MINISTRY OF HEALTH

THE KENYA GUIDELINE FOR THE USE OF CHLORHEXIDINE DIGLUCONATE 7.1% FOR PREVENTION OF NEWBORN UMBILICAL CORD INFECTION

2022 Revision

Table of Contents

FOREWORD

This guideline is for the use of Chlorhexidine Digluconate 7.1%, which delivers 4% Chlorhexidine for newborn umbilical cord care. It guides the application of Chlorhexidine both at health facilities and at home. It should be used by all health care workers who are responsible for provision of care to the newborns in all facilities. The guideline also provides instructions to, mothers, and other newborn caregivers for safe use of Chlorhexidine Digluconate 7.1% 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 a safe and effective intervention for the reduction of newborn deaths. In 2013, the World Health Organisation included Chlorhexidine Digluconate 7.1% in the WHO Essential Medicines list and the Ministry of Health has included it in the Kenya Essential Medicines List. In Kenya the use of chlorhexidine Digluconate 7.1% as a recommended intervention for prevention of newborn umbilical cord infection began in 2016. The proportion of newborns receiving CHX for cord care in Kenya currently stands at 67.1% (KHIS 2021). In line with the CHX scale up plan 2021, the goal is to further increase the uptake to 80% and above in all health care facilities by 2026.

This guideline is accompanied by simplified Information Education and Communication (IEC) materials targeting health care providers, mothers or care givers, (Annexes), providing step-by-step instructions for the application of Chlorhexidine. At health facilities, these job aids can be enlarged for use in all service delivery points The IEC materials can be replicated and issued to, mothers, and newborn caregivers to provide guidance for use of Chlorhexidine Digluconate 7.1% at home. It is envisioned that guidelines on use of Chlorhexidine Digluconate 7.1% 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. Patrick Amoth (EBS)
Director General
Ministry of Health

ACKNOWLEGMENT

The Ministry of Health appreciates all those who contributed towards the successful revision of this guideline for the use of Chlorhexidine Digluconate 7.1% for newborn umbilical cord care in Kenya. The guideline was developed through a participatory process that involved key stakeholders in the New-born Health Working Group.
The following institutions are acknowledged for their contributions:

- Ministry of Health, Department of Family Health
- World Health Organization (WHO)
- United Nations International Children's Emergency Fund (UNICEF)
- University of Nairobi
- Save the Children International
- Nutrition International
- USAID

The Ministry further recognizes the efforts of the core team that revised this guideline and worked diligently to its completion. It comprised staff from the MOH: Dr. Issak Bashir, Dr. Caroline Mwangi, Allan Govoga, Grace Wasike, Martin Matingi, Enock Sigilai and Elsa Odira, Dr. Elmelda Manguro, Dr. Roy Mwenda Moki (Pumwani Maternity Referral Hospital – Nairobi County Government); Dr. Lynn Kanyuuru, Teresa Akun and David Githinji (Save the Children International); Peter Kaimenyi (USAID), Stephen Mwangi, (Nutrition International)

ABBREVIATIONS

CHAs	Community Health Assistants
CHVs	Community Health Volunteers
CHX	Chlorhexidine Digluconate 7.1%
CMNH	Community Maternal Newborn Health
HCP	Health Care Providers
HRH	Human Resource for Health
IEC	Information Education Communication
KEML	Kenya Essential Medicine List
KQMH	Kenya Quality Model of health
LMIS	Logistic Management Information System
MCH	Maternal Child Health
MNH	Maternal Newborn Health
MOH 216	Mother Child Health Handbook
MOH 333	Maternity Register
MOH 711	Integrated Summary; Reproductive & Child Health, Medical & Rehabilitation Services
MOH	Ministry of Health
NHTWG	Newborn Health Technical Working Group
SDGs	Sustainable Development Goals
TOTs	Trainers of Trainers
WHO	World Health Organization
PPB	Pharmacy and Poisions Board
PV	Pharmacovigilance
SADR	Suspected Adavance Drug Reaction

1. INTRODUCTION

1.1 Background

Globally, child survival remains an urgent concern. The first 28 days of life – the neonatal period – are the most vulnerable time for a child's survival. Children face the highest risk of dying in their first month of life, at a global rate of 18 deaths per 1,000 live births. In 2018, an estimated 2.5 million newborn died in the first month of life– approximately 7,000 every day. About a third of all neonatal deaths tend to occur on the day of birth and close to three quarters in the first week of life[1][2].These findings suggest that focusing on the critical periods before and immediately following birth, is essential to saving more newborn lives. Accelerating the scale up of high impact intervention that address the major causes of neonatal death is critical for countries to achieve the health targets for SDG 3 of reducing neonatal mortality to at least as low as 12 per 1000 live births by 2030[3].

In Kenya, while under-5 mortality decreased by 50% since 1990, neonatal mortality (defined as death in the first 28 days of life) has remained relatively stagnant and currently stands at 22 per 1,000 live births according to the 2014 Kenya Demographic and Health Survey. Recent estimates by the UN Inter-agency Group for Child Mortality Estimation showed that neonatal mortality rate in Kenya reduced to 21 per 1000 live births in 2020. Newborn deaths account for 42% of all deaths of children under five years and 56% of infant (less than one year) deaths. The main causes of neonatal death are birth asphyxia (31.6%), prematurity (24.6%), and neonatal sepsis (15.8%). Chlorhexidine Digluconate, a broad-spectrum antiseptic, has been in use in various formulations and for various indications. Chlorhexidine Digluconate 7.1% aqueous solution or gel, (delivering 4% chlorhexidine and herein referred to as CHX 7.1%), is recommended for neonatal umbilical cord care.

