Scientific Research Publishing

Open Journal of Epidemiology, 2026, 16(2), 303-316
https://www.scirp.org/journal/ojepi
ISSN Online: 2165-7467
ISSN Print: 2165-7459

Integration of Sickle Cell Screening with Routine Immunization in Mbujimayi, a Remote City in the Democratic Republic of the Congo

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How to cite this paper: Kalombo-Munganga, S., Malemba-Citala, D., Kalala-Mwanza, A., Mbuyi-Kalambayi, D., Kasongo-Thsiala, S., Mpoyi-Kalenda, J., Opara, J.P.A. and Mbiya-Mukinayi, B. (2026) Integration of Sickle Cell Screening with Routine Immunization in Mbujimayi, a Remote City in the Democratic Republic of the Congo. *Open Journal of Epidemiology*, **16**, 303-316.
https://doi.org/10.4236/ojepi.2026.162023

Received: January 20, 2026
Accepted: May 10, 2026
Published: May 13, 2026

Abstract

Background: Sickle cell disease is the most common genetic disorder in the world. It is a real public health problem in sub-Saharan Africa. Early screening makes it possible to diagnose the disease in the first few days of life and to start early treatment to prevent serious complications. The aim of this study was to determine the prevalence of sickle cell disease in Mbujimayi among children under the age of 5 during routine vaccination. **Method:** Prospective study conducted over a period of 6 months, from 05 December 2023 to 05 June 2024, in Mbujimayi. The main intervention of the study was systematic screening for sickle cell disease in children under 5 years of age during routine vaccination. The HemoTypeSC immuno-chromatographic test was used, and SS homozygous cases were confirmed by hemoglobin electrophoresis. **Results:** The prevalence of sickle cell disease was 6% (66/1100). The HemoTypeSC test demonstrated a sensitivity of 99% and a specificity of 100%. Significant correlations were observed, showing a higher prevalence in boys ($p < 0.003$), as well as an association with a history of transfusion ($p < 0.01$), hospitalization ($p < 0.01$), unexplained pain ($p < 0.01$) and the presence of sickle cell disease in the siblings ($p < 0.01$). Acceptability of the test was 100%. **Conclusion:** This study highlights the importance of early screening for sickle cell disease in children under 5 years of age in Mbujimayi. A proactive, targeted approach not only makes it possible to detect the disease at an early stage, but also to direct efforts towards appropriate management and better prevention of the complications associated with sickle cell disease. The HemoTypeSC immunochromato-

graphic test is proving to be a valuable tool for screening for sickle cell disease in primary care.

Keywords

Early Detection, Prevalence, Sickle Cell Disease, Mbujimayi, Democratic Republic of the Congo

1. Introduction

Sickle cell disease (SCD), also known as sickle cell anemia, is a hereditary hemoglobinopathy highly prevalent in sub-Saharan Africa and associated with significant morbidity and mortality. Approximately 5% - 7% of the global population carries a gene responsible for a hemoglobin abnormality, including SCD and thalassemia, with the majority of carriers living in sub-Saharan Africa [1]-[3]. Each year, an estimated 300,000 children are born with SCD, nearly two-thirds of whom are in this region. Without early diagnosis and appropriate management, more than 80% of affected children die before the age of five [4]-[6].

In the Democratic Republic of the Congo (DRC), available data remain fragmented and are mainly derived from major urban centers. It is estimated that approximately 2% of births are affected, with around 40,000 new cases annually, placing the DRC among the most affected countries after Nigeria [7] [8]. However, the prevalence of SCD in remote regions, including the Kasai area, remains poorly documented. Previous studies conducted in other cities have suggested a significant burden of disease among populations originating from this region, but no local data is available. This gap highlights the need for strengthened epidemiological surveillance and targeted awareness strategies.

Early screening in sub-Saharan Africa remains limited due to logistical and financial constraints. Conventional diagnostic methods, such as hemoglobin electrophoresis, require substantial technical and human resources. Isoelectric focusing, although recommended for neonatal screening, is still rarely used in these settings [9]-[11]. In contrast, rapid diagnostic tests (RDTs), such as HemoTypeSC and the Sickle SCAN test, offer sensitivity and specificity close to 100% and can be performed by healthcare workers without complex infrastructure. Diagnostic confirmation can be achieved using portable devices such as Gazelle, which are particularly suitable for remote areas due to their autonomy and ease of use [12]-[14].

