Review of Omphalitis Interventions in India, Nepal and Pakistan Using Proximal, Intermediate and Distal Risk Factors

List of Interventional and Investigational Studies Summarizing Location, Methods, Results and Interpretation

Study	Location	Study Groups	Intervention	Control	Sample Size	Statistical Results	Interpretation of Results
Mullany, L. C., Darmstadt, G. L., Khatry, S. K., Katz, J., LeClerq, S. C., Shrestha, S., & ... Tielsch, J. M. (2006). Articles: Topical applications of chlorhexidine to the umbilical cord for prevention of omphalitis and neonatal mortality in southern Nepal: a community-based, cluster-randomised trial. *The Lancet* , *367* 910-918. doi:10.1016/S0140-6736(06)68381-5	Nepal	Community-based, cluster-randomized trial	4% CHX vs. Soap and Water	Dry Cord Care	15,123	4% CHX: [RR]=0.68, 95% CI 0.58-0.80; Soap/Water: [RR]=1.03, 95 % CI 0.87-1.22); Dry Cord Care: [RR]=1.00	Findings Frequency of omphalitis by all three definitions was reduced significantly in the CHX group. Neonatal mortality was 24% lower in the chlorhexidine group. Severe omphalitis in CHX clusters was reduced by 75%.
Soofi, S., Cousens, S., Imdad, A., Bhutto, N., Ali, N., & Bhutta, Z. A. (2012). Articles: Topical application of chlorhexidine to neonatal umbilical cords for prevention of omphalitis and neonatal mortality in a rural district of Pakistan: a community-based, cluster-randomised trial. *The Lancet* , *379* 1029-1036. doi:10.1016/S0140-6736(11)61877-1	Pakistan	Two-by-two factorial, Community-based, cluster-randomized trial	4% CHX	Handwashing promotion	9741	CHX application neonatal mortalitiy risk ratio reduced: [RR]=0.62, 95 % CI 0.45-0.85; p=0.003; Handwashing promotion: [RR]=1.08, 0.79-1.48; p=0.62	4% CHX to the umbilical cord was effective in reducing the risk of omphalitis and neonatal mortality in rural Pakistan. Provision of CHX in birth kits might be a useful strategy for the prevention of neonatal mortality in high-mortality settings
Mullany, L. C., Darmstadt, G. L., Katz, J., Khatry, S. K., LeClerq, S. C., Adhikari, R. K., & Tielsch, J. M. (2009). Risk of Mortality Subsequent to Umbilical Cord Infection Among Newborns of Southern Nepal: Cord Infection and Mortality. *The Pediatric Infectious Disease Journal* , *28* (1), 17–20.	Nepal	Community-based, cluster-randomized trial	Surveillance of cord infection and odds ratio of mortality	N/A	23,246	Increased odds for redness extending onto the abdominal skin: 46%, (9-98%); infections occuring after the 3rd day of life increase all-cause and sepsis specific mortality: OR 3.11, CI (1.68-5.74; 4.63 CI (2.15-9.96)	This study provides evidence that common local signs of cord infection are associated with increased risk of mortality. Where exposure of the umbilical cord to potentially invasive pathogens is high, interventions to increase hygienic care of the cord should be promoted and including hand washing, avoiding harmful topical applications, and topical cord antisepsis.
Golshan, M., & Hossein, N. (2013). Impact of ethanol, dry care and human milk on the time for umbilical cord separation. *Journal Of The Pakistan Medical Association* , *63* (9), 1117.	Iran	Single-blinded randomised clinical trial	Ethanol vs. Human breast milk	Dry Cord Care	300	Human milk: Mean 6.5, SD 1.93, CI (6.12-6.88); Dry Cord Care: Mean 7.54, SD 2.37, CI (7.07-8.01); Ethanol: Mean 8.94, SD 2.39, CI (8.47-7.94)	Topical usage of human milk on umbilical cord stump decreased separation time and incidence rate of omphalitis.
Hundley, V. A., Avan, B. I., Braunholtz, D., & Graham, W. J. (2012). Are birth kits a good idea? A systematic review of the evidence. *Midwifery* , *28* 204-215. doi:10.1016/j.midw.2011.03.004	Pakistan	Multi-stage qualitative development tool to assess need	TBA & Clean Birthing Kit	N/A	9 interviews	Tool displayed that sentiments regarding use of the CBKs and barriers	Results display the barriers in supply chair, confidence in government to allocate funds correctly. Supporters believe the CBKs would elevate quality of care provided by TBAs.

Bhutta, Z., Darmstadt, G., Hasan, B., & Haws, R. (2005). Community-based interventions for improving perinatal and neonatal health outcomes in developing countries: a review of the evidence. *Pediatrics* , *115* (2 Part 2), 519-617.	India	Neonatal mortality surveillance	N/A	N/A	216	12 neonatal mortalities due to omphalitis	Delay in breastfeeding due to thought that colostrum is not nutritive may be resulting in increased rate of deaths due to this practice.
Vural G, Kiza S. Umbilical cord care: a pilot study comparing topical human milk, povidone-iodine, and dry care. (2006). *Obstet Gynecol Neonatal Nur* ; 35(l):123-8.	India	Hospital-based, randomized trial	Povidone-iodine & topical human milk	Dry Cord Care	150	Sample size was too small to generate significant statistical data. One baby from the breast milk cohort and one baby from the povidone-iodine cohort developed omphalitis	There was no significant difference between the 3 goups in terms of omphalitis occurrence.
Imdad, A., Mullany, L. C., Abdullah H., B., Arifeen, S. E., Tielsch, J. M., Subarna K., K., & ... Zulfiqar A., B. (2013). The effect of umbilical cord cleansing with chlorhexidine on omphalitis and neonatal mortality in community settings in developing countries: a meta-analysis. *BMC Public Health* , *13* (Suppl 3), 1-11. doi:10.1186/1471-2458-13-S3-S15	Nepal, Bangladesh & Pakistan	Three cluster-randomised community trials	4% CHX	Dry Cord Care	54,624	4% CHX group reduction in risk ration: [RR] 0.77, 95 % CI (0.63, 0.94)	Appication of CHX to newborn umbilical cord can significatly reduce infection and all-cause mortality among home births in community settings.
Aghamohammadi, A., Zafari, M., & Moslemi, L. (2012). Comparing the Effect of Topical Application of Human Milk and Dry Cord Care on Umbilical Cord Separation Time in Healthy Newborn Infants. *Iranian Journal Of Pediatrics* , *22* (2), 158-162.	Pakistan	Randomized Clinical Trial	Human breast milk	Dry Cord Care	152	Human milk topical application group was 150.95 (28.68) hours and in dry cord care group 180.93 (37.42) hours	Results demonstrated that by controlling the effect of intervener variables, median time of cord separation in human milk application group was significantly shorter than in dry cord care group.