



4% Chlorhexidine for umbilical cord care

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Objectives

- To understand existing guidance for dry cord care
- To understand and review the evidence available to inform decision making

Background

- Close to 50% of neonatal deaths (3 million) occur within the first 24 hours of birth and a further 25% occurring within 7 days of life.
- According to KDHS 2014, in Kenya the neonatal mortality rate currently is 22 per 1,000 live births, this is about 42% of all under five mortality
- The main causes of neonatal mortality are, asphyxia, preterm births and ***infections (globally 15% Kenyan 7% sepsis*)***.

Background

- Cord vessels may remain potentially patent within the first 24 hours after cutting the cord offering a likely source of direct infection.
- This infection can be localized, or become systemic (sepsis – very early, early or late onset)
- Sparse data to characterize sepsis attributable to cord origin.

Background

- WHO had for a long time recommended the practice of dry cord care.
- From practice this was not happening in Kenya.
- There was need to review evidence to come up with a policy.

Topical Umbilical Cord Care for Prevention of Infection and Neonatal Mortality

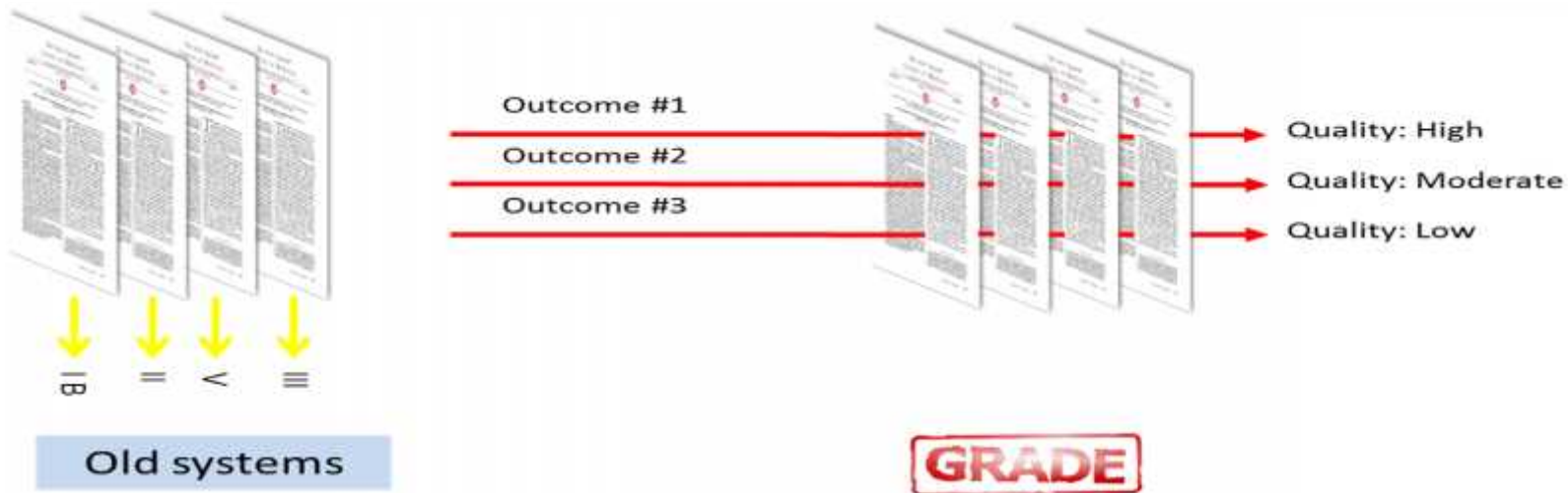
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RATING QUALITY OF EVIDENCE AND STRENGTH OF RECOMMENDATIONS

GRADE: an emerging consensus on rating quality of evidence and strength of recommendations

Guidelines are inconsistent in how they rate the quality of evidence and the strength of recommendations. This article explores the advantages of the GRADE system, which is increasingly being adopted by organisations worldwide

Overall certainty of evidence



- This refers to the combined quality of evidence across all studies for the critical outcomes.
- Consider **only** the critical outcomes, the overall grade is the **lowest** quality level assigned to the critical outcome.

