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Building a national framework for multicentre research and clinical trials: experience from the Nigeria Implementation Science Alliance

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ABSTRACT

There is limited capacity and infrastructure in sub-Saharan Africa to conduct clinical trials for the identification of efficient and effective new prevention, diagnostic and treatment modalities to address the disproportionate burden of disease. This paper reports on the process to establish locally driven infrastructure for multicentre research and trials in Nigeria known as the Nigeria Implementation Science Alliance Model Innovation and Research Centres (NISA-MIRCs). We used a participatory approach to establish a research network of 21 high-volume health facilities selected from all 6 geopolitical zones in Nigeria capable of conducting clinical trials, implementation research using effectiveness-implementation hybrid designs and health system research. The NISA-MIRCs have a cumulative potential to recruit 60 000 women living with HIV and an age-matched cohort of HIV-uninfected women. We conducted a needs assessment, convened several stakeholder outreaches and engagement sessions, and established a governance structure. Additionally, we selected and trained a core research team, developed criteria for site selection, assessed site readiness for research and obtained ethical approval from a single national institutional review board. We used the Exploration, Preparation, Implementation, Sustainment framework to guide our reporting of the process in the development of this network. The NISA-MIRCs will provide a nationally representative infrastructure to initiate new studies, support collaborative research, inform policy decisions and thereby fill a significant research infrastructure gap in Africa's most populous country.

SUMMARY BOX

⇒ Lack of research infrastructure has limited the participation of many low-income and middle-income countries (LMICs) in clinical and implementation research and the generation of scientific knowledge on diseases that primarily affect their population.
⇒ The Nigeria Implementation Science Alliance (NISA) developed the research infrastructure at 21 high-volume health facilities across all six geopolitical regions in Nigeria to create the Model Innovation and Research Centres (NISA-MIRCs) with the capacity to conduct clinical and implementation research.
⇒ Our study documents the process including implementation strategies applied in the development of the NISA-MIRCs and shares lessons learnt that could inform planning and strategy decisions in other LMICs.
⇒ The NISA-MIRCs provide an important foundation and research infrastructure that can support the growing number of professionals interested in clinical and implementation research in Nigeria.

BACKGROUND

Individuals living in low-income and middle-income countries (LMICs) bear a large proportion of the global disease burden for communicable and non-communicable diseases.[1] In order to decrease this burden, implementation science, the study of methods to promote the adoption and integration of evidence-based practices (EBP), interventions and policies into routine healthcare and public health settings, is critical.[2] Clinical trials for identification of efficient and effective new prevention, diagnostic and treatment modalities are also needed to address the disproportionately high burden of communicable (e.g., HIV, tuberculosis and malaria) and non-communicable diseases (e.g., cancer,

hypertension and diabetes) in LMICs. However, in many LMICs, especially in sub-Saharan Africa (SSA), there are limited infrastructures to conduct clinical trials and implementation research that drive scientific discovery and answer questions on local and regional health challenges, including multimorbidities such as HIV and cancer.[3 4] The process of building research collaborations that develop local research infrastructure is poorly described in the literature.

Nigeria has the largest population in Africa and the third largest HIV burden in the world with an estimated 1.7 million people living with HIV (PLWH).[5] Fifty-six per cent (estimated at 960 000) of PLWH are females aged 15 years and older, while 7.6% (130 000) are children 14 years old or younger.[5] With funding from the US President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund, plus advances in drug development, there has been significant progress in HIV treatment over the last two decades with expansion of testing and treatment access and reduction of new infections.[6–9] Since 2004 when the HIV program commenced in Nigeria, over $6 billion has been invested by global partners.[10 11] Overall, 90% of PLWH have been diagnosed, 86% of those diagnosed placed on antiretroviral therapy (ART), and 72% of those on treatment achieved viral suppression in 2020.[5]

An estimated 962 578 women are currently receiving care through PEPFAR-supported facilities in Nigeria. Although the country has made significant progress by reducing the number of new annual HIV infections among children from 58 000 in 2014[12] to 21 000 in 2020,[5 13] significant gaps remain along the prevention of mother-to-child transmission of HIV (PMTCT) continuum of care.[14] Nigeria still has a final MTCT of HIV rate of 25% and this contributes about 14% of the global burden of children infected through MTCT.[13 15] Nigeria remains as only one of the four countries in the world where annual new HIV infections among children are 10 000 or more.[13 16] Several barriers to progress in eliminating mother-to-child HIV transmission in Nigeria have been identified including low uptake of PMTCT and ART services, stigma and poor attitudes towards PMTCT, poor understanding of the impact of community-based services, and poor health financing.[17]

