INFORMATION BRIEF (RAPID REVIEW)

Non-invasive Total Haemoglobin (SpHb) Measurement for Anaemia Screening in Children

Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
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Rapid Review
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TITLE: Non-Invasive Total Haemoglobin (SpHb) Measurement for Anaemia Screening in Children

PURPOSE

This review was requested by the Nutrition Division of the Ministry of Health Malaysia to assess evidence on its effectiveness, diagnostic accuracy, and suitability of [redacted] as a non-invasive tool for anaemic screening in health clinic and community outreach programs.

BACKGROUND

Anaemia, characterised by a decreased quantity of red blood cells, diminished haemoglobin (Hb) levels, or altered red blood cell morphology, results in impaired oxygen-carrying capacity of the blood and subsequent tissue hypoxaemia.[1,2] It remains a critical global public health concern, with a prevalence of 47% among children under five years, who bear the heaviest burden of this condition.[3] According to the World Health Organization (WHO), the highest prevalence of anaemia in 2011 was observed in children, with rates of 42.6% (95% CI: 37 – 47).[1] Data from the South East Asian Nutrition Surveys (SEANUT II Malaysia) conducted from 2019 to 2020 revealed a high prevalence of anaemia in children under four years of age (40.3%), with slightly higher rates in rural areas (43.0%) compared to urban areas (39.0%).[4]

The consequences of anaemia are far-reaching, with short-term impacts on physical growth and cognitive development, and long-term effects on work productivity in adults, leading to significant economic consequences.[3] In children, iron deficiency anaemia (IDA) has been linked to disruptions in neurodevelopment, resulting in irreversible impairments in motor, cognitive, and behavioural functions.[1,2,5] Consequently, early detection and intervention, such as dietary assessment and iron supplementation, are of utmost importance.[1] Recommendations, such as those from the American Academy of Pediatrics, advocate for universal anaemia screening with Hb concentration determination at approximately one year of age.[5]

Despite its importance, diagnosing anaemia from physical examination alone is challenging. For instance, a study involving 535 preschool children found that clinical pallor in the conjunctiva, palm, and nail beds was only detected in 20% of those with Hb <11.0 g/dL and in 61% of those with severe anaemia (Hb <7.0 g/dL).[5] While the gold standard for anaemia assessment is Hb determination using automated analysers in clinical laboratories, the invasive nature of these tests poses challenges.[3] Venous blood sampling not only causes discomfort and distress but also carries the potential to induce iatrogenic anaemia, particularly in paediatric populations.[1,2]

The complexity of collecting and preserving venous blood samples in field settings has driven the development of alternative methods for Hb measurement. Devices such as HemoCue, which requires 10 µL of capillary blood, are widely used in field studies; however, they still involve invasive procedures. Data from NHMS (MCH) 2022 indicates that over 50% of

children did not attend anaemia screening using Hemocue at health clinics, with many parents or guardians withholding consent. Given the high prevalence of anaemia (46.5%) among children under 5-year-old, a non-invasive alternative could potentially improve screening rates. More recently, non-invasive technologies like [redacted] have emerged. These devices employ spectrophotometry to measure Hb (SpHb), arterial oxygen saturation (SpO2), pulse rate (PR), and perfusion index (PI), offering a less invasive and more patient-friendly option for anaemia screening.[3] The adoption of such technologies hase been said could potentially enhance screening efforts, particularly in field and outreach populations, in addition reducing the physical and psychological discomfort associated with traditional blood sampling.

Technical Features:

Figure 1: [redacted]

[redacted] is an advanced device designed for continuous, non-invasive measurement of haemoglobin concentration (SpHb) in arterial blood.[6] The device employs [redacted], which uses the principles of spectrophotometry to differentiate among various blood components, including oxyhaemoglobin (oxygenated blood), deoxyhaemoglobin (non-oxygenated blood), carboxyhaemoglobin (carbon monoxide-

bound haemoglobin), methaemoglobin (oxidised haemoglobin), and blood plasma, based on their unique absorption of visible and infrared light.[1]

[redacted] leverages photoplethysmography to detect changes in arterial blood volume within the tissue caused by the pulsatile cycle. This is achieved using a multiwavelength sensor equipped with light-emitting diodes (LEDs) that emit light across a broad spectrum (500–1400 nm). The light passes through a capillary bed (such as the fingertip, hand, or foot), and the amount of light absorbed fluctuates with the pulse. A diode detector captures the transmitted light, converts it into an electronic signal, and transmits it to the device for analysis.[6]

