**Availability and use of Continuous Positive Airway Pressure (CPAP) for neonatal care in public health facilities in India: a cross- sectional cluster survey**

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**Short title**: Availability and use of neonatal CPAP use in India

**Abstract**

## Objectives

To determine the availability of Continuous Positive Airway Pressure (CPAP) and to provide an overview of its use in neonatal units in government hospitals across India.

## Setting

Cross-sectional cluster survey of a nationally representative sample of government hospitals from across India.

**Primary outcomes**

Availability of CPAP in neonatal units.

**Secondary outcomes**

Proportion of hospitals where infrastructure and processes to provide CPAP are available. Case fatality rates and complication rates of neonates treated with CPAP.

## Results

Among 661 of 694 government hospitals with neonatal units that provided information on availability of CPAP for neonatal care, 68.3% of medical college hospitals (MCH) and 36.6% of district hospitals (DH) used CPAP in neonates. Assessment of a representative sample of 142 hospitals (79 MCH and 63 DH) showed that air-oxygen blenders were available in 50.7% (95% CI 41.4,60.9) and staff trained in the use of CPAP were present in 56.0% (45.8,65.8) of hospitals. The nurse to patient ratio was 7.3 (6.4,8.5) in MCH and 6.6 (5.5,8.3) in DH. Clinical guidelines were available in 31.0% of hospitals (22.2,41.4). Upper oxygen saturation limits of above 94% were used in 72% (59.8,81.6) of MCH and 59.3% (44.6,72.5) of DH. Respiratory circuits were reused in 53.8% (42.3,63.9) of hospitals. Case fatality rate for neonates treated with CPAP was 21.4% (16.6,26.2); complication rates were 0.7% (0.2,1.2) for pneumothorax, 7.4% (0.9,13.9) for retinopathy, and 1.4% (0.7,2.1) for bronchopulmonary dysplasia.

## Conclusions

CPAP is used in neonatal units across government hospitals in India. Neonates may be overexposed to oxygen as the means to detect and treat consequences of oxygen toxicity are insufficient. Neonates may also be exposed to nosocomial infections by reuse of disposables. Case fatality rates for neonates receiving CPAP are high. Complications might be under-reported. Support to infrastructure, training, guidelines implementation, and staffing are needed to improve CPAP use.

**Strengths and limitations of this study**

* Nationwide assessment of the availability and use of CPAP in neonates in a representative sample of public hospitals in India, through direct hospital site visits.
* Our findings apply to government facilities; the availability and use of CPAP in private hospitals, where a large proportion of inpatient care is provided in India, may be different.
* The standards used to assess the availability of essential infrastructures and processes to provide CPAP were decided by consensus among the research team, and this carries a degree of subjectivity.
* Data about infrastructures and processes were based on participants’ reports, and there might have been reporting bias.
* Data on some important determinants of neonatal mortality and morbidity were not collected, which precludes firm conclusions on the impact of lack of infrastructures and processes on the clinical outcomes reported.

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# Introduction

An estimated 2.9 million neonates die every year worldwide. Most of these deaths are in low- and middle-income countries (LMIC) and result from prematurity, intra-partum related conditions, and infections.1 Acute respiratory distress, common to these causes of death, is associated with case fatality rates as high as 20% in LMIC.2 The most basic respiratory support for neonates with acute respiratory distress is oxygen, followed by non-invasive support such as Continuous Positive Airway Pressure (CPAP), and by mechanical ventilation. Mechanical ventilation involves endotracheal intubation, an invasive procedure requiring high technical skills. In contrast, CPAP can in principle be applied by non-specialist healthcare providers.3 It is estimated that the use of oxygen in combination with CPAP for the treatment of respiratory distress contributed to a 70% increase in the survival of preterm babies in high-income countries.4 Several studies reported that CPAP is safe and effective in LMIC and its use in these settings is increasing.­5-12

However, CPAP use can lead to serious complications such as pneumothorax, or nasal trauma.13,14 Moreover, when CPAP is used with supplemental oxygen, the unregulated use of oxygen may lead to retinopathy of prematurity (ROP),15 a major cause of blindness, or bronchopulmonary dysplasia (BPD).16

CPAP is easy to initiate, but to be effective, CPAP needs to be used continuously for hours or days. This implies continuous supplies of electricity and medical gases, continuous clinical monitoring for timely detection of acute complications, and long-term follow-up for chronic complications. Consequently, the World Health Organization recommends considering the wider context of care prior to introducing and scaling-up CPAP use in LMIC.17

