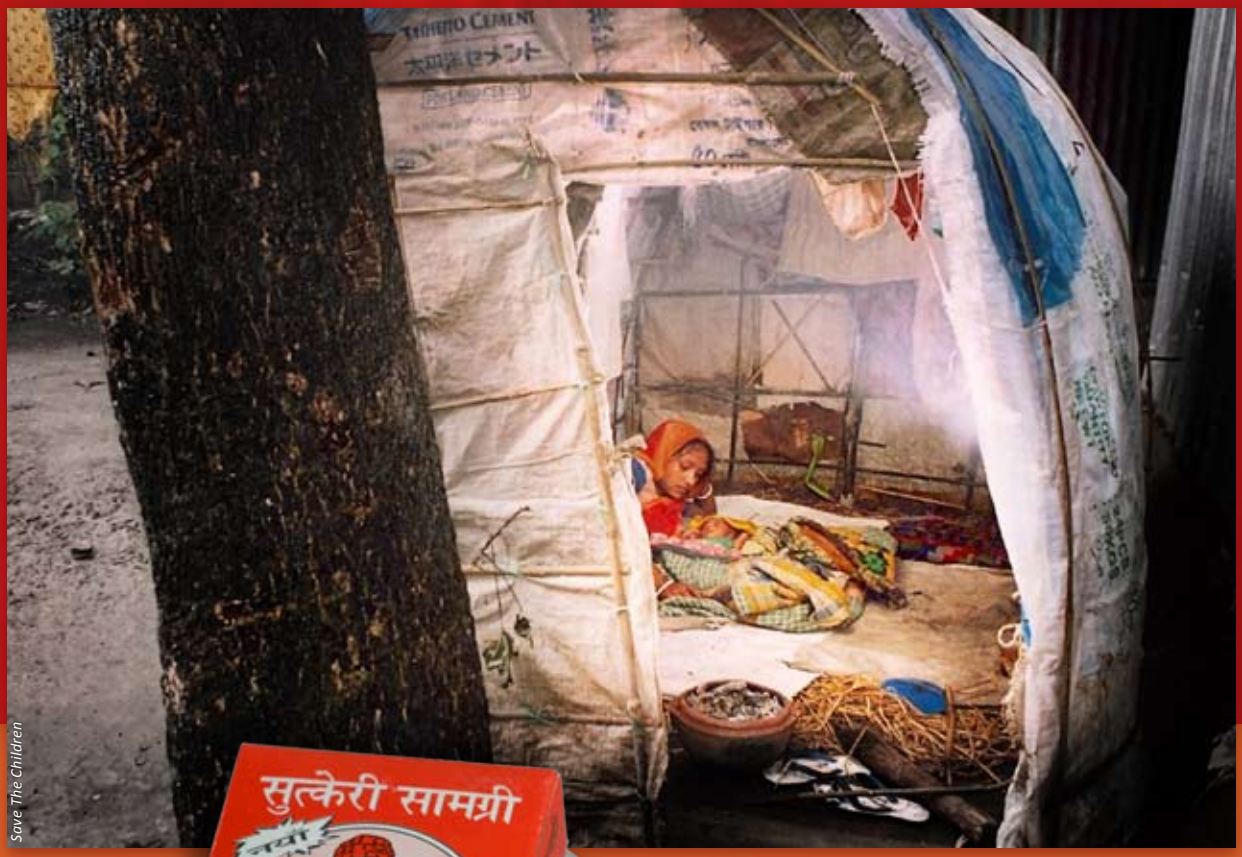
# CLEAN BIRTH KITS – POTENTIAL TO DELIVER?

## EVIDENCE, EXPERIENCE, ESTIMATED LIVES SAVED AND COST



Save The Children

# POLICY BRIEF - PURPOSE AND PROCESS

For centuries, a clean birth has been recognized as essential to the health and survival of both mothers and newborns. Nevertheless, each year an estimated 1 million newborns and mothers will die from infections soon after birth (Figure 1). This policy brief summarizes the current state of knowledge on clean birth practices and the potential role for clean birth kits (CBK) in supporting these preventive practices and for saving lives. The content draws on several recent scientific reviews and a Technical Workshop on Clean Birth Kits held in London on March 25-26th 2010. This Workshop was the first in a series of technical meetings to review issues related to commodities and kits at the time of birth. Further policy briefs are expected.

# KEY FINDINGS AND ACTIONS

## SITUATION

PAGE 4 - 5

Each year around 1 million newborns and mothers die from infections soon after birth, and this burden is highest for the poorest families. Progress for skilled attendance at birth has been slow - only 13 of 68 Countdown countries have increased coverage by more than 10% since 1990. Of the world's 60 million home births each year, many occur without adequate hygiene. Indeed some facility births also lack basic hygienic care. Immediate solutions are necessary to address this.

## SOLUTIONS

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The "six cleans" include clean hands, clean perineum, clean delivery surface, clean cord cutting implement, clean cord tying, and clean cord care. Approaches to increase uptake of these clean practices include media and public health messaging, community-based behaviour change and training, CBK distribution and facility-based training and equipment distribution. Clean Birth Kits (CBKs) are the focus of this brief and usually are defined as only including disposable items for clean birth practices e.g. soap, blade, plastic sheet etc.

## EVIDENCE

PAGES 7 - 9

A systematic review identified 30 studies showing that clean birth practices can substantially reduce neonatal mortality and morbidity from infection-related causes, including tetanus. In 3 of the studies (1 Randomized Controlled Trial (RCT)), a reduction in maternal sepsis was additionally reported. Evidence from 3 studies, including 1 RCT, supports the role of CBKs in promoting clean birth practices, although in all cases there were co-interventions. Conducting RCTs of clean birth practices compared to unclean would be unethical and as a consequence, evidence regarding clean birth practices is overall of low quality. However as there is strong biological plausibility and this is an accepted standard of care, the GRADE recommendation for clean practices at birth is strong.

