

Timely Topics
In HIV Vaccines

Capturing Participant Information for Mucosal Sampling

An Investigator's Guide

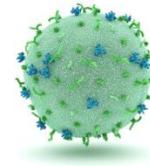
Patricia D'Souza, PhD

NIAID/NIH

May, 1 2014

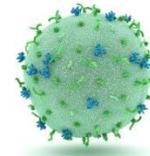


Understanding HIV-1 at Portal of Entry



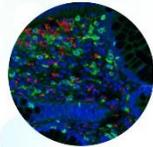
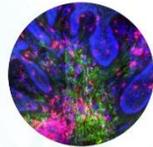
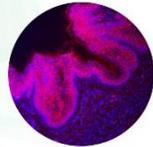
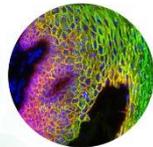
Timely Topics
In HIV Vaccines

1. To comprehend potentially protective humoral and cellular immune responses present at the mucosal site, we need high quality and reliable mucosal specimens.
2. Many factors influence the quality of the mucosal sample, so collective guidance from experienced investigators can save resources and expedite research.



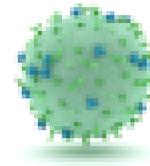
Capturing Participant Information for Mucosal Sampling

AN INVESTIGATOR'S GUIDE



A consolidated resource for organizations and investigators engaging in clinical studies with a mucosal immunology component.

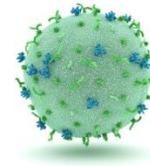
Purpose of the Guide



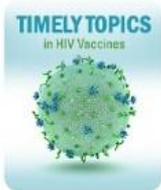
Timely Topics
In HIV Vaccines

- To consider individuals' parameters that may affect the interpretation of mucosal data
- To use in conjunction with Network procedures and policies, protocols, and CRFs
- To supplement and enhance the quality of clinical research conducted with mucosal specimens and promote cross trial data comparison.

Development of the Guide



Timely Topics
In HIV Vaccines



Organizing Committee:

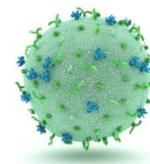
Patricia D'Souza (NIAID); Mary Gross (FHCRC); Amapola Manrique (Global HIV Vaccine Enterprise); Helene Zinzner (Global HIV Vaccine Enterprise).



Expert contributors

Michelle Andrasik (University of Washington, HVTN); Chuka Anude (National Institute of Allergy and Infectious Diseases); Rahul Bakshi (Johns-Hopkins University, MTN); Kristina Broliden (Karolinska Institutita); Susan Cu-Uvin (Brown University, ACTG), Shelly Karuna (HIV Vaccine Trial Network); Julie McElrath (Fred Hutchinson Cancer Research Center , HVTN); Ian McGowan (University Pittsburgh, MTN); Devika Singh (University of Washington, HPTN, MTN). Finally, the guide was critically reviewed and revised by an extensive group of additional experts including: Peter Anton (University of California LA); Stephen De Rosa (University of Washington); Florian Hladik (Fred Hutchinson Cancer Research Center); Rupert Kaul (University of Toronto); Douglas Kwon (Ragon Institute); Alan Landay (Rush University Medical Center); Kenneth Mayer (The Fenway Institute); Richard Novak (University of Illinois); Hariett Park (International AIDS Vaccine Initiative); Jo-Ann Passmore (University of Cape Town); Steven Safren (Massachusetts General Hospital).

Overview



Timely Topics
In HIV Vaccines

The Guide provides easy to understand, up to date rationales and references for participants' characteristics to be considered for inclusion in study records.

