HIV Prevention Treatment and Care in Africa: Ethical Considerations in Research

Phyllis J Kanki
Department of Immunology and Infectious Diseases
Harvard T.H. Chan School of Public Health

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Access and Sustainability

- Tremendous recent progress in provision of ART
- In low- and middle-income countries, ~5 million of the 15 million people in need, received ART
- UNAIDS estimates indicate a decrease in mortality
- Children still lag behind adults in receiving ART
Launched in 2003 by President George W. Bush, President’s Emergency Plan For AIDS Relief (PEPFAR) – the largest effort by any nation to combat a single disease; $22Billion.

From 2004, established and scaled up access to HIV prevention, care and treatment in low-resource settings.

PEPFAR supported the provision of treatment to > 2 million people, care to >10 million people, including > 4 million orphans and vulnerable children, and prevention of mother-to-child treatment services during ~ 16 million pregnancies.
Provided ART to 79,584 AIDS patients

Provided HIV care to 95,389 and ART to 61,891

Master Trainer Corps: Trainers treated 13,578 AIDS patients
OTSHEPENG
NCUBE
BORN 27-06-2000
DIED 28-10-2006
BURIED 31-10-2006
BHP-PEPFAR ARV Site Support Program

Masa

Master Trainer/ARV Site Support Program

Clinical

Laboratory

Monitoring & Evaluation Unit (within DHAPC):
Linked to:
• All ARV sites
• Other MOH programs
Clinical Master Trainer Program: ARV Sites Assessed and Supported

Each Mother Site has 3-4 Clinics

Mother Sites Supported

Middlepit
Bokspit
Goodhope
Palapye
Masunga
Werda
Kalkfontein
Newxade
### MDH supported sites in Dar es Salaam

#### Kinondoni

<table>
<thead>
<tr>
<th>PUBLIC</th>
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<tbody>
<tr>
<td>Mwananyamala Municipal Hospital</td>
<td>TMJ Hospital</td>
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<tr>
<td>Sinza Health Center</td>
<td>Oysterbay Hospital</td>
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<td>Tandale Health Center</td>
<td>Kinondoni Hospital</td>
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<td>UDSM Health Center</td>
<td>Mikocheni Mission Hospital</td>
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<td>Kimara Dispensary</td>
<td>Massana Hospital</td>
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<td>Hindu Mandal Hospital</td>
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<td>Mnazi Mmoja Health Center</td>
<td>Regent Hospital</td>
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<td>Khan Hospital</td>
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<td>Tumaini Hospital</td>
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<td>Vungunguti Dispensary</td>
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<td>Apollo Dispensary</td>
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#### Tembeke

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<td>Tambuka Reli Dispensary</td>
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Nutritional support

- Nutritional assessment and anthropometric measures conducted at each visit
- Lifestyle/Infant feeding counseling
- Multivitamin supplementation
- Nutritionist at each site
- Pilot – Nutty paste as a therapy to severe malnourished children
Harvard PEPFAR Nigeria

• Through Bill & Melinda Gates funding, Harvard has been working with multiple hospitals and prevention programs in Nigeria since 2000

• Started PEPFAR ART activities at 6 tertiary hospitals in 2004 and expanded to a total of 26 ART sites and 64 PMTCT sites.
Laboratory Infrastructure

HIV serologic diagnosis
64 laboratories

Automated Hematology
Chemistries for toxicity
24 laboratories

Laser-based CD4+ cell counts
24 laboratories

Sequencing
Drug resistance mutations
3 laboratories

PCR-based viral load monitoring
PCR-based early infant diagnosis
10 laboratories
Jos University Teaching Hospital

2004 - 3500 patients, 8,896 viral loads
2005 - 5,000 patients, 12,000 viral loads
2009 - 11,000 patients, 36,000 viral loads
<table>
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<tr>
<th></th>
<th>HIV rapid tests &amp; immunoblot</th>
<th>CBC</th>
<th>Chemistry</th>
<th>CD4-flow</th>
<th>Viral load</th>
<th>Infant PCR</th>
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<td>ongoing</td>
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</table>
Organization of Electronic Data System

Regular transfer to data managers’ computers for cleaning, merging, management and use.

