



CODEN [USA]: IAJPBB

ISSN: 2349-7750

INDO AMERICAN JOURNAL OF PHARMACEUTICAL SCIENCES

Available online at: <http://www.iajps.com>

Research Article

WHICH IS EFFECTIVE FOR THE PURGATION OF UMBILICAL CORD TO PREVENT OMPHALITIS? A RANDOMIZED CLINICAL TRIAL TO COMPARE METHYLATED SPIRIT AND 4% CHLORHEXIDINE

¹Dr. Qasim Mahmood Ghouri, ²Dr Ayesha Zahoor, ²Dr Sumble Shager

¹Federal government Polyclinic, Post Graduate Medical Institute, Islamabad, ²THQ Hospital
Kotmomin.

Article Received: March 2019

Accepted: April 2019

Published: May 2019

Abstract:

Background: A number of antiseptics are being utilized for umbilical cleansing which includes, methylated spirit, alcohol, iodine, silver sulphadiazine, chlorhexidine, triple dye, eosin, acriflavine and gentian violet, current antibiotic application, and human milk.

Objectives: To make a comparison between the effectiveness of 4% chlorhexidine and methylated spirit in the purgation of the umbilical cord for preventing omphalitis.

Method: This random clinical trial was carried out at Jinnah Hospital, Lahore (September 2017 to March 2018). A total of 96 healthy full-term infants of both genders weighing equivalent and over to 2.50Kg delivered through vagina were included in the study. Patients with the need of antibiotics were excluded from the study. Chlorhexidine group and Methylated spirit were named as group 1 and group 2 respectively. The researcher inspected the umbilicus by his own for omphalitis signs.

Result: In this study, the Gestational age range was 36 to 43 weeks with an average gestational age of (39 ± 1.10) week. In this research study, omphalitis prevention or normal umbilicus shedding within one week of start of therapy (efficacy) was observed in 45 (93.80%) patients within group 1, 4% chlorhexidine and in 38 (80%) patients within methylated spirit (Group 2) with value p 0.038 which is statistically very significant.

Conclusion: This study affirmed that the efficacy of four percent chlorhexidine is more as in comparison to methylated spirit to prevent omphalitis.

Keywords: Omphalitis, Chlorhexidine and Methylated Spirit.

Corresponding author:

Dr. Qasim Mahmood Ghouri,

Federal government Polyclinic, Post Graduate Medical Institute, Islamabad.

QR code



Please cite this article in press Qasim Mahmood Ghouri et al., which is effective for the purgation of umbilical cord to prevent omphalitis? A randomized clinical trial to compare methylated spirit and 4% chlorhexidine., Indo Am. J. P. Sci, 2019; 06(05).

INTRODUCTION:

Pakistan is at the 23rd number in ranking among the countries which are the highest under 5 mortality [1]. Approximately, every year, round about 45% deaths of children under five years are amongst babies within their first 28 days of life. Several newborn babies have died within the 1st week. One out of three major causes of neonatal mortality within Pakistan is due to Sepsis. The umbilical cord is the major source of infection [2]. The mortality and neonatal morbidity are reduced due to the application of antiseptic within developing countries [3 – 5]. Health care professionals had many debates on newborn's care regarding umbilical cord. Past in history, numerous practices including a variety of cleansing techniques were exercised regarding the care of umbilical cord. It is observed in recent researches that the present standards via modern infection control policies are surrounded by traditional and historic practices instead of scientific justification and investigation. These studies discourage traditional usages of antimicrobials [6, 7]. In the beginning, cord care had concerns regarding subsequent infection and bacterial colonization however, the association between infection and umbilical colonization was unclear. The delay in cord separation can be projected towards intensification of infection incidence [8]. The isopropyl alcohol usage as antimicrobial umbilical cord treatment has consistently been confirmed providing lengthening to the time of cord separation. Routinely usage of an antimicrobial agent like alcohol is recommended by health care providers [9]. Several antiseptics including alcohol, iodine, methylated spirit, Chlorhexidine, silver sulphadiazine, gentian violet, dyes (Eosin, Acriflavine and triple dye), antibiotics topical applications for instance neomycin, bacitracin, nitrofurazone, or moisture absorbing powders or tetracycline, as well as human milk is also being utilized for the cleansing of umbilical cord [10, 12]. These antiseptics reduce the rate of omphalitis up to 27% to 56% [5]. The study presented by Sinha A et al in 2015 indicated that chlorhexidine cord care within the communal setting caused a 12% decrease in mortality of neonatal mortality and a 50% decrease in the incidence of omphalitis [13]. The use of methylated spirit is very common in Pakistan for umbilical cord cleansing but locally or internationally no studies are available on the topic of using methylated spirit within omphalitis prevention. Moreover, only one study by Soofi S et al in 2012 is available on chlorhexidine within Pakistan which showed the incidence of omphalitis was 3.7% within newborn treated with 4% chlorhexidine [14]. Therefore, this study was planned on this topic. The comparison between two drugs will provide us

