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# Capacity Building of Primary Health Care Workers for Diagnosis and Counseling of Sickle Cell Disease: A Protocol of Implementation Research

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**Abstract**

Background and Objective

Sickle Cell Disease is a blood genetic disorder and a major problem among the tribal population of India. There is no structured program in action in the country for the diagnosis, treatment, and management of the disease. This study protocol aims to train health care workers i.e., Medical officers, Auxiliary Nursing Midwifery , Laboratory Technician, and Community Health Officers , for diagnosis and counseling for sickle cell disease through a training program in eight SCD-endemic tribal districts of Rajasthan, India.

Methodology

The sub-districts of Udaipur, Banswara, Sirohi, Dungarpur, Pratapgarh, Pali, Chittorgarh, and Rajsamand will be included in the study. The sub-districts having more than 50% tribal population will be included in the study. The training sessions will be organized at the CHC/PHC in eight districts. Data for this study will be collected from pre- and post-questionnaires given to healthcare professionals during the training program. A counseling module in English and the local language will be circulated to health worker to improve their knowledge regarding diagnosis, management, and prevention strategies for sickle cell disease.

Discussion

The results of this study could provide information on the necessity of bolstering the capacity for implementation research in endemic areas.

Expected outcomes

The outcomes of the study will provide a better understanding regarding the diagnosis, control, and management of sickle cell disease among the health workers. The primary outcome will be capacity building of the health workers in conducting screening of SCD and creating awareness of sickle cell disease among tribes.

**Key words**: Implementation, Tribal, Counseling, Sickle cell anemia, capacity building

## Introduction

Sickle cell disease (SCD) is an autosomal recessive blood disorder and a major problem among the tribes living in hilly area of India[1-2]. SCD patients lack the required hemoglobin throughout life; suffer severe pain, and organ damage that can result in premature death[3]. The prevalence of SCD is anticipated to rise exponentially and it is predicted that 14,242,000 will be born with the disease around the globe before 2050[4]. As a result of globalization, people will migrate more and SCD will spread more over the world in the coming decades[5].SCD has received little attention in India's health and medical research as it has been considered a neglected health issue[6-7]. In India, more than 44,000 births with SCD occurs yearly[8]. India is the second largest affected country in the world by sickle cell disease[9]. The tribal population in India is spread transversely in 30 states and union territories[10-11].Tribal residents of India are 8.6% of the total Indian population and in the state of Rajasthan, they represent 13.6% of the total state population. Many studies were conducted in the last 30 years to measure the problem and prevalence of SCA around the country. The prevalence of the sickle cell trait and sickle cell disease in India was 8.33% and 0.41% among tribal population, respectively. Out of the 98 million tribal population of the country, 11.3 million people have been screened for sickle cell disorder (Sickle Cell Disease support corner Ministry of Tribal Affairs Government of India portal). We do not have a structured SCD program in the country for the diagnosis and management of SCD. However, the Government of India has initiated the National Sickle Cell Anemia Elimination Mission to eliminate SCD by 2047. Therefore, screening of the population for SCD, treatment, and

counseling are required urgently to control the disease. There is no systematic approach in the primary health care system existing in the country for the screening of the population for SCD. The network of primary health centre is the only available resource to reach the community level for preventive, promotive and curative services. Hence, a study is being implemented to develop a structured program for the diagnosis and management of the SCD with a systematic approach. Currently, sickle cell testing is available at limited tertiary level health facilities. Therefore, we would like to expand the testing facilities at the Community health centre/Primary health centre/Sub-Centre level of the tribal area. A basic definition of a health care worker is an individual who provides direct medical care and services to the sick and injured, such as nurses and doctors, or indirect medical waste handlers, laboratory assistants, and laboratory technicians, are referred as a healthcare worker. In the present study Health Care Workers (HCWs) i.e. Medical Officers (MO), Auxiliary Nursing Midwifery (ANM), and Laboratory technician (LT) will be trained for the diagnosis of sickle cell disease. Community Health Officers will also is trained for the genetic counseling. The effective execution of SCD prevention programs greatly depends on counseling, community education, and awareness. Early diagnosis of SCD in newborn babies allows earlier treatment. Counseling may improve early diagnosis of SCD (antenatal and pre-natal check-ups); availability of treatment (availability of drugs and experience man power); and enhance knowledge among the community to be aware about SCD.

The overall objective is to develop the capacity of the public health system for screening, treating and counseling of SCD patient at the primary health care level.

## Methodology

### Study area

Eight districts selected for the study are situated in the southern part of the state of Rajasthan, India. The ratio of the tribal population to the overall population as well as the density and size of the tribal population were criteria considered while choosing the study area. These eight districts (Udaipur, Banswara, Sirohi, Dungarpur, Pratapgarh, Pali, Chittorgarh, and Rajsamand) were chosen because they have a higher proportion of the tribal population (Fig.1). All the sub-districts of the eight districts were chosen based on the proportion of tribal population residing.

