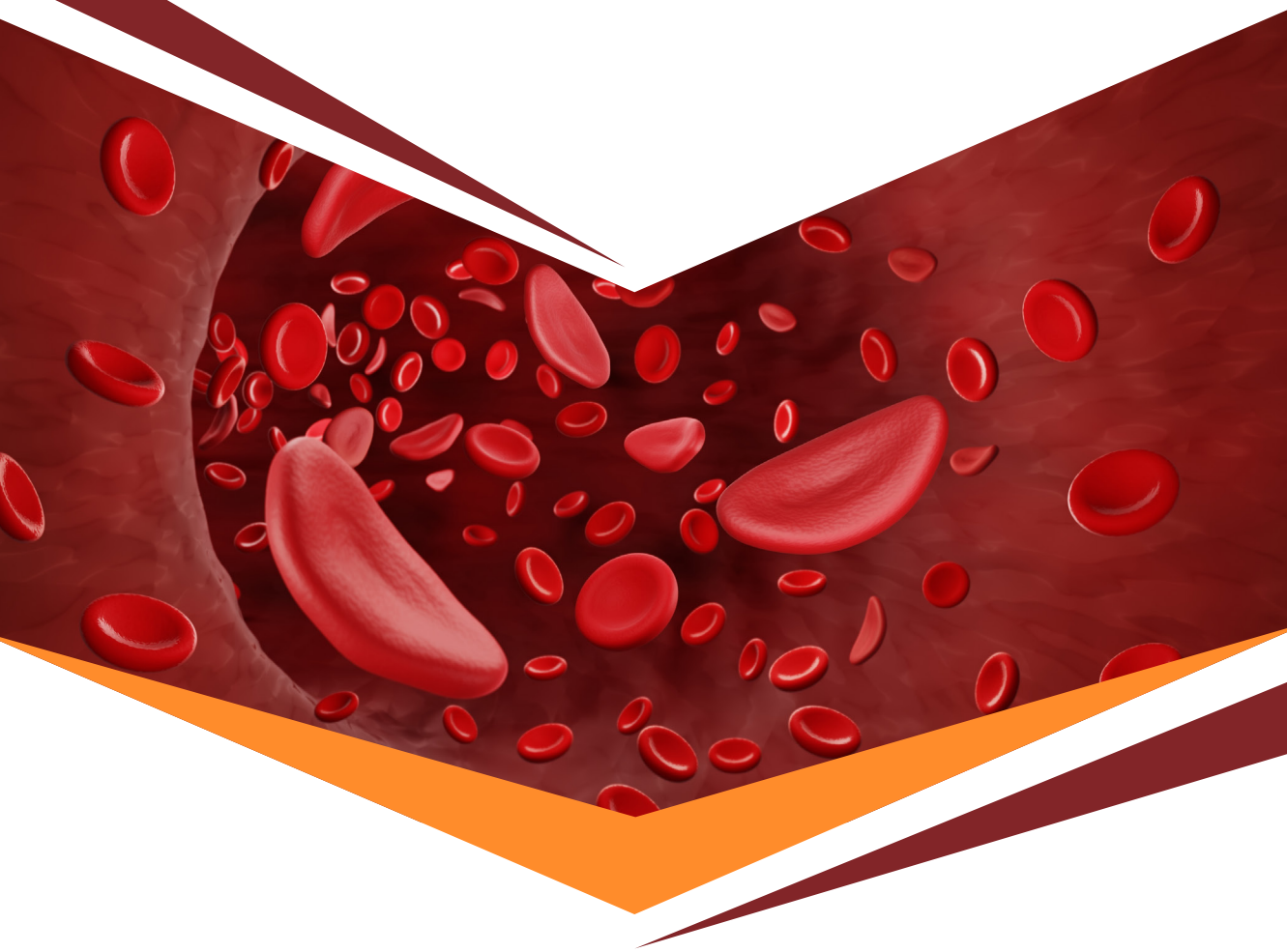
REPUBLIC OF KENYA

MINISTRY OF HEALTH



POLICY ON INFANT SCREENING FOR SICKLE CELL DISEASE

GUIDELINES FOR IMPLEMENTATION

JUNE 2023

Developed by the division of Non-Communicable Diseases Control- Ministry of Health

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FOREWORD

The Government recognizes health as one of the priority sectors that contribute to the wellbeing of the nation and therefore remains committed to providing quality health services to all of its citizens. Recognizing that a healthy population is critical to improved production and productivity, Government continues to invest in health sector in order to bring health care closer to the people and also to ensure sustainability of the nation's human capital base required for sustainable economic growth.

Sickle Cell Disease (SCD) is a significant contributor of NCD-related child mortality globally, causing 6-15% of deaths in children aged less than 5 years. The prevalence and mortality are significantly higher in Africa, being common in malaria endemic zones. Between 2 to 4 out of every 100 newborns in areas with a high burden of sickle cell gene have sickle cell disease. It is estimated that without appropriate intervention, 50%-90% of those born with the condition die before their fifth birthday. Numerous studies provide clear evidence that life-threatening early complications of SCD (sepsis, splenic sequestration crisis, etc.) can be largely avoided if the diagnosis is made early hence forming the basis of the policy on screening of infants.

