

Waterless Hand Cleansing with Chlorhexidine during Perinatal Period: Preliminary Results from a Randomized Controlled Trial



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On behalf of
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The Challenge

- Neonatal period is uniquely vulnerable
 - 24% of neonatal mortality is attributable to infections
- Observational data suggests handwashing can prevent umbilical cord infections and neonatal mortality
- Handwashing behavior, efficacious for preventing childhood infections, is stubbornly difficult to change
 - RCT from Pakistan (Soofi et al) showed no effect with a relatively light-touch intervention
- ***How do we overcome lack of handwashing habits and social norms to protect neonates?***

Motivators and Barriers to Handwashing with Soap in the Neonatal Period

- Handwashing materials **not available where needed**
- **Inconvenient** to wash hands with soap
- Mothers **feel too busy**
- Mothers try to **avoid water** during perinatal period
- **Cannot ask others** to wash hands with soap before touching the baby
- Previous trial evaluating promotion of handwashing with soap yielded modest results



→ A novel solution is needed to promote hand cleansing among mothers and household contacts of neonates

Chlorhexidine: a hygiene product for the neonate

- Chlorhexidine effective against most bacteria and enveloped viruses
- Bactericidal and bacteriostatic effects
- Well tolerated
- Neonatal cord care with chlorhexidine reduces mortality

Study objectives

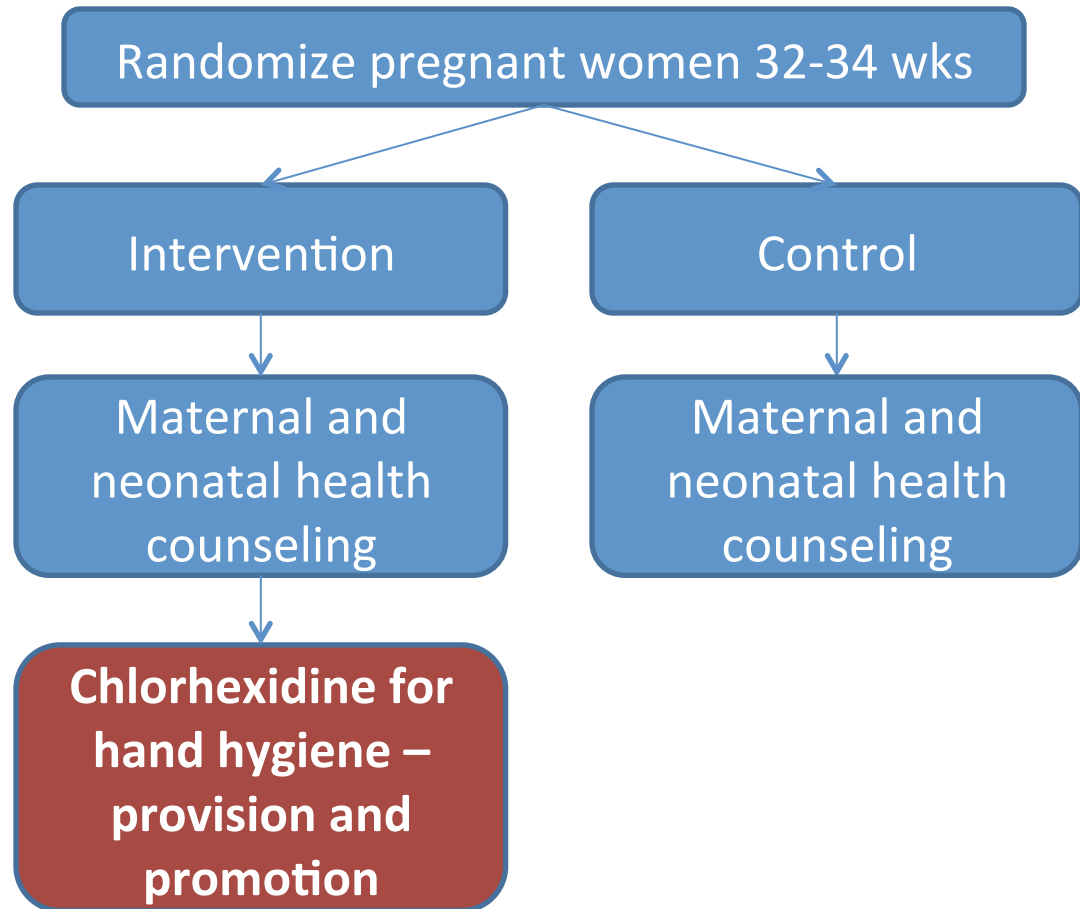
- To **demonstrate** the behavioural impact of chlorhexidine-based hand hygiene intervention on hand cleansing of
Mothers: those closest to the neonate
Family members: those most likely to introduce new organisms to the neonate
- To **evaluate the acceptability** of chlorhexidine for hand cleansing in the neonatal period among mothers and family members of neonates

