

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

William A. Blattner, MD  
Institute of Human Virology  
University of Maryland

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## ***Questions to be Addressed***

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- **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***

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- **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

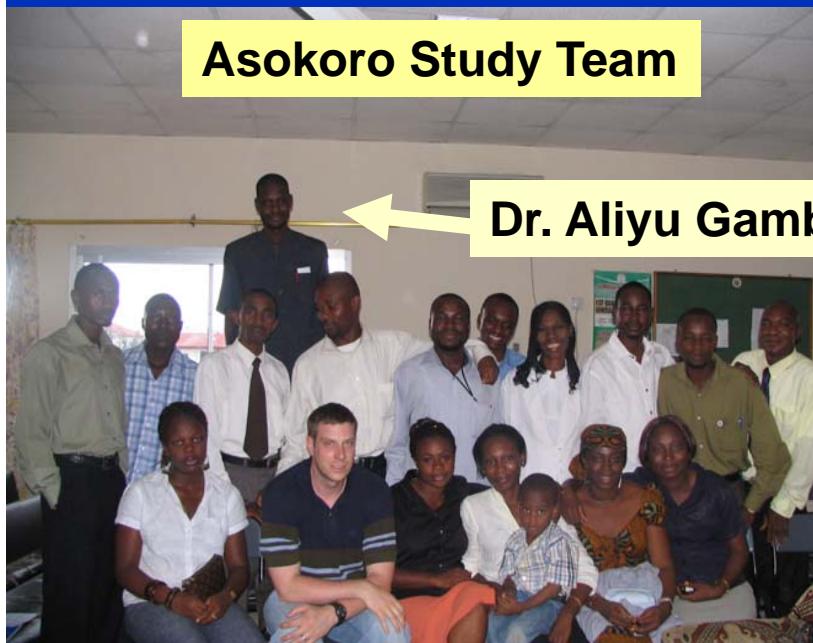


Lab Director



Nigeria PI

Asokoro Study Team



Dr. Aliyu Gambo Gumel



PLASVIREC Lab Team

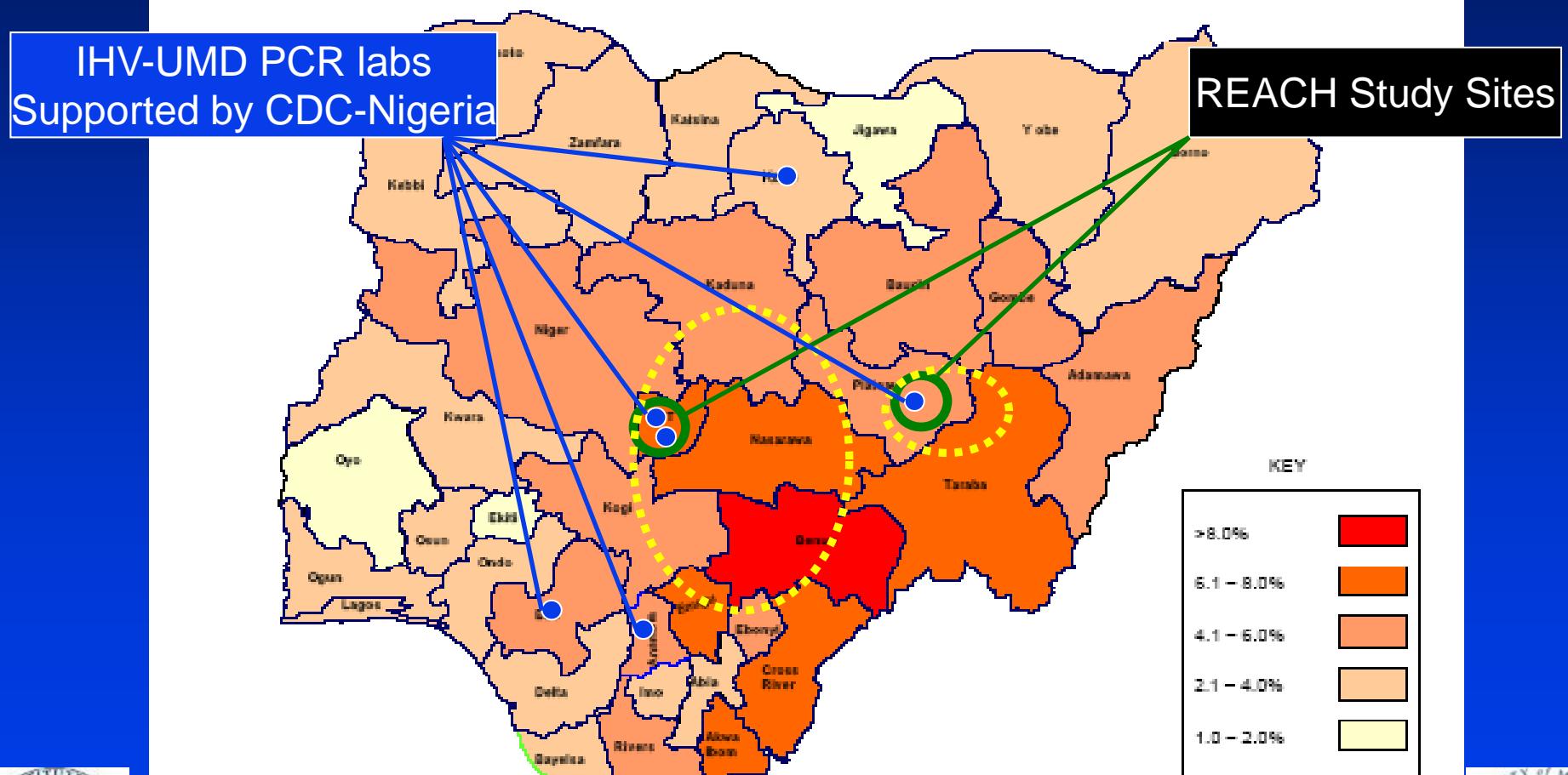
## **Objective**

- 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)



