REGULAR ARTICLE

blood advances

Newborn screening results for sickle cell disease from the ASH Consortium on Newborn Screening in Africa (CONSA)

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Key Points

- Through CONSA, ~175 000 infants in sub-Saharan Africa have been screened, documenting a high incidence of SCD and trait.
- The allele frequencies of HbS and HbC vary across the CONSA sites, along with different rates of hemoglobin variants.

The Consortium on Newborn Screening in Africa (CONSA), launched by the American Society of Hematology in 2020, is designed to initiate and expand sustainable newborn screening (NBS) programs for sickle cell disease (SCD) across sub-Saharan Africa. This multiyear pilot program includes 11 clinical sites in 7 countries, namely Ghana, Kenya, Liberia, Nigeria, Tanzania, Uganda, and Zambia. After extensive training of laboratory and clinical personnel, dried blood spots were collected from newborns and tested by isoelectric focusing at central laboratories within each country. Positive samples were confirmed, and the affected infants were invited into clinical care for penicillin prophylaxis, malaria prevention, routine immunizations, and family education. As of November 2025, almost 175 000 samples have been collected and assessed. The overall prevalence of SCD was 1.46%, with the highest prevalence in Mwanza, Tanzania (2.00%). The majority of positive screening results were homozygous HbSS (81.5%), along with compound heterozygous HbSC (11.0%) and HbSβ^+ thalassemia (7.5%). Hemoglobin S trait was common throughout the countries with an average of 16.17%, whereas hemoglobin C trait had an incidence of 1.59% and was found primarily in Ghana and Nigeria. Additional hemoglobin variants were also detected in several countries. Confirmatory samples have been documented in about one-third of infants with a positive screening result, with 87.8% of those confirmed to have SCD. Fewer than half of the affected infants have documented clinical follow-up at CONSA sites for various logistical and financial reasons. CONSA has made great strides in promoting NBS for SCD in sub-Saharan Africa, but gaps in the confirmatory testing and enrollment into clinical care persist.

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Access to the CONSA database will be considered on an individual basis and requires institutional review board–approved research protocols. Data are available from the corresponding author, Andrew Zapfel (andrew.zapfel@hematology.org), on request.

Introduction

Sickle cell disease (SCD) refers to a set of severe inherited hemoglobinopathies that feature erythrocyte sickling, susceptibility to infections, recurrent acute vaso-occlusive events, and chronic organ damage, which together lead to morbidity and early mortality.[1] The global burden of SCD is now well-recognized, with the greatest numbers in low- and middle-income countries where comprehensive care is often unavailable or suboptimal.[2] Between 2000 and 2021, the estimated global annual SCD rate increased by 13.7% (95% confidence interval, 11.1%-16.5%) to 515 000 (425 000 to 614 000) affected births per year,[3] and this number is estimated to increase by another 30% by 2050.[4]

Because of the ancestral origins of the sickle hemoglobin (HbS) mutation, as well as hemoglobin C (HbC) and other hemoglobin variants, sub-Saharan Africa accounts for ~80% of the global SCD births and has disproportionately high mortality rates early in life.[5-7] The main causes of mortality in children with SCD in Africa include malaria and bacterial infections, severe anemia, malnutrition, and cerebrovascular complications.[8,9] A recent Lancet Haematology Commission report listed specific goals and timelines to improve the management and outcomes of children with SCD, including screening and evidence-based care for preventing severe complications.[10]

In the United States, newborn screening (NBS) for SCD has been in place for decades and became universal for all states and territories by 2006 with ~2000 to 2500 affected newborns identified each year.[11,12] Universal NBS for SCD now occurs in England, France, and Germany but with more heterogeneous screening of high-risk individuals in most European countries.[13,14] Screening efforts in Canada[15] and the Caribbean[16] are expanding with expected beneficial results. Early SCD diagnosis through NBS, coupled with timely interventions such as penicillin prophylaxis, pneumococcal vaccination, parental education, transcranial Doppler screening for primary stroke risk, and early hydroxyurea therapy, can significantly reduce early morbidity and mortality.[17]

Despite having the highest disease burden, NBS programs for SCD are scarce in sub-Saharan Africa, leaving many children undiagnosed until symptomatic and often presenting with severe complications or early mortality. Pilot screening programs in Africa have been described with good success,[18-21] yet scaling up to wider or even universal screening remains an aspirational goal. Implementation challenges include limited health care infrastructure, budgetary constraints, and inconsistent political support, all of which hinder the widespread expansion of NBS and the adoption of inexpensive associated care guidelines.