India accounts for an estimated 779 000 neonatal deaths every year.1 The Government of India has launched several initiatives to reduce neonatal mortality. These include the establishment of Special Newborn Care Units (SNCU) which provide level II care including treatment for sepsis, jaundice, and respiratory distress. SNCU have been implemented in district hospitals (DH), i.e. secondary care hospitals, and in medical college hospitals (MCH), i.e. tertiary care hospitals.18 The current national recommendations in terms of respiratory support are to use oxygen in DH, and CPAP and mechanical ventilation in MCH.19 However, CPAP seems to be used in DH.20 The extent of CPAP use in neonates at the different levels of care, the availability of structures and processes to enable its use, and the clinical outcomes of this intervention in India are unclear.

The aims of this study were to determine the availability of CPAP and to provide an overview of its use in neonatal units in government hospitals across India.

# Methods

## Study design

A cross-sectional cluster survey was conducted among neonatal units using CPAP in government hospitals in India.

### **Identification of hospitals using CPAP in neonates**

Programme officers responsible for neonatal health in all Indian states and union territories were contacted to obtain a list of all government MCH and DH with SNCU or Neonatal Intensive Care Unit (NICU). NICU are neonatal units in MCH that existed before the central government launched the initiative to implement SNCU in DH and MCH. All hospitals with a SNCU/NICU were subsequently contacted to enquire whether CPAP was used in the neonatal unit.

### **Selection of hospitals**

Hospitals were selected for inclusion in the study using stratified cluster random sampling. Stratification was by:

1) district performance ranking based on a composite health index developed by the Government of India to identify districts needing priority investments in healthcare.21 High priority districts were defined as the bottom 25% of districts for health index scores; non-high priority districts were those in the top 75%.

2) type of neonatal unit - NICU or SNCU. NICU are funded and monitored by state governments. SNCU are funded and monitored by the central government. Because of these differences, we initially considered three types of neonatal units: NICU in MCH, SNCU in MCH, and SNCU in DH.

Prior to sample selection, facilities within the two strata determined by district performance were assigned to 62 clusters, typically either as a state or a subset of the districts within a state. Within each of the clusters there were between 3 and 10 facilities providing CPAP. These clusters were then stratified by type of neonatal unit.

Random sampling (among the 62 clusters) was stratified to ensure that the margin of error in each of the three facility-type strata did not exceed 10%, assuming the ICC did not exceed 0.1. A list of 42 randomly selected clusters was generated using the Runiform function in Stata® with a sequence for inclusion of hospitals within the clusters until the planned sample size (see below) in each of the three strata was achieved.

### **Sample size**

We initially estimated that the sample sizes of neonatal units required to estimate the outcomes of interest with 95% confidence and a margin of error not exceeding 10% would be:

* 36 NICU in MCH
* 51 SNCU in MCH
* 76 SNCU in DH

However, during data collection, it became evident that NICU and SNCU in MCH were not substantially different in organisation (e.g. staff deployment, purchasing and maintenance of equipment) or provision of neonatal healthcare (e.g. the same clinical guidelines where available were used). Therefore, it was decided to combine NICU and SNCU into a single stratum (called neonatal units in MCH). Treating them as one stratum for sampling, the sample size was revised to:

* 62 neonatal units in MCH
* 76 neonatal units in DH

### **Data collection**

Data were collected using a structured questionnaire and an observational checklist. The questionnaire (available as supplementary data) included 136 questions pertaining to availability of structures (infrastructure such as equipment, staffing), processes (practice of care) and outcomes (clinical outcomes) related to CPAP use, following the Donabedian framework for assessing quality of healthcare.22 The questionnaire was developed based on 11 guidelines from four countries (India, the United Kingdom, Australia and Spain) identified through a review of the literature. As there were no international standards for CPAP use in neonates, the research team (which included neonatologists, paediatricians and obstetricians) developed by consensus, a set of 21 standards for structures and 12 standards for processes. The questionnaire allowed collecting data on 17 standards for structures and all 12 standards for processes. The observational checklist allowed for direct observation of four of the remaining structures standards. Data collection tools were finalised after pilot-tests in two hospitals in Delhi.