In Mbujimayi, no study has yet assessed the prevalence of SCD. Furthermore, the implementation of systematic neonatal screening remains challenging in this setting. In this context, a strategy combining early screening with routine immunization could represent a practical and effective alternative to improve diagnosis and management of the disease.

The objectives of this study were:

1) To determine the prevalence of SCD among children aged 0 to 59 months during routine immunization sessions;

2) To assess the level of acceptance of SCD screening among mothers of children screened in Mbujimayi.

This study aims to provide essential data to inform public health policies and improve the management of SCD in this region of the DRC.

2. Method

2.1. Study Setting

This study was conducted in Mbujimayi [15], the capital of Kasai Oriental Province in the Democratic Republic of the Congo (DRC). It is the third largest city in terms of population in the country. In 2023, the population was estimated at 2,775,206 inhabitants, distributed over an area of 135.12 km^2, corresponding to a population density of 12,452 inhabitants per km^2. **Figure 1** illustrates the study area of Mbujimayi, Democratic Republic of the Congo.

Figure 1. Localization of the city of Mbujimayi in DRC.

2.2. Data Collection Sites

A total of four health facilities were selected as study sites. These facilities were chosen because they are major referral health centers in the city of Mbujimayi and receive many children during routine immunization sessions.

The Mbujimayi Pediatric Clinic (CPM), established in 2016, is one of the main centers providing care for children with sickle cell disease. It currently follows a cohort of more than 650 children who benefit from regular and free medical follow-up. The clinic is also one of the main pediatric referral facilities in Mbujimayi, located in Kasai Oriental Province. It includes a pediatric ward with a capacity of 30 beds, which are consistently occupied, as well as a neonatal unit, a maternity

ward, and a semi-automated laboratory.

The Bonzola General Referral Hospital is a major curative and preventive healthcare facility with a capacity of 500 beds. It comprises seven departments: pediatrics, gyneco-obstetrics, surgery, internal medicine, ophthalmology, otorhinolaryngology (ENT)/dentistry, and neuropsychiatry.

The SUMEDCO Polyclinic, established by the NGO "Support Médical et Technique au Congo (SUMEDCO)," is another curative and preventive healthcare facility with a capacity of 500 beds. Its main services include pediatrics, internal medicine, surgery, gyneco-obstetrics, laboratory services, and medical imaging.

The Christ-Roi General Referral Hospital, located in the Bipemba municipality, is a comprehensive healthcare facility providing both curative and preventive services, with a capacity of 450 beds. It is managed by the Sisters of Charity of Christ-Roi and Mpokolo. In addition to its laboratory, radiology unit, pharmacy, and administrative services, the hospital includes four main departments: surgery, gyneco-obstetrics, internal medicine, and pediatrics.

2.3. Population Studied and Sample

All children under five years of age attending routine immunization sessions at the four selected health facilities during the study period were eligible for inclusion. A total of 1100 children were enrolled.

Inclusion criteria comprised children presenting for routine immunization whose mothers or legal guardians provided consent for sickle cell disease screening.

Children who had received a blood transfusion within the previous three months, or who were not accompanied by a mother or legal guardian able to provide informed consent, were excluded from the study.

2.4. Diagnostic Analyses

All children included in the study were screened using a rapid diagnostic test (RDT). Positive results were subsequently confirmed by hemoglobin electrophoresis. However, RDT-negative cases were not systematically confirmed, which may have led to missed false-negative results and could therefore limit the accuracy of the sensitivity estimation. **Figure 2** illustrates the rapid diagnostic test (RDT) used for sickle cell disease screening.

2.5. Type and Duration of Study

We conducted an analytical cross-sectional study over a six-month period, from 05 December 2023 to 05 June 2024.

2.6. Data Collection

Data collection was done in two parts:

1) A questionnaire designed on surveyCTO that was completed during routine vaccination. Then the data was exported to an Excel file.

