WHO recommendation on vaginal cleansing with povidone-iodine immediately before caesarean section

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Recommendation

Vaginal cleansing with povidone-iodine immediately before caesarean section is recommended.

(Moderate - quality evidence, conditional recommendation)

Publication history

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Remarks

- The recommendation of the use of povidone-iodine out of the common antiseptics was because it was the only agent tested in all randomized controlled trials that evaluated the review question.
- The GDG noted that the main clinical benefit (reduction in post-caesarean endometritis) demonstrated in the review was largely driven by women at higher baseline risk of infections (i.e. those who were already in labour and those with ruptured membranes). However, in consideration of the similarity in the statistical findings between subgroups and the entire study population, the group acknowledged that women at lower baseline risk of infection are also likely to benefit from the intervention.
- Due to the staining of surrounding tissues, vaginal cleansing in this context may be regarded as a potentially invasive procedure, and implementation might not be easy.
- The GDG considers further evaluation of the benefits in high-risk women and potential adverse effects (especially among women with ruptured membranes and those planning to breastfeed) a research priority. Additionally, the group considers it essential to identify the most appropriate timing of the intervention to achieve benefit with minimal harm and whether other antiseptic agents (e.g. chlorhexidine) have similar beneficial effects. The group noted that shorter application and contact time are likely to be associated with less maternal and fetal exposure. Therefore, the group suggested vaginal application of povidone-iodine very close to the start of caesarean section (e.g. following bladder catheterization) to minimize the discomfort to the woman. The specified duration of vaginal cleansing with povidone-iodine in three of the seven included studies in the Cochrane review was 30 seconds.
- The use of a high concentration and/or repeated applications of povidone-iodine should be avoided to minimize maternal and fetal exposure and possible interference with the results of neonatal thyroid screening.
Background

Bacterial infections during labour and the puerperium are among the leading causes of maternal mortality worldwide, accounting for about one tenth of the global burden of maternal deaths.\(^{(1, 2)}\) While the number of deaths arising from these infections has decreased considerably in high-income settings, the situation has not improved in resource-limited settings. Most of the estimated 75,000 maternal deaths occurring worldwide yearly as a result of infections are recorded in low-income countries.\(^{(3)}\) Although the reported incidence in high-income countries is relatively low (between 0.1 and 0.6 per 1000 births), it is nonetheless an important direct cause of maternal mortality.\(^{(3, 4)}\)

Apart from deaths and acute morbidities associated with infections during or following childbirth, long-term disabilities such as chronic pelvic pain, fallopian tube blockage and secondary infertility can also occur. Maternal infections around childbirth also have a considerable impact on newborn mortality, and an estimated 1 million newborn deaths are associated with such infections annually.\(^{(5, 6)}\) In addition, infection-related morbidities and prolonged hospitalization can interfere with mother–infant bonding in the first days after birth.

Methods

The recommendation was developed using standardized operating procedures in accordance with the process described in the “WHO handbook for guideline development”, guided by the GRADE approach.\(^{(7)}\)

Outcomes used for this recommendation were aligned with the prioritized outcomes from the WHO recommendations on prevention and treatment of maternal peripartum infections (2015).\(^{(8)}\)

A Cochrane review was conducted on vaginal preparation with antiseptic agent before caesarean section for preventing postoperative infectious morbidities.\(^{(9)}\) In the review, randomized controlled trials relevant to the key question were screened by review authors, and data on relevant outcomes and comparisons were extracted. Evidence profiles (in the form of GRADE tables) were prepared for comparisons of interest, including the assessment and judgments for each outcome, and the estimated risks.

WHO convened a Guideline Development Group (GDG) meeting on recommendations on prevention and treatment of maternal peripartum infections in September 2015, where this recommendation was developed. The GDG comprised of a group of independent experts, who used the evidence profiles to assess evidence on effects on the pre-specified outcomes. GDG members discussed the balance between desirable and undesirable effects, overall quality of supporting evidence, values and preferences of stakeholders, resource requirements, cost-effectiveness, acceptability, feasibility and equity, to formulate the recommendation. Remarks were added to clarify the recommendation, and aid implementation.

Recommendation question

For this recommendation, we aimed to answer the following question:

- Among pregnant women with indications for caesarean section (P), does vaginal cleansing with an antiseptic agent prior to caesarean delivery (I), compared with no vaginal cleansing with an antiseptic agent (C), prevent post-operative maternal infectious morbidities (O)?

