

Examining Core Elements of International Research Collaboration: An International Case Study

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Questions to be Addressed

- How do you work out authorship issues?
 - Dr. Blattner
- How did you develop capacity to assure data integrity?
 - Dr. Aliyu Gambo Gumel
- How do you confirm data integrity?
 - Dr. Aliyu Gambo Gumel



Criteria for Authorship



- Substantial contributions to study conception and design, or acquisition of data, or analysis and interpretation of data;
 - AND
- Drafting the paper or revising it critically for important intellectual content
 - AND
- Final approval of the version to be published



Recruiting Acute Cases of HIV (REACH Study) in Nigeria

Collaboration:

***Institute of Human Virology, University of Maryland
School of Medicine***

***U.S. Centers for Disease Control and Prevention Division
of HIV/AIDS Prevention***

Nigerian Federal Ministry of Health



International Research Collaboration



CDC Program Officer/Grant PI



Study Director

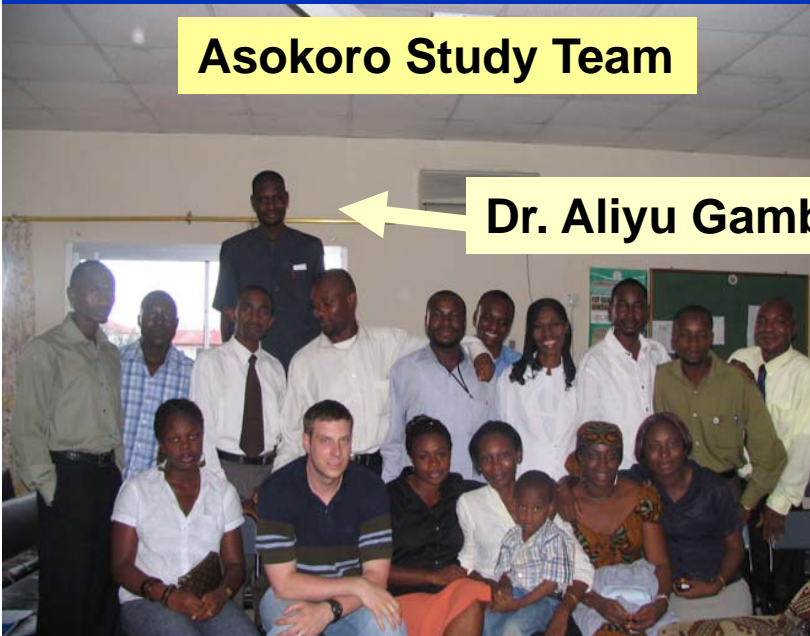


Lab Director



Nigeria PI

Asokoro Study Team



Dr. Aliyu Gambo Gumel



PLASVIREC Lab Team

Objective

- Sponsor deliverable – Create a repository of samples from non-subtype B acute HIV infection cohort
- Research goals –
 - Describe magnitude and correlates of prevalent HIV infection
 - Evaluate uptake to HIV care for HIV+ study participants
 - Describe genetic diversity of HIV among risk groups targeted
 - Evaluate performance of:
 - The Nigerian Rapid Test algorithm and the Roche Amplicor 1.5 for pooled screening for acute infections

