Dec 29, 2024

Perception of sickle cell patients on their diagnosis and management practices at the eighteen sickle cell clinics of Delta State Nigeria: The research protocol

DOI
https://dx.doi.org/10.17504/protocols.io.261gerxjjl47/v1

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OPEN ACCESS

DOI: https://dx.doi.org/10.17504/protocols.io.261gerxjjl47/v1

Protocol Citation: Uchechukuka Nnemdi Okwe, Charles C. Ofili, Ezekiel Nwose 2024. Perception of sickle cell patients on their diagnosis and management practices at the eighteen sickle cell clinics of Delta State Nigeria: The research protocol. **protocols.io https://dx.doi.org/10.17504/protocols.io.261gerxjjl47/v1**

Protocol status: Working
We use this protocol and it's working

Created: December 26, 2024

Last Modified: December 31, 2024

Protocol Integer ID: 117278

Keywords: perception of sickle cell patient, sickle cell clinics of delta state nigeria, perception of the sickle cell disease, sickle cell patient, sickle cell disease, sickle cell clinic, clinical observational study at the scd clinic, clinical observational study, national levels on appropriate scd care, management practices in delta state nigeria, selected scd patient, diagnosis, disease, retrospective clinical audits of patient, retrospective cohort study

Abstract

The broad objective of this study is to investigate the perception of the sickle cell disease (SCD) patients on their diagnosis and management practices in Delta State Nigeria. This was designed to be clinical observational study at the SCD clinics in Delta State Nigeria. This would include cross sectional and retrospective cohort studies. Data collection would utilize qualitative interview, quantitative questionnaires, and non-experimental design involving retrospective clinical audits of patients' medical records. 700 randomly selected SCD patients are set to be recruited. Statistical evaluations would involve descriptive a well as qualitative and quantitative analysis. The expected results will hopefully ensure improvement in treatments and alert policy makers in the State and National levels on appropriate SCD care.

Introduction

1 Sickle Cell Disease(SCD) is a disease of the hemoglobin and commonest genetic disease in Nigeria
Modell, 2008). It is a major public health problem with its carrier prevalence about 25% (Balogun et al., 2010). Nigeria has a population of 140 million with an annual growth rate of 3.2% and bears the greatest burden of SCD (Adewoyin, 2015). Globally, 330, 000 babies are born with major hemoglobinopathy out of which 275,000 have SCD (Aygun & Odame, 2012; Piel et al., 2013). United Nations estimates that 20 to 25 million people worldwide live with SCD of which 12-15 million live in Africa (Adigwe et al., 2023). It has been estimated that 75-85% of children born with SCD are born in Africa, where mortality rate for the under-5 is 50% to 80% (Aygun & Odame, 2012; Makani et al., 2015).
The problem includes that Nigeria has the highest burden of SCD patients and most of its data are hospital based and not population based (Galadanci et al., 2014). Most SCD crisis recorded are readily amenable to treatment but the interventions and treatments are expensive and are not accessed by majority of the patients and those that live in low resource settings (Bell et al., 2024).
In Nigeria, trained health personnel, specialized health care facilitities are limited (Adigwe et al., 2023; Collier, 2012). The survivors suffer end-organ damage which shortens their life span (Lubeck et al., 2019). Persons with SCD are often stigmatized (Leger et al., 2018). With non-adherence to treatment, there is interference in their lives, education, work and psychosocial development (Moussa et al., 2023). There are three Sickle cell referral centres for SCD patients that are functional. This is grossly inadequate to take care of the increasing number of children with SCD in Nigeria (Galadanci et al., 2014). Newborn screening and close follow-up, especially early in life (Odunvbun et al., 2008), has improved survival but these interventions require resources, technical knowledge and infrastructure. In
sub-Saharan Africa there are over 250 000 births annually which suggest that these interventions are unlikely to be implemented within the foreseeable future (Serjeant et al., 2010).
There is no documented evidence to show the perception, knowledge and attitude of the SCD patients in Delta State towards their clinical condition, their psychosocial development and efficient care despite services at the upgraded and well-equipped sickle cell clinics and referral centre in Delta State. Hence the research agenda (Table 1).

Specific objectives	Research questions
To evaluate the perspective of the SCD patient towards his/her management practices	What are the perspectives of SCD patients regarding management of their health?
To evaluate the level of care and efficacy of management of SCD	What are the perspectives of SCD patients regarding efficient health care service delivery?
To identify gaps and challenges in Delta State health system	Are there gaps or challenges in the health system that affects SCD?
To assess the effectiveness of the established use of hydroxyurea for prevention of SCD crisis in our clinics	How effective is the established mechanism of SCD crisis management with hydroxyurea?

