

Effectiveness of birthing kits for clean childbirth: a systematic review

Zohra S. Lassi^{a,*}, Zeshi Fisher^b, Prabha Andraweera^a, Alexandra Cummins^b and Claire T. Roberts^a

^aRobinson Research Institute, The University of Adelaide, North Terrace, Adelaide, South Australia 5005, Australia; ^bBirthing Kit Foundation Australia, PO Box 330 Belair South Australia 5052, Australia

*Corresponding author: +61 8313 9266; E-mail: zohra.lassi@adelaide.edu.au

Received 20 December 2018; revised 5 March 2019; editorial decision 15 March 2019; accepted 20 March 2019

Poor infection control practices during childbirth are recognised as a critical factor leading to life-threatening maternal and newborn sepsis. Therefore, this paper assesses the effectiveness of clean birth kits (CBKs) to ensure a safe birthing environment. We searched PubMed, Cochrane Library and CINAHL, as well as Google Scholar, to identify both qualitative and quantitative studies on CBKs published in English up to November 2018. Studies were included if the pregnant women or women giving birth intended to use or used a CBK. The methodological quality of included papers was assessed. A total of 37 studies, 26 quantitative and 11 qualitative studies, were included. Quantitative studies showed a positive impact of CBKs on reducing the incidence of puerperal sepsis and neonatal tetanus. The review also identified CBK use to be associated with a reduction in perinatal, neonatal and young infant mortality. Qualitative studies suggested that a lack of awareness of the importance of CBKs and clean delivery practices, unavailability of CBKs and financial constraints to purchase CBKs were the potential barriers. CBKs appear to be a promising strategy to reduce maternal and neonatal morbidity and mortality. However, the current evidence is limited and further large-scale trials are required.

Keywords: birth kits, childbirth, clean birth kits, infection

Background

An estimated 303 000 women die during pregnancy, childbirth or within 42 d of termination of pregnancy or of giving birth each year and approximately 2.62 million babies die within 28 d of being born.^{1,2} Almost all of these deaths take place in low- and middle-income countries (LMICs) and most are preventable. In 2015, the United Nations General Assembly developed the Sustainable Development Goals (SDGs) to supersede the Millennium Development Goals.^{3,4} The SDGs are a set of universal goals that have been implemented to achieve economic growth, environmental protection and social progress. Outlined in 'Transforming our world: the 2030 Agenda for Sustainable Development', goal 3 was established to 'ensure healthy lives and promote well-being for all at all ages', and specifically includes targets for the improvement of maternal and newborn health, such as national targets of no more than 140 maternal deaths per 100 000 live births and no more than 12 newborn deaths per 1000 live births.⁵ To achieve these targets in low-resource countries that have disproportionately and persistently high maternal mortality ratio and neonatal mortality rates, there is a critical need for appropriate low-cost, effective,

evidence-based interventions at and around the time of childbirth.

Infection is a leading cause of maternal and newborn morbidity and mortality,^{6–10} responsible for an estimated 10.7% of all maternal¹¹ and 44% of all newborn¹² deaths globally each year. In LMICs more than half of all deliveries take place at home, and on average 50% of mothers give birth without skilled birth attendants (SBAs).¹³ In these countries, neonatal infections are 3–20 times higher than those of facility-born neonates in high-income countries.⁷ Poor hygiene during the intrapartum period is recognised as a critical factor leading to life-threatening maternal and newborn sepsis. The risk of infection remains high in facility-based settings, as well as in the community due to poor intrapartum and postpartum infection control practices.⁷

In 1996, WHO released primary recommendations for a safe delivery; these outlined the essential principles of cleanliness, also known as the 'six cleans': clean hands of the birth attendant, clean perineum of the mother, nothing unclean to be introduced into the vagina, clean delivery surface, cleanliness in cutting the umbilical cord and cleanliness for cord care of the newborn baby.^{14–18} One approach endorsed by WHO and the

United Nations to facilitate clean delivery practices in low-resource settings has been the provision of a clean birth kit (CBK).¹⁹ CBKs may also be referred to as birthing kits, birth kits, clean delivery kits, disposable delivery kits or mama kits. To facilitate the six principles of cleanliness, WHO recommends that CBKs contain at a minimum: soap, plastic sheet, razor blade, cord ties, spirit (alcohol swabs) and gauze.^{20,21} Three previous reviews have been undertaken on this topic, which have demonstrated gaps in knowledge regarding the effectiveness of CBKs.^{19,22} This systematic review aims to build on previous work in assessing the effectiveness of CBKs for women in LMICs, and to uncover any progress in narrowing the identified research gaps. In order to do so, we have reviewed all studies on CBKs to identify their effectiveness in improving maternal and newborn health, mapped out the key barriers and facilitators of birthing kits, and identified the sustained gaps to inform recommendations for future research.

Methodology

The review protocol was registered at PROSPERO (CRD42016054088: http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42016054088). The following electronic databases were searched: PubMed, CINAHL, the Cochrane Library and Google Scholar, with an end of search date of 8 November 2018. The search strategy included terms such as 'birth kit*', 'delivery kit*', 'clean delivery kit*', 'mama kit*' and 'maama kit*'; the search was limited to English and human subjects. We also conducted a backward reference search to identify additional relevant articles.