## 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**



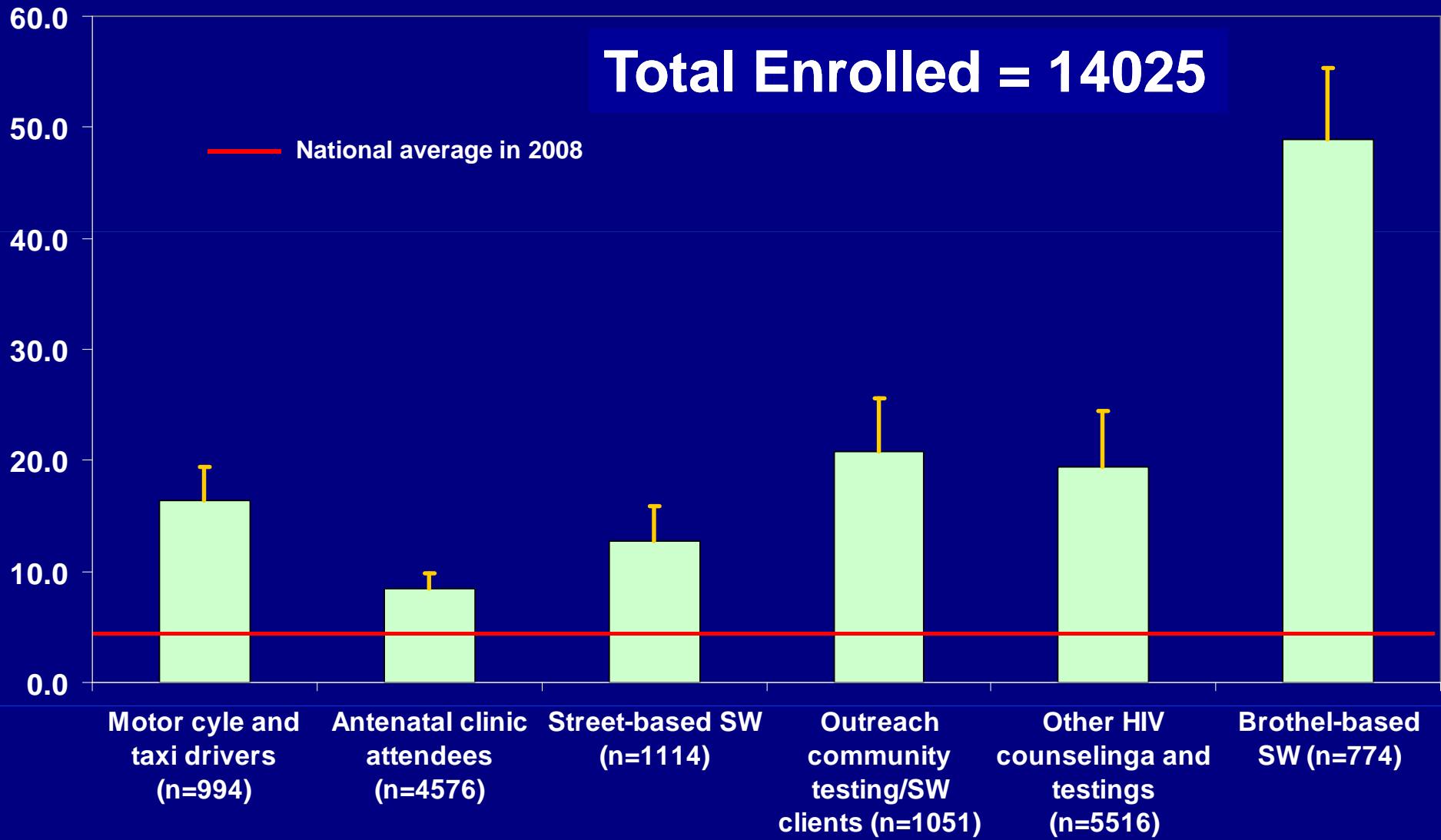


# Night recruiting on local streets and clubs

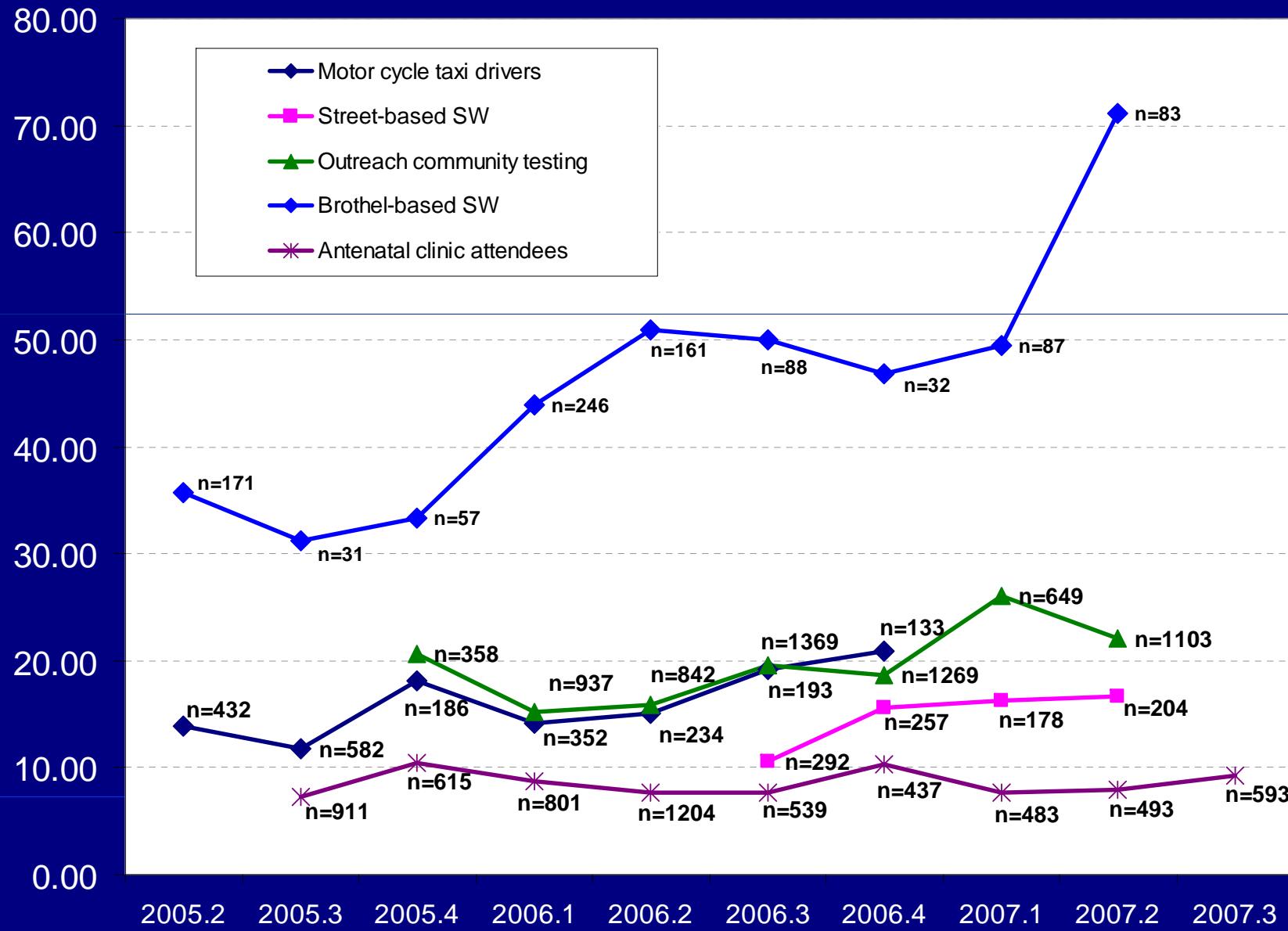


# High HIV Prevalence Across Risk-groups

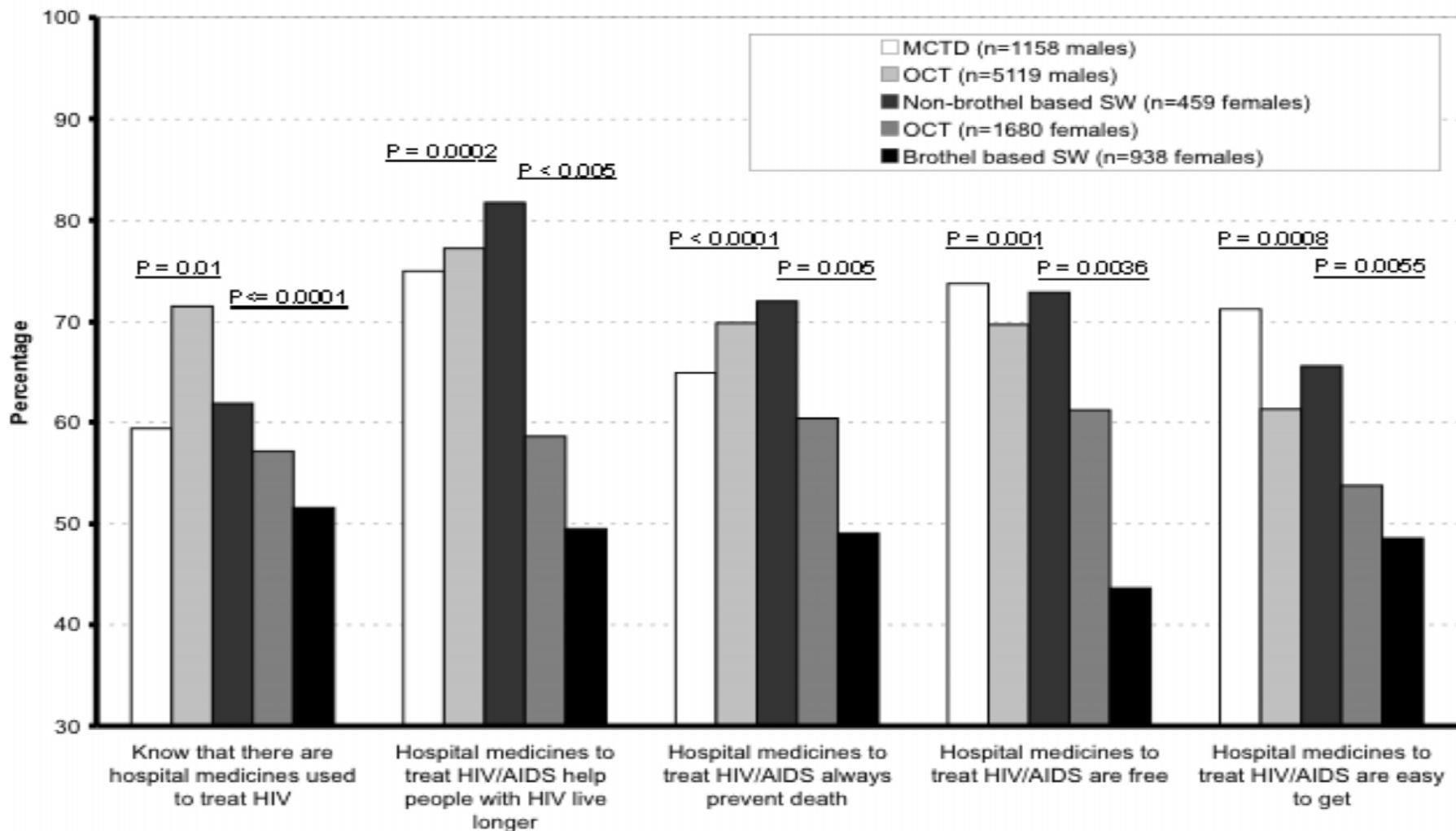
HIV prevalence according to risk groups



## *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, <b>Saidu A</b> , Delaney K, Villalba-Diebold, <b>Aliyu G</b> , Constantine N, Onoja A, Vertefeuille J, Blattner W, <b>Nasidi A</b> .	Identification of HIV Infection in 5 Populations in Abuja, Nigeria
Abstract AIDS 2008	Villalba-Diebold P, <b>Saidu A</b> , Charurat M, Martins E, <b>Gurumdi S</b> , <b>Aliyu G</b> , <b>Nasidi A</b> , 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, <b>Saidu A</b> , <b>Saleh A</b> , Croxton T, Villalba-Diebold P, <b>Aliyu G</b> , Vertefeuille J, Sill A, Busch M, <b>Nasidi A</b> , 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, <b>Saidu A</b> , <b>Aliyu G</b> , Abimiku A, Vertefeuille J, <b>Nasidi A</b> , 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, <b>Saidu A</b> , Villalba-Diebold P, <b>Aliyu G</b> , Constantine N, <b>Onoja A</b> , Vertefeuille J, Blattner WA, <b>Nasidi A</b>	HIV Counseling and testing and access to care needs of populations most-at-risk for HIV in Nigeria
Paper in progress	Charurat M, <b>Saidu A</b> , Delaney K, Eyzaguirre LM, <b>Nasidi A</b> , 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***

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- 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

