MINISTRY OF HEALTH

A guideline for the use of Chlorhexidine for newborn umbilical cord care in Kenya

April 2016

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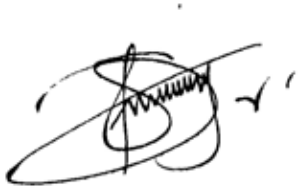
FOREWORD

This guideline is for the use of 7.1% Chlorhexidine digluconate, which delivers 4% Chlorhexidine for newborn umbilical cord care, and guides application of Chlorhexidine both at health facilities and at home. It should be used by doctors, clinical officers, midwives, nurses, and other health care workers who are responsible for the delivery and care of newborns. The guideline also provides instructions to community health volunteers, mothers, and other newborn caregivers for the use of Chlorhexidine at home. In addition, it is useful for teaching those in medical-training institutions. It provides step-by-step instructions for the application of Chlorhexidine to the umbilical cord immediately after delivery and in the immediate postnatal period.

The guideline highlights the high contribution of newborn infections to newborn mortality and provides a brief overview of the evidence supporting the use of Chlorhexidine as an effective intervention for the reduction of newborn deaths. In 2013, the World Health Organisation included Chlorhexidine in the WHO Essential Medicines list and the Ministry of Health has included it in the Kenya Essential Medicines List.

This guideline is accompanied by simplified job aids (Annexes 1 to 4), providing step-by-step instructions for the application of Chlorhexidine. At health facilities, these job aids can be enlarged for use in delivery rooms (Annexes 1 to 2), newborn units (Annexes 3 to 4), and post-natal wards (Annexes 3 to 4). The job aids can be replicated and issued to community health volunteers, mothers, and newborn caregivers to provide guidance for use of Chlorhexidine at home. It is envisioned that guidelines on use of Chlorhexidine for umbilical cord care will be integrated into other relevant Maternal and Newborn Health guidelines.

I urge all stakeholders to embrace and implement these guidelines in order to contribute to reduction of newborn morbidity and mortality in Kenya.



Dr. Jackson Kioko
Ag. Director of Medical Services
Ministry of Health

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The Ministry of Health appreciates all those who contributed towards the successful completion of this guideline for the use of 7.1% Chlorhexidine for newborn umbilical cord care in Kenya. The guideline was developed through a participatory process that involved key stakeholders in the Newborn Health Working Group.

The following institutions are acknowledged for their contributions:

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- World Health Organization (WHO)
- United Nations International Children's Emergency Fund (UNICEF)
- PATH
- University of Nairobi
- Save the Children International
- Maternal and Child Survival Project (MCSP)/Johns Hopkins Program for International Education in Gynecology and Obstetrics (JHPIEGO)
- Clinton Health Access Initiative (CHAI)

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1. INTRODUCTION

1.1. Background

In the last 15 years, the under-five mortality rate in Kenya has reduced by over 50% (from 114 to 52 deaths per 1,000 live births), while newborn mortality has reduced by 22%, (from 28 to 22 deaths per 1,000 live births).[1,2] Neonatal deaths currently account for 42% of all deaths of children under five years and 56% of deaths of infants in Kenya, with newborn infections contributing 10% of under-five mortality.[2]

Globally, infections such as neonatal sepsis, pneumonia, and tetanus are major causes of mortality among newborns accounting approximately 20% of newborn deaths. These infections can be prevented through the scale-up of clean practices at delivery and in the postnatal period as well as scale up of Chlorhexidine use for umbilical cord care.[3]

The addition of Chlorhexidine as part of newborn umbilical cord care is justified in a context where universal precautions for infection prevention in health facilities are not always observed and 39% of deliveries still occur at home.[2] Additionally, cultural practices related to umbilical cord care at home (such as the application of cow dung, soil, breast milk or other organic extracts) significantly increase the risk of infection.

