SKIN-TO-SKIN CONTACT
current evidence and future directions

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Disclosure of Financial Interest

• I, Nils Bergman, DO have a financial interest with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation, they are:

  • Affiliation/Financial Interest
  • Owner / Director

  NINO Academy

  NINO Academy produces educational and promotional materials related to Kangaroo Mother Care, and a garment for skin-to-skin contact.

  NINO Academy owns trademark for Kangaroula®

Ignaz SEMMELWEISS 1818 – 65

Hungarian obstetrician 1840’s – Vienna 30% died of puerperal fever – Pushed handwashing, cleanliness & standards: Maternal death rate from 12% to 1% in 2 years

Ostracised by peers, Died insane

LOUIS PASTEUR 1822 – 95

Germ theory did NOT EXIST!

Was being researched Between 1860- 64, same decade
Semmelweis died

Semmelweis's observations conflicted with the established scientific and medical opinions of the time and his ideas were rejected by the medical community.

Semmelweis could offer no acceptable scientific explanation for his findings ….
The Semmelweis reflex

... reflex-like tendency to reject new evidence and knowledge because it contradicts established beliefs, paradigms.

What is a paradigm?

Kuhn defines a paradigm as: “an entire constellation of beliefs, values and techniques, and so on, shared by the members of a given community”

What is a paradigm?

paradigm 3. A set of assumptions, concepts, values, and practices that constitutes a way of viewing reality for the community that shares them, especially in an intellectual discipline.

ZERO SEPARATION of mother and newborn:

PARADIGM SHIFT?

Stephane TARNIER 1828 -97

French obstetrician

Saw a warmed box for hatching chickens, had one designed for "weaklings"...

... invented incubator

PARADIGM SOURCE

Pierre BUDIN 1846 - 1907
**Pierre BUDIN 1846 - 1907**

- Friend of Tarniers...took incubators, made centres for the care of weaklings, wrote book on subject.
- Political support...France versus Germany

**Martin COUNEY 1860 - 1950**

- Born in Germany
- Took incubators, made centres for the care of weaklings, wrote book on subject.
- Political support...France versus Germany
- Berlin Exhibition 1896, success!

**Martin COUNEY 1860 - 1950**

- Born in Germany
- Claims he learned the techniques for Budin....
- Berlin 1896, success
- to USA: Buffalo → Omaha 1902-4,
- Chicago Fair 1932 2nd highest receipts, Last show New York 1940.

**Martin COUNEY 1860 - 1950**

- Born in Germany
- Claims he learned the techniques for Budin....
- Berlin Exhibition 1896, success!
- London World fair 1898, fiasco!
- All the babies died....
- “Mothers to blame”
Martin COUNEY 1860 - 1950

Couney successfully raised 5000 prems!

BUT -
used wet-nurses,
excluded mothers
(mother got free pass to the shows!)

Mothers were excluded - “germs” ...

Sarah Morris Hospital, Chicago 1923,
others followed -

accepting the
“policy of strict separation”.

SEPARATION
is a 20th century
PARADIGM

accepting the
“policy of strict separation”.

“(Our care) still views the infant as a solitary individual who sleeps most of the time in a bed.”

PARADIGM CONSTRUCT

Paradigm has internal Intelligence Honesty Integrity Consistency

BASIC ASSUMPTION:
-INFANT SLEEPS ALONE

FOUNDATION / PLATFORM / BASE

Clinics in Perinatology,
June 2004, Vol 31(2) p293

Robert White

“Mothers’ arms – the past and future locus of neonatal care?”