In Kenya, it is estimated that 14,000 children are born with sickle cell disease annually and it contributes significantly to both child and adult morbidity and mortality. This guideline lays out the implementation framework for conducting universal screening for sickle cell disease. The guideline is a critical ingredient for streamlining screening of SCD across the entire health services provision continuum. It is a strategic component in achieving universal health coverage and securing affordable health care which will in turn guarantee a healthy nation working towards sustainable development and prosperity.

We look forward to working collaboratively across the sector, partners and all other stakeholders to ensure its successful implementation.

Nakhumicha S. Wafula

Cabinet Secretary - Ministry of Health

PREFACE

Non-communicable diseases (NCDs) are the leading causes of morbidity and mortality globally and disproportionately affect the world's low and middle-income populations. In Kenya, NCDs accounts for more than 50% of total hospital admissions and over 55% of hospital deaths. Seventeen counties in Kenya have a high burden of Sickle Cell Disease (SCD). SCD is not limited to the medical costs but also other factors that contribute to reduced quality of life. These include stigma and discrimination, psychosocial and emotional challenges, absence of medical care and unemployment. It is in this regard that the Ministry of Health and partners have instituted the policy on infant screening of sickle cell disease and developed an accompanying guideline for implementation.

In line with global action plan on NCDs and as a follow-up to the 3rd United Nations high level meeting on NCDs, this guideline is meant to provide counties and health care workers with an standardized and evidence based implementation manual for instituting the policy on infant screening for sickle cell disease.

The hall mark of sickle cell disease care is early detection of the disease and commencement of appropriate care. This guideline is in itself the minimum standard of screening and act as a benchmark on quality and rights of access for the infant. It is however incremental in nature as the capacity of our health system varies greatly across the country and some county facilities may not have what is envisaged in this guideline. In this regard, these guidelines should go hand in hand with capacity building and system strengthening and reform across the national and county health levels.

We are committed to ensuring that this guideline is implemented and adopted to the reduce the burden of sickle cell disease in the country

Peter K. Tum CBS

Principal Secretary State Department for Medical Services

ACKNOWLEDGEMENT

We would like to acknowledge the collaboration of various organizations who provided both technical and financial support; special mention to Kenya Sickle Cell Federation, Academic Model Providing Access to Health Care (AMPATH), Hematological Society of Kenya, The University of Nairobi and Moi University for walking with the Ministry of Health in the development process and we hope for more collaborations during implementation and evaluation phases.

The compilation of this guideline on the Infant Screening of Sickle Cell Disease in Kenya would not have been possible without the support, hard work, and endless efforts of a large number of individuals and institutions. The process was coordinated by Dr Gladwell Gathecha who played an important role in ensuring successful completion. The development benefited greatly from the valuable contributions of Dr, Ephantus Maree, Dr. Elizabeth Onyango, Dr. Oren Ombiro, Dr. Nasirumbi Magero, Dr. Yvette Kisaka, Peris Mbugua and David Njuguna. The team guided the process, played an important role in shaping the guideline. Their active participation in each step of the study helped in obtaining the required data, best practices and in completing the report.

We are grateful to the counties of Taita Taveta, Nairobi and Kisumu for the collaboration and support during the development.

Finally, I wish to thank all those who participated in the preparation of this guideline and whose diverse contributions made it a success.

Dr. Patrick Amoth, EBS

Ag. Director General for Health

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ABBREVIATIONS

CONSA	Consortium on Newborn Screening in Africa
HBE	HB electrophoresis
IEF	iso electric focusing
NHIF	National Hospital Insurance Fund
NCD	Non-Communicable Diseases
SPARCO	Sickle cell Pan-African Research Consortium
SCD	Sickle Cell Disease
WHO	World Health Organisation

CHAPTER 1: INTRODUCTION

I. Background

Sickle cell disease (SCD) is the most common inherited (genetic) hematological disorder in Kenya and other parts of Africa. It is characterized by the presence of sickled red cells in the blood. In areas of low oxygen tension, the abnormal sickled red blood assume a sickle, and become rigid and hence can block small blood vessels, impairing blood flow.

The commonest forms of SCD in our environment in order of prevalence are HbSS, HbSC and HbSβ-thal[1]. If a person inherits two sickle haemoglobins (HbS) from both parents, the individual has HbSS; while a person who inherits one sickle haemoglobin (HbS) from one parent and another haemoglobin variant (HbC) from the other parent has HbSC. Similarly, the individual who inherits one sickle haemoglobin from one parent and another haemoglobin variant (Hb β-thalasaemia) from another parent has HbSβ-thal. It is worthy to note that SCD does not include sickle cell trait also known as the carrier state (HbAS). Recognition of the public health impact of sickle cell disease and trait is necessary so as to help establish appropriate interventions and survival policies and programmes with an aim of reducing the associated morbidity and mortality.

II. Burden of Sickle Cell Disease

Sickle cell disease affects nearly 100 million people worldwide and it is responsible for over 50% of deaths among those with the most severe form of the disease. It is estimated that each year over 300,000 children are born annually with this disease and over 70% of these births occur in Sub-Saharan Africa[2].

In Kenya, it is estimated that 14,000 children are born with sickle cell disease annually and it contributes significantly to both child and adult morbidity and mortality. The sickle cell disease burden follows malaria endemic patterns in Kenya. The high burden areas include lake-region, western and coastal region of Kenya. Due to migration patterns, Sickle Cell is also found in the urban and commercialized areas in Kenya.

III. Infant Screening of Sickle Cell Disease

Infant screening is a public health intervention that involves the screening of infants for conditions that are treatable, but not clinically evident.

