RESEARCH PAPER

# Target Oxygen Saturation Among Preterm Neonates on Supplemental Oxygen Therapy: A Quality Improvement Study

SINDHU SIVANANDAN[1], TAVPRITESH SETHI[2], RAKESH LODHA[2], ANU THUKRAL[1], M JEEVA SANKAR[1], RAMESH AGARWAL[1], VINOD K PAUL[1] AND ASHOK K DEORARI[1]

*From [1]Division of Neonatology and [2]Department of Pediatrics, All India Institute of Medical Sciences, New Delhi, India.*

*Correspondence to: Dr Ashok K Deorari, Professor and Head, Department of Pediatrics, WHO Collaborating Centre for Education& Research in Newborn Care, All India Institute of Medical Sciences, Ansari Nagar, New Delhi 110 029, India.*

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**Objective:** To avoid excessive oxygen exposure and achieve target oxygen saturation ($SpO_2$) within intended range of 88%-95% among preterm neonates on oxygen therapy. **Methods:** 20 preterm neonates receiving supplemental oxygen in the first week of life were enrolled. The percentage of time per epoch (a consecutive time interval of 10 hours/ day) spent by them within the target $SpO_2$ range was measured in phase 1 followed by implementation of a unit policy on oxygen administration and targeting in phase 2. In phase 3, oxygen saturation histograms constructed from pulse-oximeter data were used as daily feedback to nurses and compliance with oxygen-targeting was measured again. **Results:** 48 epochs in phase 1 and 69 in phase 3 were analyzed. The mean (SD) percent time spent within target $SpO_2$ range increased from 65.9% (21.4) to 76.5% (12.6) ($P$=0.001). **Conclusion:** Effective implementation of oxygen targeting policy and feedback using oxygen saturation histograms may improve compliance with oxygen targeting.

**Keywords:** *Monitoring, Oxygen management, Pulse oximetry.*

Excessive oxygen use or hyperoxia among preterm neonates is associated with morbidities like retinopathy of prematurity (ROP) and chronic lung disease (CLD) [1]. Delivering optimal oxygen involves maintaining the oxygen saturation ($SpO_2$) within a narrow range by adjusting the inspired oxygen concentration. In our neonatal intensive care unit (NICU), we observed that nurses faced difficulty in maintaining $SpO_2$ of neonates within the unit's target range, often resulting in fluctuating $SpO_2$ values. We planned this quality improvement (QI) study to evaluate the existing compliance with oxygen saturation targeting in our NICU, and whether implementation of a unit policy on oxygen administration would improve the compliance.

## Methods

This was a prospective before-and-after QI study conducted in a 10-bedded level III NICU of a tertiary care teaching hospital in India from January to May 2016 in three phases; phase-1 (6 weeks), phase-2 (4 weeks) and phase-3 (6 weeks).

We enrolled preterm neonates (26 to 34 weeks gestation) who were receiving oxygen while intubated or non-invasively by any mode for a consecutive 10 h interval (coinciding with pulse-oximetry data retrieval called an epoch) during the first week of life. Neonates with major malformations were excluded. Each enrolled neonate could contribute $SpO_2$ data for a maximum of 14 epochs (2 per day for 7 days). The oximetry data was not collected if the neonate was on high frequency ventilation or had persistent pulmonary hypertension of newborn (PPHN) or shock.

In phase-1, enrolled neonates were managed as per existing unit protocol. Intermittent survey of pulse-oximeter alarm settings was done and pulse-oximeter data was collected for measuring baseline $SpO_2$ targeting. Pulse-oximeters used were Mindray System Beneview T5 (Shenzhen Mindray Bio-Medical Electronics, China) with $SpO_2$ pick up range of 0-100% (resolution 1%, accuracy 3% between $SpO_2$ 70-100% and averaging time 7-11 seconds). The $SpO_2$ data recorded at 1-minute interval for 10-hour epoch was analyzed using R programming language.

The mean (SD) percentage of time within the target $SpO_2$ range during phase-1 was calculated to be 65.9 (21.4) %. Our aim was to improve baseline compliance of 65% by 20% over the next 10 weeks by implementing a unit policy on oxygen administration.

