pneumatic Anti-Shock Garment (NASG) is a first-aid device to reduce mortality from severe obstetric hemorrhage, the leading cause of maternal mortality globally. We sought to evaluate patient characteristics associated with mortality among a cohort of women treated with the NASG in Nigeria. Data on 1,149 women were collected from 50 facilities participating in the Pathfinder International Continuum of Care: Addressing Postpartum Hemorrhage project in Nigeria from 2007–2012. Characteristics were compared using the appropriate distributional tests, and we estimated multivariable logistic regression models to control for treatment received. There were 201 deaths (17.5%). Women who died were significantly more likely to have any co-morbidity (AOR 3.63, 95% Cl: 2.41–5.48), ruptured uterus (AOR 2.79, 95% Cl: 1.48–5.28), macerated stillbirth (AOR 2.96, 95% Cl 1.60–5.48) and to have had 6 or more previous births, (AOR 1.53, 95% Cl 1.11–2.12), after adjusting for treatment received. These results suggest certain maternal conditions, particularly the presence of another life-threatening co-morbidity or macerated stillbirth, conferred a higher risk of mortality from PPH. This underscores the need for multi-system assessment and a comprehensive approach to the treatment of women with pregnancy complications.

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Introduction

Obstetric hemorrhage (OH) is the leading cause of maternal mortality globally, responsible for at least 25% of the 287,000 maternal deaths estimated to occur annually [1,2]. Most of these deaths occur postpartum, and are due to uterine atony [3]. Other common etiologies of obstetric hemorrhage include complications of abortion, genital tract trauma, uterine rupture, retained placental tissue, and maternal coagulation disorders. Active management of third-stage labor (AMTSL), particularly the administration of prophylactic uterotonics, will prevent 20-60% of atonic postpartum hemorrhage (PPH) [4,5]. However, not all PPH is due to uterine atony. Immediate treatment is critical to prevent mortality and morbidity due to PPH and OH [6,7]. Treatment protocols include rapid administration of intravenous crystalloid fluid, uterotonics, bimanual uterine massage, manual removal of the placenta, repair of lacerations, blood transfusion and surgery [8].

In many low-resource settings, four primary delays contribute to higher rates of maternal morbidity and mortality by increasing the time from onset of the obstetric complication to receipt of care: delay in problem recognition, delay in deciding to seek skilled obstetric care, delay in reaching a facility that can provide treatment, and delay at referral facilities in providing quality emergency treatment [9,10]. The Non-pneumatic Anti-shock Garment (NASG) is a first-aid compression device that can surmount such delays by stabilizing women in hypovolemic shock secondary to obstetric hemorrhage until definitive treatment can be obtained. The NASG places circumferential pressure on the lower half of the body and compresses the uterine arteries to decrease blood flow to the uterus and reverse shock by increasing circulation to the heart, lung, and brain (Figure 1). NASG intervention as first-aid at the tertiary care level is associated with a nearly 50% reduction in the odds of death from obstetric hemorrhage [11-15]; however, it does not constitute definitive treatment. Without access to comprehensive emergency obstetric care (CEmOC), some women will die from hypovolemic shock and multiple organ dysfunction syndromes, even with use of the NASG.

While the severity of shock and hemorrhage are known to modify the risk of mortality among women despite NASG treatment, it is not known whether other maternal characteristics such as communicable and non-communicable comorbidities also affect mortality [16]. Therefore, the purpose of this analysis was to evaluate whether maternal characteristics, including pregnancy and delivery characteristics, etiology and severity of hemorrhage,



Figure 1. The Non-pneumatic Anti-Shock Garment. doi:10.1371/journal.pone.0070446.g001

treatment received, and comorbidities including HIV, malaria, hypertension, anemia, and others were associated with mortality from hypovolemic shock secondary to obstetric hemorrhage despite NASG treatment, within the context of a large-scale postpartum hemorrhage implementation project in Nigeria.

Methods

Ethics Statement

These data were obtained from a large-scale community and clinical implementation project conducted by a non-governmental organization with ministerial and institutional collaboration, with the goal of preventing and managing PPH. No consent was necessary from patients for receiving standard of care, which included the NASG at these facilities. Data were collected for evaluation purposes, and case forms did not include personal identifiers. Principal Investigator Dr. Suellen Miller sought human subjects approval from the Committee on Human Research at the University of California, San Francisco (UCSF) but was denied the requested review because the analysis involved the use of deidentified data and thus was not considered human subjects research.

Pathfinder International implemented the *Continuum of Care: Addressing Postpartum Hemorrhage* (CCA-PPH) project in Nigeria from 2007–2012. The project's five-pronged strategy to prevent and manage PPH included training providers in AMTSL; use of a method for accurately measuring blood loss after delivery; obstetric hemorrhage and shock management; use of the NASG to stabilize women in shock secondary to hemorrhage; community mobilization and behavior change communication to encourage antenatal care, birth planning, and timely recognition of emergency situations; and enhanced communication and transportation systems to get women with PPH to the care that they need [17,18]. Within the CCA-PPH project, Pathfinder implemented the NASG in 60 facilities and 42 communities in seven states (Kano, Katsina, Oyo, Lagos, Nasarawa, Ebonyi, and Yobe). Women with PPH and hypovolemic shock were treated with a standard hypovolemic shock and hemorrhage protocol, in addition to receiving the NASG [19].

Data were collected on women with severe obstetric hemorrhage and shock who were admitted to one of the 60 study facilities between July 2008 and December 2011. Although the project was designed as a PPH project, women with severe obstetric hemorrhage of all etiologies received the NASG if they developed hypovolemic shock, as providers would not reserve the NASG only for women with PPH. Women were treated with the NASG upon presentation with severe obstetric hemorrhage and shock, defined as initial estimated blood loss of >1000 mL and at least one clinical sign of shock (systolic blood pressure <90 mmHg or pulse >110 beats per minute). Providers were also trained to recognize additional signs of shock including pallor, sweating, cold skin, rapid breathing, alterations in consciousness (anxious or confused, unconscious), and oliguria (<30 ml/hr). A total of 1,279 data collection forms (DCFs) were obtained from 50 facilities. Fourteen DCFs were excluded because they were identified as duplicate abstractions on the same case. We further excluded cases where hemorrhage was due to a non-obstetric etiology (n = 4), outcome was unknown (n = 4), patients were referred to a nonstudy facility (n = 15), patients died from a non-hemorrhage cause (n = 9); and where the NASG was never applied (n = 85). After these exclusions, 1,149 cases remained in our analytic sample.

Data were collected on the following variables: age, gravidity, delivery location, booked status, systolic and diastolic blood pressure, estimated blood loss (mLs), temperature (degrees Celsius), respiratory rates, pulse, hemoglobin, hemorrhage etiology, fetal status at delivery, treatments received, and comorbidities. For study entry, estimates of blood loss were made with a variety of techniques/devices including a calibrated closed-end

plastic blood drape, visual estimation, calibrated jugs, and number of soaked clothes/rags. The severity of a woman's shock on study entry was calculated using mean arterial pressure (MAP= [2*Diastolic Blood Pressure] + Systolic Blood Pressure/3). For analysis purposes, we categorized MAP into <60 mmHg versus \geq 60 mmHg, where MAP of 60 was considered the minimum value for adequate oxygen to perfuse tissues [20]. All deliveries occurred at either the health facility, home, or were unknown/ unrecorded. Hemorrhage etiologies included uterine atony, complications of abortion, placenta previa, placental abruption, ectopic pregnancy, ruptured uterus, placenta accreta, genital lacerations, retained placenta or fragments, and other. Fetal status at delivery was categorized as alive or dead (fresh still birth or macerated stillbirth). Variables were created to assess the type and amount of treatments received, including IV fluids and blood transfusions. Comorbidities included both communicable and non-communicable disorders: anemia, hypertensive disorders of pregnancy (HDP), sepsis, malaria, HIV/AIDS, and other (convulsions; coagulopathy and pulmonary edema; and history of dizziness, weakness and fainting spells). Hypertensive disorders of pregnancy comprised gestational hypertension, pre-eclampsia and eclampsia.

Clinician data collectors were nurse/midwives or community health workers that were trained onsite in a standardized PPH and shock protocol, collection and measurement of blood loss and completion of data collection forms [18]. Data were collected prospectively during care. Data supervisors cross checked facility records for cases, and where necessary, abstracted cases from the medical records. Paper data forms were reviewed by data supervisors and the Principal Investigator, copied and sent to the University of California, San Francisco where data were entered into a Microsoft Access database (Redmond, WA, USA) and checked for errors and inconsistencies.

Differences between those who survived and those who died were compared using Wilcoxon rank sum test for non-normally distributed continuous variables, and chi-squared or Fisher's exact test for categorical variables. Finally, multivariable logistic regression models were estimated to evaluate factors significantly associated with mortality while controlling for treatment variables using STATA (v 11, College Station, TX). Differences were considered statistically significant at p < 0.05.