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]

In 2014 WHO released new guidelines on postnatal care, which included an updated recommendation for umbilical cord care: [9]. *"Daily chlorhexidine (Chlorhexidine Digluconate 7.1% 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*

[1]Lawn, Joy E., et al., 'Every Newborn: Progress, priorities, and potential beyond survival', The Lancet, vol. 384, no. 9938, 12 July 2014, pp. 189-205.

[2]Sankar, M Jeeva, et al., 'When Do Newborns Die? A systematic review of timing of overall and cause-specific neonatal deaths in developing countries', Journal of Perinatology, vol. 36 (Suppl 1: S1-S11), May 2016.

[3]Sustainable Development Goal 3. https://www.who.int/topics/sustainable-development-goals/targets/en/

[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

[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

[9] WHO 2014 Revised Recommendations on Cord Care

*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."*The addition of Chlorhexidine Digluconate 7.1% 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 home deliveries are prevalent. Additionally, cultural practices related to umbilical cord care at home (such as the application of cow dung, soil, breast milk or other organic extracts) and outdated umbilical cord care practices by health care providers (e.g. use of methylated spirit and normal saline) significantly increase the risk of infection.

1.2 Importance and choice of Chlorhexidine Digluconate 7.1% for umbilical cord care

Chlorhexidine Digluconate 7.1% (delivering 4% chlorhexidine) is the recommended concentration for prevention of newborn umbilical cord infections. 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. It is used for prevention of cord infections and not for treatment, in case of umbilical infections antimicrobials are recommended.

This evidence led the World Health Organization (WHO) to include Chlorhexidine Digluconate 7.1% for cord care in its 2013 Essential Medicines List, while in Kenya it was included in the Kenya Essential Medicines List in 2016. The Ministry of Health subsequently developed policy and guidelines for its use by health care providers in 2016.

1.3 Available formulations

Chlorhexidine Digluconate 7.1% for newborn umbilical cord care is available in two product formulations: gel and solution. WHO has recommended both forms in the Essential Medicines List and in their postnatal care guidelines. 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 formulation over the other. Therefore, the Ministry of Health (MoH) recommends the availability and use of both formulations in the country.

2. Steps for Application of Chlorhexidine Digluconate 7.1% For Prevention of New-born Umbilical Cord Infection

2.1 Umbilical cord care practice immediately after delivery

In preparation for a delivery, the health care worker should ensure Chlorhexidine Digluconate 7.1% is on the delivery tray.

a) Deliver the baby and immediately place the baby on the mother's abdomen, wipe the baby using a dry, soft and clean cloth and cover the baby with a clean dry cloth to keep the baby warm, change gloves

b) Delay clamping of the cord for 1-3 minutes. Place a cord clamp 2cm from the newborn's abdomen and forceps 5cm from the newborn's abdomen and cut in the middle.

c) Open the Chlorhexidine Digluconate 7.1%

- If using **GEL**, squeeze the container to get enough gel and spread using your index finger (refer to Annexes 1)
- If using **SOLUTION,** apply on the umbilical cord using an appropriate dropper. When using **SOLUTION,** do not spread on the cord using your finger or any other material

d) Apply the Chlorhexidine Digluconate 7.1% to the base of the umbilical cord, cord stump, and tip of the cord.

e) Ensure the entire cord is covered with Chlorhexidine Digluconate 7.1%, wait for the gel/ solution to dry.

f) Remove and discard gloves used to apply Chlorhexidine Digluconate 7.1%

g) Wash your hands with soap and running water

h) Ensure the baby is kept warm

NOTE:

- For term babies, continue applying Chlorhexidine Digluconate 7.1% gel once daily for 7 days

NB: *For PRETERM BABIES, apply ONCE after cutting the umbilical cord. Multiple applications of CHX onto the umbilical stump of preterm babies is not recommended due to their delicate skin as it may cause skin irritation.*

2.2 New-born umbilical cord care during the post-natal period

During the immediate postnatal period, CHX should be applied once daily for seven days, only for term newborns.

a) Wash your hands with soap and running water.

b) Open the Chlorhexidine Digluconate 7.1%

- If using **GEL,** spread the gel using your index finger (refer to Annexes 1)
- 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

c) Apply the Chlorhexidine Digluconate 7.1% to the base of the umbilical cord, cord stump, and tip of the cord.

d) Ensure the entire cord is covered with Chlorhexidine Digluconate 7.1%.

e) Wash hands after application with soap and running water.