A QI team was formed consisting of a neonatologist, a nurse educator, resident doctor and charge nurse of the unit. The team reviewed the literature and developed a comprehensive policy addressing saturation targets, alarm settings, an algorithm for responding to low and high $SpO_2$ alarms and issues like pre-oxygenation. The unit's goal of targeting $SpO_2$ between 90 to 93% with the low and high alarm limits set at 88 and 95%, respectively remained the same.

In phase-2, the nurse educator and resident doctor conducted educational sessions for nurses on the unit's oxygen policy over a period of 4 weeks. A pre-post test assessment was done to ensure knowledge transfer. Visual reminders in the form of postcards depicting $SpO_2$ targets, alarm limits and the algorithm were displayed in the unit. QI team provided feedback to nurses when incongruent alarm settings were noted during surveys. In phase-3**,** compliance with unit's oxygen policy was reinforced and saturation histograms made from the retrieved pulse-oximeter data were presented to nurses during morning rounds. The histograms provided immediate visual feedback of neonate's $SpO_2$ trend in the previous 10 hours.

The primary outcome measure for the study was the percentage of time per epoch spent within the target $SpO_2$ range of 88-95%. Other outcomes were the percent time per epoch spent in hyperoxia ($SpO_2$ >95%) or hypoxia ($SpO_2$ < 88%), and clinical outcomes such as in-hospital mortality, duration of supplemental oxygen therapy (in days), incidence of Bronchopulmonary dysplasia (oxygen requirement on day 28 of life) and ROP requiring therapy. As process measures, we noted the pre-post test scores of nurse's assessment after educational intervention and compliance with alarm settings in pulse-oximeter.

We estimated that a sample size of 27 patient-epochs per phase was required to provide a power of 80% using a significance level of 0.05 to detect a difference of 20% in primary outcome.

*Statistical analyses*: We considered whether percentage of time spent in various target $SpO_2$ ranges were associated with individual characteristics of the neonate using generalized estimating equation (GEE) and also adjusted for NICU characteristics (nurse strength per shift, bed occupancy per shift and the number of neonates on invasive and non-invasive ventilation modes).

## RESULTS

A total of 20 neonates; 9 in phase-1 and 11 in phase-3 contributed to 48 and 69 epochs of saturation data respectively (***Web Fig. 1***). Their demographics were comparable but NICU had significantly higher census, and more neonates on respiratory support in phase-1 (***Table* I**). The compliance with correct alarm settings was 39% in phase-1 and 100% in phase-3. Twenty out of 23 NICU nurses attended educational sessions and their assessment showed significantly improved post-test scores.

**TABLE I** CHARACTERISTICS OF THE STUDY POPULATION AND NEONATAL UNIT IN PHASE-1 AND PHASE-3 OF STUDY

| *Parameter* | *Phase-1 (n=9)* | *Phase-3 (n=11)* | *P value* |
|---|---|---|---|
| Gestational age in weeks# | 30 (29, 31) | 28 (26, 30) | 0.16 |
| Birthweight in grams* | 1088 (307) | 1035 (312) | 0.70 |
| Male gender$ | 3 (33) | 4 (36) | 0.88 |
| Appropriate for gestational age$ | 5 (55) | 8 (72) | 0.42 |
| Singleton baby$ | 7 (78) | 9 (81) | 0.82 |
| Complete steroid coverage$ | 6 (67) | 9 (82) | 0.43 |
| Vaginal delivery$ | 2 (22) | 4 (36) | 0.45 |
| Apgar score at 5 min# | 8 (7, 8) | 7 (6, 8) | 0.08 |
| CRIB II score# | 8 (3, 8) | 7.5 (4, 10) | 0.13 |
| Need for surfactant$ | 6 (66) | 9 (82) | 0.4 |
| *NICU characteristics (Nursing shifts analyzed)* | 138 | 133 | |
| Nurse's strength/ shift# | 4 (4, 5) | 4 (4, 5) | 0.66 |
| Number of neonates in NICU/shift# | 7 (6, 7) | 6 (5, 7) | <0.001 |
| Number of neonates on non-invasive mode/shift# | 2 (2, 3) | 1 (1, 2) | 0.01 |
| Number of babies on mechanical ventilation/shift# | 1 (0, 2) | 2 (1, 3) | <0.001 |

*Values are expressed *mean (SD), #median (IQR), or $n (%); CRIB II: Clinical risk index for babies score.*

**WHAT THIS STUDY ADDS?**

- Compliance with oxygen targeting can be improved by effective implementation of unit policy on oxygen administration by staff education and feedback using saturation histograms.