Giacomo Pirozzi/UNICEF

Michael Biscegli/Save The Children

Jonathan Hubschman/Save The Children


Michael Bisceglie/Save The Children

## ESTIMATES OF LIVES SAVED AND COST

PAGES 10 - 11

If 90% of all home births applied clean practices (54 million births), then the lives of an estimated 6,300 women and 102,000 newborns would be saved each year. Uptake of such practices may be catalyzed by CBKs. The estimated cost of CBKs is between $ 0.17 and $ 0.73 per birth, depending on whether made locally or imported. If CBKs are made locally this amounts to a cost of around $215 per life saved. Hence, although CBKS may avert a comparatively small proportion of all maternal and neonatal deaths, as the costs are low, they are highly cost-effective interventions for both women and babies and also most likely to benefit the poorest families. The number of lives saved would be greater for facility births since "safe as well as clean" practices could be provided, although the cost would be much higher.

## EXPERIENCE IN IMPLEMENTING CLEAN BIRTH KITS and EVIDENCE GAPS

PAGES 12 - 14

CBKs use is reported in at least 51 countries, and in some countries are national policy and widely used. We did not identify any studies comparing different approaches to implementing clean birth kits. Important research gaps remain, particularly the effect of CBKs on uptake of facility birth, and also the effect of varying implementation and distribution strategies. There is an urgent need for more data before birth kits are expanded to include additional commodities.

## ACTION NOW

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Safe birth is a basic right for mothers and newborns. Clean birth forms an important part of this right, and must be promoted alongside other proven interventions such as universal access to skilled attendance at birth and referral systems strengthening to access emergency obstetric and newborn care. Mother-held CBKs are highly cost effective and considered appropriate in conflict or humanitarian emergencies, or in settings where there is currently low coverage of facility birth, as long as they do not act as a disincentive for facility birth. If mother-held CBKS act as an incentive for facility care, wider promotion would be justifiable.


Jonathan Hubschman/Save The Children


Carolyn Watson/Save The Children

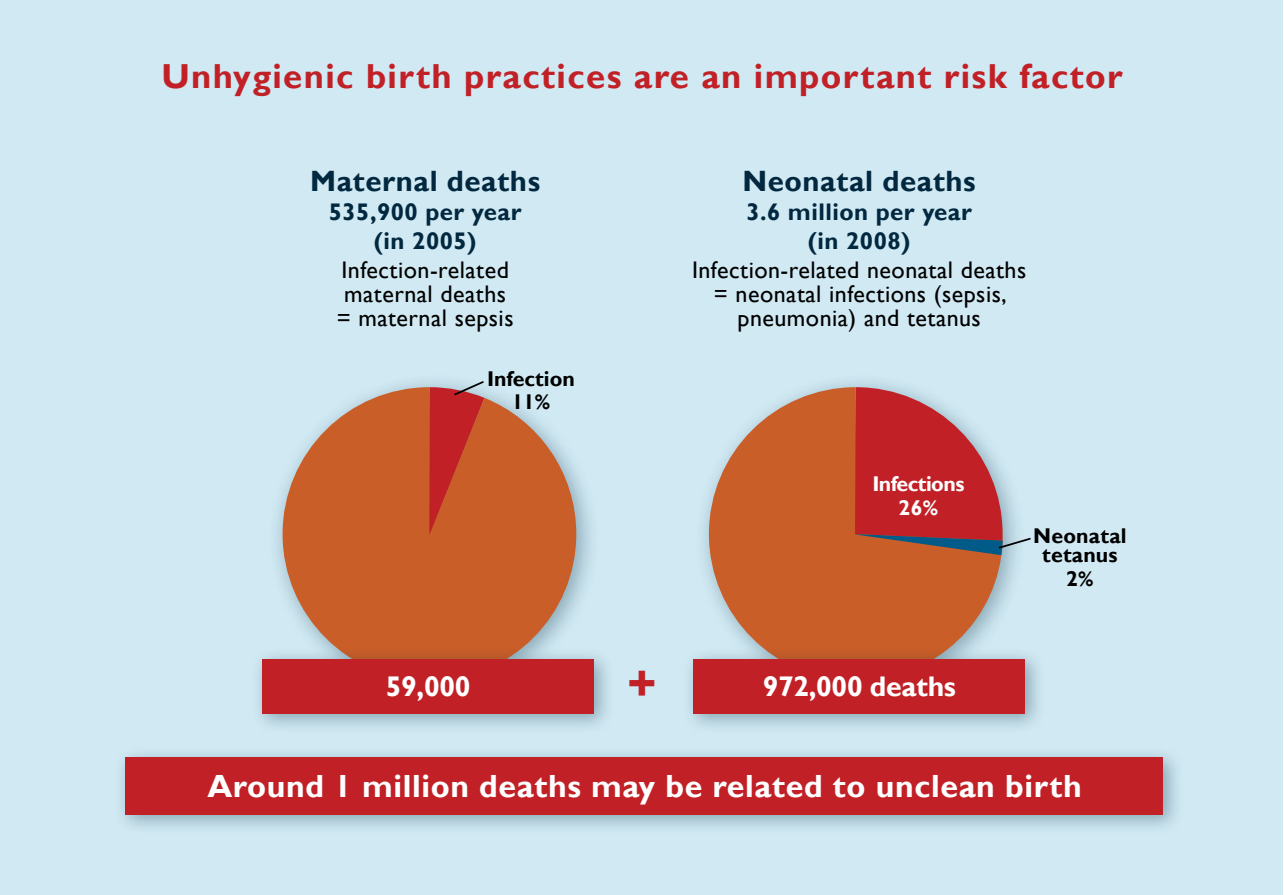

Roger Lemoyne/UNICEF

# SITUATION FOR CLEAN CARE AT BIRTH

Each year there are around 135 million births worldwide and most families can celebrate a surviving mother and newborn. However annually around half a million women die from causes related to pregnancy and childbirth. An estimated 10% (Africa) and 12% (South Asia) of these maternal deaths are estimated to be due to infection, many associated with unhygienic practices around the time of birth[1]. In addition, 3.6 million newborns die in their first month of life with 26% of these deaths due to serious infections. One third or more of these infection related neonatal deaths are estimated to be caused by unhygienic care at birth[2], and another 2% of newborns die from neonatal tetanus – now rapidly declining primarily due to increased immunisation coverage. Hence, in total, up to 1 million deaths a year may be linked to unhygienic practices at or soon after birth (see Figure 1).

