Transforming Care for Small and Sick Newborns

Webinar series: May 2021- May 2022
Transforming Care for small and sick newborns: Implementing quality care for every small and sick newborn

WEBINAR SERIES OBJECTIVE:
This series will accompany the learning and experience in implementing the WHO Standards for improving the quality of care for small and sick newborns in health facilities (2020) and related guidance for their implementation.

Upcoming webinar:
Nurturing care for every newborn: Ensuring every newborn survives and thrives (Wednesday August 25 2021, 2pm Geneva)
Immediate KMC improves survival in LBW infants

Part 1: Presentation & Panel Discussion

Presentation: Dr. Rajiv Bahl - Newborn Unit Head & Head of Research, Department of Maternal, Newborn, Child and Adolescent Health and Ageing World Health Organization, Geneva

Panelists:
- Dr. Harish Chellani - Professor of Pediatrics, Safdarjung Hospital and Vardhan Mahavir Medical College, India
- Dr. Helga Naburi - Pediatrician, Muhimbili University of Health and Allied Science, Tanzania
- Dr. Gyikua Plange-Rhule - Senior Lecturer, Department of Child Health, Komfo Anokye Teaching Hospital, Ghana
- Dr. Kondwani Kawaza - Pediatrician & Lecturer, College of Medicine, University of Malawi, Malawi
- Dr. Ebunoluwa Adejuyigbe - Professor of Paediatrics, Obafemi Awolowo University, Nigeria
- Dr. Nils Bergman - Researcher, Department of Women’s and Children’s Health, Karolinska Institute, Sweden

Part 2: Questions & Answers
Immediate KMC improves survival in LBW infants

Dr. Rajiv Bahl - Newborn Unit Head & Head of Research, Department of Maternal, Newborn, Child and Adolescent Health and Ageing

World Health Organization Geneva
Immediate KMC improves survival in LBW infants
WHO immediate KMC study group

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FUNDED BY: Bill and Melinda Gates Foundation
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 weighing 2000g 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
- **72%** reduction in hypothermia
- **88%** reduction in hypoglycemia
- **58%** reduction in hospital readmission in infancy
- *Improved* exclusive breastfeeding at 1-2 months
- *Improved* weight gain, length and head circumference
Rationale for the Immediate KMC Trial

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

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

3. 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?
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.
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)
Three Components:

1. Continuous skin-to-skin contact with mother or surrogate starting within 2 hours of birth, aiming > 20 hours/day

2. Counselling and support for exclusive breastmilk feeding / breastfeeding

3. 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

Malawi

Nigeria

Ghana
M-NICU

- Hand hygiene area
- Pantry
- Shower
- Toilet
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

- 77220 mothers and 79850 infants screened
  - 72361 not eligible
  - 4859 mothers and 5157 infants eligible
    - 1915 excluded
      - 568 could not provide/ refused consent
      - 311 mothers were sick
      - 285 resided outside study area
      - 547 infants did not breathe at 1 h after birth or had congenital malformations
      - 17 infants died before enrolment
      - 494 not approached
    - 2944 mothers and 3211 infants randomized
      - 1470 mothers and 1609 infants assigned to Immediate KMC
      - 1474 mothers and 1602 infants assigned to conventional KMC
## Characteristics of enrolled infants

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

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

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

‡ Hazard ratio ‡‡ Mean difference
### Additional breastfeeding indicators

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

* Hazard ratio
** only among discharged infants (1298 intervention; 1203 control)
## Cause-specific mortality

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

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

2. Immediate KMC provided to every 27 babies saves a life which translates to 150,000 lives globally every year.

3. M – NICU is a paradigm shift in the care of the low birth weight infant weight.
Thank you!
Panel Discussion: Immediate KMC improves survival in LBW infants

Dr. Harish Chellani, Professor of Pediatrics, Safdarjung Hospital and Vardhan Mahavir Medical College, India

Dr. Helga Naburi, Pediatrician, Muhimbili University of Health and Allied Science, Tanzania

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Dr. Nils Bergman, Researcher, Department of Women's and Children's Health, Karolinska Institute, Sweden
Questions & Answers

Facilitated by:
Dr. Rajiv Bahl, Newborn Unit Head & Head of Research, Department of Maternal, Newborn, Child and Adolescent Health and Ageing,
World Health Organization, Geneva

Please type your questions in the CHATBOX
STAY ENGAGED

- Upcoming webinars in this series:
  
  ➢ Wednesday 25 August 2021 at 2pm CEST: Nurturing care for every newborn: Ensuring every newborn survives and thrives
  ➢ Register here: bit.ly/SSNB-4

- Learn more about the series: bit.ly/SSNB2021

- Visit Quality of Care Network website: https://www.qualityofcarenetwork.org/about

- Join the Care for small and sick newborns Community of Practice - next conversation for World Breastfeeding Week, August 4 2021: Email: ssnbcop@savechildren.org