With about 2277 health facilities[18] providing comprehensive HIV treatment services across the 6 geopolitical regions of Nigeria, a total of 1.5 million people have been placed on ART.[18] More recently, there have been efforts to build on the HIV service infrastructure by integrating testing for other diseases (e.g., hepatitis B, sickle cell disease, hypertension, perinatal depression)[19–23] and integrating other health services (e.g., cancer prevention).[24]

There have been calls to also leverage these comprehensive HIV treatment sites to develop infrastructure to test new innovations, drugs and programs. Several gaps and challenges have been identified in the effort to build capacity for clinical trials and implementation research in resource-limited settings. These include insufficient funding for research, inadequate infrastructure for research, research-policy misalignment and poor mentorship.[3 25–28] Several efforts are being made to improve recruitment and participation in clinical trials around the world.[3 4 28 29] While some success has been recorded in building the capacity and infrastructure for research, sustainability remains a challenge.[3 4 30] For example, Teklu *et al* developed a clinical longitudinal cohort of PLWH in Ethiopia to study the impact of ART on women living with HIV (WLWH), but the cohort collapsed after funding ended.[28] Imam *et al* also documented challenges with recruiting sufficient in-country specialists in The Gambia.[4] A recent systematic review identified specific challenges with funding and complex regulatory and prolonged administrative processes.[3] Some of these challenges remain even in high-income countries. The USA still struggles to recruit minorities into clinical trials to achieve the diversity needed to understand the effect of drugs on its diverse population.[31–33] The National Institutes of Health (NIH) in the USA developed a framework to create a large national consortium of cohorts with one million Americans, and identified several challenges that include feasibility, coordination and ongoing funding.[29] Researchers and stakeholders in Nigeria have therefore sought to address similar challenges by forming strategic alliances and multicentre collaborative research projects to study our diverse participant population.

The Nigeria Implementation Science Alliance

Formed in 2015 in collaboration with the NIH Fogarty International Centre, the Nigeria Implementation Science Alliance (NISA) is a consortium of 20 organisations that include academic institutions, local PEPFAR-supported implementing partners (IPs), and policymakers (e.g., Ministry of Health). The core vision of NISA is to (1) create a dissemination platform to share experiences on what has worked and what is not working, (2) enhance the capacity of a well-educated workforce for research focused on implementation science and clinical trials, and (3) build research infrastructure and develop the capacity of the comprehensive HIV treatment centres to conduct clinical and implementation research.[34] NISA has been used as a case study for sustainability of research networks in LMICs with similar infrastructure being funded by Adolescent HIV Prevention and Treatment Implementation Science Alliance (AHISA) and Central and West Africa Implementation Science Alliance (CAWISA).[35 36]

Model Innovation and Research Centres

NISA had a goal to build a cohort of the existing health facilities into Model Innovation and Research Centres (MIRCs) in order to advance the implementation of evidence-based interventions to improve public health and clinical outcomes for diseases of public health importance in Nigeria.[25 37] To establish these MIRCs, NISA has leveraged the PEPFAR-supported infrastructure and the expertise among its members in cohort design, research

methodologies and participant recruitment and management. NISA also relied on the leadership of the Centre for Translation and Implementation Research (CTAIR) at the University of Nigeria which acts as the NISA research coordinating unit. Following the identification and establishment of these MIRCs, NISA has embarked on its first project, a two-step approach to build a multicentre longitudinal clinical and epidemiological cohort of HIV-infected and age-matched HIV-uninfected women of reproductive age (15–49 years). This paper reports on the process NISA used to establish the NISA-MIRCs, providing a model that could catalyse implementation science and clinical trials at the national level and across SSA. A companion paper will report on the baseline description and characteristics of participants being recruited at these centres and their health outcomes.