Screening of sickle cell disease can be done at various stages; preconception, antenatal and across the life course of a patient. The best outcome is achieved when screening is done before six (6) months of age after which most of the complications will start to set in. Without interventions nine out of ten children born with sickle cell disease in Sub Saharan Africa die before their fifth birthday.

1 Grosse, S. D., Odame, I., Atrash, H. K., Amendah, D. D., Piel, F. B., & Williams, T. N. (2011). Sickle cell disease in Africa: a neglected cause of early childhood mortality. American journal of preventive medicine, 41(6 Suppl 4), S398–S405. https://doi.org/10.1016/j.amepre.2011.09.013

2 World Health Organisation. The facts. https://www.afro.who.int/health-topics/sickle-cell-disease

Newborn screening is recommended as a method of early detection for early intervention in sickle cell disease to improve health outcomes. In countries that have adopted newborn screening, the mortality rate has reduced by 25-75% because of early interventions like prophylactic treatments[3]. Methods of newborn screening include iso electric focusing (IEF) and validated point of care rapid tests. The advantage of validated point of care tests includes increases accessibility, affordability and reduces need for high technical expertise for interpretation. Confirmation should be done by HB electrophoresis (HBE).

IV. Rationale for Screening of Sickle Cell Disease

Numerous studies provide clear evidence that life-threatening early complications of SCD (sepsis, splenic sequestration crisis, etc.) can be largely avoided if the diagnosis is made early and preferably in the first three to six months of life. Simple but very effective prophylactic measures such as vaccination, malaria prophylaxis or penicillin and Erythromycin prophylaxis can then be initiated sufficiently early. This can considerably reduce morbidity and mortality.

The World Health Organization SCD strategy for the African Region gives guidance that member states should institute new born screening programs in their countries as one of the public health interventions. Kenya has also prioritized new born screening in the recently launched National strategic plan for the prevention and control of Non Communicable Diseases 2021/2-2025/6.

Screening identifies infants with other hemoglobinopathies, hemoglobinopathy carriers, and in some states, infants with α-thalassemia syndrome.

Screening of newborns will allow the country to have data on sickle cell for policy and planning

V. Purpose of the Guideline

This guideline lays out the implementation framework for conducting universal screening for sickle cell disease. It is intended for use by healthcare workers working at all levels of health care

3 Kuznik, Andreas et al. "Newborn screening and prophylactic interventions for sickle cell disease in 47 countries in sub-Saharan Africa: a cost-effectiveness analysis." BMC health services research vol. 16 304. 26 Jul. 2016, doi:10.1186/s12913-016-1572-6

CHAPTER 2: SITUATIONAL ANALYSIS

In 2006 the World Health Assembly recognized sickle cell as a disease of public health concern. Over the last 10 years there has been progress in terms of advocacy, diagnosis, new treatment trends, availability of medicines, development of policies and guidelines, to standardize the care of sickle cell disease. WHO estimates that 70% of SCD deaths are preventable with: a) Early Identification of SCD b) appropriate clinical management; and c) patient-centered care. These are supported by guidelines which are being used in developed countries to manage sickle cell disease.

Over the past 10 years there have been concerted efforts in Africa to address the burden of SCD. Organizations within the region spearheading efforts on the response to SCD include CONSA and Sickle cell Pan-African Research Consortium (SPARCO). The Consortium on Newborn Screening in Africa (CONSA) is an international network that seeks to demonstrate the benefits of newborn screening and early interventions for children with Sickle Cell Disease (SCD) in sub-Saharan Africa. They provide standard-of-care practices for screening and early intervention therapies (such as antibiotic prophylaxis and immunizations) at participating institutions, screening 10,000 – 16,000 babies per year in each country and providing clinical follow-up for SCD-positive babies.

In July 2021 the Ministry of Health, launched its first national guidelines for the control and management of sickle cell disease in Kenya. The guidelines outline the importance of early diagnosis through newborn screening. Research and pilot programs in Kisumu, Homabay, Kilifi, Eldoret and Taita-Taveta have shown positive uptake, acceptance, and feasibility of newborn screening. Recently, Kisumu County launched its newborn screening program and centre of excellence for sickle cell disease care. This is in line with other African countries like Ghana, Tanzania and Nigeria working within the SPARCO network.

In Kenya the existence of a technical working group comprising of sickle cell disease stakeholders, coordinates national response to sickle cell disease. Advocacy groups working under the national umbrella of The Sickle Cell Federation, Kenya continue to advocate for early diagnosis and intervention for sickle cell patients through newborn screening. The major gaps identified are lack of awareness of sickle cell among the population and health providers. Furthermore, lack of access to diagnostics and late diagnosis, care and treatment have been identified as a major barrier to good health and wellbeing among sickle cell patients.

The financing of diagnosis and treatment of sickle cell disease is not covered by most insurance companies. The provision of the support by the few insurance companies is insufficient. Sickle cell disease is categorized as a congenital condition and thus fits as an exclusion by most insurance covers. Currently NHIF does not have a comprehensive care cover for the diagnosis and treatment costs of sickle cell disease. Sickle cell disease patients and their families incur significant out of pocket expenditures and suffer financial hardships accessing these services which is against the spirit of universal health coverage of leaving no one behind.

There exists skill and knowledge gaps among healthcare providers on management of SCD. The tertiary level facilities have sufficient capacity and competencies among the health workforce, yet the primary healthcare facilities where majority access their services, lack the capacity to diagnose and manage sickle cell disease. This disparity has resulted in late diagnosis and sub-optimal management. The cost of care in private facilities is prohibitive to most patients.

