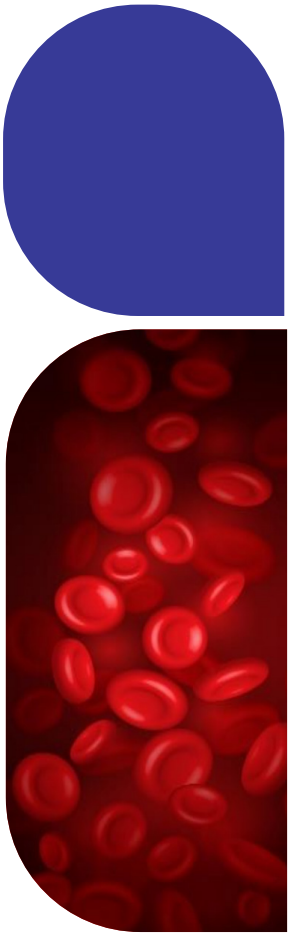
Landscape for sickle cell disease testing



Diagnosis of sickle cell disease: Landscaping of available and upcoming POCs in India to detect sickle cell disease

2025

NOVARTIS

PATH

Acknowledgement

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This landscape document is a testament to the collective efforts and shared commitment of all contributors to improving the health and well-being of individuals with sickle cell disease. We hope it will significantly enhance diagnostic services and create new opportunities to advance diagnostic technologies for sickle cell disease in India and globally.

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Abbreviations

AI	artificial intelligence
ASH	American Society of Hematology
CBC	complete blood count
CONSA	Consortium on Newborn Screening in Africa
CSIR CCMB	Council of Scientific and Industrial Research-Centre for Cellular & Molecular Biology
DBS	dried blood spot
GeM	Government e Marketplace
HbF	fetal hemoglobin
HbS	hemoglobin S
HPLC	high-performance liquid chromatography
ICMR	Indian Council of Medical Research
IISc	Indian Institute of Science
IIT	Indian Institute of Technology
LFA	lateral flow assay
MOHFW	Ministry of Health and Family Welfare
NHM	National Health Mission
NSCAEM	National Sickle Cell Anemia Elimination Mission
PCR	polymerase chain reaction
POC	point-of-care
POCT	point-of-care test
RBC	red blood cells
RBSK	Rashtriya Bal Swasthya Karyakram
SCD	sickle cell disease
SSA	Sub-Saharan Africa
TCD	transcranial doppler
WHO	World Health Organization
WHO EDL	World Health Organization List of Essential Diagnostic Tests
WHO PEN	World Health Organization Package of Essential NCD

01 Introduction

Sickle cell disease (SCD) is one of the most common, inherited, monogenic, autosomal recessive disorders worldwide. It is caused by a mutation in the hemoglobin gene that produces sickle hemoglobin (HbS). This mutation causes red blood cells (RBCs) to lose their normal disc shape and become rigid and C-shaped (sickle-shaped), reducing their flexibility. These abnormal cells can block small blood vessels, hindering blood and oxygen flow to different parts of the body. Normal RBCs live about 120 days, while sickle cells survive only 10–20 days.

The primary pathophysiology of SCD stems from the polymerization of deoxygenated HbS, which forms long fibers that distort RBCs into a sickle shape. These rigid cells break down easily and block small blood vessels, causing chronic anemia and reduced oxygen delivery. The spleen removes these abnormal cells, thereby increasing the risk of infection and leading to splenic damage. This results in complications such as anemia, pain episodes, infections, and long-term organ damage.

SCD is more commonly found in people from tropical regions, particularly Sub-Saharan Africa (SSA), India, and the Middle East, which are endemic for malaria (1). The disease is found with equal frequency in males and females. The sickle cell gene is present in many states across India, with prevalence ranging from 9.4% to 22.2% in endemic areas (1).

Types of sickle cell syndromes

The most common types of sickle cell hemoglobinopathies are HbSS, HbS β-thalassemia, and sickle cell carrier/trait.

- **HbSS:** People with the HbSS form of SCD inherit sickle cell genes (“S”) from both parents, and both β-globin genes carry the mutation. It is the most severe type, with HbS accounting for up to 90% of the total hemoglobin. This condition is commonly called sickle cell anemia/disease.
- **HbS β-thalassemia**: People with this form of SCD inherit one sickle cell gene (“S”) from one parent and a gene for β-thalassemia, another type of hemoglobinopathy, from the other parent. Those with HbS β-thalassemia usually have a severe form of SCD.

Other genotypes requiring specific attention in the Indian context include HbE and HbD. In addition to these sickle syndromes, some individuals inherit one sickle gene from one parent and a normal gene from the other. These individuals are called sickle cell carriers or have the sickle cell trait, and they are typically asymptomatic.

Clinical symptoms and the need for early diagnosis

SCD presents with a broad spectrum of clinical manifestations, including severe anemia, painful vaso-occlusive crises, recurrent infections, and organ damage affecting the brain, lungs, liver, and kidneys. It can result in life-threatening complications such as acute chest syndrome and stroke. Mortality remains high in low- and middle-income countries, where health awareness is low and access to timely diagnosis and care is often scarce. Delayed or missed diagnosis frequently causes avoidable suffering, disability, and death. Evidence shows that early diagnosis, especially through newborn screening combined with appropriate clinical management, can significantly reduce morbidity and mortality and improve quality of life (2).

Recognizing this, the World Health Organization (WHO) and the United Nations have emphasized early diagnosis and access to comprehensive care as essential priorities in the global fight against hemoglobinopathies, as outlined in the WHO SCD factsheets. In India, the National Sickle Cell Anemia Elimination Mission (NSCAEM) supports this vision by promoting mass screening, especially in high-burden regions. However, programmatic screening efforts need to be complemented by strategies to build clinical capacity for early and accurate diagnosis to bridge the large number of undiagnosed individuals and prevent complications.

In 2006, the WHO recognized SCD as a global health problem. Two years later, the 63rd United Nations Assembly designated June 19 as the “World Sickle Cell Day”, in an attempt to improve public awareness of the disease and the prospects for patients (3).

