Newborn skin cleansing with a dilute chlorhexidine solution reduces neonatal mortality in southern Nepal: a community-based, cluster randomized trial

James M Tielsch1, Gary L Darmstadt1, Luke C Mullany1, Subarna K Khatri2, Joanne Katz1, Steven C LeClerq1, Sharada R Shrestha3, Ramesh K Adhikari3

1Johns Hopkins Bloomberg School of Public Health, Baltimore MD; 2Nepal Nutrition Intervention Project, Sarlahi (NNIPS), Nepal; 3Institute of Medicine, Tribhuvan University, Nepal

Background
Progress has been made in reducing childhood mortality in developing countries; significant challenges remain for neonates

Four million infants die annually during the neonatal period; infections account for 1.44 million (36%) neonatal deaths1

Newborn Cleansing with Chlorhexidine
Combined maternal and vaginal cleansing of hospital-born newborns in Malawi2 and Egypt3 reduced neonatal mortality

Malawi – 22% reduction
Egypt – 33% reduction

No community-based studies of newborn cleansing with chlorhexidine have been conducted

Research Questions
Compared to placebo cleansing, what is the impact of a single full-body wipe of the newborn skin with 0.25% chlorhexidine on all-cause neonatal mortality?

Design / Intervention
Setting / Study Population
Sarlahi District, Nepal
September, 2002 – March 2005
Cultural, social and economic characteristics similar to northern India, Pakistan, Bangladesh

Design
Cluster-randomized, community-based trial
Communities (n=413) randomized to one of two skin cleansing regimens applied once as soon as possible after birth:
1. Cleansing with 0.25% chlorhexidine wipes
2. Cleansing with placebo wipes

Nested within a trial of three separate umbilical cord care regimens (2x3 factorial trial)
Baby wipes provided by Proctor and Gamble

Impact of Cleansing on Overall Neonatal Mortality
Mortality was 11% lower among infants in the chlorhexidine clusters – not strong statistical evidence for impact

Impact among Low Birth Weight Infants
Among low birth weight infants, mortality was significantly reduced in the 0.25% CHX group
Neonatal mortality rate was 34/1000 in the intervention group, compared to 47/1000 in the control group

RR for mortality:

0.72 (0.55, 0.95)

Conclusions
Newborn skin cleansing with 0.25% chlorhexidine reduced neonatal mortality among high risk, low birth weight infants
These infants may be at greater risk of sepsis via percutaneous invasion of pathogens
Chlorhexidine cleansing may prevent or reduce colonization of the skin with these pathogens
Further research is needed to establish the efficacy of this intervention in other settings
This inexpensive, simple intervention could significantly improve survival among high risk infants where home delivery is common and the environment is highly contaminated