There are initial efforts to create a central registry for sickle cell disease in Kenya. The research institutions and some healthcare providers have developed their own registries that are not linked to share information with other stakeholders. The missing link between private institutions and government does not allow for statistical quantification of the burden of sickle cell disease in the country.

The essential drug list in Kenya has incorporated Hydroxyurea for management of sickle cell disease. However, the diagnostic capacity is very low in most institutions because of either lack of laboratory equipment, quality assurance programs with sound maintenance programs. In Kenya there are only about five HBE machines in public health facilities. This is coupled with frequent machine breakdowns and erratic supplies of commodities and consumables. Despite the availability of validated point-of-care rapid diagnostic tests, they have not been procured for use at public facilities.

I. Policy Statement

Sickle Cell Disease (SCD) is a significant contributor of NCD-related child mortality globally, causing 6-15% of deaths in children aged less than 5 years. The prevalence and mortality are significantly higher in Africa, being common in malaria endemic zones. In Kenya, the burden of SCD is increasing with an estimated 14,000 children born with the condition every year. Between 2 to 4 out of every 100 newborns in areas with a high burden of sickle cell gene have sickle cell disease. It is estimated that without appropriate intervention, 50%-90% of those born with the condition die before their fifth birthday.

The burden of SCD is not limited to the medical costs but also other factors that contribute to reduced quality of life. These include stigma and discrimination, psychosocial and emotional challenges, absence of medical care and unemployment. Children living with sickle cell disease experience frequent school absenteeism which affects their progress in life and limits their potential. The majority of them have delayed milestones. For PLWSCD each life stage i.e childhood, adolescents and adulthood brings its own unique challenges in development and socialisation.

The annual economic burden of sickle cell disease is estimated to be KSh 1.6 billion for the 14,000 cases in Kenya. Through timely screening, on average, the country could potentially save KES 1.6 billion (translating to 0.02 percent of GDP) that would have been spent on prescriptions and medications[4].

4 Mvundura, M., et al., "Health Care Utilization and Expenditures." .....On average, Medicaid spends USD 1,049 per year on prescriptions and medications for each child with SCD.

Infant screening for sickle cell disease, with appropriate intervention, greatly reduces morbidity and mortality. Where newborn screening and treatment are well established, more than 90% of the children with sickle cell disease survive to adulthood. It is for this reasons that Kenya has adopted infant screening.

II. Guiding Principles

a. Public participation- there will be a people-centred approach and social accountability with a multisectoral lens in planning and implementation of the program.

b. Efficiency: efficient application and utilization of all resources.

c. Mutual consultation, collaboration and cooperation between the national and county governments, as well as inter-county governments.

d. Equity: There will be no exclusion based on social/ethnic/religion/regional diversity in the provision of sickle cell disease healthcare services.

e. Evidence based approach: Strategies for Screening of Sickle cell disease should be guided by scientific evidence and public health principles.

f. Integrity and accountability: Healthcare service delivery systems will be reoriented towards the application of principles and practices of social accountability, including reporting on performance, creation of public awareness, fostering transparency, and public participation in decision making on health-related matters.

CHAPTER 3: IMPLEMENTATION FRAMEWORK

The components of the implementation framework include:

a. Target for screening

b. Health education and Counseling

c. Registration of newborns/infants

d. Screening Process

e. Implementation Phases

I. Target for screening

The targeted infants will have an age limit from the period at birth upto one year of age. The focus for the screening is at the 6th week immunization appointment, as 98% of the mothers bring in their babies for this specific appointment. The reason for extending the period upto a year is to ensure babies missed at the 6th week appointment, are captured.

The services offered are summarized as below:

Table 1: List of services offered before and during screening

Services offered before and during screening	
Parent/guardian	Health education during the ante-natal clinics Pre and post-test Counselling Linkage to the pediatric/hematology clinics, the SCD focal persons and CHVs in their area
Infant	Sickle Cell Disease screening Follow up

II. Health education and Counseling

This process shall begin during the antenatal clinic, where the HCW will educate and sensitize the parent/guardian on sickle cell disease and the importance of early screening of infants. Job aids will be used to discuss and demonstrate how the disease is inherited.

During the counselling process, the health care provider will seek verbal consent from the parent/guardian, in a language best understood by the care-givers, before conducting the screening on the infant.

III. Registration of infants

The following information will be derived during registration; Infant's full names (3names), DOB (Date/Month/year), gender of infant, Parents'/guardian's full name and contacts, residence (county, sub-county, village, landmarks), whether the family has a medical cover e.g NHIF.

IV. Screening process

» *Setting*

The screening will be done in level 2 to 6 health facilities, with the involvement of private and faith-based facilities that offer immunization services.

The community level will be involved in the referral and follow-up through the community health volunteers. In these facilities, the screening will be conducted at several locations, Immunization clinic, Paediatric Outpatient Clinics, maternity wards, Paediatric wards, Out Patient Department, and Comprehensive Care Centers, outreaches and Malezi bora initiatives.

» *Tests to be used*

A validated rapid diagnostic test that is registered in Kenya, is recommended for the screening from level 2-6 health facilities.

» *Collection of sample*

The sample will be collected using a heel prick.

» *Further tests*

The confirmatory test to be used is Hb electrophoresis, this is usually found at level 4-6 health facilities.