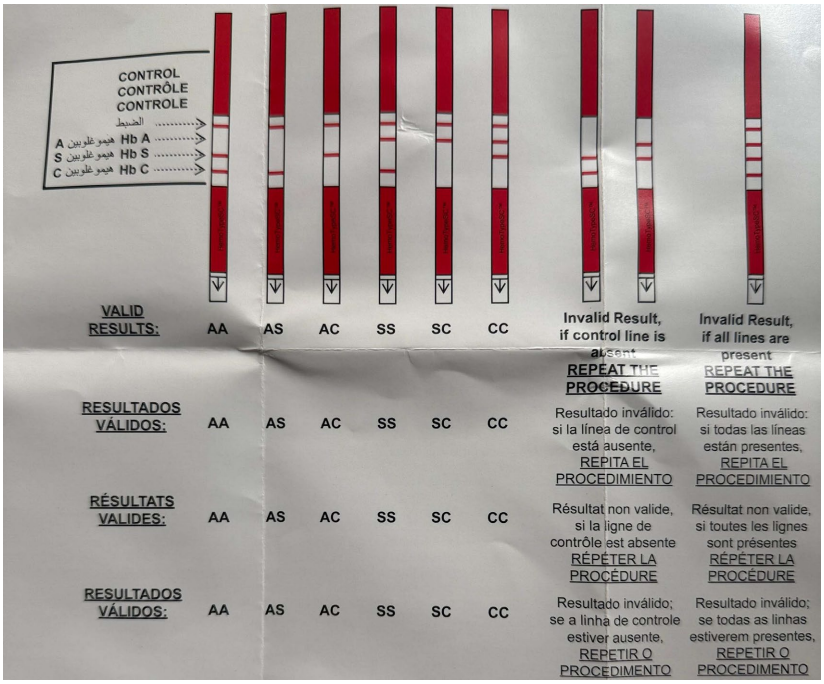

Figure 2. HemoTypeSC RDT realization.

2) Blood test for sickle cell disease in children using HemoTypeSC (Silver Lake Research Corporation, LOS ANGELES, USA) followed by confirmation of RDT positive by the Gazelle electrophoresis reader (Hemex Health, Portland, USA).

2.7. Variables Studied and Operational Definitions

The study variables and their operational definitions are presented in **Table 1**.

Table 1. Study parameters and operational definitions.

Variable	Operational definition
Pain history	Pain without trauma or disease that may explain the situation.
Transfusion history	Existence of a child who has previously been administered labile blood products (in particular, whole blood or concentrated blood cells) at a health facility.
Episode of repeated fevers	These are the successive febrile episodes that are separated by apyrexy intervals of several days or weeks.
Number of hospitalizations	Stay in a care facility for more than 24 hours.
Socio-economic level	Low socio-economic status: no android phone, no home TV. Average socio-economic level: have an android phone, have a permanent job and have a TV at home, high socioeconomic level: have a permanent job, a means of transport and other middle level.
Civil status	The purpose of this is to specify whether the woman is single, married or widowed.
Hemotype-SC results	This is a result after completion of the hemotypeScTM which is either hemoglobin SS, AS or hemoglobin AA or SC.
Acceptability of the test	Willingness to accept screening in your child.

2.8. Operational Mode

Screening was performed [16]. The results of biological analyses performed on RDT HemoTypeSC of children screened for SS were confirmed by capillary electrophoresis with the Gazelle electrophoresis reader [17].

2.9. Statistical Analysis

Data were analyzed using IBM SPSS Statistics version 20.0 and Epi Info™ CDC version 7. Results are presented in tables and figures. Quantitative variables were summarized using means and medians, while qualitative variables were described using absolute and relative frequencies.

Associations between categorical variables were assessed using the Chi-square test. A 95% confidence interval was used, and a p-value < 0.05 was considered statistically significant.

2.10. Ethical Considerations

The study protocol was submitted to and approved by the ethics committee of the Mashi Research Centre for sickle cell disease and other red blood cell disorders (N/Ref: 012/CR/CRM/CPM/YMK/2024). The study was conducted in accordance with the principles of the Declaration of Helsinki II, the objective and procedures of the study were explained to legal guardians. All parents or legal guardians of the children gave their informed verbal consent to participate in the study. Participants were informed that they could withdraw at any time without further obligation. The SS children were referred to a specialized structure for care and follow-up. The results of this study were presented to parents, and clear guidance was given in case of a positive test. All data generated or analysed during this research are available from the author upon request.

