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Comparison of Massimo Pronto-7 and HemoCue Hb 201+ with laboratory haemoglobin estimation: a clinical study.

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We prospectively studied agreement in haemoglobin estimation between two point-of-care devices (Pronto-7(®) Pulse CO-Oximetry(™), Masimo Corporation, Irvine, California, USA and HemoCue(®) Hb 201 +, HemoCue, Angelholm, Sweden) and an automated laboratory analyser (Sysmex XE5000, Sysmex Corporation, Kobe, Japan). Venous blood sampling and finger co-oximeter readings were performed on 141 pregnant women undergoing routine mid-trimester haemoglobin assessment. Three replicate measures were performed and analysis used Bayesian-based variance component modelling to provide estimates of repeatability, between person within method bias and precision. Repeatability, assessed by coefficient of variation, was higher for Pronto-7(®) (2.3%) compared to HemoCue(®) (5.2%). Fixed bias (mean difference, device - laboratory) was +1.18 (standard deviation 1.19) g/dl and -0.01 (standard deviation 1.34) g/dl for Pronto-7(®) and HemoCue(®) respectively, with no statistical evidence of proportional bias. Based upon a single device reading, the 95% prediction limits for Pronto-7(®) were -1.2 to 3.6 g.dl-1 and HemoCue(®) were -2.7 to 2.7 g/dl. For both devices precision was not meaningfully improved by averaging replicate readings. However, repeated readings may allow detection of aberrant results. Overall both devices are imprecise and 95% prediction limits wide. We present further prediction limits, derived from the posterior distribution and adjusted for any fixed bias for set levels of probability (certainty). These may be used to support clinical decisions when using these point-of-care devices.