To accelerate NBS for SCD in Africa that is linked to early intervention with a goal of long-term sustainability, the American Society of Hematology (ASH) undertook a pivotal initiative, the Consortium on Newborn Screening in Africa (CONSA) for SCD. This initiative brought together researchers, health care providers, policymakers, and advocacy groups to implement and scale sustainable NBS programs across the region. Launched in 2020, this multiyear pilot program is currently ongoing in 7 sub-Saharan African countries, namely Nigeria, Ghana, Zambia, Kenya, Uganda, Tanzania, and Liberia. The overarching goal of CONSA is to establish a coordinated network of programs across sub-Saharan Africa to institute sustainable, national, population-based newborn SCD screening and early standardized intervention procedures to reduce disease-associated pediatric mortality.[22] We now present the initial results of CONSA screening for SCD in sub-Saharan Africa.

Methods

Overview

The CONSA rationale, concept, and framework have been described previously.[22] Through the ASH Research Collaborative, the consortium has the following goals: (1) to register patient data and medical history of newborns diagnosed with SCD by the age of 3 months; (2) to initiate antibacterial and antimalarial prophylaxis by the age of 3 months; (3) to ensure immunization against *Streptococcus pneumoniae* and *Haemophilus influenzae* type b; (4) to monitor patients and update the registry after each visit; and (5) to estimate the incidence of specific SCD genotypes and identify other hemoglobin variants in each country.[22]

Strategic partnership

The NBS initiative is a strategic partnership between ASH and CONSA, and each partner has roles and responsibilities (Figure 1). ASH provided the seed funding and continues to offer financial support to 7 countries in sub-Saharan Africa for staffing costs and laboratory supplies. The ASH Research Collaborative hosts the shared data registry via its Data Hub, and the Dimagi CommCare application is used for offline data collection. ASH provides the overall administrative oversight and facilitates strategic partnerships to ensure the program's success. CONSA sites are expected to screen infants by isoelectric focusing (IEF; Revvity, Turku, Finland) using standardized CONSA laboratory procedures to identify newborns with SCD. Following screening, sites enroll patients into care and follow-up, educate and counsel families on SCD, and lead advocacy efforts for long-term sustainability of the program.

Testing procedures

The study population included infants born within each participating country's catchment area, ranging from referral hospitals to smaller health centers and community-based clinics. The mothers were approached and counseled on the need for SCD screening. Following verbal consent, (1) blood samples were collected by heel prick; (2) dried blood spots were prepared and transported to a central laboratory; (3) IEF gels were run using a CONSA standard operating procedure, including controls for hemoglobin A (adult), F (fetal), S, and C; (4) samples that tested positive for SCD (hemoglobin patterns FS, FSC, or FSA) were repeated to verify the results; and (5) the caregiver was contacted to communicate the diagnosis of SCD and schedule a CONSA clinic appointment for a confirmatory sample, initial education and counseling, and penicillin prophylaxis.

Clinical schedule

At the first postscreening clinical visit, a new blood sample was collected to confirm the diagnosis of that infant, which was performed either by repeat dried blood spot and standard IEF testing or by HemoTypeSC (Silver Lake Research Corporation, Azusa, CA), a competitive lateral flow immunoassay that yields faster, point-of-care results. Written parental consent was obtained for enrollment into

