HIV Treatment Programs and Clinical Research in East Africa: A Symbiotic Relationship

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Background

- USAMRU-Kenya is a special foreign activity of the Walter Reed Army Institute of Research

- Has conducted malaria drug and vaccine trials in Kisumu West-Kenya since the 1970s

- First clinical trial to screen study volunteers for HIV conducted in 2007

- Of 775 adult volunteers screened, 29% found to have undiagnosed HIV disease
Cascade of study enrollments

- Briefed: 1199
- Consented: 919
- Screened: 775
- HIV +ve: 226
CD4 results of screened volunteers

- HIV +ve: 226
- CD4 >250: 173
- CD4 <250: 53
Challenges faced

- Precipitated the ethical need to offer comprehensive HIV care and support for those testing positive

- GCP 4.3.2 requires investigators to inform a subject when medical care is needed for an inter-current illness

- No sites in KW offering comprehensive HIV care

- PEPFAR funding allowed KW to hire a comprehensive HIV care team
Challenges faced....

- Collaborated with clinical trials team to ensure they have skills/capacity for managing HIV+ve participants

- Recent malaria, TB, & HIV trials conducted in KW have successfully provided HIV care to study participants

- Later used Demographic & Health Surveillance System (DHSS) to decentralize HIV care services

- Information used to show specific geographical location and density clusters of HIV disease
HIV-spatial clustering in Kisumu West
Integration of Clinical Services & Research

Clinical Research
- Phase I/II/III vaccine: TB, Malaria
- Therapeutics: Artesunate, FQ, AZCQ, AL
- PHE: CLADE
- HIV cohort studies: AFRICOS
- Demographic Surveillance System

HIV Comprehensive Care
- Improved diagnostics-clinic & lab
- Clinic data: quality, availability, EMR
- Facility based services
- Community interventions
- Access to services for all

Collaborations and technology transfer develop sustainable capacity and infrastructure.

PC&T provides a comprehensive community-based platform to support ethical research.
Lessons learnt

- In areas with high HIV prevalence, screening volunteers for HIV might be considered unethical under GCP if those participants cannot obtain needed medical care.

- Coordination between HIV-care donor groups and clinical researchers can ensure that volunteers are appropriately tested and offered treatment.

- Involvement of clinical research teams in HIV-care programs can improve care by providing data resources and assisting in measurement of appropriate health care quality metrics.

- Ongoing coordination between research and program staff, helps assure the optimal success of both programs.
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