



October 2016 – SUPPORT Summary of a systematic review

Do birth kits improve newborn and maternal outcomes?

Sepsis is one of the conditions contributing significantly to both maternal and newborn mortality. Poor hygiene during the intrapartum period has been recognised as a critical risk factor for sepsis. Clean birth is an essential intervention estimated to avert 20–30% of newborn deaths due to sepsis and tetanus, and requires the availability of a few essential supplies. Since birth kits have been recommended by the World Health Organization (WHO) as a means of ensuring supplies and to ‘strengthen standards of cleanliness’ in home deliveries, more than 50 low- and middle-income countries have introduced birth kits, which are now receiving renewed international interest.

Key messages

- **The use of birth kits (together with education and/or a topical antimicrobial) compared with no intervention:**
 - probably reduces neonatal mortality rate
 - reduces neonatal tetanus related mortality
 - may reduce neonatal sepsis
 - probably reduces maternal mortality
 - probably reduces haemorrhage
 - reduces puerperal sepsis

- **Most of the included studies were conducted in low-income countries.**



Who is this summary for?

People making decisions concerning the use of birth kits to improve newborn and maternal outcomes

! This summary includes:

- **Key findings** from research based on a systematic review
- **Considerations about the relevance of this research** for low-income countries

X Not included:

- Recommendations
- Additional evidence not included in the systematic review
- Detailed descriptions of interventions or their implementation

This summary is based on the following systematic review:

Hundley VA, Avan BI, Braunholtz D, Graham WJ. Are birth kits a good idea? A systematic review of the evidence. *Midwifery* 2012; 28(2):204–15.

What is a systematic review?

A summary of studies addressing a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise the relevant research, and to collect and analyse data from the included studies

SUPPORT was an international project to support the use of policy relevant reviews and trials to inform decisions about maternal and child health in low- and middle-income countries, funded by the European Commission (FP6) and the Canadian Institutes of Health Research.

Glossary of terms used in this report:
www.supportsummaries.org/glossary-of-terms

Background references on this topic:
See back page

Background

Achieving clean birth requires the application of skills by the care provider and the availability of a few essential supplies. Births kits vary considerably in name and content. The WHO recommends content that, at a minimum, ensures ‘three cleans’: a clean surface for delivery (e.g. a plastic sheet), clean hands of the birth attendant (e.g. soap), and clean cutting of the umbilical cord (e.g. a razor blade). Three further ‘cleans’ have been added: clean perineum (e.g. soap), clean cord tying (e.g. cord ties or clamps), and clean cord care (e.g. gauze to cover cord stump or surgical spirit). Births kits have been recommended not only for home births but also for use in health facilities that lack the capacity to sterilise equipment.

How this summary was prepared

After searching widely for systematic reviews that can help inform decisions about health systems, we have selected ones that provide information that is relevant to low-income countries. The methods used to assess the reliability of the review and to make judgements about its relevance are described here: www.supportsummaries.org/how-support-summaries-are-prepared/

Knowing what’s not known is important

A reliable review might not find any studies from low-income countries or might not find any well-designed studies. Although that is disappointing, it is important to know what is not known as well as what is known.

A lack of evidence does not mean a lack of effects. It means the effects are uncertain. When there is a lack of evidence, consideration should be given to monitoring and evaluating the effects of the intervention, if it is used.

About the systematic review underlying this summary

Review objective: To assess the effects of birth kits on newborn and maternal outcomes

Types of	What the review authors searched for	What the review authors found
Study designs & Interventions	All available evidence, irrespective of study design. For the purpose of this review, a birth kit was defined as any disposable kit intended for routine use in the intrapartum period, specifically at the delivery of the baby.	9 included studies reporting effects of intervention packages including births kits: randomised trial (1), non-randomised trial (1), before-after studies (2) and cross-sectional studies (5)
Participants	Pregnant women in the intrapartum period	Pregnant women (median delivery at home 87%)
Settings	Home or health facility	Mostly rural areas from Nepal (2), Egypt (2), Pakistan (1), Kenya & Tanzania (1), Papua New Guinea (1), India (1), Tanzania (1)
Outcomes	Primary outcomes: newborn outcomes and maternal outcomes Secondary outcomes: process measures—clean birth practices	Newborn outcomes (perinatal mortality, neonatal tetanus, neonatal sepsis, and omphalitis) and maternal outcomes (maternal mortality, puerperal sepsis) Process measures—clean birth practices (clean hands, birth surface, cord cutting, cord tie)
Date of most recent search: September 2009		
Limitations: This is well-conducted systematic review with only minor limitations.		