» *Relaying of Results*

This will be done during the post-test counselling, verbally and in written form; in the MCH booklet, and a third copy from the screening register, to be retained by the patient's caregivers.

» *Linkage to Care*

Once the screening test turns positive, the caregiver will be given a copy of results and referred to the nearest facility with a sickle cell disease care clinic. On presentation at these service points, the confirmatory test will be done and those who are confirmed will be enrolled into care. Caregivers of infants found to have the sickle cell trait, will be counselled and strongly encouraged to bring the children to the health facilities when they reach adolescence for health education to enable them make informed reproductive health choices as they get into adulthood. The algorithm below explains this whole process.

For proper implementation of this program, it is important that each sub-county identify and appoint a focal person for sickle cell disease.

» *Screening Algorithm*

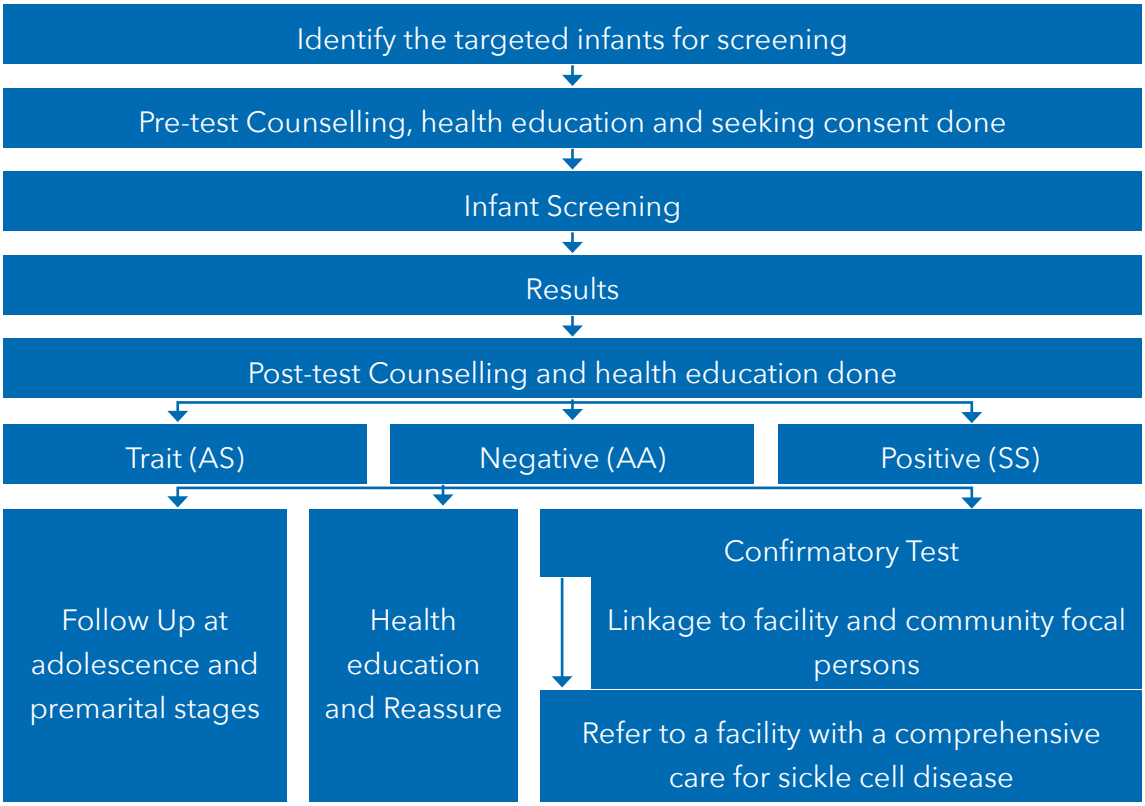


Figure 1: Screening Algorithm

CHAPTER 4: IMPLEMENTATION PHASES

The program implementation will be integrated to the existing health delivery systems.

I. Phase I- Pilot:

The pilot phase will be done in four counties, in the selected regions with a high burden of Sickle Cell Disease in Kenya, for a period of one year.

II. Phase II

This will be a scale up to the other 13 high prevalence counties for a period of five years.

III. Phase III:

The third phase scaled up to the remaining 30 counties in the country.

CHAPTER 5: ROLE OF STAKEHOLDERS

Table 2: Role of Stakeholders

Role of State Actors	
National MOH and	≈ Develop, implement, and review infant screening and sickle cell disease policy ≈ Monitor and evaluate policy development and implementation ≈ Resource mobilization for policy implementation and national activities ≈ Develop data collection tools and indicators of sickle cell disease screening and management ≈ Coordination and information sharing of national sickle cell data ≈ National registry coordination ≈ Develop and establish a sickle cell disease training curriculum ≈ Enlist and update recommended sickle cell diagnostics and consumables on essential list
Regulatory bodies	≈ Registration and approval of diagnostic, medical devices including point of care tests ≈ Accreditation of healthcare workers
Counties	≈ Mobilization and provision of resources for implementation of new-born screening ≈ Health workforce capacity building for new-born screening ≈ Creation of centres of excellence and referral mechanisms for new-born screening and sickle cell disease management ≈ Quality assurance of processes and devices for sickle cell disease newborn screening ≈ Provision of adequate infrastructure to enable newborn screening ≈ Monitoring and evaluation of implementation of newborn screening and management of sickle cell disease ≈ Generating and sharing data with National government ≈ Partner coordination ≈ Community engagement involving all stakeholders ≈ Conducting advocacy activities ≈ Ensure inclusivity of marginalized groups
NHIF	≈ Provision of a comprehensive care package for sickle cell disease management

