

# Implementing the World Health Organization Revised Recommendations on Cord Care

In 2014, the World Health Organization (WHO) released new guidelines on postnatal care, which include an updated recommendation for umbilical cord care:

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“Daily chlorhexidine (7.1% chlorhexidine digluconate aqueous solution or gel, delivering 4% chlorhexidine) application to the umbilical cord stump during the first week of life is recommended for newborns who are born at home in settings with high neonatal mortality (30 or more neonatal deaths per 1,000 live births).

Clean, dry cord care is recommended for newborns born in health facilities and at home in low neonatal mortality settings. Use of chlorhexidine in these situations may be considered only to replace the application of a harmful traditional substance, such as cow dung, to the cord stump.”

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The Chlorhexidine Working Group (CWG) has developed the following guidance to assist countries that are interested in the introduction and scale-up of 7.1% chlorhexidine digluconate (delivering 4% chlorhexidine) for umbilical cord care. This brief includes consideration of new evidence on setting and impact of use. In order to develop sound and effective services, decision-makers in every country setting must take into account global recommendations, available epidemiologic evidence, and local reality to determine the most appropriate choices in their particular circumstances. In this guidance, considerations for successful implementation of a chlorhexidine for umbilical cord care program are explored, notably the following:

1. Product dosage form: gel versus liquid.
2. Application regimen: single-day versus multiple-day.
3. Setting for use: home and/or health facilities.
4. Programmatic impact: possible outcomes of use and using performance indicators to measure coverage and use.

## Selection of Dosage Form (Gel or Liquid)

Both aqueous solution (liquid) and gel are equally effective for umbilical cord care.<sup>1</sup> The WHO Model List of Essential Medicines for Children recommends both liquid and gel. Countries should select the dosage form they want to use in their country based on:

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### **Acceptability to mothers, caregivers, skilled providers, and others who are likely to use the product.**

The optimal dosage form (gel or liquid) may vary depending on user characteristics and distribution channel (e.g., public sector, social marketing, pharmacy retailers, clean delivery kits). Formative research should be performed to validate which dosage form is most preferred by the target population.

### **Product availability (e.g., ease of production/import and supply sustainability).**

Suppliers of 7.1% chlorhexidine digluconate gel or liquid are located around the world. Countries could procure from these existing suppliers or could locally produce the product. It is important to assess both a country’s situation and how to best achieve uninterrupted supply of 7.1% chlorhexidine digluconate. Please see the [chlorhexidine page on the Healthy Newborn Network website](#).

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A primary container is the container that is in direct contact with the drug<sup>2</sup> (in this case, a bottle, tube, or sachet). Different primary containers are available for each of the dosage forms. Evaluating the primary

containers to determine if they are packaged in the same or a different way from the primary containers of other newborn medicines commonly available in the country could prevent improper use of the product by eliminating user confusion. In some settings, it may be appropriate to avoid forms of primary packaging that could easily be mistaken for eye or ear care products.

Drug regulatory officials should be closely involved in decisions regarding dosage form. It is good practice to consult with the national regulatory authority to ensure that the labeling information, patient information leaflet, and instructions for use are consistent with their requirements. Depending on the context, it is a good practice to use pictorial messages or icons on the primary packaging (e.g., tube or nozzle bottle) as well as including appropriate wording on instructions accompanying the product.

When used as directed, the safety record of chlorhexidine has been well established in adults and newborns. As with all medications, care must be taken to ensure that the product is used appropriately. Wash hands before and after use. Chlorhexidine should be kept out of eyes and ears. Remaining chlorhexidine product should be discarded after the end of the specified application period.

## Single-Day versus Seven-Day Application

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WHO recommends using chlorhexidine for the first week of life. Data show that application on the first day is the most important. To reduce mortality risk, application needs to be done on the day of birth. Application beyond day one reduces risk of local infection to the cord stump and may further reduce mortality risk.