Daily, on-site data entry by (multiple) locally-hired & trained personnel

Physician views patient data in clinical rooms

APIN

Harvard provides TA to APIN SI team

Feedback to sites

Organization of Electronic Data System

Paper Records

Daily, on-site data entry by (multiple) locally-hired & trained personnel

Regular transfer to data managers’ computers for cleaning, merging, management and use.
Each green triangle indicates one pickup of antiretroviral medications. Orange triangles indicate a change in regimen.
## HIV Care and Treatment

<table>
<thead>
<tr>
<th></th>
<th>Botswana</th>
<th>Nigeria</th>
<th>Tanzania</th>
<th>Total</th>
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<tbody>
<tr>
<td>Persons ever enrolled in HIV Care</td>
<td>18,975*</td>
<td>134,253</td>
<td>95,389</td>
<td>248,617</td>
</tr>
<tr>
<td>Persons ever initiated on ART</td>
<td>13,578*</td>
<td>83,989</td>
<td>65,040</td>
<td>162,607</td>
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<tr>
<td>Number of ART Facilities</td>
<td>154</td>
<td>26</td>
<td>50</td>
<td>230</td>
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<tr>
<td>Number of PMTCT Facilities</td>
<td>---</td>
<td>61</td>
<td>133</td>
<td>194</td>
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</tbody>
</table>

- Clinical master trainers – adult patients only – 150,000 patients on ART
PEPFAR Database & Repository Bank

- Allows secondary access to medical records and biological specimens for operational research.
- Provides IRB with more detailed information regarding data and specimen acquisition, storage, and distribution.
  - Gives PI authority and responsibility for distributing data or specimens to investigators.
  - Minimizes burden on investigators.
- Underlying data/specimens were collected from those enrolled in the APIN/Harvard PEPFAR ARV Treatment Protocols.
All patients are HIV-positive. Any breach of confidentiality could have potential consequences related to stigma and discrimination.

Requirement to provide subjects with signed copy of informed consent was waived.

Minimal risk is ensured by de-identification of data before provision to investigators for all secondary research.

"Individually identifiable": the identity of the subject is or may readily be ascertained by the investigator or associated with the information (US DHHS, Protection of Human Subjects, 45 CFR 46.102(f)(2))

For all secondary research, all identifiers must be removed or coded:

- Names, patient IDs (convert to randomized study IDs)
- Dates, including birthdates (convert to relative time from fixed time point, i.e. ART initiation date)

If coded, the investigator may not receive any key that links coded data to identifiers.
PEPFAR Database & Repository Bank: Special Considerations

- Treatment consent documents for patients enrolled <August 2008 did not inform participants of future use of data/specimens.
- Harvard IRB granted a waiver of consent for secondary research using data from patients enrolled <August 2008, because obtaining consent retroactively was **unfeasible**, and secondary research using de-identified data is **minimal risk**.
- A notice was posted indefinitely in all clinics informing patients of use of data for research.
- Patients could choose to opt out.
All consent forms, withdrawal forms, and the patient consent notice were translated into Hausa, Igbo, and Yoruba by certified translators.

Patients must be assured that care is not contingent upon participation in research (no coercion), and there are no penalties for not participating/withdrawing.
Adult Informed Consent

APIN Plus/Harvard PEPFAR Data Bank

Study Title: Harvard PEPFAR Data Bank: Data and Samples Obtained from the APIN Plus/PEPFAR-Nigeria Antiretroviral (ART) Treatment Programs for HIV/AIDS

In this treatment program, the clinic will keep a lot of information about you, and as a regular part of your medical testing, parts of your blood or other body materials (like a swab from inside your cheek, or saliva) may be taken by a doctor so that it can be tested in a lab, because the results might help the doctor take care of you. Some of these blood samples may be sent to the United States to be tested at Harvard School of Public Health, or at other partner labs in the United States, and the results would be sent back to your doctor in the clinic.

If you agree to participate, your medical information, these samples, and their results will be stored in a data bank along with similar information and samples from other HIV/AIDS patients. Information and samples from this data bank may be used in future research projects that are designed to help scientists from Nigeria, the United States or other countries learn more about HIV or HIV in Nigeria, or to help us and/or outside researchers find new treatments for HIV/AIDS or other related diseases.
Adult Informed Consent

Risks
- Since taking part in this data bank only involves storing medical information and samples into the data bank, there are no physical risks to you.
- Although the database staff will always try to protect your privacy, someone may accidentally find out that you have HIV/AIDS through the data bank. It is your choice to tell others about your health status and treatment.