The WHO in the African region released groundbreaking new guidance to help strengthen efforts to address the growing threat of SCD in the area on June 19, 2024 (4). The new WHO Africa guidance documents, titled “Guidance Framework for Sickle Cell Disease Management” and "Harmonized Guide for Sickle Cell Disease Management in Africa” form the WHO SICKLE Package of Interventions for Sickle Cell Disease Management (5, 6). These modules advocate early diagnosis through neonatal screening and prompt treatment through a comprehensive care package, which includes starting treatment with hydroxyurea from about the first year of life (6).

The United States has a mandatory newborn screening program for SCD, which enables early diagnosis and referrals to suitable providers, dramatically improving health outcomes (7).

The American Society of Hematology (ASH) established the Consortium on Newborn Screening in Africa (CONSA), which includes seven countries in SSA: Liberia, Ghana, Kenya, Zambia, Nigeria, Uganda, and Tanzania, to implement standardized newborn screening and early clinical management for children with SCD. This screening program was found feasible despite resource constraints and high SCD burden (8, 9).

This should motivate other nations with high rates of SCD prevalence to strengthen early diagnosis through newborn screening.

The WHO sickle module recommends routine blood tests, including a complete blood count (CBC) to assess hematological status, a peripheral smear to identify sickle cells, a solubility test, a sickling test, and a point-of-care test (POCT) for screening. Confirmatory diagnosis should be done with hemoglobin electrophoresis or high-performance liquid chromatography (HPLC).

As per these modules, SCD treatment should be integrated into existing health care programs such as immunization, HIV, sexual and reproductive health, maternal, newborn and child health, among others, to achieve universal health coverage in an equitable and cost-effective way. The WHO African region proposed that SCD management in SSA be fully integrated into the WHO Package of Essential NCD (PEN) interventions and PEN-Plus (6).

The Ministry of Health and Family Welfare (MoHFW) has consistently made efforts to develop a control program for hemoglobinopathies in India. In 2016, the MoHFW released detailed guidelines on prevention and control of hemoglobinopathies in the country (10). To further address the burden of SCD, the MoHFW launched the NSCAEM in July 2023 to **eliminate sickle cell as a public health problem by 2047** (11). The mission aims to screen 7 crore (70 million) people from high-burden states/districts across the country for SCD. It also seeks to improve the quality of life and life expectancy of those affected and prevent new cases. To succeed, screening activities must be conducted with a focus. Sickle cell screening and diagnostics need to be scaled up to achieve this goal.

Traditional screening and confirmatory diagnosis tools and tests are available nationwide. However, emerging technologies and innovations have significantly improved sickle cell screening and diagnosis. The process has evolved from a two-step screening and diagnosis process to a one-step approach, bringing diagnosis closer to the community and improving screening efficiency. Several new diagnostic tests are now available in the market.

Purpose of the landscaping document

This document aims to serve as a practical resource for public health program managers, policymakers, administrators, and other stakeholders involved in addressing SCD in India and globally. It highlights a range of technologies available for SCD screening and diagnosis, with particular emphasis on POCTs. The document lists and summarizes the salient features of various technologies and shares insights from experiences of using POCTs, thereby creating a platform for open discussion of their relevance and potential role in advancing these technologies and achieving the goal of eradicating sickle cell anemia.

Evolution of the document

Initially designed as a repository, this document has developed into a comprehensive landscape analysis of sickle cell diagnostics, focusing on POCTs. It relies on the Indian Council of Medical Research (ICMR)-validated technology lists as its foundation and incorporates insights from extensive global literature reviews and discussions with experts and innovators.

Each diagnostic test kit has been carefully examined for details such as the manufacturer's information, underlying techniques, cost, sensitivity, specificity, and published data on their use in both Indian and global contexts.

To evaluate reliability and provide recommendations for the use of POCT kits, experts were consulted, and WHO modules for SSA were reviewed. Meetings with several innovators offered valuable insights into emerging technologies. These innovations were further guided through the ICMR validation process.

The document currently lists 29 technologies, with most (approximately 22) being lateral flow assays (LFA). Among these are the Heethox multi-strip-based assay, which provides results for various sickle gene variants.

Beyond LFA-based technologies, the landscape also encompasses other diagnostic approaches, including automated smear preparation, smear microscopy, artificial intelligence (AI)-enabled mobile applications, microchip-based electrophoresis, and optical spectroscopy.

02 Diagnosis of sickle cell disease

Sickle cell can be diagnosed using various methods. Its evaluation involves a series of tests that determine the presence and relative amounts of sickle hemoglobin for screening and diagnosis of SCD. To determine the hemoglobin type present in a blood sample (HbSS or HbAS), the standard practice is to use two analytical methods on each sample. The first method is a two-step approach that includes screening at the primary health center and field level, followed by confirmatory testing at higher-level centers using HPLC, electrophoresis, or polymerase chain reaction (PCR) if the first step detects an abnormality.

In recent years, however, technological advancements have introduced single-step, POC testing solutions that can offer near-confirmatory results at the field level. These portable, easy-to-use kits are particularly relevant in the Indian context, where logistical challenges, limited infrastructure, and workforce constraints can hinder timely diagnosis (12).

In public health programs, decisions regarding two-step or one-step approaches should be based on resources, accessibility, costs, and ease of operation.

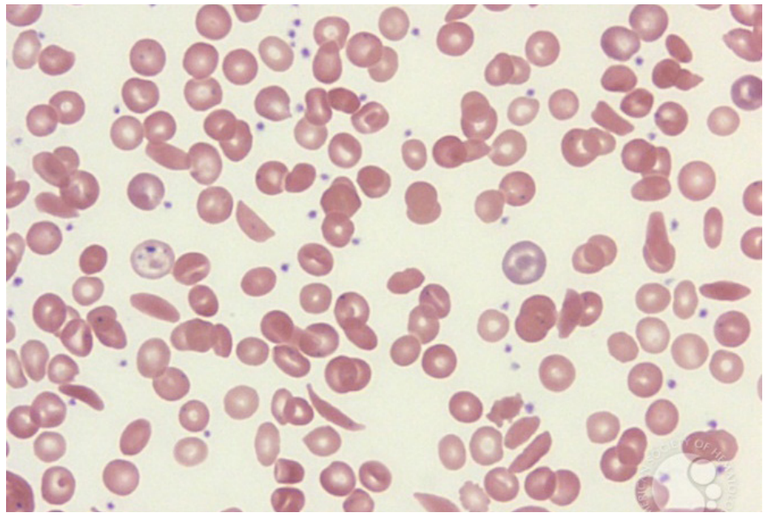


Figure 1. Peripheral smear showing sickle-shaped RBCs (12).

