Performance Evaluation of New-Generation Pulse Oximeters in the NICU:Observational Study

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This crossover observational study compares the data characteristics and performance of new-generation Nellcor OXIMAX and Masimo SET SmartPod pulse oximeter technologies. The study was conducted independent of either original equipment manufacturer (OEM) across eleven preterm infants in a Neonatal Intensive Care Unit (NICU). The SmartPods were integrated with Dräger Infinity Delta monitors. The Delta monitor measured the heart rate (HR) using an independent electrocardiogram sensor, and the two SmartPods collected arterial oxygen saturation (SpO2) and pulse rate (PR). All patient data were non-Gaussian. Nellcor PR showed a higher correlation with the HR as compared to Masimo PR. The statistically significant difference found in their median values (1% for SpO2, 1 bpm for PR) was deemed clinically insignificant. SpO2 alarms generated by both SmartPods were observed and categorized for performance evaluation. Results for sensitivity, positive predictive value, accuracy and false alarm rates were Nellcor (80.3, 50, 44.5, 50%) and Masimo (72.2, 48.2, 40.6, 51.8%) respectively. These metrics were not statistically significantly different between the two pulse oximeters. Despite claims by OEMs, both pulse oximeters exhibited high false alarm rates, with no statistically or clinically significant difference in performance. These findings have a direct impact on alarm fatigue in the NICU. Performance evaluation studies can also impact medical device purchase decisions made by hospital administrators.