



MILK Study Newsletter

April – June 2022



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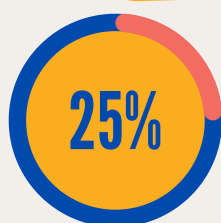
Hello and welcome to the first Maternal and Infant Lactation Pharmacokinetics (MILK) study newsletter.

The MILK study aims to generate high-quality evidence made available and accessible to others to promote breastfeeding wherever possible, especially for women with medical conditions requiring pharmacotherapy.

Around half of all women worldwide require medication whilst breastfeeding. Historically, breastfeeding women have been excluded from drug research, largely with the intention of protection from harm. However, the lack of data to inform safe medication use in this population itself brings risk.

In much of the world, including Uganda, the first-line treatment for uncomplicated malaria is artemether-lumefantrine (AL). Despite having been in use for more than a decade, including in breastfeeding mothers, the amount of medicine that transfers through the breastmilk to the breastfed infant has never been studied. This is important to understand because lumefantrine stays in the body for quite a long time, and has the potential to accumulate in the breastmilk.

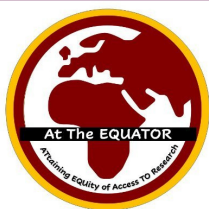
Achieving the 25% Recruitment Milestone



What is the best way to drive innovative research work? Important clues hide in the daily effort stories of the team members and the teamwork that gets things moving.

In the quarter ending in June, the Maternal and Infant Lactation Pharmacokinetics (MILK) team celebrated a 25% recruiting milestone for the Tuberculosis (TB) protocol under the study.

Ms. Jovia Tabwenda, a research nurse under the MILK study attributes the success to the high level of collaboration and the strong foundation that was laid in the initial stages of the study strategizing





Jovia Tabwenda

“It was a very well thought out plan to have Memorandums of Understanding (MoUs) with the Ministry of Health and Kampala Capital City Authority Centers where we managed to get focal persons that alert and send us participants. We have good communication and understanding on both sides which eases the workflow and eliminates the hurdles of running from one place to another,” Jovia shares.

Jovia also attributes the milestone to the extraordinary teamwork exhibited by the MILK study team right from the Principal Investigator, the coordinator, modelers, and public engagement, up to the lab runner.

“There is open communication among the team and all ideas are welcome. We have several communication channels under our public engagement which has ensured that information is timely shared with all team members and the general public.”

The study's Principal Investigator Prof. Catriona Waitt is delighted about the milestone and is very hopeful about achieving the set targets.

“Tuberculosis remains a big problem in pregnant and postpartum women. We were able to achieve recruitment ahead of expected timelines through working with several Kampala Capital City Authority (KCCA) clinics.”



Prof. Catriona Waitt

The study Coordinator Ritah Nakijoba attributes the 25% milestone in just four months to the well-coordinated study and steadfast teamwork to reach the target participants.



Ritah Nakijoba

“We started enrollment in March, but we are already registering good feats. Breastfeeding mothers on TB medication are not to get as participants in a study considering the high stigmatization in our communities. The strategy of working with up to six sites has paid off and we are hopeful we will hit the 100% mark.”

Public Engagement – ‘It Takes a Village’

Engaging key decision-makers in your research—namely, community leaders, the general public, policymakers, donors, elected officials, donors, and advocacy organization is more crucial than ever.

We have been implementing the public involvement project, 'It Takes a Village', in Hoima City between 2020 and 2022. The main outcome was the co-creation of Information, Education, and Communication materials that include job aids and posters with messages promoting positive health around early infant nutrition in the context of HIV.

Several workshops and periods of fieldwork were undertaken by the Village Health Teams in order to determine how rural communities were best able to understand information. The major themes were that the messages should be kept simple and that photographs of people and places that the communities could easily identify with were very helpful.

The MILK study Principal Investigator Prof. Catriona Waitt notes that whilst this pilot project has reached its conclusion, the partnership between the MILK study team at IDI and the VHTs in Hoima district will continue through the Wellcome funded At The EQUATOR grant which will explore equity of access to research.



Prof. Catriona Waitt

It is essential that both rural and urban communities are represented and we very much look forward to learning from the insights of the team in Hoima. Communities tend to appreciate and use materials that they too have contributed to developing because can easily interpret and pass on the messages.

Adelline Twimukye, a behavioral scientist at Infectious Diseases Institute who has been a trainer in the public involvement project says government structures should intentionally involve the Village Health Team (VHT) members in all public engagement activities if they are to attain sustainability

“Village Health Teams are motivated by the prestige of being selected as health promoters, especially when it comes to caring for pregnant and breastfeeding mothers. This is a role they perform voluntarily on a daily basis. There is a need to recognize train and reward them to boost their morale”



Adelline Twimukye

Jackie Kyeyune has under the MILK project had her first hands-on public engagement experience and she believes these are lessons that will take her to another step in her career. She has been actively involved in documentation and filming activities, which has enhanced her knowledge and skills



Jackie Kyeyune

We received training in public engagement and especially the use of digital media to pass on information. As a team, every contribution counts and is valued regardless of who you are. This has boosted self-esteem among the team members. I am now equipped with the technical skills in using social media and I will be at the forefront of creating awareness of the importance of research and achievements of the MILK study. This will improve the public's response and involvement in research.