CAUTION: *In case Chlorhexidine Digluconate 7.1% accidentally gets into the eyes, rinse both eyes thoroughly with clean running water or normal saline and urgently seek medical review in the nearest health facility*

Dos	Don'ts
7.1% CHX is used to prevent umbilical cord infections	Don't use 7.1% CHX to treat umbilical cord infections.
7.1% CHX is only intended for umbilical cord care	Don't apply 7.1% CHX to any other body surface except the Umbilical cord
1st application of 7.1% CHX is immediately after birth or within 24hrs after delivery.	Don't apply 7.1% CHX on an infected cord
1st application of 7.1% CHX is supposed to be done by health care worker. Demonstrate to the caregiver on proper application of 7.1% CHX before discharge.	Don't issue 7.1% CHX to mothers or caregivers without demonstrating its proper use. Don't apply anything else after applying 7.1% CHX
Always clean and dry the umbilical cord with warm water before subsequent new application	Don't clean off 7.1% CHX from the umbilical cord after first application. Wait for 24 hours

2.3 Pharmacovigilance of Chlorhexidine Digluconate 7.1%

Pharmacovigilance (PV) is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problem (WHO, 2002). The Ministry of Health through the Pharmacy and Poisons Board (PPB) conducts pharmacovigilance of Chlorhexidine Digluconate 7.1% (CHX) to ensure availability of high standards of quality, efficacious CHX and promote its safe and rational use in the country.

2.3.1 Safety profile of Chlorhexidine Digluconate 7.1%

When used as directed, the safety profile of chlorhexidine Digluconate 7.1% has been well established in newborns. As with all medications, care must be taken to ensure that the product is used appropriately. Chlorhexidine Digluconate 7.1% should only be applied on the umbilical stump and the skin around the base of the umbilical cord.

The appropriate use of Chlorhexidine Digluconate 7.1% for umbilical cord care has shown to be safe, however, side effects such as rashes and skin erythema have been reported with the use of dressings containing a different concentration of chlorhexidine. In the event the health care provider suspects an adverse drug reaction following the use of Chlorhexidine Digluconate 7.1%, stop application. 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%), 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, nose and ear canal.

It is important that health care providers and stakeholders responsible for using and distributing Chlorhexidine for umbilical cord care, ensure that accurate instructions on the appropriate use of the product, including appropriate warnings to the end user.

In an effort to bolster pharmacovigilance reporting, the PPB has developed digital platforms for collection and processing of information through the following platforms;

1. Web portal (PvERS II) via the link https://pv.pharmacyboardkenya.org/
2. Toll free USSD code *271# for PV reporting at community level
3. PPB_APP, a mobile phone-based application available on play store as "mPvERS"

The scope of reports for pharmacovigilance of chlorhexidine Digluconate 7.1% includes:

1. Report on any suspected adverse drug reactions of chlorhexidine Digluconate 7.1% that could include local hypersensitivity reactions and severe allergic reactions including anaphylaxis (characterized by wheezing difficulty in breathing, facial edema, severe rash or hypotension and shock) - Annex 3.2 (a) SADR form
2. Reports on medication errors associated with inappropriate use / mistaken application of Chlorhexidine Digluconate 7.1% such as wrongful application of chlorhexidine Digluconate 7.1% in the eyes, ears nose and mucus membrane or dispensing of the wrong concentrations of chlorhexidine other than chlorohexidine Digluconate 7.1% umbilical cord care (recommended by WHO and MOH) – Annex 3.2 (b) medication error reporting form
3. Reporting on any poor-quality chlorhexidine and post market surveillance in the Kenyan market. e.g., damaged package, defective, colour change particulate matter in the gel or solution – Annex 3. 2 (c) form for reporting suspected poor quality medical products and health technologies.

2.4 Documentation and reporting

Proper documentation and reporting of chlorhexidine Digluconate 7.1% use at the health facility is critical for the safe and affective use of this intervention in Kenya. The Ministry of Health has put in place an information system to facilitate accurate, complete, and timely reporting of CHX intervention in the Kenya Health Information System (KHIS). The CHX data elements have been incorporated in primary data sources including the Mother and Child Health Handbook (MOH 216) and the Maternity Register (MOH 333) to be completed by health care workers in the maternity. In addition, CHX indicator is summarized and reported through MOH 711 from each facility and uploaded in the KHIS at the end of every month.

This information is useful in tracking coverage and assess the quality of care for newborns at county and national level, forecasting, quantification and costing of CHX commodity to ensure sustainable availability of the product in all heath care facilities.

3. ANNEXES

3.1. ANNEX 1: CHX IEC MATERIALS

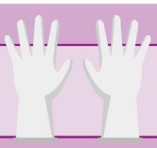
a) Job aid

Ministry of Health

CHLORHEXIDINE DIGLUCONATE 7.1% GEL FOR UMBILICAL CORD CARE HEALTH WORKERS JOB AID

MoH Kenya and WHO now recommend Chlorhexidine Digluconate 7.1% gel as the safest and most effective intervention for umbilical cord care.

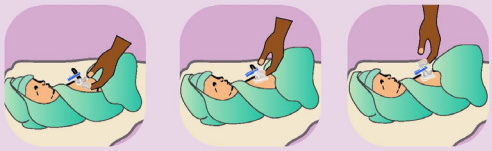
1. Wear clean gloves.



2. Open tube/ sachet of the Chlorhexidine Digluconate 7.1% gel.

3. **Immediately after cutting the cord**, apply Chlorhexidine Digluconate 7.1% gel on the base, then proceed to the stump and finally the tip of the umbilical cord.

   Do this daily (once every 24 hours) for seven days or until the cord falls off, whichever comes first.



