

TRAINING MANUAL
FOR

APPROPRIATE
UMBILICAL CORD CARE
IN NEWBORNS

CONTENTS 4

Acknowledgement.....	3
Introduction.....	4
Purpose of this Training.....	6
Objectives of the Training.....	6
MODULE 1.....	(7-10)
Importance of Appropriate Umbilical Cord Care in Newborns.....	7
Signs and Symptoms of an Infected Cord.....	7
Complications of an Infected Cord.....	8
Inappropriate Umbilical Cord Care Practices in Ghana.....	8
Key Messages of Essential Newborn Care.....	9
MODULE 2.....	(11-15)
Efficacy and Effectiveness of Chlorhexidine.....	11
Advantages of Chlorhexidine over Methylated Spirit.....	14
MODULE 3.....	(16-23)
Application Procedure for Chlorhexidine 7.1% Gel.....	16
General Indication for Hand Hygiene.....	17
Social / Routine Hand washing.....	17
Requirements for Social / Routine Hand washing.....	18
A Procedure for Social and Hygiene Hand washing.....	19
Application of Chlorhexidine Gel to Umbilical Cord in Newborns.....	23
MODULE 4.....	(24-27)
Educating Care Givers.....	24
Post Natal (At Home or Facility).....	25
Key Messages.....	27

MODULE 5.....	(28-33)
Safety Monitoring (Pharmacovigilance) of 7.1% Chlorhexidine Digluconate Gel in the management of Cord Care in Newborns.....	28
Some definitions in Pharmacovigilance.....	28
Guide to Reporting Adverse Drug Reactions.....	30
Confidentiality in Pharmacovigilance.....	33
ADVICE ABOUT ADR REPORTING.....	34
Management of ADRs.....	34
Some Side Effects of Chlorhexidine Digluconate.....	34
APPENDIX XYZ: Adverse Reaction Reporting Form.....	35
Advice about Voluntary Reporting.....	38

ACKNOWLEDGEMENT ●●●●●

This Training Manual is a result of a collaborative effort of Ghana Health Service, USAID's Strengthening Health Outcomes through the Private Sector projects (SHOPS) and partners.

We are grateful to the following members of the Steering Committee who contributed immensely to the development of the Training Manual.

Members of the Steering Committee

Dr. I. Sagoe - Moses	<i>Ghana Health Service</i>
Dr. Edward Antwi	<i>Ghana Health Service</i>
Joyce A. Amponsah	<i>Ghana Health Service</i>
Prof. Evelyn Ansah	<i>University of Health and Allied Sciences</i>
Dr. Roseline Doe	<i>World Health Organisation, Ghana Office</i>
Dr. Amanua Chinbuah	<i>PATH</i>
Dr. Daniel Amaning Danquah	<i>Pharmacy Council</i>
Frederica Enyonam Hanson	<i>Ghana Registered Midwives Association</i>
Alice Dora Amoyaw	<i>Ghana Registered Midwives Association</i>
Dr. Robert Yeboah	<i>USAID Systems for Health Project</i>
Martha Serwah Appiagyei	<i>JHPIEGO</i>
Alhaji Inua Yusuf	<i>MOH/Office of Chief Pharmacist</i>
Joseph Addo - Yobo	<i>USAID/SHOPS project</i>
Odartei Lamptey	<i>USAID/SHOPS project</i>
Beatrix Pieterston	<i>USAID/SHOPS project</i>
Virtuous Semenyah	<i>USAID/SHOPS project</i>

I. INTRODUCTION

Neonatal mortality constitutes a high proportion of the global infant mortality. Each year, 3 million newborns die globally; approximately 13% of these deaths are caused by infections¹. Other common causes of neonatal mortality include: complications of prematurity, low birth weight and adverse intra-partum events (including birth asphyxia). Recent data from United Nations Children's Emergency Fund (UNICEF) indicates that the primary causes of newborn deaths in Ghana are as follows (*see fig. 1*): infections (31%), preterm birth complications (29%) and intra-partum related events (27%).² There are also parental and community practices that put newborns at high risk of infections that can lead to deaths, if not treated in a timely manner. These include application of non- recommended substances such as Maggi cube, toothpaste, cow dung, cola nuts, shea butter, rat feaces, among others to the umbilical cord aimed at speeding up cord separation.

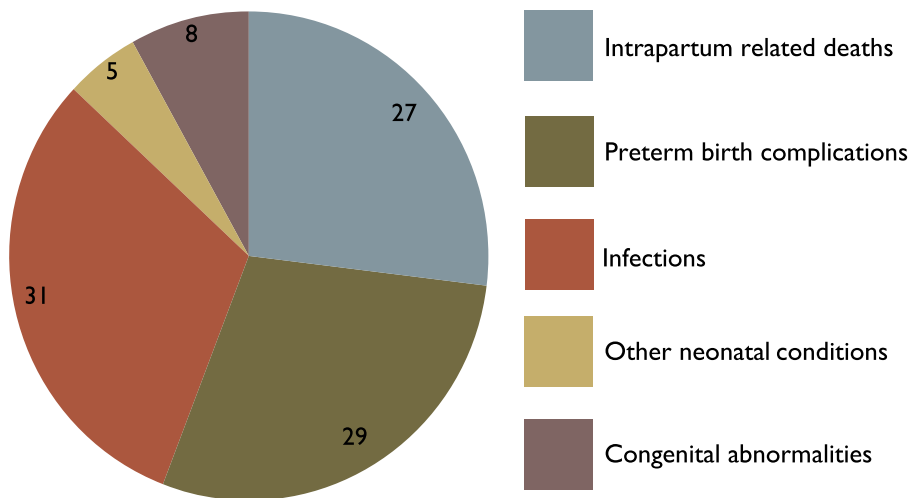
Neonatal sepsis may arise from the recently cut umbilical cord, which is a potential entry point for bacteria. Umbilical cord infection (omphalitis) is a risk factor for neonatal sepsis and mortality in low-resource settings where home deliveries are common.³

¹ Liu I, Johnson HL, Cousens S, et al. Child Health Epidemiology Reference Group of WHO and UNICEF, regional, and national causes of child mortality: An updated systematic analysis for 2010 with time trends since 2000. *Lancet* 2012; 379 (9832):2151-2161.

