ANNUAL REPORT

2023

Kintampo Health Research Centre

Contact us

Postal Address:
Kintampo Health Research Centre
Post Office Box 200, Kintampo
Bono East Region, Ghana
West Africa

Digital Address: BK-00006-2937

Telephone number(s):
Administrative and general enquiries:+233 (0) 35 209 2038
Ethics/protocol submission enquiries:+233 (0) 50 427 0501

Our Website Address: www.kintampo-hrc.org
For enquiries contact us through: enquiries@kintampo-hrc.org
For questions on Ethics, approvals contact us through: iec.sec@kintampo-hrc.org

Connect with us through the following social media platforms:
- https://facebook.com/Kintampohrc
- https://twitter.com/KhrcGhana
- https://www.linkedin.com/company/kintampo-health-research-centre-khrc/

Table of Contents

Table of Contents

Table of Contents

Acronyms/Abbreviations

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
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

Acronyms/Abbreviations

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
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
	Severe Acute Respiratory Infections
SARS-CoV-2	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

Mission, Vision, Core Values and Guiding Principles

MISSION

Use our expertise and core values to:

• 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.

VISION

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

CORE VALUES

• Team work
• Excellence
• Collaboration
• Capacity development
• 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.

MALARIA INTERVENTIONS AND RESEARCH ACTIVITIES

Epidemiology study of malaria transmission intensity in sub-Saharan Africa

Investigators

Dr. Kwaku Poku Asante, Prof. Seth Owusu-Agyei, Dr. Seyram Kaali, Mr. Owusu Boahen, Dr. Samuel Ekow Harrison, Dr. Prince Agyapong Darko.

Funder:

GlaxoSmithKline Biologicals

Study duration:

10 years

Project start date:

20th August, 2014

Project end date:

3rd June, 2024

Background

This epidemiology study (EPI-MAL-005) is planned to run in parallel with two conservative safety monitoring vaccine studies (EPI-MAL-002 and EPI-MAL-003) which will monitor incidence rate of protocol defined adverse events of specific interest (AESI) and non-communicable and traumatic serious adverse events (NC/NT-SAE).

It is a multi-centric, epidemiology longitudinal cross-sectional study at centres in Sub-Saharan Africa that are participating in GSK's EPI-MAL-002 and EPI-MAL-003 studies. This study will involve up to 10 annual cross sectional surveys during malaria peak transmission.

Objectives

- To obtain longitudinal estimates of P. falciparum parasite prevalence in order to characterise malaria transmission intensity in a standardised way at centres conducting the EPI-MAL-002 and EPI-MAL-003 studies before and after the introduction of the malaria vaccine RTS,S/AS01E in sub-Saharan Africa.

- To obtain longitudinal estimates of the use of malaria control interventions in centres conducting the EPI-MAL- 002 and EPI-MAL-003 studies before and after the introduction of the malaria vaccine RTS,S/AS01E in sub- Saharan Africa.

Methodology

A multi-centric, epidemiology longitudinal cross-sectional study at centres in Sub-Saharan Africa that are participating in GSK's EPI-MAL-002 and EPI-MAL-003 studies.

This study would involve up to 10 annual cross-sectional surveys during malaria peak transmission. There would be no study vaccine administered in this epidemiology study. Subjects 6 months to <10 years of age are involved in the study. All medications that may influence malaria parasitemia within 14 days prior to each survey are being recorded. Axillary body temperature of all subjects at the time of the survey are being recorded. A capillary blood sample are being obtained for evaluation of malaria infection by blood slide and Nucleic Acid Amplification Test (NAAT).

In the event of measured fever at the time of the visit (axillary temperature ≥37.5°C) or fever reported in the last 24 hours or other symptoms/signs of clinical malaria, a rapid diagnostic test (RDT) will be conducted. If the RDT is positive, treatment will be given according to National guidelines. Should a subject for whom no RDT was required is identified as being parasite positive following microscopy, National guidelines should be followed for clinical management of the subject.

Microscopy and NAAT are been used to evaluate the level of asexual and sexual parasitaemia. Serious adverse events (SAEs) associated with the study procedure (capillary blood sampling) are also being collected.

Expected outcomes

To obtain longitudinal estimates of P. falciparum parasite prevalence in order to characterise malaria transmission intensity in a standardised way at centres conducting the EPI-MAL-002 and EPI-MAL-003 studies and also longitudinal estimates of the use of malaria control interventions in centres conducting the EPI-MAL- 002 and EPI-MAL-003 before and after the introduction of the malaria vaccine RTS,S/AS01E in sub-Saharan Africa.

Progress

The study went well. The study team had conducted 10 annual surveys. A total of 9,000 participants aged between 6 months to < 10 years participated in the surveys.

Publication: Estimating Annual Fluctuations in Malaria Transmission Intensity and in the use of Malaria Control Interventions in Five Sub-Sahara Africa Countries Am. J. Trop. Hyg., 2020

The Impact of a Combination of the RtS,S/As01e Malaria Vaccine and Perennial Malaria Chemoprevention In Ghanaian Children

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

Funder:

PATH

Collaborators:

Ghana Health Service

PMI

Project start date:

October, 2023

Project end date:

October, 2027

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

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.

Methodology

This will be an individually randomized, double-blind, placebo controlled trial 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 will 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 will be 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

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

The team received ethical approval from KHRC Institutional Review Committee and Ghana Health Service Ethics Review Committee prior to the start of the study. KHRC Institutional Review Committee, Ghana Health Service Ethics Review Committee, LSHTM Ethics Review Committee and Food and Drugs Authority issued approval certificates on 20 Jul 2023, 8 Aug 2023, 10 Jul 2023 and 15 Sep 2023 respectively.

The first participant was enrolled on 12 October 2023. Enrollment and follow up of participants are ongoing.

Acceptability and potential implementation feasibility of malaria vaccination combined with perennial malaria chemoprevention

Investigators

Principal 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:

GiveWell, California, USA

Collaborators:

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

Project start date:

March 2024

Project end date:

February 2026

Study duration:

24 months

Background

The burden of malaria in children in sub-Saharan Africa is still. Many countries are currently, or will shortly consider, deploying perennial malaria chemoprevention (PMC) and/or malaria vaccination, but there is no empirical evidence to support the combination of these interventions. The RTS,S/AS01E malaria vaccine and PMC (MalVac-PMC) trial which started in 2023 in Ghana is investigating the potential benefits of combining PMC using either SP or SPAQ with the RTS,S/AS01E vaccine. This is the first time that the combination of RTS,S/AS01E and PMC, both delivered to children up to two years of age via the essential programme on immunisation (EPI), is being considered.

Objectives

The Social Science study aims to determine the acceptability and potential implementation feasibility of combining malaria vaccination with PMC among health providers responsible for delivering these interventions, and the communities receiving them. This sub-study fits within the overall framework of MalVac-PMC trial that is being conducted by the Kintampo Health Research Centre and London School of Hygiene and Tropical Medicine.

Methodology

This will be a mixed methods study with two components. First, in-depth interviews and focus groups discussions will be conducted among caregivers of children receiving the interventions, and health workers and managers delivering them to assess acceptability, the contextual factors influencing the acceptability of giving PMC alongside RTS,S, and the feasibility of delivering the combined intervention through the routine health system.The qualitative data will be collected in two rounds to capture perceptions both when children are receiving the initial doses of malaria vaccine and PMC-SP/SPAQ/placebo in infancy, and when children are receiving the later doses in the second year of life. Second, findings from the qualitative study will be used to design a discrete choice experiment (DCE) to quantify the preferences of health workers for either RTS,S/AS01E vaccination alone, or RTS,S/AS01E with PMC-SP or PMC-SPAQ, and their schedules and delivery within the EPI.

Expected Outcome

The study will generate 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.

Development of a First Generation Malaria Vaccine Research Agenda

Investigators

Kintampo Health Research Centre, Ghana: Kwaku Poku Asante, Thomas Gyan, Samuel Afari-Asiedu, Abraham Hodgson, Cornelius Depuur

Funder:

PATH, USA

Collaborators:

PATH, USA: Samantha Herrera, Megan Littrell, Maia Cullen, Annie Arnzen, Kim Vu

Project start date:

13 March, 2023

Project end date:

28 February, 2024

Background

In 2021, the RTS,S/AS01 (RTS,S) malaria vaccine was recommended by WHO for use in children living in regions with moderate to high transmission of malaria caused by Plasmodium falciparum. The recommendation was based on findings from clinical trial and pilot implementation of RTS,S in Ghana, Kenya, and Malawi through the Malaria Vaccine Implementation Program (MVIP). WHO, Gavi, and the Malaria Vaccine Coordination team identified the need to develop a malaria vaccine research agenda that will inform program design, implementation, and optimization for the broader rollout of the vaccine.

The agenda built on research and learnings from the MVIP which generated evidence on the safety and impact of the vaccine, operational feasibility, acceptability, and the economics of vaccine implementation. PATH in collaboration with the U.S. President's Malaria Initiative (PMI) Insights project and the Kintampo Health Research Centre, co-led the process to develop the research agenda, in coordination with WHO, Gavi, and the project's Technical Advisory Committee. The main objective of the project is to develop a research agenda that identifies and addresses key operational challenges or knowledge gaps about the design, implementation, and optimization of the rollout and scale up of the malaria vaccine. The research agenda focuses on Gavi-eligible countries with moderate to high transmission of P. falciparum malaria in sub-Saharan Africa.

Methodology

The process for developing the research agenda used mixed methods approach consisting of document review and stakeholder consultations in five-step process. First, ten (10) member technical advisory committee was constituted to support the development of the research agenda. Second, over 50 documents were reviewed to identify relevant research questions that have been explored through completed or ongoing studies and research gaps identified in literature. Twenty key informant interviews (KII) were conducted with stakeholders in government, and research institutions as well as with Global and regional bodies. Fifty five (55), Civil Society Organization (CSO) members were consulted through online survey.

Subsequently, data were synthesized and organized across the seven thematic areas including (1) implementation feasibility, (2) acceptability of, and demand creation for the vaccine, (3) safety, (4) equitable coverage, (5) synergies and antagonisms of the malaria vaccine with other health or malaria interventions, (6) economics and cost-effectiveness of the vaccine, and (7) the impact or effectiveness of the vaccine. Lastly, online survey was used by stakeholders to rank identified research topics across the thematic areas based on the broad relevance of topic across country settings, urgency of the topic for informing vaccine introduction and scale-up, and feasibility of undertaking a research study to address the topic.

Findings

The main findings were summarized under three central themes covered in the stakeholder consultations including 1) operational challenges and barriers for the rollout of the vaccines, 2) evidence gaps identified and 3) prioritized research topics identified. Key operational challenges include difficulties with delivering additional doses outside routine EPI schedules, promoting vaccine acceptance and uptake by countering hesitancy and building advocacy to sustain other malaria interventions, and improving systems to monitor adverse events, waning immunity and malaria rebounds over time.

Knowledge gaps identified highlight the need for better understanding and guidance for how to target and deploy the vaccine sub-nationally, how best to leverage partnerships and other sectors to support the delivery of the vaccine, strategic communication and community engagement, effective strategies for delivering the vaccine in hard-to-reach areas, and information gaps related to safety of the vaccine in vulnerable populations, how to ensure surveillance systems can be strengthened to be able to monitor vaccine effectiveness over time, and how missed doses or delayed delivery of the vaccine impacts the overall effectiveness of the vaccine. A total of 32 research topics were identified and ranked across the seven thematic areas.

Conclusion

This project is developing a research agenda with priority research topics to address key operational barriers and knowledge gaps for the design, implementation, effective rollout and scale up of the RTS,S malaria vaccine in Africa. The final agenda is intended to serve as a global resource that can help facilitate a more coordinated and efficient approach to address the identified research priority areas.

A prospective study to evaluate the safety, effectiveness and impact of the RTS,S/AS01E 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

Funder:

GlaxoSmithKline (GSK) Biologicals S.A.

Study duration:

5 years

Project start date:

21st March, 2019

Project end date:

14th July, 2024

Background

GSK Biologicals has developed Plasmodium (P.) falciparum malaria vaccine, RTS,S/AS01E, for routine immunisation of children living in malaria-endemic countries of Sub Sahara Africa. RTS,S/AS01E is the first vaccine implemented for the prevention of malaria and is the first malaria vaccine implemented in the paediatric population.

Objectives

- To estimate the incidence of AESI's, and of other AE's leading to hospitalisation or death, in children vaccinated with RTS,S/AS01E.
- To estimate the incidence of aetiology-confirmed meningitis in children vaccinated with RTS,S/AS01E.

Methodology

Approximately 45,000 children have been recruited within the collaborating study site into the active surveillance. These participants are being actively followed up through home visits and through continuous monitoring of outpatient visits and hospitalizations 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 Outcome

To estimate the incidence of Adverse Events of Specific Interest, and of other Adverse Events leading to hospitalisation or death, and an etiology confirmed meningitis in children vaccinated with RTS, S/AS01E.

Progress so far

The study is going on well. In all, twelve thousand (12,000) children have been enrolled into the active surveillance arm of the study by the Kintampo Health Research Centre. In the Enhanced hospitalization cohort of the study, the Kintampo Health Research Centre (KHRC) has enrolled a total of nineteen thousand, six hundred and seventy-two (19,672) children into the study. The enrolment into the enhance hospitalization cohort for the unexposed cluster ended 31st October, 2022 due to end of pilot RTSS vaccine implementation program.

Figure 1: A picture of clinicians at work

An evaluation of the cluster-randomised pilot implementation of RTS,S/AS01 through routine health systems in Ghana: A Post-Authorization Observation Study
(Malaria Vaccine Pilot Evaluation (MVPE)

Investigators

Dr. Kwaku Poku Asante, Dr Abraham Oduro, Prof. Col. Edwin Andrews Afari (rtd), Prof. Tsiri Agbenyega, Prof. Daniel Ansong, Dr Thomas Gyan, Prof. Fred Binka, Prof. Kwadwo Koram, Dr. Abraham Hodgson

Funder:

World Health Organization (WHO)

Collaborators:

Ministry of Health, Ghana Health Service, World Health Organisation (WHO)

Project start date:

27th October, 2018

Project end date:

30th June, 2024

Study duration:

5 years 6 months

Background

The RTS,S/AS01 malaria vaccine was introduced sub-nationally in phased pilot introductions through the routine health system in Ghana. Kenya and Malawi are also participating in the programme. The Ministry of Health and Ghana Health Service introduced the vaccine introduction in selected districts randomly assigned to receive the vaccine at the beginning of the pilots. In the context of this programmatic activity, the Malaria Vaccine Pilot Evaluation (MVPE) is observational evaluations during early vaccine introduction, include a series of 3 household surveys, and sentinel hospital and community mortality surveillance, building on routine systems.