1.2. Importance and choice of Chlorhexidine for umbilical cord care

Chlorhexidine digluconate is a broad-spectrum antiseptic that has been used for many years as an antiseptic in various formulations and for various indications. Chlorhexidine for umbilical cord care has a concentration of 7.1% chlorhexidine digluconate, which delivers 4% chlorhexidine. It is specifically formulated for umbilical cord care and is safe and effective for reducing bacterial colonization on the skin and umbilical stump of the newborn. The evidence supporting the use of Chlorhexidine as an effective intervention for the reduction of newborn deaths is drawn from Clinical studies as well as from systematic reviews. The results of these studies pulled together showed that the application of Chlorhexidine on the umbilical cord immediately after cord cutting reduces neonatal mortality by up to 23% and prevents infection by 38-68%. [4,5,6,7,8,9]

[1] Central Bureau of Statistics, Kenya. Ministry of Health, ORC Macro, ORC Macro. MEASURE/DHS+ (Programme). Kenya: demographic and health survey 1997. *Central Bureau of Statistics*. 1998.
[2] Central Bureau of Statistics, Kenya. Ministry of Health, ORC Macro, ORC Macro. MEASURE/DHS+ (Programme). Kenya: demographic and health survey 2013. *Central Bureau of Statistics.* 2014.
[3] 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. *The Lancet.* 2015;385(9966):430-440.
[4] El Arifeen S, Mullany LC, Shah R, et al. The effect of cord cleansing with chlorhexidine on neonatal mortality in rural Bangladesh: a community-based, cluster-randomised trial. *The Lancet.* 2012;379(9820):1022-1028
[5] Mullany LC, Darmstadt GL, Khatry SK, et al. Topical applications of chlorhexidine to the umbilical cord for prevention of omphalitis and neonatal mortality in southern Nepal: a community-based, cluster-randomised trial. *The Lancet.* 2006;367(9514):910-908.
[6] Soofi S, Cousens S, Imdad, et.al, Topical application of Chlorhexidine to neonatal umbilical cord for prevention of oomphalitis and neonatal mortality in a rural district of Pakistan; a community based, cluster randomised trial, Lancet 2012,379:1029-1036

This evidence led the World Health Organization (WHO) to include Chlorhexidine in its 2013 Essential Medicines List, and recommend the use of Chlorhexidine once daily for the first week of life for newborns who are born at home in settings with high neonatal mortality (30 or more neonatal deaths per 1,000 live births). This is a shift from the previous WHO recommendation, which encouraged health care workers and mothers to practice dry cord care and discouraged the application of substances to the cord, although use of an antimicrobial to the cord was recommended according to a local situation.

In 2013, the Kenya Ministry of Health (MOH) and its partners constituted a panel that reviewed the existing evidence and recommended the use of Chlorhexidine for newborn umbilical cord care at the health facility level and for continued use at home until the cord separates.

1.3. Available formulations

Chlorhexidine for newborn umbilical cord care is available in two forms: gel and solution. The WHO has recommended both forms in the Essential Medicines List and in their postnatal care guidelines.[9,10]

A country's adoption and use of either the gel or solution form could be determined by information from formative research results, government or stakeholder consultations, and the available product supply. In Kenya, a market survey conducted in 2014 showed that there was no strong preference by recently pregnant women, policymakers, and health care providers for one form over the other. Therefore, the Ministry of Health (MoH) recommends the availability and use of both forms in the country.[11]

[7] 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(3):1

[8] Karumbi J,Mulaka M, Aluvaala J, English M, Opiyo N, Topical umbilical cord care for prevention of infection and neonatal mortality Pediatr Infect Dis J . 2013;32(1):78-83

[9] World Health Organization (WHO). 18th WHO Model List of Essential Medicines. Geneva: WHO; 2013.

[10] World Health Organization (WHO). WHO recommendations on postnatal care of the mother and newborn. Geneva: WHO; 2014