Costs of Participation
- Participation in the data bank will not cost you anything.
- You will not be paid for your participation.

Benefits
- Research which takes place using the data bank may help future HIV patients.
- You may not be helped directly by participating in this data bank. However, if any important information is discovered about your health through any research on your samples from the data bank, we will give that information to your doctors to use for providing medical care to you.

Protecting your Privacy:
- Your name will be on your medical records, but will not be on your samples. Samples will be labeled only with your APIN Plus identification number. If your samples are provided to researchers outside this program, they will NOT receive your name or other identifying information.
- Any medical information stored on computers or held as a part of the data bank will be stored in computers which are protected with passwords. Only authorized clinic staff persons have the passwords to these computers.
- The researchers in this program will use your samples or information only as described in this form. If they publish the research, they will not identify you unless you allow it in writing. These rules apply even if you take back this permission.
Adult Informed Consent

Your Rights

- It is up to you to decide whether or not you want to participate in the data bank.

- If you decide to participate, you may decide to withdraw at any time. If you do so, you may also tell them to remove all of your information and samples from the data bank.

- If you do not want to be included in the bank, it will not affect whether or not you can get medical care at this clinic in the future.
Adult Informed Consent

CONSENT STATEMENT
Name of Patient (First, Last): ______PEPID:_______
I have read (or have been read to) and understand the informed consent form for the APIN Plus/Harvard PEPFAR ARV Care and Treatment Program (including the Risk and Drug Side Effects of ARV Treatment) and the APIN Plus/Harvard PEPFAR Data Bank. I have been given the chance to ask questions about these programs. I understand that I can withdraw my consent at any time for any reason.

APIN Plus/Harvard PEPFAR ARV Care and Treatment Program:
☐ I agree to be a part of the APIN Plus/Harvard PEPFAR ARV Care and Treatment Program and to allow my blood and other body samples taken during my treatment to be used by the clinic and others to treat me and to oversee my care.

APIN Plus/Harvard PEPFAR Data Bank (Check one):
☐ I agree to allow my medical information and samples to be included in the APIN Plus/Harvard PEPFAR Data Bank for use in HIV/AIDS-related research only.

☐ I agree to allow my medical information and samples to be included in the APIN Plus/Harvard PEPFAR Data Bank for use in any kind of research.

☐ I do NOT agree to allow my medical information and samples to be included in the APIN Plus/Harvard PEPFAR Data Bank.

________________________________________
Signature of Patient

Date: _________/___________/___________

________________________________________
Signature of Legally Authorized Representative (if applicable)

Date: _________/___________/___________

Name of Legally Authorized Representative (if applicable)

I have read aloud and explained the details APIN Plus/Harvard PEPFAR ARV Care and Treatment Program and the APIN Plus/Harvard PEPFAR Data Bank to the above-named patient and have answered questions about this information.

________________________________________
Signature of Counseling Health Care Worker

Date: _________/___________/___________
Pediatric Informed Consent

CONSENT STATEMENT
Name of Parent/Guardian (First, Last): __________
Name of Patient (First, Last): ___PEPID: ________

I have read (or have been read to) and understand the informed consent form for the APIN Plus/Harvard PEPFAR ARV Care and Treatment Program (including the Risk and Drug Side Effects of ARV Treatment) and the APIN Plus/Harvard PEPFAR Data Bank. I have been given the chance to ask questions about these programs. I understand that I can withdraw my consent at any time for any reason.

APIN Plus/Harvard PEPFAR ARV Care and Treatment Program:
☐ I agree to permit my child to be a part of the APIN Plus/Harvard PEPFAR ARV Care and Treatment Program and to allow my child’s blood and other body samples taken during his/her treatment to be used by the clinic and others to treat my child and to oversee his/her care.

APIN Plus/Harvard PEPFAR Data Bank (Check one):  
☐ I agree to allow my child’s medical information and samples to be included in the APIN Plus/Harvard PEPFAR Data Bank for use in HIV/AIDS-related research only.

☐ I agree to allow my child’s medical information and samples to be included in the APIN Plus/Harvard PEPFAR Data Bank for use in any kind of research.

☐ I do NOT agree to allow my child’s medical information and samples to be included in the APIN Plus/Harvard PEPFAR Data Bank.

__________________________________________________________     Date: __________/___________/___________
Signature of Parent/Guardian

☐ Check here for children old enough to provide assent (at least 7 years old), and please have the child sign the child assent form statement.