Table 1 lists various types of tests used for the diagnosis of SCD, with their advantages and limitations (1.11). These tests can be used at various levels and for different purposes.

Table 1. List of sickle cell diagnostic tests.

S. no.	Type of test/ technology	Screening/ confirmatory	Advantages	Limitations
1.	**Peripheral smear** Smear shows sickle-shaped RBCs, Howell-Jolly bodies indicative of asplenia	Can be used to screen for suspected individuals or for a preliminary diagnosis of sickle cell disorder	- Easily available - Can help in the preliminary diagnosis of sickle cell disorder in limited resource settings	- Needs trained human resources to be able to visualize sickle-shaped RBCs - Cannot differentiate between trait and disease - Need further confirmation with HPLC/ electrophoresis for definitive diagnosis of SCD
2.	**Sickling test** The addition of sodium metabisulfite induces sickling of RBCs, on the blood film (positive sickling test)	Screening	- Easily available at all levels of health care - Easy interpretation - Good for mass screening activities	- Cannot differentiate between trait and disease, needs a confirmatory diagnosis with HPLC/ electrophoresis - High false positive results
3.	**Hemoglobin solubility testing** Test tube-based turbidity test. HbS is an insoluble hemoglobin molecule. It forms crystals in the buffer and produces turbidity in sickle cell cases	Screening Used as a screening test under NSCAEM	- Easily available at all levels of health care - Rapid test (takes 5 min) - Reliable with straightforward interpretation and minimal observer variation - Cost-effective - Good for mass screening activities	- Chances of human error - Cannot differentiate between trait and disease and needs a confirmatory diagnosis with HPLC/ electrophoresis - At the field level, sensitivity and specificity are variable due to factors like incorrect reading/ interpretation of results, due to lack of proper training of staff, quality check, and maintenance of buffer solution, etc.
4.	**Electrophoresis*** It analyzes different types of hemoglobin in the blood. It can be of three types: gel, capillary, and isoelectric focusing	Confirmatory	- Provides confirmatory diagnosis - Can differentiate between sickle cell trait and disease - Can quantify various types of hemoglobin present	- Require trained technicians and a laboratory set up, usually available at secondary care facilities. - The cost per test may be higher compared to screening tests
5.	**High-performance liquid chromatography*** It analyzes different types of hemoglobin in the blood and provides confirmatory, quantitative results	Confirmatory Used as the confirmatory test under NSCAEM	- Provides a confirmatory result - Quantifies HbF and HbA2 along with detecting other variants in a single test - Sensitive, specific, reproducible, less time-consuming, and requires less human resources	- Requires trained professionals and a well-established lab set-up - Can be available at secondary and above levels - May require sample transportation logistics for ensuring testing - Cost per test may be higher compared to screening tests
6.	**Molecular testing*** Beta globin gene (HBB) analysis using deoxyribonucleic acid sequencing or PCR	Confirmatory	- Provides a confirmatory diagnosis for both sickle cell trait and disease	- Requires trained professionals and a PCR laboratory - At the moment limited to detecting sickle disease. Detection of β-thalassemia is being researched

*The cost per test for electrophoresis, HPLC, and molecular tests depends on logistics, equipment availability, and access to trained human resources.

After diagnosing the disease, tests such as abdominal ultrasound, pulmonary function tests, renal function tests, urinary microalbumin-to-creatinine ratio, ophthalmologic examination, transcranial Doppler (TCD), and serum ferritin may be needed at appropriate intervals to monitor treatment and detect complications early (5, 14).

Figure 2. Solubility testing.

Figure 3. Hb electrophoresis machine assembly.

Note: This is a representational image

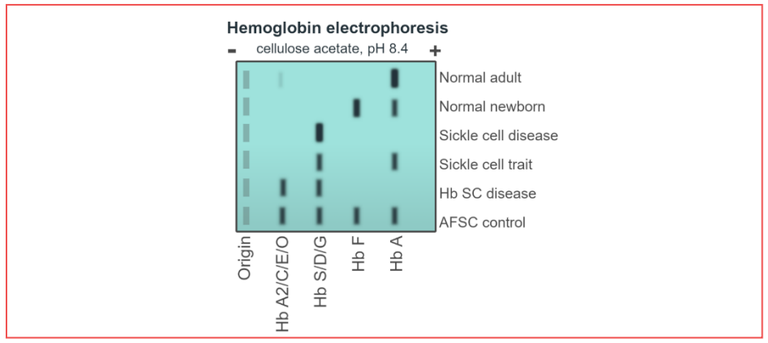


Figure 4. Hb electrophoresis.

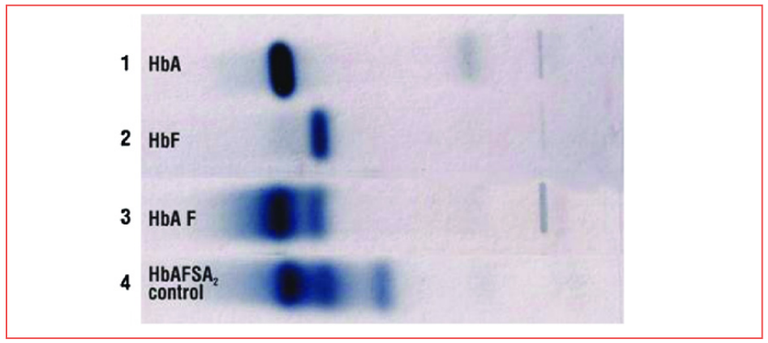


Figure 5. Alkaline gel hemoglobin electrophoresis.

