Remarks:

International AIDS Society and STI & HIV World Congress Leadership

Speaker order:

IAS/Nyaradzo M Mgodi – U. Zim
IAS/Roger Pebody – Aidsmap
STI/Charlie Petersen – UIC
STI/Dr. Anu Hazra – UC, HBH
AVAC
Global Advocacy for HIV Prevention

THE CHOICE AGENDA

HIV prevention research - a new forum for advocacy on the latest

avac.org/project/choice-agenda
Are you a TCA subscriber?
Tales from Two Cities Playlist

- Down Under
  KUJAN

- Brighter Days
  Cajmere (feat Dajae)

- Padam Padam
  Kylie Minogue

- My Kind of Town (Live)
  Frank Sinatra

- Take Me to Church
  Sinéad O’Connor

DJ Jimberly
How do People Who Use/Inject Drugs Fit into PrEP Research and Service Delivery?

September 6, Wednesday, 2023
9:00 AM – 10:30 AM Eastern

REGISTER tinyurl.com/pwudprep

Webinar brought to you by The Choice Agenda and International Network of People Who Use Drugs
The Choice Agenda presents

Tales from Two Cities

HIV and STI research highlights from Brisbane and Chicago

August 3  9 AM eastern
Register & more info
tinyurl.com/talesfromtwocities
The latest in HIV and STI Prevention

Highlights from IAS 2023

Nyaradzo M. Mgodi (MBChB, MMed)
University of Zimbabwe
Faculty of Medicine and Health Sciences
nmgodi@uz-ctrca.org

IAS 2023
23 – 26 July · Brisbane and virtual
ias2023.org
Track C
Epidemiology and prevention science

Katherine Gill, South Africa
Skye McGregor, Australia
Nyaradzo Mgodi, Zimbabwe
Richard Gray, Australia
Towards HIV elimination

Challenges associated with highly efficacious LA PrEP and treatment

Colliding epidemics

Sexual reproductive Health and STIs

Human-centred approaches – integrated and differentiated services
Towards HIV Elimination

Providing a social network approach to HIV testing could help reach the “first 95” and contribute to the goal of eliminating HIV as a global health threat.

Session: OALBC06
Still a long way to go to achieve targets in a range of settings Australia has achieved 91-92-98 – ongoing progress not guaranteed (Gray)

Unplanned treatment interruptions impacted mortality in the South Africa IeDEA-SA cohort (Moolla)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Adjusted hazard ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Interruption status</strong></td>
<td></td>
</tr>
<tr>
<td>No interruption</td>
<td>1 (reference)</td>
</tr>
<tr>
<td>Early interrupters</td>
<td>2.32 (2.06-2.61)</td>
</tr>
<tr>
<td>Late interrupters</td>
<td>1.90 (1.68-2.15)</td>
</tr>
</tbody>
</table>

Male gender, age, and lower baseline CD4 count, and increased duration of interruption, were also associated with increased mortality.
OAC01: Progress towards HIV elimination, are we there yet?

High HIV incidence among people who inject drugs in South Africa - NACOSA (Artenie)
Province the primary association for increased incidence risk
People who received OST or higher number of harm reduction packs tended to have a lower risk of HIV
Low number re-tested a limitation

- Impact of ART initiation timing on virological failure, mortality, and loss to follow up, using Universal Health Coverage data (Teeraananchai).
- VF was higher in the treatment >3 months group, mortality lowest in the same day treatment initiation group, and LTFU highest in the same day and lowest in the >1-3 months treatment initiation group.
East and Southern Africa are on track to meet elimination targets (57% reduction), but other regions lag or are seeing substantial increases (Grulich)

88% reduction in inner Sydney, but 31% in outer suburbs: different patterns of access to prevention

With zero risk of vertical transmission in context of U=U, what is the role for neonatal PEP? (Laufer)

Transmissions without neoPEP in context of detectable viral load only.