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were followed in conducting this systematic review.²² Studies in which pregnant women or women giving birth using a CBK were eligible for inclusion, regardless of women's obstetric or medical characteristics, level of risk, education or socioeconomic status. We also included studies where qualitative information on birth kits were collected from professional and non-professional health workers. We defined a CBK as a disposable or non-disposable pack/kit that is made up of items used in the intrapartum period for actual birth of the baby. Kits that included pharmaceutical items such as misoprostol and chlorhexidine and only reported the impact of those additional items were excluded. Studies that only reported on the intervention strategy and not the effectiveness of the kit or only focused on handwashing were also excluded. There was no restriction on study design and we considered all experimental, observational and qualitative studies on CBKs. The included quantitative studies were compared for maternal and newborn morbidity (particularly infections), mortality and process-related outcomes such as clean cord care and cord cut. The included qualitative studies were reviewed to identify the facilitators and barriers related to usage of birth kits.

In pairs, four authors (ZSL and PA; ZF and AC) independently screened all of the search results, initially for consideration of inclusion as per eligibility criteria based on titles and abstracts. After the initial screening, full texts were obtained and independently assessed for inclusion and extraction by the authors

(ZSL and PA; ZF and AC). The discrepancies were resolved through discussions and, if required, a third review author was consulted. A final cross-check of all extracted data against each publication was also conducted (ZSL).

The following data were extracted from each study: study design, geographical setting, aim of the study, information on birth kit, educational component, results and the methodological quality. The methodological quality was assessed for experimental studies using Cochrane Risk of Bias assessment criteria,²³ for observational studies using Strengthening the Reporting of Observational studies in Epidemiology (STROBE)²⁴ and for qualitative studies using the Joanna Briggs Institute Checklist for Qualitative Research.²⁵ At least two authors (ZSL, PA, ZF and/or AC) independently assessed the quality of each study included in the review. The discrepancies were resolved through discussions and, if required, a third review author was consulted. We could not pool experimental studies because of content heterogeneity; however, each study has been synthesised and summarised in detail.

Results

A total of 37 studies from 15 countries were included in this review (Figure 1). We identified 26 comparative studies consisting of 17 observational, 4 intervention and 5 evaluation studies. Of these, 6 were from Nepal,²⁶⁻³¹ 4 from Pakistan^{21,32-34} and 3 each from Tanzania^{15,35,36} and Uganda;³⁷⁻³⁹ there were 2 each from Egypt,^{16,40} Ethiopia^{41,42} and Papua New Guinea (PNG)^{43,44} and the remaining 5 were from Bangladesh,⁴⁵ India,⁴⁶ Kenya,³⁵ Senegal⁴⁷ and Tibet.⁴⁸ Of the 11 qualitative studies, 4 were from Nepal,⁴⁹⁻⁵² with the 7 others from Ethiopia,⁵³ Ghana,⁵⁴ Madagascar,⁵⁵ Nicaragua,⁵⁶ Pakistan,⁵⁷ PNG⁵⁸ and Uganda.⁵⁹ The methodological quality of included studies were low to moderate on their respective scales (Table S1).

Studies assessed the impact of CBKs in terms of maternal and newborn morbidity and mortality, as well as the broader educational, social and behavioural influence of CBK use. The identified barriers and facilitators of CBKs related to the decision to seek or obtain a CBK (grouped as shown in Figure 2), the procurement and use of a CBK at birth, and the correct utilisation of CBK components. The evaluation of CBKs was rarely found in isolation from intervention packages involving education programmes or service delivery. Components of the kits varied in each study, which may impact upon the comparability of the studies.

Effectiveness of CBK on improving maternal and newborn infections and reducing maternal and neonatal mortality

The literature on CBKs in LMICs revealed reduced rates of puerperal sepsis and cord infection, particularly when used in conjunction with other measures such as the training of traditional birth attendants (TBAs). Jokhio et al.'s 2005 cluster randomised controlled trial (RCT) from Pakistan reported a reduction in puerperal sepsis (OR 0.18, 95% CI 0.14 to 0.22) with the introduction of community-based intervention packages including provision of CBKs, while a 2009 cross-sectional study from Egypt reported