I have read aloud and explained the details APIN Plus/Harvard PEPFAR ARV Care and Treatment Program and the APIN Plus/Harvard PEPFAR Data Bank to the above-named Parent and have answered questions about this information.

__________________________________________________________     Date: __________/___________/___________
Signature of Counseling Health Care Worker
Background. Despite the benefits of antiretroviral therapy (ART), tuberculosis (TB) is the leading cause of mortality among human immunodeficiency virus (HIV)-infected persons in Africa. Nigeria bears the highest TB burden in Africa and second highest HIV burden globally. This long-term multicenter study aimed to determine the incidence rate and predictors of TB in adults in the Harvard/AIDS Prevention Initiative in Nigeria (APIN) and President’s Emergency Plan for AIDS Relief (PEPFAR) Nigeria ART program.

Methods. This retrospective evaluation used data collected from 2004 to 2012 through the Harvard/APIN PEPFAR program. Risk factors for incident TB were determined using multivariate Cox proportional hazards regression with time-dependent covariates.

Results. Of 50,320 adults enrolled from 2005 to 2010, 11,092 (22%) had laboratory-confirmed active TB disease at ART initiation, and 2021 (4%) developed active TB after commencing ART. During 78,228 total person-years (PY) of follow-up, the TB incidence rate was 25.8 cases per 1000 PY (95% confidence interval [CI], 24.7–27.0) overall, and it decreased significantly both with duration on ART and calendar year. Risk factors at ART initiation for incident TB included the following: earlier ART enrollment year, tenofovir-containing initial ART regimen, and World Health Organization clinical stage above 1. Time-updated risk factors included the following: low body mass index, low CD4+ cell count, unsuppressed viral load, anemia, and ART adherence below 80%.

Conclusions. The rate of incident TB decreased with longer duration on ART and over the program years. The strongest TB risk factors were time-updated clinical markers, reinforcing the importance of consistent clinical and laboratory monitoring of ART patients in prompt diagnosis and treatment of TB and other coinfections.

Keywords. antiretroviral therapy; HIV; incidence; Nigeria; tuberculosis.
Used only secondary data that was previously collected as part of routine clinical care in the Harvard/APIN PEPFAR ART Program 2004-2012 and stored in Harvard PEPFAR Database & Repository.

Investigator had access to identifiable information, which was de-identified for the analyses.
  - Approved by Harvard IRB

APIN authors only contributed in programmatic expertise and review of manuscript
  - No international local approval required.
Short Communication:
Transmitted HIV Drug Resistance in Antiretroviral-Naive Pregnant Women in North Central Nigeria

Godwin E. Imaide,1,2 Atiene S. Sagay,1,2 Beth Chaplin,3 Philippe Chebu,1 Jonah Musa,1 Jonathan Okpokwu,1 Donald J. Hamei,3 Ishaya C. Pam,2 Oche Agbaji,1 Jay Samuels,4 Seema Meloni,3 Jean-Louis Sankale,5 Prosper Okonkwo,4 and Phyllis Kanki3

Abstract

The World Health Organization (WHO) recommends periodic surveillance of transmitted drug resistance (TDR) in communities in which antiretroviral therapy (ART) has been scaled-up for greater than 3 years. We conducted a survey of TDR mutations among newly detected HIV-infected antiretroviral (ARV)-naive pregnant women. From May 2010 to March 2012, 38 ARV-naive pregnant women were recruited in three hospitals in Jos, Plateau state, north central Nigeria. Eligible subjects were recruited using a modified version of the binomial sequential sampling technique recommended by WHO. HIV-1 genotyping was performed and HIV-1 drug resistance mutations were characterized according to the WHO 2009 surveillance drug resistance mutation (SDRM) list. HIV subtypes were determined by phylogenetic analysis. The women’s median age was 25.5 years; the median CD4+ cell count was 317 cells/μl and the median viral load of 16 was 261 copies/ml. Of the 38 samples tested, 34 (89%) were successfully genotyped. The SDRM rate was <5% for all ART drug classes, with 1/34 (2.9%) for NRTIs/NNRTIs and none for protease inhibitors 0/31 (0%). The specific SDRMs detected were M41L for nucleoside reverse transcriptase inhibitors (NRTIs) and G190A for nonnucleoside reverse transcriptase inhibitors (NNRTIs). HIV-1 subtypes detected were CRF02_AG (38.2%), G’ (41.2%), G (14.7%), CRF06-CPX (2.9%), and a unique AG recombinant form (2.9%). The single ARV-native pregnant woman with SDRMs was infected with HIV-1 subtype G’. Access to ART has been available in the Jos area for over 8 years. The prevalence of TDR lower than 5% suggests proper ART administration, although continued surveillance is warranted.
Transmitted HIV Drug Resistance in Pregnant Women, Jos, Nigeria

- Tested secondary samples collected as part of routine clinical care at one Harvard/APIN PEPFAR ART site May 2010 – Mar 2012.