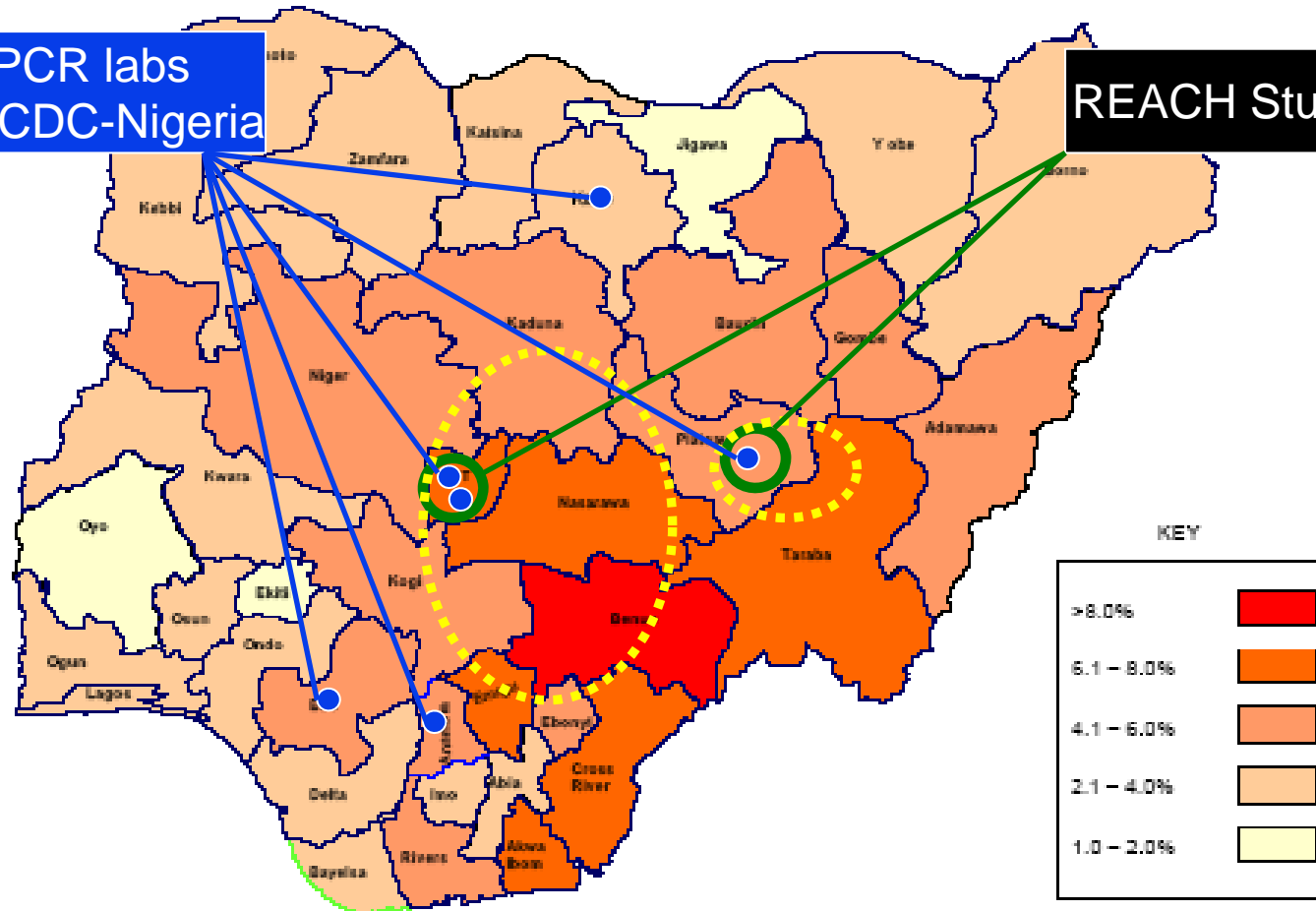


REACH Study Sites and Mobile VCT Coverage

HIV Prevalence by state (Nigeria 2005)

IHV-UMD PCR labs
Supported by CDC-Nigeria

REACH Study Sites



Recruitment Strategy

- **Facility-based**
 - ANC attendees
 - GOPD/STI attendees
- **Community-based via mobile VCT**
 - Brothel-based sex workers
 - Street-based sex workers
 - Motorcycle taxi drivers “Okada” (MCTD)
 - Outreach community groups
- **Two-stage informed consent**
 - Screening consent for all individuals counseled and tested
 - Seroconverter follow-up consent for acute infections identified
- **Enroll persons not previously known to be HIV infected and greater than 18 years of age**
- **Provide PwP (Prevention w/ Positives) and refer to care and treatment**



