Assessment of the Use Of Chlorhexidine Digluconate Gel for Cord Care at Kangundo Level 4 Hospital

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***Abstract*- Background:** Sepsis continues to be an important cause of morbidity and mortality in neonates. One of the most important portals of entry for infections is the umbilical cord. In Kenya, the use of chlorhexidine digluconate (CHX) gel was introduced to scale in 2016 and received with mixed reactions in some hospitals with reports of medication errors and ineffectiveness received. This study sought to find out the knowledge, practices and attitude on its use in Kangundo Level 4 hospital.

Methodology: The study was carried out at Kangundo level 4 hospital between June and August 2019. It was a descriptive cross-sectional study with both quantitative and qualitative components. A questionnaire was used for the quantitative data collection while focus group discussions were held for the qualitative data collection. Ethical approval was sought prior to commencement of data collection.

Results: A total of 19 clients and 24 healthcare workers were interviewed and two focus group discussions held. All the 19 clients had delivered in the hospital and only three were first-time mothers. Education on how to use chlorhexidine (CHX) was given to 16/19 (84%) of the clients interviewed. Duration of application varied among clients; 4 days 5/19(26%), 7 days, 12/19 (64%) and until the stump falls off, 2/19 (10%). While frequency of application varied from OD 15/24 (62%), BD 3/24 (13%) and TID 6/24(25%).

Conclusion and recommendation: There was poor understanding on the use of CHX among both clients and HCWs at Kangundo level 4 hospital.. There is need for training and development of a standard operating procedure on use of CHX.

***Index Terms*-** CHLORHEXIDINE DIGLUCONATE 'SEPSIS, UMBILICAL CORD,

I. Introduction

1.1 Background

The umbilical cord connects the baby and the placenta while in the womb. It is made of blood vessels and connective tissue cells and immersed in amniotic fluid. The umbilical cord is covered by amnion which is continuous with the outer epithelial layer of the embryo at the attachment of the umbilicus (1).After delivery, the umbilical cord is cut separating the mother and her baby. This leaves behind a stump that is expected to dry, fall off leading to the healing of the wound. This open wound can sometimes be a portal of entry for pathogenic micro-organisms that can cause infection at the site or in the blood stream (septicemia). It is therefore paramount that the cord stump be kept clean. Sources of the pathogens could be the mother's birth canal, the care giver's hands or the environment where the new born is(2). The umbilical stump is therefore an important portal of entry of microorganisms that can lead to morbidity and mortality.

Good umbilical cord care is important in decreasing the incidence of omphalitis and neonatal tetanus (3). Various public health interventions have proven effective in decreasing the incidence and death from these infections. A study in Nepal showed that the use of chlorhexidine (CHX) decreased the incidence of omphalitis by 75% and neonatal mortality by 24% compared to dry cord care. There is inadequate evidence to support the use of topical antimicrobials on cord stump to prevent sepsis. The studies done worldwide have been carried out in developed countries and do not give the probability of effectiveness when the interventions are used in resource limited settings. A systematic review of randomized controlled trials and quasi-randomized controlled trials by Zupan and Garner (4) did not find any studies from developing countries regarding cord care..

1.2 Neonatal mortality rates

It is estimated that about 3.3 million deaths occur in neonates annually (5) and more than 30% of these are caused by infections (6). The main causes of neonatal deaths include preterm birth, asyphixia, pneumonia,neonatal tetanus, diarrhea and sepsis (7). The rate of neonatal mortality globally stands at 22 deaths per 1000 live births and 41 % of the deaths in children occur during the neonatal period (5). The neonatal mortality rate in Kenya is 24 deaths per 1000 live births (8) and neonatal deaths account for 42% of deaths in children under 5 years and 56 % of all infant deaths (9). In Kangundo hospital, neonatal sepsis accounted for 34% of all the admissions in the newborn unit in 2018 and was responsible for 15 % of the deaths reported in neonates (10). Septic cords are an important cause of neonatal sepsis and neonatal death as they are open wounds and act as ports of entry for disease causing microorganisms. The incidence rate of omphalitis in low-income countries is estimated to range from 2 to 77 per 1000 live births in hospital settings and probably higher in home deliveries (11).

