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Evaluation and costs of different haemoglobin methods for use in district hospitals in Malawi

A Medina Lara, C Mundy, J Kandulu, L Chisuwo, I Bates

Aims: To evaluate the characteristics of manual haemoglobin methods in use in Malawi and provide evidence for the Ministry of Health in Malawi to enable them to choose a suitable method for district hospitals.

Methods: Criteria on accuracy, clinical usefulness, user friendliness, speed, training time, and economic costs were determined by local health professionals and used to compare six different manual haemoglobin methods. These were introduced sequentially into use in a district hospital in Malawi alongside the reference method.

Results: HemoCue was the optimal method based on most of the outcome measures but was also the most expensive (US$0.75/test). DHT meter and Jenway colorimeter were the second choice because they were cheaper (US$0.20–0.35/test), but they were not as accurate or user friendly as HemoCue.

Conclusions: The process for choosing appropriate laboratory methods is complex and very little guidance is available for health managers in poorer countries. This paper describes the development and testing of a practical model for gathering evidence about test efficiency that could be adapted for use in other resource poor settings.

As part of the Malawi government’s Poverty Reduction Strategy, the Ministry of Health and Population has developed an Essential Health Package. This aims to provide better access to quality services for common conditions that disproportionately affect the poor. In Malawi, all health care is free so patients do not pay a fee for the service. To complement the Essential Health Package, the Ministry of Health and Population is developing a model package of essential laboratory services to improve the cost effectiveness of district hospital laboratories. The model is being developed and piloted in selected typical district hospitals in Malawi before being adapted for national implementation. Haemoglobin measurement is a key component of this service, so it is necessary to identify a method that is practical, accurate, and economically viable for use at district level.

'This is the first time that such a detailed effectiveness study involving all the processes required to determine the suitability of a test has been undertaken in a district hospital in a developing country.'

Haemoglobin measurement is the most commonly performed laboratory test worldwide and is an essential component of any health system. In sub-Saharan Africa, haemoglobin estimations are used in district hospitals for individual patient management, to guide transfusion practice, and in the management of antiretroviral therapy. Surveys of haemoglobin concentrations are also used as tools to provide public health data, such as nutritional status, and to monitor malaria interventions. Despite the wide range of manual methods available for measuring haemoglobin in developing countries, no single technique has emerged as the most appropriate for this setting.

To support their Essential Health Package, the Ministry of Health and Population in Malawi needed to identify a method for measuring haemoglobin that was simple, accurate, fast, and cheap and required minimal training and supervision that could be used in district hospital laboratories. Therefore, our study assessed the effectiveness, including technical, economic, and managerial aspects, of different manual techniques for measuring haemoglobin in routine practice in a typical district hospital in Malawi against criteria predetermined by local health professionals. To our knowledge, this is the first time that such a detailed effectiveness study involving all the processes required to determine the suitability of a test has been undertaken in a district hospital in a developing country. The project received ethical approval from the Liverpool School of Tropical Medicine, UK and the Ministry of Health and Population in Malawi.

MATERIALS AND METHODS

Our study was carried out in Ntcheu District Hospital in the central region of Malawi. This district has a population of 500,000 and is served by a single hospital with 240 inpatient beds. The laboratory in the Ntcheu District Hospital performs approximately 6000 haemoglobin tests each year. It normally has a complement of two or three staff (laboratory assistants and qualified technicians), but two extra technicians were seconded to assist with our study.

The six haemoglobin methods to be evaluated were chosen because they were already in use in Malawi or at district level in other countries, and they could be supplied quickly for widespread use in Malawi.

The Lovibond comparator (ECHO International Health Services Limited, Coulsden, Surrey, UK)

This is the predominant method used in Malawian district hospitals and assessments were carried out using the equipment already in routine use. It is based on the oxyhaemoglobin method and involves matching the colour of the diluted blood sample with colours on a disc equivalent to known haemoglobin values in 20 g/litre increments.

Abbreviations: HCN, haemoglobin cyanide
The haemoglobin colour scale (Copack GmbH; Oststeinbek, Germany) provides a direct readout of the haemoglobin result. A microcuvette is inserted into the photometer and the haemoglobin is converted to haemiglobincyanide. The Jenway colorimeter (Jenway 6051; Jenway, Dunmow, UK) has a direct readout of the haemoglobin estimation. This is based on the oxyhaemoglobin method and has a direct readout of the haemoglobin value of all samples was also measured by the Haemoglobin colour scale (Copack GmbH; Oststeinbek, Germany). A drop of undiluted blood is placed on specific chromatography paper and matched against a range of colours representing different haemoglobin values in 20 g/litre increments.

