### **Opinion Article**

# Using 7.1 chlorhexidine gel for umbilical cord care: implication for WHO's recommendation for a standard cord care practice

#### 4 ABSTRACT

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5 Neonatal mortality has been a bane especially in the developing world. Neonatal infection is the second cause of neonatal death after prematurity. The umbilical cord is one such vulnerable route 6 via which newborns are infected, the responsible organisms most likely originate from the 7 maternal genital tract and are acquired during labor and delivery. Such high-infection-related 8 9 deaths make it necessary to identify simple and cost-effective interventions that can be implemented in all settings across the world. WHO has recommended the use of 7.1% 10 11 chlorhexidine gel in areas of high neonatal mortality to replace the use of harmful substances on the umbilical stump. However, in Nigeria, studies are needed to establish the umbilical cord 12 13 separation time, mothers' compliance and satisfaction with use of chlorhexidine.

14 **Keywords:** chlorhexidine gel, umbilical cord, omphalitis, neonatal mortality

#### 15 Introduction

Each year, about 3 million newborns die globally (Liu, Johnson et al, 2012) accounting for 40 % 16 of global under-five mortality (Nangia, Dhingra et al, 2016); this is of great concern especially in 17 developing countries. Annually, serious infections account for nearly 30 % of the 3 million 18 neonatal deaths (Sankar, Chandrasekaran et al 2016); in settings with high-mortality rates, this 19 20 proportion is closer to 50 % (Oestergaard, Inoue et al, 2011). Such high-infection-related deaths make it pertinent therefore to identify simple and cost-effective interventions that can be 21 implemented in all settings across the world. Use of topical antiseptics is one such intervention 22 that is been envisaged to reduce the incidence of infections by preventing or limiting bacterial 23 24 colonization of the skin or umbilical cord in newborns. Five countries namely India, Nigeria, Congo, Pakistan and China alone account for half (2.440 million) of the global deaths from 25 infections and 53.3 % (1.636 million) of neonatal deaths (Liu et al, 2012). Community based 26

studies from developing countries found that infection accounts for about 8 to 80 % of all
neonatal mortality, and as many as 42 % deaths in first week of life (Thaver & Zaidi, 2009).

In Nigeria, an estimated 276,000 neonatal deaths occurs annually; 60,000 of these deaths stem 29 30 from infection, while about 20,000 of these deaths are umbilical cord related (Chorhexidine Working Group (CWG), 2016). Most of these deaths occur in rural areas and northern Nigeria 31 (Akinyemi, Bamgboye et al, 2015). Nigeria has the second highest number of neonatal deaths in 32 the world after India (CWG, 2016). The Nigeria demographic and health survey (NDHS) 2013, 33 estimated its neonatal mortality rate as 37 per 1000 live births, which constituted about 54% of 34 infant mortality. Nigeria contributed 6% to the global neonatal deaths in 2005, while the country 35 moved from the third to the second position in terms of the highest number of neonatal deaths in 36 the world between 2000 and 2010 (Lawn, Kinney et al, 2012). 37

38 Omphalitis is an important cause of neonatal mortality and preventing this condition and its 39 associated neonatal mortality is of high public health importance. While the use of clean birth kits, hand washing and careful attention to hygiene in the days after birth may all be important 40 components of a program to reduce neonatal sepsis; however, none of these interventions have to 41 date provided unequivocal evidence that they can reduce infection-related neonatal mortality. 42 The three randomized controlled trial systematically reviewed by Imdad, Mullany et al (2013) 43 provided substantial evidence that umbilical cord stump treatment with 4% chlorhexidine (CHG) 44 reduces both omphalitis and neonatal mortality, with the impact likely greater in preterm and low 45 birth weight infants. 46

#### 47 The umbilical stump: an important locus of infection in newborns

Newborns are particularly prone to infections for a number of reasons which includes a relatively 48 49 immature immunological system, exposure to maternal vaginal organisms during the birth process and exposure to various pathogens in the first few days of life, often transmitted by 50 physical contact with the caregivers, delivery surfaces and instruments. One vulnerable area for 51 infection for all infants is the umbilical cord stump usually cut, tied/clamped shortly after birth, 52 53 and allowed to dry and detach spontaneously after some days, the cord stump provides necrotic tissue for organisms to colonize and a point of easy entrance of microbes to the neonate 54 (Goldenberg, McClure & Saleem, 2014). 55

The umbilical stump acts as a bacterial reservoir especially in first few days of life, supporting 56 the growth of some beneficial microorganisms (commensals) whereas others are harmful (for 57 example, clostridium tetani). Umbilical Cord infection can be limited to the umbilical cord area 58 (omphalitis) or, after entry into the blood stream via the umbilical vein becomes systemic 59 (neonatal sepsis) (Nangia et al, 2016). The responsible organisms most likely originate in 60 maternal genital tract and are acquired during labor and delivery. In most developing countries, 61 many neonatal infections are environmentally acquired because of higher number of home 62 deliveries, unsafe traditional practices, unskilled birth attendants and unclean living conditions, 63 all of which pose an increased risk of umbilical cord infection (Namgia et al, 2016). Local signs 64 of umbilical cord infection mayinclude redness, tenderness, swelling, pus, warmth and foul 65 odour. Infectious organisms may get directly transmitted from patent umbilical vein to the 66 systemic circulation without evident sign of local cord infection. 67

