

# Immediate KMC improves survival in LBW infants



Department of Maternal, Newborn, Child and Adolescent Health, and Ageing

### WHO immediate KMC study group

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### Global burden of LBW

- Every year 20 million (~15% of all births) infants are born with LBW
- >95% are in LMICs
- Account for 70-80% of all neonatal deaths
- LBW infants are also at increased risk of early growth retardation and developmental delay





### Kangaroo Mother Care – current WHO recommendations



KMC is recommended in health facilities for the routine care of newborns weighing2000g or less at birth.



Brief sessions of KMC should be initiated when clinical condition begins to stabilize.



As close to
continuous KMC
as possible should be
provided when
clinically stable



### Kangaroo Mother Care – Cochrane review 2016

40 reduction in neonatal mortality

65% reduction in sepsis

reduction in hospital readmission in infancy

72 reduction
in hypothermia

**Improved** exclusive breastfeeding at 1-2 months

reduction in hypoglycemia

**Improved** weight gain, length and head circumference



### Rationale for the Immediate KMC Trial



Studies included in Cochrane mortality review: mean age of randomization ~3 days (range 10 h to 24.5 d)

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About half of preterm deaths occur in first 24h, over three quarters in the first week



Thus, majority of preterm deaths occur before KMC can be initiated as per current guidelines



### **Research question**

Does continuous KMC initiated immediately after birth (immediate KMC) compared with current guidelines improve newborn survival?

### KMC before stabilization

Two small studies in Vietnam and South Africa had shown that skin to skin contact started immediately after birth is safe and helps LBW babies stabilize faster

#### ACTA PÆDIATRICA

Acta Pædiatrica ISSN 0803-5253

#### **REGULAR ARTICLE**

Newly born low birthweight infants stabilise better in skin-to-skin contact than when separated from their mothers: a randomised controlled trial

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Acta Pædiatr 93: 779-785. 2004



Randomized controlled trial of skin-to-skin contact from birth versus conventional incubator for physiological stabilization in 1200- to 2199-gram newborns

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### Immediate KMC study design



Randomized Controlled Trial





Multi-country, multi-center Referral hospitals in Ghana, India, Malawi, Nigeria and Tanzania



Population
Mothers and babies,
if birth weight
1.0 to <1.8 kg



Intervention\*

KMC initiated as soon as possible after birth by mother or surrogate



Control\*

KMC initiated only after baby is stable

\*Both groups received WHO minimum package for small babies



### Immediate KMC study

# Intervention group (n=1609)



As soon as possible after birth: Continuous KMC in M-NICU



Throughout in M-NICU: Continuous KMC



Baby stable:
Shifted to KMC ward:
Continuous KMC in KMC ward

# Control group (n=1602)



After birth baby receives care in warmer or incubator in NICU



In NICU: after baby starts recovering, brief sessions of KMC



Baby stable:
Shifted to KMC ward:
Continuous KMC in KMC ward



### Eligibility criteria

#### **INCLUSION CRITERIA:**



Livebirth with birth weight between 1.0 and <1.8 kg

#### Even if:

- 1) Twins (both babies allocated to the same group)
- 2) Babies born by caesarean section

#### **EXCLUSION CRITERIA:**

- Mother unable to provide consent
- Major maternal complications surely expected to preclude STS the first three days (e.g., eclampsia, shock, major surgery)
- Triplets and quadruplets
- Neonates unable to breathe spontaneously within 1 hour
- Congenital malformation that interferes with the intervention, or the intervention interferes with the required care.
- Place of residence outside the study area
   (defined to make 28-day follow up feasible)





### Intervention

### **Three Components:**

- Continuous skin-to-skin contact with mother or surrogate starting within 2 hours of birth, aiming > 20 hours/day
- Counselling and support for exclusive breastmilk feeding / breastfeeding
- Provision of required medical care for mother and baby in STS contact without separation, as much as possible