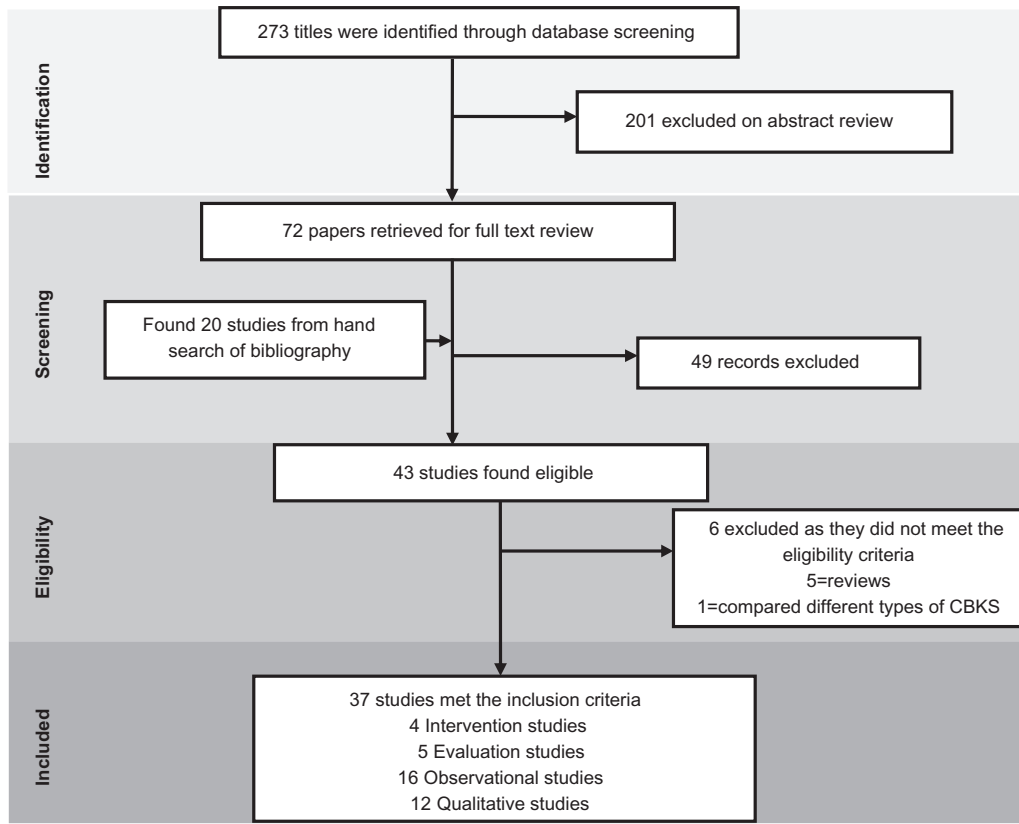


Figure 1. Search flow diagram.

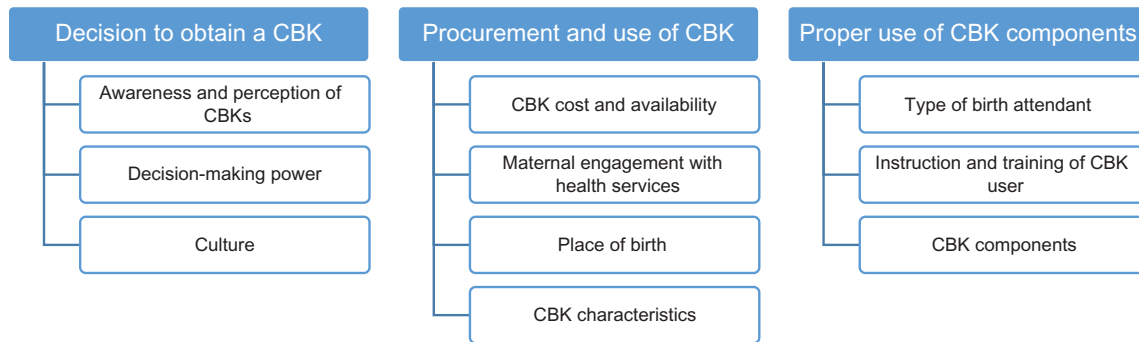


Figure 2. Factors associated with CBK use.

that mothers of neonates who used a CBK were less likely to develop a cord infection (OR 0.42, 95% CI 0.18 to 0.97), and mothers who used a CBK were less likely to develop puerperal sepsis (OR 0.11, 95% CI 0.01 to 1.06).^{32,40} A cross-sectional study from Tanzania reported that newborns whose mothers did not use a CBK were 13.1 times more likely to develop cord infection than infants whose mothers used the kit (OR 13.1, 95% CI 5.16 to 33.53), and the women who used the CBK were 3.2 times less likely to develop puerperal sepsis than women who did not use the kit (OR 3.2, 95% CI 1.85 to 5.63).¹⁵ A 2012 case control study from Ethiopia found that women who were given a CBK (consisting of a plastic mat, razor blade, tie cord

and soap) had fewer symptoms of puerperal sepsis ($p=0.00$) and cord infection among their newborns ($p<0.001$).⁴² A Kenyan study reported a 25% reduction in neonatal tetanus rates (RR 0.75, range 0–3/1000 births).³⁵ Jokhio et al.'s study, which provided a community-based intervention package including providing TBAs with CBKs, reported 87.2% usage of CBKs at the end of the trial, with a 30% reduction in perinatal deaths (OR 0.70, 95% CI 0.59 to 0.82) and a 26% reduction in maternal mortality (OR 0.74, 95% CI 0.45 to 1.23).³² Similarly, studies from Kenya³⁵ and Tanzania¹⁵ that trained TBAs and provided CBKs (including sterile blade, sterile umbilical clamp, sterile thread and surgical spirit) reported reductions in total mortality rates in infants less

than 6 weeks (from 307 to 50/1000 live births in intervention areas compared with 233 to 294/1000 live births in the control areas). A study from India that trained TBAs to register women for antenatal care, distribute iron and folic acid tablets, immunise women with tetanus toxoid injections, provide health education and distribute sterilised CBKs [containing gauze pieces, razor blade (half) and thread] reported a significant reduction in neonatal mortality from 42.3/1000 live births to 17.9/1000 live births in 15 years.⁴⁶

Decision to obtain a CBK

Women's attitudes towards the use of CBKs may influence CBK usage in LMICs, and levels of awareness about the existence and/or benefits of using a CBK have been identified as a key factor influencing the decision to obtain a CBK.^{50,52,59} A qualitative study from Nepal on the acceptability and use of CBKs for births at home found that limited awareness was a common characteristic of mothers who had not used a CBK.⁵⁰ Perceptions of these mothers included a perceived lack of importance, lack of understanding of potential benefits and/or a lack of availability of CBKs, which led to a reduced prioritisation of CBK purchase prior to birth.⁵⁰ Another study from Nepal, exploring the utilisation of CBKs, found that while birth preparation in general was common, readiness for some mothers including the purchase of CBKs was prevented not only by a lack of knowledge but also 'poverty, carelessness, and disempowerment'.⁵² In this study, CBK promotion was seen as inadequate and in some cases a cause for confusion due to misalignment with national priorities for facility births.⁵² Among women who had chosen to use a CBK, a study from Uganda reported that women were mobilised to use CBKs to protect themselves from possible HIV infections,³⁸ and a study from Nepal reported that women used CBKs for ease, safety and for health reasons.²⁷