#1: Initial test condition
— infant sleeps alone, is bottle fed,
and has little or no parental contact

#2: Derive measurements of infant sleep under these conditions

From James McKenna,
Notre Dame Sleep Laboratory
Culture Producing Science Producing Culture: How A Folk Myth Achieved Scientific Validation

1. Initial test condition
   - Infant sleeps alone, is bottle fed, and has little or no parental contact

2. Derive measurements of infant sleep under these conditions

3. Repeat measurements across ages, creating an “infant sleep model”

4. Publish clinical model on what constitutes desirable, healthy infant sleep.

5. To produce “healthy” infant sleep, replicate the test condition

From James McKenna

Why babies should never sleep alone: A review of the co-sleeping controversy in relation to SIDS, bedsharing and breastfeeding

James J. McKenna and Thomas McDade

* CIRCULAR SCIENCE - A SELF-FULFILLING PROPHECY

PARADIGM CONSTRUCT

Paradigm: “in the philosophy of science, a generally accepted model of how ideas relate to one another, forming a conceptual framework within which scientific research is carried out”

MSN Encarta

BASIC ASSUMPTION:
- INCUBATORS STABILIZE
FOUNDATION / PLATFORM / BASE

Specifically, all the recommendations involving clinical medicine in a CME activity must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contra-indications in the care of patients.

BASIC ASSUMPTION:
- INCUBATORS STABILIZE
FOUNDATION / PLATFORM / BASE
Both babies and their parents may experience a stay in the newborn intensive care unit (NICU) as a traumatic or a ‘toxic stress,’ which can lead to dysregulation of the hypothalamic–pituitary–adrenal axis and ultimately to poorly controlled cortisol secretion.

… strongly linked to poor health outcomes

… trauma-informed care is an approach to caregiving based on the recognition of this relationship.
The Semmelweis reflex

... reflex-like tendency to reject new evidence and knowledge because it contradicts established beliefs, paradigms.

ZERO SEPARATION
of mother and newborn: the science behind the concept

... reflex-like tendency to reject new evidence and knowledge because it contradicts established beliefs, paradigms.

1988 – 1994

Origin of Immediate KMC

Drs Rey & Martinez
1979 Bogota, Colombia
LATE KMC
1985 Andrew Whitelaw
1987 Agneta Jurisoo
BIRTH KMC

DEFINITION of KMC (1990)

MANAMA, ZIMBABWE

# Skin-to-skin contact from birth, continuous
# Breastmilk from birth & exclusive breastfeeding
# Psychological support to mother

KMC as above used regardless of weight and gestation. KMC provides the baby with very intensive care.

KC (in the USA) – In-hospital skin-to-skin contact, any duration, primarily adjunct to CMC (Conventional Method of Care).
**Results - Manama**

*(Born 1000g to 1500g)*

**Survival before KMC** 10%

**Survival with KMC** 50%

*(Stabilized in 6 hours)*

**Weight gain per day** 30 g/d

**Breastfeeding rate** 100%

---

**Historical control**

1994

**Mortality 1000g-1500g**
- **pre KMC**: 90%
- **with KMC**: 50%

**KMC** = 40% reduction in mortality

INCLUDED UNSTABLE

---

**Is there an alternative for premature infants??**
Is THIS an alternative for premature infants??

The Semmelweis reflex
... reflex-like tendency to reject new evidence and knowledge because it contradicts established beliefs, paradigms.

NEUROSCIENCE & EVIDENCE & SKIN-TO-SKIN CONTACT
1996 - 2003

... baby’s condition MUST BE STABLE, ... breathing without additional oxygen.
WHO, 2003

The PLACE MODEL
→ scientifically derived
→ alternative approach
→ hypothesis falsifiable/testable

IMMEDIATE SKIN-TO-SKIN CONTACT
the primary ecology for mothering, and also NICU care.
www.skintoskincontact.com

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(From Greek: οἶκος, “house”, or “environment”; -λογία, "study of")
There are only these two habitat choices available.