APPROACH

Implementation framework

We used the Exploration, Preparation, Implementation, Sustainment (EPIS) framework to organise the reporting of the development of the NISA-MIRCs.[38 39] EPIS is a process and determinant framework that was developed to facilitate the implementation and sustainment of EBP in public sectors.[38 39] We selected this framework because of its importance in guiding the implementation process in different settings, including low-income countries.[39] EPIS comprises four key phases (EPIS), enumerates potential influencing factors (i.e., determinants and mechanisms) in each phase across levels of outer and inner contexts, and considers the 'bridging factors' that represent unidirectional or bidirectional influences between the outer system and inner organisational contexts, and characteristics of the innovation(s) being implemented.[38 39] The outer context (system) represents larger, often external, factors such as federal, state or local policies, funding, leadership and interorganisational environment and networks that can either facilitate or hinder implementation.[38 39] The inner context (organisation/clinic) represents the factors within the organisations that are implementing EBPs, such as organisational characteristics (e.g., culture/climate), leadership, organisational staffing processes, workflows, and individual characteristics of service providers that can influence implementation.[38 39]

During the development of the NISA-MIRCs, we used 19 of the 73 implementation strategies from the Expert Recommendations for Implementing Change (ERIC) compilation (see table 1). These 19 strategies are from 5 of the 9 clusters including—use evaluative and iterative strategies (3 strategies), provide interactive assistance (3 strategies), adapt and tailor to context (3 strategies), develop stakeholder interrelationships (8 strategies), and train and educate stakeholders (2 strategies).[40 41] These strategies were deployed as needed all through the establishment and development of the NISA-MIRCs.

EXPLORATION

Need assessment

During the annual NISA conferences in 2016 and 2017, we used the Nominal Group Technique[42 43] to identify barriers and challenges to conducting research and clinical trials in LMICs.[25 26] During this process, we identified several additional barriers to those noted from our literature review[44–46] and also identified potential strategies to overcome these challenges. The identified barriers include funding gaps, poor research focus, inadequate training for early-stage investigators, inadequate research infrastructure, poor collaboration and partnership among local IPs and academic institutions, research–policy dissonance, poor leadership buy-in, limited research opportunities, and poorly defined roles on potential research projects.[25 26] These sessions demonstrated the need for building a robust research infrastructure in Nigeria that will attempt to address these gaps and barriers.[3]

Stakeholder meetings

We conducted several stakeholder meetings to identify why children are still being infected with HIV in Nigeria and potential strategies to overcome these barriers.[17] The identified barriers included poor coordination among government, implementers and researchers, poor health-seeking behaviours among women, low uptake of antenatal, delivery and postnatal care services, inadequate community-based interventions to support women through pregnancy and postpartum periods, challenges with transitioning mothers from PMTCT to ART services and back, inadequate skilled health workers in the rural areas, among others. Some of the proposed strategies were for NISA to develop a continuous training program for health workers in the HIV space, support a learning health system, and strengthen tracking services for mother-baby pairs.[17]

PREPARATION

Establish governance structure

NISA established four broad levels of governance for the NISA-MIRCs (see figure 1).

- Health facilities: This level of governance is made up of the health facility personnel including the data clerk, the site research coordinator, site investigators and the hospital administration. Each participating NISA-MIRC will be represented at this level of governance that will be responsible for the facility implementation of all research studies.
- Scientific committee: Members of this committee were chosen from university researchers, investigators from IPs and investigators from collaborating

Table 1 Implementation strategies and clusters used for the development of the NISA-MIRCs

Implementation strategies	Description of implementation strategies as used for NISA-MIRCs
Cluster: Use evaluative and iterative strategies	
1. Assess for readiness and identify barriers and facilitators	Assessed readiness of the health facilities by developing and applying criteria for inclusion. Potential barriers and facilitators were discussed with the IPs and NASCP.
2. Purposefully reexamine the implementation	We re-examine the NISA-MIRCs implementation every week at the Monday and Friday meetings
3. Conduct local need assessment	We conducted local need assessments at the NISA annual conferences from 2015 to 2017
Cluster: Provide interactive assistance	
1. Facilitation	We facilitate problem solving by providing a WhatsApp communication platform with all the 21 hospitals. We also call the hospitals every week.
2. Provide local technical assistance	Local technical assistance is provided through weekly phone calls and the established WhatsApp platform that allows collaborative learning and peer-to-peer exchange
3. Centralise technical assistance	The CTAIR team serves as a centralised provider of technical assistance for the NISA-MIRCs
Cluster: Adapt and tailor to context	
1. Tailor strategies	Each week, the team identifies challenges and tailor strategies to address them
2. Use data experts	Among the CTAIR team, we have data experts who built the NISA-MIRCs database, and the data collection tools. The IPs also have highly skilled strategic information experts with multiple years of experience handling sensitive patient data and building needed systems to handle such data.
3. Use data warehousing techniques	The CTAIR head office at University of Nigeria serves as the data warehouse for the NISA-MIRCs
Cluster: Develop stakeholder interrelationships	
1. Identify and prepare champions	We identified champions among the government agencies and the NISA CEOs. These champions are prepared to support this cohort until it achieves self-sustainability
2. Build a coalition	We built a coalition of IPs, health facilities, government agencies, and academic institutions.
3. Obtain formal commitments	The NISA CEOs made a formal commitment to support and sustain this cohort.
4. Conduct local consensus discussion	We conducted local consensus discussion during the annual NISA conference and the NISA board meetings to determine the need for the cohort.
5. Use advisory boards and workgroups	We have a scientific committee and program committee that provide advice to the Stakeholder Committee
6. Use an implementation advisor	The program committee includes very experienced implementation experts and advisors that have in-depth experience in research and program implementation.
7. Involve executive boards	Some members of the stakeholder committee are fully involved in the development of the cohort.
8. Promote network weaving	The NISA-MIRCs lead and the CTAIR team continue to promote network weaving by strengthening existing relationships and building new ones.
Cluster: Train and educate stakeholders	
1. Conduct educational meetings	We conducted educational meetings by having weekly calls with the IPs and health facilities. We also had a training on research ethics for the facilities, IPs, and CTAIR team.
2. Conduct educational outreach visits	We conducted educational outreach visits to the health facilities to show them how to use the data collection tools and address health facility specific challenges