Evidence Summary

Evidence on vaginal preparation with antiseptic agent before caesarean section for preventing postoperative infectious morbidities was extracted from a Cochrane systematic review of seven trials involving 2816 women (2635 analysed).\(^{(9)}\)
Trials were conducted in low-, middle- and high-income countries: one trial each in Iran, Pakistan and Turkey, and four trials in the USA. All seven trials compared preoperative povidone-iodine solution preparation with a control group. Where specified, the concentration of povidone-iodine applied ranged from 1% to 10%. Control group was no vaginal cleansing in six trials and saline vaginal wash in one trial. Most trials included women undergoing either a scheduled or emergency caesarean delivery. Two trials excluded women with chorioamnionitis. Prophylactic antibiotics were used in all trials. None of the trials reported severe maternal infectious morbidity, side-effects of antiseptic agent or the cost of care.

**Vaginal preparation with antiseptic agent versus control: all women (EB Table 14a)**

- Women receiving vaginal cleansing with povidone-iodine experienced significantly reduced risk of post-caesarean endometritis (RR 0.45, 95% CI 0.25 to 0.81; 7 trials, 2635 women).
- There was no significant difference between the comparison groups for postoperative fever (RR 0.90, 95% CI 0.74 to 1.10; 6 trials, 2475 women), wound infection (RR 0.86, 95% CI 0.54 to 1.36; 6 trials, 2205 women) or any wound complication (RR 0.63, 95% CI 0.37 to 1.07; 2 trials, 729 women).

**Vaginal preparation with antiseptic agent versus control: by presence or absence of labour before caesarean section (EB Table 14b)**

- Four trials stratified data for women according to whether they were in labour or not before the caesarean section.
- Women in labour who received vaginal preparation with povidone-iodine solution preoperatively had lower risk of endometritis (RR 0.56, 95% CI 0.34 to 0.95; 3 trials, 523 women), but there were no differences observed for postoperative fever (RR 0.68, 95% CI 0.42 to 1.08; 2 trials, 307 women) or wound infection (RR 0.72, 95% CI 0.24 to 2.21; 2 trials, 307 women).
- Among women who were not in labour, no significant differences were observed between the intervention and the control groups for postcaesarean endometritis (RR 0.89, 95% CI 0.52 to 1.54; 3 trials, 871 women), postoperative fever (RR 0.96, 95% CI 0.61 to 1.49; 2 trials, 658 women) or wound infection (RR 0.64, 95% CI 0.27 to 1.56; 2 trials, 652 women).
- However, the test for subgroup differences did not show evidence of any differences between the subgroups.

**Vaginal preparation with antiseptic agent versus control: by status of amniotic membranes (EB Table 14c)**

- Four trials stratified data for women according to the status of amniotic membranes.
- Women with ruptured membranes who received vaginal preparation with povidone-iodine solution had lower risk of post-caesarean endometritis (RR 0.24, 95% CI 0.10 to 0.55; 3 trials, 272 women), but there were no differences observed for postoperative fever (RR 0.62, 95% CI 0.34 to 1.12; 2 trials, 200 women) or wound infection (RR 1.22, 95% CI 0.46 to 3.20, 3 trials, 272 women).
- Among women with intact membranes, no significant differences were observed between the intervention and the control groups for postcaesarean endometritis (RR 0.63, 95% CI 0.36 to 1.06; 3 trials, 857 women), postoperative fever (RR 0.93, 95% CI 0.63 to 1.36; 2 trials, 769 women) or wound infection (RR 0.72, 95% CI 0.35 to 1.52; 3 trials, 857 women).
- There was evidence of subgroup differences only for post-caesarean endometritis.

**Implementation considerations**

- The successful introduction of this recommendation into national programmes and health-care services depends on well-planned and participatory consensus-driven processes of adaptation and implementation. The adaptation and implementation processes may include the development or revision of existing national guidelines or protocols based on this recommendation.
- The recommendation should be adapted into a locally appropriate document that can meet the specific needs of each country and health service. Any changes should be made in an explicit and transparent
manner.

- A set of interventions should be established to ensure that an enabling environment is created for the use of the recommendations, and that the behaviour of the healthcare practitioner changes towards the use of this evidence-based practice.
- In this process, the role of local professional societies is important and an all-inclusive and participatory process should be encouraged.

Research implications

The GDG identified that further research on the following high-priority questions is needed:

- What is the comparative effectiveness and safety of chlorhexidine and povidone-iodine for vaginal cleansing among women undergoing caesarean section in preventing maternal infection morbidities?
  - What are the effects of vaginal cleansing immediately before caesarean section among women at potentially higher risk of infection (e.g. women with ruptured membranes)?
  - Is there any difference in the incidence of maternal infection morbidities between vaginal cleansing performed before or immediately after caesarean section?

Related Links


Supporting systematic review:


References

8. WHO recommendations for prevention and treatment of maternal peripartum infections. 2015