#### 68 Current World Health Organization recommendation for umbilical cord care

In January 2014, the WHO issued a new recommendation for umbilical cord care. Daily 69 application of 7.1% chlorhexidine digluconate aqueous solution or gel, delivering 4% 70 chlorhexidine to the umbilical cord stump during the first week of life for newborns delivered at 71 72 home in settings with high neonatal mortality (30 or more neonatal deaths per 1000 live births). While clean, dry cord care is recommended for newborns delivered in health facilities and at 73 home in low neonatal mortality settings. The use of chlorhexidine in these situations may be 74 considered only to replace application of a harmful traditional substance, such as cow dung, to 75 the umbilical cord stump (WHO, 2013). 76

WHO in 1998 initially recommended dry umbilical cord care (that is, not applying anything to the cord); but study by Chlorhexidine working group (2016) has shown that90% of mothers apply one substance or the other to the umbilical stump. This practice ofmandatorily using substances on the umbilical cord appears to have a psychological and/or cultural inclination that requires thorough health education to curb. It was on this premise that WHO recommended use of chlorhexidine gel if at all something must be applied to the cord stump.

# Example of some traditional cord care practices that called for WHO's recommendation of a standard cord care agent

Various health institutions and cultures adopt different methods of cord care. While most orthodox health institutions in Nigeria currently advocate the use of methylated spirit, WHO (2013) recently introduced 7.1% chlorhexidine in countries with high neonatal mortality; while advising no treatment at all but keeping the cord clean and dry for developed countries. Some cord care practices in some countries include:

- Nigeria:non beneficial practices such as use of hot compress, herbs, native chalk, salt, sand, saliva, palm oil, menthol-containing balm, petroleum jelly and toothpaste substances were used alone or in combination and mainly applied at home (Abhulimhen-Iyoha & Abidin, 2012). Others include fomentation with dry heat, application of white powder, charcoal andbandaging to preventinfection (Adejuyigbe, Odebiyi et al, 2008)
- Turkey: use of dry coffee, sugared fat, oliveoil, rotten tree powder,myrtle, hellebore, black
   sesame, burnt cloth, tyingthe belly with a rope andputting a butteredcloth over the
   infant'sinfected belly (Alparslan, Demirel et al, 2013).
- Zambia: Different substanceshad different purposes. If cord is too brittle, cracking, bleeding, 98 then a substance that increases softness is been used (Vaseline, cooking ormotor oil, mabono 99 100 (wildfruit) oil, or cream fromsour milk). If cord takes too long toseparate, items to dry itare used such as: baby powder, charcoal dust, dried cowdung, dried chickendroppings (roaster for 101 male babies and hen for female babies), dust fromthreshold of home, ashfrom burnt 102 pumpkinstem, crushed loma(wasps nest), or mud.Any of these would bepounded or ground 103 intoa fine powder.Medicinal substances: pythonsnake oil, breast milk, banana, cowdung, 104 mukunku (treebark), traditional herbs, and dirt from poundingstick are also used (Herlihy, 105 Shaikh et al, 2013) 106
- Bangladesh: Turmeric, boricpowder, mustardoil, ash, coconutoil, Nebanol ointment,ginger,
   chewed rice, heat treatment of cord (Alam, Ali et al, 2008); talcum powder, Savlon, *chular mati* (earthfrom a clay oven), smashed garlic (Moran, Choudhury et al, 2009).
- Uganda:Herbs, onions, ash fromburnt papyrus,petroleum jelly, powder,saliva, ghee, soot mixedwith ghee, water, butter (Byaruhanga, Nsungwa-Sabiiti et al, 2011); salty water, vaseline, normalsaline, ripe banana, sap, ash (Kayom, Kakuru et al, 2015); lizard droppings (Waiswa, Peterson et al, 2010)

Tanzania: Saliva, dirty doorpowder from old door, hotknife, charcoal powder, ground sea shells, burning wood, banana steam, fish bone, talcum powder, and fire steam (Dhingra, Gittelsohn et al, 2014); traditional herbs + cooking oil or water that was used to wash the genitals of an elderly woman (Mrisho, Schellenberg et al, 2008)

- Pakistan:Coconut oil, mustard oil,ghee, olive oil, surma/kohl, turmeric, machineoil,
   Antimony, detol and wheat flour (Gul, Khalil et at, 2014)
- Napel:Mustard oil, antiseptic,ash, mud, breast milk, herbs/spices, saliva (Karas, Mullany et al, 2012), plain water, toothpaste (Sharma, van Teijlingen et al, 2016).
- India:Turmeric, burning tipwith castor oil lamp,antiseptic ointment (Kesterton, Cleland et al, 2009).
- Haiti: dirt from house threshold, burnt nutmeg, ash burned cotton, crushed charcoal, palm
   oil, mixture of leaves and animal dung (Walsh, Norr et al, 2015)
- Sierra Leone: pounded cassava (Sharkey, Yansaneh et al, 2016).