1.3 Cord care practices

When cord care is inadequate, infections can occur locally at the cord stump (omphalitis) or in the blood stream. The umbilicus provides direct access to the blood stream and is fertile ground for bacterial growth (12). Infections of the cord are preventable in most cases and the best practices should be employed to prevent neonatal morbidity and mortality. Many practices have been used to ensure that the cord remains aseptic and free of infections. However, it has not been concluded which practice is superior to others in most cases (4). Most commonly used methods include use of antiseptics such as alcohol, iodine, silver sulphadiazine, chlorhexidine and dyes. Use of antibiotics such as tetracycline, bacitracin, neomycin and nitrofurazone has been advocated for in some countries. Other studies have shown that natural drying of the cord is more effective than use of alcohol (13)and had a shorter cord separation period. A study done in France showed that dry cord care was non-inferior to use of antiseptics and should be used instead of antiseptics which were unnecessary, expensive and constraining in high income countries(14). The world health organization recommends the use of topical antiseptics (chlorhexidine) where hygienic conditions are poor and or infection rates are high(15).

A systematic review of studies on umbilical cord care practices conducted in 1999 found no significant difference in the effectiveness of different methods (3). However, some products such as chlorhexidine showed increased separation time with reduced bacterial colonization but there was no change in infection rates. A randomized controlled trial comparing the use of sterile water and sterile alcohol and found no difference in bacterial colonization of the umbilical cord (16). In a randomized control trial done in India in 2011, CHX was found to be superior to dry cord care by significantly reducing the amount of blood-culture confirmed sepsis and having a shorter separation time (17). A recent systematic review showed that use of CHX was beneficial in reducing neonatal morbidity and mortality in infants born at home but there was no evidence of the benefit of CHX over dry cord care for infants born in hospitals (18). It recommended the use of CHX for all births in Kenya to ensure an all-inclusive policy in the country.

1.4 Kenyan guidelines

Until 2015, the Kenyan guidelines recommended dry cord care but there were varying practices across the country ranging from use of alcohol, methylated spirit and povidone iodine for cord care(8). To standardize practices, a systematic review was conducted to evaluate available evidence on the best cord care practices whose results informed the development of the current guidelines on cord care that were released in 2016. The current Kenyan guidelines for care of the newborn direct that CHX should be used to prevent umbilical cord sepsis(9). A pilot study was conducted in one county after which scale-up to the whole country was implemented. Prior to scaling up of use of CHX for cord care in Kenya, a study was carried out in the pilot county to determine the perceptions of the health care workers (HCWs). The study found out that CHX was acceptable to both the HCWs and the community but recommended that prior to scale up, community sensitization, staff training ,dissemination of guidelines and protocols be done.(19)

In the recent past, guidance on handling of the umbilical cord has been changing hence requiring continuous training of the workforce on the best practices. Many developing countries have had challenges adjusting to this with reports of non-standard practices such use of antibiotics, antiseptics and even dry cord care. This could be attributed to insufficient training of the health care work force.

1.5 Problem Statement

There have been increased reports of medication errors in the use of chlorhexidine for cord care and reports of its ineffectiveness in the Country received by the Pharmacy and Poisons Board (PPB) (20). Similarly, Kangundo Hospital have also received such reports. The investigation by the pharmacy and poisons board did not address the reservations that some healthcare workers have on the effectiveness of CHX. This lack of confidence in the product and personal beliefs of Health care workers has contributed to non-use or poor use by clients. Lack of training upon scale up of CHX use has contributed to the knowledge gap.The survey done by PPB did not include Kangundo hospital in the sites that were assessed. Faced with a rise in the number of complaints and non-standard care of the umbilical cord at the hospital, there is need to document the complaints and assess the level of knowledge of health care workers on the use of chlorhexidine and be able to address the gap.

1.6 Research questions

1. What is the level of knowledge on the use of Chlorhexidine for cord care among HCWs and clients at Kangundo?
2. What are the perceptions of HCWsregarding the effectiveness of chlorhexidine vs methylated spirit in preventing neonatal sepsis and time to separation of the cord?