² Ghana National Newborn Health Strategy and Action Plan 2014-2018. A road map to reduce neonatal death nationwide. Available at < https://www.healthynewbornnetwork.org/hnn-content/uploads/Ghana_Newborn_Flyer-FINAL.pdf>

³ Imdad A, mullar 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 . 2013. Available at <<https://dx.doi.org/10.1186%2F1471-2458-13-S3-S15>>

Fig 1: Causes of neonatal deaths in Ghana, 2012(%)



Source: Ghana National Newborn Health Strategy and Action Plan 2014-2018⁴

The success of any approach to reduce neonatal mortality arising from cord infection depends on ensuring optimal cord care at birth till the cord separates and the wound is completely healed.

In January 2014, the World Health Organization (WHO) issued a new recommendation for umbilical cord care: *“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 1000 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 application of a harmful traditional substance such as cow dung to the cord stump.”*⁵

In light of the above WHO recommendation, Ghana has opted for Chlorhexidine digluconate 7.1% gel as the recommended product for cord care to replace methylated spirit which has been used for cord care for several years. This recommendation is included in the newly published Standard Treatment Guidelines and the Essential Medicines List (2017) as the treatment of choice for cord care in all newborns.

⁴ Ghana National Newborn Health Strategy and Action Plan 2014-2018. A road map to reduce neonatal death nationwide. Available at < https://www.healthynewbornnetwork.org/hnn-content/uploads/Ghana_Newborn_Flyer-FINAL.pdf >

⁵ World Health Organization. WHO Recommendations on Postnatal Care of the Mother and Newborn, 2013. http://apps.who.int/iris/bitstream/10665/97603/1/9789241506649_eng.pdf

Chlorhexidine has an excellent safety record and is acceptable, feasible and cost effective. It can be easily administered by health professionals, trained volunteers, community health extension workers, as well as care givers. An implementation research study in Ghana indicated care givers and health workers preference for chlorhexidine gel.

II. Purpose of this manual:

The health worker is KEY in the promotion and implementation of improved umbilical cord care in newborns according to the new national guidelines. With the information provided in this training manual, the health worker will be well prepared to implement the use of chlorhexidine 7.1% digluconate gel for the appropriate management of umbilical cord in all newborns; counsel caregivers on appropriate cord care in newborns and ultimately contribute to reducing preventable neonatal mortality in Ghana.

III. Objectives of the training:

After completing this training session participants should be able to:

- Explain the need for appropriate umbilical cord care in newborns
- Correctly apply chlorhexidine 7.1% digluconate gel to the umbilical cord of newborns
- Describe the benefits of chlorhexidine 7.1% digluconate gel for umbilical cord care in newborns
- Teach caregivers to appropriately apply chlorhexidine 7.1% digluconate gel to umbilical cord of newborns
- Counsel caregivers on the use of chlorhexidine 7.1% digluconate gel for umbilical cord care in newborns

MODULE 1

1.1 Importance of Appropriate Umbilical Cord Care in Newborns

In order to ensure appropriate umbilical cord care at birth until the cord falls off and the wound heals, it is critical to adopt a strategy that prevents life threatening sepsis and cord infections. The freshly cut umbilical cord is a common portal of entry for invasive bacteria that cause newborn sepsis and death. Bacteria rapidly colonize the moist cord stump and have direct access to the bloodstream through umbilical vessels that remain patent for the first few days after birth.

In addition, bacterial colonization may lead to cord infection (omphalitis) with the potential of spreading to the surrounding tissues. Sources of these bacteria include the mother's birth canal, the environment in which the neonate is delivered and hands of the person assisting with the delivery. Application of substances that are not recommended for cord care and poor hygienic practices by caregivers are other sources of infections.

Signs and symptoms of an infected cord

Omphalitis is the medical term for infection of the umbilical cord stump in the neonatal period, most commonly attributed to a bacterial infection⁶. These infections are usually caused by *Staphylococcus aureus*, *Streptococcus (SP)*, and *Escherichia coli*⁷. The infections are typically caused by a combination of Gram-positive and Gram-negative organisms.

Signs and Symptoms of an infected cord include:

- Redness around the base of the cord
- Swelling of the cord stump
- Pus from the umbilical cord stump (usually foul smelling discharge)
- Bleeding from the stump

Other general symptoms are fever, jaundice (yellow skin), poor feeding and fast heart rate.

⁶ Jones, Kevin, MD, Neayland, Beverly, MD. "[Brief Review of Omphalitis](#)" (PDF). dead link. UNSOM Department of Pediatrics. Retrieved 23 July 2013

⁷ Cunningham, F et al (2014). *Williams Obstetrics: The Newborn (24 ed.)*. McGraw-Hill

Complications of an infected cord

Complications such as Omphalitis, if not well managed, can quickly progress to [sepsis](#). **Sepsis** is a life-threatening condition that arise when the body's response to [infection](#) causes injury to its own tissues and organs. Most commonly, the infection is [bacterial](#), but it may also be caused by [fungi](#), [viruses](#) or [parasites](#). Other complications may include: [necrotizing fasciitis](#) of the abdominal walls and or genitalia (infection of the skin, subcutaneous fat, superficial and deep fascia), myonecrosis (infection of the muscles), pneumonia, endocarditis, liver abscess, abdominal complications (eg. spontaneous evisceration, peritonitis, bowel obstruction, abdominal abscess etc.) and death.

1.2 Inappropriate umbilical cord care practices in Ghana

In 2016, the Health Research and Development directorate and Family Health directorate of the Ghana Health Service (GHS) conducted a Knowledge Attitudes and Practices study on umbilical cord care in newborns across the three (3) ecological zones of Ghana. The study obtained information from over 1,800 caregivers (i.e. mothers of newborns, grandmothers, etc.). In addition to methylated spirit, caregivers reported the use of a wide range of substances applied to the umbilical cord to facilitate its separation by the third day. These included: hot water, gentian violet, shea butter, charcoal, salt, chalk, cola nuts, Maggi cube, tooth paste, hot stone, snail shell, palm oil, lizard feaces, ash, variety of herbs and many more.