Data were collected during site visits to each hospital by paediatric trainees or senior paediatricians who had been trained and had participated in pilot-testing of data collection tools. In each hospital, doctors and nurses who were present on the day of the visit answered questions on structures that were not observable (for example the availability of a doctor in the neonatal unit 24/7) and processes. Data for all neonates treated with CPAP during the three months preceding the visit were extracted from registers/records to assess clinical outcomes. Following this, the neonatal unit was visited and assessed using the observational checklist to assess availability of observable structures.

All assessments were conducted between May and September 2016. Data were collected electronically on iPads®.

### **Statistical analysis**

Descriptive statistics were derived with sampling errors, to provide 95% confidence intervals, that account for the variation in sizes and values for the clusters sampled. The analysis was performed with SPSS 23.0®. On average, data for infrastructure, practice of care and clinical outcomes were missing from 0.8%, 8.5%, and 44% of hospitals, respectively. Missing data for infrastructure and practice of care were considered as “item not available in the hospital”, while missing data for outcomes were not considered in the analysis.

To examine whether facilities with better infrastructure and practice of delivering CPAP have lower case fatality rates, we carried out an additional analysis: an index was defined which measures the proportion of 18 infrastructure criteria (all infrastructure criteria, except availability of BPD, ROP screening, and ROP treatment, as these criteria do not have direct impact on immediate mortality) and the 12 practices criteria met at each facility. A hospital with all criteria met would have an index of 1, while a hospital with no criteria met, an index of 0. This index was then used as a covariate in logistic regression analysis for case fatality rates of newborns treated with CPAP. The analysis was weighted to account for the variation in numbers of cases between facilities. Estimates are reported as odd ratios with corresponding 95% confidence intervals.  The additional analysis was performed using Stata version 15®.

### **Ethics**

The study was approved by the Ministry of Health and Family Welfare of India and by the Liverpool School of Tropical Medicine’s Research and Ethics Committee (Reference 15-032).

**Patient and public involvement**

There was no patient or public involvement.

# Results

### **Availability of CPAP**

In total, 232 neonatal units in MCH and 462 in DH were identified across the states. Information on whether the neonatal unit used CPAP could not be obtained for 12.9% (30/232) of MCH and 0.6% (3/462) of DH. Overall 138 of 202 neonatal units at MCH (68.3%) and 168 of 459 neonatal units at DH (36.6%) used CPAP. Of these, 142 neonatal units (79 at MCH and 63 at DH) from 33/62 clusters in 18 states and union territories were assessed (Figure 1). Twenty-one facilities (8 MCH and 13 DH) from six of the 33 sampled clusters could not be assessed because of time constraints and local events (strikes, political unrest). Thus, there was a 17% shortfall in the planned number of DH facilities (76) but an excess for MCH.

### **Infrastructure for CPAP**

Forty-six MCH (58.2%, 95% CI: 44.6-70.7) and 44 DH (69.8%, 95% CI: 54.1-82) used commercial CPAP machines exclusively. These included bubble CPAPs, infant flow CPAP systems, mechanical ventilators with CPAP mode, or high flow nasal cannula systems. Bubble CPAP was the commonest system: 87.3% (95% CI: 80.3-92.1) of all hospitals used this system (see supplementary data for more details on other systems). The remaining hospitals used a mixture of commercial and indigenous (home-made) devices.

General infrastructure (i.e. electricity, medical gases) was usually available, although 23.6% of hospitals did not have access to technical maintenance for CPAP equipment. None of the hospitals met all the stipulated standards for infrastructure (Table 1).

## Table 1. Availability of infrastructure for Continuous positive airway pressure (CPAP) at Medical College Hospitals (MCH, n=79), District Hospitals (DH, n= 63) and for both combined (n= 142)