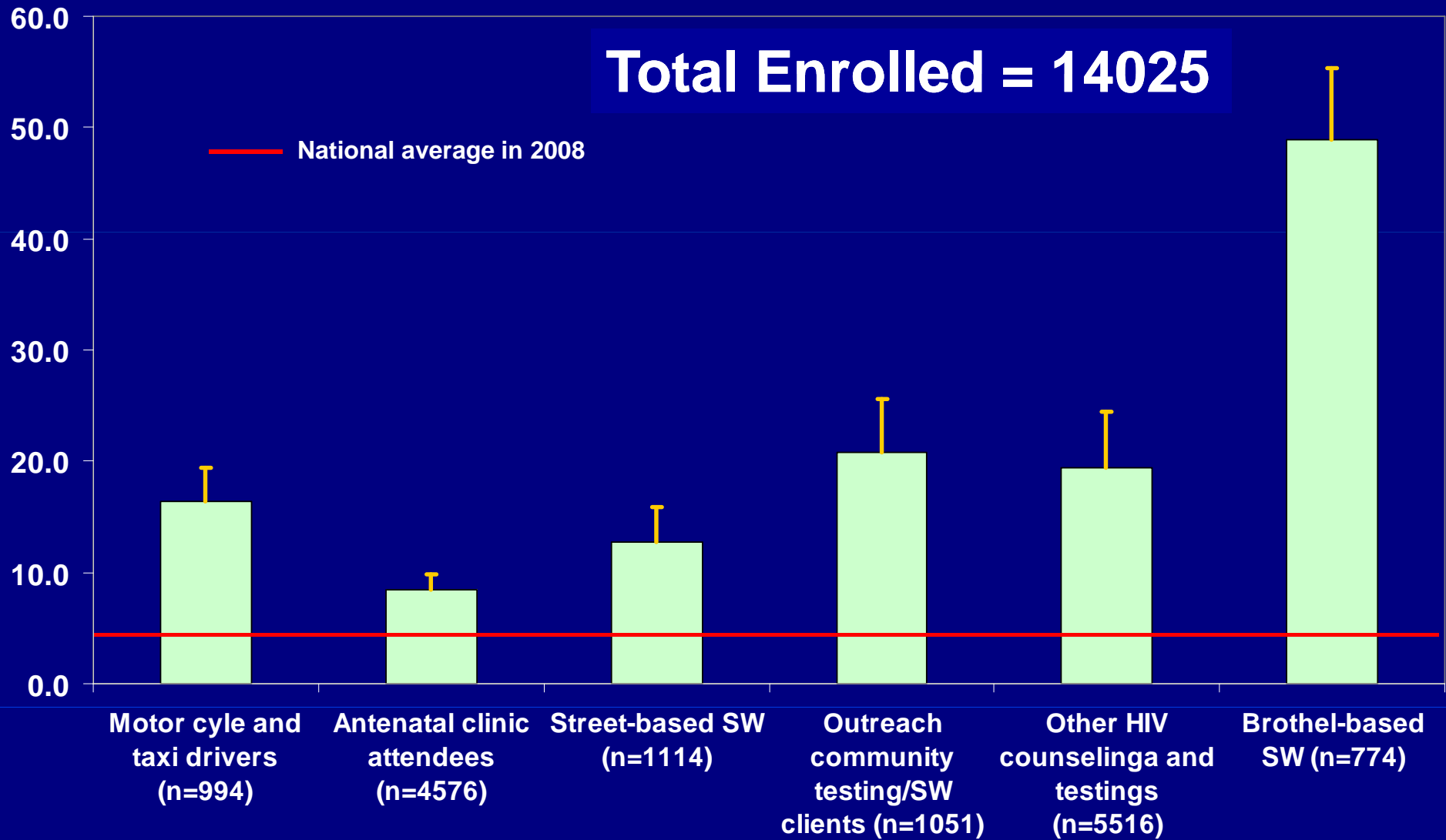


Night recruiting on local streets and clubs

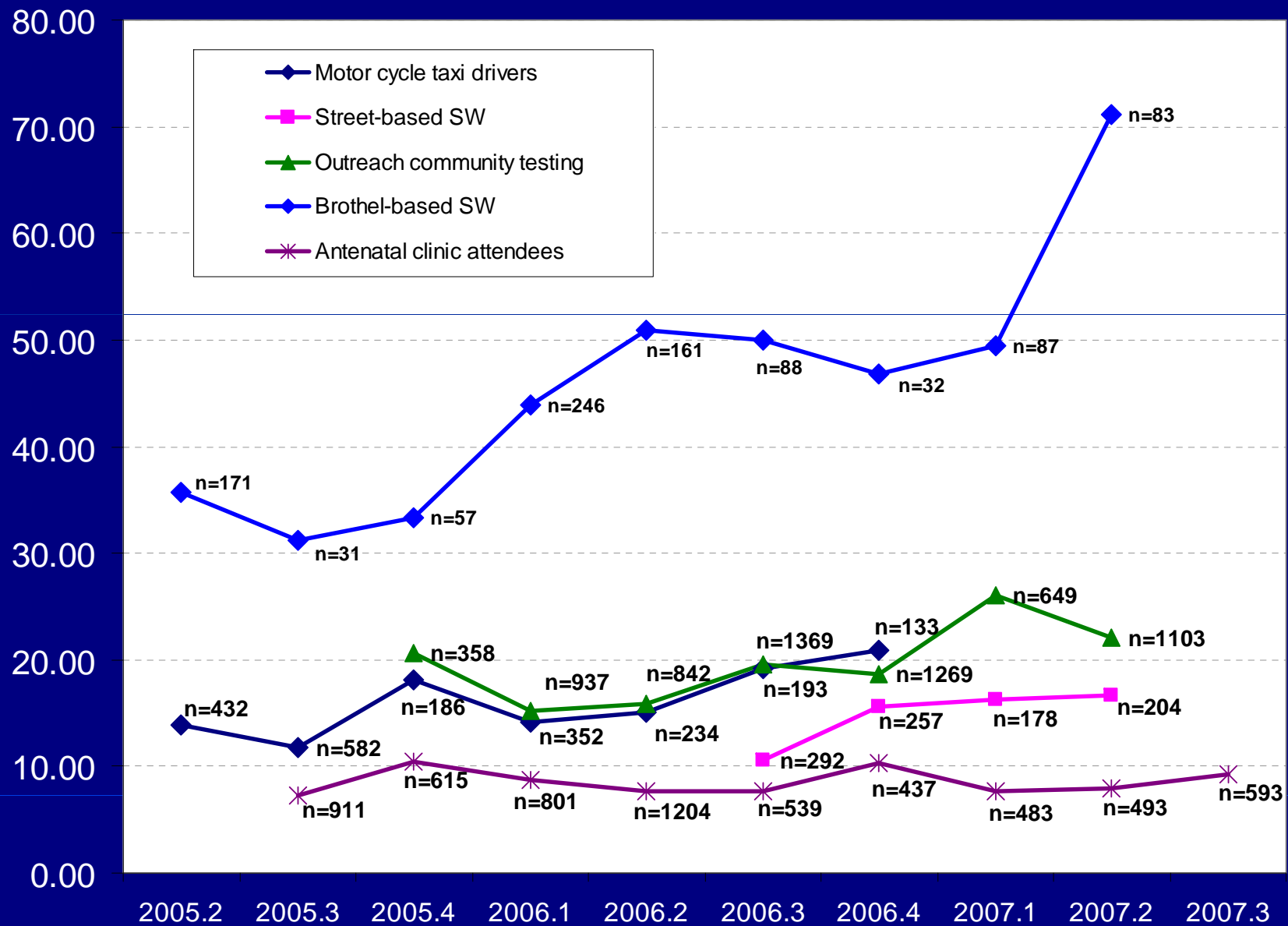


High HIV Prevalence Across Risk-groups

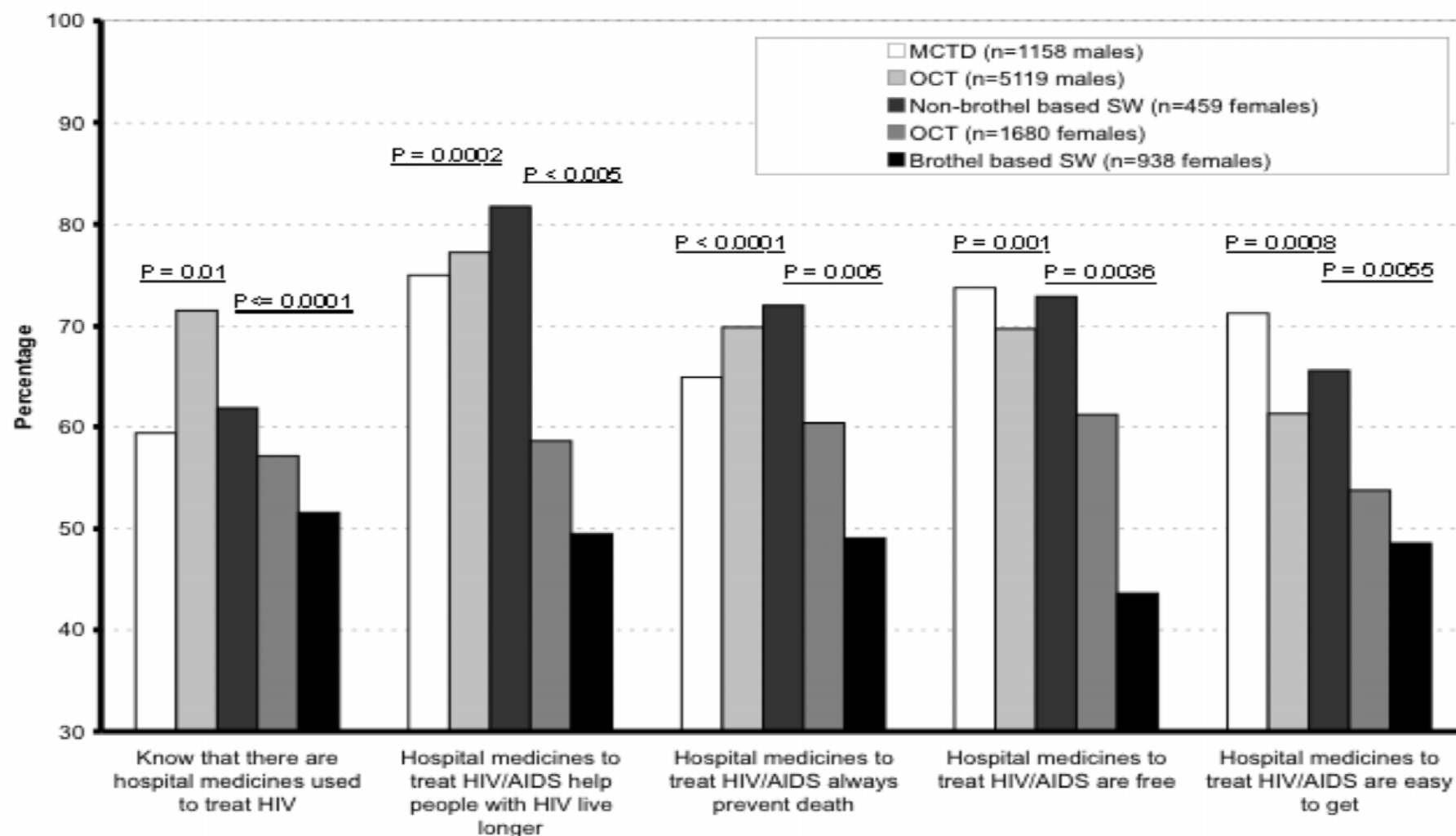
HIV prevalence according to risk groups



HIV prevalence may be increasing in certain risk groups



Lower Awareness of HIV Care Services among Female Sex Workers



List of Abstracts and Papers – Nigerian Co-Authors in Red

Types	Authors	Title
Abstract ICASA 2006	Charurat M, Saidu A , Delaney K, Villalba-Diebold, Aliyu G , Constantine N, Onoja A, Vertefeuille J, Blattner W, Nasidi A .	Identification of HIV Infection in 5 Populations in Abuja, Nigeria