Birth is the moment in the continuum of care when both mothers and newborns are at greatest risk. Yet data from *Countdown to 2015 for maternal, newborn and child health* show that for many countries this is the moment of lowest and most inequitable coverage of care. Giving birth with a skilled attendant is even

**Figure 1: Global maternal and neonatal deaths due to infections**




*Adapted from Lawn IJGO 2009 [14]. Data sources: Maternal deaths: WHO/UNICEF/UNFPA estimates, Hill K et al, 2007 [15]. Maternal cause of death Khan et al 2006. Neonatal deaths: WHO (UNICEF 2009. Infection neonatal deaths based on CHERG/WHO estimates updated for 2005 for Countdown 2008 based on methods from Lawn et al., 2006 [16].*

**Data footnote –** The data and analysis input in this brief reflect the latest estimates as of March 2010 (London CBK workshop). Updated data on MMRs, and maternal and neonatal cause of death is expected in mid 2010 but was not available for this brief.

lower for the poorest women. For example, while 6% of women in Ethiopia overall have a skilled attendant at birth, 25% of the wealthiest quintile do and only 1% of the poorest.

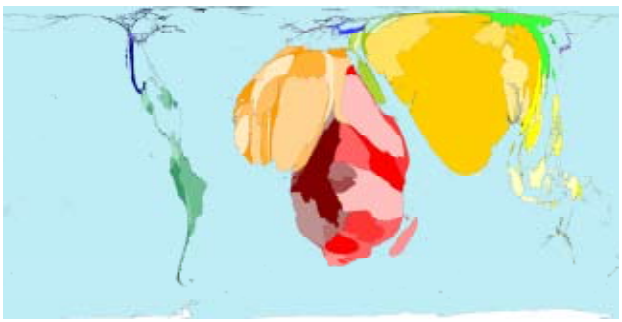
An estimated 60 million women each year give birth not in a health facility and 50 million deliver without assistance from a skilled attendant (midwife, nurse or doctor). It is important to recognize that the person present at home births varies widely between regions and even within countries. For example, in Africa just over half of births are at home, and of home births, two-thirds have no attendant at all and one third have a traditional birth attendant (TBA). In contrast, in South Asia almost two-thirds of births take place at home and of these, the majority deliver with a TBA. The only region with a significant number of home births attended by skilled attendants is South East Asia. This pattern is driven largely by Indonesia where community midwives are widely available. Nevertheless, across the region, twice as many home births are attended to by TBAs than by community midwives[3].

Although health facilities births are typically cleaner than home births, interventions to improve hygiene at birth are needed in both environments in most low and middle income countries.

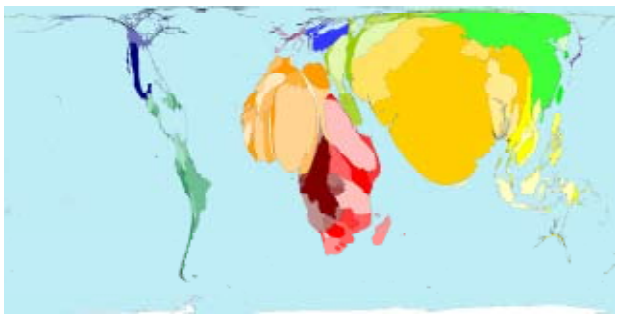
**Figure 2: The gap for clean and safe care at birth**

