U=U Research Forum • Munich • July 22, 2024
Setting the Agenda for Future U=U-Related Research and Collaboration
Summary of Top Research Priorities, Presenter Key Points, and Open Discussion Themes

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A link to the videorecording of the forum can be found here.

Top Research Priorities

1. To examine the impact of U=U messaging on clinical, public health, and cost effectiveness outcomes
2. To identify low-cost interventions to promote U=U acceptance among policymakers, healthcare providers, and other stakeholders integral to U=U message delivery
3. To collaborate on parallel studies across multiple countries/contexts simultaneously to improve research efficiency, comparability of study findings, and strength of evidence
4. To expand research on U=U messaging and psychosocial outcomes to priority populations beyond sexual minority men (SMM)[1]
5. To address limited and inequitable access to HIV information (e.g., U=U) and resources (e.g., antiretroviral therapy [ART])
6. To determine how to communicate new HIV risk information (e.g., "negligible" risk among people living with HIV [PLWH] whose viral load is 200-1000 copies/mL) without confounding the U=U message or reversing associated advances

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Presenter Key Points

Session A Presentations

1. **Disseminating U=U at HIV counseling improves retention and viral suppression: Evidence from a randomized trial in South Africa**
   Dorina Onoya, Health Economics and Epidemiology Research Office, South Africa
   - A "U=You" app designed to share testimonials of PLWH regarding what U=U means to them was highly acceptable.

[1] Throughout this document, we use the term "sexual minority men" (SMM) to refer to "men whose sexual identities, orientations, or behaviors differ from the heterosexual majority" (Timmins & Duncan, 2020, p. 1667).

- Compared with the control condition, the app condition was associated with 17% greater retention in care and 19% greater viral suppression to an undetectable level (<200 copies).
- *U=U can favorably affect PLWH's retention in care and viral suppression.*

2. **Improving young people's beliefs and understanding towards U=U**
   Linda Joseph Robert, Naguru Youth Health Network, Uganda
   - Health workers must proactively communicate U=U to young PLWH due to psychosocial benefits (e.g., stigma reduction), clinical/health benefits, and ethics/human rights.
   - Young people in the Global South deserve access to U=U interventions found to be successful in other countries.
   - *Young people have the right to know about U=U and can benefit greatly from it; access to this information is crucial and should not be geographically limited.*

3. **Gay, bisexual, and queer men's confidence in U=U: Longitudinal qualitative analysis of the sexual decision-making of PrEP users over time**
   Daniel Grace, University of Toronto, Canada
   - Some PrEP users expressed greater acceptance of U=U and openness to sex with PLWH over time.
   - PrEP affected how PrEP-using SMM thought about U=U and sex with PLWH.
   - *U=U belief can foster openness to serodifferent partnering for some PrEP users; U=U should be considered in the context of the larger prevention landscape.*

4. **Beliefs in and enactment of U=U among Asian gay, bisexual+ men who have sex with men in Australia**
   Limin Mao, UNSW Sydney, Australia
   - It was common for Asian SMM to believe that they were highly likely to get HIV from a PLWH whose viral load was undetectable (30%) and to avoid sex with PLWH regardless of viral load (55%).
   - *Unawareness of/disbelief in U=U and serosorting irrespective of viral load persists, which may be associated with stigma and other social/structural barriers.*

5. **Gender and human rights as underexplored cornerstones for U=U research**
   Laura Ferguson, University of Southern California, USA
   - Gender and human rights considerations have largely been absent in U=U research and interventions.
   - It is important to reflect upon who decides what U=U research and interventions get done, with whom they are done, who benefits, and—likewise—who gets left behind.
   - *Human rights and gender are essential considerations up front and throughout the process of research and intervention.*

Session B Presentations

1. **PLHIV communities & U=U top-up**
   Seum Sophal, Joint Forum of Network of PLHIVs and KPs, Cambodia
   - U=U knowledge sharing can impact 95-95-95 goals by offering hope and motivating HIV testing.
   - Community involvement/leadership is key.
   - *Community-driven U=U initiatives can significantly impact HIV outcomes.*

2. **Understanding acceptability and adoption of U=U programming from a behavioral public policy lens**
   Alison Buttenheim, University of Pennsylvania, USA
   - It is important to consider behavioral barriers to U=U implementation at the level of policymakers (behavioral public policy).
   - Policymaker behavior is influenced by the same cognitive biases and mental models as providers and others (e.g., bias toward sticking with status quo [default bias], pre-existing beliefs about HIV transmission and treatment effectiveness).
   - *More research should focus upstream at the policy level and consider policymakers' behavioral barriers to U=U programming.*

3. **Improving HIV testing, linkage, and retention in care among South African men through U=U messaging: Two sequential hybrid type 1 effectiveness-implementation randomized controlled trials**
   Nkosiyapha Sibanda, University of Cape Town and Desmond Tutu Health Foundation, South Africa; presented by Philip Smith
   - U=U messaging was developed using behavioral economics principles in collaboration with men from the local community (human-centered design) and is currently being evaluated relative to HIV continuum outcomes.
   - Implementation challenges have included: (1) developing an effective U=U message at low cost, (2) addressing policymaker and staff reluctance about U=U, (3) differentiating new U=U message/intervention from U=U messaging already in effect, and (4) newly adding an unanticipated measure/cost (STI testing).
   - *Research aimed at assessing impact of U=U on HIV continuum outcomes must consider these and other implementation challenges.*

4. **Can biomedical HIV prevention narrow the serodivide? Insights from Australian research**
   James MacGibbon, UNSW Sydney, Australia
   - HIV-negative/status-unknown SMM who were open to serodifferent sexual and romantic partners were more likely to perceive U=U as accurate and to know 1+ PLWH.
   - Those who were open to serodifferent sexual partners were also more likely to be using PrEP.