*This table is adapted from Waltz *et al*.[41] and Powell *et al*.[40]
CEOs, Chief Executive Officers; CTAIR, Centre for Translation and Implementation Research; IPs, implementing partners; NASCP, National AIDS, Viral Hepatitis and Sexually Transmitted Infections Control Programme; NISA-MIRCs, Nigeria Implementation Science Alliance Model Innovation and Research Centres.

institutions. This committee is responsible for identifying core research focus areas. They are also responsible for reviewing new study proposals and requests for collaboration.

- Program committee: Members of this committee were selected from the IP program leads (e.g., leads for PMTCT and strategic information [SI]) and CTAIR staff. Members of this committee serve as regional referral coordinators for the regions where their supported NISA-MIRCs hospitals are located.
- Stakeholder committee: Membership of this committee was designed to represent patients, providers, policymakers and payers. Specifically, this would include WLWH, a HIV service provider, a HIV researcher, the chief executive officers (CEOs) of NISA participating indigenous IPs, and the Healthy Sunrise Foundation. Additional members would represent policymakers, for example, National AIDS, Viral Hepatitis and Sexually Transmitted Infections Control Programme (NASCP), the National Agency

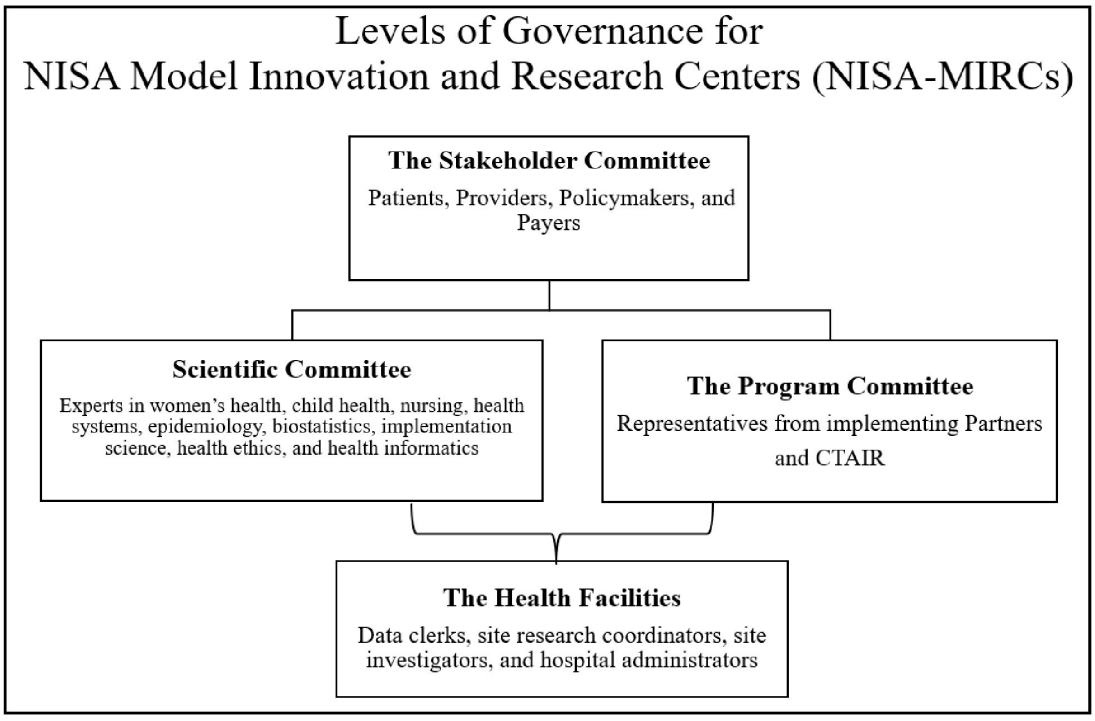

Figure 1 Governance structure for NISA-MIRCs. CTAIR, Centre for Translation and Implementation Research; NISA, Nigeria Implementation Science Alliance.

for the Control of AIDS (NACA), the National Cancer Control Programme, and the Federal Ministry of Health (FMoH). Representatives from Nigeria's global partners are also included in this committee (e.g., the US Centers for Disease Control and Prevention, the United States Agency for International Development, and the World Health Organization (WHO).

Select and train core research team

We assembled a core team of researchers with capacity and experience in clinical trial designs, HIV research and program implementation, epidemiology, health policy and systems strengthening, implementation science, mixed methods and health economic evaluation. All members of our core research team have completed the CITI training on the ethics of human subject research.

Stakeholder outreach and engagement

We conducted several engagement visits and meetings with our stakeholders.

- Engagement with IP CEOs: Several focused meetings and discussions were held by the NISA board for the establishment of the cohort during the annual NISA conferences from 2015 to 2017 that revealed the need for establishing the NISA-MIRCs. The concept was further developed at subsequent board meetings and the need for regional representation was finalised and agreed on.
- Outreach to Government Agencies: Following the go-decision by the NISA board, the CTAIR team reached out to the government agencies (NASCP and NACA). NASCP became the lead government agency involved in this infrastructure development.