Results

Of the study population (n = 1, 149), 948 women (82.5%)survived and 201 women (17.5%) died within the hospitalization period. The demographic characteristics, hemorrhage etiologies, fetal outcomes, cause of hemorrhage, condition on study entry and treatments received are presented in Table 1. The proportion of women with high gravidity (≥ 6 previous pregnancies) was significantly higher for women who died compared to those who survived (49.7% vs. 40.9%, p = 0.026). The distribution of treatment facility type varied significantly by outcome, with a higher proportion of those who died treated in a tertiary care facility (63.7% vs. 52.3%, p = 0.002). We observed a significantly different distribution of hemorrhage etiology by outcome, where higher proportions of women who died had uterine atony (51.8% vs. 46.9% for survived versus died, respectively), placental abruption (11.4% vs. 8.3%), placenta previa (4.7% vs. 3.2%), and ruptured uterus (7.8% vs. 3.7%). There were also significant differences in fetal outcome: 16.2% of women that died had a macerated fetus, vs. only 6.2% of survivors (p<0.001).

Certain characteristics of maternal condition on study entry varied by survival status (Table 1). Women who died had 500 mL

higher median estimated blood loss (1500 vs. 1000, p = 0.001), and higher respiratory rate (34.7 vs. 30.1, p < 0.001) than women who survived. Comorbidities were significantly more prevalent among women who died (24.4% vs. 8.0%, p < 0.001). Specifically, women who died had higher rates of anemia (13.9% vs. 3.2%, p < 0.001), HDP (9.0% vs. 4.5%, p = 0.011), and sepsis (2.5% vs. 0.2%, p = 0.002) than those who survived.

Treatments administered during resuscitation from hypovolemic shock are also presented in Table 1. While there was no significant difference in the proportion of women who received IV fluid treatment, women who survived received 20% lower median volume IV fluid than those who died (2000 mL vs. 2500 mL, p=0.058). The proportion of women who received blood transfusion was significantly lower among those who died (70.2% vs. 89.5%, p<0.001). Furthermore, among those who received blood, the median number of units received was lower among those who died than those who survived (1 unit vs. 2 units, p<0.001). Lower rates of blood transfusion were also observed among women who died when analysis was limited to a subset of women with MAP<60 (79.1% vs. 92.7%, p=0.004).

Multivariable logistic regression analyses were conducted to evaluate whether the association between characteristics significantly associated with death from OH in bivariate analyses persisted when adjusting for treatment with blood transfusions and IV fluids (Table 2). Compared to survivors, women who died were significantly more likely to have any comorbidity (AOR 3.63, 95% CI: 2.41–5.48). Disaggregated, the individual comorbidities that were associated with significantly higher odds of mortality included anemia (AOR 4.64, 2.65–8.10), HDP (AOR 2.13, 95% CI 1.18–3.85), and sepsis (AOR 9.60, 95% CI 1.73–52.36). Mortality was also significantly associated with ruptured uterus (AOR 2.79, 95% CI 1.48–5.28), macerated stillbirth (AOR 2.96, 95% CI 1.60–5.48) and high gravidity (AOR 1.53, 95% CI 1.11– 2.12).

Discussion

These results suggest that certain characteristics or conditions of the woman and of the health care system are associated with the risk of death from obstetric hemorrhage despite application of the NASG. The 201 women who died regardless of NASG treatment were significantly more likely to have a comorbidity, a macerated stillbirth, or ruptured uterus hemorrhage etiology, even when controlling for receipt of blood transfusion and IV fluid. Women who died were also less likely to have received blood transfusion.

We found that the presence of any comorbidity conferred a four-fold increased risk of death. Evaluated individually, sepsis, anemia and HDP were all significantly associated with increased odds of mortality, whereas malaria was not. Of the individual comorbidities, sepsis had the strongest association with mortality, at 9.6 the odds of mortality, followed by anemia at 4.6 and HDP, at 2.1. These conditions are individually associated with increased risk of maternal death; however, whether an additive or multiplicative interaction effect occurs when in conjunction with hemorrhage is not evident from the literature. Sepsis is considered a primary contributor to maternal death, particularly in lowincome countries, and is estimated to be responsible for 9.7% of maternal deaths in Africa [2,21]. Anemia has been found to contribute to maternal death for both acute onset and chronic conditions, including cardiac failure, susceptibility to infection, and more severe postpartum blood loss [2,22-25]. Malaria is another contributor to anemia in pregnant women; however, the prevalence of malaria infection in our sample was relatively low and did not vary across maternal outcome. Previous to 2012,

Table 1. Characteristics of Women with Hypovolemic Shock Secondary to Obstetric Hemorrhage at Time of Study Entry, Nigeria (n = 1, 149).

Characteristic	Survived	Died	Р
Number of women	948 (82.5)	201 (17.5)	
Age, mean (sd) $^{\delta}$	29.1 (6.7)	30.5 (6.9)	0.031
Gravidity, mean (sd) $^{ m \phi}$	5.1 (3.4)	5.7 (3.5)	0.032
High gravidity (≥6) ^{ଡ଼}	358 (40.9)	94 (49.7)	0.026
Booked [€]	52 (10.7)	10 (11.0)	0.930
Delivery at Health Facility [£]	512 (57.7)	99 (63.9)	0.152
Treatment Facility Type $^{\lambda}$			
Primary	101 (10.7)	9 (4.5)	0.002
Secondary	345 (36.4)	61 (30.4)	
Fertiary	496 (52.3)	128 (63.7)	
lemorrhage Etiology [¥]			0.001
Jterine Atony	439 (46.9)	100 (51.8)	
Retained Placenta or Fragments	219 (23.4)	26 (13.5)	
Complications of Abortion	69 (7.4)	7 (3.6)	
Placental Abruption	78 (8.3)	22 (11.4)	
Placenta Previa	30 (3.2)	9 (4.7)	
Ruptured Uterus	35 (3.7)	15 (7.8)	
acerations	38 (4.1)	8 (4.2)	
Ectopic Pregnancy	15 (1.6)	0 (0)	
Placenta Accreta	2 (0.2)	0 (0)	
Dther	12 (1.3)	6 (3.1)	
Fetal Outcome [∞]			0.001
Alive	418 (61.6)	58 (52.3)	
Dead: Fresh still birth	219 (32.3)	35 (32.5)	
Dead: Macerated	42 (6.2)	18 (16.2)	
MAP<60 mmHg [⊥]	273 (43.8)	43 (41.8)	0.704
Γemperature <37.0 C ^α	218 (49.3)	44 (60.3)	0.083
Respiratory Rate, mean (sd) ^β	30.1 (13.7)	34.7 (19.3)	0.000
Pulse, mean (sd) π	108.4 (21.3)	112.9 (19.1)	0.066
Estimated blood loss, median (range) ^P	1000 (100–6000)	1500 (150–4700)	0.001
V Fluid received	847 (89.4)	173 (86.1)	0.181
Volume IV Fluid, median (range) ⁹	2000 (300–12700)	2500 (100–7500)	0.058
Blood Received	848 (89.5)	141 (70.2)	0.000
Units of Blood Received, median (range) $^{ m m A}$	2 (0.5–12)	1 (0.5–14)	0.000
Blood Received if MAP<60 mmHg $^{\Sigma}$	253 (92.7)	34 (79.1)	0.004
Comorbidities			
Any Comorbidity	76 (8.0)	49 (24.4)	0.000
Anemia	30 (3.2)	28 (13.9)	0.000
Hypertensive Disorders of Pregnancy	43 (4.5)	18 (9.0)	0.011
Sepsis	2 (0.2)	5 (2.5)	0.002
Malaria	4 (0.4)	1 (0.5)	1.000
HIV/AIDS	0 (0)	1 (0.5)	0.175
Other	3 (0.3)	0 (0)	1.000

⁸N° women survived: 890, N° women died: 183; [®]N° women survived: 875, N° women died: 189; [€]N° women survived: 487, N° women died: 91; [£]N° women survived: 887, N° women died: 155; ^XN° women survived:942, N° women died:198; ^{*}N° women survived: 937, N° women died: 193; [©] N° women survived: 679, N° women died: 111; ^µ N° women survived: 624, N° women died: 103; [«] N° women survived: 442, N° women died: 73; ^β N° women survived: 596, N° women died: 104; ^π N° women survived: 627, N° women died: 104; ^P N° women survived: 586, N° women died: 109; ⁹ N° women survived: 847, N° women died: 173; ³ N° women survived: 848, N° women died: 141; ³ N° women survived: 273, N° women died: 43.

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Table 2. Odds Ratios for Death by Selected Participant Characteristics, Unadjusted and Adjusted for Treatment Receipt, Nigeria (n = 1,149).