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Type of hospital** | | **Total**  **(n=142)**  **% (95% CI)** |
| **Medical College hospitals (n=79)** | **District hospitals (n=63)** |
| **% (95% CI)** | **% (95% CI)** |
| **ESSENTIAL INFRASTRUCTURE** | | | |
| **General infrastructure** | | | |
| Technical maintenance | **77.2** (66.0-85.6) | **73.0** (57.0-84.7) | **75.4** (66.2-82.6) |
| Emergency electricity source | **93.7** (87.3-97.0) | **87.3** (68.8-95.6) | **90.8** (82.3-95.5) |
| Air and oxygen | **91.1** (83.0-95.6) | **88.9** (73.8-95.8) | **90.1** (82.8-94.5) |
| **CPAP-specific infrastructure** | | | |
| Air-oxygen blender for each CPAP device | **51.9** (39.7-63.8) | **49.2** (32.6-66.0) | **50.7** (41.4-60.9) |
| Range of sizes of nasal interfaces | **86.1** (75.6-92.5) | **87.3** (76.4-93.6) | **86.6** (79.6-91.5) |
| Guidelines for CPAP use available in the immediate area of care | **27.8** (19.4-38.2) | **34.9** (19.5-54.3) | **31.0** (22.2-41.4) |
| **Staffing levels** | | | |
| >1 doctor 24/7 | **93.7** (85.0-97.5) | **65.1** (44.8-81.1) | **81.0** (69.6-88.8) |
| >1 doctor 24/7 trained in CPAP use | **63.3** (51.7-73.5) | **46.8** (29.8-64.5) | **56.0** (45.8-65.8) |
| >1 doctor technically competent in the management of pneumothorax available 24/7 | **75.9** (64.5-84.6) | **41.3** (25.7-58.8) | **60.6** (49.9-70.3) |
| CPAP training plan available | **48.1** (34.3-62.2) | **41.3** (25.7-58.8) | **45.1** (34.4-56.2) |
| **Monitoring** | | | |
| Neonatal pulse oximeters | **82.3** (72.2-89.2) | **93.7** (85.3-97.4) | **87.3** (80.9-91.8) |
| X-ray 24/7 | **86.1** (77.4-91.8) | **54.0** (35.0-71.9) | **71.8** (60.6-80.9) |
| Transilluminator | **17.7** (10.4-28.7) | **6.3** (1.5-23.5) | **12.7** (7.4-20.9) |
| Retinopathy of prematurity (ROP) screening | **89.9** (77.2-95.9) | **60.3** (44.0-75.6) | **76.8** (66.0-84.9) |
| Broncho-pulmonary dysplasia (BPD) screening | **62.0** (49.0-73.5) | **22.2** (12.5-36.3) | **44.4** (34.8-54.4) |
| **Management of complications** | | | |
| Availability of equipment specific to the management of neonatal pneumothorax | **63.3** (49.8-74.9) | **20.6** (9.8-38.3) | **44.4** (34.1-55.2) |
| **OTHER IMPORTANT INFRASTRUCTURE** | | | |
| Availability of caffeine | **82.3** (71.6-89.5) | **58.7** (40.3-75.0) | **71.8** (60.3-81.1) |
| Availability of surfactant | **77.2** (66.6-85.2) | **49.2** (31.9-66.8) | **64.8** (53.5-74.6) |
| Availability of humidifiers | **55.7** (43.1-67.6) | **63.5** (48.8-76.1) | **59.2** (49.6-68.0) |
| Availability of antenatal corticosteroids | **93.7** (85.7-97.3) | **85.7** (75.9-91.9) | **90.1** (84.6-93.8) |
| Availability of cryotherapy or laser therapy for the treatment of ROP | **44.3** (30.9-58.5) | **7.9** (2.9-20.0) | **28.2** (19.4-39.0) |

**Standard of Practice**

In general, practice was in line with standards regarding general monitoring of a neonate receiving CPAP, except for continuous monitoring of respiratory rate and assessment of respiratory distress which were practised in about half of all hospitals (Table 2). A predefined oxygen saturation range was used in 94.9% of MCH and 92.1% of DH. Of these, 72% (95% CI: 59.8,81.6) of MCH and 59.3% (95% CI: 44.6,72.5) of DH reported using an upper oxygen saturation limit of above 94% (Figure 2). Processes followed less often were those related to infection prevention; for example, single use of respiratory circuits was practised in only 46.8% (95% CI: 34.0,60.1) of MCH and 47.6% (95% CI: 31.5,64.2) of DH. Two DH met all the standards for practice.