guidance in choosing better drugs and to prevent omphalitis, thus for making policy to reduce morbidity and neonatal mortality.

METHOD:

The main object of the study was to compare the Methylated spirit with the efficacy of 4% chlorhexidine within the Umbilical cord cleansing to prevent omphalitis. This random clinical trial was carried out at Jinnah Hospital, Lahore (September 2017 to March 2018). The randomized clinical trial method was used. None of the studies is available for comparison of methylated spirit with the efficacy of chlorhexidine henceforward the sample size was calculated from the research study conducted in Pakistan by Soofi S et al in 2012 [14] that displayed the chlorhexidine efficacy as 96.3%, for the prevention of omphalitis. In our ward, twenty newly born babies were observed following Methylated spirit administration for omphalitis development under the setting for seven days duration. Sixteen out of twenty newborn babies were having normal umbilicus shedding within 7 days of the start of therapy. However, four newly born babies developed redness around the umbilical site with pus in it. Efficacy was found to be 80% within the prevention of omphalitis. The design effect was taken as 1. Since the ratio of sample size for each group was 1:1 the sample size was measured as total 96 keeping 48 in both groups and taking confidence level at 95% and power is taken at 80% calculated through sample size software. Non-probability, consecutive sampling was used as a sampling technique. Healthy full-term male and female babies with the weight 2.5Kg or more and delivered through the vagina in the hospital setting were included in the research study. The Newly born babies with the need of antibiotics within the initial 48 hours of life as well as the babies with umbilical catheters were excluded from the study. For the progression of data, collection procedure the researcher kept contact with the Gynecology department for information for the record of delivery cases conducted within the Gynecology Department. Informed consent was obtained from the parents/guardian of babies. Necessary approvals were obtained by the local ethical committee of the hospital. Patients were allotted group 1 and Group 2 through the lottery method. Demographic information, as well as weight and brief history, was taken. The group 1 and group 2 were considered as Chlorhexidine group and Methylated spirit group respectively. The researcher instructed the parents/guardians the process of applying the drugs to the tip of the cord and to the stump and around the base of the stump with clean hands. Each baby took his/her first dose by the hand of

parents/guardians in the presence of researcher parents/guardians were asked to repeat the practice of application once in a day and for the total number of five days. To avoid any type of noncompliance the researcher was available for contact with the parents/guardians through mobile phones on a daily basis. The parents/guardians of group 1 were provided with the drug 4% chlorhexidine as well as parents/guardians of group 2 were provided with methylated spirit for use at home. The parents and guardians were instructed to bring the baby instantly if in case the umbilicus colour is changed into red. In normal circumstances, they were to report with the baby on the seventh day. The researcher inspected the umbilicus for observing omphalitis signs e.g. oozing of pus from the umbilicus and presence of redness within the periumbilical zone. In the case of absence of omphalitis signs, efficacy was observed (omphalitis prevention or usual umbilicus shedding in seven days of start of therapy). All data was noted on Performa. The SPSS was used for Statistical data evaluation.

Mean \pm S.D for the weight of newborn and gestational age and Percentage and Frequencies for gender were presented. Academic qualification of parents, as well as efficacy, was noted. p-value $<$ 0.05% was significant and a comparison was made among two groups in terms of efficacy applying the Chi-Square Test.

