Assessing hemoglobinometers for maternal care

Target product profile and landscape analysis

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Introduction

Screening for anemia during pregnancy is recommended by the World Health Organization and is included in most national maternal health guidelines.¹ However, anemia persists as a serious and highly prevalent global health problem, particularly affecting pregnant women in South Asia and sub-Saharan Africa.² Making available and accessible the most appropriate anemia diagnostics for resource-poor settings could significantly improve the quality of care received by women during the prenatal and postnatal periods and, in turn, reduce maternal and perinatal mortality, low birth weight and preterm birth, and infant anemia.

A reliable, accurate, safe, and low-cost method of measuring hemoglobin is urgently needed. Reports from experts and practitioners suggest that currently available anemia screening tools are not appropriate for antenatal care (ANC) in low- and middle-income countries: they are too costly, unreliable, or ill-suited for use at the point of care (POC). Moreover, available data on new and emerging anemia diagnostic products are incomplete.³⁻⁵

To better understand this evidence gap on diagnostic products, including their availability, performance, and desired characteristics, PATH conducted expert interviews and reviewed literature in order to develop a target product profile (TPP) for a hemoglobinometer for use in ANC settings. This TPP provides guidance to manufacturers, practitioners, and policymakers interested in developing and introducing appropriate POC hemoglobin measurement tools. In addition, PATH conducted a landscape analysis of current and emerging approaches and tools for anemia screening. Where information was available, we assessed the degree to which these products—which included several commercially available portable hemoglobinometers—aligned with key criteria from the TPP. The purpose of this analysis was to describe the market landscape of current and emerging products and characterize the attributes, with respect to the TPP.
Approach

Target product profile (TPP) development

PATH developed a TPP which serves as a framework for evaluating commercially available and pipeline hemoglobinometers to understand which options are best suited for the intended use case. Starting with a TPP outline provided by the Bill & Melinda Gates Foundation, PATH conducted a literature review of hemoglobinometer performance and usability evaluations. PATH interviewed 11 key informants using a semi-structured interview guide in April and May of 2019. Interview questions focused on the availability of existing anemia screening tools, including the advantages and disadvantages shaping their use and uptake, as well as ideal and actual settings of use and the product requirements that would constitute an improved screening tool. Questions covered the following areas: (1) current tools, users, and screening challenges, (2) intended use case, (3) performance, (4) product requirements, and (5) price and channels to market. Interview participants were selected in coordination with the Bill & Melinda Gates Foundation and purposively sampled based on their expertise in ANC and anemia screening. The findings from the literature review and expert interviews were compiled and used to inform and annotate minimum and optimistic criteria for each product attribute.

Table 1. Description of experts interviewed.

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<thead>
<tr>
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Note: ANC, antenatal care; DHS, M&E, monitoring and evaluation; MCHN, maternal and child health and nutrition; MQSUN, Maximizing the Quality of Scaling Up Nutrition; R&D, research and development.
Landscape analysis

PATH conducted a landscape analysis of commercial products and late-stage prototypes for anemia screening. The purpose of this analysis was to describe current methods used for screening at the point of care, identifying promising tools and characterizing product attributes. To conduct this analysis, between May and June, 2018, PATH completed a literature review and gathered additional insights through outreach to industry contacts. We searched PubMed, Google, grey literature, and several online medical-device product repository websites, including the UNICEF Supply Catalogue, VIA Global Health, and Medical Expo. Additional commercial products and prototypes were identified through the expert interviews. Finally, PATH evaluated a subset of products and prototypes identified against the key minimum criteria listed in the TPP.
Conclusions

A robust, low-cost, accessible, and accurate POC hemoglobin measurement tool is needed for use in maternal care. The landscape analysis indicates that there are multiple commercially available products. The HemoCue® (HemoCue AB, Ängelholm, Sweden) serves as the reference standard for POC screening. This invasive method has adequate performance, but the cost and need for consumable materials mean that policymakers and practitioners may continue to explore alternate options. Noninvasive methods are promising, but there was consensus among stakeholders that currently there is insufficient performance data to warrant replacement of invasive tools with these methods. As such, additional research and product development is needed. Furthermore, differences in evaluation methodologies have limited the ability to compare products. Different reference methods are often used. Other factors, such as protocols, quality control, type of blood (capillary vs. venous), populations, blood collection methods/techniques, geography/context, and equipment also limit comparability. Policymakers and practitioners would benefit from clear guidance and recommendations regarding which of the many hemoglobin measurement tools are appropriate for their setting.

Stakeholders, particularly those looking to use the hemoglobinometer to inform immediate clinical decision making, expressed interest in additional markers that would give an indication of the root cause of anemia. For example, patients may have become anemic due to parasitic infections, hemoglobinopathies, or dietary deficiencies. This information could inform more targeted treatment and follow-up.

PATH identified some specific TPP domains where more information is needed in order to better define minimal and optimistic criteria. Target cost warrants further exploration. Stakeholders interviewed indicated that the cost per result should be only a few cents per test. The willingness of manufacturers to meet such low price points, in a relatively undefined market, should be carefully considered. The total cost of the test would include the cost of the reader plus any consumable component. For invasive tests, this would include any disposable strip or cuvette, and for noninvasive tests, this would include any sensor or probe needed. More costing and cost-effectiveness data are needed to understand the minimal and optimistic criteria for test cost across these device types.

Channels to market should be further explored, including regulatory approvals and policy changes that may be required before tests can be used in the intended setting. Operational research and cost effectiveness studies would support further specification of criteria related to the intended use, end users, and test complexity. Finally, more evidence is needed to inform criteria for diagnostic performance, particularly with respect to precision and accuracy using capillary samples. Ensuring consistent sampling techniques and sufficient sample volume are frequently cited issues.

Recent initiatives such as the “Anemia Free India” campaign and the release of new WHO guidelines for ANC represent an opportunity to introduce and scale tools for hemoglobin measurement. Further development of the TPP will help ensure that, among the many available and emerging tools, the most appropriate options can be evaluated, made accessible, and adopted by end users.
Summary of recommendations

1. Develop and disseminate standardized protocols to enable the generation of comparable evidence on available and pipeline hemoglobinometers.

2. Invest specifically in the development and evaluation of noninvasive technologies and next generation anemia tools that provide an indication of the root cause of anemia.

3. Further refine the TPP with a focus on cost and channels to market.

Further recommendations that take into account findings from the usability and verification study in addition to the TPP and landscape analysis will be provided at the close of the project.
References