The importance of decision-making agency in obtaining a CBK prior to birth was highlighted in studies from Nepal^{50,52} and Ghana.⁵⁴ In Nepal, the general disempowerment of women and status of women in the home were recognised as barriers to CBK acquisition⁵² and the decision to use a CBK was predominantly that of the husband or mother-in-law, not the attendant or mother herself.⁵⁰ Similarly, in a study exploring the utilisation of clean birth practices in rural northern Ghana, it was shown that mothers were often dependent on others for decisions about the care they received.⁵⁴

Both studies from Nepal identified that cultural beliefs may influence the decision to obtain a CBK in a timely manner prior to labour.^{50,52} Women's preparations for birth were found to be prioritised in relation to 'traditional perceptions of the causes of illness and death'.⁵⁰

Procurement and use of a CBK at birth

Several factors impacting upon the procurement and use of CBKs were identified within the literature, primarily cost and availability. A study in rural Nepal, which found that the lack of local availability, travel distance to the marketplace and cost were significant for families and care providers who were expected to purchase CBKs, also reported an increase in facility

births and an associated decrease in demand for CBKs. Subsequently, CBKs were being sold on.⁵² Similarly, a 2017 Ugandan study that explored the provision of in-kind goods as an incentive for facility births found the sale of kits to be prevalent and the cost to be perceived as high.⁵⁹ A study from Senegal made birth kits free to women, but problems with supplies and costs relating to other factors meant that most women experienced a charge of some kind.⁴⁷ In Uganda, the government distributed birthing kits for free to women through community distribution days, antenatal clinics and facilities.³⁸

Maternal engagement with health services was found to be instrumental in determining access to and use of CBKs. In Uganda, the promise of kits in conjunction with insufficient stock negatively affected access to CBKs for mothers who arrived otherwise unprepared.⁵⁹ In PNG, a study to assess the feasibility and acceptability of providing an enhanced kit determined that the free provision of CBKs through antenatal clinics was important to increase the availability of supplies to mothers regardless of their intended or actual place of birth.⁵⁸ An intervention study in Egypt exploring the impact of CBKs on clean birth practices also made a strong correlation between antenatal visits (more than one) and increased CBK use at birth.¹⁶

Ease of use and guidance given within the pack were found to be important attributes contributing to the use of CBKs in Ethiopia⁵³ and the contained, portable nature of CBKs with all of the items in one place was also significant for respondents in two studies from Nepal.^{50,52}

Proper utilisation of CBK components

CBKs may contribute to improved maternal and newborn infection rates and reduce mortality when used properly; yet in some instances, kits have been misused or not used as intended. Both studies from Nepal^{50,52} found that among all users, soap in the kit was used foremost for bathing the newborn and not for cleanliness during birth. A high level of re-use of birthing kit items was also reported.⁵⁰ Evidently, users of CBKs may need a level of training to ensure their effective use, as informed by participants in a 2012 review of a CBK national-level decision tool from Pakistan.⁵⁷ In Madagascar, training for TBAs was shown to improve both TBAs' and mothers' understanding of the importance of clean birth practices.⁵⁵ Similarly, in PNG, mothers received one-to-one education and were required to demonstrate the correct use of each item in the kit prior to receiving a CBK. This 2016 study found that in nearly all of the 99 unsupervised births, all of the items (piece of soap, a pair of non-sterile gloves, a plastic sheet, a scalpel blade and two cord ties) were reported as having been used as instructed.⁵⁸ In Ghana, births attended in a facility or by skilled personnel were more likely to adhere to recommendations for clean births than births at home attended by traditional or untrained attendants.⁵⁴

Usage of CBKs

CBK usage varied among the included studies, ranging from 17.1 to 96.9%. A cross-sectional study from Pakistan reported that 32% of women, 40% of female health workers and 8% of

TBAs used CBKs.³³ Another cross-sectional study from Tibet⁴⁸ reported 96.9% usage of CBKs for childbirth. A study from Egypt reported that among CBK users, 96.7% used the kit's blade to cut the cord, 70% used the kit's cord clamp and 50% used the kit's gauze to cover the umbilical stump. A majority (89.1%) of kit users indicated their intention to use it again in future.¹⁶ A case-control study from Pakistan reported 17.1% usage of CBKs during births and, after adjusting for socioeconomic factors, both CBK use (OR 2.0, 95% CI 1.3 to 3.1) and SBAs (OR 1.7, 95% CI 1.1 to 2.7) were independently associated with neonatal tetanus.²¹

A study from Nepal assessed the knowledge, attitude and practices of TBAs regarding maternal and newborn care.²⁶ The study identified that practices such as using a clean cord-cutting instrument (89%) and handwashing with soap before childbirth (74%) were common.²⁶ One study from Uganda reported that interventions such as training health workers, provision of medical supplies, community mobilisation using village health teams, music, dance and drama groups and male partner access clubs have shown significant improvements in the rates of institutional births and utilisation of CBKs from 55.2 to 99.3% in 6 months.³⁹ A study from Bangladesh reported that 80% of women in the study delivered at home, 6% used blades from a CBK and 90% used blades from another source, 4% used other instruments such as bamboo strips and scissors and 51% applied a substance (e.g. antibiotic powder/ointment, alcohol/spirit, mustard oil with garlic, boric powder, turmeric and chewed rice) to the stump after the cord was cut.⁴⁵ Women who had received no education or only primary education were less likely to use a blade from a CBK compared with women who had a higher level of education (OR 0.33, 95% CI 0.16 to 0.90 and OR 0.47, 95% CI 1.00 to 3.08, respectively). Women in the poorest categories were less likely to use a blade from the CBK compared with women in richer categories (OR 0.5, 95% CI 0.29 to 0.87). Women who delivered in healthcare facilities or elsewhere were more likely to use CBK blades than women who delivered at home (OR 8.06, 95% CI 2.17 to 29.80).⁴⁵

