**The INCUBATOR**

Journal Club Notes

**Title:** Oxygen Saturation and Outcomes in Preterm Infants

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**Journal:** NEJM, 2013

**Background**

* **What’s the question?**
* **Is it a valid question?**

**Methods:**

* **Study design:**
* **Inclusion criteria:**

Infants were eligible if they had been born within the past 24 hours and before 28 weeks' gestation.

* **Exclusion criteria:**

Infants were excluded if they were considered to be unlikely to survive, had a major congenital abnormality, or would not be available for follow-up.

* **Intervention:**

Infants were randomly assigned to treatment with the use of an oxygen-saturation target of 85 to 89% (lower-target group) or 91 to 95% (higher-target group). To mask the intervention, the study oximeters were modified internally so that readings of 85 to 95% showed an oxygen saturation that was either 3 percentage points higher or 3 percentage points lower than the actual value. Thus, a displayed reading of 90% corresponded to an actual oxygen saturation of 87% in one group and 93% in the other. To achieve the intended oxygen-saturation range in either group, clinical staff members targeted displayed readings in the range of 88 to 92%. Displayed oxygen-saturation values gradually reverted to actual values when the measured value was outside the range of 85 to 95%.

* **Primary Outcome:**
* **Secondary Outcomes:**

**Results:**

* **Baseline characteristics:**
* A total of 2448 infants were enrolled in the three trials (973 in the United Kingdom, 1135 in Australia, and 340 in New Zealand). Of these infants, 1261 (51.5%) were treated with the use of the original oximeter-calibration algorithm and 1187 (48.5%) with the use of the revised algorithm. Baseline demographic and clinical characteristics were similar in the two target groups, among the three trials, and in the two algorithm groups
* Among the 1187 infants for whom the revised oximeter-calibration algorithm was used, those in the lower target group had a higher rate of death than those in the higher-target group before hospital discharge (23.1% vs. 15.9%; relative risk in the lower-target group, 1.45; 95% confidence interval [CI], 1.15 to 1.84; P=0.002), but Among the 1261 infants for whom the original oximeter-calibration algorithm was used, there were no significant between-group differences in outcomes at hospital discharge.
* In all data combined, there was no significant difference in rate of death in the lower-target group, as compared with the higher-target group (19.2% vs. 16.6%; relative risk, 1.16, 95% CI, 0.98 to 1.37; P=0.09), but infants in the lower-target group had a reduced rate of treatment for retinopathy of prematurity (10.6% vs. 13.5%; relative risk, 0.79; 95% CI, 0.63 to 1.00; P=0.045) and an increased rate of necrotizing enterocolitis requiring surgery or causing death (10.4% vs. 8.0%; relative risk, 1.31; 95% CI, 1.02 to 1.68; P=0.04).
* **Primary outcome:**
* **Secondary outcomes:**
* **Other interest results:**

**Study takeaways:**

The present trials were closed early when a pooled interim safety analysis showed that infants in the group treated with an oxygen-saturation target of 85 to 89%, as compared with 91 to 95%, had an increased rate of death at 36 weeks

**Strength/limitations:**

**How will this change my practice?**

**Other follow up papers**