1.7 Objectives

The main objective of the study was to determine the level of knowledge and practice in use of chlorhexidine digluconate for cord care .

Specific objectives

1. To determine the knowledge on use of chlorhexidine for cord care among healthcare workers and clients
2. To evaluate the current practice in use of chlorhexidine among healthcare workers and clients and how it could affect the effectiveness of chlorhexidine
3. To determine the attitudes towards use of chlorhexidine among health care workers
4. To assess the comparative effectiveness between chlorhexidine and methylated spirit from the perspectives of healthcare workers and clients

II. METHODOLOGY

2.1 Study design and study site

The study was conducted in Kangundo level 4 hospital, in Machakos county which is a secondary health facility offering both basic and specialized health care services. The study was a descriptive cross-sectional study with both qualitative and quantitative components. The quantitative section involved data collection using a pre-developed questionnaire while the

qualitative section involved collection of views of health care workers through a focused group discussion (FGD) The study was conducted in the months of July and August 2019. The target population were healthcare workers working in maternity, post-natal ward, newborn unit (NBU) and maternal and child health unit (MCH).It also targeted clients who were in postnatal ward or mothers to neonates visiting the MCH. Census was used as the sampling technique to determine the number of healthcare workers and clients to be interviewed. All nurses working in the departments mentioned above were included in the study. All clients in the postnatal ward on the day of data collection were included in the study. All clients visiting the MCH department with neonates were included in the study. The focused group discussion had two representatives from each department. This sample was sufficient based on the number of staff assigned to work in each unit and the average number of clients visiting the facility on a given day.

2.2 Data Collection and Analysis

Quantitative data was collected was collected using the developed questionnaire. The questionnaires were fed into a excel spreadsheet, collated, then stored in a password protected computer for cleaning. Prior to analysis, quantitative data was exported to MS Excel then later exported to SPSS for analysis. Data analysis was carried out using univariate analysis techniques. This involved frequency distributions for categorical variables and descriptive statistics (means, medians, standard deviations) for continuous variables. Categorical variables (e.g. uptake of CHX, etc.) were presented using bar charts, pie charts and frequency distribution tables. Box plot were used to present continuous variables. Univariate analysis was used to determine the prevalence of CHX use and to give an understanding of the characteristics of the study participants. Statistical Package for Social Sciences (SPSS) version 20.0, was used for data analysis while MS Excel was used to create charts and graphs.

Qualitative data was collected through focus group discussions which were audio recorded, transcribed, and analyzed for themes and patterns. Descriptive analysis of the data was then conducted. The process was used to develop themes and sub-themes that emerge from the ground based on responses to the questions. Data presentation was done through verbatim.

III. RESULTS

A total of 19 clients and 24 healthcare workers were interviewed and two focus group discussions held.

Table 1. Demographics of the clients

Category	Number
Education	Primary-5 Secondary- 11 Tertiary – 3
Parity	Primi-3 Multiparous-16
Place of delivery	Hospital – All

Table 2: Distribution of the Health Care Workers

Cadre	No.	Department	No.
Medical officers	5	Maternity ward	10
Clinical officers	5	Post-natal ward	4
Nurses	14	MCH	6
		New born unit	4

Education on how to use chlorhexidine (CHX) was given to 16/19 (84%) of the clients interviewed.
Duration of application varied among clients; 4 days, 5/19(26%), 7 days, 12/19 (64%) and until the stump falls off, 2/19 (10%).