4. Ensure application of the Chlorhexidine Digluconate 7.1% gel to all parts of the umbilical cord.

5. Instruct and observe the mother/ caregiver on how to apply Chlorhexidine Digluconate 7.1% gel while observing aseptic technique.

6. Counsel male partners and family members on the use of Chlorhexidine Digluconate 7.1% gel for umbilical cord care.

7.
   - Chlorhexidine Digluconate 7.1% gel for umbilical cord care should be available at all labour and post-natal wards (after delivery).
   - Mothers can also buy it from the chemist. It is safe, accessible and affordable; compared to treating sepsis cord infection.

- **DO NOT** wipe off Chlorhexidine Digluconate 7.1% gel from the umbilical cord after application until after 24 hours.
- **DO NOT** apply anything other than Chlorhexidine Digluconate 7.1% gel for umbilical cord care.
- **If** applied to the eye, it causes blindness. DO NOT apply on any other part of the body.

NOTE:

For term babies admitted in hospital, continue applying Chlorhexidine Digluconate 7.1% gel once for 7 days or until the umbilical cord falls off (whichever is earlier).

REMEMBER:

- Emphasize on Chlorhexidine Digluconate 7.1% gel for umbilical cord care during ante-natal clinic visits, after delivery and before discharge.
- Advise the mother to immediately return to hospital and stop application of Chlorhexidine Digluconate 7.1% gel in case of redness of the umbilical cord, hotness of the body, draining pus, inability to breast-feed and reduced movements/ physical activity of the new born.

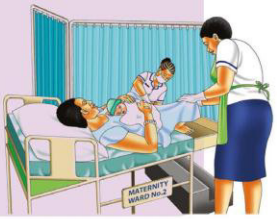
b) Key messages

Ministry of Health

UMBILICAL CORD CARE
KEY MESSAGES

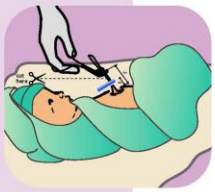
For Umbilical Cord Care, use Chlorhexidine Digluconate 7.1% Gel.

1. Deliver the baby and immediately place the baby on the mother's abdomen.



2. Wipe the baby using a dry, soft and clean cloth; and cover the baby with a clean dry cloth to keep the baby warm.

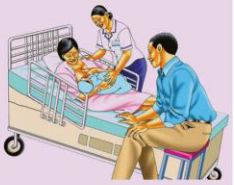
3. Delay clamping of the cord for 1-3 minutes or until the cord stops pulsating. Place a cord clamp 2cm from the newborn's abdomen and forceps 5cm from the newborn's abdomen and cut in the middle.



4. **Immediately after cutting the cord**, apply Chlorhexidine Digluconate 7.1% gel on the base, then proceed to the stump and finally the tip of the umbilical cord.

   Do this daily (once every 24 hours) for seven days or until the cord falls off, whichever comes first.

5. Initiate breastfeeding within one hour after delivery; and delay bathing the baby at least 24 hours after birth.



6. Ensure the baby is kept warm.

7. In case Chlorhexidine Digluconate 7.1% gel accidentally gets into the baby's eyes, rinse both eyes **thoroughly** with clean running water or normal saline and urgently seek medical review.

c) Posters

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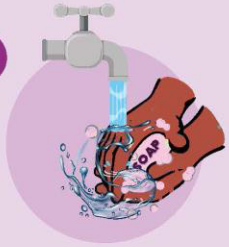
APPLICATION OF CHLORHEXIDINE DIGLUCONATE 7.1% GEL FOR NEWBORN CORD CARE AFTER BIRTH.

1

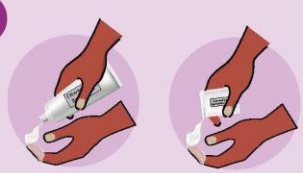


Wash hands properly with soap under running water.

2

Open Chlorhexidine Digluconate 7.1% gel for umbilical cord care.

3



Squeeze the Chlorhexidine Digluconate 7.1% gel on the finger

Daily use of Chlorhexidine Digluconate 7.1% for umbilical cord care to prevent infection in the newborn is recommended for 7 days or until the cord falls off (whichever is earlier).

4

Apply gel on the base of the umbilical cord and ensure application to all parts of the base.

5

Apply gel on the stump of the umbilical cord.

6

Apply gel on the tip of the umbilical cord.

REMEMBER:
Always clean and dry the umbilical cord before subsequent new applications.

DO NOT

- **DO NOT** clean off any Chlorhexidine Digluconate 7.1% gel from the umbilical cord after FIRST application. Wait for 24 hours.
- **DO NOT** apply anything else on the umbilical cord after applying Chlorhexidine Digluconate 7.1% gel.
- **DO NOT** use Chlorhexidine Digluconate 7.1% gel if umbilical cord is infected. **STOP APPLICATION** immediately and seek medical advice from the nearest health facility.

d) Flipchart first

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CHLORHEXIDINE DIGLUCONATE 7.1% GEL FOR UMBILICAL CORD CARE FLIP CHART

e) Fact sheet

Ministry of Health

CHLORHEXIDINE DIGLUCONATE 7.1% GEL FOR UMBILICAL CORD CARE

FACT SHEET

According to Kenya Demographic and Health Survey (KDHS) 2014 Neonatal deaths account for 42% of deaths for children under five years. Newborn infection contributes to 10% of under 5 mortality.

