Diagnostic efficacy of digital hemoglobinometer (TrueHb), HemoCue and non- invasive devices for screening patients for anemia in the field settings

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Policy Brief

Recommendations

- *Invasive devices shows overall better performance than Non-invasive devices in the field settings.*
- *For screening of Anemia, HemoCue (AUC 0.92, 95% CI 0.88-0.94) and True Hb (AUC 0.85, 95% CI 0.83-0.89) are comparable with no statistically significant difference between the two.*
- *For screening of Severe Anemia, TrueHb (AUC 0.91, 95% CI 0.85-0.97) fares better than all other devices including HemoCue (AUC 0.73, 95% CI 0.67-0.79)*
- *Both True Hb and HemoCue overestimates Hb in extreme cold weather conditions.*
- *Overall it appears that TrueHb is better than HemoCue in estimating Hb including severe anemia*
- *The cost of True Hb device is less but the running cost is high as compared to HemoCue.*

Summary

A Heaith Technology Assessment was conducted to establish the diagnostic accuracy of Digital Hemoglobinameter TrueHb (newer version), HemoCue and Non invasive Masimo and AJO spectroscopic device against automated analyzers (gold standard) for screening of anemia in laboratory and community settings. Invasive devices shows overall better performance than Non-invasive devices in the field settings. Among the invasive devices TrueHb fares better than all other devices including HemoCue in case of severe anemia.

Background

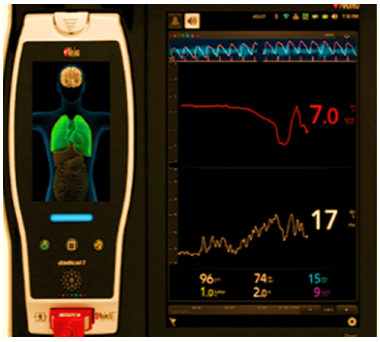
Anaemia, defined as a low blood haemoglobin concentration and it has been shown to be a public health problem that affects low-, middle- and high-income countries and has significant adverse health consequences, as well as adverse impacts on social and economic development. Most reliable methods for hemoglobin estimation requires equipped laboratory that may not be available everywhere, especially rural areas. Moreover these methods are not always cost effective and have operational challenges. Therefore, it is important to evaluate simple, cost-effective, user friendly and portable methods for diagnosis of anaemia where there are no or minimal laboratory facilities.

A comprehensive Health technology assessment (HTA) was conducted to assess and to obtain the evidence against the clinical and cost-effectiveness of various devices for hemoglobin estimation. The study was intended to get a scalable method of hemoglobin estimation, even to "Hard to Reach" can be obtained and this method could be incorporated with the public health programs for anemia prevention. The primary objective of the study was to establish the diagnostic accuracy of Digital Hemoglobinometer TrueHb (newer version), HemoCue and non invasive devices (AJO Spectroscopic device and Masimo Pulse Oximeter) against automated analyzers (gold standard) for screening of anemia in laboratory and community settings. The study also aimed to establish the level of agreement in the classification of anemia as reported by ANM (using the device that will be found better) and laboratory technician. The study concluded Invasive devices shows overall better performance than Non-invasive devices in the field settings.

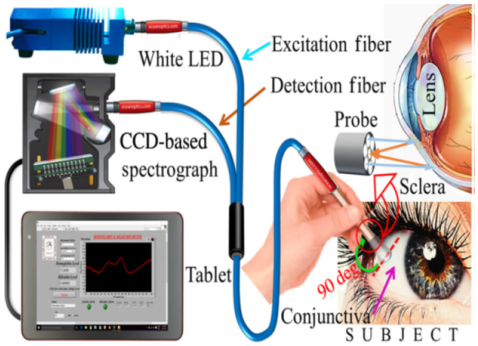
Devices available for Hemoglobin Estimation

(a) (b)

Figure 1: Invasive (a) TrueHb (b) HemoCue



(c)



(d)

Figure 2: Non-Invasive (c) Masimo's device (d) AJO spectroscopic device

Findings

- A total number of 1398 patients were included in the analysis, 752 in Puducherry and 646 in Kolkata. Their distribution as per ICMR Classification of Anemia is given below (Table 1).
- Table 2 shows the Diagnostic Accuracy Parameters for testing anemia and no anemia by ANM/ frontline workers (capillary sample) is given below. The overall performance of Hemocue is better as compared to all other devices with a sensitivity of 89.9% and Area under ROC of 0.92.

Table 1

Hb % (in gm%)	Total (n=1398)	Puducherry (n=752)	Kolkata (n=646)
Mean (SD)	11.64 (±2.7)	12.31 (±2.4)	10.8 (±2.8)
Range	2-20.2	2-20.2	4.2-18.6
No Anemia (Hb>11gm%)	938 (67.1%)	580 (77.1%)	358(55.4%)
Mild anaemia(Hb-10.10.9 gm%)	124 (8.8%)	58 (7.7%)	66 (10.2%)
Moderate anaemia (Hb 7-9.9 gm%)	240 (17.2%)	94 (12.5%)	146 (22.6%)
Severe anaemia (Hb<7 gm%)	96 (6.8%)	20 (2.6%)	76 (11.7%)