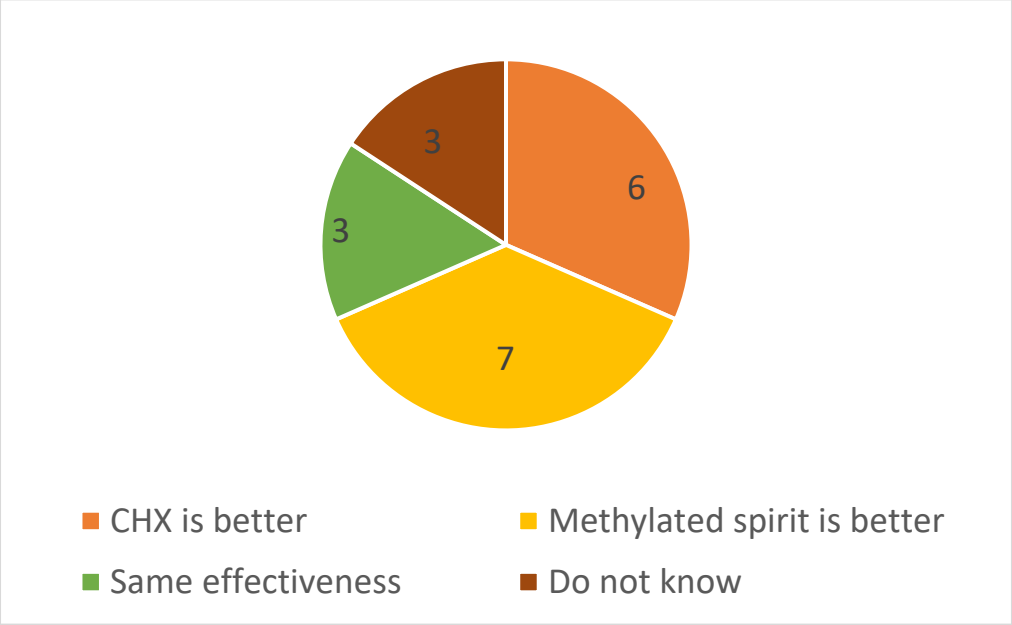

Figure 1: **Client perceptions on the effectiveness of CHX and Methylated spirit**

Twenty of the 24 HCWs (83%) interviewed advised the patients on cleaning the cord prior to application of CHX, frequency of application varied from OD 15/24 (62%), BD 3/24 (13%) and TID 6/24(25%).

