Original article

Cost-effectiveness of point-of-care devices for detection of anemia in community settings in India

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1. Background

Anemia is a public health problem affecting 46.3% of the population in India.¹ It affects 58% children under five years of age, 54% adolescent girls of 15–19 years of age, 53% women of reproductive age, 50% pregnant mothers, and 29% adolescent boys in the country.² Detection of anemia is important for institution of appropriate management. Several methods are available for diagnosis of anemia especially in outreach and field settings where well-equipped laboratories are unavailable. The devices have been tested in diverse settings and have yielded varied levels of accuracy.^{3–7} In the absence of a concrete evidence, there is a need to examine the devices that have the potential to be included in public health programs. Given the fact that most of the screening happens in community and outreach settings where provision for a laboratory support seems difficult, the device ought to be tested in field settings with health workers (Auxiliary Nurse Midwives or ANMs) as end users.

Currently four such devices have been identified that have the potential to be used in public health settings, namely, digital hemoglobinometers (True Hb and Hemocue), and non-invasive devices, i.e. Masimo Pulse Oximetry test and Spectroscopic spectroscopic device test.⁸ Identification of a suitable device for public health services warrants analysis of parameters other than the diagnostic accuracy. Some such parameters include cost of devices, cost effectiveness, user-friendliness and operational factors.

There is a need to evaluate them in order to identify the most cost effective device suitable for use in Indian and similar settings.

A multicentric study across four sites was undertaken to assess the diagnostic accuracy (effectiveness) of these devices (described elsewhere).⁹ The objective of the current study is to estimate the cost effectiveness of the devices by evaluating the incremental cost for each case detected from the health systems perspective. The secondary objective is to assess the user friendliness and operational issues of the devices for detection of anemia in field settings in India.

2. Methods

2.1. Context

An analysis of the performance of some such devices was undertaken recently. Four devices (index tests) namely, True Hb Digital Hemoglobinometer, HemoCue, Masimo's non-invasive device and Spectroscopic Spectroscopic devices were examined for diagnostic accuracy on an adequate sample of adult population attending field practice areas of Medical colleges in India: Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry, and Calcutta Medical College, Kolkata, West Bengal. To test the accuracy in different weather conditions, the devices were additionally tested at All India Institute of Medical Sciences (AIIMS) Jodhpur and Rural hospital, Reckong Peo (Himachal Pradesh). The index tests were compared against auto-analyzer (gold standard). Accuracy was expressed by sensitivity, specificity, likelihood ratios, predictive values and area under the curve (AUC) and levels of agreement. According to this study, HemoCue and TrueHb performed better than Massimo and spectroscopic devices.

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Detection of anemia by technicians was similar between TrueHb and HemoCue (AUC 0.92 v/s 0.90, $p > 0.05$). Community workers performed better with Hemocue for detecting anemia compared to TrueHb (AUC 0.92 v/s 0.90, $p < 0.05$). For detection of severe anemia, accuracy of TrueHb was significantly better with technicians (AUC 0.91 v/s 0.70; $p < 0.05$) and community workers (AUC 0.91 v/s 0.73; $p < 0.05$). HemoCue showed a bias or mean difference (95%CI) of 0.47 g/dl (0.42, 0.52), and 0.92 g/dl (0.82, 1.03) for severe anemia. For TrueHb, it was -0.28 g/dl (-0.37, -0.20) for all readings, and 0.06 g/dl (-0.52, 0.63) for severe anemia.⁹

2.2. Design

This study on cost effectiveness was undertaken alongside the diagnostic accuracy study with cross-sectional design. The data collection for the study was conducted between August 2018 and March 2019. The protocol of the cost-effectiveness analysis approach has been published elsewhere.¹⁰