Role of State Actors	
KEMSA Other suppliers	≈ Coordinate with county governments and other service providers in regards to stocking essential medicines and diagnostics for sickle cell disease screening and management
The National Treasury	≈ Support resource mobilisation effort for sickle cell disease activities ≈ Provide adequate budgetary allocation for sickle cell disease diagnosis and management
Role of Non-State Actors	
Professional associations	≈ Provide technical advice to national and county government ≈ Upskill healthcare workers through CMEs, newsletters, webinars etc
Private sector	≈ Partner with national and county government to provide infant screening, sickle cell disease care and management, reduce cost for treatment, strengthen health systems within the laid down framework ≈ Data generation and reporting into the national health information system from private facilities
NGOs, CBOs, FBOs, CSOs, and other patient support groups	≈ Raise awareness of sickle cell disease infant screening and provision of subsidized care to marginalized communities ≈ Protect and champion rights to health ≈ Health workforce capacity building in national and county levels ≈ Advocacy, education, training, and research of sickle cell disease using the national guidelines ≈ Psychosocial support of sickle cell patients and their families ≈ Resource mobilisation. ≈ Financial support for infant screening and care
Academic and research institutions	≈ - Capacity building in training, research, and care ≈ - Publication and dissemination of information on research activities ≈ - Inclusion of sickle cell disease training in the academic curriculum
Opinion leaders (Political, religious, community, influencers)	≈ Advocacy for infant screening for sickle cell disease ≈ Creating awareness
Development partners	≈ Technical support and fund all other stakeholders in policy implementation

CHAPTER 6: MONITORING & EVALUATION

I. Introduction

This chapter outlines mechanisms to be used to measure process implementation, use and achievement of outlined targets.

Monitoring processes are essential functions to ensure that priority health actions outlined are implemented as planned against stated objectives and desired results. Monitoring involves the collection of routine data that measure progress toward achieving program objectives. It is used to track changes in program performance over time with the purpose being to permit stakeholders to make informed decisions regarding the effectiveness of programs and the efficient use of resources.

The evidence gathered through monitoring and reporting processes will be used to:

a. Guide decision making in the screening of newborns by characterizing the implications of progress (or lack of it) being made.

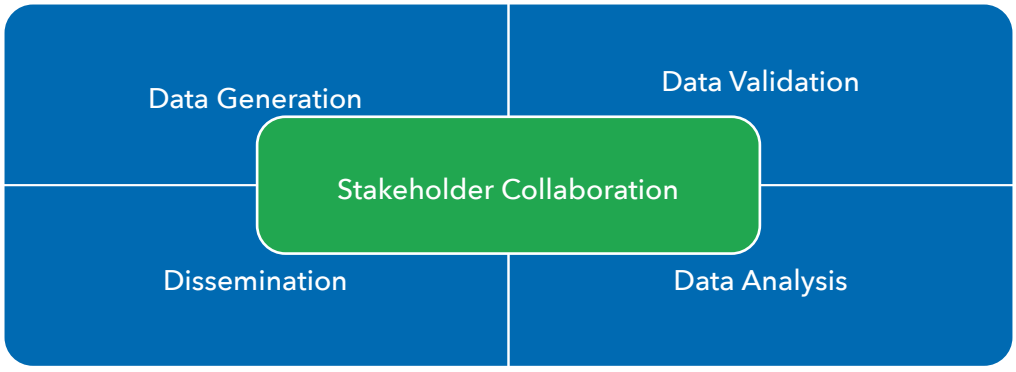
b. Guide implementation of the guidelines by providing information on progress and results.

c. Provide a unified approach to monitoring progress by all stakeholders involved service delivery.

d. The monitoring and reporting system will respond to meet the growing interest and demand for quality data for decision-making, measurement, learning, accountability and policy dialogue.

In order to achieve a robust monitoring system, effective policies, tools, processes and systems should be in place and adequately disseminated. The collection, tracking and analysis of data will make implementation effective to guide decision making. The critical elements to be monitored are: Resources (inputs); Service statistics; Service coverage/Outcomes; Investment outputs; Access to services; and impact assessment. The key monitoring processes as outlined in Figure 2 will involve:

Figure 2. Monitoring Process



II. Data Generation

a. Various types of data will be collected from different sources including non-governmental organizations to monitor the implementation progress. These data will be collected through routine methods, surveys, and periodic assessments, among others.

b. Routine activity data will be generated using the existing mechanisms for example training activity reports, among others.

c. Data flow from the primary source through the levels of aggregation to the national level will be guided by reporting guidelines and reach the MOH by agreed timelines for all levels.

III. Data Validation

a. Data validation through regular data quality assessment to verify the reported progress from source to aggregated values to ensure that data are of the highest quality. Annual and quarterly data quality audits will be carried out, to review the data across all the indicators.

IV. Data analysis

a. This step ensures transformation of data into information which can be used for decision making at all levels.

b. It requires a team with strong analytic skills to make sense out of the presented data.

c. The analysis will be done during the quarterly and annual performance reviews, where achievements will be compared against set targets.

V. Information dissemination

a. Information products for example annual performance review reports, developed will be routinely disseminated to key sector stakeholders and the public as part of the quarterly and annual reviews and feedback on the progress and plan provided.