All methods were performed in accordance with the manufacturers’ instructions. The methods were evaluated sequentially on a total of 600 consecutive, unselected EDTA blood samples (that is, 100 samples for each method) sent to the laboratory for routine haemoglobin estimations during a two month period during the malaria season. To assess the accuracy of each method in routine use, the haemoglobin values were regarded as wasted tests. This cutoff was chosen because local clinicians indicated that a result that deviated more than 20 g/litre from the true value would probably result in mismanagement of the patient and was therefore of no clinical use.

### WPA colorimeter (WPA CO700D from WPA, Pocklington, York, UK) and Jenway colorimeter (Jenway 6051; Jenway, Dunmow, UK)

These methods are based on the conversion of haemoglobin to haemiglobincyanide. The Jenway colorimeter has a direct readout.

### DHT meter (HMB.010; Developing Health Technology, Ipswich, UK)

This is based on the oxyhaemoglobin method and has a direct readout of the haemoglobin estimation.

### HemoCue (HemoCue AB-haemoglobin photometer; Angelholm, Sweden)

Undiluted blood is placed directly into a microcuvette where the haemoglobin is converted to haemiglobincyanide. The microcuvette is inserted into the photometer and the machine provides a direct readout of the haemoglobin result.

### Haemoglobin colour scale (Copack GmbH; Oststeinbek, Germany)

A drop of undiluted blood is placed on specific chromatography paper and matched against a range of colours representing different haemoglobin values in 20 g/litre increments.

### Comparative Analysis

<table>
<thead>
<tr>
<th>Method</th>
<th>Mean (g/l)</th>
<th>Median (g/l)</th>
<th>SD</th>
<th>Range</th>
<th>95% limit below reference method</th>
<th>95% limit above reference method</th>
</tr>
</thead>
<tbody>
<tr>
<td>HemoCue</td>
<td>94</td>
<td>104</td>
<td>46</td>
<td>1.6–16.5</td>
<td>6%</td>
<td>16%</td>
</tr>
<tr>
<td>HCN</td>
<td>94</td>
<td>106</td>
<td>46</td>
<td>1.9–16.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jenway colorimeter</td>
<td>65</td>
<td>59</td>
<td>30</td>
<td>1.9–16.1</td>
<td>14%</td>
<td>10%</td>
</tr>
<tr>
<td>HCN</td>
<td>67</td>
<td>60</td>
<td>30</td>
<td>2.1–16.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WBA colorimeter</td>
<td>58</td>
<td>52</td>
<td>25</td>
<td>1.9–14.5</td>
<td>31%</td>
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</tr>
<tr>
<td>HCN</td>
<td>61</td>
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<td>28</td>
<td>1.9–16.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haemoglobin colour scale</td>
<td>81</td>
<td>80</td>
<td>35</td>
<td>4.0–14.0</td>
<td>48%</td>
<td>37%</td>
</tr>
<tr>
<td>HCN</td>
<td>78</td>
<td>72</td>
<td>35</td>
<td>2.3–17.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DHT meter</td>
<td>81</td>
<td>77</td>
<td>30</td>
<td>2.8–16.8</td>
<td>19%</td>
<td>33%</td>
</tr>
<tr>
<td>HCN</td>
<td>75</td>
<td>68</td>
<td>30</td>
<td>1.9–15.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lovibond</td>
<td>105</td>
<td>110</td>
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<td></td>
</tr>
</tbody>
</table>

One hundred different samples were used for each method.

### Accuracy and Clinical Usefulness

The level of agreement between haemoglobin values generated by the individual methods compared with the reference HCN method was determined according to the statistical method of Bland and Altman.4 Statistical analyses were performed using SPSS version 10. The percentage of tests for each method that varied from the reference value by more than ±20 g/litre were regarded as wasted tests. This cutoff was chosen because local clinicians indicated that a result that deviated more than 20 g/litre from the true value would probably result in mismanagement of the patient and was therefore of no clinical use.

### User Friendliness

Local technicians themselves identified the five key attributes of an ideal method for haemoglobin measurement in a district hospital in Malawi as: technically undemanding, minimal training and supervision requirements, direct reading of results, simple quality control checks, and not reliant on electricity supply. The technicians independently rated each of these criteria on a scale of 1 (very poor) to 5 (excellent) for each test method and this was used to devise a score of user friendliness for each method (maximum score for each method, 25).

### Time taken to learn and perform tests

As each new method was introduced, the time taken to learn the method so that laboratory technicians and attendants could perform it independently was recorded. The time taken to perform each test during routine use was documented, and the time spent on internal quality control and calibration processes for each batch of tests was included in the calculation and divided between the number of tests for each batch. The training costs for each method were calculated from the cost of practice tests and the salary of the trainee for the total training time. The Lovibond comparator was excluded from this analysis, because it was the method already in routine use in the laboratory, so it was familiar to the technicians.

