Simply Sickle: A Point of Care Test for Diagnosis and Management of Sickle Cell Disease

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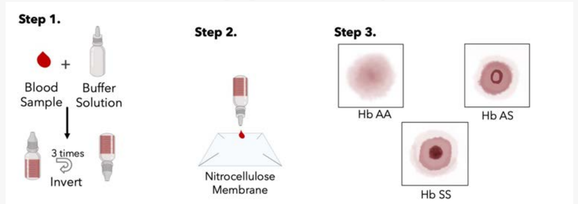
INTRODUCTION

- **Sickle Cell Disease: A Common and Detrimental Blood Disorder**
  - Sickle cell disease occurs when red blood cells contort into a sickle shape. The cells die early, leaving a shortage of healthy red blood cells, which can cause infections, pain and fatigue. Sickle cell disease is a predominant source of infant death in many countries such as India and sub-Saharan Africa. Over 50% of infants with sickle cell disease die without diagnosis.
- **Radial Flow Assay**
  - This assay has been developed and tested in the Locke Laboratory. It uses a small volume of blood from a finger prick mixed with a lysing buffer. A drop of this solution is deposited onto a small square of nitrocellulose paper and analyzed.



EXISTING SOLUTIONS

- **Laboratory techniques**
  - HPLC, Hb electrophoresis, blood counts, peripheral blood tests, etc.
  - Laboratory tests require venous blood samples in larger quantities taken by medical professions in clinic settings. This highly reduces the availability of testing in resource constrained environments.
- **Other Radial Flow Assays**
  - Other radial flow assays for sickle cell disease diagnosis have been published or released, however they do not include any quantitative results to patients. Quantitative results are crucial in determining next steps for patients.

NEEDS ASSESMENT

A new way to detect sickle cell disease in newborns living in low- and middle-income countries in a low-cost and user-friendly way that provides quantitative results of percent sickled hemoglobin

PROBLEM STATEMENT

We need to re-design a current sickle cell detection device to be field-suitable, sanitary, and effective. This includes

- creating a low-cost alternative to a mobile imaging device.
- Designing a single use sample collection cartridge
- Designing hardware to support a machine learning classification model
- Meeting WHO ASSURED Criteria for diagnostics

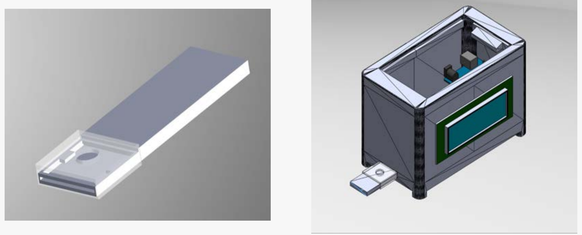
DESIGN METHOD

- Initial design focused on substituting the smartphone for something less expensive but still powerful enough to communicate over Wi-Fi or store a large model.
- Introduced Raspberry Pi and subsequent camera module .
- Prototyped different layouts for most easy-to-use diagnostic process.
- Ensured design met WHO ASSURED Criteria and was suitable for field use.

PROTOTYPES

Fig. 1. Original prototype using expensive smartphone and exposed nitrocellulose.

Fig. 2. Second prototype with drop shield on cassette and Raspberry Pi Imaging



FINAL DESIGN

- Cassette preloaded with nitrocellulose membrane and drop shield to reduce user error and eliminate need for laboratory supplies such as pipette.
- Disposable dropper pre-loaded with buffer as well as a lancet .
- Raspberry Pi camera model and LCD display screen .
- Communicate with the machine learning algorithm through Wi-Fi capability *or* with the model loaded onto an SD card. Image capture and analysis is started with a large tactile button.
- Battery pack to eliminate need for outlets.
- LEDs and black PLA for consistent imaging conditions.

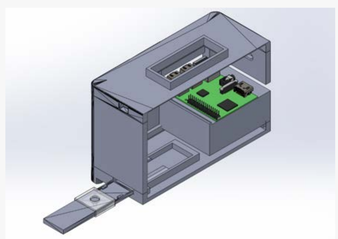


Fig. 3. Cross Section of CAD Assembly

Fig. 4. Assembled Image Box with Cassette Inserted

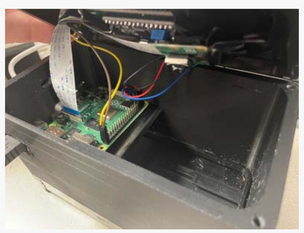


Fig. 5. Internal Imaging Hardware

Fig. 6. Example image of negative test using synthetic control blood

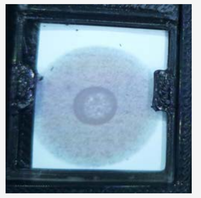
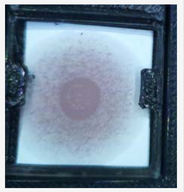
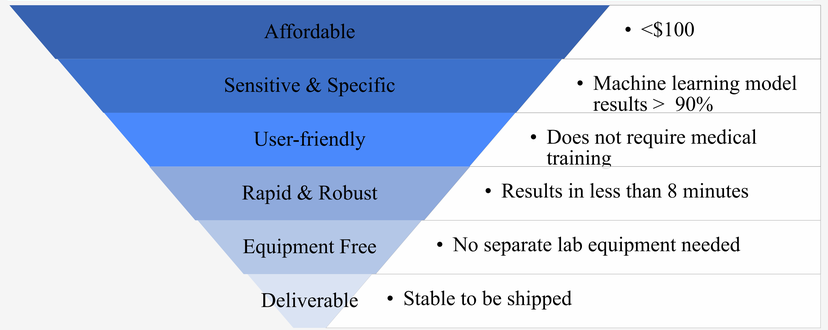


Fig. 6. Example image of positive test using synthetic control blood (25% HbS)



WHO ASSURED CRITERIA



CONCLUSIONS & FUTURE WORK

- Our upgraded device and procedure meet all WHO ASSURED Criteria and is a working diagnostic prototype that addresses our problem statement.
- Our design fully supports quantitative analysis that will be expanded upon in future work.
- The impact of this work is increased testing & community knowledge, increased necessary medical interventions, and the prevention of unnecessary deaths.
- We will begin building a training set of images for the machine learning algorithm from the Raspberry Pi camera to replace the previous smartphone image database.
- We will experiment with injection molding to lower the cost and increase ease of manufacturing of our device.
- In the long term, we would love to see this device used for different hematological assays if possible.

PROTOTYPE DEMONSTRATION VIDEO

Please scan to see our pitch video

Please scan to see our prototype demo

ACKNOWLEDGEMENTS

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