Annual Report 2024

KINTAMPO HEALTH RESEARCH CENTRE (KHRC)

30th Anniversary Grand Durbar

Prof. Kwaku Poku Asante, Director of KHRC Recognized by the American Society of Tropical Medicine and Hygiene (ASTMH), as a Distinguished International Fellow

2024 MAJOR EVENTS

30th Anniversary Staff Thanksgiving Service held on 19th October 2024

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Acronyms/Abreviations

ACT	Artemisinin-based Combination Therapy
AEs	Adverse Events
AESI	Adverse Events of Special Interest
AFI	Acute Febrile Illnesses
ALT	Alanine amino transferase
AMR	Antimicrobial Resistance
ANC	Antenatal Clinic
AST	Aspartate amino transferase
CEM-gH	Consortium to Evaluate Mosquirix in Ghana
CHPS	Community-Based Health Planning and Services
CO	Carbon Monoxide
COPD	Chronic Obstructive Pulmonary Disease
CTCAE	Common Terminology Criteria for Adverse Events
DHFR	Dihydrofolate reductase
DHPS	Dihydropteroate synthase
DNA	Deoxyribonucleic Acid
DSMb	Data Safety and Monitoring Board
EPI	Expanded Programme on Immunization
FDA	Food and Drugs Authority
FEV1	Forced Expiratory Volume in 1second
gbS	Group B streptococcus
gCS	Ghana Cookstove Study
gHS	Ghana Health Service

Acronyms/Abreviations

gHS ERC	Ghana Health Service Ethical Review Committee
gRAPHS	Ghana Randomized Air Pollution and Health Study
gRIP	Group B streptococcus (GBS), Respiratory syncytial virus (RSV) Influenza, and Pertussis
GSED	Global Scale for Early Development
gSK	GlaxoSmithKline
HAP	Household Air Pollution
HAPIT	Household Air Pollution Intervention Tools
Hb	Hemoglobin
IPTp-SP	Intermittent preventive treatment in pregnancy using sulphadoxine-pyrimethamine
ISAAC	International Study of Asthma and Allergies in Childhood
KHRC	Kintampo Health Research Centre
KHRC IEC	Kintampo Health Research Centre Institutional Ethics Committee
KNUST	Kwame Nkrumah University of Science and Technology
LbW	Low Birth Weight
LPg	Liquified Petroleum Gas
LSHTM	London School of Hygiene and Tropical Medicine
NC/NT-SAE	Non- communicable and Traumatic Serious Adverse Events
NCDs	Non-communicable Diseases
NHLbI	National Heart Lung Blood Institute
NIH	National Institute of Health
PATH	Program for Appropriate Technology in Health
PE/E	Preeclampsia/eclampsia

Acronyms/Abreviations

PF	Practice Facilitation
PKR	Pyruvate Kinase-Red Blood Cell
PM2.5	Particulate Matter (PM) that have a diameter of less than 2.5 micrometers
PrCr	Protein Creatinine
RCT	Randomized Control Trial
RE-AIM	Reach Effectiveness Adoption Implementation Maintenance Framework
RSV	Respiratory syncytial virus
RTS,S/AS01E	Malaria Vaccine
SAbAUSE	Sociocultural determinants of antibiotic access and use
SARS-CoV-2	Severe Acute Respiratory Infections Respiratory Syndrome – Coronavirus 2
SCD	Sickle Cell Disease
SEforALL	Sustainable Energy for All
SP	Sulphadoxine Pyrimethamine
SSA	Sub-Saharan Africa
TASSH	Task Strengthening Strategy for Hypertension Control
TSF	Task Strengthening Facilitation
UC	Usual Care
WHO	World Health Organization
WRA	Women of Reproductive Age
VE	Vaccine Effectiveness
VOC	Vaso-Occlusive Crises

ABOUT US

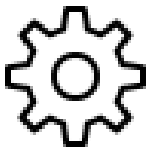
The Kintampo Health Research Centre (KHRC) is one of three field research Centres of the Research and Development Division (RDD) of Ghana Health Service, established in 1994. We are a well-established, African-based, research Centre that conducts health and biomedical research aimed at shaping health policies and guiding programme implementation to improve healthcare delivery in Ghana and beyond.

Vision

Be a centre of excellence that conducts high quality research to shape local and international health policy, programs and practices.

Mission

- Conduct public health and biomedical research that will influence policy direction and programme implementation that seek to significantly improve well-being and reduce ill-health.
- At all times be committed to the conduct of high-quality research that is ethical.
- Ensure integrity of data generated.



Core Values

- Team Work
- Excellence
- Collaboration
- Integrity
- Accountability
- Innovation
- Equity
- Diversity

Guiding Principles

- Population based research
- High quality and cost-effective research
- Strategic partnerships
- Formidable data management
- Inter sectorial collaboration
- Evidence-based practice.
- Publications and dissemination of findings.

OUR MANAGEMENT TEAM

Prof. Kwaku Poku Asante
Director

Mr. Ben Toffah
Administrator

Mrs. Charlotte Tawiah
Chief Health Research Officer

Mr. Owusu Boahen
Chief Health Research Officer

Dr. Seyram Kaali
Principal Medical Officer

Mr. Eliezer Odei-Lartey
Head of Data Science

Dr. David Dosoo
Deputy Chief Biomedical Scientist

Dr. Dennis Adu-Gyasi
Deputy Chief Biomedical Scientist

Mr. Abdul-Karimu Alhassan
Financial Administrator

OUR RESEARCH AREAS

Evaluating the Effectiveness and Cost-Effectiveness of Integrating Mass Drug Administration for Helminth Control with Seasonal Malaria Chemoprevention in Ghanaian Children (MALHELMIN)

Investigators

Prof. Kwaku Poku Asante (KHRC), Dr. Dennis Adu-Gyasi (KHRC), Dr. Theresa Tawiah (KHRC), Dr. Muhammed O. Afolabi (LSHTM), Lucy Paintain (LSHTM), Dr. Sanni Ali (LSHTM), Prof. Brian Greenwood (LSHTM).

Funder

London School of Hygiene & Tropical Medicine, UK

Collaborating Institutions

London School of Hygiene & Tropical Medicine (LSHTM), London, UK
Kintampo Health Research Centre (KHRC), Ghana

Study Duration

12 Months
Start date: 3rd June 2024
End date: 2nd June 2025

Introduction

The Kintampo Health Research Centre (KHRC), with funding from the London School of Hygiene, and Tropical Medicine is implementing this MALHELMIN drug trial, a study aimed at improving malaria and helminth treatment and control, in Bono East Region. The study is testing how effective and affordable it is to combine treatments for worm infections with seasonal malaria prevention in Ghanaian school-aged children.

Background

Malaria remains a major health challenge in Sub-Saharan Africa (SSA), excessively affecting children under five, with over 90% of malaria cases and related fatalities occurring in this region. The situation is intensified by the prevalence of helminth infections, which affects over 1 billion individuals globally, including more than 800 million children in SSA. Among these, worms that infect us from the contact with the soil (such as hookworm, pinworm, roundworm, and whipworm) and parasites that cause bloody urination (Schistosoma species) are prevalent, contributing to severe health consequences. These co-infections can worsen malaria outcomes, such as anaemia, which leads to higher mortality and impacts growth, cognitive development, and educational attainment among children.

Despite efforts such as the 2012 London Declaration on Neglected Tropical Diseases, aimed for 75% treatment coverage for parasitic worms by 2020, current programs have not met these goals. However, the Seasonal Malaria Chemoprevention (SMC) initiative has exceeded 75% coverage and effectively reduced uncomplicated and severe malaria cases in children. This success prompted the World Health Organization (WHO) to recommend expanding SMC programs to include other high-risk age groups and areas with high seasonal malaria infections.

Objectives

The main objective of this study is to evaluate the effectiveness of combining SMC and deworming drugs on anaemia prevalence and intensity of malaria-helminth co-infection in school-aged children. This study also seeks to determine the costs and cost-effectiveness of delivering an integrated malaria-deworming approach to the children.

Methodology

This is a cluster randomised controlled, pragmatic programme-led study to evaluate the effectiveness of co-administration of SMC and Mass Drug Administration (MDA) for schistosomiasis and STH in reducing anaemia being implemented in Pru East in the Bono East region of Ghana. Malaria and helminth infections are common at this site. The study uses medications approved by the World Health Organization (WHO), such as sulphadoxine-pyrimethamine and amodiaquine for malaria, and albendazole and praziquantel for helminths.

The trial involves over 1,200 children,aged 5 to 10 years, who are split evenly between two communities: one group receives a combined treatment of SMC and deworming drugs, while the other receives SMC with Vitamin A and Zinc. Researchers will then analyse anaemia prevalence and compare the effectiveness and cost-effectiveness of the integrated approach. Health assessments are done before and after the treatments to check their haemoglobin levels, clinical malaria cases, and any side effects.

Doses were based on the children's ages, and what the control programmes (National Malaria Elimination Programme and National Neglected Tropical Diseases Programme) recommend for the two diseases under supervision. Before starting, samples were collected, and this will be repeated at the post-treatment evaluation visit.

Informed consent was sought from parents or guardians before all study activities begun. After consultations and health evaluations, qualified children were enrolled in the trial and closely monitored by study staff from KHRC during treatment.

Safety and Monitoring

Trained staffs monitored children for adverse reactions, particularly during the initial SMC and MDA cycles, while caregivers were instructed to report any issues. Serious adverse events were reported within 24 hours to Ghana's regulatory authority. Local health centres were also prepared to manage severe cases.

Expected Outcomes

The integration of malaria and helminth treatments could lead to improved health outcomes in children through reduced anaemia and malaria severity. By combining drug administration, the intervention is expected to lower costs and increase coverage effectiveness, maximizing the health impact among malaria endemic populations.

Progress of Study Activities

The study has received all ethical and regulatory approvals. Implementation of the study protocol began in July 2024 in the Pru East District, where about 1,400 participants from 20 selected schools have received the needed interventions. Currently, the research team is conducting a post-treatment survey in the field, with plans to complete this phase by the end of December 2024. Any sample analyses that cannot be conducted concurrently with the fieldwork will be done at the Seth Owusu-Agyei Medical Laboratory at KHRC.

Conclusion

This study seeks to improve child health in Sub-Saharan Africa by combining SMC with helminth control, potentially establishing a model for integrated disease management in regions with high co-infection rates. The structured monitoring and cost-analysis approach will offer data on both health impacts and financial sustainability.

Through the MALHELMIN drug trial, KHRC is not only working to expand the range of effective malaria treatments but is also exploring innovative trials that can adapt to evolving challenges in malaria care, especially in children.

Figure 1: Staff administering the drug to study participants

Figure 2: Staff on their way to the study communities

A Prospective Study to Evaluate the Safety, Effectiveness and Impact of the RTS,S/ASO1E Vaccine in Young Children in Sub-Saharan Africa. (EPI MAL 003)

Investigators

Dr. Kwaku Poku Asante. Dr. Seyram Kaali, Dr. Samuel Bernard Ekow Harrison, Dr. Prince Darko Agyapong, Dr. Cynthia Bema

Collaborating Institutions

London School of Hygiene & Tropical Medicine (LSHTM), London, UK
Kintampo Health Research Centre (KHRC), Ghana

Funder

GlaxoSmithKline (GSK) Biologicals S.A.

Study Duration

5 years+
Start date: 21st March, 2019
End date: 21st February, 2025

Introduction and Background

KHRC is making progress in this study that evaluates the safety, effectiveness, and impact of the RTS,S/AS01E malaria vaccine in young children across sub-Saharan Africa. The RTS,S/AS01E malaria vaccine, developed by GlaxoSmithKline (GSK) Biologicals, marks an important milestone in global health as the first malaria vaccine implemented for routine immunization in malaria-endemic regions. The vaccine, which targets Plasmodium falciparum, is designed to protect children in sub-Saharan Africa, where malaria remains a leading cause of morbidity and mortality.

Objectives

The study seeks to estimate the incidence of adverse events of specific interest (AESIs), including severe events leading to hospitalization or death in children vaccinated with RTS,S/AS01E. The study also aims to estimate cases of aetiology-confirmed meningitis among children vaccinated with RTS,S/AS01E.

Methodology

The study involves approximately 45,000 children who have been recruited across the collaborating study sites into the active surveillance system. These participants are being actively followed through home visits and continuous monitoring of outpatient and hospital admissions at all health care facilities in the study areas. The study uses multiple data source, to increase opportunity to capture the event of interest such as home visits, hospitalization visit and outpatient visits.

Expected Outcomes

The study expects to deliver a comprehensive assessment of the vaccine's safety profile, including adverse events leading to hospitalization or death and cases of confirmed meningitis in children vaccinated with RTS, S/AS01E. These findings will contribute to global efforts to enhance malaria prevention and improve child survival rates in sub-Saharan Africa.

Study Progress

The study is progressing well with KHRC enrolling a total of 12,000 children into the active surveillance arm. Also, 20,779 children have been recruited into the enhanced hospitalization cohort. Enrolment for the unexposed cluster of the enhanced hospitalization cohort ended on October 31, 2022, following the completion of the pilot RTS,S vaccine implementation program. Currently, all activities related to participants in the unexposed cluster have been completed. However, enrolment for the exposed cohort is ongoing, alongside follow-up visits for the active participants.

Conclusion

As this critical EPIMAL-003 study approaches its conclusion, the findings are expected to provide invaluable insights into the safety and efficacy of the RTS,S/AS01E vaccine. The data will inform future malaria prevention strategies and solidify the vaccine's role in protecting the health of children in sub-Saharan Africa.

Figure 1: a supportive supervision visit by the process lead monitor of the study to review health facility register in a health facility.

The Impact Of A Combination Of The RTS,S/AS01E Malaria Vaccine And Perennial Malaria Chemoprevention In Ghanaian Children (MALVAC-PMC)

Investigators

Kwaku Poku Asante, Daniel Chandramohan, Kaali Seyram, Samuel B. E. Harrison, Prince Agyapong Darko, Owusu Boahen, David Dosoo, Dennis Adu-Gyasi, Elvis Wilson, Afia Korkor Opare.

Funders

US President's Malaria Initiative (PMI),
GiveWell
Gates Foundation through the PMI Insights Project

Collaborating Institutions

London School of Hygiene and Tropical Medicine (LSHTM)
Program for Appropriate Technology in Health (PATH)
U.S. President's Malaria Initiative (PMI)
Centers for Disease Control and Prevention (CDC)
Ghana Health Service (GHS)
National Malarial Elimination Program (NMEP)

Study Duration

36 months
Start date: October 2023
End date: July 2027

Introduction

The MALVAC-PMC trial is testing new ways to prevent malaria by combining the RTS,S/AS01E malaria vaccine with either perennial malaria chemoprevention and sulfadoxine/pyrimethamine (PMC-SP) or PMC-SPAQ (PMC-SP plus amodiaquine). This combination could greatly reduce malaria cases, hospital visits, and deaths in children. To ensure accurate and reliable results, the study is using a double-blind, placebo-controlled design, where neither participants nor researchers know who receives the treatment or placebo. Advanced tools are being used to collect data and monitor any side effects. If successful, this approach could be recommended by the World Health Organization (WHO) and included in Ghana's routine immunization program to protect more children from malaria.

Background

Intermittent preventive treatment of malaria with sulfadoxine/pyrimethamine (SP) in infants (IPTi) was recommended for deployment in countries with a high burden of malaria in infants, and a low prevalence of SP resistance by the World Health Organization (WHO) in 2010. Recently, the IPTi regimen was renamed perennial malaria chemoprevention (PMC) and now focuses on flexible dosing regimens and age groups extending beyond infancy and allows for utilization of treatments other than SP. Over ten countries are currently implementing or planning to implement PMC as a malaria control intervention. A trial undertaken in young children in Burkina Faso and Mali showed that combining the RTS,S/AS01E malaria vaccine with Seasonal Malaria Chemoprevention (SMC) with SP and amodiaquine (SPAQ) substantially reduced the incidence of uncomplicated malaria, hospital admissions with severe malaria, and deaths attributable to malaria by 60%, 70%, and 70% respectively, in addition to the substantial impact obtained in children who received either intervention given alone.

Combining RTS,S/AS01E with PMC, and extending the period of administration of the latter into the second year of life, could have a strong synergistic effect. Many countries are currently, or will shortly consider, deploying PMC-SP and/or the RTS,S/AS01E intervention, but there is no empirical evidence to inform whether these interventions should be combined.

Evidence generation on the effectiveness of PMC-SP is ongoing in current pilot studies. SPAQ is likely a more effective chemoprevention regimen, especially in countries where SP resistance is high. Therefore, this study sets out to investigate the efficacy of adding PMC□SP or PMC-SPAQ to RTS,S/AS01E administered through the expanded programme on immunization (EPI) delivery system in Ghana.

Objectives

The objective of this study is to determine the efficacy of the combination of RTS,S/AS01E and PMC with sulphadoxine/pyrimethamine (PMC SP) or RTS,S/AS01E and PMC with SP and amodiaquine (PMC-SPAQ) against clinical malaria among children up to 24 months of age compared with RTS,S/AS01E vaccine administered alone.

Methodology

This study uses an individually randomized, double-blind, placebo controlled design undertaken in Atebubu Amantin Municipality of the Bono East Region of Ghana to validate the hypothesis that RTS,S/AS01E combined with PMC-SP or PMC SP-AQ will be superior to RTS,S/AS01E given alone in reducing the incidence of clinical malaria in young children. Approximately 2,040 infants are expected to be recruited at 14 to 18 weeks of age and randomized 1:1:1 to receive RTS,S/AS01E + PMC-SP with AQ placebo, or RTS,S/AS01E + PMC-SPAQ or RTS,S/AS01E + PMC SPAQ placebo. There is no stratification in recruiting study participants. Each participant will remain in the study for 22 months (from 3 months – 24 months inclusive).

A participant will be considered to have completed the study if he or she has completed all phases of the study including the last visit. A number of sub-studies will be undertaken to address the immunological responses to RTS,S/AS01E in each group, the impact of PMC-SP + RTS,S/AS01E or PMC-SPAQ + RTS,S/AS01E on the overall immune response to malaria. In vivo and molecular investigation of the efficacy of the SPAQ combination and SP. Studies on tolerability and acceptability of the interventions and studies which will inform the widespread deployment of the combined intervention if it shown to be effective will be done. Details of these sub-studies will be presented in separate protocols. In the case of all sub-studies, the investigators will ensure that there is no impact on the primary objectives of the trial as set out in this protocol.

Expected Outcomes

The study is expected to measure the incidence of clinical malaria defined as fever of >37.5oC or a history of fever in the past 48 hours, and a positive malaria blood film with a parasite density of 5,000 per µl or greater in children up to 24 months of age.

Progress of Study Activities

Participant Enrollment and Follow-Up

The study achieved its target enrolment of 2,310 participants on October 31, 2024. All participants are now in the follow-up phase. During the enrolment process, eight (8) individuals refused to participate, sixteen (16) did not meet the screening criteria, and three (3) withdrew their consent. The informed consent process used two approved forms: the PMC-RTS,S Trial Final ICF Version 2.0 and its Twi translation, both dated June 30, 2023.

Figure 1: Vaccination site visit by study investigators from collaborating institutions

Figure 2: On-site support provided by investigators from LSHTM

Figure 3: Group photo from the malaria diagnosis and management workshop in Atebubu

Site Visits

Four site monitoring visits were conducted in February, May, August, and November 2024 to ensure compliance with the study protocol, Good Clinical Practice (GCP), and local regulations. The monitors did not find any major issues. In addition to the routine monitoring, collaborators from PMI, CDC, and PATH visited the site on 19th February. Investigators from the London School of Hygiene and Tropical Medicine (LSHTM) provided onsite support on 9th March, while Dr. Malla Rao from the NIH visited the site on 21st May.

Community Engagement

The study team visited the Sene West District Hospital and St. Mathias Hospital to present the project to health workers in these facilities and seek their collaboration in tracking health events of study participants seeking care in their facilities.

Training and Capacity Building

Capacity-building programmes were also a key part of the study. The Bono East Health Directorate organized a workshop to build the capacity of health workers in in the Atebubu-Amantin Municipality on malaria diagnosis and management. The workshop aimed to build the capacity of health workers to improve the care and treatment of malaria and other febrile illnesses in the study area. A malaria microscopy workshop was also conducted for laboratory personnel to ensure accurate diagnosis and management of malaria.

Support Services

The study continues to support lower-level health facilities with limited diagnostic capacity, such as CHPS compounds, by processing malaria blood smears at the KHRC clinical laboratory and relaying the results to assist with clinical decisions.

An evaluation of the cluster-randomised pilot implementation of RTS,S/ASO1 through routine health systems in Ghana: A Post-Authorization Observation Study (MVPE)

Investigators

Dr Kwaku Poku Asante, Dr Thomas Gyan, Dr Abraham Oduro, Prof Tsiri Agbenyega, Prof Daniel Ansong, Prof Fred Binka, Prof Kwadwo A. Koram, Dr Abraham Hodgson.

Collaborating Institutions

Ministry of Health
Ghana Health Service
World Health Organization (WHO)

Funders

World Health Organization (WHO)
GAVI, the Vaccine Alliance

Study Duration

Six (6) years
Start date: 01 October 2018
End date: 31 December 2024

Introduction

The RTS,S/AS01 malaria vaccine, introduced as part of a six-year pilot program in Ghana, Kenya, and Malawi, has shown encouraging outcomes in reducing child mortality. The pilot programme, which began in October 2018 and runs until December 2024, was led in Ghana by investigators from KHRC, Ghana Health Service, Ministry of Health and the World Health Organization (WHO).

This MVPE programme, which was funded by WHO and GAVI, the Vaccine Alliance, was carried out through regular health services and aimed to find out how practical, safe, and effective it is to give the RTS,S malaria vaccine to children aged 5 months and older in four doses.

Background

Malaria remains a major health challenge in Sub-Saharan Africa (SSA), excessively affecting children under five, with over 90% of malaria cases and related fatalities occurring in this region. The RTS,S/AS01 malaria vaccine was rolled out in Ghana as part of a phased pilot program within the routine health system. Similar pilot programs were also launched in Kenya and Malawi.

In Ghana, the Ministry of Health and Ghana Health Service selected specific districts, which were randomly assigned to begin administering the vaccine. To assess the vaccine's early impact, the Malaria Vaccine Pilot Evaluation (MVPE) program conducted observational studies. These included three rounds of household surveys, hospital-based monitoring of severe malaria cases such as cerebral malaria and meningitis, and community surveillance of mortality, all integrated into existing health systems.

Objectives

The project evaluated the impact of RTS,S by collecting data to answer the following questions:

- The programmatic feasibility of delivering a four (4) dose schedule.
- Safety in routine use, with focus on cerebral malaria and meningitis.
- The impact of the malaria vaccine in routine use on severe malaria and all-cause mortality.

Methodology

Across the three countries (Ghana, Kenya and Malawi), a total of 150 clusters were randomized to introduce RTS,S in 2019 (implementing) or later (comparison) through national routine immunization programs using a four-dose schedule beginning at 5-months of age. Vaccine uptake was monitored through routine administrative data and coverage through household surveys. Impact and safety were measured through community-based mortality and sentinel hospital surveillance among children aged 1-59 months. Primary outcomes were vaccine uptake and all-cause mortality, excluding injury. Incidence rate ratios (IRR) compared event rates among vaccine age-eligible and age-ineligible populations in implementing versus comparison clusters

Expected Outcomes

The study sought to measure several key outcomes, including: the total number of deaths from any cause, the number of children hospitalized with probable or confirmed meningitis, and the number of children admitted with cerebral malaria. It also sought to evaluate the proportion of children aged 12-23 months who have completed the primary three-dose series of the malaria vaccine, as well as the number of children aged 27-38 months who have received the fourth dose.

Progress of Study Activities

The dissemination of results from the 46-month evaluation of the RTS,S malaria vaccine program has been actively conducted both locally and internationally, ensuring that key stakeholders are informed of the study's progress and impact. Efforts to document the findings in scholarly publications are ongoing, with significant milestones already achieved. Notably, the evaluation of the program's first 24 months was published in The Lancet on April 4, 2024.

Also, a manuscript detailing the impact of the RTS,S vaccine on all-cause mortality over the 46-month period has been submitted to The New England Journal of Medicine as of October 17, 2024, and is currently under review. These publications represent critical steps in sharing the program's achievements and advancing the global understanding of malaria vaccine implementation.

Key Findings

Over 46 months, 1.29 million children received the first dose of the RTS,S malaria vaccine across Ghana, Kenya, and Malawi. The study analyzed the impact of the vaccine on child mortality and safety over time, revealing the following key results:

1. **Vaccine Coverage:**
    - About 30 months after the vaccine was introduced:
        - In Ghana, 74% of children received the third dose while 52% received the fourth dose.
        - In Kenya, 69% received the third dose, and 34% received the fourth dose.
        - In Malawi, 62% received the third dose, and 32% received the fourth dose.

2. Reduction in Child Mortality:

- Among children eligible for at least three doses, there were 5,576 deaths in areas where the vaccine was introduced compared to 6,152 deaths in areas where the vaccine was not introduced.
- The vaccine was linked to a 13.2% reduction in deaths from all causes (excluding injuries), with a confidence interval of 2.7% to 22.6%.

3. No Evidence of Major Side Effects:

- The vaccine did not lead to an increase in cerebral malaria cases (incidence rate ratio 0.94, 95%CI 0.63-1.39).
- No increase was observed in meningitis cases (incidence rate ratio 0.98, 95%CI 0.63-1.52).
- There was no significant difference in mortality between boys and girls (interaction term 1.04, 95%CI 0.93-1.15).

These findings show that introducing the RTS,S vaccine through national immunization programs can significantly reduce child deaths, even with moderate coverage for the third dose and limited coverage for the fourth dose. This highlights the vaccine's potential to save lives in regions heavily impacted by malaria.

Figure 1: Group photo of Ghana and WHO MVPE teams during a writing and analysis meeting in Accra

Strengthening the Evidence on the RTS,S/AS01 Malaria Vaccine: Assessment of Safety and Effectiveness Using Case-Control Studies Embedded in the Malaria Vaccine Pilot Evaluation (MVPE-CC)

Investigators

Dr Kwaku Poku Asante, Dr Thomas Gyan, Dr Abraham Oduro, Prof Daniel Ansong, Prof. Tsiri Agbenyega.

Funders

European and Developing Countries Clinical Trials Partnership (EDCTP)
World Health Organization (WHO)
GAVI, the Vaccine Alliance

Collaborating Institutions

Kintampo Health Research Centre of Research and Development Division, Ghana Health Service.
European Vaccine Initiative (EVI), Germany.
College of Medicine (CoM), University of Malawi, Malawi.
African Research Collaboration for Health Limited, Kenya.
Kenya Medical Research Institute (KEMRI), Kenya.
London School of Hygiene and Tropical Medicine (LSHTM), UK.
PATH, United States.

Study Duration

Four (4) Years, Two (2) Months
Start date: 01 April 2021
End date: 06 June 2025

Introduction and Background

The ongoing Malaria Vaccine Pilot Evaluation (MVPE) is being carried out in Ghana, Malawi, and Kenya using community-based and sentinel hospital surveillance systems, alongside household surveys to track vaccine coverage. Embedded within this initiative is the Malaria Vaccine Pilot Evaluation-Case Control (MVPE-CC), which involves case-control studies to investigate clinical and mortality outcomes. For each identified case, four control participants will be required, and caregiver consent will be obtained before proceeding with any study activities.

These observational case-control studies provide additional information to those gathered through the MVPE programme. The study seeks to assess the safety of the malaria vaccine in children, particularly in relation to cerebral malaria, meningitis, and severe malaria. In addition to checking its safety, the studies evaluate the vaccine's impact on overall mortality rates among boys and girls. It also aims to encourage the adoption of case-control approaches by Expanded Programmes on Immunization (EPI) and malaria control programmes for broader public health implementation.

Objectives

The main objective of the study is to determine how safe and effective the RTS,S/AS01 malaria vaccine is for children who receive it, complementing broader population-level findings from the World Health Organization's Malaria Vaccine Implementation Project. The research seeks to answer these key questions:

1. Do children who receive at least one dose of the RTS,S vaccine have a higher risk of meningitis compared to those who are not vaccinated?
2. Are children who receive at least one dose or three doses of the vaccine at a higher risk of developing cerebral malaria than unvaccinated children?
3. If children receive three doses but miss the fourth, does this increase their chances of severe malaria compared to children who were never vaccinated (a potential "rebound effect")?

4. How effective is the RTS,S vaccine at preventing severe malaria after three doses and after the fourth dose?
5. Does the vaccine increase the risk of death in girls, or is it less effective in preventing deaths in girls compared to boys?

