Background: Sickle cell disease (SCD) is highly prevalent in sub-Saharan Africa; however, resources for accurate diagnosis and treatment are largely unavailable. Prior to December 2014, neither neonatal screening nor standardized methods for SCD diagnosis were routinely available in Malawi.

Methods: We initiated alkaline hemoglobin electrophoresis (HbE) for SCD diagnosis in the capital city of Lilongwe in November 2014. Alkaline HbE is an affordable and reliable diagnostic test for hemoglobinopathies including SCD. Site-specific standard operating procedures and protocols were developed and incorporated into an existing laboratory facility maintained by UNC Project Malawi, a 20 year old collaboration between the Malawi Ministry of Health and UNC. An imperative of this work was to train local Malawian laboratory technicians and clinicians on how to use and interpret the test results to ensure long term viability of the test.

Findings: Between January and May 2015, a total of 137 sequential patients with clinically suspected SCD were enrolled. Of those enrolled, 117 patients were confirmed to have HbSS, two were HbAS, 12 were HbAA, and the diagnosis was uncertain in six patients. Of 125 children who were chronically cared for as SCD patients prior to enrollment, 107 (86%) were confirmed to have HbSS. Patients were principally from the central region of Malawi with most living within the Lilongwe city limits. However, 9% of patients presented from non-Lilongwe districts and some patients were from up to 500 km away. Alkaline HbE easy to set up and operate, inexpensive compared to other gold standard tests, and reliably delivered prompt and clinically meaningful results to patients and clinicians. We found that HbE was easily accommodated within existing UNC Malawi laboratory infrastructure. Our estimates put the cost per test at 3-4 USD, accounting for equipment and reagents but not indirect costs such as electricity, space, and personnel.

Interpretation: The implementation of decades-old technology now provides a foundation for future studies to understand the natural history of SCD in Malawi and develop intervention strategies appropriate for the setting to improve outcomes.

Funding: UJMT Fogarty Global Health Fellows Program (grant #R25TW009340), The Medical College of Georgia at Georgia Regents University, Augusta, Georgia, 3University of North Carolina, Chapel Hill, North Carolina