

Field evaluation of a novel haemoglobin measuring device designed for use in a rural setting

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Objective. To evaluate the use of a robust, cheap method for haemoglobin estimation by non-laboratory-trained personnel in a rural setting.

Design. Comparative study.

Setting. Tintswalo Hospital, Acornhoek.

Participants. 7 nursing sisters, 4 medical students, 2 lay persons.

Outcome measures. Haemoglobin estimates obtained with the colour scale were compared with the 'true Hb' values determined by the H*3 Bayer-Technicon automated blood analyser.

Results. Although individuals varied in their abilities to use the colour scale, its performance was generally very good when measured against automated haemoglobinometry, as determined by bias and regression analysis and also in terms of its capacity to detect anaemia, as measured by sensitivity, specificity and positive and negative predictive values.

Conclusions. Haemoglobin estimates obtained with the World Health Organisation colour scale are generally reliable, although cognisance should be taken of individual variability. While the utility of the device in monitoring response to therapy remains to be seen, it promises to be a suitable method for mass screening for anaemia.

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Anaemia is one of the commonest medical problems affecting populations worldwide. Based on data collected from various epidemiological surveys up until 1980, the World Health Organisation estimates that 31.5% of the world's population are anaemic, with developing countries carrying the major burden. The highest prevalence rates were found in southern Asia (48%) and Africa (41%), with infants, young children and pregnant women being particularly vulnerable.¹

Haemoglobin (Hb) estimation is essential for the detection of anaemia, patient management decisions and monitoring of response to therapy, but in these resource-poor settings, high cost, inadequate training and lack of facilities generally prevent the use of technologically advanced equipment for anaemia screening. A suitable method would need to be cheap, reliable, durable and independent of a power source; it must not require large quantities of consumable reagents and should give immediate results.

Various techniques have been developed in attempts to fulfil these criteria. The commoner ones include the Tallqvist method, the Lovibond comparator, micro-haematocrit determination and portable haemoglobinometers such as the BMS and AO Spencer haemoglobinometers.² Several of these techniques have been evaluated for mass screening and although some appear to be reasonably accurate (in particular the AO Spencer haemoglobinometer, BMS haemoglobinometer, Hemocue and the copper sulphate method), none fulfils all the previously mentioned criteria, the major drawbacks being cost, availability and stability of reagents.³⁻⁵

On behalf of the WHO, Stott and Lewis recently devised a new colour scale for the estimation of Hb levels which appears to meet the necessary criteria for use in wide-scale Hb testing.⁶ We have tested the ability of qualified laboratory technologists and haematology registrars to use this device at our laboratory, an academic and tertiary referral centre. This work formed part of preliminary trials conducted worldwide and which have shown encouraging results.⁶

The objective of this study was to establish the reproducibility of these results when obtained in a rural setting by various categories of personnel with no specific laboratory training. These included nursing sisters, medical students, and lay people with no medical background whatsoever.

Materials and methods

The colour scale consists of a series of colour standards mounted on a rigid card (Fig. 1). The colours correspond to haemoglobin (Hb) levels of 4, 6, 8, 10, 12 and 14 g/dl, respectively, increasing from light to darker shades of red. A circular 9 mm aperture is placed in the centre of each colour standard. A drop of blood is placed on a test strip of a selected batch of Whatman 31 ET Chr paper. The paper has no special additives and has been selected for use because of its physical properties, in particular its thickness, the rate of absorbance of blood and the limited spread thereof.⁶ As soon as the blood stain has lost its sheen, the colour is compared in unshadowed light to the standards, by moving it up and down behind the aperture. The equivalent Hb value is then recorded. Comprehensive instructions for use are provided with the device.

The study was conducted over a 2-day period on an open verandah in the grounds of Tintswalo Hospital and involved seven qualified nursing sisters, working either in the maternity ward or satellite primary health care clinics, four medical students and two lay people. Four of the nursing sisters worked in pairs, constituting two of the five nursing sister entities evaluated; the other three evaluated were individuals. The pairs were not the same on the 2 test days.

