Accuracy of the WHO Haemoglobin Colour Scale for the diagnosis of anaemia in primary health-care settings in low-income countries: a systematic review and meta-analysis

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Summary

Background Anaemia is a major cause of morbidity and mortality in low-income countries. Primary health-care workers in resource-poor settings usually diagnose anaemia clinically, but this is inaccurate. The WHO Haemoglobin Colour Scale (HCS) is a simple, cheap quantitative method to assess haemoglobin concentration outside of the laboratory. We systematically reviewed the literature to assess the accuracy of the HCS in primary care to diagnose anaemia, and compared this with clinical assessment.

Methods We searched the electronic databases including MEDLINE, EMBASE, SCOPUS, Web of Science, Cochrane library, CINAHL plus, Popline, Reproductive Health Library, and Google Scholar and regional databases up to Nov 14, 2014, "haemoglobin colour scale" in alternative spellings published in any language. Two reviewers independently screened studies, extracted data, and assessed quality using the QUADAS-2 instrument. Statistical analyses were carried out in STATA using the bivariate model.

Findings Of 141 records and abstracts screened, 14 studies were included. The pooled sensitivity of the HCS to diagnose anaemia was 80% (95% CI 68–88) compared with 52% for clinical assessment ([95% CI 36–67]; p=0·008). Specificity was similar between the HCS (80% [95% CI 59–91]) and clinical assessment (75% [56–88]; p=0·8250). For severe anaemia, diagnostic accuracy was again higher overall for the HCS (p<0·0001); sensitivity was 57% (36–76) for the HCS and 45% (95% CI 12–83) for clinical assessment, but specificity was 99·6% (95% CI 95–99·9) versus 92% (62–99). Combining clinical assessment and the HCS could result in higher sensitivity (anaemia: 91% [95% CI 81–96]); severe anaemia 83% (33–98), but at the expense of specificity (anaemia: 59% [35–79]; severe anaemia 90% [40–99]). Individual studies were highly heterogeneous but pooled results did not differ substantially in a series of sensitivity analyses for indicators of study robustness.

Interpretation In so-called real-life primary health-care conditions, HCS can significantly reduce misdiagnosis of anaemia compared with clinical assessment alone. Future research is required to optimise training, and assess clinical outcomes and cost-effectiveness.

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See Comment page e218

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Introduction

Anaemia is a major global cause of maternal, perinatal, and child mortality. Additionally, it causes low birthweight, impaired or delayed child physical and mental development, and an increased susceptibility to infections,[1] and contributes greatly to economic loss due to reduced productivity of workers.[2] About 1·62 billion people are affected.[1] Most are non-pregnant women (468·4 million), preschool age children (293·1 million), and pregnant women (56·4 million) predominantly in low-income countries, where prevalence rates are up to five times higher than in high-income countries and are inversely correlated with economic status.[3,4]

In these low-income societies, iron deficiency anaemia is believed to account for about 50% of all cases of anaemia,[5] but other causes are frequent and often co-exist, including malnutrition, micronutrient deficiencies, parasitic infections, other chronic inflammatory conditions, or hereditary haemoglobinopathies.[3]

Accurate quantitative point-of-care diagnostic tests are able to confirm the diagnosis of anaemia through measurement of a decreased amount of red blood cells or decreased haemoglobin concentration in the blood,[6] but these are not suitable in most primary health-care settings with very low resources, because they either require constant quality control by trained staff, use toxic or expensive reagents and consumables, or depend on an electricity supply.[7]

Diagnosis is thus often based on clinical signs alone such as conjunctival, palmar, and nailbed pallor. None of these signs, whether combined or singly, yield an acceptable diagnostic accuracy.[8] This leaves many cases undetected and untreated and also poses the risk of unnecessary and potentially harmful blood transfusions, increasing the risk of transmission of blood-borne

Research in context

Evidence before the study

The WHO Haemoglobin Colour Scale (HCS) became commercially available in 2001 as an instrument for health-care workers in resource-poor settings, who usually have to base the diagnosis of anaemia on signs and symptoms, to quantitatively assess the anaemia status of their patients. The first and only systematic review to date to assess the diagnostic accuracy of the HCS was published in 2005, which included 14 studies, but most of these were laboratory-based with only four taking place in primary care in low-income settings, under which the HCS is supposed to be used in practice. The reported estimates of diagnostic accuracy from this 2005 review were very heterogeneous (sensitivity 75–97% and specificity 41–98% for the detection of anaemia), and were less accurate in the four field studies (sensitivity 76–88%; specificity 41–100%). The authors did not compute summary estimates from individual studies, except for the five laboratory studies.