**AM I SAFE HERE??**

**THE PLACE MODEL**

SKIN-TO-SKIN CONTACT

CORTISOL

**THE OLD BRAIN HAS 3 PROGRAMMES**

DEFENCE  NUTRITION  REPRODUCTION

The brain has three programmes:

1. **Defence**
2. **Nutrition**
3. **Reproduction**
THE PLACE MODEL

- Breast-vagal feeding (PSNS) → growth
- Other → protest, stress, survival or despair (SNS)

→ alternative approach
→ hypothesis falsifiable/testable

KANGAROO MOTHER CARE FROM BIRTH COMPARED TO CONVENTIONAL INCUBATOR CARE

Research funded by THRASHER RESEARCH FUND, U.S.A.

Admin and stats by MEDICAL RESEARCH COUNCIL, R.S.A.

Primary hypothesis

SSC (skin-to-skin contact) from birth is superior to incubator care for low birthweight infants.

ONLY PLACE DIFFERS

SKIN-TO-SKIN CONTACT FROM BIRTH

THE ONLY DIFFERENCE = THE PLACE or the HABITAT

Results

Minimisation technique ensured groups balanced for confounders.

( n = 34)

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean Weight [g]</th>
<th>Mean GA [w]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>1813</td>
<td>34.2</td>
</tr>
<tr>
<td>Intervention</td>
<td>1866</td>
<td>35.3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Male/Female</th>
<th>Control</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>50%</td>
<td>60%</td>
</tr>
<tr>
<td>Female</td>
<td>50%</td>
<td>40%</td>
</tr>
</tbody>
</table>

(p 783)
**BAILOUT points … INSTABILITY**

“physiological parameters exceeding normal limits, requiring medical assessment and or intervention”

1. Skin temp consistently <35.5°C
2. Heart rate <100; or > 180 bpm
3. Apnoea longer than 20 seconds
4. O₂ sats below 89% (x2), (CPAP/60% O₂)
5. Blood glucose < 2.6mmol/l, (laboratory)

Bergman et al 2004

**Hb (SPECIFIC)**

Doctor summoned:

**INCUBATOR** 92%

**SKIN-TO-SKIN** 17%

---

**THE PLACE MODEL**

**SKIN-TO-SKIN CONTACT**

**MOTHER**

17% UNSTABLE

**OTHER**

92% UNSTABLE

**SEPARATION**

---

**“Stability of Cardio-Respiratory system In Preterm Infants”**

<table>
<thead>
<tr>
<th>SCERP SCORE</th>
<th>2</th>
<th>1</th>
<th>0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart rate</td>
<td>Regular</td>
<td>Deceleration to 80-100</td>
<td>Rate &lt;80 or &gt;200 bpm</td>
</tr>
<tr>
<td>Respiratory rate</td>
<td>Regular</td>
<td>Apnoea&lt;10s or periodic breathing</td>
<td>Apnoea&gt;10s Tachyypnoea &gt;80 pm</td>
</tr>
<tr>
<td>Oxygen saturation</td>
<td>Regular &lt;87%</td>
<td>Any fall to 80-87%</td>
<td>Any fall below 80%</td>
</tr>
</tbody>
</table>

Score allocated for a five minute period of continuous observation, maximum six for period

**STABILITY**

Fischer et al, 1988
"100% SCRIP STABILITY"

<table>
<thead>
<tr>
<th></th>
<th>S</th>
<th>C</th>
<th>M</th>
<th>C</th>
<th>M</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>1200g to</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2200g</td>
<td>1</td>
<td>6h</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I - 6h</td>
<td>56%</td>
<td>11%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>@ 6h</td>
<td>100%</td>
<td>46%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1200g to</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1800g</td>
<td>1</td>
<td>6h</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>I - 6h</td>
<td>44%</td>
<td>0%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>@ 6h</td>
<td>100%</td>
<td>25%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Stabilization 1200g - 1800g

Skin-to-skin

Hourly average of SCRIP score, 2nd to 6th hour

INCUBATORS DE-STABILISE NEWBORNS

Bergman et al. 2004

Physiological stabilisation

THE PLACE MODEL
SKIN-TO-SKIN CONTACT

MOTHER

OTHER

PROTEST

STRESS

SURVIVAL or DESPAIR

DYS-REGULATION

SEPARATION

CORTISOL
Premature babies are not in incubators because they are unstable.