## Table 2. Practice of providing Continuous positive airway pressure (CPAP) against process standards in Medical College Hospitals, District Hospitals and for both combined. (n=142)

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Type of neonatal unit** | | **Total**  **(n=142)**  **% (95% CI)** |
| **Medical College hospitals (n=79)**  **% (95% CI)** | **District hospitals (n=63)**  **% (95% CI)** |
| **ESSENTIAL PROCESSES** | | | |
| **General clinical monitoring** | | | |
| Continuous monitoring of oxygen saturation | **88.6**(79.5-94.0) | **92.1** (82.9-96.5) | **90.1** (84.1-94.0) |
| Continuous monitoring of heart rate | **89.9** (81.0-94.9) | **92.1** (81.5-96.8) | **90.8** (84.7-94.7) |
| Continuous monitoring of respiratory rate | **60.8** (45.2-74.4) | **50.8** (37.4-64.1) | **56.3** (45.8-66.3) |
| Regular assessment of respiratory distress | **40.5** (30.1-51.8) | **49.2** (30.8-67.8) | **44.4** (34.3-54.9) |
| **CPAP** | | | |
| Use of a predefined initial pressure level | **86.1** (78.4-91.3) | **85.7** (71.6-93.5) | **85.9** (78.9-90.9) |
| Use of a predefined oxygen saturation range | **94.9** (88.3-97.9) | **92.1** (77.7-97.5) | **93.7** (87.1-97.0) |
| Verification of air and oxygen temperature | **43.0** (30.8-56.1) | **57.1** (34.2-77.3) | **49.3** (37.1-61.6) |
| Monitoring of nasal condition | **75.9** (62.8-85.5) | **79.4** (59.4-91.0) | **77.5** (66.7-85.5) |
| Use of a standardized CPAP weaning process | **50.6** (38.4-62.8) | **61.9** (40.6-79.4) | **55.6** (44.2-66.5) |
| **Infection prevention** | | | |
| Respiratory circuit replaced after one week of use | **38.0** (27.3-50.0) | **47.6** (28.2-67.8) | **42.3** (31.5-53.9) |
| Single use of respiratory circuits | **46.8** (34.0-60.1) | **47.6** (31.5-64.2) | **47.2** (36.9-57.7) |
| Single use of nasal interface | **41.8** (31.4-52.9) | **47.6** (30.4-65.4) | **44.4** (34.7-54.5) |

**Table 3. Clinical outcomes for babies treated with Continuous positive airway pressure (CPAP) at Medical College Hospitals (MCH), District Hospitals (DH) and for both combined**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Outcome (number of MCH and DH reporting data** | **Medical College hospital** | | | **District hospital** | | | **All facilities** | | |
| **n/Na** | **(%)** | **95%CI** | **n/N a** | **(%)** | **95%CI** | **n/N a** | **(%)** | **95%CI** |
| **Case Fatality Rate (CFR)** | | | | | | | | | |
| CFR for babies admitted to neonatal care unit (77+62) | 6,625/50,244 | 13.2 | (10.7-15.7) | 1,532/20,634 | 7.4 | (5.7-9.1) | 8,157/70,878 | 11.5 | (9.7-13.3) |
| CFR for babies receiving CPAP (50+38) | 446/2,256 | 19.8 | (14.6-24.9) | 197/748 | 26.3 | (15.7-37.0) | 643/3,004 | 21.4 | (16.6-26.2) |
| **Complications of CPAP** | | | | | | | | | |
| Pneumothorax (65+39) | 14/2,315 | 0.6 | (0.2-1.0) | 6/576 | 1.0 | (0-7-2.8) | 20/2,891 | 0.7 | (0.2-1.2) |
| Nasal lesion (49+38) | 51/1,148 | 4.4 | (1.5-7.4) | 26/453 | 5.7 | (1.1-10.3) | 77/1,601 | 4.8 | (2.3-7.3) |
| Necrotizing enterocolitis (56+34) | 64/1,837 | 3.5 | (1.5-5.5) | 2/393 | 0.5 | (0-1.3) | 66/2,230 | 3.0 | (1.3-4.6) |
| Retinopathy of prematurity (55+28) | 139/1,655 | 8.4 | (0.7-16.1) | 6/311 | 1.9 | (0.1-3.8) | 145/1,966 | 7.4 | (0.9-13.9) |
| Bronchopulmonary dysplasia  (55+30) | 25/1,404 | 1.8 | (0.9-2.7) | 0/377 | 0 | (0-0) | 25/1,781 | 1.4 | (0.7-2.1) |
| **Other outcome** | | | | | | | | | |
| Rescue mechanical ventilation (64+43) | 770/2,861 | 31.4 | (16.5-46.3) | 248/790 | 26.9 | (19.6-34.2) | 1,018/3,651 | 27.9 | (21.2-34.5) |

a Numbers of cases, i.e, (N) and deaths / complications (n) reported in the previous 3 months aggregated over facilities for which consistent sources were available (register when available, otherwise case notes).

