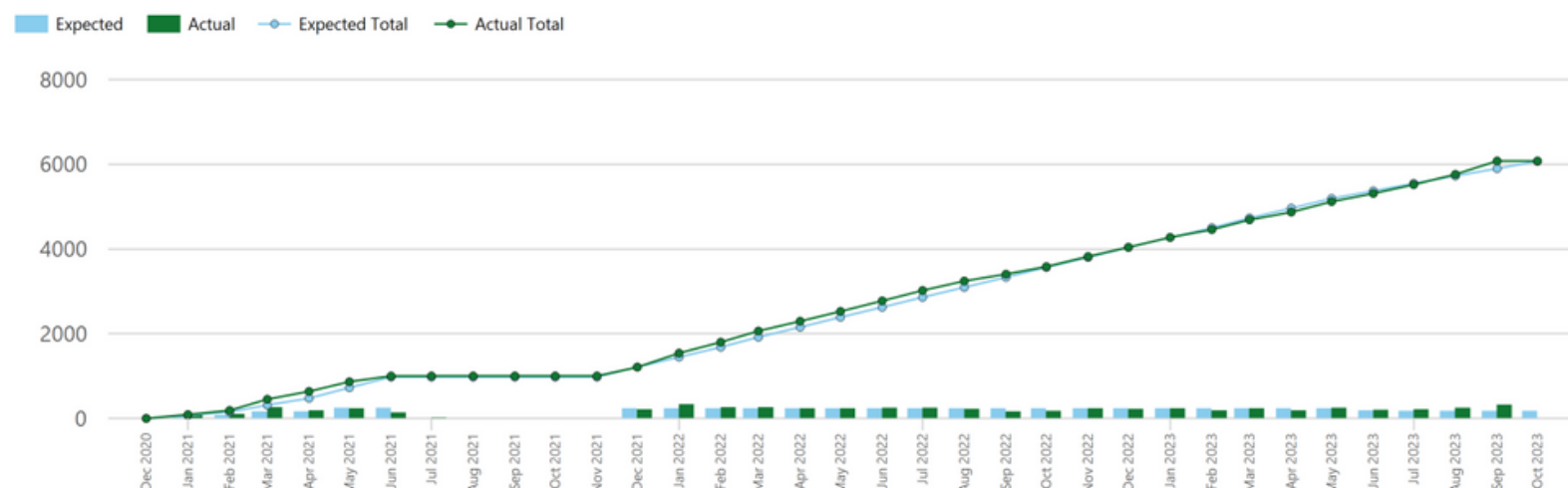


BabyGel Newsletter

Overall recruitment



BabyGel



Despite the many challenges, you have shown great mental strength and dedication to drive this project near to its closure! You have gone above and beyond to make this project a success and to ensure the conclusions drawn from the data are statistically and clinically sound. We hope to publish the results from the study as soon as possible, with dissemination meetings scheduled for summer 2024.



EDCTP

This newsletter was produced by BabyGel which is part of the EDCTP2 programme supported by the European Union (grant number RIA2017MC-2029 — BabyGel). The views and opinions of the authors expressed herein do not necessarily state or reflect those of EDCTP.

Recruitment Update!

On behalf of the whole management team, we want to say a huge “THANK YOU” to each and every one of you who has worked so hard to screen and recruit women to the study. Recruitment has been amazing. As of 29 September 2023, we have successfully recruited 6,107 women, surpassing our 5,932 target! The graph above shows the total number of participants we expected to recruit and the numbers we actually recruited for each month.

