

# Chlorhexidine Cord Cleansing

**September, 2011**  
**Nepalgunj, Nepal**



# CHX Background



- **Broad spectrum antiseptic solution**
- **Common worldwide, excellent safety**
- **Millions of babies have received cord cleansing with CHX since 1970s**
- **WHO recommendations include CHX cleansing when exposure risk is high**
- **Is on WHO Model List of Essential Medicines for cord cleansing**



# Clearing up misconceptions



- **CHX is NOT related to hexachlorophene**
- **CHX cord cleansing (7.1%) not to be confused with other CHX interventions**
  - vaginal cleansing (0.16 – 0.60%)
  - neonatal skin wiping (0.16 – 0.60%)
  - eyewash (.05%), dental wash (0.12%), or pre-operative skin cleansing (2.0%)
- **CHX cord cleansing is direct application of CHX formulations to the cord stump**



# More background?



- **Could have other slide(s) to expand upon background, hx, etc**

# Nepal Chlorhexidine Trial (2002 – 2006)

## Design and Results



# Cord Care Trial - Nepal



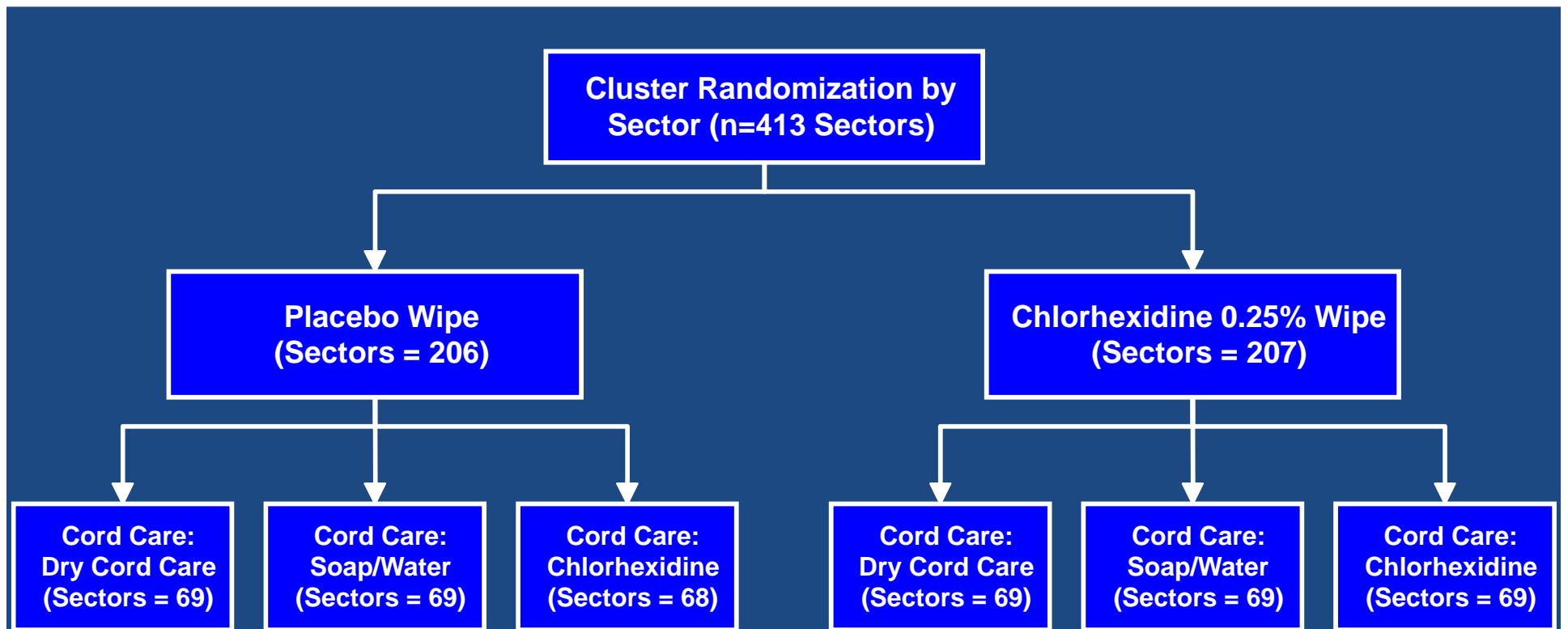
- Community-based cluster randomized trial to examine impact of chlorhexidine cord cleansing on:
  - Umbilical cord infection
  - Neonatal mortality