**Global distribution of the burden of maternal and neonatal deaths**

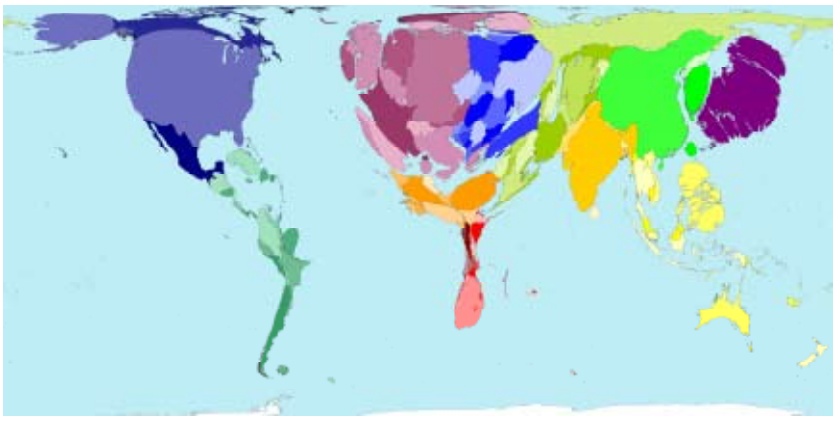
**540,000 maternal death (2005)**



**3.6 million neonatal deaths (2008)**



**BUT...**
**Global distribution of midwives**



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# SOLUTIONS TO PROMOTE CLEAN BIRTH PRACTICES

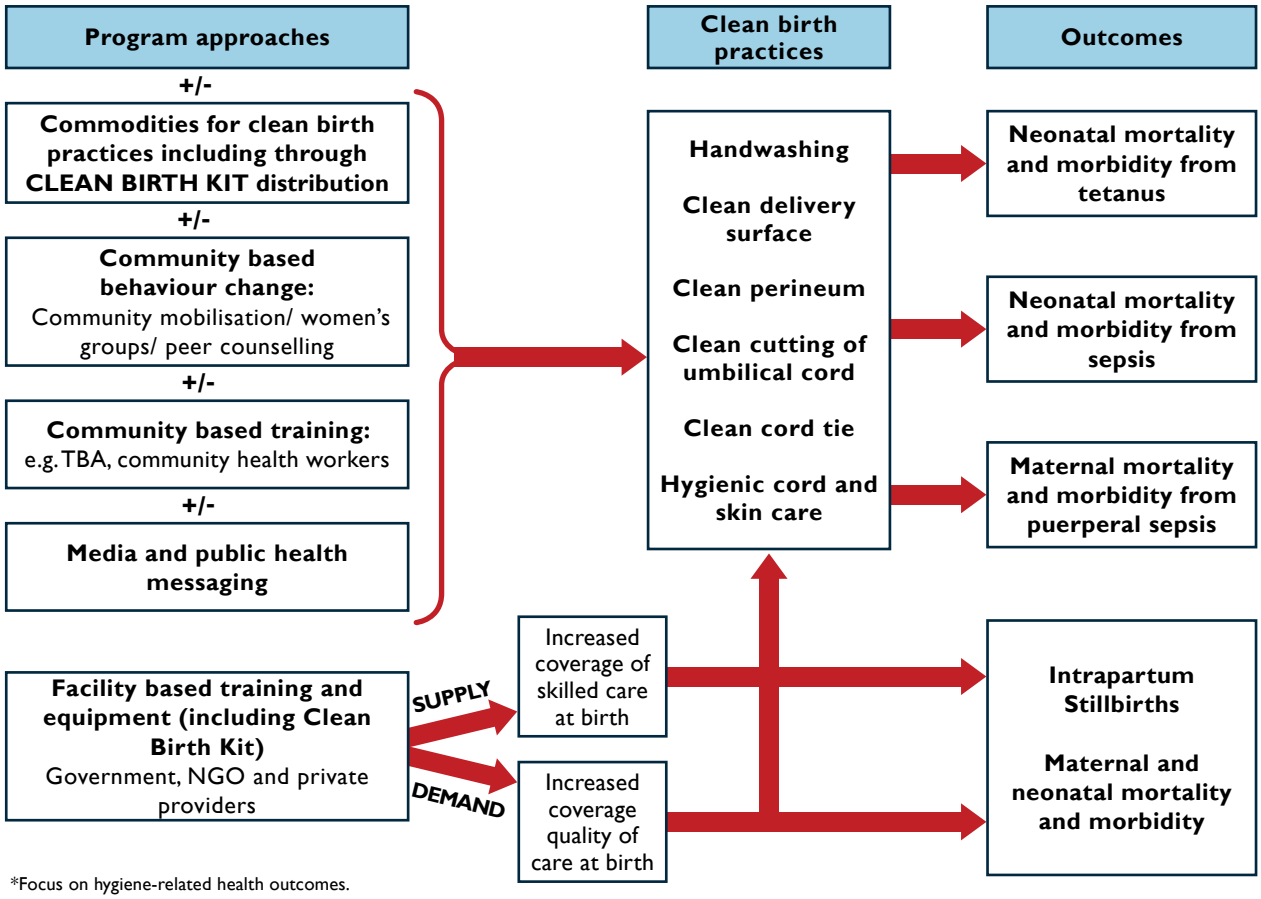
Knowledge about the importance of clean birth has been available for centuries. The practices are often summarized as the "six cleans":

1. **clean hands**
2. **clean perineum**
3. **clean delivery surface**
4. **clean cord cutting**
5. **clean cord tying**
6. **clean cord care**

A few basic commodities are required in order to achieve the "6 cleans": soap (to wash hands and perineum), a piece of plastic (to provide a clean delivery surface), a clean blade (to cut the cord) and clean thread (to tie the cord). Unfortunately, these commodities are unavailable in many settings or may be too expensive for families to purchase. In other instances these commodities are available but not used; complex behavioural change may be required to ensure birth attendants practise the "six cleans" and to ensure cultural acceptability to women and their families. Universal access to clean birth thus requires addressing implementation issues on both the supply of commodities and demand or behavior change. Figure 3 shows the potential points for action on the pathway to assuring clean birth and other elements of quality care at birth.

**Each year 60 million women give birth at home, many in situations that are not hygienic**
**Facility births may also lack essential hygiene**

**Figure 3: Reducing neonatal and maternal deaths from infections by improving clean birth practices and the potential role of program strategies including clean birth kits**




*Focus on hygiene-related health outcomes.

*Source: adapted from Blencowe et al[4]*

# SUMMARY OF THE EVIDENCE

**What is the evidence for the effect of improved hygienic practices on maternal and newborn mortality? And what are the effects of interventions which include clean birth kits on these outcomes?**

## Overview of findings

Box 1 summarizes the aims and methods of two complementary reviews.

*Review I* focused on the effect of clean birth practices on newborn outcomes and included 30 studies. There is little high or moderate quality data assessing the effect of hygienic birth practices and clean birth kits on newborn outcomes. However, going forward, it would clearly be unethical to randomize individual women or babies to receive unhygienic practices. Randomized trials have tested the effect of packaged community-based clean care interventions (some including innovative additions such as chlorhexidine wash or wipes) compared to standard clean birth care. There are challenges in separating the effect of specific practices, or components such as CBKs from other concurrent interventions such as tetanus immunization or other health promotions. In addition specific contextual factors may affect the generalizability of the findings – for example local cultural practices for cord applications may elevate risk but be very amenable to change. *Review I* findings regarding neonatal outcomes, and potential role of CBKs are summarized on the next page.

*Review II* examined the effect on maternal and neonatal outcomes (see page 8) and roles of CBKs. Kit use was identified in 51 less developed countries, however only nine studies were identified that examined the effectiveness of an intervention involving a clean birth kit; only one of these was a randomized controlled trial. In two studies, clean birth kit use as part of package of care significantly increased the likelihood of the attendant having clean hands, irrespective of whether the delivery took place at home or within a health facility.

None of the studies in either review reported any adverse effects from interventions including a CBK, however, none explicitly stated that they had looked for negative effects.

## Evidence review methods

**Box 1: Two independent and complementary systematic reviews were carried out to identify studies or reviews of:**

I. Clean birth practices (including clean birth kits) on neonatal mortality and morbidity from infectious causes as part of a larger exercise to provide mortality effect estimates for the Lives Saved Tool (LiST) [4].

II. Clean birth kits: content, uptake, effects on maternal and neonatal outcomes [5]

**Methods:**

1) Searches were carried out in multiple electronic databases to identify published and unpublished reports (*Review I:* 780 abstracts, *Review II*: 110 abstracts)
2) Titles and abstracts of identified studies were screened by two researchers for relevance.
3) Inclusion and exclusion criteria were applied and full text papers were reviewed and data extracted using a standardized structured form[6].
4) The quality of evidence was assessed using adapted GRADE (*Review I*) or SIGN criteria (*Review II*)
5) Where appropriate, meta-analysis were undertaken (*Review I*)
6) For interventions with low quality evidence but a clear biological mechanism, a Delphi process was conducted to arrive at expert consensus for effectiveness estimates (*Review I*).
7) A narrative approach was used to produce a summary of regarding kits and implementation (*Review II*)

## Effect on maternal outcomes

The effect of clean birth kits on promoting clean practices and reducing maternal mortality and sepsis was considered in *Review II* [5]. Unclean environment and practices during labour and birth are widely acknowledged as contributing to maternal puerperal sepsis. Despite this there is a paucity of high quality published research on the effect of clean birth practices on maternal mortality from sepsis, and the precise magnitude of the impact when these practices are employed is not known.