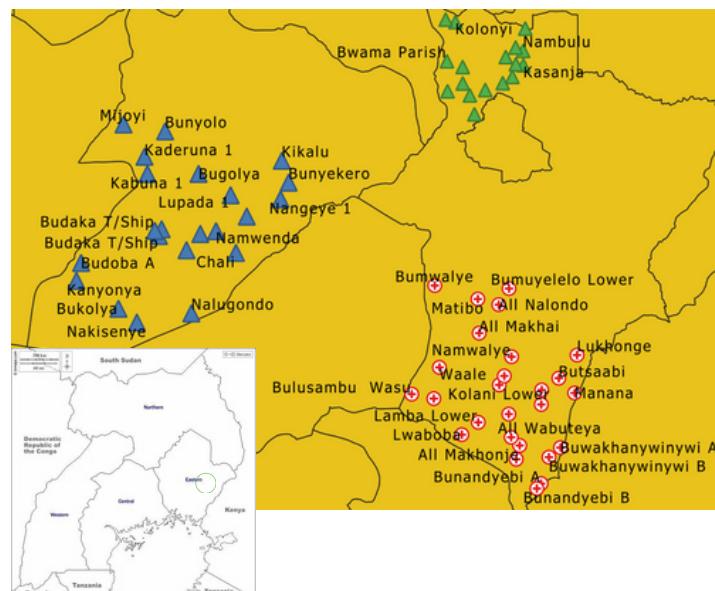
Thank you for your incredible work in achieving these milestones!

WHAT IS BABYGEL?

BabyGel is a phase 3, open-label, 2-arm, stratified cluster randomized clinical trial to evaluate the effectiveness of alcohol based hand rub (ABHR) for the prevention of sepsis, diarrhoea and pneumonia in Ugandan infants in 72 different villages.

Those mothers in the control arm, received standard antenatal care, Maama birth kits, antenatal education and are monitored in the same way as those in the intervention clusters (apart from ABHR trainer visits). Those mothers in the intervention arm also received 6 litres of ABHR and the aforementioned ABHR trainer visits.

Eligible mothers (those of 34 weeks of gestation, consented to the trial, and resided in one of the 72 villages) were then followed up with a minimum of 9 visits (more if mother is in intervention arm and/or has a long pregnancy)



A map of Uganda and of the 72 villages in Uganda, Mbale, where the BabyGel study is being conducted in - main hubs are Budaka, Busia/Busui and Kolonyi.

DID YOU KNOW...

Each year, 141,000 infants in Uganda die before reaching their 5th birthday - 1/3 of these occur in the neonatal period [1].

PRIMARY OBJECTIVE

- **To compare the effect of ABHR on severe illness or death in children in the first 3 months of life born to mothers who are enrolled in the BabyGel trial.**

The BabyGel protocol was published in the Trials journal.

It can be accessed at

<https://doi.org/10.1186/s13063-023-07312-1>

SECONDARY OBJECTIVES

- **Infant (in the first 3 months of life)**
 - To compare the effect of ABHR on:
 - Rates of diarrhoea
 - rates of respiratory tract infection
 - rates of omphalitis
 - rates of other infections
 - linear and ponderal growth
 - economic outcomes for the family and health services
- **Mother**
 - To explore the effect of ABHR provision on maternal behaviour
 - To compare the effect of ABHR on rates of maternal sepsis

1) Mbonye AK, Sentongo M, Mukasa GK, Byaruhanga R, Sentumbwe-Mugisa O, Waiswa P, et al. Newborn survival in Uganda: a decade of change and future implications. Health Policy Plan. 2012;27(Suppl 3):iii104–iii117.

DATA MANAGEMENT UPDATE

Well done to the Data Management team, Research Midwives, and Trainers for the vast amount of data collected and cleaned on the BabyGel study. We have almost reached our target! Lots of time is being dedicated to data cleaning right now.



Dr David Mukunya (Trial Manager) presenting at the Site Initiation Visit

WE MUST REMEMBER THE IMPORTANCE OF DATA ACCURACY, SO PLEASE MAKE SURE YOU DOUBLE-CHECK THE PID NUMBER BEFORE ENTERING DATA.

- Have you selected the correct participant?
- What is the name of the village?
- Is the baby a boy or a girl?
- What is the date of birth?

Congratulations to the data management team for completing courses in Advanced REDCap and Microsoft PowerBI!

DID YOU KNOW...

We have cleared 9062 data queries - that is an incredible amount of work!