RESULTS:

In this research study, Gestational age ranged from 37 to 42 weeks with the average gestational age (38.93 ± 1.18) weeks. The average gestational age within group 1 and group 2 was (38.90 ± 1.18) and (39.30 ± 1.18) weeks respectively. The average weight of the baby was (3.55 ± 0.50) kg. In this research study, efficacy (omphalitis prevention or normal umbilicus shedding in seven days of start of therapy) was observed in 45 patients 93.76% within group 1 (4% chlorhexidine) and in 38 patients 79.20% within group 2 (methylated spirit) and with a p-value of 0.037 which is significant statistically.

Table – I: Group Wise Gestational Age and Weight (Mean \pm SD)

Variables	Group - A (48)		Group - B (48)		Total	
	Mean	SD	Mean	SD	Mean	SD
Gestational Age	38.88	1.18	39.29	1.18	38.92	1.18
Weight	3.5	0.46	3.6	0.53	3.54	0.51

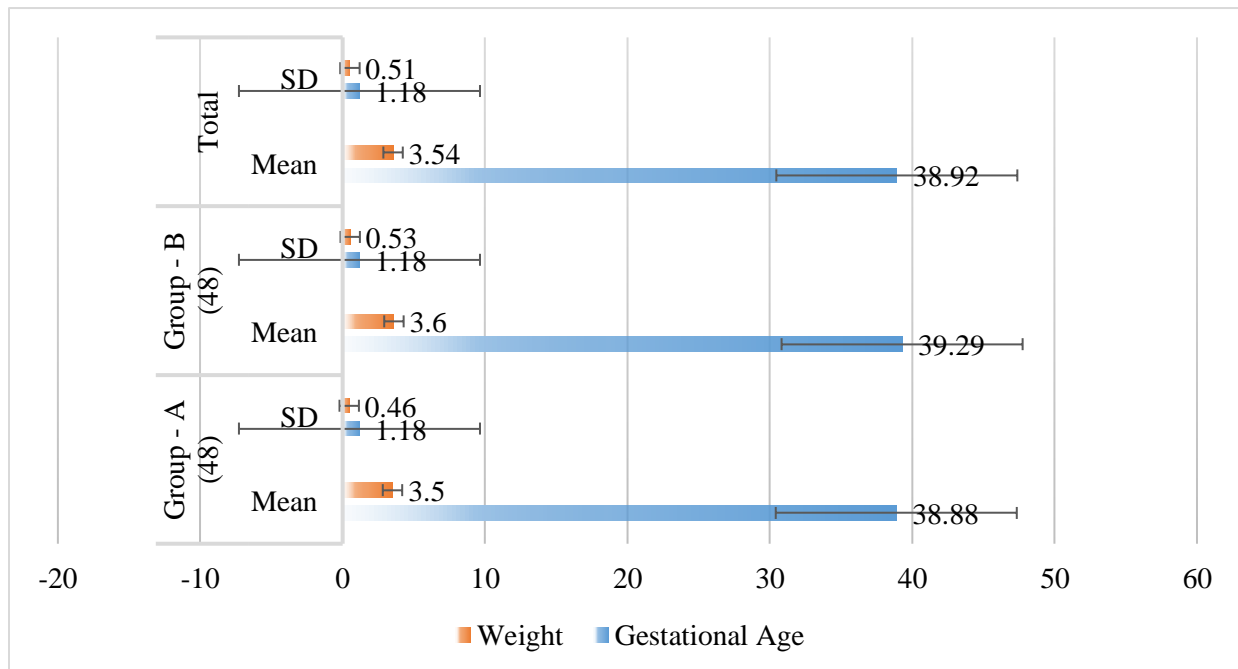
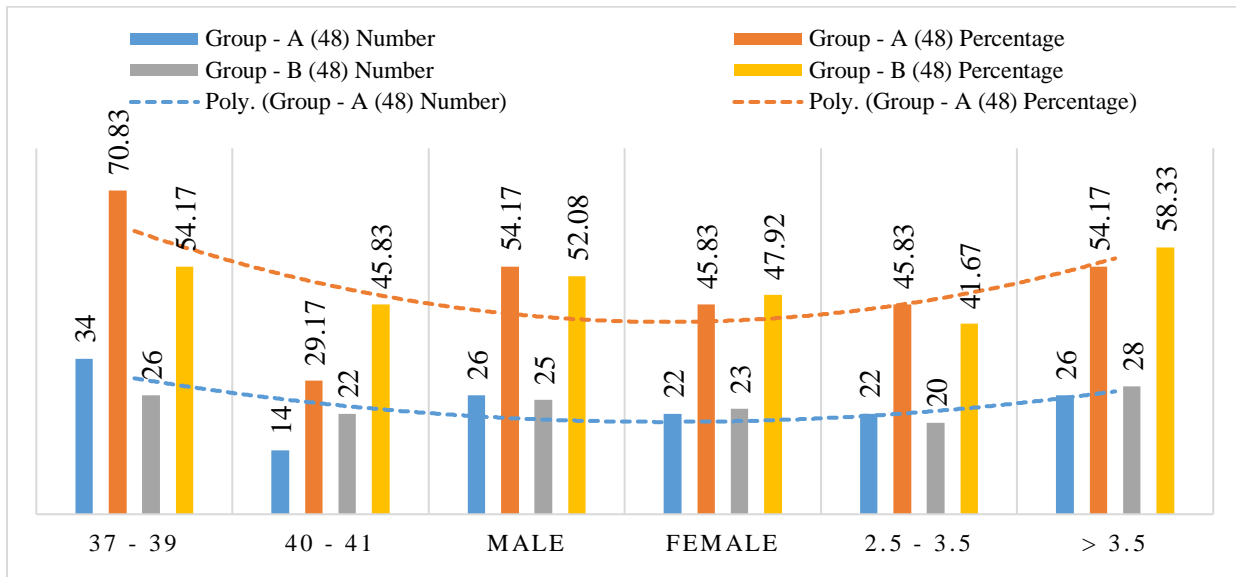
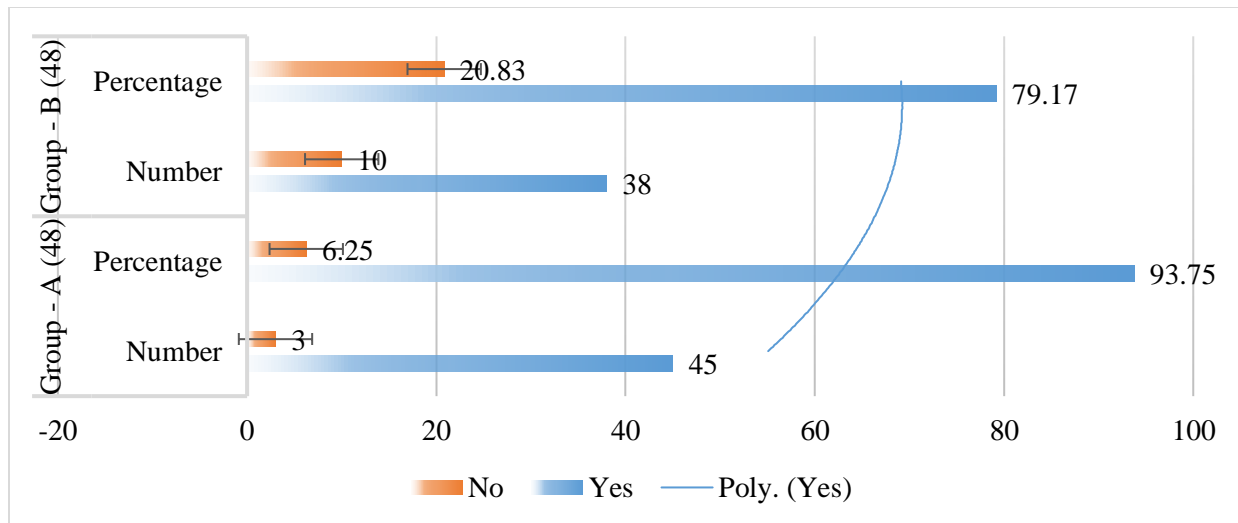