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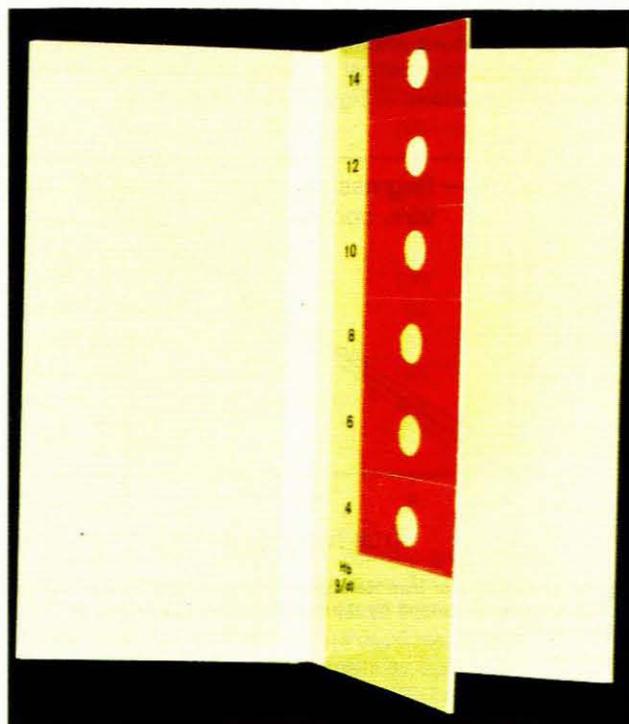


Fig. 1. An example of the WHO Hb colour scale.

After a general introduction, the use of the Hb colour scale was demonstrated. The participants were then given the opportunity to determine the Hb value of a series of reference laboratory pre-standardised blood samples ranging from 4 to 14 g/dl with 2 g/dl increments, using the colour scale under supervision. Once they felt confident about their abilities they were tested on a further 20 coded blood samples in random order. The results were recorded by independent observers who were blind to the true Hb value. The procedure was repeated the following day. As the colour scale has an upper limit of 14 g/dl, for qualitative comparison a reading of 14+ was recorded as 16 g/dl in line with the 2 g/dl increments of the scale. Similarly, a reading below 4 g/dl was recorded as 2 g/dl.

The blood samples were supplied by the haematology laboratory of Johannesburg Hospital, SAIMR. The specimens were selected from the routine peripheral blood samples submitted for full blood count in ethylene diamine tetra-acetic acid (EDTA) tubes. The Hb concentration of the random samples ranged from 2 to 17.1 g/dl as determined by the H*3 Bayer-Technicon automated blood analyser. For the standardised samples, Hb values of 4, 6, 8, 10, 12 and 14 g/dl (± 0.1 g/dl) were used.

The blood was collected on a Friday, stored at 4°C and then transported in a cold bag from Johannesburg to Tintswalo Hospital and again placed in cold storage until required for testing on the following Monday. In between the 2 test days the blood samples were again placed in a refrigerator at 4°C.

To check stability under storage conditions the Hb level of random blood samples was measured by the H*3 analyser in our laboratory and colour stability was determined by the colour scale over a 3-day period. As the outcome was considered to be satisfactory, the 'true Hb' value determined in the laboratory was considered to be valid for the field

study 3 - 4 days later. A random subset of samples was subjected to repeat Hb analysis by the H*3 analyser on return, confirming the stability of the Hb level.

Results

The Hb value estimates obtained with the WHO Hb colour scale were compared with the actual Hb concentration measured by the H*3 Technicon automated blood analyser.

The results obtained for the five nurse observers on day 1 are shown in Fig. 2. The coefficient of correlation (r) obtained from the mean values is 0.94988. Mean rather than individual results were used for analysis in an attempt to overcome the limitations of comparing absolute values (H*3 analyser) with ranges representing 2 g/dl increments (colour bands).

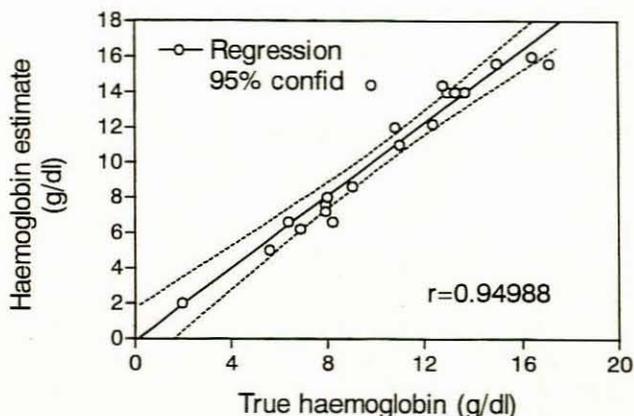


Fig. 2. Comparison of true Hb concentration with the mean values of Hb estimates obtained by nurses on day 1 using the colour scale.

