COMMENTARY

An Integrating Model for Rapid Reduction of Maternal Mortality Due to Primary Postpartum Haemorrhage - Novel Use of the Catalyst Approach to Public Health

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Abstract

On average 16%-53% of maternal deaths are from postpartum haemorrhage (PPH), with confidence intervals for Eastern Asia reaching beyond 60%. Success in preventing PPH mortality across many large low-resource populations has been fairly limited. Niger's government and an international non-governmental organization (NGO) have developed a model aiming to rapidly reduce primary postpartum haemorrhage mortality, combining relatively new technologies, misoprostol, condom tamponade, and non-inflatable anti-shock garment, with systematic measurement of blood loss and a set of traditional public health tools that constitute the Catalyst Approach to Public Health, with action steps for each phase if haemorrhage occurs. This paper describes each component and testing of the hypothesis that the model can effectively reduce PPH mortality on a national scale. The Niger model is a 'complex intervention' aiming to maximise impact from existing health system resources even in remote areas. The broad applicability of Niger's approach to address a serious global public health problem, and its innovative nature warrant describing the model itself, with results to be published separately. Combining this set of individually proven technologies and a set of organisational tools from disease eradication settings as a single 'complex intervention', has to our knowledge not been described before. *(Afr J Reprod Health 2019; 23[2]: 18-26).*

Keywords: Postpartum haemorrhage, maternal mortality prevention, public health innovation, complex interventions, resource-constrained settings, cost-effectiveness

Résumé

En moyenne, 16% à 53% des décès maternels sont dus à une hémorragie postpartum (HPP), les intervalles de confiance pour l'Asie orientale dépassant 60%. Le succès de la prévention de la mortalité par HPP chez de nombreuses grandes populations à faibles ressources a été assez limité. Le gouvernement du Niger et une organisation non gouvernementale (ONG) internationale ont mis au point un modèle visant à réduire rapidement la mortalité par hémorragie postpartum primaire, associant des technologies relativement nouvelles, le misoprostol, la tamponnade du préservatif et un vêtement antichoc non gonflable, avec une mesure systématique de la perte de sang. Et un ensemble d'outils de santé publique traditionnels qui constituent l'approche catalyseur de la santé publique, avec des étapes d'action pour chaque phase en cas d'hémorragie. Cet article décrit chaque composant et teste l'hypothèse selon laquelle le modèle peut réduire efficacement la mortalité par HPP à l'échelle nationale. Le Niger model est une intervention complexe visant à maximiser l'impact des ressources du système de santé existantes, même dans des zones reculées. La large applicabilité de l'approche du Niger pour faire face à un grave problème de santé publique mondial et son caractère novateur justifient la description du modèle lui-même, les résultats devant être publiés séparément. La combinaison de cet ensemble de technologies éprouvées individuellement et d'un ensemble d'outils organisationnels issus des environnements d'éradication des maladies en une intervention complexe unique n'a, à notre connaissance, pas été décrite auparavant. *(Afr J Reprod Health 2019; 23[2]: 18-26).*

Mots-clés: Hémorragie post-partum, prévention de la mortalité maternelle, innovation en matière de santé publique, interventions complexes, environnements aux ressources limitées, rapport coût-efficacité

Introduction

The aim of this article is to help other low-income countries reduce primary postpartum haemorrhage mortality more resolutely than has been done internationally up until now, by sharing a 'complex intervention' model being used by Niger's Ministry of Health and by describing how the model is being tested for its ability to prevent primary postpartum haemorrhage mortality. Maternal mortality has been reduced in most countries in recent years, from a global 385/100,000 live births in 1990 to an estimated 216/100,000 in 2015, a period during which 13.6 million women died maternal deaths[i]. Sub-Saharan Africa had an estimated maternal mortality rate (MMR) of 987 and 546/100.000 live births in 1990 and 2015, respectively[1]. Worldwide, haemorrhage, most of it postpartum, is estimated to cause for example 16%-53% of maternal deaths, one estimate for the global average being 27%[2,3].

Up to 18% of births entail bleeding beyond the 500 ml threshold that defines primary postpartum haemorrhage (PPH)[4]. Roughly 10.5% of births entail severe excessive maternal bleeding (≥ 1000 ml) if nothing is done to prevent it[5]. Where many women are already severely anaemic, even 250 ml (normal) blood loss can cause clinical problems[4]. 'PPH can transform a normal woman in labour to a critically ill patient within minutes'[4]. Death from primary postpartum bleeding often occurs within two hours[6]. Even in 'developed' countries PPH is responsible for 16.3% of maternal deaths and remains the most frequent cause[2].