Only those sub-districts in each district were chosen where the proportion of tribal population was greater than 50%.

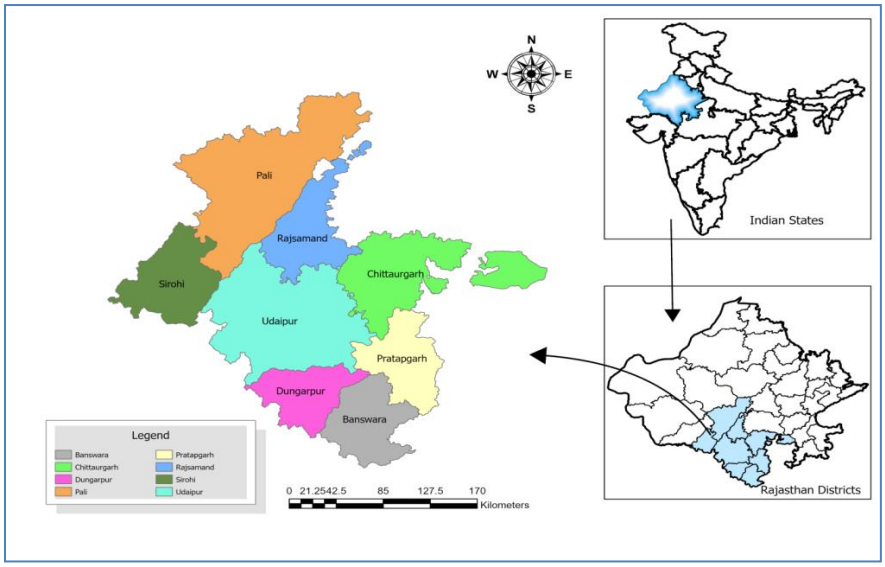


**Figure 1. Eight districts to be screened for sickle cell diseases under the tribal sub-plan region of Rajasthan, India.**

## Study participants

About 2700 healthcare workers i.e., Medical officers, Auxiliary Nursing Midwifery (ANM), Laboratory Technician (LT), and Community Health Officers (CHO) of selected study areas will targeted for training for screening, treating and counseling.

## Study design

The implementation study has cross-sectional and qualitative components and will be conducted in a community as well as hospital settings. Data will be gathered for this hypothesis by the qualitative study from the scores of the pre-and post-questionnaires were given to healthcare professionals. One of the techniques available for assessing the effectiveness of an educational training program is the pre-post survey. Its aim is to evaluate the impact of training heath care workers knowledge and skills to perform screening and management of SCD. The questionnaire for HCWs was developed by brain storming with scientists working in SCD and previous studies[12, 13, 14, 15.] HCW and MaaBaadi (School) coordinators of the schools will be involved through the government machinery system. The training will be divided into four parts: a) an

introductory part regarding sickle cell disease[16]: b) a demonstration for screening of sickle cell disease [17] c) hands-on skill of solubility kit and point of care test [18-19] d) counseling for the SCD participants. A question-and-answer session will also be there for solving the problem. Feedback and suggestion from the training session and their search team will also be taken after the training is finished at CHC/PHC level. The feedback and suggestions will be analyzed after each training session. Health workers will do solubility tests in their respective MaaBaadi Centre and hostel after being trained and upload their screened details on the National Sickle Cell Anemia Elimination Mission Portal with the help of a mobile application created by the health ministry.

After training qualitative methods will be used to identify facilitators and barriers (of the primary/community health care system) in accessing the SCD screening and management and other similar program of the government health system with the help of closed-ended questions for implementing screening programs.

**Screening& confirmatory test for sickle cell disease**

A solubility test will be used to detect the presence of sickle hemoglobin (HbS). This method is primarily used for large-scale screening in a short time. HbS has decreased solubility in the deoxygenated state in a hypotonic buffer which produces turbidity.2mL whole blood sample will be collected in EDTA containing vacutainer from sickle cell screen positive individuals for confirmation of genetic status. The blood samples in a vacutainer will be transported to their respective district hospital and stored at 4°C till analysis. Written informed consent of individuals will also be taken in the local language for research and publication purpose. An advanced laboratory will be established in each district for the analysis of hemoglobin. Cation Exchange-High Performance Liquid Chromatography (HPLC) system will be installed in four districts. Samples from the adjacent areas will be sent for analysis. Additionally, health professionals will also be trained for conducting the confirmatory test by Cation Exchange-High Performance Liquid Chromatography (HPLC). High Performance Liquid Chromatography (HPLC) of whole blood samples of positive cases and some negative cases will be carried outusing Bio-Rad Variant-II. The instruments will be calibrated with commercially available controls, and samples will also be cross-checked for quality control from time to time. The training will be given to the laboratory technicians of medical college or district hospitals as described by Mohanty and Colah (2008)[20]. After the confirmatory test, sickle cell trait and sickle

cell disease individuals will be counseling for further treatment. The SCD individual will be referred to their respective PHC, CHC, and district hospital for treatment as per programme guidelines [21].