Studies from Tanzania reported that out of 58% of CBKs provided for home births and 38% in the facilities, 59% were used by a healthcare provider.^{15,36} A study from Nepal reported 99% usage of CBKs in 92% of total supplies for home births.³⁰ Similar findings were reported in a study from PNG, where 97% usage was reported.⁴³ However, another study from PNG found 19% usage among total distribution.⁴³ The usage of CBK is detailed in Table 1.

Impact of CBKs

The literature suggests that CBKs have a positive impact on community and health service engagement, gender equality and behaviour change. In Ethiopia, a programme that provided CBKs was able to promote health service linkages for mothers who may otherwise not have been seen by or connected to healthcare providers, and to facilitate the connection of rural health workers with coordinators and SBAs to learn and report on events and practices in the communities through the replenishment of CBK supplies.⁵³ The Ugandan intervention using CBKs to attract mothers to health facilities noted a sustained increase

in facility births beyond the presence of kits, which was attributed by the authors to the potentially positive exposure of women to other health services such as health education.³⁹ Provision of CBKs in Ethiopia—as an item specifically for mothers—has been found to address gender inequality in a health system that is generally more accessible by men.⁵³

The perception of quality of childbirth care received was heightened in mothers who had used a CBK in Uganda.⁵⁹ In a study exploring mothers' expectations and experiences of maternity care in Nepal,⁵¹ of the 29% of respondents who were satisfied with birth care, 75% attributed their satisfaction to safer delivery services. In Egypt, a study of the impact of CBK use on clean birth practices revealed that 89.1% (n=230) of mothers who used a CBK intended to utilise one again for subsequent deliveries.¹⁶ Similarly, in a study in PNG, 96.5% (n=200) of mothers who used a CBK stated that they would use a CBK for subsequent deliveries and that they would recommend CBKs to others.⁵⁸ In Ethiopia, it was noted that the demand for 'clean sheet' delivery at health centres had grown with the increasing presence of CBKs.⁵³ It was also found that the provision of CBKs to trained TBAs in Ethiopia acted as an encouragement to 'build a culture of safe motherhood'.⁵³

Discussion

This review found 37 studies (26 quantitative and 11 qualitative) from 15 countries and the major findings identified are summarised in Figure 3. Quantitative studies showed the positive impact of CBKs on reducing the incidence of puerperal sepsis and neonatal tetanus infections. The review also identified CBK use to be associated with a reduction in perinatal, neonatal and young infant mortality. However, the results need to be interpreted with caution as most of the evidence comes from single studies and cannot be pooled because of heterogeneity among the studies. Findings from the qualitative studies suggested that a lack of awareness about the importance of CBKs and clean birth practices, unavailability of CBKs and financial constraints to purchase CBKs were the potential barriers. Importantly, it was highlighted that the decision to use a CBK lay predominantly with other family members and not the mother herself.

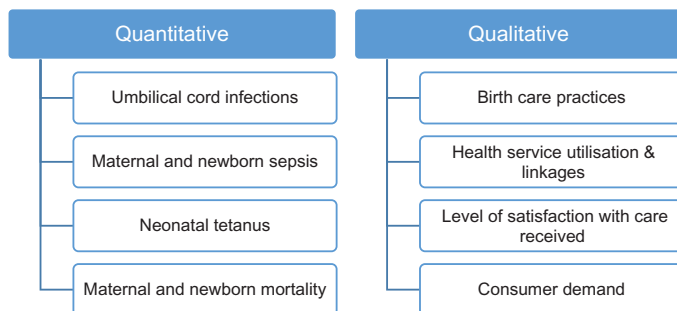
Comparability of study methodology and outcome assessment are of prime importance in compiling evidence. All the included studies were conducted predominantly in sub-Saharan Africa and south East Asia. As discussed earlier, these countries bear the major burden of maternal and newborn morbidity and mortality with little access to healthcare facilities and SBAs. Provision and usage of CBKs in such countries can bring major improvements in maternal and newborn health outcomes. Considering these findings, the results of this review can be applied to other LMICs.