Table 2

Device	Sensitivity % (95% CI)	Specificity % (95% CI)	Positive predictive value (PPV) (95% CI)	Negative Predictive value (NPV) (95% CI)	Positive likelihood ratio (LR+) (95% CI)	Negative likelihood ratio (LR-) (95% CI)	Area under ROC (95% CI)
HemoCue	89.9% (85.1-93.6)	93.3 % (90.5-95.4)	86.7 (81.6-90.9)	95 (92.5-96.8)	13.37 (9.43-18.94)	0.11 (0.07-0.16)	0.92 (0.89-0.94)
TrueHb	86.3% (81.0-90.6)	84.7 (81.2-87.8)	71.9 (66.0-77.2)	93.2 (90.4- 95.3)	5.63 (4.54-6.99)	0.16 (0.12-0.23)	0.85 (0.83-0.88)
Masimo's Pulse Oximetry Device	66.0% (59.2- 72.4)	97.5% (95.5- 98.7)	92.6 (87.2-96.3)	85.6 (82.2- 88.6)	25.99 (14.39- 46.96)	0.35 (0.29-0.42)	0.82 (0.78-0.85)
AJO Spectroscopic Device	56.4% (48.8- 63.7)	75.4% (71.3-79.2)	46.6 (39.8-53.4)	82 (78-85.5)	2.29 (1.87-2.81)	0.58 (0.49-0.69)	0.66 (0.62-0.70)

Table 3

Device	Sensitivity % (95% CI)	Specificity % (95% CI)	Positive predictive value (PPV) (95% CI)	Negative Predictive value (NPV) (95% CI)	Positive likelihood ratio (LR+) (95% CI)	Negative likelihood ratio (LR-) (95% CI)	Area under ROC (95% CI)
Hemocue	46.8 (34.0-59.9)	99.2 (98.1-99.7)	85.3 (68.9-95)	94.8 (92.7-96.4)	56.3 (22.6-140.2)	0.54 (0.42-0.68)	0.73 (0.67-0.79)
True Hb	87.1 (70.2-96.4)	95.7 (93.9-97.1)	48.2 (34.7-62.0)	99.4 (98.4-99.8)	20.15 (13.77-29.5)	0.13 (0.05-0.34)	0.91 (0.85-0.97)
Masimo Pulse Oximetry Device	17 (7.6-30.8)	99.8 (99.1-100)	88.9 (51.8-99.7)	93.8 (91.7-95.6)	101.2 (12.94-792.6)	0.83 (0.73-0.95)	0.58 (0.53-0.64)
AJO Spectroscopic Device	28 (12.1-49.4)	95.9 (94-97.3)	21.2 (9-38.9)	97.1 (95.5-98.3)	6.81 (3.27-14.16)	0.75 (0.59-0.96)	0.62 (0.53-0.71)

- Table 3 shows Diagnostic Accuracy Parameters for testing severe anemiaby ANM/ frontline workers (capillary sample) is given below. The overall performance of TrueHb fares better than any other device with a sensitivity of 87.1% and area under ROC of 0.91.
- Projected costs of resources for each test for measuring Hemoglobin (in INR) is given in table 4.
- Costs of the device and running cost for each test for measuring Hemoglobin (in INR)

Table 4

Component	HemoCue		TrueHb		AJO		Masimo's	
	Rural	Urban	Rural	Urban	Rural	Urban	Rural	Urban
Human resource (ANM)	16.7 (13.9%)	17.7 (10.7%)	17.1 (12.5%)	17.5 (9.9%)	18.1 (16.5%)	18.1 (12.9%)	16.6 (15.8%)	18.3 (12.6%)
Equipment (device, charger, adapter)	0.2 (0.1%)	0.2 (0.1%)	0.004 (0%)	0.004 (0%)	0.05 (0.04%)	0.05 (0.04%)	3.4 (3.2%)	3.4 (2.3%)
Accessories (Micro cuvettes/ strips)	11.9 (9.9%)	11.9 (7.2%)	26.4 (19.3%)	26.4 (14.9%)	0.0 (0%)	0.0 (0%)	0.0 (0%)	0.0 (0%)
Consumables (items used in the test)	12.3 (10.2%)	19.7 (12.0%)	12.3 (9.0%)	19.7 (11.1%)	6.1 (5.6%)	4.3 (3.1%)	6.1 (5.8%)	4.3 (3.0%)
Non-medical (items in facility rooms)	78.8 (65.5%)	113.4 (69.0%)	80.8 (59.0%)	112.3 (63.3%)	85.4 (77.6%)	116.4 (82.9%)	78.3 (74.7%)	117.2 (81.0%)
Capital space (rental)	0.4 (0.3%)	1.6 (0.9%)	0.4 (0.3%)	1.5 (0.9%)	0.5 (0.4%)	1.6 (1.1%)	0.4 (0.4%)	1.6 (1.1%)
Total cost / test	120.3	164.3	137.0	177.4	110.1	140.4	104.8	144.7

Table 5

Component	HemoCue		TrueHb	
	Rural	Urban	Rural	Urban
Equipment (device, charger, adapter)	0.2	0.2	0.004	0.004
Accessories (Microcuvettes/ strips)	11.9	11.9	26.4	26.4
Consumables (items used in the test)	12.3	19.7	12.3	19.7
Total cost per unit test	24.4	31.8	38.7	46.1

Conclusion

Invasive devices shows overall better performance than Non-invasive devices in the field settings and among the invasive devices TruHb appeared to perform better be . Overall it appeared that TrueHb is better than HemoCue in estimating Hb including severe anemia. However, both the devices over estimate Hb in cold and high altitude. TrueHb is also cheaper than HemoCue but the running cost is higher than HemoCue.