Methodology

The study focuses on three types of cases: children admitted to the hospital with meningitis, children with severe malaria, and children who died. The study is limited to children who were eligible to receive the RTS,S/AS01 malaria vaccine based on their birth date and were living in areas where the vaccine was being given, within the coverage area of a sentinel hospital. For each child in the study, four other children from the same neighborhood, born within one month of the case child's birth date, will be selected as comparisons.

Expected Outcomes

The study seeks to achieve the following outcomes.

a) Primary Outcomes: The study will measure the following:

1. Excess risk of meningitis
2. Excess risk of severe malaria
3. Excess risk of cerebral malaria
4. Excess risk of mortality
5. Excess risk of mortality among girls

b) Secondary Outcomes: The study will also measure the following:

1. Excess risk of severe malaria in relation to the 4th dose of RTS,S.
2. Excess risk of cerebral malaria in relation to the 4th dose of RTS,S.
3. Excess risk of mortality in relation to the 4th dose of RTS,S.
4. Excess risk of mortality among girls in relation to the 4th dose of RTS,S.

Progress of Study Activities

The project team has made significant progress in several key areas.

Enrollment of Participants

As of November 30, 2024, a total of 14,041 participants with documented vaccine record comprising 2,820 eligible cases and 11,221 controls have been recruited into the clinical outcomes and mortality outcome case control studies across three countries (Ghana, Kenya, Malawi). The breakdown is provided in the table below:

Outcome	Number recruited	
	Cases	Controls*
Severe malaria	1478	5,888
Cerebral malaria	173	691
Meningitis	39	156
Mortality	1,130	4,486

*For each case, four community controls are recruited.

Monitoring Activities/Site Visits

External monitoring, conducted by the CRO Muden Ventures, has been ongoing across the three participating countries. A feedback report has been given to the team. In addition to the external monitor's visits, the Ethics Advisor has been monitoring the study in all three countries, and has provided the teams with feedback reports.

Meetings

A four-day MVPE-CC Investigators meeting was held in Accra, Ghana, from September 2–5, 2024, which facilitated collaboration and strategic discussions around conducting a preliminary analysis of the case-control study data, identifying key study outputs and crafting clear messages for dissemination. They also identified timelines and opportunities to share the study's findings, among other critical study issues.

Submission of Reports

The year-three technical and financial report was successfully submitted to the project funder, and feedback has been received to guide ongoing efforts. The project team has also presented updates at WHO's DSMB and SAGE/MPAG working group meetings on malaria vaccines and received feedback to enhance the study's impact and implementation.

Figure 1: MVPE-CC Investigators meeting, Accra

Figure 2: Group Picture of MVPE-CC Investigators

DEVELOPMENT OF A MALARIA VACCINE RESEARCH AGENDA

Investigators

Kwaku Poku Asante, Thomas Gyan, Samuel Afari-Asiedu, Abraham Hodgson, Cornelius Debpuur, Samantha Herrera, Annie Arnzen, Kim Lindblade, Mary J. Hamel, Lindsey Wu, Rafiq Okine, Eliane Furrer, John Francis, Stephen Sosler, Josea Rono.

Technical Advisory Committee

Rose Jalang'o, Don Mathanga, Jimmy Opigo, Eucebio Macete, Kwame Amponsa-Achiano, Terri Hyde, Margaret Gyapong, Matt Coldiron, Robert Bednarczyk, Perpetua Uhomoibhi, NMEP Nigeria

Funder

U.S. President's Malaria Initiative/PATH

Collaborating Institutions

Kintampo Health Research Centre (KHRC) of Research and Development Division, Ghana Health Service.
PMI Insights, PATH, District of Columbia, USA
World Health Organization (WHO), Geneva, Switzerland
Gavi, the Vaccine Alliance, Geneva, Switzerland

Study Duration

One (1) Year, Eight (8) Months
Start date: April 2023
End date: November 2024.

Introduction and Background

In October 2021, the World Health Organization (WHO) recommended the first malaria vaccine, RTS,S/AS01 (RTS,S), following decades of research to develop a safe and effective vaccine. Two years later, WHO recommended a second vaccine, R21/Matrix-M (R21), based on pre-clinical and clinical trial data showing a good safety and efficacy profile. About 30 countries in Africa plan to introduce malaria vaccine as part of national malaria control plans, and wider roll-out beyond the pilot countries started in 2024. It is estimated that malaria vaccine introduction could result in an additional half a million lives saved over the next 12 years.

A malaria vaccine coordination team (MVCT) including representatives from Gavi, WHO, UNICEF, The Global Fund, USAID/CDC, World Bank, PATH, CHAI, Africa CDC, and the Gates Foundation was established to advise and assist in defining conditions for successful implementation of the malaria vaccine. As a means to guide the introduction and scale-up of the malaria vaccine, WHO, Gavi, and the MVCT, identified the need to develop a malaria vaccine research agenda to inform the design, implementation, and scale-up of the vaccine.

Objectives

The research agenda aimed to help facilitate a more coordinated approach across funders and partners to address key knowledge gaps and information needs identified by countries taking up the vaccine. The agenda builds upon existing research and other ongoing research efforts for RTS,S and R21.

Methodology

The research agenda was developed using a mixed methods approach, consisting of a document review and a consultation process with key stakeholders from national immunization and malaria control programs, civil society organizations, global and regional bodies, research institutions, and technical partners working in malaria or immunization programming, policy, and/or research.

A technical advisory committee (TAC) was established to provide input to WHO on the design of the stakeholder consultation and the outcomes of the research prioritization process. Stakeholders were engaged to provide input into the research agenda through a mix of in-depth interviews, online surveys, and virtual engagement sessions.

The scope of the research agenda encompassed six key thematic areas:
(1) safety of the vaccine.
(2) implementation feasibility.
(3) acceptability of and demand creation for the vaccine.
(4) integration of the vaccine with other health interventions.
(5) impact and effectiveness of the vaccine.
(6) economics, costing, and cost effectiveness of the vaccine.

In total, 132 stakeholders provided inputs to define the agenda. Research topics identified through the consultation process were subsequently ranked by stakeholders across the following criteria: (1) broad relevance of the topic across malaria-endemic settings; (2) urgency of addressing the topic to inform vaccine rollout and scale-up; and (3) feasibility of undertaking the research. Scores were calculated for each research topic based on the stakeholder rankings across the three criteria.

Key Findings

During consultations, stakeholders identified several challenges that could arise during the rollout of the vaccines, along with important knowledge gaps that need to be addressed to ensure successful deployment. Based on these discussions, 32 potential research topics were initially identified. After review and refinement by WHO and Gavi, a final list of 28 research topics was developed.

The topics were grouped into six main areas:

- Safety (3 topics)
- Implementation Feasibility (8 topics)
- Acceptability and Demand Creation (2 topics)
- Integration with Other Health Interventions (5 topics)
- Impact and Effectiveness (7 topics)
- Economics and Cost-Effectiveness (3 topics)

The research agenda focused on practical and critical aspects of vaccine deployment, including:

- The best strategies and schedules for delivering the vaccine, such as age-based or seasonal approaches, and whether to use routine immunization or special campaigns.
- Evaluating the safety, feasibility, and effectiveness of using RTS,S and R21 vaccines in the same schedule.
- Assessing the impact of delivering the vaccine alongside malaria control measures or other health interventions, and how this could affect the broader health system.
- Identifying ways to strengthen key parts of the health system needed for successful vaccine delivery.

- Understanding how well the vaccines work over time and in different regions or populations.
- Exploring the economic impact of the vaccine and comparing the costs of various delivery methods.

These findings provide a roadmap for addressing key challenges and ensuring the vaccines reach those who need them most effectively and efficiently.

Conclusion

This research agenda prioritized list of 28 topics are important for guiding the rollout and scale-up of the new malaria vaccine. This research agenda was timely, given many countries have already begun or will begin to introduce the vaccine in 2024. The priority research list should be used to inform future investment decisions in malaria vaccine operational and implementation research. Given the rapid pace in which the malaria vaccine landscape is changing, it will be important to track progress against this agenda and review it periodically to ensure its continued relevance and to capture new topics that may emerge.

Acceptability and Potential Implementation Feasibility of Malaria Vaccination Combined with Perennial Malaria Chemoprevention

Investigators

Samuel Afari-Asiedu, Jane Grant, Jayne Webster, Seth Author. **Main Trial Investigators:** Kwaku Poku Asante, KHRC, Ghana, Daniel Chandramohan, LSHTM, UK, Brian Greenwood, LSHTM, United Kingdom, Rose Zulliger, USAID, USA, Nana Wilson, CDC, Ghana, Laura Steinhardt, CDC, USA, Julie Gutman, CDC, USA

Funder

PATH, USA

Collaborating Institutions

Kintampo Health Research Centre, Research and Development Division, Ghana Health Service, Ghana
London School of Hygiene &Tropical Medicine (LSHTM), United Kingdom

Study Duration

Two (2) Years
Start date: March 2024
End date: February 2026

Introduction

KHRC and LSHTM are conducting this study as part of the MalVac-PMC trial to assess how well people accept and how practical it is to combine perennial malaria chemoprevention (PMC) using either SP or SPAQ, with the RTS,S/AS01E malaria vaccine, to protect children from malaria. The study will also try to understand how health workers, caregivers, and communities feel about delivering and receiving this combined treatment. Funded by PATH, this study also seeks to provide evidence on the practical challenges of implementing the combined intervention in the routine health system.

Background

Malaria remains a major health problem for children in sub-Saharan Africa. Many countries are now considering, or will soon consider, using a combination of malaria prevention methods such as year-round malaria chemoprevention (PMC) and/or malaria vaccination. However, there is no existing evidence to show how well these two methods work together.

To address this, the MalVac-PMC trial began in Ghana in 2023. This study is exploring the potential benefits of combining PMC, using either SP or SPAQ, with the RTS,S/AS01E malaria vaccine. It is the first trial to investigate this combination, with both interventions being delivered through the essential immunization program (EPI) to children under two years old.

Objectives

This study looks at how acceptable and practical it would be to combine malaria vaccination with PMC. It focuses on the views of healthcare workers who deliver these services and the communities that receive them. This study is part of the larger MalVac-PMC trial led by the Kintampo Health Research Centre and the London School of Hygiene and Tropical Medicine.

Methodology

This study uses a mixed-methods approach with two main components.
First, in-depth interviews (IDIs) and focus group discussions (FGDs) will be conducted with caregivers of children receiving the interventions, as well as health workers and managers delivering them. These discussions will explore how acceptable it is to combine PMC with the RTS,S malaria vaccine, the factors that influence this acceptability, and whether it is feasible to deliver both through the routine health system. Qualitative data will be collected in two phases: the first when children are receiving their initial doses of the malaria vaccine and PMC-SP/SPAQ/placebo in infancy, and the second when they are receiving follow-up doses in their second year of life.

Secondly, the insights from the qualitative data will be used to develop a discrete choice experiment (DCE). This experiment will measure health workers' preferences for delivering either the RTS,S/AS01E vaccine alone or in combination with PMC-SP or PMC-SPAQ, considering the schedules and delivery methods within the routine immunization program (EPI).

Expected Outcomes

The study is expected to develop a comprehensive understanding of the acceptability and implementation feasibility of the combined malaria vaccine and PMC intervention from multiple stakeholder perspectives. It will also strengthen understanding of health worker preferences and suggested delivery approaches. The findings will be used alongside the trial result to inform policy decisions within Ghana and to strengthen global evidence on whether and how to co-administer these two interventions.

Progress of Study Activities

The first round of data collection is currently ongoing and is expected to end by January 2025. At the community level, 55 in-depth interviews (IDIs) have been completed with health workers, community health volunteers, caregivers, and participants who chose not to join the trial. In addition to this, five focus group discussions (FGDs) have been held with caregivers.

Interviews with health managers are also in progress. So far, eight IDIs have been conducted with staff from regional and district health directorates. At the national level, one interview has been completed with the National Malaria Elimination Programme, and another is planned with the Director of the Expanded Programme on Immunization (EPI) at the Ghana Health Service headquarters.

All completed interviews have been transcribed, and the transcripts are being coded and analyzed. This analysis will guide the design of the discrete choice experiment, which is set to begin in March 2025. The findings from the qualitative study will be shared at a stakeholder meeting in March 2025.

MALARIA SLIDE BANK

Investigators

Kwaku Poku Asante, Seth Owusu-Agyei, David Dosoo, Dennis Adu-Gyasi (KHRC); Nicole Whitehurst (MCDI); Samuel Kaba, Williams Mills-Pappoe (ICD); Ralph Ntumy, Felicia Amoo-Sakyi (Impact Malaria), Mohammed Adams (MCDI)

Funders

Kintampo Health Research Center (KHRC).
Medical Care Development International (MCDI).
PATH Malaria Care.
Impact Malaria.
World Health Organization.

Collaborating Institutions

Institutional Care Division (ICD).
Ghana Health Service, Impact Malaria.
PATH MalariaCare.
Improving Malaria Diagnosis (IMaD).
Centres for Disease Control & Prevention (CDC).
World Health Organisation (WHO).
Medical Care Development International (MCDI).
United States Agency for International Development (USAID), Partners.

Introduction

KHRC with support from the collaborating partners has prepared about 6,000 malaria blood slides as an update to the existing malaria slide bank (MSB). These new set of slides have been validated (by expert malaria microscopists and molecular techniques) for training of laboratory professionals.

Progress of Activities

The Giemsa-stained malaria blood slides from the MSB are being used to train medical laboratory professionals across Ghana. The slides from the MSB have also been used for competency assessments, and Outreach Training and Support Supervision (OTSS) for malaria diagnosis by the Clinical Laboratory Unit of the Institutional Care Division of the Ghana Health Service and the National Malaria Elimination Programme (NMEP).

In addition to slides in the MSB, there are more than 2,000 placental tissue blocks fixed in paraffinwax and the corresponding Haematoxylin and Eosin (H & E) stained slides from the placental tissues. These samples were prepared from a birth cohort study that enrolled and followed about over 2,000 pregnant women till at least six months after giving birth to their babies. These slides are also being used for training of placental malaria microscopists.

Figure 1: A Cabinet Containing the Malaria Slides

Figure 2: The Malaria Slides

A Parallel-Group, Phase III, Multi-Stage, Modified Double-Blind, Multi-Armed Study to Assess the Efficacy, Safety, and Immunogenicity of Two SARS-CoV-2 Adjuvanted Recombinant Protein Vaccines (monovalent and bivalent) for Prevention Against COVID-19 in Adults 18 Years of Age and Older as a Primary Series and Open-Label Extension to Assess Immunogenicity, Safety, Efficacy of a Monovalent Booster Dose of SARS-CoV2 Adjuvanted Recombinant Protein Vaccine (Sanofi Phase III COVID-19 Vaccine Trial)

Investigators

Dr. Kwaku Poku Asante, Dr. Seyram Kaali, Dr. Samuel Harrison, Dr. Prince Darko Agyapong, Dr. Cynthia Yaa Bema, Dr. Felicia Serwah, Dr. Afia Korkor Opare Yeboah, Mr. Elvis Ato Wilson, Mr. Owusu Boahen, Mr. Francis Mensah Kornu, Mr. Zakariah Buwah, Mr. Kingsley Kayan, Mr. Elisha Adeniji.

Funder

Sanofi Pasture Inc.

Study Duration

Three (3) Years

Start Date: August 2021

Introduction

KHRC is implementing this Sanofi Phase III COVID-19 Vaccine trial to test the effectiveness and safety of two new COVID-19 vaccines. This study, which is funded by Sanofi Pasteur Inc., aims to find better ways to protect people from COVID-19, especially with the emergence of new variants.

Background

COVID-19 first appeared in Wuhan, China, in December 2019 and quickly became a global pandemic. COVID-19, the illness caused by SARS-CoV-2, affects people in different ways. Most cases are mild, with some individuals not showing any symptoms at all. Common symptoms include fever, cough, and difficulty breathing. However, in severe cases, it can lead to serious breathing problems (acute hypoxemic respiratory failure) requiring ventilators and, in some instances, can be fatal. Even after recovering, many people experience lingering symptoms like fatigue and shortness of breath for up to two months.

Adults over 50 years of age and people with chronic medical conditions are more likely to experience severe complications or death from COVID-19. To address this, Sanofi Pasteur has developed a new vaccine designed to protect adults aged 18 and older from COVID-19. This vaccine targets a key part of the virus called the spike protein (S Protein), which helps the virus enter human cells. By focusing on this protein, the vaccine aims to prevent infections and reduce severe illness.

Objectives

The main objectives of the study are to assess the clinical efficacy of the candidate vaccine for the prevention of symptomatic COVID-19 occurring at least 14 days after the second dose and to assess the safety of the candidate vaccine compared to a placebo throughout the study.

Study Methodology

This study is a parallel multi-centre, multi-country, multistage phase III randomized double-blind placebo-controlled study. Participants have been screened for eligibility criteria at the time of inclusion and then randomized to either the investigational vaccine or placebo in a 1:1 ratio in each stage. In stage I, eligible participants have received the monovalent D614 vaccine or placebo and in stage II, eligible participants have been randomized to receive the bivalent D614 + B.1.351 vaccine. A total of 21,046 participants aged ≥ 18 years are planned to be enrolled in both stages. Randomized participants were followed up for approximately 12 months.

Active and passive surveillance was used to identify and record COVID-19-like illnesses during the follow up period. All COVID-19-like cases will undergo nasopharyngeal and oropharyngeal sampling for confirmation of COVID-19 by Nucleic Acid Amplification Testing (NAAT). Participants also be followed up for safety, beginning in the immediate post-vaccination period and throughout the study. All serious adverse events, medically attended events and adverse events of special interest will be recorded and reported as per protocol. In the event that either or both the monovalent and bivalent vaccines are deemed safe and effective, participant will undergo a blinded cross-over in which those who received the placebo will be given the beneficial vaccine.

Expected Outcomes

The study seeks to achieve two main outcomes: preventing the occurrence of symptomatic COVID-19 and ensuring minimal or no serious adverse events (SAEs) related to the investigational product throughout the study.

Progress of Study Activities

A total of 1599 participants were screened, and 1116 randomly assigned to different groups. Out of this number, 766 were enrolled in Stage I, and 350 in Stage II. Participants are still being monitored. Interim analysis of data across all study sites show that the vaccines are 100% effective in preventing severe COVID-19 and hospitalizations, 75% effective against moderate or severe COVID-19, and 57.9% effective against any symptomatic COVID-19. Both vaccines also showed favorable safety profiles.

The study received approval to proceed to the Crossover/Booster phase. In this phase, participants who initially received the active investigational product will get a booster shot, while those who received a placebo will get both the vaccine and a booster vaccine after unblinding. Out of the 651 eligible participants, 520 consented to continue with this phase. All participants have successfully completed the study, and researchers are currently cleaning and analyzing the collected data.

A Multi-center, Multi-national, Prospective Surveillance Study of Respiratory Syncytial Virus Disease in Infants and Toddlers 6 to < 22 Months of Age (Prospective Surveillance of Respiratory Syncytial Virus Disease in Infants and Toddlers)

Investigators

Dr. Seyram Kaali, Dr. Samuel Harrison, Dr. Prince Darko Agyapong, Dr. Cynthia Yaa Bema, Dr. Felicia Serwah, Mr. Francis Mensah Kornu, Mr. Zakariah Buwah, Mr. Kingsley Kayan, Mr. Elisha Adeniji.

Funder

Sanofi Pasture Inc.

Study Duration

Six (6) Months for Each Participant

Start Date: July 2022

End Date: January 2025

Introduction

Researchers at KHRC, with funding from Sanofi Pasture Inc., are conducting this study to understand how Respiratory Syncytial Virus (RSV) affects young children in Ghana and beyond. Over a period of six months, the study will track how common RSV is among infants and toddlers aged six (6) to twenty-one (21) months and how the illness effects these children.

Background

Human Respiratory Syncytial Virus (RSV) is a ubiquitous virus and the most common cause of acute lower respiratory tract infection in children younger than five. The burden of infection is highest in children under 2 years age. In Ghana, the prevalence of RSV infection among hospitalized children under five years diagnosed with ALRTI is estimated to be about 23% with the highest burden in children below 1 year of age. RSV infection demonstrated significant seasonal variation with the highest burden occurring between June and December. RSV group B accounted for majority (61%) of cases. Risk factors for RSV infection include low birthweight, crowded living conditions, tobacco and air pollution exposure, day-care attendance, family history of asthma, congenital heart disease, chronic respiratory disease, and poor socio-economic status.

There is currently no vaccine to protect against RSV infection in children. The purpose is to generate seroprevalence data to estimate the proportion of infants and toddlers who had been previously exposed to RSV or RSV antibodies (monoclonal or maternal), to test the RSV illness definitions, and to evaluate the incidence of lower respiratory tract disease (LRTD) and ARD cases associated with reverse transcription polymerase chain reaction (RT- PCR) confirmed RSV in the targeted population (incidence over the study duration of approximately one RSV season), and the proportion of LRTD among ARD cases.

Objectives

This study has two main objectives:

- To assess how common RSV infections are both within our country and globally.
- To measure the number of positive RSV illness cases recorded during the study period.

Study Methodology

This was a multi-center, multi-national, prospective surveillance study to describe the baseline seroprevalence of RSV and incidence of RSV-related lower respiratory tract infection (LRTI) in children aged 6 to < 22 months. Following informed consent and screening, participants were followed up with active and passive surveillance for RSV-like respiratory tract infection. Active surveillance involved contacting participants through home visits and telephone calls once weekly throughout the follow-up duration.

Parents and caregivers were asked to contact the study team whenever their child showed signs of illness. If a child exhibited symptoms resembling RSV, they were referred to the study clinic for evaluation by a study clinician. During these visits, appropriate samples were collected in line with the study protocol. Additional follow-up visits were scheduled for children with RSV-like symptoms as required by the protocol. Each child participated in the study for a total duration of six months.

Expected Outcomes

The study is expected to produce a baseline data to determine the prevalence of RSV-A and RSV-B in Ghana and other part of the world and also expected to determine how often children develop serious infections in their lower respiratory track, caused by RSV.

Progress of Study Activities

Fifty (50) participants aged 6 to 21 months were enrolled into the study between July and November 2023. Fifty-six percent (56%) were females. On average, each child was followed up for about 6.4 months to monitor their health. Within this period, we identified 119 cases of RSV-like illnesses. This means that for every 1,000 children, 372 became sick with RSV-like symptoms each month. The most common illness was an infection of the upper respiratory tract, such as a cold, followed by more serious conditions like pneumonia and ear infections, known as otitis media. We plan to end the study by January 2025, at which point we will have a clearer picture of how RSV affects young children over time.

A Prospective, Multicenter Study to Measure the Impact of a Speaking Book on Patient UNderstanDing of Clinical Research Knowledge (The SOUND Study)

Investigators

Dr. Seyram Kaali, Dr. Samuel Harrison, Dr. Prince Darko Agyapong, Dr. Cynthia Yaa Bema, Dr. Felicia Serwah, Mr. Fred Kanyoke, Mr. Francis Mensah Kornu, Mr. Zakariah Buwah, Mr. Elisha Adeniji.

Funder

Novartis

Study Duration

Two (2) Months

Start Date: January 2024

Introduction

KHRC conducted this Innovative two-month Study to help improve public understanding of clinical trials using an innovative tool called the Speaking Book. This 'SOUND Study' funded by Novartis and sought to address a significant challenge: lack of awareness, misconceptions, and stigma surrounding clinical trials, especially in low- and middle-income countries. Findings from this study will go a long way to encourage more people to participate in clinical trials to ultimately improve health outcomes globally.

Background

It is important for innovative health care solutions to reach remote corners of the world including low- and middle-income countries; however, one of the key barriers for access is the lack of data generated in this population which is attributed to lack of awareness, misconceptions and social stigma associated with clinical trials. There is a sharp contrast in participants enrolled in clinical trials and the global population especially in low-to-middle income countries where there is an increasing trend in noncommunicable disease such as cancer, diabetes, metabolic syndrome, and other maladies. Considering the disease burden and other factors such as low costs, medical expertise and good hospital facilities, these countries could be attractive for many Multinational Companies conducting trials.

Several articles talk about increase in number of clinical trials (CTs) and revenues but few talks about "Trial Participants (TPs)" who contribute to the advancement of science and to the revenue. Few researchers have looked at whether the TPs who get recruited in CTs are aware of what CTs are and if participation agreement is purely their conscious decision. Studies have made known that fear, distrust or suspicion of research, apprehension and skepticism could hinder awareness about the CTs, especially among minorities. Language and literacy barriers may make it difficult for some people to understand which may be the main barrier for awareness

Objective of the Study

The objective of this study is to evaluate the improvement in clinical trial knowledge with the Speaking Book.

Methodology

The primary objective is to evaluate the Improvement in clinical trial knowledge with the Speaking Book in adults with benign haemoglobinopathy who have never participated in a clinical trial or have little clinical research awareness, targeting about 205 participants in at least four countries (Ghana, Kenya, India and Egypt). The target number for the Kintampo site is 30 participants. The eligible participants will be grouped randomly into the CONTROL (participants who will not receive the speaking book) and REVIEW (participants receiving the speaking book) groups in 1:1 ratio.

At Visit 1/Day 1/Baseline, all centers will conduct their normal standard procedure for explaining clinical trial participation to patients enrolled in the Control Group.
The study team will then administer the Clinical Trial Knowledge Questionnaire (CTKQ) to these patients and ask them to return to the center at Visit 2.
Once procedures for the Control Group are complete, the Review Group will undergo their baseline/Visit 1 procedures.
The site team will review the Speaking Book with the patients to ensure they have a good understanding of the contents.

Expected Outcomes

The study aims to show that participants who use the Speaking Book (known as the review group) will have at least 25% better understanding of clinical trials compared to those who only receive the standard education from their clinic team (known as the control group).

Progress of Study Activities

Participant enrollment for the study began on January 18, 2024, starting with the control group. After the first 15 participants in the control group completed their first visit (Visit 1) activities, enrollment for the review group commenced. Participants in the review group were given the Speaking Book as part of their educational process.

Follow-up activities (Visit 2) were conducted at least two weeks after the first visit for each participant. The final participant completed Visit 2 on February 29, 2024, marking the end of all field activities with study participants on the same date. Since then, the data collected during the study has been thoroughly cleaned and is currently undergoing analysis. The study team reported a smooth process, with no challenges encountered during data collection.

A PHASE 1B, SAFETY AND IMMUNOGENICITY STUDY OF A LASSA FEVER VACCINE, CHADOX1LASSAJ, IN HEALTHY VOLUNTEERS AGED 18 – 55 YEARS IN GHANA.

Investigators

Dr. Seyram Kaali, Dr. Samuel Harrison, Dr. Anthony Ibrahim Siibu, Dr. Felicia Serwah, Dr. David Dosoo, Mr. Francis Mensah Kornu, Mr. Zakariah Buwah, Mr. Kingsley Kayan, Mr. Elisha Adeniji.

Funder

Coalition for Epidemic Preparedness Innovations (CEPI)

Sponsor

University of Oxford

Study Duration

Two (2) Years

Introduction

KHRC is preparing to launch this important study to test the safety and effectiveness of a new Lassa fever vaccine developed by the University of Oxford. This study, sponsored by the University of Oxford and funded by the Coalition for Epidemic Preparedness Innovations (CEPI), will recruit healthy participants aged 18 to 55 years. This study could lead to the roll-out of a life-saving vaccine that saves lives and protects millions of people from the harmful effects of Lassa fever.

Background

Lassa (LASV) is a zoonotic arenavirus and a leading cause of haemorrhagic fever globally. The Lassa fever virus is prevalent in rodents (Mastomys Natalensis) and is endemic to many West African countries. There have been documented cases of Lassa fever in Nigeria, Mali, Ghana, Benin, Guinea, Sierra Leone, Togo, Cote D'Ivoire and Liberia. Human infection may be acquired through ingestion or inhalation of rodent excrement or through eating the meat of a contaminated animal. It can also be acquired by human-to-human transmission through contact with infected bodily fluids. It has been identified as an emerging outbreak pathogen by the World Health Organization and the UK Health Security Agency classifies it as a high consequence infectious disease.