- Outreach to IPs: The CTAIR team subsequently held several meetings and discussions with program leads from the IPs. These meetings provided a better understanding of the current HIV program implementation and reporting systems, and a review of routinely reported aggregate data from the health facilities. The team also discussed and agreed on the variables to be obtained from the health facilities.
- Outreach to sites: The program team working with the CTAIR team had several meetings and discussions with the site focal persons for PMTCT and SI. These meetings helped to explain the NISA-MIRCs to the health facilities, answer questions, clarify the terms of engagement and plan for future research projects.

Develop criteria for site selection and assess site readiness for research

The scientific and program teams led the development of the criteria to select the NISA-MIRCs. The criteria for the selection of these health facilities are that they: (1) offer comprehensive HIV care and treatment services to women, men, and children; (2) have functional Electronic Medical Record (EMR) systems; (3) have dedicated management and clinical teams on-site; (4) have at least 1000 women on ART; (5) are easily accessible by road and (6) are in a community devoid of any significant communal unrest or security problems. These criteria were applied to the list of sites submitted by the IPs and all the sites were ranked. After the ranking, a list

of the top five sites from each state where the IPs work was generated.

IMPLEMENTATION

Site selection

The scientific and program team worked together to select sites to be included in NISA-MIRCs following the criteria defined above. The NISA-MIRCs are made up of both secondary and tertiary health facilities. The core IPs that contributed sites to the NISA-MIRCs are APIN Public Health Initiatives (APIN), Caritas Nigeria, Centre for Integrated Health Programmes (CIHP), Nigeria, Family Health International 360, and Institute of Human Virology Nigeria (IHVN). Collectively, these 5 IPs support 1300 health facilities that provide HIV care and treatment services across Nigeria. The site selection was in two phases. The first phase included an initial 12 health facilities that were selected based on the number of women on ART (>1000), the number of women attending antenatal care and the representativeness of all 6 geopolitical regions in Nigeria and the 5 IPs. The second phase included an additional 9 high-volume health facilities with >2000 women on ART. These nine health facilities were selected independent of the geopolitical region and IPs. This process gave a total of 21 sites with a potential 60 000 women on ART who may be eligible for enrolment into research and clinical trials. The selection of the NISA-MIRCs was guided by the need for representativeness across all zones in the country. The first round of selection was for equality where each geopolitical region has two sites, while the second round was to achieve equity when looking at the burden of disease. In the future, other sites will continue to be evaluated and added to the NISA-MIRCs as needed. The list of the selected health facilities can be found in table 2 and the geographical distribution is shown in figure 2.