3. Results

A total of 1100 infants were screened for sickle cell disease during routine immunization visits in Mbujimayi. Socio-demographic characteristics are presented in Table 2. The median age at screening was 6 months [IQR: 3 - 21 months], with a sex ratio of 1. Most infants were screened between 0 and 19 months of age.

Table 2. Distribution of cases according to the socio-demographic data of mother and child.

Variables	Frequency (N = 1100)	Percentage	$CI_{95\%}$
Gender*			
Male	529	48	45.8 - 50.95
Female	571	52	49.05 - 55.94
Age of children (in months) (mean age was 6 months)			
0 - 9	972	88.36	84.1 - 92.5
10 - 19	118	10.73	7.03 - 13.8

Continued

20 - 29	6	0.55	0.12 - 0.88
30 - 39	0	0	0 - 0
40 - 49	2	0.18	0.08 - 0.35
50 - 59	2	0.18	0.08 - 0.35
Municipality of residence			
Kanshi	326	29.64	27.01 - 32.40
Diulu	359	32.64	29.93 - 35.46
Muya	106	10.55	8.87 - 12.54
Dibindi	178	16.1	14.12 - 18.48
Bipemba	121	11	9.17 - 12.85
Educational level of mothers			
Primary or secondary	611	55.5	52.59 - 58.46
Higher or university	449	44.45	41.54 - 47.41
Marital status of mothers			
Married	857	77.91	71.35 - 80.26
Single, widowed or divorced	243	22.09	19.74 - 24.64
Hospital			
Bonzola General Reference Hospital	103	9.36	7.78 - 11.23
Christ-Roi Hospital	84	7.64	6.21 - 9.36
Mbujimayi Pediatric Clinic	710	64.55	61.67 - 67.32
Sumedco Polyclinic	201	18.27	16.10 - 20.67
Parity of mothers			
Primipare	319	29	26.4 - 31.75
Multipare	781	71	68.25 - 73.62
Socio-economic level			
Low or Medium	852	77.45	75.23 - 79.12
High	248	22.54	20.88 - 24.77

*Sex-ratio: 1.

The prevalence of sickle cell disease among children under five years of age in Mbujimayi was 6% (66/1100). Males were more affected than females ($p = 0.003$). Infants with HbSS genotype (Table 3) were more likely to have a history of blood transfusion in the family, hospitalization, pain episodes, and a family history of sickle cell disease among siblings (all $p < 0.01$).

The test acceptability was 100% (Table 4). The HemoTypeSC test showed a sensitivity of 99% and a specificity of 100%. Figure 3 illustrates hemoglobin electrophoresis used for confirmation.

Table 3. Distribution of cases according to the results of the SC Hemo Type.

	TypeHb			Total n (%)	p-value
	AA n (%)	AS n (%)	SS n (%)		
Sex					
Male	270 (51.0)	225 (44.5)	34 (6.5)	529 (100)	0.003
Female	342 (58.2)	197 (34.4)	32 (5.6)	571 (100)	
History of transfusion in the family					
Yes	194 (59.9)	80 (24.7)	50 (15.4)	324 (100)	<0.01
No	408 (52.6)	352 (45.4)	16 (2.1)	776 (100)	
Number of hospitalizations					
<5	157 (67.9)	34 (14.7)	40 (17.3)	231 (100)	<0.01
≥5	733 (84.3)	61 (7)	26 (8.6)	869 (100)	
History of pain					
Yes	45 (47.9)	39 (41.5)	10 (10.6)	94 (100)	<0.01
No	788 (86.7)	26 (2.9)	56 (11.5)	909 (100)	
History of sickle cell disease					
Yes	3 (7.3)	2 (4.9)	6 (5.6)	41 (100)	<0.01
No	625 (59.0)	374 (35.3)	60 (5.6)	1059 (100)	
Electrophoresis of hemoglobin					
Yes	53 (80.3)	2 (3.03)	11 (16.67)	66 (100)	0.901
No	1 (100)	0 (0)	0 (0)	1 (100)	

Table 4. Distribution of cases according to test acceptability.

