सत्यमेव जयते
Department of Health Research
Ministry of Health and Family Welfare
Government of India

Rapid Health Technology Assessment of Gazelle for Sickle Cell Disease/Trait diagnosis among high-risk population in India

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RECOMMENDATIONS

- Gazelle is a highly sensitive Point of care (POC) test for screening Sickle cell disease (SCD) with confirmation of all positive cases with HPLC test at public healthcare settings.
- At current price of Gazelle machine (INR 2.5 lakhs) and per kit price (INR 180), the cost per case detected using Gazelle followed by confirmation with HPLC is INR 19062.64 as compared to Solubility test with HPLC which is INR 7762.29
- Even though the cost of Gazelle is high, in the study cohort, Gazelle detected 37365 more cases of SCD compared to the Standard of Care (SOC), Solubility test followed by confirmation with HPLC.
- The total health system costs of the screening program at public healthcare settings for Gazelle followed by confirmation with HPLC at current price would be INR 1271.93 crores. The health system costs for the comparator Solubility test with confirmation by HPLC is INR 488.92 crores.
- The marginal costs of implementing the screening program for Gazelle followed by confirmation with HPLC for a cohort of 39954483 is estimated to be INR 1040.00 crores and for Solubility test followed by confirmation with HPLC would be INR 322.03 crores.
- At INR 40 per test kit and INR 90,000 cost of Gazelle machine the cost per case detected of Gazelle with confirmation by HPLC would be at par with the existing cost of Solubility followed by confirmation with HPLC

BACKGROUND

- Sickle Cell Disease (SCD) is a common genetic disorder prevalent in states of India's central region such as Madhya Pradesh, Chhattisgarh, Bihar, Odisha, Gujarat, Maharashtra Tamil Nadu, and Karnataka. SCD is most frequent among tribal communities.
- The National Sickle cell elimination mission (2023) aims to eliminate SCD as a public health problem in India before 2047. The prevention strategy of universal screening and early detection is a part of the objectives of this mission.
- Solubility test followed by confirmation with Electrophoresis/HPLC is the standard screening modality in public healthcare settings.
- Several Point of Care tests such as Hemotype Sc, Sickle Scan and Sickle CERT have been introduced in India that can differentiate between disease or trait and sickle- β-thalassemia.
- Gazelle, is a HemeChip cellulose acetate paper-based microchip electrophoresis system consisting of a Gazelle reader and Cartridge manufactured by Hemex Health India (Rajashthan).
- Gazelle is also one of the POC test that it capable of differentiating between disease or trait and sickle- β-thalassemia. The sensitivity for Gazelle test is 100% and its specificity is 99%.
- A Health Technology Assessment was recommended to be carried out to assess the cost per case screened and detected for Gazelle in screening for sickle cell disease/trait.

AIM

- To conduct an Health Technology Assessment on Gazelle for screening for Sickle cell disease/ traits.

PURPOSE

- To collate evidence on clinical-effectiveness of Gazelle vs Solubility test followed by confirmation with HPLC to diagnose sickle cell trait/disease
- To estimate cost of test per case screened and detected using Gazelle
- To assess the health system costs of using Gazelle for facility-based screening