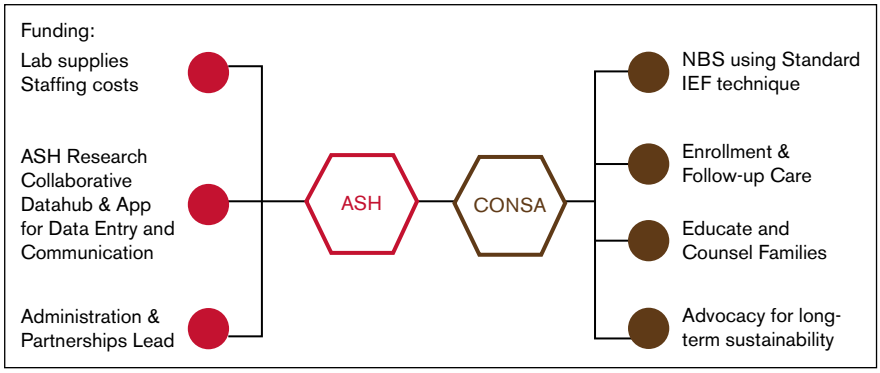

Figure 1. Strategic approach between ASH and CONSA. The NBS program has roles and responsibilities for both ASH and the CONSA consortium with multiple country sites.

the CONSA registry for clinical follow-up and data collection, ideally by 3 months of age. Penicillin prophylaxis was initiated with folic acid supplementation, protein conjugate pneumococcal and other immunizations were each verified or administered, and malaria prevention was provided using insecticide-treated nets and/or chemoprophylaxis according to national guidelines. A second CONSA clinic visit by 6 months of age included review of the confirmatory hemoglobinopathy test, parental education and counseling about SCD, complete blood count analysis with differential and reticulocyte count, and malaria smear with parasite density. Subsequent clinic visits ideally occurred every 3 to 6 months until 5 years of age. Hydroxyurea treatment and monitoring were encouraged according to individual national policy and guidelines, based on local availability of the drug.

Quality control

Revvity and the CONSA Laboratory and Diagnostics Subcommittee provided hands-on training for each site, including periodic calls to improve the gel quality and scoring. Regular quality checks ensured laboratory data accuracy at each site. The CONSA program leadership performed periodic site visits, virtually or in person, and assessed all aspects of program implementation, including operational and technical review of the gels and scored results as described.[23]

Data collection

The ASH Research Collaborative Data Hub provides online data collection tools and expert services and serves as the data repository. Each country/site has a data manager who complies with the quality assurance and quality improvement requirements for data management training, troubleshooting, networking, and scheduled reviews of the de-identified data. All enrolled infants were assigned a unique study identification number.

Biostatistical analysis

The SCD birth prevalence was estimated for each site and the consortium overall using the HbS and HbC allele prevalence identified across the screened infants. The Hardy-Weinberg equilibrium was tested using χ^2 tests to examine evidence for either assortative mating or excess prescreening mortality.

Results

As of November 2025, a total of 174 996 infants have been screened and scored across all 11 CONSA sites in 7 countries (Table 1). The number of samples in each country ranged from 7 766 in Zambia to 51 890 in Nigeria. The overall disease rate was 1.46% across the whole population, ranging from 0.90% in Zambia to 1.73% in Ghana, with a total of 2554 infants with SCD identified. The highest prevalence for an individual site was in Mwanza, Tanzania, where 2.00% of the infants were affected. The vast majority of SCD diagnoses were HbSS with 2081 of 2554 (81.48%) SCD cases producing an abnormal FS result. An additional 281 of 2554 (11.00%) SCD diagnoses were HbSC and were found almost exclusively in Ghana and Nigeria. The remaining SCD diagnoses, 192 of 2554 (7.52%), had an abnormal FSA result consistent with HbS/β^+ thalassemia, and almost all of these were identified in Kaduna State, Nigeria (Table 1).

Hemoglobinopathy trait was identified in 17.76% of samples, ranging from 6.19% in Liberia to 23.47% in Ghana. A total of 31 071 infants with the trait were scored, including 28 289 (91.05%) with FAS pattern (HbAS) and 2782 (8.95%) with FAC (HbAC), the latter found almost exclusively in Ghana and Nigeria. IEF testing and scoring also identified many additional hemoglobin variants, ranging from 0.00% in Zambia to 3.37% in Liberia (Table 1), which affected a total of 2067 infants (Table 1).

After a positive SCD screening result, families were contacted by site personnel for an initial clinic visit, which included obtaining a confirmatory blood sample. The number and percentage of confirmatory blood samples varied across sites but overall, 87.8% of the second samples confirmed the original diagnosis. The reasons for incorrect screening results have not been formally analyzed but are likely related to challenges in scoring imperfect IEF gels.