It should be noted that not all of the studies reported the CBK components. Among the included studies, the evaluation of CBKs was rarely made in isolation from intervention packages involving education programmes or service delivery and the components of the kits varied in each study. A study in India⁴⁶ assessed the impact of the provision of CBKs used in conjunction with training TBAs to register women for antenatal care, distribute iron and folic acid tablets, immunise women with

Table 1. Utilisation rates of CBKs from studies

Study	Country	Usage of CBK
Jhokio et al 2005 ³²	Pakistan	87.2% of the births (n=19 557)
Darmstadt et al 2009 ⁴⁰	Egypt	72% usage (n=334)
Balsara et al 2009 ¹⁶	Egypt	74% usage (n=334)
Hassan et al 2012 ³³	Pakistan	32% by women (n=72), 40% by CHWs (n=19) and 8% by TBAs (n=2)
Raza & Avan 2013 ²¹	Pakistan	17.1% of the births (n=420)
Dickerson et al 2010 ⁴⁸	Tibet	96.9% of the births (n=378)
Winani et al 2007 ¹⁵	Tanzania	59% of the births (n=3262)
Winani et al 2005 ³⁶	Tanzania	59% of the births (n=3262)
Mullany et al 2007 ³⁰	Nepal	99% usage (n=17 198)
Garner et al 1994 ⁴³	Papua New Guinea	97% usage (n=131)
Falle et al 2009 ²⁶	Nepal	47% usage (n=93)
Sreeramareddy et al 2006 ²⁹	Nepal	19.2% usage (n=240)
Beun & Wood 2003 ⁵⁰	Nepal	10% usage
PATH 2002 ⁴⁹	Nepal	10% usage
Osrin et al 2002 ²⁸	Nepal	8% usage (n=5411)
Edia et al 2013 ³⁹	Uganda	99.3% of the births
Valley 2016 ⁵⁸	Papua New Guinea	59% of the births (n=115)

CHWs=community health workers; TBAs=traditional birth attendants

**Figure 3.** Impact of CBKs from quantitative and qualitative studies.

tetanus toxoid injections and provide health education as well as distribute sterilised CBKs.⁴⁶ These intervention packages resulted in a significant reduction in neonatal mortality over 15 years but do not explicitly measure the separate effect of the CBK. Nonetheless, the benefit of using a CBK can not be refuted based on such a study and instead it can be argued that a CBK is a powerful tool best utilised with community-based interventions. This notion was similarly supported by other studies.^{32,53} A study from Pakistan reported a reduction in puerperal sepsis with the introduction of community-based intervention packages that included the provision of CBKs.³² Programmes in Ethiopia⁵³ and Uganda³⁹ found that CBKs strengthened health-care linkages for marginalised others as well as impacting their perception of the quality of care they received.⁵⁹ Although the lack of studies evaluating the isolated impact of CBKs in LMICs is minimal, and thus is a limitation to the overall completeness and applicability of the evidence, there is sufficient evidence to

suggest that CBKs have multifaceted benefits when used in conjunction with other community-based interventions. Studies also reported misusing items for other purposes that indicate women and healthcare workers need frequent refresher and reinforcement of proper use.⁵⁰

Notwithstanding these limitations, this review has some strengths. First, the review clearly specified inclusion and exclusion criteria and used a systematic and comprehensive search strategy for the identification of relevant studies. Second, screening, selection and extraction were independently undertaken by two review authors and, in the case of any discrepancy, a consensus was reached by discussion with a third review author. Third, the protocol was published with a priori methodology. However, most of the quantitative and qualitative studies were rated moderate to low on methodological quality.

The findings from this review are comparable with three previous systematic reviews.^{20,60,61} Hundley et al. reviewed 28 articles that described a total of 21 CBKs in 40 different countries and reported that the level of CBK use varies considerably (8–99%) with higher levels being reported when kits are distributed free as part of a research programme; also, identifying the user of the kit was difficult and that evidence regarding training requirements for birth kit use was conflicting.⁶⁰ They also reported that although most studies report positive effects of CBK use, it is difficult to identify the effectiveness of CBKs separately from other broader intervention packages that additionally include other strategies.²⁰ Two recent systematic reviews evaluated the facilitators and barriers that affect the implementation of the use of CBKs.^{61,62} These reviews demonstrate that socio-cultural beliefs are barriers to using CBKs but that when used, CBKs are accepted by women and healthcare workers as

convenient and clean items that help to reduce delays. These findings are compatible with those of our systematic review. However, our review is current and up-to-date and contains literature published up to November 2018. Earlier reviews included either only quantitative or qualitative studies; however, this review included both quantitative and qualitative studies to consolidate all the evidence in one paper.

Conclusion

CBKs appear to be a promising strategy to achieve the SGD country targets of reducing maternal and neonatal morbidity and mortality. However, the current evidence is limited by small study size, lack of RCTs and difficulty in assessing the individual effects of CBKs in isolation from other intervention packages. However, in settings where clean birth practices are limited, CBKs should be made available to mothers or healthcare providers involved in childbirth.

Supplementary data

Supplementary data are available at *International Health* online (<http://inthehealth.oxfordjournals.org/>).

Authors' contributions: All authors contributed in conceptualising the idea, formulating research questions, preparing the protocol and identifying and extracting information from the selected studies. ZSL, PA, AC and ZF contributed in drafting the manuscript and all of the authors contributed to the final preparation of the manuscript.

Acknowledgements: None.

Funding: The research is supported by the Robinson Research Institute Engaging Opportunity Grant 2016 and Robinson Research Institute Strategic Research Initiative 2018.

Competing interests: None declared.

Ethical approval: Not required.