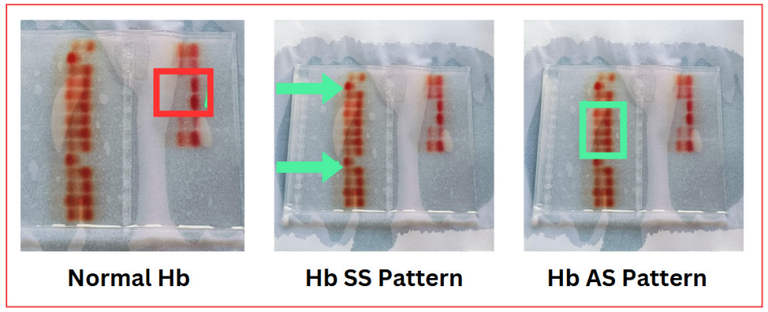


Figure 6. Hb pattern in gel electrophoresis.

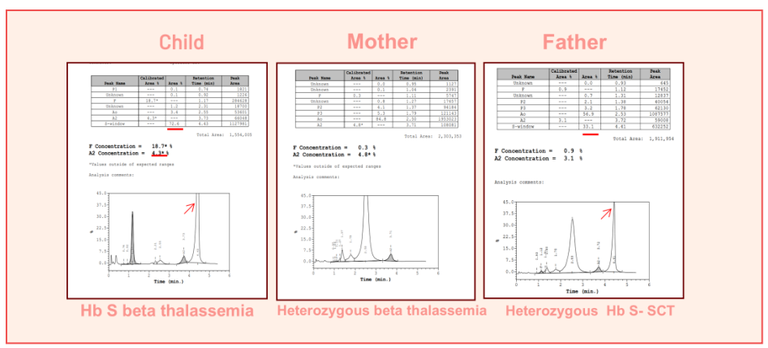


Figure 7. HPLC graph.

03 POCT for sickle cell disease

The NSCAEM aims to screen 70 million individuals for SCD over three years. However, the screening activities in the field face significant challenges due to systemic and contextual factors. The country's vast and diverse population, with a high burden of hemoglobin disorders among tribal and socioeconomically disadvantaged non-tribal communities, complicates screening and management. Many affected regions are remote, with poor road access and limited health care services. Seasonal migration further disrupts continuity of screening, confirmatory diagnosis, follow-up care, and ongoing treatment. Tackling these geographic and demographic challenges requires customized solutions to ensure comprehensive health care delivery.

The health system often lacks the capacity to address these challenges effectively, and there is a shortage of trained health care personnel, particularly in rural and tribal areas with the highest disease burden. Inadequate diagnostic infrastructure leads to repeated blood tests due to improper sample collection when relying on traditional laboratory-based diagnostics. Additionally, logistical challenges in transporting samples from remote locations to central laboratories contribute to delays. The multi-step diagnostic process, which requires follow-up visits for confirmatory testing, often results in significant loss to follow-up, delaying timely clinical decision-making and treatment initiation.

POC technologies offer practical solutions to many of these barriers. These portable diagnostic tools enable quick, on-site testing, reducing reliance on centralized laboratories and minimizing logistical challenges. By delivering fast, same-day results, POC devices decrease patient dropouts and support timely detection and early treatment. Their minimal infrastructure requirements make them ideal for remote settings, and frontline health care workers can be easily trained to operate them, thereby expanding diagnostic coverage in hard-to-reach areas.

Decentralizing diagnostics with POC technologies helps improve access and capacity gaps, promoting health equity in under-resourced settings. As health care systems evolve, integrating POC testing into routine care pathways has the potential to change how hemoglobinopathy screening and management are done, fostering a more inclusive public health approach.

POC testing for SCD

POCT for SCD involves conducting tests at the point of patient care, enabling quick diagnosis with faster turnaround times compared to conventional lab-based testing (15). These tests are often card-based kits, making them easy to use in remote or resource-limited settings. The cost of such tests is generally low, typically up to INR 100 per test, though it may vary depending on the quantity procured and economies of scale. They can be obtained through government platforms like the GeM (Government e Marketplace) portal or other authorized suppliers, ensuring affordable and accessible diagnostic options for broad community screening and early intervention.

Advantages

The advantages of POCT are as follows:

- Can be used for door-to-door mass screening activities
- No laboratory set-up required, quick card-based test
- Can be performed by frontline health workers
- Can differentiate between sickle cell trait and disease
- Single test with high sensitivity and specificity

Limitations

The following are the limitations of POCT:

- May provide false positive results in individuals who have had a recent blood transfusion
- Variability in results observed across different geographies
- Requires confirmatory diagnosis with HPLC/electrophoresis before starting treatment

According to the NSCAEM guidelines, ICMR-validated POCTs can be used as a one-step confirmatory test for sickle cell for mass screening. However, the vast array of POC kits available in the market presents a significant challenge for state health authorities in selecting the most accurate and reliable option. Several critical factors must be carefully considered before adopting any POCT kit as a confirmatory test, especially when considering its use as a replacement for electrophoresis, which is currently the confirmatory test for sickle cell diagnosis (16).

04 POC landscaping

An extensive landscape analysis was conducted to identify POCTs designed for diagnosing SCD. This analysis provided a detailed assessment of various devices and technologies, examining key parameters such as brand and manufacturer names, sensitivity, specificity, the ability to detect carrier and disease states, market availability, regulatory approvals, and the underlying technology used for hemoglobin measurement.

A total of 29 POCTs were identified (refer to Table 2), leveraging different diagnostic principles. Most of these tests rely on lateral flow technology, either through immunoassays or chromatography for detection. Notably, some tests employ smear microscopy, including one developed by Indian Institute of Technology (IIT) Bombay. Additionally, Indian Institute of Science (IISc) Bangalore, in collaboration with Shanmukha Innovations, has introduced the Sickle Cert rapid diagnostic kit, which uses optical spectroscopy.