Hundley VA, Avan BI, Brauholtz D, Graham WJ. Are birth kits a good idea? A systematic review of the evidence. *Midwifery* 2012; 28(2):204-15.

Summary of findings

Nine studies examined the effectiveness of an intervention package, which included a birth kit. The other interventions delivered alongside birth kits varied between studies and included, for example, education (from a simple explanation of kit contents to a more detailed training course) or the provision of a topical antimicrobial.

Three cross-sectional studies comparing users and non-users, , examined areas of practice in relation to birth kit use. There was a consistent higher proportion of birth kit users than non-users among those that applied clean childbirth practices (home and birth attendant hand washing, clean cord tie or clamp being used, clean blade being used, use of a clean delivery surface, the mother's perineum having been washed and clean cord care), but the effects of birth kits on these process outcomes are uncertain.

1) Newborn outcomes

An intervention package that included a birth kit was associated with reduced newborn mortality in three studies. Two of the studies provided the neonatal mortality rate, while the third reported 'total mortality' in the first six weeks of life. Birth kit use was also associated with advantageous outcomes in relation to tetanus-related mortality in two of the studies. Four studies investigated the impact of an intervention package including a birth kit on omphalitis or cord infection. An examination of individual components of the birth kit found that only soap showed an association with omphalitis.

In three additional studies where birth kit use was increased because of a community intervention (excluded from the review), the neonatal mortality rate was reduced in two studies: odds ratio (OR)=0.70 (95% CI 0.53, 0.94), OR=0.93 (95% CI 0.80, 1.09), Risk Ratio=0.72 (95% CI 0.56, 0.91).

→ The use of birth kits (together with education and/or a topical antimicrobial) compared with no intervention:

- probably reduces neonatal mortality rate. The certainty of this evidence is moderate.
- reduces neonatal tetanus related mortality. The certainty of this evidence is high.
- may reduce neonatal sepsis. The certainty of this evidence is low.

→ It is uncertain if use of birth kits reduces neonatal omphalitis. The certainty of this evidence is very low.

About the certainty of the evidence (GRADE) *



High: This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different† is low.



Moderate: This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different† is moderate.



Low: This research provides some indication of the likely effect. However, the likelihood that it will be substantially different† is high.



Very low: This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different† is very high.

* This is sometimes referred to as 'quality of evidence' or 'confidence in the estimate'.

† Substantially different = a large enough difference that it might affect a decision

See last page for more information.

Birth kits - newborn outcomes		
People	Pregnant women in the intrapartum period	
Settings	Home or health facility	
Intervention	Birth kits (as part of an intervention package that also includes education and/or a topical antimicrobial)	
Comparison	Usual care	
Outcomes	Impact	Certainty of the evidence (GRADE)
Neonatal mortality rate	Relative decrease ranged from 23% to 83% (95% CI 77-87%).	⊕⊕⊕○ Moderate
Tetanus related mortality	Relative decrease ranged from 99% (95% CI 91-99.9%) to 100%.	⊕⊕⊕⊕ High
Sepsis	Relative decrease of 88% (95% CI 7-98%)	⊕⊕○○ Low
Omphalitis	Median relative decrease of 49% (ranging from an increase of 15% to a reduction of 92%)	⊕○○○ Very low
GRADE: GRADE Working Group grades of evidence (see above and last page)		

2) Maternal outcomes

Three studies considered maternal outcomes in relation to an intervention package including a birth kit, and in all of these, there was an impact on the incidence of puerperal sepsis. One study examined maternal mortality as one of the primary outcomes and haemorrhage, the leading cause of maternal mortality in low-income countries. The effect on haemorrhage could be explained by co-interventions to clean birth.

In three additional studies where birth kit use was increased because of a community intervention (excluded from the review), the maternal mortality rate showed inconsistent results: odds ratio (OR)=0.22 (95% CI 0.05, 0.90), OR=0.70 (95% CI 0.46, 1.07), OR=2.02 (95% CI 1.11, 3.68).

→ The use of birth kits (alongside education or a topical antimicrobial) compared with no intervention:

- probably reduces maternal mortality. The certainty of this evidence is moderate.
- probably reduces haemorrhage. The certainty of this evidence is moderate.
- reduces puerperal sepsis. The certainty of this evidence is high.