1.3 KEY MESSAGES

Cord Care

1. Wash your hands with soap under running water before handling your baby's cord
2. Air-dry your hands by shaking them for a while
3. Chlorhexidine gel is for antiseptic purposes
4. Apply chlorhexidine to the tip of the umbilical cord and spread it around the cord with your finger
5. Apply chlorhexidine **once daily** in the morning until baby's cord falls off and continue until the wound heals completely.
6. **DO NOT** apply any **OTHER** substance to the cord **EXCEPT CHLORHEXIDINE GEL**
7. After applying the dressing to the umbilical cord, leave cord to dry
8. Keep the baby's cord clean and dry at all times
9. Fold the diaper or napkin below the level of the umbilical cord to prevent it from rubbing the cord and to keep it dry and clean
10. Put on loose clothing, this will allow air to circulate around the cord and help keep it dry
11. Cord usually falls off between **7 to 10** days. However, if by the **12th day** it hasn't fallen off see a health provider
12. Do not force the cord to fall off. It is **VERY DANGEROUS**
13. **DO NOT APPLY GEL TO THE EYE IT IS VERY DANGEROUS TO DO SO**
14. Report to the nearest health facility when you see the following signs around your baby's cord:
 - a. Redness around the base of the cord
 - b. Swelling of the cord stump
 - c. Pus from the umbilical cord stump (usually foul smelling discharge)
 - d. Bleeding from the stumpOther general signs are fever, jaundice (yellow skin), poor feeding and fast heart rate
15. Always put the baby on his or her side to sleep (with support) until cord falls off and wound heals completely
16. Visit the health facility two (2) times in the first week after birth for you and your baby to be checked and treated if necessary
17. Always take your sick child to a health facility for early treatment
18. Tell mother to bath body baby once a day till the cord falls and wound heals completely
19. Apply **only** chlorhexidine gel **once daily** in the morning until baby's cord falls off and continue until the wound heals

1.4 Key Messages Of Essential New Born Care

- Dry baby thoroughly immediately after birth using a soft, clean and dry cloth
- Replace the wet cloth with another dry cloth to keep baby warm
- Check baby's breathing while baby is still on mother's abdomen
- Wait 2 – 3 minutes before clamping the cord. Cut cord with a clean sterile cutting instrument
- Keep the baby naked on the mother's chest (skin to skin) covered with the dry cloth
- Cover the baby's head with a cap or the cloth. Keep the baby in this skin to skin position for one hour uninterrupted except for checking vital signs
- Whilst baby is skin to skin, initiate breastfeeding within 30 minutes of birth
- Provide cord care within 90 minutes of birth
- Clean the cord with chlorhexidine 7.1% digluconate gel and leave to dry
- Continue daily application of chlorhexidine 7.1% digluconate gel until cord falls off and wound completely healed.
- Provide other essential care including eye care, vitamin k, temperature, weight and examination within the first 90 minutes of birth
- Delay bathing for at least 6 hours or up to 24 hours after birth.

MODULE 2

Efficacy and Effectiveness of Chlorhexidine

2.1. Historical use of Chlorhexidine and safety record

Chlorhexidine digluconate (CHX) is a broad-spectrum antiseptic, effective against major causative agents of neonatal sepsis. Since its development in 1950, chlorhexidine has been widely used in a range of applications including hand washes, preoperative body shower, cosmetics, oral hygiene, wound care, general disinfection, and veterinary care. Common formulations can be water-based, alcohol-based, gels, or powders and are commonly applied to adult, infant and neonatal skin. Considering the extent of its use as a topical antiseptic on humans, reported side effects are rare, but included delayed reactions such as contact dermatitis and photosensitivity. Today, topical 4% chlorhexidine solutions are commonly used for wound care and are widely available over the counter in Ghana under multiple branded and generic labels.

KEY FACTS ABOUT CHLORHEXIDINE

1. Chlorhexidine is an antiseptic with a broad spectrum of activity against gram negative and gram positive bacteria.
2. Chlorhexidine has been applied to the umbilical cord for about 40 years in developed countries. It has also been used widely as a pre-surgical and an oral antiseptic.
3. The safety record has been well established in adults as well as in newborns. For umbilical cleansing Chlorhexidine digluconate 7.1% (equivalent to chlorhexidine 4%) was selected to be sufficiently potent as an antiseptic, but at a low enough concentration to ensure safe chlorhexidine levels in the blood.
4. Chlorhexidine does not necessarily cause the cord to fall off quickly.

2.2 Evidence on the effectiveness of chlorhexidine for umbilical cord care

Clinical trials were conducted in Nepal, Bangladesh, Pakistan, Nigeria and Zambia. These five countries have many factors in common: neonatal mortality is a high proportion of under-5 mortality and reduction has stagnated in the latter half of the first decade of this century. In each of these countries, institutional deliveries are increasing, but majority of births still take place at home.

In addition, all these countries have well developed essential newborn care policies and guidelines, as well as policies on “clean and dry” umbilical cord care. The national neonatal mortality rates range from moderate to high. Challenges to the health systems are similar including insufficient coverage of existing high priority interventions. All studies used first day applications of 4% chlorhexidine, followed by once daily applications ranging from 7 to 14 days post birth. The studies were cluster randomized control trials, so the evidence is high grade.

Table1: Evidence on the effectiveness of Chlorhexidine for umbilical cord care in 5 Countries

Study Characteristic	Nepal	Bangladesh	Pakistan	Nigeria	Zambia
Overall NMR* (at time of study)	30/1000	36/1000	30/1000	37/1000	24/1000
Percentage of births at home (at time of study)	92%	88%	80%	63.2%	27%
Total Sample Size	15,123	29,760	9,741		37,856
Primary Outcomes	<ul style="list-style-type: none"> • Neonatal mortality • Omphalitis 	<ul style="list-style-type: none"> • Neonatal mortality • Omphalitis 	<ul style="list-style-type: none"> • Neonatal mortality • Omphalitis 	Neonatal mortality	Neonatal mortality
Comparison Group	Dry cord care	Dry cord care	Dry cord care	Dry cord care	Dry cord care
*Frequency of multiple Applications (day)	1,2,3,4,6,8,10	1,2,3,4,5,6,7	Daily for 14 days	Daily for 14 days	Daily until 3 days after the stump separates fully
Intervention Provider	Project staff	Project staff	<ul style="list-style-type: none"> • Traditional Birth Attendant • Caretaker 	<ul style="list-style-type: none"> • Health workers • caretaker 	<ul style="list-style-type: none"> • Birth attendant • Caretaker

*Neonatal mortality rate.

*Refers to days under which application were made

Key Findings: Nepal

- Compared to dry cord care, chlorhexidine cord cleansing reduced neonatal mortality by 24% and reduced severe omphalitis by 75%;
- Neonatal mortality was reduced by 34% if chlorhexidine was applied within 24 hours of birth.