In the UK, for example, the 1985-2011 decline in PPH mortality was not statistically significant, and PPH caused 20.5% of maternal deaths in even as highly developed a country with a strong health system as Japan in 2009[7,8]. Elsewhere, PPH causes 24.5% (16.9-34.1) of maternal deaths in sub-Saharan Africa, 29.5% (8.5-61.7) in Oceania, 29.9% (15.2-51.3) in South Eastern Asia, 30.3% (14.0-54.8) in Southern Asia, 35.8% (10.9-68.2) in Eastern Asia, and 36.9% (24.1-51.6) of maternal deaths in Northern Africa[2]. Though enormously ambitious, if innovation can hasten the halving of PPH mortality as Niger is striving to do, it warrants testing.

Niger's Ministry of Health aims to rapidly reduce primary postpartum haemorrhage mortality by innovatively combining low-cost, relatively new, proven high-impact technologies, with a strategically chosen to set of traditional public health tools. Niger's model seems applicable in low-resource African and Asian settings, and perhaps some middle-income districts and hospitals in Latin America.

It is known that organisational intervention to strengthen health systems and technologies of various kinds can reduce maternal mortality. Sweden put midwives in place as far back as the 1800s, in what was then a poor country, and that helped to reduce maternal mortality considerably. Even so, midwives were neither as simplistically nor as universally impactful as some have claimed. And midwives were not the sole cause of the observed maternal mortality reduction[9]. Educating girls leads to lower maternal mortality[10]. Caesarean section and symphysiotomy are obviously life-saving in specific obstetric emergencies and prevent tragedies such as obstetric fistula when done early enough[11-13].

While some exclude surgical procedures from the definition of 'complex intervention', successfully providing caesarean and symphysiotomy operations, especially in resource-constrained settings, is a 'complex intervention' because of the 'multifaceted nature and dependence on social context'; to succeed one must combine external societal elements with organisational elements within health systems (e.g. 'recruiting' appropriate patients at an appropriate time, communication, logistics, the presence of various types of skilled health workers, a hospital building with operating theatre, etc.) with technologies (e.g. lighting, anaesthesia, surgical equipment, and surgical supplies such as compresses and suturing material)[11,12]. The present model combines a number of elements into one complex intervention that Niger is using to supplement traditional maternal mortality reduction efforts which have a longer time horizon.

Internationally, active management of the third stage of labour has been promoted widely but requires skilled birth attendance[13,14]. External uterine massage continues to be recommended[15]. A

sublingual prevention dose (400ug) of misoprostol in the absence of oxytocin reduces PPH incidence to 3.1%, 83% lower than the 18% seen if nothing were done[4,16]. It is recommended to use local garments to estimate blood loss[17-20]. When PPH occurs, Niger implements a 3-Step treatment protocol described below, each component of which is well documented.

Evidence supports each technology that Niger has combined to reduce PPH mortality. A misoprostol prevention-dose demonstrably reduces PPH incidence cost effectively in a hot climate where sustaining a cold-chain for oxytocin may be unreliable[21-24]. Routine measurement of primary postpartum bleeding volume is recommended using the woman's own cloth, called a 'pagne' in Niger's case[23]; a treatment dose of misoprostol effectively reduces mortality among those who bleed more than 500ml[25]; when misoprostol is insufficient, intrauterine compression using a condom tied onto a catheter as a water-filled balloon often stops severe PPH[21,22]; and when women are in pre-shock or shock due to primary postpartum bleeding, lives can be cost-effectively saved when a non-inflatable anti-shock garment (NASG) is applied and definitive surgical treatment provided[23,24].

Description

Principles for designing a better approach to prevent PPH mortality include maximizing impact from existing health system resources and achieving measurable outcome-improvement while adding little, to augment chances for sustainability. Other guiding principles are to 'Prevent, Measure, Treat if necessary' in that order. Niger's National Consultative Ethics Committee considered and approved monitoring and evaluation aspects (Deliberation 006/2016/CCNE, letter dated 24 March, 2016) because a portion of those are structured as a study, whereas Ministry of Health implementation of the interventions themselves as a normal programme, strengthening its reproductive health services using well documented technologies, does not require Committee approval.

Documenting effectiveness of this complex intervention is done using observational techniques in agreement with criteria proposed by Black[25], Craig *et al*[15], and Glasziou *et al*[26]. Though not all agree, randomised trials seem unnecessary, and observational studies are arguably better suited to documenting effectiveness when quick effect of treatment is easy to demonstrate in rapidly progressive conditions[32].