Chlorhexidine is a broad spectrum antiseptic that has been used for many years in various formulations for various indications.

World Health Organization (WHO) recommends Chlorhexidine Digluconate 7.1% gel as the safest and most effective intervention for reducing bacterial colonization of the umbilical cord and reducing sepsis among newborns.

Chlorhexidine Digluconate 7.1% gel should be used with an aim of preventing sepsis among new born babies.

Clinical studies and systematic reviews have shown that the application of Chlorhexidine Digluconate 7.1% gel on the umbilical cord **immediately after cutting the umbilical cord** reduces Neonatal Mortality by up to 23% and prevents infection by 38 - 68%.

1. Chlorhexidine Digluconate 7.1% gel for cord care is an available and affordable gel that is applied to the umbilical cord once daily for seven days or until the cord falls off, whichever comes first. This protects the Newborn from infection.
2. Chlorhexidine Digluconate 7.1% gel has been proved to prevent one quarter of newborn deaths, and two thirds of severe neonatal infections.
3. Chlorhexidine Digluconate 7.1% gel for umbilical cord care does not require refrigeration. However, it must be used, stored and discarded as recommended.

Neonatal deaths account for 42% of deaths for children under five years

Newborn infections contribute to 10% of under 5 mortality

Clinical studies and systematic reviews have shown that the application of Chlorhexidine Digluconate 7.1% gel on the umbilical cord immediately after cutting the umbilical cord reduces Neonatal Mortality by up to 23% and prevents infection by 38 - 68%.

Use Chlorhexidine Digluconate 7.1% Gel for Umbilical Cord Care.

For more information or enquiries, kindly contact:

Ministry of Health, Kenya,

Department of Family Health,

Division of Neonatal & Child Health and Division of Reproductive & Maternal Health,

Website: **www.health.go.ke**

Email: **ps@health.go.ke**

Phone: **+254-20-2717077**

f) FAQs

Ministry of Health

Frequently Asked Questions (FAQs) about Chlorhexidine Digluconate 7.1% gel for Umbilical Cord Care.

1 What is Chlorhexidine Digluconate 7.1% gel for cord care?

It is a broad spectrum antiseptic for umbilical cord care.

2 What is it used for?

Chlorhexidine Digluconate 7.1% gel for cord care is the best way to protect the umbilical cord from infection.

3 Is it safe for use?

Yes. World Health Organization and Ministry of Health (Kenya) recommends **Chlorhexidine Digluconate 7.1% gel** as an **available, affordable, safe and effective** intervention for umbilical cord care.

4 When is it applied?

a. **Immediately after cutting the cord**, then daily for 7 days or until the cord falls off, whichever comes first.

b. For preterm babies, it is applied **only once** after cutting umbilical cord.

5 How is it applied?

a. **Wash hands thoroughly before and after** with soap and clean running water. Squeeze Chlorhexidine Digluconate 7.1% gel on a clean finger and apply at the base of the umbilical cord. Spread the gel from the base through to the stump and finally to the tip of the umbilical cord.

b. After the initial application of Chlorhexidine Digluconate 7.1% gel, remember to clean and dry the umbilical cord every 24 hours before applying a fresh layer of gel. Do this for 7 days or until the cord falls off, whichever comes first.

CAUTION: It SHOULD NEVER be applied in the EYES, EARS, NOSE or MOUTH.

6 Who applies it?

a. The health care provider in labour ward **immediately after cutting the cord**.

b. The Mother or caregiver post-natally/ at home for 7 days or until the cord falls off, whichever comes first.

7 Why is it the recommended option for cord care?

Evidence has shown that the application of Chlorhexidine Digluconate 7.1% gel on the umbilical cord immediately after it is cut reduces Neonatal Mortality by up to 23%.

8 Where can I get Chlorhexidine Digluconate 7.1% gel for umbilical cord care?

It is available at all public health facilities and can also be bought from pharmacies or chemists.

9 What are the CONTRAINDICATIONS of Chlorhexidine Digluconate 7.1% gel?

It should not be applied on a cord that has a pus discharge.

11 What are the possible undesired side effects?

A mild skin rash is the most common but it is a mild side effect.

NOTE

- **In the event that you observe redness around the cord, a pus discharge, hotness of the body and / or refusal to feed, please seek immediate medical attention.**
- **In the event that there is wrongful application/ instillation in the eye, rinse with clean water thoroughly then IMMEDIATELY go to hospital.**

For more information or enquiries, kindly contact:
Ministry of Health, Kenya,
Department of Family Health ,
Division of Neonatal & Child Health and Division of Reproductive & Maternal Health,
Website: **www.health.go.ke**
Email: **ps@health.go.ke**
Phone: **+254-20-2717077**

3.2. ANNEX 2 PHARMACOVIGILANCE TOOLS

a) Suspected adverse drug reaction form-pv1 (-yellow)

(FOM001/MIP/PMS/SOP/001)

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD
P.O. Box 27663-00506 NAIROBI
Tel: (020)-3562107 Ext 114, 0720 608811, 0733 884411 Fax: (020) 2713431/2713409
Email: pv@pharmacyboardkenya.org

IN CONFIDENCE

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

REPORT TITLE: .....