Key Findings: Bangladesh

- Single chlorhexidine application on the first day of life reduced neonatal mortality by 20%, and moderately reduced severe omphalitis, as well as cord bacterial colonization;
- 7 day chlorhexidine application reduced severe cord infection by 65% and reduced bacterial colonization; neonatal mortality was 6% lower in this group.

Key Findings: Pakistan

- Neonatal mortality was reduced by 38% in the chlorhexidine group compared to the dry cord care group;
- Severe cord infection was reduced by 42% for chlorhexidine cord cleansing compared to the dry cord care group.

Key Findings: Zambia

- Chlorhexidine did not reduce neonatal mortality compared with dry cord care in the Southern Province of Zambia;
- Researchers report this is a result of the context of relatively high rates of facility delivery (63%) and lower neonatal mortality rate in the research location (14.4 deaths per 1000 live births).

2.3 Advantages of Chlorhexidine over Methylated spirit

Chlorhexidine has a number of advantages over methylated spirit making it the preferred choice for umbilical cord care in newborns.

MECHANISM OF ACTION

Chlorhexidine	Methylated Spirit
<ul style="list-style-type: none"> It is an antiseptic that works by strongly adsorbing to bacteria cell membranes causing it to rupture 	<ul style="list-style-type: none"> It acts as a dehydrating agent that disrupts the osmotic balance across cell membrane
<ul style="list-style-type: none"> The rupture of the cell wall causes leakages of small molecules (low concentration 0.2%) and precipitation of cytoplasmic proteins (high concentration 2.0%) 	

SPECTRUM OF EFFICACY

Chlorhexidine	Methylated Spirit
<p>Chlorhexidine has broad spectrum activity.</p> <ul style="list-style-type: none"> It is active against gram-positive, gram-negative, facultative anaerobes, aerobes and yeast 	<ul style="list-style-type: none"> Methylated spirit has a very narrow spectrum of activity
<ul style="list-style-type: none"> It is efficacious in terms of bactericidal activity at lower concentration 	
<ul style="list-style-type: none"> It has immediate bactericidal action 	
<ul style="list-style-type: none"> It has long duration of action 	

SAFETY PROFILE

Chlorhexidine	Methylated Spirit
<ul style="list-style-type: none">• It has no burning sensation	<ul style="list-style-type: none">• Burning sensation
<ul style="list-style-type: none">• It has low toxicity	<ul style="list-style-type: none">• It is highly flammable
<ul style="list-style-type: none">• It does not lose its potency at high temperatures	<ul style="list-style-type: none">• It loses its potency at high temperatures
<ul style="list-style-type: none">• It does not evaporate at room temperature	<ul style="list-style-type: none">• It evaporate at room temperature

APPLICATION

Chlorhexidine	Methylated Spirit
<ul style="list-style-type: none">• The gel is easy to apply	<ul style="list-style-type: none">• Must be applied with cotton wool
<ul style="list-style-type: none">• It has a positive residual effect on the skin	<ul style="list-style-type: none">• It does not have a positive residual effect on the skin

MODULE 3

3.1 Application Procedure for Chlorhexidine 7.1% digluconate Gel



Source: www.hopefornigeriaonline.com/urgent_public_service_announcement-product

Source: www.hopefornigeriaonline.com/urgent-public-annoucement-product-withdrawal to save the sight of our children.

Before applying chlorhexidine gel to the umbilical cord, it is important to wash hands with soap and water

Hand washing is the single most effective method used in preventing the spread of infections. Proper hand hygiene reduces the number of potential infection-causing germs on the hands, and decreases the incidence of infection transmission in the health facility.

General Indications for Hand Hygiene

Specific occasions for hand hygiene for healthcare workers are:

- Before donning gloves and wearing Personal Protective Equipment (PPE)
- On entry into isolation room/area
- After touching a patient's surroundings
- Before making contact with a patient
- After making contact with a patient
- Before a clean/aseptic procedure
- After risk of body fluid exposure
- After removal of PPE upon leaving the care area

3.2. Types of Hand Hygiene

There are three major types of hand hygiene. These are:

1. Social/routine hand washing
2. Hand antiseptics with alcohol or non – alcohol hand rub
3. Surgical hand wash/scrub

Social/routine hand washing

This is hand washing with plain soap and running water for at least 40-60 seconds to remove most transient germs (e.g., E. coli) and soil from the hands.

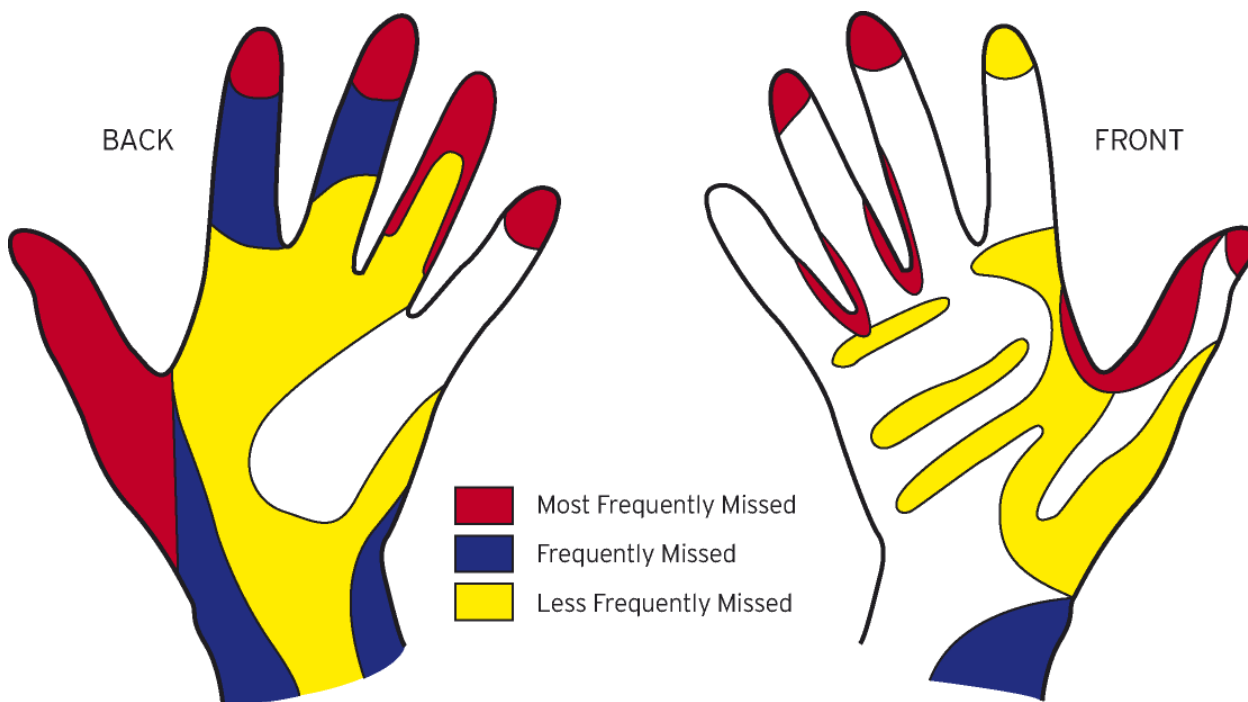
Social hand washing shall be done:

- Before and after handling or eating food
- After visiting the toilet
- Before and after attending to patients in situations such as bathing and feeding
- When hands are soiled
- On arrival to work and after

Requirements for social/routine hand washing

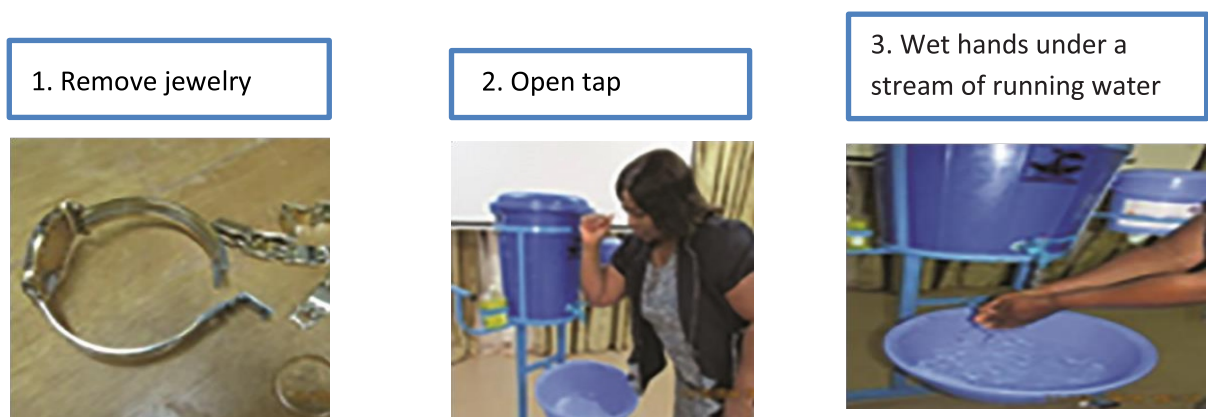
In social or routine hand washing, liquid, bar/cake, or powdered forms of plain soap are acceptable. When bar/cake soap is used, cut it into smaller pieces and keep in a rack that facilitates drainage of water.

Fig 3: Areas of hands frequently missed during ordinary hand washing



Ordinary hand washing may result in some areas of the hand being missed hence the potential for contamination still persist. To address this, a stepwise approach to hand washing with soap has been developed to ensure no area is missed. The recommended stepwise approach is shown in the diagram (Fig 4) below. Caregivers should be taught this approach to hand washing using soap to reduce the risk of infecting the baby to the barest minimum.

Fig 4: A procedure for social and hygienic hand washing



4. Dispense soap



5. Evenly spread soap over palms and hands. Rub to make lather.



6. Rub hands together, palm to palm



7. Palm to dorsum 1



8. Palm to dorsum 2



9. Rub the webs of the fingers



10. Cup them together to massage the finger tips



11. **OR** rub the fingers in the palm in a circular manner



12. Rub the thumbs



13. Wash the wrists



14. Rinse thoroughly



15. Pick single-use hand-drying material



16. Dry hands



17. Use single-use hand towel or paper to turn off the faucet



18. Discard single-use paper towel in appropriate receptacle



NB: Avoid using hot water: Repeated exposure to hot water may increase risk of dermatitis.

Source/credit: National policy and guidelines for infection prevention and control in healthcare settings, GHS 2015

NB: FOR CAREGIVERS HANDS SHOULD BE AIR DRIED AFER WASHING

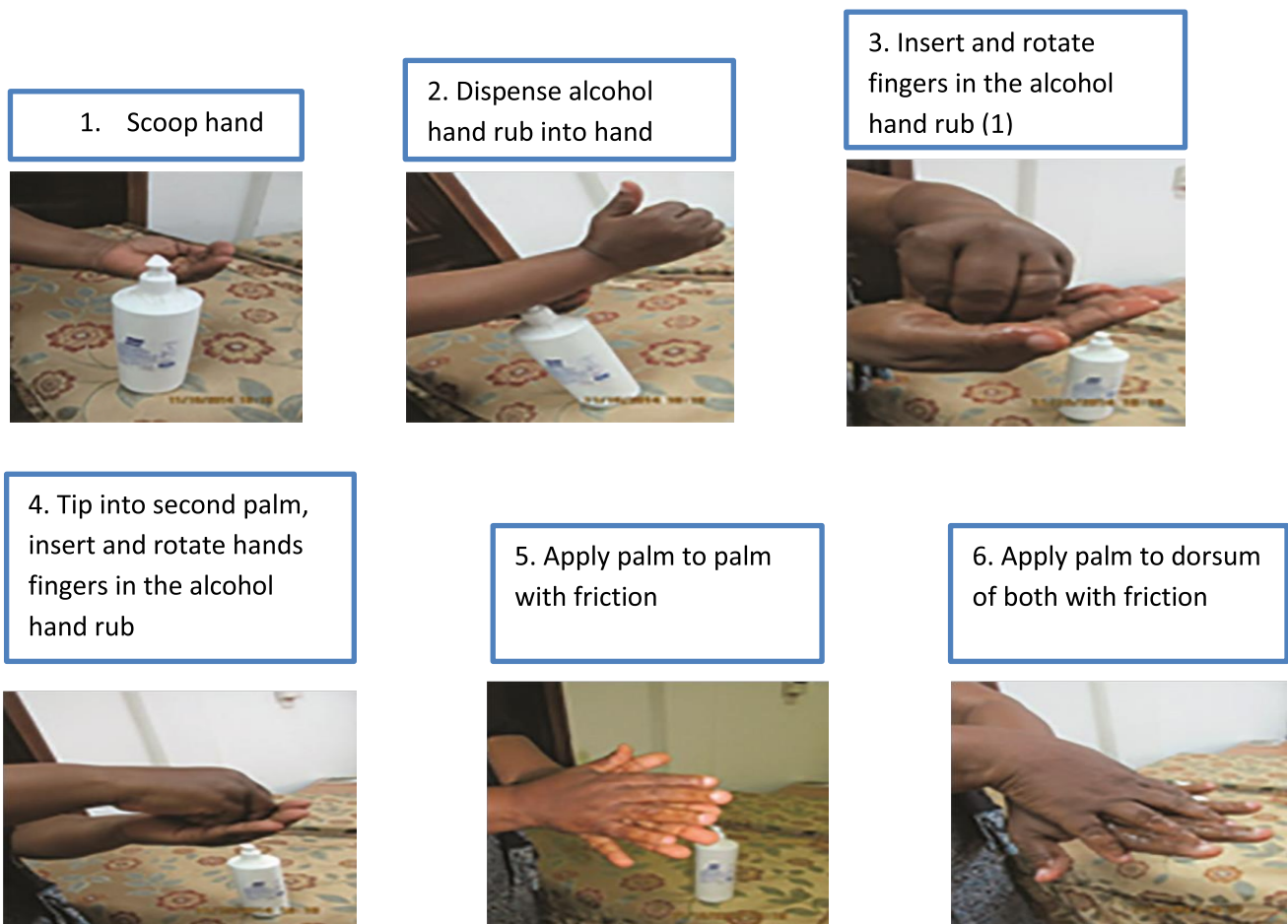
Hand antiseptis with alcohol or non-alcoholic hand rub

