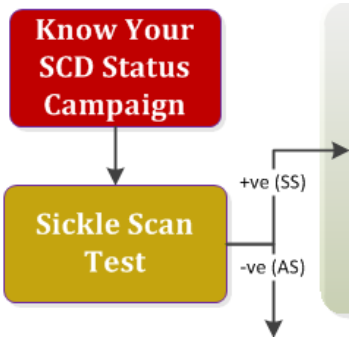
RaPoC

Rapid Point of Care Screening Program for Sickle Cell Prevention and Management

in Cameroon's North-West Region



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November 2015

Draft - confidential

Introduction

Sickle cell disorders are serious and can be life threatening. They can cause severe disability and even death if the disorder is not detected early and treated or controlled.

June 1975: Within a few months of birth in Bafut, Engelbert, the healthy looking baby, developed swellings in his wrists and arms. He was taken to the local health center where pain medications were administered and discharged. Shortly after, the symptoms resurfaced now accompanied by fever. He was anemic on his return to the health center where he received his first blood transfusion. At six, he developed a squinting eye; suffered a stroke (and lost speech and partial movement in the right arm) at seven. At eight he developed a very high fever and was sent to the lab to be screened for Malaria. The result was sickle cell anemia. No one in his family knew what sickle cell was nor what its treatment was.

October 2012: At the FJK Sickle Cell Center in Bamenda, Ma Bih, held her three year old daughter on her laps closed to her chest. She did not know what the child was sick of. The child had very white and weak eyes. Her right wrist was swollen and she was "hot" to the touch. Asked where it was hurting the child pointed to the swollen wrist and chest. With teary eyes the mother told the Center's Executive Director to do something because she could not afford to loose her child. This will be her second. The first was slightly older than the one she now carries, and had experienced exactly the same symptoms before she died. Another relative, she explains, had a child with similar characteristics who died many years ago. Ma Bih's child was later diagnosed with sickle cell anemia.

Relatives describe cases of children with similar symptoms who have died. Infections, resulting from lack of early detection in children under five account to 15% of deaths in some West African Countries (Streetly, et al., 2008). Recognizing sickle-cell anemia as a public health problem (UN. 2008) the World Health Organization recommended a set of priority interventions to reduce the public health burden through which the complications of the many Engelberts and baby Ma Bih, today and tomorrow, can be prevented (World Health Organization, 2010).

These include supportive measures like early diagnosis and treatment of complications, immunization and prophylactic antibiotics, early identification and implemented screening programs for newborns, children and prenuptial persons. Reduced infant mortality (Streetly, et al., 2008) preventable complications and infections (Weatherall & Clegg, 2001) have been reported in countries where screening programs for early identification and care have been implemented (Antonarakis & Delozier-Blanchet, 2015). Pre-nuptial screening to identify affected and carriers have been proposed and implemented elsewhere (Al-Nood, 2013) as a measure to prevent affected births.

Cameroon does not have a sickle cell screening program. FJK Foundation is going to address this need through a proposed Rapid Point of Care Screening Program, RaPoC SP, that utilizes a simple tool with thye capability of differentiating sickling conditions for adults and newborns. RaPoC Screening Program aims at:

1. identifying carriers and giving them enough information to make informed decisions on the risk of passing on a genetic disorder.
2. addressing the question of preventable infection or severe anemia for children under five

3. educating families on the importance of early detection and aggressive management of the disease in children and newborns.

The expected outcome of RaPoC SP is a decrease in the incidence of affected birth and reduction in sickle cell disorder burden.

