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Evaluation of a New Point-of-Care Diagnostic Tool for Newborn Screening in Ghana

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OBJECTIVE

To evaluate the diagnostic accuracy of Gazelle™, a microchip-based, cellulose acetate electrophoresis, point-of-care device, for point-of-care screening of newborns for sickle cell disease.

PREVALANCE AND IMPACT OF SICKLE CELL DISEASE

- Sickle cell disease (SCD) is a group of inherited disorders of haemoglobin (Hb) synthesis, first described in the medical literature by James Herrick in 1910.
- Each year about 300,000 infants are born with SCD, including more than 200,000 cases in sub-Saharan Africa alone.
- In Ghana, approximately 2% of newborns have SCD (corresponding to ~16,000 infants with SCD born per year), 98% of whom are genotypes SS and SC.

BARRIERS TO NEWBORN SCREENING

- In resource-rich countries, SCD newborn screening (NBS) performed in centralized laboratories has led to substantial reduction in SCD mortality. SCD NBS requires sensitive detection of low levels of certain haemoglobin (Hb) variants (i.e., sickle Hb, HbS) in presence of high levels of other Hb variants (i.e., fetal Hb, HbF).
- The current centralized tests used for NBS for SCD use high performance liquid chromatography (HPLC) and isoelectric focusing.
- However, in sub-Saharan Africa and central India, where >90% of SCD births occur, implementation of NBS programs has been challenging due to the cost as well as technical and logistical burden.
- There remains a need for affordable, portable, user-friendly and accurate point-of-care (POC) diagnostic tests to facilitate decentralized Hb testing in limited-resource settings for enabling nationwide NBS.

Figure 1. Korle Bu Teaching Hospital, the largest public hospital in Ghana

GAZELLE POINT-OF-CARE TECHNOLOGY

- The rugged, lightweight, battery-powered Gazelle™ Diagnostic Device can withstand high temperatures and humidity.
- Health workers can easily take Gazelle to any point-of-care testing site.
- Hemoglobin types and percentages, as well as interpreted results, are displayed onscreen within 8 minutes, and available in a detailed patient report.
- Gazelle stores test results locally, along with patient data and GPS location. Data can be uploaded to cloud applications for storage or connection to other databases.

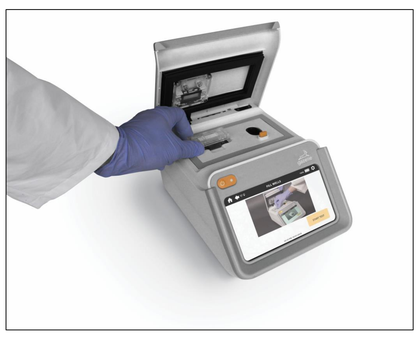
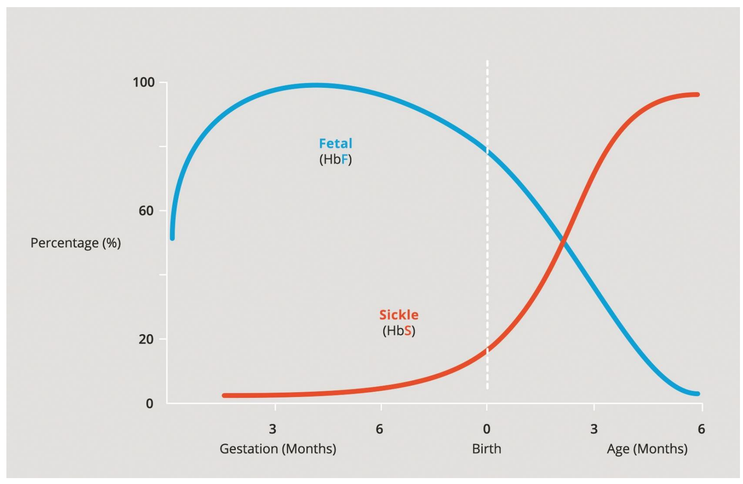


Figure 2 (left). The Gazelle Diagnostic Device

Figure 3 (below): Hemoglobin production during prenatal and postnatal periods, demonstrating the decrease in fetal Hb and rise in sickle Hb over time



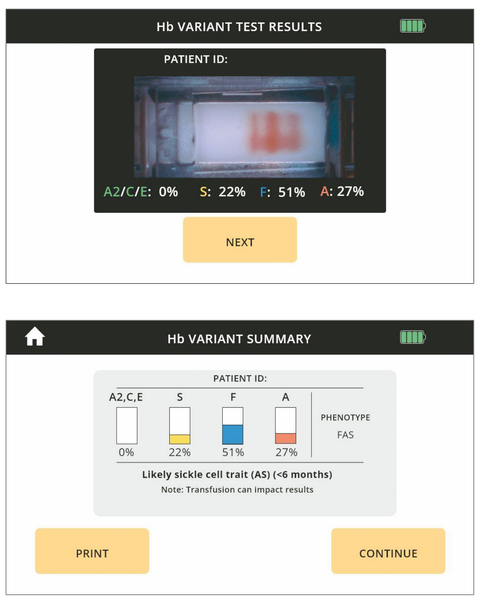


Figure 4: Gazelle test results for an infant with high HbF and sickle cell trait. Infants with the sickle cell mutation have a small concentration of Hb S present at birth. Gazelle can detect very low levels of Hb S, enabling testing of infants born as early as 37 weeks.

METHODS

- A total of 379 newborns were enrolled in the study from the postnatal ward of the Department of Obstetrics and Gynecology at Korle Bu Hospital, Accra, Ghana, which handles about 8,000 deliveries a year.
- Blood samples were collected via heel prick, tested on the Gazelle™ Diagnostic Device, and compared to High-Performance Liquid Chromatography (HPLC).

RESULTS

- Gazelle yielded high diagnostic accuracy for all Hb variants compared to standard laboratory tests (HPLC).
- Sensitivity was 100% for disease vs. normal and disease vs. trait, and 96.6% for trait vs. normal.
- Specificity was 99.7% for disease vs. normal, 100% for disease vs. trait and 95.3% for trait vs. normal.
- The Gazelle Hb Variant test displayed an overall diagnostic accuracy of 98.4% in comparison to reference standard methods for all Hb variants.

Statistical Data	Disease vs Normal	Disease vs Trait	Trait vs Normal
True Positive	4	4	56
False Positive	0	0	0
True Negative	500	500	500
False Negative	0	0	0
Sensitivity	100.00	100.00	100.00
Specificity	100.00	100.00	100.00
Accuracy	100.00	100.00	100.00

Chart 1. Summary of true positive, true, negative, false positive, false negative, sensitivity, and specificity of the clinical testing among 379 subjects conducted at Korle Bu Teaching Hospital, Korle Bu, Ghana

CONCLUSION

- Gazelle enables cost-effective and rapid identification of common Hb variants in newborns at the point of care.
- Overall, Gazelle is a versatile system that enables affordable, accurate, rapid, decentralized NBS for SCD in resource-limited settings where the prevalence of SCD is high.

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