The Work Ahead

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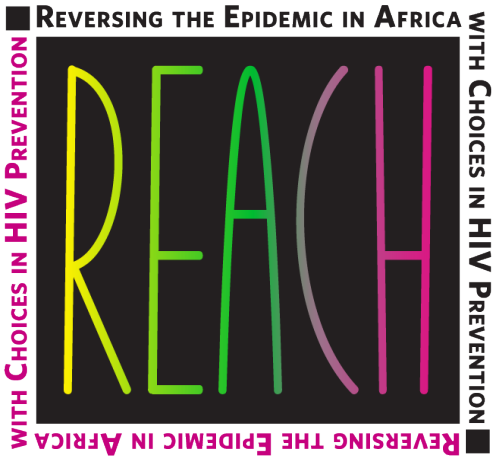
Collaborative Research Programme

Meeting the HIV Prevention Needs
of Adolescent Girls and Young Women
Zimbabwe Stakeholders Meeting on REACH
24 February 2017, Harare



Getting Ready for REACH

Overall Study Timeline

February 2017	• Protocol Version 1.0 approved by NIAID/NIH and sent to sites
March – August 2017	• IRB/regulatory submissions and approvals
September – December 2017	• Final preparations at sites
Before end of 2017	• Sites expected to begin enrolling participants
Mid-2020	• Study follow-up completed: 18 months per participant

Ethics and in-country approvals

- The study team will submit the protocol and consent materials (informed assent, informed consent and parental/guardian permission form) to the site's two Institutional Review Board/Ethics Committees
  - The Medical Research Council of Zimbabwe (MRCZ)
  - UCSF Committee on Human Research (UCSF CHR)
  - We aim for submissions end of March (2017)
  - Separate reviews are conducted
- Both IRB/ECs may ask questions (not necessarily the same), request additional information, or request revisions
  - Process can take up to two months
  - Because the study involves minors, reviews may take longer
- After both IRB/ECs grant approval, we submit the protocol to the Medicines Control Authority of Zimbabwe (MCAZ)

The process is important because…

- The protocol review process is vital to ensuring that a participant's safety, rights and welfare are protected, and that the research being conducted has scientific merit

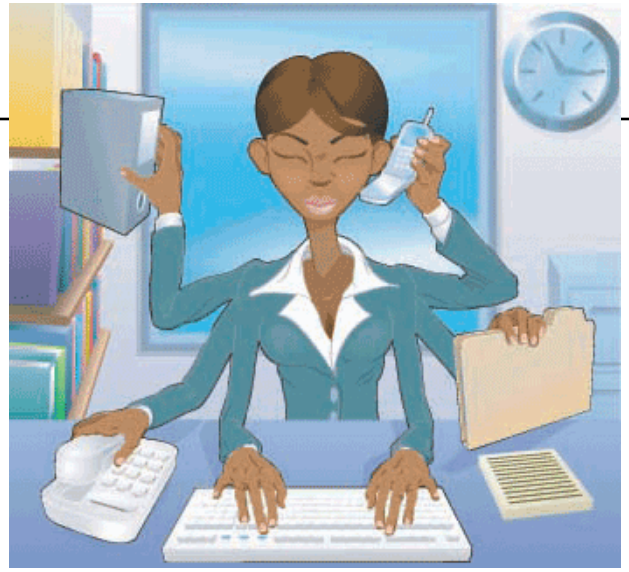
We don’t wait – the work has already begun!

- Each site must prepare several documents, procedures and forms
- The clinic, pharmacy, laboratory must meet specific criteria and be approved for the study
- For REACH, we will be working to ensure youth-friendly clinic space
- Additional staff may be hired to ensure the team has people with the right skills, experience and personal qualities for the study
- Site staff will undergo days of training, conduct mock participant visits and counseling sessions

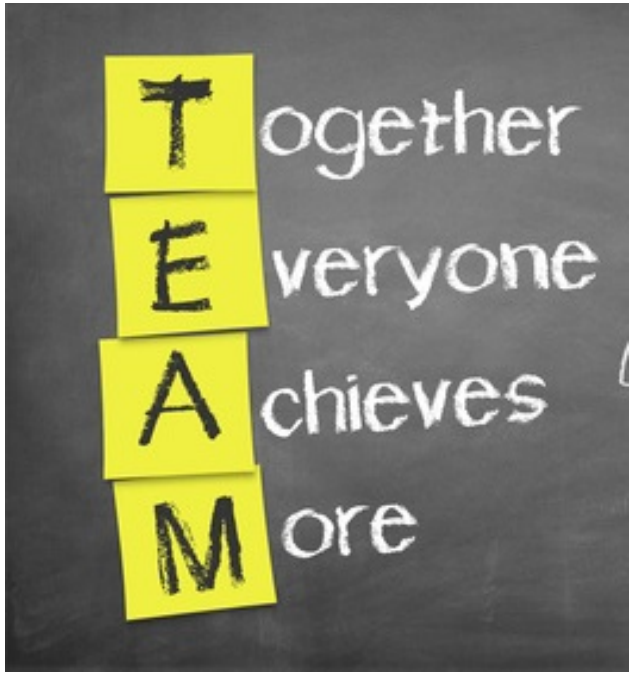
Community Engagement Plans

- Outreach activities with CAB and community stakeholders ramp up
- Creation and IRB/EC approval of community and participant education materials
- Planning for participant and community engagement
  - To support recruitment, retention, adherence
  - To ensure community support
  - To address concerns and rumors up front

There is a lot to do!