Premature babies are unstable because they are in incubators.

Effectiveness of Skin-to-Skin Contact to stabilize low birth weight infants at birth.
Luong Kim Chi, Nguyen Tien Long, Huynh Thi Duy Huong, Nils Bergman

Ho Chi Minh CITY, Vietnam
60,000 deliveries per year
Obstetric beds: 1200
Neonatal beds: 180
16,200 neonatal cases/year 2012 in neonatal department
Low birth weight rate Vietnam 9%, this hospital 12.5%
The Semmelweis reflex

... reflex-like tendency to reject new evidence and knowledge because it contradicts established beliefs, paradigms.

Stabilization 1200g - 1800g

Skin-to-skin

SKIN-TO-SKIN INCUBATOR

17%
92%

Incubator
Does the incubator make the small baby unstable?

Historical control

The ‘kangaroo-method’ for treating low birth weight babies in a developing country

N. J. Baggavan MRM WM
T. A. Hlatshwayo WM
Marumo Modern Hospital, PW Col 1985, Groote, Zimbabwe

Mortality 1000g-1500g pre KMC: 90%
with KMC: 50%

KMC = 40 % reduction in mortality

1994 INCLUDED UNSTABLE

Preschool pre-neo
Ages 1-4

2015

Death (proportion of U5MR)

38%
45%

Current definition
IS ONLY FOR STABLE

Baby
Almost every small baby can be cared for with KMC. Babies with severe illness or requiring special treatment may wait until recovery before full-time KMC begins. During that period babies are treated according to national clinical guidelines.* Short KMC sessions can begin during recovery when baby still requires medical treatment (IV fluids, low concentration of additional oxygen). For infants who have been preterm KMC is not the best option: the baby must be breathing spontaneously without additional oxygen. The ability to feed (by suck and swallow) is not an essential requirement. KMC can begin during tube-feeding. Once the baby begins recovering, discuss KMC with the mother.

PRETERM BIRTH TRANSITION SEPARATION FAILS

CASCADING DYSREGULATION

Hypoxia
Hypothermia
Infection
Bradycardia
Hypoglycemia
Cerebral Haemorrhage
Inflammation
Hypoglycaemia
Stress
Respiratory and cardiovascular dysfunction

Early physiological dysregulation

Excluded from KMC studies

Skin-to-skin STABILIZES & PREVENTS INSTABILITY

PRETERM BIRTH TRANSITION SEPARATION FAILS

INSTABILITY

1990
2015

MORTALITY

Deaths (proportion of U5MR)
‘Kangaroo mother care’ to prevent neonatal deaths due to preterm birth complications

Joe E. Lawal, Judith Meiswina-Kaimubwelo, M Berta L. Horta, Fernanda E. Barros* and Simon Guarino*

1. United Nations Children’s Fund, Cape Town, South Africa 2. United Nations Children’s Fund, South Africa 3. Department of Public Health, Faculty of Health Sciences, University of Cape Town, Cape Town, South Africa 4. Research Department Head and Nutrition Programmes Exploratory Research Unit, London School of Hygiene and Tropical Medicine, London, UK.

Conclusion: This is the first published meta-analysis showing that KMC substantially reduces neonatal mortality among preterm babies (birth weight < 2000g) in hospital and is highly effective in reducing severe morbidity, particularly from infection. However, KMC remains unavailable at scale in most low-income countries.

- This evidence is sufficient to recommend the routine use of KMC for all babies < 2000g as soon as they are stable. Up to half a million neonatal deaths due to parental complications could be prevented each year if this innovation were implemented at scale.

The Semmelweis reflex

Semmelweis’s observations conflicted with the established scientific and medical opinions of the time and his ideas were rejected by the medical community.

Semmelweis could offer no acceptable scientific explanation for his findings.

SKIN-TO-SKIN CONTACT

Current research and mediating mechanisms.