Source: <http://www.askasia.org/image/maps/nepal1.htm>



# Trial Design



- Cleansing groups masked



# Methods

- **Pregnancies identified through weekly surveillance by local female staff (n=413).**
- **6<sup>th</sup> month of pregnancy**
  - Vitamin A (weekly), iron-folic acid supplements, albendazole
  - Clean delivery kits / cord & newborn care education
  - Maternal tetanus toxoid
- **Newborn infants enrolled at first visit**
- **Home visits throughout the neonatal period**
  - Days 1-4, 6, 8, 10, 12, 14, 21, 28





**Infants in the chlorhexidine and soap and water groups received umbilical cord cleansing on Days 1,2,3,4,6,8, and 10.**



**At each household visit, field workers collected morbidity and vital status data.**



**At each visit, axillary temperature and respiratory rate were recorded, and the cord examined for signs of infection.**



# Signs Evaluated



- **At each visit signs of cord infection collected:**
  - Pus present (Yes/No)?
  - Redness at the base?
  - Swelling at the base?
    - (For redness and swelling – none / mild / moderate / severe)
- **No umbilical cord stumps were cultured for bacterial colonization**



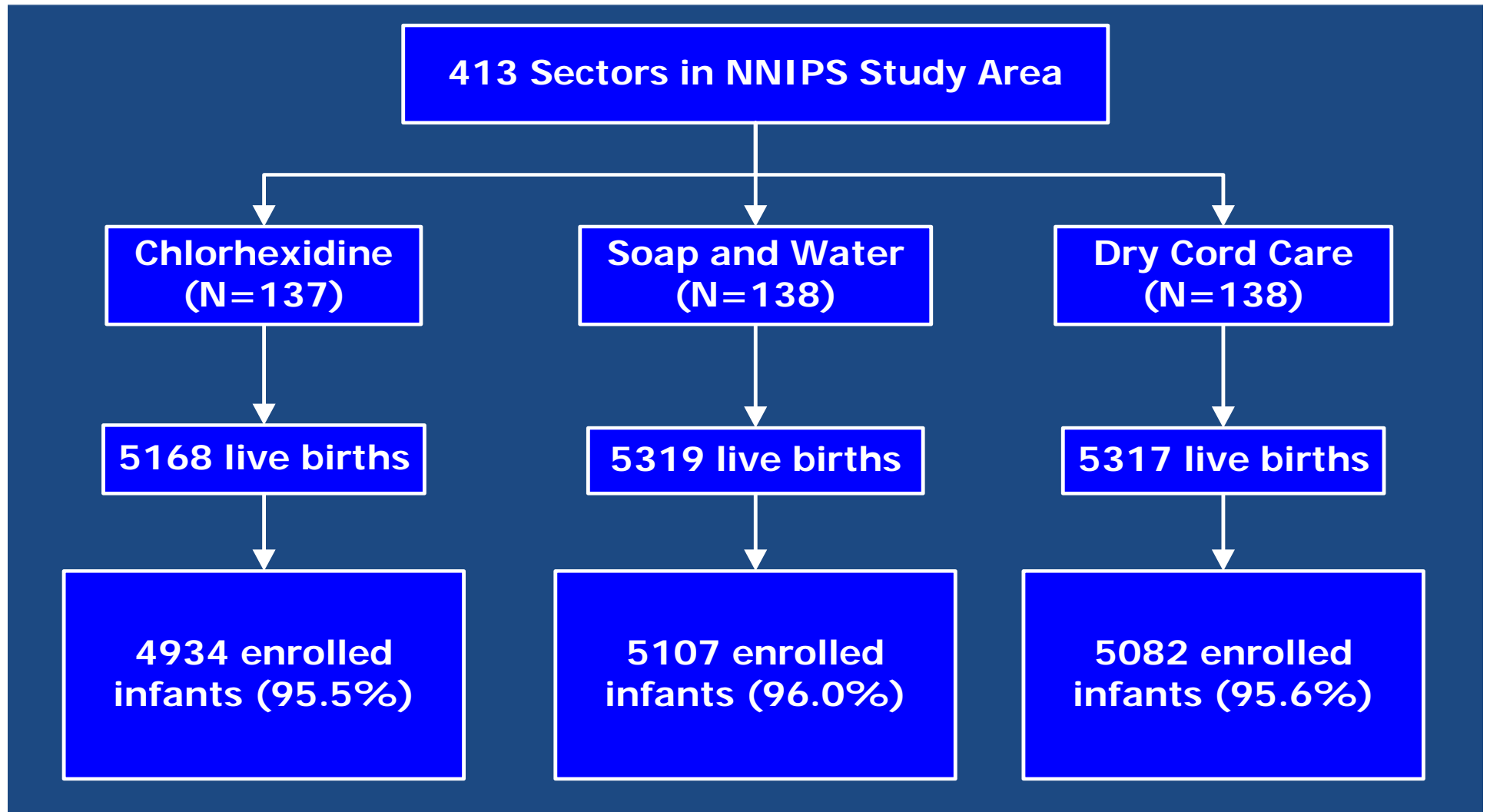
# Data Analysis



- **Incidence-density of cord infection**
- **Neonatal mortality – estimated as deaths per enrolled infants**
- **Stratified by:**
  - Early/late intervention time
  - Full-body cleansing allocation
- **GEE to account for clustered design**



# Study Flowchart





# Randomization Balance



- Demographic characteristics
- Labor and delivery characteristics
- Weight at birth and gestational age
- Household socioeconomic characteristics
- Ethnicity and caste