Lassa fever is caused by a virus that poses a threat to a population of approximately 60 million people living in West Africa. Whilst the majority of individuals who develop it only have mild symptoms, for some it can be fatal. The virus is carried by a common rodent within West Africa which passes the disease to other rodents, their offspring and can also pass it to humans on occasion. This may be due to accidental exposure to rodent's excrement, or through eating the meat of a contaminated animal. It is also possible for it to be spread from human to human through contact with infected bodily fluids. This has led to cases occurring in countries far away from West Africa. Whilst it is not fully understood why some individuals get severe disease and others only suffer from mild illness, in certain groups, such as pregnant woman and their unborn babies, the disease is always serious. Additionally, long term consequences such as hearing loss and balance problems can affect individuals who recover from the illness, irrespective of how unwell they were with the initial infection.

Given the significance of the infection, the potential long-term consequences for the survivors and number of people at risk of this disease, it is important we find a vaccine to help protect against the disease.

Objective of the Study

The main objectives of this study are:

1. To assess the safety and tolerability of ChAdOx1LassaJ candidate vaccine in healthy volunteers aged 18 – 55 years.
2. To assess how the immune system of healthy adults aged 18 to 55 responds to the ChAdOx1LassaJ vaccine.

Methodology

This study will recruit 51 healthy adults to test the ChAdOx1LassaJ vaccine. Participants are randomly divided into groups, and the trial uses a placebo for comparison. The first stage will include six (6) participants (Cohort A). After that, 45 more participants (Cohort B) will join in three different groups:

1. Group 1 (up to 20 participants): This group will receive two doses of the Lassa vaccine, 12 weeks apart.
2. Group 2 (up to 20 participants): This group will receive one dose of the Lassa vaccine followed by a saline placebo injection,12 weeks later.
3. Group 3 (5 participants): They will receive one dose of the vaccine followed by a placebo injection 12 weeks later.

Each participant will be monitored for a year to ensure the vaccine is safe. Regular follow-up visits will include blood tests to check how their immune systems respond to the vaccine.

Expected Outcomes

The study is expected to show whether there are any expected or unexpected side effects after people receive the ChAdOx1 LassaJ vaccine. It will also check how the body's immune system responds to the vaccine, both through antibodies (a part of the immune system that fights infections) and the actions of immune cells.

Progress of Study Activities

A five-member team from the Oxford Vaccine Group visited KHRC on Monday, October 7, 2024 to discuss key aspects of the study, including the trial's implementation strategy, laboratory protocols, and data management. The team also used the opportunity to tour the Centre's facilities to assess its capacity to conduct the trial. The team was made up of Professor Maheshi Ramasamy, Senior Clinical Researcher and Principal Investigator, Sarah Kelly, Senior Clinical Program Manager, Dr. Benjamin Curtis, Global Clinical Fellow, Dr Elizabeth Clutterbuck, laboratory lead and Yama Mujadidi, Programming and Data Management Director. The study team is developing the study protocol and other study documents together with the sponsor's team.

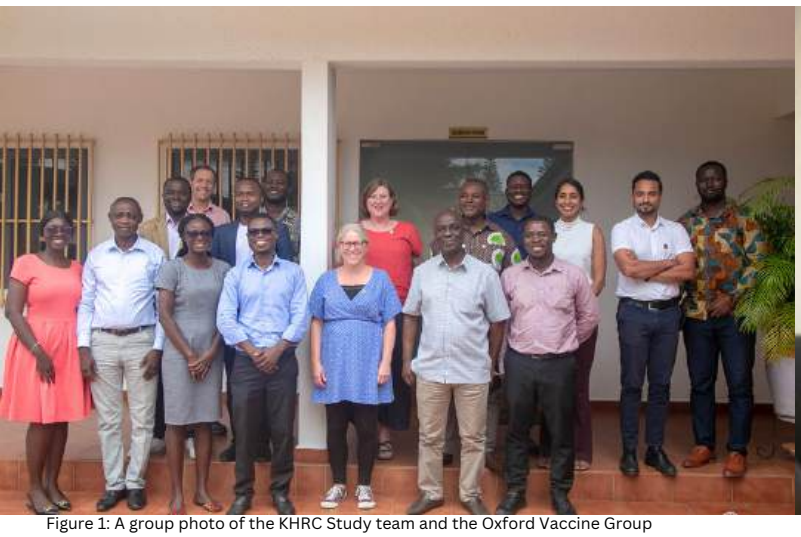


Figure 1: A group photo of the KHRC Study team and the Oxford Vaccine Group team during their visit to KHRC

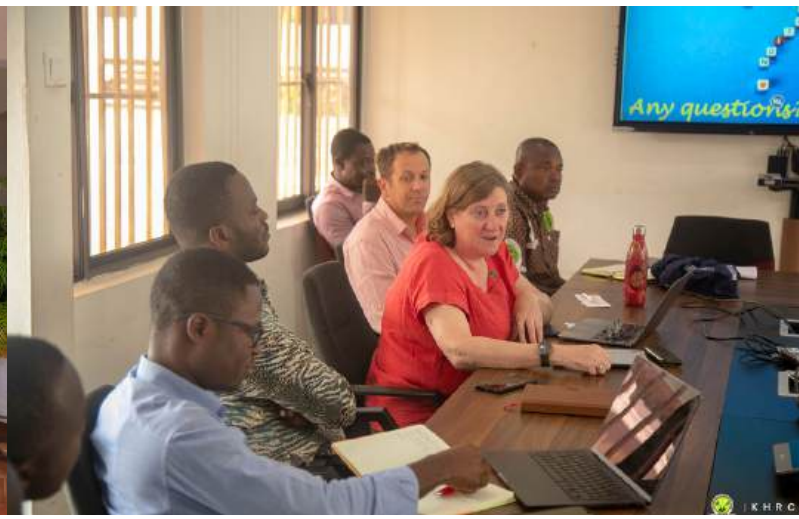


Figure 2: The study teams from KHRC and Oxford Vaccine Group discussing the study's implementation during the visit

A Phase 3, Multi-Center, Randomized, Double-Blind, 24-Week Study of the Clinical and Antiviral Effect of S-217622 Compared with Placebo in Non-Hospitalized Participants with COVID-19 (ACTIV 2D STUDY)

Investigators

Dr. Seyram Kaali, Dr. Kwaku Poku Asante, Dr. Samuel Harrison, Dr. Prince Darko Agyapong, Dr. Cynthia Yaa Bema, Dr. Felicia Serwah, Dr. Afia Korkor Opare Yeboah, Mr. Elvis Ato Wilson, Mr. Zakariah Buwah, Mr. Francis Mensah Kornu.

Funder

National Institute of Allergy and Infectious Diseases (NIH), Division of AIDS (DAIDS)

Study Duration

One (1) Year

Start Date: September 2023

End Date: September 2024

Introduction

KHRC has ended this ACTIV 2D study, that explored a new treatment for COVID-19, potentially reducing hospitalizations and saving lives. The study, funded by the National Institute of Allergy and Infectious Diseases (NIH), Division of AIDS (DAIDS), tested the antiviral drug S-217622 and was conducted across multiple research centers.

Background

COVID-19, caused by the SARS-CoV-2 virus, was first identified in Wuhan, China, in December 2019 and quickly spread worldwide, becoming a pandemic. Vaccination has been an important tool to reduce infection and complications of infections, and vaccination campaigns are underway globally with variable reach, course completion, and uptake.

Unfortunately, new variants of SARS-CoV-2 have appeared that spread more easily and may weaken the effectiveness of vaccines, especially as time passes. During the Omicron surge, studies showed that vaccine protection against symptoms and, in some cases, hospitalization declined after 3 to 4 months. This means that even people who are fully vaccinated or have received booster shots can still get COVID-19. Some may even experience severe illness, especially if their vaccine protection has weakened over time or if they have higher risk factors like a weakened immune system or older age.

Even though some treatments, like emergency-approved COVID-19 antibodies and repurposed drugs, are being used in the U.S. and other countries, effective medications for adults with COVID-19 who aren't hospitalized are still hard to find or access. As a result, deaths from COVID-19 are still happening around the world.

Objective of the Study

The main objective of the study was to evaluate the efficacy of S-217622 vs. placebo. The study also seeks to determine whether S-217622 reduces COVID-19- related hospitalization (adjudicated) and all deaths regardless of occurrence outside of hospital or during hospitalization (not adjudicated) through Day 29.

Methodology

This study was conducted at multiple locations and involved participants with mild or moderate COVID-19 who were not at high risk of severe illness. Participants were randomly assigned to three groups:

1. A low-dose group receiving S-217622 (375 mg on the first day, then 125 mg daily for 4 days).
2. A high-dose group receiving S-217622 (750 mg on the first day, then 250 mg daily for 4 days).
3. A placebo group receiving no active treatment. All three groups received 5 days of total treatment.

The study had two main phases:

- Phase 2a tested if repeated doses of S-217622 could reduce the virus in the body and helped decide the right dose to be implemented in Phase 3 studies.
- Phase 2b/3 checked how well the treatment worked in participants with mild, moderate, or no symptoms and no risk factors for severe disease.

The study also looked at how long it took for participants to stop spreading the virus, for symptoms to improve or disappear, and whether those without symptoms developed any. Around 2,600 people were expected to take part in the study.

Expected Outcomes

The ACTIV-2d study is expected to generate evidence towards the discovery of a safe and effective medicine that will relieve participants of symptoms of COVID-19 as well as prevent hospitalization of covid-19 positive participants.

Progress of Study Activities

Recruitment for the study started on October 14, 2023. A total of Sixty-nine (69) participants were pre-screened, out of which five (5) qualified for further screening, and three were ultimately enrolled. All enrolled participants successfully completed all required study visits. The study officially concluded on September 15, 2024, and the analysis of data collected is ongoing.

Conclusion

This study has laid the foundation for further research into S-217622, which could become a n effective treatment for COVID-19. The results hold promise for reducing the burden of the disease, especially for those unable to access hospital care. As data from this study is analyzed, it may lead to more effective therapies being made widely available to combat COVID-19 globally.

An Adaptive, Randomized, Placebo-controlled, Double-blind, Multi-Center Study of Oral FT-4202, a Pyruvate Kinase Activator in Patients with Sickle Cell Disease (PRAISE Study)

Investigators

Dr. Seyram Kaali, Dr. Kwaku Poku Asante, Dr. Samuel Harrison, Dr. Prince Darko Agyapong, Dr. Cynthia Yaa Bema, Dr. Felicia Serwah, Dr. Afia Korkor Opare Yeboah, Dr. David Dosoo, Mr. Kingsley Kayan, Mr. Elvis Ato Wilson, Mr. Zakariah Buwah, Mr. Francis Mensah Kornu.

Funder

Novo Nordisk A/S.

Study Duration

Three (3) Years

Start Date: June 2023

End Date: November 2026

Introduction

KHRC is carrying out this Phase 2 PRAISE study to explore a new treatment for sickle cell disease (SCD). This study is funded by Novo Nordisk A/S and seeks to test the effectiveness and safety of a drug called FT-4202 in adolescents and adults with sickle cell disease (SCD). The study will compare the effects of FT-4202 to a placebo (a treatment with no active ingredients) in people aged 12 to 65 who have SCD.

Background

Sickle cell disease is a chronic hemolytic anemia caused by inheritance of a mutated form of hemoglobin (Hb), sickle Hb (HbS). It is the most common inherited hemolytic anemia, affecting approximately 100,000 patients in the United States (US) (CDC 2020). The global burden is even greater and is expected to continue to rise. The disease is characterized by polymerization of HbS in RBCs when HbS is in the deoxygenated state,resulting in a sickle-shaped deformation of RBCs. Sickled cells aggregate in capillaries precipitating vaso-occlusive events that generally present as acute and painful crises resulting in tissue ischemia, infarction, and long-term tissue damage. Red blood cells in SCD patients tend to be fragile due to sickling and other factors, and the mechanical trauma of circulation causes hemolysis and chronic anemia.

Finally, damaged RBCs have abnormal surfaces that adhere to and damage vascular endothelium, provoking a proliferative/inflammatory response that underlies large-vessel stroke and potentially pulmonary- artery hypertension. Collectively, these contribute to the significant morbidity and increased mortality associated with this disease.

Currently, therapeutic treatment of SCD is inadequate. Potentially curative therapies, such as bone marrow transplant or gene therapies, are invasive andsuch high-risk procedures are limited to only a subset of patients. For most patients, treatment involves supportive care for management of vaso-occlusive crisis (VOC) or the use of hydroxyurea (HU), to stimulate production of fetal Hb (HbF) and reduce Hb polymerization. While inducing HbF can be effective therapeutically, HU can be myelosuppressive and is a teratogen (Sampson et al. 2010). Although HU is considered to have an acceptable therapeutic index, the myelosuppressive and teratogenic risks limit its effectiveness.

Objective of the Study

The main objectives of the study are:

1. To assess the efficacy of FT-4202 in adolescents and adults with SCD as compared to placebo as measured by improvement in haemoglobin (Hb).

2. To assess the efficacy of FT-4202 as compared to placebo on the annualized Vaso-occlusive crisis (VOC) rate.

Methodology

This study is a randomized, placebo-controlled, double-blind, multicenter Phase 2/3 study of patients, age 12 to 65 years (inclusive), with SCD. Participants under rigorous screening to select only those who meet strict eligibility criteria. Following eligibility assessment, patients are randomized to receive the FT-4202 or pacebo. In the phase portion of the study, a randomization ratio of 1:1:1 to one of two dose levels of FT-4202 or placebo (dose determination portion) was used. The higher dosing regimen was selected for further evaluation in the phase 3 portion of the study. Participants are currently being enrolled into the phase 3 component. Overall study duration is 104 weeks including a 52-week double blind phase and another 52-week open-label extension phase.

Expected Outcomes

The study is expected to show whether FT-4202 can increase hemoglobin levels at week 24 (increase of > 1 g/dL from baseline) during the blinded treatment period, and reduce the number of painful episodes over the course of the 52-week blinded treatment period.

Progress of Study Activities

Recruitment began on June 22, 2023. Thirty-two (32) participants were consented and screened. Out of this number, twenty (20) met the criteria for screening and were enrolled. All participants are being monitored for safety.

A Global Phase 3, Randomized, Double-Blind and Placebo-Controlled Study Evaluating the Efficacy and Safety of Etavopivat in Adolescents and Adults with Sickle Cell Disease (HIBISCUS 2 Study)

Investigators

Dr. Seyram Kaali, Dr. Kwaku Poku Asante, Dr. Samuel Harrison, Dr. Prince Darko Agyapong, Dr. Cynthia Yaa Bema, Dr. Felicia Serwah, Dr. Afia Korkor Opare Yeboah, Dr. David Dosoo, Mr. Kingsley Kayan, Mr. Elvis Ato Wilson, Mr. Zakariah Buwah, Mr. Francis Mensah Kornu.

Funder

Novo Nordisk A/S.

Study Duration

Four (4) Years

Introduction

KHRC is about to start this Phase 3 HIBISCUS 2 study as a follow up to the Phase 2 study to test the effectiveness and safety of the etavopivat (FT-4202) drug in a larger population of adolescents and adults with sickle cell disease (SCD). This four-year study, also funded by Novo Nordisk A/S is trying to find new ways to treat SCD, which is a serious genetic condition that affects millions of people worldwide, including Ghana.

Background

Sickle cell Disease (SCD) is a group of genetic disorders of red blood cells characterized by the presence of two abnormal haemoglobins, one of which is haemoglobin S. SCD is inherited in an autosomal recessive pattern in which an individual inherits 2 copies of any combination of abnormal haemoglobin genes. The annual prevalence of SCD among newborns is approximately 2%, and 20% of the Ghanaian population carry the sickle cell trait. The abnormal HBS causes haemoglobin polymerization which distorts erythrocyte membrane leading to sickling and impaired flow and deformability. These changes make the RBCs fragile, easily destroyed, and unable to move smoothly within small blood vessels, thus blocking and depriving organs of blood and oxygen. Currently, there is no cure for SCD. This study aims to test the a new disease-modifying drug for the treatment of sickle disease is adolescents and adults.

Objective of the Study

The main objectives of the study are:

1. To demonstrate superiority of treatment with etavopivat versus placebo in adolescents and adults with SCD.

2. To evaluate clinical efficacy measures of etavopivat treatment versus placebo in adolescents and adults with SCD.

Methodology

This is an interventional, multi-national, multi-center, randomized (2:1), double-blind, placebo-controlled phase 3 study in participants aged12 and older with SCD, who had 2−15VOCs in the year prior to screening and who have moderate to severe anemia.

Participants will be randomized in a blinded fashion (2:1) to the etavopivat or placebo dosing groups. A totalof 408 participants are expected to be enrolled in the study and receive treatment for 52 weeks in the double-blind treatment period. A maximum of 100 participants will be adolescents (12 to 17 years).A maximum of 50% of participants enrolled will have 2−3 VOC in the 12 months prior to screening and a minimum of 50% of participants enrolled will have 4−15 VOCs in the 12 months prior to screening.

Participants will be stratified by age at randomization (12 to 17 or 18 years and older), number of VOCs in the preceding 12 months (2−3, or 4−15) and concomitant disease modifying treatment (e.g., HU or l-glutamine [Endari®]) use at the time of screening (Yes or No). Following randomization, all participants enrolled will continue blinded treatment for 52 weeks.
Following the 52 weeks of double-blind treatment, participants will enter a 52-weeks etavopivat OLE treatment period. Thus, the maximum duration of the treatment period for an individual participant is 104weeks. Participants who do notfinish the 52 double-blind treatment period may not enter the OLE period.

Expected Outcomes

The expected outcomes include a reduction in the number of adjudicated Vaso-occlusive crisis (VOC) event with a medical contact from baseline to week 52 during the blinded treatment period, as well as a change in hemoglobin (Hb), Change in lactate dehydrogenase (LDH), Change in absolute reticulocyte count, Change in indirect bilirubin from Baseline (week 0) to week 52.

Progress of Study Activities

The study is still in the preparatory phase. The team has received scientific and local ethics approvals for the study and are awaiting central ethics and regulatory approvals.

A Phase 1 Randomized, Blinded, Placebo Controlled, Dose-Escalation and Dosing Regimen Selection Study to Evaluate the Safety and Immunogenicity of rVSV-Vectored Lassa Virus Vaccine in Healthy Adults at Multiple Sites in West Africa (Lassa Fever Phase 1 Trial)

Investigators

Dr. Seyram Kaali, Dr. Samuel Harrison, Dr. Prince Darko Agyapong, Dr. Cynthia Yaa Bema, Dr. Felicia Serwah.

Study Duration

Two (2) Years

Start Date: 12th July 2022

End Date: 4th May 2024

Funder

Emergent Bio-Solutions

Introduction

KHRC has successfully completed this Lassa Fever Phase 1 Vaccine Trial that tested a candidate vaccine for Lassa fever called EBS LASV on humans for the very first time. This trial was conducted to investigate the vaccine's safety and ability to help the body produce an immune response, to protect against Lassa fever. This study was funded by Emergent Bio-Solutions.

Background

Lassa fever is a viral disease that is prevalent in rodents (Mastomys Natalensis) and is common in many West African countries. There have been confirmed cases of Lassa fever in Nigeria, Mali, Ghana, Benin, Guinea, Sierra Leone, Togo, Cote D'Ivoire and Liberia. People can catch Lassa fever by touching or inhaling rodent droppings, eating meat from an infected animal, or coming into contact with the bodily fluids of an infected person. It has been identified as an emerging outbreak pathogen by the World Health Organization and the UK Health Security Agency classifies it as a high consequence infectious disease.

Despite its dangerous effects, there is currently no approved therapeutic treatment or prophylactic vaccine for the prevention of LASV infection or Lassa fever. To address this unmet medical need, this first-in-human (FIH) study has been conducted to evaluate the safety and immunogenicity of the candidate vaccine, EBS LASV. The target population were healthy adults ≥18 to ≤50 years of age.

Objective of the Study

The objectives of the study were devided into two main parts.

Safety objective

1. To evaluate safety and tolerability of increasing dose levels of EBS-LASV vaccine administered as a single dose or two-dose series
2. To evaluate in vivo replication, bio distribution, and shedding of EBS-LASV vaccine.

Primary Immunogenicity Objective;
1. To evaluate humoral immune responses to EBS-LASV vaccine at various dose levels and dosing schedules for the purpose of selecting two regimens (dose and schedule) for further evaluation in a Phase 2 study.

Exploratory Immunogenicity Objective;
1. To evaluate the cellular immune response to EBS-LASV vaccine.

Methodology

This study was a Phase 1, first in human (FIH) clinical study. The target population were healthy adults 18 to 50 years of age. The goals for the study were to assess the safety and tolerability of a low, medium, and high dose of EBS-LASV when administered as a two-dose series. Healthy adult volunteers were identified from selected communities and invited to the study clinic, where they underwent consenting and screening procedures. Participants were enrolled into three cohorts in a sequential dose escalation manner. The Randomization ratio was 3:1 to either the active treatment arm or the placebo arm. The duration of participation was 28 weeks for each enrolled participant.

Expected Outcomes

The expected outcomes for the Lassa fever phase 1 study were to show that the candidate vaccine (EBS-LASV) is both safe and capable of producing enough antibodies to protect against the virus. The study also sought to prove how the vaccine performs at different dose levels, demonstrating its safety and effectiveness in causing an immune response.

Key Findings

Key findings from the study showed that while the EBS-LASV candidate vaccine was safe, it did not cause the immune response needed to protect against the Lassa fever virus. This means that participants who received the vaccine did not produce the required levels of antibodies to defend against future infections.

The difference in antibody levels between participants who received the vaccine and those who were given a placebo (a substance without any active ingredients) was minimal. Also, none of the participants in the three dosage groups, also known as cohorts, produced the required antibody levels to fight the virus effectively.

Participants in Cohort 1 received a low dose of the vaccine, those in Cohort 2 received a medium dose, and Cohort 3 participants received a high dose. Despite the lack of immune response, there were no serious adverse effects reported among participants.

Ten (10) individuals were unable to join the study due to screening failures. This included participants who tested positive for hepatitis B surface antigen, HIV, or had positive drug tests in their urine, making them ineligible for the study.

Progress of Study Activities

A total of 37 participants were screened with 18 randomized to receive investigational products. Of the 18 participants recruited, 2 were enrolled into cohort 1, 10 participants were enrolled into cohort 2 and 6 participants into cohort 3. There were no serious adverse events reported. However, 21 non-serious adverse events were recorded. The last participant-last-visit occurred on 5th July 2023. The Final Clinical Study Report was submitted to Ethics Committees and FDA on 16 Sep 2024.

A Multi-Part, Multi-Center PLATform Study to Assess the Efficacy, Safety, Tolerability and Pharmacokinetics of Anti-Malarial Agents Administered as Monotherapy and/or Combination Therapy IN Patients with Uncomplicated Plasmodium Falciparum Malaria (PLATINUM)

Investigators

Dr. Samuel Harrison, Dr. Kwaku Poku Asante, Dr. Seyram Kaali, Dr. Felicia Serwah, Dr. Anthony Siibu.

Study Duration

Twenty-One (21) Months

Start Date: March 2024

End Date: June 2025

Funder

Novartis Pharma AG

Introduction

This PLATINUM drug trial is a two-year Phase 2A study that is carried out to test how effective, safe, and tolerable different anti-malarial drugs are, including their behavior in the body, for treating uncomplicated Plasmodium falciparum malaria. Using both single-drug and combination therapies, the PLATINUM trial seeks to tackle major challenges like drug-resistant malaria to help improve malaria treatments in countries most affected by malaria.

Background

Malaria remains a critical health challenge worldwide, responsible for 241 million cases and 627,000 deaths in 2020 alone, with the highest burden in sub-Saharan Africa where P. falciparum and P. vivax cause most malaria cases. Following a mosquito bite, Plasmodium parasites initially infect the liver and subsequently invade red blood cells, leading to symptoms such as fever, headaches, and muscle aches. If untreated, infections can escalate to severe malaria, with complications such as coma, respiratory distress, and severe anaemia, posing a risk of death, especially in young children under five who accounted for 67% of malaria deaths in 2020.

Although Artemisinin Combination Therapies ACTs remain effective in many regions, resistance to artemisinin-based drugs has been recorded. In response, efforts to develop new anti-malarial agents focus on targeting resistant strains, enhancing efficacy, and reducing treatment complexity. The Medicines for Malaria Venture (MMV) has outlined a target profile for these agents: they should be highly effective against resistant strains, safe for children and pregnant women, administered in a short regimen, cost-effective, and stable in tropical climates. The goal is to achieve a one-dose cure in combination therapy to increase compliance and minimize resistance risk.

Objective of the Study

The objectives of the study include:

1. To assess how long it takes for the new antimalarials to cure malaria as combination therapy versus the standard of care in patients with uncomplicated P. falciparum malaria.
2. To assess the safety and tolerability of each anti-malarial agent administered orally as monotherapy and/or as combination therapy [Part B] in patients with uncomplicated P. falciparum malaria.

Methodology

This study is being conducted at several sites across countries in West, East, and Central Africa. It has two parts: Part A and Part B. Part A will test anti-malarial drugs when used alone, while Part B will focus on testing these drugs in combination.

KHRC is involved in Part B, which plans to enroll about 60 participants. Participants will be randomly assigned to receive either a combination of two medications (KAE609 and KLU156) or COARTEM. The medication doses will be based on each participant's body weight.

Participants diagnosed with malaria through confirmed tests at health facilities in the study area will be approached, and the study will be explained to them. Those who agree to join the study will be transported to the study clinic, where they will go through consent and screening procedures. Participants who pass screening will be entered into a randomization system to determine their treatment group. They will stay at the study clinic for three days for specific procedures, with follow-up activities scheduled as outpatients on specific days through to Day 43.

Expected Outcomes

This study is expected to find new antimalarial agents that are effective and safer to be used in further studies.

Progress of Study Activities

The study has not yet started enrolling participants.

A Randomized, Open-Label, Multicenter Study to Compare Efficacy, Safety and Tolerability of KLU156 with Coartem® in the Treatment of Uncomplicated Plasmodium Falciparum Malaria in Adults and Children ≥ 5 kg Body Weight Followed by an Extension Phase with Repeated KLU156 Treatment (KALUMA)

Investigators

Dr. Samuel Harrison, Dr. Kwaku Poku Asante, Dr. Seyram Kaali, Dr. Felicia Serwah, Dr. Anthony Siibu.

Funder

Novartis Pharma AG

Study Duration

Three (3) Years

Start Date: September 2024

End Date: July 2027

Introduction

This KALUMA drug trial is a three-year Phase 3 study that is testing how effective, safe, and tolerable a new drug, KLU156, is in comparison to Coatem, a widely used antimalarial treatment. This study, funded by Norvartis, will go a long way to help reduce malaria in children aged five and older.

Background

Malaria is one of the leading causes of death in Africa, with children under 5 years being the most at risk. The disease is caused by six types of Plasmodium parasites, with Plasmodium falciparum being responsible for most cases and the deadliest form. Over time, medicines like chloroquine have stopped working, and there are reports of resistance to the current malaria treatments.

This highlights the need for new medicines that are safe and effective in curing malaria to support its elimination. This study aims to find out if a new medicine, KLU156, a combination of ganaplacide (KAF156) and lumefantrine (lumefantrine-SDF) can safely and effectively treat malaria.

Objective of the Study

The objectives of the study include:

1. To check how well KLU156 works in treating adults and children weighing at least 5 kg and aged 2 months or older who have uncomplicated malaria caused by P. falciparum (with or without infection from other Plasmodium species).
2. To evaluate the safety and how well KLU156 is tolerated when used repeatedly over up to 2 years in adults and children weighing at least 5 kg and aged 2 months or older with uncomplicated malaria caused by P. falciparum (with or without other Plasmodium species).

Methodology

This study is being conducted in several African countries to compare the effectiveness and safety of two malaria treatments: KLU156 and Coartem. Participants who agree to join the study are randomly assigned to receive one of these treatments. The study has two parts: a core phase lasting 43 days and an optional extension phase lasting up to two years.

Around 1,500 male and female participants are expected to take part. The dose of the medication is based on the participant's body weight. People diagnosed with malaria after a confirmed test are invited to join the study, and the details are explained to them.

Once they agree, participants are taken to the study clinic, where they give their consent and go through screening. Those who pass screening are randomly assigned to one of the treatment groups. Participants stay at the study clinic for four days for specific procedures and then return for scheduled outpatient visits until day 43, when they complete the core phase.

In the optional extension phase, participants who agree will be treated with KLU156 whenever they have confirmed malaria. This phase will assess the safety, tolerability, and effectiveness of repeated treatments with KLU156 over up to two years.

Expected Outcomes

This study is expected to show that KLU156 is safe and works as well as, or better than, Coartem for treating uncomplicated malaria caused by P. falciparum (with or without other Plasmodium species) in adults and children weighing at least 5 kg and aged 2 months or older.