2. STEPS FOR APPLICATION OF CHLORHEXIDINE FOR NEWBORN UMBILICAL CORD CARE

2.1. Umbilical cord care practice immediately after delivery

- In preparation for the delivery, ensure the Chlorhexidine is on the delivery tray.
- Delay clamping of the umbilical cord for 2 to 3 minutes.
- Change gloves, this means remove gloves used to deliver baby, wash your hands properly with soap and running water, put on another pair of sterile gloves.
- Clamp and cut the umbilical cord at 2 cm and 5 cm from the baby's abdomen.
- Ensure there is no bleeding. **If bleeding is noted, place a second tie between the skin and the first tie.**
- Open the container of Chlorhexidine. Apply Chlorhexidine to the base of the umbilical cord, the cord stump, and the tip of the cord. Ensure that the entire cord is covered with Chlorhexidine.
    - If using gel, spread the gel using your index finger **(refer to Annex 1).**
    - If using solution, apply the Chlorhexidine on the umbilical cord by squeezing the dropper bottle. When using solution, do not spread the Chlorhexidine on the cord using your finger or any other material **(refer to Annex 2).**
- Do not clean off the Chlorhexidine from the umbilicus after application. Do not wrap or bind the umbilical area after Chlorhexidine application. Do not apply anything else, except for Chlorhexidine.
- In the postnatal period, apply Chlorhexidine once daily up to the seventh day or until the umbilical cord falls off, whichever happens first.
- Remove and discard gloves used to apply Chlorhexidine

2.2. Umbilical cord during the postnatal period

- Wash your hands with soap and running water.
- Open the container of Chlorhexidine. Apply the Chlorhexidine to the base of the umbilical cord, cord stump, and tip of the cord. Ensure the entire cord is covered with Chlorhexidine.
    - If using gel, spread the gel using your index finger **(refer to Annexes 1 and 3).**
    - If using solution, apply the Chlorhexidine on the umbilical cord using an appropriate dropper. When using solution, do not spread the Chlorhexidine on the cord using your finger or any other material **(refer to Annexes 3 and 4).**
- Wash hands after application.
- Do not clean off the Chlorhexidine from the umbilicus after application. Do not wrap or bind the umbilical area after Chlorhexidine application. Do not apply anything else, except for Chlorhexidine.
- Continue application once daily up to the seventh day or until the umbilical cord falls off, whichever happens first.