Identify technology needs

The team considered technology framework to be a critical part of this research infrastructure development. The team evaluated the technology needs and established that a robust routine clinical data collection system was already in place in the 21 NISA-MIRCs via the EMR systems supported by Government of Nigeria and PEPFAR. All the 21 NISA-MIRCs operate functional EMR systems that are approved by Nigeria's FMoH. There are two major systems – the Nigerian Medical Record System (NMRS) and the Lafiya Management Information Systems (LAMIS). The NISA-MIRCs will rely on the NMRS and LAMIS as data sources for the historical health records of participants who enrol in the epidemiological cohort. Both systems use open-source software. The EMRs also interact seamlessly with many data platforms like the National Data Repository (NDR), which was established in 2014 as a national database of all PLWH who are receiving treatment across the 36 states in Nigeria.[18] Other EMR-accessible data platforms include the District Health Information Software,[47] a real-time data reporting and aggregation platform; the Laboratory Information Management System (LIMS),[48] a national portal for rapid review of lab results; and the Nigeria orphans and vulnerable children (OVC) Management Information System,[49] a user-friendly software for OVC programming.

In addition, we will strengthen the already existing system to support research data collection, transmission, storage, and analyses. The team built a research data collection and management system using the Research Electronic Data Capture (REDCap) and Microsoft Azure cloud-based information technology infrastructure as-a-service. REDCap is a secure, web-based software platform designed to support data capture for research studies, providing (1) an intuitive interface for validated data capture; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages and (4) procedures for data integration and interoperability with external sources.[50 51]

Identify and train key site personnel and data clerks

At the level of the health facility, the team identified two focal persons—the PMTCT focal person and a data clerk. In August 2021, we conducted a virtual training on Informed Consent and Research Ethics for a total of 84 participants involved with the NISA-MIRCs. The participants included health facility staff (57), IP staff (11) and CTAIR staff (16). This training was to ensure the highest ethical standards among the research staff. Additionally, we have created a group communication platform using WhatsApp. The WhatsApp group includes members of the CTAIR team and the health facility focal persons, and provides opportunities for easy flow of communication, ongoing group learning and progress updates.[52]

SUSTAINMENT

Identify and train clinical research coordinators

The selection and training of regional research coordinators who are embedded with the IPs' HIV service programs are part of our sustainability plan. They remain as champions within the programs and are ready to lead scale-up when new strategies, products, and programs are found to be effective thereby contributing to the learning health system. Our plan for sustainment is to continue to identify, recruit, and train clinical research coordinators both at the health facility level and regional levels as NISA-MIRCs participation in implementation research and clinical trials evolve. These trained personnel will have continuing education to increase their skill set and help job retention over time and will be able to support the epidemiological cohort needs for participant recruitment, follow-up and project implementation for multiple clinical trials.

Identify and apply for external funding

Our team is actively seeking opportunities to expand and maintain the NISA-MIRCs. We are open to collaborations

Table 2 Health facilities in the NISA Model Innovation and Research Centre

S/N	Name of health facility	Level of care	Geopolitical region	Women on ART*	Women attending ANC*
1	Adeoyo Maternity Hospital, Ibadan, Oyo State	Secondary	South-West	3239	3273
2	Annunciation Specialist Hospital, Emene, Enugu State	Secondary	South-East	1939	353
3	Calabar General Hospital, Calabar, Cross River State	Secondary	South-South	2689	1400
4	Central Hospital, Agbor, Delta State	Secondary	South-South	2592	4817
5	Dalhatu Araf Specialist Hospital, Lafia, Nasarawa State	Secondary	North-Central	3717	2986
6	Faith Alive Foundation, Jos, Plateau State	Secondary	North-Central	3917	5399
7	Federal Medical Centre—Keffi, Nasarawa State	Tertiary	North-Central	3418	1660
8	Federal Medical Centre—Makurdi, Benue State	Tertiary	North-Central	7481	2915
9	Dr. Gwamna Awan General Hospital, Kaduna, Kaduna State	Secondary	North-West	2189	3881
10	General Hospital, Alimosho, Lagos State	Secondary	South-West	2930	14725
11	General Hospital, Billiri, Gombe State	Secondary	North-East	1406	3438
12	General Hospital, Funtua, Katsina State	Secondary	North-West	2076	1565
13	Gombe State Specialist Hospital, Gombe, Gombe State	Secondary	North-East	2919	2428
14	Mother of Christ Specialist Hospital, Ogui, Enugu State	Secondary	South-East	2203	1197
15	Oron General Hospital, Oron, Akwa Ibom State	Secondary	South-South	2806	2193
16	Plateau State Specialist Hospital, Jos, Plateau State	Secondary	North-Central	2958	1621
17	Rivers State University Teaching Hospital, Port Harcourt, Rivers State	Tertiary	South-South	3028	1743
18	Sankera General Hospital, Sankera, Benue State	Secondary	North-Central	4314	350
19	State Hospital - Ijebu Ode, Ogun State	Secondary	South-West	2458	1896
20	University of Calabar Teaching Hospital, Calabar, Cross River State	Tertiary	South-South	2043	1605
21	University of Uyo Teaching Hospital, Uyo, Akwa Ibom State	Tertiary	South-South	2534	1899
	Totals			62856	61344