Three studies considered maternal outcomes in relation to an intervention which included CBK use and all are consistent with a substantial impact on puerperal sepsis. Two observational studies comparing adopters of CBK versus non adopters found that mothers who used a CBK had considerably lower rates of puerperal infection (OR = 0.11, 95% CI 0.01-1.06) and OR = 0.31(95% CI 0.18 to 0.54). Only one study was ranked as of high quality. This cluster RCT found a reduction in puerperal sepsis (OR = 0.17; 95% CI 0.13 to 0.23). It was the only study to examine maternal mortality as one of the primary outcomes but was not large enough to precisely estimate the relative reduction (OR = 0.74; 95% CI 0.45 to 1.23). However, the reduction in maternal mortality seen in this study could also be attributed to the education and support for TBAs, and increased referral.


Michael Bisceglie/Save The Children

***Overall, the contribution of clean birth practices to maternal mortality reduction cannot be estimated from the studies identified. However, since the GRADE recommendation for clean birth practices is strong, a Delphi expert consensus was subsequently performed in order to estimate the expected size of mortality reduction (Box 2).***

## Effect on neonatal outcomes

Fourteen studies reported on the effect of clean birth practices on neonatal tetanus, 11 on neonatal mortality and 9 on neonatal morbidity (sepsis and cord infections). Giving birth in a facility rather than at home was associated with a 70%* lower risk of death from neonatal tetanus, after controlling for major confounders including tetanus immunization coverage (Figure 4). Three studies found no difference in rates of cord infection between facility births compared to home births [4].

Hand washing by the birth attendant with soap prior to delivery was associated with a lower risk of neonatal tetanus (4 studies, 50% reduction*), neonatal mortality (1 study - 20% reduction) and omphalitis (2 studies, 30% reduction*(Figure 5)). Insufficient evidence was found regarding the effect of other clean practices on neonatal mortality or morbidity e.g. sepsis or omphalitis. Clean delivery surface, topical antimicrobial and a clean cord cutting implement were all associated with reductions in tetanus, but there was insufficient evidence to understand the effect of a clean perineum and clean cord tying [4].

Interventions which included a clean birth kit were associated with improved outcomes in neonatal mortality (3 studies, 2 of which also reported reduction in neonatal tetanus), neonatal sepsis (1 small study with ~90% reduction) and omphalitis (4 studies). All these studies included a clean birth kit as part of a package, but additional interventions and delivery mechanisms varied, as did the context, e.g. current practices, background tetanus rates. One cluster RCT of a complex TBA-delivered package found ~30% reduction in all-cause neonatal mortality, however it was not possible to quantify the relative role of the CBK in this decline.

Two other studies in populations with high baseline neonatal tetanus rates reported a 20% and an 80% reduction in neonatal mortality. No adjustments were made for potential confounders in their analyses, and the virtual elimination of neonatal tetanus in these populations due to the intervention may have been a major contributor to the large reduction in overall neonatal mortality. Four low-quality studies reported the effect of

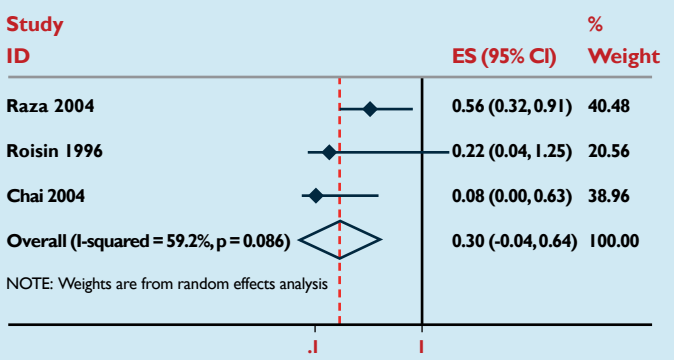
*based on pooled estimate from case-control and cohort studies adjusting for potential confounding variables in their analysis

CBKs on the incidence of omphalitis. There was marked heterogeneity in the study designs, and in definitions of omphalitis and 'kit use'. Three studies reported lower rates of omphalitis among kit users compared to non-'kit-users'(49 – 92% reduction). One study found no difference in omphalitis between 'kit users' and non- 'kit-users' who used a clean blade to cut the cord. (RR=1.04, 95%c.i. 0.64 to 1.71) [4].

*Review 1* found low grade evidence that facility delivery and birth attendant hand washing with soap were associated with a reduction in neonatal tetanus [4]. There was insufficient evidence for the individual effects of the remaining clean practices or of clean birth kits alone. Facility delivery, compared to home birth was found to be protective for neonatal tetanus. There was insufficient evidence of the effect of facility delivery on other outcomes studied.

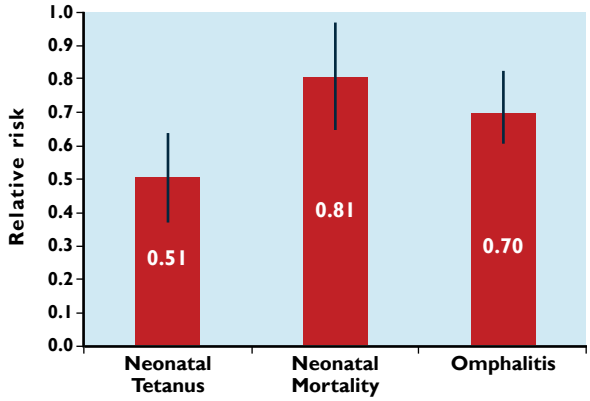
***Overall the evidence for the effect of clean birth practices on neonatal outcomes is of low quality. However using the WHO GRADE approach, the recommendation for clean practices at birth is strong as there is strong biologically plausible mechanism and this was standard practice of care before RCTs were common. Hence a Delphi process was used to estimate the likely effect of clean practices at home or in facilities on infection and tetanus related neonatal mortality (Box 2).***