Added value of this study

We restricted our systematic review to real life studies (n=14), identifying ten more than available at the time of the previous review. We were also able to compare the performance of the HCS directly against the diagnosis of anaemia by clinical signs, because most studies directly compared these two tests. This is important because clinical assessment is the standard procedure to diagnose anaemia in most primary health-care settings in low-income countries. We also estimated diagnostic accuracy for simultaneous testing (HCS and clinical signs). Despite heterogeneous outcomes, we undertook meta-analysis of individual studies using the bivariate random effects model, and we used an evidence informed tool (QUADAS 2) for the assessment of the methodological quality of studies, allowing a series of sensitivity analyses.

Implications of all the available evidence

There is sound evidence that the HCS can improve the accuracy of diagnosis of anaemia and severe anaemia by primary health-care workers under resource-poor conditions. This finding is consistent in a variety of sensitivity analyses accounting for study quality and threshold effects. The HCS is significantly more sensitive for the diagnosis of anaemia than assessment of clinical signs, and the improvement in sensitivity could be clinically important in practice. Evidence concerning how training and supervision might affect the overall performance of the device, as well as its cost-effectiveness in reducing anaemia-related mortality and morbidity in practice, is lacking.

pathogens, and wasting resources in case of mis-diagnosed severe anaemia.

In response to the need for a "simple, cheap, and robust device to measure haemoglobin by health workers outside the laboratory"[9,10] the WHO Haemoglobin Colour Scale (HCS) was developed and has been produced and distributed under licence agreement by Copack (Oststeinbek, Germany) since 2001.[10–12] The scale comprises a small card of six shades of red (lighter to darker), each representing a haemoglobin concentration of 40 g/L, 60 g/L, 80 g/L, 100 g/L, 120 g/L, and 140 g/L, respectively. A drop of blood absorbed onto a standardised chromatography filter paper is compared with the colour scale, allowing assessment of the patient's haemoglobin concentration, including an estimation of intermediate results, in 10 g/L steps.[13]

The usefulness of the device in practice has been disputed,[14,15] but in 2005 a systematic review of 14 studies showed that, under ideal conditions, the HCS might improve diagnosis of mild and moderate anaemia with reasonable accuracy (sensitivities from 85% to 99% and specificities from 91% to 100% in five laboratory-based studies).[16] Ideal conditions are defined as studies taking place in a laboratory setting, including trained laboratory staff operating or supervising the HCS measurements after intensive training, from blood samples of hospital populations or blood donors. The diagnostic accuracy tended to be lower in the four so-called real-life studies (sensitivities 76–88%, apart from one outlier, and specificities from 41% to 100%), leading to the conclusion that further research was needed to assess the usefulness of the HCS in real-life situations. Real life conditions are defined as studies that were carried out in patient populations attending routine primary health clinics or public schools, with the HCS undertaken by primary health-care workers or a person with comparable skills or training. Only a minority (5 of 14) compared the accuracy of HCS with clinical diagnosis. We are aware of no systematic reviews of the performance of HCS since 2005, although additional "real life" studies have been published.

We aimed to do an updated systematic review to assess the accuracy of the HCS to diagnose anaemia and severe anaemia in resource-poor primary health-care settings compared with the accuracy of diagnosis by clinical assessment, wherever such data are available.

Methods

Search strategy and selection criteria

Following PRISMA guidelines, we searched the electronic databases MEDLINE, EMBASE, SCOPUS, Web of Science, Cochrane library, CINAHL plus, Popline, Reproductive Health Library, TRIP Database, ADOLEC, BDENF, DESASTRES, HISA, MedCarib, LILACS, IMEMR, IMSEAR, WPRIM, and Google Scholar, all from inception up to Nov 14, 2014. To increase sensitivity of the search strategy,[17] we searched only the keywords "haemoglobin colour scale" without any filters using alternative spellings in English, Spanish, and French. A citation search on "Critchley and Bates 2005 systematic