Feasibility of an innovative, ultra-low-cost, bubble Continuous Positive Airway Pressure (bCPAP) package with a novel blender in Maharashtra, India

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“Strength does not come from physical capacity. It comes from an indomitable will.”

-Mahatma Gandhi
Background - Problem

- Nearly 3 million newborns die each year during the first 28 days of life
- >70% of these deaths occur in Southern Asia and sub-Saharan Africa
- The main causes these neonatal deaths are:
  - Prematurity
  - Complications during labor and birth
  - Infections (pneumonia, sepsis)
- Respiratory distress is implicated in all three causes
- In many district or provincial hospitals in LMICs, the case fatality for severe respiratory distress can be as high as 20%
Continuous Positive Airway Pressure (CPAP)

• CPAP is an effective, **non-invasive ventilatory support** for individuals with respiratory distress
  • Distends alveoli
  • Increases functional residual capacity (FRC)
  • Improves chest wall stability
  • Decreases work of breathing
  • Reduces the need for mechanical ventilation
  • Reduces RDS-specific mortality
bubble CPAP

• Transmits **small-amplitude, high-frequency pressure oscillations** created by bubbling at the air-water interface of a submerged expiratory tube
  • Pressure determined by depth of tube below surface of water
  • Aids alveolar recruitment
  • Improves gas exchange

• Safe and effective alternative to conventional CPAP in **low-resource settings**
  • Reduces the need for mechanical ventilation
  • Can be effectively administered by nurses and other health workers in LMICs
  • Implementation of bubble CPAP shown to be feasible in low-resource settings
Every Second Matters – Newborn and Infant Respiratory Bundle (ESM-NIRB)

Includes:

• Innovative ultra-low-cost bCPAP device (~7 USD) with novel blender
• Hospital grade pulse oximeter
• Clinical pathway wall chart
• Safety checklist
• Training manual
• Two-day training program
Every Second Matters – Newborn Respiratory Bundle (ESM-NRB) Safety Checklist

- Confirm need for bubble CPAP (see ESM-NRB Clinical Pathway)
- Complete ESM-NRB Patient Clinical Record
- Place and keep patient in a high dependency area
- Obtain equipment:
  - Oxygen source
  - ESM-NRB kit
  - Humidifier
  - Pulse oximeter
  - EOS tube
- Confirm oxygen source full, connected to humidifier, and able to attach to inspiratory tubing
- Connect oxygen tubing to humidified oxygen source
- Connect blender between tubing to oxygen source and inspiratory tubing
- Using the “Y” connector, connect the inspiratory tubing and exsoratory tubing to the two prongs of the “Y” connector, furthest away from the inspiratory and exsoratory tubing
- Connect inspiratory tubing to thick green tubing
- Fill reservoir with water or normal saline to level “Y”
- Not using normal saline, add 1 carpful 5% sugar to filled reservoir
- Coolimeter and insert green tubing until tip submerged to the ECM level on the reservoir
- Turn on oxygen source and confirm flow throughout system
- Place fingers under nasal cannula to feel flow
- Ensure bubbling in reservoir when nasal prongs are occluded
- Apply pulse oximeter to patient if not already done so
- Apply nasal cannula with spings attached to patient name, curved down
- Ensure a closed system with no leakage
- Titrate oxygen flow and pressure to achieve oxygen saturations (SpO₂) between 95-99% and respiratory severity score ≤ 4
- Limit pressure (depth of green tubing in fluid reservoir) to 5cm for all patients, if required, do not exceed 8cm (see manual for titration)
- Place EOS tube and initiate appropriate feeds:
  - Breast milk or tube feeds
  - Unable to give EOS feeds, give IV fluids
- Respiratory severity score ≥ 5 or failure to achieve SpO₂ 90-99%
- Discuss with senior clinical provider
- Prepare for transition to higher care
- Follow ESM-NRB Clinical Pathway and complete ESM-NRB Patient Clinical Record every 8 hours
- Complete ESM-NRB Equipment Checklist once applied at the beginning of each shift
Objective

• Determine the feasibility of the innovative, ultra-low-cost bubble CPAP package (ESM-NIRB) in resource-limited hospitals in Maharashtra, India

• Define the impact of the package:
  • Clinical course and discharge rate of newborns and infants with respiratory distress
  • Evaluate provider experiences in utilizing ESM-NIRB
Methods

• Staff from 4 hospitals in India completed the training and implemented ESM-NIRB within their own facilities
  • Locations: Nagpur, Sawangi, Gondia, Sevagram

• Data was collected prospectively each time ESM-NIRB was applied through data collection cards
  • Weekly database update between in-country facilities and Boston office

• Clinical course and outcomes of all patients supported by ESM-NIRB were analyzed

• Qualitative phenomenological analysis of provider experiences with ESM-NIRB
  • Interviews conducted with providers from each facility, including residents, physicians, neonatologists, and nurses
## Patient Clinical Record: Every Second Matters – Newborn Respiratory Bundle (ESM-NRB)