Objectives

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

1. The programmatic feasibility of delivering a 4 dose schedule

2. Safety in routine use, with focus on cerebral malaria and meningitis;

3. The impact of the malaria vaccine in routine use on severe malaria and all-cause mortality

Methodology

This is an observational evaluation of the pilot implementation of RTS,S/AS01 by the Ministry of Health/Ghana Health Service using a cluster-randomized design, with some areas (Districts) introducing RTS,S/AS01 malaria vaccine at the beginning of the programme (vaccinating areas) and other areas, initially without RTS,S/AS01, acting as comparison areas (non-vaccinating areas). Participants for study includes children living in the vaccinating and in non-vaccinating areas aged 1-59 months (Feasibility survey), who are hospitalized in 8 sentinel hospitals (sentinel hospital surveillance) and those whose deaths are reported in the vaccinating and in non-vaccinating areas (community mortality surveillance).

Key findings

During the first 4 years of RTS,S implementation in the pilot countries, there was a substantial impact on all-cause mortality and on the incidence of hospital admission with severe malaria in eligible age groups of children:

- 13% (95%CI 2%-22%) reduction in all cause deaths excluding deaths due to injury

- 22% (95%CI 6%-37%) reduction in incidence of hospital admission with severe malaria

This impact was achieved in the context of relatively high coverage of the three primary doses (63% to 75% in final surveys) and despite suboptimal uptake of dose 4 (33% to 53%). Safety data further strengthens the evidence on safety reviewed by WHO in 2021.

Expected outcomes

- The number of deaths of any cause
- Number of children admitted with a diagnosis of probable and confirmed meningitis cases.
- Number of children admitted with a diagnosis of cerebral malaria
- Number of children aged 12-23 months who have completed the primary series (the 3-dose regime) of the malaria vaccine
- Number of children aged 27-38 months who have completed the 4th dose of the malaria vaccine

Progress

- Completed analysis of the month 46 data.
- Dissemination of the month 46 results planned for the next coming weeks across Ghana and internationally
- Maintained surveillance in Ghana and two other countries to identify cases for the ongoing European & Developing Countries Clinical Trials Partnership, EDCTP funded case-control study

The month 24 results paper has been accepted for publication in the Lancet. The preprint version has been published, 27 July 2023

Figure 1: A group photo of participants and facilitators at the Safety training for hospital staff and site coordinators from 11th – 13th October, 2023.

Figure 2: Dr. Justice Sylvaken, demonstrating a procedure to participants during the training for hospital and coordinators

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.

Malaria Vaccine Pilot Evaluation-Case-Control Studies (MVPE-CC)

Investigators

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

Funder:

European and Developing Countries Clinical Trials Partnership (EDCTP)

Collaborators:

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), United Kingdom
PATH, United States

Project start date:

1st April, 2021

Project end date:

31st December, 2024

Study duration:

48 months

Background

The ongoing Malaria Vaccine Pilot Evaluation (MVPE) is being conducted in Ghana, Malawi and Kenya through community and sentinel hospital surveillance systems and a series of household surveys (to measure vaccine coverage). The Malaria Vaccine Pilot Evaluation-Case Control (MVPE-CC) is embedded within MVPE comprising case-control studies of clinical and mortality outcomes. Each case will require four controls, and caregiver informed consent will be required prior to study activities.

The observational case control studies are measuring as complementary information to what is being collected through MVPE:

1. Safety among children who received the malaria vaccine, with focus on cerebral malaria, meningitis and severe malaria

2. The impact of the malaria vaccine on all-cause mortality for boys and girls, and

3. Promote use of case-control approaches by Expanded Programmes on Immunization (EPI) and malaria control programmes.

Objectives

To determine the safety and effectiveness of the RTS,S/AS01 malaria vaccine in vaccinated children to complement the population level measures of impact obtained through the WHO's Malaria Vaccine Implementation Project. The study aims to answer the following research questions:

1. Are children who receive RTS,S vaccination (at least 1 dose) at increased risk of meningitis compared to unvaccinated children?

2. Are children who receive RTS,S vaccine (at least one dose), or children who receive 3 doses, at increased risk of cerebral malaria compared to unvaccinated children?

3. What is the increase in incidence of severe malaria in children who received 3 doses, but failed to receive a 4th dose, compared to children who did not receive the vaccine (the rebound effect)?

4. What is the effectiveness of RTS,S (following 3 doses, and following the 4th dose) in preventing severe malaria?

5. Is there any evidence that RTS,S vaccine increases mortality in girls, or is less effective in preventing death in girls than in boys?

Methodology

Cases of three types are been studied: children admitted to hospital with meningitis, or with severe malaria, and children who died. The study is limited to children who would have been eligible, based on their date of birth, to have received RTS,S/AS01 vaccine, and who were living in an RTS,S/AS01 implementation area in catchment area of sentinel hospital. For each case, four control children who were born within one month of the date of birth of the case child will be recruited from the same neighbourhood.

Key findings

Data collection has been ongoing for the past 24 months.

Expected outcomes

Primary outcomes:

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

Secondary outcomes:

1. Excess risk of severe malaria in relation to the 4th dose of RTS,S

Figure 1: A visit by EDCTP to KHRC

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 so far

As at 31 October 2023, a total of 10,462 participants comprising 2,170 eligible cases and 8,292 controls have been recruited into clinical outcomes and mortality outcome case control studies across three countries (Ghana, Kenya, Malawi) as follows:

1. Severe malaria – 920 cases and 3,509 controls recruited

2. Cerebral malaria – 93 cases and 366 controls recruited

3. Meningitis – 17 cases and 67 controls recruited

4. Mortality – 1,140 cases and 4,350 controls recruited

- *Muden Ventures (CRO) for MVPE-CC completed total of 7 monitoring visits to KHRC from 27 April 2022 - 24 Jul 2023. Feedback reports were received and all actioned*

- *On October 2, 2023, European and Developing Countries Clinical Trials Partnership (EDCTP), funders of the ongoing MVEP-CC in Ghana, Kenya, and Malawi completed monitoring visit to KHRC. Feedback report has been received and actioned*

- *Completed refresher training for case-control researcher officers and project managers, 26 May 2023*

Figure 2: A visit by Expanded Programme on Immunization (EPI) and National Malaria Control Programme (NMCP) managers

Figure 3: A group picture of staff after a refresher training

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)

Funder:

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

Collaborators:

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), United Kingdom PATH, United States

Background

KHRC with support from the collaborating partners has prepared about 6,000 malaria blood slides as an update to the existing malaria slide bank. The new set of slides are validated and will be established for international recognition within the sub-region for training of professionals.

Activities

Kintampo Health Research Centre Institutional Ethics Committee (KHRC-IEC) reviewed and approved the proposal to collect blood samples from voluntary donors to prepare over 6,000 slides comprising negative, P. falciparum (different densities), P. malariae, P. ovale, and mixed infection. These slides were validated by at least WHO Level 1 Expert Malaria Microscopists in Kenya. KHRC laboratory performed the species identification of positive slides using real time PCR method. The slides with microscopy results from all six microscopists agreeing with the molecular results were considered validated.

The validated slides are packed in slide cabinets and logged into a database platform to facilitate the ease of retrieval.

Slides from the malaria slide bank (MSB) have been used for training of medical laboratory professionals and other institutions. 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, Ghana Health Service.

Added to the bank are more than 2,000 placental tissue blocks fixed in paraffin wax and the corresponding H & E stained tissues from the placental tissues. These samples were prepared from a birth cohort study that enrolled and followed about 2,000 pregnant women till at least one year after their new born babies.

CLINICAL STUDIES

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 Agyapong, Dr. Cynthia Bema, Dr. Felicia Serwah

Funder:

Sanofi Pasture Inc.

Study duration:

6 months

Project start date:

18th July, 2023

Project end date:

12th June, 2024

Background

This is an observational study of respiratory syncytial virus (RSV) disease in which the participants will not receive any study vaccine but will be followed for 6 months for any acute respiratory disease (ARD). The participant will be follow up for the following symptoms Cough, Runny Nose, Fever, Shortness of Breath, Ear pain or Discharge. If the participant have any of the symptoms mentioned, he or she will be invited to the study clinic for assessment and treatment. Blood sample will be collected from each participant on the day of enrollment to determine if you already or previously had RSV infection. If the participant developed any of the above symptoms, Nasal swab will collected for testing to determine the cause.

Objectives

- To assess how common RSV is in our country and the world as a whole
- To assess the number of positive RSV illnesses cases during the study period

Methodology

The study is a multi-center, multi-national, prospective surveillance study in which a maximum of 1000 children from 6 to < 22 months of age had been enrolled in 10 countries, 2 sites per country, targeting approximately 100 participants per country. The study participants did not receive any study vaccine but provided blood sample on D01 (ie, V01) and was followed for 6 months. The blood sample collected at D01 was used to determine the participant's RSV serostatus at baseline.

RSV-LI was monitored through passive and active surveillance. Participants' parents / legally acceptable representative (LAR) was instructed to contact the site if the participant experiences symptoms of a RSV-LI at any time during the study or if they have a positive RSV test from any other source (ie, passive surveillance). The active surveillance includes contacting the participants' parents / LAR once a week throughout the study to inquire about any symptoms of RSV-like illness, to schedule an illness visit in case of any, and to remind participants' parents / LAR to contact study staff if they experience symptoms of RSV-LI.

During the illness visit, the participants were evaluated for the occurrence of ARD, LRTD, and AOM and a nasal swab specimen was collected from the participant and tested for the presence of RSV, hMPV, and PIV3 among others. Study participant who was hospitalized, a nasal swab for the study was collected as soon as possible and not later than 5 days after onset of symptoms. Follow-up contact will be performed once a week as per the active surveillance plan.

Expected Outcome

A baseline data will be collected to determine RSV season in Ghana and other part of the world. To determine the incidence of RSV Like illnesses.

Progress

Enrollment and follow up has ended

A Phase 3, multicenter, 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

Investigators

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

Funder:

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

Study duration:

1 year

Project start date:

15th September, 2023

Project end date:

25th September, 2024

Background

A novel pneumonia caused by a previously unknown beta coronavirus emerged in Wuhan, China, in December 2019. The virus is closely related to SARS-CoV-1, which caused an outbreak in 2003, and has been named SARS-CoV-2. The human disease caused by SARS-CoV-2 is called COVID-19. 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, variants of SARS-CoV-2 have emerged that are more transmissible and may reduce vaccine efficacy, especially over time.

During the omicron surge, vaccine efficacy has been shown to wane after the initial 3 to 4 months for protection against both symptomatic disease and, in some series, hospitalization. Thus, it has become clear that fully vaccinated and/or boosted individuals can still develop COVID-19 and may develop severe disease, due to waning vaccine efficacy or risk factors for infection, such as being immunocompromised or of older age.

Despite the Emergency Use Authorized of anti-SARS-CoV-2 mAbs for emergency use in the US and some other countries, as well as off-label use of repurposed agents under evaluation for SARS-CoV-2 treatment in some regions of the world, effective therapeutics for non hospitalized adults with COVID-19 are not widely available or accessible, and deaths due to COVID-19 continue to accumulate.

Objectives

1. The main intent of the study is to evaluate the efficacy of S-217622 vs. placebo.

2. 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 is a multicenter, randomized, double- blind, placebo-controlled study in participants with mild and moderate disease and without risk factors for severe disease. The study consists of 3 intervention groups: S-217622 lower dose group (initial dose of 375 mg followed by 125 mg daily), S-217622 higher dose group (initial dose of 750 mg followed by 250 mg daily), and placebo group, each with 5 days of total treatment. The main purpose of the Phase 2a part is to confirm the antiviral effect of multiple doses of S-217622. The Phase 2a part provided antiviral proof of concept and determined the dose to be implemented in Phase 3 studies.

The Phase 2b/3 part is to verify the efficacy in mild, moderate, and asymptomatic participants with SARS-CoV-2-infection without risk factors for severe disease. The study is examining time to cessation of virus shedding and time to improvement/resolution of symptoms in the participants with symptomatic disease. In asymptomatic participants, the study is assessing the occurrence of symptomatic disease. It is planned to include approximately 2600 participants in these studies, which will provide supportive safety and efficacy data for the ACTIV-2d/5407 study.

Expected Outcome

The ACTIV-2d/A5407 study is expected to generate evidence towards the discovery of a safe and efficacious medicine that will relieve participants of symptoms of covid as well as prevent hospitalization of covid positive participants.

Progress

The site prescreened 69 participants, 5 were positive however only 3 consented to be part of the study and were enrolled. Enrollment has concluded, and participants are currently undergoing follow-up.

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 I study)

Investigators

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

Funder:
Emergent Bio-Solutions

Study duration:
2 years

Project start date:
12th July, 2022

Project end date:
4th May, 2024

Background

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, the Sponsor is conducting this first-in-human (FIH) study to evaluate the safety and immunogenicity of the candidate vaccine, EBS LASV. The target population is healthy adults ≥18 to ≤50 years of age. The study was originally planned to be conducted in two parts – part A and part B. The goals of part A were to assess the safety and tolerability of low, medium, and high dose of EBS-LASV administered as two-dose series.

A total of 18 participants were enrolled into 3 cohorts corresponding with the low, medium and dose regimens. Two participants were enrolled into cohort 1, ten in cohort 2, and six in cohort three. The goals of part B were to select the two safest and most immunogenic regimens for further evaluation. A total of 72 participants from both participating sites were planned to be enrolled into part B.

Objectives

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

Methodology/Study Design: This is a Phase 1, first in human (FIH) clinical study. The target population is healthy adults ≥18 to ≤50 years of age.
Part A – Dose Escalation: Randomized, double-blind, placebo-controlled, sequential group dose-escalation with three active treatment arms.
The goals for Part A are to assess the safety and tolerability of a low, medium, and high dose of EBS-LASV when administered as a two-dose series and to select two dose levels for further evaluation in Part B of the study.