**Clinical outcomes**

Overall case fatality rates (CFR) for neonates admitted to neonatal units were 13.2% (95% CI: 10.7,15.7) in MCH and 7.4% (95% CI: 5.7,9.1) in DH. The case fatality rate among neonates treated with CPAP in MCH and DH were 19.8% (95% CI: 14.6,24.9) and 26.3% (95% CI: 15.7,37.0) respectively. The most commonly reported complication in MCH was ROP (8.4%; 95% CI: 0.7,16.1). At DH level, nasal lesions were the most frequently reported complication (5.7%; 95% CI: 1.1,10.3) (Table 3).

In terms of the relationship between the availability of infrastructures, the practice of providing CPAP, and CFR, the CFR of hospitals with more infrastructure and practices was not significantly different from the CFR of hospitals with less infrastructure and practices in place (OR 4.65, 95% CI 0.46-47.2, p =0.30).

# Discussion

Two thirds of MCH and one third of DH use CPAP in neonates. No hospital met all 21 infrastructure standards, but two DH met all 12 standards for practice. A third of hospitals use home-made devices. Although general infrastructure (e.g. electricity, medical gases, etc.) is usually available, only half of all hospitals have air-oxygen blenders for every CPAP machine. Basic monitoring equipment is generally available. However, diagnostic equipment to identify complications of CPAP and/or to manage these is limited, especially at DH level. More than half of the hospitals re-use respiratory circuits or nasal interfaces. Most hospitals use predefined initial pressure levels and oxygen saturation ranges, but 72.0% of MCH and 59.3% of DH use upper oxygen saturation limits above 94%. On average, one nurse provides care for seven neonates. Mortality rate for babies on CPAP is 21.4%. Pneumothorax is reported in < 1%, and ROP and BPD are reported in 7.4% and 1.4%, respectively.

Our study identified several areas for improvement:

Not all hospitals follow the national recommendation that CPAP should be used only in MCH and not in DH.

Not all the infrastructure, manpower and skills needed to implement CPAP safely are in place. Some hospitals use home-made devices. Home-made devices are more likely to lack an air-oxygen blender for titration of oxygen; this increases the risk of oxygen toxicity. In line with our findings, a survey by Sundaram and colleagues found that only a third of neonatal units in India were equipped with air-oxygen blenders23 Moreover, respiratory circuits and nasal interfaces are frequently reused, which can expose neonates to nosocomial infections. Circuits and interfaces cannot be autoclaved. Hence, in India, they are usually disinfected with activated glutaraldehyde solutions. Arai and colleagues in Brazil found that anaesthesia circuits were still colonised with pathogens in 39.3% of circuits after disinfection with activated glutaraldehyde solutions.24 Studies from England and the Netherlands have reported episodes of infection outbreaks in neonatal and paediatric intensive care units associated with reutilization of respiratory consumables that were disinfected but not sterilized.25,26 In terms of staffing, a nurse: patient ratio of 1:7 is problematic. It is less than the Indian standard of 1:4 for SNCUs,19,27 and insufficient for units providing CPAP. In high income countries, the nurse: patient ratio for advanced care is 1:228 to ensure continuous clinical monitoring. Insufficient staffing has already been reported in the India Newborn Action Plan as a barrier to ensuring quality neonatal care.29 In terms of skills, the finding that most nurses report using upper oxygen saturation limits above 94% is a concern. The range to be used in neonates is subject to debate,30 but an upper oxygen saturation limit in preterm neonates of below 94% is recommended both internationally31 and nationally.19 The combination of the lack of air-oxygen blenders, the high number of patients monitored per nurse, and the use of high upper oxygen saturation limits may expose neonates to excessive oxygen. ROP was indeed the commonest complication reported in MCH and is a major health issue in India.32-37

The case fatality rate for neonates treated with CPAP in this study is in line with reports from India,9,38-43 Iran11 and South Africa,8,44-46 but other countries, such as Fiji,6 Latin American countries, 7,47,48 and high income countries13 have reported lower mortality rates. The reported rate of pneumothorax in this study is similar to other studies from India 9,38-40,42 and South Africa,44 but lower than in Latin America7,47 and Iran.12 The rate of ROP was lower than in other reports from India,31,49,50 Latin America,47 and Iran.12

The higher rate of mortality in neonates treated with CPAP in India may be a consequence of the lack of infrastructure and the shortfalls in the practices of care presented above, while the lower rates of complications could be linked to the lack of equipment to identify them. However, in our study, the CFR of neonates who received CPAP in better equipped hospitals was not significantly different to the CFR of less equipped hospitals.