VI. Stakeholders' collaboration

a. Effective engagement of other relevant Departments and Agencies in the health sector monitoring and reporting process is key. Each of these stakeholders generates and requires specific information related to their functions and responsibilities.

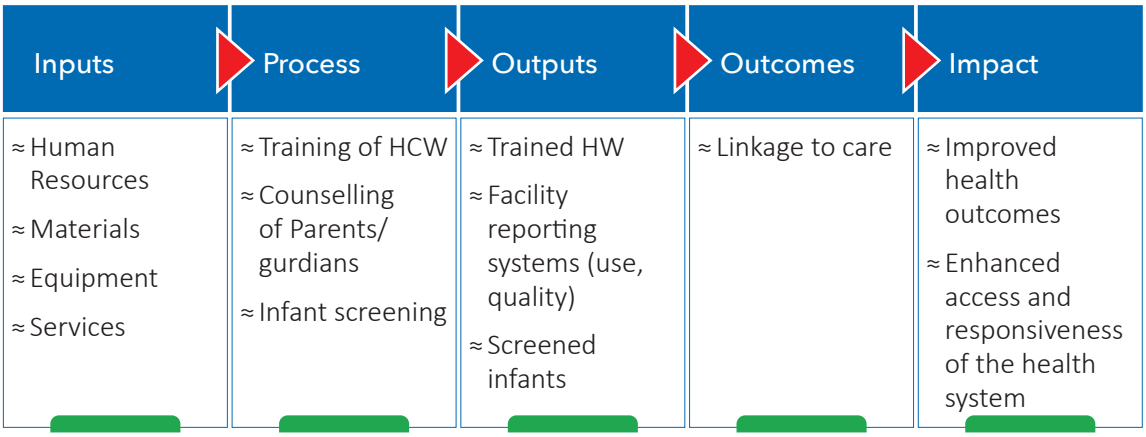
b. The information generated by all these stakeholders is collectively required for the overall assessment of performance.

VII.Logic Model

A clear framework is essential to guide monitoring and reporting. A framework in figure 3 explains how the programme is supposed to work by laying out the components of the initiative and the

order or the steps needed to achieve the desired results. The logic model as outlined looks at what it takes to achieve intended results, thus linking results expected, with the strategies, output and input, for shared understanding of the relationships between the results expected, activities conducted, and resources required.

Figure 2: Monitoring Logical framework



VIII. Indicators for Infant Screening of Sickle Cell

The indicators are based on the respective domain areas. The indicators to be monitored will include:

» *Impact Indicators*

a. Infant/child mortality rate due to sickle cell disease

b. Infant/child morbidity rate due to sickle cell disease

» *Outcome Indicators*

a. Proportion of infants enrolled on care for SCD

b. Proportion of infants still on care for SCD at one year from the date of enrollment

» *Output Indicators*

a. Proportion of infants screened on SCD

b. Proportion of infants who turned positive for SCD (SS)

c. Proportion of infants who have a Sickle cell trait (AS)

d. Proportion of infants who have been referred for confirmation of diagnosis

e. Proportion of infants initiated into care

» *Input Indicators*

a. Percentage of facilities implementing the Sickle Cell Disease infant screening program

b. Proportion of facilities with equipment for confirmatory tests

Table 3: Progress Monitor

Domain area		Baseline 2022
Impact	Reduce child/infant mortality due to SCD by 20% annually	-
	Reduce proportion of hospitalizations by 20% annually	-
Outcome indicators	Increase the proportion of infants enrolled on care for SCD by 20% yearly	-
	Increase the proportion of infants still on care for SCD at one year from the date of enrollment by 20%	-
Output Indicators	Increase the proportion of infants screened on SCD by 20% annually	-
	Increase the Proportion of infants who have been referred for confirmation of diagnosis and initiation of care by 20% annually	-
Input indicators	Increase the percentage of facilities implementing the Sickle Cell Disease infant screening program by 10% annually	<1%
	Increase the proportion of facilities with equipment for confirmatory tests	<1%

IX. Data Review and Performance monitoring processes

The two levels of government and all the stakeholders in health will work together in order to achieve the stipulated targets. The data review and performance monitoring processes are useful for documenting lessons learnt and measures of success during the implementation. A transparent system of periodic data and performance reviews that involves key health stakeholders will be ensured. All data review, performance monitoring and reporting processes will produce targeted and actionable recommendations.

» *Quarterly and Annual reports*

The health sector will prepare and consolidate quarterly and annual reports. A forum will be organized to share the annual reports and share experiences, best practices and identify any areas for improvement. The following are the monitoring reports and their periodicity:

Table 4: Monitoring Reports

Process/Report	Frequency	Responsible	Timeline
Annual Work Plans	Yearly	Facility, County, Sub-county and National Levels	End of June

Process/Report	Frequency	Responsible	Timeline
Health Data Reviews	Quarterly	Facility, County, Sub-county and National Levels	End of each quarter
Monthly reports submissions	Monthly	Facilities	5th of every month
Quarterly reports	Quarterly	Facility, County, Sub-county and National Levels	After 21st of the subsequent Month

CHAPTER 7: ANNEXES

I. Annex I:

Requirements for Infant Screening

a. Registers
b. Sickle cell rapid testing kits
c. Trained personnel
d. Gloves
e. Lancets
f. Sharps box containers
g. Alcohol swabs
h. Handwashing facilities
i. Vacutainer tubes
j. Courier services
k. Cooler boxes