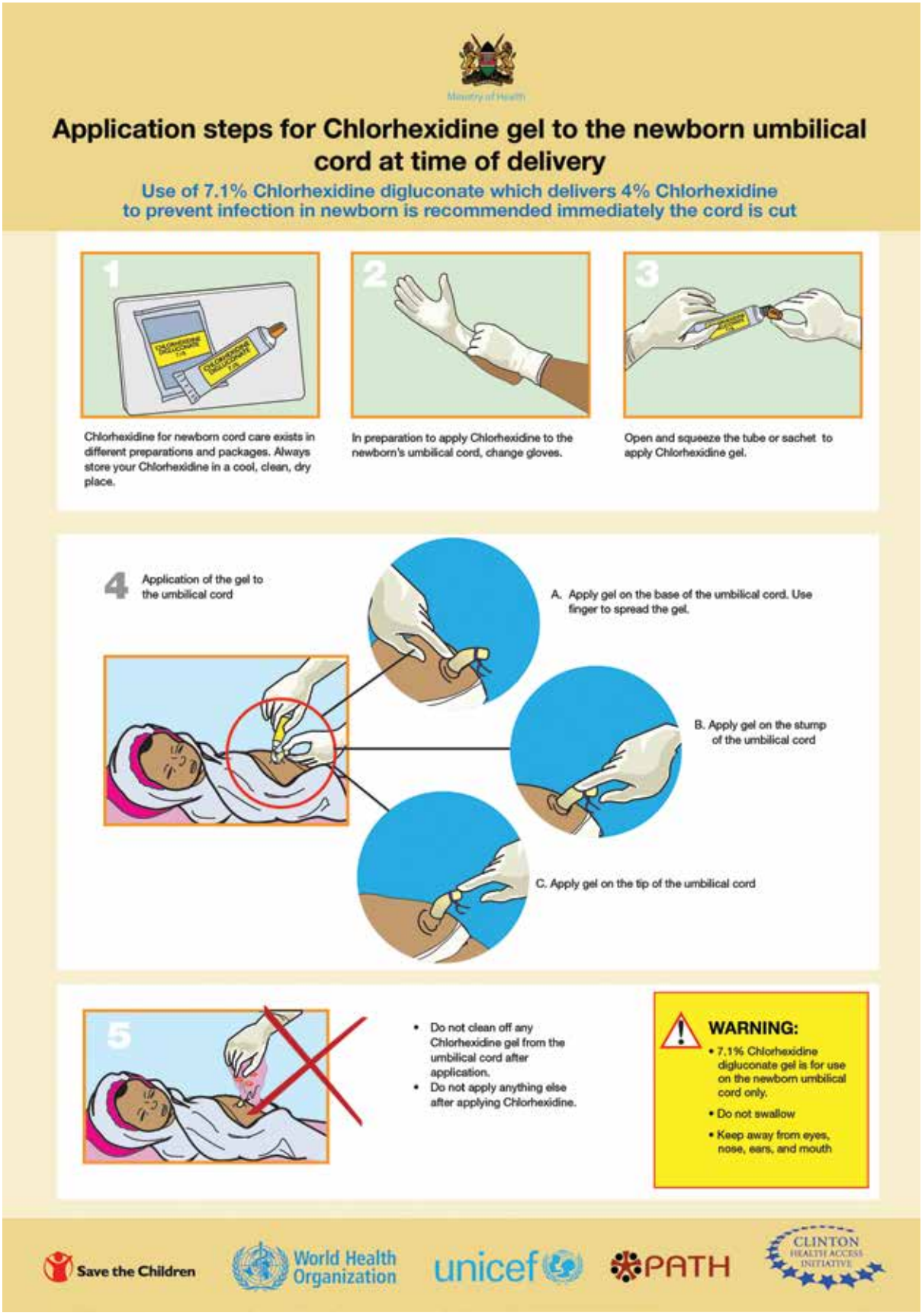
3. SAFETY PROFILE OF CHLORHEXIDINE

There have been no documented side effects associated with Chlorhexidine use for umbilical cord care when used as described earlier; however, rashes and skin erythema have been reported with the use of dressings containing a different concentration of chlorhexidine digluconate in preterm babies. A case of severe anaphylaxis has been reported in an adult. If a mother or newborn caregiver notices any unusual reaction, he or she should be advised to consult a health care worker.

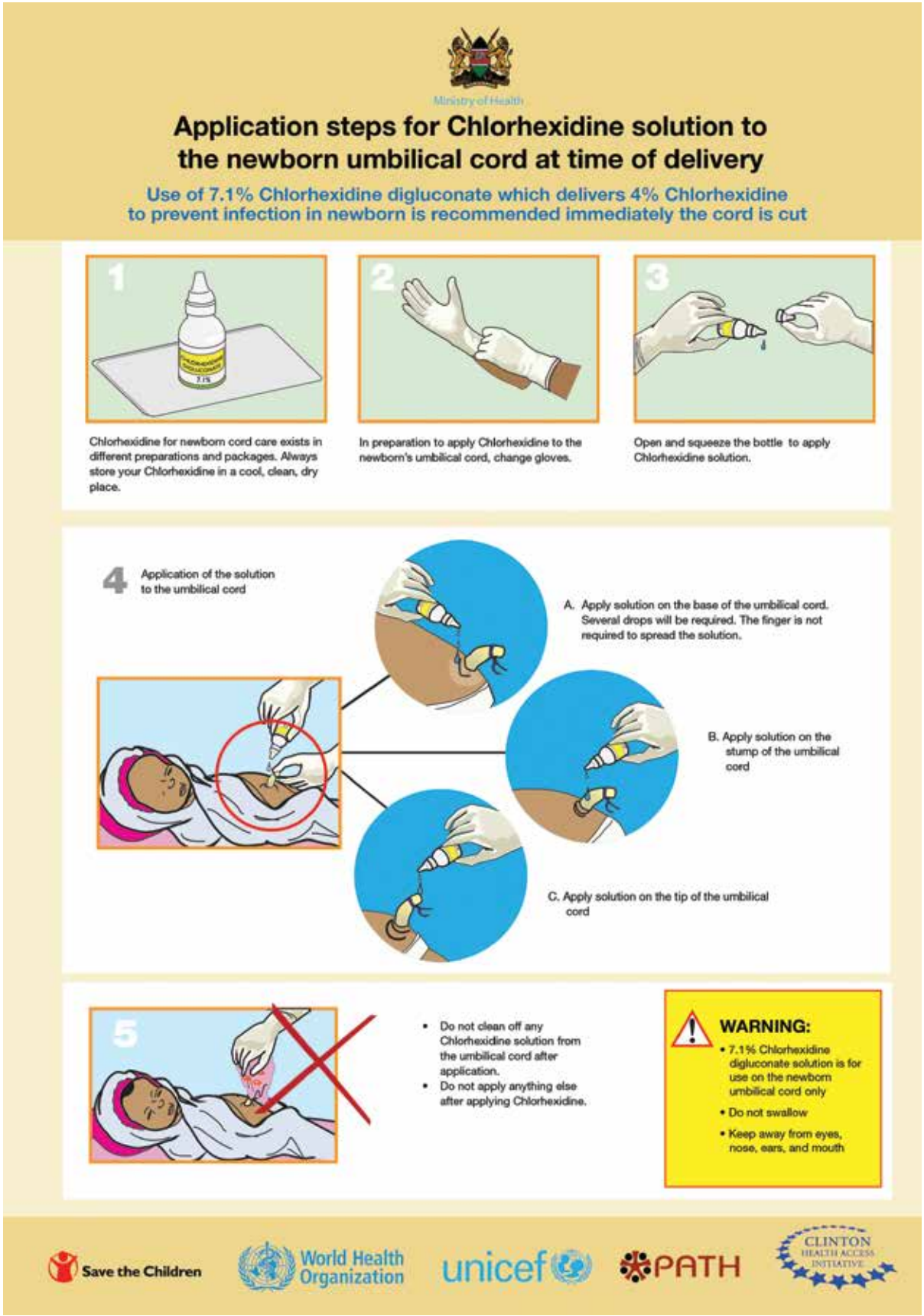
Health care providers should note that the formulation of Chlorhexidine used for umbilical cord care (7.1% w/v), when used as directed, is effective in preventing neonatal sepsis due to bacterial exposure through the fresh umbilical stump. However, it can cause serious harm if applied to the eyes and should not be put into the ear canal. It is important that persons and organizations responsible for using Chlorhexidine for umbilical cord care programs and for distributing Chlorhexidine for umbilical cord care to caregivers ensure that instruction is provided on the appropriate use of the product, including appropriate warnings.