	Unadju	sted	Adjusted	
	OR	95% CI	OR	95% CI
Any comorbidity	3.70	(2.48, 5.51)	3.63	(2.41, 5.48)
Anemia	4.95	(2.89, 8.50)	4.64	(2.65, 8.10)
HDP	2.07	(1.17, 3.67)	2.13	(1.18, 3.85)
Sepsis	12.07	(2.32, 62.64)	9.60	(1.73, 53.26)
Malaria	1.18	(0.13, 10.61)	1.54	(0.17, 13.89)
Cause of Hemorrhage: Ruptured Uterus	2.17	(1.16, 4.06)	2.79	(1.48, 5.28)
Fetal outcome: Macerated stillbirth	2.94	(1.62, 5.31)	2.96	(1.60, 5.48)
High Gravidity (≥6)	1.43	(1.04, 1.94)	1.53	(1.11, 2.12)
No Receipt of Blood	3.61	(2.50, 5.21)	3.66	(2.47, 5.15)
No Receipt of IV Fluids	1.36	(0.87, 2.13)	1.21	(0.76, 1.93)

Note: adjusted analyses controlled for treatment variables: any blood transfusion and any IV fluid receipt.

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providers had questioned whether pre-eclamptic/eclamptic patients might face an increased risk of cerebral intracranial hemorrhage with NASG intervention, which increases blood flow to the heart, lung, and brain; however, an analysis by Ismail, et al. indicated that the NASG intervention among pre-eclamptic and eclamptic patients actually reduced the odds of an extreme adverse outcome by 74% (OR 0.26, 95% CI 0.07-0.93) [26]. Results from the current analysis suggest that women with HDP who receive the NASG may be more at risk of dying of conditions related to their hypertension or eclamptic sequelae, such as disseminated intravascular coagulation (DIC) or HELLP syndrome, than conditions related to their hemorrhage. The finding that women suffering from any comorbidity, and in particular, from sepsis, anemia and HDP, have a greater risk of death than those without, emphasizes the need for clinicians to conduct multi-systems assessments of women seeking emergency care for obstetric hemorrhage, so that they can effectively manage all conditions that may influence her survival.

One unexpected finding was that malaria and HIV infection were not found to be associated with increased risk of death for women with obstetric hemorrhage. Other studies have found four and five-fold increases in maternal death rates among HIVinfected women [27,28]. One possible explanation is that HIV/ AIDS and malaria were under-reported in this data. The median prevalence of HIV/AIDS among pregnant women in Nigeria is 4.1%, and ranges regionally to at least 8.2% [29,30], compared to our data where the prevalence is 0.1%. One study suggested the prevalence of malaria to be 7.7% among pregnant women in Lagos [31] compared to 0.5% reported in our data. It is possible that had our dataset been representative of national rates of HIV/ AIDS and malaria, we might have seen an association between mortality and these comorbidities.

Our analysis found that women who delivered a macerated stillbirth were three times as likely to die as women with a different fetal outcome (i.e., live birth, fresh stillbirth). The association of life-threatening hemorrhage and DIC with a dead fetus was recognized as early as 1901, when DeLee reported "temporary hemophilia" in a woman with a macerated fetus [32]. Recent hematology studies on women with intrauterine fetal demise have noted elevated fibrin degradation products, believed to be mediated by thromboplastin from the macerated fetus [33]. In a study of macerated stillbirths, Habek noted that potential maternal complications induced by autolytic lesions include DIC, uterine atony, and postpartum hemorrhage [34]. This finding supports efforts to encourage a rapid delivery among women identified to be carrying a dead fetus.

We also found that women with hemorrhage etiology of ruptured uterus were nearly three times as likely to have died as women with another hemorrhage etiology, a result that is consistent with the literature. Uterine rupture typically results in significant intraperitoneal bleeding, requires large amounts of IV fluids and blood, and treatment requires surgical intervention to repair the tear or for a complete hysterectomy. While uterine rupture is uncommon, research suggests that the incidence is higher in areas with higher than average incidence of neglected and obstructed labor due to inadequate access to medical care (0.11%) [35].

Women who did not receive blood transfusion were nearly four times more likely to die than those that did, despite use of the NASG. This finding is consistent with the fact that the NASG is not a replacement for treatment; it is a first-aid device intended to stabilize women with hypovolemic shock until they receive definitive treatment. It may buy the woman more time to enable her to survive longer while waiting for a blood transfusion, but blood replacement may still be necessary. In many low-resource settings, as in Nigeria, such therapy may not be available at all health care facilities, particularly at the primary and secondary level. The lack of universal receipt of blood transfusion (86.1% overall), and the low volume transfused (median 2 units) among those that received blood might be attributable to poor blood availability at health care facilities. Many factors are responsible for this problem, including gross underfunding of the National Blood Transfusion Service of Nigeria, persistent power shortages, and misconceptions among potential blood donors. Private initiatives have begun to improve the availability of blood in some areas, such as Cloverleaf's funding of solar banks to secure and provide emergency blood for obstetric emergencies [36], but large scaling up of such projects in combination with broader structural investment is required to overcome a dire situation.

Prior studies of the NASG at the tertiary care facility level have indicated that greater severity of condition at study entry, described by MAP, was associated with greater risk of death [16,37,38]. We did not observe the same relationship in the current analysis; however, the blood pressure variables used to calculate MAP were not consistently reported thus impeding our ability to fully explore this particular relationship.

Strengths of this analysis include the large sample of women within similar care contexts who received the NASG for treatment of hypovolemic shock secondary to obstetric hemorrhage and the use of the NASG in real world situations of busy, understaffed facilities. However, there are several important limitations to consider while interpreting these findings. First, these data are not the result of a randomized clinical trial, but are observational. Second, the methods for data collection were not carried out as initially planned. Data collection forms were to have been filled in concurrently with patient care or immediately after resuscitation and updated in real-time until patients were discharged. Due to demands on the time of health providers, forms were often completed retrospectively, after the patient had been treated or even after discharge. In the worst cases, data collection forms were completed based on medical record abstraction up to three months after the patient's discharge. Included in this process is a dependence on provider report of comorbidity; the implementation project did not prespecify the analysis that we conducted. Data were recorded for monitoring and evaluation purposes only, thus there is a possibility that comorbidities may be under- or overreported within this sample and lacked important detail, such as the type of sepsis. Third, data on dates and times of NASG application and removal were not always complete; less than two hours of NASG treatment is considered to be inadequate for resuscitation, however we were not able to calculate the duration of NASG treatment for some women in our dataset and therefore unable to determine if the women who died despite receiving NASG had actually received adequate NASG resuscitation. Fourth, data from only 50 of the 60 participating facilities were available for analysis; the 10 facilities that did not contribute forms were low-volume primary health care facilities which likely saw fewer cases of obstetric hemorrhage and referred earlier due to more limited capacity for treatment. The majority of the forms came from only three of the seven states (Kano, Katsina and Oyo); these three states were also all involved in prior research and thus had greater experience with the NASG which may mean that they had more completely integrated it into their standard of care. Finally, there are high proportions of data missing for several characteristics, which precluded our ability to investigate those predictors. It is also important to note that we continued with an analysis of fetal outcome and death despite a high rate of missing data on fetal outcomes, particularly among women who died.

Conclusions

Our results suggest that while the NASG contributed to the survival of the majority of women suffering from hypovolemic shock secondary to obstetric hemorrhage within a continuum of care for PPH implementation project, efficacy was negatively affected by certain maternal conditions, particularly the presence of another life-threatening comorbidity or carrying a dead fetus.

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This underscores the need for clinicians treating women suffering from hypovolemic shock secondary to obstetric hemorrhage to conduct a multi-systems assessment to identify and treat any comorbidities that may adversely affect a woman's pregnancy outcome even if she receives life-saving interventions for hemorrhagic shock. Furthermore, while NASG intervention may mitigate blood loss after application, and buy time during delays in obtaining a transfusion, it does not replace the need for rapid and adequate blood and fluid replacement.

Reducing maternal mortality from obstetric hemorrhage and hypovolemic shock requires timely treatment with IV fluids, adequate blood replacement, and identification and treatment of comorbidities. The NASG is a first-aid device that helps women with hemorrhage survive transport and delays in accessing quality definitive treatment; however, the efficacy of the NASG is enhanced when used in a functioning health system prepared to manage all maternal complications. More investments are needed to strengthen the health system generally to be able to provide quality emergency obstetric care.

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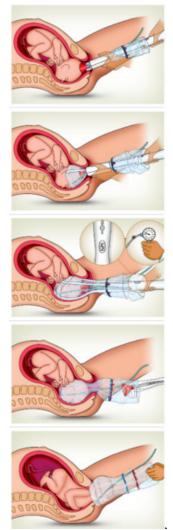
Author Contributions

Conceived and designed the experiments: AE SR FJ SM. Performed the experiments: FJ YO. Analyzed the data: AE SR. Wrote the paper: AE SR FJ YO SG SM EB.