Table – II: Group Wise Stratification of Gestational Age, Gender and Weight

Variables		Group - A (48)		Group - B (48)		Total	
		Number	Percentage	Number	Percentage	Number	Percentage
Gestational Age (Weeks)	37 - 39	34	70.83	26	54.17	50	52.08
	40 - 41	14	29.17	22	45.83	36	47.92
Gender	Male	26	54.17	25	52.08	51	53.13
	Female	22	45.83	23	47.92	45	46.87
Weight	2.5 - 3.5	22	45.83	20	41.67	42	43.75
	> 3.5	26	54.17	28	58.33	56	56.25

**Table – III:** Group Wise Efficacy

Efficacy	Group - A (48)		Group - B (48)		P-Value
	Number	Percentage	Number	Percentage	
Yes	45	93.75	38	79.17	0.037
No	3	6.25	10	20.83	



DISCUSSION:

Approximately above 3 million newborn's deaths happened in the whole world [15] and out of which 30% were caused by infections [16, 17]. Umbilical cord infection is also part of these infections. The area of umbilical cord promotes the development of some beneficial microorganisms like commensals, while many others are damaging, for example, *Clostridium tetani*. The setting where neonate is delivered, and the birth canal of the mother, can provide a source of bacteria. The infection of Cord can be confined to omphalitis (The umbilical cord) or become systemic (neonatal sepsis) after entering into the bloodstream. The Data related to omphalitis incidence is rare in developing countries, the present data approximation indicates the risk to range between 3 and 78 over 1000 live births within the setting of a hospital, and fatality rates of amid one percent and fifteen percent in accordance with the definition of omphalitis [18]. Community-based data displays higher infection rates [18, 19]. Unusually, at present no data is available from many countries in Africa where neonatal mortality remains high and several deliveries still happen within the home. The infection of the cord should be avoidable in most cases, best cord care practices have great importance for reducing neonatal morbidity and mortality and for offering an alternative to damaging applies [20]. Such practices included: saliva, vegetable oil, breast milk, cow dung, powder ground from local trees, application of ash, traditional herbs with cooking oil, pumpkin flowers fluid, water used in washing an adult woman's genitals, can be harmful [21, 22]. This study was conducted for the comparison of methylated spirit with the efficacy of 4% chlorhexidine within the cleansing of the umbilical cord to prevent omphalitis. In this research study, the gestational age ranged from 37 to 41 weeks with an

average of the gestational age of 38.92 ± 1.18 weeks. In our research study, omphalitis prevention or normal umbilicus shedding within seven days of start of therapy (efficacy) was observed in 45 patients (93.75%) within group 1 (4% chlorhexidine) and in 38 patients (79.17%) within group 2 (methylated spirit) with a statistically significant p-value of 0.037. In a study presented by Sinha A et al in 2015 stated in their assessment that, care of chlorhexidine cord within the setting of the community resulted in half (50%) decrease in the omphalitis incidence and a 12% decrease in mortality of neonatal [13]. In a study presented by Soofi et al., stated that, a omphalitis reduction within the purgative group of CHX [14], while in a study presented by Mullany et al., stated a decrease by depending upon the definition of omphalitis, moderate / severe redness and severe redness alone or pus and redness ranging to umbilicus base This decrease of intense omphalitis was higher if the interference was with the incidence rate ratio of 0.13, 95% CI: 0.07– 0.31) at birth's first day [23]. The study by Arifeen et al., stated a decrease in numerous infection (pus with redness), a lower decrease within the single cleansing group of CHX [24]. A small evidence from a small hospital-based studies suggested that using antimicrobials have no better results[25, 26], in a study presented by Pezzati et al., made a comparison salicylic sugar powder, with 4% CHX within preterm infants but stated only a single sepsis case within each arm [25], while in the study presented by Ahmadpour et al [11], and Erenel et al.,[27] Moreover, in studies by Hsu et al.,[28] and Suleman et al.,[26] stated sepsis or very few omphalitis cases. Three cluster-randomized community trials within a meta-analysis conducted different countries that evaluated CHX application influence to the infant's umbilical cord to prevent