A total of 36 subjects will be enrolled in Part A of the study, with 12 in each cohort. Subjects will be randomized 3:1 to either the active treatment arm or the placebo arm and dosed on both Days 1 and 29 of the vaccine depending on assigned cohort.

A Safety Monitoring Committee (SMC) will review and assess the safety data up to two weeks post-initial vaccination (i.e., Day 15), including all safety-based laboratory data up to seven days post-initial

vaccination (i.e., Day 8), prior to the start of the next escalated dose level cohort. Safety-based laboratory data to be reviewed does not include viral vector shedding data. The SMC will be notified if viral vector shedding is observed. Initiation of the next dose level may only occur after the safety of the previous cohort has been confirmed. Additionally, the Principal Investigator (PI) and Sponsor's Medical Monitor (MM) will review the available safety data on a by-subject basis prior to the second dose on Day 29 in each arm for Cohorts 1-3.

Part B – Dose and Schedule Selection: Randomized, double-blind, placebo-controlled, parallel-group with eight treatment arms.

The goals for Part B (Cohort 4) are to select two regimens (dose/schedule) for a planned future Phase 2 clinical study and to further evaluate safety and tolerability of EBS-LASV.

Cohort 4 will consist of 8 arms, each with 9 subjects for a total of 72 subjects. Based on safety and immunogenicity results from Part A, two dose levels (i.e., selected from low, medium and/or high dose) will be further assessed for safety and immunogenicity.

Progress

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. Recruitment into part A is completed and all participants have exited the study. There was no serious adverse events reported. However, 21 non-serious adverse events were recorded.

The last participant visit was conducted on 5th July 2023. On 10th October 2023, the Food and Drugs Authority was notified on status of the clinical study protocol that part B of study EBSI-LV-074-001 will not be performed. This is because the interim analysis of the immunogenicity results at Day 57 of part A do not support the goals of part B which was to select a dose and schedule for future evaluation.

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

Funder:

Novartis Pharma AG

Study duration:

2 years

Project start date:

Project end date:

6th june, 2025

Background

Despite malaria being a preventable and curable disease, there were an estimated 241 million cases worldwide in 2020 with over 95% occurring in the WHO African Region and 99.7% being caused by P.falciparum. Artemisinin derivatives remain the mainstay of antimalarial combination therapies, however, resistance to artemisinin has been reported. This has increased the urgency and a strong medical need to develop new anti-malarial drugs with new mechanisms of action. Research efforts have been focused on identifying drugs that with different mechanism(s) of action from the artemisinin derivatives and are potent, rapid acting in nature and have a sustained parasite killing with a short treatment regimen in order to improve compliance and reduce development of resistance.

A platform study assessing many treatments in one population is considered an effective way to screen for pharmacologic properties of treatments either as monotherapy or in combination. The purpose of this platform study is to evaluate the parasiticidal effect and potential cure with different anti-malarial agents administered as monotherapy and/or in combination therapy in adults and adolescents with uncomplicated Plasmodium falciparum malaria.

Objectives

Primary objective

1. To assess the 28-day cure rate of an anti-malarial agent administered orally as combination therapy versus the standard of care(SoC) in patients with uncomplicated P.falciparum malaria.

Secondary Objective;

1. To assess the parasite clearance time (PCT) of oral . combinations of anti-malarial agents versus standard of care (SoC) in patients with uncomplicated P. falciparum malaria.
2. To assess the 28-day cure rate of an anti-malarial agent administered orally as combination therapy versus the standard of care (SoC) in patients with uncomplicated P.falciparum malaria.

Exploratory Objective;

To assess the 42-day cure rate of an anti-malarial agent administered as combination therapy versus the standard of care (SoC) in patients with uncomplicated P.falciparum malaria.

Methodology

This is a phase 2a, multi-part, multi-center, open label platform study including a randomized, parallel and adaptive sequential dose level design in part A and a randomized , control design in part B.

Part A will be conducted in male and female participants (≥18 years of age) with acute uncomplicated P.falciparum malaria mono-infection at screening confirmed by a parasite count between 5,000 to 150,000 asexual parasite count/ul of blood.

Part B will be conducted in male and female participants (≥12 years of age) with acute uncomplicated P.falciparum malaria mono-infection at screening confirmed by a parasite count between 1,000 to 150,000 asexual parasite count/ul of blood.

The study is divided into screening, treatment period (randomization and drug administration) and follow up phases. The screening phase will last a maximum of 6 hours for each participant after which the treatment period will follow for three days followed by the follow up phase which will last p to 40 days from the treatment phase KHRC will take part in the Part B and a minimum of 14 participants are expected to be recruited by the site.

Expected Outcome

The study will help generate the necessary evidence to support the discovery of novel non-artemisinin-based effective treatment options for malaria. The study will explore the potential for single dose cure for uncomplicated malaria.

Progress

The study has obtained approvals from Kintampo Health Research Centre Institutional Ethics Committee, the Ghana Health Service Ethics Review Committee and the Food and Drugs Authority. The study is yet to be initiated after which recruitment will follow.

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 Covid-19 vaccine trial)

Investigators

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

Funder:

Sanofi Pasture Inc.

Study duration:

4 years

Project start date:

19th August, 2021

Project end date:

15th February, 2025

Background

An outbreak of severe respiratory illnesses in Wuhan City, Hubei Province, China in December 2019 heralded the appearance of a novel coronavirus, SARS-CoV-2, in the human population. The clinical profile of COVID-19, the illness caused by SARS-CoV-2, is variable. In the majority of cases, the manifestations are mild, or individuals may be asymptomatic. Among those with symptoms, typical presentations include fever, cough, and shortness of breath. More severe manifestations include acute hypoxemic respiratory failure requiring intubation and mechanical ventilation, in some cases resulting in death. While mostly self-limited, symptoms such as fatigue and dyspnea appear to persist in many individuals for up to 2 months after illness onset despite viral clearance.

Adults over 50 years of age and individuals with chronic medical conditions are at a higher risk of severe outcomes and death. Sanofi Pasteur's candidate vaccine is being developed in the setting of a pandemic for the active immunization and prevention of SARS-CoV-2 infection and COVID-19 disease. The initial intended use of the vaccine is for adults, 18 years of age and older. The candidate antigen is a stabilized prefusion trimer of the SARS-CoV-2 S protein. The coronavirus S protein is the major viral envelope glycoprotein and mediates attachment and entry into host cells.

Objectives

1.To assess the clinical efficacy of the candidate vaccine for the prevention of symptomatic COVID-19 occurring ≥ 14 days after the dose two.

2. To assess the safety of the candidate vaccine compared to placebo throughout the study

3. To describe the neutralizing antibody profile at D01 and at 21 days and 6 months after last crossover injection in the placebo group and booster injection in each study group for participants in the Random Immunogenicity Sub cohort.

Methodology

All participants will receive 2 injections given 3 weeks apart: the first injection will be at D01 (Vaccination [VAC] 1) and the second injection will be at D22 (VAC2).

All participants in Stage 1 and Stage 2 will be unblinded and informed of the results of the study. Study Investigators will discuss the possibility of receiving the (authorized/approved) vaccines available to them outside of the study.

Based on decisions of the Study OG, participants will be invited upon consent to continue participation as part of an unblinded crossover / booster study design. The participant unblinding and consent will trigger the end of the initial double-blind primary series design and the start of the Crossover / Booster design, which includes a primary series vaccination for initial placebo recipients (ie, crossover vaccination) and a booster for both initial placebo and vaccine recipients (ie, booster vaccination).

Non-naïve participants who initially received placebo and are 18-59 years of age will be offered the opportunity to receive the investigational CoV2 preS dTM-AS03

monovalent (D614) vaccine if authorized/approved vaccines are not available or if they choose not to receive an authorized/approved vaccine series. Naïve participants 18-59 years of age and all participants ≥ 60 years of age who initially received placebo will be recommended to receive an authorized/approved vaccination series.

Expected Outcome

To generate data required for approval of each of the vaccines for the prevention of COVID-19 disease caused by SARS-CoV-2 in adults. The data collected during this study are planned to support future development in other populations (eg, pediatrics, pregnant women).

Progress

There were a total of 1599 screened and 1116 randomized. Out of this 766 were enrolled in stage I and 350 in stage II. Participants are currently being followed up. There have been 57 COVID-19-like illnesses and 29 serious adverse events reported so far. Interim analysis of data across all participating sites shows 100% efficacy against severe COVID-19 and hospitalizations, 75% efficacy against moderate or severe COVID-19 and 57.9% efficacy against any symptomatic COVID-19. Both vaccines showed favorable safety profiles. After unblinding, 651 participants were eligible for the crossover/Booster Phase. 518 participants were successfully enrolled.

ENVIRONMENTAL HEALTH RESEARCH

Targeted subsidy for LPG adoption study

Investigators

Dr. Kwaku Poku Asante, Dr. Sulemana Watara Abubakari, Ms. Theresa Tawiah, Mr. Alexander Appiah

Funder:

Columbia University

Collaborators:

Columbia University: Darby Jack University of California Santa Barbara: Kelsey Jack

Project start date:

1st September, 2018

Project end date:

30th September, 2023

Study duration:

2 years

Background

Household air pollution represents the largest energy-related health risk, leading to nearly 2.3 million preventable pollution-related deaths per year. Recognizing the costs associated with the use of biomass fuels for cooking, the Government of Ghana has committed to giving 50 percent of Ghanaian households' access to LPG fuel for cooking, but progress towards this goal has been slow. Previous efforts in other countries to drive clean fuel transitions by targeting subsidies to the poor have largely been unsuccessful. Adopting a "smart subsidy" approach, this project relies on targeting strategies that aim to balance the heavy cost of subsidization with the social benefits of clean fuel use. In the context of a randomized controlled trial in Techiman, Ghana, the project evaluated the role of smart subsidies in increasing LPG use among the poor.

Objectives

Specific aims

This study was structured around the following specific aims:

Aim 1: Design a targeting strategy to increase LPG uptake among poorer households in Techiman.

Aim 2: Test the effectiveness of the targeting strategy designed in Aim 1 in Techiman.

Aim 3: Quantify the air pollution reduction benefits from LPG adoption and characterize gender-dependent distribution of air pollution exposure within the home.

Aim 4: Comparatively evaluate men and women household heads' motivations for selecting household energy sources, and assess their implications for decision-making related to clean fuel adoption.

Methodology

The study used randomized controlled trial (RCT) to design (Aim 1) and test (Aim 2), the feasibility and effectiveness of a pricing mechanism designed to target larger LPG subsidies to poorer households. We also aim to disaggregate based on gender the air pollution reduction benefits that can be obtained through LPG adoption (Aim 3) and the motivations for clean fuel adoption (Aim 4). A key feature of our approach is that Aim 1 and 2 will be treated as complementary stages (stage 1 and 2 respectively) as part of a "design then test" model.

As such Stages 1 and 2 will be implemented in a similar manner, with Stage 2 leveraging the findings of Stage 1 to provide a restricted set of subsidy options to participants and thus maximizing separation between wealthier and poorer households. At the beginning of the study, participants will be able to purchase an LPG

starter kit (stove+LPG cylinder) on deposit. They will then be able to choose between contracts allowing them to refill their LPG cylinders at a discounted price for the duration of the study. The subsidy amounts will vary between contracts but once chosen, the subsidy level stipulated on the contract will apply and remain constant for the duration of the study. Participants will be able to exchange study-branded LPG cylinders at a designated LPG exchange depot (up to 5) established for study purposes in collaboration with Andev, an LPG supply company. We have successfully set up similar exchange depots in the ongoing demand study (Adoption Aim 4). Exchange subsidies will be valid for three months, with no cap on the number of times a participant can exchange.

Expected outcomes

The proposed study is to generate data that will allow the Government of Ghana to create efficient subsidy mechanisms to maximize LPG uptake by low-income households. This study is also expected to increase understanding of the distribution of HAP reduction benefits within the home, which is currently poorly characterized.

Progress

Stage one

The following key milestones were all completed as part of stage one:

- A smart subsidy package, designed as a targeting strategy to increase LPG adoption and use in Techiman, was implemented between March 2022 and October 2022. In all, a total of 524 households were involved.
- Personal exposure to air pollution monitoring for both men and women across 175 households were conducted between August and December 2022.
- These measurements were done at two time points – baseline and endline, with the goal to characterizing the gender-dependent distribution of air pollution reduction benefits that can be achieved through LPG adoption.
- Four focus group discussions, held separately for men and women were also undertaken to understand households' motivations for purchasing clean cooking technologies and the dynamics of intra household decision making on clean fuels.

Stage Two

- Field activities for stage two is completed.
- A total of 859 LPG cylinders were distributed in the stage 2 of the study. Out of this number, 245 were 3kg cylinders and 614 were also 14.5kg.
- Analysis of the data is currently ongoing.

Figure 1: The team stocking one of the LPG depots in Techiman.

Reducing Household Air Pollution in Ghana through Community-Level Transitions to Clean Cookstoves and Fuels

Investigators

Dr. Kwaku Poku Asante, Dr. Sulemana Watara Abubakari, Mr. Alexander Appiah

Funder:

Columbia World Projects

Collaborators:

Columbia University: Darby Jack University of California Santa Barbara: Kelsey Jack

Project start date:

1st November, 2019

Project end date:

31st October, 2024

Study duration:

5 years

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). In Ghana, air pollution 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.

A number of interventions over the last decade have not significantly reduced the negative impact of the use of traditional cookstoves. Study participants continue to use polluting energy systems, and emissions from neighbors, effectively negate the health benefits of any one household's transition to clean energy systems. This study consolidates past experiences with clean household energy – with a particular focus on behavioral and cultural questions – and also draws on novel insights into both clean cooking technologies and behavioral antecedents to their sustained use

Objectives

The primary objective is to reduce household air pollution exposure by promoting community-level transitions to clean cooking with the target of achieving WHO health-based air quality targets.

Methodology

This study has assessment and intervention phases. The assessment phase used a quantitative cross-sectional design to collect data from sampled districts in all 16 regions of Ghana, covering about 7,400 household-level respondents in 370 enumeration areas (EAs); across 177 urban EAs and 193 rural EAs. Face-to-face interviews were conducted at home. The questionnaire was designed to elicit information on primary, secondary, and tertiary cooking stoves and fuels.