Study design

Approach: Randomized controlled trial
- individual randomization

Setting: Existing demographic surveillance system in Mirzapur

Estimated sample size: 300



Hand Cleansing Intervention

Motivators for hand cleansing

Nurture

Cue

Convenience



Steps for using chlorhexidine



Fixed times for hand cleansing

Morning



Noon

Night



Times for hand cleansing by mothers and others



Measurement of outcomes of interest

- Hand cleansing by mothers, family members, visitors
 - Structured observation
 - Presence of chlorhexidine/hand washing materials
 - Chlorhexidine consumption

Baseline Demographic Characteristics

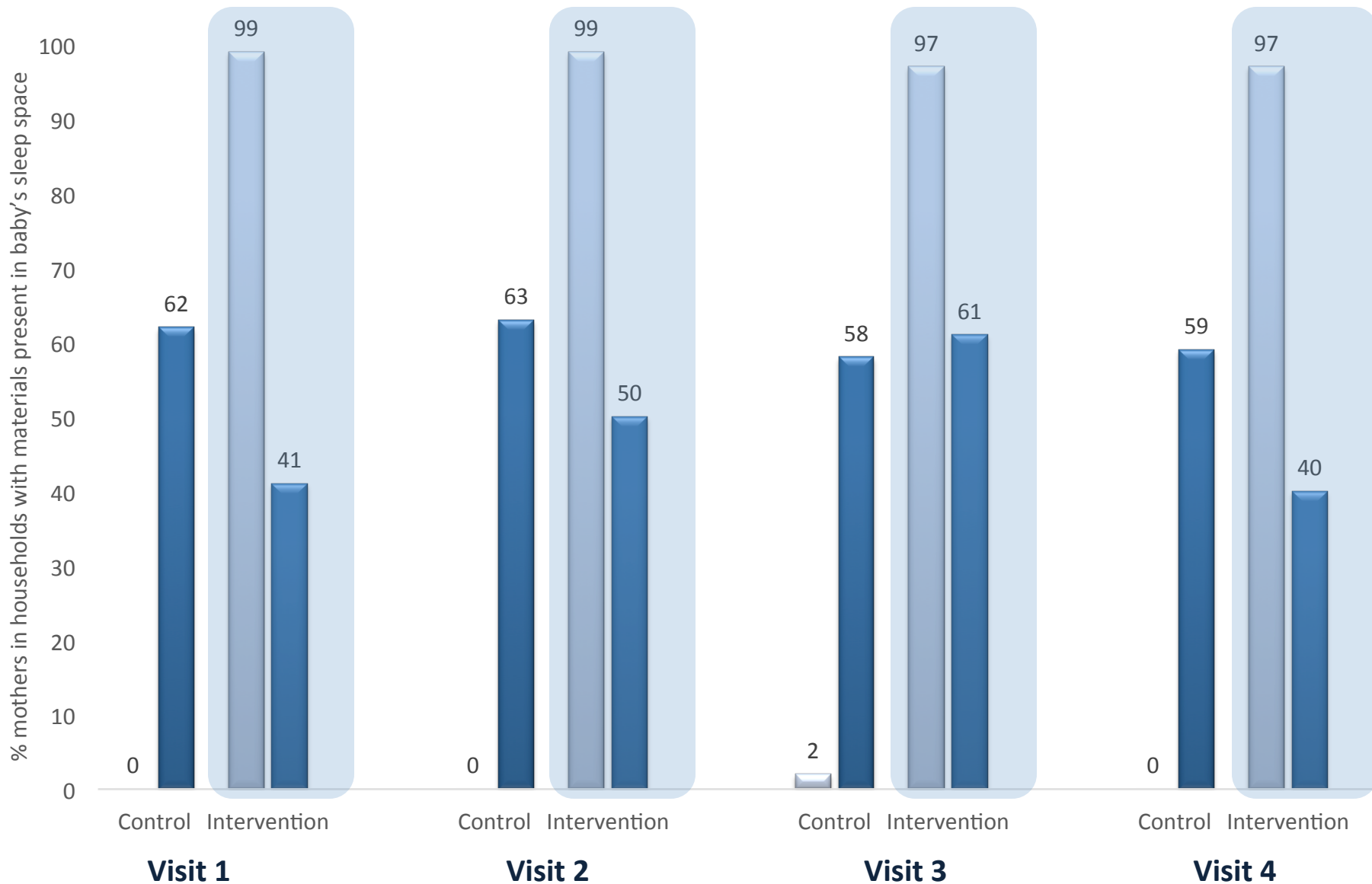
Characteristic	Control (N=128)	Intervention (N=130)
Age of respondent Median (IQR)	24 (20-29)	25 (20-28)
Years education of respondent Median (IQR)	7 (5-9)	7 (5-9)
Muslim	92%	88%
Median number of rooms for sleeping (IQR)	2 (2-3)	2 (1-3)
Median number of people living in home (IQR)	4 (3-6)	4 (3-5)