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www.odondevice.org/device.php

The Odon Device

The story of the Odon device's conception is quite remarkable: it was invented in 2005 by Jorge Odon, an Argentinian car mechanic with no formal medical education or training. He adapted his party trick of getting a trapped cork out of a bottle, and applied a similar concept to facilitate obstructed childbirth (Requejo & Belizan, 2013).

The device consists of a polyethylene sleeve material that is placed circumferentially between the baby's head and the birth canal. Once secured, traction and reduced friction between the sleeve surfaces enable the device to achieve the same result as a vacuum extractor.

The Odon device has been heralded as a feasible innovation that should be introduced to low-resource settings. It requires minimal training and has been shown to improve obstetrical outcomes in the setting of complex and obstructed labors; as such, this device is especially valuable the context of limited resources, and inaccessible advanced obstetrical care (i.e. caesarean sections). Completion of the WHO's three-phased study assessing the Odon's efficacy and comparative results to that of forceps and vacuum extractors is anticipated in the near future (Requejo & Belizan, 2013).

EDITORIAL



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Odon device: a promising tool to facilitate vaginal delivery and increase access to emergency care

Jennifer Harris Requejo^{1*} and José M Belizán²

Abstract

The last innovation in operative vaginal delivery happened centuries ago with the invention of the forceps and the vacuum extractor. The World Health Organization Odon Device Research Group recently published a protocol for a feasibility and safety study for a new device (Odon device) which aims to revolutionize assisted vaginal delivery. This editorial discusses the device and its pathway to global use. Although preliminary results look promising, the rigorous three-phased WHO protocol needs completion before the device can be determined, based on the evidence, to be safe and effective.

In this journal, the World Health Organization Odon Device Research Group describes the protocol for a feasibility and safety study of a new device (Odon device) for assisted vaginal deliveries [1]. This device is a low cost, easy to use technological innovation to facilitate operative vaginal delivery when complications occur during the second stage of labor. It is designed to minimize trauma to the mother and the baby, and may be possible for application by mid-level providers. These features combined make the Odon device a potentially revolutionary development in obstetrics. As the article points out, the last innovation in operative vaginal delivery happened centuries ago with the invention of the forceps and the vacuum extractor, both of which require a high level of skill to use and are associated with certain risks of injury to mother and baby. Similarly, caesarean delivery a third option for clinical management of prolonged second stage of labour - is out of reach for many women living in low resource settings, making innovations like the Odon device essential for increasing women's access to needed obstetrical care.

Complications related to prolonged second stage of labor are responsible for countless women's and children's deaths and long-term disabilities [2,3]. The Odon Device represents a promising novel way to potentially prevent these deaths and improve obstetrical outcomes for both mother and baby. Given its simplicity and the likelihood

¹Institute for International Programs, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, USA that mid-level providers can be trained on its use, the device could increase multi-fold women's access to quality emergency obstetrical care – particularly the most vulnerable populations who struggle to reach tertiary care facilities when something goes wrong during childbirth. The possibility that use of the device could have additional benefits such as counteracting the worrisome rise in caesarean deliveries worldwide, and reducing perinatal infections acquired through the birth canal during childbirth must also be explored.

The seeds of innovation – the Odon device's humble origins

The story of the development of the Odon Device is a tribute to human ingenuity, and gives further credence to Albert Einstein's adage, "imagination is more important than knowledge". In 2005, Mr. Jorge Odon, a car mechanic from Argentina with no medical training, was inspired to design the device after thinking carefully about the basic scientific principles underlying a simple trick he used to perform for his friends. This trick involved removing a cork from the inside of an empty bottle without breaking it. His eureka moment happened when he realized that the solution to the cork challenge could be adapted to a method for facilitating childbirth.

What followed this initial spark was a rapid uptake of the idea from Mr. Odon's first collaboration in 2006 with the Center for Medical Education and Clinical Investigation (CEMIC) in Buenos Aires, Argentina and professionals from WHO, to the testing of the device in 2008 on a simulator at Des Moines University, Iowa, USA, to the



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approval in 2009 of a World Health Organization study protocol to test the device on human beings, and, finally, to the awarding in 2011 of a "Saving Lives at Birth: A Grand Challenge for Development" grant to further test the potential of the device to save women's and children's lives at the time of birth when the majority of maternal and newborn deaths occur.

Where are we now? The pathway to global use

The World Health Organization Odon Device Research Group's article in this journal describes in detail the first phase of the WHO's three-phased study protocol aimed at bringing the Odon Device from a clever, long-overdue idea into the 'obstetric arsenal' – expanding the clinical management tools available to practitioners for assisted vaginal delivery. The first phase is underway and involves the testing of the device under normal delivery conditions in tertiary hospitals in Argentina and South Africa. The next two phases will assess preliminary efficacy in facilitating delivery when women are experiencing prolonged second stage of labor with no fetal distress, and compare the effectiveness of the device to the vacuum extractor and forceps.

Although preliminary results look promising, the rigorous three-phased WHO protocol needs completion before the device can be determined, based on the evidence, to be safe and effective.

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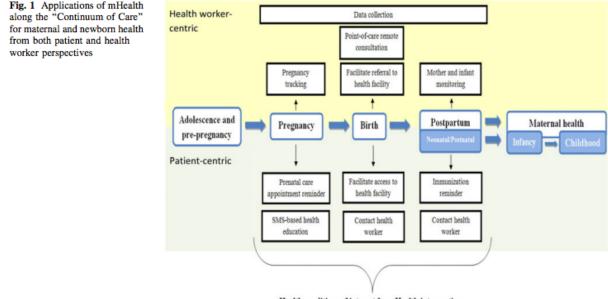
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Mobile Health

The potential of mobile health (mHealth)—telecommunication and multimedia—has been progressively realized over the years in both high and low resource settings. The impact of mobile health has traditionally consisted of telehealth, whereby information and care can be exchanged instantaneously. However, the potential use of mHealth in bridging gaps in care and enhancing self-management is still being explored.

With globalization and the improvement of technology, "telecommunication mobile coverage has increased to reach 90% of the world's total population and 80% of the global population in rural areas" (Tamrat & Kachnowski, 2011). As such, mobile technology provides an organic and effective platform by which medical information can be gathered and informal service delivered.

A literature review looking at mobile technology from 2000 to 2010 was performed by Tamrat and Kachnowski (2011). From this review, the applications of mHealth along the obstetric continuum of care was determined to include pregnancy (pregnancy tracking, prenatal care, SMS-based health education), birth (referral and access to health facility, point-of-care remote consultation, contact health worker), and postpartum (mother and infant monitoring, immunization reminder, and contact health worker) (Figure 1). Broader functions of mHealth include: emergency medical response, point-of-care support, health promotion, and data collection and management. Newer research, however, has expanded to assess concerns surrounding mHealth, such as patient confidentiality and safey.



Health conditions of interest for mHealth interventions

Tamrat & Kachnowski, 2011

Special Delivery: An Analysis of mHealth in Maternal and Newborn Health Programs and Their Outcomes Around the World

Tigest Tamrat · Stan Kachnowski

Published online: 19 June 2011 © Springer Science+Business Media, LLC 2011

Abstract Mobile health (mHealth) encompasses the use of mobile telecommunication and multimedia into increasingly mobile and wireless health care delivery systems and has the potential to improve tens of thousands of lives each year. The ubiquity and penetration of mobile phones presents the opportunity to leverage mHealth for maternal and newborn care, particularly in under-resourced health ecosystems. Moreover, the slow progress and funding constraints in attaining the Millennium Development Goals for child and maternal health encourage harnessing innovative measures, such as mHealth, to address these public health priorities. This literature review provides a schematic overview of the outcomes, barriers, and strategies of integrating mHealth to improve prenatal and neonatal health outcomes. Six electronic databases were methodically searched using predetermined search terms. Retrieved articles were then categorized according to themes identified in previous studies. A total of 34 articles and reports contributed to the findings with information about the use and limitations of mHealth for prenatal and neonatal healthcare access and delivery. Health systems have implemented mHealth programs to facilitate emergency medical responses, point-of-care support, health promotion and data collection. However, the policy infrastructure for funding, coordinating and guiding the

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S. Kachnowski e-mail: swk16@hitlab.org sustainable adoption of prenatal and neonatal mHealth services remains under-developed. The integration of mobile health for prenatal and newborn health services has demonstrated positive outcomes, but the sustainability and scalability of operations requires further feedback from and evaluation of ongoing programs.