### Table 1: Accuracy of Various Haemoglobin Methods Compared with the Reference Haemiglobincyanide (HCN) Method

<table>
<thead>
<tr>
<th>Method</th>
<th>Mean (g/l)</th>
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<td></td>
</tr>
</tbody>
</table>

One hundred different samples were used for each method.
Economic costs
To estimate the costs for each method, the actual value of all resources used to perform the 100 haemoglobin estimations (including control and calibration procedures) was calculated from: the cost of apportioned annualised capital equipment, supplies, and technician’s time taken to perform each test. An appropriate portion of the laboratory’s total electricity costs was included for all methods that used power. Building maintenance costs were assumed to be the same, irrespective of the method, and were therefore excluded from the cost analysis. These estimations were used to project the total annual costs of the haemoglobin workload for each method. Prices were obtained from the Malawi central medical store catalogue or directly from the suppliers, and included the standard 12% government discount rate. Costs were expressed in US$. 

RESULTS
Accuracy and clinical usefulness
HemoCue was the most accurate method because it had mean and range values closest to those of the HCN reference method (table 1); 95% of HemoCue results differ by only 6% below and 16% above the reference results. None of the tests showed systematic bias and the degree of imprecision is reflected in the limits of agreement. The proportion of tests that were too inaccurate to be clinically useful varied from 1% for HemoCue to 99% for the Lovibond comparator (table 2).

User friendliness
HemoCue was rated as the most user friendly method by the technicians, achieving the maximum possible score of 25. The least user friendly methods were the reference HCN method and the WBA colorimeter because neither of these had a direct readout of the haemoglobin result (table 3).

Time taken to learn and perform tests
Competency was achieved most quickly for the HemoCue method by both grades of laboratory staff (table 4). In routine use, the average time taken to perform a single test varied between three minutes (haemoglobin colour scale), five minutes (DHT meter, HemoCue, and Lovibond), and 15 minutes (colorimeters and HCN method). The training costs to achieve competency varied from US$18 to US$236, depending on the method. They were lowest for the DHT meter, the haemoglobin colour scale, and HemoCue. They were five to 10 times higher for the WBA and Jenway colorimeter methods and the HCN reference method.

Economic costs (table 5)
There was a fivefold variation in cost/test, from US$0.12 for the haemoglobin colour scale to US$0.75 for the HemoCue method.

In our study, the Ministry of Health and Population in Malawi has decided to introduce HemoCue as the standard haemoglobin technique at all their 32 district hospitals and urban health centres. Its major drawback is the cost of the disposable cuvettes which comprise 86% of the overall annual cost of this method, resulting in HemoCue having the highest annual costs at US$0.75/test. For all other methods except the haemoglobin colour scale, supplies make up less than

<table>
<thead>
<tr>
<th>Method</th>
<th>Training time* in minutes</th>
<th>Number of practice tests required</th>
<th>Total training costs† 2001 US$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lab attendant</td>
<td>LA/JT</td>
<td>Experienced technician</td>
</tr>
<tr>
<td>DHT meter</td>
<td>200</td>
<td>90</td>
<td>60</td>
</tr>
<tr>
<td>Haemoglobin colour scale</td>
<td>160</td>
<td>60</td>
<td>30</td>
</tr>
<tr>
<td>HemoCue</td>
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<td>20</td>
</tr>
<tr>
<td>WBA colorimeter</td>
<td>6000</td>
<td>4000</td>
<td>3000</td>
</tr>
<tr>
<td>Jenway colorimeter</td>
<td>6000</td>
<td>4000</td>
<td>3000</td>
</tr>
<tr>
<td>HCN</td>
<td>7000</td>
<td>5000</td>
<td>4000</td>
</tr>
</tbody>
</table>

*Training time excludes tutor’s time; †Total training costs comprise trainees’ time, the cost of supplies for the number of practice tests required, and an apportioned element of the capital cost.

HCN, haemiglobincyanide; JT, junior technician; LA, laboratory assistant.

Table 3 User friendliness of different haemoglobin methods

<table>
<thead>
<tr>
<th>Characteristics (maximum score 5 each)</th>
<th>HemoCue</th>
<th>DHT meter</th>
<th>Haemoglobin colour scale</th>
<th>Jenway colorimeter</th>
<th>Lovibond</th>
<th>WBA colorimeter</th>
<th>HCN reference method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Easy to use</td>
<td>5</td>
<td>4</td>
<td>5</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Minimal training/supervision required</td>
<td>5</td>
<td>3</td>
<td>5</td>
<td>2</td>
<td>5</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Simple reading of results</td>
<td>5</td>
<td>5</td>
<td>2</td>
<td>5</td>
<td>2</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Simple internal quality</td>
<td>5</td>
<td>2</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Suitable for village use</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>1</td>
<td>4</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Total (max 25)</td>
<td>25</td>
<td>19</td>
<td>17</td>
<td>15</td>
<td>15</td>
<td>13</td>
<td>10</td>
</tr>
</tbody>
</table>