Dr Nils Bergman
MB ChB, DCH, MPH, MD
Cape Town, RSA

The Neuroscience of Birth & Breastfeeding

2008-2018...

IPISTOSS
Immediate Parent-Infant Skin-TO-Skin

Research proposal

KMC on stable babies: 11000 babies per year.

400 000 deaths ... could be prevented ... ONLY IF ... KMC starts at birth
Recently, attention has been drawn to caregiving environments that evolved to optimize development of the young. Every animal has a niche for its offspring that matches up with the maturational schedule of the infant and represents a set of inherited extra-genetic features that foster thriving or optimal development in offspring.

Maternal-Preterm Skin-to-Skin Contact Enhances Child Physiologic Organization and Cognitive Control Across the First 10 Years of Life

Ruth Feldman, Zehava Rosenthal, and Arthur I. Eidelman

Expected = early difference → but ‘catch-up’, No long-term difference.

Actually – difference increased!
Moore et al (n 1055)
5th WEEK of life:
Contact diary >3 days; minutes per day.
Distress behaviour diary

5th YEAR of life:
Buccal swabs (n 94)

Moore et al

Epigenetic correlates of neonatal contact in humans

CANDIDATE GENES
NR3C1 stress

Meaney rat study
NO evidence here!
**CANDIDATE GENES**

- NR3C1: stress biology
- GRIN1: reward bonding
- OXTR: social bonding
- BDNF: neuroplasticity

---

**WHOLE GENOME analysis for DNAm**

(Basically ‘fishing’ for differences)

5 significant areas

- LDHAL6A: metabolism
- Intergenic 1
- Intergenic 2
- HLA-DRB5: T-cell response, immunity
- ZFAN2A: Zinc

Amount of contact in early life leaves a permanent epigenetic signature.

---

**EPIGENETIC AGE DEVIATION.**

(Basically marks showing development differences)

- High contact: NOT DIFFERENT from low contact
- HOWEVER - WITH DISTRESS
  - CRYING baby with HIGH contact: increased epigenetic age → shows improved development
  - CRYING baby with LOW contact: decreased epigenetic age → IMPAIRED development

---

**A crying baby needs regulation**

CRYING baby with LOW contact: decreased epigenetic age → IMPAIRED development

---

**The Neuroscience of Birth & Breastfeeding**

The DNA → Behaviour

- Environment
- Sensitization
- Resilience
- Vulnerability
- Health
- Disease

---

**IPISTOSS**

- **A** Transitions & Physiology
- **B** Epigenetics
- **C** Microbiota
- **D** Breastfeeding
- **E** Domiciliary Health
- **F** M-J Interaction
- **G** Long-Term Outcomes
Stabilized with his aunt, after cesarean, since the father did not make it from work. Peripheral line inserted SSC. At term age the boy still sleeps very well in his aunt’s arms.

Even sick babies should receive breastmilk from the first day of life.

Elvin, 30 min old. 1354g. w28+2

Huddinge, Stockholm, SWEDEN
Twins after caesarean, grandma.

Siren Rettedal
Experiences from the Scandinavian iKMC study (IPISTOSS)

Siren Rettedal, Head of Neonatal Intensive Care Unit, Stavanger, Norway
Sponsored by Laerdal Foundation

Video Clip
AVOID early cord clamping
Immediate WARM CHAIN
Immediate CPAP
Immediate MONITORING
PARENTS are present / central
Immediate CONNECTION
Breastmilk should be collected early.

Thea, 48h old
On CPAP, Phototherapy, IV lines
Trophic feeds etc

Continuous >20 h/day

Procedures can be done skin to skin

Clinical care must be the same – only place of care differs

Why are we doing this study in Scandinavia?