Keywords mHealth · Prenatal · Neonatal · Mobile technology · Maternal

Introduction

The global proliferation of mobile technology has generated a new tool to address public health challenges and shift the paradigm of health care access and delivery. According to the International Telecommunications Union, mobile coverage has increased to reach 90% of the world's total population and 80% of the global population living in rural areas [1]. The growing ubiquity and penetration of mobile phones has helped fuel the initiation of mobile health (mHealth), the integration of mobile telecommunication and multimedia into increasingly mobile and wireless health care delivery systems [2, 3]. Mobile phones, in particular, are thriving in resource-limited health systems despite the scarcity of other technologies and infrastructure; the organic permeation offers new means to address health needs, particularly in the global south [3–10].

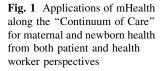
This article examines the use of mHealth along three stages of the continuum of care for maternal, newborn, and child health (MNCH) as defined by the World Health Organization (WHO). The MNCH consists of a comprehensive trajectory for the health needs of women and children beginning with adolescence/pre-pregnancy to the postpartum and maternal phase of the mother; among children, the continuum commences with the neonatal period and extends through infancy and childhood (Fig. 1) [11]. Specifically, this study focuses on the modalities and limitations of mHealth interventions that target the prenatal and neonatal components of the continuum, covering the period from conception to 28 days following birth. It represents a critical window in which up to 75% of maternal and 70% of newborn mortality could be averted, respectively, through comprehensive and evidence-based interventions [7].

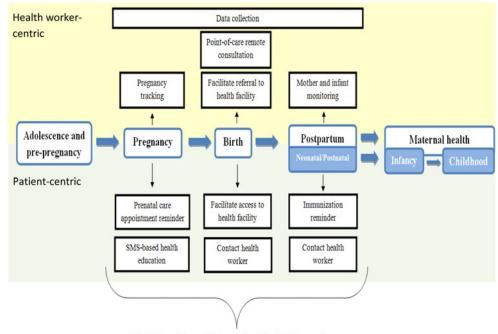
Previous studies have highlighted the ways in which mHealth can improve health information systems and bolster health services including treatment adherence, disease surveillance, emergency medical response, health promotion, and point-of-care support [3, 7, 12]. In addition, there is substantial literature linking mHealth with the Millennium Development Goals (MDGs), the United Nations-endorsed global targets for health and development indicators to be achieved by 2015 [3]. Studies demonstrate that leveraging mHealth can be an effective strategy for MDG targets 4-6, which aim to reduce child mortality; improve maternal health; and combat HIV/AIDS, malaria, and other diseases [3, 13–16]. Moreover, the slow progress and funding constraints in achieving the MDG targets for child and maternal health have stimulated the use of mHealth for these public health priorities [3, 4, 13–16]. Despite this escalation, few studies have focused exclusively on mHealth's use in the prenatal and neonatal arena.

Methods

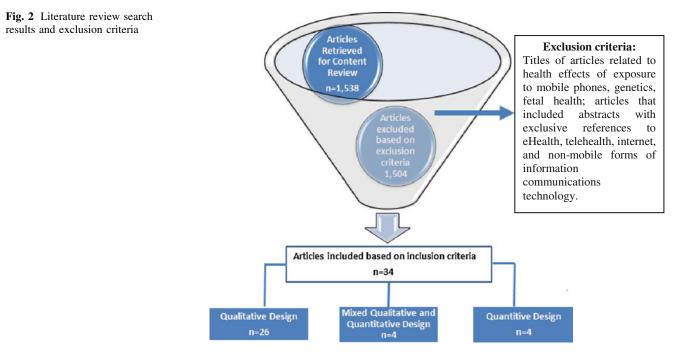
To identify discussions of the implementation of mHealth for prenatal and neonatal healthcare, we conducted an electronic literature review in December 2010 of six databases: Google, Google Scholar, PubMed, Web of Science, Science Direct and ProQuest. Both authors contributed to selecting search terms that would incorporate mHealth and maternal and newborn topics, including keyword combinations of "maternal," "mobile," "technolog*," "informatics," "health," "eHealth," "ICT," "tele*," "newborn," "neonatal," "antenatal," and "prenatal."

The authors limited the review to English-language peer-reviewed articles, presentations, and institutional reports published between 2000 and 2010, which yielded a total of 1,538 possible documents for review (Fig. 2). The primary author reviewed all document titles based on inclusion/exclusion criteria pre-determined by both authors. The exclusion criteria filtered out articles with titles that referred to genetics, fetal exposure to mobile phones, or pertained exclusively to eHealth, telehealth, and non-mobile forms of information communications technology (ICT.) Eligible articles were included for review only when abstracts contained explicit information about the uses of mobile technologies in maternal and newborn health or in reference to the MDGs. Researchers also scoured reference lists to identify other papers that fit the inclusion criteria.





Health conditions of interest for mHealth interventions



The primary author extracted information from eligible articles to identify the following details for each study: target population, geographic location of the intervention, maternal and/or newborn health need addressed, health indicators assessed, financing scheme for implementation, and limitations and strategies for the sustainable integration of the mobile technology. The information was then classified by the primary author according to themes identified in policy papers [2–4, 7, 12].

Results and Discussion

In total, 34 articles satisfied the inclusion criteria, which included studies with quantitative (n = 4), qualitative (n = 26), and mixed (n = 4) designs (Fig. 2). The articles revealed specific evidence of the impact of mobile technologies on prenatal and newborn health needs (Table 1) or highlighted the best practices and impediments for sustaining such mHealth activities.

Accordingly, the findings of this review first describe the outcomes of mHealth prenatal and neonatal programs implemented across the globe (Fig. 3). The studies are organized according to common functions of mobile technologies identified in previous studies [2–4, 7, 12] as the following:

- Emergency medical response
- Point-of-care support
- Health promotion
- Data collection and management

Secondly, the literature review examined barriers and strategies as they relate to the following themes for operationalizing mHealth interventions, as identified in previous studies [2, 4, 12]:

- Financial issues
- Policy frameworks
- Socio-cultural context

Impact of mHealth on Prenatal and Neonatal Health Outcomes

Emergency Medical Response

Studies show that mHealth tools can help minimize time barriers and facilitate urgent care during emergency obstetric referrals [7, 12, 14, 17-26]. One of the earlier reports supporting this observation involved the Rural Extended Services and Care for Ultimate Emergency Relief (RESCUER) program launched in 1996 in rural Uganda [22]. The program trained community-based volunteer Traditional Birth Attendants (TBAs) on the signs and protocols for pregnancy complications and equipped them with walkie-talkies linked to health units, along with basic clinical obstetric instruments. Upon the recognition of delivery-related challenges, TBAs used the walkietalkies to notify referral health centers for emergency transport [22]. Following this comprehensive intervention, the maternal mortality rate in the study locations decreased by approximately 50% due to increases in referrals to health facilities, although the study author cited some

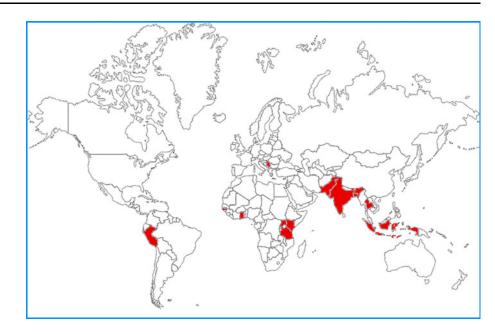
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mHealth function	Location	Intervention	Target population/size	Findings	Funding
Emergency medical support	Rural northwest Bangladesh	Observational study among families who own mobile phones	11,451 families with mobile phones	55% of families used mobile phone for pregnancy emergencies, of which 72% called a health provider, 57% asked for medical advice, 33% arranged transport, 21% asked for financial aid [Unpublished data]	Johns Hopkins University [5]
Emergency medical support/ Health promotion	Dangme West District, Ghana	Provision of mobile phones and phone credit	21 health professionals; 7 community health volunteers; 30 pregnant women and recent mothers interviewed	Program not yet evaluated but pre-intervention research indicates mHealth can expedite emergency obstetric referrals; mHealth can promote prenatal behavior changes among expecting mothers	Bill and Melinda Gates Foundation [7]
Emergency medical support	Brikama, The Gambia	Provision of mobile phones and phone credit	83 Traditional Birth Attendants;48 volunteer health workers	Facilitated emergency referrals; shortage of skilled health professionals and funds for emergency transport challenged sustainability	World Health Organization [20]
Emergency medical support	Iganda District, Uganda	Provision of walkie-talkies and tricycles	Catchment population of 6 health units and 1 referral health unit. 5 midwives; 10 traditional birth attendants; 3 project administrators; 4 women of reproductive age interviewed	Increased referrals, maternal mortality ratio decreased by 50% in 3 years; challenges in emergency transport	World Bank [22]
Emergency medical support	Madya Pradesh, India	24-h obstetric help lines, health workers using community members' mobile phones and logistical resources	Community members and health workers	24-h obstetric help lines in previous pilot programs contributed to reducing delays associated with deciding when to seek medical care, identifying health facilities for appropriate services, and care delivery	UNICEF [7, 26]
Point-of-care support	Muzaffargarh & Chakwal, Pakistan	Provision of mobile phones and phone credit	242 community health workers	Not yet studied; expected to increase emergency obstetric referrals	GSMA Development Fund and UNFPA [21]
Point-of-care support	Remote Locations, Pakistan	Toll-free interactive voice response service	Community health workers	Not yet studied; application still under development	Microsoft Research [23]
Point-of-care support/ data collection	Aceh Besar, Indonesia	Provision of mobile phones and phone credit	123 midwives; 15 midwife coordinators	Midwives with mobile phones more likely to turn to health center personnel for medical advice; increased confidence in accurate data collection and storage	World Vision [24]
Point-of-care support	Aceh Besar, Indonesia	Provision of mobile phones and phone credit	224 midwives; 15 midwife coordinators	Increased communication flows and knowledge- seeking behavior among midwives with mobile phones; challenges in sustaining financial cost of mobile credits	World Vision [27]
Health promotion	Serbia	Automated SMS-based prenatal health support based on pregnancy stage	3,200 pregnant women (as of 2007)	No outcomes research available	European Union and National Ministry of Health [7]

