

## Umbilical Cord Cleansing May Not Be Effective in Reducing Neonatal Mortality in African Settings

Interventions that aim to reduce neonatal mortality through umbilical cord cleansing with antiseptic chlorhexidine solution may not be effective in African settings. In a controlled trial conducted in Zambia between 2011 and 2013,<sup>1</sup> the mortality rate of infants within their first 28 days of life was 15.2 per 1,000 live births among those treated with chlorhexidine and 13.6 per 1,000 among those not treated. In another controlled trial conducted in Tanzania between 2011 and 2014, neonatal mortality was 10.5 per 1,000 among infants treated with chlorhexidine and 11.7 per 1,000 among those not treated.<sup>2</sup> Neither study found a statistically significant difference in neonatal mortality between intervention and control groups.

Findings from randomized controlled trials in rural areas of south Asia with high rates of home delivery and neonatal mortality suggest that umbilical cord cleansing with chlorhexidine solution reduces neonatal mortality; however, no research had evaluated the practice in African settings. To address this gap, two studies were conducted: a cluster-randomized controlled trial in Southern Province, Zambia, and a community-based, individually randomized controlled trial on Pemba Island, Tanzania.

For the Zambia study, investigators randomly assigned half of 90 health facility-based clusters to an intervention group and half to a control group. Between February 2011 and January 2013, some 42,356 pregnant women visiting health centers within catchment areas were screened, and 39,679 who were older than 15, in their second or third trimester of pregnancy and planning to stay in the area for at least 28 days postpartum were eligible for and enrolled in the study. During the study period, women in the intervention group had 18,510 live births and those in the control group had 19,346. Field monitors visited participating women once before and four times after delivery (on days 1, 4, 10 and 28 postpartum). Women in the intervention group were supplied with 4% chlorhexidine solution and instructed to apply it to their newborn's umbilical stump once a day until three days after full

cord separation; women in the control group were instructed to keep their infant's cord dry and free of topical substances. Field monitors collected data on mothers' and newborns' health during postnatal visits. Generalized estimating equations were used to compare neonatal mortality across groups.

For the Tanzania study, all healthy infants aged 1–48 hours and born in a health facility or in the community on Pemba Island between May 2011 and August 2014 were eligible for inclusion; half of newborns (18,015) were randomly assigned to the intervention group and half (18,384) to the control group. Maternal and child health workers conducted home visits on days 1, 4, 10 and 28 postpartum, and instructed mothers of infants in the intervention group to apply 4% chlorhexidine solution to the umbilical stump once per day until three days after cord separation; mothers of infants in the control group were instructed to provide dry cord care. Poisson regression models and Cox survival regression models were used to compare neonatal mortality and umbilical stump infection (omphalitis) across groups.

Sixty-four percent of births in the Zambia study occurred in a health facility; the proportion in the Tanzania study was 53%. Neither study found a statistical difference in neonatal mortality between intervention and control groups. In Zambia, the total neonatal mortality rate was 15.2 per 1,000 live births among infants treated with chlorhexidine and 13.6 per 1,000 among those not treated; in analyses that excluded deaths that occurred within the first 24 hours after birth, the mortality rates were 10.9 and 9.7 per 1,000, respectively. In Tanzania, the overall neonatal mortality rate was 10.5 per 1,000 for the intervention group and 11.7 per 1,000 for the control group. The Tanzania study did find a difference between groups in the rate of omphalitis: Compared with infants in the control group, those in the intervention group had a lower risk of any umbilical stump infection (relative risk, 0.7). Rates of omphalitis were also examined in the Zambia study, but did not differ between groups.

The investigators of the Zambia study and those of the Tanzania study conclude that their findings do not support application of chlorhexidine to reduce neonatal mortality in their study settings. Authors of an accompanying comment regarding the findings of the two studies mention that “the latest WHO guidelines recommend application of chlorhexidine...for infants born at home in environments with high neonatal mortality rates (>30 deaths per 1000 live births).”<sup>3</sup> Given the high rates of facility-based delivery and the low neonatal mortality rates found in the two African studies, the comment's authors recommend that no changes be made to the current WHO guidelines for cord care.—*J. Rosenberg*

### REFERENCES

1. Semrau KEA et al., Effectiveness of 4% chlorhexidine umbilical cord care on neonatal mortality in Southern Province, Zambia (ZamCAT): a cluster-randomised controlled trial, *Lancet Global Health*, 2016, [http://dx.doi.org/10.1016/S2214-109X\(16\)30215-7](http://dx.doi.org/10.1016/S2214-109X(16)30215-7).
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