These questions can help confirm that it is the correct participant before any data is entered and these checks will help to reduce any additional data queries. Thank you for all your hard work. We wouldn't be able to do it without you!



Authored by
Magdalena Namuyomba
Finance Manager

FINANCE TEAM UPDATE



Finance is the heart of any project/ organization - we therefore cannot ignore it in the success of the BabyGel project. Having been at the centre of managing the finances of the implementing partner, I must say it was a complex matrix because of the sizeable number of participants involved. This meant we had to employ a substantial workforce which included 117 VHTs, 18 VHT supervisors, and our own staff who were approximately 56 in number, distributed in 3 hubs/health centers and the central office.

Before commencing recruitment, we had developed different finance systems to enable us to have thorough control over the finances; however, at the start of recruitment we realized that a few of them were not compatible with the communities involved in the study. Eventually, the team developed robust cost-effective financial systems tailored to the communities, which ultimately contributed to the success of the study.

The expenditures for the study varied from fixed costs for example salaries, utility bills, rent, etc., to variable costs like medicines, medical equipment and other supplies based on the study needs which were dependent on participant consumption and one-time costs. The cycle of expenditure involved requests from the hubs sent to the central office then procurement and storage of items done centrally and further distributions of items to the respective hubs were done.

The study did not go with financial challenges but with the unceasing support from The University of Liverpool, we have been able to prevail over them.

Just like Benjamin Franklin said, **"An investment in knowledge pays the best interest"**. The study was worth the investment. Thank you, our donors and sponsors, for the support.



Pauline Beattie (from EDCTP) in discussion with the local SAFRI site team.



One of the recruited mothers on the BabyGel trial with her newborn child.

EDCTP VISIT - MAY 2023

On 15 May 2023, EDCTP carried out a productive visit to the BabyGel project.



We extend our heartfelt gratitude to all those who played a role in coordinating and facilitating the visit.



The EDCTP team expressed great satisfaction with the progress of the study, leading to the approval of an additional funding grant of 200,000 EUR to successfully conclude the project.



With this, we were able to fund further contract extensions to staff, to enable the steady continuation of BabyGel.

Showcasing our achievements

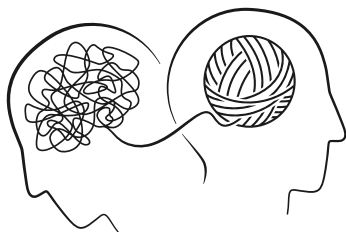
Liverpool Global Maternal Health Group meeting 07 June 2023

Congratulations to Dr Agnes Napyo, Dr Martin Chebet and Dr John Wogabaga for their outstanding presentations on BabyGel work during the Liverpool Global Maternal Health Group! Their presentations were highly successful and well-received!



BABYGEL CAPACITY BUILDING

BabyGel is also supporting multiple postgraduate projects as part of the trial.



Congratulations to our PhD students for their exceptional achievement in having their abstracts accepted for the upcoming conferences:

Say hello to our PhD students!

Francis Okello: *Understanding the Economic Impact of Universal Household Hand Hygiene in Children under five in Uganda*

Martin Chebet: *Incidence and Aetiology of term stillbirths in Eastern Uganda*

Noealla Okalany: *Congenital Cytomegalovirus Infection in Eastern Uganda*

Say hello to our Masters students!

Wogabaga John: *Incidence and predictors of Omphalitis in Eastern Uganda*

Itabanji Ambrose: *Validity of EPDS compared to Mini DSM among postpartum mothers in Eastern Uganda*

Weere Winfred: *Perceptions and acceptability to donating breastmilk in Eastern Uganda*

Thank you to our partners!



BabyGel



EDCTP FORUM, 7TH—10TH NOVEMBER 2023

Comorbidity-related inequality in COVID-19 deaths in Eastern Uganda: Implications for priority setting for equitable access to pandemic vaccines.

Authors: Okello F, Obbo J, Alaroker F, Etolu W, Paasi G, Abeso J, Ndila C, Abongo G, Olupot-Olupot P

ECTMIH CONGRESS, 20TH—23RD NOVEMBER 2023

Gender disparity in malnutrition among children with severe malaria in Eastern Uganda.