2.3. Costs and cost-effectiveness analysis

The costs were captured through primary data collection using a micro-costing (bottom up) methodology from the study sites. At the first step, every input consumed in the detection of anemia using the point-of-care devices in an individual was identified. Secondly, the quantity of each resource item, such as human resource (ANM time for each test), equipment (device, charger, adapter), accessories (micro cuvettes/strips), consumables (used in test), non-medical (items in facility rooms), and capital space (i.e. the space used for conducting the tests) was identified. At the third step, unit costs were calculated for each of these resource items. Inputs from device manufacturers were used to cost the equipment and accessories, while procurement costs were considered for consumables and non-medical costs items. Unit cost for ANM was calculated by dividing the total salary per month divided by the time taken by ANM for each test (i.e. 26 working days with 7 h per day was time considered per month for receiving full salary). Other resource costs was calculated by multiplying the per unit costs with the total units consumed. Rental value for the space used for testing was captured using reference rental values prevalent in the area. Since the study sites were government hospitals, shared costs, and administrative costs were not captured as the administration requirement for receiving this data was time-consuming, hence these costs were not included in the total cost analysis.

Data on costs and sensitivity of the devices for anemia detection were collected simultaneously at each study site.

Effectiveness is defined here as the case detection rate or sensitivity of the devices to detect anemia and severe anemia. The details are available elsewhere.¹⁰

Cost effectiveness analysis was performed to assess the relative efficiency of the invasive and non-invasive methods for detecting anemia by health workers. The Incremental Cost Effectiveness Ratios (ICERs) were calculated from costs (reported in this study) and effectiveness (reported elsewhere).⁹ The ICER was calculated as: [(Mean cost per test) device A - (Mean cost per test) device B]/[(Detection rate) device A - (Detection rate) device B]. The accuracy of the devices was compared against the autoanalyzer (gold standard) in the main study. However, the utility of autoanalyzer and point of care devices are very different and hence comparison for cost effective analysis was difficult. In the absence of a suitable comparator, for the purpose of calculations, we considered HemoCue against which all other devices were compared. Since the data for both costs and effectiveness were for an annual year, the costs were not discounted as per standard guidelines for economic evaluations.¹¹

Sensitivity analysis was conducted with lower and upper bounds of sensitivity of diagnostic parameters across all medical devices.

Scenario analysis for detection of anemia in an annual year was also

conducted with the assumption that an ANM can screen patients 2 days/week for 1 year (approximately 50 weeks), and assuming 10 min for each test, will be able to examine 6 patients in 1 h or 42 patients per day (assuming 7 h of work per day). The scenario also assumes that the ANMs will be conducting testing for anemia with no outside work.

The analysis was done from a quasi-health system perspective with a time horizon of one year. The outcome measure was 'correct diagnosis' that referred to the sensitivity of the devices i.e. ability of the devices to identify true positives. Given the fact that severe anemia is a priority of the national program, cost effectiveness was calculated separately for anemia and severe anemia. Reporting of study findings followed CHEERS guidelines.¹¹

Although cost utility analysis would have been a better estimate, this was not deemed appropriate in the current study. Hence, it was not included.

2.4. Additional components

Operational issues while using a device also aid in taking a decision on the feasibility of its use in field settings. We therefore explored different aspects like ease of use, portability, objectivity in readings, average time taken to perform each test, expertise required and strip/cuvette wastage. These were gathered from specifications mentioned in product inserts, from the manufacturers and research staff involved in the study. None of the patients had any immediate complications following needle pricks although we could not record any long term effects due to logistic reasons. Laboratory technicians and ANMs independently asked to rate each of the following criteria: ease of use, efficiency in daylight, scope of subjective errors, portability, convenience to patient, interpretation of hemoglobin (Hb) results, need for power/battery, average time taken for performing one test, and expertise required, on a scale of 1 (very poor) to 5 (excellent) for each device method. The total score across each of these parameters for laboratory technicians and ANMs were used to identify user friendliness for each method (maximum score for each method). These were subjective assessments to understand the perspectives of the users (4 per study site, 16 health workers in total).