#### 127 Caregivers' reasons for cord care

Studies by(Amare, 2014) found out two main reasons behind caregivers' intention of applying a 128 substance to the umbilical cord. The first reason is to promote healing of the so called "unique 129 130 wound"; secondly, is to hasten the separation of the cord either by keeping the cord stump moist or by drying it out stimulating its occurrence within the first few days of life despite the fact that 131 studies by Imuetinyan (2011) have shown that normal cord separation time can extend for as 132 long as 28 days in some cases. Other reasons include preventing" wind" (evil spirit) from going 133 into the baby: to prevent pains and bad smell(Degefie, Amare et al, 2014 Africa, mothers are 134 often desperate to hasten the time of cord dropping; the longer time the umbilical cord takes to 135 drop, the more likely it is that a more harmful intervention is introduced, and the greater the risk 136 of infection. They tend to indulge in various cultural practices to hasten even the time for a 137 healthy normal cord to separate thereby, introducing infection. This uncalled-for-interventions is 138 common in some cultures where the mother or baby's activity of daily living is restricted (for 139 example, not allowing the mother or baby to go out, delaying baby's bath)until the umbilical 140 stump falls off. 141

#### 142 Chlorhexidne digluconate

Chlorhexidine digluconate is the gluconate salt form of chlorhexidine, a biguanide compound 143 used as an antiseptic agent with topical antibacterial activity. Chlorhexidine gluconate is 144 positively charged and reacts with the negatively charged microbial cell surface, thereby 145 destroying the integrity of the cell membrane. Subsequently, chlorhexidine gluconate penetrates 146 into the cell and causes leakage of intracellular components leading to cell death (National 147 Center for Biotechnology Information, 2016). Chlorhexidine has the following advantageous 148 properties as a topical cord care agent: it released slowly, longer duration of action, not affected 149 by the presence of body fluids, dissolve easily in water, it has an excellent safety profile, is rarely 150 associated with bacterial resistance, is easy to administer and costs few naira per application 151 (Nangia et al, 2016). Available high-quality evidence from the recently conducted Cochrane 152 review indicates that cord cleansing with 4 % chlorhexidine reduces the risk of neonatal 153 mortality by 12 % and omphalitis/infections by 50 % in low-resource community settings 154 including Nepal, Bangladesh, and Pakistan (Sinha, Sazawal et al, 2015). However, the review 155 showed that in hospital settings, chlorhexidine cord cleansing reduces the risk of 156 omphalitis/infections by 52 % and may lead to no difference in neonatal mortality as compared 157 158 to dry cord care. In spite of these benefits, studies by Imdad, Bautista et al (2013) have shown that it prolongs the time for the cord to drop when compared with other methods like dry cord 159 care. Contrary to the findings from South Asia countries, the only two randomized controlled 160 trials conducted in Africa (Tanzania and Zambia) on chlorhexidine use gave no significant 161 162 reduction in neonatal mortality when compared to dry cord care.

In Nigeria, various state government are investing into the lives of the citizens; programs has been put up to scale up the use of chlorhexidine with Sokoto stategovernment taking the lead, followed by Bauchi and Ogun state government. Recently, on 14th March, 2017 the governor of Kogi state flagged off the adoption of chlorhexidine gel for umbilical cord care to replace the use of methylated spirit in the state with the vision of reducing neonatal mortality.

Now how do we reconcile these high evidence studies from South Asia countries and those conducted in Africa so as to implement best policies? If the use of chlorhexidine gel prolongs umbilical cord separation time when compared with other cord care methods, it means that desperate mothers are likely to introduce other harmful methods to hasten the cord separation thereby, increasing the likelihood of infection thus, the essence WHO introduced chlorhexidine

gel is defeated. Also if there is no significant difference in neonatal mortality between the use of chlorhexidine and dry cord care in settings of high neonatal mortality (more than 30 in 1000), then there is no point incurring economic cost from the purchase of chlorhexidine. However, a detailed pooled meta-analysis from different settings across the globe is needed to inform policies.

#### 178 **Recommendation**

179 Chlorhexidine gel for umbilical cord care is still a novel intervention in Nigeria, and no study 180 was found on its use in Nigeria; More evidence based studies will be of benefit in the following 181 areas: its effect on cord separation time, effect on mortality/morbidity, Mother's compliance and 182 satisfaction with use, factors that will impede its use and its effect on very low birth weight 183 babies.

#### 184 Conclusion

The desire to care for the umbilical cord has been found to be universal culturally; a myriad of substances are used by different cultural groups. Though some of these substances are not totally harmful, but there therapeutic effect has not been establishedempirically. WHO has recommended the use of 7.1% chlorhexidine gel especially in settings with high neonatal mortality. To gurantee that mothers will use this gel judiciously as recommended; it is pertinent therefore, to put up more studies on this novel cord care agent so as to inform better policies.

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