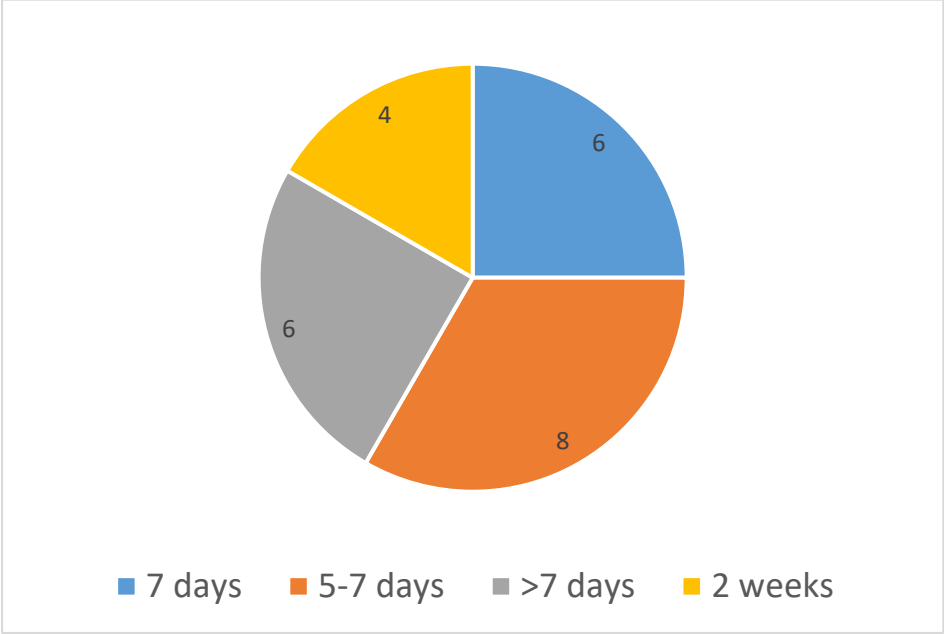

Figure 2: **Duration mother advised to use CHX gel**

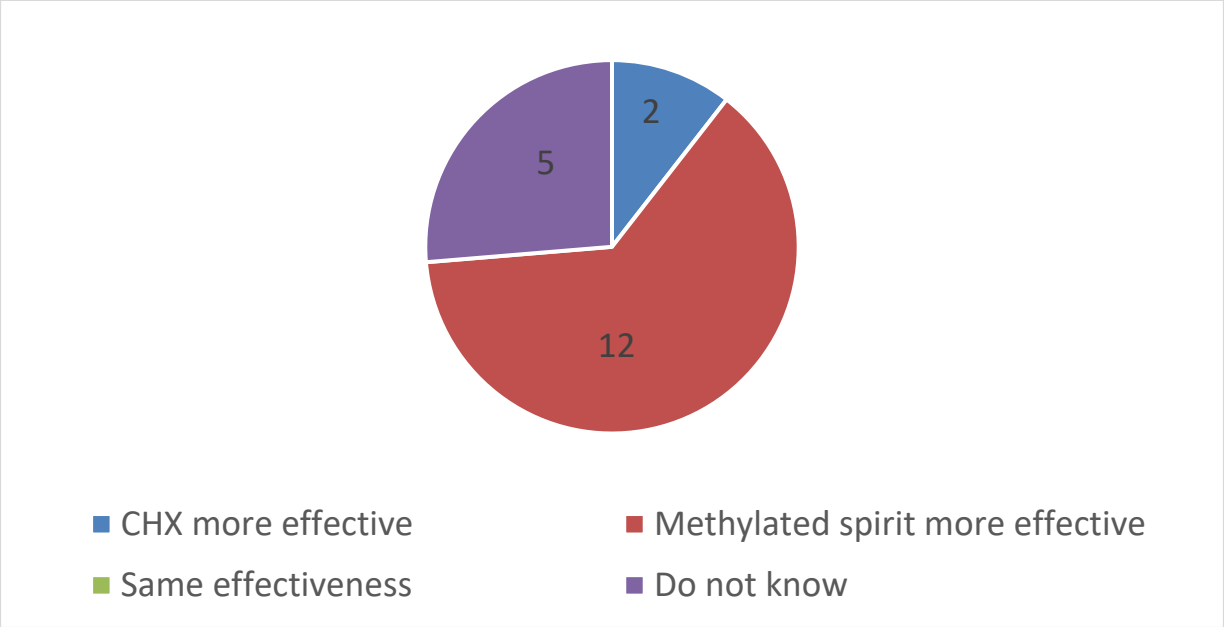

Figure 3: **Health care workers' perception on the effectiveness of CHX and Methylated spirit**

Two FGDs were held for HCW; lack of training and clear instructions on how to use the gel were the major contributors to ineffectiveness of CHX. Most of the participants in the FGD felt that methylated spirit was more effective than CHX. Gel was not applied immediately after birth in maternity as recommended. There was no clear direction on whether the cord was to be cleaned before application. Those who opted to clean either used saline water or just warm water. There was erratic supply of the gel ,leading to reverting to use of methylated spirit.

I do not like using the chlorhexidine gel as it forms a dry coat on the cord that is not easy to clean. I tell mothers to clean using methylated spirit, which we provide in the ward. Sometimes the CHX gel is not available.

We were using the CHX gel for some time until it ran out of stock and we reverted to use of methylated spirit. The stumps were falling off when some patients were still in the ward. It was like magic!

The supply is so erratic and sometimes they supply the gel and sometimes the drops. The drops were better since they do not form a coat around the stump. The product is out of stock most of the time and its not stocked in local chemists where the mother can purchase. We keep going back to use methylated spirit.

Table 3: Themes arising from the Focused Group discussions

Training on use of CHX	No training Guidelines were provided but most HCWs have not seen them
Use of CHX	No standard way of using CHX.
Instructions given to the mothers on use of CHX	To clean the stump using cotton wool soaked in saline water Apply CHX once daily for seven days
Instructions in the guideline and product insert	Conflicting instructions guideline:- apply from top to stump Insert: apply from stump going up
Effectiveness of CHX	Initially not effective as the layer of CHX was applied on top of the existing coat. Cleaning was not done as this step was not in the guidelines
Availability and cost of CHX	Not readily available at the hospital Frequent stock outs. Retail cost is prohibitive.