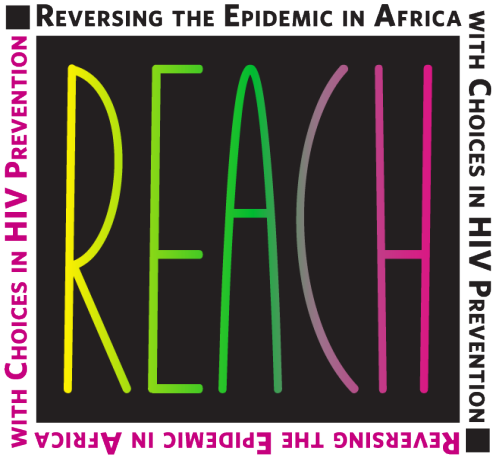


- It may take up to 6 months from the time of submission before the site is ready to begin enrolling participants



- Doctors, nurses, counselors, pharmacy staff, lab technicians, clerks, drivers, custodians and cooks -- everyone must be ready before the study can begin to ensure successful implementation and conduct of the study.

Questions?



The Realities and Requirements for Participating in REACH

Who may take part in REACH?

- For a young woman to join the study, she must meet the following requirements:
  - Be between 16-21 years old
  - Be able to comply with study requirements
  - Not be HIV-infected
  - Have had sex at least once
  - Not be pregnant
  - Been using an effective contraception for at least 2 months before enrollment
  - Not have any active STIs or other infections
  - Be generally healthy, as per physical and pelvic exams, as well as laboratory tests

A research study isn't for everyone

- For REACH, girls must be willing to come to the study clinic every month, for 1 ½ years
  - There are many medical tests and exams – some study visits may take several hours
- They must have had sex – and for those under age 18, must have a parent's permission
  - This means girls will need to admit they are having sex
- Participants should be willing to use the study products as directed
  - And if unable to use the products, to be open and honest about her experiences
  - Researchers need to understand these challenges so they can try to address them

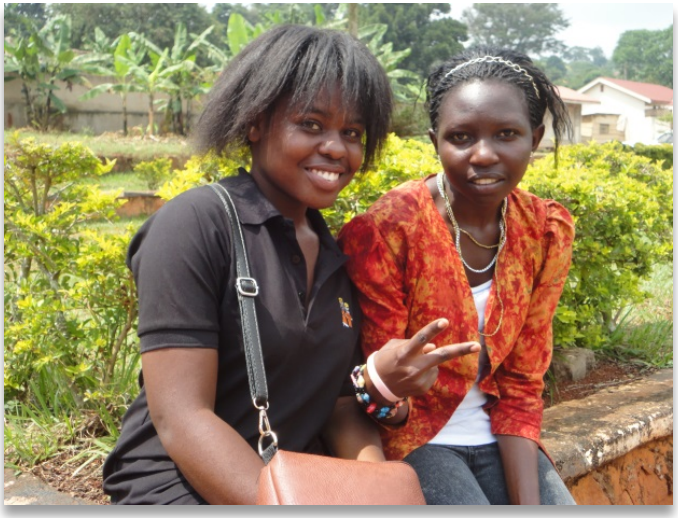
Services provided as part of the study

- Monthly visits will always include:
  - HIV and pregnancy testing
  - HIV/STI risk reduction, contraceptive counseling and provision of condoms
  - Individualized product adherence counseling
- Contraception counseling and services
- Social harms assessments, physical exams and pelvic exams will also be conducted at some visits
- Referrals will be provided for any issue the site cannot manage or cannot include as part of the study, such as HIV counseling and treatment, pregnancy and antenatal care and/or specialized counseling or other services.

Deciding to join the study

- In-depth informed assent and consent discussions with potential participants and their parents will be critical to ensuring that participants clearly understand the study procedures, time commitment, and importance of a successful study.
- Participation is voluntary. Likewise, participants may choose to leave the study at any time

- Enrolling in a research study is a commitment
- Enrolling in REACH requires commitment, but also a sense of purpose – to wanting to make a difference in the lives of adolescent girls and young women in their communities and around the world



REVERSING THE EPIDEMIC IN AFRICA WITH CHOICES IN HIV PREVENTION

REACH

Questions?