Table 1: Specific research objectives and questions

Method

2 ***Research design***

The proposed research design for the study is cross-sectional, descriptive, quantitative, qualitative, non-experimental among 700 randomly-selected SCD participants (Okwe et al., 2024). The random selection was adopted from an entrepreneurship-informed proportionate sampling research (Engidaw, 2021). The qualitative study features individual interviews with 60 teenagers (male and female) randomly-selected (balloting). The teenagers will be 20 (10 females and 10 males) aged 13 -19years from the busiest clinics in the 3 senatorial districts. Information to be obtained will be on the knowledge, attitude and perception of the SCD patient towards SCD diagnosis and management practices at the SCD clinics. The qualitative study is on In-depth understanding of the existing management practice challenges present at the sickle cell clinics.

A sequential method will be used to elicit this information starting with the individual interviews before the questionnaire based study. There will be a retrospective chart review (Jesuthasan, 2023; Vassar & Holzmann, 2013) on the use of hydroxyurea and frequency of crisis recorded at the clinics. The statistical designs for each specific objective is as indicated on table 2.

Specific objectives	Hypothesis	Study design
To evaluate the perspective of the SCD patient towards his/her management practices	There is no significant association between the SCD client age and his/her perceptive on management practice.	Cross-sectional, descriptive; quantitative analysis
To evaluate the level of care and efficacy of management of SCD	There is no significant association between the benefit of the SCD and efficient health care service delivery at the clinics	Cross-sectional, descriptive; qualitative, quantitative analysis
To identify gaps and challenges in Delta State health system	There is no significant association between challenges and gaps in our health system that affect SCD management	Exploratory quantitative and qualitative analysis
To assess the effectiveness of the established use of hydroxyurea for prevention of SCD crisis in our clinics	There is no significant association between the established mechanism of prevention of SCD crisis with hydroxyurea and management of SCD crisis	Quantitative analysis

Table 2: Statistical designs for the specific objectives

Research setting

This Research is going to be conducted in 18 sickle cell clinics located in the primary, secondary and tertiary health facilities in 24 Local Government Areas at the 3 senatorial districts of Delta State. The clinics were randomly selected due to their very busy nature and patient load recorded there. Each clinic has a number of registered sickle cell patients monitored by the Genetic counselors and supervised by the Medical Directors.

The Genetic counselors are mainly nurses and Doctors who have been trained and charged with the sole responsibility of health care delivery, management and counseling of sickle cell patients and their parents. Monthly Data of the newly diagnosed SCD patient and the already diagnosed SCD patient at the clinic are recorded. (Hospital Sickle cell registry records).

Research Participants

The participants are sickle cell patients randomly selected and registered at the 18 sickle cell clinics located at the 24 local Government areas of Delta State. 6 sickle cell clinics were randomly selected from each senatorial district. The teenagers are chosen because of their outspokenness in expressing emotional and behavioral clues to questions on challenges of assess of quality care at the sickle cell clinics.