Also underlying the present model is the hypothesis that some non-eradicable diseases can essentially be eliminated as a public health problem while health systems are strengthened, if we add disease eradication tools that optimise the effectiveness of existing resources (the catalyst approach to public health) together with a few low-cost technologies, within existing health systems.

The catalyst approach to public health (Box 1) comprises a specific set of traditional public health tools, combined under particular circumstances, with the aim of achieving greater impact on outcomes than can otherwise be achieved using the same level of inputs[27]. As an example, the catalyst approach has been shown to rapidly reduce all-cause birth-related maternal mortality and obstetric fistula incidence on a public health scale in a severely resource-constrained setting where the population is almost universally illiterate[28]. A precondition for the catalyst approach to work is that even illiterate people can diagnose the disease or key factors pertaining to the disease precisely.

The catalyst approach to public health can be used in a more generalised form than the community-based version initially outlined, and it includes an eleventh tool (Box 1) that was accidentally omitted from the original description[34].

Specific elements of PPH Prevention, Measurement, and 3-Step Treatment as implemented in Niger comprise the following:

Prevention in hot community health facility settings without reliable refrigeration is by providing misoprostol tablets costing less than $1 US Dollar per dose. One dose of misoprostol is distributed to each woman who attends her third-trimester prenatal consultation, together with verbal instruction and a low-literacy instruction pamphlet describing when and how to use it. She is strongly encouraged to give birth in a health setting, bring the tablets with her when she comes

Box 1: Eleven elements are arguably essential in The Catalyst Approach to Public Health[1]

1. **A few people who really care**. 5-10 deeply committed people in a handful of organisations.
2. **A data manager and programme manager in each country**. Data managers usually work full-time for the programme. Programme managers are usually Ministry of Health professionals, whether full- or part-time.
3. **An organisation.** One or two people with considerable expertise in epidemiology must, through friendly insistence, collect data from countries, analyse them promptly, and provide monthly feed-back to all partners. A fast, non-bureaucratic organisation is best.
4. **Resident technical advisors in each country.** Usually expatriates, resident advisors must work collaboratively but be funded from outside the infrastructure with which they work. They must have some funds for meetings, travel, and stimulation of activities, yet have no formal power. The combination of independence, commitment, and lack of formal power, makes them effective.
5. **International meetings.** Staff from countries and supporting agencies present data, plans, budgets, achievements, problems, and seek solutions, ideally twice a year. Broad annual meetings and smaller reviews 6 months later (e.g. organised by language) may be best.
6. **Annual programme review meetings in each country**. Representatives from all levels of the national programme discuss successes, problems, and ways forward.
7. **Annual training and re-training for peripheral-level contributors.** Health workers, and village volunteers if volunteers are used, receive 1-2 day updates on progress in their localities, country, and elsewhere. They brush up and are given new technical information.
8. **A network of supervisors.** In the approach's full-fledged community-based form, supervisors visit each village volunteer at least monthly, gather collected data, and relay messages between villages and national level. They encourage volunteers, visit homes with them, and help them become more proficient. Regular, announced and unannounced visits by national staff are part of the supervisory system. Announced but also spontaneous supervision visits to all levels of the health system are also key in monthly supervision activity under a PPH mortality prevention initiative, though priority is then given to localities reporting especially excellent or poor results. One tries to visit all districts and all health centres and hospitals from time to time.
9. **Transportation.** From bicycles to 4-wheel-drive vehicles and the occasional camel or boat for supervisors, transportation needs include annual funding for fuel and maintenance, and replacement of vehicles every 4-6 years.
10. **Course-correction mechanisms.** Continuous research is needed to improve technical tools and approaches specific to the health initiative.
11. **Mobilising political support**: This is such a natural part of all Catalyst Approach work that it was accidentally omitted when the approach was first described. From local administrative, political, traditional, and religious community leaders, through to national authorities, support for the interventions being implemented, based on their genuine understanding of the importance of the issues and a perspective of respect being shown to the population, is absolutely essential if public health interventions are to succeed. This of course also applies to interventions being implemented through a catalyst approach.

[1]***A National Task Force*** *is sometimes established, traditionally one per disease. In Togo, a Task Force for Parasitic Diseases and Family Health maintains the focus of individual programmes while maximizing the effect of scarce resources and strengthening collaboration. Although potentially useful, national task forces are apparently non-essential.*

to give birth, and instructed to in any case take the tablets immediately after the baby is born and her abdomen has been palpated to be sure no twin remains inside. Given a sublingual PPH prevention dose of misoprostol, only 3.1% of birthing women experience PPH, while none among 321 women in the misoprostol arm had blood loss of ≥1000 ml[19].