4. ANNEXES

Annex 1: Application steps for Chlorhexidine gel to the newborn umbilical cord at time of delivery



Annex 2: Application steps for Chlorhexidine solution to the newborn umbilical cord at time of delivery



Annex 3: Application steps for Chlorhexidine gel to the newborn umbilical cord in the immediate post delivery period

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Application steps for Chlorhexidine gel to the newborn umbilical cord in the immediate post delivery period

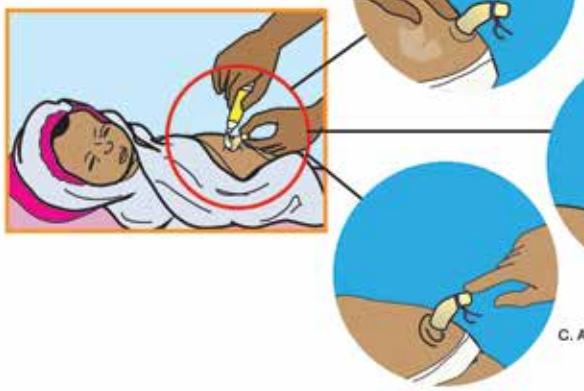
Daily use of 7.1% Chlorhexidine digluconate which delivers 4% Chlorhexidine to prevent infection in the newborn is recommended for 7 days or until the cord falls off

Chlorhexidine for newborn cord care exists in different preparations and packages. Always store your Chlorhexidine in a cool, clean, dry place.

Wash hands properly with soap under running water.

Open and squeeze the tube or sachet to apply Chlorhexidine gel.

4 Application of the gel to the umbilical cord



A. Apply gel on the base of the umbilical cord. Use finger to spread the gel.

B. Apply gel on the stump of the umbilical cord

C. Apply gel on the tip of the umbilical cord

- Do not clean off any Chlorhexidine gel from the umbilical cord after application.
- Do not apply anything else after applying Chlorhexidine.