Abstract AIDS 2008	Villalba-Diebold P, Saidu A , Charurat M, Martins E, Gurumdi S , Aliyu G , Nasidi A , Farley J, Blattner W.	Linking Community Information with Prevalence Data to Identify Underserved Most-at-risk Populations in Need of Access to Services
Abstract IAS 2009	Delaney K, Charurat M, Constantine N, Owen M, Keating S, Candal D, Ethridge S, Saidu A , Saleh A , Croxton T, Villalba-Diebold P, Aliyu G , Vertefeuille J, Sill A, Busch M, Nasidi A , Blattner W	Evaluation of Five Incidence Assays Using Nigerian Seroconversion Specimens: Implication for Surveillance Programs in Nigeria.
Abstract AIDS 2010	Delaney K, Charurat M, Villalba-Diebold P, Saidu A , Aliyu G , Abimiku A, Vertefeuille J, Nasidi A , Blattner W	Counseling and Testing for Nigerian Sex Workers: Increased Knowledge, Increased Condom Used, No Change in Risk of Infection
Paper AIDS 2010	Charurat M, Delaney K, Saidu A , Villalba-Diebold P, Aliyu G , Constantine N, Onoja A , Vertefeuille J, Blattner WA, Nasidi A	HIV Counseling and testing and access to care needs of populations most-at-risk for HIV in Nigeria
Paper in progress	Charurat M, Saidu A , Delaney K, Eyzaguirre LM, Nasidi A , Carr J, Blattner W.	Identification and Characterization of Acute HIV-1 Infections in High-Risk Population In Nigeria
Abstract HIV Diag 2010	Curtis, KenneCurtis KA, Kennedy S, Charurat M, Owen M, Delaney K	IgG3 as a Biomarker for Distinguishing Recent from Established HIV-1 Infection
Abstract HIV Diag 2010	Masciotra S, Dobbs T, Candal D, Hanson D, Delaney K, Rudolph D, Charurat M, Harrigan R, McDougal S, Owen S	Antibody avidity-based assay for identifying recent HIV-1 infections based on Genetic System ½ olus O EIA
Abstract HIV Diag 2008	Constantine N, Croxton T, Charurat M, Villalba-Diebold P, Abimiku A, Blattner W.	Alternative Confirmatory Testing Strategy Using Rapid HIV Assays



Goals of International Research Collaboration

- **Develop of culture of mutuality**
- **Strengthen Capacity of international collaborators to participate in all phases of research per authorship criteria**
- **“Level the playing Field” through international training and the practical application of research principles to protocol development and implementation**
- **Support international partners in obtaining independent research funding for projects of their own design**