Progress of Study Activities

The study began on September 20, 2024, with recruitment starting on September 30, 2024. So far, 32 participants have been pre-screened. Of these, 31 qualified for screening, and 29 have been enrolled. Fifteen participants have completed the core phase, with 13 now in the extension phase. The remaining participants are still in the core phase.

Antenatal, Intrapartum and Postnatal Care: A Prospective, Longitudinal Study of Maternal and Newborn Health of the Pregnancy Risk Stratification Innovation and Measurement Alliance (PRISMA Study)

Figure 1: A study participant going through an ultrasound Scan

Investigators

Dr. Kwaku Poku Asante, Prof. Sam Newton, Mrs. Charlotte Tawiah Agyemang.

Funder

Bill and Melinda Gates Foundation (BMGF)

Study Duration

Three (3) Years
Start Date: December 2022
End Date: December 2025

Collaborators

George Washington University: Dr. Emily Smith, Ms. Jamie Marquis, Ms. Sasha Bauman and Ms. Megan Talej.
Columbia University: Dr. Blair Wylie

Collaborating Sites

Ghana: Kintampo Health Research Centre (KHRC)
India: Christian Medical Centre (CMC) Vellore, Society for Applied Sciences (SAS)
Pakistan: Vital Pakistan Trust (VPT) and Aga Khan University (AKU)
Kenya: Kenya Medical Research Institute- Center for Global Health Research (KEMRI-CGHR)
Zambia: University of North Carolina Global- Projects.

Introduction

KHRC is carrying out this study on maternal and child health to better understand the risks, challenges, and outcomes of pregnancy in low- and middle-income countries. The information gathered will help us understand how common these risks are and develop innovative strategies to improve the health of mothers and their babies.

Background

A growing number of countries are realizing the value of quality antenatal and postnatal (including maternal, newborn, and infant) care services. There are increasing percentages of women attending antenatal care (ANC) across low- and middle-income countries (LMICs). However, the ANC coverage rate is much lower among more vulnerable populations (e.g. lower quintile, rural regions), and the quality of care that women receive is inconsistent, often poor, and frequently fails to detect risks in a timely fashion or to prepare women for the birth process.

Robust data on pregnancy risks, including medical history, clinical symptoms and diagnostics, social determinants, as well as antenatal and intrapartum care are critical to developing strategies to effectively manage pregnancy risk and improve outcomes, within resource-constrained environments.

Objectives

The main objectives of the study are:

1. To improve the global understanding of key risk factors for morbidity and mortality among pregnant women during antenatal and postnatal care.
2. To provide population-based baseline estimates of key maternal and child health outcomes.
3. To collect data to enable the application of novel analytical techniques to create risk prediction tools.
4. To advance clinical knowledge of anemia during pregnancy and postpartum period.

Methodology

This is a multi-country population-based study involving five countries in Sub-Saharan Africa and South east Asia: Ghana, Kenya, Zambia, Pakistan and India. In Ghana, the study is being conducted in the Kintampo North Municipality and South district. The population, women of reproductive age between 15 to 49 years who meet the eligibility criteria are identified and screened, and pregnancies below 20 weeks are enrolled through pregnancy surveillance systems. Pregnant women are assessed at <20, 20, 28, 32, and 36 weeks gestation, at labor and delivery, at 3 days and 1, 4, 6, 26, and 52 weeks postpartum. Infants are similarly assessed at 3 days and 1, 4, 6, 26, and 52 weeks of age. It is expected that about 3000 pregnant women will be enrolled into the study.

Expected Outcomes

This study is expected to develop a harmonized data set to improve our understanding of pregnancy risk factors, vulnerabilities, and morbidity and mortality and to estimate the burden of these risk factors and outcomes in Low and Middle-Income Countries. Specifically, the datasets will focus on the following.

Maternal Outcomes

-Maternal Mortality

-Maternal Anemia

-Severe complications such as severe postpartum hemorrhage, severe preeclampsia, eclampsia, sepsis/severe systemic infection, ruptured uterus

Fetal/Neonatal Outcomes

-Stillbirth

-Pre-term birth

-Neonatal mortality

-Low birth weight

-Small for gestational age

Progress of Study Activities

Recruitment and follow-up activities for the study are progressing steadily. By December 2024, ultrasound scans had been performed on 2,977 pregnant women, resulting in the enrollment of 2,123 participants. So far, 1,526 deliveries have been recorded, out of which, 1,435 were live births. Meanwhile, 144 participants have successfully completed the one-year follow-up period and exited the study.

A series of activities have been undertaken as part of the implementation of the study during the year. These include:

Data collection: Project staff have conducted regular field visits to gather comprehensive health data from participants. These assessments include measurements of weight, height, arm circumference, and the collection of blood and urine samples. Ultrasound scans have also been performed as part of the data collection process.

Field workers training: In November, 30 new field worker trainees were taken through a three-week intensive training program to equip them with essential skills to support the PRISMA study. After the training, the trained field workers were assessed to ensure their understanding of the study procedures.

Figure 2: PRISMA field workers training

Figure 3: PRISMA field workers training

Figure 4: Group photo of PRISMA study team and new field worker trainees

The Impact of Maternal Anaemia on Neurodevelopmental Outcomes Among Infants: A Prospective Maternal-Infant Birth Cohort Follow Up Study In Low-And Middle-Income Countries (ReMIND)

Figure 1: Portable Hyperfine MRI scanning activities

Investigators

Dr. Kwaku Poku Asante, Dr. Kenneth Ae-Ngibise, Solomon Nyame, Francis Agbokey, Veronica Agyemang, Stephaney Gyaase, Charlotte Tawiah and Prof Sam Kofi Newton.

Funder

Bill and Melinda Gates Foundation

Study Duration

Three (3) Years

Start Date: January 2023

End Date: December 2025

Collaborating Institutions

Ghana: Kintampo Health Research Centre, Ghana Health Service

Kenya: Kenya Medical Research Institute (KEMRI)-Center for Global Health Research (KEMRI-CGHR)

Zambia: University of Zambia School of Medicine, UNC Global Projects Zambia, University of North Carolina School of Medicine

India: Christian Medical College, Vellore

India: Society for Applied Studies, New Delhi

Pakistan: Aga Khan University

USA: George Washington University

Introduction

The Kintampo Health Research Centre (KHRC), with funding from the Bill and Melinda Gates Foundation, is leading this study to assess the impact of maternal anaemia on infant brain development and early childhood health. This study is a sub-study under the "Pregnancy Risk, Infant Surveillance, and Measurement Alliance" (PRISMA) Study. This initiative, first of its kind, is being carried out across four research sites in Ghana, India, Kenya, Pakistan, and Zambia, and seeks to identify infants under 12 months old who may have developmental challenges linked to maternal anaemia, allowing for early detection and timely intervention.

Background

Women of reproductive age (WRA), particularly those who are pregnant or lactating, face a heightened risk of anaemia. Globally, approximately 33% of WRA, equivalent to around 613 million women, are estimated to be anaemic. The prevalence of anaemia among WRA is particularly high in low- and middle-income countries (LMICs).

In 2016, the World Health Organization (WHO) reported anaemia rates of 46% in South-East Asia and 39% in sub-Saharan Africa among WRA. Low haemoglobin levels during pregnancy are associated with adverse maternal and neonatal health outcomes. While many low- and middle-income countries bear a high burden of disease with increased risk of poor neurodevelopmental outcomes in children, access to Magnetic Resonance Imaging (MRI) is limited.

Objectives

The main objectives of the study are:

1. To evaluate the impact of maternal anaemia on infant neurodevelopment and brain morphology.
2. To assess the feasibility, usability, and acceptability of using low-field Magnetic Resonance Imaging (MRI) technology in LMICs.

Methodology

The ReMIND sub-study is a prospective observational study designed to evaluate the impact of maternal anaemia on infant neurodevelopment and brain morphology. The study will recruit 1,600 to 2,000 mother-infant pairs in the Kintampo North and South Districts. The study involves data collection using the Global Scale for Early Development (GSED) Short and Long Forms, the Family Care Indicator (FCI), Qualitative research on the usability of the Hyperfine Low-Field Scanner and Brain imaging using the portable Swoop® MRI system to assess structural and functional brain development patterns in a subset of infants. This approach aims to identify potential variations linked to neurological, psychiatric, and cognitive developmental outcomes. The GSED short form will be administered to all participants, while the long form will be administered to 300 participants randomly sampled.

Planned Data Analysis

The association between maternal anaemia and outcomes of interest such as neurodevelopmental, functional and brain morphology will be evaluated with a linear multivariate regression. Basic descriptive statistics and linear regression model with Generalized estimating equations will be used to assess the effect of anaemia on an infant's neurodevelopment based on GSED score at 3 or 6 and 12 months adjusting for demographic characteristics per each country and across countries. Cross-sectional and longitudinal analysis will be performed using the MRI data to investigate the impact of maternal anaemia on infant brain development. All analysis will be done in STATA and R at a two-sided level of significance.

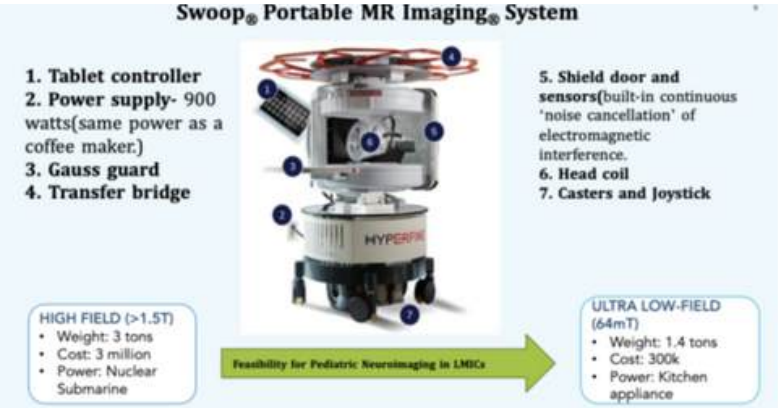


Figure 2: Hyperfine portable, bedside, low-field magnetic resonance imaging device at Kintampo Health Research Centre

Expected Outcomes

This study is expected to characterise the relationship between maternal anaemia and infant neurological developmental outcomes, as well as brain microstructure, at 3 or 6 months and 12 months of age. It will also assess the impact of maternal anaemia on these outcomes. Additionally, the study will generate comparable data to validate the use of the GSED scale for assessing infant neurodevelopment across diverse settings. Importantly, the ReMIND study seeks to identify infants under 12 months of age with potential neurodevelopmental deficiencies linked to maternal anaemia across the study sites, enabling early detection and intervention.

Progress of Study Activities

Participants Enrollemnt

Participants recruitment has started for all study procedures. So far, data collection using GSED Short and Long Forms and Family Care Indicator (FCI) is currently ongoing. Acquisition of MRI data is ongoing. We have also started conducting brain scans on 3-month-old babies for the very first time using the Hyperfine Low-Field MRI scanner. These babies are scheduled to have a repeat scan at 12-months-old. Qualitative data collection focused on assessing the usability, feasibility, and acceptability of the Hyperfine Low-Field MRI Scanner is also ongoing.

Capacity Building and Meetings

A series of training activities have been undertaken as part of the implementation of the study during the year. These include:

March 2024: There was a Global Scale for Early Development in person training in Kenya, where one staff member participated. There was also an online training on the same topic, where 5 staff from KHRC also participated.

May 2024: Staff of KHRC participated in the 2024 UNITY ISMRM & ISMRT Annual Meeting and Exhibition in Singapore. This meeting served as a robust platform for knowledge exchange, networking, and collaboration among global stakeholders in the medical imaging field.

July 2024: Eight staff from KHRC participated in a Hyperfine MRI in person refresher training in Kintampo.

Figure 3: Group photo after the Hyperfine MRI in person refresher training in Kintampo

A Double-Blind Randomized Control Trial of a Synbiotic vs. Placebo Among Pregnant Women to Evaluate Colonization of the Gut Microbiota of Their Infants with Lactobacillus Plantarum (Probiotics Pilot in Ghana).

Investigators

Dr. John Amoah, Dr. Dennis Adu-Gyasi, Dr. Kaali Seyram, Miss Irene Azindow, and Mr. Ato Wilson.

Collaborators

Dr. Nelly Amenyogbe, Prof. Tobias R. Kollman, and Prof. Pinaki Panigrahi.

Funder

Kintampo Health Research Centre (KHRC)

Study Duration

Mothers: Six months

Infants: One-year safety follow-up

Introduction

KHRC is conducting this study to investigate how probiotics given to pregnant women can improve the gut (digestive system) health of their babies and reduce the risk of infections during early life. The study focuses on pregnant women and their infants, aiming to understand how a specific probiotic strain named Lactobacillus plantarum, taken during pregnancy influence the microorganisms that live in the digestive tract of babies. This study could help address serious health challenges faced by newborns, including infections that claim over 1 million infant lives annually.

Background

The newborn stage is the most vulnerable period in a person's life, with the highest life-time risk of invasive infections. Globally, more than 1 million infants lose their lives to infections each year. Unfortunately, there are currently no effective solutions to reduce preterm births (PTB) or significantly reduce infection-related illnesses and deaths in newborns. the only strategies in place to prevent infectious morbidity and mortality in newborns are limited to the promotion of clean birth, skin-to-skin contact, and exclusive breastfeeding during the neonatal period. exclusive breastfeeding in the newborn period. Other medical interventions include the administeration of vitamin K and antibiotic eye drops at birth.

Recent research has shown promise in using probiotics during pregnancy to lower the risk of PTB. Recent clinical trials in low- and middle-income countries have also demonstrated that neonatal probiotic supplementation can significantly reduce neonatal and early infant infection rates, with excellent safety outcomes and no reported adverse effects.

This study therefore aims to evaluate how well probiotics taken during pregnancy can colonize the gut microbiome of infants. By supplementing pregnant women in their fifth to sixth month, this pilot study will afford us the opportunity to explore the impact of probiotic supplementation on birth outcomes and pave the way for improved maternal and child health strategies.

Study Objectives

Primary Objective

The study seeks to conduct a pilot trial to evaluate the effectiveness of administering probiotic supplements to pregnant women in their fifth to sixth month of pregnancy and assess how effective these probiotics colonize the gut microbiome of their infants by one month after birth.

Secondary and Exploratory Objectives

1. To assess the compliance of pregnant women to a symbiotic product (Lp + FOS) during the study period.
2. To assess whether maternal and infant stool microbiomes can serve as indicators for predicting preterm birth (PTB) and/or possible serious bacterial infections (pSBI) in newborns.
3. To assess if maternal stool microbiome profoundly changes from immediately after childbirth to one month postpartum.
4. To characterize the diversity of vaginal microbiomes among pregnant women in the study area.
5. To determine the safety of administering probiotic supplementation to pregnant women from their fifth to sixth month of pregnancy until up to two weeks postpartum.

Methodology

This study is a prospective, randomized, double-blinded, placebo-controlled design. Pregnant women in their fifth to sixth months of pregnancy from the Kintampo North Municipality and South District were enrolled in the study after providing informed consent. Participants were randomly assigned, using computer-assisted programmes, to receive either a daily synbiotic supplement (Lp + FOS) or a placebo throughout the rest of their pregnancies and up to two weeks postpartum. Weekly probiotic supplementation also began upon enrolment, with follow-up assessments conducted one month after delivery.

To ensure proper administration of the supplement, participants received pictorial instructional materials. They also receive guidance from the study team to take two capsules with water every morning within one hour of waking-up, avoiding solid food or beverages other than water. The study team supervised the initial dose on-site and monitored adherence throughout the study. The supplements were checked weekly, and the pills were resupplied as needed.

Data on participants' demographic details, physical measurements, and health records were collected over the study period. Participants received standard medical care when unwell during the trial. Biological samples, including vaginal swabs (where possible), stool samples from mothers and infants, and breast milk were also collected at predetermined intervals for molecular analysis. Each participant of the study exited after one month postpartum. However, at the end of the study, all newborns exposed to the study intervention will receive follow-up care for one year under by a study paediatrician to monitortheir health.

Expected Outcomes

This study hopes to achieve the following outcomes.

1. Identify the presence of probiotic strains in the gut microbiota of infants one month after birth, whose mothers received probiotic supplementation during pregnancy.
2. The level of compliance in the administration of the probiotic supplement among pregnant women.
3. Comparison of birth outcomes between participants who received the probiotic supplement and those who were given a placebo.

4. Gain Insights into the relationship between maternal and newborn gut microbiomes and their potential impact on infant health or susceptibility to infections.
5. Analysis of the diversity of vaginal microbiomes among pregnant women in the study region.
6. Collection of essential birth-related clinical data, including the length of labor, duration of membrane rupture, and use of prenatal antibiotics.
7. Exploration of the relationship between maternal and infant gut microbiomes, newborn illnesses, and the prevalence of bacteria among healthy mother-infant pairs.
8. Understanding the influence of maternal factors, such as pregnancy stage, postpartum period, and diet, on stool and breastmilk microbial communities.

Progress of Study Activities

All participants have successfully completed the study. The one-year safety follow-up for infants is ongoing and currently 70% complete. Key collaborators, including international experts, have visited the study sites to meet participants and observe the fieldwork.

Conclusion

This study is an important step to understand how probiotics can address some of the biggest challenges in maternal and child health. By focusing on simple, safe, and accessible interventions, the research could offer hope to families in Ghana and other low- and middle-income countries.

Establishing a Maternal Immunisation Readiness Network in Africa and Asia (MIRNA) to Identify, Characterise and Support the Platform, Policy, and Preparedness Requirements for the Introduction of Potential New Maternal Vaccines to Prevent Infectious Diseases.

Investigators

Prof. Kwaku Poku Asante, Dr. Samuel Afari-Asiedu, Mrs Irene Apewe Adjei, Ms. Theresa Afia Serwaa Tawiah, Mr. Kwame Kesse Adjei, Prof. Yeetey Akpe Kwesi Enuameh, Prof. Samuel Antwi Oppong.

Collaborators

Prof Janan Dietrich, Prof Nellie Myburgh, Ijeoma Edoka, Jacqui Miot, Dr Clare Cutland, Prof Mark Jit, Dr Simon Procter, Sarah Malycha, Heidi Larson, Emilie Karafillakis, Kirsten Maertens, Dr Ranju Baral, Clint Pecenka, Tracey Goodman, Özge Tunçalp, Lisa Menning, Lisa Nogochi, Rosemary Njoku,

Funder

Bill & Melinda Gates Foundation

Collaborating Institutions

University of the Witwatersrand (Wits) Vaccines & Infectious Diseases Analytics (VIDA) Research Unit (South Africa).
College of Health Science, Haramaya University (Ethiopia).
Kintampo Health Research Centre, Research and Development Division, Ghana Health Service.
Kenya Medical Research Institute, Centre for Global Health Research.
Aga Khan University and VITAL Pakistan Trust.
Makerere University College of Health Sciences (Uganda).

Study Duration

Two (2) Years
Start Date: January 2024
End Date: December 2025

Introduction

KHRC is actively involved in ongoing efforts to improve maternal and infant healthcare through the Maternal Immunisation Readiness Network in Africa and Asia (MIRNA). This consortium, involving countries across Africa and Asia, aims to provide evidence to guide the successful introduction and adoption of potential new maternal vaccines to fight infectious diseases caused by Group B Streptococcus (GBS) and Respiratory syncytial virus (RSV) in mothers and their infants.

Background

Maternal immunization (MI) is a promising approach to reduce the burden of maternal and infant morbidity and mortality and complements existing interventions in mother-infant care. New maternal vaccines are in clinical development for the prevention of respiratory syncytial virus (RSV) disease in infants and group B streptococcus (GBS) in neonates. As development of these vaccines progresses, programs will shift away from research and development towards implementation. Successful implementation of maternal vaccines will be key to reach the desired improvement in maternal, perinatal and infant outcomes for RSV and GBS, and reduce neonatal and infant mortality.

This success will be dependent on generating compelling evidence for adoption of MI in low and middle income countries (LMIC) and developing quality antennal care (ANC) delivery platforms which are well- integrated with the Expanded Program on Immunization (EPI). Identifying barriers to maternal vaccination access and uptake, mapping regulatory and financial mechanisms for new products, assessing the health system at different levels, establishing the evidence from a burden and cost perspective, supporting implementation, and understanding how to drive uptake need to be addressed well in advance of planned introduction. Cross-institutional and cross-country/regional collaboration will there be critical to the successful introduction, uptake and coverage of maternal vaccination in LMICs.

A consortium of countries representing key regions in Africa and Asia has been established to ensure a unified approach to maternal immunisation platform strengthening and facilitate early and successful adoption of new maternal vaccines after licensure.

Objectives

The study seeks to develop a comprehensive readiness agenda for maternal immunization (MI) concerning new vaccines in selected sub-Saharan African and South Asian countries.

Methodology

A consortium has been established including partner institutions in Ghana, Uganda, Ethiopia, Kenya and Pakistan, coordinated by the University of the Witwatersrand in South Africa. Study activities is being conducted under five work packages; 1) Situational analysis of MI delivery pathways and care levels, 2) Synthesis of in-country burden of disease data and identification of systems to capture prospective disease data, 3) Synthesis of existing work on disease modelling and cost-effectiveness of products, identifying critical data gaps, and undertaking additional analyses as needed, 4) Select, adapt and apply social science approaches to understand vaccine demand and hesitancy, 5) Stakeholder mapping and building communities of practice in partner countries and globally. This work will build on, expand and adapt previous efforts to advance MI programmes.

Expected Outcomes

The development of a Consortium of partner institutions in Africa and Asia will ensure a unified approach to MI platform strengthening and facilitate early and successful adoption of new maternal vaccines after licensure. The processes and learning from this study will contribute to a toolkit to support maternal immunisation acceleration in LMICs. Evidence generated will inform policy and decision making bodies (e.g. Ministries of Health, National Immunisation Technical Advisory Groups) and provide the foundation for communication to professional bodies who are responsible for guiding recommendations.

Progress of Study Activities

The team has received ethical clearance from the Kintampo Health Research Centre Institutional Ethics committee and Ghana Health Service Ethics Review committee. Training of study staff and subsequent data collection will commence in January 2025. All other study activities including desk, scoping, systematic reviews that do not require ethics approval are ongoing under the various work packages. The team is also preparing for the second MIRNA consortium meeting in Kenya in February, 2025.

Meetings and Workshops

The study team participated in the first MIRNA consortium meeting held in Johannesburg, South Africa, from the 21st-22nd February 2024. The meeting was held to discuss and finalize activities for the five work packages of the MI study.

The first stakeholder's engagement meeting was held online on 11th June 2024 to introduce the study and solicit for their support during implementation. The virtual meeting brought together experts and health mangers from the national, regional and district levels. Participants provided insights into ongoing study activities and pledged their support for the study.

Figure 1: The KHRC study team in Johannesburg for the MIRNA consortium meeting

Redefining Anaemia: A Multicenter, International, Population-Based Study to Establish and Validate Global Reference Values for Anaemia in Pregnancy (ReMAPP)

Investigators

Kintampo Health Research Centre (KHRC), Ghana: Dr. Kwaku Poku Asante, Mrs. Charlotte Tawiah, Ms. Veronica Agyemang
Kwame Nkrumah University of Science and Technology (KNUST), Ghana: Prof. Sam Newton
Korle Bu Teaching Hospital (KBTH), Ghana: Dr. Amma Benneh Kwasi-Kuma
George Washington University, United States: Prof. Emily Smith, Ms. Sasha Bauman.

Funder

Bill & Melinda Gates Foundation

Study Duration

Two (2) Years
Start Date: 01 Jul 2023
End Date: 31 Dec 2025

Introduction

The ReMAPP study is part of a larger study called PRISMA and is designed to better understand anaemia (low blood levels) in pregnant women to improve the health of mothers and their babies. The study, funded by the Bill and Melinda Gates Foundation, is being conducted in several countries, including Ghana, Kenya, Zambia, India, and Pakistan. The study will collect important information to help create better global guidelines for identifying and diagnosing anaemia in pregnant women. This will ensure that mothers get the care they need to stay healthy during pregnancy and after childbirth.

Background

Anaemia is a deficiency in oxygen-rich blood and is characterized by low blood haemoglobin concentration and/or low red blood cell (RBC) count insufficient to meet physiological needs. Women of reproductive age (WRA), especially pregnant and lactating are disproportionately affected by anaemia affecting about 613 million and this is associated with increased risk of adverse outcomes for both mother and newborn. The burden of anaemia is more pronounced in low and middle-income countries (LMICs). The World Health Assembly aims to reduce anaemia in WRA by 50% by the year 2025. The causes of anaemia are multifaceted, however iron deficiency accounts for over 50% in WRA.

Objectives

The overarching objective of this study is to advance clinical knowledge of anaemia during pregnancy and contribute high quality, globally representative data toward establishing haemoglobin thresholds linked to functional outcomes. Nested within already established surveillance sites (Ghana, Kenya, Zambia, India and Pakistan) implementing a Pregnancy Risk, Infant Surveillance and Measurement Alliance (PRISMA) Maternal and Newborn Health (MNH) study, three primary aims of this study will be:

Aim 1: To define normal haemoglobin values in healthy women during pregnancy and within 42 days postpartum and estimate related statistical thresholds for anaemia diagnosis in these populations;

Aim 2: To establish haemoglobin thresholds for anaemia diagnosis in pregnancy based on the link with adverse maternal, fetal, and newborn health outcomes.

Methodology

Each participating site will recruit 1600 to 2000 pregnant women from the MNH study into the aim 2 cohort at gestational age of less than 20 weeks, with an effort to recruit in the first trimester (<14 weeks). Serial haemoglobin measurements will be done during the antenatal period (13 weeks, 20 weeks, 28 weeks, 36 weeks) and 42 days postpartum. Both mother and infant(s) will continue to be followed up until 1 year after delivery.

A sub cohort of 1200 to 2000 women from the aim 2 cohort will be further screened to identify a healthy pregnant population of 600 participants for the aim 1 (establishing reference values). Aim 3 will include a cross-section of 300 women (100 per trimester), randomly sampled from those screened for the Aim 1 sub-cohort, to participate in a biomarker intensive sub-study to determine the underlying contributing factors to anaemia.

Expected Outcomes

The study will contribute to a growing body of evidence that could inform new global guidelines for diagnosing maternal anaemia and identifying high-risk pregnancies based on haemoglobin levels.

Progress of Study Activities

Recruitment of Study Participants

The recruitment process for the study began in December 2022. By November 2024, we successfully enrolled the target of 2,000 participants into the primary cohort. Recruitment for the Aim 3 arm started on February 23, 2024, and was completed on June 7, 2024. Biomarker-intensive measurements are currently underway to better understand the causes of anemia among participants.

Collaborator's Visit

In August 2024, collaborators from George Washington University, USA, visited our team. The visiting group included Christopher Mores, Sarah Trisch, and Precious Williams. During the visit, Sarah Trisch, who had undergone specialized training from the Center for Disease Control and Prevention (CDC), USA, on microbiologic assays (MBA) for measuring serum and red blood cell folate, provided hands-on training for selected members of the KHRC laboratory team. This training enhanced their capacity in performing MBA techniques.

Figure 1: A group photo of KHRC study team and collaborators, Chris, Sarah and Precious during their visit in August 2024

CLIMATE AND HEALTH EVALUATION FOR ADOPTIVE RESILIENCE (CLEAR)

Investigators

Dr. Kwaku Poku Asante (KHRC), Dr Patrick Ansah (NHRC), Prof Leonard Amekudzi (KNUST), Dr Darby Jack (CU), Dr Alison Lee (ISMMS), Dr Cascade Tuholske (MSU)

Funder

Wellcome Trust, UK

Collaborating Institutions

Navrongo Health Research Centre (NHRC, Ghana), Dodowa Health Research Centre (DHRC, Ghana), Kwame Nkrumah University of Science and Technology (KNUST, Ghana), Colombia University (CU, USA), Icahn School of Medicine at Mount Sinai (ISMMS, USA) and Montana State University (MSU, USA).

Study Duration

Three (3) Years

Start Date: May 2024

End Date: April 2027

Introduction and Background

Climate change is eroding global health gains, particularly in low-and middle-income countries, where capacity for climate-compatible policy planning in sensitive areas like health is weak. Accurate estimates of climate sensitivities are essential for justifying mitigation policies and planning adaptation. While researchers have made progress in quantifying these sensitivities, key studies lack data from Africa. This leaves African policymakers without reliable information on the climate impact, forcing them to rely on data from other regions as proxies. Without localized estimates, governments and stakeholders in Africa struggle to forecast and prepare for climate impacts.