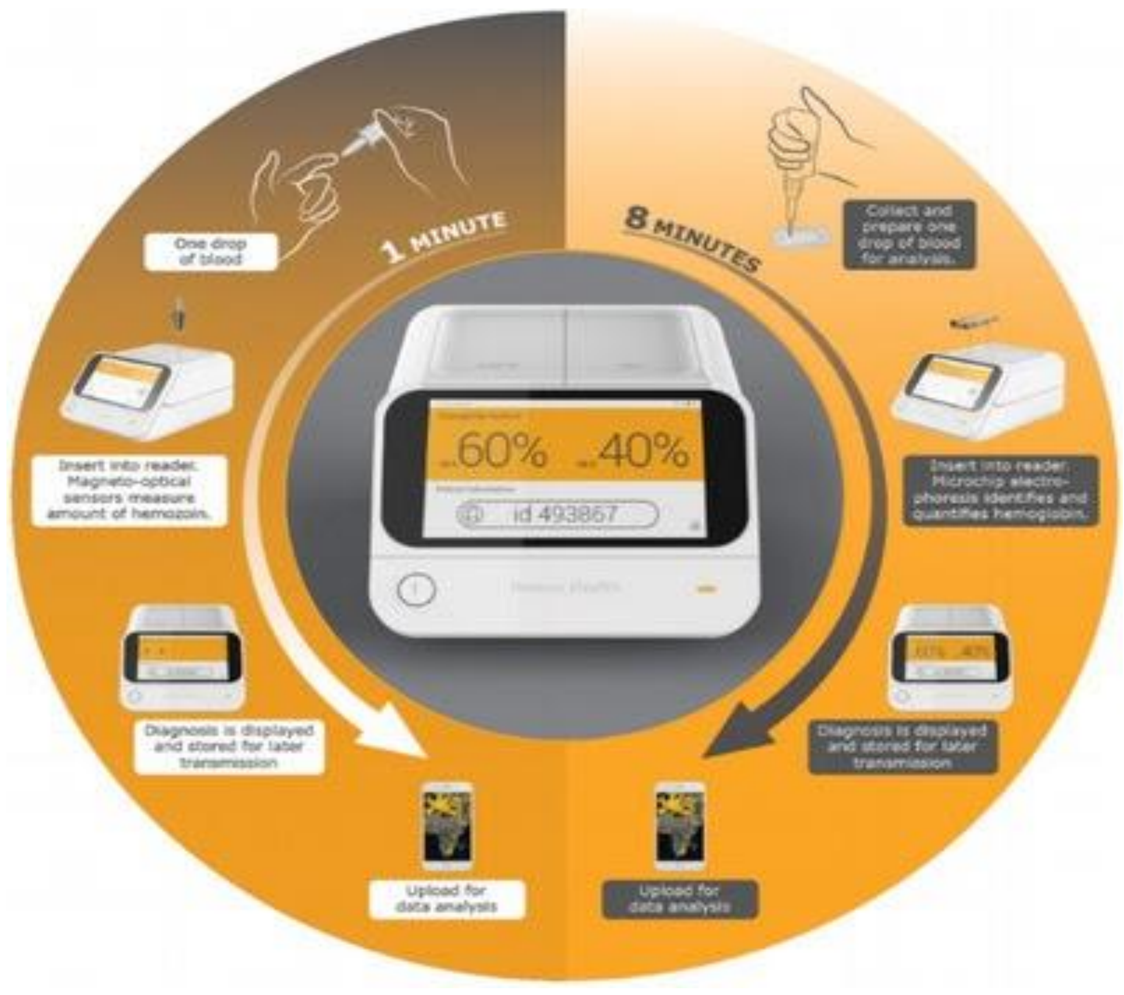

Figure 1: Representation of the Gazelle test

METHODS

- A rapid economic assessment was conducted to estimate the cost per case screened, cost per case detected, number of cases detected, and number of cases undetected using Gazelle with confirmation by HPLC compared with (SOC) Solubility test at primary and secondary level followed by confirmation with HPLC and HPLC alone at tertiary level.
- A tribal population cohort from 6 weeks to 40 years from six endemic states (Madhya Pradesh, Maharashtra, Gujarat, Tamil Nadu, Odisha and Chhattisgarh) was considered.
- Sensitivity Analysis was done to ascertain the upper and lower limits of the outcomes.
- The health system costs for implementing the screening program and the marginal costs of Gazelle and Solubility test for screening of SCD were also determined.
- The costs of the Gazelle machine and kit test were varied to identify the cost per case at the willingness to pay threshold.

RESULTS

- The Gazelle test followed by confirmation with HPLC test detected 37,365 additional cases as compared to the standard of care (SOC) of Solubility followed by confirmation with HPLC for SCD screening.
- Among the 6,67,239 SCD individuals, Gazelle could detect all the true positive cases as compared to SOC which had 37,365 cases undetected. The Gazelle test also detected 392872 false positive which were excluded through confirmatory test by HPLC.
- At current price of the Gazelle machine INR 2.5 lakhs and per kit INR 180, the estimated cost per case detected for Gazelle followed by confirmation with HPLC is INR 19,062 and for Solubility followed by confirmation with HPLC is INR 7,762.
- The total health system cost of the screening program at public healthcare settings for Gazelle with confirmation by HPLC would be INR 1271.93 crores. The health system cost for the comparator Solubility test with confirmation by HPLC is INR 488.92 crores.
- The marginal costs of implementing the screening program for Gazelle followed by confirmation with HPLC are estimated to be INR 1040.00 crores and with Solubility test with confirmation by HPLC would be INR 322.03 crores.
- At INR 40 per test kit and INR 90,000 cost of Gazelle machine the cost per case detected of Gazelle with confirmation by HPLC would be at par with the existing implementation program cost of Solubility followed by confirmation with HPLC.

Table 1: Outcomes for screening program of SCD in India

Parameters	Values (All cost in INR)
Cost per case screened	
Gazelle + HPLC	**INR 318.35** (158.86, 474.62)
Solubility + HPLC	**INR 122.37** (60.00, 181.90)
Cost per case detected	
Gazelle + HPLC	**INR 19062.64** (9565.08, 28229.49)
Solubility + HPLC	**INR 7762.29** (3691.15, 11839)
Additional number of cases detected by Gazelle + HPLC vs Solubility + HPLC	**37365.43** (18809.05, 56400.91)

Table 2: Health system and marginal costs for screening program of SCD in India

Parameters	Gazelle + HPLC	Solubility + HPLC
Health system costs of rolling out the screening program	**INR 1271.93 crores**	**INR 488.92 crores**
Marginal costs for rolling out the screening program	**INR 1040.00 crores**	**INR 322.03 crores**

Table 3: Health system and marginal cost for screening program of SCD in India

Gazelle Machine cost (INR)	Kit cost (INR)	Cost per case detected (INR)	Marginal Cost of rolling out Gazelle (INR)
250000	180	19062.64	1040.00 crores
240000	160	17672.71	947.26 crores
220000	120	14892.84	761.77 crores
200000	90	12711.77	616.25 crores
150000	70	10552.52	472.17 crores
90000	**40**	**7602.13**	**275.31 crores**

CONCLUSIONS

- HPLC is the gold standard for sickle cell disease screening but access to this strategy for mass screening is limited. Gazelle has performance efficiency similar to HPLC. In comparison with HPLC, Gazelle takes less time to obtain the results. The cost for the machine is also less than HPLC. Gazelle does not require the expertise for performing and interpreting the test as it is required for HPLC. Therefore, a public health facility-based screening of high risk populations with Gazelle as a POC test would improve access to screening using a highly sensitive test.
- This test can also be used to diagnose thalassemia. It is essential to plan a multi-centric study for further evaluation on the application of Gazelle for screening neonates for SCD and diagnosis of thalassemia.