Requirements for confirmatory test

a. Hb electrophoresis machines
b. Gloves
c. Alcohol swabs
d. Reagents
e. Trained laboratory personnel
f. Registers
g. Syringes and needles
h. Vacutainer tubes
i. Hand-washing stations
j. Sharps box containers

II. Annex 2

» *Screening Form*

Ref No: NAME OF FACILITY

LEVEL OF FACILITY

MFL CODE

INFANT SICKLE CELL DISEASE SCREENING FORM (To be filled in triplicate)

1. NAME OF PATIENT: SURNAME FIRST SECOND
2. GENDER: M ☐ F ☐ OTHERS ☐
3. DOB: DD/ MM/ YYYY
4. MOTHER'S NAME: _____

   FATHER'S NAME: _____

   GUARDIAN'S NAME: _____

   MOBILE NUMBER 1: _____ (mother/father/guardian)

   MOBILE NUMBER 2: _____ (mother/father/guardian)
5. CURRENT RESIDENCE:

   COUNTY: _____ SUB-COUNTY: _____

   WARD: _____ VILLAGE/ESTATE: _____

   LANDMARK: _____
6. DATE TEST DONE _____
7. RESULTS AS ☐ AA ☐ SS ☐
8. REMARKS/ACTION _____

This information will be transferred to the screening register and MCH

» *List of External Reviewers*

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2. Prof Fred Were	University of Nairobi and Kenya Paediatric Research Consortium
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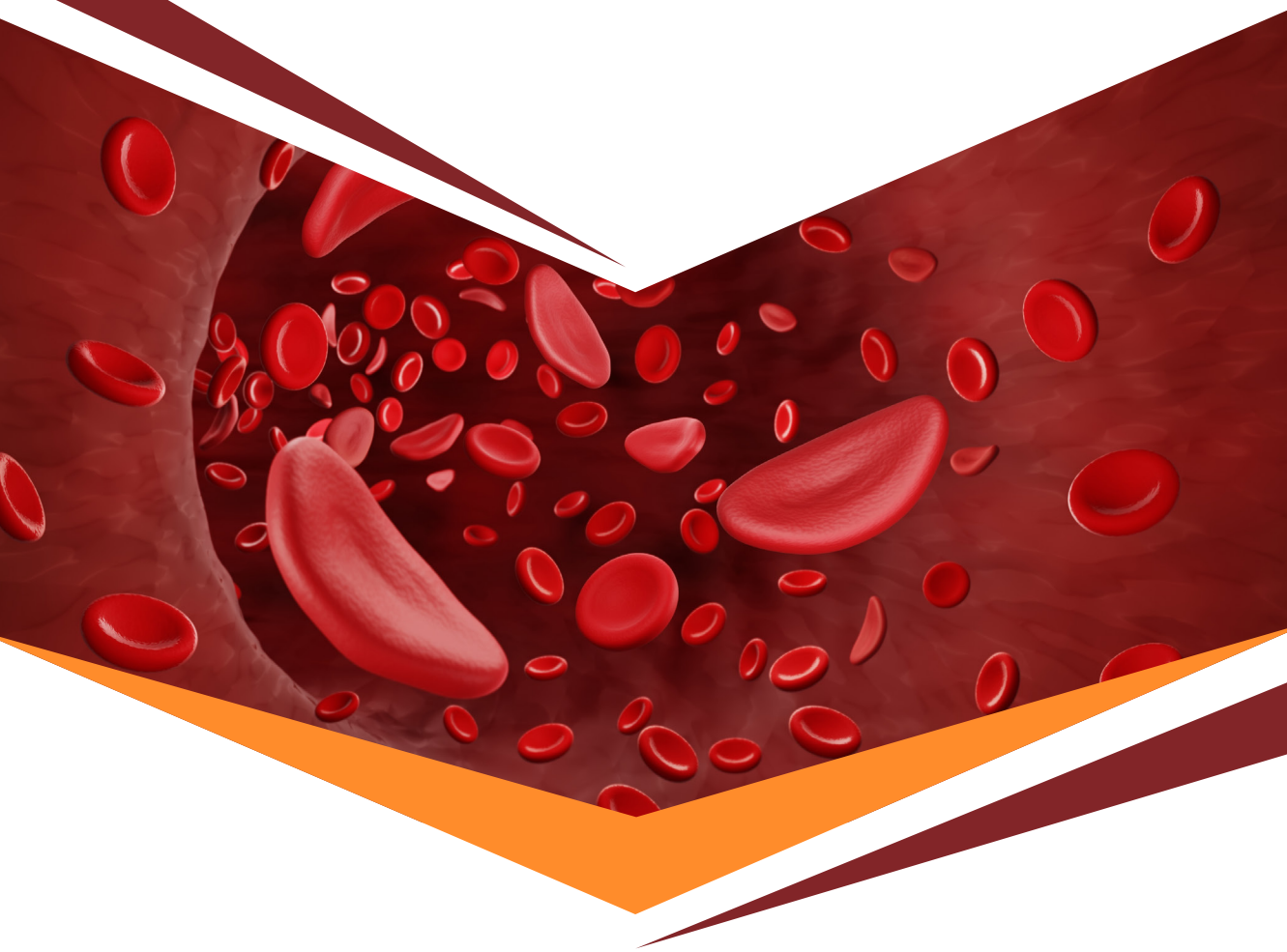

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