WARNING:

- 7.1% Chlorhexidine digluconate gel is for use on the newborn umbilical cord only.
- Do not swallow
- Keep away from eyes, nose, ears, and mouth

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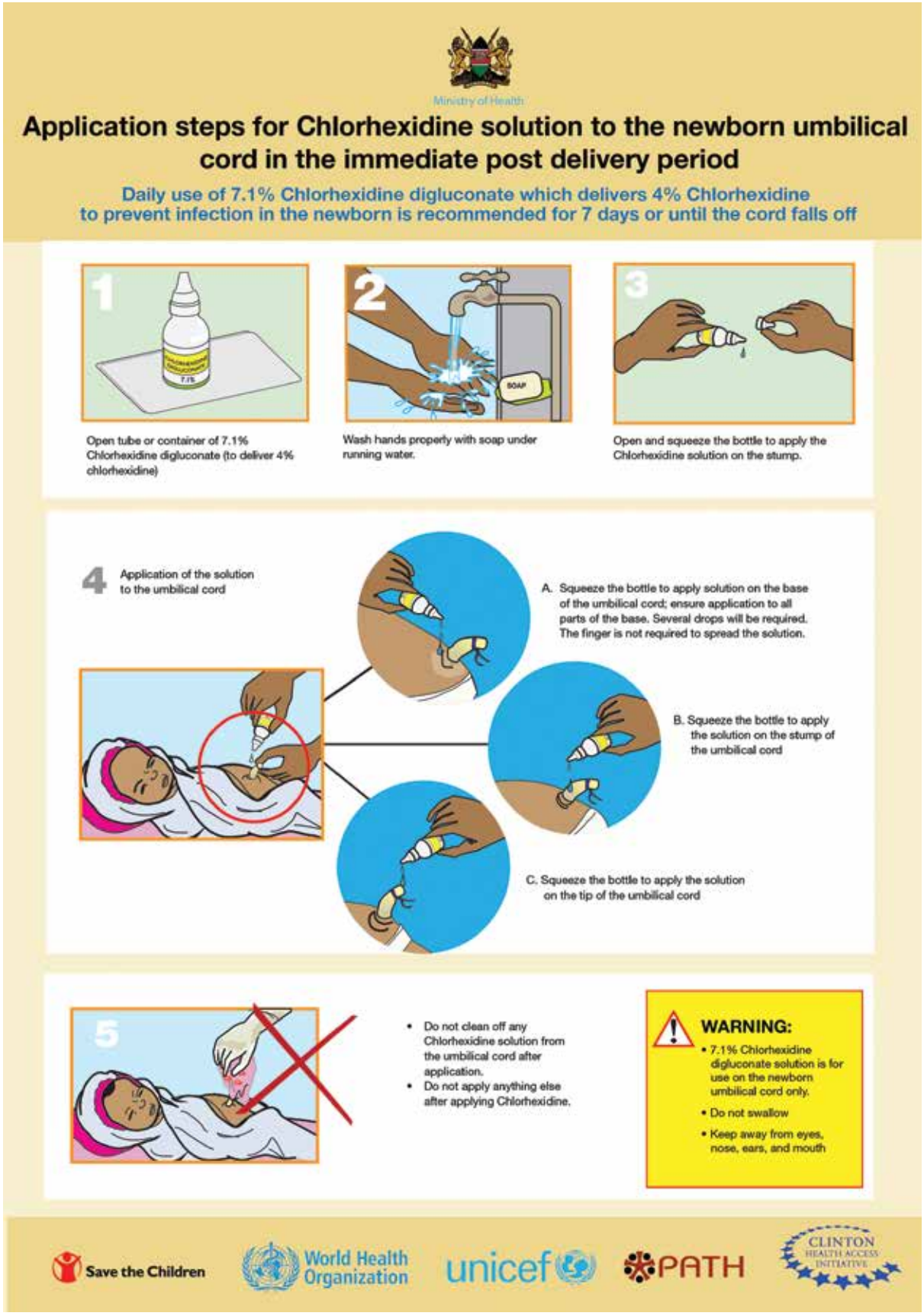
Annex 4: Application steps for Chlorhexidine solution to the newborn umbilical cord in the immediate post delivery period



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