Some POCTs, like HemoType SC, Sickle Scan, VoxPress Rapid Kit, and Alpine Sickle Screen, can detect hemoglobin variants, including HbC, in addition to HbA, HbS, and HbF (fetal hemoglobin). This wider detection enhances their use in global markets. For instance, Hemotype SC is approved in the European Union, Saudi Arabia, Ghana, Sierra Leone, and Tanzania, and is included in the WHO's Essential Diagnostics List (WHO EDL) 2021.

Most of these POC kits have been validated by the ICMR for diagnostic accuracy, with sensitivity and specificity exceeding 98% during the validation process. Most of these tests can be easily administered by field workers with proper training, without requiring expert laboratory technicians. This ease of use, along with low infrastructure requirements, makes these kits ideal for mass screening efforts, particularly in resource-limited settings where advanced techniques such as electrophoresis are unavailable.

It is important to recognize that, while some kits have shown promising results, the sample sizes and methodologies vary. Ongoing evaluations are necessary to confirm their reliability across diverse populations and settings. Proper training of field workers is essential before using the POCT to prevent errors.

Table 2. POCT kit repository.

S. no.	Test name	Type of test	ICMR validation (Yes/No)	Stage of development	Sensitivity (%)	Specificity (%)	Spectrum of diagnosis (SCD/SCT)		Level of automation	Type of human resource needed	Deployment experiences/ published study	Cost reference	Information leaflet links
1	HemoType SC by Silver Lake Research Corporation	Lateral flow immunoassay incorporating monoclonal antibodies	Yes	Available in the market	98.1	99.1	HbSS and trait		NA	Can be used by a field-level worker	https://academic.oup.com/ajcp/article/153/1/82/5552705?login=-false	https://www.indiamart.com/proddetail/hemotype-sc-rapid-card-test-for-sickle-cell-disease-25860211133.html	https://www.hemotype.com/
2	Sickle Scan by Biomedomics Inc.	Lateral flow immunoassay incorporating monoclonal antibodies	Yes	Available in the market	>92.4	>99.1	HbSS and trait		NA	Can be used by a field-level worker	https://ashpublications.org/blood/article/128/22/1308/96109/Hemoglobin-S-Screening-Using-the-Sickle-Scan	https://www.indiamart.com/proddetail/sicklescan-20-test-27600329691.html	https://www.biomedomics.com/products/hematology/sicklescan-2-2/
3	Meriscreen by Meril Diagnostics Pvt. Ltd	Lateral flow immunoassay incorporating monoclonal antibodies	Yes	Available in the market	100	100	HbSS and trait		NA	Can be used by a field-level worker	-	-	-
4	Sickle Check by Tulip Diagnostics	Lateral flow immunoassay incorporating monoclonal antibodies	Yes	Available in the market	98.1	99	HbSS and trait		NA	Can be used by a field-level worker	-	-	https://www.tulipgroup.com/PDFs/Rapid_Tests/IFU/SICKLECHECK-IFU.pdf
5	Voxpress Rapid Kit by Voxtur Bio Ltd	Lateral flow immunoassay incorporating monoclonal antibodies	Yes	Available in the market	100	100	HbSS and trait		NA	Can be used by a field-level worker	-	-	https://sicklecelltest.in/
6	Alpine Sickle Screen Rapid Test by Alpine Biomedical Pvt Ltd	Lateral flow immunoassay incorporating monoclonal antibodies	Yes	Available in the market	99	99	HbSS and trait		NA	Can be used by a field-level worker	-	-	https://alpinebiomedicals.com/product/sickle-scan-rapid-test/
7	Rapichex Sickle Cell Rapid Test by Paramcare Life Sciences Pvt. Ltd	Lateral flow immunoassay incorporating monoclonal antibodies	Yes	Available in the market	98.6	99	HbSS and trait		NA	Can be used by a field-level worker	-	https://www.indiamart.com/proddetail/rapichek-sickle-cell-rapid-test-kit-2851516576791.html	-
8	Navigene HB™ by Navigene Genetic Science Pvt. Ltd	-	Yes	-	99.2	99.2	-		-	-	-	-	-
9	Heethox-K Sickle Cell Rapid Test Kit by Heethox K Pvt. Ltd.	Lateral flow immunochromatography	-	Clinical trial being initiated. Ferretin test ready for market sale	>99	>99	Can read HbA, S, F, E, C, D, and ferritin levels		Automated reading and interpretation	Can be used by a field-level worker	-	-	-
10	Sickle CERT Rapid Diagnostic Kit by Shanmukha Innovations (IISc Bangalore)	High-performance optical spectroscopy	Yes, CDSCO approved	Available in the market	100	100	HbSS and trait		Automated reading and interpretation	Lab technician	-	https://www.indiamart.com/proddetail/sicklecert-sickle-cell-anemia-diagnostic-test-kit-2850264521562.html	https://sminnovations.in/sicklecert/
11	Sickle Cell Anemia Screening on Mobile Phone, IIT Bombay alumni initiative, by Neodocs Healthcare Pvt. Ltd	AI-enabled mobile application	Yes, CDSCO approved and ISO certified	-	-	-	HbSS and trait		-	-	-	-	-