**Figure 4: Meta-analysis of effect of facility delivery on neonatal tetanus**




*Source: Blencowe et al[1]*

**Figure 5: Effect of birth attendant hand washing on neonatal outcomes**




*Source: Blencowe et al[1]*

*Jonathan Hubschman/Save The Children*

# ESTIMATED LIVES SAVED AND COST

We used the Lives Saved Tool (LiST) to estimate lives saved for clean care at birth. LiST is built into a free and widely accepted demographic software package (Spectrum™) and incorporates recent mortality rates and cause of death data for 68 Countdown Priority countries. LiST includes a menu of evidence based interventions for women, newborns and children. The user can change the current coverage of these interventions and set annual coverage levels up to the year 2015 (MDG target year). The increases in coverage are linked to a cause-specific mortality effect, resulting in estimates for lives saved for mothers, newborn and children for each year and each cause for that country. The mortality effect for each intervention comes from standard systematic reviews organized and published by the Child Health Epidemiology Reference Group. LiST software, manual and more information can be downloaded at:
http://www.jhsph.edu/dept/ih/IIP/list/index.html


Jonathan Hubschman/Save The Children

### Box 2: The Delphi process for maternal and neonatal outcomes

**Methods**

A panel of 30 experts participated, representing five WHO regions (South Asia, Africa, Western Europe, North America, Latin America Caribbean). The panel was multi-disciplinary, including clinicians (obstetrics, gynaecology, newborn health) programme managers, researchers, epidemiologists and public health experts. Each panel member independently filled-in a form which included the background and aims of the Delphi process and requested effect estimates for eleven different clean birth practices. The median response and range were determined for each question. Consensus was defined *a priori* as when the inter-quartile range of responses to a given question was $\leq$ 30%.

**Results**

***Neonatal outcomes:*** When compared to unattended home birth without 'clean birth' practices, expert consensus estimated that clean birth practices at home reduces mortality from neonatal infections by a median of 15% and from tetanus by 30%. Clean birth practices at home with a skilled attendant were estimated to reduce mortality from neonatal infections by a median of 23% and from tetanus by 35%. Clean birth practices in a facility were estimated to reduce mortality from neonatal infections by a median of 27% and from tetanus by 38%.

***Maternal outcomes:*** Expert opinion estimated that clean birth practices at home would reduce maternal mortality from infections by a median of 20%. Clean birth practices with a skilled attendant were estimated to reduce mortality from sepsis by a median of 35% at home and 55% in a facility.

*Source [4]*

We used LiST to estimate the lives that could be saved for women and newborns if 90% of all home births in the 192 UN countries (restricted to low and middle income) were to apply clean birth practices. This applies to 54 million births per year. We estimate that 6,300 maternal and 102,000 neonatal lives would be saved each year (figure 6). These numbers may be an underestimate of the potential lives saved because only 90% of current home births are included. Additional lives would be saved if full hygienic care were practiced for all facility births and it may be that mother-held CBKs could be taken to facilities and improve hygienic practices there. Currently however, estimates of facility lives saved are unable to be calculated due to a lack of routine, representative data regarding clean birth practices in facilities.

We must never lose sight that the ideal target is for every birth to occur with a skilled attendant and that every birth has ready access to comprehensive emergency obstetric care. It is estimated that if these targets were realized for 90% of all births then 814,000 newborn deaths would be prevented each year. Note that this analysis does not include additional high impact interventions at birth such as antenatal steroids for preterm birth and neonatal resuscitation. If these ideal targets were achieved the impact on maternal mortality would be expected to be high as well. Cost estimates were not undertaken for this part of the analysis. Other analyses have been shown that facility based obstetric care is highly cost effective - although costs are substantial, the mortality effect is also substantial [7].

To analyse the cost of CBKs, we examined two options:

***Option 1: Imported kits*** (UNFPA CBK cost of $1.34) plus distribution cost and including media and campaigns. The incremental cost is approximately $0.73 cents per pregnancy (2 cents per capita), or about US$ 99.5 million to reach 90% of all current home births. The cost per life saved on average is $921.

***Option 2: Locally made kits*** (CBK cost of $0.45 based on a median direct cost of CBKs for 4 Asian countries range $0.32-1.00). The incremental cost is approximately $0.17 cents per pregnancy (<1 cent per capita), or about US$22 million to reach 90% of all current home births. The cost per life saved on average is $215.

In both scenarios this intervention would meet World Bank criteria for being highly cost effective given that the cost per life saved is less than 3 x GNI per capita even in the lowest income countries.

**Figure 6: Estimated lives saved with clean birth practices by 90% of current home births**

| | Total numbers of deaths (~2005) | Effectiveness of clean birth practices | Lives saved number in one year |
|---|---|---|---|
| Maternal (maternal sepsis) | 59,000 | 20% | 6,300 |
| Neonatal<br>- Sepsis<br>- Tetanus<br>- Total | <br>991,000<br>160,000<br>1,151,000 | <br>15%<br>30% | <br>76,000<br>26,000<br>102,000 |

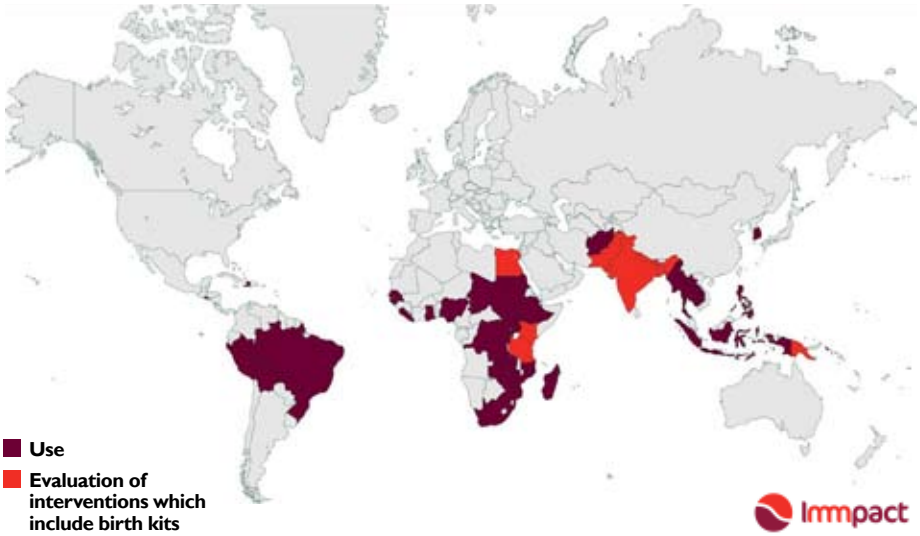
**Approx 108,300 lives saved**
**Cost per life saved of $215 to $921**

# EXPERIENCE OF IMPLEMENTATION WITH CLEAN BIRTH KITS

## What has been done already and what can we learn?

Lessons on the use of CBKs were identified for 51 less developed countries based on a structured literature search yielding 28 papers or reports.[8] Evaluations of the effects of CBKs were only available for 9 countries, and all involved co-interventions (Figure 7).

