Noninvasive Hemoglobin Monitoring: How Accurate Is Enough?

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Evaluating the accuracy of medical devices has traditionally been a blend of statistical analyses, at times without contextualizing the clinical application. There have been a number of recent publications on the accuracy of a continuous noninvasive hemoglobin measurement device, the Masimo Radical-7 Pulse Co-oximeter, focusing on the traditional statistical metrics of bias and precision.

In this review, which contains material presented at the Innovations and Applications of Monitoring Perfusion, Oxygenation, and Ventilation (IAMPOV) Symposium at Yale University in 2012, we critically investigated these metrics as applied to the new technology, exploring what is required of a noninvasive hemoglobin monitor and whether the conventional statistics adequately answer our questions about clinical accuracy. We discuss the glucose error grid, well known in the glucose monitoring literature, and describe an analogous version for hemoglobin monitoring.

This hemoglobin error grid can be used to evaluate the required clinical accuracy $(\pm g/dL)$ of a hemoglobin measurement device to provide more conclusive evidence on whether to transfuse an individual patient. The important decision to transfuse a patient usually requires both an accurate hemoglobin measurement and a physiologic reason to elect transfusion. It is our opinion that the published accuracy data of the Masimo Radical-7 is not good enough to make the transfusion decision.