<table>
<thead>
<tr>
<th>Patient name and ID</th>
<th>Facility name</th>
<th>bCPAP kit no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient date of birth</td>
<td>Gestational age at birth</td>
<td>Birth weight</td>
</tr>
<tr>
<td>Date and time bCPAP started</td>
<td>Date and time bCPAP removed</td>
<td></td>
</tr>
<tr>
<td>APGAR scores at birth (if known)</td>
<td>Pregnancy complications</td>
<td></td>
</tr>
<tr>
<td>Past medical history</td>
<td>Past surgical history</td>
<td></td>
</tr>
<tr>
<td>Diagnosis</td>
<td>Admission weight</td>
<td></td>
</tr>
</tbody>
</table>

### RESPIRATORY SEVERITY SCORE

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Synchronized: None</td>
</tr>
<tr>
<td>1</td>
<td>Lag on inspiration: Just visible</td>
</tr>
<tr>
<td>2</td>
<td>See-saw inspiration: Easily seen</td>
</tr>
<tr>
<td></td>
<td>Expiratory grunt: Heard by ear</td>
</tr>
</tbody>
</table>

**TOTAL SCORE**: Healthy newborns have a cumulative respiratory severity score close to 0. Severely depressed newborns have a score close to 10. bCPAP may be initiated for scores >4. Respiratory Severity Score modified from: Silverman and Andersen, Pediatrics 1955; 17:1.
<table>
<thead>
<tr>
<th>Date</th>
<th>Day</th>
<th>Month</th>
<th>Time</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory rate</td>
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<td></td>
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<tr>
<td>Patient SpO2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory severity score</td>
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<td></td>
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<tr>
<td>bCPAP pressure (cmH20)</td>
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<td></td>
<td></td>
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<tr>
<td>Temperature</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart rate</td>
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<td></td>
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<tr>
<td>Blood pressure</td>
<td></td>
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<td></td>
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<tr>
<td>Capillary refill (sec)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>bCPAP O2 flow (L/min)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suctioning done (Y/N)</td>
<td></td>
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<tr>
<td>Any labs obtained? If yes, please describe which and value (blood culture, CBC, etc.) in Notes</td>
<td></td>
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<tr>
<td>Notes (include date and time)</td>
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<tr>
<td>Patient Outcomes: Every Second Matters – Newborn Respiratory Bundle (ESM-NRB)</td>
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<td>---------------------------------------------------------------------------</td>
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</tbody>
</table>

Please provide summary notes (including initial value when starting bCPAP, when bCPAP is stopped, and range over admission) covering the entire period of bCPAP treatment. Please add any other details at the bottom of the sheet.

- Respiratory rate (include when bCPAP initiated, bCPAP stopped, and range over admission)
- Pulse-oximetry SpO2 (include when bCPAP initiated, bCPAP stopped, and range over admission)
- Resp severity score - admission
- Resp severity score - when bCPAP discontinued
- bCPAP pressure (cm H2O) (include when bCPAP initiated, bCPAP stopped, and range over admission)
- bCPAP O2 flow (L/min) (include when bCPAP initiated, bCPAP stopped, and range over admission)
- Total length of time on bCPAP
- Vitals when bCPAP discontinued
- Medications received while on bCPAP and for what indication
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<tr>
<td>Time</td>
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<tr>
<td>Oxygen flow (L/min)</td>
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<tr>
<td>Humidifier okay (Y/N)</td>
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<tr>
<td>Visible bubbles (Y/N)</td>
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<tr>
<td>bCPAP pressure (cm)</td>
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<td></td>
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<tr>
<td>Leaks in bCPAP system (Y/N)</td>
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<tr>
<td>Nasal prongs (size)</td>
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<td></td>
</tr>
<tr>
<td>Prongs fit properly (Y/N)</td>
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<tr>
<td>Any adaptations (Y/N)? (explain below in Notes)</td>
<td></td>
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</tr>
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Notes (include date and time)
Results

• From May 26, 2017 to March 12, 2018, 78 newborns were placed on an ESM-NIRB bCPAP device for impending respiratory failure

• 34 (43.6%) of the 78 were premature and 63 (80.8%) survived to discharge

• Among newborns with initial RSS between 4 and 8, the RSS decreased on average by 1.31 [95% CI 0.88, 1.75; p-value 0.000139] over 6 hours of treatment with the ESM-NIRB bCPAP device
Preliminary Results – Qualitative Analysis

• **Themes** from provider interviews included:
  • Ease of use
  • Consistency and reliability of the device
  • The need for an upgraded blender able to adjust oxygen concentrations
  • More hands-on training
  • An increase in the number of ESM-NIRB devices
Discussion

• Need for cost effective analysis
• Parallel study in Kenya
Conclusion

• Implementation of an ultra-low cost ESM-NIRB package that does not require electricity or pressurized air was feasible across these four hospitals in India.

• The authors are responding to the findings and have developed an adjustable blender and plan for increased hands on training.

• Further research to refine the ESM-NIRB package and develop a strategy for scale is under way.
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