

Implementing RCTs in Sub Saharan Africa

The Rakai Story

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HUMAN RESOURCE

- Employed as coordinator of a community randomized trial in 1995.
 - Naïve in research, managing people and resources.
 - Very few people had research training
- Study tools given
 - Charged with training data collectors
 - First time to see study tools and to train
 - Pls 3-4 hrs drive away, no phones, internet
 - Read and 'understood' tools



LESSON

- **Recruit** qualified & experienced staff.
- **Thorough staff training**
- **Mentoring**
- **Recruit enough staff**

INFRASTRUCTURE

- Assigned a 12x12 ft office
 - Research , records, supplies, transport office
- Powered by National grid
 - Load shedding
 - Store and process samples
 - No work when power off
- Assigned vehicles
 - Roads were too bad - 4WD
 - Homes off roads - heavy tools
- Water - Labs etc
 - Need reservoirs



LESSON

- Plan for **enough office space**
- **Backup power**
- **Appropriate transport**
- **Water reservoirs**

DATA COLLECTION

- Community based data collection
 - We had to work with and in the community
- Completeness of records
 - Missing data - Data quality
- Interviewer Bias
 - data collectors are more aggressive in intervention arms.
- Participants - Cross over
 - Especially non blinded studies



LESSON

- **Community involvement**
 - political, religious, local leaders
 - Community linkages - CAB, CHWs
- **Data editors/QCs**
- **Re-training**
- **Regular data monitoring**
 - Check comparability of arms

DATA MANAGEMENT AND ANALYSIS

- Fresh graduates
 - No experience in screen design
 - Randomization & analysis in US
- Data entry, cleaning, analysis and reporting
 - No e-meetings then



LESSONS

- **Partnership** with others
 - Mentor & Support Training
- Routine **data monitoring** needed
 - Timely reporting
 - Regular conference calls

ETHICAL ISSUES

- Study approvals and renewals – IRC/IRBs
 - Delays – 2-3 months
- Consent for
 - Minors - Parent /guardian
 - Women - Spouses
- Compensation for time
 - How much is undue inducement?
 - May be different for different studies
- Requirement for staff to get ethics training
 - online HSP
 - In house GCP trainers, CITI
- Regulatory office
- Internal monitors to ensure ethical compliance
- PI anxiety especially in studies with DSMBs
 - Be patient
 - Both negative and positive findings are informative

ADMINISTRATION

- Clear organizational structure
- Policy guidelines and SOPs
 - HR, Finance, Fleet, Procurement, etc
- Supply chain
 - Minimize stock outs
 - Segregation of procurement and stores roles
- Finance management system
 - Checks and balances
 - Proper budgeting



Strategies for success in community interventions

- Government support – Central & Local
 - Eases translation to policy
- Collaborations/partnerships
 - Support/Expertise in different specialties
- Community Involvement – at all levels
- Provision of feed back – progress reports, dissemination,
- Provision of services or referral – study related
- Training and capacity building
- Infrastructure development

Human Resource Capacity building *Fogarty Trainees*

9 PhD degrees

32 Masters degrees

*JHU (20), Alabama (3),
Makerere (5) Regional (4)*

**18 Bachelors degrees,
Makerere**

65 Diplomas, Certificate

13 Post doc / Sabbatical



THANKS