People should be empowered to make decisions about chest/breastfeeding in this context, while ensuring risks were clear.
The effect of primary health care on AIDS incidence and mortality: A cohort study of 3.4 million Brazilians

**Session title: “Achieving HIV prevention and treatment at scale”**

The benefits of community based primary health care programs at scale was demonstrated by Priscilla Pinto who showed that Brazil’s Family Health Strategy had a substantial impact on AIDS incidence and mortality using data from a linked longitudinal cohort of > 3.4 million.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Untreated N=605,890</th>
<th>Treated N=2,829,178</th>
<th>Total N=3,435,068</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIDS incidence</td>
<td>25.57 (23.71-27.58)</td>
<td>13.21 (12.65-13.80)</td>
<td>15.00 (14.45-15.58)</td>
</tr>
<tr>
<td>AIDS mortality</td>
<td>8.28 (7.25-9.45)</td>
<td>3.88 (3.58-4.20)</td>
<td>4.51 (4.22-4.83)</td>
</tr>
</tbody>
</table>

Table 1. AIDS incidence and mortality rates according to Family Health Strategy (FHS) coverage, Brazil, 2007–15

<table>
<thead>
<tr>
<th>FHS coverage</th>
<th>AIDS incidence n=3,435,068 RR (CI 95%)</th>
<th>AIDS mortality n=3,435,068 RR (CI 95%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;20%</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>100%</td>
<td>0.76 (0.68-0.84)</td>
<td>0.68 (0.56-0.82)</td>
</tr>
</tbody>
</table>
Towards HIV Elimination

“Nothing that we do, is done in vain. I believe, with all my soul, that we shall see triumph.”

— Charles Dickens, A Tale of Two Cities
Highly efficacious LA PrEP and treatment

Challenges
SY11- HIV testing in the context of long-acting PrEP

Summary

- Resistance risk with acquiring HIV on dapivirine is low
  - Low systemic drug levels
  - Equivalent rates of resistance in active and placebo arm of trials
  - Efficacy of ring against NNRTI-resistant strains unknown

- Resistance risk with acquiring HIV on CAB-LA is high when HIV diagnosis is delayed
  - Drug concentrations at the sites of transmission may be insufficient to block transmission but concentrations elsewhere (e.g., blood, lymph nodes) are sufficient to select resistance
  - Secondary transmissions have not been reported but will be important to monitor

HIV VL COVERAGE

National policy on routine viral load testing for monitoring ART and implementation status among adults and adolescents living with HIV in low- and middle-income countries, July 2022

VL testing still suboptimal in high burden countries

88% (22 of 25) had VL testing coverage ≤90%

32% of the countries reported ≤50% viral load testing coverage

As numbers on CAB increase via CATALYST and other implementation studies...

- Will national algorithm-based testing continue to result in detection delays & inadvertent CAB-LA initiations/reinjections?
- What alternative testing approaches may be better? At what cost?
- What are the most common scenarios of complex/delayed diagnoses emerging?
- Which tests/combination of tests are best for adjudicating/definitively diagnosing such cases?
- What are the characteristics/frequency of LEVI syndrome?
- What are 1st vs. 2nd line ART considerations subsequent to CAB mono/therapy among those with HIVDR?
- Does systematic clinical/behavioral assessment of ART adherence reduce inadvertent CAB-LA starts? As well as inadvertent reinfection among those significantly delayed in returning?
Conducting clinical trials in an era of highly effective agents will be a challenge given it is no longer ethical to use a placebo control.

Several approaches to estimating the background HIV incidence using a “counterfactual placebo” were presented by Deborah Donnell.

All approaches rely on assumptions and there are several practical challenges that will need to be overcome.

Estimate counterfactual placebo incidence rate
1. Placebo data from external trials
2. HIV incidence in registrational cohort
3. Cross-sectional incidence assessed using recency assay during screening for enrollment in “untreated” participants
4. Estimating placebo incidence using reliable predictor(s) of HIV exposure risk

Estimate efficacy of active control to counterfactual placebo
5. Using adherence-efficacy relationship of active control
6. Using immune biomarkers of effective vaccine/mAb as mediators of prevention efficacy (monoclonal Ab and vaccine)
Colliding epidemics
This session focused on the impact of other infectious diseases and public health interventions on people living with HIV or at-risk of HIV infection. The presentations really demonstrated the importance of person centred and integrated care.