GRADE

Table 2: Term babies evidence profile: antibiotic prophylaxis vs no antibiotics

Patient or population: preterm neonates born to mothers with no risk factors ¹ Settings: Any setting ² Intervention: Antibiotics prophylaxis Comparison: no or delayed antibiotics									
Quality assessment						No of patients		Effect	Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Antibiotic prophylaxis	No or delayed antibiotic treatment	Relative Risk (95% CI)	
All-cause mortality (follow-up 21 days; assessed with: numbers/proportions)									

¹ (low resource and high resource settings)
² the study reports that there was no concealment or blinding
³ no concealment or blinding
⁴ This is a single study
⁵ The choice of control is not valid
⁶ the sample size was small (95% CI not estimable)
⁷ Not estimable as there are no events

- Clarification
- Judgements
- Transparency

...t or no treatment arms, no details how this was done
 ...d to detect a difference in mortality

Three large trials

- **Nepal 2002-2005**

- A community based cluster randomized trial
- Three equal arms, (4%CHX, soap and water, dry care)
- The intervention was delivered by a female community worker.
- The population was 15,000 newborns visited in the first 10 days.
- Follow up was up to 28 days.
- Neonatal mortality rate was 32 per 1000
- Omphalitis rates 105/1000 live births

Mullany et al 2006

Three large trials

- **Bangladesh 2007-2009**

- Community based cluster randomized trial
- 29,760 newborns visited within 7 days by a CHW.
- Three similar groups (multiple cleansing with 4% CHX, single cleansing with 4% CHX and dry cord care)
- Neonatal mortality rate was about 36/1000 live births

Arifeen et al 2012

Three large trials

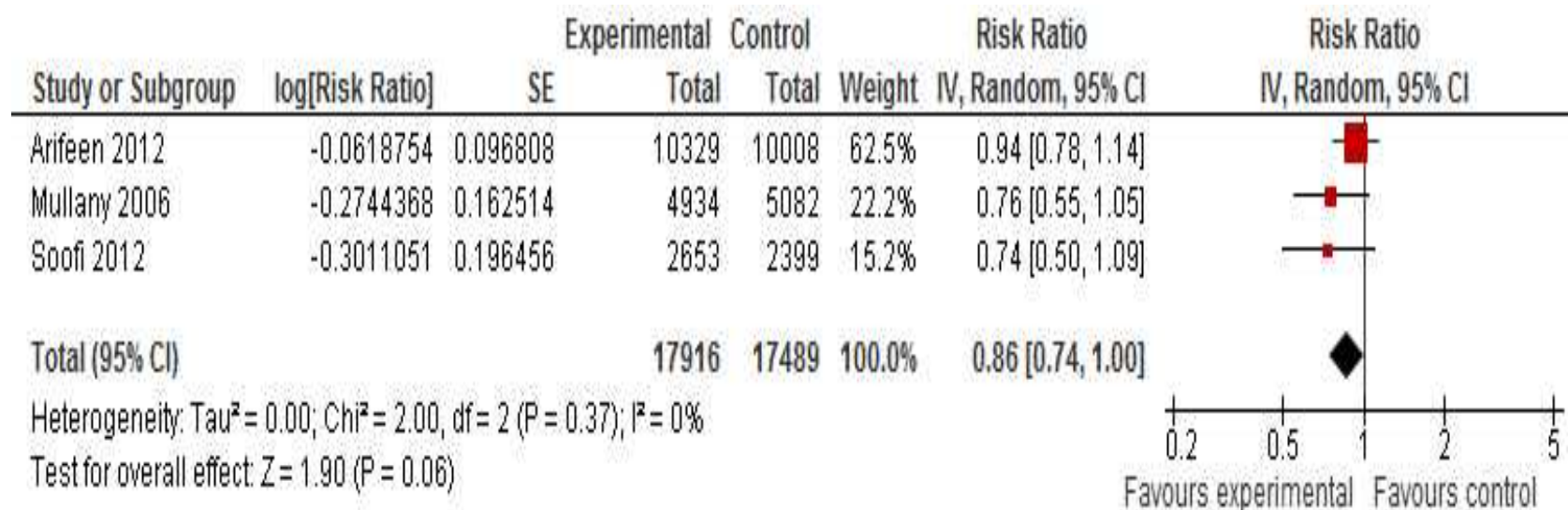
- **Pakistan 2007-2009 (N=9,741)**

- A community-based, cluster-randomized trial
- Neonatal mortality rate 53/1000
- Traditional practices are prevalent, ash, lead-based concoctions, oil, cow dung etc
- Mainly delivered through TBAs
- Four similar arms (two by two factorial design)
 - 4% CHX + bar soap
 - Soap
 - 4% CHX
 - No soap or CHX
- Omphalitis rates 217/1000