mortality and cord infection. Any CHX application led to 22% decrease in all cause death of neonatal within the intervention group. The decrease within omphalitis range 28 % to 57 % in comparison with the control group dependent on infection's intensity [3]. At present time practical approaches of umbilical cord care differ in dissimilar areas of the country and none of the uniform protocol is being followed. A variety of local antiseptics are being practiced for cord care including triple dye, antibiotic ointment, alcohol, povidone iodine, water, and soap or no treatment at all and no one among these have proven greater in limiting sepsis at the health facility level. Practical regarding Unhygienic cord care is dominant in community settings.[29] and traditional substances like turmeric, Surma, ash, powder and mustard oil, etc. are still being used by people for the care of the cord [30].

CONCLUSION:

This study affirmed that the efficacy of four percent chlorhexidine is more as in comparison to methylated spirit to prevent omphalitis and it is recommended that four percent chlorhexidine should be routinely used to prevent from omphalitis and mortality and morbidity our population.

REFERENCES:

1. El Arifeen S, Mullany LC, Shah R, Mannan I, Rahman SM, Talukder MRR, et al. The effect of cord cleansing with chlorhexidine on neonatal mortality in rural Bangladesh: a community-based, cluster-randomised trial. *Lancet* 2012;379(9820):1022-8.
2. Pezzati M, Rossi S, Tronchin M, Dani C, Filippi L, Rubaltelli FF. Umbilical cord care in premature infants: the effect of two different cord-care regimens (salicylic sugar powder vs chlorhexidine) on cord separation time and other outcomes. *Pediatrics* 2003;112(4): e275-e.
3. Suliman AK, Watts H, Beiler J, King TS, Khan S, Carnuccio M, et al. Triple dye plus rubbing alcohol versus triple dye alone for umbilical cord care. *Clin Pediatr* 2010;49(1):45-8.
4. Erenel AŞ, Vural G, Efe ŞY, Özkan S, Özgen S, Erenoğlu R. Comparison of olive oil and dry-clean keeping methods in umbilical cord care as microbiological. *Mat Child Health J* 2010;14(6):999-1004.
5. Hsu W-C, Yeh L-C, Chuang M-Y, Lo W-T, Cheng S-N, Huang C-F. Umbilical separation time delayed by alcohol application. *Ann Trop Paediatr* 2010;30(3):219-23.
6. Alam MA, Ali NA, Sultana N, Mullany LC, Teela KC, Khan NUZ, et al. Newborn umbilical cord and skin care in Sylhet District, Bangladesh: implications for the promotion of umbilical cord cleansing with topical chlorhexidine. *J Perinatol* 2008;28(S2): S61.
7. Fikree FF, Ali TS, Durocher JM, Rahbar MH. Newborn care practices in low socioeconomic settlements of Karachi, Pakistan. *Soc Sci Med* 2005;60(5):911-21.
8. Dore S, Buchan D, Coulas S, Hamber L, Stewart M, Cowan D, et al. Alcohol versus natural drying for newborn cord care. *J Obstet Gynecol Neonat Nurs* 1998;27(6):621-7.
9. Medves JM, O'Brien BA. Cleaning solutions and bacterial colonization in promoting healing and early separation of the umbilical cord in healthy newborns. *Can J Public Health* 1997;88(6):380-82.
10. Novack AH, Mueller B, Ochs H. Umbilical cord separation in the normal newborn. *Am J Dis Child* 11. 1988;142(2):220-3.
12. Mendenhall AK, Eichenfield LF. Back to basics: caring for the newborn's skin. *Contemp Pediatr* 2000;17(8):98-.
13. Golombek SG, Brill PE, Salice AL. Randomized trial of alcohol versus triple dye for umbilical cord care. *Clin Pediatr* 2002;41(6):419-23.
14. Ahmadpour KM, Zahed PY, Hajian K, Javadi G, Talebian H. The effect of topical application of human milk, ethyl alcohol 96%, and silver sulfadiazine on umbilical cord separation time in newborn infants. *Arch Iran Med* 2006;9(1):33-9.
15. Chawla G, Diwakar K. Comparison of umbilical cord cleansing using sterile water and povidone iodine-spirit during early neonatal period: A double blind randomized control trial. *J Clin Diag Res* 2015;9(7):SC01.
16. Sinha A, Sazawal S, Pradhan A, Ramji S, Opiyo N. Chlorhexidine skin or cord care for prevention of mortality and infections in neonates. *Cochrane Database Syst Rev* 2015.
17. Soofi S, Cousens S, Imdad A, Bhutto N, Ali N, Bhutta ZA. Topical application of chlorhexidine to neonatal umbilical cords for prevention of omphalitis and neonatal mortality in a rural district of
18. Pakistan: a community-based, cluster randomised trial. *Lancet* 2012;379(9820):1029-36.
19. Oestergaard MZ, Inoue M, Yoshida S, Mahanani WR, Gore FM, Cousens S, et al. Neonatal mortality levels for 193 countries in 2009 with trends since 1990: a systematic analysis of progress, projections, and priorities. *PLoS Med* 2011;8(8): e1001080.