Table 4 Comparison of training time and costs for different haemoglobin methods

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supervision and monitoring.

times will probably be those that require the least external
supervisory visits, and participation in external quality
general laboratory system, such as training programmes,
supervisory systems. The inputs needed to support the
may have no technical qualifications, and there are no
countries where the workload is high, many laboratory staff
too demanding for use in rural laboratories in poorer

that methods that do not give a direct readout and which
slightly on accuracy for haemoglobin methods that are used
available at the referral hospital. Therefore, it has been
suggested that the haemoglobin colour scale might be
considered for use in antenatal and paediatric screening
programmes. None of the other methods assessed in our
study was ideal for district hospital use, where an accurate
method is essential, because they involve a dilution step. This
is a major source of inaccuracy in poorer countries where
automatic pipettes are unavailable.

One of the major roles that international organisations
could play would be to provide detailed, independent evaluations of new laboratory methods”

The results of our study confirm findings from elsewhere
that show that the Lovibond method currently in use in
Malawi has an unacceptably low accuracy. It also indicates
that methods which do not give a direct readout and which
require the construction of calibration curves are technically
too demanding for use in rural laboratories in poorer
countries where the workload is high, many laboratory staff
may have no technical qualifications, and there are no
supervisory systems. The inputs needed to support the
general laboratory system, such as training programmes,
supervisory visits, and participation in external quality
assurance systems, have not been included in our analysis.
However, the simplest methods with the shortest training
times will probably be those that require the least external
supervision and monitoring.

Our study demonstrates the complexity of the decision
making processes that are involved in an apparently simple
task of deciding on an appropriate haemoglobin method for
district hospitals in Malawi. In consultation with local users,
we have developed and tested a model that can be used to
assist in this process, and which could be adapted to suit
other types of health technology and other settings. The
appropriateness of tests will vary according to local clinical
need and resources available, so the results of our study
cannot be extrapolated directly to other studies. However, the
evidence gathering, analysis, and decision making processes
that we have described and that were developed in close
collaboration with local users and suppliers of laboratory
services, provide a model that could be adapted to other tests
and settings.

Health managers in poorer countries do not have technical
training in laboratory issues and have great difficulty in
obtaining the evidence that will enable them to make rational
decisions about purchasing technological services. They need
to take account not only of costs, but also simplicity,
accuracy, speed, available manpower, and technical skills of
their laboratory workforce and the health needs of the
population. Although the World Health Organisation does
provide guidance on the selection of laboratory tests, details
of all the components needed to make an evidence based
judgement, such as we have provided in our study, are
lacking. One of the major roles that international organisa-
tions could play would be to provide detailed, independent
evaluations of new laboratory methods, which include
information about start up and recurrent costs, training
duration and costs, complexity of the method, and the inputs
needed to maintain calibrations and quality. This type of
independent and comprehensive information would be
invaluable to health purchasers in developing countries,
who face conflicting pressures over equipment purchase from
agencies such as bilateral donors, charities, and the com-
mercial sector.

ACKNOWLEDGEMENTS
We acknowledge the support received from the Ministry of Health
and Population in Malawi, in particular Mr A Khuvi. The project was
funded by the Department for International Development, UK. The
Department for International Development accepts no responsibility
for the information or views expressed in this paper.
ECHO

Single sample doubles as cervical and chlamydia screen

Screening for chlamydia is potentially possible at first invitation for cervical screening with a liquid based system for collecting samples, a feasibility study in England has shown. The National Institute for Clinical Excellence has since approved liquid based cytology for national cervical screening.

Samples obtained by conventional means for chlamydia testing and by the ThinPrep Pap test system for cervical screening, when tested for chlamydial DNA by ligase chain reaction (LCR), all showed concordant results between sample pairs. Nineteen were positive for chlamydia and 562 negative out of 581 samples. A subset of 16 positive samples stored at ambient temperature remained positive for at least five months—the time of reporting. The double call-recall service for chlamydia and cervical smears that is provided locally would be an issue for national screening, though, the authors predict.

Three colposcopy services—two hospital services and a community based service—in Wirral, north west England, took part. The study directly compared suitability of residual sample from the ThinPrep test system with a paired conventional swab sample taken immediately afterwards for detecting chlamydia by standard LCR during May 2001–2. The ThinPrep test system uses a sampling device to collect cervical cells into a transport medium for later cytological examination.

Detecting chlamydia early would reduce potential complications of the infection and public health costs of about £100m a year. The study extends a government funded pilot screening programme with the LCR system within a national strategy to improve sexual health.