*Data from the last reporting year (October 2019 to September 2020).
ANC, antenatal care; ART, antiretroviral therapy; NISA, Nigeria Implementation Science Alliance.

Figure 2 Map of Nigeria showing the distribution of the 21 NISA-MIRCs. NISA-MIRCs, Nigeria Implementation Science Alliance Model Innovation and Research Centres.

that build equitable partnerships with both local and international researchers, institutions and organisations. Having developed these centres, we will embark on cohort development. We are actively applying for multiple research grants from NIH and other funders of biomedical research.

Challenges

Our team faced significant challenges in establishing the NISA-MIRCs. The greatest challenge that faced our team was inadequate financial and human capacity. Highly qualified and trained personnel are needed to propose, initiate and implement clinical trials and other types of studies.[3 4] Such human resource development requires relatively stable, well-resourced research institutions and well-established science governance systems, which have not been the case in Nigeria and other LMICs.[30] We have summarised the challenges and strategies used to address them in table 3.

CONTRIBUTIONS TO RESEARCH PRACTICE

The establishment of NISA-MIRCs will enable Nigeria to answer globally relevant research questions that it had previously been ill equipped to address with efficiency and rigor. As designed, NISA-MIRCs will systematically gather and create evidence using effectiveness-implementation hybrid designs,[53] while applying the most promising evidence to improve care. This will be a gradual process and will expand over time thereby contributing to a learning health system.[54] The process of selecting at least two MIRCs from each of the six geopolitical zones in Nigeria provides the opportunity to understand how the different contexts and cultures impact the health systems and health outcomes.

While clinical trials are important to scientific understanding and discovery, LMICs, especially those in Africa have often been sidelined. For example, as of November 2021, only 3.3% (13,034 of 395,555) of clinical trials globally were in Africa.[55] This inequity poses significant challenges to the achievement of global goals like the UNAIDS 95-55-95, WHO cervical cancer elimination 90-70-90 goals, and the health-related Sustainable Development Goals (SDGs).[56–58] It is also important to note that clinical trials need to be established on strong pre-existing institutional infrastructures, so as to achieve smooth operationalisation and sustained outcomes

Table 3 Challenges encountered during the establishment of the NISA Model Innovation and Research Centres (NISA-MIRCs)

Core areas	Challenges	Strategies to address challenges
Leadership	Competition among Implementing Partners (IPs)	1. Developed a clear vision for NISA-MIRCs 2. Separated research from programs and had a commitment from the core research team at CTAIR not to compete for program grants 3. Created a governance structure agreed to and trusted by the IPs. There is an independent chair of the NISA Board of Trustees who is not part of any of the IPs
Funding	Sustainability	1. To ensure long-term sustainability, we intentionally decided to seek direct local support at the beginning rather than external funding 2. NISA, CTAIR and HSF provided support for a 3-person research administration team who work on this project full time 3. The 21 data clerks at each facility are supported by NISA
Infrastructure	Lack of basic infrastructure to support research (e.g., database, cloud storage, tablets)	1. Tablets were provided to all the 21 sites for data collection 2. A doctoral student (EE) helped build the REDCap database during his internship with NISA 3. Emails created for all core research team members for more secure communication and log-in to project database
Training	Deficits in research capacity	1. Identified individuals with commitment to research and built transdisciplinary collaborations 2. Four-hour remote research meeting every week for the team of investigators 3. Training on ethics and good clinical practice for the data clerks
Government Engagement	Government support for research	1. Letter from the government to engage the hospital leadership at the 21 sites 2. Commitment from the 21 sites to accept the single national IRB for research and clinical trials 3. Government involvement was instrumental in building needed confidence in the process of establishing the NISA-MIRCs