S. no.	Test name	Type of test	ICMR validation (Yes/No)	Stage of development	Sensitivity (%)	Specificity (%)	Spectrum of diagnosis (SCD/SCT)		Level of automation	Type of human resource needed	Deployment experiences/ published study	Cost reference	Information leaflet links
12	Mediclone Biotech Sickle Cell Test Card by Mediclone Biotech Pvt. Ltd	-	-	Available in the market	-	>99%	Both		NA	Can be used by a field-level worker	-	-	-
13	Sickle Cell Rapid Test Kit by Biogenix Inc. Pvt. Ltd	Lateral flow immunochromatography	Yes	Available in the market	100	100	HbSS and trait		NA	Can be used by a field-level worker	-	https://www.indiamart.com/proddetail/sickle-cell-rapid-test-2851923555791.html	https://pdf.indiamart.com/impdf/2851923555791/MY-13815832/sickle-cell-rapid-test.pdf
14	Gazelle Sickle Cell Test by Hemex Health	Microchip-based electrophoresis	yes	Available in the market	98.9	98.9	Can read HbA, F, S		Automated reading and interpretation	Lab technician	-	https://mkp.gem.gov.in/poct-point-care-test-bio-markers/gazelle-reader-with-200-hb-variant-test/p-5116877-31695790765-cat.html#variant_id=5116877-31695790765	-
15	Biocard Sickle Cell Rapid Test Kit by Trivitron Healthcare	Lateral flow chromatography immunoassay	Yes	Available in the market	100	100	HbSS and trait		NA	Can be used by a field-level worker	-	https://mkp.gem.gov.in/point-care-rapid-test-kits-v2/sickle-cell-rapid-test-kit/p-5116877-25261422391-cat.html#variant_id=5116877-25261422391	https://www.trivitron.com/products/point-of-care-test/biocard-sickle-cell-rapid-test-kit
16	Erbaqik Sickle Cell Rapid Card (HbA, S, C) by Transasia Biomedicals	Lateral flow immunoassay incorporating monoclonal antibodies	Yes	Available in the market	100	100	HbSS and trait		NA	Can be used by a field-level worker	-	-	-
17	Sickle Cell Rapid Test Device by Bio Sci Healthcare	Lateral flow immunoassay incorporating monoclonal antibodies	Yes	Available in the market	100	100	HbSS and trait		NA	Can be used by a field-level worker	-	-	-
18	Sickle Cell Rapid Test Kit by Vimek Bioconcepts Pvt. Ltd.	Lateral flow immunoassay incorporating monoclonal antibodies	Yes	Available in the market	96.7	100	HbSS and trait		NA	Can be used by a field-level worker	-	-	-
19	Erbaqik Sickle Cell Rapid Card (without Hb C) by Transasia Biomedicals	Lateral flow immunoassay incorporating monoclonal antibodies	Yes	Available in the market	100	100	HbSS and trait		NA	Can be used by a field-level worker	-	-	-
20	Sickle Cell Rapid Test Kit by MyLab Discovery Solutions Pvt. Ltd.	Lateral flow immunoassay incorporating monoclonal antibodies	ICMR, CDSCO approved	Available in the market	100	100	HbSS and trait		NA	Can be used by a field-level worker	-	-	-
21	LordsMed ShapeDx AI Software-based POC System by Lords Mark Industries Pvt. Ltd	Smear microscopy	Yes	Under development	100	100	HbSS and trait		NA	-	-	-	-

S. no.	Test name	Type of test	ICMR validation (Yes/No)	Stage of development	Sensitivity (%)	Specificity (%)	Spectrum of diagnosis (SCD/SCT)		Level of automation	Type of human resource needed	Deployment experiences/ published study	Cost reference	Information leaflet links
22	Automatic Smear Generating Machine: Sickle Cell Rapid Test by Prof Mahesh, IIT Bombay	Smear microscopy, measuring the length of the smear on a smear card	-	Under development (automatic smear machine is licensed to a private manufacturer)	-	-	HbSS and trait		Automated smear making	Lab technician	-	-	-
23	Sickle Cell Rapid POC Device by Genebio Health Pvt. Ltd		Yes		97	100	-		-	-	-	-	-
24	Sickle Cell POC Kit by Avience Biomedicals Pvt. Ltd	Lateral flow immunochromatographic assay	Yes	Available in the market	98.1	100	-		-	-	-	https://mkp.gem.gov.in/point-care-rapid-test-kits-v2/sickle-cell-rapid-test-kit/p-5116877-75699330485-cat.html	-
25	Sickle Cell Rapid Test Device by Accent Pharmaceuticals	-	Yes	-	100	100	-		-	-	-	-	-
26	Sickle Cell Rapid Test Device by Aspen Laboratories Pvt. Ltd	-	Yes	-	100	100	-		-	-	-	-	-
27	Sickle Cell Test POC Kit by Encore Biomedicals Pvt. Ltd	Lateral flow chromatography	Yes	Available in the market	100	100	HbSS and trait		NA	Can be used by a field-level worker	-	https://mkp.gem.gov.in/point-care-rapid-test-kits-v2/enssure-sickle-cell-rapid-test-kit/p-5116877-41425503539-cat.html#!	https://www.encorebiomedicals.com/shop/product_detail/enssure-sickle-cell-rapid-test-kit
28	Sickle Cell POC Kit by Medsource Ozone Biomedicals Pvt. Ltd	-	Yes	-	100	100	-		-	-	-	-	-
29	Vanscan SCD RT-PCR Kit by Vanguard Diagnostics Pvt. Ltd	-	Yes	-	100	100	-		-	-	-	-	-
30	Chrogene by Chrogene Aarogyam Biotech Pvt. Ltd	Non-invasive test based on the principle of analyzing the epithelial cell response to environmental situations using finger probe and SCD reading device	Validated by Thalassemia and Sickle Cell Society	-	-	-	-		-	-	-	-	https://www.chrogeneaarogyam.com/index.html

Figure 8. HemoTypeSC POC test kit

Source: www.hemotype.com

Figure 9. Hemex Gazelle equipment.