**Figure 7: Studies reporting use or evaluation of birth kits**




Reported utilisation rates in the descriptive observational studies were low, whilst those testing a specific intervention report considerably higher rates of CBK usage. Birth kits were predominantly used at home. Although in some studies women subsequently delivered in a facility, only three studies compared birth kit use in home and facility settings. In all three studies, women who delivered at home reported higher birth kit use than those who delivered in facilities[5].

National population based data on CBK use are also available from Demographic and Health Surveys (DHS) for three countries. These surveys confirm relatively low levels of birth kit use in home deliveries approximately 18% in Nepal, 23% in India and 40% in Pakistan.

## What do clean birth kits include?

The contents of the CBKs varied, although most birth kits contained the minimum requirements to facilitate clean cutting and tying of the cord (Figure 8).[9] The most common additional components were gloves, aprons, gauze swabs or sponges, a cutting surface, and cord stump treatments. A number of studies mentioned the need to compromise between what was desired by attendants and what was feasible to include, since additional components increased the cost of the CBK.

**Figure 8: Components of birth kits**

| Source | Blade | Cord tie / clamp | Soap | Antiseptic | Plastic sheet | Instructions Material |
|---|---|---|---|---|---|---|
| Jokhio et al (2005) | ✓ | ✓ | ✓ | ✓ | | |
| Meegan et al (2001) | ✓ | ✓ | | ✓ | | |
| Garner et al (1994) | ✓ | ✓ | | ✓ | | |
| Kapoor et al (1991) | ✓ | ✓ | | | | |
| Mullany et al (2007/8) | ✓ | ✓ | ✓ | 1 | ✓ | ✓ |
| Darmstadt et al (2009) | ✓ | ✓ | 2 | ✓ | ✓ | ✓ |
| Balsara et al (2009) | ✓ | ✓ | 2 | ✓ | ✓ | ✓ |
| Winani et al (2007) & PATH (2005) | ✓ | ✓ | ✓ | | ✓ | ✓ |
| Tsu (2000) | ✓ | ✓ | ✓ | | ✓ | ✓ |

[1] Although CBK did not have an antiseptic, it was part of CRCT of topical chlorhexidine
[2] 10% povidone iodine instead of soap

## How can kits be developed locally or distributed and what do they cost?


Information is available from a variety of international organisations (such as PATH, PSI, UNICEF) that fund or assist local groups in the production of clean birth kits. There are two main distribution mechanisms:

- social marketing to generate demand for pregnant women to purchase CBKs through local shops,
- supply to service providers, and clinics who then further distribute to pregnant women.

In intervention studies CBKs were usually distributed free to women through clinics or primary care workers. The descriptive studies, however, tended to report routine implementation with women or their families often purchasing the CBK. Three studies provided information regarding the place of purchase and the cost to women: pharmacies and shops were the most common source of clean birth kits [8]. There is little data on production costs of birth kits but as reported by Birthing Kit Foundation from Australia, there is evidence that local production reduces costs[10].

## Are clean birth kits an incentive or disincentive for facility birth?

CBK provision to each pregnant woman may address the shortfall in basic hygienic commodities for care at birth at frontline facilities. On the other hand, it has been proposed that distributing CBKs to women during pregnancy could encourage mothers to give birth at home rather than travel to a health facility [11]. There is some evidence to suggest that provision of birth kits directly to facilities may increase the number of women who choose to deliver there [12]. However more systematic analysis and additional data are required to fully answer these questions regarding disincentive and incentive for facility birth.

### Box 3: National scale-up of clean birth kits – an example from Nepal

**Development -** In Nepal in the mid 1990s less than 10% of births were with a skilled attendant. Qualitative research was conducted using focus group discussions with traditional birth attendants and women who had given birth to at least one child, supplemented by in-depth interviews with consumers and small shop owners. Information was obtained regarding childbirth practices and beliefs as well as possible kit contents, packaging and the instructional insert. The results enabled the development of a birth kit which met local needs. This development phase was locally led with technical assistance from PATH and Save the Children and funding from USAID, UNICEF, and UNFPA (1993 to 1994).

**Scale-up -** A strong market demand for the nationwide expansion of the birth kit was identified. A Nepalese company (MCH Products Pvt., Ltd) manufactured and sold CBKs in Nepal staring in 1994. The CBK was targeted for individual women and TBAs, and promoted through radio and newspaper advertisements.

**Evaluation -** A 3 district evaluation in 2000 found that among the attendants using CBKs, the kit was perceived as hygienic, convenient, and culturally acceptable[13]. However population level awareness and use of the kit were low, and the influence was limited on hygienic birth practices. A recommendation was made to retarget promotional efforts to individuals who hold decision making power regarding buying and using the kit.

DHS survey data support increasing kit use amongst women who deliver at home from 2% in 1996 to nearly 18% in 2006. However an equity gap still exists, with the poorest and those with no formal education least likely to use a kit.

# EVIDENCE GAPS

Clean birth kits have a role in promoting clean birth practices and may have the potential to act as a catalyst to improve quality of care at birth. However, a significant number of research questions remain.

One critical issue to understand is whether mother-held CBKs act as an incentive for facility birth? Or is there evidence of a disincentive effect? Further information will be gained through an upcoming programme survey, analysis of existing research datasets and selected country case-studies. Further questions regarding how to best distribute and implement programs involving CBKs, including in emergency contexts, will be critical to address.

Another important research priority is regarding the effect, cost and health system implications of kit add-ons such as chlorhexidine or misoprostol (Box 4). A systematic review is underway to inform recommendations. Some countries such as Nepal already plan to expand kit content with both these agents and some agencies are rolling out Mother-baby HIV kits. Implementation research will be essential before wide scale up of mother held kits with these additional materials.

Facility-based kits could be much more extensive, and implementation research is required to examine if a kit-based approach has advantages in efficiency over alternative approaches to strengthening the supply of commodities. Possible content may include clinical check lists and partograph, equipment such as blood pressure device, resuscitation bag-and-mask, suction device/mucus extractor and essential drugs such as oxytocin injection, magnesium sulphate, antibiotics, antenatal steroids, and vitamin K.