**TABLE II** PERCENTAGE OF TIME SPENT PER EPOCH WITHIN, ABOVE AND BELOW THE TARGET SATURATION RANGE

| *Outcome* | *Phase-1 Epochs (N=48)* | *Phase-3 Epochs (N= 69)* | *P value (95% CI)* | *Change from Phase-1* |
|---|---|---|---|---|
| *Time per epoch (%)* | | | | |
| Within the target saturation range ($SpO_2$ 88-95%) | 65.9 (21.4) | 76.5 (12.6) | 0.001 | 10.6(4.3 to16.8) |
| Above the target saturation ($SpO_2$ >95%) | 27.3 (22.7) | 12.5 (13.8) | <0.001 | -14.8(-12.6 to -8.2) |
| Below target saturation ($SpO_2$ <88%) | 6.7 (5.7) | 11.0 (8.7) | 0.003 | 4(1.4 to 7.1) |
| Less than 80% | 2.0 (2.2) | 2.6 (2.9) | 0.18 | 0.6(-0.3 to 1.6) |

*Value in mean (SD).*

The mean (SD) percent time spent within target saturation range increased from 65.9% (21.4) to 76.5% (12.6) (*P*=0.001) (***Table* II**). The percentage of time spent in hyperoxic range decreased significantly but we noted an increase in hypoxic time from 6.7% (5.7) to 11% (8.7) in phase-3. However, the percent time below significant hypoxia (SpO2 <80%) did not increase.

On adjusted analysis using GEE, the improved compliance within the target range and reduction in hyperoxia was statistically significant (***Web Table* I**). The temporal distribution of saturation of enrolled neonates using a density histogram (***Web Fig.* 2**) showed a shift away from hyperoxia but towards the hypoxia side in phase-3 compared to phase-1.

There was no difference in clinical outcomes like bronchopulmonary dysplasia, ROP or mortality in either phase. Five neonates (45%) had patent ductus arteriosus (PDA) requiring therapy in phase-3 compared to none in phase-1 (*P*=0.03).

## DISCUSSION

This QI study demonstrated better oxygen saturation targeting and reduction in hyperoxic period after implementation of unit policy on oxygen administration.

Many units have demonstrated improved oxygen targeting using strategies like implementing written unit policy on $SpO_2$ targets [2,3], practice change models/QI initiatives [4-7] like educating caregivers on the hazards of hypo and hyperoxia and implementing guidelines for adjusting fraction of inspired oxygen ($FiO_2$). Our baseline compliance is similar to an earlier report [8]. Oxygen saturation histograms for feedback has been used in some earlier studies [9,10] in addition to other strategies but failed to demonstrate significant improvement in oxygen targeting.

The limitations of our study include: (*i*) the interventions namely staff education and visual reminders were introduced over 4 weeks followed by use of histograms in next 6 weeks. We did not study the impact of each of these interventions in a stepwise PDSA-based approach mainly because of the difficulties involved in pulse-oximeter data retrieval and analysis; (*ii*) while we could analyze adequate epochs for study purpose, only 20 neonates were enrolled that limits the repertoire of cases. The study was not adequately powered to detect differences in clinical outcomes; hence the higher incidence of PDA in phase-3 needs further investigation; and (*iii*) possibility of Hawthorne effect of nurses being observed cannot be ruled out.

The ideal method of oxygen targeting is a bedside nurse with a single patient assignment who can maintain $SpO_2$ within the target range by making manual $FiO_2$ adjustments [8]. In a busy unit where nurses have high workload and multiple responsibilities, such dedicated attention becomes difficult. This QI study shows that with the available equipment and nursing strength, it is possible to improve oxygen targeting by implementing a written policy through staff education. In order to sustain the improvement, we continue to use visual reminders, periodic checks on pulse-oximeter alarm settings, and regular in-service education. Use of saturation histograms for regular feedback is possible only with the help of pulse-oximeters with built-in program and needs to be explored further.