Selection criteria

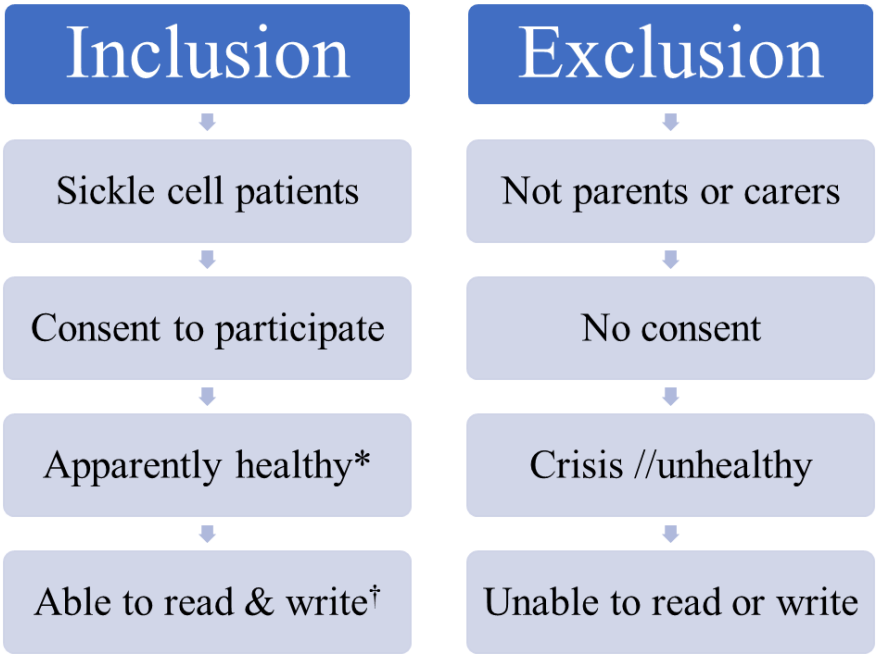

Fig 1. Inclusion vs exclusion

The protocol in graphics

3 ***Data collection locations***

State Districts	SCD Clinics	No of Clients*	Interviews
Delta Central	Eku, Oghara, Orerokpe, Otujeremi, Sapele, Ughelli	233	20
Delta North	Agbor, Asaba, Kwale, Gov't Secretariat, Ogwashi-uku, Okwe	234	20
Delta South	Warri, NPA, Oleh, Koko, Burutu, Bomadi	233	20
	18 facilities	**700**	**60**

Table 3: Sample size distribution across facilities
* ≈239 participants per SCD clinic for the survey

