"Advances in HIV post-exposure prophylaxis (PEP): Regulatory challenges and clinical trial designs“

Symposium Introduction

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WITS-RHI

Veronica Miller, PhD

Forum for Collaborative Research, UC Berkeley

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University of the Witwatersrand
WITS RHI

UC Berkeley Public Health

ARV implementation to end the epidemic

- New opportunities for PEP
  - New drugs and deliver/dosing modes = simpler implementation and program options
- Little human PEP efficacy/effectiveness data exists
- No regulatory indication for PEP
  - Opportunities for better program and financial coverage
    - Inform best implementation practice
- Opportunity for consensus development
  - Role of pre-clinical and human PK/PD data
  - Feasible/pragmatic clinical trial designs

HIV Post-Exposure Prophylaxis Summit

May 11-12, 2026, Johannesburg, South Africa

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Focus

- Evidence generation for LA- ARV-based PEP
  - Normative guidelines
  - Regulatory approval
    - Path should be product agnostic

- Guidelines and regulatory approval are not mutually exclusive
- Robust evidence needed for both purposes

Context

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- Highlighted the African Continent
  - Collaboration w RHI
  - Participants, especially regulatory authorities
  - Specific /regional needs and implementation programs
- Included implementation models from Brazil and US
- Emphasized cross-regional learnings and collaboration

- Populations
  - **Young women/adolescent girls**
  - **Sexual assault survivors**
  - MSM
- Settings
  - Sexual assault/emergency centers
  - Community based dispensing
  - Pharmacy based dispensing
  - PEP-in pocket/vending machines

Perspectives

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- Communities and end-users
- Regulators
- Normative organizations (WHO)
- Clinical researchers
- Biostatisticians
- Implementers and dispensers
- Pharmaceutical industry

PEP Summit Leadership & Working Group Members

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PROJECT CO-CHAIRS

- **Helen Rees** Wits RHI
- **Veronica Miller** Forum for Collaborative Research
- **Ken Mayer** Fenway Health

ACADEMIA

- **Susan Buchbinder** SFDPH
- **Connie Celum** Univ. of Washington
- **Sinead Delany-Moretlwe** Wits RHI
- **Deborah Donnell** Fred Hutchinson / HPTN
- **Mark Feinberg** IAVI
- **Charles Flexner** Johns Hopkins Univ.
- **Julie Fox** King's College London
- **Marion Gruber** IAVI
- **Andrew Grulich** Kirby Institute, UNSW
- **Renee Heffron** UAB
- **Jon Heinrichs** IAVI
- **Craig Hendrix** Johns Hopkins Univ.
- **Raphael Landovitz** UCLA and HPTN
- **Geoffroy Liegeon** APHP
- **Sarah Magni** Genesis Analytics
- **Kenneth Mayer** Fenway Health
- **Christopher Miller** UC Davis
- **Jean-Michel Molina** Univ. Paris Cité / APHP
- **Andrew Mujugira** Univ. of Washington
- **Vincent Muturi-Kioi** IAVI
- **Helen Rees** Wits RHI

REGULATORY

- **Audrey Chigome** SAHPRA
- **Mimi Darko** African Medicines Agency
- **Alex Dodoo** ACC Pharmacovigilance
- **Farisai Kuonza** Africa CDC
- **Kedibone Malatji** SAHPRA
- **Helen Ndagije** Uganda Nat. Drug Auth.
- **Priscilla Nyambayo** MCAZ
- **Maja Sommerfelt Grønvold** EMA
- **Kim Struble** FDA
- **Elvis Temfack** Africa CDC
- **Jörg Zinserling** BfArM / EMA
- **Boitumelo B. Semete** SAHPRA

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INDUSTRY

• **Silas Holland**	Merck & Co. Inc.
• **Rebeca Plank**	Merck & Co. Inc.
• **Christian Ramers**	Gilead Sciences, Inc.
• **Michael Reid**	Gilead Sciences, Inc.
• **Luisa Stamm**	Merck & Co. Inc.
• **Vani Vannappagari**	ViiV Healthcare

COMMUNITY

• **Stacy Hannah**	AVAC
• **Imelda Mahaka**	Pangaea Zimbabwe
• **Mitchell Warren**	AVAC
• **Kenly Sikwese**	AFROCAB
• **Adaobi Olisa**	Root to Rise

PHILANTHROPY & NON-PROFIT

• **Sarah Hamm Rush**	Gates Foundation
• **Max Lataillade**	Gates Foundation
• **Linda Lewis**	CHAI
• **Melynda Watkins**	CHAI

ETHICS

- **Jeremy Sugarman** Johns Hopkins Univ.
- **Jerome Singh** Univ. of KwaZulu-Natal

MULTI-LATERAL AGENCIES

• **Heather-Marie Schmidt**	WHO / UNAIDS
• **Michelle Rodolph**	WHO

US CDC

• **Gerardo Garcia-Lerma**	CDC
• **Walid Heneine**	CDC

Consensus

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- Importance of evidence-based guidelines from normative bodies for new antiretrovirals with potential for PEP
- Importance of considering a regulatory indication for PEP to facilitate implementation, broad access, and coverage among those who need PEP
- Need for a simple/pragmatic protocol to generate evidence to support guidelines and a potential regulatory authority's approval
- Agreement between key stakeholders to convene a joint meeting with EMA, AMA, SAHPRA

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- WITS RHI team
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