The documented clinic visits are summarized in Table 2, which shows that a total of 935 infants (37%) visited a CONSA site for at least 1 visit. Penicillin prophylaxis, folic acid, and insecticide-treated bed nets were provided or recommended for the vast majority of babies, starting at the first visit. Similarly, immunization against *Streptococcus pneumoniae* was routinely administered or confirmed, whereas vaccines against *Haemophilus influenzae* type b and meningococcal disease were less commonly administered. A smaller number of infants have had documented second and subsequent additional visits with continued treatments and vaccinations, and some hydroxyurea prescriptions began at around an age of 12 months (Table 2). Telephone conversations documented numerous reasons for families not attending the clinic visits, including healthy appearance of the baby, denial of the

Table 1. CONSA newborn screening results and prevalence rates of disease, trait, and variant by country and site

	Sickle cell disease						Trait				Variant		Normal		
Country	**FS**	**%**	**FSC**	**%**	**FSA**	**%**	**FAS**	**%**	**FAC**	**%**	**FAX**	**%**	**FA**	**%**	**Total**
Ghana	140	0.75	182	0.97	1	0.01	2 568	13.73	1821	9.74	241	1.29	13 745	73.51	18 698
Kenya	382	1.08	0	0.00	1	0.003	6 057	17.13	0	0.00	56	0.16	28 861	81.63	35 357
Liberia	148	1.49	3	0.03	7	0.07	591	5.95	24	0.24	335	3.37	8831	88.85	9 939
Nigeria (all)	601	1.16	93	0.18	180	0.35	10 449	20.14	936	1.80	1028	1.98	38 603	74.39	51 890
Abuja	382	1.12	77	0.23	1	0.00	7 184	21.09	833	2.45	50	0.15	25 540	74.97	34 067
Kaduna	219	1.23	16	0.09	179	1.00	3 265	18.32	103	0.58	978	5.49	13 063	73.29	17 823
Tanzania (all)	331	1.28	0	0.00	0	0.00	3 341	12.88	1	0.004	6	0.02	22 256	85.81	25 935
Dar es Salaam	98	0.68	0	0.00	0	0.00	1 723	12.04	1	0.01	0	0.00	12 487	87.27	14 309
Mwanza	233	2.00	0	0.00	0	0.00	1 618	13.92	0	0.00	6	0.05	9 769	84.03	11 626
Uganda (all)	412	1.62	3	0.01	0	0.00	4 231	16.65	0	0.00	401	1.58	20 364	80.14	25 411
Jinja	221	1.67	0	0.00	0	0.00	2 264	17.13	0	0.00	206	1.56	10 524	79.64	13 215
Lira	178	1.47	0	0.00	0	0.00	1 959	16.14	0	0.00	195	1.61	9 808	80.79	12 140
Zambia (all)	67	0.86	0	0.00	3	0.04	1 052	13.55	0	0.00	0	0.00	6 644	85.55	7 766
Lusaka	30	1.44	0	0.00	1	0.05	264	12.68	0	0.00	0	0.00	1 787	85.83	2 082
Ndola	16	1.43	0	0.00	2	0.18	195	17.14	0	0.00	0	0.00	907	80.98	1 120
TOTAL	2 081	1.19	281	0.16	192	0.11	28 289	16.17	2782	1.59	2 067	1.18	139 304	79.60	174 996

In some countries, there were incomplete data regarding the specific site location of babies with positive screening results.

diagnosis, inability to spend a day without work, and unavailability of hydroxyurea at the clinical site. Some families have opted to receive care at local health care facilities instead of the main referral hospital.