The intervention phase will involve the use of a cellphone-based application for linking consumers with LPG suppliers (referred to as GasPay). GasPay will enable 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 a feasibility pilot, the Combating Household Air Pollution (CHAP) project, a partnership between Kintampo Health Research Centre (KHRC, Ghana Health Service), the Columbia University, the University of California - Santa Barbara (UCSB), seeks to test this digital platform, GasPay that we hypothesize will help optimize supply chains and increase LPG use among marginalized consumers. Results of the feasibility pilot will inform a larger randomized trial to evaluate impacts on expenditures and consumption and inform the Government of Ghana's LPG promotion policy.

Figure 1: GasPay consultative meeting with stakeholders

Progress

For the assessment phase, the team has successfully organized a stakeholder virtual dissemination workshop in July 2021, and an in-person workshop that included policy makers in November 2021. The team is currently developing six manuscripts for peer-reviewed publication. One of the manuscripts is published. Two are going through peer review whilst the remaining three are at various stages of development.

For the intervention phase, the team is planning to launch a feasibility pilot that will be implemented in two stages by constructing two samples of 50 and 1,000 households in Techiman, Bono East Region. Based on the findings of the pilot, the main study will be launched in the Kintampo town also in the Bono East Region, Central Ghana.

Child Lung Function Study

Investigators

Dr. Kwaku Poku Asante, Dr. Seyram Kaali, Mr. Mujtaba Mohammed Nuhu, Dr. Sulemana Watara Abubakari.

Funder:

National Institute of Health (NIH)

Collaborators:

Columbia University: Darby Jack, Steven Chillrud.
Mount Sinai School of Medicine: Alison Lee

Project start date:

1st April, 2018

Project end date:

31st March, 2028

Study duration:

10 years

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), nitrous oxides, formaldehyde, and polycyclic aromatic hydrocarbons (PAHs). Exposure occurs indoors or in the immediate vicinity of the home, hence the term HAP. HAP exposure during pregnancy 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.

Objectives

Aim 1: Early Life Cookstoves Intervention Status Affects Respiratory Outcomes (Intention to Treat). We hypothesize that Cookstove intervention status (LPG versus 3-stone fire) used from the second trimester of pregnancy through age one will independently predict:

a) Outcome 1: Lung function at ages four (impulse oscillometry (IOS)) and seven (IOS and spirometry). We hypothesized that LPG will be associated with better lung function at ages four and seven.
b) Outcome 2: Prevalence of wheeze age 1-7.

We hypothesize that LPG use will predict decreased wheeze.

Aim 2: Relationship Between Household Air Pollution (HAP) Exposures and Respiratory Out-come (Exposure Response).

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 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, 1,415 maternal-infant pairs were recruited and followed up over a period of four years to quantify 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.

Figure 1: Pictures showing activities of the Mechanistic Aim of the child lung function study

Key Findings

Children with poorer anthropometrics through to age 4 years had higher airway resistance in early childhood. These findings have implications for lifelong lung health, including pneumonia risk in childhood and reduced maximally attainable lung function in adulthood.

Expected outcomes

a) Outcome 1: Lung function at ages four (impulse oscillometry (IOS)) and seven (IOS and spirometry). We hypothesize that LPG will be associated with better lung function at ages four and seven.

b) Outcome 2: Prevalence of wheeze age 1-7. We hypothesize that LPG use will predict decreased wheeze.

Progress

Surveys on all the aims of the study have been successfully completed. Data cleaning, analysis, and report writing for phase 1 is ongoing. A number of manuscripts have been published with two currently under review in peer reviewed journals. However, we had additional funding for a mechanistic aim and other respiratory study objectives on the effect of household air pollution on respiratory outcomes, this five-year additional funding grant will end in 2027. Work has started for the mechanistic aim component of the child lung function study where exposure to household air pollution for sugar and toxic substances as a result of cooking with firewood started on 26th October 2023. The mechanistic aim of the child lung function study is going on well. We are supposed to complete the activities by cooking 6 Rounds of Banku (local food) using the three types of firewood (Senya, Mango, and Dawadawa). These activities were completed on the 20th of November 2023 before Harmattan.

Child Lung Function and Cardiovascular Health Study

Investigators

Dr. Kwaku Poku Asante, Dr. Kaali Seyram, Dr. Mujtaba Mohammed Nuhu, Dr. Sulemana Watara Abubakari

Funder:

National Institute of Health (NIH)

Collaborators:

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

Project start date:

1st April, 2023

Project end date:

31st March, 2027

Study duration:

4 years

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. 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

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.

- 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.
- 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. 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.

- Aim 2a. We hypothesize that LPG intervention assignment will be associated with lower airborne metal concentrations and altered composition compared to control.

- 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.

- Aim 3a. We will assess the association of airborne metal concentrations and urine biomarkers of metal exposures with Aim 1 measures of CVH. • 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 Randomized 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, 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.

Progress

Enrolment is ongoing for the 630 participants in 2023, and preparation is far in advance for the first phase of the Exposure Monitoring for PM2.5 to begin at ages 10. The project is currently on the monthly follow-up of the study cohort at their homes to ascertain caregivers' reports on symptoms, specifically wheezing, 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.

- Age 10, 11, and 12 exposure assessment Air pollution Exposures in the ongoing CLF study: To estimate exposures at ages 10, 11, and 12, we combine real-time/filter integrated measurements of (a) individual-specific 48-hour personal (UPAS), (b) community-level ambient (E-Sampler, Met-One in Grants Pass, OR), and (c) continuous central site (Research Centre) ambient [E-Sampler and Purple Air (PA, PurpleAir, or other low-cost sensors)] and meteorological (Onset U30, Bourne, MA) measurements, to estimate exposures for each child in the year preceding each lung function assessment.

Pre- and postnatal Exposure to Household Air Pollution and Neurodevelopment in Ghana

Investigators

Dr. Kwaku Poku Asante, Dr. Seyram Kaali, Mr. Mujtaba Mohammed Nuhu, Dr. Sulemana Watara Abubakari

Funder:

Collaborators:

Columbia University Mailman School of Public Health: Pam Factor-Litvak, PhD Darby Jack, PhD Steven Chillrud, PhD

Columbia University Irving Medical Centre: Amy Margolis, PhD

Project start date:

1st December, 2023

Project end date:

31st May, 2024

Study duration:

6 months

Background

The growth of knowledge-based economies emphasizes the need for optimal neurodevelopment and cognitive function as an essential public health outcome, especially for low- and middle-income countries. Decreased neurodevelopment and cognition in early life due to air pollution can have lifelong impacts including educational and economic disadvantage. Prenatal exposure to outdoor, ambient air pollution has been associated with alterations in children's brain structure, white matter surface and microstructure, cognitive ability, attention and executive function, and academic skills, however, this has not yet been investigated. Our proposed study will be the first to examine such effects and moreover will use an experimental framework (randomized controlled trial of HAP exposure reduction) to document the causal contributions of early life (i.e. in utero and first year) HAP on children's brain structure. Our study will be the first large study to evaluate the effects of perinatal exposure to HAP on brain structure and the first to test the effects of household exposure to air pollution within an experimental – as opposed to quasi-experimental— framework.

Objectives

- Aim 1: Establish and evaluate a protocol for acquiring structural MRI data from 8-10-year-old children in the cohort. We will recruit 50 families and track the refusal rate; we anticipate recruiting 44 children and acquiring useable MRI data from 40 children.
- Hypothesis: It will be feasible to acquire structural MRI data from 8-10-year-old children in the GRAPHS cohort and obtain consent, transport children to perform MRI, and report data.

- Aim 2: Establish an image processing pipeline and optimize methods for analyzing data acquired from 1.5T <RI.
- Hypothesis: We will be able to measure the cortical thickness of regions shown to be associated with outdoor air pollution (right precuneus, pars opercularis and orbitalis, superior frontal gyrus, rostral middle frontal, lateral orbitofrontal region, and left cuneus and fusiform gyrus).

- Aim 3: Estimate effect sizes of group differences and dose-response relationships (prenatal HAP - brain structure) to generate required sample sizes for planned R01.
- Hypothesis: Higher levels of HAP will be associated with thinner cortices in the regions of interest (ROIs), controlling for postnatal exposure.

Methodology

The Ghana Randomized Air Pollution and Health Study (GRAPHS) (R01ES019547, N=1,414) cohort is an actively followed birth cohort in Kintampo North Municipality and Kintampo South District in Ghana

Eligible children in the cohort (age 8-10; available prenatal exposure data; no metal exclusion) will be invited to complete one visit consisting of an MRI scan and cognitive assessment at Kintampo Research Health Center within one month of the MRI visit. The child's parent will complete parent-report measures, but no MRI scan. The visit is overnight and will take place at Kintampo Health Research Centre and Spectra Health Imaging and Interventional Radiology in Kumasi. Participants and caregivers will be transported to Kumasi and have one-night accommodation provided to enable a successful MRI scan. Women were recruited prior to 24 weeks gestation, for the purpose of studying the effects of prenatal exposures to household air pollutants (HAP) on neurodevelopmental outcomes through age 6.

Progress

The protocol received full approval from both the KHRC Institutional Ethics Committee. However, our USA collaborators are currently going through IRB approval processes.

Electricity, Clean Energy and Climate Change Adaptation Study

Investigators

Dr. Sulemana Watara Abubakari, Mr. Alexander Appiah, Dr. Kwaku Poku Asante

Funder:

International Growth Centre and Abdul Latif Jameel Poverty Action Lab (J-PAL)

Collaborators:

University of California Santa Barbara: Flavio Malagutti

Project start date:

1st September, 2022

Project end date:

31st August, 2024

Study duration:

2 years

Background

Globally, nearly 1 billion people lack access to electricity. 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 is designed to generate evidence for whether firm-households are misusing commercial electricity and investigate the underlying reasons behind it. Specifically, we ask: do firm-households separate their residential and commercial electricity uses across their residential and commercial accounts? If not, what drives their energy consumption in and across each meter?

Methodology

Our research methods involve questionnaire-based data collection and a field experiment with firm-households in Techiman. First, we visit firm-households and administer a questionnaire. After the questionnaire, we will implement a randomized controlled trial, with the introduction of two experimental groups: group (1) will receive electricity rebates, group (2) will receive an unconditional cash transfer evaluated to be equivalent to the electricity discount group. As part of the study, NEDCo will provide the team with meter-level data for customers (residential and commercial) in its Techiman Administrative.

The team will calculate the average electricity consumption in each meter and convert this statistic into information that will be provided to study participants about their own consumption (how many units they consume, price per unit, etc.).

Figure 1: Field team in a participant's shop for enrolment into Techiman

Again, we will be looking for evidence that by providing study participants with more information and clarifying questions about electricity prices, they will become more aware (and perhaps more responsive) to the price differences between their commercial and residential meters. We track this behavior by following the evolution of each participant's electricity consumption in the NEDCo data after our visit.

And finally, by matching participants' information in the questionnaire data with their electricity use records, we can understand how electricity use correlates with household health, demographics, and fuel choices and stacking.

Expected Outcome

The proposed study is 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;

(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.

(iii) Whether firm-household members actually do have high demand for electrical appliances but place them in their businesses, instead of in their homes.

Progress

The team is currently embarking on a pilot of this study in Techiman with 57 participants.

- Of these numbers, 30 participants are in the electricity discount group, where participants source their discount in the form of electricity from a 3rd party vendor in the Techiman municipality. Participants were made to choose their preferred vendors.
- The remaining 27 participants receive direct cash transfers from a staff at KHRC, whenever they are due. This pilot study is to last for four (4) months, with the last participant exiting in March, 2024.

MATERNAL AND CHILD HEALTH RESEARCH

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)

Investigators (Ghana)

PI: Dr. Kwaku Poku Asante. **Co-PI**s: Prof. Sam Newton, Mrs. Charlotte Tawiah Agyemang
Project/Study Coordinators: Mrs. Irene Apewe Adjei, Dr. Ellen Boamah-Kaali, Mr. Lawrence Gyabaah Febir, Mr. Kenneth Wiru
Data Managers: Mr. Eliezer Ofori Odei-Lartey.
Statistician: Ms. Stephaney Gyaase
Biomedical Scientist/Laboratory Technologist: Dr. Dennis Adu-Gyasi, Mrs. Veronica Agyemang and Mr. Dennis Konadu Gyasi.

Funder:

Bill and Melinda Gates Foundation (BMGF)

Collaborators:

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

Project start date:

December, 2023

Project end date:

December, 2025

Duration:

3 years

Collaborating Sites

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.
Ghana: Kintampo Health Research Centre

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 ANC 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

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.

Figure 1: Study midwife conducting ultrasound scan

Expected Outcome

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

Recruitment and follow up activities are ongoing. Ultrasound scans were conducted for 1,599 pregnant women and 1,071 participants were enrolled in the study by the end of December 2023. A total of 574 deliveries have been recorded out of which 553 were live births.

Figure 2: Fieldworker interviewing study participant

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

(MIND Study)

Investigators

Ghana: Dr. Kwaku Poku Asante, Dr. Kenneth Ae-Ngibise, Solomon Nyame, Veronica Agyemang, Stephaney Gyaase, Charlotte Tawiah and Professor Sam Kofi Newton
USA: Dr Emily R. Smith.
Kenya: Dr. Dickens Onyango, Dr. Bernard Awuonda and Dr. Victor Akelo
Zambia: Dr. Joan Price, Dr. Jeff Stringer, and Dr Margaret Kasaro
India (Christian Medical College, Vellore): Professor Beena Koshy, Professor Venekata Raghava Mohan and Professor Santosh Benjamin
India (Society for Applied Studies, New Delhi): Sarmila Mazumder (PI), Arun Jadaun, Neeraj Sharma
Pakistan: Dr. Zahra Hoodbhoy, Dr. Imran Nisar, Dr Fyezah Jehan

Funder:

Bill & Melinda Gates Foundation

Collaborators:

1. **Ghana**: Kintampo Health Research Centre, Research and Development Division, Ghana Health Service
2. **Kenya**: Kenya Medical Research Institute (KEMRI)-Center for Global Health Research (KEMRI-CGHR)
3. **Zambia**: University of Zambia School of Medicine, UNC Global Projects Zambia, University of North Carolina School of Medicine
4. **India**: Christian Medical College, Vellore
5. **India**: Society for Applied Studies, New Delhi
6. **Pakistan**: Aga Khan University
7. **USA**: George Washington University
8. Bill & Melinda Gates Foundation
9. **United Kingdom:** Kings College London

Project start date:

9th January, 2023

Project end date:

30th June, 2025

Study duration:

3 years

Background

Women of reproductive age (WRA), especially pregnant and lactating women, are disproportionately vulnerable to anaemia. Globally, 33% of WRA, or about 613 million, are estimated to be anaemic. Prevalence of anaemia among WRA is highest in low- and middle-income countries (LMICs). In 2016, the World Health Organization (WHO) estimated the prevalence of anaemia in South-East Asia and sub-Saharan Africa (SSA) to be 46% and 39% respectively among WRA. Low hemoglobin concentrations in pregnancy are linked to adverse maternal and neonatal health outcomes.