Authors: Francis Okello, Martin Chebet, Charles Okalebo, Denis Amorut, Paul Ongodia, George Paasi, Cate Namayanja, Peter Olupot-Olupot

Impaired Extrauterine Growth among Preterm Infants in Eastern Uganda: The Role of Intrauterine Growth Restriction.

Authors: Okalany N, Okello F, Ikiror J, Acom L, Burgoine K

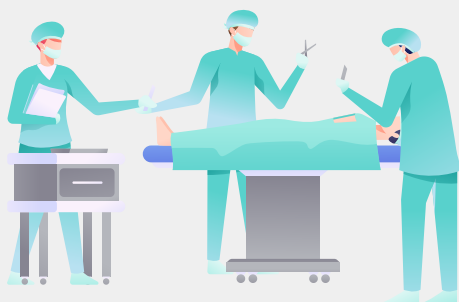


Authored by Amanyah Daphine (left) and Nambozo Brenda (right).

“Wolayo”: the BabyGel near miss

Wolayo, a 34-year-old mother of 5, was recruited into BabyGel in June 2023 when she was 34 weeks pregnant. She was well throughout her pregnancy until she went into labour on 13 September 2023.

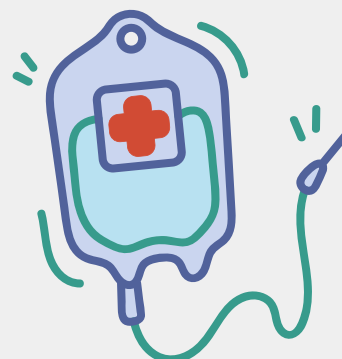
She was taken to the nearest health centre where she was admitted and monitored until the next day. She was later diagnosed with poor labour progress due to cervical dystocia. A decision was made by the BabyGel Medical Officer to perform an emergency cesarean section.



The medical officer quickly called for help and resuscitated her. She was immediately referred to MRRH for further management including blood transfusions and high-dependency unit services with her caregivers gravely terrified.



Wolayo was taken to the theatre, where the operation was performed successfully, and she delivered a 3.6 kg baby boy. In the post-operation ward, the medical officer went to review an hour later, and she observed that Wolayo was covered in sweat, delirious, and very pale - Wolayo was in shock due to severe anaemia!





Authored by Amanyah Daphine (left) and Nambozo Brenda (right).

“Wolayo”: the BabyGel near miss

Wolayo at MRHH

Wolayo was received by the BabyGel research midwife, who was instrumental in outsourcing the necessary medical resources to manage her. She was admitted to the High Dependency Unit on 14/09/2023 with a diagnosis of severe anaemia, four hours after the emergency cesarean. She was unconscious and put on oxygen therapy and a blood transfusion. She was transfused with several units of blood, with her family extremely worried at her bedside.



Entrance to MRHH

Wolayo later developed a distended and tender abdomen. An obstetric ultrasound scan was done which revealed an echo complex left adnexal mass and diagnosed with a broad ligament hematoma. She was still being managed on blood transfusion and antibiotics, but her Hemoglobin level was very low. She had to be taken back to the theatre for an exploratory laparotomy. The MRRH team successfully secured enough blood units for Wolayo after a long search.



Wolayo was later taken to the theatre for an ex-lap and hysterectomy to stop the bleeding. In the following days, she developed maternal sepsis. She was well-managed on strong antibiotics for a month by the MRHH and BabyGel team.



Authored by Amanyah Daphine (left) and Nambozo Brenda (right).

“Wolayo”: the BabyGel near miss

Wolayo’s aftercare

Wolayo and her family are so grateful for the abundant support and dedication, provided by the BabyGel team. Her caretakers testify that if it wasn't for BabyGel's support, Wolayo would have lost her dear life.



Mbale Regional Referral Hospital

She reported she got the courage to fight for her life through the persistent monitoring and care given to her by the BabyGel team while at MRRH and back home. Staff provided her with hospitalization upkeep, covered her medical expenses, and still kept checking on her while she was discharged to ensure she was coping well with life.