To address this challenge, the Kintampo Health Research Centre (KHRC) with funding from Wellcome Trust, UK, is leading a three-year study to evaluate the health impacts of climate change in West Africa to influence climate policy. This study is implemented in collaboration with the Navrongo Health Research Centre (NHRC, Ghana), Dodowa Health Research Centre (DHRC, Ghana), Kwame Nkrumah University of Science and Technology (KNUST, Ghana), Colombia University (CU, USA), Icahn School of Medicine at Mount Sinai (ISMMS, USA) and Montana State University (MSU, USA).

The study uses longitudinal data from our Health and Demographic Surveillance System (HDSS) and cohort studies to identify the health outcomes associated with climate change, along with vulnerability and resilience factors, to inform policy and practice. This initiative also focuses on creating a scalable framework for climate health research in Ghana and support similar health research institutions across sub-Saharan Africa.

Objectives

This study has three main objectives:

1. Quantify the impact of temperature and precipitation on mortality, examining factors such as age, cause of death, gender, and household wealth.
2. Quantify the effect of temperature on birth outcomes and child growth, analyzing variations by household wealth, child gender, and maternal education.
3. Engage with policy stakeholders, communities, and researchers, to communicate the climate-related health sensitivities identified in first two objectives to key climate policymakers in the Government of Ghana and advocate for their integration into climate policy.

The study works closely with communities in the three HDSS (Health and Demographic Surveillance System) areas to gather insights into their lived experiences of climate change, amplifying local voices in climate discussions. The study also aims to build a community of researchers dedicated to climate impact studies in Ghana and establish the three HDSS regions as future Climate and Health Cohorts by expanding data collection to include information on health outcomes, agricultural productivity, nutrition, and household wealth.

Expected Outcomes

The outcomes include an understanding of climate change sensitivities related to health, which will be communicated to policymakers and used to support climate-compatible strategies. By identifying climate vulnerabilities and resilience factors, this study will support Ghana's policy stakeholders in planning health responses to climate risks. It will also establish climate-health cohorts, providing an evidence-based approach to climate policy in Ghana and setting a model for sub-Saharan Africa.

Methodology

The study will cover communities within the Kintampo, Navrongo, and Dodowa HDSS areas, each with distinct ecological and demographic characteristics. The Kintampo area, for example, falls within the Volta Basin with semi-arid grassland ecology, while Navrongo and Dodowa are part of the Guinea Savannah and Coastal Savannah belts, respectively.

The study is divided into **three (3) work packages (WPs)**:

Work Package 1 uses existing health and demographic surveillance systems (HDSS) data to assess the impact of climate exposure on mortality rates, considering demographic factors such as age, wealth, and gender. The average sample size is approximately 480,000 persons under surveillance.

Work Package 2 analyzes the effects of temperature and precipitation on birth and early childhood outcomes, leveraging previously collected data including the Ghana Randomized Air Pollution and Health Study (GRAPHS) and Pregnancy Risk, Infant Surveillance, and Measurement Alliance (PRISMA) pregnancy cohorts.

Work Package 3 engages communities, policy stakeholders, and advocacy groups through focus group discussions, oral histories, and community consultations to capture perceptions of climate change impacts. Community leaders, religious figures, and local historians will contribute insights to contextualize climate effects on agriculture, health, and livelihoods.

In addition to regular reviews by the Scientific and Ethics Committees, the study is guided by a Steering Committee of international experts and an Executive Committee of primary investigators to ensure progress and align research activities with policy objectives.

Progress of Study Activities

The study has received ethical clearance from the KHRC Ethics Committee and is currently awaiting ethical clearance from the Ghana Health Service Ethics Review Committee.

As part of preparatory activities, a five-day climate and health outcomes data analysis workshop was conducted for study teams from KHRC, Navrongo Health Research Centre (NHRC), Dodowa Health Research Centre (DHRC), Colombia university, Montana State University, Icahn School of Medicine at Mount Sinai and Kwame Nkrumah University of Science and Technology (KNUST). This workshop took place in KHRC from Monday, 4 to Friday, 8 November 2024.

Figure 1: Data Analysis Training Workshop at KHRC

Figure 2: Data Analysis Training Workshop at KHRC

Figure 3: Group photo of the study team

Conclusion

By developing a 'climate cohort' in Ghana, this study will build a critical evidence base on the health impacts of climate change in West Africa, informing health and climate policies that aim to enhance resilience against climate-related health risks.

The findings will serve as a valuable resource for climate-health research across sub-Saharan Africa. This initiative represents a critical step in regional climate resilience, with potential implications for improving health and quality of life across the continent.

Learn more: CLEAR Study

CHILD LUNG FUNCTION STUDY

Investigators

Dr. Kwaku Poku Asante, Dr. Seyram Kaali, Mr. Mujtaba Mohammed Nuhu, Mr. Osei Musah.

Collaborators

Icahn School of Medicine at Mount Sinai: Darby Jack, Steven Chillrud.
Mount Sinai School of Medicine: Alison Lee

Funder

National Institute of Health (NIH)

Study Duration

Ten (10) Years
Start Date: April 2018
End Date: March 2028

Introduction

KHRC, with funding from the National Institute of Health (NIH) is conducting this Child Lung Function Study to tackle household air pollution (HAP), a silent but serious global health problem. The study looks at how using cleaner cooking methods can improve children's lung health and reduce illnesses caused by harmful smoke from traditional cooking stoves. This study forms part of the Ghana Randomised Air Pollution and Health Study (GRAPHS), which is a community-based research initiative that investigated the effects of transitioning from traditional three-stone cookstoves to cleaner alternatives like Liquefied Petroleum Gas (LPG) stoves and Biolite improved cookstoves.

Background

Household air pollution (HAP) has emerged in the last 15 years as a top-priority global health issue. About 2.8 billion people – 40% of the world's households – cook with solid fuels, and combustion typically occurs in inefficient cookstoves. Incomplete combustion generates a complex mixture of pollutants, many of which are known toxicants (e.g., particulate matter, carbon monoxide (CO), nitrous oxides, formaldehyde, and polycyclic aromatic hydrocarbons (PAHs). Exposure occurs indoors or outdoors, hence the term HAP. In utero, HAP exposure is associated with low birth weight and respiratory symptoms and infections in childhood and is an independent predictor of childhood mortality. In adults, WHO estimates that 35% of chronic obstructive pulmonary disease (COPD) worldwide is attributable to HAP.

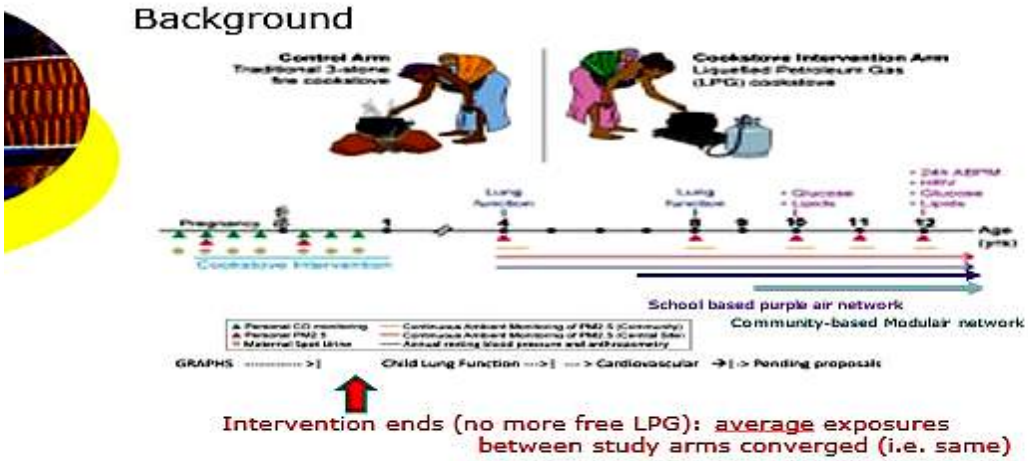


Figure 1: Intervention chart

Objectives

The study seeks to determine whether reducing air pollution exposure during the perinatal period leads to lasting improvements in children's lung function and respiratory health, which are important predictors of respiratory diseases in later life.

Aim 1: Assess the Impact of Early Life Cookstove Interventions on Respiratory Health Outcomes
We hypothesize that the type of cookstove intervention (Liquefied Petroleum Gas [LPG] versus traditional three-stone fire) used from the second trimester of pregnancy through the child's first year will independently predict:

a) Lung Function at Ages Four and Seven: Children exposed to LPG stoves will demonstrate better lung function, as measured by impulse oscillometry (IOS) at age four and both IOS and spirometry at age seven.

b) Prevalence of Wheezing from Ages One to Seven: Children using LPG stoves will have a lower prevalence of wheezing between ages one and seven.

Aim 2: Examine the Relationship Between Household Air Pollution (HAP) Exposure and Respiratory Health Outcomes

To investigate how varying levels of household air pollution exposure affect respiratory outcomes in children, establishing an exposure-response relationship.

Methodology

This study takes advantage of a well-designed community randomized cookstove intervention trial, the Ghana Randomised Air Pollution and Health Study (GRAPHS), to evaluate the independent effect of LPG cookstoves on adult respiratory health. GRAPHS used a cluster-randomized design to compare two cookstove interventions: Liquefied Petroleum Gas stoves (LPG) and the Biolite improved cookstove to the traditional three-stone cookstove (control arm).

In all, 1415 maternal-infant pairs were recruited and followed up over a period of four years to measure the impact of clean cookstove intervention on birth weight and incident pneumonia during the first year of life. In this Child Lung function study, a subset of 800 women belonging to the LPG, Biolite, and control arm is being followed up.

During this extended follow-up, data on exposure monitoring will be collected on all participants at four-time points, while respiratory symptoms and lung function will be collected on all participants at two time points when children are four years and seven years respectively.

Expected Outcomes

This study is expected to produce the following outcomes:

1.Health Improvements
Reduction in Respiratory Symptoms: Participants using LPG cookstoves are expected to experience fewer and less severe respiratory symptoms, such as coughing, wheezing, and shortness of breath, compared to those using traditional biomass stoves.
Lower Incidence of Respiratory Diseases: A measurable decline in cases of respiratory diseases like chronic obstructive pulmonary disease (COPD) and asthma, linked to the adoption of LPG cookstoves.

2.Air Quality Improvement

Improved Indoor Air Quality: Improvement in indoor air quality metrics, reflected by lower levels of particulate matter (PM2.5) and other harmful pollutants commonly associated with biomass cooking.

3.**Policy and Advocacy Implications**

Evidence for Public Health Policy Development: The study is expected to generate reliable data to support the development of policies and fuel transition strategies aimed at improving indoor air quality and promoting the transition to cleaner cooking technologies.

4.**Long-term Health Monitoring**

Sustained Health Impact Assessment: The study is also expected to establish a framework for long-term health monitoring of participants to evaluate the long-term benefits of LPG use on respiratory health over time.

Key Findings of the Study

1. **Impact of Prenatal HAP Exposure**: It was found that higher prenatal exposure to household air pollution (HAP), measured through carbon monoxide (CO) levels, is linked to reduced lung function at age four, with boys potentially being more vulnerable.

2. **Anthropometric Influence:** It was also found that children with poorer growth metrics up to age four exhibited higher airway resistance in early childhood.

3. **Long-term Risk of Impaired Lung Function:** The study found that reduced lung function and stunted lung growth in childhood increase the risk of developing chronic respiratory diseases later in life. These findings have implications for lifelong lung health, including pneumonia risk in childhood and reduced maximally attainable lung function in adulthood.

Progress of Study Activities

We secured additional funding to extend the child lung function study for five years, which will end in 2027. This extension includes the mechanistic aim and other respiratory research objectives to focus on the impact of household air pollution on respiratory health outcomes.

Conclusion

By providing evidence of the health benefits of cleaner cookstove technologies, the study will advocate for widespread adoption, potentially transforming the health and quality of life for millions in sub-Saharan Africa and beyond. Household air pollution remains a top global health priority; therefore, this research stresses the urgent need for cleaner, safer cooking solutions to protect the most vulnerable in our societies.

CHILD LUNG FUNCTION AND CARDIOVASCULAR HEALTH STUDY

Investigators

Kintampo Health Research Centre: Kwaku Poku Asante, MD PhD, Kaali Seyram, MD, MSc, Mujtaba Mohammed Nuhu, MPH, Osei Musah MSc, Yussif Tawfiq, MSc
Columbia University Mailman School of Public Health: Darby Jack, PhD, Steven Chillrud, PhD, Ana Navas-Acien, PhD, Kiros Berhane, PhD
Icahn School of Medicine at Mount Sinai: Alison Lee, MD, MS, Elena Colicino, PhD

Funder

National Institute of Health (NIH)

Study Duration

Four (4) Years
Start Date: April 2023
End Date: May 2027

Introduction

This Child Lung Function and Cardiovascular Health Study is part of a broader study named Ghana Randomised Air Pollution and Health Study (GRAPHS). The study is investigating how exposure to air pollution impacts the cardiovascular health (CVH) of children. It involves monitoring a group of children, starting from birth, to understand how early-life exposure to air pollutants affects the health of their heart as they grow.

Background

Cardiovascular disease (CVD) is the leading cause of global mortality, and nearly 80% of CVD deaths occur in low- and middle-income countries (LMICs). Exposure to fine particulate matter pollution (PM2.5) is the leading environmental risk factor for CVD, and toxicity may be partially driven by metal composition. In LMICs, ~2.8 billion people are exposed daily to high levels of household air pollution (HAP) from cooking with solid fuels in inefficient stoves.

In 2019, HAP was responsible for 2.3M premature deaths and 91.5M disability-adjusted life years (DALYs) with an estimated ~43% of mortality and ~31% of DALYs attributed to CVD.Pregnant women, often the primary household cook, are highly exposed. Early life (prenatal to age 1) is a critical window of developmental plasticity when environmental exposures may harm early life cardiovascular health (CVH) and program future CVD risk. A critical step in identifying and addressing lifelong risk is characterizing exposures and mechanisms that lead to and maintain this early predisposition.

Our proposed longitudinal study leverages a birth cohort derived from a cluster-randomized stove intervention trial begun prenatally and continued through age one year. We seek to investigate the contribution of early-life HAP exposure to poorer CVH in childhood and to characterize the role that the metal composition of PM2.5 plays in the CVH effects of HAP. CVH in adolescence has been associated with adult cardiac structure and function. Thus, early life is a critical time of cardiovascular development and programming of child CVH and future disease risk.

Objectives

The objectives of this study have been categorized as follows:

Aim 1: Estimate effects of an early life LPG cookstove intervention and resulting HAP exposure changes on CVH through age 12 years. We define CVH by lower systolic BP and DBP, measured annually from age 4 to 12, better height, weight, and body mass index from birth to age 12, and lower biomarkers of CVD risk (glucose, fasting lipids) at ages 10 and 12.

a) Aim 1a. Intention-to-treat: We hypothesize that children in the LPG intervention arm will have better CVH through age 12 as compared with children in the control arm.
b) Aim 1b. Exposure-Response: We hypothesize that higher early-life PM2.5 and CO exposures will be associated with poorer CVH through age 12. Other air pollution sources resulted in heterogeneity of exposure within the study arms. We will estimate the associations between early-life HAP exposures and CVH.

Aim 2: Assess the contribution of HAP exposure to metals exposures. Here, we will evaluate associations between 1) the GRAPHS intervention arm and airborne metal concentrations measured on maternal prenatal PM2.5 filters; and 2) airborne metals and established biomarkers of metal exposures in prenatal maternal urine.

a) Aim 2a. We hypothesize that LPG intervention assignment will be associated with lower airborne metal concentrations and altered composition compared to control.
b) Aim 2b. We hypothesize that airborne metal concentrations will be associated with urine biomarkers of metal exposures.

Aim 3: Estimate the association between prenatal metal exposures and childhood CVH.
a) Aim 3a. We will assess the association of airborne metal concentrations and urine biomarkers of metal exposures with Aim 1 measures of CVH.
b) Exploratory Aim 3b: We will assess the association between study arm assignment and prenatal HAP exposure, considered separately, and CVH before and after accounting for metal concentrations (airborne or urinary metal biomarkers, separately), using mediation analyses.

Methodology

The Ghana Randomised Air Pollution and Health Study (GRAPHS), a well-designed community randomized cookstove intervention trial, is used in this study to assess the independent impact of LPG cookstoves on adult respiratory health. Liquefied Petroleum Gas (LPG) stoves and the upgraded Biolite cookstove were compared to the conventional three-stone cookstove (control arm) in GRAPHS using a cluster-randomized design.

In order to measure the effect of the clean cookstove intervention on birth weight and incident pneumonia during the first year of life, a total of 1415 maternal-infant couples were recruited and followed up over a period of four years. A subset of 800 women from the LPG, Biolite, and control arms are being followed up on in this investigation on child lung function. In this prolonged follow-up.

In this prolonged follow-up, information on exposure monitoring will be gathered for each participant four times, and information on lung function and respiratory symptoms will be gathered for each participant twice, when the children are seven and four years old, respectively. Following completion of the final lung health assessment, children who actively followed the study were recruited into the cardiovascular health study. We anticipate that n=630 children will be recruited into this research protocol at age 9, resulting in n=570 children available for the age 12 assessment.

Expected Outcomes

This study expects to produce the following outcomes:

1. We expected the statistical analysis to reveal significant negative correlations between elevated early-life PM2.5 and CO levels and cardiovascular health indicators, such as blood pressure and heart rate variability.

2. Findings may demonstrate that children exposed to different sources of air pollution exhibit varying degrees of impact on cardiovascular health, highlighting the complexity of air quality effects.

3. Development of comprehensive risk profiles for children based on their exposure history, allowing for targeted interventions and public health recommendations.

4. Lower Blood Pressure: Children in the LPG intervention group are expected to exhibit lower systolic and diastolic blood pressure readings compared to the control group.

5. Evidence generated may inform policy decisions regarding air quality regulations and the promotion of cleaner cooking technologies to protect children's cardiovascular health.

Progress of Study Activities

Enrollment for the first phase of the Exposure Monitoring for PM2.5, targeting 630 participants, started in 2023 and is ongoing for children aged 10 years. Currently, the project team is conducting monthly follow-up visits to participants' homes. These visits aim to gather caregiver-reported data on symptoms, particularly wheezing, observed in the past month using the ISAAC study tool.

The following activities will be performed in the course of the study.

- **Maternal and Child Venous Blood Collection:** A trained, pediatric phlebotomist will collect fasting, and peripheral blood for measurement of biomarkers of cardiovascular health. 5mL of blood will be collected which is ~<2% of their total circulating volume and ~1% of an adult woman's circulating volume.
- **Heart Rate Variability:** Cardiac autonomic function assessed via HRV will be measured with age 12 ABPM and exposure measurement. Participants will wear a fitted Hexosin shirt with a data logger (Carré Technologies Inc.).
- **Ambulatory Blood Pressure Monitoring** (ABPM) We will measure oscillometric ABPM with the Spacelabs 90217A (SpaceLabs Healthcare, WA, USA) or an updated model that has been validated in children. Trained FWs will follow a cuff selection protocol to properly fit a BP cuff on the participant's non-dominant arm.
- **Exposure Assessment of Air pollution in the Ongoing CLF Study**: To estimate exposures at various ages 10-13, we combine real-time/filter integrated measurements of (a) individual-specific 48-hour personal (UPAS), (b) Continuous central site and community-level ambient monitoring using (Modulair, PurpleAir devices to measurements, and estimate exposures for each child in the year preceding each lung function assessment

The team has amended the master CLF&CVH protocol to include microbiome and virome analyses. This updated protocol, which focuses on the role of the gut microbiome, virome, and lung function, has been submitted to the KHRC and Ghana Health Service ethics committees for review and approval.

KHRC Low-Cost Sensor (QuantAQ Modulair) Network, Bono East Region

Figure: 1 Shows sensor collocation on-going

Investigators

Kintampo Health Research Centre: Dr. Kwaku Poku Asante, Dr. Kaali Seyram, Mr. Mujtaba Mohammed Nuhu.

Columbia University Mailman School of Public Health: Darby Jack, PhD, Steven Chillrud, PhD, Dan Westervelt.

Icahn School of Medicine at Mount Sinai: Alison Lee, MD, MS.

Funder

Clean Air Fund

Study Duration

Three (3) Years

Start Date: September 2023

End Date: August 2026

Introduction and Background

Air pollution exposures are widespread, and children are uniquely vulnerable. Particles in the PM2.5 size range are small enough to penetrate deep into the lungs and even enter the bloodstream. According to the Global Burden of Disease Study 2019 from the Institute for Health Metrics and Evaluation, PM2.5 pollution–both outdoor and indoor–is the fourth highest risk factor for death globally, after high blood pressure, tobacco use, and dietary risk factors.

The goal of the Bono East Low-Cost Sensor network is to assess ambient air pollution to address critical evidence gaps and to demonstrate how early-life air pollution exposure affects health outcomes. The project is part of the Pregnancy Risk, Infant Surveillance, and Measurement Alliance (PRISMA) project, a large birth cohort study funded by the Bill and Melinda Gates Foundation and led by Kintampo Health Research Centre. Our air monitoring work will augment air pollution estimates to this already-funded birth cohort, allowing us to expand our knowledge of the relationship between early-life air pollution exposure and birth outcomes.

Objectives

The objectives of the study are as follows:

1. To assess community particulate air pollution concentrations in 40 PRISMA cohort communities.
2. To carry out source apportionment studies in 5 PRISMA communities.
3. To carry out analyses linking ambient air pollution concentrations to child health outcomes in the PRISMA cohort.

Methodology

This study is implemented in the PRISMA/GRAPHS communities in the Bono East region of Ghana. 40 Air pollutant monitors were deployed to these study areas. Figure 2 shows the locations of the monitors.

The study will also adopt Community Engagement strategies involving stakeholder meetings with local community members and organizations to discuss the importance of environmental monitoring and data collection.

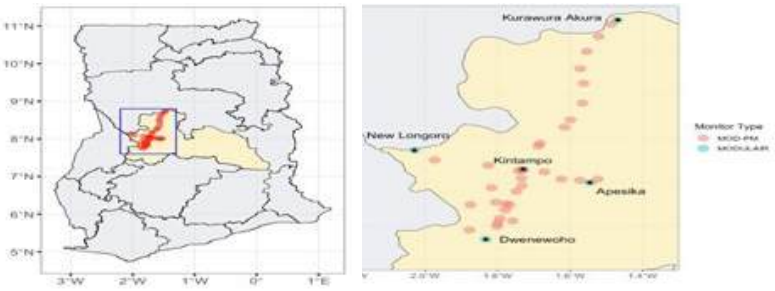


Figure 2: Locations of the 40 modulair monitors around the Bono East Region.

Preliminary Findings

Preliminary findings indicate an increase in air pollutants during the dry season, which can be attributed to the dust from harmattan winds. Figure 3 below presents the grand averages of particulate matter (PM) concentrations over the study period. The first panel shows the mean PM1 concentration, which averages 40.8 µg/m³, the second panel displays PM2.5 data, averaging 48.9 µg/m³, and the third panel presents PM10 levels, with a mean concentration of 137 µg/m³.

Each panel indicates periods of elevated PM levels, with noticeable peaks occurring during the dry season, likely attributable to increased dust from Harmattan winds. Notably, the PM1, PM10, and PM2.5 values trend together over time, suggesting that the sources influencing particulate matter levels affect all size fractions similarly.

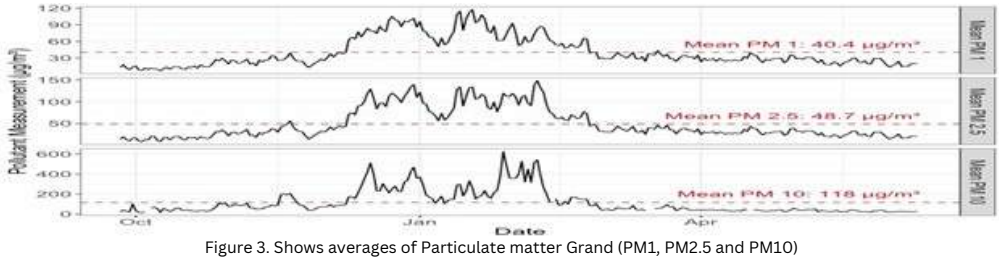


Figure 3. Shows averages of Particulate matter Grand (PM1, PM2.5 and PM10)

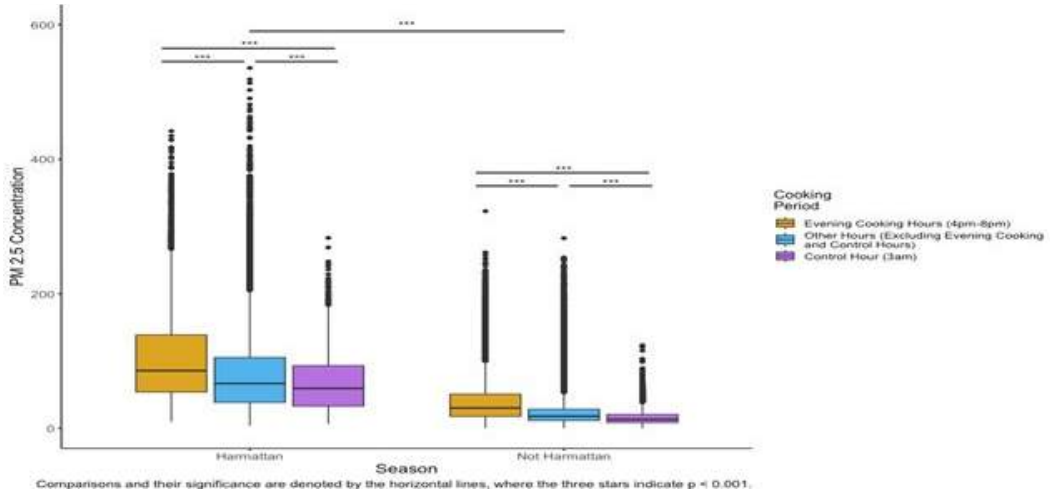


Figure 4. Shows Ambient PM2.5 Concentrations During Cooking Periods

Figure 4 above also examines the relationship between seasonal harmattan, peak evening cooking times, and air pollution. For this analysis, Harmattan was defined from December 1st to March 1st. Primary cooking hours were defined as 4–8 pm, although it is worth noting that the heatmap in Figure 4 suggests that the fires smoke for some time after the actual cooking is completed, leading to continued increased PM content beyond 8 pm. With this effect in mind, the pollution levels during evening cooking hours were compared to both a control hour defined as 3–4 am, a period sufficiently after evening cooking and before morning meal preparation to ensure it is unaffected by cooking activities, and all other times of the day/night (excluding both the cooking hours and the control hour).

PM2.5 concentration was higher (M = 84.4, SD = 59.8) during Harmattan months than non-Harmattan months (M = 26.2, SD = 23.9), with the difference statistically significant ($p < 0.001$). There was also a statistically significant ($p < 0.001$) difference in PM2.5 concentration levels between cooking and non-cooking hours — PM 2.5 concentration was higher (M = 59.8, SD = 55.3) during cooking hours than during other hours (M = 41.3, SD = 45.0) or the control (M = 32.2, SD = 35.3).

Expected Outcomes

This study expects to produce the following outcomes:

1. **Network Expansion:** Continue to expand the sensor network to cover additional areas within the middle melt of Ghana.
2. **Enhanced Data Analysis:** Collaborate with local and international universities to conduct more in-depth data analysis and research.
3. **Policy Advocacy:** Use collected data to advocate for improved environmental policies and practices at the rural and urban levels.
4. **Sustainability Planning:** Develop a sustainability plan to ensure the ongoing operation and maintenance of the sensor network.

Progress of Study Activities

We established a network of 35 QuantAQ ModulairPM (PM1, PM2.5, and PM10) and five QuantAQ Modulair (PM as above plus CO, NO, NO2, and O3) sensors across approximately 40 PRISMA/GRAPHS locations (including both rural communities and Kintampo township) where the monitors were deployed On September 26, 2023. Several stakeholder meetings and community engagement forums have been conducted to discuss the importance of environmental monitoring and data collection.

Figure 5. A project staff is educating District Health Committee on how the monitors work

Conclusion

The establishment of the Low-Cost Sensor Network in the Bono East Region represents a significant step toward improving environmental monitoring and public health. The project has successfully engaged local communities and is consistently collecting valuable data to support informed policy decisions and promote healthier living environments.