3. Results

The individual cost of every device is shown in Table 1. The cost of conducting each test was minimum with Massimo (INR 104.8) in rural areas and with Spectroscopic (INR 140.0) in urban and maximum with TrueHb (INR 137.0 in rural and 177.4 in urban areas). Costs in urban areas are more than in rural areas. Additional cost to the health system for conducting each test in rural areas was found to be INR 24.4 with HemoCue while it was INR 38.7 with TrueHb. (Table 1).

The cost of consumables of testing devices contributed highest among Hemocue (12.1% of total cost), and True Hb (11.5% of total) in urban areas. The non-medical items in the examination room (such as furniture-examination table chairs, cupboards, curtains, wash basins, soaps, buckets, light, fan etc) contributed to the majority of the total costs for each device.

The cost calculated per case detected and effectiveness results (case detection rate or sensitivity) were calculated to compute the ICER for every device. HemoCue was found to be more cost effective than True Hb for detection of anemia while TrueHb is more cost effective for detection of severe anemia for both urban and rural areas. Since the users in the study were ANMs and we are primarily looking at rural areas where such point of care devices will be better utilized, we present the results of rural areas (Table 2). Sensitivity analysis for upper bound of sensitivity values of diagnostic tests showed higher costs per detection rate.

Table 3 provides results of scenario analysis across all anemia and severe anemia. HemoCue will detect 1869 cases per year per ANM with a cost of INR 224840 per device year, with a wastage of INR 27789.30, for

Table 1
Costs of resources for each test for measuring Hemoglobin (in INR).

Component	Data sources	Hemocue		True Hb		Spectroscopic device		Masimo	
		Rural	Urban	Rural	Urban	Rural	Urban	Rural	Urban
Human resource (ANM)	Health systems data	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)	Device manufacturers	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)	Device manufacturers	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)	Collected from hospital records	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)	Collected from hospital records	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)	Collected from hospital records	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 (INR)		120.3	164.3	137.0	177.4	110.1	140.4	104.8	144.7

Table 2
Incremental cost effectiveness ratios (ICER) of devices for detection of anemia and severe anemia (costs in INR).

Components	HemoCue	TrueHb	Spectroscopic device	Massimo
Anemia				
Base case	Reference	−464.3	30.4	65.1
Lower bound of sensitivity	Reference	−407.7	28.0	60.0
Upper bound of sensitivity	Reference	−557.1	34.0	73.3
Severe anemia				
Base case	Reference	41.5	54.1	52.2
Lower bound of sensitivity	Reference	46.2	46.4	58.9
Upper bound of sensitivity	Reference	45.8	96.8	53.4

all anemia. In comparison TrueHb will identify 1806 cases with an cost of INR 247422 per device per year, with a wastage of INR 402278. With regards to severe anemia, TrueHb will detected 73 cases with cost of detection at INR 11508 per year. While HemoCue will be able to detect only 39 cases of severe anemia with cost of detection at INR 10105 per year.

While choosing a device for programmatic use, several parameters were taken into consideration. Although accuracy across the spectrum of the condition (anemia in our case) gains maximum weightage, other factors also influence this decision. Of the four devices, HemoCue was rated the best by the health workers followed by TrueHb, Massimo and Spectroscopic device (Table 4). HemoCue fared better in terms of user friendliness, wastage per test, shelf life of the equipment and the accessories, and number of tests that can be done in field settings with fully charged batteries. On the other hand, True Hb outweighed HemoCue with regards to portability of the device, range of temperature for its use and storage, and feasibility to use it in community settings without having to use batteries (Table 5). Besides, HemoCue showed a bias or mean difference of 0.92 g/dl (0.82, 1.03) for severe anemia.⁹ Over-estimation by nearly 1 gm% may change the category of anemia and this can influence subsequent management.

4. Discussion

The analysis of the four devices shows that HemoCue is more cost effective than TrueHb for detection of anemia whereas True Hb is more cost effective for severe anemia. The HemoCue was found to be more user friendly than TrueHb as mentioned the health workers. With regards to the operational issues, TrueHb outweighed HemoCue for most factors.