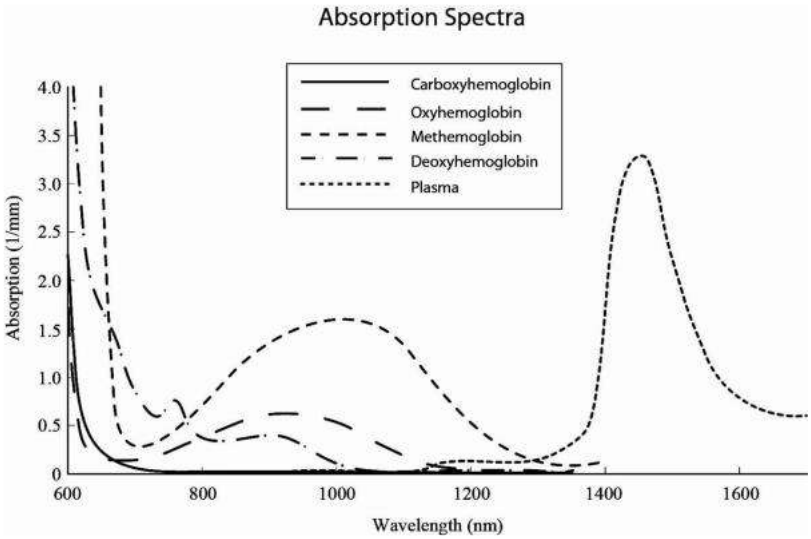

Figure 2: [redacted] uses a multi-wavelength sensor to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide, oxidized blood and blood plasma[6]

Once the signal is received, the [redacted] utilizes proprietary algorithms to calculate key physiological parameters, including functional oxygen saturation (SpO2 [%]), total haemoglobin concentration (SpHb [g/dL]), and pulse rate (PR). The device simultaneously measures multiple parameters non-invasively, such as carboxyhaemoglobin, methaemoglobin, oxyhaemoglobin, plethysmography variability index (PVI), and perfusion index (PI), making it a comprehensive tool for monitoring oxygenation and haemoglobin levels.[7]

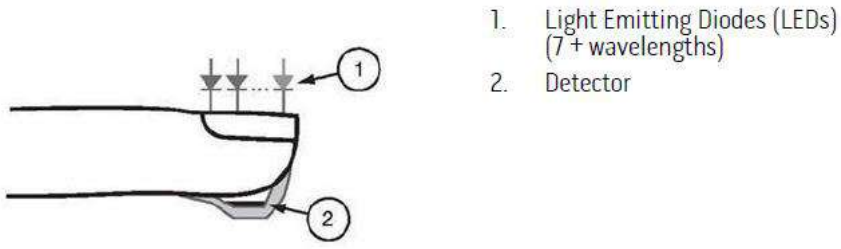

Figure 3 [redacted] utilises a sensor with various LEDs that pass light through the site to a diode (detector).[6]

EVIDENCE SUMMARY

A total of 118 titles were retrieved from the scientific databases such as MEDLINE (R), EBM Reviews via OVID, using the search term; *CHILD, PAEDIATRICS, INFANT, PRESCHOOL, ADOLESCENT, HEMOGLOBINOMETRY, TOTAL HEMOGLOBIN, SpHb, PULSE CO-OXIMETRY*. Search were limited to *English, Human and time frame of past 15 years.* The last search was run on 11 November 2024. After removing duplicates, and screening tittles and abstracts, there were nine articles included in this review which comprised of prospective observational, comparative diagnostic accuracy, cross-sectional, and validation studies. As the scope of the review is for screening of anaemia in children, only healthy population were included. Any articles mentioning the usage of non-invasive haemoglobin (SpHb) measurement in population such critically ill, haemodynamic unstable, and peri-operative were excluded from this review.