Consent to screening	Sample size (n = 1100)	Percentage
Yes	1099	99.9
No	1	0.1

Figure 3. Electrophoresis by the Gazelle Hb.

4. Discussion

This study aimed to contribute to the epidemiological description of sickle cell disease in DRC, specifically in 4 health units in the city of Mbujimayi. The discussion of our results will take place in three stages; first on the prevalence, then on the reliability of diagnostic tools and finally on the sociodemographic characteristics studied with the homozygous sickle cell patients in our series.

4.1. Prevalence of Sickle Cell Disease

The test was 100% acceptable, which suggests that mothers are interested in the disease and participate. This suggests the possibility of neonatal screening. In this study conducted in Mbujimayi, the prevalence of sickle cell disease was 6% for homozygous sickle cell hemoglobin (HbSS), 38% for sickle cell trait (HbAS) and 56% for normal hemoglobin (HbAA). In Kindu, a neonatal screening study found a prevalence of 1.9% HbSS and 26% for sickle cell trait [18]. In Kisangani, 2.2% SS homozygosity and 21% AS sickle cell trait were observed [19] [20]. In Lubumbashi, prevalence was 5% for HbSS, 26% for HbAS and 66% for HbAA [21], while in Nigeria, 21% were found for SA and 1% for SS [22]. Recent studies in other African countries show that, for example, in the Congo Brazzaville (AS 19% and SS 1.35%) [23] and in Gambia (SS 1.3, AS 17.5%) [24]. These results demonstrate a high prevalence of sickle cell disease in Mbujimayi and other cities across the country, confirming that the DRC is the third most affected country in the world and the second most affected country in Africa after Nigeria [4]. Studies of the prevalence of sickle cell disease in DRC are fragmented and do not report the true reality of the importance of the disease. Prevalence studies in the DRC are concentrated in large cities such as Kinshasa and Lubumbashi, leaving the problem of sickle cell disease undervalued, especially in the provinces. The prevalence of sickle cell disease in the provinces would be the hidden part of the iceberg. A national survey of the 26 provinces is essential to better understand the extent of the disease and improve management. The National Sickle Cell Control Programme (PNLCD) lacks representativeness in some provinces of the country and financial means, which hampers its actions. Government and bilateral partners need financial support to implement the national sickle cell strategic plan, which was drafted in 2021 but has not been funded to date. Concerted efforts by all stakeholders are crucial to raise awareness of the importance of this disease and improve management of sickle-cell children, more than 80% of whom die before age 5 without adequate care [4] [21].

4.2. Reliability of Diagnostic Tools

In this study, the HemotypeSC rapid test was used primarily to screen all children for routine vaccination. The results obtained demonstrated a sensitivity of 99% and a specificity of 100% for the Hemotype SC test, thus confirming its reliability in the screening of sickle cell disease. The positive cases identified by the HemotypeSC test were then confirmed by Gazelle electrophoresis (An R, Franco E), re-

inforcing the validity of the results obtained. In addition, the data collected in this study was compared with other research, including those by authors such as Samuel Ademola Adegoke in Gambia, Aldiouma Guindo in Mali and Chinwe O Okeke in Nigeria [24] [25] [26]. The results of these different studies converged to confirm the effectiveness of the HemotypeSC test, with high sensitivity and specificities, up to 100%. This evidence supports the use of this test for diagnosis and screening of sickle cell disease, including in neonatal screening.

One of the major advantages of HemotypeSC is its affordability and ease of access, as well as the fact that it does not require complex logistics or power supply, making it particularly suitable for contexts where resources are limited. In sum, the results of this study confirm the relevance and effectiveness of the HemotypeSC test in the control of sickle cell disease by providing a reliable, cost-effective and easily deployed method for screening and early diagnosis of this genetic disease.

4.3. Socio-Demographic and Clinical Data

This study included 1100 children screened for sickle cell disease during routine immunization sessions. The overall sex ratio was 1, and the mean age of participants was 6 months (range: 0 - 59 months). Males were slightly more affected than females ($p = 0.003$); however, as sickle cell disease is an autosomal recessive disorder, no biological sex predisposition is expected. This observed predominance may reflect a sampling bias, such as differences in family participation or attendance at vaccination sessions [12] [27].