We want to know if not being separated from the mother is better for premature babies

February 19, 2018

Cognitive Outcomes of Children Born Extremely or Very Preterm Since the 1990s and Associated Risk Factors
A Meta-analysis and Meta-regression

Feb 19, 2018

Conclusions and Relevance:
Extremely or very preterm children born in the antenatal corticosteroids and surfactant era show large deficits in intelligence. No improvement in cognitive outcome was observed between 1990 and 2008.

Bronchopulmonary dysplasia was found to be a crucial factor for cognitive outcome. Lowering the high incidence of BPD may be key to improving long-term outcomes after EP/VP birth.

February 19, 2018

Cognitive Outcomes of Children Born Extremely or Very Preterm Since the 1990s and Associated Risk Factors: A Meta-analysis and Meta-regression
The Stockholm Neonatal Family Centered Care Study: Effects on Length of Stay and Infant Morbidity

n = 366

CONCLUSIONS: This study demonstrated a reduction in total length of hospital stay for infants born prematurely by providing facilities for parents to stay in the NICU 24 hours/day from admission to discharge. Analyses of secondary outcomes also suggested a reduction in pulmonary morbidity, such as moderate-to-severe BPD.

The Science behind Family Centred Care

The Neuroscience of Birth & Breastfeeding

"buffering protection of adult support"

BERGMAN COMMENTARY – NEWBORN
Reducing toxic stress IS VERY EASY!!

The Science behind Family Centred Care

RESILIENCE (= STRESS RESISTANCE)

“capacity to maintain healthy emotional functioning in the aftermath of stressful experiences”

BERGMAN COMMENTARY – NEWBORN
Reducing toxic stress IS VERY EASY!!
SKIN-TO-SKIN CONTACT
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The Neuroscience of Birth & Breastfeeding

KMC on stable babies: 11000 babies per year.

400 000 deaths ... could be prevented ... ONLY IF ... KMC starts at birth

Planning grant from Bill & Melinda Gates Foundation.
KMC: Evidence, gaps and ongoing research

RAJIV BAHL
Department of Maternal, Newborn, Child and Adolescent Health
WHO, Geneva

Evidence: mortality

Survival benefit clear for continuous KMC, insufficient evidence for intermittent KMC.

Note trend in favour of CONTINUOUS
Note trend in favour of **EARLIER** start

**WHO recommendations**

- Learning how to implement KMC at scale to reach population coverage of at least 80% (ongoing, ~50% coverage reached)
- Efficacy of home-initiation of KMC in reducing neonatal and infant mortality (ongoing, 70% enrolled)
- Efficacy of KMC initiated immediately after birth in reducing neonatal mortality (initiated Dec 17 in India, Jan 18 in Nigeria)

**Evidence gaps: key research priorities**

- How can facility based initiation of effective KMC for stable small babies be scaled up?
- Can community-based initiation of KMC reduce neonatal mortality of clinically stable small babies?
- Does initiation of KMC immediately after birth, even for unstable babies, improve survival?

**New WHO coordinated research**

- In Ethiopia and India, 7 populations of about a million each in different geographic regions
- Understanding barriers to implementation and addressing them systematically
- Accurate weighing of all newborns, referral, implementing KMC in health facilities, supporting continued KMC at home
- Independent population-based evaluation of coverage

**KMC scale up study**

- Learning how to implement KMC at scale to reach population coverage of at least 80% (ongoing, ~50% coverage reached)
- Efficacy of home-initiation of KMC in reducing neonatal and infant mortality (ongoing, 70% enrolled)
- Efficacy of KMC initiated immediately after birth in reducing neonatal mortality (initiated Dec 17 in India, Jan 18 in Nigeria)
Home-initiated KMC study

- Individually randomized controlled trial in India. Sample size 10,500
- Low birth weight infants <48 hours old, born at home or discharged from health facilities without KMC
- Families allocated to intervention group supported to provide skin to skin contact, exclusive breastfeeding
- Primary outcome mortality to 1 and 6 months of age
- Early learnings: almost universal acceptance, average KMC duration about 9.5 hours per day achieved.