EFFECTIVENESS

Children:

Arai Y et al. (2023) conducted a comparative diagnostic accuracy study in Japan to evaluate the accuracy of total haemoglobin (SpHb) measured by the [redacted] compared to haemoglobin (Hb) concentrations obtained from an automated laboratory analyser (Hb_{LAB}) in children. This prospective study was carried out at Juntendo University Hospital between January 2020 and December 2021 and included both paediatric inpatients and outpatients. A total of 109 children aged 1 to 5 years were enrolled. Patients with congenital heart disease, haematologic or oncologic diseases, acute infections, vasculitis syndrome, or chronic kidney disease were excluded. Ultimately, 102 patients were included in the final analysis after excluding 7 patients with insufficient SpHb data. The study cohort consisted of 49 boys and 53 girls, with an average age of 3.7 years. Participants were divided into two age groups: 54 infants (1–3 years) and 48 children (4–5 years). The largest subgroup (24%) attended follow-up clinics for prematurity, with 19 of this having a history of very low birth weight. Other conditions included food allergies (14%), short stature (9%), and hypothyroidism (9%). The average haemoglobin values were 13.1 ± 0.89 g/dL for SpHb and 12.9 ± 1.03 g/dL for Hb-Lab. Regression analysis revealed a moderate to low correlation between SpHb and Hb-Lab values (correlation coefficient r = 0.548, 95% CI: 0.329–0.615), with the regression equation SpHb = 7.002 + 0.4722 Hb-Lab. However, SpHb tended to overestimate haemoglobin when Hb-Lab values were above 13.3 g/dL and underestimate when Hb-Lab values were below this threshold. Bland–Altman analysis showed a mean bias of 0.188 g/dL (with SpHb being higher), a standard deviation of 0.919 g/dL, and 95% limits of agreement ranging from −1.613 to 1.988 g/dL. The difference between SpHb and Hb-Lab was within 1.0 g/dL for 75% of patients and within 1.5 g/dL for 87.3%.[1]

Park YH et al. (2018) conducted a retrospective study in Korea to assess the accuracy of non-invasive haemoglobin (SpHb) monitoring during preoperative preparation in different

age-based patient subpopulations. The study measured SpHb levels during pre-anaesthesia visits for patients undergoing elective surgery and compared these values with laboratory-measured haemoglobin (Hb_{LAB}) in adult and paediatric populations. SpHb levels were obtained using the [redacted] and electronic medical records from June to December 2015 were analysed retrospectively. In the paediatric group (50 patients), the mean SpHb value was 11.4 ± 0.9 g/dL, while the mean Hb_{LAB} value was 13.3 ± 1.4 g/dL, with a median bias of −1.2 ± 1.0 g/dL (95% CI: −1.5 to −0.9). The correlation between SpHb and Hb_{LAB} was low ($r = 0.35$, $P < 0.05$), and bias showed a significant inverse correlation with Hblab ($r = −0.54$, $P < 0.001$), indicating that SpHb underestimated Hb at higher Hb_{LAB} levels. Bland–Altman analysis revealed limits of agreement ranging from −3.2 to 0.8 g/dL, indicating narrower variability in bias compared to adults but still highlighting some inaccuracy.[8]

Humaran Im et al. (2017) conducted a validation study in Mexico to evaluate the accuracy and precision of the [redacted] and [redacted] devices for measuring haemoglobin (Hb) in epidemiological studies, using venous blood samples as the gold standard. The study involved a field sample of 148 children aged 1 to 5 years, with Hb concentrations measured using [redacted], [redacted], and an automated laboratory analyser. After excluding 11 children with implausible Hb values, 137 Hb measurements were analysed. The mean Hb concentrations measured by [redacted] and [redacted] were significantly lower than laboratory values, with paired differences of −1.51 g/dL for [redacted] and −1.62 g/dL for [redacted] ($p < 0.001$ for both). Regression analysis showed high predictability for both devices ([redacted]: 98.7%, [redacted]: 98.6%), but regression coefficients [redacted] = 0.887, [redacted] = 0.876) were significantly below 1 ($p < 0.001$), indicating a downward bias. The concordance correlation coefficient (CCC) was low, reflecting poor agreement with the gold standard ([redacted]: 0.183, [redacted]: 0.166, $p < 0.001$). Bland-Altman analysis revealed mean differences of −1.51 g/dL ([redacted]) and −1.62 g/dL ([redacted] with negatively skewed limits of agreement. Variance analysis using a hierarchical linear model identified high within-subject variance as the largest contributor to total variance, suggesting poor reliability of Hb measurements for children in field settings. However, repeated measures with [redacted] showed consistent means and standard deviations over time, indicating some stability. Overall, both devices demonstrated significant downward bias and limited reliability for Hb measurement in children.[3]