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Although the WHO consultation recommended seven-day application, the question of the possible superiority of multiple-day over single-day is not clearly resolved. Trials to date have primarily tested multiple-day application; thus, that is what we have the most evidence for. However, in the original Nepal study, one-third of those randomized to chlorhexidine had application initiated only *after* the first day of life. This group had mortality risk just as high as the control group. By contrast, those starting *on* the day of birth had one-third lower mortality, thus indicating the importance of starting the intervention early. In the Bangladesh study, a single application applied within the first day showed a reduction in mortality risk that was at least as effective in reducing mortality risk as multiple-day, although the difference between multiple-day and control groups was not statistically significant.

Country programs could consider the evidence and specific country situation to determine if they want to implement the chlorhexidine intervention with single-day or seven-day application. Factors that countries could consider include:

- What are current and traditional cord care practices in-country? Caregivers may be more amenable to substituting 7.1% chlorhexidine for a traditional and possibly harmful cord care substance, which is generally used for many days rather than just one time at birth.
- How will introduction of 7.1% chlorhexidine for umbilical cord care affect current cord care messaging, which has encouraged dry cord care (keeping the cord clean and dry and not applying anything to the cord stump)? Single-day application allows caregivers to adhere to a dry cord care regimen once they administer an initial application of chlorhexidine product.
- For greatest impact, a high proportion of the population needs to receive the intervention delivered in a culturally appropriate way that ensures its effectiveness.

7.1% chlorhexidine digluconate is available as a gel or as an aqueous solution (liquid). Based on the experiences of countries that have already introduced 7.1% chlorhexidine digluconate, the global CWG recommends the following product sizes. These sizes account for potential wastage and provide a sufficient quantity for the specified period of application.

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## SINGLE-DAY APPLICATION

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### Gel

3 grams

### Liquid

10 milliliters

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## SEVEN-DAY APPLICATION

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### Gel

10 grams

### Liquid

30 milliliters

## Home and/or Facility Use

WHO recommends use only on newborns who are born at home. Their recommendation is based on results from clinical trials published at the time the recommendations were formulated. In these trials, application was done only in the home setting. However, more recently published data on outcomes for newborns receiving chlorhexidine application who were born in health facilities in Nepal and Bangladesh (N=3,223) demonstrate at least as great a reduction in mortality as for those born at home.<sup>3,4,5</sup> These data were not available at the time of the WHO review. Further, hygiene conditions and the amount of time spent in a facility before discharge to home should be considered when determining in what settings to introduce chlorhexidine use for cord care. Giving birth in a facility does not necessarily reduce the chance of infection. Infection prevention practices are substandard in many facilities, as evidenced by, for example, hospital nursery outbreaks of highly resistant gram-negative bacteria.<sup>6</sup> In addition, many women who deliver in a health facility may return home quickly (within 6 to 24 hours) to the same conditions in which a home birth would have taken place, thus exposing the newborn to the risk of infection via the freshly cut umbilical stump. Mothers and other caregivers might be more easily convinced to use chlorhexidine if health facilities clearly endorse use of chlorhexidine. Health workers can serve as role models for promotion of chlorhexidine if they are using it for newborn cord care at the time of facility birth.

## Expected Impact

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The impact will depend on the target population. It is important to track coverage and use of this new intervention.

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Because the risk of microbial exposures to the cord and distribution of causes of neonatal deaths vary considerably by setting, the impact on overall neonatal mortality rate (NMR) can also be expected to vary by setting. Chlorhexidine appears to have a similar protective effect for cord infection regardless of setting. As for any intervention, to achieve greatest impact a high proportion of the population at risk needs to receive the intervention, and the intervention must be delivered in a manner that ensures its effectiveness. Countries should consider the following when developing monitoring and evaluation plans for introduction and scale-up strategies:

- The application of 7.1% chlorhexidine to the umbilical cord reduces risk of omphalitis, even in low-mortality settings where there is no clear evidence of impact on overall newborn mortality risk.
- Although substantial reductions in mortality were seen in trials in South Asia,<sup>3</sup> application of 7.1% chlorhexidine to the umbilical cord did not significantly reduce NMR in the study sites in Tanzania<sup>7</sup> or Zambia.<sup>8</sup> This means that although study results have shown a clear impact on mortality risk in populations with high NMR (30-40 deaths/1,000 live births), we do not have evidence for an impact on mortality risk in populations with low NMR ( $\leq 17$  deaths/1,000 live births).
- In high-mortality settings, use of 7.1% chlorhexidine on the umbilical cord reduced deaths regardless of whether infants were born at home or in a facility.<sup>5,6</sup>
- Country programs should consider the programmatic context and level of risk in the population rather than place of birth or geographic location when deciding whether or not to prioritize

chlorhexidine introduction.

- Do not expect a measurable mortality reduction benefit from this intervention in countries with low NMR and where hygiene conditions around birth and the first days of life are reliably good.
- It is important to track coverage and use of this new intervention. Suggested performance indicators are available here: <https://www.healthynewbornnetwork.org/hnn-content/uploads/Performance-Indicators-CHX.pdf>.
- The performance indicator list provides a set of common measures for evaluating progress of the chlorhexidine for umbilical cord care intervention scale-up. It is intended to guide monitoring and evaluation efforts at country level, thereby facilitating the tracking of both national and global impact. It is understood that countries are using different strategies for the chlorhexidine intervention and, therefore, have different measurement needs. Country stakeholders and governments should adapt these performance indicators to fit local country contexts based on available evidence and data sources.
- The performance indicator list consists of four indicators: two indicators to measure process, (1) supply chain and (2) commodity distribution; and two indicators to measure outcome, (3) availability and/or geographic coverage and (2) population coverage. Health impact is measured by a change in the neonatal mortality rate (NMR) and is not usually included in programmatic monitoring and evaluation efforts.

## Additional Information

The **Chlorhexidine Working Group** is an international collaboration of organizations committed to advancing the use of 7.1% chlorhexidine digluconate for umbilical cord care through advocacy, research, and technical assistance. For more information on introducing chlorhexidine in your country or for more information on this intervention, contact the Chlorhexidine Working Group at [chx@healthynewbornnetwork.org](mailto:chx@healthynewbornnetwork.org), or visit the technical resource page at <http://www.healthynewbornnetwork.org/issue/chlorhexidine-for-umbilical-cord-care>.

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### References

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- <sup>2</sup> US Department of Health and Human Services, Food and Drug Administration (FDA). *Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics*. Rockville, MD: FDA; 1999.
- <sup>3</sup> Imdad A, Mullany LC, Baqui AH, et al. The effect of umbilical cord cleansing with chlorhexidine on omphalitis and neonatal mortality in community settings in developing countries: a meta-analysis. *BMC Public Health*. 2013;13(Suppl 3):S15.
- <sup>4</sup> Hodgins S. Chlorhexidine and newborn omphalitis and mortality. *The Lancet Global Health*. 2017;5(3):270-271.
- <sup>5</sup> Mullany LC, Arifeen SE, Khatri SK, et al. Impact of Chlorhexidine Cord Cleansing on Mortality, Omphalitis, and Cord Separation Time Among Facility-Born Babies in Nepal and Bangladesh. *Pediatric Infectious Disease Journal*. 2017.
- <sup>6</sup> Zaidi AKM, Huskins WC, Thaver D, Bhutta ZA, Abbas Z, Goldmann DA. Hospital-acquired neonatal infections in developing countries. *The Lancet*. 2005;365(9465):1175–1188.
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- <sup>8</sup> Semrau KEA, Herlihy J, Grogan C, et al. Effectiveness of 4% chlorhexidine umbilical cord care on neonatal mortality in Southern Province, Zambia (ZamCAT): a cluster-randomised controlled trial. *Lancet*. 2016.