## Strengths and limitations

To the best of our knowledge, this is the first nation-wide assessment of the availability and use of CPAP in a representative sample of public hospitals in India. All units were assessed through site-visits. Our results should be interpreted considering some limitations. Our findings only apply to government facilities; the availability and use of CPAP in private hospitals, where a large proportion of inpatient care is provided in India, may be different. The selection of standards for CPAP use presented in this paper was decided by consensus and carries a degree of subjectivity. Data about infrastructure and practice of providing CPAP were based on participants’ reports, and there might have been reporting bias. Clinical outcome data were obtained from existing records with some variability in the availability and quality of these. Finally, we did not collect data on important determinants of neonatal mortality and morbidity, such as gestational age, the severity of disease, nor on whether neonates had received surfactant or antenatal corticosteroids, which preclude making firm conclusions on the impact of shortfalls in infrastructure and practice of care on clinical outcomes.

**Implications for practice and further research**

While confirming and supporting the strong commitment of the Indian Government and healthcare providers to use an intervention that contributes to improved survival, it is important to take a relook at the current use of CPAP in neonatal units of public hospitals, the current national guidelines,19 and the implications for scalability.

More MCH should use CPAP, and the recommendation of using CPAP should be expanded to DH as well. The current preference of a commercial bubble system should be supported, as this type of CPAP system is more likely to have in-built mechanisms to control pressure, air-oxygen mix, temperature and humidity of medical gases, and is less invasive than CPAP provided by mechanical ventilators. Neonatal units should have enough single-use consumables. Staff working in neonatal units should comply with recommendations when providing oxygen. More nurses should be made available to provide neonatal care, and further discussion and guidance are required to establish what the minimum nurse/patient ratio should be in the context of LMIC settings.

Ensuring all the above should improve the effectiveness of CPAP use. However, additional data such as the case mix of patients in terms of gestational age, severity of disease and co-morbidities, as well as the use of surfactant and antenatal corticosteroids should be collected to better identify the determinants of clinical outcomes of CPAP use in India. Moreover, longitudinal studies, interrupted time studies, and pragmatic randomised controlled trials are needed to assess the effectiveness of CPAP in improving neonatal clinical outcomes in the Indian context. Finally, international standards for CPAP use in neonates should be developed to guide the implementation, monitoring, and evaluation of this intervention.

# Conclusions

India is embracing the use of CPAP for neonatal care. While electricity, medical gases, and basic monitoring equipment are widely available, further support is needed to ensure availability of trained staff, equipment to provide oxygen safely, and sufficient quantities of disposables to avoid reuse. Neonates may be overexposed to oxygen, while the means to detect and treat the consequences of oxygen toxicity are insufficient. Neonates may also be exposed to nosocomial infections because of the reuse of disposables. Case fatality rates for neonates receiving CPAP are higher than in other countries, and complications might be under- reported. Additional studies are needed to identify the determinants of clinical outcomes when CPAP is usedin neonatesand to assess the effectiveness of this intervention in India.

## Contributorship statement

Dr Dewez conceptualised and designed the study, oversaw data collection, conducted the analyses, drafted the initial manuscript, and revised the manuscript. Prof van den Broek and Dr White contributed to study design, data analyses, and critical reviews of manuscripts. Prof Nangia and Prof Chellani contributed to study design, oversaw data collection and provided critical reviews of manuscripts. Prof Mathai oversaw data collection and data analyses, critically reviewed, revised and finalized the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work

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The map of India was created using MapChart (<https://mapchart.net/>) under the terms of the CC BY 4.0 License ([Creative Commons Attribution-ShareAlike 4.0 International License](http://creativecommons.org/licenses/by-sa/4.0/)).

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**Figure 1**. Hospitals from Indian states and union territories included in the assessment

**Figure 2**. Upper oxygen saturation limits used