The pair difference versus pair mean plot of the results for the nurses on day 1 is shown in Fig. 3. The outlier shown in Fig. 3 is a blood specimen with a true Hb value of 9.8 g/dl which was consistently overestimated by all participants; this suggests that the bias is inherent to that specific sample rather than the technique. If this specimen is excluded from the analysis, the mean of the differences becomes 0.042 g/dl and the standard deviation of the differences becomes 0.83 g/dl.

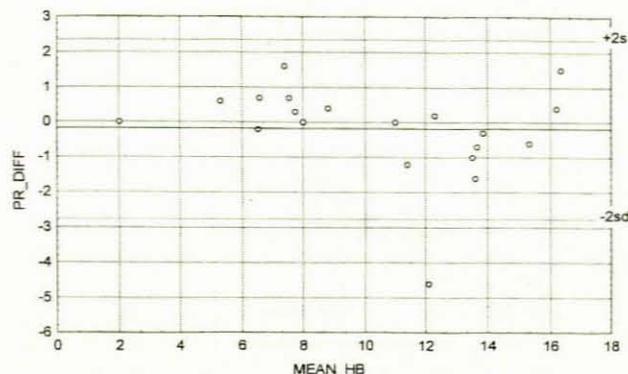


Fig. 3. Difference against mean for Hb values (MEAN HB = mean of Hb estimate and true Hb in g/dl; PR DIFF = difference between Hb estimate and true Hb in g/dl. The mean of differences is -0.19 g/dl. The standard deviation of the differences is 1.3 g/dl).

On day 2, observers were specifically requested to interpolate their results and individual results have therefore been recorded as shown in Fig. 4. The r -values ranged from

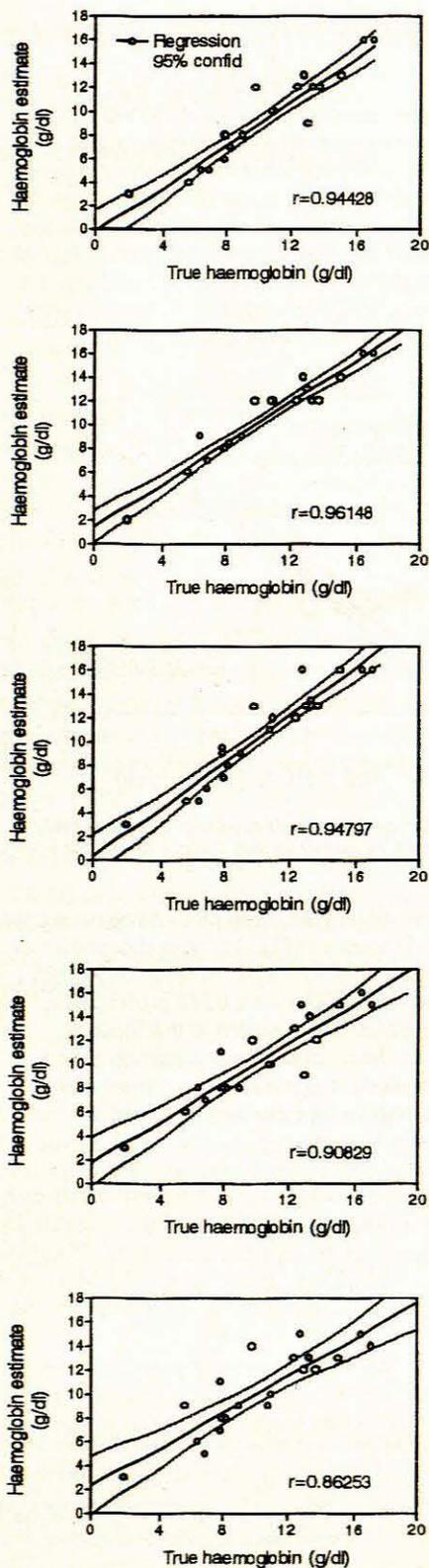


Fig. 4. Comparison of true Hb concentration with the Hb estimates obtained by each of the five nurse evaluators on day 2 using the colour scale.