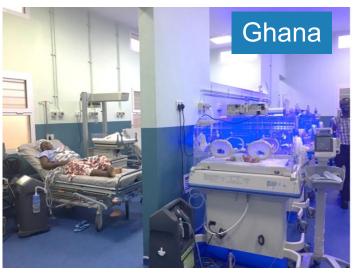
### New Mother-Newborn ICU





### Part of NICU re-modelled to Mother-Newborn ICU









## Provision of respiratory support with KMC



Mean duration of KMC 17 hours/day





### Control group: KMC after stabilization

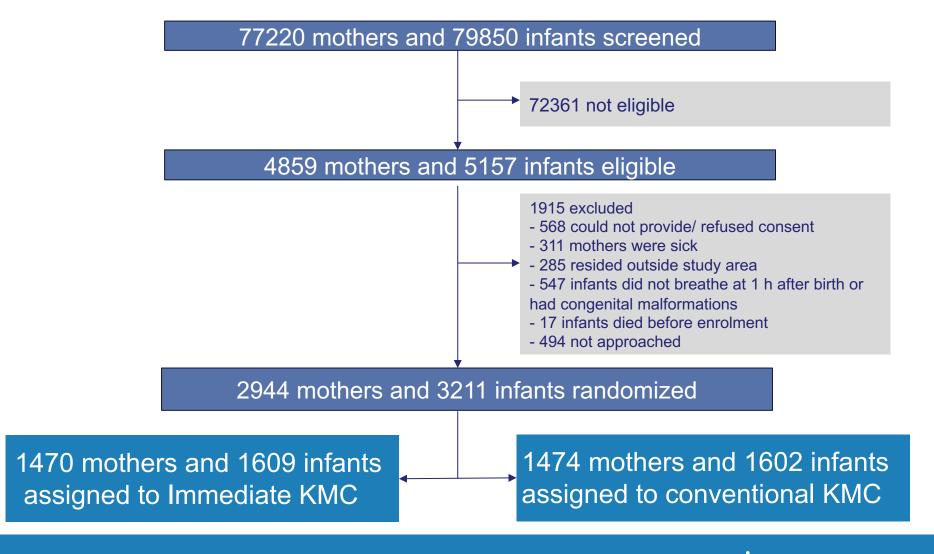
# Continuous KMC initiated after the baby is stable and shifted out of NICU







### Results of the Immediate KMC Study: Participant flowchart



### Characteristics of enrolled infants

	Immediate KMC	Control
	N=1609	N=1602
Age at randomization in minutes (median, IQR)	35 (20,55)	33 (20,54)
Birth weight in kg, mean (SD)	1.5 (0.2)	1.5 (0.2)
Gestational age at birth, mean (SD)*¥	32.6 (3.0)	32.6 (2.8)
Male, n (%)	752 (46.7)	748 (46.7)
Infants born as twin, n (%)	430 (26.7)	430 (26.8)
Delivery by C-section, n (%)	559 (34.7)	614 (38.3)
Respiratory distress in first 7 d of life, n(%)	691 (43.3)	705 (44.0)



## Primary and Key Secondary Outcomes

Outcome	Intervention (N=1609)	Control (N=1602)	Risk Ratio, Hazard Ratio, or Difference (95% CI)†	P Value
Primary				
Death between enrollment and 28 days — no./total no. (%)	191/1596 (12.0)	249/1587 (15.7)	0.75 (0.64–0.89)	0.001
Death between enrollment and 72 hr after birth — no./total no. (%)	74/1606 (4.6)	92/1599 (5.8)	0.77 (0.58–1.04)	0.09
Secondary:				
Hypothermia — no./total no. (%)∫	90/1609 (5.6)	133/1602 (8.3)	0.65 (0.51–0.83)	
Suspected sepsis — no./total no. (%)**	361/1575 (22.9)	434/1561 (27.8)	0.82 (0.73–0.93)	



