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Indian Integrated Management of Neonatal and Childhood Illness Strategy

• Based on the template and approach of IMCI, retains its strengths: simple, evidence based, addresses main killers

• Increased focus on disease prevention, early recognition and care seeking for illness
  - Home visits in the first week of life for newborn care
  - Community activities to generate demand
  - Treatment of neonatal and childhood illnesses close to homes

• Increased focus on management of neonatal illness
  - "Young infant" redefined to include the first week of life
  - 50% of training time dedicated to the young infant (4 of 8 days)
Evaluation of IMNCI

**Aim:** To generate evidence of impact on mortality, necessary for continued and increased investment for scale-up

**Primary objective:** To determine the effectiveness of implementing the IMNCI strategy on a district-wide scale in reducing neonatal and infant mortality

**Secondary objectives:** To determine the effect of IMNCI on
- newborn and infant care practices
- prevalence of neonatal and infant illness
- care seeking for illness
Study Design

- Cluster randomized effectiveness trial in district Faridabad, Haryana, with a population of ~1.1 million
- Random allocation of 18 clusters (Primary Health Centre areas) to intervention or control, after a baseline survey
Study Site

- Primarily rural setting
- Schooling (median years): men 9, women 3
- 62% population uses open fields for defecation
- Over half the deliveries occur at home

Health care system

- Village level: AWW, ASHA
- Health sub-centre: ANM
- Primary health centre: Physicians
- Private practitioners within or near village most common source of child health care (~ 60%)
Sample Size

33,000 births per group; sufficient to detect a difference between the intervention and control groups of:

- 18% in Infant Mortality
- 20% in Neonatal Mortality

Assumptions:
- IMR 60 per 1000; NMR 40 per 1000 (baseline survey)
- 80% power
- 95% confidence
- inter cluster coefficient of variation (k) of 0.11
- 10% attrition
## The intervention

<table>
<thead>
<tr>
<th>Put in place: Jan-Dec 2007</th>
<th>Intervention Clusters</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improving CHW skills to promote newborn care practices</td>
<td>8 day basic IMNCI training + training on how to conduct meetings</td>
<td>No</td>
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<tr>
<td>Improving Case Management Skills of CHW and HW</td>
<td>8-d IMNCI training for CHW, nurses and physicians, Orientation for private providers (6h) &amp; TBAs (4h)</td>
<td>No</td>
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<tr>
<td>Strengthening Health System to Implement IMNCI</td>
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<tr>
<td>- Supervision of CHW/HW</td>
<td>Temporary contractual hiring, IMNCI &amp; supervision training</td>
<td>No</td>
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<tr>
<td>- Task-based incentives for IMNCI activities</td>
<td>Incentives for home visits, women's group meetings, sick child contacts</td>
<td>No</td>
</tr>
<tr>
<td>- Ensuring supply of medicines</td>
<td>Medicine depots in villages</td>
<td>No</td>
</tr>
</tbody>
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Intervention Delivery

Initiated January 2007; was fully in place December 2007

- Intervention planned by the research team and the District Health and ICDS systems
- Intervention delivered by the District Health and ICDS systems
- Role of the research team in intervention delivery:
  - organizing training courses for CHW, HW and their supervisors
  - ensuring two health supervisors in each intervention cluster
  - strengthening the supply system for medicines
- The team that supported intervention delivery did not participate in impact evaluation
Home visits for newborn care by AWW
Treatment close to homes by ASHA
Case management by physicians and ANMs using IMNCI

Assess and Classify the Sick Young Infant
Age Upto 2 Months

Assess
Ask: The Mother What the Young Infant’s Problems Are
- Determine if this is an initial or follow-up visit for this problem.
- If follow-up visit, use the follow-up instructions on the bottom of this chart.

Classify
A child with a pink classification needs urgent attention, complete the assessment and pre-referral treatment immediately so referral is not delayed.

Identify Treatment
(urgent pre-referral treatments are in bold print)

Check for Possible Bacterial Infection / Jaundice

Ask:
- Has the infant had convulsions?

Look, Listen, Feel:
- Count the breaths in one minute. Repeat the count if elevated.
- Look for severe chest indrawing.
- Look for nasal flaring.
- Look and listen for grunting.
- Look and listen for bulging fontanelle.
- Look for pus draining from the ear.
- Look at the umbilicus. Is it red or draining pus?
- Look for skin pustules. Are there 10 or more skin pustules or a big boil?
- Measure axillary temperature (if not possible, feel for fever or low body temperature).
- See if the young infant is lethargic or unconscious.
- Look at the young infant’s movements. Are they less than normal?
- Are the palms and soles yellow?

Classify
Classify ALL Young Infants
- Young Infant Must Be Calm

Signs
- Convulsions or
- Fast breathing (60 breaths per minute or more)
- Severe chest indrawing
- Nasal flaring
- Grunting
- Bulging fontanelle or
- 10 or more skin pustules or a big boil
- If axillary temperature 37.5°C or above (or feels too hot to touch) or temperature less than 35.6°C (or feels cold to touch) or
- Lethargic or unconscious or
- Less than normal movements.