Alcohol hand rub is only one kind of antiseptic hand rub. This method can be used when hand washing with antiseptic and running water is not possible or practical—as long as hands are not visibly soiled with dirt, blood, or other organic materials.

To use alcohol hands rub solution:

- Cup dominant hand and dispense 3-5 mls of alcohol hand rub into it without touching the dispenser with your fingers
- Dip and rotate fingers of the second hand in the alcohol rub
- Pour hand rub into second hand, dip and rotate fingers of the dominant hand in the alcohol rub
- Rub to cover all surfaces of the hands and wrist. It is recommended that after 6 applications of alcohol rub, a social hand wash must be done.

Fig 5: Hand hygiene with alcohol or non- alcohol based handrub



7. Apply to both thumbs



8. Apply to both wrists



9. Continue applying till the rub dries. It is most effective when dry.

NB: Alcohol hand rub should be used only when hands are not visibly dirty or soiled

Source/credit: National policy and guidelines for infection prevention and control in healthcare settings, GHS 2015

Fig. 6: Application of Chlorhexidine gel to umbilical cord in newborns



Source: www.hopefornigeriaonline.com/urgent_public_service_announcement-product

Source: www.hopefornigeriaonline.com/urgent-public-annoucement-product-withdrawal to save the sight of our children.

MODULE 4

4.1 Educating Care Givers

Greet the mother and find out how she is doing after the delivery. If she has any concerns which need immediate attention, attend to those before continuing with caring for the cord.

Ask her if she has a helper/family member present in the facility who will be helping her with caring for the baby at home. If she answers in the affirmative, invite the person to be present before you continue. Make sure that other mothers' privacy is not compromised.

Be polite to the mother and other caregivers and take time to explain every step as you demonstrate. Ask mother and helper to watch you carefully and encourage them to ask questions.

- Start by telling the mother and helper that the umbilical cord needs to be cared for properly in order to avoid dangerous germs from entering through it into the baby's body
- Tell them that if things are not done as you are about to show her the cord can get infected, this infection can spread to the rest of the body and make the baby very sick and at risk of death
- Tell them that you are about to apply a medicine called Chlorhexidine which will kill any germs and prevent the cord from getting infected
- Tell them that it is important to wash hands very well before touching the baby and applying chlorhexidine
- Let the mother watch you wash your hands while you talk them through the steps for hygienic handwashing followed by air drying
- Show them the tube of chlorhexidine and emphasize that it is only for application to the cord. Emphasize that on no occasion should it be applied to the eyes or any other part of the body
- Next, apply chlorhexidine gel to the cord in the recommended manner while talking to the mother/caregiver explaining each step
- After the application of chlorhexidine fold down the diaper to keep it away from the cord. The baby should also be dressed in loose clothing. Explain to the mother and caregiver that these are important to keep the cord dry and clean at all times
- If the baby is a boy tell them to make sure the penis points downwards before fastening the diaper

- Emphasize that chlorhexidine gel should be applied to the cord once a day only after bathing or cleaning the baby; that chlorhexidine should be applied every day until the cord falls off and the wound is completely healed
- **BEFORE CONTINUING, ASK MOTHER AND HELPER WHETHER THEY HAVE ANY QUESTIONS SO FAR. IF SO, RESPOND TO THEIR QUESTIONS**
- Tell the caregivers to repeat what you have said so far and demonstrate where appropriate
- Praise them for correct answers and anything they do well. Correct any misunderstanding or confusion
- Tell the mother to return to the health facility for postnatal care on the 6th or 7th day for a general check of the baby and herself in order to make sure they are well. She should bring along the tube of chlorhexidine, whether it is finished or not
- Next, tell them about the danger signs to look out for in relation to the umbilical cord. Show them pictures of these in the Maternal and Child Health Records or other photographs. Tell them to return immediately with the baby if they see any of these signs even if it is before the 6th day
- Tell them to look for any other signs such as rashes or sores around the base of the cord which could arise as a result of adverse reactions to chlorhexidine. If any is observed, chlorhexidine application should be stopped immediately while they bring the baby to the health facility
- Ask the mother to tell you when she will return for postnatal clinic
- Ask her to tell you the danger signs for which she will return immediately
- Praise the mother and caregiver for giving correct answers
- Correct any mistakes
- At the end, thank them and encourage them not to hesitate to ask questions whenever they come to the health facility

4.2 Post Natal (At home or Facility)

(Situate the discussions within the general Post-natal discussions at each visit as indicated in the maternal health record book.

First Visit – 24hrs to 72hrs after delivery

Second Visit – 6 to 7 days after delivery

Third Visit – 6 weeks after delivery

In addition to physically assessing the mother and her newborn, you will need to communicate effectively with the mother and any other care giver accompanying the mother to assess how the newborn is doing. You need to provide practical guidance and support for cord care and other care in the home for the baby.