Joseph Puyat’s presentation highlighted the potential need for flexible and adaptable guidelines for COVID vaccinations among people who inject drugs and those living with HIV who have faster waning of vaccine effectiveness (though lot of uncertainty) and hence may need more frequent boosters.
Claire Pederson described an intervention study of the integration of a HIV PrEP service and assisted partner notification program in STI clinics in Malawi. **One of the recipients of the MSD/IAS Prize for Research in Long-Acting HIV Prevention and Treatment: Annual prize at the conference.**

This program was able to reach people at risk of HIV and provide them PrEP and efficiency find people living with HIV but not taking ART, including those to not be part of a priority population.

*from 86 index participants*
Human-centred approaches

CAB-LA is acceptable for teens in Southern Africa and provides another critical option in HIV prevention choice for young African women.

Session: OALBC06
Integration of PrEP services and assisted partner notification into an STI clinic in Lilongwe, Malawi

Claire Pedersen (Winner of a prize! IAS )

Colliding epidemics: Prevention of HIV and co-infection. OAC2 Monday 24/723 1600.

*from 86 index participants

48% of named partners in a priority population
PL05: Towards elimination

East and Southern Africa are on track to meet elimination targets (57% reduction), but other regions lag or are seeing substantial increases (Grulich)

88% reduction in inner Sydney, but 31% in outer suburbs: different patterns of access to prevention

With zero risk of vertical transmission in context of U=U, what is the role for neonatal PEP? (Laufer)

Transmissions without neoPEP in context of detectable viral load only.

People should be empowered to make decisions about chest/breastfeeding in this context, while ensuring risks were clear.
Sinead Delany-Moretlwe presented results related to the choices and preferences of women participants related to using injectable cabotegravir or oral PrEP. CAB was chosen by 78% of women in the HPTN 084 trial of injectable cabotegravir (CAB) in women but there was a wide disparity of preferences and women were happy with their choice.
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AMP trials provide proof-of-concept that bnAbs can prevent HIV infection

Proof of concept
- HIV prevention with 1 bnAb is possible
- VRC01 protected only against acquisition of highly neutralization-sensitive viruses
  - Prevention efficacy of 75% (45 – 88%)
  - Established putative marker of protection: PT80

Corey L et al., NEJM 2021; Gilbert et al., Nat Med 2022
AMP trials - summary

- HIV bnAbs are safe and generally well tolerated.
- VRC01 protects against acquisition of HIV-1 to viruses that are highly sensitive to the antibody.
- More resistant viruses break through.
- The study validates the TZM-bl target cell assay which may be predictive of protection.
- AMP established putative marker of protection: PT80.
- Future bnAb trials will require trispecific Abs or combinations of more potent antibodies with better coverage to improve overall prevention efficacy.
- Trials of these antibodies are already under way.

Corey et al., *NEJM* 2021; Takuva et al., *JAIDS*, 2022; Gilbert et al., *Nat Med* 2022

Photo: NIAID/NIH Vaccine Research Center (VRC)
Multiple antibody neutralization against HIV

Thanks to Lisa Donohue for this video.
The bnAb HIV prevention field is evolving faster than ever.

- Research must reflect diversity, equity, and inclusion
- Target highest prevalence regions and special populations
  - pregnant and breast-feeding persons, infants, adolescents, gender-diversity, women.
- Begin with the end in mind
  - access manufacturing, licensing, delivery methods.
- Research should be framed by a human-rights-based approach and
- Uphold justice and beneficence

"Respect for all and harm to none."

Aboriginal Proverb
Sexual reproductive Health
STIs
PL04: The latest in STI and HIV prevention

Jean Michel Molina

Doxycycline Post-Exposure Prophylaxis for STIs: Time for Implementation?