Classify As
- Possible Serious Bacterial Infection
- Local Bacterial Infection
- Severe Jaundice
- Jaundice
- Low Body Temperature

Identify Treatment
- Give first dose of Intramuscular ampicillin and gentamicin.
- Treat to prevent low blood sugar.
- Warm the young infant by Skin to Skin contact if temperature less than 35.6°C (or feels cold to touch) while arranging referral.
- Advise mother how to keep the young infant warm on the way to the hospital.
- Refer URGENTLY to Hospital
- Give oral neotriamcinolone or amphotericin for 5 days.
- Teach mother to treat local infections at home.
- Follow up in 2 days.
- Treat to prevent low blood sugar.
- Warm the young infant by Skin to Skin contact if temperature less than 35.6°C (or feels cold to touch) while arranging referral.
- Advise mother how to keep the young infant warm on the way to the hospital.
- Refer URGENTLY to Hospital
- Advise mother to give home care for the young infant.
- Follow up in 2 days.
- Warm the young infant using Skin to Skin contact for one hour and reassess
- Treat to prevent low blood sugar.

If referral is not possible, see the section Where Referral is Not Possible in the Module Treat the Young Infant and Counsel the Mother.
Supportive supervision
Medicine depots at home of ASHA
Evaluation
1 January 2008 – 11 April 2010

Evaluation identical for intervention and control areas

- **Birth and Death surveillance**
  - Field workers allocated 2000-3000 households
  - Monthly pregnancy surveillance; identification of births
  - Home visits to ascertain vital status: 1, 3, 6, 9, 12 months of age
  - Verbal autopsy for all stillbirths, neonatal and infant deaths (separate team)

- **Care practices, morbidity and care seeking for illness**
  - Interviews with randomly selected mothers at infant ages 1, 6 and 12 months

- **Process of intervention delivery**
  - Observations of home visits, sick child contacts, women's group meetings; interviews with mothers
Statistical Analysis

Intention to Treat Analysis
- Pregnancy identified through surveillance, outcome live birth or stillbirth
- Vital status known at least for the neonatal period
- **Subgroup analysis**: above, plus born at home

- Cluster-level analysis, weighted for births in cluster
- Comparison using Poisson regression models
- Rate ratios adjusted for two important differences in baseline survey: distance from the highway and proportion of health facility births
Trial Profile

18 clusters randomized
(Pregnancy surveillance: 1 Jan 2008 to 31 March 2010)

9 INTERVENTION CLUSTERS
Pregnancies documented
37741

- 8 Pregnant woman died
- 23 Pregnant woman left area permanently
- 2646 Miscarriage (foetal loss <28 wk gestation)
- 4619 No outcome until end of study follow up

Pregnancy outcome live birth (29782) or stillbirth (663)
30445

- 663 Stillbirths
- 28 Left area permanently
- 1 Refused
- 86 Temporarily away

Day 29 vital status known
29667

- 1244 Died during neonatal period
- 393 Left area permanently
- 1 Refused
- 12140 Not completed 12 mo at end of study

12 month vital status known
15889

9 CONTROL CLUSTERS
Pregnancies documented
39846

- 12 Pregnant woman died
- 242 Pregnant woman left area permanently
- 2501 Miscarriage (foetal loss <28 wk gestation)
- 5335 No outcome until end of study follow up

Pregnancy outcome live birth (30920) or stillbirth (836)
31756

- 836 Stillbirths
- 34 Left area permanently
- 3 Refused
- 70 Temporarily away

Day 29 vital status known
30813

- 1326 Died during neonatal period
- 770 Left area permanently
- 3 Refused
- 12659 Not completed 12 mo at end of study

12 month vital status known
16055
Summary of key Findings
Intervention Coverage

- **Home visits**: 90% newborns visited; but only 43% visited thrice and 57% within the first 2 days
- **Women's group meetings**: 45% caregivers attended a meeting
- **Case management**: 60-80% of sick newborns and children sought treatment; but only half of them from an appropriate provider
Newborn Care Practices improved

- Initiation of breast feeding within an hour of birth (40.7% vs. 11.2%)
- Exclusive breastfeeding at 4 weeks of age (77.6% vs. 37.3%)
- Delayed bathing (84.5% vs. 46.2%)
- Nothing or only GV paint applied on cord (84.1% vs. 39.5%)
Reduced morbidity and improved care seeking

- Severe morbidity in newborns 22% (CI 5-35%) lower, diarrhoea and pneumonia in infancy 33-42% lower
- Care seeking within 24 hours from an appropriate provider severe newborn illness (39.7% vs. 23.5%)
- Care seeking within 24 hours from appropriate provider for pneumonia (21.3% vs. 10.1%) and diarrhoea (14.5% vs. 7.8%) in infants aged 6 months
Impact on Mortality

- 13% (CI 1-23%) reduction in neonatal, 18% (CI 11-35%) reduction in infant mortality

- 19% (CI 5 to 31%) and 24% (CI 14-32%) reductions in neonatal and infant mortality in sub-group of home births
Important strengths of the Study

- Large cluster-randomized controlled trial in over a million population to evaluate a complex child survival intervention
- Effectiveness design, intervention delivery within the health system
- IMNCI operationalized in a realistic manner open to innovation, and possible to scale up
- Separate evaluation team; identical system in intervention and control clusters
Limitations

- Relatively few clusters: clusters large, PHC area unit of randomization to avoid contamination
- Some cluster level baseline differences despite stratified randomization: Results adjusted for baseline differences
- Some aspects of the intervention beyond routine IMNCI implementation in India: additional aspects realistic and possible to scale up
Implications

• Comprehensive, integrated strategies such as IMNCI are feasible to deliver and improve newborn and infant survival.

• This strategic approach should be scaled up to help achieve MDG4 in India and other developing countries.

• To maintain and increase impact beyond that in the trial:
  – Quality training, adequate supervision, timely supplies, and task-based CHW incentives are critical
  – Proportion of early postnatal visits can be increased by adding home visits during pregnancy to IMNCI design
  – Access to referral care can be increased by improving links of community and health facility with district and sub-district hospitals
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