Counseling module will also be circulated to health workers to improve their knowledge of the management and prevention strategies of sickle cell disease. Evaluation of the health professional will be done just after the training and counseling part, by filling of a well-tested post-questionnaire.

**Formative Research for existing health facility**

1. Assessment of knowledge and skills of HCWs.

2. Assessment of manpower and infrastructure required for screening and management of SCD.

**Implementation plan**

**Inclusive partnership approach**

During the initiation of the study, a meeting will be held with the TADD commissioner, CMHO, and BCMO of respective health centers to finalize the agenda and schedules of the training. The research team of the ICMR-NIIRCD, Jodhpur, will visit each of the districts and will train medical officers, technicians, and paramedical staff for the solubility test. They will be trained to diagnose the common symptoms of sickle cell disease and its management. They will be informed about the intervention for the unhealthy person suffering from a sickle cell disorder. Counseling training will be provided to the health professionals. The experienced researcher of the team will train and assist in capacity building of the health care system, which further will help in the implementation of the plan and will be reported in the final analysis. According to guidelines received from NHM, ANM will do screening at their respective sub-center and Community Health Officers will impart genetic counseling to them[22].

The design and execution of the project will entail a broad representation of tribal communities and staff from the health care, state government, and non-governmental organizations. This training is mandatory for health care professionals by the office order, if anyone is absent on the day of training second attempt or training will be given by video conferencing.

**Execution of strategies**

After the training sessions, ANM will do initial screening at the community level, Schools, MaaBaadi, Aanganwadi centers, Hostel residents, etc. with the help of ASHA and MaaBaadi teachers. Laboratory technician will do screening at the CHC/PHC level. All the individuals found positive will be enrolled in the National Sickle Cell Anemia Elimination Mission and their details will be uploaded by HCW on the National Portal of MoTA. Community health officer will impart prevention and control strategies for sickle cell disease burden at the household, community, school levels.

**Evaluation of the strategy:**

This study will be evaluated by the RE-AIM framework which is a guide to planning and evaluation of programs according to the 5 key RE-AIM outcomes: Reach, Effectiveness, Adoption, Implementation, and Maintenance [23].

**Reach:**

- Target Population: the tribal populations residing in eight districts of the southern part of Rajasthan with a high tribal population ratio.
- Demographics: Newborn to 40 years.
- Participation: Community settings, hospitals, and schools, ensuring a broad reach.

**Effectiveness:**

- Outcome measurement: Knowledge, attitude, and practices of healthcare workers before and after the training, intervention via pre- and post-questionnaires followed by qualitative inquiry.
- Disease detection: Using solubility tests and confirmatory tests like HPLC.

**Adoption:**

- Engagement of Stakeholders: Adoption of the screening plan at different organizational levels.
- Training components: Solubility testing, counseling, referral

**Implementation:**

- Training quality: Training and its feedback mechanism will provide insights into the quality and effectiveness of the training.
- Screening and Testing:
- Role Delegation:

  - ANM for initial screenings,

  -Laboratory Technicians at CHC/PHC levels, and

-Community Health Officers for imparting prevention strategies

**Maintenance:**

- Sustainability: The number of organizations and NGOs indicate involvement
- Data Management: The uploading of details on the National Sickle Cell Anemia Elimination Mission Portal (GoI)
- Long-Term Strategy: By referring individuals with confirmed sickle cell disease to respective health facilities for treatment and offering genetic counseling.