*Contributors*: SS: concept, implementation, data collection,

analyses and drafted the manuscript; TS: data collection and data analysis; RL: supervised data collection, analyses and manuscript writing; AT, MJS and RA: concept and design, implementation and manuscript writing; VKP: concept and study design, AKD: concept, design, supervised implementation and manuscript writing.

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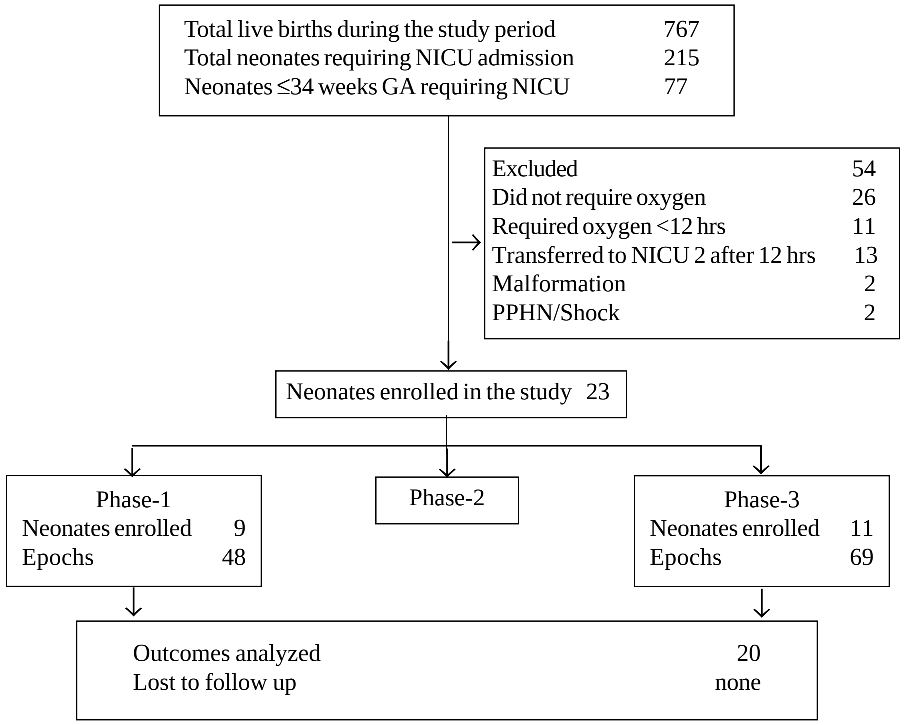
## REFERENCES

1. Stenson BJ. Oxygen saturation targets for extremely preterm infants after the NeOProM Trials. Neonatol. 2016;109:352-8.
2. Vijayakumar E, Ward GJ, Bullock CE, Patterson ML. Pulse oximetry in infants of <1500 gm birth weight on supplemental oxygen: A national survey. J Perinatol. 1997;17:341-5.
3. Hagadorn JI, Furey AM, Nghiem TH, Schmid CH, Phelps DL, Pillers DA, *et al*. Achieved versus intended pulse oximeter saturation in infants born less than 28 weeks' gestation: the AVIOx study. Pediatrics. 2006;118: 1574-82.
4. Ford SP, Leick-Rude MK, Meinert KA, Anderson B, Sheehan MB, Haney BM, *et al*. Overcoming barriers to oxygen saturation targeting. Pediatrics. 2006;118:S177-86.
5. Chow LC, Wright KW, Sola A, CSMC Oxygen Administration Study Group. Can changes in clinical practice decrease the incidence of severe retinopathy of prematurity in very low birth weight infants? Pediatrics. 2003;111:339-45.
6. Coe K, Butler M, Reavis N, Klinepeter ME, Purkey C, Oliver T, *et al*. Special Premie Oxygen Targeting (SPOT): A program to decrease the incidence of blindness in infants with retinopathy of prematurity. J Nurs Care Qual. 2006;21:230-5.
7. Ellsbury DL, Ursprung R. Comprehensive oxygen management for the prevention of retinopathy of prematurity: The pediatrix experience. Clin Perinatol. 2010;37:203-15.
8. Claure N, Gerhardt T, Everett R, Musante G, Herrera C, Bancalari E. Closed-loop controlled inspired oxygen concentration for mechanically ventilated very low birth weight infants with frequent episodes of hypoxemia. Pediatrics. 2001;107:1120-4.
9. Laptook AR, Salhab W, Allen J, Saha S, Walsh M. Pulse oximetry in very low birth weight infants: Can oxygen saturation be maintained in the desired range? J Perinatol. 2006;26:337-41.
10. Arawiran J, Curry J, Welde L, Alpan G. Sojourn in excessively high oxygen saturation ranges in individual, very low-birthweight neonates. Acta Paediatr. 2015;104:e51-6.