References

- WHO. Trends in maternal mortality: 1990 to 2015: estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division. Geneva: World Health Organization; 2015.
- IGME. Levels and trends in child mortality: estimates developed by the UN Inter-agency Group for Child Mortality Estimation. New York: UNICEF, WHO, World Bank Group, United Nations; 2015.
- UNDP. Sustainable Development Goals. <http://www.undp.org/content/undp/en/home/sustainable-development-goals.html>. 2017. (accessed 27 November 2018).
- WHO. Transforming our world: the 2030 Agenda for Sustainable Development. Geneva: World Health Organization; 2015.
- Simkiss D. The Millennium Development Goals are dead; long live the Sustainable Development Goals. *J Trop Pediatr* 2015;61:235–7.
- Darmstadt GL, Lawn JE, Costello A. Advancing the state of the world's newborns. *Bull World Health Organ* 2003;81(3):224–5.
- Zaidi AKM, Huskins WC, Thaver D et al. Hospital-acquired neonatal infections in developing countries. *Lancet* 2005;365(9465):1175–88.
- Morrison J, Jacoby C, Ghimire S et al. What affects clean delivery kit utilisation at birth in Nepal? A qualitative study. *Asia Pac J Public Health* 2015;27(2):1263–72.
- Thaver D, Zaidi AKM. Burden of neonatal infections in developing countries: a review of evidence from community-based studies. *Pediatr Infect Dis J* 2009;28(1):S3–9.
- Akter T, Dawson A, Sibbritt D. What impact do essential newborn care practices have on neonatal mortality in low- and lower-middle income countries? Evidence from Bangladesh. *J Perinatol* 2016;36:225–30.
- Say L, Chou D, Gemmill A et al. Global causes of maternal death: a WHO systematic analysis. *Lancet Glob Health* 2014;2(6):e323–33.
- Liu L, Oza S, Hogan D et al. Global, regional, and national causes of child mortality in 2000–13, with projections to inform post-2015 priorities: an updated systematic analysis. *Lancet* 2015;385:430–40.
- Montagu D, Yamey G, Visconti A et al. Where do poor women in developing countries give birth? A multi-country analysis of demographic and health survey data. *PLoS One* 2011;6(2):e17155.
- Mosha F, Winani S, Wood S et al. Evaluation of the effectiveness of a clean delivery kit intervention in preventing cord infection and puerperal sepsis among neonates and their mothers in rural Mwanza Region, Tanzania. *Tanzan Health Res Bull* 2005;7(3):185–8.
- Winani S, Wood S, Coffey P et al. Use of a clean delivery kit and factors associated with cord infection and puerperal sepsis in Mwanza, Tanzania. *J Midwifery Womens Health* 2007;52(1):37–43.
- Balsara ZP, Hussein MH, Winch PJ et al. Impact of clean delivery kit use on clean delivery practices in Beni Suef Governorate, Egypt. *J Perinatol* 2009;29(10):673–9.
- Callister LC. By small and simple things: clean birth kits. *MCN Am J Matern Child Nurs* 2016;41(4):255.
- World Health Organization. WHO Safe Childbirth Checklist Implementation Guide: Improving the quality of facility-based delivery for mothers and newborns. Geneva: World Health Organization; 2015.
- Blencowe H, Cousens S, Mullany LC et al. Clean birth and postnatal care practices to reduce neonatal deaths from sepsis and tetanus: a systematic review and Delphi estimation of mortality effect. *BMC Public Health* 2011;11(Suppl 3):S11.
- Hundley VA, Avan BI, Brauholtz D et al. Are birth kits a good idea? A systematic review of the evidence. *Midwifery* 2012;28:204–15.
- Raza SA, Avan BI. Disposable clean delivery kits and prevention of neonatal tetanus in the presence of skilled birth attendants. *Int J Gynaecol Obstet* 2013;120(2):148–51.
- Moher D, Liberati A, Tetzlaff J, Altman DG, PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *Ann Intern Med* 2009;151(4):264–9.
- Higgins JPT, Green S. *Cochrane Handbook for Systematic Reviews of Interventions*. Version 5.1.0 [updated March 2011]. The Cochrane Collaboration; 2011.
- Von Elm E, Altman DG, Egger M et al. Strengthening of Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies. *Int J Surg* 2014;12(12):1495–9.
- JB. Reviewer's Manual. Adelaide: Joanna Briggs Institute; 2014. <https://joannabriggs.org/assets/docs/sumari/ReviewersManual-2014.pdf> (accessed 21 June 2017).
- Falle TY, Mullany C, Tatte N et al. Potential role of traditional birth attendants in neonatal healthcare in rural southern Nepal. *J Health Popul Nutr* 2009 27(1):53–61.