Clinical benefit is expressed not only in terms of quality of life but

using diagnostic yield. Economic evaluation of diagnostic tests is different from that of drugs or interventions.¹² Rapid technology upgradation very often does not allow evaluation of clinical effectiveness.^{13,14} In our case, outcome of anemia is linked to treatment apart from diagnosis that cannot be disaggregated. Moreover, efficacy of the device depends on the users and costs of the devices may vary considerably depending on the numbers of users. There are reports on the possibility of use of Multiple Criteria Decision Analysis (MCDA) to address these challenges, but there is still no definite solution to overcome these with CEA of diagnostic devices.¹⁵

In a similar study from Malawi, HemoCue was compared to different methods for estimation of Hb.¹⁶ Based on accuracy, user friendliness and simplicity, HemoCue was recommended for use in district hospitals. While the authors in that study used accuracy for detection of anemia, we have used accuracy for anemia and severe anemia separately, keeping in mind the requirement of the health system in the country. Supplies and accessories contributed maximally to the cost of an individual test in Malawi while in our case non-medical costs in health facilities had the greatest contribution.

The desirable features that should be highlighted while identifying a device for a national program are accuracy across different field situations in the absence of recalibration and user-friendliness.¹⁷ We could assess the user-friendliness with health workers as the end users. We also assessed the accuracy across different field situations. However, the devices provided to us were new and the manufacturers mentioned that recalibration of digital hemoglobinometers was not required. We are not quite certain about the requirement of recalibration and therefore this remains a big limitation.

We were not able to calculate the full cost structure due to limited data on costs of training, differential costs and cost of delivering the test. Moreover, the study was done on adult patients for ascertainment of accuracy. The national program deals primarily with anemia in pregnant women and children. Any future economic evaluations, if at all done should be able to calculated for population group comprising of pregnant women and children.

This study draws both cost and effectiveness data from a primary study conducted in a low and middle income country (LMIC), i.e. India, which offers strength to this analysis. This is particularly important because evidence from higher economies may tend to focus on most effective solutions regardless of cost.¹⁷ Diagnostic accuracy tends to vary with the prevalence of the underlying disease condition and hence it is best ascertained in a place where it is likely to be used in future.¹⁸ Technology development is an iterative process that relies heavily on the experiences of the users, transparent communication between all concerned, and efforts to create an enabling environment best suited for a particular market.¹⁹

Table 3
Scenario analysis for detection of anemia in year using point of care devices.

	Haemo Cue	True Hb	Spectroscopic device	Masimo
Detection of anemia				
Total Cost Per unit Test (INR)	120.3	137	110.1	104.8
Total number of tests in 1 year per ANM (approx) ^a	4200	4200	4200	4200
Expected number of cases of anemia @50% prevalence	2100	2100	2100	2100
Total number of cases of anemia (true positives based on sensitivity data) detected per test	0.89	0.86	0.56	0.66
Total number of anemia cases detected per year	1869	1806	1176	1386
Cost for detection of anemia using the device per year (INR)	224840.7	247422	129477.6	145252.8
Total cost for the system for detection of anemia per year (INR)	252630	287700	231210	220080
Wastage to the system (INR)	27789.3	40278	101732.4	74827.2
Detection of severe anemia				
Total Cost Per unit Test (INR)	120.3	137	110.1	104.8
Total number of tests in 1 year per ANM	4200	4200	4200	4200
Expected number of cases of severe anemia @2% prevalence (based on available estimates eg NFHS)	84	84	84	84
Total number of cases of severe anemia detected per test	0.47	0.87	0.28	0.17
Total number of cases detected per year	39.48	73.08	23.52	14.28
Cost for detection of severe anemia using the device per year (INR)	4749.44	10011.96	2589.55	1496.54
Wastage to the system (INR)	5355.75	1496.04	6658.84	7306.65
Total cost for the system for detection of anemia per year (INR)	10105.2	11508	9248.4	8803.2