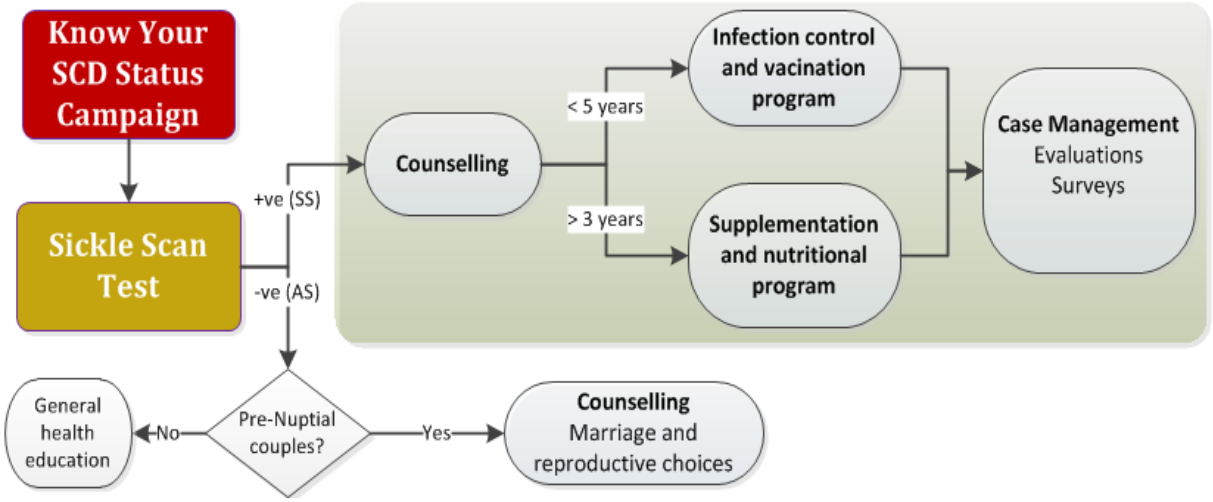
Scope

The target populations for screening include newborn babies, pre-nuptial couples, high school students, children and pregnant women who have never been tested for SCD should be screened.

The primary base of program administration will be the FJK Sickle Cell Center Bawum Bafut beginning with the Bafut Health District and extending to other Health Districts in the North-West region. Priority will be given to health districts with high concentrations of SCD families according to the FJK 2014 survey. DOVE, the mobile unit of the sickle cell center will be utilized for rural communities.

Design and Implementation

RaPoC Screening is designed after FJK's SCD management paragon in which persons made aware of the diseases are tested and appropriately counseled based on the outcome. All three components can be done at the point of care and contact.



Know Your SCD Status Campaign

The Screening program will commence with a "Know Your SCD Status Campaign,launched through the Foundation's Community Outreach services and partner/coolaborator channels. Know Your SCD Status Campaign will be conducted via distribution of brochures, face to face meetings through faith based organizations, cultural groups, and social clubs and school Parent Teachers Associations, texting (SMS) and radio programs. The Foundation currently runs a 30 minutes weekly broadcard on a dedicated radio channel. The service will be staffed with a dedicated sickle cell mobile telephone line that patients can reach for additional information and directives.

Singles and prenuptial couples will be encouraged to take a SCD class or information session. These classes can be organized in a formal setting, or through a general education class in secondary schools, church groups and cultural, social clubs.

Sickle Scan Test

Screening will be done using Sickle Scan a, portable, multiplexed qualitative point-of-care immunoassay used for the rapid diagnosis of sickle cell disorders. The test is made up of three indicators which detect the presence of hemoglobins A, S, and C, allowing the user to rapidly distinguish between normal, carrier, and sickle cell samples.

Newborn babies 48 hours and older will be tested before discharge from the health center or hospital. Older children can be screened during routine follow up at the clinics or outreach rural community centers on arranged, advertised days. For singles, pre-nuptials and adults, can be screened on a walk in basis, by appointment. Parties will be screened and appropriate counseling administered if necessary.

Sickle Scan was selected because of its portability, which makes the screening program accessible, available and affordable to those in the rural areas. Persons with the condition or trait will be readily and quickly identified. Educating and caring for families of the affected, as such, will be effective and cost-efficient. Additionally, the test:

- can be administered and results obtained, under 10 minutes, at the point of care.
- does not require transfer of blood samples from point of care or contact to a centralized laboratory.

No clinical or high capital investment laboratory equipment with specialized instruments and professionals are required to administer the test. Sickle Scan is unlike the electrphoresis system which is rather expensive to acquire, operate and maintain. Details of Sickle Scan including testing method per manufacturer specifications are in Appendix A.

Counselling

The sickle cell counseling and education service will provide patients and their families with culturally appropriate counseling about the disease process, warning signs of illness, when to seek prompt treatment, and encourages family members to be tested.

Newborn and Children

For positive cases, the parents or guardians will be enrolled into a counseling program, while children under five will have the option of being placed enrolled in an infection prevention monitoring program. Older Children will be enrolled into the Hemoxide therapy intervention program.

Singles and Pre-Nuptials

The objective is to enable couples know their carrier status and be in an informed position to make decision on their futures (prevent affected birth). Those positively identified with the condition or are at risk, along with families will receive counseling and education and general information on the sickle cell health effects on children/family members.

Data Reporting

FJK Foundation has developed an electronic database for capturing results for aggregation, analysis and reporting. A ready to use template will be available through which results can be reported electronically or sent in hard copy.

FJK and remote partners will maintain a log that is a replica of what is reported in the template for each tested person and location.

A protocol that includes patient conscent and confidentiality, for collecting and monitoring data will be established and managed by a screening coordinator. For each person tested/screened demographic information and test results must be collected and reported. Tested individuals will have a copy of their test results to take away as part of their medical record.