Birth kits - maternal outcomes		
People	Pregnant women in the intrapartum period	
Settings	Home or health facility	
Intervention	Birth kits (as part of an intervention package that also includes education or a topical antimicrobial)	
Comparison	Usual care	
Outcomes	Impact	Certainty of the evidence (GRADE)
Mortality	Odds Ratio=0.74 (95% CI 0.45, 1.23)	⊕⊕⊕○ Moderate
Hemorrhage	Odds Ratio=0.61 (95% CI 0.47, 0.79)	⊕⊕⊕○ Moderate
Puerperal sepsis	Odds Ratio=0.17 (95% CI 0.13, 0.23) Two observational studies showed consistent results: OR=0.11 (95% CI 0.01, 1.06) and OR=0.31 (95% CI 0.18, 0.54)	⊕⊕⊕⊕ High
GRADE: GRADE Working Group grades of evidence (see above and last page)		

Relevance of the review for low-income countries

→ Findings	▷ Interpretation*
APPLICABILITY	
→ Most of the included studies were conducted in low-income countries.	▷ Given the setting of the included studies and the low cost and simplicity of birth kits, the findings are likely to be applicable to low-income countries. However, the availability, acceptability and cost of the birth kits should be considered.
EQUITY	
→ The studies were mostly conducted in rural, underserved areas. → There was no information in the included studies regarding differential effects of the interventions on disadvantaged populations.	▷ If the use of birth kits is targeted at underserved populations or other disadvantaged populations, it will likely decrease inequities. ▷ However, resources needed for birth kits may be less available in more disadvantaged settings.
ECONOMIC CONSIDERATIONS	
→ The systematic review did not address economic considerations.	▷ Scaling up the use of birth kits requires resources. Local costings should be undertaken. ▷ The cost of items purchased separately, could be higher than as a kit. Re-use of items could reduce costs.
MONITORING & EVALUATION	
→ There is no evidence of the effects of birth kits separate from those achieved by a broader intervention package. → Most studies have been conducted in rural settings, primarily in the context of home births.	▷ Larger and more rigorous studies are required to determine the benefits, harms and the cost-effectiveness of birth kits. ▷ Studies should describe the components of birth kits and intervention packages that include birth kits in sufficient detail that the programmes can be replicated. In addition, they should describe factors that facilitate correct use of birth kits and the context (home or health facility) in which they are delivered. ▷ Studies should assess whether birth kits can act as an incentive or a disincentive for skilled birth attendance or facility-based deliveries.

*Judgements made by the authors of this summary, not necessarily those of the review authors, based on the findings of the review and consultation with researchers and policymakers in low-income countries. For additional details about how these judgements were made see: www.supportsummaries.org/methods

Additional information

Related literature

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.

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Conflict of interest

None declared. For details, see: www.supportsummaries.org/coi

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The summary should be cited as

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About certainty of the evidence (GRADE)

The “certainty of the evidence” is an assessment of how good an indication the research provides of the likely effect; i.e. the likelihood that the effect will be substantially different from what the research found. By “substantially different” we mean a large enough difference that it might affect a decision. These judgements are made using the GRADE system, and are provided for each outcome. The judgements are based on the study design (randomised trials versus observational studies), factors that reduce the certainty (risk of bias, inconsistency, indirectness, imprecision, and publication bias) and factors that increase the certainty (a large effect, a dose response relationship, and plausible confounding). For each outcome, the certainty of the evidence is rated as high, moderate, low or very low using the definitions on page 3.

For more information about GRADE:
www.supportsummaries.org/grade

SUPPORT collaborators:

The Cochrane Effective Practice and Organisation of Care Group (EPOC) is part of the [Cochrane Collaboration](http://www.cochrane.org). The Norwegian EPOC satellite supports the production of Cochrane reviews relevant to health systems in low- and middle-income countries. www.epocoslo.cochrane.org

The Evidence-Informed Policy Network (EVIPNet) is an initiative to promote the use of health research in policymaking in low- and middle-income countries. www.evipnet.org

The Alliance for Health Policy and Systems Research (HPSR) is an international collaboration that promotes the generation and use of health policy and systems research in low- and middle-income countries. www.who.int/alliance-hpsr

Norad, the Norwegian Agency for Development Cooperation, supports the Norwegian EPOC satellite and the production of SUPPORT Summaries. www.norad.no

The Effective Health Care Research Consortium is an international partnership that prepares Cochrane reviews relevant to low-income countries. www.evidence4health.org

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