^a The total numbers of tests an ANM is required to perform was estimated from a population of 7000–8000 that she has to cater to. The approximate number of pregnant women/@ crude birth rate of 20/1000 results in 150–180 pregnant women and Hb estimation at every visit makes it (1000 tests/yr) plus non-pregnant women (1000/yr); Adolescents @15% of population (1100/yr) and @15% of population children (1100/yr) plus some wastage. Assuming that an ANM can perform 15–20 tests/days for 5–6 days a week throughout the year, the approximate number of tests per year was assumed to be 4200.

5. Conclusion

To conclude, based on the diagnostic accuracy of the devices across different field conditions, costs and detection rate, for anemia and severe anemia, digital hemoglobinometers performed better than non-invasive devices. Among the versions of digital hemoglobinometers evaluated, we found that for detection of anemia, Hemocue is most cost effective. However, for detection of severe anemia (which is directly related to mortality and other complications), TrueHb was found to be more cost effective. With the evolution of technology, a detailed HTA will be required for re assessment of newer versions of the devices and to revisit the decision.

Table 4
An assessment of user-friendliness of the devices by health workers
1 = Poor, 2 = Below average, 3 = Average, 4 = Above Average, 5 = Excellent.

Parameters	HemoCue	TrueHb	Spectroscopic device	Massimo device
Ease of Use	4	4	3	4
Efficiency in daylight	4	5	3	4
Portability	5	5	2	4
Convenience to Patient	5	4	2	5
Need for Power/Battery	5	5	2	4
Average time taken for performing one test	5	3	3	4
Expertise required	5	4	2	4
Total Score (out of 35)	33	30	17	29

Table 5
Features of digital hemoglobinometers (HemoCue and TrueHb).

Parameters	Hemocue	True Hb
Accuracy (all categories; Case detection rate or sensitivity)	+++ (90%)	+++ (86%)
Mean diff in Hb compared to Gold standard for all categories	+++ (0.18)	+++ (−0.22)
Accuracy (Severe Anemia).. Case detection rate or sensitivity	- (47%)	+++ (87%)
Mean diff in Hb compared to Gold standard in severe anemia	- (0.84)	+++ (−0.06)
Accuracy at different weather conditions	±	+
Data storage	- (no data)	+ (only Hb values)
Portability (weight of the device)	+ (500 gms)	+++ (60 gms)
Portability (dimensions) (in inches)	+ (5.5 × 2.7 X6.2)	+++ (4.7 × 2.3 x 0.3)
Ease of use by health workers (user friendliness)	+++	++
Ease and duration of training	+++ (4–5 h)	+++ (4–5 h)
Objectivity in readings	+++	+++
Patient convenience	+++	+++
Need for recalibration (NR- Not required)	+++ (NR)	+++ (NR)
Strip/cuvette wastage per test (Number per test)	++ (1.2)	+ (1.35)
Operating temperature	+ (10– 40 ^o C)	++ (5–45 ^o C)
Strip/Cuvettes Storage conditions	+ (10– 40 ^o C)	++ (5–45 ^o C)
Shelf life of the equipment	+++ (7 years)	++ (5 years)
Shelf life of strips/ microcuvettes	++ (2 years)	+ (1 year)
Source of power in facility	++ (AC adapter)	++ (Charger)
Source of power in community	++ (4 AA batteries)	++ (device should be fully charged, no batteries needed))
Number of tests in field settings (fully charged/ batteries)	++ (510)	+ (200)
Biomedical waste management	Lancet and microcuvettes	Lancet and strips
Approvals	FDA approved, CLIA compliant	CLIA compliant, ISO approved, FDA under process

+++ Very good, ++ Good, +Average, - Poor, ± Equivocal.

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Declaration of competing interest

All the authors declare that they do not have conflict of interest.

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