Immediate KMC study

- Individually randomized controlled trial: hospitals in Ghana, India, Malawi, Nigeria and Tanzania. Sample size 4,200
- Newborns <1.8 kg will be allocated to intervention or control group
- Those allocated to intervention receive skin to skin care starting immediately after birth, and continued thereafter
- Those allocated to control receive conventional care until considered stable, KMC initiated after that
- Primary outcome neonatal mortality

Minimal package of care for a newborn baby

- Preparation for birth and newborn resuscitation
- Thermal care
- Breastfeeding and assisted feeding
- Fluid management
- Respiratory distress, oxygen, CPAP and monitoring
- Infection
- Monitoring of newborn baby
- Prevention of infection

2 weeks training BEFORE study starts

Equipment provided

Training given
WHO «Minimum package of care for small babies»

- Study sites harmonized, both control and intervention patients receive WHO «minimal package of care for small babies».
- Any difference in the two study arms may not be attributed to a lack of standard care.

Immediate Parent Infant Skin-To-Skin Study (IPISTOSS) – A Multicenter Randomized Controlled Trial Comparing Skin-to-Skin Contact Initiated Within First 60 Minutes of Life and Continued Until Stabilization with Separation (Conventional Care) in Neonates with Birth Weight of 1000-1800g.
Immediate KMC study

### Challenge !! Obstetric and neonatal care

### Teams !! Around the clock

### Pre-screening, fitness form, pre-delivery consent

### Baseline, daily monitoring form, teams, and more !!

**Detailed description of clinical standardized operational procedure (SOP) for intervention and control.**
Intervention training given:
to regular staff and research team.

Jill Bergman    (Norway, Tanzania)

Malawi – official launch, pre-screening

Randomization

Tanzania

Immediate

Breastmilk collected early by KMC supporter.

KMC by definition has several components,
includes breastfeeding support.

All subjects (intervention and control)
get early milk expression.

Intervention subjects support is:
‘put at breast’ - recorded once an hour
Actual breastfeeding is an outcome
Safdarjung, New Delhi: “MOTHER-NICU”

“MOTHER-NICU” Ghana
All get same INTENSIVE level of care (L2)

Ward for “unstable continuous” KMC.

“MOTHER-NICU” Malawi
Cases and controls in same ward (identical staffing levels)

KATH, Kumasi, GHANA
Surrogate starts, mother takes over.

Muhimbili, Dar es Salaam, TANZANIA
Twins after vaginal birth.

NOVEL HEALTH CADRE
KANGAROULA
KANGAROO Mother Care
plus DOULA care
**iKMC** (Immediate – till stable)
~ 4200 babies

**Mortality reduction**

WHO
Bill & Melinda
Gates Foundation

Enrolment started
December 2017

To be completed
December 2019

Results EARLY 2020

Follow-up for 2 years
funding committed.

**LIC**
Tanzania Malawi Ghana Nigeria India

**MIC**

**HIC**

**Smaller but similar studies ongoing in**
The Gambia
Uganda

Immediate KMC on
temperature (India)
Zambia 2018

NOTE: not a LIC solution,
not a third world, third rate solution ....
Intervention is state of art neonatal care
(IPISTOSS precedes iKMC)

**IPISTOSS**

**Mortality reduction**

WHO
Bill & Melinda
Gates Foundation

Karolinska, Sweden
Laerdal, others
BabyBjorn ...

**IKMC** (Immediate – till stable)
~ 4200 babies

**Mechanisms research**

**LIC**
Tanzania Malawi Ghana Nigeria India

**MIC**

**HIC**

Vietnam & RSA
Norway Sweden

**iKMC** (Immediate – till stable)
~ 4200 babies

**IPISTOSS** (Immediate – till stable)
~ 1200 babies

**Survive**

Three continents

**Thrive**

Every baby is born with one guardian angel:
Its mother

- RAJIV BAHL
  - Department of Maternal, Newborn, Child and Adolescent Health
  - WHO, Geneva