Source: www.hemexhealth.com

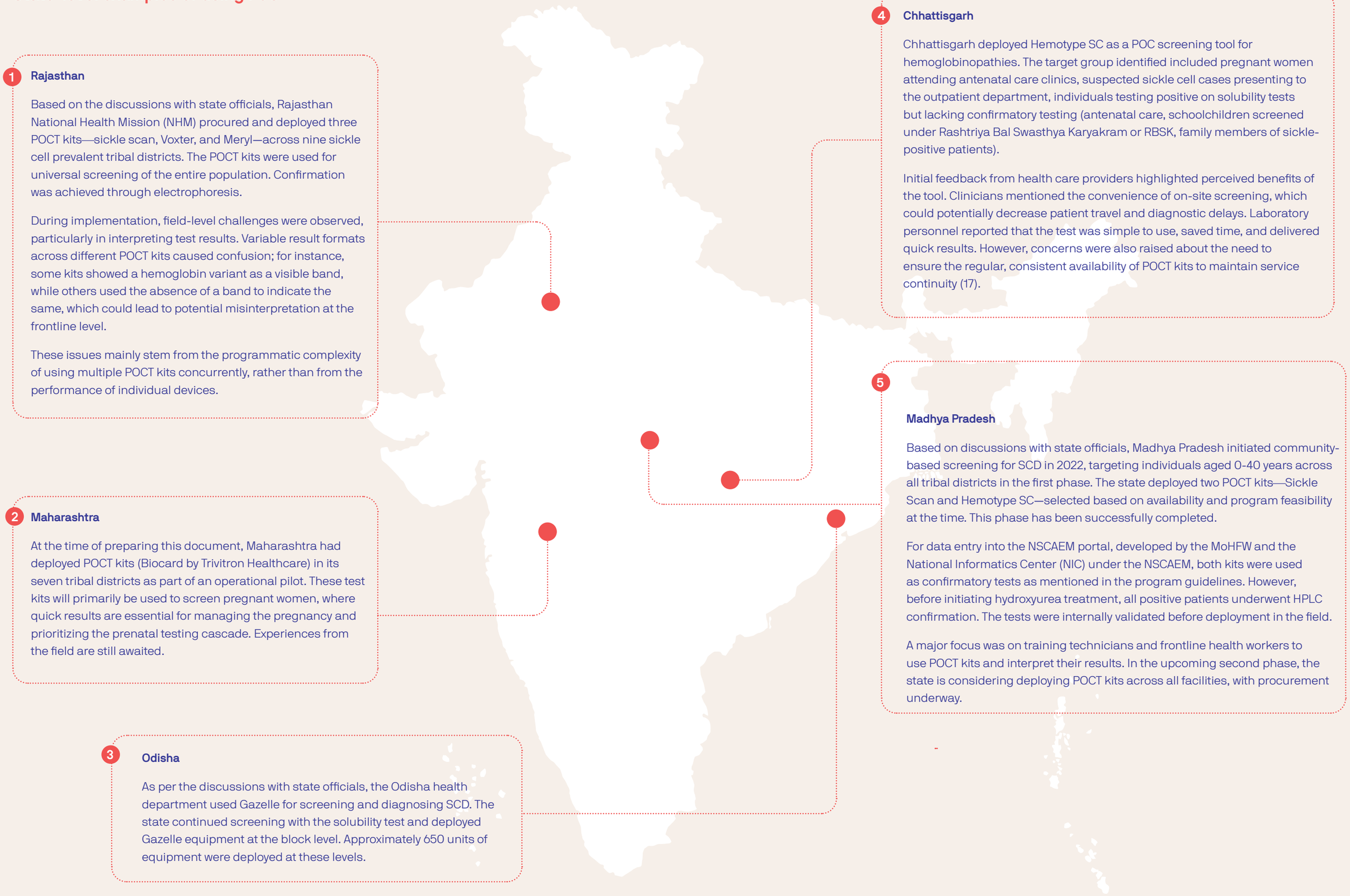
Figure 10. Sickle SCAN by BioMedomics.

Source: www.biomedomics.com

Figure 11. Biocard Sickle Cell Rapid Test Kit

Source: www.trivitron.com

State-level examples of using PoC



1 Rajasthan

Based on the discussions with state officials, Rajasthan National Health Mission (NHM) procured and deployed three POCT kits—sickle scan, Voxter, and Meryl—across nine sickle cell prevalent tribal districts. The POCT kits were used for universal screening of the entire population. Confirmation was achieved through electrophoresis.

During implementation, field-level challenges were observed, particularly in interpreting test results. Variable result formats across different POCT kits caused confusion; for instance, some kits showed a hemoglobin variant as a visible band, while others used the absence of a band to indicate the same, which could lead to potential misinterpretation at the frontline level.

These issues mainly stem from the programmatic complexity of using multiple POCT kits concurrently, rather than from the performance of individual devices.

2 Maharashtra

At the time of preparing this document, Maharashtra had deployed POCT kits (Biocard by Trivitron Healthcare) in its seven tribal districts as part of an operational pilot. These test kits will primarily be used to screen pregnant women, where quick results are essential for managing the pregnancy and prioritizing the prenatal testing cascade. Experiences from the field are still awaited.

3 Odisha

As per the discussions with state officials, the Odisha health department used Gazelle for screening and diagnosing SCD. The state continued screening with the solubility test and deployed Gazelle equipment at the block level. Approximately 650 units of equipment were deployed at these levels.

4 Chhattisgarh

Chhattisgarh deployed Hemotype SC as a POC screening tool for hemoglobinopathies. The target group identified included pregnant women attending antenatal care clinics, suspected sickle cell cases presenting to the outpatient department, individuals testing positive on solubility tests but lacking confirmatory testing (antenatal care, schoolchildren screened under Rashtriya Bal Swasthya Karyakram or RBSK, family members of sickle-positive patients).

Initial feedback from health care providers highlighted perceived benefits of the tool. Clinicians mentioned the convenience of on-site screening, which could potentially decrease patient travel and diagnostic delays. Laboratory personnel reported that the test was simple to use, saved time, and delivered quick results. However, concerns were also raised about the need to ensure the regular, consistent availability of POCT kits to maintain service continuity (17).

5 Madhya Pradesh

Based on discussions with state officials, Madhya Pradesh initiated community-based screening for SCD in 2022, targeting individuals aged 0-40 years across all tribal districts in the first phase. The state deployed two POCT kits—Sickle Scan and Hemotype SC—selected based on availability and program feasibility at the time. This phase has been successfully completed.

For data entry into the NSCAEM portal, developed by the MoHFW and the National Informatics Center (NIC) under the NSCAEM, both kits were used as confirmatory tests as mentioned in the program guidelines. However, before initiating hydroxyurea treatment, all positive patients underwent HPLC confirmation. The tests were internally validated before deployment in the field.

A major focus was on training technicians and frontline health workers to use POCT kits and interpret their results. In the upcoming second phase, the state is considering deploying POCT kits across all facilities, with procurement underway.