The Infant Neurodevelopment Sub-Study [INS] is a prospective observational study which aims to assess the impact of maternal anaemia on infant neurodevelopment and brain morphology among a birth cohort study in Ghana, India, Kenya, Pakistan and Zambia.

Objectives

1. To assess the Feasibility and usability of the Hyperfine scanner across study sites

2. To assess the impact of maternal anaemia on infant neurodevelopment by GSED scores at 3 or 6 and 12 months of age.

3. To assess the association between maternal characteristics (age, education, occupation, ethnicity, religion, maternal depression, anaemia status) and childhood neurodevelopmental outcomes at 3 or 6 and 12 months of age.

4. Assess association between preterm/vSGA and neurodevelopmental outcomes measured by GSED.

5. Assess stimulation and support available to a child in the home environment using the Family Care Indicator (FCI) at 3 months and 12 months.

6. To assess the impact of maternal anaemia on infant brain volumetry and microstructure at 3 and 12 months of age.

7. Assess the association between preterm/vSGA and neurodevelopmental outcomes measured by hyperfine.

Methodology

About 1600 – 2000 mother and infant's dyad will be recruited per site into the study. Also, INS aims to use the Global Scale for Early Development (GSED) for data collection. The GSED is a tool for measuring early child development (ECD) under three years of age. The GSED has been validated alongside other psychometric tools in a cohort of children in seven diverse countries to assess ECD at both population and programme level. Along with the GSED, the current INS study will use a portable Swoop® Magnetic Resonance Imaging (MRI) to also characterise structural and functional brain development patterns among a subset of infants in Ghana, Pakistan and Zambia to identify possible variations associated with neurologic, psychiatric and cognitive developmental outcomes. 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.

Expected Outcome

This study is expected to characterise the association of maternal anaemia with infant neurological developmental outcomes and brain microstructure of infants at 3 or 6 and 12 months of age and evaluate the impact of maternal anaemia on both. The study will further generate data to support the use of the GSED scale for assessing infant neurodevelopment in different settings.

Progress

Recruitment started in August 2023

Redefining anemia: A multicenter, international, population-based study to establish and validate global reference values for anemia in pregnancy

(ReMAPP_Redefining Maternal Anemia in Pregnancy and Post Partum)

Investigators

Dr. Kwaku Poku Asante, Prof. Emily Smith, Prof. Sam Newton, Mrs. Charlotte Tawiah, Dr. Amma Benneh Kwasi-Kuma, Mrs. Veronica Agyemang, Ms. Sasha Bauman.

Funder:

Bill and Melinda Gates Foundation

Collaborators:

KNUST, Ghana: Prof. Sam Newton KBTH, Ghana: Dr. Amma Benneh Kwasi-Kuma George Washington University, United States: Prof. Emily Smith, Ms. Sasha Bauman.

Project start date:

1st July, 2023

Project end date:

31st December, 2025

Study duration:

2 years

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;

Aim 3: To describe the underlying contributing factors to anaemia during pregnancy.

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 1,200 to 2,000 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.

Figure 1: The Director of KHRC and the Principal Investigator of the ReMAPP Study visits Zambia

Expected Outcome

The proposed study would 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.

Progress

Recruitment into the study begun in December 2022 and as at 30th November 2023, 1005 participants out of the 2000 participants in the primary cohort had been recruited into the study.

Figure 2: KHRC Visits Kenya, 2023

Figure 3: KHRC Visits Zambia, 2023

Assessing the relationship between gender disparity and anemia among pregnant women in the middle-belt of Ghana

(Gender disparity and Anemia study)

Investigators

Kwaku Poku Asante Lawrence Gyabaa Febir, Martha Ali Abdulai, Samuel Afari-Asiedu, Stephaney Gyaase, Emily Smith, Sam Kofi Newton, Charlotte Tawiah,

Funder:

Bill and Melinda Gates Foundation

Collaborators:

Kwame Nkrumah University of Science & Technology. Kumasi Ghana George Washington University. USA

Project start date:

2nd February, 2022

Project end date:

31st December, 2023

Study duration:

24 months

Background

Globally, 33% of Women in Reproductive Age, or about 613 million, are estimated to be anemic. Low hemoglobin concentrations in pregnancy are linked to adverse maternal and neonatal health outcomes. A meta-analysis (n=95 studies) found haemoglobin <11 g/dL was associated with increased odds of postpartum haemorrhage, preeclampsia, preterm birth, low birth weight, small-for-gestational-age, stillbirth, neonatal death, and perinatal death. Women have traditionally been disadvantaged due to gender inequality including restrictions on nutrition. Socio-cultural practices especially within dominant patriarchal societies play a critical role in gender inequalities.

Objectives

- To explore socio-cultural beliefs around food for women especially during pregnancy.
- To explore contextual (social, cultural and economic) factors and behaviors that influence gender disparity and anemia.
- To understand the perception of pregnant women on anemia and its associated outcomes.
- To explore gender disparity and anemia mitigation strategies among pregnant women and gatekeepers

Methodology

This was an exploratory qualitative study. Data collection was through In-depth Interviews (IDIs) and Focus Group Discussions (FGDs) sequenced in three phases

Phase 1: FGDs and IDIS were conducted among pregnant women, husbands/partners in-laws, and community opinion leaders, health workers and community opinion leaders. FGDs and IDIs will explore cultural, social, and economic factors that influence gender disparity and anemia, and beliefs around food for women especially during pregnancy.

Phase 2: Information from FGDs and IDIs from phase 1 will be used to design participatory action research among pregnant women on how they perceive anemia related outcomes using community participative ranking methodology.

Phase 3: FGDs and IDI will be conducted among pregnant women to validate emerging themes from data gathered from phase 1 and 2.

QSR NVivo qualitative analysis software version 12 was used to highlight common themes and was used in the management of the data. Thematic approach was used for the analysis

Fifty-five IDIs were conducted among pregnant women, husbands/partners, in-laws, health workers and community opinion leaders. Twelve FGDs were also conducted among dominant ethnic groups in the area.

Key findings

Socio-cultural underpinnings that recognize the legitimacy of the household head to the best part of household food may entrench gender disparity and anemia.

- Decisions around major household items were largely made by the men while women did smaller purchases.
- Among some ethnic some ethnic groups the following taboos were noted: Pregnant women are forbidden from eating roasted food, among another ethnic group also it is the elderly person or the man in the family that shares the meat, pieces are given to each and every member of the family after they have eaten.
- The majority of the pregnant women perceived anemia to be no blood, reduced blood or low levels of blood and that that anemia was by caused alcohol, cigarette smoking, energy drinks, and inadequate balanced meals
- Participants mostly elaborated on anemia symptoms to include fainting, body shakes, dizziness, fainting, fatigue, weakness and loss of appetite

Expected Outcome

- Socio-cultural beliefs around food for women especially during pregnancy.
- Contextual (social, cultural and economic) factors and behaviors that influence gender disparity and anemia.
- Perception of pregnant women on anemia and its associated outcomes.
- Gender disparity and anemia mitigation strategies among pregnant women and gatekeepers.

Progress so far

A preliminary report is being put together for submission to the Bill and Melinda Gates Foundation whiles coding of the data is still underway. A final report will be submitted after data collected in phase 1 & 2 has been validated in phase 3

Figure 1: An Indepth Interview session with a pregnant woman

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. Kaali Seyram, Dr Dennis Adu- Gyasi, Dr John Amoah, Irene Azindow, Elvis Wilson

Funder:

KHRC

Collaborators:

Nelly Amenyobge, Prof Tobias Kollman, Prof Pinaki

Project start date:

9th February, 2022

Project end date:

19th June, 2024

Study duration:

6 months

Background

The newborn period has the highest lifetime risk of invasive infections and globally each year more than 1 million infants die from infection; a large fraction of these infectious deaths relates to preterm birth (PTB). There were 13.4 million babies born pre-term in 2020. There is therefore the need for safe, protective, and affordable interventions to reduce the burden of PTB.

Probiotics administered during pregnancy have shown to reduce PTB. Clinical trials on probiotic supplementation have shown to reduce infections in newborns Panigrahi, in his study, showed that supplementation of probiotics for 1 week resulted in reduction of infections. Therefore, this pilot study seeks to evaluate effective colonization of the infant gut by giving probiotic supplementation to women with 5 to 6 months old pregnancy.

Objectives

Giving probiotics supplement to 100 pregnant women (5-6 months) in order to boost the health status of the infant.

Methodology

The study is a prospective, randomized, double-blinded, placebo-controlled design. Hundred (100), with randomization of 3:1, pregnant women at 5 to 6 months in Kintampo North and South districts were enrolled and probiotic supplementation administered weekly till two weeks after delivery and followed up till one-month post-partum and their infants followed till they are one month old.

The randomization. The total duration of the study is 6 months and until the last child is followed up. At the end of the study, all newborns exposed to study intervention are followed for one year by the study pediatrician.

Expected Outcome

To improve the health status of participants infants by reducing preterm births and infections.

Progress so far

Recruitment has been completed and half of the participants have completed the study.

Figure 1: A visit by Nelly Amenyobge, a Probiotics study collaborator

Evaluation of Electronic Pregnancy Registers and Mobile Applications as a Potential Tool for Promoting Antenatal Care and Monitoring Pregnancy Outcomes (EVAPREAP)

Investigators

Dr Kwaku Poku Asante, Dr David Dosoo, Mr. Japhet Anim, Mr. Eliezer Ofori Odei-Lartey, Dr Samuel Afari-Asiedu

Funder:

European Commission

Collaborators:

European Vaccine Initiative (EVI), Germany
Fondation pour la Recherche Scientifique (FORS), Benin, Groupe de Recherche Action en Santé (GRAS), Burkina Faso and Malawi University of Science and Technology (MUST)

Project start date:

June, 2022

Project end date:

May, 2024

Study duration:

2 years

Background

Malaria during pregnancy remains a major public health problem. A consortium from Africa and Europe is further advancing the clinical development of two placental malaria (PM) vaccine candidates. These vaccines have previously been shown to be safe, well-tolerated and able to produce antibodies against PM. Monitoring pregnancy outcomes during pregnancy is very important in assessing the effectiveness of interventions against PM. The increased availability of mobile phones makes them a potential tool for improving quality of care for pregnant women, accurately collecting and reporting pregnancy outcomes in identified cohorts of pregnant women.

Data on the feasibility and acceptability of the mobile applications for tracking pregnancy outcomes in the areas targeted for clinical testing of candidate PM vaccines is, however, limited. This study will explore the creation of electronic pregnancy registers and evaluate pregnancy mobile applications as a potential tool for monitoring pregnancy outcomes in future PM vaccine trials, as well as for the implementation of other future interventions in Ghana, Burkina Faso, Benin and Malawi.

Objectives

The study seeks to explore the creation of electronic pregnancy registers and to evaluate pregnancy mobile applications as a potential tool for monitoring pregnancy outcomes in future placental malaria (PM) vaccine trials, as well as for the implementation of other future interventions in Ghana, Burkina Faso, Benin and Malawi.

Methodology

The study will be carried out in two phases. The first phase will involve the mapping of health application tools, and the selection of one of the tools for the registration of pregnancies at each of the participating sites. The second phase will involve the assessment of the feasibility and acceptability of mobile application. At the evaluation phase, qualitative methods will be used to assess the feasibility and acceptability of using the selected mobile application for tracking pregnancy outcomes. The selected app will be tested by pregnant women. In-depth interviews (IDIs) and focus group discussions (FGDs) will be used to explore the perceptions of pregnant women and health workers on the feasibility, usability, and acceptability of open-source mobile applications for tracking pregnancy outcomes among pregnant women.

Pregnant women who will be able to use the electronic application and are willing to participate in the interviews will be purposively selected, and health workers sampled from the health facilities.

Expected Outcome

The assessment of mobile applications for monitoring pregnancy outcomes and development of pregnancy registers will build the base for future PM vaccine trials and any other interventions tackling PM. If acceptability and feasibility is demonstrated, mobile applications could be linked to other tools that will provide support to front line healthcare workers and patients to ensure uptake and continued access to essential maternal and neonatal care services through responsive customized needs of patients in view of routine care packages.

Progress so far

Ethical clearance has been obtained in all participating sites and data collection is progressing well.

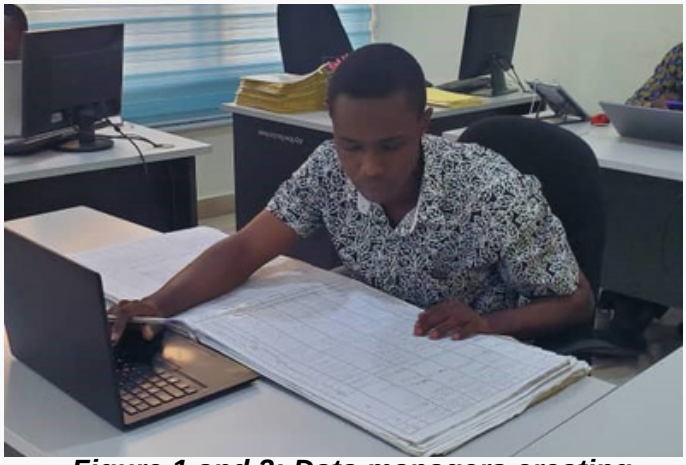

Figure 1 and 2: Data managers creating electronic pregnancy registers from paper source

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. Ali Sambah, 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- Ghana Office

Project start date:
15th January, 2022

Project end date:
31st March, 2024

Study duration:
2 years

Background

The emergence of the novel severe acute respiratory syndrome – Coronavirus 2 (SARS-CoV-2), which resulted in COVID-19 disease in late 2019, affecting almost every country in the world. Following that, World Health Organization (WHO) advised all countries cross the world and implementing influenza surveillance for severe acute respiratory infections (SARI) to use such systems to also monitor severe SARS-CoV-2 cases by collecting data that would allow for the measurement of COVID-19 Vaccine Effectiveness (VE).