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Table 1 continued	nued				
mHealth function	Location	Intervention	Target population/size	Findings	Funding
Health promotion/ data collection	Zanzibar, Tanzania	Provision of mobile phones and phone credit; SMS- based prenatal health support	2,400 pregnant women	Increased odds for skilled delivery attendance and prenatal care visits among pregnant women with mobile phones	DANIDA [25]
Health promotion/ data collection	Thai/Myanmar Border, Thailand	Automated SMS-based reminders for prenatal care visits	280 pregnant women	Increased odds for on-time prenatal care visits among women who received reminders	Thailand Ministry of Public Health [29]
Health promotion/ data collection	Bangkok, Thailand	SMS-based prenatal health support	68 pregnant women	Pregnant women who received SMS had increased satisfaction and confidence in health workers during delivery	Mahidol University [30]
Data collection	Ucayali, Peru	Provision of smartphones to collect and communicate data among health workers	Outreach health workers; medical experts	No outcomes research available	USAID [4]
Data collection	Haryana, India	Provision of handheld computers to collect data on immunization, prenatal care visits, and demographic changes	Outreach health workers	No outcomes research available	Dimagi, Media Lab Asia, All India Institute of Medical Sciences [7]
Data collection	Andhra Pradesh, India	Provision of handheld computers to collect and monitor nutrition, maternal and child health activities	800 rural outreach workers, 250 frontline health workers	No outcomes research available	UNICEF [16]

Fig. 3 Geographic coverage of prenatal and neonatal mHealth programs featured in literature review



logistical issues, which may have compromised the study outcomes [22].

According to a presentation by Labrique, the Johns Hopkins-sponsored "JiVitA" program in rural Bangladesh linked the use of mobile phones with pregnancy-related complications. Researchers found that 55% of families who had phones used them during emergencies: 72% of those families contacted a healthcare provider, 57% sought medical advice, 33% arranged transport, and 21% asked for financial support [5(unpublished)].

Other reports point to the breadth of possible implementation schemes, but reveal the complexity of improving processes and obtaining outcomes data. Emergency services departments in the Gambia furnished mobile phones to TBAs and outreach workers trained to recognize pregnancy complications and refer women exhibiting signs of obstetric complications [20]. Health records from the project indicate improvements to the emergency response system in which 101 pregnant mothers and newborns received critical assistance between May 2007 and March 2010 [20]. However, the article does not provide details on the percent change and mentions that challenges such as the shortage and low morale of health workers at facilities and unreliable transportation services diminished the efficacy of the program.

A UNICEF-funded program in Madhya Pradesh, India offered pregnant women a health telephone helpline, complimentary ambulance system, and drivers equipped with mobile phones in the effort to reduce delays in seeking obstetric care [7]. Although the literature did not render any project evaluations, qualitative evidence from pilot programs in similar locations in India demonstrated that 24-hour obstetric mobile-phone-based helplines mitigated delays associated with deciding when to seek medical care, identifying appropriate health facilities, and receiving treatment [7, 26]. These studies also cited the need for improved household-level awareness of pregnancy complications and upgraded capacity of health facilities to provide critical services such as blood transfusions [26]. Similarly, the Kenyan Ministry of Health has implemented a mHealth program to enable communication and promote institutional deliveries and referrals [7]; however, the program is in the pilot stage and did not offer project assessment reports to be included in this review.

These studies also demonstrated that it is not sufficient to just distribute cell phones; successful programs incorporate a comprehensive approach that also addresses logistical and human resource constraints. For example, all of the aforementioned initiatives provided mobile communications tools as part of a broad emergency maternal health response strategy that included training on the early detection of pregnancy risks and the provision of transport facilities to minimize logistical barriers [7, 20, 22, 26]. However, researchers of the interventions in Uganda and the Gambia reported that unreliable emergency transport, coupled with poor quality of services at health facilities, compromised the health outcomes.

Point-of-Care Support

Health systems are also leveraging mHealth to address the low coverage of qualified health personnel and alleviate the professional seclusion of mid- and low-level health workers delivering care with minimal guidance [3]. WorldVision's

2005 mobile-midwives project in Aceh Besar, Indonesia, presents evidence on healthcare providers using mobile technology to bolster point-of-care support [24, 27]. This program equipped midwives with mobile phones and phone credit to consult with specialists while providing obstetric care in remote locations [24]. Findings highlighted the strengthened capacity of midwives to address more complex cases, and improved collaboration with both patients and the health professionals based at referral sites [24, 27]. Midwives demonstrated a statistically significant increase in their confidence to solve challenging health problems (p < 0.10). In addition, midwives with mobile phones had more frequent consultations with experienced health staff (p < 0.10) and access to medical information from facilitybased health personnel (p < 0.10) [27]. Qualitative evaluations of this project also substantiated the increased confidence in accurate data management and more attuned knowledge-seeking behavior among midwives equipped with mobile phones [24].

Similarly, Global System for Mobile Association (GSMA) documented the use of mobile technology among community-based "Lady Health Workers" in Pakistan who utilize handsets to contact supervisors for consultation and timely referrals of emergency cases [21]. Also for use in rural Pakistan, Microsoft Research is devising toll-free voice response mechanisms for health outreach workers with low literacy to reinforce their limited training when delivering health services in remote locations [23]. Both programs in Pakistan are in their infancy and have not produced conclusive evidence on attaining their objectives.

Health Promotion

mHealth also supports the exchange of information for health promotion, often through an asynchronous modality [28] that generates short-message service (SMS) to expecting mothers [25, 29, 30]. Thailand's "Better Border and Healthcare Program" disseminated information via SMS regarding antenatal care appointment visits and the expanded program on immunization (EPI) for women along the Thai-Myanmar border [29]. After this intervention, Kawekungwal et al. [29] reported that the odds of ontime antenatal visits and EPI increased by 1.91 and 2.13, respectively, for mothers enrolled in the program. Similarly, the "Wired Mothers" project in Zanzibar, Tanzania employed mobile phones to link pregnant women with health units, send reminders on antenatal care appointments, and faciliate access to skilled attendants for obstetric care [25]. Preliminary data indicates 42% of the pregnant women with mobile phones called their midwives, and the group's odds for skilled delivery attendance and antenatal care visits increased [25].

In addition, a randomized controlled trial in an urban hospital in Thailand researched the emotional health of women who received SMS-based guidance throughout the course of their pregnancy [30]. The findings of the study revealed that pregnant women receiving messages during the prenatal period were significantly less anxious and felt more confident about health workers at the time of delivery (p < 0.05); however, there were no significant differences on the pregnancy outcomes of the two groups [30]. Lastly, an overview report identified the Beba Dolazi program in Serbia, which sends weekly health education messages via SMS to pregnant women on based on the progression of their pregnancy [7], but this study could not retrieve information on the health outcomes of women enrolled in the program.

Data Collection and Management

The introduction of mHealth has also improved mechanisms for data collection and management. Often, health workers collect data in tandem with the delivery of other health services such as the execution of referral care and immunization programs [4, 18, 29, 30]. For example, in the prenatal health promotion programs in Tanzania and Thailand, SMS services were linked to central health data systems that contained records of pregnant women and their weekly progression [25, 29, 30]. In Haranya, India, outreach workers used handheld computers to collect data on immunization records, prenatal care schedules, and routine demographic information that fed into centralized electronic health records for easy access by rural paramedics [7]. By entering the household number, frontline nurses could track and respond to the health needs of individuals within the identified household [7]. Midwives in Indonesia [7, 24] and outreach workers in Peru [4] also collected patient information and communicated it to databases at medical facilities in order to expedite the ability of health professionals to monitor progression and prescribe therapy, even though they were physically separated from patients.