As you ask the mother questions, remember to use simple appropriate language, treat any concerns she raises about the baby or her role as a mother / caregiver with respect. (All mothers/care givers need lots of support to reassure them that they are caring for their babes appropriately.)

You should maintain trust at all times so that she will come to you when she has any concerns about the cord.

Provide information on the process of cord care by showing the mother/ caregiver how to care for the cord during this period. You can communicate this information by active demonstration, for example showing the mother how to prevent the cord from getting wet during bathing, how to dress the cord and stump, how to strap-on the diaper / napkin and how to lay the baby to sleep so that they can see what to do. Give the mother/ caregiver the opportunity to demonstrate the process of cord care in your presence. Give the mother / caregiver the opportunity to ask questions and clarify any problem.

At each postnatal Visit;

- Ask about how mother is doing
- Ask if she has any concerns about the baby (cord)
(To break the ice)
- Ask her how she cared for the cord
- Ask her if she handled the cord herself
- Ask her if she had any difficulties or any questions
- Ask her to demonstrate how she does the handwashing
- Ask her to demonstrate how the dressing of the cord is done
- Tell her when to return immediately if they encounter any danger signs
- Ask her to enumerate the danger signs
- Ask her about the next scheduled visit
- Fill up any missing information at the end and correct any wrong
- Ask her if she added any other thing to the chlorhexidine gel
- Praise and encourage them

Encourage mothers / caregiver to ask questions

4.3 KEY MESSAGES

Cord Care

1. Wash your hands with soap under running water before handling your baby's cord
2. Air-dry your hands by shaking them for a while
3. Chlorhexidine gel is for antiseptic purposes
4. Apply chlorhexidine to the tip of the umbilical cord and spread it around the cord with your finger
5. Apply chlorhexidine **once daily** in the morning until baby's cord falls off and continue until the wound heals completely.
6. **DO NOT** apply any **OTHER** substance to the cord **EXCEPT CHLORHEXIDINE GEL**
7. After applying the dressing to the umbilical cord, leave cord to dry
8. Keep the baby's cord clean and dry at all times
9. Fold the diaper or napkin below the level of the umbilical cord to prevent it from rubbing the cord and to keep it dry and clean
10. Put on loose clothing, this will allow air to circulate around the cord and help keep it dry
11. Cord usually falls off between **7 to 10** days. However, if by the **12th day** it hasn't fallen off see a health provider
12. Do not force the cord to fall off. It is **VERY DANGEROUS**
13. **DO NOT APPLY GEL TO THE EYE IT IS VERY DANGEROUS TO DO SO**
14. Report to the nearest health facility when you see the following signs around your baby's cord:
 - a. Redness around the base of the cord
 - b. Swelling of the cord stump
 - c. Pus from the umbilical cord stump (usually foul smelling discharge)
 - d. Bleeding from the stumpOther general signs are fever, jaundice (yellow skin), poor feeding and fast heart rate
15. Always put the baby on his or her side to sleep (with support) until cord falls off and wound heals completely
16. Visit the health facility two (2) times in the first week after birth for you and your baby to be checked and treated if necessary
17. Always take your sick child to a health facility for early treatment
18. Tell mother to bath body baby once a day till the cord falls and wound heals completely
19. Apply **only** chlorhexidine gel **once daily** in the morning until baby's cord falls off and continue until the wound heals

MODULE 5

SAFETY MONITORING (PHARMACOVIGILANCE) OF 7.1% CHLORHEXIDINE DIGLUCONATE w/v IN THE MANAGEMENT OF CORD CARE IN NEW BORN

Pharmacovigilance is defined as the science and activities relating to the knowledge, detection, assessment and prevention of adverse effects (including adverse drug reactions) or any drug-related problem.

Why Pharmacovigilance of Chlorhexidine digluconate in Management of Cord Care in New Borns

The Ministry of Health, Ghana has adopted the World Health Organization (WHO) recommendation for the use of 7.1% Chlorhexidine digluconate w/v as aqueous solution or gel in the management of umbilical cord care.

Although, Chlorhexidine digluconate has excellent safety records and also countries that have introduced it for the management of cord care have not reported any safety issues it is important to monitor, diagnose, manage and report any adverse drug reactions which may be identified during the use of this product.

Also information on adverse events to Chlorhexidine digluconate received from other countries may not be relevant to Ghana because genetic differences, traditions, the use of the drug, disease patterns, prescribing practices and the concomitant use of traditional and complimentary medicines (e.g. herbal medicines) differs from country to country and may affect drug metabolism and the nature of adverse events.

Please, note that 7.1% Chlorhexidine digluconate w/v is for external use only.

Some definitions in Pharmacovigilance

Adverse Events: Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment. The key point here is that an unwanted event occurs during or after the use of a drug. It encompasses “adverse drug reactions” and other unwanted reactions.

Adverse Drug Reaction (ADR): An unwanted or harmful reaction experienced following the application (or administration) of a drug or combination of drugs under normal conditions of use, which is suspected to be related to the drug.

The key point in this definition is that a patient experiences an unwanted and/or harmful reaction following the use of a medicine. Individual factors may play an important role but the phenomenon experienced must be noxious.

An adverse drug reaction may be expected or unexpected. An *unexpected adverse drug* reaction occurs when the nature or severity of the reaction is NOT consistent with domestic labeling or market authorization, or expected from characteristics of the drug.

Serious ADR: A noxious and unintended response to a drug, which occurs at any dose and results in any of the following:

- hospitalization or prolongation of existing hospitalization
- causes congenital malformation
- results in persistent or significant disability or incapacity
- is life-threatening
- results in death
- requires medical intervention to prevent permanent damage

The term '*severe*' is not synonymous with '*serious*'.

'**Severe**' is used to describe the intensity of a specific event as in mild, moderate or severe. 'Seriousness' is based on patient/event outcome. It serves as guide for defining regulatory reporting obligations.

Side Effect: This is defined as any unintended effect of a pharmaceutical product occurring at doses normally used in humans, which is related to the pharmacological properties of the drug.

Such effects may or may not be beneficial. Side effects are related to the known properties of the drug and can often be predicted.

Signal: Reported information on a possible causal relationship between an adverse event and a drug, the relationship normally is unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information.

Sequelae: Any medical condition that results from the adverse drug reaction.