ANRS DOXYVAC Trial
Time to First Chlamydia or Syphilis Infection

Preliminary results among 502 MSM on PrEP with a history of STI

Median follow-up: 9 months (IQR: 6 to 12) in 501 participants

49 subjects infected
36 in No PEP arm (incidence: 35.4/100 PY)
13 in Doxy PEP arm (incidence: 5.6/100 PY)

Adjusted Hazard Ratio: 0.18 (95% CI: 0.08-0.30, p<0.0001)

Summary
- Short-term benefits of Doxycycline PEP among MSM
  - Strong reduction of syphilis and chlamydia incidence
  - Impact on gonorrhea likely to be limited
  - Well tolerated with high acceptability and adherence
- Long-term uncertainties: Continue research
  - Selection and clonal dissemination of more resistant STIs
  - Impact on the microbiome
- Time for cautious DoxyPEP implementation?
  - Identify the population who will benefit the most
  - Monitor AMR and impact on the microbiome
  - Involve community and all stakeholders

Molina JM, CROI 2023
No association between in utero PrEP use (self-report) and height and bone mineral density in infants, at 36 months, in Kenya (Wu)

PrIMA trial in Kenya - cofactors of HIV self-testing and PrEP use among pregnant women at high risk of HIV

HIV self-testing was more acceptable than PrEP (69% vs 18%)

HIV self-testing increased awareness of partners HIV status from 4.7% to 82.0%

Co-factors influenced the choice of prevention.
The iFACT3 study in Thailand (Akarin) examined drug-drug interactions among transgender women (FHT and PrEP).

No clinically significant difference in concentration of drugs.

HIV Stigma Index 2.0 study (Lyons)

Significant impact of reproductive coercion in women living with HIV, across Eastern Europe and Central Asia, and Sub-Saharan Africa.

Sex workers, migrants, women who inject drugs, and young women had greater odds of reproductive coercion.
Thank you
Highlights from AIDS 2023
12th International AIDS Society Conference on HIV Science

Roger Pebody
Managing Editor, www.aidsmap.com

The Choice Agenda, 3 August 2023
A perfect storm for stigma: gay and bisexual men’s experiences of mpox

Krishen Samuel | 27 July 2023 | Estimated reading time 6 minutes

Qualitative study, 13 gay/bi men

“It would be the worst pain I have ever experienced in my life... I was in tears.”

Health services: inadequate pain management, judgement regarding sexual behaviour and traumatic experiences

“It’s still giving me trouble in terms of like social anxiety, nightmares, flashbacks. Every time I’m near the hospital, my heart rate goes up and I almost have a panic attack.”

Qualitative research found that most Australian gay and bisexual men diagnosed with mpox (previously known as monkeypox) had highly distressing experiences due to severe symptoms, long isolation periods and stigmatising healthcare providers. Dr Anthony Smith from the Centre for Social Research in Health at the University of New South Wales presented the results at the 12th International AIDS Society Conference on HIV Science (IAS 2023) this week.

Following the acute illness, there were also longer-term physical and social effects. While cases of mpox are currently on the decline, Dr Smith stressed that mental health support is crucial to help men recover from their experiences.
What’s happened to services for key populations in Uganda following the Anti-Homosexuality Act?

Edith Magak | 1 August 2023 | Estimated reading time 4 minutes

Before the discussion around Uganda’s Anti-Homosexuality Act, drop-in centres providing HIV prevention and treatment services to key populations saw an average of 40 clients per week. However, as the discussion continued in Ugandan media, the number of clients decreased significantly.

By the time the first version of ‘one of the world’s harshest anti-gay laws’ was debated and approved in the Ugandan Parliament in mid-March 2023, drop-in centres only saw an average of

- 84 PEPFAR-supported centres for key pops
- Drastic reduction in client flow, temporary closures, increased assaults, etc.
- Response: telehealth, home delivery, security, flexibility

“We are concerned about protecting the human rights of all Ugandan citizens. We want to ensure our investments in health, especially in HIV and AIDS, reach the intended beneficiaries, like key populations.” – Ambassador Natalie Brown
Coercive reproductive healthcare practices reported by many women living with HIV

Human rights threatened in Africa, eastern Europe and central Asia

Bakita Kasadha  26 July 2023  Estimated reading time 3 minutes

Women with HIV are at an increased risk of reproductive coercion by healthcare professionals across sub-Saharan Africa, eastern Europe and central Asia. Sex workers, women who use drugs and migrants who are also HIV positive are more likely to receive sub-standard and stigmatising reproductive care. This was reported by Dr Carrie Lyons from the Johns Hopkins School of Public Heath at the 12th International AIDS Society Conference on HIV Science (IAS 2023) in Brisbane, Australia.