Evaluating the performance of COVID-19 vaccines post-licensure is critical as several factors can impact on the real-world VE, including transportation and storage conditions, vaccines administration, advanced age, underlying medical conditions and previous SARS-CoV-2 infection. In addition, post-licensure evaluations of the pandemic vaccines allow public health authorities not only to understand the duration of protection of the vaccines but also advise the need for re-vaccination where applicable. This study was initiated to utilize the hospital-based influenza surveillance sentinel sites scattered across all the 16 regions of Ghana, to recruit individuals diagnosed with SARI and to collect clinical and vaccination data to inform estimates of the COVID-19 vaccine effectiveness against SARI in persons of the vaccination target groups in 21 selected SARI sentinel sites in Ghana.

Objectives

The primary objective is 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.

Methodology

The study is a test-negative case-control design (TND) being conducted in 32 hospitals located in the 16 regions of Ghana and implementing Influenza surveillance and the well-established sentinel sites. Severe Acute Respiratory Infection patients in Ghana. The TND design has been used in the over the past 10 years for estimating annual influenza VE worldwide including Ghana. The principle behind this design is to evaluate SARS-CoV-2 laboratory results among persons who meet the standard SARI case definition. The design categorizes SARI patients who test positive for SARS-CoV-2 as “cases” and those with a negative test result as “controls”

Findings

With 73% enrolment target achieved, preliminary analysis from the cleaned and validated data of 1655 records indicates that the prevalence of SARS-CoV-2, together with some flu viruses such as Flu A subtype AH3, Flu A subtype SwH1N1pd09 and Flu B VIC as tested in this study are 7.36%, 3.37%, 1.7% and 2.2% respectively. Omicron is the only isolated variant in all SARS-CoV-2 positives sequenced, with CT values below 30. Co-infection reported includes 3 SARS-CoV-2 / Flu A subtype AH3 and 1 SARS-CoV-2/ SwH1N1pd09.

Expected Outcome

The outcome of interest is SARS-CoV-2 detection in patients of age group eligible for vaccination and hospitalized with SARI symptoms. SARS-CoV-2 infection is defined as laboratory-confirmed by PCR techniques either on admission at the hospital or documented within 14 days prior to hospital admission. 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

Progress

The initial sample size of 1,110 participants was achieved within 11 months of implementation June 2022-January 2023) without enough data to estimate the vaccine effectiveness. Therefore, the study protocol was revised with a new sample of 2577 and increased the number of study hospitals from 21 to 32 for a wider coverage. As of, December 2023, 73% (1879/2577) of the new sample size has been completed, with SARS-CoV-2 positivity rate of 7.4 %. Although the study is progressing well in terms of enrollment, there has been a general decline in the number of reported cases of COVID-19 in Ghana since August 2022. Since the declaration by WHO of COVID-19 over as global health emergency, there has been reduced vaccine campaign countrywide. Low vaccine coverage, coupled with the declined number of reported cases, has potentially affected the effort to estimates the vaccine effectiveness.

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

Dr. Kwaku Poku Asante, Dr. Nicholas Amoako, Dr. Patrick Ansah, Dr. John E. O. Williams

Funder:

Ministry of Health-Ghana

Collaborators:

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

Project start date:

11th May, 2022

Project end date:

8th March, 2024

Study duration:

2 years

Background

Coronavirus disease (COVID-19) is a febrile respiratory illness, 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 diseases other AFIs result in a significant delay in the diagnoses and turnaround times.

In a differential diagnosis approach, this study have employed a combined laboratory and clinical methods to diagnose the 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

Study aim: 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) The specific objectives are as follow:

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 is taking 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 targets individual of all age and sexes and having fever (axillary temperature >37.5oC).

Each participant is tested for COVID-19 using RDT and PCR, malaria is diagnosed by microscopy and RDT. Clinical and demographic data are collected using RedCap and all diagnosis made are documented.

Findings

Preliminary analysis 1102 patients have been enrolled out of 1263 expected with 83 (7.5%) tested positive for SAR-CoV-2 virus using both PCR and antigen test. Among other test conducted, Plasmodium malaria (366/1102; 3.2%) is the most common diagnosis among all participants enrolled so far. Other diagnosis includes diarrheal diseases, respiratory infection, and skin diseases. Associated symptoms for most of the reported diagnosis include headache, fever, cough, and general body pains.

Expected Outcome

The main outcomes include COVID-19 hospitalization rate and deaths, co-morbidities and predisposing risk factors that lead to severity of COVID-19. Sensitivity some COVID-19 antigen tests kits would be determined.

Progress

Of the 1,263 study participants are expected to be enrolled from the 3 sites, 87% (1102/1263) of recruitment is achieved in 17 months of study implantation. Both Kintampo and Navrongo have achieved their enrollment target and so Dodowa is the only site still recruiting participants but at a slow pace due to low OPD attendance

Stored sample for further Laboratory testing and analysis

- ***As part of the study procedure, different sample types such as nasal swabs, whole blood, plasma have been collected and stored for molecular testing for diverse pathogens including viruses, bacteria, and other protozoans.***

Collaboration for funding support

- ***Due to inadequate funding to perform more testing on the samples collected, the study PI has initiated talks with the partner University to provide support to perform molecular analysis for the stored samples***

Uptake of Task-Strengthening Strategy for Hypertension Control within Community Health Planning Services in Ghana: A Mixed Method Study (TASSH Study)

Investigators

Kintampo Health Research Centre: Dr. Kwaku Poku Asante, Mr. Solomon Nyame, Mr. Kwame Adjei, Dr. John Amoah Kwame

N**krumah University of Science and Technology**: Prof. Kweku Bedu-Addo, Kezia Gladys Amaning Adjei, Mr. Kingsley Apusiga

New York University: Prof. Gbenga Ogedegbe, Dr. Joyce Gyamfi, Prof. William Chaplin, Dr. Angela Aifah, Deborah Onakomaiya

S**aint Louis University**: Prof. Juliet Iwelunmor"

Funder:

National Institute of Health/National Heart Lung Blood Institute

Collaborators:

Olugbenga Ogedegbe, Kwaku Bedu Addo, Juliet Iwelunmor, Joyce Gyamfi, Keziah Gladys Amaning Adjei, Deborah Onokomaiya, Angela Aifah

Project start date:

1st, June 2017

Project end date:

31st May, 2024

Study duration:

7 years

Background

The Ghana Demographic and Health Survey 2014 found that the prevalence of hypertension among people aged 15-49 years is 8.8% in rural areas and 15.8% in urban areas. The 2016 annual report of the Ghana Health Service also states that the prevalence of adult hypertension ranges from 19% to 48%. However, this number is expected to increase due to unhealthy lifestyles and rapid urbanization. Guided by the Consolidated Framework for Implementation Research and the Reach Effectiveness Adoption Implementation and Maintenance framework, the goal of this study is to evaluate, in a hybrid clinical effectiveness-implementation design, the effect of practice facilitation (PF) on the uptake of an evidence-based Task-Strengthening Strategy for Hypertension control (TASSH), among 700 adults who present to 70 Community-Based Health Planning Services (CHPS) zones with uncontrolled hypertension (HTN).

Components of the PF strategy include a) an advisory board that provides leadership support for implementing the intervention within the CHPS zones; and b) trained Task task-strengthening facilitators (TSFs) who serve as practice coaches to provide training and performance feedback to community health officers (CHOs) who will deliver TASSH at the CHPS zones. For this purpose, the TSFs are trained to identify, counsel and refer adults with uncontrolled HTN to community health centres in the Bono East Region of Ghana. So, in a nutshell, the UPTAKE TASSH study is all about evaluating the effectiveness of practice facilitation in CHPS compounds using the TASSH program interventions. We will be looking at factors that influence the adoption of TASSH, and its clinical effectiveness.

Objectives

1. To determine the readiness of CHPS zones to control high blood pressure and create a culturally customized strategy using qualitative research methods.

2. We will assess the impact of PF compared to Usual Care (UC) on the adoption of TASSH across 70 CHPS zones after 12 months

3. Assess how well the TASSH program has been sustained in the CHPS zones after 24 months

Methodology

First, there will be a pre-implementation qualitative phase. During this phase, the Consolidated Framework in Implementation Research (CFIR) will be used to assess the factors within the CHPS zones that may influence the adoption of TASSH. This will include looking at the inner setting variables and provider characteristics.

Next, we have the implementation phase. This phase will involve a cluster randomized controlled trial (RCT) to evaluate the impact of the PF strategy compared to usual care. We will be looking at the adoption of TASSH and its clinical effectiveness in reducing systolic blood pressure over a period of 12 months post-randomization across the CHPS zones. Additionally, we will be examining the factors that mediate the adoption of TASSH within a CHPS compound. Finally, we have the post-implementation phase. This phase will assess the sustainability of TASSH implementation across the participating CHPS zones. We will be evaluating this at the 24-month mark, which is one year after the completion of the trial.

Key Findings

1. Facilitators to hypertension management included the availability of blood pressure (BP) monitors, policy reform to ensure that antihypertensive medications are available at the facilities, and motivation for health workers.

2. Four themes were identified as barriers: lack of functional BP monitors, medication cost, transportation cost, and limited staff capacity building, which fell under CFIR inner and outer setting, intervention characteristics, and process domains

Expected Outcome

1. The between-group difference in systolic Blood Pressure (SBP)

2. Mediators of adoption of TASSH at the CHPS compounds.

3. The sustainability of TASSH uptake.

Progress

The team has completed the Month 12 Follow up. The team is currently doing the month 24 follow-up. So far, the study team followed up with 647 participants out of 700 for month 12. Currently, the team is conducting the Month 24 follow-ups. Regarding month 24 follow-ups 454 are due for follow up and the team has completed 412. So far, the team has received reports of 11 deaths as of the end of January 2024. The team is currently reviewing the data which will shared with the Data Safety and Monitoring Board and the Steering Committees. Over the period also, the team also undertook some dissemination activities within the Ghana Health Service. Our team also hosted the Annual Consortium Meeting and at the Annual conference on the science of Dissemination and Implemention, 2023.

Figure 1: TASSH Study and Collaborators Host Annual Global Research On Implementation and Transition Science Coordinating Center (GRIT CC) Consortium Meeting

Revision and validation of the short 10/66 dementia diagnostic assessment for older populations in Kintampo, Ghana.

(Dementia 2 Study)

Investigators

Kintampo Health Research Centre: Dr. Kwaku Poku Asante, PhD; Solomon Nyame, MA; Kenneth Ae-Ngibise, PhD; Richard Tetteh, MSc.
University of Ghana, School of Public Health: Naana Agyeman, PhD
French National Research Institute for Sustainability: Dr. Maëlenn Guerchet; Prof. Pierre-Marie Preux

Funder:

Global Brain Health Institute

Collaborators:

Dr. Maëlenn Guerchet; Prof. Pierre-Marie Preux

Project start date:

1st, July 2021

Project end date:

30th June 2024

Study duration:

2 years

Background

The development of a dementia assessment, with robust training methods to guarantee the expected level of quality and validity, is therefore critical.A diagnostic assessment, culturally adapted and not influenced by the level of education, accompanied by a computerized algorithm to ascertain dementia status were developed and validated by the 10/66 Dementia Research Group in Asia, Latin America and only one African site - Nigeria. This structured assessment can be administered by appropriately trained lay interviewers, without requiring specialist clinical diagnosis.

A short-form assessment and algorithm, with comparable performances, were developed in order to provide an alternative in settings where the full assessment is not feasible or acceptable. However, data from recent studies carried out in several sub-Saharan countries raised concerns about the robustness of assessments that are core to this dementia diagnostic assessment.

Objectives

The aim of this project is to analyze existing data from SSA in order to identify any source of measurement bias and explore assessment quality (training and administration) in Kintampo (Ghana). This will allow to recalibrate the diagnostic algorithm before the revised one-stage dementia diagnostic assessment can be validated in the same setting.

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 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 fidelity of administration and rating, and problems with comprehension. Particular attention will be given to technical issues of administration (e.g. how to distinguish between 'often' and 'sometimes' in the CSI-D

informant) and translation (following the WHO recommendations for translation and adaptations of instruments). For aim two, 160 individuals will be interviewed in the two districts.

Findings

Of over 1600 study participants who were contacted to participate, 1131 were screened for dementia and 469 were not screened because there was no available informant. We are currently doing the analysis to determine the positive screen rate.

Expected Outcome

Outcomes from this project will be a culturally adapted and validated version of the 10/66 short-form dementia diagnostic assessment and algorithm, alongside development of protocols for enhanced training and protocols for 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.

Progress

About 1500 community members 60+ years have been contacted and 1038 have been screened. The analysis is currently ongoing to determine older adults with probable dementia and the risk factors for probable will be reported at the conference if the abstract is accepted. A local expert meeting is planned to be held at KHRC following the pilot testing and focus groups, involving social scientists, epidemiologists, mental health specialists, and clinicians. The aim is to review in detail the assessment and the training/supervision instructions to identify the necessary modifications following the results from the 2 exercises.

This meeting is planned to be held around November 2023. Following the community screening held in the Kintampo Municipality, participants with low performances and reports of cognitive impairment will be invited for clinical assessment. This confirmation phase will involve KHRC and external collaborators in Ghana (psychiatrist, clinical psychologist, neurologist). A seminar will be held ahead of this period to discuss the content of this assessment and practical organization. This phase is expected to be held over October and November 2023. Clinical examinations will be carried out with older people until we identify 80 participants with mild to moderate dementia. Controls matched to age (+/-5 years) and sex will be identified from the list of participants.

Antimicrobial Resistance Studies

Investigators
Dr. Kwaku Poku Asante, Dr. Samuel Afari-Asiedu, Dr. Martha Ali Abdulai, Ms Theresa Tawiah, Dr. Dennis Adu Gyasi, Mrs Latifatu Abubakar Alhassan

Funder:
Wellcome Trust, UK
Collaborators:
Kintampo Health Research Centre (KHRC), Radboud University Medical Center, Netherlands, National Antimicrobial Resistance Platform/Ministry of Health, Ghana

Project start date:
July, 2020

Project end date:
July, 2023

Community-level antibiotic access and use (ABACUS II)

Introduction

In 2023, KHRC continued to explore the context of antibiotic access and use at the community level. This is part of ABCUS II consortiums effort of building on findings from ABACUS I-Scientific Publications – ABACUS project (abacus-project.org) to explore the case for a standardized appearance of oral antibiotics ABACUS II project in Africa and Asia. ABACUS II received a one yesr cost extention from wellcome trust due to COVID-19 related delays. The final close out meeting was held with Wellcome Trust in January, 2024. Below are updates on the four sub-studies under the project.