The UNICEF-funded Sisu Samrakshak (SSK) program in Andhra Pradesh, India, which has been running since 2000, also exemplifies the incorporation of data management into primary health care services using mobile technology [16]. This initiative equips frontline "Anganwadi" workers with handheld devices that monitor the health development in their catchment area and communicate the data to the nearest rural health centers. Subsequently, the same mobile device disseminates necessary information related to topics such as pregnancy, nutrition, and immunizations [16], although the literature did not provide any outcomes data. Barriers and Strategies in Integrating mHealth for Maternal and Newborn Health Services

Financial Issues

The financial considerations of implementing mHealth programs pose some barriers for their sustainable integration. One major challenge is the cost to both pregnant women and local health workers, as studies indicate that mobile communication fees may be prohibitive and discourage users to continue with introduced mHealth services [20, 24, 27, 31]. Health systems have to negotiate the financial implications for all stakeholders, including platform providers, government bureaus, donors, and end users who all participate in evaluating the returns and value of the mHealth service [2, 31, 32]. Vital Wave Consulting examined these sets of financial relationships and elucidated on value chain models that outlined incentives for various actors, including the patient, mobile subscriber, health care provider, foundation, equipment provider, and government [4]. According to this value chain model, lowscale operations pose greater financial costs because there is a limited volume for diffusing the fees from private telecommunications businesses [4]. However, the financial inputs are less intensive for one-way SMS-based activities because they primarily require an initial investment with a relatively low and stable operational cost, regardless of the scale of the program [4].

Ideally, initiatives that offer the potential to maximize volume and scalability can better distribute the costs by increasing users, thereby optimizing the returns among stakeholders [4]. As such, interventions require thorough financial analysis to ensure that the target populations of mothers and health personnel have access to the mHealth services using tested, cost-effective means.

Another financial issue that affects the incorporation of mHealth services is the source and availability of funding. International non-governmental and United Nations organizations supported the implementation of the majority of the mHealth interventions we reviewed. This reliance on external parties contributes to the precariousness of programs once donors phase out. Accordingly, the evaluators of the mobile-midwives project in Indonesia recommend extensive exit strategies that hand over implementation to government agencies and educate society members on the social benefits of the services [27]. One example of a sustainable program has been the "Better Border Healthcare Program" of Thailand in which the Ministry of Public Health has absorbed the financial costs of generating SMS to pregnant women and permitted the program to sustain its operations [29]. Furthermore, this financing scheme substantiates the value chain model of one-way SMS-based operations [4], in which text messages offer a less

prohibitive maintaince cost, and relieve some of the financial strains associated witht adopting mHealth programs.

Lastly, a common funding challenge cited in the literature includes the interaction between mHealth programs and the infrastructure constraints of the broader under-resourced health ecosystem. Many of the reviewed articles documented that the costs of sustaining emergency transport systems, such as fuel and vehicle maintenance, and payment for health services contributed to challenges in the continuation of programs [20, 22, 24]. The emergency care programs implemented in the Gambia and Uganda demonstrated the interdependence between mHealth and the overall health ecosystem, in which breakdowns in the transportation system and unavailability of qualified health staff hampered the delivery of health services. In addition, prohibitive healthcare financing schemes such as user fees constrict access to mHealth services [7, 17, 33].

Policy Frameworks

The dearth of overarching policy and management frameworks within national health strategies presents another challenge to the scaled adoption of mHealth services [12]. A policy framework offers the opportunity to ensure that projects align with objectives for national maternal and newborn health care and to devise strategies for synergizing these initiatives with other health sectors such as HIV/ AIDS [10, 34, 35]. In addition, coordination between different government bureaus is essential to establish and enforce guidelines on the content and technological design of services, exchange of data, and ICT infrastructure, including network coverage [12]. Furthermore, policy frameworks may delineate protocols for health workers executing treatment based on support from remote consultations, health personnel prescribing therapy despite their physical isolation, and intermediaries involved during patient referalls. For example, 31% of midwives in Indonesia who used mobile phones for point-of-care support were apprehensive about trusting the information emanating from remote consultations due to the lack of guidelines for quality assurance and assigning accountability [27].

In addition, mHealth operations require more analytical evaluations that can guide and influence national health strategies to appropriately invest in and scale up activities [12]. Governments can then work towards developing informed practices that could promote the integration of mHealth, such as the gradual adoption of toll-free services for health related mobile communication in Rwanda [36]. The toll free services are currently operating in Mayange, Rwanda, but NGOs, government bureaus and the platform provider Mobile Telephone Networks (MTN) are negotiating ways to extend this amenity to other mHealth project sites in Kenya, Tanzania, and Uganda [36].

Socio-Cultural Context

Engaging local partners to develop culturally appropriate and language-friendly messages is another common theme for the integration and sustainability of mHealth applications [4, 22, 24, 27]. The mobile-midwives project in Aceh Besar demonstrated that technologies which permitted the use of the local Indonesian Bahasa were more accessible and effective compared to other digital media that solely used English [27]. Similarly, the "Wired Mothers" study in Zanzibar, Tanzania showed that SMS services intended for pregnant women had to be adapted to the local context in order for the adoption of the behavioral change practices [25].

Interventions also often employed a strategy that anchored mHealth programs at the community level and utilized personnel with the most immediate outreach capacity to pregnant women. Invariably, emergency response and point-of-care support programs incorporated frontline workers, volunteer auxiliaries and paid health workers who were embedded in their communities' health ecosystem [7, 20, 22-27]. For example, the RESCUER program in Uganda demonstrated that empowering community-based health workers with mobile communication provided the opportunity to strengthen linkages between community members and health facilities [22]. In addition, the "Lady Health Worker" initiative in Pakistan worked with ubiquitous and socially accepted health workers who had easy access to mothers and could bridge disenfranchised populations with the formal health system [21]. Accordingly, programs should build upon the local context and resources while still introducing an innovative tool for healthcare delivery.

Conclusion

mHealth presents a new and pervasive platform for addressing prenatal and newborn health, and evidence indicates that mobile technology is an effective tool that empowers pregnant women and healthcare providers [6, 7, 10-20]. The scope of mHealth programs retrieved in the literature review focused primarily on the global South due to its relatively dismal maternal mortality ratios and consequent concentration of funding for interventions (Fig. 3). Generally, programs focused on specific points of the MNCH continuum of care such as emergency responses during birth, with fewer projects that intervened at multiple points along the continuum (Fig. 1).

Overall, mHealth can be part of a comprehensive approach in expediting emergency obstetric referrals and enabling health workers to collaborate and improve delivery of care. Likewise, the use of mHealth can bolster preventive services through the enhanced dissemination of prenatal and neonatal education and promotion of antenatal care. However, the literature review revealed the paucity of project evaluations and a general lack of management and policy frameworks for guiding and coordinating the adoption of mHealth services into the broader health system.

Limitations

The relative scarcity of articles with a quantitative design challenged the ability to statistically corroborate the impact of mHealth. Although qualitative studies provided thematic assessments, this review could have benefitted from articles with outcomes data that explicitly correlated with maternal and newborn health indicators.

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Improvement of maternal health services through the use of mobile phones

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Summary OBJECTIVE To analyse, on the basis of the literature, the potential of mobile phones to improve maternal health services in Low and Middle Income Countries (LMIC).

METHODS Wide search for scientific and grey literature using various terms linked to: maternal health, mobile telecommunication and LMIC. Applications requiring an internet connection were excluded as this is not widely available in LMIC yet.

RESULTS Few projects exist in this field and little evidence is available as yet on the impact of mobile phones on the quality of maternal health services. Projects focus mainly on the delay in receiving care – that is in recognizing the need and making the decision to seek care – and the delay in arriving at the health facility. This is achieved by connecting lesser trained health workers to specialists and coordination of referrals. Ongoing projects focus on empowering women to seek health care.

DISCUSSION There is broad agreement that access to communication is *one* of several essential components to improve maternal health services and hence the use of mobile phones has much potential. However, there is a need for robust evidence on constraints and impacts, especially when financial and human resources will be invested. Concurrently, other ways in which mobile phones can be used to benefit maternal health services need to be further explored, taking into consideration privacy and confidentiality.

keywords maternal health, mobile phones, mHealth eHealth, communication

Introduction

Progress in achieving Millennium Development Goal (MDG) 5, to improve maternal health by reducing maternal mortality and improving access to reproductive health, is lagging behind the targets. New impulses are needed to attain the goals. Two recent international initiatives recommend mobile phones as a means to improve maternal health services (ITU 2010; mHealth Alliance 2010).