- Stigma Index data, 2021-2022
- Experiences in past 12 months
- 11 African countries + 5 eastern European and central Asian countries
- Forced sterilisation (1%, 3%)
- Coerced family planning (2%, 4%)
- Coercion related to pregnancy (5%, 10%)
- Higher risks for migrants, sex workers, drug users.
The amber light: the World Health Organization’s position when an HIV viral load is “suppressed but not undetectable”

Gus Cairns  |  24 July 2023  |  Estimated reading time 9 minutes

The risk of transmission by someone who has a viral load too low to be quantified by some viral load tests, but where the test still detects HIV’s presence, is “almost zero or negligible” in the words of the World Health Organization (WHO), the 12th International AIDS Society Conference on HIV Science (IAS 2023) in Brisbane, Australia heard yesterday.

Dr Lara Veinov, Diagnostics Advisor in WHO’s Global HIV, Hepatitis and STI Programme, was speaking at IAS 2023.

• Two key elements
• *Lancet* systematic review of viral load and transmission risk (esp with low level viraemia)
• Consideration of how to apply U=U message globally, in settings with diverse testing methods
The risk of sexual transmission of HIV in individuals with low-level HIV viremia: a systematic review

J. van Beek, L. V. van Baarle, E. ten Eyck, L. van Gerven

Summary

Background: The risk of sexual transmission of HIV from individuals with low-level HIV viremia receiving antiretroviral therapy (ART) has important public health implications, especially in resource-limited settings that use alternative to plasma-based viral load testing. This article summarises the evidence related to sexual transmission of HIV at varying HIV viral load levels to inform messaging for people living with HIV, their partners, their health-care providers, and the wider public.

Methods: We conducted a systematic review and searched PubMed, MEDLINE, Cochrane Central Register of Controlled Trials, Embase, Conference Proceedings Citation Index-Science, and WHO Global Index Medicus. Data published from January 1, 2010, to November 17, 2022, were included if they reported sexual transmission between discordant couples at various levels of viremia, the science behind undetectable-instrumentalisation, the public health impact of low-level viremia. Studies were excluded if they did not specify viral load thresholds or a definition for low-level viremia or did not provide quantitative viral load information for transmission outcomes. Results: 3294 studies were identified and eight were included in the analysis, comprising 7762 semidiscordant couples across 21 countries. The certainty of evidence was moderate: the risk of bias was low. Three studies showed no HIV transmission when the partner living with HIV had a viral load less than 100 copies/ml. Across the remaining four prospective studies, there were 319 transmission events; none were considered statistically suppressed on ART. Across all studies, there were two cases of transmission when the index patient’s (ie, patient with previously diagnosed HIV infection) most recent viral load was less than 1000 copies/ml. However, intervention at both cases was complicated by long intervals (ie, 90 days and 53 days) between the transmission date and the most recent index viral load result.

Interpretation: There is almost zero risk of sexual transmission of HIV with viral loads of less than 1000 copies/ml.

These results provide a powerful opportunity to destigmatise HIV and promote adherence to ART through downscaling of this positive public health message. These findings can also promote access to viral load testing in resource-limited settings for all people living with HIV by facilitating uptake of alternative sample types and technologies.

Lancet: 7762 couples in 8 studies

2 transmission events with viral load <1000 copies/ml

(617 and 872 copies/ml, both taken ~50 days before transmission)

“There is almost zero risk of sexual transmission of HIV with viral loads of less than 1000 copies/ml”
THE ROLE OF HIV VIRAL SUPPRESSION IN IMPROVING INDIVIDUAL HEALTH AND REDUCING TRANSMISSION

POLICY BRIEF

World Health Organization

The ultimate goal for all people living with HIV is to reach and sustain undetectable viral loads. Taking antiretroviral therapy as prescribed will support this goal, prevent transmission to their sexual partner(s) and/or children, and improve their own clinical well-being.