IV. DISCUSSION

The study identified major gaps in the utilization of CHX for cord care at Kangundo level 4 that could be contributing to the perceived ineffectiveness of the product. From the quantitative survey, it emerged that the duration of use of CHX varied widely among the HCWs interviewed. . The clients also reported different durations and frequencies of applying CHX. There was no clear guidance on whether to clean the cord prior to application of CHX. From the FGDs, the participants reported lack of training and clear SOPs on the use of CHX. There were some instructions in the guidelines that conflicted with those on the product insert and caused confusion among HCWs. The supply of CHX was erratic leading to reverting to unrecommended cord care practices.

There are still mixed cord care practices in Kenya according to a study carried out in 2016 . Methylated spirit, normal saline are among the most common products used for cord care(19). The same problem still exists today in our facility with most of the healthcare workers still not sure which product to use despite the guidelines being clear. The time to drop off of the cord and complete healing is reported to have increased since onset of use of CHX. There have also been unverified reports of an increase in the number of septic cords in the child welfare clinic . This is in contradiction to the findings reported in a study done in 2016 that showed high acceptability of CHX owing to its fast action in cord drop off (19).

In a study comparing use of various antiseptics and water for cord care in developed countries, found that use of water had a shorter cord-separation time than alcohol. There was therefore no advantage of using antiseptic in developed countries. However, the study recommends use of antiseptics in certain situations where there is a high risk of infections such as in pre-term babies, babies in intensive care units and in institutions in developing countries such as ours(21).

Recommendations by a study that supported the scale up of CHX use have not been fully implemented; These include community sensitization through CHVs, staff training, providing CHX for free and ensuring constant supply of the medication(19). There is need to conduct the above in order to ensure that the use of CHX is as recommended by the guidelines.

The scale-up of CHX use was met with reports of medication errors some of which led to adverse drug reactions. Most of the reported ADRs were associated with a particular formulation- the drops that were confused for eye-drops. The pharmacy and poisons board conducted investigations on the allegations (20) and later issued a circular to market authorization holders directing how packaging of the product should be done for marketing in the country(22).

A study done in a referral hospital in India comparing the effect of CHX versus dry cord care showed a significant difference in time to separation with the CHX showing a separation time of 9 days versus 10 days with the dry cord care. There were no micro-organisms isolated on culture in the CHX group compared to several micro-organisms *(Acinetobacter, Enterococcus,Klebsiella and Stapyllococcus))* that were isolated in the dry cord care group. The neonates treated with dry cord care were ten times more likely to get sepsis as compared to those treated with CHX(17). This contradicts the findings in this study where most of the HCWs and clients perceive CHX to be less effective .

A study conducted in Ibadan, Nigeria to compare the incidence of umbilical cord infections among neonates receiving CHX gel and methylated spirit found no significant difference(23). However, this study found a higher non-compliance incidence in the group receiving CHX. Mothers had to use other products to clean the cord due to the dry flakes left by the gel. This is similar to the findings of this study where both HCWs and clients complained of not knowing what to do with the accumulated CHX gel on the cord.

In conclusion, studies done in many countries have not shown therapeutic superiority of CHX over other products or dry cord care. However, it is recommended that CHX be used in situations where infections of the cord are likely to happen if dry cord care is practiced. The world health organization recommends that CHX be used in low and middle income countries for cord care and this was added to its essential medicines list in 2014The product recommended for use in Kenya is CHX. However, there needs for clear standard operating procedures on the use of chlorhexidine gel for cord care in order to achieve its maximum therapeutic benefits. There was poor understanding on the use of CHX among both clients and HCWs at Kangundo level 4 hospital. There is need for training and development of a standard operating procedure on use of CHX.

Ethical consideration

Ethical approval was sought from the Mount Kenya University ethics review committee (ERC) before commencement of the study (approval number 851). Informed consent was sought from health care workers and clients before data collection commenced. This was done through reading and signing the informed consent form. All data was captured anonymously and no data bore direct personal identifiers.

Competing interests

Authors declare no competing interests

Authors contributions

Clarice Ambale participated in proposal development, data collection and analysis, manuscript writing

Brian Ngatia participated in proposal development and data collection

Jonathan Nthusi participated in proposal development and data analysis

Jacinta Mukonzo participated in manuscript writing

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