Assessing the potential impact of and obstacles to standardizing the physical appearance of commonly used oral antibiotics

This sub-study explored perspective of experts and stakeholders to inform the co-creation of an international system to facilitate the recognition of oral antibiotics. Six roundtable meetings were conducted in Africa, Asia and Europe. Findings from the roundtable meetings were included in a viewpoint published in 2023 (Through round table discussions, this sub-study explored the perspective of experts and stakeholders to inform the co-creation of an international system to facilitate the recognition of oral antibiotics.

A total of six round table meetings were held in Africa, Asia and Europe.

). The viewpoint discusses how oral antibiotics and other commonly used medicines like painkillers can be challenging to distinguish based on physical appearance alone. The authors report further expert consultations on improving antibiotic recognition through more standardized appearance or labelling. Challenges include costs for manufacturers, risks of increasing inappropriate demand if antibiotics become too recognizable, and potential for falsified labelling. Next steps include working with regulators on a labelling system, alongside improving public awareness and responsible antibiotic use.

Health economics analysis related to inappropriate identification of oral antibiotics.

This study used data collected in the ABACUS I project (household surveys and exit-interviews among consumers buying antibiotics), scientific literature and stakeholder consultations to make costs saving projections of potential effects of future interventions that improve antibiotic use. Inappropriate antibiotic use leads to substantial preventable economic costs in low resource setting which investment in innovative strategies to avoid needless expenses. Follow the link below for details of the finding

https://aricjournal.biomedcentral.com/articles/10.1186/s13756-022-01096w#:~:text=This%20study%20indicates%20that%20inappropriate,result%20in%20considerable%20cost%20reductions.

Assessing how identification of oral antibiotics impacts appropriate community-based antibiotic use

This was a qualitative study which used focus group discussions (FGDs) and in-depth interviews (IDIs) conducted in two phases in the Kintampo Districts of Ghana between 2021 and 2022. First, seven FGDs and 17 IDIs were conducted among community members (52) and medicine dispensers respectively to explore perspectives on antibiotic appearance and recognition. Based on finding the first round of data collection, four FGDs and six IDIs were conducted among community members (30) and dispensers respectively to explore the potential impact of standardizing the physical appearance of the antibiotics. Symbols, images, colors and labels were major facilitators for the identification of medicines. A common examples is “an image of a skeleton with muscles” on the packet of diclofenac, which indicates that one will be released of joint, and muscle pain after taking the medicine. Community members were able to identify antimalarial by the image of mosquitoes on the packet of the medicine.

Community members and dispensers suggested that an image or a symbol such as “AB”, an abbreviation for the word ‘antibiotic’, or images showing indications for antibiotic would help to ensure uniformity in the appearance of antibiotics for easy identification.Some health workers mentioned that a danger sign should be placed on antibiotics to indicate it cannot be used without prescription. Quick-Response (QR) codes were considered very valuable in providing appropriate use guidance but their value mainly lay in the (near) future as not everyone has a smartphone. Some participants thought that easy identification of antibiotics could potentially increase misuse. A manuscript has been drafted for publication.

Assess the proportion of substandard and falsified oral antibiotics among three commonly sold antibiotics

The primary objective of this sub-study is to estimate the quality of three essential antibiotics in four LMIC including Ghana, using laboratory tests against reference criteria. About 8,400 dosages units of antibiotics (Amoxicillin, Ciprofloxacin and Cotrimoxazole) were sampled using mystery shoppers or overt approach. Samples collected are being analysed in a central laboratory (Mission for Essential Drugs and supply) in Kenya.

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:

RTI International

Collaborators:

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

Project start date:

1st May, 2023

Project end date:

30th April, 2025

Study duration:

3 years

Background

Verbal Autopsy (VA) is the main means of ascertaining causes of death in the Kintampo Health and Demographic Surveillance System to inform health policy. However, this approach is challenged by inadequate objective diagnostic information, recall bias, and difficulties in distinguishing between diseases with similar clinical presentations, which consequently affects the effectiveness of national public health programmes. This study seeks to use the Minimal Invasive Tissue Sampling (MITS) techniques to strengthen the cause of death determination and improve decision-making.

Objectives

The main objective of this project is to strengthen the KHDSS mortality surveillance system by integrating MITS as a standard tool to improve the cause of death data. Specifically, the study seeks to explore the feasibility of integrating MITS into the KHDSS to improve the determination of the cause of death, among others.

Methods

The study will be conducted in the Kintampo North Municipal, Kintampo South District, Techiman South Municipal, and Techiman North District within the Bono East Region of Ghana. Both quantitative and qualitative methods of data collection will be used. opinion leaders and relatives of deceased persons.

Quantitatively, a total of 300 deceased persons registered in the Kintampo Health and Demographic Surveillance System (KHDSS) would be enrolled in the study over three (3) years across the study sites. These would include 50 stillbirths, 150 under-five children, and 100 adults who are 60 years and above. Tissue and non-tissue samples including samples of the brain, lung, blood, heart, urine, and stool samples will be taken for histopathological, microbiological, and molecular analysis. This will be done using biopsy needles.

The samples will be collected at the mortuary facilities of the Kintampo Municipal Hospital, the Jema District Hospital, and the Holy Family Hospital in Techiman. In addition to the results of these samples, the available de-identified clinical information of the study participants would be used by a panel of specialists (comprising a Pathologist, a Paediatrician, a Physician Specialist, a Microbiologist, a Clinician, and a Social scientist) to determine the causes of death.

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.

Figure 1: Training on MITS Sample Collection

Expected Outcome

At the end of the study, we expect to have: a). Trained lower-level health personnel (non-clinical pathologists) capable of performing MITS procedures b). Incorporated MITS into the mortality surveillance programme of the KHDSS c). MITS-informed accurate cause of death data for health planning purposes and service delivery, and to have positioned KHRC to collaborate and share MITS data with other MITS partner sites to inform health policy decisions.

Progress

A series of activities were undertaken as part of the implementation of the study during the year under review.

These included:

- Meetings with Stakeholders' engagement meetings were held with key stakeholders across the health system and health management teams, political and administrative units including the birth and death registry, and the traditional and religious leaders within the study areas. All stakeholders assured the study team of their support for the study.

- Training on the MITS Procedures All study staff were trained on the study protocol in March 2023. Further training on the MITS procedures was held for selected healthcare professionals. In all, 13 healthcare professionals with various backgrounds have been trained on the MITS procedures to support sample collection for the study and they include medical officers, midwives, nurses, and biomedical laboratory scientists.

- Implementation Visit by Study Partners Three members of the RTI international visited the study team ahead of the implementation of the study in April 2023. The main purpose of the visit was to assess the readiness of the study facilities and procedures to ensure a smooth start.

- Participant Recruitment Recruitment started in May 2023 at the Kintampo Municipal Hospital while the Techiman site was initiated in September 2023. As of 31st December 2023, a total of 63 MITS samples had been collected out of 41 eligible cases. This consisted of 41 adults, 11 children under five, and 11 stillbirths. Molecular microbiological analysis has been done for 61 cases, and 30 of the histopathological samples have been analyzed.

- The Determination of Cause of Death Panel (DeCoDe Panel) A team of specialists comprising a Pathologist, Epidemiologist, Family Health Physician, Microbiologist, and Pediatrician was constituted to determine the cause of death of dead persons recruited into the study. They were trained in August 2023 by going through the study protocol and the procedures for the DeCoDe process. The first meeting of the DeCoDe Panel was held in September 2023. The cause of death has been determined for ten (10) of the participants recruited. The process is ongoing.

- Meeting The MITS Surveillance Alliance held a meeting in Kenya in October 2023 and this was attended by one study team member. The team made a presentation on the progress of the project and the lessons learned.

Figure 2: Decode panel

Kintampo Health and Demographic Surveillance System (KHDSS)

Background

The Kintampo Health and Demographic Surveillance System (KHDSS) is an important resource for health research at the Kintampo Health Research Centre. It covers the resident population of six administrative districts within the Bono East Region of Ghana and these have been categorized into three (3) Health and Demographic Surveillance System (HDSS) sites for data and field management purposes. These are 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 current operations are limited to the communities with all-year-round accessibility, and this involves a total of 344 communities with 80,328 active compounds, and 115,152 active households. In all, we cover about 83% of the administrative population across the Six districts

Objectives

The main aim of the KHDSS is to accurately document the health and demographic information of the resident population within its catchment. This provides a baseline information to inform further research activities. It provides a sampling frame for selecting potential study participants for surveys, and clinical trials, among other studies carried out by the Centre.

Field Activities during the period

Two update rounds were conducted during the year under review. In each round, core demographic events (births, deaths, and migration) and pregnancies that occurred after the previous round were registered. All new individuals, households, and compounds identified during the period were registered in the system. In addition, the educational level of individuals, and the socio-economic status of all households (profile), were also updated.

Verbal Post-Mortems (VPMs) were conducted by trained field workers using the WHO 2022 verbal autopsy questionnaire to help ascertain the causes of deaths. During the year under review, 82.8% of the available VPMs were completed.

An additional module on Smartphone access and usage was introduced in October 2023 to determine the usage patterns of smartphones among a cross-section of the Kintampo HDSS population.

Data collection was done electronically during the year under review. The Open Health and Demographic System (OpenHDS) application was used during the first round of updates (i.e. from January to June 2023), while an in-house developed software application was used during the second round of updates.

Demographic Characteristics of the HDSS

The total resident population of the HDSS as of December 2023 was 553,566 across the three sites, with 52.8% of the population being females. Children under five years constitute 11.9% of the total population. The Kintampo HDSS area is gradually becoming urbanized with 51.6% of the population living in urban areas, with an average household size of 4.8. In 2022, a total of 14,619 births, and 2,816 total deaths were recorded across the three sites, including 242 under-five deaths. Some demographic characteristics of the Kintampo HDSS are presented in the Table below.

Personnel

The KHDSS team is led by the Director of KHRC and a Senior Research Fellow. The team comprises 4 Research Fellows, 2 Research Officers, 2 Data Managers, 7 Field Supervisors, 65 Field Workers, and 1 National Service person. Below is a cross-section of the KHDSS Staff.

Table 1: Demographic Characteristics of the Kintampo HDSS by Site

Characteristics of the resident population as of 31st December 2023	Kintampo	Nkoranza	Techiman	Total
Total Population (N, %)	193,131 (34.9)	125,265 (22.6)	235,170 (42.5)	553,566 (100)
Male Population (n, %)	93,177 (48.2)	59,188 (47.3)	108,780 (46.3)	261,145 (47.2)
Female Population (n, %)	99,954 (51.8)	66,077 (52.7)	126,390 (53.7)	292,421 (52.8)
Under-five Population (n, %)	25,128 (13.0)	14,338 (11.4)	26,420 (11.2)	65,886 (11.9)
Rural Population (n, %) *	110,425 (57.2)	78,859 (63.0)	78,671 (33.5)	267,955 (48.4)
Urban Population (n, %) *	82,706 (42.8)	46,406 (37.0)	156,499 (66.5)	285,611 (51.6)
Number of Communities Covered	161	98	85	344
Number of Active Compounds	27,757	20,333	32,238	80,328
Number of Active Households	37,106	25,990	52,056	115,152
Average Household size	5.2	4.8	4.5	4.8
Birth and Deaths Recorded in 2022 by site				
Number of Births Recorded	5,774	3,013	5,832	14,619
Total Number of Deaths	1,085	644	1,087	2,816
Number of Under-Five Deaths	124	44	74	242

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

Figure 1: A cross-section of the KHDSS Staff

Contact persons:	**Email Addresses**
Dr.Kwaku Poku Asante	kwakupoku.asante@kintampo-hrc.org
Grace Manu	grace.manu@kintampo-hrc.org
Mahama Abukari	abukari.mahama@kintampo-hrc.org
Abdul Razak	abdul.razak@kintampo-hrc.org
Charles Zandoh	charles.zandoh@kintampo-hrc.org

CLINICAL LABORATORY
Seth Owusu-Agyei Medical Laboratory

The Seth Owusu-Agyei Medical Laboratory (SOAML) provides laboratory support to all projects in KHRC. KHRC Management ensures adequate numbers of qualified laboratory professionals, well-functioning equipment, quality supplies and other components of laboratory quality management system are in place to ensure reliable results from the Laboratory. The laboratory consists of the following units: Bacteriology, Clinical Chemistry, Entomology, Haematology, Immunology, Bioanalytics, Molecular Biology, and Parasitology. The activities and capacities of the units, as well as quality assurance systems are described below:

Bacteriology

The 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, swabs (nasopharyngeal, vaginal, wound, ear, etc.) 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 reliable, the unit participates in External Quality Assessments provided by the United Kingdom National External Quality Assessment Scheme (UK NEQAS), for which excellent results have been obtained. Daily, weekly and monthly internal quality controls on both equipment and reagents are performed to ensure they are all working effectively.

The unit provides support to the children s ward of the Kintampo Municipal Hospital by processing patient samples. The unit also plays an important role in the diagnosis of cholera and meningitis in samples collected from various facilities in the Bono East Region, especially during outbreaks. The unit also organizes external quality assessment in CSF testing for the 8 sentinel sites of the Malaria Vaccine Pilot Evaluation (MVPE) study.

Two microbiologists from the unit were participants of a 4-day workshop organized by the National Public Health and Reference Laboratory on Isolation and identification of Vibrio cholera and other bacteria of Public Health importance.

Figure 1: C02 Incubator

Clinical Chemistry

A Horiba-Pentra C200 automated clinical chemistry analyzer is in the unit for carrying out analyses such as liver function tests, kidney function tests, lipid profile, glucose, glycated haemoglobin 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. In addition to internal quality control systems, the unit is enrolled onto the External Quality Assessment (EQA) schemes organized by the College of America Pathologists (CAP).

