

# Point-of-care estimation of haemoglobin concentration in neonates and infants

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**Objective.** The HemoCue is a point-of-care analytical system for haemoglobin concentration (Hb) measurement. Point-of-care testing has been validated in hospitals and outpatient departments to assist with urgent patient management by providing rapid laboratory test results.

**Method.** In this prospective study we compared the analytical performance of the HemoCue with that of the Advia 120 haematology analyser with regard to accuracy, precision and linearity in the measurement of Hb in neonates and infants.

**Results.** Samples from 44 patients were analysed by both instruments and the results compared using difference plots. The mean Hb value for the HemoCue (11.8 g/dl; range 4.8 - 18.7) was comparable to that for the Advia (11.8 g/dl; range 5.2 - 19.2). The Bland-Altman difference plot revealed good agreement. Bias between the two methods was small and the imprecision was within acceptable limits. Hb measurement was linear in the range 4.8 - 20 g/dl.

**Conclusion.** In neonates and infants, the diagnostic accuracy of the HemoCue point-of-care device is comparable with that of the Advia 120 analyser. In neonatal and paediatric units, where the volume of blood available is limited and turnaround time critical, an appropriately quality-assured HemoCue can replace standard haematology analysers in the measurement of Hb.

Point-of-care testing (POCT) or near-patient testing is the fastest-growing segment of laboratories in the developed world. Laboratories have become increasingly involved in supporting testing away from the conventional laboratory setting to improve the quality and efficiency of patient care by providing rapid test results to aid in immediate patient management decisions. POCT has been validated within hospitals to assist with urgent patient management in casualty, theatre, intensive care units (ICUs), neonatal units and renal dialysis centres as well as outpatient departments.

The full blood count (FBC) is the most common screening test and therefore has an important role in POCT. While a FBC performed in a laboratory with review of the peripheral smear by qualified laboratory personnel is preferable to a POCT, in specific clinical settings such as a neonatal unit introduction of a POCT would offer distinct advantages. These include improved turnaround time, small sample volume requirements and long-term cost saving. Neonates in the ICU require frequent haemoglobin concentration (Hb) measurements. Sampling in this age group is often technically difficult and distressing. With technological advances, improved devices are available for measuring Hb with enhanced speed, simplicity and analytical performance.<sup>1,2</sup>

The most widely used haemoglobinometer is the HemoCue (Aktiebolaget Leo Diagnostics, Helsingborg, Sweden), which is a small bench-top device. It measures Hb by converting haemoglobin into haemoglobinazide.<sup>3</sup> It provides a result almost immediately and requires a sample volume of only 10 µl. This device shows good agreement with automated haematology analysers, with a reported correlation of 99% when used by trained operators. It complies with the International Committee on Standardization in Haematology (ICSH, 1996) standards for haemoglobin measurement.<sup>4</sup>

The HemoCue device will be introduced at the Charlotte Maxeke Johannesburg Academic Hospital neonatal unit in the near future. The aim of this study was to evaluate the analytical performance of the HemoCue device with regard to accuracy, precision and linearity in the measurement of [Hb] in neonates and infants.

## Materials and methods

### Ethical approval

Ethical approval for the study was obtained from the University of Witwatersrand Research Ethics Committee. This validation was performed, as far as possible, in accordance with the ICSH (1993) and the method comparison from the Clinical and Laboratory Standards Institute (CLSI EP9, USA).<sup>5</sup>

### Study period

The validation was performed by the laboratory staff of the National Health Laboratory Service at Charlotte Maxeke Johannesburg Academic Hospital over a 2-week period.

### Patient samples

Blood samples used were those left after routine diagnosis done on neonates and infants at the Charlotte Maxeke paediatric intensive care unit. EDTA samples obtained by venepuncture, heel prick or from arterial lines with volumes more than 20 µl from neonates and infants aged 6 months and less were used.

### Evaluation procedure

For the method comparison study, a prospective, side-by-side comparative study of the HemoCue haemoglobinometer against the Advia 120 automated haematology analyser (Bayer Diagnostics, Tarrytown, NY) was performed. Hb measurement was done in duplicate on 44 paediatric patient samples referred for routine testing.

The samples were analysed sequentially by the same technologist on the HemoCue and Advia 120 haematology analysers using the respective instrument standard operating procedures. There was no aliquoting or sample splitting. Within-run precision evaluation was performed with the normal and abnormal HemoTrol reference control analysed 20 times. Linearity was assessed by diluting known patient samples with high Hb levels 1:2; 1:4; 1:8; and 1:16 with Isoton or normal saline. The linearity findings were used to determine the analyser's reportable range and lower limit of detection.