Data collection methods

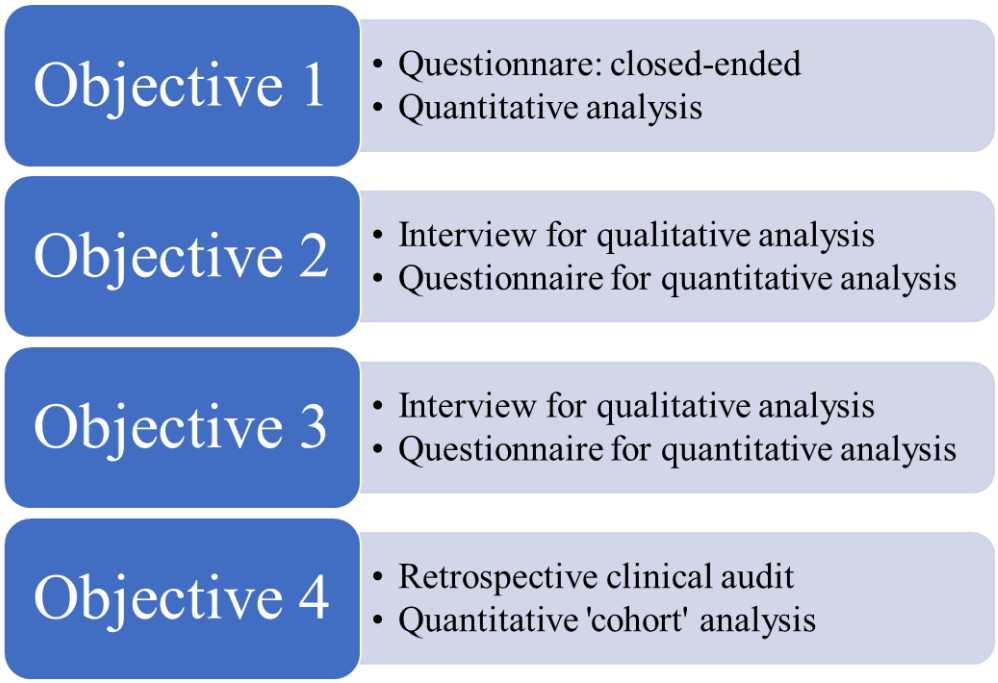

Fig 2: Outline of data collection methods and evaluation approach

Retrospective cohort study aspect

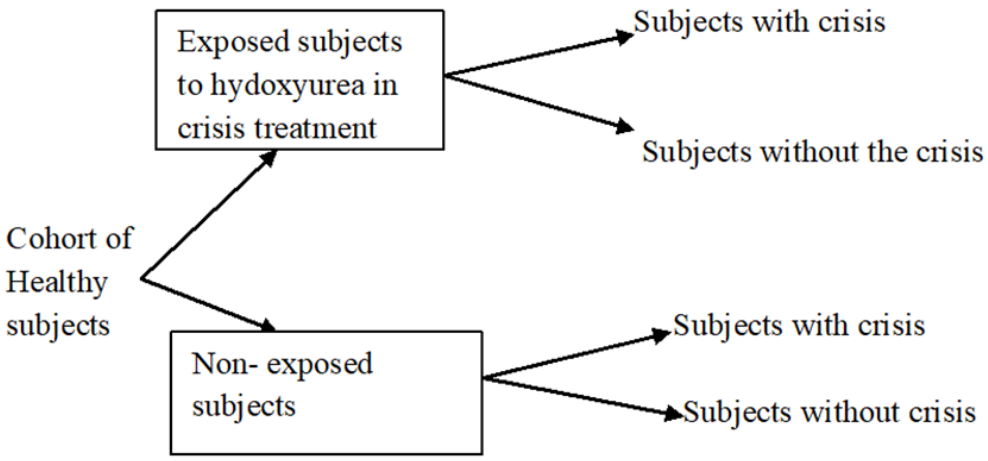

Fig 3: Graphic representation of a retrospective cohort study

Research instrument

Research questionnaire was adopted from (Gupta et al., 2016). The study is designed to use quantitative method of data collection (mainly). This will be applied to 700 participants. A structured questionnaire design based on the objectives of the study, which consist of five (5) sections namely"

Section A: Social demographic variables of respondents (from question 1 to 8)

Section B: Perception/ knowledge of information about SCD and attitude towards the diagnosis.
Section C: Attitude of healthcare givers and factors influencing access to treatment
Section D: Gaps and challenges in the SCD health care (Question teenagers)

Operational plan

4 ***Data collection personnel***

Three research assistants from within the Ministry of Health who have been trained on program monitoring and evaluation will be recruited and trained on the modalities of instrument administration and collection. They will assist in the quantitative aspect of this study (administration and collection of questionnaire). The individual interviews are to be done by the principal investigator, who will visit the clinics on their SCD clinic days. Questionnaires administered to the SCD patients will be checked for proper completion on collection from participants. The collected data will be coded and kept confidential.

Statistical analysis

This will be both descriptive and inferential at 95% confidence level using the statistical package for social sciences (SPSS Inc. Chicago 11.) computer software version 20.0. A P-value of less than 0.05 will be considered statistically significant. Daily checking of filled questionnaires will be carried out by the researcher at the end of each field day, to avoid incomplete data collection and to also ensure accuracy of data. For the retrospective study, there will data collection on the use of hydroxyurea from charts review of 90 sickle cell patients in 3 major clinics in the 3 senatorial districts of Delta state and the frequency of sickle cell crisis and its control. This will take 6 months to complete.

Validity and reliability

The research questionnaire tool was adopted and modified from a validated method based on published peer-reviewed literature (Gupta et al., 2016). The validity of the modified questionnaire will be established through face and content validity criteria. Content validity measure will be according to literatures (Feinstein, 1987; Rodenberg, 2009; Swan et al., 2023). In addition, the instrument will be checked for content, clarity, scope, appropriateness, and ability to elicit accurate information with respect to research objectives, questions and hypotheses according to published literature (Masuwai et al., 2024).

The reliability will be ensured using a test-retest approach (Zaki et al., 2012) using 10% of the sample size administered in a sickle cell clinic different from the one chosen from the study. The internal consistency reliability will be calculated using Cronbach's alpha (Vaske et al., 2017).

Ethical considerations

5 ***Approval:***

Ethical clearance will be gotten from the Novena University, Ogume and Delta State Ministry of Health, Ethical Committee (MOHREC) Asaba. Application of permission will be gotten from the individual hospitals to enable access to the sickle cell clinics domiciled within the hospitals.

Consent to participate

Consent from the respondents will be obtained before the actual study and their confidentiality assured using a typed consent form. The content and scope of this study will be explained to them to elicit their co-operation in each of the clinic and they will be requested to respond to the questions. They will be informed about the purpose of the research, the questionnaire introduction section will be explained and there will be freedom of choice.

Confidentiality of data*:*

Respondents will be informed that any information discussed and collected during the course of study will be kept confidential; the researcher will ensure that the research instruments will be kept anonymous and the results will be made accessible to them.

Significance of study

6 Study will further the evidence-based approach by policy makers to address obstacles preventing sickle cell management services, particularly public attitude, cultural beliefs and practices. It will provide information that could be useful to policy makers in shaping early genetic screening programs(neonatal new born screening) in Nigeria. It will serve as a reference to health experts and policy makers when implementing sensitive health promotion programs and intervention strategies.

It may alert the Ministry of Health of the appropriate measures that could be taken to save the lives of children living with SCD by educating them and providing a universal health insurance scheme for care. The knowledge that will emanate from the study will help to design interventions that will improve uptake, early diagnosis and ultimately improve outcomes from SCD and its complications.

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