Figure 2: Chemistry auto analyzer for organ function analysis in study participants

Entomology

The unit has one Entomologist and two Research Officers. The unit has been pivotal in studies that collect insects (mosquitoes at various stages and ticks) for speciation and classification as well as further molecular analysis. Major equipment in the unit include: An ELISA plate reader and washer, CDC light traps and accessories WHO vertical test tubes for susceptibility bioassays Insecticide susceptibility papers, Mosquito rearing cages, Stereo dissecting microscope. The unit requires an insectary to enhance testing of the efficacy of insecticides and other interventions. The unit is collaborating with the US Naval Medical Research Unit to screen for the presence or absence of arboviruses in monthly collections of mosquitoes and ticks in the study area. The mosquitoes and ticks are morphologically identified and stored for further analyses.

Figure 3: Staff performing species identification of mosquitoes collected from the field

Haematology

This is a very active unit since most studies require a full blood count to assess health status in recruiting and monitoring participants for clinical trials and other studies. The unit is equipped with a Sysmex XN-330 and XN-350. Automated Haematology analyzers for performing Full Blood Counts (with 5-part differential white blood cell counts), SD Biosensor point-of-care Glucose-6-phosphate dehydrogenase (G6PD) device. haemoglobin variants are measured using a Thermo Scientific High Performance Liquid Chromatography (HPLC) analyzer. Other tests performed include ABO and Rhesus (D) blood grouping. The unit participates in external quality assessment organised by the United Kingdom National External Quality Assessment Scheme (UK NEQAS) and the College of American Pathologists (CAP), with excellent performance over the years.

Figure 4: Conducting complete blood count analysis with auto haematological analyzer

Immunology

The unit has separate sections for cellular and humoral assays, with equipment such as a class II biosafety cabinet, laminar flow cabinet, carbon dioxide incubator, refrigerated centrifuge, ELISA microplate reader & washer, and pipetting accessories. The unit is also equipped with -80oC and -150oC freezers and liquid nitrogen tanks. Isolation and cryopreservation of peripheral blood mononuclear cells (PBMCs) are performed in the unit. There are plans to acquire a Flow Cytometer and Luminex analyzer to support upcoming studies at the Centre. This will reduce the need to ship samples externally for analysis.

Figure 5: Multiplex ELISA platform.

Molecular biology/Virology

The unit has a newly installed Applied biosystems 7500 Fast Real Time PCR machine with 96-Well Fast Reaction, as well as an AGS Real-Time PCR machine with 48-well Reaction. The molecular biology unit with the presence of the Real-Time PCR machines has established protocols for bacterial and parasitological molecular analysis to minimize the shipment of samples to external laboratories after sample collection on most projects within KHRC.

The following are among tests the unit has carried out: Plasmodium species identification (as part of validation of blood smears for malaria microscopy), Merozoite Surface Protein 2 (MSP-2) genotyping, Glucose-6-phosphate dehydrogenase (G6PD) genotyping Haemoglobin genotyping, Knock-down-resistance (kdr), Anti-malarial drug resistance. The Unit also has a 4-module GeneXpert analyzer for the detection of both Mycobacterium tuberculosis and rifampicin resistance.

The unit over the period continued with PCR tests for SARSCOV-2 virus detection and triplex PCR tests for the detection of the three (3) main aetiologic agents of bacterial meningitis, i.e., Streptococcus pneumoniae, Haemophilus influenza, and Neisseria meningitidis. The unit participates in external quality assessments for SARS COV-2 organized by the National Public Health Reference Laboratory and the WHO, with excellent performance.

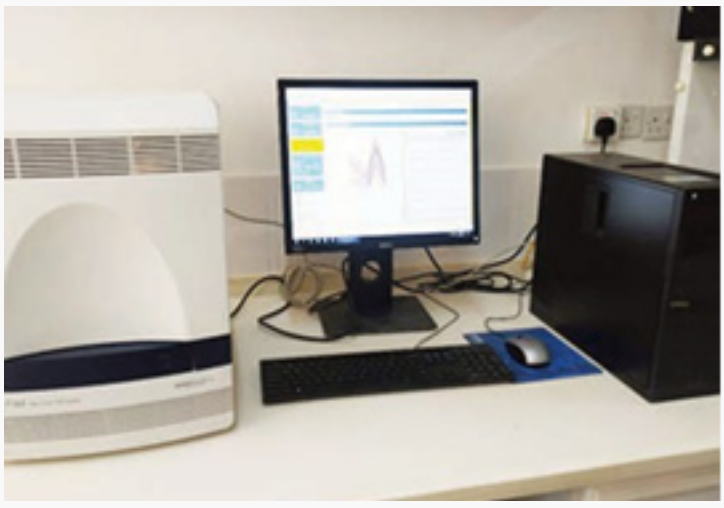

Figure 6: Some selected equipment and qPCR set up in the Clinical Laboratory of KHRC.

Figure 7: A scientist using Genexpert equipment for TB testing

Bioanalytics

A High Performance Liquid Chromatography (HPLC) machine with auto-sampling, UV Scanning Spectrophotometer and a Quansys analyzer are the major equipment at the Unit. The HPLC machine is currently used to determine serum retinol concentrations and haemoglobin variants, but has the capability of measuring other micronutrients and drug concentrations when required. The Quansys analyzer is a multiplex system which allows the simultaneous measurement of 7 different analytes, including transferrin and C-Reactive Protein (CRP) using very low volumes of sample.

Figure 8: Vitamin A and Haemoglobin variant analysis using HLPC and DAD and autosampler

Parasitology

This unit is one of the most active ones in the Clinical Laboratory as most studies require malaria microscopy results, e.g. the just ended Malaria Transmission Intensity (EPI-MAL005) and ongoing PRISMA studies. The core team for the unit is made up of one Medical Laboratory Scientist, two Laboratory Technicians and one Laboratory Assistant. For quality purposes, each malaria blood smear is examined by two independent certified microscopists. Discordant slides are examined by a third microscopist. For external quality assessment, the unit participates in the following malaria External Quality Assessment Schemes: Clinical Laboratory Services (CLS) South Africa (with over 15 microscopists graded as EXPERT), and College of American Pathologists (CAP). The unit also has capacity for detection and quantification of parasites in stool specimen using the wet mount, formol-ether concentration and the Kato-Katz techniques.

Figure 9: Slide reading with a microscope for blood borne pathogens

Quality Assurance Systems

The laboratory undergoes periodic assessments by study sponsors (such as GSK, Novartis) and regulatory inspections (Foods and Drugs Authority, Ghana).

External calibration of equipment is performed by the Ghana Standards Authority. We acknowledge the support of Clinical Lab Services (CLS) - South Africa and the Institutional Care Division/Clinical Laboratory Unit (ICD/CLU) of the Ghana Health Service for quality management system support received. The laboratory undergoes periodic assessments by study sponsors (such as GSK, Novartis) and regulatory inspections (Foods and Drugs Authority, Ghana). External calibration of equipment is performed by the Ghana Standards Authority. We acknowledge the support of Clinical Lab Services (CLS) - South Africa and the Institutional Care Division/Clinical Laboratory Unit (ICD/CLU) of the Ghana Health Service for quality management system support received.

Other activities

The SOAML also contributes to the training and capacity building needs of students at various levels and from different institutions. This includes students on attachment and interns from institutions such as the College of Health and Wellbeing (Kintampo), Kwame Nkrumah University of Science and Technology, University of Ghana, Radford University College, University for Development Studies, University of Cape Coast.

The laboratory also played a leading role in the preparation of validated malaria blood slides to restock the national Malaria Slide Bank, which is used for the training and competency assessment of malaria microscopists. This was funded by Impact Malaria, and supported by partners, including the National Malaria Elimination Programme (NMEP), WHO – Ghana Office, and the Clinical Laboratory Unit of the Ghana Health Service.

Data Science Department (DSD)

Introduction

The Computer Centre is now known as the Data Science Department, and it is made up of three units: information technology, data management, and biostatistics. The department is expanding its use of innovative applications to achieve more efficient data collection and processing. The paperless systems are still operational, and we are actively investigating digital repositories to improve data preservation and archiving.

Data Collection and Processing

The implementation of paperless systems has advanced to the point where we have begun rolling out customised remote data capture tools. One example is the AnTPosT application, which monitors pregnancies and deliveries for up to a year after birth. Another application in the pipeline is a participant-facing mobile application for use in routine care. Although a few clinical trials studies still use paper questionnaires to collect data from the field, we believe this is changing because the most recent perennial malaria chemoprevention (PMC) trial transitioned to a paperless system.

ICT Infrastructure

The Paul Arthur block has been fully renovated and outfitted with the necessary infrastructure for managing computing systems and data. The NAS backup system has also been restored, with two additional backups installed. The Cloud Service is functioning very well. Although the subscription cost increases with each usage, the overall value when compared to a locally maintained system is worthwhile. We continue to optimise its use in order to keep costs to a minimum. The alpha version of the cloud-based ethics application was made available for review. We expect the beta version to be released in the first quarter of 2024.

Staff

Staff development is still a high priority in the data science department to keep our employees up to date and motivated. Two of our employees are nearing the end of their MSc programmes, and another two are working to complete their PhD programmes. We intend to launch a series of short data science-related courses for the entire data science department staff.

We anticipate a significant drop in the number of DECs and SUPs in the coming year, as one of the largest clinical trial projects comes to an end. However, we are hopeful that new ones of similar size will emerge almost at the same time. Regardless, a number of our DECs and DSups have received sponsorships for additional studies into health programmes, which will potentially qualify them for public employment. At the same time, knowledge transfer is extremely effective, as some SUPs are already taking on data management responsibilities, such as developing data capture tools with complex branching logics.

Conclusion

The Data Science Department is rapidly evolving in the development of novel distributed and mobile applications to aid large-scale research studies. We are looking at the possibility of establishing a digital repository for international use and augmenting the science of data to attract funding within the space of computing technology.

Contact:

Eliezer Ofori Odei-Lartey
Email: eliezer.lartey@kintampo-hrc.org
Elisha Adeniji
Email: elisha.adeniji@kintampo-hrc.org
Stephaney Gyaase
Email: stephaney.gyaase@kintampo-hrc.org

Administration

Collaborators/Funders

The Kintampo Health Research Centre maintained its working relationship with a number of organisations including a few new ones. The centre collaborated with the institutions listed below:

External	Internal
GlaxoSmithKline Biologicals S.A. (GSK)	Ghana Health Service
Columbia University, NY	Kwame Nkrumah University of Science and Technology (KNUST), University of Ghana (UG), University of Cape Coast (UCC), University of Health and Allied Sciences (UHAS) , University of Energy and Natural Resources (UENR) and Other Local Universities
National Institute of Health	Agogo Malaria Centre, Navrongo Health Research Centre (NHRC), Dodowa Health Research Centre (DHRC)
Program for Appropriate Technology in Health (PATH)	Newmont Ghana Gold Limited
United Nations Foundation	National Malaria Control Programme (NMCP) in Ghana
World Health Organisation (WHO)	Kwame Nkrumah University of Science and Technology
The David and Lucile Packard Foundation	University of Ghana, School of Public Health
Barcelona Institute for Global Health (ISGLOBAL)	Kumasi Centre for Collaborative Research in Tropical Medicine (KCCR)
University of Massachusetts	Noguchi Memorial Institute for Medical Research (NMIMR)
European and Developing Clinical Trial Partnership (EDCTP)	UNICEF Ghana
The Liverpool School of Tropical Medicine	
Novartis Pharma AG/Quintiles Clindepharm (Pty)	
Bill and Melinda Gate Foundation (BMGF)	
European Commission	
Brown University	
London School of Hygiene and Tropical Medicine (LSHTM)	
Massachusetts General Hospital	
European Vaccine Initiative (EVI)	
African Research Collaboration for Health Limited	

External	Internal
University of Malawi, College of Medicine	
Kenya Medical Research Institute (KEMRI)	
Fogarty International Center	
George Washington University (GWU)	
Harvard's Beth Israel Deaconess Medical Center, Boston	
George Town University	
The International Vaccine Institute (IVI)	
Columbia World Projects	
National Institute for Health and Care Research (NIHR)-UK	
The Wellcome Trust Limited	
Icahn School of Medicine at Mount Sinai	
President's Malaria Initiative ("PMI")	
Sanofi Pasteur Inc	
Research Triangle Institute (RTI International)	
Forma Therapeutics, Inc	
Radboud University Medical Center, Netherlands	

Staff

KHRC recorded a total staff strength of 582 during the year under review. These staff worked on different projects. In line with the Centre's strategic plan to make it attractive to partners, the existence of a Health and Demographic Surveillance System (KHDSS) offers support to all projects at the Centre. Again, there is a database that informs prospective collaborators in making informed decisions about research activities. The KHDSS currently has 78 staff.

Study areas

The centre continued to operate in six (6) contiguous districts of the Bono East and Bono regions namely Kintampo North, Techiman South Municipal and Techiman North District, the Kintampo South, Nkoranza North and South districts with the Kintampo North municipality being the Headquarters. The centre maintained links with Afrancho, Akumadan and Nkenkesu communities in the Ashanti Region. The centre also operated in the Volta and Central regions.

Transport

The centre has seven 4X4 pickups, one Tata truck, four troopers, four trooper carriers, 2 land cruiser 100, 2 prados and one welfare bus.

Guest House

The facility offers decent accommodation for visitors to KHRC. The guest house is about a 15 minute walk from the centre. It has a 24-hour security service. The rooms are fitted with air conditioners and fans. Also, it has a 24/7 Internet service.

There are mosquito nets fitted in all the rooms. All of that is to ensure visitors have a comfortable stay. The rate per night at the guest house is US$50, while meals are $5 for breakfast and $7 for lunch and dinner. There is a bar which is stocked with a large variety of drinks. There is also a standby generator to provide power when the national grid goes off. The guest house received 104 visitors within the period under review.

"The Pentagon"

This is the staff eating place. Breakfast, lunch and dinner can be arranged at the Pentagon. Special meals can also be requested for.This can be served at either the Pentagon or the at the guest house depending on the visitor's preference.

Website

The centre's website continues to be the outlet which provides information to the outside world about activities at the centre.

Auditing

To ensure that funds given to the centre by funders and donors are judiciously used and accounted for, the centre hosted Ghana Audit Service and Price Water House Cooper Ghana during the year under review.

Visitors

The centre was privileged to host important personalities during the 2023 fiscal year.