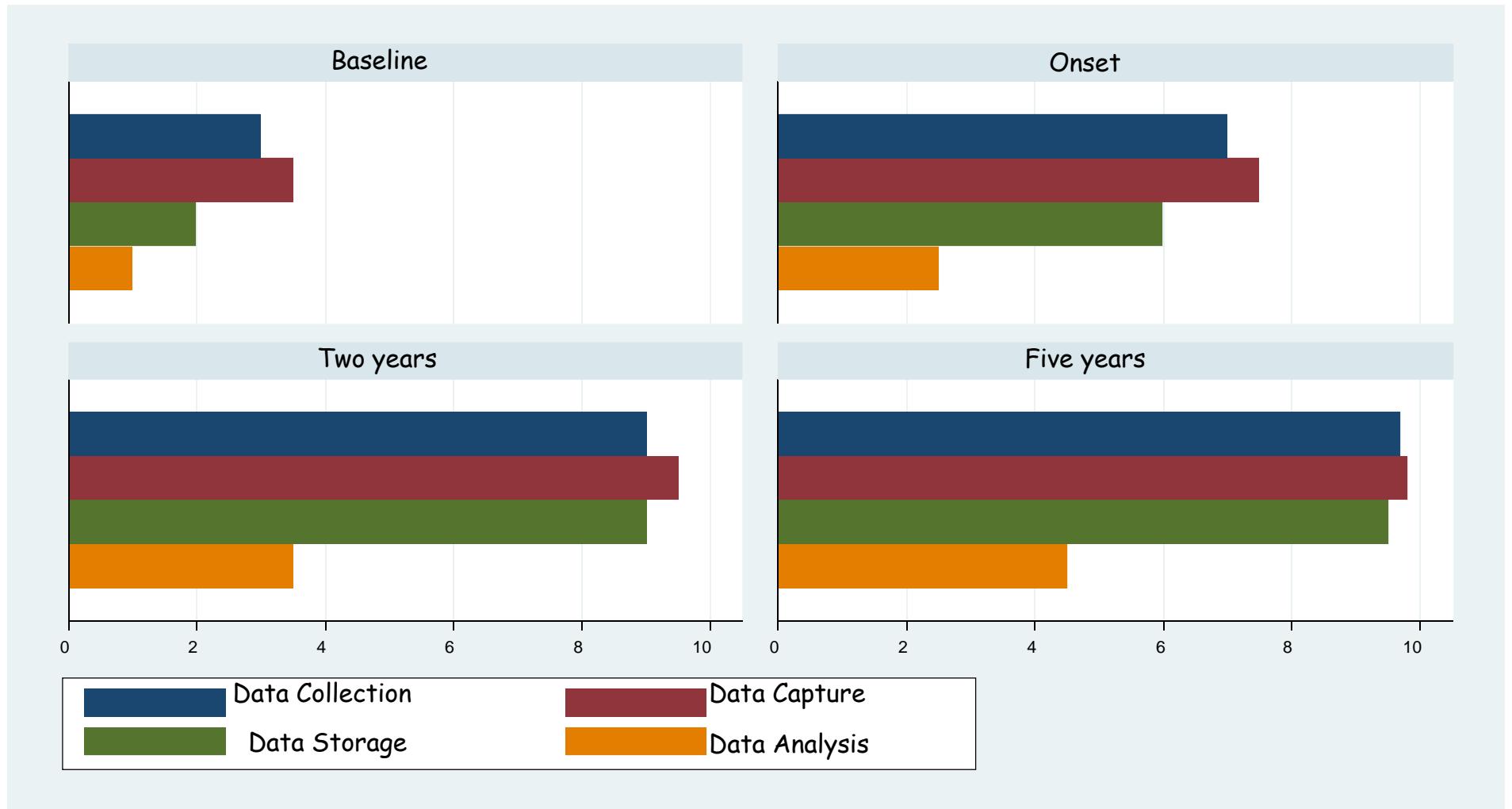
Fogarty Fellow

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