Bhat A et al. (2016) conducted a prospective comparison study at the Neonatal Intensive Care Unit (NICU), Paediatric Intensive Care Unit (PICU), and paediatric outpatient unit of LLLRM Medical College, India, from January to August 2014. The study aimed to assess the validity of non-invasive transcutaneous haemoglobin (SpHb) estimation using [redacted] in both healthy and critically ill children, compared to traditional laboratory haemoglobin (Hb_{LAB}) measurement. The study population included 80 neonates (average age: 3.9 ± 2.1 days) and 70 children (average age: 5.8 ± 2 years), evenly distributed between healthy subjects and critically ill patients with shock. In healthy subjects, SpHb demonstrated strong performance for anaemia detection, with a sensitivity of 97.14% and specificity of 87.5%, yielding a positive predictive value (PPV) of 87.18% and a negative predictive value (NPV) of 97.2%. The mean Hb levels measured were 12.1 ± 4.8 g/dL (Hb-Lab) and 11.55 ± 3.8 g/dL (SpHb), with a mean bias of −0.77 ± 1.2 g/dL (95% CI: −1.05 to −0.5 g/dL). Bland-Altman analysis indicated that 94% of measurements fell within the limits of agreement, with a strong correlation between SpHb and Hb_{LAB} (Pearson $r = 0.90$, $p < 0.001$). The mean time lag for SpHb detection was 174.4 ± 38 seconds, and SpHb underestimated Hb levels by

more than 1.5 g/dL in 45.3% of healthy subjects. Perfusion index (PI) values were significantly higher in healthy subjects (3.1 ± 1.3) compared to critically ill patients, and regression analysis showed that maintaining a PI >1.7 reduced SpHb's bias to less than 1.5 g/dL. These findings suggest that SpHb is a reliable tool for anaemia screening in healthy children, though accuracy is influenced by perfusion conditions.[2]

Wittenmeier E et al. (2015) conducted a prospective comparative study to evaluate the practicality and clinical agreement of non-invasive haemoglobin (SpHb) measurement compared to laboratory haemoglobin (Hb_{LAB}) measurements in small children. The study included children aged 0–8 years weighing at least 3 kg, with ASA classifications ranging from 1 to 3. Exclusion criteria included children undergoing emergency procedures, those with known allergies to adhesive patches, peripheral arterial disease, haemoglobinopathy, or signs of severe infection or sepsis. Non-invasive haemoglobin (SpHb) was measured using the [redacted] and compared to capillary blood gas analyser results [redacted] and laboratory blood sample analyser results [redacted] Out of 70 children included in the study, data from 60 were analysed after excluding 10 due to various reasons. A total of 60 SpHb, 60 Hb_{LAB} (laboratory haemoglobin), and 59 Hb_{BGA} (blood gas analyser haemoglobin) measurements were obtained. Difficulties in SpHb signal assessment occurred in 38% of the children, but the child's age had no significant impact on measurement quality (median age for difficult and non-difficult measurements: 2.8 years, P = 0.958). During 8.4% of the evaluation period, SpHb readings were unavailable or inadequate (PI < 1). SpHb showed a mean bias of −0.65 g/dL (95% CI: −1.0 to −0.3 g/dL) compared to Hb_{LAB}, with Bland-Altman limits of agreement (LOA) ranging from −3.4 to 2.1 g/dL. The absolute bias was 1.1 g/dL, with a standard deviation of 1.37 g/dL, and 44% of SpHb values differed by more than 1 g/dL from Hb_{LAB}. Sensor placement influenced accuracy, with SpHb measurements being 0.7 g/dL lower when the sensor was placed on the finger compared to the toe (P = 0.012). There was no significant correlation between SpHb accuracy and age (r = 0.027, P = 0.837) or perfusion index (r = 0.231, P = 0.076). In comparison, Hb_{BGA} showed a mean bias of 1.14 g/dL (95% CI: 0.79 to 1.5 g/dL) with LOA of −1.6 to 3.9 g/dL. The absolute bias was 1.5 g/dL, and 66% of Hb_{BGA} values were out of range (differing by more than 1 g/dL from Hb_{LAB}). SpHb demonstrated better agreement with Hb_{LAB} than Hb_{BGA}, with a lower absolute bias (1.1 g/dL vs. 1.5 g/dL, P = 0.024) and fewer outliers (44% vs. 66%, P = 0.029).[9]