# Other secondary outcomes

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Outcome	Intervention (N=1609)	Control (N=1602)	Risk Ratio, Hazard Ratio, or Difference (95% CI)†
Secondary:			
Exclusive breast-feeding at end of neonatal period — no./total no. (%)	1208/1401 (86.2)	1140/1336 (85.3)	1.01 (0.98–1.05)
Fully breast-fed (i.e., by suckling) at hospital discharge — no./total no. (%)	62/1435 (4.3)	55/1376 (4.0)	1.06 (0.73–1.53)
Median time to clinical stabilization — hr (IQR)¶	73.8 (26.8–138.5)	74.8 (25.3–140.6)	0.98 (0.90–1.07)
Hypoglycemia at any time between 0 and 36 hr after birth — no./total no. (%)††	82/799 (10.3)	66/651 (10.1)	1.15 (0.85–1.56)
Mean duration of hospital stay — days‡‡	14.9±0.2	15.2±0.2	1.07 (0.99–1.16)
Mean score for maternal satisfaction∬	9.2±1.0	9.1±1.2	0.11 (0.03-0.19)¶¶
Maternal depression — no./total no. (%) $\ $ $\ $	2/1276 (0.2)	7/1231 (0.6)	0.23 (0.05–1.14)

∥ Hazard ratio ¶¶ Mean difference



## Additional breatfeeding outcomes (pest to capalyses)

	Intervention	Control	RR (95% CI)
Outcome	(n=1609)	(n=1602)	KK (93% CI)
Initiation of breastmilk feeds within 24 hr, n (%)	941 (58.5%)	729 (45.5%)	1.29 (1.20–1.37)
Infant put to breast before 72 hr of age, n (%)	1108 (68.9%)	832 (51.9%)	1.32 (1.24–1.41)
Age Infant first put to the breast in hr, median (IQR)	41 (21–83)	66 (36–138)	1.50 (1.40–1.62)*
Reached full breastmilk feeds within 7d, n (%)	1261 (78.4%)	1105 (69.0%)	1.14 (1.09–1.19)
Discharge on exclusive breastmilk feeding**, n (%)	1208 (93.1%)	1067 (88.7%)	1.05 (1.02–1.08)

<sup>\*</sup> Hazard ratio



<sup>\*\*</sup> only among discharged infants (1298 intervention; 1203 control) \* Hazard ratio

<sup>\*\*</sup> only among discharged infants (1298 intervention; 1203 control)

# Cause-specific mortality

Cause of death	Intervention n= 1596	Control n= 1587	RR (95% CI)
Sepsis, n (%)	70 (4.4%)	109 (6.9%)	0.64 (0.48–0.86)
Preterm birth complications*, n %)	79 (4.9%)	83 (5.2%)	0.95 (0.70–1.28)
Perinatal asphyxia, n (%)	12 (0.8%)	18 (1.1%)	0.66 (0.32–1.37)
Congenital malformation, n (%)	10 (0.6%)	10 (0.6%)	0.99 (0.42–2.38)
Other specific cause, n (%)	4 (0.3%)	5 (0.3%)	0.80 (0.21–2.96)
Sudden death, n (%)	16 (1.0%)	20 (1.3%)	0.80 (0.41–1.53)
Undetermined, n (%)	0	4 (0.3%)	-



### M- NICU



- → Hand hygiene area
- → Pantry
- → Washing area
- → Infection control

### Implications: System Changes

### **POLICY**

to permit Mother & surrogate in NICU 24/7

## **M-NICU**

to keep the mother and baby together right from birth with zero separation

Revolutionize the way neonatal intensive care is currently practiced



### Conclusions

Immediate KMC for 1.0 and <1.8 kg infants significantly reduces the risk of neonatal death by 25%

- Immediate KMC provided to every 27 babies saves a life which translates to 150,000 lives globally every year
- M NICU is a paradigm shift in the care of the low birth weight infant weight





# Thank you!



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