Pharmacokinetic Modeling

Pharmacokinetic (PK) modeling is the use of mathematical models to characterise the change in measured drug concentrations across time in an individual or for a group of individuals in a population. Nonlinear mixed-effects modelling is the most widely used approach for PK modelling. This involves characterisation of the changes in drug concentrations across time, simultaneously characterising the typical (most likely) profiles in the whole population, variability between and within individuals in the population, and very important, the patient/treatment-related factors that affect the change in drug concentrations across time.

How PK Modeling is used to conduct research

PK modelling is primarily used to estimate parameters that characterise the change in concentration of a drug over time (or disposition of a drug): These parameters describe the processes of drug absorption from the site of administration to the systemic (blood) circulation, the distribution of the drug to various parts of the body and elimination of the drug from the body. This enables characterisation of the rate and extent of exposure to the drug and forms the basis for understanding the beneficial or adverse treatment outcomes.

What has been its impact so far under the MILK study

PK sampling is currently ongoing in the MILK studies and the drug concentration data is not yet available for PK modelling. However, PK modeling concepts have already been employed to inform how many, and when to conduct PK sampling, to obtain more informative drug concentration data, to ensure patient comfort and reduce the financial and logistical burden of conducting the studies

What inspired you to apply and why were you interested to join the MILK Study



Dr. Francis Ojara Williams

The Postdoc research position under the MILK study was appealing for two major reasons. It offered me the opportunity to pursue research in a critical and overwhelmingly understudied population; breastfeeding mothers and their infants. Secondly, it was an opportunity for career growth in various regards like improving my research capabilities through the day-to-day project work, better project management, and grants application skills, expanding my collaboration network, and working with different partner institutions. In addition, it provided a platform to grow the field of pharmacometrics research and clinical use for improved patient care, something that I am very passionate about.

What has been your experience working under the MILK study?

“It has been amazing to meet and work with various colleagues within the MILK study and Infectious Diseases Institute (IDI) as a whole. The multi-disciplinarity including clinicians, nurses, statisticians, laboratory experts, and communication specialists within the MILK team and the IDI provides an intellectually nourishing environment and opportunity to learn different views on common themes. Within four months, there is progress on several project objectives including approval of study protocols, working on review manuscripts, and core community engagement activities. Given our current trajectory, I am optimistic about learning and further career growth with my time on the study.”

The MILK Study Community Advisory Board

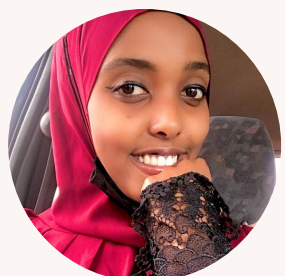
Community engagement is a key component of health research. One of the ways health researchers ensure community engagement is through Community Advisory Boards (CABs).

The MILK study held its first Community Advisory Board meeting on 17th May 2022 at IDI Mulago. The CAB will serve as a voice for the community and local study participants and provide input into study design and local study procedures. Membership of the MILK study includes community members, cultural and religious leaders, representatives of local government leadership, representatives of health facilities, and professionals with relevant research and scientific expertise.

Engagement with the community should not only be done at the end of a research project in order to share results. Communication should take place at all stages from protocol design, and the undertaking of the study right through to analysis and dissemination. Insights from our CAB meeting enabled refinement of the study protocol prior to ethics submission. We plan to continue to meet several times a year for dialogue relating to this study and other potential future studies.



Prof. Catriona Waitt



Asia Mustafa - Intern

My experience as an intern under the MILK study was coupled with a lot of educative moments in the clinical and public engagement in which I participated most. I never knew what CAB was before. It was great hearing ideas from different people who take up different social roles in the community, giving ideas about the malaria protocol for the good of the participants. As I continue with my studies in Biomedical Science, if the opportunity surfaces at IDI in the near future, I would really love to apply for it

Pictorial



Spotlight Johnson Magoola Lab Runner

What has been your experience working as a lab runner under the research department?

The most important experiences are the opportunities that the department offers you to learn new things and understand the ethics and sensitivity since confidentiality is very key in research.

Tell us about yourself

My names are Johnson Magoola and I work as a lab runner under the MILK study at IDI. I have been working as a lab runner for the last 10 years. I am punctual, honest, dependable and you can count on me to complete assignments on short notice and during emergencies. I am passionate about learning new skills and I have completed a few online trainings on safety and some courses about transportation of hazardous materials. Over time, I have learned and mastered the importance of safety and handling study samples.

When did you join IDI?

I started as a part-time lab runner and was excited to be offered a full-time contract in 2013. I have gladly been serving up to date.

What has been your experience under the MILK study?

I have worked under different studies but the Milk study experience has been a whole new experience in a very short time. The teamwork and open communication make it very easy for all of us to fit in and timely handle the assigned tasks. The weekly meetings have been of great importance when it comes to sharing information, updates, and planning for the weeks ahead. We will achieve great milestones.

Where do you see yourself in the next 5 years?

With the experience that I have amassed over time, I want to develop skills in project planning and management. I am hopeful that with more knowledge and skills, I will be able to expand on my responsibilities within this role.

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