Handwashing at Baseline

Characteristic	Control (N=128)	Intervention (N=130)
Water present at existing handwashing station	95%	96%
Soap present at existing handwashing station*	30%	30%
Self-reported frequency of washing hands before touching a baby	Always: 20% Sometimes: 59% Never: 22%	Always: 15% Sometimes: 57% Never: 28%
Are you able to ask others to clean their hands?	Always: 27% Sometimes: 59% Never: 13%	Always: 20% Sometimes: 61% Never: 19%

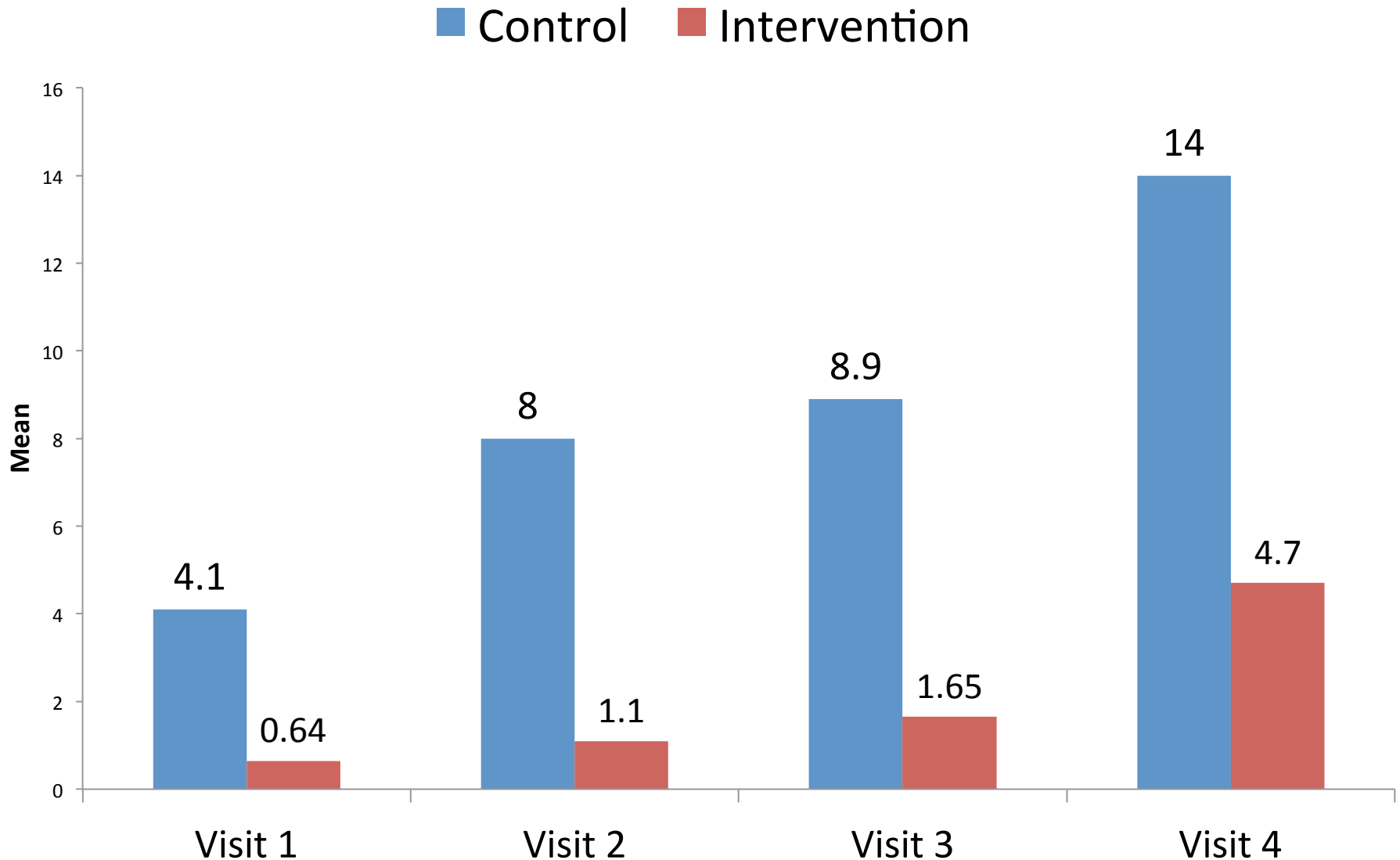
Handwashing material present in baby's sleep space