THE GASPAY STUDY

Investigators

Kintampo Health Research Centre: Dr. Kwaku Poku Asante, Dr. Sulemana Watara Abubakari, Dr. Kaali Seyram, Ms. Theresa Tawiah, Mr. Alexander Appiah, Mr. Mohammed N. Mujtaba.
Columbia University Mailman School of Public Health: Darby Jack, Heather Lahr, Erin Harned, Annelise
University of California Santa Barbara: Kelsey Jack

Funder

Columbia University

Study Duration

Seventeen (17) Months
Start Date: February 2024
End Date: June 2025

Introduction

KHRC is conducting the GasPay Study to test a digital platform which seeks to increase access to liquefied petroleum gas (LPG) especially in underserved communities. This study addresses air pollution caused by traditional cooking fuels such as firewood and charcoal. GasPay is a mobile app designed to make it easier and more affordable for families to use LPG for cooking. With the app, users can save money for LPG refills in a special mobile money wallet, schedule deliveries, and share feedback with suppliers. The app also helps improve how LPG is distributed to encourage households to shift from traditional fuels to cleaner options.

Background

Globally, about 3 billion people use traditional fuels (wood, kerosene, animal and crop waste, and coal) for cooking, resulting in millions of premature deaths each year, unsustainable clearing of forests, and emissions of greenhouse gasses and particles (primarily CO2 and black carbon). According to a WHO report from 2022, over 237000 deaths of children under the age of five in 2020, were attributed to household air pollution. Annually, household air pollution from polluting fuels was responsible for an estimated 3.2 million deaths. According to the report, household and ambient air pollution accounts for 6.7 million premature deaths every year. The report also revealed that household air pollution was a major cause of lung cancer, ischemic heart disease, stroke, and chronic obstructive pulmonary disease (COPD), among other non-communicable diseases. Women and children according to the report, bear the cost of these exposures because they are usually the ones doing household activities like cooking and gathering firewood.

In Ghana, air pollution is ranked as the second-highest risk factor for death and disability in 2019. To reduce costs related to air pollution, the Government of Ghana has committed to providing 50% of households access to liquefied petroleum gas (LPG) - the most widely available clean fuel in Ghana - by 2030. As part of the push toward LPG, Ghana is transitioning from a refill model, in which households choose the quantity to fill their LPG cylinder at a filling station, to a cylinder recirculation model (CRM), in which households trade in empty cylinders for full ones dispersed by vendors. This change will entail a higher upfront cost than the current practice among many LPG users of high-frequency purchases of small quantities of LPG. GasPay is a cellphone-based application that links consumers with LPG suppliers. It enables users to save for an LPG purchase in a dedicated mobile money wallet, purchase LPG, schedule a delivery, and give feedback to the LPG supplier.

Through this study, the Combating Household Air Pollution (CHAP) project, a partnership between Columbia University, the University of California - Santa Barbara (UCSB), and the Kintampo Health Research Centre (KHRC, Ghana Health Service), seeks to test this digital platform that we hypothesize will help optimize supply chains and increase LPG use among marginalized consumers.

Objectives

The study aims to understand;

1. Whether a digital payment system could facilitate charcoal to LPG transitions.
2. What features are most useful to consumers and LPG vendors?
3. How GasPay can reduce personal air pollution exposures.
4. The tradeoffs between impacts and profits.

Methodology

The study is implemented in three (3) stages. The first stage, known as the pre-pilot stage will recruit 50 participants. Data from these 50 participants will help the team refine the study procedures. Again, this data will help the team fine-tune survey instruments to ensure that, variables of interest set by the team are measurable. A month after the stage 1 rollout, an end-line survey will be conducted among these populations to learn about their experience with the application. This stage will also identify and address any issues with the app's design and functionality for both users and vendors.

After data analysis, stage two (2), which is the main pilot will involve 1,000 households in Techiman area in the Bono East Region. Participants will be introduced to the GasPay app, assisted with registration, and their baseline demographic and fuel use data collected during the first visit. Three months later, a follow-up visit will assess LPG use, the transition from traditional fuels, and attitudes toward LPG, credit, and mobile money. Analytics from the app will track usage, while household surveys will provide insights into outcomes. This phase will also help address any further app design or functionality issues.

Stage three (3), which is the main study will start in January 2025 and enroll 3000 people from Techiman Metropolitan Assembly and Kintampo-North Municipality. It will focus on identifying the best saving incentives and hire-purchase credit options to maximize LPG adoption and profitability.

Expected Outcomes

The Study is expected to improve supply chains and make it easier for underserved communities in Ghana to use LPG.

Progress

Stage One

Key milestones achieved during stages one and two include:

- The team utilized findings from a previous study in the Techiman Municipality (Target Subsidy for LPG Adoption) to identify study participants.
- Developed the GasPay Application, enabling users to make daily savings for LPG refills.
- Conducted a pre-pilot study with 50 participants, resolving most bugs in the GasPay Application before launch.
- Offered a 97% discount (equivalent to 175 Ghana cedis) to all 50 participants when the LPG price was 180 Ghana cedis during the study period.
- Observed a significant increase in LPG demand among participants during this phase.
- Data analysis for stage one is currently ongoing.

Stage Two

Stage two began in April 2024, targeting a population of 1,000 participants. So far, 905 participants out of the targeted 1,000 have been enrolled onto the study. The main pilot study is expected to end in December 2024.

Stage Three

The team is finalizing the plans for stage three, which is the main part of the study. We are working with the National LPG Promotion Programme, under the Ministry of Energy, to include stove beneficiaries from Kintampo-North Municipality and Techiman Metropolitan Assembly in the study.

Conclusion

By addressing barriers to LPG adoption, findings from the GasPay Study will improve household air quality, reduce health risks, and contribute to Ghana's clean energy goals. This study could provide a model for other countries tackling similar challenges. This study continues to move closer to its vision of cleaner, healthier homes across the country.

Electricity, Clean Energy, and Climate Change Adaptation Study

Investigators

Kintampo Health Research Centre: Dr. Kwaku Poku Asante, Dr. Sulemana Watara Abubakari.

University of California Santa Barbara: Flavio Malagutti

Funders

International Growth Centre

University of California, Santa Barbara

Study Duration

Twelve (12) Months

Start Date: September 2023

End Date: September 2024

Introduction

This innovative study is being conducted to understand how family-owned businesses in Ghana balance electricity usage between their homes and workplaces. The study, titled "Electricity, Clean Energy, and Climate Change Adaptation" is funded by the International Growth Centre and the University of California, Santa Barbara. Findings from this study will shape energy policy and promote sustainable energy use in Ghana.

Background

Nearly 1 billion people lack access to electricity worldwide. Ghana has taken energy access seriously. The country has one of the highest electrification rates in sub-Saharan Africa with 85% of its population connected to the grid. As Ghana closes the electricity access gap, policymakers are challenged to incentivize households toward using it as their primary energy source. At the household level, electricity is the cleanest alternative to biomass combustion, which is the most prevalent source of energy in Ghanaian households. When it comes to cooking energy, electricity is even cleaner than LPG.

Firm-households are special because their decision processes (and thus the incentives they respond to) are more complex than those that do not own businesses. Households that own businesses need to balance their choices and internalize costs and benefits across two locations, their residence and commercial enterprise. It follows that household members need to allocate resources to optimize two separate problems: household welfare and firm profits. Crucially, the more profitable the family business, the larger the household's budget and ability to care for its members. This simple logic suggests that household members would be sure to allocate their resources first to maximize their firms' profits. In this study, we hypothesize they do not and investigate why.

Objectives

This study aims to examine whether firm-households are misusing commercial electricity and to explore the reasons behind this behavior. Specifically, it seeks to answer the following questions:

1. Do firm-households seperate their residential and commercial electricity usage across their respective accounts?
2. If not, what factors influence their energy consumption patterns across residential and commercial meters?

Methodology

This study uses a combination of questionnaire-based data collection and a field experiment targeting firm-households in Techiman. The research process begins with household visits, during which a structured questionnaire is administered to collect detailed information. This initial phase sets the foundation for the subsequent field work.

After administering the questionnaire, a randomized controlled trial (RCT) is implemented and participants randomly divided into two experimental groups. The first group receives electricity rebates as an incentive to potentially influence their consumption behavior. The second group receives an unconditional cash transfer, equivalent in value to the rebate offered to the first group. This design allows for the evaluation of different forms of financial incentives and their impact on electricity use.

As part of the study, the Northern Electricity Distribution Company (NEDCo) provides meter-level data on residential and commercial electricity consumption for customers in its Techiman administrative area. This data is used to calculate the average electricity consumption for each meter, which is given as information to study participants to know about their energy consumption. The feedback given to participants includes information such as the number of units consumed and the cost per unit, helping participants understand their energy usage in detail.

The study also seeks to determine whether providing participants with detailed consumption information and clarifying electricity pricing mechanisms, increases their awareness of the price differences between residential and commercial meters. The researchers monitor changes in participants' electricity consumption behaviors over time, using NEDCo's data to track trends and shifts following the intervention.

Finally, the study integrates data from the questionnaires with electricity usage records to explore the relationship between energy consumption patterns, household health, demographics, and fuel choices, including fuel stacking behaviors. This comprehensive approach aims to dicover insights into the factors driving electricity use among firm-households and the potential for targeted interventions to influence energy consumption behaviors.

Expected Outcomes

The study is expected to generate knowledge on how family-led microenterprises allocate electricity usage between their households and firms and respond to incentives to use clean energy sources at home. Again, this study will provide evidence on the following.
(i)Whether firm-households have a reasonable understanding of their electricity tariffs and the amount of electricity used by their appliances.
(ii) Whether credit constraints prevent households and firms from adopting more energy-efficient appliances.
(ii)Whether firm-household members actually do have a high demand for electrical appliances but place them in their businesses, instead of in their homes.

Progress of Study Activities

In September 2023, the team initiated a pilot study involving 57 shops in Techiman. Among the participants, 30 were assigned to the electricity discount group, where they received their discounts in the form of electricity credits from third-party vendors within the Techiman municipality. Participants had the option to select their preferred vendors. The remaining 27 participants were provided with direct cash transfers, distributed by KHRC staff as scheduled. The pilot study lasted for four months and the last participant exited the study in March 2024.

In April 2024, the team commenced the main study, targeting 700 shops within Techiman Metropolitan and Kintampo-North Municipality. By the end of the enrollment phase, 668 shops were successfully enrolled. Half of the participants received mobile money transfers, while the other half were provided with electricity purchase discounts, which could be redeemed through third-party vendors in Techiman and Kintampo. These discounts were issued monthly over a four-month period. Data collection for the study has been completed, and analysis is currently ongoing.

CLIMATE-HEALTH SUPPLEMENT STUDY

Investigators

KHRC: Dr. Kwaku Poku Asante, Dr. Sulemana Watara Abubakari, Dr. Seyram Kaali

Collaborators: Alison Lee, Darby Jack, Steven Chillrud, Cascade Tuholske, Elena Clicino

Funder

National Institute of Health (NIH)

Study Duration

Twelve (12) Months

Start Date: September 2023

End Date: June 2024

Introduction

KHRC is near the end of its climate-health supplement study, which examines the impact of climate change on human health. The study also seeks to strengthen the skills of scientists through workshops and training programmes. Funded by the National Institute of Health (NIH), this sub-study will nurture climate change experts in Ghana who will apply their expertise to shape health policies and improve the overall health and well-being of individuals.

Background

Climate change disproportionately affects LMIC populations, yet little data is available to inform adaptive strategies in LMICs. Climate change is driven by fossil fuel combustion in high-income countries, but the burden of climate change is disproportionately borne by those who have contributed the least, including persons living in LMICs. The Intergovernmental Panel on Climate Change (IPCC) synthesis identifies that Africa, including Western Africa, is currently experiencing an increase in hot extremes and agricultural and ecological drought and, with high confidence, is highly vulnerable to health systems (e.g. water availability and food production, health and wellbeing) and ecosystems (e.g., changes in ecosystem structure) impacts of climate change. Further, the health impacts of climate change are estimated to disproportionately impact the poorest communities, many of which – particularly from a global perspective – contribute little data to known health sensitivities.

Indeed, the Climate Impacts Lab estimated that "the effect of an additional hot day on mortality in the >64 groups is ~50% larger in regions of the world where mortality data are unavailable". Policy decisions for those most vulnerable to the impacts of climate change are thus being made with incomplete and inconsistent information. Despite the importance of characterizing humidity and air temperatures during heat waves, few studies have investigated how humid heat relates to health outcomes like maternal-child health or mortality in Africa. This is due to a lack of data – there are only ~200 weather stations with a robust, longitudinal reporting record for Africa and only one in Ghana.4 Mortality and morbidity and climate modelling from sub-Saharan Africa is urgently needed to provide better estimates on which policy and community leaders can develop adaptive strategies. Evidence from high-income countries, and largely urban communities, suggests that temperature extremes are associated with a higher risk for mortality. Few studies have examined cause-specific mortality or begun to conceptualize life course temperature exposures instead of short-term temperature extremes in LMICs.

Objectives

This study focuses on two main objectives:

Aim 1: To engage with key stakeholders and enhance climate research capacity in Ghana.

1a) Collaborate with community and government stakeholders to share study findings and identify priority areas for action.
1b) Build the expertise of climate scientists through training workshops and mentored research, focusing on future heat-related mortality within the context of an ongoing Demographic and Health Surveillance System (DHSS).

Aim 2: To assess effects of preconception and prenatal i) humid-heat and drought; ii) precipitation on birth outcomes, childhood growth, and maternal CVH using the well-characterized GRAPHS data repository.

2a) Examine time-varying associations between Wet-Bulb Globe Temperature (WBGT), Standardized Precipitation-Evapotranspiration Index (SPEI), and Vapor Pressure Deficit (VPD), considered independently, on birth outcomes, childhood growth, and maternal blood pressure.
2b) Map health sensitivities to future projections of humid heat and drought.
2c) Identify factors contributing to resilience and vulnerability.
2d) Expand climate-related data collection in the GRAPHS study to include additional prospective metrics.

Methodology

This study focuses on analyzing secondary data from the GRAPHS-CLF study, which has tracked maternal and child health variables since 2013. GRAPHS is a well-documented pregnancy cohort with active, long-term follow-up of mothers and their children up to age 13. The data will be obtained from the Kintampo Health Research Centre database, with analysis conducted using R software. This novel research aligns with the four core pillars of the Climate Change and Health (CCH) Initiative.

1. This study developed two innovative and complementary climate cohorts to examine the links between climate, health outcomes, including morbidity and mortality, resilience, and vulnerability, with a focus on health equity.

2. The study used a novel climate dataset created by co-investigator, Tuholske. This dataset features detailed, gridded historical and prospective climate data, enabling new predictions of how climate impacts health in the past and future.

3. The study actively involved policy makers and community stakeholders to ensure that its findings were relevant and actionable for health equity and intervention strategies.

4. This study provided valuable mentorship and professional development for Ghanaian scientists, strengthened their expertise and positioned researchers from KHRC as leaders in climate policy and science.

Expected Outcomes

This study is expected to establish urgently needed climate expertise in Ghana and create two complementary "climate cohorts." These cohorts will produce valuable retrospective and prospective data, offering insights into health sensitivities, resilience, and vulnerability factors. The findings from this study will be highly relevant for shaping health policies and addressing community needs.

Progress of Study Activities

- The study team, led by investigators at KHRC, has collaborated with the Ghana Environmental Protection Agency (EPA) and the Ghana Health Service to identify critical policy-relevant data gaps. The proposed approach was developed in consultation with these organizations.

- Key informant interviews have been conducted with community stakeholders from about 20 selected GRAPH communities to understand the impacts of climate change on health and livelihoods. Plans are in place to organize eight (8) focus group discussions in the remaining 15 GRAPH communities, involving stakeholders from these areas.

- A five-day intensive capacity-building workshop was held in Accra, Ghana, to train Ghanaian scientists from the KHRC, Dodowa Health Research Centre (DHRC) and Navrongo Health Research Centre (NHRC), in analyzing climate data. These three health research centers operate under the Research and Development Division of the Ghana Health Service.

Figure 1: Capacity building for research scientist in Ghana (KHRC, NHRC and Dodowa research centres on climate change and Health outcomes in Ghana

Assessment of COVID-19 Infection Burden and its Impact on the Diagnosis of Febrile Illness Among Patients Receiving Health Care in Three Hospitals in Ghana (COVID-19 Differential Diagnosis Study)

Investigators

KHRC: Dr. Kwaku Poku Asante, Dr. Nicholas Amoako, Dr. Patrick Ansah,Dr Slyvester Dassah, Dr Frank Atuguba, Dr. John E. O. Williams.

Collaborators

Kintampo Health Research Centre (lead institution)
Navrongo Health Research Centre
Dodowa Health Research Centre

Funder

Ministry of Health-Ghana

Study Duration

Nineteen (19) Months
Start Date: May 2022
End Date: November 2024

Introduction

KHRC conducted this COVID-19 Differential Diagnosis Study to understand how common COVID-19 was among patients with fever and how the pandemic affected the diagnosis and treatment of other illnesses. The study enrolled 1,202 participants across three hospitals and used advanced testing methods to identify diseases causing fever, such as malaria. This study was conducted in collaboration with Dodowa Health Research Centre and Navrongo Health Research Centre, and with support from the Ministry of Health.

Background

Coronavirus disease (COVID-19) is a febrile respiratory illness and has been described as one of the biggest pandemics of all time. Apart from its direct effects on mortality, it also impacts on the diagnosis and management of other acute febrile illnesses (AFI) such as malaria due to overlap in clinical presentation and diagnostic challenges. Lack of reliable data on the current burden and predisposing risk factors coupled with non-availability standardized point of care test to discriminate COVID-19 from other AFIs, result in a significant delay in the diagnoses and turnaround times. In a differential diagnosis approach, this study employed a combined laboratory and clinical methods to diagnose disease-causing pathogens in febrile patients in a cross-sectional survey, to determine the COVID-19 infection burden and associated co-morbidities, as well as the predisposing risk factors among febrile patients three hospitals in Ghana.

Objectives

The main aim of this study is to determine the burden of COVID-19 among febrile patients and assess how the current management of COVID-19 impacts on the diagnosis of acute febrile illness (AFIs). Specifically, the study sought to determine the following.

1. To determine the burden of COVID-19 disease by accessing COVID-19 infection prevalence, hospitalization rate and deaths among patients presenting with fever.
2. To determine risk factors for COVID-19 transmission, disease severity and death.
3. To determine the correlation between coinfections and their role in the exacerbation of severe disease in COVID-19 patients leading to fatal outcomes.

4. To determine the impact of the COVID-19 pandemic on diagnosis of AFIs in the three participating hospitals.
5. To evaluate the diagnostic performance of three FDA approved RDTs (V-chek SARS-CoV-2 Ag rapid RDT, Lumiradx SARS-CoV-2 antigen Ag RDT and Huihai 2019 nCoV antigen RDT test kit) using reverse transcriptase-PCR as gold standard.

Methodology

This cross-sectional study took place in three hospitals located in three geographically distinct localities with different disease burden in Ghana, namely the Kintampo Municipal hospital, Kintampo in the Bono East region, War memorial hospital in Navrongo in the Upper East region and Shai Osudoku District Hospital, Dodowa in the Greater Accra region of Ghana. Recruitment targeted individual of all age and sexes and having fever (axillary temperature >37.5oC). Each participant was tested for COVID-19 using RDT and PCR and malaria is diagnosed by microscopy and RDT. Clinical and demographic data were collected using RedCap and all diagnosis made are documented.

Outcome

The main outcomes include COVID-19 hospitalization rate and deaths, comorbidities and predisposing risk factors that lead to severity of COVID-19.

Study Results and Progress

Overall, a total of 1,263 study participants were expected to be enrolled, out of which 1202 (95%) participants enrolled from May 2022 to November 2024 from the three recruiting sites (Kintampo, Navrongo and Dodowa) as shown on the table below. Participants recruitment started earlier in Kintampo in May 2022, followed by Navrongo in July 2022 and later by Dodowa in September 2022, although other non-field activities had already started in January 2022, in all the study sites.

STUDY SITE	NUMBER EXPECTED	NUMBER ENROLLED	%
KHRC	421	421	100
NHRC	421	421	100
DHRC	421	360	86
Total	1263	1202	95

Table 1: Enrolment Figures for All Three Study Sites

By November 2024, all the three sites had ended participants enrolment and the data from the three sites had been pooled and cleaned for analysis. For the 1202 febrile patients enrolled out of 1263 expected and haven 72 of them tested positive for SAR-CoV-2 virus using both RT-PCR and antigen test, the positivity rate of COVID-19 estimated was 6% for the two and halve years period (May 2022 to November 2024).

The mean and median age of the participants were 48.96 ± 19.09 and 44.5, respectively. Among SAR-CoV-2 positives, the male gender accounted for 68% (49 cases) of the COVID-19 patients. A total of 46 participants who tested positive for COVID-19 with the Ag-RDT, also tested positive with the SARS-CoV-2 RT-PCR, which represented 3.8% of the total participants.

The age group from 3-years to 35-years accounted for about 3% (38) of affected children and adolescents who contracted COVID-19. Among other test conducted, Plasmodium malaria (224/1202; 19%) is the most common diagnosis among all the participants enrolled. The proportion of malaria-COVID-19 co-morbidity was 5% (11/224) for the malaria cases identified. Some of the common symptoms reported includes diarrheal diseases, respiratory infection, and skin diseases. Associated symptoms for most of the reported diagnosis include headache, fever, cough, and general body pains.

On the performance evaluation of the antigen detection of the rapid diagnostic test (Ag-RDT), the results shown that the Ag-RDT was less sensitive than RT-PCR in the detection of SARS-CoV-2 infection, but it demonstrated a good sensitivity for individuals with N genes with Ct value < 25. The Ag-RDT had a sensitivity of 86% and specificity of 97%, using RT-PCR reference.

The study also indicate that COVID-19 pandemic had effect on parasitological diagnostics. These laboratories prioritised SARS-CoV-2 tests and as a result had to suspend or reduce their typical parasitological testing duties, which had a significant impact on the number of diagnosed cases of human parasitosis. The decrease in the number of ordered and performed parasitological diagnostics tests was seen in these laboratories. However, we do not have the full data on these preliminary findings.

Stored Sample for Further Laboratory Testing and Analysis

As part of the screening procedure, different sample types such as nasal swabs, whole blood, plasma were collected which have been stored for molecular testing for diverse pathogens including viruses, bacteria, and other protozoans of public health interest when fundings become available. The funding received could mainly support the field activities and the running of basic tests for patients' management.

Support for Molecular Testing

Due to inadequate funding to perform more testing on the samples collected, the study PI and other investigators are looking for financial support to perform the molecular analysis for the stored samples but are yet to receive favorable response from organization contacted.

Study Challenges

The study experienced a slow rate of recruitment at the three recruiting sites due to low OPD attendance. This resulted in only 4 participants being enrolled on average per week instead of 20 participants initially envisaged and therefore a delay in the recruitment process.

Conclusion

The study progressed very well at the 3 recruitment centres with the support of the Directors of the Kintampo, Navrongo and Dodowa Health Research centers as well as the Director of the Research and Development division of the Ghana Health Service. Despite the financial challenges to complete other components, most of the study objectives were achieved and the analysis will continue to highlight the relevance of the study to funders and policy implementors. The team will continue to look for additional funding to complete the outstanding test to achieve the ultimate goals of the study.

COVID-19 Vaccine Effectiveness Against Severe Acute Respiratory Infections (SARI) Hospitalizations Associated with Laboratory-Confirmed SARS-CoV-2 in Ghana (COVID-19 VE STUDY)

Investigators

Dr. Kwaku Poku Asante (PI), Dr. Nicholas Amoako, Dr. Abraham Oduro, Dr. Prince Agyapong, Prof. Seth Owusu-Agyei, Prof. Kwabena Duedu, Prof. William Ampofo, Prof. Ernest Kenu, Prof. George Obeng Adjei, Dr Micheal Rockson, Prof. Ellis Owusu Dabo, Dr. John Amuasi, Dr. Franklin Asiedu-Bekoe, Dr. Dennis Laryea, Dr. Francis Kasolo, Dr. Sally-Ann Ohene.

Funder

World Health Organization (WHO)

Collaborators

Kintampo Health Research Centre (lead institution), Noguchi Memorial Institute for Medical Research, University of Health and Allied Sciences and Kwame Nkrumah University of Science and Technology/KCCR and WHO Country Office-Ghana.

Study Duration

Two (2) years

Start Date: January 2022

End Date: March 2024

Introduction

This COVID-19 VE Study was conducted to measure how effective COVID-19 vaccines were in preventing severe respiratory infections in Ghana. Funded by the World Health Organization (WHO), the study aimed to provide important evidence into how vaccines protect against severe acute respiratory infections (SARI) caused by COVID-19. Findings from this study will enable policymakers make informed decisions about vaccination campaigns to protect people against future outbreaks.

Background

Coronavirus disease (COVID-19) has been described as one of the biggest pandemics in history. The use of vaccines to urgently respond to the COVID-19 pandemic generated the need for monitoring vaccine effectiveness in the context of new viral variants and changing epidemiology. This study measured the COVID-19 vaccine effectiveness (VE) against laboratory-confirmed SARS-CoV-2 in hospitalized patients diagnosed with severe acute respiratory infections (SARI) in Ghana.

Objectives

The primary objective of this study was to measure overall and product-specific COVID-19 vaccine effectiveness (CVE) against laboratory-confirmed SARS-CoV-2 in hospitalized SARI patients belonging to the target group(s) for COVID-19 vaccination.

Study Method

The study used a test negative case-control method among patients over 15 years old who visited 32 selected hospitals across Ghana between June 2022 and March 2024. These hospitals are part of a national system that monitors influenza. To identify COVID-19 cases, researchers collected nasal and throat swabs from the patients and tested them using PCR. They also gathered information about the patients' medical history and vaccination status.

The effectiveness of the COVID-19 vaccines (VE) was calculated by comparing the odds of being vaccinated among those who tested positive (cases) and those who tested negative (controls). The vaccine's protection was expressed as a percentage. Two reference groups were used: patients who had never been vaccinated (absolute VE) and those unvaccinated plus those vaccinated more than a year before showing symptoms (annual VE).

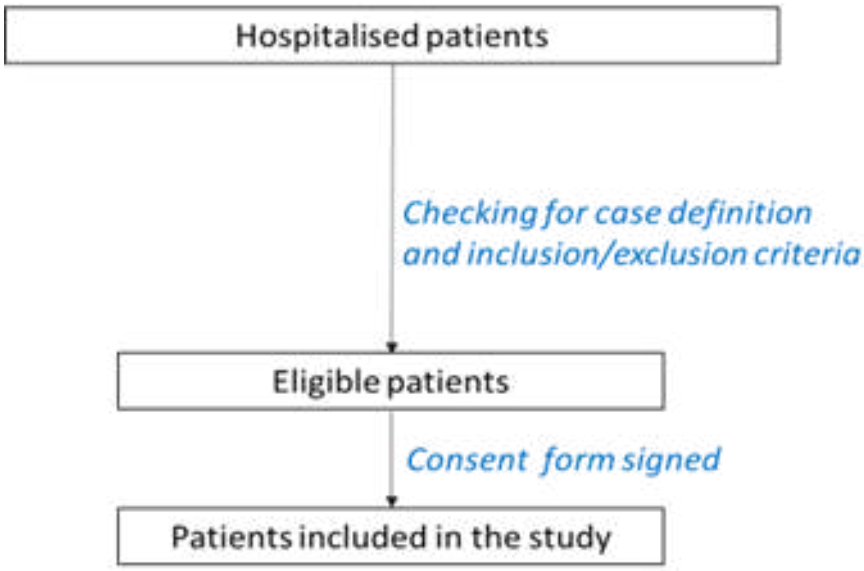


Figure1: Inclusion algorithm for systematic screening of all admitted patients

Outcome

The outcome of interest severe disease with SARS-CoV-2 infection in patients of age group eligible for COVID-19 vaccination and hospitalized with SARI symptoms. Secondary outcomes include genetic variants of SARS-CoV-2 in hospitalized SARI patients of the vaccination target age groups (15 years and above) and markers of severity of disease during hospitalization, length of stay (LOS), oxygen therapy, intensive care unit (ICU) admission, mechanical ventilation, in-hospital death, clinical signs of pneumonia, severe respiratory rate > 30 breaths/min, severe respiratory distress, acute respiratory distress syndrome (ARDS), oxygen saturation <90% on room air, sepsis and septic shock.

Study Results and Progression

The study, which ended in March 2024 after two years of data collection, enrolled 1,796 (91%) of the 1,974 identified SARI patients. The participants included 929 males (52%) and 867 females (48%), with 167 (9.3%) reporting at least one chronic medical condition and 10% aged 60 years or older.
Among the participants, 118 (7%) tested positive for SARS-CoV-2. Of these, 29 (25%) had received at least one dose of a COVID-19 vaccine (including Sputnik V, Vaxzervria, JCovden, Spikevax, or Comirnaty), and 60 (51%) were female.