CTAIR, Centre for Translation and Implementation Research; HSF, Healthy Sunrise Foundation; NISA, Nigeria Implementation Science Alliance; REDCap, Research Electronic Data Capture.

which both builds on and further strengthens the pre-existing infrastructure, making it available for other substudies, clinical trials or implementation research.[59] In this instance, collaborations are critical; Africa cannot afford to continue with research infrastructure that fails and collapses when the external funding ends.[3 4 28 59]

Our approach to developing the 21 NISA-MIRCs has several strengths, the first of which is the representativeness of all 6 geopolitical regions of Nigeria and the potential size of the corresponding clinical and epidemiological cohort (NISA-WICS). The collaboration of health facilities, government agencies, academic institutions and IPs, facilitated by NISA, which was established in 2015, is also an important strength that will support the sustainability of this research infrastructure. Additionally, since the foundation of NISA-MIRCs is locally funded, there is limited fear of the collapse of this collaboration, as has been seen with other cohorts in SSA.[28] Finally, the availability of EMR systems in the selected health facilities also provides the opportunity to obtain consistent clinical records of enrolled participants, averting recall bias that may arise from self-report. The main limitation to the NISA-MIRCs is security challenges in parts of Nigeria that could potentially limit technical assistance and support to the site. However, as part of our selection criteria, we have attempted to address this by selecting health facilities located in areas with no significant security challenges, while at the same time achieving a national representation.

Our team set out to build a research infrastructure that could support clinical and implementation research and thus could also carry out hybrid-type study designs,[53] which are increasingly important in LMIC contexts. This paper is the first of a two-paper series—(1) the first is to describe the establishment of the research infrastructure that can host clinical, implementation and health system research, and (2) the second will focus on using this infrastructure to educate and recruit women into research studies and trials. Although we are building on existing HIV infrastructure, it is not limited to HIV research. This infrastructure will also be used to conduct health system and policy research or research on other

diseases. It will provide the infrastructure to design and test aspects of the six pillars of the health system.[60] For example, the NISA-MIRCs can be used to test the effectiveness of task-shifting strategies (health workforce); the comparative effectiveness of mental health services delivered via telepsychiatry compared with trained lay mental health providers (service delivery and health information); and strategies to implement the national cancer treatment guidelines (policy).

The development of this cohort of sites will have far-reaching implications for research and practice in Nigeria and SSA. The NISA-MIRCs will be a valuable resource for research evidence in maternal and child health, epidemiology, implementation science, health services, and chronic diseases like cancer, hepatitis, diabetes and cardiovascular diseases.[61] This cohort of sites and the corresponding clinical and epidemiological cohort (NISA-WICS) will provide crucial information on disease-specific maternal and child health outcomes, and their associated factors, similar to cohorts in other settings.[62–67] Additionally, the NISA-MIRCs will provide a nationally representative infrastructure to initiate new studies, support scientific collaborative research projects, and provide preliminary data to support research grant applications and graduate-level student research projects in a region where such infrastructure is limited and data is often unavailable, thereby filling a significant research gap in Africa's most populous country.[68 69] Finally, the process described here can be a model for others looking to catalyse implementation science and clinical trials at a national level or across SSA. While the NISA-MIRCs may not be generalisable to other LMICs facing similar challenges, we hope that our approach could inform the strategies they choose to develop sustainable research infrastructure in their respective countries.

CONCLUSION

Our participatory approach and the systematic process of developing the NISA-MIRCs have been critical to the progress to date. This process highlights the significance of engaging relevant stakeholders and using implementation strategies in establishing large cohorts in low-resource settings. NISA provides a collaborative platform to effectively engage with relevant stakeholders, which is not only important for smooth operational processes, but also for the dissemination of research findings and best practices. This process will also serve as an example for other researchers in Nigeria and other LMICs on how to build effective collaborations and develop local research infrastructure for clinical and implementation research, thereby taking these countries a step closer to achieving their biomedical and health-related goals.

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Ethics approval Ethical clearance for the development of the epidemiological cohort (called the NISA Women and Infant Cohort Study (NISA-WICS)) was obtained from the National Health Research Ethics Committee of Nigeria (NHREC, Approval number: NHREC/01/01/2007-25/03/2021). This single national Institutional Review Board (IRB) approval was critical because it covered all the 21 NISA-MIRCs, thereby avoiding the need for multiple ethical approvals from each hospital. This approval covered the team to approach patients and consent them for the longitudinal clinical cohort (the first project embarked on by NISA-MIRCs). Ethical approval will be obtained for any additional clinical trials or implementation research.

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