- *Belief in U=U, humanizing HIV, and PrEP use may increase openness to serodifferent partnering among HIV-negative people.*

5. **Durability of viral suppression in a South African national HIV cohort**
   Jacob Bor, Boston University, USA
   - In a sample of 2.4 million PLWH with an undetectable viral load (<200 copies/mL), 73% remained on ART and had a viral load test at 12 months, of which 87% continued to have an undetectable viral load.
   - Only 5% had a VL of 1000+ at 12 months.
   - *Among PLWH who remain on ART and in care, viral suppression is durable over time.*

Open Discussion Themes

- **Research needed for policy change and U=U implementation**
  - There are barriers that need to be overcome at multiple phases of rollout:
    - Adoption of U=U as national policy
    - Implementation of U=U
    - Buy-in from healthcare providers
  - How do we motivate behavior change at the policymaker, provider, and individual level?
    - How can we facilitate movement from U=U awareness to U=U acceptance to behavior change that promotes U=U?
  - Public health/clinical outcome data needed
    - Effects of U=U messaging/interventions on testing, adherence, viral suppression, retention, etc. are understudied but essential for policy change and provider buy-in.
    - Such data have the potential to sway critics who are unconvinced by psychosocial outcome data.
  - Modeling/cost-effectiveness data needed
    - What is the return on investment for U=U programs?
    - Does U=U translate to cost savings? How?
    - It would be valuable to show that there is cost savings to proactively intervening/preventing unwanted HIV continuum outcomes (e.g., loss to follow-up) via U=U vs. responding to these outcomes reactively (e.g., interventions designed to locate PLWH lost to follow-up); such evidence could be persuasive to policymakers and clinicians.
  - Policymaker and provider concerns need to be addressed:
    - Identified concerns include:
      - Risk compensation and impact on STIs
      - Social conservatism
      - Blame and perceived legal culpability for transmission
        - Providers may not be communicating U=U clearly (using definitive language) because of concern about

liability; providers need reassurance that definitive language is endorsed/approved
        - What are the other concerns? What kind of data could overcome these concerns?
        - Provider interventions and data to show effectiveness are needed
    - Identification of *low-cost* interventions to promote U=U needed
        - Could a patient-targeted app be adapted for use with providers?
        - How could AI be leveraged?
    - More research is needed to clarify transmission risk in the 200-1000 copies/mL range; could the zero-risk threshold be higher, particularly given the effectiveness of current ART regimens?

- **International research and collaboration**
    - U=U implementation barriers vary be country; it would be valuable to coordinate studies across countries and use the same methods (e.g., same interview guide) to compare/identify similarities and differences.
    - The Prevention Access Campaign or another entity could publicize the most essential U=U studies needed (e.g., for policy change) in a central location and make drafted study materials (e.g., protocols, consent forms) readily accessible to researchers in different countries. This could accelerate study execution in multiple countries and generate comparable data given the shared methods/materials used.
    - A significant barrier for policymakers implementing new policies is that supporting studies showing a given outcome have not been performed in the local country or context; conducting studies in multiple countries simultaneously could yield data that would help to address this barrier.
    - Existing interventions could potentially be adapted and used in other countries vs. reinventing the wheel.

- **Populations, access, and equity**
    - There is a need to extend U=U social behavioral research (e.g., U=U acceptance, openness to serodifferent partnering) to populations other than SMM, including heterosexual women, people who inject drugs, youth, and older adults.
    - Research is needed to address HIV colonialism and information barriers faced by the Global South.
        - Vital information and resources are being withheld from the Global South.
        - Information and resources should be openly shared with the Global South to allow development and implementation of tailored messaging/interventions.
    - If U=U drives demand for testing, ARVs, and access to other services, it is imperative that we ensure supply can meet this demand.
    - U=U is a privilege unless structural barriers are addressed, including policy and clinical practice.

- There is a need to consider structural barriers and complex needs as challenges to viral suppression.
- HIV transmissibility through breastfeeding when a mother's viral load is undetectable is currently under-researched; more information is needed to allay concerns.

- **Messaging**
  - We need to better understand whether and how to communicate information about transmission risk in 200-1000 copies/mL range per the 2023 WHO policy brief.
    - There is concern that messaging related to "almost zero" risk and "negligible" risk will detract from the U=U message and confuse community members.
  - How can we incorporate pleasure in U=U messaging (vs. focusing on risk)?
  - U=U messaging needs to be tailored for different groups (e.g., heterosexuals, people who inject drugs, youth, and older adults).

- **Additional comments/considerations**
  - Research on the effectiveness of U=U vs. PrEP vs. condoms in eliminating HIV transmission was recommended to highlight the superiority/non-inferiority of U=U.
  - The percentage of PLWH "lost to care" in studies is likely an overestimate of the percentage actually disengaged from care; many may have relocated and are receiving care elsewhere.
  - The WHO policy brief characterizing transmission risk for virally suppressed but detectable (200-1000 copies/mL range) as "negligible" could be beneficial in the court of law/HIV criminalization cases.
  - People who are virally suppressed and but have detectable viral loads (200-1000 copies/mL) need to reduce their viral load for their own health (i.e., this 200-1000 range should be a temporary state) and follow-up viral load monitoring needs to be more frequent than annual.
  - How could U=U mitigate intimate partner violence and other adverse outcomes of HIV status disclosure among heterosexual women?