In comparison, 1,678 participants (93%) tested negative for SARS-CoV-2, with 412 (25%) having received at least one vaccine dose. Among the 492 pregnant participants, 5 (9.5%) tested positive for SARS-CoV-2. The study found that the overall vaccine effectiveness (VE) against COVID-19-related SARI hospitalization was 21.6% (95% Confidence Interval (CI): -107–70.3) for those who received their last vaccine dose within 179 days. However, effectiveness declined significantly after six months, with annual VE estimated at 19.3% (95% CI: -113.2–50.2%). This highlights the need for booster doses to sustain immunity.

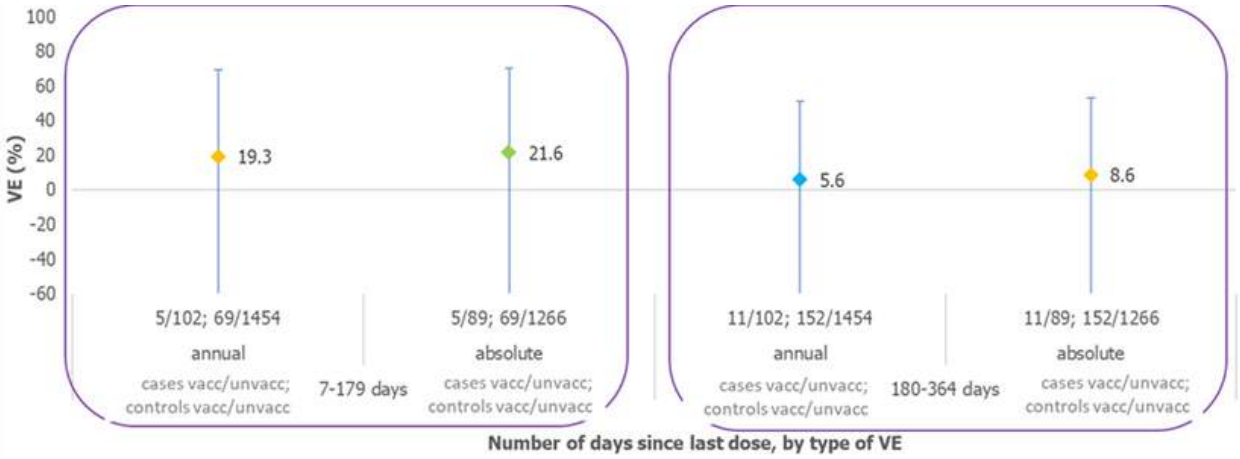


Figure 2: Annual and Absolute COVID-19 vaccine effectiveness against SARS-CoV-2-confirmed hospitalization for SARI, among adults aged ≥15 years old, by six months intervals since date of last vaccine from 2022-2024

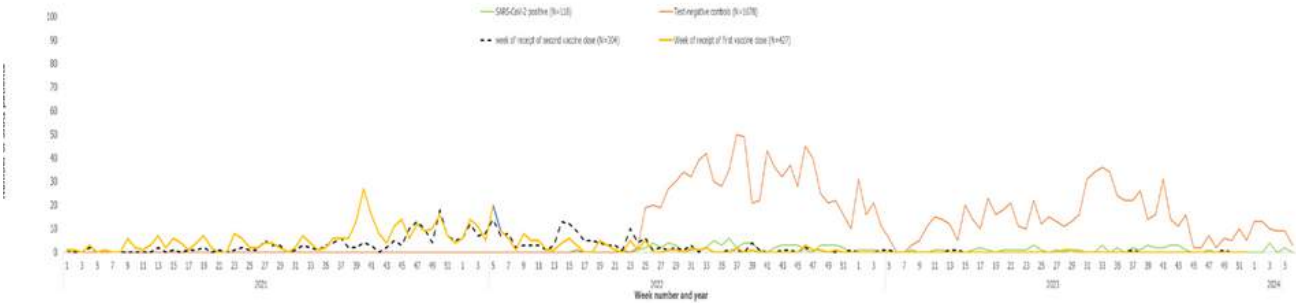


Figure 3. Year and week of sample collection of SARS-CoV-2-positive cases and SARS-CoV-2-negative controls, dates of receipt of first and second vaccine doses, among vaccinated SARI patients included into the study from, June 2022–March 2024

Conclusion

COVID-19 vaccines used in Ghana prevented one in four COVID-19-related severe acute respiratory infection (SARI) hospitalizations during the first six months of the study. However, their effectiveness declined over time, similar to observations in other countries, highlighting the importance of booster vaccination to sustain protection.

Uptake of Task-Shifting Strategy for Blood Pressure Control in Community Health Planning Services: A Mixed Method Study (TASSH)

Investigators

Dr. Kwaku Poku Asante, Prof. Jacob Plange-Rhule, Prof. Gbenga Ogedegbe, Prof. Juliet Iwelunmor, Solomon Nyame, Kwame Adjei, Dr. John Amoah, Joyce Gyamfi, William Chaplin, Kezia Mantey, Kingsley Apusiga

Funder

National Institute of Health (NIH)/NHLBI

Collaborators

New York University (USA), Saint Louis University (USA), Kwame Nkrumah University of Science and Technology (Ghana).

Study Duration

Seventy-Two (72) Months

Start Date: 28th May 2017

End Date: 31st May 2024

Introduction

KHRC has concluded its TASSH study, conducted over seven years, to demonstrated how community health workers can play a key role in controlling high blood pressure (hypertension) in Ghana. The study sought to examine the adoption of the task-shifting strategy recommended by the World Health Organization (WHO), to train community health workers and nurses to handle tasks usually done by doctors, such as screening for high blood pressure, providing lifestyle advice, and referring patients for further care when necessary. This study is funded by the National Institute of Health (NIH).

Background

In countries like Ghana, hypertension, once a rare disease, has become a major public health problem, and the 2nd leading cause of morbidity in adults. Results from an epidemiological study on hypertension conducted between October 2015 and December 2016 as part of the Kintampo Non-Communicable Disease Initiative revealed that the prevalence of hypertension was 24.6%. Also, approximately 55% of those with hypertension did not know their status, hence, were not on any medication.

Thus, intervention was needed. One of the greatest challenges to optimal hypertension control in Sub-Saharan Africa (SSA) is the acute shortage of healthcare workers. The World Health Organization (WHO) launched a series of evidence-based practices for low middle-income countries including WHO Cardiovascular Disease (CVD) Risk package utilizing the Task Shifting strategy to improve the shortage of health workers for CVD prevention and control. These strategies of using non-physician health workers, such as community health workers and nurses, are proven to be viable and cost-effective.

Objectives

The study aims to identify the practice capacity for TASSH adoption at CHPS compounds and develop a culturally tailored PF strategy using qualitative methods. Again, the study aims to evaluate the uptake of a Practice Facilitation (PF) strategy versus Usual Care (UC) in managing blood pressure within Community Health Planning Services through a stepped-wedge cluster randomized control trial. We also aim to compare the PF strategy's and UC's clinical effectiveness on systolic BP reduction among adults with uncontrolled hypertension in a stepped-wedge cluster RCT.

Methodology

This is a mixed-methods, "Hybrid Type II" Effectiveness-Implementation study that takes place in three (3) contiguous districts in the Brong Ahafo of Ghana (Kintampo North, Kintampo South, and Nkoranza North). A culturally acceptable practice facilitation strategy will be developed based on recommendations from key stakeholders guided by Damshroeder's Consolidated Framework for Implementation Research (CFIR). Community Health Officers will be trained based on the practice facilitation strategy developed. Seventy (70) CHPS zones will be selected and randomized into intervention and control groups.

The intervention group will implement the practice facilitation strategy, whereas the control group will provide the usual care in the first year. In the second year, the usual care group will implement the facilitation strategy, whereas the implementation group will provide the usual care. At the post-implementation phase, the study team will evaluate the adoption and sustainability of TASSH in participating CHPS zones using the Reach Effectiveness Adoption Implementation and Maintenance (RE-AIM) framework.

Expected Outcomes

The study is expected two main outcomes.

Primary Outcome: The rate of adoption of TASSH at the CHPS compounds.
The following measures will assess the primary outcome:

1. The number of newly detected hypertensive patients by the CHOs using the WHO Risk Prediction Chart
2. The proportion of patients who received lifestyle counseling by the CHOs
3. The proportion of eligible patients were referred to physicians and specialists for further care.

Secondary Outcomes:

1. The between-group difference in systolic BP
2. Mediators of adoption of TASSH at the CHPS compounds
3. The sustainability of TASSH uptake.

Key Findings

Out of the 2000 study participants, 64% were women, and 36% were men. The largest age group was people aged 70 and above, making up 31% of the group. Most participants (57%) had a healthy Body Mass Index (BMI).

At the beginning, the average upper blood pressure (systolic) was about 155 mmHg for both the group receiving treatment (intervention group) and the group not receiving it (control group).

Over time, blood pressure went down in both groups. In the treatment group, it dropped by 12.3 points on average, and in the control group, it dropped a bit more, by 13.6 points. The extra 1.3-point drop in the control group wasn't significant enough to matter. For lower blood pressure (diastolic), the control group also had a slightly bigger drop, and this difference was meaningful.

After 12 months, people in the treatment group were slightly more likely (1.07 times) to have their blood pressure under control compared to the control group. After 24 months, the likelihood was still higher but only by a small amount (1.01 times).

Conclusion

This study was aimed at improving the skills of frontline health workers to better manage high blood pressure (hypertension) in communities. It shows how important it is to use proven, community-based strategies to control hypertension and tackle the growing problem of heart-related diseases. The research highlights the need to bring healthcare closer to people, especially in rural and underserved areas.

We created a model that actively involves the community, making sure the strategies fit the local culture and are easier to accept. A key part of the study was using local health workers and community leaders to set up a system for health screening and referrals. The results offer valuable guidance for decision-makers on how to use evidence-based strategies to strengthen healthcare services and control hypertension within Ghana's health system. This approach can also serve as an example for similar programs in other low- and middle-income countries.

Figure 1: Group photo of TASSH study participation in a roundtable discussions to improve Hypertension care in Ghana

Figure 2: Group photo after a National, Regional And District Steering Committee Meeting for the TASSH study

Revision and Validation of the Short 10/66 Dementia Diagnostic Assessment for Older Populations in Kintampo, Ghana.

Investigators

Kintampo Health Research Centre: Kwaku Poku Asante, Solomon Nyame, Kenneth Ae-Ngibise, Naana Agyeman, Richard Tetteh

French National Research Institute for Sustainable Development/Université de Limoges: Maëlenn Guerchet and Pierre-Marie Preux

Funder

Global Brain Health Institute

Study Duration

Two (2) Years

Start Date: 1st, July 2021

End Date: 30th June 2024

Introduction

KHRC has conducted this study in collaboration with French National Research Institute for Sustainable Development/Université de Limoges, to improve how dementia is diagnosed in older adults in rural Ghana. The study sought to adapt and validate a tool called the 10/66 Short-Form Dementia Diagnostic Assessment to better suit the Ghanaian culture, language, and environment. This study is funded by the Global Brain Health Institute

Background

Dementia is a word doctors use to describe problems with memory, concentration, and thinking if they become serious enough to affect day-to-day life. This problem affects older people in particular; around one in 20 of all those aged 65 years and over. Several different disease processes can cause it, the commonest of which is Alzheimer's disease. We are keen to understand more about dementia from Ghana, where the problem has been little studied. One of the reasons it has been little studied in Ghana and other parts of Africa and the world is that it is difficult to evaluate the symptoms present in older people using its language and considering where they live.

Instruments allowing this evaluation need to be adapted and validated to ensure we consider the environment where older people live. Symptoms might seem common for an old person and not reported or seen by their family. They might also present differently in Ghana than in other parts of the world. We aim to investigate how to improve our evaluation and make it adapted and efficient for older people in Kintampo and Ghana.

The lack of standardization of dementia diagnostic assessments and algorithms has been recognized as a major issue in estimating disease burden across cultures. Standardization is difficult to achieve because of the diversity of language, culture, and literacy levels in the different regions of the world. Less attention has been given to the validity of survey diagnostic approaches in Sub-Saharan Africa (SSA) compared with other regions. While most population-based studies in SSA have been using two-stage diagnostic approaches, this approach might not be feasible for large-scale surveys, given the lack of specialist resources.

Although the evidence on the epidemiology of dementia has substantially increased recently, our understanding of the epidemic and its burden in this region is limited, while the economic and social impact of dementia could be disproportionately high. As for other countries of the region, dementia research needs in Ghana were recently highlighted, including diagnosis, which would contribute to filling the gap regarding dementia prevalence.

Objectives

The study aims to address the significant gap in dementia research and diagnosis in Ghana, particularly in rural settings. Specifically, the study seeks to:

1.Make changes in the diagnostic assessment and explore assessment quality as well as deviations from protocol.

2. Check whether the revised version of the 10/66 short-form dementia diagnostic assessment is able to identify individuals with dementia in Kintampo.

Methodology

The study will take place in Kintampo, North and South. The study setting is predominantly rural, and data suggest that the population group of 60 years and above forms about 7% of a population of about 151898. This cross-sectional validation study will use a mixed methods approach to collect data that will answer the research objectives. A quantitative approach will validate the 10/66 short-form dementia diagnostic assessment.

A qualitative approach will explore concept elicitation, cognitive debriefing, and usability testing. Eligible older residents aged 60 years and over drawn from the register in the catchment area will be included. Caregivers / close family members (preferably spouses and/or adult children) living with them will also be asked to answer part of the assessment. For aim one, we will conduct 30 pilot interviews, 30 pilot administrations of core measures after basic training (using the standard approaches applied in previous surveys), and cognitive interviewing of the translated versions of the instruments.

Pilot administration will be digitally recorded to assess the fidelity of administration and rating and problems with comprehension. Particular attention will be given to technical administration issues (e.g., distinguishing between 'often' and 'sometimes' in the CSI-D informant) and translation (following the WHO recommendations for translation and adaptation of instruments). For aim two, 160 individuals will be interviewed in the two districts.

Expected outcomes

Outcomes from this project will be a culturally adapted and validated version of the 10/66 short-form dementia diagnostic assessment and algorithm, alongside developing protocols for enhanced training and supervision methods to ensure high standards of fidelity of administration and rating. The instrument's revision and validation will be published in an open-access international journal.

Prevalence of Dementia

In 2015, collaborative research was conducted in the Kintampo area. Overall prevalence was 5.0% (95% CI=3.6–6.8), and a standardized prevalence of 6.6% (95% CI=3.6–6.8), for all ages. In addition, qualitative data ascribed the symptoms of dementia to normal aging and linked them to other comorbidities of aging.

Progress of Study Activities

Currently, community screening activities are ongoing in the two districts. So far, about 1263 community members 60+ years have been contacted, and 1038 of them have been screened using a prescreening instrument designed using ODK and installed on Samsung Android tablets. Analysis is currently ongoing to determine older adults with probable dementia and the risk factors for probable dementia.

Conclusion

The study aims to address the significant gap in dementia research and diagnosis in Ghana, particularly in rural settings like Kintampo. By validating and culturally adapting the 10/66 short-form dementia diagnostic assessment, the project seeks to overcome challenges related to language, culture, and literacy levels that hinder the accurate evaluation of dementia symptoms in Sub-Saharan Africa. The research highlights the importance of standardization in dementia diagnosis to estimate disease burden accurately and develop targeted interventions.

Preliminary findings underscore the prevalence of dementia in the region and the tendency to attribute its symptoms to normal aging and other age-related conditions, emphasizing the need for greater awareness and diagnostic precision. Ongoing community screening activities have demonstrated the feasibility of utilizing innovative tools and methodologies, such as ODK on Android tablets, to effectively identify probable dementia cases and associated risk factors.

The outcomes of this study will include a validated diagnostic instrument tailored to the Ghanaian context, along with training protocols to ensure reliable implementation. These advancements are expected to contribute significantly to improving dementia diagnosis, enhancing care for affected individuals, and informing public health strategies in Ghana and similar settings. The dissemination of findings through open-access publication will facilitate global knowledge sharing and inspire further research in low-resource settings.

Figure 1: A Study participant undergoing screening at her home

Figure 2: study participants undergoing screening in their homes

NCD AND ENVIRONMENTAL RESEARCH STRENGTHENING TRAINING (NERST)

Investigators
Dr Kwaku Poku Asante, Japhet Anim, Solomon Nyame, Yvette Eyram Avorgbedor.

Collaborating Institutions
University of Ghana School of Public Health (UGSPH).
Icahn School of Medicine at Mount Sinai (ISMMS).
The Trustees of Columbia University in the City of New York.
Lamont Doherty Earth Observatory

Funder
National Institute with Health (NIH)

Study Duration
Five (5) Years
Start Date: 2024
End Date: 2029

Introduction
KHRC is implementing this research training programme in collaboration with the University of Ghana School of Public Health, Columbia University (CU, USA), and the Icahn School of Medicine at Mount Sinai (ISMMS, USA,) to train Ghanaian researchers to address critical public health challenges through epidemiological research focusing on environmental exposures and Non-Communicable Diseases (NCD). This programme is funded by the National Institute with Health (NIH).

Background
Forty-one million people die every year from NCDs, accounting for >70% of all global deaths. Cardiovascular diseases (CVDs) affect nearly 18 million people each year; chronic respiratory diseases and metabolic disease also carry a high burden (>4 million and 1.5 million, respectively). In Ghana, the burden of NCDs is high - about 94,000 NCD deaths are estimated to occur per year, and stroke and ischemic heart disease form about 50% of all NCD deaths.

Metabolic factors (high blood pressure, high body mass index, high fasting blood sugar) and environmental (air pollution) are among the top 10 risk factors for mortality. Evidence-based strategies to address the growing NCD burden are urgently needed. To sustainably move this agenda forward, a training pipeline must be developed to provide Ghanaian scientists with expertise in public health-relevant research and to build institutional research capacity.

Objectives
The programme has the following objectives:

1.To strengthen the capacity of LMIC institutions to conduct NCD research and train a cadre of experts such that KHRC and UGSPH partners will become a national, regional and international center of expertise in NCD research.

2.To support NCD multidisciplinary research training and implementation science.

3.To develop NCD research experts that will directly affect public health policy and care implementation in Ghana, particularly given that NCDs are a demonstrated public health priority.

4.Build critical research infrastructure that will support research capabilities, for example program and grants administration; grant and scientific manuscript writing; data management and information technologies.

5.Build networks for research training within Ghana, with a forward view of expanding to West Africa.

Methodology

The programme will leverage the extant well-characterized, longitudinal cohorts operationally led by KHRC provide robust data and sample repositories for mentored research opportunities. The programme will leverage four main cohorts:

1) the well-characterized Ghana Randomized Air Pollution and Health Study (GRAPHS), a continuously funded pregnancy cohort initiated in 2010 with extensive mother-child dyad health assessments and environmental exposure data and specimen repository.

2) the actively enrolling Pregnancy Risk Stratification Innovation and Measurement Alliance (PRiSMA) study which is enrolling n=3000 pregnant persons with funded longitudinal mother-child follow-up.

3) The Kintampo Hypertension Program (KHP), a program that identified the burden of hypertension In 2015 and has currently screened ~10,000 community members to identify, educate and refer hypertension cases for further management using an implementation science approach (TASSH -Task Strengthening Strategy for Hypertension).

4) the Kintampo Health and Demographic Surveillance System (KHDSS), a progressive surveillance cohort started in 2003 that currently follows 540,000 individuals with 6-month morbidity and mortality surveillance.

Taken together, these cohorts provide an opportunity to take a life course approach and examine how environmental exposures beginning prenatally shape future NCD risk (GRAPHS, PRISMA); how, once risk factors develop, environmental exposures accelerate NCD progression (KHP, GRAPHS mothers cohort); and finally, how environmental exposures are associated with all-cause and cause-specific mortality (KHDSS).

Figure 1: Launch of the NErST Programme in Accra

Expected outcomes

This programme is expected to strengthen core research skills in Ghana and develop a pipeline of experts focused on life-course non-communicable disease (NCD) risks. These experts will work on creating and implementing evidence-based solutions to tackle the rising NCD burden in Ghana and other West African countries.

Progress of Study Activities

The programme was successfully launched in Accra on November 19, 2024. Partners reviewed the program's administrative setup and discussed the selection process and timelines for candidates. Applications for PhD and Master's programs will open on January 1, 2025.

Evaluating the Implementation Process of the Networks of Practice Programme in Ghana: An Implementation Research Project (NoP)

Investigators

Dr John Williams, Prof Kwaku Poku Asante, Dr. Solomon Narh Bana, Dr Martha Abdulai, Miss Theresa Tawiah, Dr. John Amoah, Dr Samuel Chatio

Collaborating Institutions

Dodowa Health Research Centre (DHRC) as the lead,
Kintampo Health Research Centre (KHRC)
Navrongo Health Research Centre (NHRC).

Funder

World Bank

Study Duration

Three (3) Years
Start Date: 2023
End Date: 2026

Introduction and Background

This Network of Practice (NoP) program is one of Ghana's flagship strategies to attain Universal Health Coverage (UHC) with a focus on primary health care. The program, which is led by the Dodowa Health Research Centre, in collaboration with KHRC and Navrongo Health Research Centre, aims at improving quality health services, partnership and innovation. The NoP program connects healthcare facilities within specific areas to form networks that ensure accessible and comprehensive healthcare services. These networks include public, private, and quasi-government health facilities, organized around a central hub (usually a health center.)

These networks are intended to ''maximize efficiencies in the use of resources towards improving quality and coverage" by connecting primary care service points around a "hub". These networks, are organized primarily at the sub-district level, includes public, private, and quasi-government service providers and are nested within a district with strong linkages to district hospitals. The Government of Ghana has identified health centers (HCs), a level of care that falls between first level hospitals and Community-based Health Planning and Services (CHPS) facilities as an important component of networks of practice. In most cases, a HC will be the "hub" of a particular NOP. Currently, this level of care is relatively under-utilized by populations who `tend to bypass it, even for basic services, for higher-level care in hospitals. In a recent study of bypassing in Ghana, 19% of people bypassed primary care facilities for antenatal care, 33% for childbirth and 38% for postnatal care. In sub-districts without any HC, a more developed Community-based Health Planning and Services (CHPS) facility, a polyclinic or a district hospital may be the network's hub.

Recognizing the relatively new nature of the NOP approach, the Ghana Health Service would like to embed an implementation research (IR) program into the national scale-up, to learn from the scale-up, iterate, adapt, and improve the model as it spreads. IR outcomes of interest are: acceptability, adoption, appropriateness, feasibility, fidelity, cost, penetration, and sustainability.

Objectives

The aim of this implementation research is to evaluate the implementation process of the NoP programme in Ghana for the period 2023–2026 to provide critical data for scale-up and adaptation of the NoP program. Specifically, the study intends:

1. To explore the agreement and enabling environment of implementing the NoP programme.
2. To evaluate operational standards guiding the implementation of the NoP programme.
3. To evaluate the quality, efficiency and responsibility of implementing the NoP programme.
4. To identify the learning points and provide feedback for adaptation by the NoP programme.

Methodology

Study Site

The study is being conducted in some selected districts in all regions of Ghana. Ghana has been divided into 16 administrative regions and these are grouped into three geographical belts, with each led by the 3 research centres; the southern (DHRC), middle (KHRC) and northern (NHRC) belts. The southern belt is made up 6 regions (Western, Western North, Central, Gt. Accra, Volta, and Eastern Regions), the middle belt is made up 5 regions (Ashanti, Bono, Bono East, Ahafo, and, Oti), and finally, the Northern belt (Northern, Savannah, North East, Upper East, and Upper West) is also made up of 5 regions.

Study design and Sampling

This study is implementation research using a modified stepped wedge sampling technique to evaluate the scale-up of the NoP implementation programme in Ghana. It employs both quantitative and qualitative approaches, curating primary as well as secondary data.

Thirty-four (34) districts in all regions in Ghana will be purposively sampled and assessed by the end of the four-year period of the evaluation. These 34 districts may have an existing network or no network at the time of selection but will be potentially networked by the end of the evaluation period. In each region, two districts are sampled and included in the evaluation. An additional two districts, one piloted NoP each from Bono and Volta regions are purposively sampled and included as part of the networked districts as additional areas of evaluation since Volta and Bono regions have already established many networks.

Data collection

The evaluation is conducted every 6 months for a period of four years, from 2023 to 2026. The 6-monthly data collection is done in the same districts and facilities, in a longitudinal fashion, resulting in a panel of data for analysis at the end of the evaluation. Data is collected twice yearly over the entire period of the study for an Evidence Translation Firm to use to support the GHS in making decisions on program adaptations.

Expected Outcome

The expected outcome of this programme includes the acceptability, adoption, appropriateness, feasibility, fidelity, cost, penetration, and sustainability of the NOP.

Progress of Study Activities

The team have recruited and trained research assistants and have completed 2 rounds of data collection across the country.

Figure 1: NoP Training in Techiman for Field Staff

A Mixed-Method Study to Determine the Cause of Death in Stillbirths, Children Under Five, and Persons 60 Years and Above Using Minimal Invasive Tissue Sampling (MITS) and Verbal Autopsy (VA) in the Bono East Region of Ghana (Stillbirths, Children under-five and Adult Deaths Study. (SCADS)

Investigators

Dr Kwaku Poku Asante, Ms Grace Manu, Dr Samuel Ekow Harrison, Dr Dennis Adu-Gyasi, Dr Seyram Kaali, Dr Ernest Adjei, Mr. Charles Zandoh, Dr Abubakari Sulemana Watara.

Funder

Bill & Melinda Gates Foundation through the MITS Surveillance Alliance Secretariat, led by RTI International

Collaborators

Dr Abraham Oduro, Research and Development Division, Ghana Health Service, the Bono East Regional Health Directorate, ERNPHIL Laboratory Services Ltd- Kumasi.

Study Duration

Three (3) years

Start Date: July 2022

End Date: June 2025

Introduction

KHRC is conducting this SCADS study to evaluate the use of Minimal Invasive Tissue Sampling (MITS), a method that collects small tissue and fluid samples for laboratory analysis, to determine the cause of death. This procedure offers a cost-effective, less complex alternative to Complete Diagnostic Autopsy (CDA) while maintaining accuracy. The study aims to improve the quality of mortality data, which is essential for guiding health policies, enhancing healthcare services, and reducing deaths. By integrating MITS into the Kintampo Health and Demographic Surveillance System (KHDSS), the research seeks to address current challenges in cause-of-death determination and strengthen mortality surveillance programs in the Bono East Region of Ghana and beyond.

Background

Accurate cause of death (COD) data is critical to inform health policy, improve healthcare delivery and reduce mortality. Civil Registration and Vital Statistics (CRVS) systems are the primary administrative structures for continuously collecting mortality data (1). However, this remains a major challenge in many low- and middle-income countries (LMICs). Complete Diagnostic Autopsy (CDA) remains the appropriate option for determining the cause of death. But it is not fully utilized in most LMICs due to resource constraints and cultural reasons.

Verbal Autopsy (VA) has been the alternative method of determining cause of deaths in most LMICs. But this is also limited by lack of objective diagnostic information, recall bias and difficulty in distinguishing diseases with similar clinical presentations. Minimal Invasive Tissue Sampling (MITS) procedures involve extracting tissue specimens for histopathological, microbiological, and molecular analysis to support cause of death determination. It has been proven to have comparable accuracy to the CDA, yet less resource-intensive. However, there is limited evidence on how the MITS approach can be integrated into existing mortality surveillance programs.

Objectives

The main aim of this study is to strengthen the KHDSS mortality surveillance program by integrating MITS as a standard tool to improve cause of death determination and data quality.

Specific Objectives include:

1. To explore the feasibility of integrating MITS into the KHDSS to improve the determination of the cause of death.
2. To determine the accuracy of the clinician-determined cause of death using MITS as a reference
3. To test the validity of the VA cause of death using the MITS as a reference.
4. To determine the acceptability or otherwise of the MITS program in the study area.
5. To determine the cost-effectiveness of incorporating MITS into the KHDSS.
6. To produce MITS cause of death data in the study area that could be used as a reference for future studies or comparing similar MITS CoD data.

Methodology

The study is being conducted in the Kintampo North Municipal, Kintampo South District, Techiman South Municipal, and Techiman North District, all in the Bono East Region of Ghana. Both quantitative and qualitative methods of data collection are used.