20. Lawn J, Cousens S, Zupan J. 4 million neonatal deaths: when? Where? Why. *Lancet* 2005;365(9462):891-900.
21. Mullany LC, Darmstadt GL, Katz J, Khatry SK, LeClerq SC, Adhikari RK, et al. Risk of mortality subsequent to umbilical cord infection among newborns of southern Nepal: cord infection and mortality. *Pediatr Infect Dis J* 2009;28(1):17.
22. Mir F, Tikmani SS, Shakoor S, Warraich HJ, Sultana S, Ali SA, et al. Incidence and etiology of omphalitis in Pakistan: a community-based cohort study. *J Infect Developing Countries* 2011;5(12):828-33.
23. Mullany LC, Darmstadt GL, Khatry SK, LeClerq SC, Katz J, Tielsch JM. Impact of umbilical cord cleansing with 4.0% chlorhexidine on time to cord separation among newborns in southern Nepal: a cluster-randomized, community-based trial. *Pediatrics* 2006;118(5):1864-71.
24. Capurro H. Topical umbilical cord care at birth: RHL commentary. WHO Reproductive Health Library 2004.
25. Mrisho M, Schellenberg JA, Mushi AK, Obrist B, Mshinda H, Tanner M, et al. Understanding home-based neonatal care practice in rural southern Tanzania. *Trans Royal Soc Trop Med Hygiene* 2008;102(7):669-78.
26. Mullany LC, Darmstadt GL, Katz J, Khatry SK, LeClerq SC, Adhikari RK, et al. Risk factors for umbilical cord infection among newborns of southern Nepal. *Am J Epidemiol* 2006;165(2):203-11.
27. Mullany LC, Darmstadt GL, Khatry SK, Katz J, LeClerq SC, Shrestha S, 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. *Lancet* 2006;367(9514):910-8.
28. 2006;367(9514):910-8.
29. World Health Organization. World health statistics 2015: World Health Organization; 2015.
30. Das JK, Rizvi A, Bhatti Z, Paul V, Bahl R, Shahidullah M, et al. State of neonatal health care in eight countries of the SAARC region, south Asia: how can we make a difference? *Paediatr Int Child Health* 2015;35(3):174-86.
31. Imdad A, Mullany LC, Baqui AH, El Arifeen S, Tielsch JM, Khatry SK, 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 Pub Health* 2013;13(3): S15.
32. Karumbi J, Mulaku M, Aluvaala J, English M, Opiyo N. Topical umbilical cord care for prevention of infection and neonatal mortality. *Pediatr Infect Dis J* 2013;32(1):78.
33. Imdad A, Bautista RMM, Senen KAA, Uy MEV, Mantaring III JB, Bhutta ZA. Umbilical cord antiseptics for preventing sepsis and death among newborns. *Cochrane Database Syst Rev* 2013.