- Investigator from JUTH, and testing performed at JUTH
  - Approved by Jos University Teaching Hospital ethical review board.

- Harvard co-investigators, and testing performed at HSPH
  - Approved by Harvard IRB.

- Approved by both Harvard PI and APIN Regulatory Affairs for use of secondary data and samples.
Simple Amplification-Based Assay: A Nucleic Acid-Based Point-of-Care Platform for HIV-1 Testing

Helen H. Lee,1 Magda A. Dineva,1 Yii Leng Chua,1 Allyson V. Ritchie,1 Ines Ushiro-Lumb,2 and Craig A. Wisniewski1

1Diagnostics Development Unit, Department of Haematology, University of Cambridge, Cambridge, and 2Department of Virology, Barts and The London NHS Trust, London, United Kingdom

Background. A new nucleic acid–based assay (simple amplification-based assay [SAMBA]) for rapid visual detection of human immunodeficiency virus–type 1 (HIV-1) by dipstick is described. The assay was designed to be simple, stable, robust, self-contained, and capable of detecting a broad spectrum of HIV-1 subtypes and recombinant forms.

Methods. The performance of the SAMBA HIV-1 test (amplification and detection chemistry) was evaluated using the World Health Organization HIV-1 RNA Genotype Reference Panel, with clinical samples representing various viral subtypes and recombinant forms common in sub-Saharan Africa. Sixty-nine randomly selected and blinded clinical samples that had undergone HIV-1 genotypic resistance analyses in a large London teaching hospital were also tested. These samples included 14 different viral subtypes or recombinant forms with viral loads of 78–9.5 × 10^6 copies/mL.

Results. The sensitivity and viral subtype coverage of the SAMBA HIV-1 test were either comparable to or better than those of the commercially available nucleic acid–based HIV-1 diagnostic tests.

Conclusions. The unique characteristics and competitive performance of the SAMBA HIV-1 test render it suitable for point-of-care and near-patient testing in both developed and developing countries.
In-country Validation and Evaluation of SAMBA Point-of-Care Assays for Early Infant Diagnosis and Viral Load Monitoring of HIV-1 Infection in Nigeria

- Investigational device

- Collaboration among University of Cambridge, Harvard School of Public Health, NIMR, JUTH, and APIN
  - Approved by Harvard, NIMR, JUTH, and APIN

- Consent
  - Used excess blood samples collected as part of standard HIV care and treatment → no new consent
  - HIV-negative samples from anonymous blood donors → consent waived

- Special considerations:
  - Each site laboratory maintains key that links patient ID with study ID to allow viral load results that are part of routine care back into patients’ charts.
  - If exposed infant tests positive on SAMBA assay, should they be put on treatment?
  - What if SAMBA and Roche CAP/CTM HIV-1 Qual (standard of care) assays are discordant?
Kanki Lab

Charlotte Chang
Beth Chaplin
Lana Dinic
G. Eisen
Don Hamel
Jalal Hosseini
M-F McLane
Seema Meloni
Chris Mullins
Nzovu Ulenga
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L. Dinic
J. Hosseini
C. Smith
H. Reyes
C. Wen

P. Okonkwo
T. Jolayemi
B. Aluko
S. Ochigbo
R. Olaitan
J. Samuels
P. Akande
T. Oyebode
B. Akinyemi
O. Eberendu
C. O’ Martins
I. Adewole
D. Olaleye
J. Idoko
S. Sagay
O. Agbaji
O. Idigbe
D. Onwujekwe
C. Okany
R. Nkado
W. Gashau
H. Muktar
J. Abah
C. Chukwuka
S. Akanmu
F. Ogunsola

All our colleagues at the APIN PEPFAR sites in Nigeria
Most of all, our patients

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