

Provision of alcohol based handrub (ABHR) to mothers does not prevent severe illness and death in Ugandan infants: a community cluster randomised trial

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Objective

- To determine whether provision of ABHR to pregnant women to be used before touching the baby prevents severe illness and death among infants up to three months of age.

Methodology

- Phase 3, open label, two-arm parallel cluster superiority randomised trial
- 72 villages (clusters) in Eastern Uganda
 - target cluster size: 850 people
 - excluding villages inaccessible by motorcycle during the wet season
 - distance between clusters was at least 2 km
- Publicly randomised to receive 6 litres ABHR or standard care, stratified by cluster size
- We recruited pregnant women at least 34 weeks of gestation, residing in the clusters.
 - Identified by Village Health team members and enrolled by research midwives
 - All received chlorhexidine for cord care and a Maama birthing kit.
- Followed-up to 3 months postnatally
- Primary outcome: severe illness or death
- Secondary outcomes: individual infections and community hygiene practices



Study participant with alcohol hand rub for use in the study*



Publicly randomising the villages. Representatives blindly picked one of 4 red or yellow pool balls from an opaque rucksack (stratified by cluster size) to see their allocation; the oldest member then repeated this to see which colour would receive the intervention.

Results

- We enrolled 6,089 pregnant women between January 2021 and September 2023; 5,791 had available data
- Participants from both arms had similar baseline characteristics.
- Intention to treat analysis: proportion of infants with severe illness or death was 17.4% (477/2749) in intervention arm and 16.4% (499/3042) in the control arm (adjusted risk ratio 1.05, 95% confidence interval 0.92 to 1.20; p = 0.49).
- No difference in occurrence of individual outcomes, and no treatment related harms
- Women in the intervention clusters reported significantly more hand cleaning

Table 1: Participants' demographic data

	Alcohol hand rub	Control	Total
	No (%)	No (%)	No (%)
Hub			
Budaka	1073 (37.1)	1107 (34.6)	2180 (35.8)
Busiu	671 (23.2)	954 (29.8)	1625 (26.7)
Kolonyi	1146 (39.7)	1138 (35.6)	2284 (37.5)
Mother's age (years)			
Mean (SD)	25.12 (5.93)	25.05 (6.06)	25.08 (6.00)
Mother can read			
Yes	2384 (82.5)	2597 (81.2)	4981 (81.8)
Residence			
Peri-urban	624 (21.6)	650 (20.3)	1274 (20.9)
Rural	2266 (78.4)	2548 (79.7)	4814 (79.1)
Household size (number of people)			
1-5	1908 (66.0)	2077 (64.9)	3985 (65.5)
6 – 10	887 (30.7)	1009 (31.6)	1896 (31.1)
11 or more	94 (3.3)	112 (3.5)	206 (3.4)
Main source of water			
River stream / Open well / Collected open well water / Swamps	125 (4.3)	176 (5.5)	301 (4.9)
Protected well / Borehole / Collected rainwater	2518 (87.2)	2684 (83.9)	5202 (85.5)
Tapped water	240 (8.3)	332 (10.4)	572 (9.4)
Other	6 (0.2)	6 (0.2)	12 (0.2)
Type of toilet			
Open/nothing	68 (2.4)	140 (4.4)	208 (3.4)
Pit latrines	2,720 (94.2%)	2988 (93.4%)	5,708(93.8%)
Ventilated improved pit (VIP) latrine	74(2.6%)	46(1.4%)	120(2.0%)
Flush toilet	18 (0.6)	11 (0.3)	29 (0.5)

Table 2: Hand hygiene **after the intervention**: How often are hands cleaned before touching or caressing the baby?

	Often / always		Adjusted win ratio	
	Alcohol HR	Control	Ratio (95% CI)	P value
Mother	91%	74%	2.41 [2.15, 2.70]	<0.0001
Partner	74%	61%	1.45 (1.31-1.61)	<0.0001

Table 3: Primary and secondary outcomes

Primary Outcome (ITT analysis)	Alcohol hand rub n = 2749 No (%)	Control n = 3042 No (%)	Adjusted relative risk [95% CI]
Severe illness or death of baby (p value=0.49)	477 (17.4%)	499 (16.4%)	1.05 [0.92, 1.20]
Secondary Outcomes	Alcohol hand rub No (%)	Control No (%)	Adjusted relative risk [95% CI]
Mortality			
Death of baby (up to 3 months)	56/2749 (2.0%)*	61/3042 (2.0%)^	1.05 [0.77, 1.43]
Death of mother	2/2747 (0.07%)	6/3071 (0.20%)	0.39 [0.09, 1.83]
Infective secondary outcomes			
Diarrhoea (Baby)	70/2770 (2.5%)	73/3084 (2.4%)	1.01 [0.69, 1.48]
Respiratory tract infection (Baby)	439/2770 (15.9%)	441/3084 (14.3%)	1.05 [0.88, 1.26]
Omphalitis (Baby)	11/2770 (0.4%)	7/3084 (0.2%)	1.70 [0.68, 4.26]
Meningitis (Baby)	8/2770 (0.3%)	13/3084 (0.4%)	0.72 [0.32, 1.65]
Tetanus (Baby)	1/2770 (0.04%)	1/3084 (0.03%)	0.99 [0.07, 14.93]
Acute otitis media (Baby)	1/2770 (0.04%)	3/3084 (0.1%)	0.35 [0.03, 3.72]
Skin infections (Baby)	80/2770 (2.9%)	84/3084 (2.7%)	1.09 [0.82, 1.46]
Malaria (Baby)	63/2770 (2.3%)	77/3084 (2.5%)	0.91 [0.60, 1.37]
Sepsis (Mother)	95/2781 (3.4%)	80/3086 (2.6%)	1.23 [0.84, 1.80]



Home visit by field data collector



Researcher going to collect data in the villages



Map of Uganda (Mbale in red, Budaka in Blue)

Conclusion

Providing alcohol handrub to women for hand hygiene improved hand hygiene episodes but had no effect on severe illness or death in infants up to 3 months old.

Implications:

The current practice of hand washing with soap and water should continue to be promoted.