0.86253 to 0.96148 (mean $r = 0.95554$), clearly indicating that some individuals are more precise than others.

The results of the medical students' and lay persons' Hb estimations are shown in Figs 5 and 6, respectively.

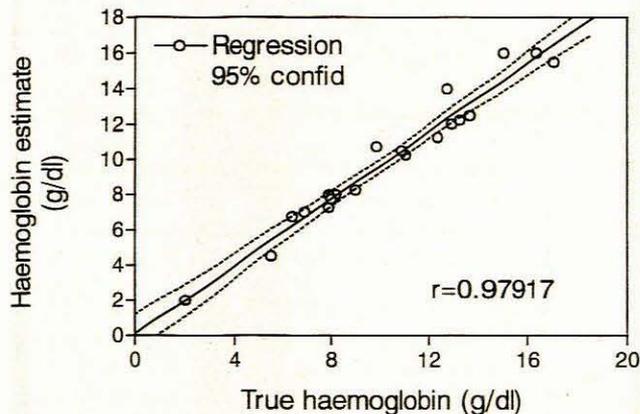


Fig. 5. Comparison of true Hb concentration with the mean values of Hb estimates obtained by the medical students using the colour scale.

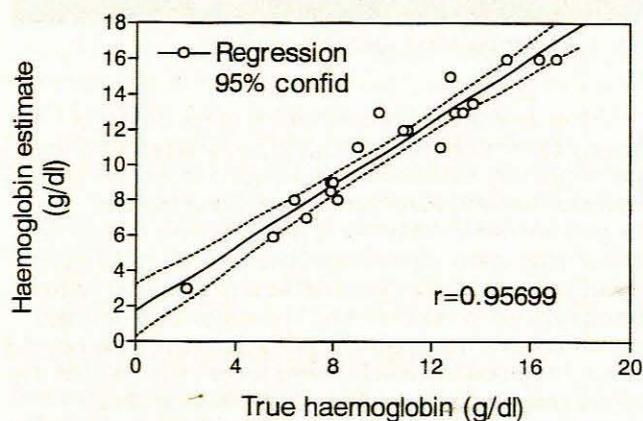


Fig. 6. Comparison of true Hb concentration with the mean values of Hb estimates obtained by lay persons using the colour scale.

As an adjunct to what is visually depicted in Figs 2, 4, 5 and 6, the linear regression data indicating the coefficient of correlation (r), the y intercept and the slope of the regression line are shown in Table I.

Table I. Regression data

Evaluator	Coefficient of correlation (r)	Y intercept	Slope
Nurses — day 1 (mean)	0.94988	-0.1129	1.0292
Nurse 1 — day 2	0.94428	0.1132	0.9231
Nurse 2 — day 2	0.96148	1.4565	0.8753
Nurse 3 — day 2	0.94797	0.3520	0.9940
Nurse 4 — day 2	0.90829	1.8321	0.8270
Nurse 5 — day 2	0.86253	2.3480	0.7676
Medical students	0.97917	0.0987	0.9581
Lay people	0.95699	1.7286	0.8944

Table II. Statistical data for detection of anaemia (Hb < 12 g/dl) and severe anaemia (Hb ≤ 8 g/dl) using the colour scale

Participant	Anaemia (Hb < 12 g/dl)				Severe anaemia (Hb ≤ 8 g/dl)			
	Sensitivity	Specificity	PPV	NPV	Sensitivity	Specificity	PPV	NPV
Nurses — day 1	83	100	100	80	100	93	86	100
Nurse 1 — day 2	92	88	92	88	100	93	86	100
Nurse 2 — day 2	75	100	100	73	88	100	100	93
Nurse 3 — day 2	83	100	100	80	71	92	83	86
Nurse 4 — day 2	92	88	92	88	86	85	75	92
Nurse 5 — day 2	92	100	100	89	71	92	83	86
Medical students	100	88	100	100	100	92	88	100
Lay people	92	88	92	88	57	92	80	80
Mean	89	94	97	86	84	92	85	92
SD	7.8	6.4	4.1	8.1	16.3	4.0	7.2	7.6

All figures are percentages.