Amano I et al. (2013) conducted a study in Japan to compare non-invasive haemoglobin (SpHb) measurements using the [redacted] with complete blood count (CBC) results obtained from a haematology analyser in preschool children. The study included 110 three-year-old Japanese kindergarten pupils (58 boys, 52 girls) who underwent a medical check-up, during which SpHb levels and perfusion index (PI) were measured once using the [redacted]. The results of anaemia screening revealed that SpHb levels ranged from 10.8 to 13.7 g/dL, with a mean of 12.1 ± 0.64 g/dL. Only 0.9% of the samples had Hb levels below 11.0 g/dL, while 60% had levels ≥12.0 g/dL. In a subgroup of 43 paediatric patients (21 boys, 22 girls; mean age: 2.2 ± 2.0 years, range: 0–8 years), concordance between non-invasive SpHb measurements [redacted] and capillary Hb measurements [redacted] was assessed. Linear regression showed a moderate correlation (r = 0.602, P < 0.0001), while Bland–Altman analysis revealed that 95.3% of measurements were within the limits of agreement, with no significant bias observed. Among the children, four were identified with both SpHb and capillary Hb levels below 11.0 g/dL. These children received nutritional education, and two were prescribed iron supplementation, resulting in the resolution of

anaemia in all cases. To ensure measurement accuracy, SpHb data were accepted only when the PI was ≥2, as recommended by the device manufacturer.[5]

There is ongoing clinical trial done in Malaysia by Department of Paediatrics, University Malaya Medical Centre where 1215 children aged ≥6 months to ≤36moths seen at Mother and Child Health Clinic (MCHC) were recruited from July 2022 to Dec 2022. The main purpose of this study is to determine the prevalence of Malaysian children aged ⩾ 6 to ⩽ 36 months at risk of anaemia by measuring Total Haemoglobin (SpHb) using a non-invasive haemoglobin assessment using [redacted] However, this study is yet to be completed and no data has been published till the date of this review is written.[10]

Neonates:

Kazanasmaz H et al. (2021) conducted a prospective cohort study in Turkey to evaluate the accuracy of non-invasive haemoglobin (SpHb) measurements compared to total haemoglobin (tHb) levels measured from venous blood in neonates. The study was carried out in a level III NICU in Sanliurfa between March 25 and November 29, 2019. A single SpHb measurement using the [redacted] was compared to laboratory Hb levels obtained through venous blood samples analysed by a haematological laboratory analyser [redacted]. Neonates with inborn metabolic disease, hypothermia, hyperthermia, prolonged capillary refill time (>2 seconds), congenital cardiac disease, newborn jaundice, haemoglobinopathy, sepsis, or those receiving intravenous inotropic support were excluded from the study. A total of 310 neonates were included, with 49.4% being female. The neonates had a mean age of 12.76 ± 10.65 days and average birth metrics of 2608 ± 724 g (weight), 35.81 ± 3.34 weeks (gestational age), 46.61 ± 3.76 cm (height), and 32.23 ± 2.91 cm (head circumference). The haemoglobin levels measured non-invasively (mean SpHb: 14.11 ± 4.5 g/dL) and through venous blood (mean tHb: 14.16 ± 4.42 g/dL) were closely aligned, with a strong positive correlation ($r = 0.965$, $p < 0.001$) and a minimal mean bias of 0.05 g/dL (limits of agreement: −1.85 to 1.96 g/dL). There were no statistically significant differences between the two methods (CUSUM test, $p = 0.98$), demonstrating that non-invasive SpHb measurement provides comparable accuracy to venous Hb measurement in neonates.[7]

Wittenmeier E et al. (2019) conducted a prospective cohort study in Germany to compare the accuracy of four alternative haemoglobin (Hb) measurement methods with a laboratory haematology analyser (reference method) in term and preterm neonates. The study also evaluated the impact of patient characteristics on measurement accuracy. Over a five-month period, 63 Hb measurement series were performed on 41 neonates, with data missing for 3 Hb_{BGA} (blood gas analyser haemoglobin), 1 Hb_{LAB} and 1 SpHb measurement. The neonates showed significant variations in body weight and Hb levels. Bland–Altman analysis ranked the accuracy of the alternative methods compared to the reference as follows: Hb_{BGA} > [redacted] > [redacted] > SpHb, with [redacted] and SpHb showing distinctly lower accuracy. The SpHb method demonstrated systematic errors, overestimating Hb at low Hb_{LAB} levels and underestimating Hb at high levels, with a regression coefficient of $b = −0.67$ ($p < 0.001$). Reliability challenges for SpHb were notable, with the signal unavailable in 26.1% of the total measurement time. Achieving a stable SpHb signal required a median of 1 sensor placement (range: 1–4) and took a median of 2 minutes (range: 2–90 minutes). The mean within-subject coefficient of variation for SpHb values was 6.1% (SD 2.4%). Body weight, sex, and perfusion