**Box 4: Research regarding potential innovative additions to mother-held disposable birth kits**

**Chlorhexidine –** Evidence from one cluster RCT of chlorhexidine applications to the cord shows neonatal mortality reduction and the results of a further two trials will be reported soon. This may be a useful adjunct to clean cord care, especially in regions where harmful cord applications are common.

**Misoprostol –** Used successfully to manage postpartum haemorrhage in rural India and now recommended as a safe and inexpensive medication for low resource settings. A recent randomized trial, confirmed the suitability of misoprostol in settings where oxytocin is not feasible. While community-based use of misoprostol has been shown to be safe and feasible in some countries, some concerns remain about widespread distribution of the drug, in particular to women in early pregnancy.

**Vitamin A for newborns –** Evidence from Asia supports early administration of vitamin A to newborns may reduce neonatal and infant mortality. Further research is underway in Africa. If the benefit is confirmed, a birth kit may provide a means to facilitate timely administration soon after birth.

**Other possibilities for birth kit inclusion:**

- Gloves
- Educational materials re clean birth practices, danger signs, promotion of healthy practices after birth
- Transport vouchers
- Intermittent presumptive malarial treatment for mother, bednets or bednet vouchers
- HIV antiretrovirals and PMTCT interventions
- Maternal iron supplementation
- Contraception
- Sanitary towels
- Towel to dry the newborn
- Knitted cap for the newborn
- Wrap for positioning a preterm baby for kangaroo mother care
- Emollients for preterm babies
- Single dose tetracycline dispenser (prophylaxis against ophthalmia neonatorum)

# ACTIONS NOW

There has been significant progress in reducing under 5 deaths as well as increasing the provision of essential child survival commodities, such as immunization and ITNs. However, in order to further accelerate progress towards achieving MDGs 4 and 5 a major focus must be placed on increasing coverage and quality of care before, during and immediately after birth. This requires massive investment in frontline workers, connected with communities, supported by District Health Teams, and equipped with essential commodities for basic and comprehensive safe birth services and for family planning. Improving the availability of commodities at health facilities, either as kits or by sterngthening supply logistics, requires implementation and economic evaluation.

There are still 60 million home births each year. There is evidence to support the importance of clean birth practices - such practices can and must be promoted. Clean birth kits (CBKs) have already been made available to mothers in over fifty less developed countries, however robust evaluations are lacking regarding the contribution of these kits. We consider that mother-held CBKs are appropriate in conflict or humanitarian emergencies, or in settings where there is currently low coverage of facility birth, as long as CBKs do not act as a disincentive for facility birth. Before making recommendations for wide scale up of mother-held disposable CBKs or to expand kit contents, more data are urgently needed on this specific question of whether mother-held disposable CBKs disincentivise (or incentivise) women to come to facilities for care. For those countries that are already expanding mother-held kits to include additional commodities (e.g. chlorhexidine, misoprostol) it is imperative to collect data on implementation, effects and direct and indirect costs.

Michael Bisceglie/Save The Children

## Credits

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## References (limited list - for more information and details of the workshop see http://www.immpact-international.com/birth-kits)

1. Ronsmans, C. and W.J. Graham, *Maternal mortality: who, when, where, and why.* Lancet, 2006. **368**(9542): p. 1189-200.
2. Zaidi, A., ed. *CHERG Neonatal Sepsis Global Burden of Disease* 2009: Lee AC ed. London, UK.
3. Darmstadt, G.L., et al., *60 Million non-facility births: who can deliver in community settings to reduce intrapartum-related deaths?* Int J Gynaecol Obstet, 2009. **107 Suppl 1**: p. S89-112.
4. H Blencowe, S Cousens, and L.M. Anne CC Lee, Kate Kerber, Steve Wall, Gary Darmstadt, Joy E Lawn, *Hygienic birth and newborn care practices to reduce neonatal deaths from sepsis and tetanus.* A review for LiST effectiveness supplement. In press 2010.
5. Hundley, V., et al., *Are disposable birth kits a good idea? A systematic review of the evidence.* Paper in submission. 2010.
6. Walker N, F.-W.C., Bryce J, Bahl R, Cousens S, writing for the CHERG Review Groups on Intervention Effects., *Standards for CHERG Reviews of Intervention Effects on Child Survival.* International Journal of Epidemiology, 2010. **39 (suppl 1)**: p.i21 - 31.
7. Adam, T., et al., *Cost effectiveness analysis of strategies for maternal and neonatal health in developing countries.* BMJ, 2005. **331**(7525): p. 1107.
8. Hundley V, Avan B, Braunholtz D, Fitzmaurice A, Graham W. *Lessons regarding the use of Birth Kits in Developing Countries.* Paper in submission, 2010.
9. Hundley, V., et al., *Inventory of disposable kits for use during pregnancy and childbirth.* Immpact, University of Aberdeen March 2010.
10. *Birthing Kit Project Completion Report 2008-2009.* Birthing Kit Foundation (Australia) 2009; Available from: www.birthingkitfoundation.org.au
11. Alto, W.A., R.E. Albu, and G. Irabo, *An alternative to unattended delivery--a training programme for village midwives in Papua New Guinea.* Soc Sci Med, 1991. **32**(5): p. 613-8.
12. Republic of Uganda, Ministry of Health (UMOH) and World Health Organisation (WHO) (n.d.) *Maama kit: making childbirth clean and safer.* Geneva: WHO publication
13. Tsu, V., *Nepal Clean Home Delivery Kit - Evaluation of the health impact.* Program for Appropriate Technology in Health (PATH), 2000.
14. Lawn JE, Lee AC, Kinney M, Sibley L, Carlo WA, Paul VK, *et al.* Two million intrapartum-related stillbirths and neonatal deaths: Where, why, and what can be done? *Int J Gynecol Obstet* 2009;107:S5–19 [www.ijgo.org/issues/contents?issue_key=S0020-7292%2809%29X0010-X].
15. Khan KS, Wojdyla D, Say L, Gulmezoglu AM, Van Look PF. WHO analysis of causes of maternal death: a systematic review. *Lancet* 2006; 367(9516).
16. Lawn JE, Wilczynska-Ketende K, Cousens SN. Estimating the causes of 4 million neonatal deaths in the year 2000. *Int J Epidemiol* 2006; 35(3).

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Maternal Health Task Force

Norad

Massachusetts General Hospital
Division of Global Health & Human Rights