REACH STUDY

Perspective of the Host Investigator

Gambo Gumel Aliyu

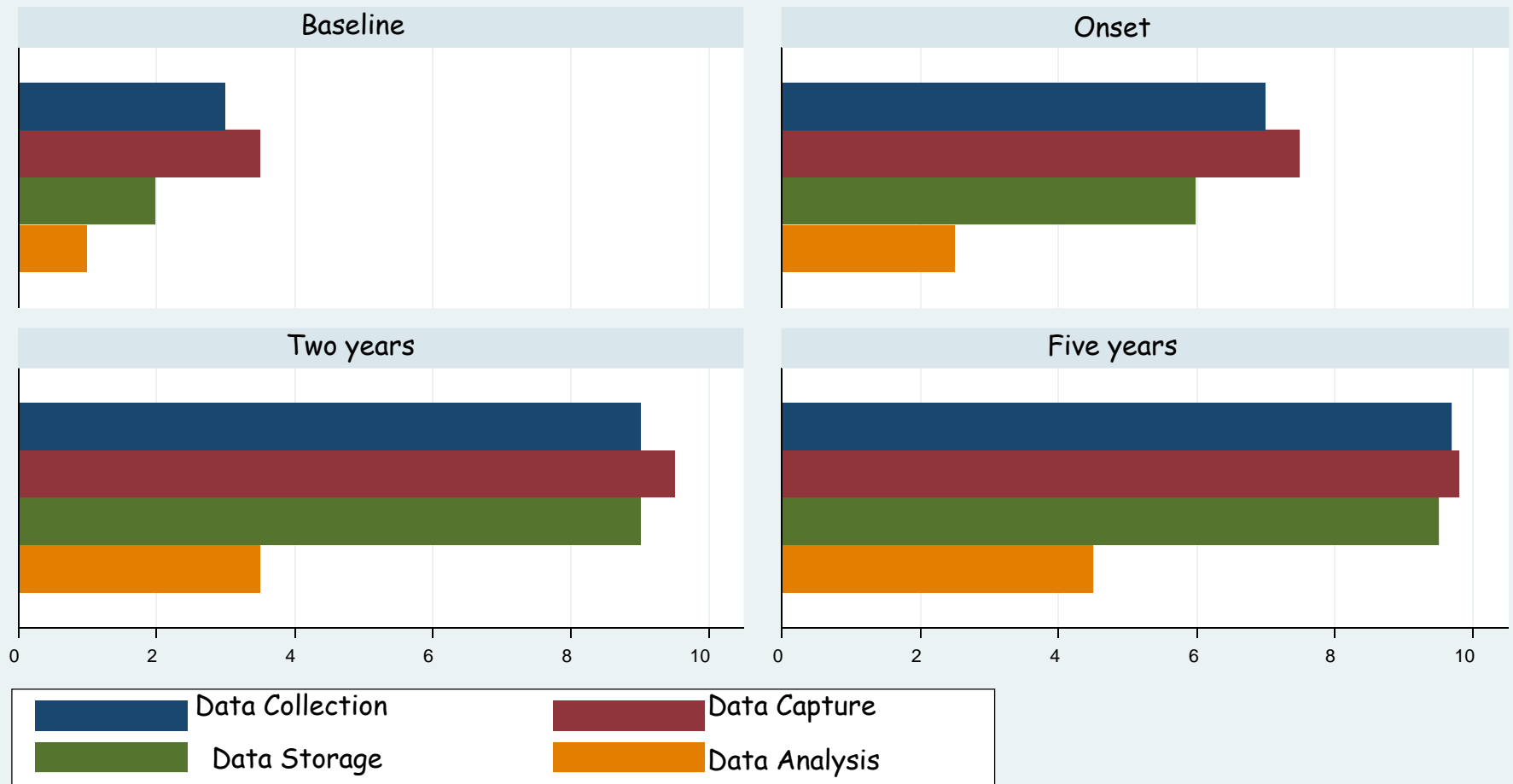
Fogarty Fellow

IHV-UMD

Questions

1. How was the team empowered to:
 - Collect
 - Capture
 - Store/transmit
 - Analyze/interpretdata that were correct and consistent for the REACH study?
2. How did we minimize errors in the process?

Capacity for data integrity



Capacity development

- Site trainings (baseline and in the process) mainly by IHV and occasionally local resource persons
- 3 teams (counselors, lab. tech and data)
- 1 year from baseline to kick off
 - Data collection (paper forms)
 - Counseling
 - consent taking
 - survey administration
 - sample collection
 - Laboratory assays

Capacity development

- capturing and storage

- Microsoft access
- Forms labeling
- Storage of hard copies
- Storage of electronic data
- Transfer of electronic data

Capacity development

- Analysis and interpretation
 - Over 90% done in the US
 - Huge gap
 - Not much capacity developed
 - Responsible for the imbalance in manuscript development and authorships
- Privacy and confidentiality
- Responsible conduct of research

Capacity development

- Well written SOP
 - outlined all study procedures
 - responsibilities of every staff
- Other resources
- Office facility
- Equipment
- Consumables
- Regular fund transfer

Challenges

- Collection
 - Multiple screenings
 - Same IDs for different participants
 - Missing forms
 - Unsigned consent
- Data entry
 - Missing data
 - Multiple entries
 - Data base design issues

Challenges

- Storage and transfer
 - Weak back ups at the beginning
 - Flash drives, CDs
 - Unstable electricity supply

Validation

- Direct supervision
 - Host investigator
 - Monitor and evaluate
 - Log books
 - SOPs
 - Weekly meetings
- External monitoring
 - Weekly conference calls
 - Regular visits by IHV, CDC

Strengthening Capacity for data integrity

- Trainings: Long and short term
 - conduct
 - analysis
 - interpretation
- Reflecting on self
 - Short term training
 - Developed a proposal
 - Conducted the study
 - Long term training
 - Analyzed
 - Published

Strengthening Capacity

- Long term..
- Designed a study to look at the possible association between HIV and bovine TB in Nigeria for the PhD thesis
- Developed
 - Protocol, forms, SOPs, Data base and secure ethical approvals
 - Concluded site preparations
 - To begin data collection next month