- Season of enrollment



# Mortality – Enrolled Babies



Group	Live Births	Deaths	Rate	RR (95% CI)
CHX	4,924	72	14.6	<b>0.76 (0.55, 1.04)</b>
Soap&H <sub>2</sub> O	5,107	98	19.2	1.00 (0.76, 1.31)
Dry Care	5,082	98	19.3	





# Mortality – Enrolled Babies



## Stratified by Age at Enrollment

Group	Early (>24 hours)	Late (>= 24 hours)
	RR (95% CI)	RR (95% CI)
CHX	<b>0.66 (0.46, 0.95)</b>	1.02 (0.54, 1.92)
Soap&H <sub>2</sub> O	0.95 (0.69, 1.31)	1.14 (0.68, 1.90)
Dry Care	1.00	1.00



# Omphalitis



## Redness (Moderate or Severe)

Group	Cases	Babies	Inc	RR (95% CI)
CHX	438	4236	10.3	<b>0.68 (0.58, 0.80)</b>
Soap&H <sub>2</sub> O	660	4214	15.7	1.03 (0.87, 1.22)
Dry Care	638	4196	15.2	1.00



# Omphalitis



## Severe Redness OR Pus w/Redness

Group	Cases	Babies	Inc	RR (95% CI)
CHX	147	4676	3.1	<b>0.46 (0.36, 0.59)</b>
Soap&H <sub>2</sub> O	280	4702	6.0	0.88 (0.69, 1.12)
Dry Care	315	4652	6.8	1.00



# Omphalitis



## Severe Redness with Pus

Group	Cases	Babies	Inc	RR (95% CI)
CHX	13	4839	0.3	<b>0.25 (0.12, 0.53)</b>
Soap&H <sub>2</sub> O	53	4962	1.1	1.01 (0.58, 1.77)
Dry Care	52	4930	1.1	1.00



# Summary of Results



## Chlorhexidine substantially reduced:

- **Risk of death within 28 days**
  - 24% reduction overall
  - 34% if applied early
- **Risk of cord infection**
  - 32-75% reduction, depending on severity
  - Cord infection is related to subsequent death
- **Soap and water did not reduce risks**



# Support



- **National Institutes of Health, NICHD, R01 HD44004**
- **USAID Cooperative Agreement Nos. HRN-A-00-97-00015-00 & GHS-A-00-03-00019-00 provided infrastructure support**
- **Procter & Gamble Company provided commodity support**