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# Analytical Treatment Interruption in Pediatric Populations in Low-Income and Middle-Income Countries

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&

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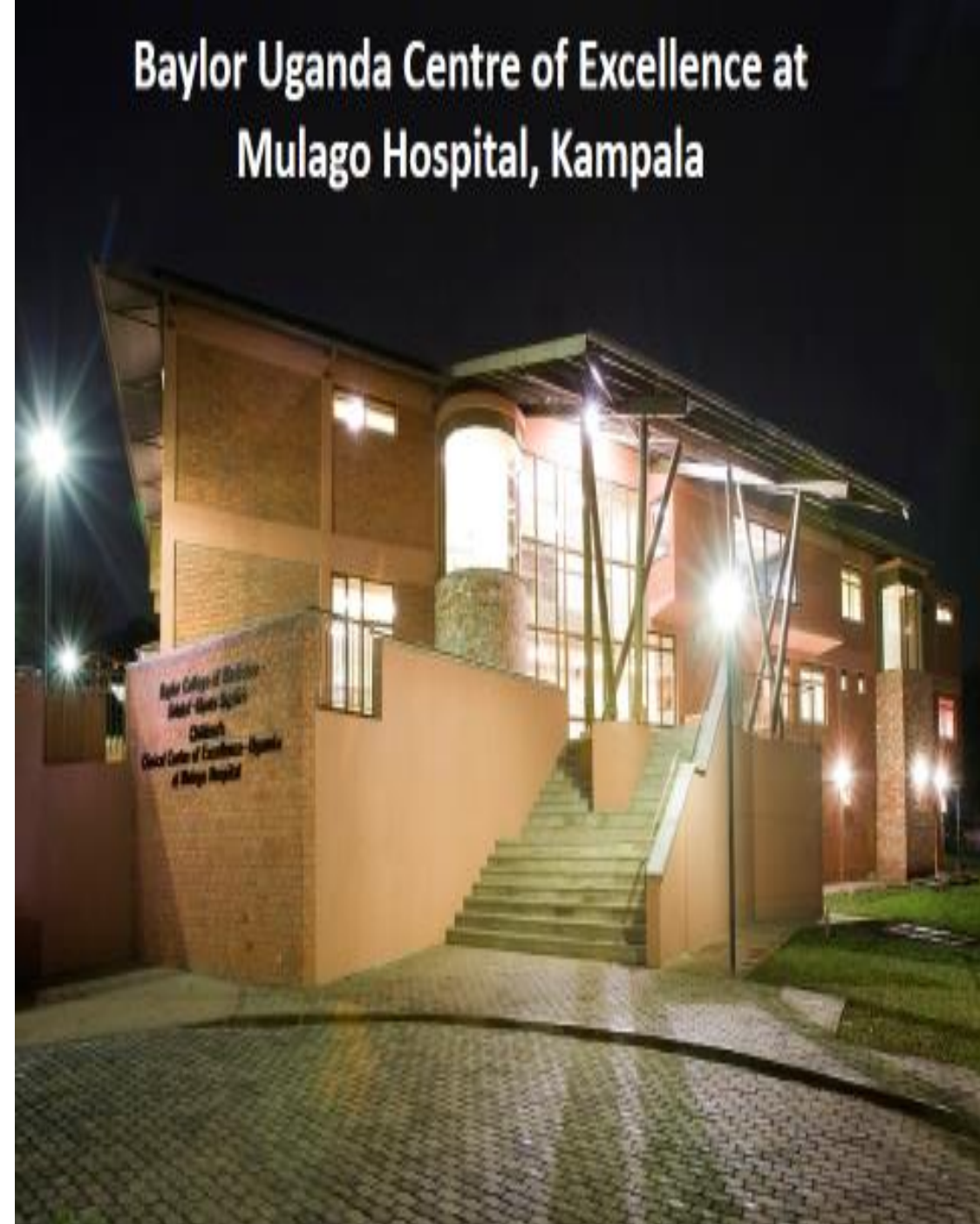
Baylor-Uganda CRS #31798



# Implementing IMPAACT P1115 at Baylor-Uganda CRS#31798

# Introduction

- The Baylor-Uganda CRS is located in Kampala, Uganda within the national HIV/AIDS clinic. The clinic caters to about 8,731 clients on cART (37% are aged <1 -19).
  - Over 90% are vertically infected
- Postpartum women with HIV and their newborns were recruited from labour wards of China Uganda Friendship Hospital and 04 Kampala Capital City Authority Health centers in the suburbs of Kampala
- For version 1.0, we had to test 617 newborns to get 10 neonates with in-utero infection of HIV
- 4 participants qualified for Analytic Treatment Interruption (ATI)





# Resources

- Partnerships with Hospitals and Health centers from which participants were recruited
- Partnerships with Central Public health laboratory for early testing (DNA PCR)
- A qualified team: Counselors, Doctors, Nurses, Midwives, Pediatricians, Pharmacist, phlebotomists, lab staff, Field officers, Drivers, Data officers, translators
- Proximity- the CRS is located at the Mulago National Referral Hospital; therefore, referrals can be made as per the participant's needs e.g. psychiatry, in-patient care
- John's Hopkins University Clinical Trial Unit team



# Resources cont'd

- HIV Care and treatment and wrap-around services are offered onsite
- Protocol team who aid in clarifying or troubleshooting
- SMC who review the data to ensure participant safety
- IRB, National Drug Authority & Uganda National Council of Science and Technology
- DAIDS-approved lab and pharmacy
- In-house community advisory board
- Training provided by the protocol team and also in-house training

# Ethical considerations

- Informed consent was sought at each Step, and the ethical balance between potential benefits (advancing HIV cure research) and risks (participant health) was carefully managed. The informed consent is reviewed at every study visit
- Participants' safety was prioritized to minimize harm; hence regular reviews are carried out, and the participants are encouraged to contact the site team at any time



# Psychosocial support, Challenges, Conclusions and Future directions

Associate Prof Emeritus Adeodata R Kekitiinwa (IoR of IMPAACT P1115)

Baylor-Uganda CRS #31798

# Psychosocial support

- Extensive psychosocial support for ATI study families should be provided by personnel within the study team
  - nurse/counselor/clinician/psychologist
  - This support may go beyond the site to the homes depending on whether the carer consented to be visited at home or not
  - Sometimes, this may include referrals for economic strengthening as these mothers are often young, vulnerable with questionable social support
- Staff must understand the context of each participant
- Long-standing trusting relationship with the participant
- 24-hour availability for the participant and family



# Challenges

- Despite the small number of participants, the amount of resources required to maintain these participants is quite high compared with per participant cost
- Because Uganda does not have a national insurance policy, when referrals are made, they have to join the long queues at the national referral hospital since there are no funds for private services
- Relocation of participants means that the site may incur extra costs to ensure that the participants come to the site for their visit

# Conclusions and Future Directions

- It is possible to implement ATIs in pediatric populations in low-income countries, but this requires resources and linkages with HIV care and treatment services
- Need more ATI studies in regions burdened with HIV
- Need more consensus guideline recommendations
- Build the capacity of the local investigators which results in career development within the institution
- This provides opportunities for long-standing trusting relationship with the participants



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- JHU CTU team
- The IMPAACT P1115 protocol team



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