

**Impact of cord cleansing with
chlorhexidine (CHX) on neonatal mortality
in rural Bangladesh: a community-based,
cluster-randomised trial**

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Projahnmo Study Group in Bangladesh

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PROJAHNMO in Bangladesh: Context

- Partnership of Bangladesh MOHFW, ICDDR,B, Shimantik and Johns Hopkins University in USA
- Established in 2001 to improve newborn and maternal health
- Study Site: Sylhet district in about 500,000 population
- Facility delivery rate = 9%
- Skilled attendance at delivery = 13%
- NMR ~ 50/ 1,000



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Projahnmo-1: 2001-2006

- Developed, implemented and evaluated a basic Package of community-based MNH intervention package
- Two antenatal home visit to promote
 - ANC, TT, IFA supplementation
 - Facility delivery/skilled attendance at delivery
 - Recognition of maternal danger signs, and care seeking and
 - ENC, newborn danger sign, care seeking
- Three postnatal home visits on day 1, 3 and 7
 - To reinforce ENC, newborn danger sign, care seeking
 - To assess, classify, and manage sick newborns

Projahnmo-1: Key Findings

- A community-based package of MNH interventions reduced NMR by 34% (Baqui et al., Lancet, 1998) – contributed to the design of Bangladesh national neonatal health strategy
- Early postnatal home visits by a trained CHW was associated with 2/3rd lower NMR (Baqui et al, BMJ, 2009)- contributed to WHO-UNICEF joint statement recommending early home visit as a strategy for new-born survival
- Early identification and management of new-born infection, either at first level health facility or at home, had added impact on neonatal mortality (Baqui et al, PIDJ, 2009)

Projahnmo-Bangladesh CHX Trial: Context

- Neonatal mortality remained high (estimated at 36 / 1000 live births)
- Home delivery rate = 88%
- ~ 30% low birth weight
- ~ 20% preterm
- CHX cord care trial was designed to replicate Nepal results

Projahnmo-Bangladesh CHX Trial: Aims

- To assess the impact of two different regimens of chlorhexidine cord care on neonatal mortality compared to “dry cord care”
- To assess the impact of these regimens on omphalitis and cord colonization compared to “dry cord care”

Projahnmo-Bangladesh CHX Trial

- Bangladesh trial was different from Nepal in two ways:
 - Examined the effect of CHX cleansing in the context of a basic package of MNH interventions
 - Examined the effect of single CHX cleansing in addition to multiple CHX cleansing on neonatal mortality and cord infection

Cord Care Regimens

- **Single Cleansing:** 4.0% CHX once as soon as possible after birth
- **Multiple Cleansing:** 4.0% CHX as soon as possible after birth and daily for 7 days
- **Dry cord care:** No cord application, basic messages regarding keeping cord clean and dry

CHX Trial: Study Design

- Cluster randomized trial
- Unit of randomization: CHW areas/clusters
 - Average clusters size (~4000 persons)
 - Total 133 clusters, randomized to one of the three cord care regimen
- All babies met alive within 7 days of birth regardless of intervention status was considered enrolled
- CHWs delivered a basic package of MNH care with or without CHX across all clusters

Follow-up visits

- CHWs conducted home visits:
 - As soon as possible after birth (preferably within 24 hours)
 - Days 3, 6, 9, 15, and 28 of birth
- Examined newborns' cord for signs of infection
- Assessed for other signs of morbidity
- Ascertained survival status at day 28

Mortality risk by study arm

Overall

- Single CHX cleansing: 20% lower NMR, statistically significant
- 7 day CHX cleansing: 6% lower mortality, not significant

Preterm

- Single CHX cleansing: 34% reduction of NMR, statistically significant
- 7-day CHX cleansing: 12% lower NMR, not significant

Effect on cord infection and cord colonization

Cord Infection

- 7-day CHX cleansing reduced severe cord infection by 65% – statistically significant
- Single CHX cleansing reduced severe cord infection by 23% – not significant

Cord Colonization

- 7-day cleansing associated with 36% lower cord colonization - significant
- Single cleansing associated with 18% lower cord colonization - significant

Key findings

- Single CHX cleansing: Moderate effect on cord infection and colonization; 20% statistically significant reduction of neonatal mortality
- 7-day CHX cleansing: Maximum reduction of cord infection and colonization but no significant neonatal mortality reduction
- Mortality reduction was greatest in preterm babies

Interpretation and Conclusion

- Lack of mortality effect in 7-day CHX group cleansing likely due to chance because:
 - No group difference in background characteristics, age at enrollment, and intervention coverage
 - The 7-day group had the lowest cord infection and cord colonization rates
 - Prior data from Nepal and concurrent data from Pakistan showed significant reduction of NMR with multiple (7-10 days) cleansing
 - Chance of missing an effect was 20%; chance of seeing an erroneous effect was 5%

**We recommend introduction of
CHX cord care intervention in
community-based MNH
programs**

Backup slides

Results - Omphalitis

Group	Live Births	Cases	Risk / 1000	RR	95% CI
<u>Redness extending to skin OR pus</u>					
Dry Cord Care	9915	1544	155.7		
CHX – 1 Day	9350	1252	133.9	0.89	0.62 – 1.26
CHX – 7 Days	10251	1405	137.1	0.89	0.62 – 1.26
<u>Redness extending to skin</u>					
Dry Cord Care	9915	403	40.6		
CHX – 1 Day	9350	339	36.3	0.93	0.61 – 1.43
CHX – 7 Days	10251	327	31.9	0.78	0.50 – 1.22
<u>Redness with Pus, or Severe Redness</u>					
Dry Cord Care	9915	258	26.0		
CHX – 1 Day	9350	211	22.6	0.90	0.55 – 1.45
CHX – 7 Days	10251	151	14.7	0.55	0.31 – 0.95
<u>Severe Redness with Pus</u>					
Dry Cord Care	9915	42	4.2		
CHX – 1 Day	9350	31	3.3	0.77	0.40 – 1.48
CHX – 7 Days	10251	16	1.6	0.35	0.15 – 0.81

Crude Colonization Rates

Group	Enrolled Babies	Positive (Any Growth)	Proportion	PRR	95% CI
<u>Overall</u>					
Dry Cord Care	1785	1708	95.7	1.00	
CHX – 1 Day	1537	1192	77.6	0.82	0.78 – 0.85
CHX – 7 Days	1912	1157	60.5	0.64	0.60 – 0.68
<u>NC 01</u>					
Dry Cord Care	646	605	93.7	1.00	
CHX – 1 Day	569	396	69.6	0.75	0.70 – 0.81
CHX – 7 Days	705	466	66.1	0.71	0.66 – 0.77
<u>NC 03</u>					
Dry Cord Care	578	563	97.4	1.00	
CHX – 1 Day	501	381	76.1	0.78	0.74 – 0.82
CHX – 7 Days	614	363	59.1	0.61	0.57 – 0.65
<u>NC 06</u>					
Dry Cord Care	561	540	96.3	1.00	
CHX – 1 Day	467	415	88.9	0.92	0.89 – 0.96
CHX – 7 Days	593	328	55.3	0.57	0.53 – 0.63