“Wolayo means that, “she tested death and survived it”, and this was a nickname she was given after she was discharged from hospital.”



JENA'S STORY - "BABYGEL: MY SAVIOUR"

Jena (pseudonym to protect privacy) almost succumbed to maternal sepsis if it wasn't for BabyGel.

Authored by Monicah Nakyazze

JENA'S BIRTH EXPERIENCE

Jena was 17 when she was recruited on to BabyGel on the 26th March 2021. Jena sought care on the 1st June 2021 at Nakaloke HCIII where it was confirmed that she had severe malaria in the latent phase of labour. Jena was carrying big baby so the health center staff decided to refer her to MRRH for appropriate care.

At MRRH she was admitted by one of our BabyGel Research Midwives and given anti-malarial treatment. After the second day in hospital, Jena's mother ran inpatient. The traditional birth attendant (TBA) oversaw care for 36 hours, however; unfortunately, Jena's pregnancy did not progress.

The TBA had now sent Jena back to the MRHH, as he was afraid of maternal death occurring on his watch - but now Jena was in obstructed labour.

BABYGEL LOSS

On the 5th June 2021, at 9 a.m. the decision was made for Jena to have an emergency cesarean section (CS). She was operated on, but unfortunately, it was a fresh stillbirth. Our baby had died, and we had no one to follow up - it was so sad. Jena had also lost a lot of blood during the CS and almost went into shock.

JENA'S CONDITION DETERIORATES

On the second day post-CS Jena was taken back to the theatre by the BabyGel Medical Officer for an exploratory laparotomy. On the third day post-CS, her wound started oozing pus and it was confirmed it was maternal sepsis. Jena was then admitted to the sepsis unit, where the BabyGel team could visit and accord her the support she needed.



The obstetrician (right) who undertook Jena's (left) secondary closure surgery.



JENA'S STORY - "BABYGEL: MY SAVIOUR"

JENA'S BATTLES COVID-19

A few weeks later Jena contracted COVID-19. Whilst in the COVID-19 ward, her wound is neglected and worsens each day. The anxiety of watching people die each day couldn't late her feed. BabyGel staff members still had to act to prevent Jena from dying amidst the COVID-19 pandemic. The responsible midwife disobeyed all the curfew rules set by His Excellence, rushing to get Jena's medication on time. Unfortunately, the MRHH midwife also contracted COVID-19, leaving Jena alone.

NO MOTHER OR BABY MUST DIE

BabyGel concludes Jena's 36 days of hospitalization. Jena went through a lot - having 4 surgeries in 1 month but BabyGel was there. Her wound was now ready for secondary closure and the teams joined forces to see this happen.

JENA'S MOTHER SAYS...

"The Sanyu basawo really helped me, as you see this home, I do not have anything. They provided money for food and drugs. All the drugs Jena used were expensive: there were none that cost only 10000 shillings. All the drugs were 40000 shillings and above."



The staff at MRHH in hazmat suits due to the COVID-19 pandemic, who cared for Jena.

A FEW WORDS FROM OUR INVESTIGATORS...

"Running a study in which 6000 women and babies are recruited from 72 villages in eastern Uganda is very complex. However, SAfRI has managed to conduct a very high-quality study, working with the local community. The European partners are incredibly impressed with the work of SAfRI and we look forward to future work together."

Dr Andrew Weeks - Chief Investigator



One of our Research Midwives taking part in the Site Initiation Visit



Dr Martin Chebet (left) with the trial manager (right).



Our Research Midwives practicing their clinical skills.

"With the help of our foot soldiers (the research midwives, ABHR trainers, medical officers and data supervisors) at the hubs and community participation, we have been able to enroll and follow participants in the BabyGel trial effectively. The BabyGel management that has held several meetings through the Trial Monitoring Group(TMG) and other groups such as the data management meetings have ensured that the quality of research activities and data collected is high."

Dr Martin Chebet - Principal Investigator