Measuring blood loss is the first step after the infant is born, after the prevention dose of uterotonic has been given and the cord has been cut (in that order). In home and health centre settings a traditionally available cloth of fairly standardised size is placed under the buttocks. Women bleeding 500 ml or more, as judged when the cloth becomes soaked with blood (soaked once in the case of Niger), are judged to have PPH. The 3-Step Treatment below is provided to any woman bleeding 500ml or more, and after smaller blood losses in women who become hemodynamically unstable because of low pre-birth haemoglobin. A high brittle pulse and decreasing blood pressure are indicative of hemodynamic instability.

3-Step Treatment is in the hands of health workers. **1)** Give the woman a treatment-dose of misoprostol[29]. If the bleeding does not stop within 25 minutes, **2)** Place a Condom Tamponade (Figure 1), a condom tied onto a catheter, inserted into the bleeding uterus, and inflate with 300-500ml of water. If that does not stop bleeding

Figure 1: Intrauterine Condom Tamponade Kit and its contents

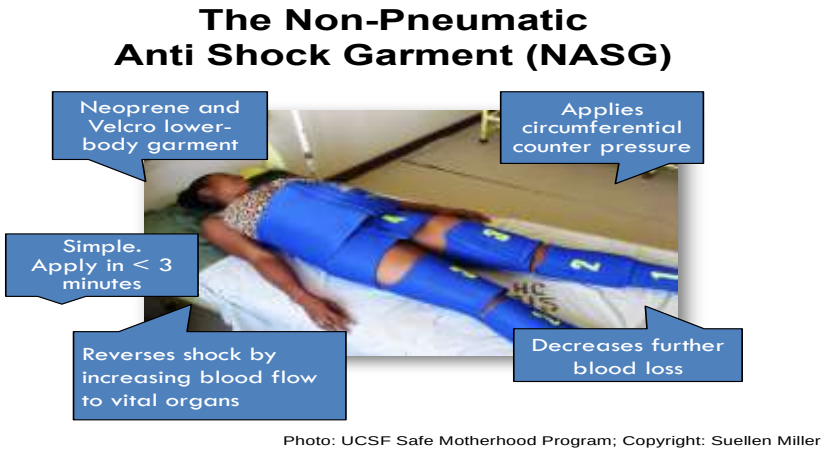

Figure 2: Non-inflatable anti-shock garment (NASG)

within 6-12 minutes, 3**)** Apply a Non-inflatable Anti-Shock Garment (NASG) (Figure 2) and get her to surgery, even if far away. Antibiotics are included in each Tamponade Kit to protect against infection because clean but unsterile equipment are inserted into the uterus.

Health workers receive an initial stock of supplies and two hours of on-site training at their health facility. Teams of trainers receive two days of training on issues surrounding PPH, the initiative's structure within the national health care system, how re-supply of inputs, prevention of stock-outs, monthly reporting of data from all levels of the health care system, and monthly supervision are to function. Training on each intervention and emphasis on how the training of health workers in hospitals and health centres is to be conducted are also key aspects in training of trainers.

Niger's Ministry of Health (MOH) and its partnering NGO are prospectively measuring the impact of this approach on PPH mortality, mainly in two ways based on monthly reporting from, in principle, all health facilities where births occur: 1) comparing the proportion of health-facility maternal deaths due to PPH with what the broader

literature and historical records from Niger lead one to expect, aiming for a 50% reduction; 2) comparing prospective health facility PPH mortality with what was found retrospectively during a nationwide facility- and community-baseline survey covering the 12-month period previous to when the intervention was expected to start, again aiming for a 50% reduction. If funds for a post-intervention survey become available, one will also seek to compare community-based mortality and the proportion of birth-related maternal deaths caused by PPH, pre- and post-intervention. In addition, MOH invited Gynuity Health Projects (New York) to study the model's implementation completely independently, using a different methodology (not reported here), which includes interviews with providers and women who give birth at selected facilities.

Discussion

Niger's 'complex intervention' consists of a defined set of low-tech, low-cost, quite new, proven technologies, combined in an innovative way with organisational tools from the Catalyst Approach to Public Health.