The report is on:
☐Suspected adverse drug reaction ☐Therapeutic ineffectiveness

Report Type:
☐Initial Report ☐Follow Up Report

Product category (Tick appropriate box)
☐Medicinal product ☐Blood and blood products. ☐Herbal product. ☐Cosmeceuticals. ☐Others.....

Institution details

Name of Institution	Contact/Tel No.	Facility Code:	County:

1. Patient Information
Patient name/initials: ..... IP/OP. No: .....
D.O.B/Age: ..... Patient address: ..... WARD/CLINIC:.....
(NAME/NUMBER)
Gender: ☐ Male ☐ Female

Any known allergy ☐No ☐Yes (specify).....
Pregnancy status
☐ Not Applicable ☐ Not pregnant
☐ 1st Trimester ☐ 2nd Trimester ☐ 3rd Trimester
Weight: ..... kg Height: .....cm

2. Suspected Adverse Reaction
Date of onset of reaction: .....
Brief description of reaction:.....

3. Medical History. (Other relevant history including pre-existing medical conditions e.g. allergies, smoking, alcohol use, hepatic/ renal dysfunction etc)
.....
.....

4. List all medicines being currently used by the patient including OTC, and herbal products (* Tick the suspected medicine)**

Tick (√) Suspected drug	INN/ Generic Name	Brand Name	Batch/ Lot No.	Manufacturer	Dose	Route	Frequency	Treatment Period		Indication
								Start date	Stop Date	

5. Past medication history (List all medicines used in the last 3 months including OTC, herbals, if pregnant indicate medicines used in the 1st trimester)

INN/Generic Name	Brand Name	Batch/Lot No.	Manufacturer	Dose	Route	Frequency	Treatment Period		Indication
							Start date	Stop date	

6. Dechallenge/Rechallenge
Did the reaction resolve after the drug was stopped or when the dose was reduced?
☐ Yes. ☐No ☐Unknown. ☐N/A
Did the reaction reappear after the drug was reintroduced?
☐ Yes. ☐ No. ☐Unknown ☐ N/A

7. Any lab investigations and results.....
.....

8. Grading of the reaction /event
I. Severity of reaction : ☐ Mild ☐ Moderate ☐ Severe ☐ Fatal ☐ Unknown
II. Is the reaction serious? ☐Yes ☐No
III. Criteria/reason for seriousness : ☐ Hospitalization/Prolonged Hospitalization ☐ Disability. ☐ Congenital anomality ☐ Life threatening ☐ Death
IV. Action taken : ☐ Drug withdrawn. ☐ Dose reduced. ☐ Dose increased. ☐ Dose not changed ☐ Not applicable. ☐ Unknown
V. Outcome : ☐ Recovered. ☐ Recovered with sequelae. ☐ Recovering ☐ Not recovered ☐ Death. ☐ Unknown

9. Any other comment .....
.....

10. Reporter Details

Name of Initial reporter:	Cadre/designation:	Mobile no: Email:	Date of report:
Name of Person Submitting to PPB if different from reporter:	Cadre/designation:	Mobile no: Email:	Date of Submission:

You need not be certain..... just be suspicious!

Your support towards the National Pharmacovigilance system is appreciated
Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the event.
Patient's identity is held in strict confidence and program staff is not is not expected to and will not disclose reporter's identity in response to any public request.
Information supplied by you will contribute to the improvement of drug safety and therapy in Kenya. Once completed please send to:
The Pharmacy and Poisons Board on the above address

FOR OFFICIAL (PPB) USE ONLY	
ADR Report No: ...../...../.....	Date Received ...../...../.....
Vigiflow Entry Number.....	Date Committed ...../...../.....

b) Medication error reporting form (Light blue)

(FOM21/MIP/PMS/SOP/001)

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD
P.O. Box 27663-00506 NAIROBI
Tel: (020)-3562107 Ext 114, 0720 608811, 0733 884411 Fax: (020) 2713431/2713409
Email: pv@pharmacyboardkenya.org

IN CONFIDENCE

MEDICATION ERROR REPORTING FORM

1. Date of event (dd/mm/yyyy):...../...../..... **2. Time of event** (hh/mm): .....

3. Institution details

Name of Institution:	Contact/Tel No:	Facility Code:	County:

4. Patient Information

Patient initials: ..... D.O.B/Age: ..... Gender: ☐ Male ☐ Female

5. Details on the medication error

Location of event:

☐ Ward (Specify: medical, paeds, ortho) .....
☐ Clinic (Specify: outpatient, dental, specialist) .....
☐ Pharmacy (paeds, main, inpatient, outpatient) .....
☐ Accident & Emergency/Casualty
☐ Others: (Please specify) .....

6. Please describe the error. Include description/ sequence of events and work environment (e.g. change of shift, short staffing, during peak hours). If more space is needed, please attach a separate page. .....

7. In which process did the error occur?
☐ Prescribing
☐ Dispensing (includes filling)
☐ Administration
☐ Others (Please specify)
.....

8. Did the error reach the patient?
☐ Yes ☐ No

9. Was the correct medication, dose or dosage form administered to or taken by the patient?
☐ Yes ☐ No

10. Describe the direct result on the patient (e.g. death, type of harm, additional patient monitoring e.g. BP, heart rate, glucose level etc)
.....
.....
.....