1. Demographic



2. Reproductive History



3. Medical History



4. Sexual History



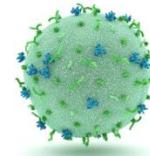
5. Risk Behaviors



6. Symptoms



Guide Content



1. Demographic

- 1.1. Age
- 1.2. Race/Ethnicity/Tribe
- 1.3. Sex at Birth/
Self-identified
Gender
- 1.4. Relationship Status
- 1.5. Education,
Employment Status,
Income



2. Reproductive History

- 2.1. Menopausal Status
- 2.2. Menstrual History
- 2.3. Pregnancy status
and history
- 2.4. Contraception
- 2.5. Vaginal and Rectal
Products or Devices
- 2.6. Female Reproductive
Tract Surgeries
- 2.7. Male Reproductive Tract Surgeries
- 2.8. Sexually-transmitted and Reproductive
Tract Infections (STIs/RTIs)
- 2.9. Abnormal Cervical or Rectal Cytology
and Dysplasia



3. Medical History

- 3.1. Medical conditions
- 3.2. HIV status
- 3.3. Vaccinations
- 3.4. Medications
- 3.5. Allergies
- 3.6. Body Mass Index
(Height/Weight)



4. Sexual History

- 4.1. Sexual Practices
- 4.2. HIV Status
of Partner(s)



5. Risk Behaviors

- 5.1. Drug use
- 5.2. Smoking
- 5.3. Alcohol
consumption
- 5.4. Sexual
Risk Behavior
of Partner
- 5.5. Risk Behavior
of Partner

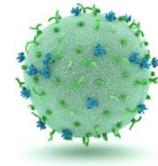


6. Symptoms

- 6.1. Constitutional
Symptoms
- 6.2. Vaginal Discharge
- 6.3. Rectal Discharge
- 6.4. Pelvic Pain



- Rationale
- Considerations
- Selected references
- CRF examples



Example

2. Reproductive History

2.8. Sexually-transmitted and Reproductive Tract Infections (STIs/RTIs)

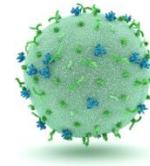
Points to consider in the **RATIONALE**

Data support that active GI or GU STI/RTI tract infections that cause local inflammatory responses in the mucosal compartment confound interpretation of mucosal immune responses.

The screening of STIs in asymptomatic study participants is a critical part of obtaining interpretable mucosal specimens.

May consider enrolling participants with STI who are treated and cured.

Example



Timely Topics
In HIV Vaccines

Points developed in the **CONSIDERATIONS**

Important STI/RTI information to record may include:

- History of STIs
- History of treatment for STIs
- Genital or rectal sores, ulcers, fistulas, fissures
- Genital or rectal discharge
- Genital or rectal pain
- Skin rashes in the genital and rectal areas

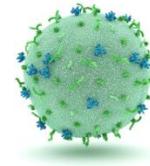
Treatment decisions for a lab-diagnosed STI may be limited as local public health standards for diagnosing STI/RTI are empiric or syndromic- so offer diagnostic testing

How to inform the participant?

Post-hoc use of STI test results for protocol eligibility?

- entirely ineligible vs. eligible after treatment; is a test for cure necessary?
- consequences for study size, protocol timing and budget

How to Access and Distribute the Guide:



Timely Topics
In HIV Vaccines

The Guide is free to access online or in print.

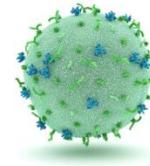
Get **the booklet version** of the Guide for you and your colleagues for multiple copies, please email requests to:

timelytopics@vaccineenterprise.org

The online version, fully downloadable, with links to resources, can be easily found on the Global HIV Vaccine Enterprise website at:

www.vaccineenterprise.org/mucosal-sampling-guide

How to Contribute



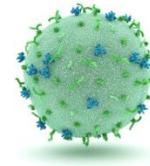
Timely Topics
In HIV Vaccines

Include a link to the Guide on your organization's website

Be a contributing expert

The field of mucosal immunology is rapidly evolving and the Guide is a living document; consider volunteering to be included in an expert member for future updates.

Thank you!



Timely Topics
In HIV Vaccines

timelytopics@vaccineenterprise.org

www.vaccineenterprise.org/