The sensitivities, specificities, positive predictive values (PPVs) and negative predictive values (NPVs) of this device in detecting the presence of anaemia (Hb < 12 g/dl) and severe anaemia (Hb ≤ 8 g/dl) are depicted in Table II. For anaemia detection the mean sensitivity, specificity, PPV and NPV were 89% (standard deviation (SD) 7.8%), 94% (SD 6.4%), 97% (SD 4.1%) and 86% (SD 8.1%), respectively. For severe anaemia detection the values for the above parameters were 84% (SD 16.3%), 92% (SD 4%), 85% (SD 7.2%) and 92% (SD 7.6%), respectively.

One blood sample (actual Hb value 9.8 g/dl) was consistently overestimated (mean 12.6 g/dl) by all observers on both days.

Discussion

Our results demonstrate that Hb estimates obtained with the WHO colour scale are generally reliable. However, individuals show definite variation in their ability to use this device, as depicted by the range of *r*-values obtained. This limitation could be overcome by evaluating individuals prior to assigning them the task of haemoglobin screening. Alternatively, the mean of several observers could be used, as illustrated by the results obtained for the nurses on day 1. This principle of replicate measurements to achieve accuracy is well established, even in sophisticated instrumentation. As most clinics are usually understaffed, this is obviously impractical and multiple readings by an individual may therefore help to alleviate this problem to a degree. This has been demonstrated in separate studies (S M Lewis — unpublished data).

The Hb colour scale was tested over a large range of Hb values (2 - 17.1 g/dl). Fig. 3 indicates that there is no bias in these results (mean of the difference -0.19 g/dl). All but one of the specimens were estimated to be within 1.6 g/dl of the true value. Such a difference would be clinically insignificant in anaemia screening programmes. Similarly, the sensitivities for the detection of anaemia (89%; SD 7.8%) and severe anaemia (84%; SD 16.3%) suggest that this device would be suitable for large-scale anaemia screening. The range of sensitivities for the various participants, as with the range of *r*-values, reconfirms individual variability and the need for

training and proper evaluation prior to the use of the colour scale in clinical practice.

The apparently poor sensitivity of 57% for severe anaemia detection by lay people would appear to be caused by the shortcomings of the device in view of the limitations of comparing Hb estimates using the colour scale's increments of 2 g/dl with true Hb values using an automated analyser that is accurate to several decimal places. For example, an estimate of 8.5 g/dl for a true value of 7.9 g/dl has to be assigned a false-negative value (i.e. Hb > 8 g/dl) although it would otherwise be considered a 'perfect match'. Direct analysis of the results of the lay people, together with the *r*-value of 0.95699, suggests that specific technical/medical training is not a prerequisite for the use of the colour scale.

Very high specificities were obtained by all participants for both anaemia and severe anaemia detection — 94% (SD 6.4%) and 92% (SD 4.0%), respectively. This indicates that anaemia would be correctly indicated as absent in the vast majority of cases. The PPVs and NPVs as shown in Table II are similarly high, indicating that patients are unlikely to be treated unnecessarily.

Repeat blood counts in the laboratory failed to elucidate any reason for the discrepancy in one blood sample in which the Hb level was consistently overestimated on the colour scale. This suggests, however, that factors other than deoxyhaemoglobin may influence the colour of the blood. Although it would be of interest to investigate this further, this is unlikely to detract from the reliability of this device in Hb screening in the vast majority of cases. Another issue that requires investigation is whether or not colour blindness would be problematic for users of this device, although we do not anticipate this to be the case.

As this device is relatively new, it requires more extensive formal comparison with techniques currently utilised in field settings. A recent study in Thailand suggests that it is superior to microhaematocrit estimations in detecting the level of anaemia (G J Stott — personal communication).

Given the restrictions in rural areas, there is obviously no ideal method for estimating Hb concentration. Simplicity can often only be achieved with loss of accuracy.

Despite minor limitations, the colour scale has many features that make it a strong contender for extensive use in mass Hb screening in primary health care settings. A major

advantage of the device is its low cost: a single test paper would be in the region of 7 cents. For the preliminary studies the scale has been provided as a service by the WHO. The cost when produced in large numbers should not exceed R10 for each device, which can be used repeatedly. As treatment of anaemia is easy in most cases, the simple ascertainment of its presence and severity would go a long way to improve the well-being of a great number of people.

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