11. Please tick the appropriate Error Outcome Category (Tick one appropriate box below):

NO ERROR	ERROR, HARM	
☐ Potential error, circumstances/events have potential to cause incident	☐ Treatment /intervention required-caused temporary harm ☐ Initial/prolonged hospitalization-caused temporary harm	☐ Caused permanent harm ☐ Near death event

ERROR, NO HARM		ERROR, DEATH
☐Actual error-did not reach patient	☐ Actual error-caused no harm ☐ Additional monitoring required-caused no harm	☐ Death

12. Indicate the possible error cause(s) and contributing factor(s) below (Tick the appropriate box(es):

Staff factors	Work and environment	Task and technology
☐ Inexperienced personnel	☐Heavy workload	☐ Failure to adhere to work procedure
☐ Inadequate knowledge	☐ Peak hour	☐ Use of abbreviations
☐ Distraction	☐ Stock arrangements/storage problem	☐ Illegible prescriptions
Medication related		☐ Patient information/record unavailable/ inaccurate
☐ Sound alike medication		☐ Wrong labelling/instruction on dispensing envelope or bottle/container
☐ Look alike medication		☐ Incorrect computer entry
☐ Look alike packaging		☐ Others (please specify): .....

13. Product details: Please complete the following for products involved. Kindly attach a separate page for additional products

Product Description	Product No. 1 (intended)	Product No. 2 (error)
13.1 Generic name (active ingredient)		
13.2 Brand/ Product Name		
13.3 Dosage form		
13.4 Dose, frequency, duration, route		

Please fill in 13.5-13.7 if error involved look alike (similar) product packaging:

Product Description	Product No. 1 (intended)	Product No. 2 (error)
13.5 Manufacturer		
13.6 Strength/concentration		
13.7 Type and size of container		

14. Suggest any recommendations, or describe policies or procedures you instituted or plan to institute to prevent future similar errors. If available, kindly attach an investigational report e.g. Root Cause Analysis (RCA) .....
.....

Reporter Details

Name of Initial reporter:	Cadre/designation:	Mobile no: Email:	Date of report:
Name of Person Submitting to PPB if different from reporter	Cadre/designation:	Mobile no: Email:	Date of Submission:

FOR OFFICIAL (PPB) USE ONLY	
Medication error report no: ...../...../.....	Medication error type.....
Date report received (dd/mm/yyyy):...../...../.....	Medication error category .....
Vigiflow Entry Number..... Date Committed ...../...../.....	

Your support towards the National Pharmacovigilance system is appreciated

Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the event.

Patient's identity is held in strict confidence and program staff is not is not expected to and will not disclose reporter's identity in response to any public request. Information supplied by you will contribute to the improvement of medicine safety and therapy in Kenya.

Once completed please send to: The Pharmacy and Poisons Board on the above address

3.2.1. Form for reporting poor quality medical products and technologies-pv6 (-pink)

(FOM001/MIP/PMS/SOP/001)

IN CONFIDENCE

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD
P.O. Box 27663-00506 NAIROBI
Tel: (020)-3562107 Ext 114, 0720 608811, 0733 884411 Fax: (020) 2713431/2713409
Email: pv@pharmacyboardkenya.org

FORM FOR REPORTING SUSPECTED POOR-QUALITY MEDICAL PRODUCTS AND HEALTH TECHNOLOGIES

Product category (Tick appropriate box):

☐Medicinal product ☐Blood and blood products. ☐Other.....
☐Herbal product ☐Medical device/ Invitro Diagnostics
☐Vaccine ☐Cosmeceuticals

Name of Facility: County: Sub- County:
Facility Address. Facility Telephone:

PRODUCT IDENTITY

Bran Name				Generic Name			
Batch/Lot Number/ Unique identifiers (blood & blood products)		Date of Manufacture		Date of Expiry		Date of Receipt	
Name of Manufacturer		Address		Country of Origin			
Name of Distributor/ Supplier		Distributor/ Supplier's Address		Telephone			

PRODUCT FORMULATION
(Tick appropriate box)

☐Oral tablets/capsules ☐Powder for reconstitution of injection
☐Oral suspension/syrup ☐Eye drops
☐Injection ☐Ear drops
☐Diluent ☐Nebulizer solution
☐Powder for reconstitution of suspension
☐Cream / Ointment / Liniment / Paste
☐Other .....

COMPLAINT
(Tick appropriate box/boxes)

☐Color change ☐Moulding
☐Separating ☐Change of Oduor
☐Powdering / crumbling ☐Mislabeling
☐Caking ☐Incomplete pack
☐Therapeutic ineffectiveness
☐Other.....

FOR MEDICAL DEVICE AND INVITRO DIAGNOSTIC

☐Packaging	☐Mechanism	☐Data	☐Failure to Calibrate
☐Labelling	☐Electrical	☐Software	☐Results
☐Sampling	☐Data	☐Environmental	☐Readings

Describe complaint in detail.....
.....
Was the cold chain maintained for both transportation and storage?.....
.....(Attach sample for physical evaluation)

Storage Conditions

Does the product require refrigeration?	☐ Yes	☐ No	Other details (if necessary):
Was product available at facility?	☐ Yes	☐ No	
Was product dispensed and returned by client?	☐ Yes	☐ No	
Was product stored according to manufacturer / MoH recommendations?	☐ Yes	☐ No	

Reporter Details

Name of Initial Reporter:	Cadre/Designation:	Mobile no: Email :
Name of Person Submitting to PPB if different from reporter:	Cadre/Designation:	Mobile no: Email :

FOR OFFICIAL (PPB) USE ONLY

Report No: ...../...../..... Date Received ...../...../.....