Discussion

The CONSA program represents an ambitious partnership with selected clinical sites in sub-Saharan Africa to demonstrate the feasibility and effectiveness of NBS for SCD and to catalyze its future expansion into a nationwide, full-scale public health intervention. At the inception of CONSA, ASH convened meetings with SCD leaders from each site to develop a commonly agreed-upon protocol and standard operating procedures. The ongoing support from ASH has ensured purchasing of the IEF testing equipment at bulk pricing, repeated training of site personnel, and an online database to record results. From the perspective of the clinical sites, the partnership included a commitment to follow CONSA laboratory procedures rigorously, followed by efforts to enroll infants with a positive result into clinical care (Figure 1). In addition, CONSA has secured the support of multiple industry and pharmaceutical sponsors for activities related to NBS. Uniquely, CONSA has also enabled new South-South partnerships and empowered regional peer mentoring.

To date, the CONSA program has successfully launched at 11 sites in 7 countries, and NBS activities have progressed at all locations. Several sites already had pilot screening programs but CONSA enabled growth and sustainability. Almost 175 000 samples have been collected as of November 2025 with all sites

Table 2. Clinic visits and medical interventions

	First clinical visit	Second clinical visit	Total subsequent clinical visits
Total babies identified with SCD (%)	935 (37)	499 (53)	369 (74)
Treatments prescribed			
Penicillin (%)	861 (92)	477 (96)	1051 (97)
Folic acid (%)	875 (94)	481 (96)	1055 (97)
Insecticide-treated bed nets (%)	871 (93)	448 (90)	1032 (95)
Hydroxyurea (%)	0 (0)	0 (0)	82 (8)
Vaccinations administered			
Pneumococcus (conjugated) (%)	794 (85)	432 (87)	966 (59)
Haemophilus influenzae (%)	547 (59)	302 (61)	683 (63)
Meningococcal (%)	319 (34)	182 (36)	435 (40)

Infants with an initial screening diagnosis of SCD were invited to attend clinical visits for confirmatory testing and sickle cell management. The number of infants at the first and second visit are recorded, as well as a cumulative tally of all subsequent clinic visits with the percentage attendance based on eligibility or completing a previous visit. Prescribed treatments and vaccinations are also recorded.

contributing based on the population in their catchment area, disease prevalence, and resources (Table 1). Ongoing communication between the CONSA Laboratory Diagnostics Subcommittee and the clinical sites has been valuable in identifying and rectifying problems with laboratory testing and gel scoring, which are the targets of ongoing formal quality assurance efforts.

Across the entire program, hemoglobinopathy trait has been identified in 17.76% of samples (Table 1), which fits with estimates from previous studies in sub-Saharan Africa.[5,18-21] As expected, the vast majority of these trait samples showed HbAS (sickle cell trait) owing to the broad distribution of the HbS allele across the continent. In contrast, HbAC (hemoglobin C trait) has been identified almost exclusively in Ghana and Nigeria, consistent with the unicentric origin of that mutation.[24,25] The goal of CONSA, however, is to identify all infants with SCD, including HbSS, HbSC, and HbS/β^+ thalassemia, which has been identified in 1.46% of all samples screened through the CONSA program. These proportions of both trait and disease for HbS and HbC are broadly consistent with population-level equilibrium as predicted by Hardy-Weinberg calculations, which are complex when multiple variant alleles are present, as in this case.

Additional hemoglobin variants were identified at all CONSA sites except in Zambia and Dar es Salaam, Tanzania, and were observed in >3% of samples in Kaduna, Nigeria, and Liberia (Table 1). Both α-globin and β-globin variants can be identified by IEF, so it is likely that a variety of hemoglobin variants exist across the CONSA map. Previous genetic analyses of variants found in the Uganda Sickle Surveillance Study documented 2 α-globin variants (Hb Stanleyville II, Asn78Lys; and Hb G-Pest, Asp74Asn), 1 β-globin variant (Hb O-Arab, Glu121Lys), and 2 fusion globin variants (Hb P-Nilotic, β31-δ50; and Hb Kenya, $^{A}\gamma$81Leu-β86Ala).[26] These are likely present in East African CONSA sites (Uganda, Tanzania, and Kenya), but other variants may be more common in Liberia, Nigeria, and Ghana. Further testing using DNA sequencing will be needed to elucidate these hemoglobin variants identified in the CONSA samples. In addition, infants identified with the FSA pattern likely have HbS with β^+ thalassemia trait, but additional IEF and even formal DNA testing will be needed to confirm this diagnosis.