There is some disagreement about the optimal misoprostol dose to prevent PPH. There is no evidence for increased clinical efficacy beyond 400ug, and WHO's 2012 recommendation explicitly says there is no evidence for the 600ug dose being more effective than 400ug, though the committee that considered the issue found more evidence at that time concerning 600ug, which it therefore suggested. Because 90% of those given PPH prophylaxis would not experience severe PPH even without the uterotonic, using 600ug exposes huge numbers of healthy women to much more frequent and sometimes severe, even life-threatening side-effects compared with the 400ug dose of misoprostol. Therefore, Hofmeyr and others argue for using 400ug of misoprostol for PPH prevention[24,25,30]. '...400ug of misoprostol were found to be safer than $\underline{\geq}$ 600ug, and just as effective'[25]. In this case, increasing the dose beyond one that produces full clinical effect leads to more frequent, more severe side-effects, and it increases procurement costs by 50%. That is significant for national programmes with very limited resources that aim to reach hundreds of thousands of women annually.

It cost on the order of $700 000 USD to put the model in place nationwide in Niger in 2014, of which $120 000 USD was for a baseline survey. Based on the 2014 population estimate of close to 17.4 million and the officially expected 702 000 births that year, this represents a cost of $ 0.04 USD/person and $ 1 USD/pregnant woman.

We expect $9.9 million US Dollars of annual cash benefits for the population, approximately 12 times greater than annual running costs. Cash benefits include expenditures averted due to deaths averted, and prevented loss of income from severe anaemia among PPH survivors, conservatively using three months loss of income as being the cost of each severe anaemia case, half the WHO Burden of Diseases estimate[31]. We used $1 USD/day as the estimated average income for the population of Niger.

Individual technologies applied under this model are known, and several are being applied elsewhere by ministries of health and other groups. Yet, Niger is to our knowledge the first government to implement a nationwide initiative by combining this complete set of effective technologies with a specific set of organisational tools that has mostly been used by disease eradication programmes, to resolutely address the most frequent cause of maternal mortality.

We are also unaware of any other nationwide initiative being implemented with such an ambitious quantitative goal. Niger aims to reduce maternal mortality by 50%, more quickly than even optimists consider possible using traditional health systems strengthening approaches. That this model aims to simultaneously, measurably strengthen the existing health system is also new. While superficially appearing to be 'vertical' and thus arguably unsustainable, Niger's Prevention and 3-Step Treatment model for PPH mortality reduction conceptually bridges the 'horizontal-vertical' divide. Optimizing the impact of existing resources is key to the model's success.

The potential for impact is considerable. When a single low-cost, heat-stable intervention brings

83% lower PPH incidence as documented above, including three additional cost-effective interventions ought to produce outcomes that are at least as good. While hugely ambitious, this strategically combined set of interventions can therefore reasonably be expected to produce results on the order of the 50% PPH mortality reduction that the Republic of Niger is aiming for, if implemented using a set of organisational tools that are demonstrably effective when combined properly in low-resource settings, even in conflict-ridden countries.

Next steps

Beyond Niger fully analysing and publishing its encouraging preliminary results from over 630 000 births under this Initiative, it is important to test Niger's PPH mortality reduction approach on a public health scale in other settings, as a state in Nigeria is currently doing across its population of 3 million, as Liberia has decided to do, and as three districts in Uganda are seeking to do. It is also important that Tool 5 from the Catalyst Approach to Public Health (Box 1) be introduced by the international community, now that two or more countries are implementing the Niger approach to PPH mortality reduction.

Conclusion

In July 2014, Niger's Ministry of Health launched a nationwide *Initiative to Prevent Women from Bleeding to Death at Childbirth* with technical and financial support from a Norwegian-American non-profit organisation, HDI (Health & Development International). While results will be reported separately, the model itself seems broadly applicable. Implementing parts or all of the described approach as a single complex intervention may help to rapidly reduce maternal mortality in under-resourced health systems, and within tertiary hospitals, in several low- and middle-income countries.

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Author Contributions

ARS conceived the model for PPH mortality prevention and drafted the manuscript. ZA, AL, and IS contributed to refining the design of the model. ZA and AL contributed to writing and IS to reviewing the manuscript. All authors have approved the final version for submission and publication.

Competing Interests

ARS is founder and executive director of HDI Inc and HDI Norway. ZA has been employed by Health and Development International in Niger since November 1, 2008. IS has been Niger's Director General of Reproductive Health during the period discussed. AL declares that he has no conflicts of interest.

Ethical Consideration

Niger's National Consultative Ethics Committee considered and approved monitoring and evaluation aspects (Deliberation 006/2016/CCNE, letter dated 24 March, 2016) because a portion of those are structured as a study, whereas Ministry of Health implementation of the interventions themselves as a normal programme, strengthening its reproductive health services using well documented technologies, does not require Committee approval.

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