Validation of Masimo Pronto 7 and HemoCue 201 for hemoglobin determination in children from 1 to 5 years of age

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Objective To evaluate the accuracy and precision of HemoCue 201 (HemoCue) and Masimo Pronto 7 (Masimo) devices for measuring hemoglobin (Hb) in epidemiological studies, having venous blood samples as a gold standard.

Material and methods We measured Hb concentrations in a field sample of 148 children from one to five years of age. Masimo and HemoCue were used for capillary blood samples and an automatic analyzer for venous blood samples. Regression models with no intercept were constructed to measure precision and predictability, concordance correlations to measure accuracy and precision, and Bland-Altman limits of agreement as well as hierarchical linear models to estimate variance.

Results Both HemoCue and Masimo underestimated Hb concentrations compared to the gold standard. They respectively yielded the following results: regression coefficients of 0.887 and 0.876 with 98.7% and 98.6% predictability; concordance correlation coefficients of 0.183 ($p<0.001$) and 0.166 ($p<0.001$); and Bland-Altman variances of -1.51 and -1.62. With regard to Masimo specifically, the three-level Hierarchical Linear Model showed that 57.9% of total variance stemmed from random errors in repeated measures from the same subject.

Conclusions HemoCue and Masimo measure lower Hb concentrations than the gold standard. Their accuracy and precision levels are comparable. It is essential to ensure proper use of devices through enhanced training of field workers.