index (PI) did not significantly influence the agreement between alternative methods and the reference, nor did fetal hemoglobin (HbF), as correlation coefficients ranged from r = −0.150 to r = 0.28. Overall, while Hb(gas) and Hcueven showed greater reliability, SpHb faced limitations in terms of accuracy, reliability, and practicality, making it less effective for precise Hb measurement in neonates.[11]

Jung YH et al. (2013) conducted a prospective study in Korea to evaluate the usefulness of non-invasive haemoglobin (SpHb) measurement using Pulse CO-Oximetry in neonates. The study took place in the NICU of Seoul National University Children's Hospital between March and April 2011. Laboratory Hb (Hb_{LAB}) values were measured using a [redacted] haematology analyser, while non-invasive Hb values were obtained using the [redacted] (Masimo Corp). A total of 158 paired Hb measurements were performed on 56 neonates, with 137 pairs included in the final analysis after excluding 21 pairs due to the inability to obtain SpHb readings. The study population included neonates with gestational ages ranging from 24+1 to 40+5 weeks, birth weights between 370 and 4,230 g, and postnatal ages from 1 to 98 days. The mean Hb_{LAB} was 12.5 ± 3.1 g/dL (range: 7.4–23.7 g/dL), while SpHb values were slightly higher at 13.3 ± 2.6 g/dL. A strong correlation between SpHb and Hb_{LAB} was observed ($r = 0.758$, $p < 0.001$), with a coefficient of determination ($r^2 = 0.58$, 95% CI: 0.53–0.72). Bland-Altman analysis showed a bias of 0.86 ± 3.40 g/dL, with 94.8% of measurements falling within two standard deviations of the mean difference. The accuracy of SpHb, expressed as Arms (average root mean square error), was 2.21 g/dL, with the highest accuracy seen in the Hb range of 12 to 18 g/dL (Arms = 1.68 g/dL). However, for Hb levels >18 g/dL, the Arms increased to 3.28 g/dL, and the correlation between SpHb and Hb_{LAB} was no longer significant. Bivariate analysis indicated that bias was not significantly influenced by factors such as birth weight, body weight, postnatal age, or postmenstrual age.[12]

SAFETY

From the nine articles included in this review, the safety of using non-invasive haemoglobin (SpHb) measurement in healthy children is generally well-established, with no major adverse events reported. Non-invasive haemoglobin measurement devices offer minimal physical risk by eliminating the need for blood sampling, making the process painless and significantly less stressful for children. This approach avoids the common risks associated with venipuncture, such as pain, infection, and anxiety, particularly in paediatric populations.[1,2] However, sensor-related concerns can impact accuracy, as repeated adjustments may be required to obtain stable readings. The placement of the sensor, such as on the finger versus the toe, influences the reliability of results, and improper placement or movement during measurement can lead to signal instability and inaccuracies.[2,11]

The [redacted] has received clearance from the United States Food and Drug Administration (USFDA) and is CE-marked. In Malaysia, the [redacted] has also been approved for market use by the Medical Device Authority (MDA).[6, 13]

COST-EFFECTIVENESS

There is no evidence retrieved on cost-effectiveness of non-invasive haemoglobin measurement in children for screening of anaemia. However, the price for a unit of the [redacted] quoted in [redacted] and [redacted] were [redacted] and [redacted] respectively.[14,15]

ORGANIZATIONAL

Non-invasive haemoglobinometer is easy to be operated on with reported time required to train new operator is less than 30-45 minutes with a fast result obtained.[16]

CONCLUSION

There is sufficient evidence showing moderate performance of non-invasive Hb measurement for anaemia screening in healthy children which offering a painless, quick and practical option in certain setting. Non-invasive haemoglobin measurement devices often underestimate Hb values compared to laboratory methods, with biases ranging from −0.65 to −1.62 g/d. While non-invasive devices may be served as an initial screening method, laboratory confirmation remains essential for accurate diagnosis and clinical decision-making, especially when it involves high-stakes situations.

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