Clinic visits to the CONSA site are recommended for all infants with a positive screening result to ensure timely initiation of life-saving interventions, including penicillin prophylaxis and age-appropriate vaccinations. To date, just more than one-third of the infants who tested positive have attended the CONSA clinic in the first 3 months of life, and fewer than 20% have attended 2 clinic visits. Similar challenges with postscreening follow-up and infant retrieval have been reported across NBS programs globally, including in the United States.[27] Within CONSA, the reasons for clinic nonattendance were multifactorial. A major contributor was parental nonacceptance of the diagnosis owing to denial, driven, in part, by the absence of overt clinical symptoms during the first 6 months of life in children with SCD. This was compounded by the stigma and discrimination typically associated with the diagnosis of SCD, which discouraged some parents from seeking medical care. Structural barriers associated with access also played an important role. Many families lacked the financial resources to attend the CONSA site clinics that may be located far from their households and require significant travel time, transportation costs, and loss of wages. In addition, some families perceived that there was limited value in attending a clinic visit that focused primarily on counseling and preventive care and not on specific intervention or medication. Notably, some parents felt that access to hydroxyurea would make the visits worthwhile, but this drug was not always available or affordable.

Reassuringly, follow-up investigations revealed that, in some cases, families opted to attend local health care facilities that were closer to home and required less challenging travel. This suggests that, in some cases, the infants were still receiving essential SCD care, albeit not within the CONSA site network. Efforts are underway to systematically track and link these children to ensure continuity of care and to better understand patterns of health care utilization beyond the CONSA sites.

To improve retention of children with SCD, the CONSA program has implemented several targeted strategies. First, the recent integration of point-of-care testing into the CONSA protocol for the confirmatory blood sample enabled results to be delivered more rapidly, thereby creating an opportunity for immediate education and engagement with families during that clinic visit. This approach is expected to strengthen early linkage to care.[28] Second, CONSA is actively providing health education on SCD for the community and simultaneously training community health workers at each of the CONSA sites to address misconceptions, reduce stigma, and improve understanding of SCD within local communities. Third, the consortium is working to increase the availability of hydroxyurea across the region. Since CONSA was established, pivotal clinical trials in sub-Saharan Africa have conclusively shown the dramatic benefits of hydroxyurea in reducing vaso-occlusive episodes and other disease complications in patients with SCD across the African continent.[29-35] Although hydroxyurea is not currently supported by the CONSA budget, partnerships with governmental and private entities are underway to develop affordable formulations and strategies for the region. As awareness of hydroxyurea's safety and efficacy grows and as its use in treating infants with SCD becomes progressively incorporated into national guidelines, improved availability may serve as a powerful driver that could increase clinic adherence and provide effective and affordable disease-modifying therapy.

This trial had several limitations, including the inaccuracy of initial screening in that 12.2% of newborn samples that screened positive for SCD were not confirmed on repeat testing. Programmatic efforts to train/retrain laboratory staff to improve the quality of the IEF gels and the accuracy of interpretation of the results are ongoing. In addition, the diagnosis of compound heterozygotes of HbS with β^+-thalassemia, as well as accurate identification of other hemoglobin variants, is currently challenging and limited by the technology used.

For long-term sustainability of the CONSA program, it will be critical to ensure engagement and ownership by national health care authorities and each country's regional and national governments. This will require ongoing advocacy that is supported by the robust data generated by the CONSA program, which demonstrates both the burden of disease and the effectiveness of NBS. Toward this goal, ASH has implemented advocacy training for all CONSA site leaders with a structured curriculum. As of January 2026, all CONSA sites are actively involved in advocacy efforts

and engaging governments to secure the resources needed to sustain and expand NBS for SCD into large-scale programs.

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Authorship

Contributions: B.A.O. was involved in the study design, data collection, and writing of the first draft of the manuscript; C.K., L.C., P.C.F., O.E.N., E.E.A., L.G.D., C.M.C.-L., and C.I.S. were involved in the study design and data collection; and A.Z., M.-A.B., I.O., V.N.T., M.O.A., A.A.T., N.S.G., N.B., E.M.N., T.L.C., and R.E.W. were involved in study design, data analysis, and manuscript writing.

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