Soofi et al 2012

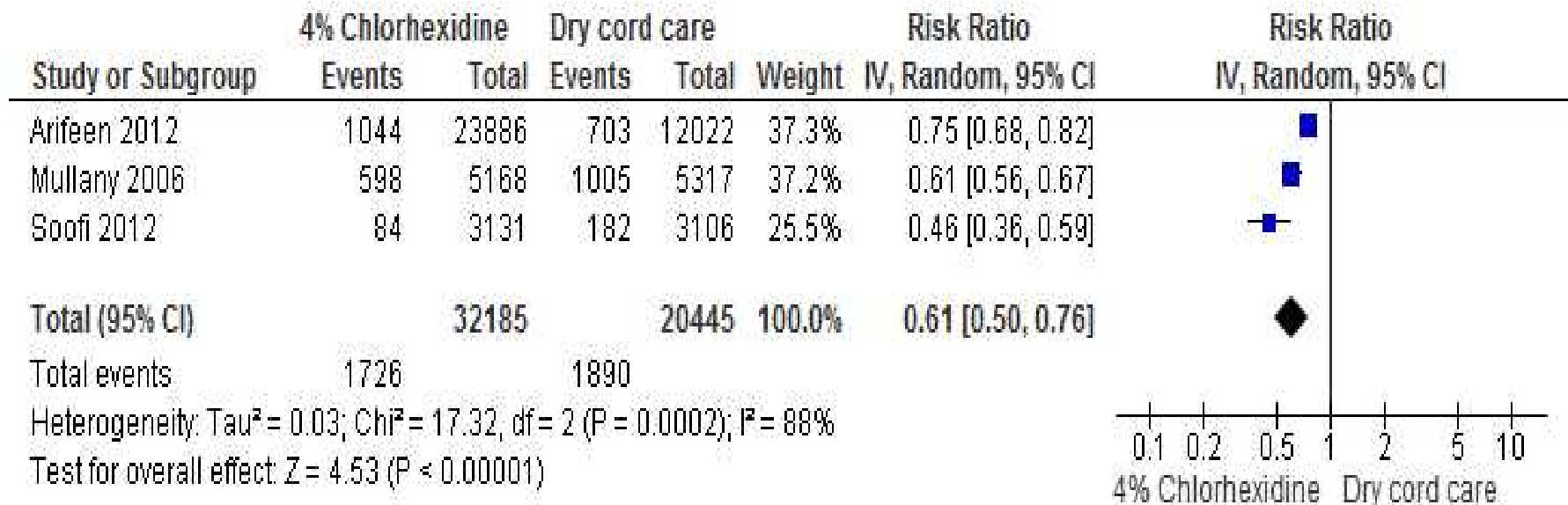
Pooled results from 3 community RCTs

After adjusting for clustering, there was a 14% reduction in mortality with limits of Between 26% and 0%.



Pooled results, community RCTs

- From 3 trials, 4% CHX reduces the risk of omphalitis when compared to dry care.
 - The risk of Omphalitis by any definition, was reduced by 39% with limits of 50% to 24% reduction.



Hospital data

Facility based interventions

Study/setting	Popn	Interventions	Control	Results
Pezzati 2003 (Italy)	244	4% CHX	Salicylic sugar powder	No beneficial effect (1 sepsis in each arm)
Ahmadpour-Kacho 2006(Iran)	312	Breast milk Alcohol Silver sulfadiazene	No treatment (dry care)	No infection in any group Breast milk shortens the time to cord separation
Erenel 2009 (Turkey)*	150	Olive oil	Dry care	No significant difference
Hsu 2010 (Taiwan)	150	Alcohol	Dry care	No infections Alcohol prolongs time to separation

These facility based hospital based studies did not have data on mortality but they were not adequately powered to do that(mortality was not the primary outcome)

Summary of findings table from the community setting

4% Chlorhexidine compared to dry cord care

Patient or population: Newborn neonates >28 weeks and >1000g in weight

Settings: Community (Nepal, Bangladesh, Pakistan)

Outcomes	Impacts			Quality of Evidence
	Dry cord care (per 1000)	4% CHX (per 1000)	RR 95% CI	
Mortality	26 per 1000	23 per 1000	RR 0.84 (0.74 to 1.00)	⊕⊕⊕⊕ high
Omphalitis/sepsis	109 per 1000	65 per 1000	RR 0.61 (0.50 to 0.76)	⊕⊕⊕⊖ moderate

WHO recommendations on **Postnatal care of the mother and newborn**

OCTOBER 2013

RECOMMENDATION 6: Cord care

Daily chlorhexidine (7.1% chlorhexidine digluconate aqueous solution or gel, delivering 4% chlorhexidine) application to the umbilical cord stump during the first week of life is recommended for newborns who are born at home in settings with high neonatal mortality (30 or more neonatal deaths per 1000 live births).

Clean, dry cord care is recommended for newborns born in health facilities and at home in low neonatal mortality settings. Use of chlorhexidine in these situations may be considered only to replace application of a harmful traditional substance, such as cow dung, to the cord stump.

Strong recommendation based on moderate quality evidence

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DANKE!

THANK YOU

KONGOI

THENGIO

SHUKRAN

EROKAMANO