Quantitative Data Collection: A total of 300 deceased persons (including stillbirths, under-fives, and adults 60 years and above) registered in the Kintampo Health and Demographic Surveillance System (KHDSS) are enrolled in the study. Tissues and fluid samples from the brain, liver, and other pre-defined organs are collected using biopsy needles for molecular, microbiological, and histopathological analyses. The samples are collected at the mortuary facilities of the Kintampo Municipal Hospital, the Jema District Hospital, and the Holy Family Hospital in Techiman. Available clinical histories are then extracted from hospital records of the deceased, and a verbal autopsy is conducted within three months of death. A panel of experts including a Pathologist, Pediatrician, Microbiologist, Family Health Physician and Epidemiologist to determine the cause of death based on laboratory results, clinical history, and VA open narratives.

Qualitative Data Collection: For the qualitative aspect of the study, Focus Group Discussions (FGDs) and In-depth Interviews (IDIs) will be conducted to determine the acceptability or otherwise of the MITS procedures. This will be done among opinion leaders and relatives of deceased persons. The study has ethical approval from the Institutional Ethics Committee of the Kintampo Health Research Centre and the Ghana Health Service Ethics Review Committee.

Expected Outcomes

By the end of the study, we aim to achieve the following outcomes:

1. Train lower-level health personnel, including non-clinical pathologists, to competently perform MITS procedures.
2. Successfully incorporate MITS into the mortality surveillance program of the KHDSS.
3. Generate accurate cause-of-death data through MITS to support health planning and improve service delivery.
4. Position KHRC as a key partner for collaboration and data sharing with other MITS sites (countries and institutions conducting the MITS study), to ultimately contribute to informed health policy decisions.

Progress of Study Activities

Recruitment for the study began in May 2023. As of November 30, 2024, a total of 139 MITS samples had been collected, comprising 100 adults, 19 children under five, and 20 stillbirths.

Quality Assurance

The MITS Quality Assurance Team, consisting of two pathologists and a microbiologist from Kenya, conducted a site visit to review the study procedures. They inspected the specimen collection sites (mortuaries) and the laboratories analyzing the samples; KHRC for molecular and microbiological tests and Ernphil Laboratory Services in Kumasi for histopathological analysis. The visit, led by Dr. Edwin Walong (Pathologist), took place from June 10 to 14, 2024.

Capacity Building

The following training activities were conducted to strengthen the capacity of the study team.

- A refresher training session for the MITS specimen collection team was held on February 16, 2024, at the Holy Family Hospital in Techiman. This training focused on ensuring high-quality sample collection for histology, microbiology, and molecular analysis required for the SCADS study. It was facilitated by Dr. Samuel Harrison, Mr. Jones Opoku Mensah (MITS Specialists), and Mr. Farid Boadu (Microbiologist).

- A specialist pathologist supporting the lead pathologist in MITS histopathological sample analysis participated in the MITS Laboratory Diagnostics Training in Kenya from September 16 to 20, 2024.

Conclusion

By successfully integrating MITS into our mortality surveillance data system, we aim to improve the accuracy of death records. This will provide better data for health research and policy-making, ultimately helping to save more lives.

Figure 1: MITS Quality Assurance Team visits KHRC

SETH OWUSU-AGYEI MEDICAL LABORATORY

Introduction

The Seth Owusu-Agyei Medical Laboratory (SOAML) generates quality laboratory results to support studies and research projects conducted at KHRC. The laboratory is made up of eight (8) specialized units, including Bacteriology, Clinical Chemistry, Entomology, Haematology, Immunology, Bio-Analytic (formerly Micronutrients), Molecular Biology, Virology, and Parasitology.

The SOAML has a team of 26 professionals, including 15 biomedical scientists, 7 medical laboratory technicians, and 4 laboratory assistants. It is equipped with advanced, state-of-the-art equipment to deliver high-quality testing and analysis of samples, to effectively support the diverse needs of the research Centre. The specific activities carried out by each unit are detailed below:

Bacteriology Unit

The Bacteriology Unit is equipped with a class II biosafety cabinet which is the main workstation, a carbon dioxide (CO2) incubator, two BACTEC 9050 machines for blood cultures and an autoclave. Samples processed include blood, cerebrospinal fluid (CSF), urine, nasopharyngeal swab, ear swab and stool. Culturing, identification and antimicrobial susceptibility testing are performed according to Clinical Laboratory Standard Institute (CLSI) guidelines.

To ensure that results generated from this unit are of high quality and are reliable, the unit participates in External Quality Assessments (EQAs) provided by the United Kingdom National External Quality Assessment Scheme (UK NEQAS). In addition to the participation in EQAs, daily, weekly and monthly internal quality controls on both equipment and reagents are performed to ensure they are all working effectively.

Figure 1: Seth Owusu-Agyei Medical Laboratory

Clinical Chemistry Unit

This unit is equipped with a Horiba Medical Pentra C200 automated clinical chemistry analyzer to carry out analyses including liver function tests, kidney function tests, lipid profile, glucose and uric acid. The equipment has the capacity to be programmed and used for quantitative estimation of other substances including G6PD activity, Urine protein and creatinine, etc. A stand-alone Electrolyte analyzer is also available for estimation of sodium, potassium and chloride in serum and urine samples. In addition to internal quality control systems, the unit is enrolled onto the External Quality Assessment (EQA) schemes organized by the College of American Pathologists (CAP).

Entomology Unit

The Entomology unit has played crucial roles in studies that collect insects of medical importance (such us mosquitoes and ticks) for speciation and classification as well as serological and molecular analysis. This unit is equipped with an ELISA plate reader, an automated plate washer, and a Stereo Dissecting Microscope. The unit is currently building an insectary to support testing of the efficacy of insecticides and other interventions.

Haematology Unit

The Unit is equipped with two Sysmex XN-330 one XN-350 analyzers for performing full blood count (FBC) analysis. It also has a Coagulometer for performing coagulation testing. Other tests performed in the unit include glucose-6-phosphate dehydrogenase (G6PD), blood grouping and haemoglobin genotyping. In addition to internal quality controls, the unit performs very well in EQAs organized by the CAP and UK NEQAS.

Figure 2: A medical laboratory technician performing a full blood count analysis with a Sysmex XN-330 one XN-350 analyzers

Immunology Unit

This unit has separate sections for cellular and humoral assays, with equipment such as a class II biosafety cabinet, refrigerated centrifuge and pipetting accessories. The unit is also equipped with a laminar flow cabinet, a carbon dioxide incubator, -80oC and -150oC freezers and liquid nitrogen tanks. Currently, isolation and cryopreservation of peripheral blood mononuclear cells (PBMCs) is being done. The unit plans to introduce flow cytometry, Luminex, and T-Cell ELISpot assays.

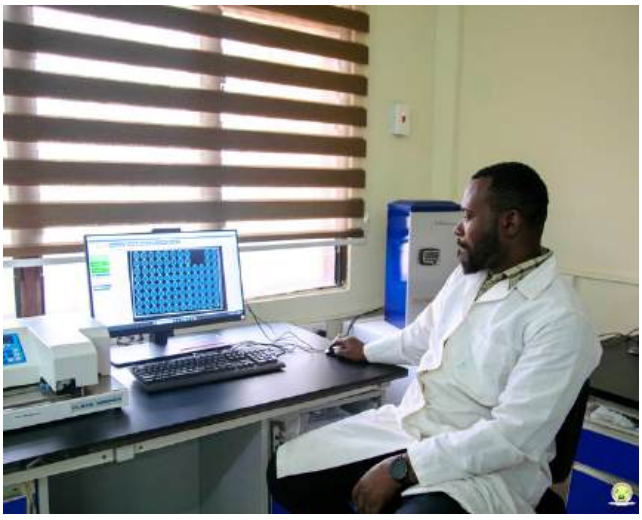


Figure 1: A biomedical scientist is using a Quansys machine to measure micronutrients of a study participant

Molecular Biology Unit

The Molecular Biology unit has two real-time PCR machines (Applied biosystems 7500 Fast Real Time PCR and AGS PCR machine). The unit also has a Cepheid GeneXpert (provided by the Ghana Health Service) for testing of tuberculosis (detection and drug resistance), trichomonas/Gonorrhoea, and COVID-19.

Figure 3: A medical laboratory technician is using the chemistry auto analyzer for organ function analysis in study participants

Figure 4: A biomedical scientist using a Roche Cobas analyzer for thyroid function analysis

The unit has also established protocols for bacterial and parasitological molecular analysis to enable the Centre to perform such analysis at the SOAML. This step will minimize the shipment of samples to external laboratories for analysis.

Bio-Analytic (Micronutrient) Unit

The unit has a High-Performance Liquid Chromatography (HPLC) machine with auto-sampling, UV Scanning Spectrophotometer for testing haemoglobin variants, glycated haemoglobin and serum retinol. The unit is also equipped with a Quansys machine to measure micronutrients, and a Zinc Protoporphyrin (ZPP) analyzer.

Parasitology Unit

This unit supports all studies that require malaria microscopy results and other blood borne infections. To ensure quality and accurate test results, each malaria blood smear is examined by two independent certified microscopists while discordant slides are examined by a third microscopist. The unit has more than 10 microscopes. The unit participates in EQAs provided by CAP, Swiss Tropical and Public Health Institute, and IQLS.

Quality Assurance

The SOAML adheres to Good Clinical Laboratory (GCLP) and ISO 15189:2012 Standards. The Clinical Laboratory undergoes periodic assessments by study sponsors and regulatory inspections by the Foods and Drugs Authority, Ghana.

Capacity Building

The SOAML prioritizes staff development. This year, six (6) microscopists from the Parasitology Unit attended a one-week microscopy training organized by Novartis, in Kintampo from the 25th to 29th March, 202. The Parasitology Unit also conducted a one-week microscopy training for 11 participants from Atebubu Municipal Hospital, Sene West District Hospital, Matthias Hospital, Parambo Health Centre, Nyamoase CHPS, Garadima CHPS, Fakwasi CHPS, and Oil Mills Centre. The training was held from 20th to 25th May 2024.

Support Services

The Seth Owusu-Agyei Medical Laboratory continues to offer technical support to laboratories across the Bono East Region. Specifically, the clinical laboratory has assisted the Kintampo Municipal Hospital, Kintampo South District Hospital in Jema, Atebubu Municipal Hospital, St. Theresa's Hospital in Nkoranza, and Holy Family Hospital in Techiman in establishing and maintaining robust Quality Assurance systems. It facilitated the registration of the Atebubu Municipal Hospital, Holy Family Hospital in Techiman, and Kintampo Municipal Hospital onto the UK NEQAS scheme for full blood count analysis.

The SOAML also supports the children's ward at Kintampo Municipal Hospital by processing patient samples and provides testing assistance to health facilities within the Bono East Region during outbreaks of meningitis, typhoid, and cholera.

Figure 5: Laboratory Training For Lab scientists from five health facilities in the Bono East Region

Figure 6: Group Photo of SOAML Team and the training participants

KINTAMPO HEALTH AND DEMOGRAPHIC SURVEILLANCE SYSTEM (KHDSS)

Introduction

The The Kintampo Health and Demographic Surveillance System (KHDSS) monitors the health and demographic dynamics of six administrative districts within the Bono East Region of Ghana in 2024. These were categorized into three (3) Health and Demographic Surveillance System (HDSS) sites for data and field management purposes and included the Kintampo site (Kintampo North Municipal and Kintampo South District), Techiman site (Techiman South Municipal and Techiman North District), and the Nkoranza site (Nkoranza South Municipal and Nkoranza North District). The KHDSS operations are limited to communities with all-year-round accessibility. A total of 342 communities with 81,460 active compounds, and 118,471 active households were covered in 2024. This represents about 83% of the administrative population across the Six districts.

Objectives

The primary aim of the HDSS is to accurately record the health and demographic details of the population within its coverage area. This data serves as a foundational resource for guiding future research, creating a sampling framework for selecting participants for surveys, clinical trials, and other studies conducted by the Centre.

Field Activities

This year, two update rounds were conducted. Each round captured core demographic events, including births, deaths, migrations, and pregnancies that occurred since the previous round. Newly identified individuals, households, and compounds were also registered in the system. Additionally, updates were made to individuals' educational levels and the socio-economic profiles of all households. To determine causes of death, trained field workers conducted Verbal Post-Mortems (VPMs) using the WHO 2022 verbal autopsy questionnaire.

Add-on Modules

A new module on smartphone access and usage, introduced in October 2023, was successfully completed in June 2024. The main purpose was to determine smartphone usage patterns among a cross-section of the Kintampo HDSS population. The unit plans to introduce additional modules focusing on One Health in the coming year.

Data Collection and Management

Data was collected electronically and managed using an in-house developed software application during the year under review.

Closure of the Techiman/Nkoranza HDSS Sites

The HDSS activities in the Techiman and Nkoranza sites were implemented to support the malaria studies conducted in these areas. However, with the conclusion of the studies, operations at these HDSS sites ended in June 2024.

Demographic Characteristics of the Kintampo HDSS

The total resident population of the HDSS as of June 30, 2024, was 563,139 across the three sites, with 52.9% of the population being females. Children under five constituted 11.0% of the total population. The Kintampo HDSS area is gradually becoming urbanized with 52.9% of the population living in urban areas, with an average household size of 4.8. Across the three sites, a total of 4,494 births and 1,053 deaths, including 103 under-five deaths, were recorded in 2024. Verbal Autopsies were completed for 83.5% (879/1,053) of all deaths that occurred in the year. A summary of key descriptive characteristics of the KHDSS is provided in the table below.

Table 1: Descriptive Characteristics of the Kintampo HDSS by Site

Descriptive Characteristics	Kintampo as of December 5, 2024	Nkoranza as of June 30, 2024	Techiman as of June 30, 2024	Total as of June 30, 2024
Total Population (N, %)	200,702 (35.6)	12,7191 (22.6)	235,246 (41.8)	563,139 (100)
Male Population (n, %)	96,575 (48.1)	59,948 (47.1)	108,922 (46.3)	265,445 (47.1)
Female Population (n, %)	104,127 (51.9)	67,243 (52.9)	126,324 (53.7)	297,694 (52.9)
Under-five Population (n, %)	25,872 (12.9)	12,807 (10.1)	23,408 (10.0)	62,087 (11.0)
Rural Population (n, %) *	107418 (53.5)	79,748 (62.7)	78,345 (33.3)	265,511 (47.1)
Urban Population (n, %) *	93284 (46.5)	47,443 (37.3)	156,901 (66.7)	297,628 (52.9)
Number of Communities Covered	159	98	85	342
Number of Active Compounds	28,326	20,590	32,544	81,460
Number of Active Households	39,179	26,516	52,776	118,471
Average Household size	5.1	4.8	4.5	4.8
Number of Births Recorded	3,092	471	931	4,494
Total Number of Deaths	621	137	295	1,053
Number of Under-Five Deaths	79	7	17	103
Verbal Autopsies (VAs)	438	137	304	879
2023 Records of Births and Deaths by Site				
Number of Births Recorded	5,692	2,666	4,714	13,072
Total Number of Deaths	1,075	581	954	2,610
Number of Under-Five Deaths	152	44	75	271

NB: *Rural and Urban populations are classified based on the population size of an area, Areas with a population of less than 5,000 are classified as rural while areas with a population of 5,000 or more are classified as urban.

Staff

The KHDSS unit is led by the Director of KHRC and a Principal Research Fellow. During the first half of 2024, the unit had a total of 81 staff members, including 9 senior staff (4 Research Fellows, 2 Research Officers, 2 Data Managers, and 1 National Service person) and 72 junior staff (7 Field Supervisors and 65 Field Workers). However, following the completion of malaria studies and the closure of the Techiman and Nkoranza sites, the staff strength was reduced to 37, with 27 junior staff.

Staff Development

Two members of the unit participated in a stakeholder engagement workshop on developing a Sample Mortality Surveillance System for Ghana. The event, organized by the Ministry of Health with support from USAID, was held on April 25, 2024, in Koforidua in the Eastern Region. During the workshop, a presentation was delivered on death registration and determining causes of death using Verbal Autopsy (VA) and Minimal Invasive Tissue Sampling (MITS). Also, two field workers were enrolled in Diploma programs with support from KHRC.

Contact Persons

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Introduction

The Data Science Department at Kintampo Health Research Centre oversees the design and management of data collection systems, ensuring accuracy and consistency in data entry, verification, cleaning, and analysis of data. It develops comprehensive database management applications for both paper-based and digital data collection systems, generates essential project statistics, and maintains regular data backups to guarantee reliability.

In addition to data processing, the department manages the Centre's ICT infrastructure, providing robust and cost-effective systems to align with operational processes. The department also handles the secure storage and retrieval of case report forms, using best practices to maintain confidentiality and facilitate efficient access to stored data.

The Data Science Department comprises three integrated units: Information Technology, Data Management, and Biostatistics. Together, these teams are dedicated to developing advanced solutions that enhance data collection, streamline workflows, and improve the overall efficiency of the Centre's research initiatives.

The Biostatistics Unit

The biostatistics unit plays a vital role in the data processing value chain. It analyzes complex health findings from research studies conducted by the Centre. The unit's primary goal is to support the design, analysis, interpretation, and conclusion of research through advanced computer applications and strategies. The unit uses various statistical tools, including STATA, R, SPSS, Python, etc., to conduct its analyses. The unit also supports national health initiatives, analyzes demographic and health data, and assists Ghana Health Service staff with statistical analysis, contributing to better health outcomes in Ghana and beyond.

Data Collection and Processing

The Data Science Department has continued to expand its use of innovative technologies for efficient data collection, processing, and analysis. Building on existing systems, the department introduced several customized tools over the past year, including:

ADVANCE Mobile Application: This app was developed to enhance communication between healthcare providers and pregnant women, improving pregnancy monitoring and facilitating communication in low-resource settings.

MALVAC Listings Application: This is a web-based application designed to help fieldworkers access the follow-up visit schedules for study participants, streamlining the coordination of study activities.

ARCHIVE Application: Developed to modernize the Centre's archiving processes, this tool digitizes paper documents, transforming them into organized digital files that enhance efficiency, accessibility, and sustainability.

Staff Development

The department has a staff strength of 42 comprising biostatisticians, data managers, IT managers, data supervisors and data entry clerks. The department places a strong emphasis on staff development, recognizing it as a cornerstone for sustained growth and adaptability. Key achievements this year include:

Education and Professional Growth: Four Data Entry Clerks have enrolled in diploma programs. Similarly, two Data Supervisors have also enrolled in diploma programs, aiming to strengthen their technical expertise and supervisory capabilities. In addition to these enrollments, two Data Managers have successfully completed MSc programs. Furthermore, two staff members are progressing towards the completion of their PhDs.

Also, the Head of Biostatistics Unit participated in a short course on Advanced Epidemiological Analysis at the London School of Hygiene and Tropical Medicine from September 9-20, 2024. The course provided in-depth training on a range of statistical methods and study designs, emphasizing their real-world applications.

Knowledge Transfer: Data Supervisors have received training in developing data entry forms using REDCap, significantly enhancing their data management skills.

ICT Infrastructure

The department continues to innovate and expand its technological infrastructure, with key additions including:

Hyperfine MRI Scanner and Flywheel Platform: A portable, low-field imaging system that enables high-quality neuroimaging data collection, supported by Flywheel, a data management platform designed for biomedical research.

Nsroma GPS Tracker: Enhances real-time monitoring and navigation for field teams, improving data accuracy and coordination, especially in geographically distributed studies.

Hikvision Facial Recognition Device: This device utilizes AI-driven technology and high-resolution cameras for biometric security, aiding in access control and attendance tracking.

Software Server: An Ubuntu Server dedicated to software testing and integration, optimizing resource use while ensuring reliable performance for developing, testing, and deploying applications.

Data Capture Tools: The department developed several in-house applications to support data collection:

1.ANTPOST: This application facilitates near-real-time data collection on pregnant women, from pregnancy to one year post-delivery.

2.HDSS CAPTURE: This application is used by the Health and Demographic Surveillance System (HDSS) team, this application includes advanced search functions and summary reporting features.

3.ADVANCE: This is a mobile application that improves communication between healthcare providers and pregnant women.

Conclusion

Throughout 2024, the Data Science Department has demonstrated resilience, adaptability, and a commitment to excellence. From significant infrastructure enhancements and staff development initiatives to the adoption of innovative digital solutions, the department remains well-prepared to support the research goals of KHRC in the years to come.

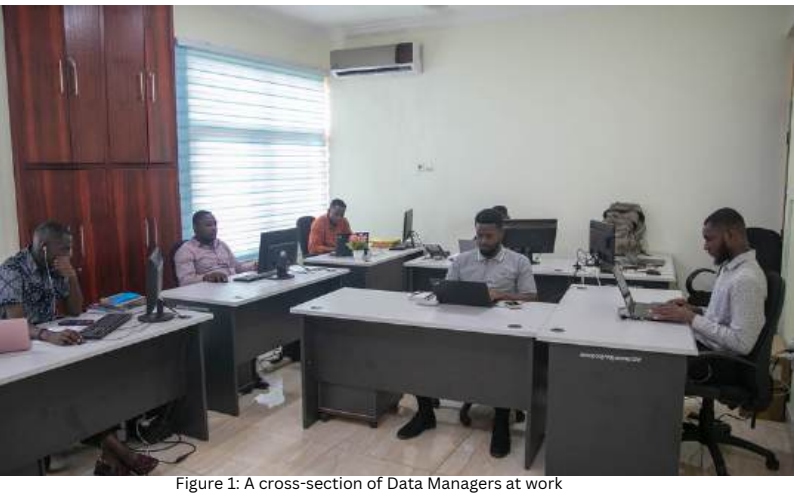

Figure 1: A cross-section of Data Managers at work

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Introduction

The Administration Department is responsible for managing the Centre's overall administrative operations. The department consists of multiple specialized units, all coordinated under the leadership of the Director.

Office of the Administrator oversees daily administrative functions. Human Resources Office manages staffing, employee welfare, and development.

The Accounts Unit handles financial management and reporting while Procurement and Transport Unit facilitates the acquisition of goods and services and oversees the Centre's transport operations.

Stores Unit manages inventory and supply chain logistics. The Communications Unit coordinates internal and external communication strategies, and the office of Ethics Administration ensures compliance with ethical standards in all Centre activities.

Together, these units work collaboratively to support KHRC's mission by ensuring efficient administrative systems and processes.

Study Areas

The Centre continued its operations across five contiguous districts in the Bono East and Bono regions: Kintampo North, Techiman South Municipal, Techiman North District, Kintampo South, and Atebubu Amantin Municipal, as well as Yeji in the Pru East. Kintampo North municipality serves as the Headquarters.

The Centre also maintained connections with the Afrancho, Akumadan, and Nkenkesu communities in the Ashanti Region and extended its operations into the Oti, Volta, and Central regions.

Staff Capacity

In 2024, KHRC recorded a total staff strength of 493, actively engaged across various projects. To strengthen its attractiveness to partners, the Centre has implemented a robust Health and Demographic Surveillance System (KHDSS) that supports all ongoing research initiatives. Furthermore, KHRC maintains a comprehensive database to assist potential collaborators to make well-informed decisions about research activities. The KHDSS currently employs 35 staff members.

Guest House

The KHRC guest house offers comfortable and secure accommodations for visitors, conveniently located just a 15-minute walk from the Centre. It features 24-hour security, air-conditioned rooms with ceiling fans, and round-the-clock Internet access. To ensure a restful stay, all rooms are equipped with mosquito nets.

The nightly accommodation rate is $50, with meals available at $5 for breakfast and $7 for lunch and dinner. A standby generator ensures uninterrupted power supply during national grid outages. The guest house hosted 132 visitors this year.

Audit

To ensure the prudent use and proper accounting of funds provided by donors and funders, the Centre hosted the Ghana Audit Service and Price Waterhouse Coopers Ghana in 2024.

Transport

The Centre's vehicles include seven 4x4 pickups, one Tata truck, four troopers, four trooper carriers, two Land Cruiser 100 vehicles, two Prados, and one welfare bus.

Visitors

The Centre was privileged to host important personalities from Ghana and abroad this year.

Website

KHRC's website (www.kintampo-hrc.org) serves as a platform that provides information about the Centre's activities, projects, studies and impacts. It acts as a central hub for sharing news, updates, research findings, upcoming events, and other relevant resources. The website enhances visibility, and offers easy access to important information for visitors, funders, collaborators and the general public.

"The Pentagon"

This is the staff dining area where breakfast, lunch, and dinner can be arranged at the Pentagon. Special meal requests can also be accommodated and served either at the Pentagon or at the guest house, depending on the visitor's preference.

Ethics Unit (KHRCIEC)

The Kintampo Health Research Centre Institutional Ethics Committee (KHRCIEC) is an independent body responsible for reviewing, evaluating, and making decisions on the ethical merits of research protocols. The Committee ensures that the rights, safety, and well-being of study participants and communities under its jurisdiction are protected. It is authorised to grant full approval, conditional approval, request resubmissions, or reject research proposals.

The Committee currently has 16 members, including KHRC staff (two social scientists, a reproductive health expert, a biomedical scientist, and a clinician), three community representatives, a civic educationist, a nurse, two clinicians, and another biomedical scientist. The KHRC Director and the two Administrators serve as non-voting members in decision-making on research proposals.

Activities of the Unit

In 2024, the Committee convened 10 full board meetings and reviewed 36 new research proposals. One (1) proposal was exempt from review while the other 35 proposals underwent full review. Out of this number, two (2) received full approval after the initial review and 33 were granted conditional approval, with 28 subsequently receiving full approval.

Breakdown of Reviewed Proposals

23 proposals came from KHRC (6 Clinical trials, 3 PhD and 2 Master's students and 12 biomedical and social science studies). We also received 12 External submissions (11 Student projects: 3 PhD, 9 Master's and 1 Independent researcher. For Continuing Review Activities, we have recieved and approved 14 Study amendments and submitted 20 Progress reports.

Capacity Development

The Unit conducted a two-day training workshop from October 8-9, to strengthen the capacity of the IEC to ensure the ethical conduct of research involving human participants.

Contact Persons
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Figure 1: Group Picture of Ethics Committee Members

Figure 2: IEC Training on Protecting Human Participants in Research

OUR COLLABORATORS/FUNDERS

The Kintampo Health Research Centre (KHRC) has maintained its working relationship with a number of local and internation organizations. This year, the Centre has gained new funders and collaborators to help advance our course towards improving health outcomes locally and globally. We appreciate our collaborations and the support we receive to advance our work. The Centre collaborated with the following institutions.

Internal Collaborators/Funders
Agogo Malaria Centre
Dodowa Health Research Centre (DHRC)
Ghana Health Service
Kumasi Centre for Collaborative Research in Tropical Medicine (KCCR)
Kwame Nkrumah University of Science and Technology
National Malaria Control Programme (NMCP) in Ghana
Navrongo Health Research Centre (NHRC)
Newmont Ghana Gold Limited
Noguchi Memorial Institute for Medical Research (NMIMR)
University of Energy and Natural Resources (UENR) and Other Local Universities
University of Ghana (UG)
University of Cape Coast (UCC)
University of Health and Allied Sciences (UHAS)
UNICEF Ghana

Table 1: List of KHRC's Internal Funders and Collaborators

Our Collaborators/Funders Cont.

External Collaborators/Funders	
African Research Collaboration for Health Limited	Massachusetts General Hospital
Barcelona Institute for Global Health (ISGLOBAL)	National Institute for Health and Care Research (NIHR)-UK
Bill and Melinda Gate Foundation (BMGF)	National Institute of Health (NIH)
Brown University	Novartis Pharma AG/Quintiles Clindepharm (Pty)
Columbia University, NY	Oxford Vaccine Group
Columbia World Projects	President's Malaria Initiative (“PMI”)
European and Developing Clinical Trial Partnership (EDCTP)	Program for Appropriate Technology in Health (PATH)
European Commission	Radboud University Medical Center, Netherlands
European Vaccine Initiative (EVI)	Research Triangle Institute (RTI International)
Fogarty International Center	Sanofi Pasteur Inc
Forma Therapeutics, Inc	The David and Lucile Packard Foundation
George Town University	The International Vaccine Institute (IVI)
George Washington University (GWU)	The Liverpool School of Tropical Medicine
GlaxoSmithKline Biologicals S.A. (GSK)	The Wellcome Trust Limited
Harvard’s Beth Israel Deaconess Medical Center, Boston	United Nations Foundation
Icahn School of Medicine at Mount Sinai	University of Malawi, College of Medicine
Kenya Medical Research Institute (KEMRI)	University of Massachusetts
London School of Hygiene and Tropical Medicine (LSHTM)	World Health Organisation (WHO)
Malawi University of Science and Technology (MUST)	Zero Point Five (ZP5) Therapeutics, USA

Table 2: List of KHRC’s External Funders and Collaborators

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