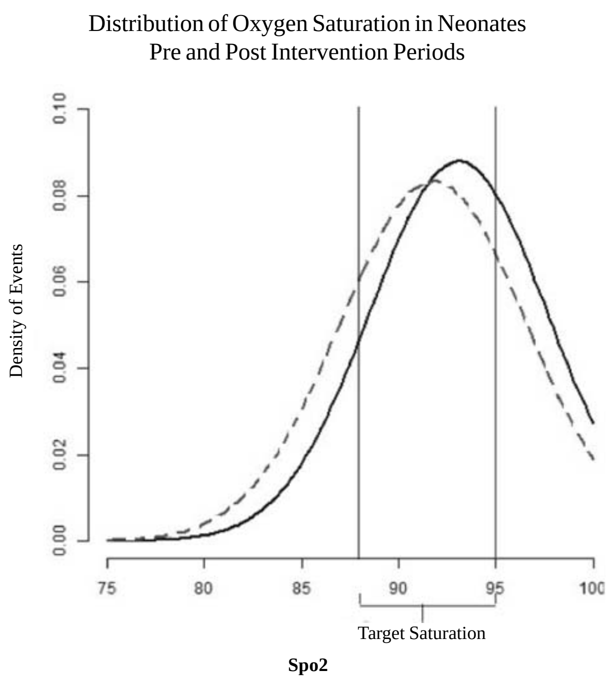
**WEBTABLE I** GENERALIZED ESTIMATING EQUATION (GEE) POPULATION AVERAGED MODEL FOR OXYGEN SATURATION PROPORTION ADJUSTED FOR NICU OPERATIONAL CHARACTERISTIC IN PHASE-1 AND PHASE-3 OF STUDY

| Time/10-hour epoch spent (%) | *Phase of study* | | *Unadjusted GEE* | | *Adjusted* GEE* | |
|---|---|---|---|---|---|---|
| | *Phase-1 (n=48)* | *Phase-3 (n=69)* | *Co-efficient (95% CI)* | *P-value* | *Coefficient (95% CI)* | *P-value* |
| In target $SpO_2$ range 88-95% | 65.9 (21.4) | 76.5 (12.6) | 12.0(3.0 to 21.0) | 0.009 | 5.4(0.7 to 10.0) | 0.024 |
| In hypoxia: ($SpO_2$ <88%) | 6.7 (5.7) | 12.5 (13.8) | 2.5(-2.3 to 7.2) | 0.31 | 1.9(-0.6 to 4.1) | 0.13 |
| In hyperoxia: ($SpO_2$ >95%) | 27.3 (22.7) | 12.5 (13.8) | -15.2(-26 to -4.3) | 0.006 | -7.8(-13.5 to -2) | 0.008 |

**Adjusted for nurse strength per shift, bed occupancy, neonates on non-invasive ventilation and neonates on mechanical ventilator support per epoch; Value in mean (SD).*




**WEB FIG. 1** *Study flow.*




**WEB FIG. 2** *Pooled density histograms of all enrolled neonates showing the proportion of time spent at each saturation value in the different phases of the study. The dashed line denotes Phase-3 and the solid line Phase-1. The density histogram in Phase-3 shows a shift away from hyperoxia but towards the hypoxia side.*