Rechallenge: The re-introduction of the suspected drug after the adverse reaction has subsided.

Dechallenge: Withdrawal of the suspected drug after the adverse reaction has occurred.

Medication Error: Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer

5.1 Guide to reporting Adverse Drug Reactions

Who, What, When and How to Report ADRs

Who Should Report ADRs

All healthcare professionals including doctors, pharmacists, nurses, physician/medical assistants, laboratory technicians are requested to report all suspected adverse reactions to zinc used in diarrhoea management in children.

Patients are also encouraged to report adverse drug reactions that their children may experience.

What to Report

Report all adverse reactions to chlorhexidine use in umbilical cord of new borns. This may include:

- All *expected* and *unexpected adverse reactions*(i.e. not consistent with the product package, insert or labelling)
- Serious adverse reactions even if the reaction is well known,
- increase in frequency of known adverse reactions
- Suspected product quality defects,
- counterfeits

NB: Any reaction that causes concern in the caregiver or the patient should be reported.

Information to be provided on the Reporting Form

Patient Details

- Name/Initials/Folder no, Age/Date of Birth, Sex, Weight, Name of the health facility or treatment centre, telephone number or any information that will help contact the patient in case of follow up.

Reaction Details

- A detailed description of the suspected adverse drug reaction.
- Date of onset of the reaction and date ended.
- Outcome of the reaction (whether the patient has recovered, not recovered or the outcome unknown)

Details of the Suspected Product

- The name (generic and brand if known)
- Manufacturer, batch number and expiry date (if known)
- Date therapy was initiated and the date therapy stopped.
- Reason(s) for use

- Concomitant medications (including medicines taken within reasonable time)

Reporter Details

- Name, phone number, e-mail address and postal address. This is important to enable the National Pharmacovigilance Centre follow up or give feedback on the report submitted.

If in doubt, Report!

Please do not hesitate to report any suspected adverse reaction of clinical concern, even if you are unable to supply all the details!

When to Report

Reporting to the National Pharmacovigilance Centre may be done in an expedited or unexpedited manner.

Expedited reporting should be done immediately and in not later than 7 days from becoming aware of the adverse drug reaction.

- All serious ADRs should be reported in an expedited manner.
- Any suspected increase in the frequency of unserious reactions shall also be

reported on an expedited basis.

All other reports of ADRs that do not qualify under expedited reporting should be reported within a period of 28 days.

How to Report

All suspected ADRs should be reported to the National Pharmacovigilance Centre.

Reporting should be done by completing Adverse Reaction Reporting Form (Appendix xyz) available from the following sources;

- FDA Head Office
- FDA Regional Offices
- FDA website: www.fdaghana.gov.gh

Reports may be hand delivered, posted, faxed or e-mailed through any of the Food and Drugs Authority's addresses.

Confidentiality in Pharmacovigilance

Information and data collected on patients during pharmacovigilance are treated as confidential and are not disclosed to third parties.

Information obtained from ADR reports submitted may result in regulatory actions that will ensure patient safety and promote rational use of medicines and other products in Ghana.

ADVICE ABOUT ADR REPORTING

Management of ADRs

- The drug suspected of causing the ADR should be withdrawn especially if the reaction is serious e.g. anaphylactic shock.
- In less serious cases the decision to stop the drug should be based on the prescribers' assessment of the risks and benefits of continuing therapy and the patient's wishes.
- If several drugs are being used the drug most likely to cause the event should be withdrawn first.
- If the reaction is likely to be dose-related dose reduction should be considered.
- If the patient cannot manage without a drug that has caused the adverse reaction, providing a symptomatic relief while providing the essential treatment should be considered.

Some Side effects of Chlorehexidine digluconate

Reported side effects are rare, but have included delayed reactions such as contact dermatitis and photosensitivity.

Side effects as a result of inadvertent application to the ear with access to the inner ear through a perforated tympanic membrane, and, in very rare cases, hypersensitivity reactions such as anaphylactic shock have also been reported.

D) SUSPECTED PRODUCT(S) (Attach sample or product label if available)

Brand name	Generic name	Batch no.	Expiry date	Manufacturer
Reasons for use (Indication):		Dosage Regimen:	Daily dose:	Route of Administration:
Date started: (dd/mm/yyyy).....		Date stopped: (dd/mm/yyyy).....		
<i>Did the adverse reaction subside when the drug was stopped (de-challenge)?</i> Yes () No ()				
Was the product prescribed? Yes <input type="checkbox"/> No <input type="checkbox"/>		Source of Drug:		

Was product re-used after detection of adverse reaction (re-challenge)? Yes () No ()

Did adverse reaction re-appear upon re-use? Yes () No ()

(E) CONCOMITANT DRUGS INCLUDING HERBAL MEDICINES TAKEN PRIOR TO THE ADVERREACTION

(Attach a separate sheet when necessary)

Name of Drug	Daily dose	Date started	Date stopped	Reason(s) for use

Attach all relevant laboratory tests/data

(F) DETAILS OF REPORTER

Name of Reporter:Profession.....

Address:.....

Signature:Tel.....E-mail.....

Date (dd/mm/yyyy) : / /

For all questions relating to Suspected Adverse Reactions, please call the Food and Drugs Authority on

- Landline: +233 (0302) 233 200/ 235 100
- Mobile: +233 (024) 4310 297
- Hotline: +233 (029) 9802932/3
- Toll Free Line: 0800151000 (Only for Vodafone and Airtel):
- Fax: +233 (0302) 229 794
- E-mail: drug.safety@fdaghana.gov.gh
- Shortcode: 4015

Please return the completed form to:

Food and Drugs Authority, P. O. Box CT 2783, Cantonments-Accra, Ghana

You can report directly or download this form from the Food and Drugs Authority's website:
www.fdaghana.gov.gh

Please, note that this report does not constitute an admission that the reporting medical professional or the suspected product caused or contributed to the event.

Fold along this line

.....

ADVICE ABOUT VOLUNTARY REPORTING

Report all suspected adverse reactions to regulated products:

- Drugs (allopathic/ herbals)
- Vaccines
- Cosmetics
- Medical devices
- Blood and blood products

Report on all:

- Adverse Drug Reactions
- Lack of Efficacy/ Therapeutic Failure
- Suspected Defect
- Medication Error
- Suspected Counterfeit

Report even if:

- *You're not certain the product caused the event
- *You don't have all the details