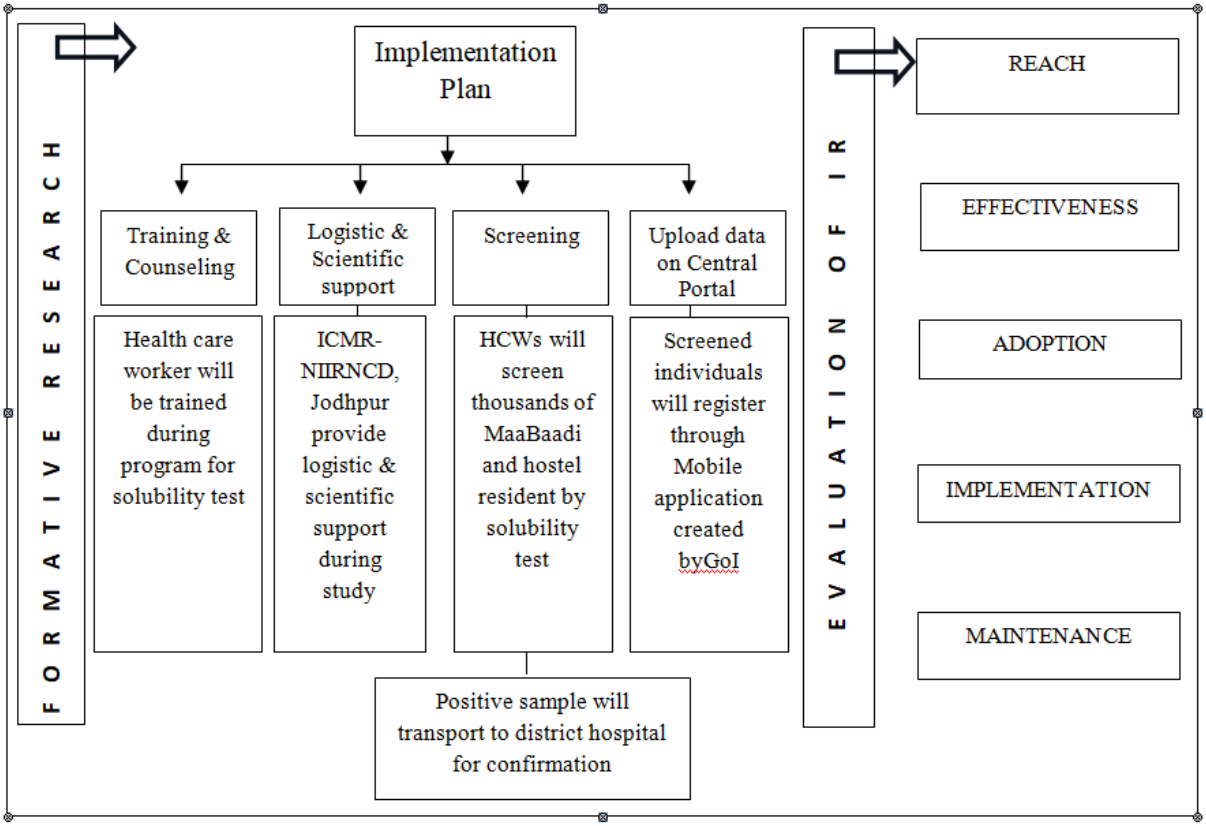


**Fig. 2 – Flow chart of the implementation research strategy**

## Data Management and Analysis

Demographic and sickle status data of the individual will be entered at the National Health Mission portal (https://sickle.nhm.gov.in/). Credentials of this portal have been provided to the principal investigator by the National Health Mission. All the pre- and post-training assessment information will be collected from each healthcare worker by researcher and will be analyzed to assess the impact of training and capacity building activities.

## Expected outcomes

The outputs of this study will help in better understanding of sickle cell disease; capacity building of the health professionals in conducting screening tests and enhancing awareness in the public and active involvement of society in the fight against Sickle Cell Disease. The paramedical staff will screen the population of the tribal region in the future and also identify barriers& challenges during screening.

## Discussion

About diagnostic and prevention methods for sickle cell disease in the nation, this study will provide a deeper understanding of sickle cell disease. Additionally, to help tribe's health in this study, treatment for SCD will benefit from early diagnosis and an awareness campaign. Counseling through primary healthcare system towards community level play a very significant role in the successful implementation of SCD prevention programs. The results of this study could document that makes a case for the necessity of bolstering capacity for implementation research in the endemic areas in addition to providing insights into how sickle cell disease healthcare initiatives could be implemented more effectively.

## Declaration of competing interest

We declare no competing interests.

## Supplementary files

All appendixes are given as supplementary data here:

1. Questionnaire

## Data availability

No data is associated with this article.

## Funding

This study has been funded by the Tribal Area Development Department, Udaipur, Government of Rajasthan. (Grant No.F-1(M)/4(CTD)/Medical/sickle cell/ 2019-20/22865).India

**Ethics:** The Institutional Ethics Committee for Research on Human Subjects gave its approval to the project (Approval number- D/05/SAC&SAG/2021-22/880 dated 12-12-2022). Teachers, wardens, and guardians will give written informed consent for all the participants below 10 years of age. Participants between the ages of 10-18 years will give their assent and consent will be taken from the guardians. All the adults will give their consent before participating in the study. The ethical concerns will be handled following the values outlined in the Helsinki principle.

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**Credit authorship contribution statement:** SSM, MT, RKH, RKS, and AP conceived and designed the study. SP, SSM, MT, and BVB wrote the protocol. All authors contributed to the drafts before submission.

**Data Availability Statement**: No data associated with this manuscript.

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