Your support towards the National Pharmacovigilance system is appreciated

Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the event.
Patient's identity is held in strict confidence and program staff is not is not expected to and will not disclose reporter's identity in response to any public request.
Information supplied by you will contribute to the improvement of drug safety and therapy in Kenya. Once completed please send to:
The Pharmacy and Poisons Board on the above address

NB: THE BOARD WILL CONTACT YOU INCASE MORE SAMPLES ARE REQUIRED FOR ANALYSIS. IN SUCH SITUATIONS THISIS AN INDICATIVE GUIDE ON THE NUMBER OF SUSPECTED POOR QILAOTY SAMPLES TOBE SUBMITTED

FORMULATION	PACK SIZE	MINIMUM NO. OF SAMPLES REQUIRED
Tablets/ capsules	All	100 Tablets/Capsules
Suspension/Syrups	≤ 50mL	20 Bottles
	10 – 100mL	
	> 10mL	
	≥ 100mL	
Injectables	≤ 10mL	100 Vials/Ampoules
	10 – 100mL	50Vials/Ampoules/Bottles
	≥ 100mL	10 Bottles
Creams/Ointments	≤ 5g	50 Tubes
	5 – 50g	20Tubes/Jar
	≥ 50g	5Tubes/Jars
Eye/Ear Drops	< 10mL	100 Bottles
	≥ 10mL	50 Bottles
Inhalers	All	10 Packs
Raw material	All	5g
Medical Devices /Invitro Diagnostics	ALL	As shall be advised

EXPLANATION FOR PRODUCT PROBLEMS FOR MEDICAL DEVICES AND DIAGNOSTICS	
• Packaging – damaged, defective, suspect tampered • Labelling– insufficient instructions for use, illegible • Sampling – device doesn't collect/transfer specimen • Liquid – leak, splash • Mechanical – misalignment, jam • Electrical - unable to charge, power loss or fluctuation • Data – capture, display, or storage affecting product functionality	• Software – network, program, algorithm, or security affecting product functionality • Environmental – noise, temperature, humidity/ moisture, fungal/bacterial growth, or dust affecting product functionality • Failure to calibrate • Results- Increased rate of invalid or unreturnable test results • Reading-Obviously incorrect, inadequate or imprecise result or readings, Unable to obtain reading

3.3. ANNEX 3: STAKEHOLDERS ROLES AND RESPONSIBLITIES

	Stakeholders Matrix on CHX use for prevention of umbilical cord care	
	Name	**Roles and responsibilities**
1	National MoH-DFH	• Policy and guidelines development and dissemination. • Capacity building and technical assistance to counties. • Coordination of partners. • Advocacy communication and social mobilization. • Resource mobilization and allocation. • Monitoring, Evaluation, Accountability and Learning (MEAL) • Operational research. • Quality assurance. • Inclusion of 7.1% CHX in the procurement of essential medicine list.
2	MOH- County	• Implementation and dissemination of 7.1% CHX guidelines. • Development of strategic plans and County Integrated Development Plan (CIDP). • Resource mobilization and allocation. • Support capacity building and technical assistance • Coordination of partners at county level • Conduct KAP study • Commodity management on 7.1% CHX (quantification, forecasting, procurement and distribution). • Advocacy and awareness creation
3	Health managers / Health care providers	• Rational use of 7.1% CHX • Health education about 7.1% CHX use at service delivery point • Commodity management on CHX (quantification, forecasting, procurement and dispensing) • Ensure availability of CHX commodity at service provision point (maternity) • Advocacy and demand creation for use of CHX • Documentation and reporting on CHX use • Pharmacovigilance (poor quality product, adverse event, medication error)
4	Donors/ partners	• Provision of technical assistance. • Resource mobilization. • Study and research. • Advocacy for CHX scale • Participation in guidelines development and review. • Participate in implementation, monitoring and evaluation.

5	Academic, professional and regulatory bodies	• Curriculum review and implementation. • Advocacy and communication • Setting of standards and regulations. • Studies and operational research agenda. • Capacity building and provision of technical assistance. • Document best practices. • Provision of licenses to professionals. • Support in upholding ethics in provision of health services.
6	Pharmacy and Poisons Board (PPB)	• Registration of medicines, health products and technologies. • Standards and regulations. • Pharmacovigilance. • Advisory role to manufacturers. • Provision of licenses to practitioners and manufacturers. • Post market surveillance
7	Manufacturers/ Suppliers	• Production of the quality medicines, health products and technologies. • Compliance to quality standards. • Social marketing, market survey. • Ensure availability of quality medicines, health products and technologies.
8	Communities	• Advocacy and demand creation on CHX. • Social mobilization. • Dissemination of key messages. • Participate in implementation, monitoring and reporting. • Increase the acceptance and use of CHX. • Promote open maternity open days.

MINISTRY OF HEALTH

Save the Children

NUTRITION INTERNATIONAL
Nourish Life

unicef | for every child

Division of Neonatal & Child Health
Ministry of Health