- 27 Tsu V. Clean home delivery kit: evaluation of the health impact. Seattle, WA: PATH; 2000.
- 28 Osrin D, Tumbahangphe KM, Shrestha D et al. Cross sectional, community based study of care of newborn infants in Nepal. *BMJ* 2002; 325(9):1–5.
- 29 Sreeramareddy CT, Joshi HS, Sreekumaran BV et al. Home delivery and newborn care practices among urban women in western Nepal: a questionnaire survey. *BMC Pregnancy Childbirth* 2006 6:27.
- 30 Mullany LC, Darmstadt GL, Katz J et al. Risk factors for umbilical cord infection among newborns of southern Nepal. *Am J Epidemiol* 2007; 165(2):203–11.
- 31 Gurung G. Practices on immediate care of newborn in the communities of Kailali district. *Nepal Med Coll J* 2008;10:41–4.
- 32 Jokhio AH, Winter HR, Cheng KK. An intervention involving traditional birth attendants and perinatal and maternal mortality in Pakistan. *N Engl J Med* 2005;352:2091–9.
- 33 Hassan H, Jokhio AH, Winter H et al. Safe delivery and newborn care practices in Sindh, Pakistan: a community-based investigation of mothers and health workers. *Midwifery* 2012;28(4):466–71.
- 34 PAIMAN. *Clean delivery kit –a low cost solution for neonatal mortality and maternal morbidity*. Pakistan Pakistan Initiative for Mothers and Newborns (PAIMAN).
- 35 Meegan ME, Conroy RM, Lengeny SO et al. Effect on neonatal tetanus mortality after a culturally-based health promotion programme. *Lancet* 2001;358(9282):640–1.
- 36 Winani S, Coffey P, Wood S et al. Evaluation of a clean delivery kit intervention in preventing cord infection and puerperal sepsis in Mwanza, Tanzania. Seattle, WA: PATH; 2005.
- 37 Gardiner E. *Uganda Launches Clean Delivery Kit*. Washington, DC: Population Services International (PSI); 2002.
- 38 Republic of Uganda MoH/Ua/WHOW. *Maama kit: making child birth clean and safer*. Geneva: World Health Organisation.
- 39 Ediau M, Wanyenze RK, Machingaidze S et al. Trends in antenatal care attendance and health facility delivery following community and health facility systems strengthening interventions in Northern Uganda. *BMC Pregnancy Childbirth* 2013;13:189.
- 40 Darmstadt GL, Hassan M, Balsara ZP et al. Impact of clean delivery-kit use on newborn umbilical cord and maternal puerperal infections in Egypt. *J Health Popul Nutr* 2009;27(6):746–54.
- 41 Alemayehu E, Tolessa A, Moore M. Introduction of the ‘Simple Delivery Kit’ in East Hararghe Zone and the effect on traditional practices in Ethiopia. *Midwives* (1995) 1997;110(1311):79–81.
- 42 Onolemhemen D. The Ethiopian Birth Kit Project. Paper presented at: 13th World Conference on Public health 2012; Addis Abba, Ethiopia.
- 43 Garner P, Lai D, Baea M et al. Avoiding neonatal death: an intervention study of umbilical cord care. *J Trop Pediatr* 1994;40(1):24–8.
- 44 Alto WA, Albu RE, Irabo G. An alternative to unattended delivery—a training programme for village midwives in Papua New Guinea. *Soc Sci Med* 1991;32(5):613–8.
- 45 Andrews JY, Dalal K. Umbilical cord-cutting practices and place of delivery in Bangladesh. *Int J Gynaecol Obstet* 2011;114(1):43–6.
- 46 Kapoor SK, Reddaiah VP, Lobo J. Control of tetanus neonatorum in a rural area. *Indian J Pediatr* 1991;58(3):341–4.
- 47 Witter S. Report on Key informant interviews, evaluation of free delivery policy. Senegal: Immpect, Aberdeen; 2007.
- 48 Dickerson T, Crookston B, Simonsen SE et al. Pregnancy and Village Outreach Tibet: a descriptive report of a community- and home-based maternal-newborn outreach program in rural Tibet. *J Perinat Neonatal Nurs* 2010;24(2):113–27.
- 49 PATH. Use of the clean home delivery kit in Nepal: a qualitative study. Seattle, WA: Program for Appropriate Technology in Health (PATH); 2002.
- 50 Beun MH, Wood SK. Acceptability and use of clean home delivery kits in Nepal: a qualitative study. *J Health Popul Nutr* 2003;21(4): 367–73.
- 51 Dhital SR, Dhital MK, Aro AR. Clients’ perspectives on the quality of maternal and neonatal care in Banke, Nepal. *Health Sci J* 2015;9(2): 10.
- 52 Morrison J, Jacoby C, Ghimire S et al. What affects clean delivery kit utilization at birth in Nepal? A qualitative study. *Asia Pac J Public Health* 2015;27(2):263–72.
- 53 Jackson R. Using birthing kits to promote clean birth practices in Ethiopia. *Dev Pract* 2014;24(3):339–52.
- 54 Moyer CA, Aborigo RA, Logonia G et al. Clean delivery practices in rural northern Ghana: a qualitative study of community and provider knowledge, attitudes, and beliefs. *BMC Pregnancy Childbirth* 2012;15 (12):50.
- 55 Lucey O, Andriatsihosena M, Ellis M. Impact of a training package for community birth attendants in Madagascar. *J Trop Pediatr* 2011;57 (1):59–61.
- 56 Mitchell EM, Steeves R. The acceptability of clean delivery kits on the atlantic coast of Nicaragua: a focused ethnography. *Hisp Health Care Int* 2012;10(1):36–41.
- 57 Hundley VA, Avan BI, Ahmed H, Graham WJ, for the Birth Kit Working Group. Clean birth kits to improve birth practices: development and testing of a country level decision support tool. *BMC Pregnancy Childbirth* 2012;12:158.
- 58 Vallely LM, Homiehombo P, Walep E et al. Feasibility and acceptability of clean birth kits containing misoprostol for self-administration to prevent postpartum hemorrhage in rural Papua New Guinea. *Int J Gynaecol Obstet* 2016;133(3):301–6.
- 59 Austin-Evelyn K, Sacks E, Atuyambe L et al. The promise of Mama Kits: perceptions of in-kind goods as incentives for facility deliveries in Uganda. *Glob Public Health* 2017;12(5):565–78.
- 60 Hundley VA, Avan BI, Braunholtz D et al. Lessons regarding the use of birth kits in low resource countries. *Midwifery* 2011;27(6): e222–30.
- 61 Colomar M, Cafferata ML, Aleman A et al. Supply kits for antenatal and childbirth care during antenatal care and delivery: a mixed-methods systematic review, the qualitative approach. *Reprod Health* 2017;14(1):48.
- 62 Aleman A, Tomasso G, Cafferata ML et al. Supply kits for antenatal and childbirth care: a systematic review. *Reprod Health* 2017;14(1): 175.