Chlorhexidine Any soap



Material present at handwashing station for baby care

Number of steps from handwashing station to baby's sleep space



Mean number of times hands washed or cleansed by mothers during 3-hour structured observations

Mothers						
	Week 1 Observation			Week 3 Observation		
	Control n=107	Intervention n=105	RR (95% CI) p-value	Control n=117	Intervention n=118	RR (95% CI) p-value
Handwashing with water ≥ 1 time n (%)	70	57	0.8 (0.7, 1.0) 0.05	68	60	0.9 (0.7, 1.1) 0.19
Handwashing with soap ≥ 1 time (SD)	32 (30)	25 (24)	0.8 (0.5, 1.2) 0.3	38 (32)	34 (29)	0.9 (0.6, 1.3) 0.5
Handwashing with soap or chlorhexidine ≥ 1 time (SD)	32 (30)	73 (70)	2.3 (1.7, 3.2) <0.0001	38 (32)	92 (78)	2.4 (1.8, 3.2) <0.0001

Chlorhexidine Consumption

95% of participants used the product at least 5 times

Median number of grams consumed during the neonatal period: 176 (IQR 95 – 305 grams)

→ a median of 7.8 grams of chlorhexidine consumed per day (IQR 4.2 – 13.8)

→ median of 2.4 uses per day (IQR 1.4 – 4.6)

Number of events of various types observed among mothers

Event type	Control (N=128)	Intervention (N=130)
Baby care	849	851
Fecal contact	261	284
Respiratory secretion contact	5	13
Food contact	321	323
Total	1441	1475

Hand cleansing with soap or chlorhexidine at events observed among mothers

Event type	Control	Intervention	Absolute difference	RR (95% CI)
Baby care	5%	26%	21%	5.6 (4.0 – 7.7)
Fecal contact	12%	49%	37%	4.1 (2.9 – 5.9)
Respiratory secretion contact	0%	29%	29%	-
Food contact	6%	8%	2%	1.4 (0.8 – 2.6)
Total	6%	26%	20%	4.30 (3.45, 5.35)

Number of baby care events observed among various household members

Relation to neonate	Control (N=128)	Intervention (N=130)
Mother	849	851
Other adult female	224	215
Adult male	10	14
Boys	40	39
Girls	92	97

Observed hand cleansing with soap or chlorhexidine before baby care events, among mothers and other household members

Relation to neonate	Control	Intervention	Absolute difference	RR (95% CI)
Mother	5%	26%	21%	5.6 (4.0 – 7.7)
Other adult female	3%	34%	31%	10.9 (5.1 – 23.1)
Adult male	0%	29%	29%	-
Boys	0%	44%	44%	-
Girls	1%	40%	39%	37.0 (5.2 – 263.7)

Positive attributes of chlorhexidine: findings from qualitative investigation

- Perceived more effective than soap for preventing illness, and killing germs
- Waterless
 - Can avoid frequent water handling
- Easy to use
- Easy to carry
- Easier to ask others to clean hands with chlorhexidine than to wash hands with soap

Barriers to chlorhexidine use

- Long drying time (e.g. 5 minutes)
- Before breastfeeding
 - Concern about baby swallowing chlorhexidine if mother cleanses hands
 - Mother prefers to soothe baby quickly than to wait 5 mins for hands to dry
 - If acceptable, addition of alcohol would facilitate drying
- Lotion feels oily / sticky
 - Discomfort when eating
- Male participants felt intervention didn't adequately involve them

Acceptability of chlorhexidine

“Hexidine, it is easier to use and faster hand washing process. If I use soap then I need some time and go to the outside washing place for cleansing the hands. But hexidine does not require more time for cleansing. It is time saving and easy to use without any trouble”

-- IDI_431_High user

Implications

- Promotion and provision of a waterless chlorhexidine-based hand cleanser increased hand cleansing
 - 5-fold among mothers (20 pct pt)
 - 11-37 times in other adult caregivers and children
 - There may have been some reactivity to observation
- Chlorhexidine valued by participants for being waterless, effective, convenient, and facilitating ability to ask others to clean hands
- **Such increases in hand cleansing behavior could substantively reduce serious bacterial infections in neonates**
- Similar effects may be observed using more readily available alcohol-based sanitizer but further behavioral and microbiological study needed

Where do we go from here?

Refine communication approaches to foster greater behavior change

Expand efforts to include birth attendants in and out of facilities

Integrate into MNH programmes in facilities and communities

Measure effectiveness

Rebrand handwashing as an essential maternal and newborn care practice

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“Clean hands for healthy babies”



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