Children with a family history of transfusion (50/66, $p = 0.01$) or hospitalization (56/66, $p = 0.01$) were more frequently affected. Conversely, the absence of a family history of painful crises (60/66, $p < 0.01$) or sickle cell disease (60/66, $p < 0.01$) did not prevent occurrence of the disease. These findings underscore the importance of early and systematic screening, even among children without known family history, and highlight the utility of incorporating clinical history—such as previous hospitalization, transfusion, or recurrent pain—into screening strategies to identify children at risk [28] [29].

High rates of hospitalization and reported pain were observed despite a very young median age of 6 months, suggesting that some events may not be exclusively related to sickle cell disease. In endemic settings such as Mbujimayi, common conditions in infancy, including malaria, respiratory infections, and acute gastroenteritis, may produce similar symptoms and thus confound clinical assessment [30]. This represents a limitation of the study.

Overall, these results indicate that integrating clinical history into targeted screening, alongside routine immunization programs, may facilitate earlier detection and appropriate management of sickle cell disease in resource-limited [17] [31].

5. Limitations of the Study

This study has several limitations that should be considered when interpreting the

findings. Screening was conducted only among children attending routine immunization sessions in four reference health facilities, which may limit the generalizability of the results to the entire pediatric population of Mbujimayi, particularly to children not reached by vaccination services. In addition, although the HemoTypeSC rapid diagnostic test showed excellent performance, negative results were not systematically confirmed by hemoglobin electrophoresis, which may have led to a slight underestimation of the true prevalence of sickle cell disease.

Some clinical information relied on parental recall, potentially introducing recall bias, especially in an endemic setting where common childhood illnesses may present with symptoms like those of sickle cell disease. Finally, the cross-sectional design and relatively short duration of the study did not allow evaluation of long-term clinical outcomes or the impact of early screening on morbidity and mortality.

Despite these limitations, the study provides the first local epidemiological data on sickle cell disease in Mbujimayi and demonstrates that integrating sickle cell screening into routine immunization programs is feasible, acceptable, and relevant in resource-limited settings, thereby supporting its potential role in strengthening early diagnosis strategies.

6. Conclusion

This study shows a high prevalence of sickle cell disease among children under five years of age in Mbujimayi and demonstrates that screening integrated into routine immunization is feasible and highly acceptable. The use of a rapid diagnostic test enabled early identification of affected children in a resource-limited setting. Integrating sickle cell disease screening into routine immunization services may represent an effective strategy to improve early diagnosis and access to care.

Contribution of Our Study to Knowledge

To our knowledge, this is the first published study on the prevalence of sickle cell disease in Mbuji-Mayi, Kasai Oriental Province, Democratic Republic of the Congo. Our study highlights the extent of sickle cell disease in a remote city in DRC and the importance of raising awareness among individuals and communities about this disease and reorienting disease control strategies in the region.

Overall, our study suggests early preventive interventions, which aim not only at an early detection of sickle cell disease coupled with routine vaccination to put early antibiotic prophylaxis and folic acid, but above all to put in place an active program to combat sickle cell disease with synergistic actions of two parts, education and medical intervention, which can guarantee the success of the said program.

Authors' Contributions

B.M.M. coordinated the study during the publication, correction, and finalization

of the manuscript. She provided important criticisms for improving the content and provided guidance and support for publication. S.K.M. is the main author of the study, of the questionnaire design, and of the data collection and interpretation for publication. J-P.A.O., D.M.C., A.K.M., D.M.K., S.K.T. and J.M.K. contributed to the data collection and reading of the article. All the authors declare that they have read and approved the final version of the manuscript.

Acknowledgements

The authors wish to thank all the mothers who agreed to screen their infants during routine immunisation in Mbujimayi. The authors would also like to thank all the health personnel in the health facilities who agreed to take part in the study for their time and expertise.

Conflicts of Interest

The authors declare that they have no conflicts of interest. The authors are solely responsible for the content and writing of this article.

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