Maternal health

Every 90 seconds a woman dies of complications related to pregnancy and childbirth, resulting in more than 340 000 maternal deaths a year (Hogan *et al.* 2010). Millions of women suffer from pregnancy-related illnesses or experience other severe consequences such as infertility, fistula and incontinence (UNICEF 2009). Delay is considered the key factor leading to women not accessing health services. There are three phases of delay: (i) recognizing the need for health care and in the decision-making process; (ii) arrival at a health facility; and (iii) receiving appropriate and adequate care at the health facility (Maine 1994). Underlying determinants that cause the delays are the position of women in society, large geographical distances, weak health systems, poverty and lack of education (Ronsmans & Graham 2006; UNICEF 2009).

Mobile phones

MDG 8 addresses the need to make benefits of new technologies available, especially those related to information and communication. The fastest growing new technology worldwide is the mobile phone. In Africa and Asia, where the burden of maternal mortality is greatest (WHO & UNICEF 2010), the expectations are that by 2012, 50% of the people will have access to a mobile phone (ITU 2009). The uptake of mobile phones varies; it is inversely proportional to poverty rates, but also influenced by the competitiveness and thus the price levels of the relevant markets (UNCTAD 2010). The use of mobile phones in health systems is called mHealth. This article

discusses the potential of mobile phones to improve maternal health services in LMIC by strengthening communication throughout different levels of the health system.

Method

Our literature search limited to English publications combined terms linked to: maternal health, mobile telecommunication, and LMIC. Only publications considering the basic use of mobile devices (without requiring internet access) were included, as poor internet coverage, high illiteracy rates and low levels of experience in using technology make more advanced use of mobile technology difficult in LMIC.

Searches initiated in PubMed, Embase, Cochrane Library, Scopus, Science Direct and African Journals Online retrieved a large amount of mHealth-related publications, of which only eight were relevant; these articles address maternal health services in LMIC, the use of mobile devices and reported preliminary results. The search was subsequently expanded to grey literature, and reference lists were also screened for further relevant sources.

Literature findings

A recently published paper on mobile phone technology for health care in LMIC (Mechael *et al.* 2010) reviewed literature on mHealth, such as treatment compliance, data collection and disease prevention. The authors see great potential for mHealth; however, there is not much evidence of actual and wide-scale impacts yet. We analysed resources for the particular area of maternal mHealth and confirmed a lack of evidence-based studies focusing on the efficacy and effectiveness of interventions. Most documentation referred to pilot studies and often lacked baseline data, a control group and clear outcome indicators.

Accessing emergency obstetric care

Before the wider use of mobile phones, several project publications considered improved communication through radio systems as one component among several aimed at improving access to emergency obstetric care and referral systems. These projects mainly focused on reducing the second phase of delay. Traditional Birth Attendants (TBAs) and/or midwives were equipped with walkie-talkies, enabling them to contact supervisors and ambulances when facing difficult situations. Concurrently, other components such as the overall quality of the health services were improved through more reliable transport means, increased capacity, medical equipment and reduction of financial barriers.

Projects in Mali, Uganda, Malawi, Sierra Leone and Ghana, which implemented the above mentioned components, noted a significant reduction in maternal deaths and an increase in supervised births when comparing the situation before and after the interventions. Faster modes of communication and transport were named as important factors in improving access to emergency obstetric care (Samai & Sengeh 1997; Musoke 1999, 2002; Matthews & Walley 2005; Lungu & Ratsma 2007; Fournier *et al.* 2009). The projects in Uganda and Ghana additionally considered the first phase of delay by connecting traditional health providers to the biomedical health system. As TBAs are frequently at the homes of pregnant women, they can speed up the process there.

Krasovec (2004) concluded that studies provided only weak empirical evidence regarding the actual impact of communication systems and that access to tools of communication is not the solution for decreasing maternal deaths in isolated areas. The tight timeframe in which a woman requires emergency obstetric care (due to e.g. severe bleeding) implies that quality services need to be accessible at short notice and supported by effective infrastructure management. In a more recent review, Lee *et al.* (2009) confirm the need for more rigorous assessments.

Information regarding plans for scaling-up projects that use radio systems was only found for the pilot project in Uganda. These plans were not realized due to high costs, inability to maintain equipment and lack of integration into the health system. However, in this project the radio system was later replaced by mobile phones, which were found to be a cheaper and a more practical solution (UNFPA 2007).

Improving the capacity of lesser trained health workers

More recent projects introduced mobile phones to improve the capacity of lesser trained health workers by connecting them to better trained medical staff, thus aiming to reduce the third phase of delay. In Indonesia, Chib *et al.* (2008) selected 15 health facilities through random sampling; midwives in eight of the facilities received a mobile phone. Perceived benefits reported were that: (i) mobile phones made it easier to contact patients, midwives and supervisors, (ii) time efficiency increased due to the ability to coordinate visits, and (iii) if complications occurred assistance was only a call away. Despite these advantages, constraints included the costs, poor mobile phone network infrastructure in rural areas, increased demand for

consultation, difficulties in uptake of higher technology programmes for data analysis, and hesitation in contacting supervisors due to organizational hierarchy (Chib *et al.* 2008; Chib 2010).

A recently launched project in Rwanda went a step further by using text messaging to facilitate and coordinate the communication as well as data exchange between community health workers, health centres and hospitals. Preliminary data suggested a positive effect on access to maternal health services and consequently lower death rates (Holmes 2010).

An initiative in Tanzania designed a phone-based application that contained forms and protocols meant to support pregnant women before, during and after delivery (Svoronos *et al.* 2010). The results of a pilot project seemed positive; however, the authors mentioned the need to further assess the impact of the project.

Empowering women to contact health services and access information

To decrease the first phase of delay, several programmes aimed to empower women to contact health services and access information; however, data was still being processed at the time this article was written. In Zanzibar, a study following 2 500 women investigated the impact of both voice and text messages on maternal health (Lund 2009, 2010a). Text messages were sent to pregnant women containing basic health education and reminders for routine health care appointments. Expectant mothers received vouchers and phone numbers that they could use to contact services for questions and emergencies. The study assessed the impact on quality of services, health seeking behaviour and maternal morbidity and mortality. The data was being processed at the time of writing this article; the study promised to yield useful information (Lund 2010b).

MoTECH is an ongoing project in Ghana aiming to determine how mobile phones can best be used to increase the quantity and quality of antenatal care (Mechael 2009). Results from randomized treatment and control groups were not yet available (Mailman School of Public Health 2010).

Gender discrepancies in access to and use of the technology

The analysis of the potential of mobile phones for maternal health requires examining how mobile phones may relate to the root cause of poor maternal health, namely the position of women in society (UNICEF 2009). Globally, a woman is 21% less likely to own a mobile phone than a man (GSMA *et al.* 2010). This discrepancy in the uptake of

mobile phones is highest in South Asia, followed by Sub-Saharan Africa.

Women who do have access to a mobile phone often use it for business, banking and employment opportunities (GSMA *et al.* 2010; Hellström 2010; Macueve *et al.* 2009) and thus to make themselves more independent. Several projects use mobile phones to improve access to basic education for women, for example text message-based literacy programmes (GSMA *et al.* 2010).

The main reason for not owning a mobile phone lies in the associated costs, illiteracy and lack of electricity (GSMA *et al.* 2010; Hellström 2010). Being practical, especially women in Africa are likely to borrow a phone if they do not own one (Macueve *et al.* 2009). Other discrepancies in the ownership of mobile phones exist between countries and in rural areas versus urban areas, mainly due to poor network coverage (Comfort & Dada 2009).

Discussion

Robust studies providing evidence on the impact of introducing mobile phones to improve the quality or increase the use of maternal health services are lacking. However, there is broad agreement that access to communication is an essential component of improving the use and quality of maternal health services. The mobile phone has a high potential as it is small, portable, widely used, relatively cheap and the extending network coverage increasingly enables communication with rural and isolated areas.

The extremely quick uptake of mobile phones worldwide can shorten delays in seeking and receiving health care. The available literature suggests great potential in connecting traditional and biomedical health care, as well as connecting the different levels within a health care system, provided that women are not restricted due to their position in society, lack of finance or means of transport.

To fully realize the benefits of mobile communication, research needs to generate the evidence-basis for scaling up mHealth and enabling informed mHealth policy-making, and to analyse its benefit in ensuring timely delivery of medical equipment, provide health education and improve access to reproductive health services, e.g. for family planning.

So far, projects mainly focus on acute, life threatening situations, but mobile phones can also be used to deliver mass health messages to pregnant women, recalling women with risk factors to present themselves at an antenatal clinic or referring women who suffer from complications such as fistula, incontinence and infertility. Possibilities related to connecting them to specialized hospitals need to

be integrated into research and project designs. In addition, all the different applications, best practices, constraints and lessons learned need to be documented.

The quick uptake of the mobile phone and its use in health care requires policies and guidance of governments, especially related to issues such as privacy and confidentiality. An overuse of text messaging by the private and public sector will soon be regarded as spam, making it lose its effectiveness. In addition to privacy, governments need to ensure confidentiality of sensitive information.

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