Partners and Collaborators

In addition to existing collaborators, FJK is opened to collaborative efforts with interesting Health institutions, cultural groups, companies. Those interested can request and obtain informative materials to include "Sickle Cell Screening Guide", "Know Your SCD Status brochures".

Regional Delegation of Health

FJK Foundation and the Regional Delegation of Health signed an MOU for managing Sickle Cell Disease. Under the terms of the MOU Health Districts in the region will:

- develop engagement protocols for their districts based on the MOU.
- assist in the "Know Your SCD Status" campaign
- provide on the spot facilities for screening
- integrate the program into the existing systematic framework of the vaccine and malaria programs.

BioMedomics

BioMedomics, a US based company and developer of Sickle SCAN Test is committed to ensure availability of the assay on demand.

Bafut Health District

Fr John Kolkman work in collaboration with the Bafut Health District under the terms of a Memorandum of Understanding (MOU) with Regional Delegation of Public Health.

Total Health Enhancement (THE)

A long time collaborator since 2010 THE has renewed its commitment with FJK Foundation to make available Hemoxide SCA as long as the demand is there.

Personnel

Screening Coordinator

- establish and maintain monitoring, data gathering and reporting protocols
- maintain and adequate inventory and supply of test kits, educational and counseling materials like pamphlets and flyers
- collect and report missing/incorrect data for tested cases
- serve as contact person and facilitator to inform and educate persons about the program and its guidelines, and disseminate information as reports, news, flyers, etc.

Nurse

- conduct the test and document results
- consult and take notes on SCD complications and other ailements as observed
- make appropprive referrals and recommendations

Driver

- bring the team to the rural communities as needed

- drop off patients seeking medical attention to appropriate health facility or hospital
- dispatch test kits and training materials at needed locations

Case Manager Counselor

- Design and conduct couseling sessions as needed.
- Followup with referral cases for positive cases
- Review case and medical notes to determine cause of action and offer appropriate interventions.

Program Timeline and Phases

To be determined and detailed per the outline below.

Phase 1

- Strategic planning of approach to include scheduling
- Development and acquisition of campaign materials
- Staff development: sickle scan, data gathering and reporting tools, professional patient handling and confidentiality

Phase 2

- Campaign, Testing and Counselling
- Data collection and analysis

Phase 3

- Report of Pilot
- Review and presentation of Report

Success Factors

A successful implementation of the program is based on the coordinated efforts of partners, collaborators and an active participation of healthcare providers.

- Government's quick approval of the Sickle Scan assay for use.
- Governmental, educational instituitions and community support
- Children who get tested are enrolled in a vaccine (routine immunization) and infection prevention program.
- Integration with existing public health programs like malaria, typhoid and vaccine.
- Continuous availability of the Sickle Scan assay.
- Public Health intervention policy requiring all new born babies in the region to be screened within 2 to 8 days of age.
- Sufficient levels of awareness and public education to enforce the significance and value of early detection and management and parental information of the availability of the test.
- Collaborative participation of health care institutions.
- Tracking and monitoring those positively identified in order to assist families to cope with the situation.
- Timely reporting of test results to FJK Foundation for entry into a central registry.

- Assistance with fuel for DOVE – mobile unit for outreach.

Challenges and Threats

- Lack of interest in participation for those who lack the financial means to enroll into any of the programs.
- FJK Foundation is viewed as a healthcare economic commercial competitor.
- Religious, social and cultural beliefs of individuals
- Traditions and ethnic heritage, attitudes of individual couples
- Level of education and literacy
- Economic viability of families

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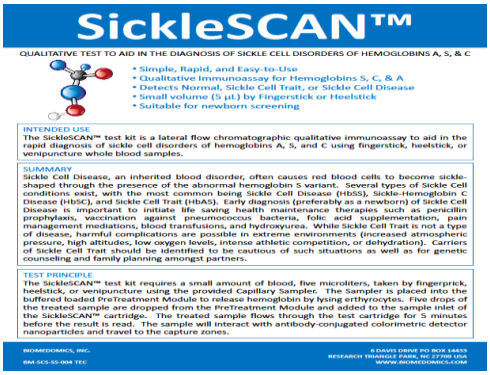
Appendix

Sickle Scan



Brochure Material

What is sickle cell disease screening

Screening is the process of identifying people who appear healthy but may be at increased risk of a disease or condition.

What is sickle cell disease?

Sickle cell disease is the name for a group of related conditions which affect the quality of hemoglobin and the capacity to carry oxygen around the body. The most serious form of the disease is sickle cell anemia.

How is testing done?

A drop of blood will be obtained by pricking a baby's heel (others, a finger) with a capillary tube.

How long does it take to get my test results

You can get your results at the point of testing in under 10 minutes from the time your sample is collected.