Upcoming technologies

Dried blood spot: PCR

This test is developed by the Center of Scientific and Industrial Research – Center for Cellular and Molecular Biology (CSIR-CCMB) (18). Blood samples are spotted onto Guthrie cards via heel-prick blood collection and then transported to the hub laboratory for molecular confirmation. These dried blood spots (DBSs) are used as templates for allele-specific ARMS-PCR reaction to detect SCD mutation. DBS PCR is a rapid, robust, and cost-effective technique for SCD screening and diagnosis.

Early detection is an effective strategy for addressing SCD; implementing newborn screening with a one-step confirmation technique like DBS PCR can be beneficial. The WHO strongly recommends a universal approach to neonatal screening, followed by early treatment to help lower SCD-related infant and childhood mortality (5).

States need to assess the feasibility and affordability of using this technique in different field settings.

Pre-implantation genetic diagnosis (19)

When both parents know that they carry the SCD gene and prefer not to have a child with SCD, they can opt for pre-implantation genetic diagnosis to control the fertilization process.

This process is similar to in-vitro fertilization, which involves removing eggs from a woman's ovaries and fertilizing them in a laboratory setting. The embryo can then be tested for sickle cell anemia and implanted into the woman's womb only if the results are negative. It is a relatively new procedure and can be costly to carry out.

Integrated technologies for sickle cell test and ferritin levels

During the landscaping process, the team identified technologies that enable integrated testing capabilities, including Heethox and Gazelle.

These technologies support integrated testing for various hemoglobin variants, aiding the diagnosis of conditions such as β-thalassemia and SCD. Additionally, these test kits provide semi-quantitative or quantitative measurements of ferritin levels, which are essential for effective patient management. Beyond their role in managing hemoglobinopathies, assessing ferritin levels can also improve the management of anemia.

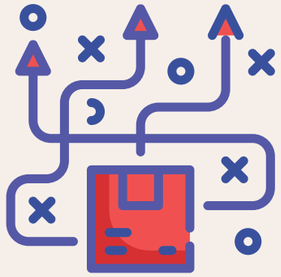
05 Way forward and action plan

Over the past few decades, significant advancements in diagnostic techniques have revolutionized the detection and management of genetic diseases, including SCD. Modern diagnostic modalities are continuously evolving, with molecular testing and human genome analysis being regarded as the most reliable approaches. However, while molecular diagnostics provide high accuracy with few false positives, they can be costly and challenging to access at the grassroots level.

POCT rapid diagnostic technologies have emerged as transformative tools, offering quick, reliable, and on-site solutions, especially for community-based screening. These technologies are particularly relevant for SCD, where timely diagnosis and intervention are crucial. Further research is needed to evaluate whether POCTs can ultimately replace traditional electrophoresis methods for SCD detection.

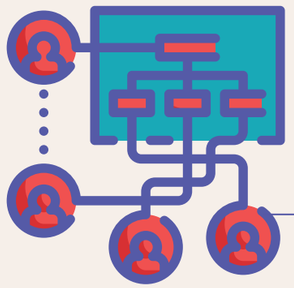
As India aims to eliminate SCD as a public health challenge by 2047, deploying rapid, sensitive, and easy-to-use diagnostic tools like POCTs is crucial. These tools can facilitate mass screening, reduce diagnostic delays, and minimize loss to follow-up resulting from inefficiencies in multi-step testing protocols.

ACTION PLAN



Procurement and supply chain management:

Ensure sufficient availability of POCT kits to cover the unscreened population. Advance planning to identify and estimate the target population is essential for efficient distribution.



Evaluation and pilot testing:

Assess the sensitivity, specificity, and cost-effectiveness of POCT kits. Conduct pilot studies across diverse target groups to evaluate their accuracy and operational feasibility. Formalize memorandum of understanding based on pilot outcomes to streamline procurement processes.

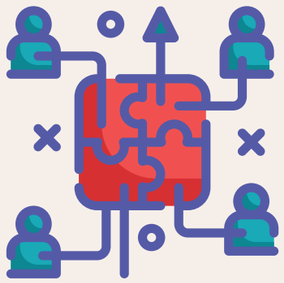
With over 25 POCT kits available

Standard operating procedures:

Develop clear and consistent guidelines for using POCT kits, indicating whether they are intended for screening or confirmatory testing based on state priorities.

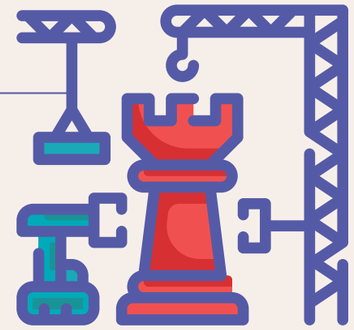
Training and capacity-building:

Train health care workers on the proper use of POCT kits. Emphasize the importance of distinguishing between screening and confirmatory testing.



Operational support and maintenance:

Raise awareness among health care staff about procedures for handling technical malfunctions or device failures, including support contact points.

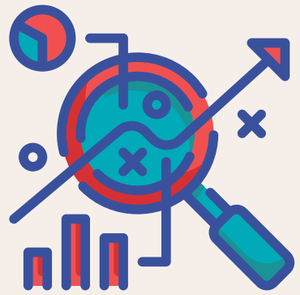


Leveraging existing infrastructure:

Integrate POC testing within the framework of integrated public health labs and block public health units to enhance diagnostic access. Connect POC testing sites to these facilities to enable confirmatory diagnosis using HPLC.

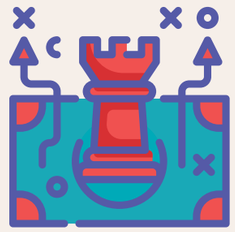
Research and development:

Conduct studies to ascertain whether POCTs can replace HPLC, particularly in high-prevalence areas.



Evaluation and scalability:

Conduct comprehensive assessments of deployed POCT kits to validate their diagnostic accuracy and cost-effectiveness, guiding potential scale-up at national and state levels.



Monitoring and quality assurance:

Implement regular supervision and data recording practices to ensure the quality and reliability of diagnostic outcomes. Additionally, a system needs to be established to conduct regular quality monitoring of the POCT kits in accordance with the Central Drugs Standard Control Organisation guidelines and ICMR validation, to prevent any inflation or deflation of results.

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