### Statistical analysis

Results were collated on an Excel spreadsheet, tabulated and graphically summarised using standard statistical methods. The agreement between results obtained on different analysers was evaluated using standard scatter and difference plots.

### Results

Forty-four samples were identified and qualified for analysis by both instruments. The mean Hb value for the HemoCue (11.8 g/dl; range 4.8 - 18.7) was comparable with that for the Advia (11.8 g/dl; range 5.2 - 19.2). The Bland-Altman difference plot revealed good agreement. Bias between the two methods was small (0.2%). The limit of agreement between the two methods is demonstrated in the difference plot according to Bland-Altman (Fig. 1). The intra-assay coefficients of variation (CV) were within allowable limits of performance in the normal and pathological range (1.75 % and 1.51%, respectively). Hb measurement was linear in the range 4.8 - 20 g/dl.

### Discussion

We evaluated the accuracy of point-of-care Hb determination with the HemoCue device in hospitalised neonates and infants aged 0 - 6 months at Charlotte Maxeke Johannesburg Academic Hospital neonatal and paediatric ICU. The HemoCue is a portable haemoglobinometer introduced into the clinical setting over 20 years ago for Hb measurement. Several research groups have demonstrated its clinical utility in hospitalised neonates and infants. Introduction of POCT has improved patient care and accessibility.<sup>6-8</sup>

The findings of this study concur with other studies performed in this age group.<sup>6-8</sup> This study demonstrated acceptable agreement between the HemoCue and laboratory measurement with the Advia 120 automated haematology analyser. Ninety-five per cent of the values had a clinically significant difference of <1 g/dl, making this an acceptable method. The HemoCue was accurate over a wide Hb range, reflecting the wide Hb range in the first 6 months of life.

Introduction of the HemoCue in neonatal and paediatric units has proven advantageous. The HemoCue allows rapid Hb determination using small sample volumes (10 µl). The most common error reported when measuring Hb in the laboratory is an insufficient sample, as most analysers require a minimum sample volume of 500 µl. The small

sample required will in turn reduce the risk of iatrogenic anaemia and make sampling easier.

In addition to being simple to operate, the HemoCue offers potential savings in cost. Initially there will be increased expenses as a result of the cost per unit which includes analyser, cuvettes and reagents, which will need to be supplied and distributed. The initial introduction may also result in increased over-servicing, and this will need to be closely monitored. However, the literature has demonstrated the potential long-term cost saving benefits of implementation of the HemoCue in a hospital setting. These include elimination of the pre-analytical and many of the analytical steps in the diagnostic process, some of which include skilled staff, bar codes, equipment and reagents. Specific to our current local setting, where the power supply is inconsistent, the HemoCue, which is a battery-operated device, will prove highly beneficial.

It is imperative that implementation of POCT in a neonatal and paediatric unit be accompanied by guidelines reflecting current best practice.<sup>9</sup> These guidelines should be strictly adhered to by all staff who operate the device. A quality system should be defined where results are validated by satisfactory performance in internal and external quality assessment schemes. For example, an internal quality control (IQC) test should be performed at the start of the day before any patient analysis is performed. Further IQC tests should also be performed with every new batch of cuvettes to ensure that there has been no deterioration during storage. Moreover, abnormal results must be appropriately flagged. A system should be established for appropriate referral to the supporting local reference laboratory for out-of-range results for further investigation. In specific settings, FBC analysis and repeat samples may be required. Close co-operation with the local laboratory service is also required to ensure adequate training and education of the staff who will be performing the tests.

### Conclusion

In this cohort of neonates and infants in a quaternary care setting, the HemoCue has accuracy and precision comparable with that of the Advia 120 analyser. With adequate training and monitoring the HemoCue can be used to provide accurate and reliable Hb measurements with a small sample volume, improved turnaround time and long-term cost savings.

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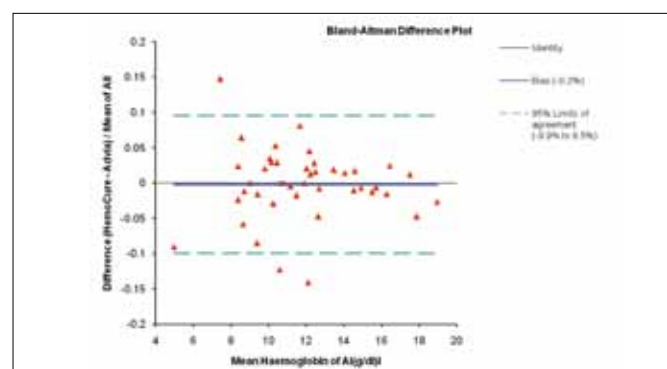


Fig. 1. Bland Altman difference plot for Hb measurement with the HemoCue and Advia.