* Not detected by the test or sample type used.
Social network intervention increases HIV self-testing among African fishermen by 50%

Edith Magak  |  27 July 2023  |  Estimated reading time 3 minutes

An approach relying on the social connections between men is a promising method for engaging hard-to-reach populations of men in HIV testing, prevention, and treatment. A randomised controlled trial, presented at the 12th International AIDS Society Conference on HIV Science (IAS 2023) in Brisbane, Australia, this week showed a 50% increase in HIV testing among fishermen in Kenya and a 53% increase in linkage to health facilities.

In Africa, men have a higher likelihood of being unaware of their HIV status compared to women.

- Mobile men, high HIV prevalence, low use of health services
- Use social connections between men to promote HIV self-testing, PrEP and ART
Here is what transgender women across Asia want in PrEP

Edith Magak | 31 July 2023 | Estimated reading time 4 minutes

If PrEP were free, injectable, had no side effects, could be accessed through peer-led community clinics every 6-12 months, and STI testing was offered as an additional service at the clinics, the uptake among transgender women in Asia could increase to up to 87%, This was reported by Waritha Tiosapajaroen from the Melbourne Sexual Health Centre at the 12th International AIDS Society Conference on HIV Science (IAS 2023) in Brisbane last week.

As of 2023, 15.6% of people living with HIV were in the Asia-Pacific region, with 260,000 new infections reported. Reports from an online survey of ~1500 trans women in 11 Asian countries showed that 48% had unmet PrEP need.

Cost much more important than any other issue in discrete choice experiment.

Most wanted PrEP service:
- Free injectable PrEP with no side effects
- Access at peer-led community clinic that provides STI testing
- 6-12 monthly visits
Two modelling studies ask: will injectable PrEP ever be cost-effective at achievable prices?

- South Africa and Brazil
- Price needs to be much less than $100 annually
- Compares $40 oral PrEP
- Compares voluntary license estimate $250
- Brazil analysis considers how many people can be reached with a fixed budget
Injectable HIV treatment unlikely to be arriving soon in the global south

Roger Pebody | 2 August 2023 | Estimated reading time 6 minutes

While there is a path to injectable PrEP becoming available in the next five years, the widespread use of injectables to treat people living with HIV in low- and middle-income countries is unlikely in the near future. The combination of injectable cabotegravir and rilpivirine has only been approved by a handful of countries, it’s not clear whether rilpivirine will be available as a generic, and the regimen has complexities which make it less attractive than the preferred oral regimens.

Classify:

But injectable HIV treatment could have a future in the global south

- How much better than oral ART?
- Practical challenges
- Cost
- Lack of generic rilpivirine
- Guidelines with a public health approach: one size fits all
Pitavastatin lowers risk of cardiovascular events in people living with HIV

Primary prevention study enrolled people with HIV who would not normally be prescribed a statin

Liz Highleyman | 24 July 2023 | Estimated reading time 9 minutes

- The big clinical study at IAS 2023
- Large RCT with diverse global participation
- 7769 people with HIV aged 40-75, at low to moderate risk of cardiovascular disease
- Major cardiovascular events: 4.8 per 1000 person-years (pitavastatin) vs 7.3 per 1000 person-years (placebo) – 35% reduction.
- Lowers LDL cholesterol and inflammation
- Guidelines likely to change

A widely used statin medication reduced the risk of heart attacks, strokes and other cardiovascular events when given to people with HIV who are at low to moderate risk for cardiovascular disease, according to results from the REPRIEVE study presented at the 12th International AIDS Society Conference on HIV Science (IAS 2023) in Brisbane, Australia. The findings suggest that statin use could help to reduce the risk of a first cardiovascular event in people living with HIV.
**Diabetes**

**Integrase inhibitors raise the risk of diabetes regardless of weight gain**

Keith Alston | 31 July 2023 | Estimated reading time 5 minutes

Integrase inhibitors increase the risk of developing type 2 diabetes regardless of how much weight is gained while taking one, a large international cohort study has found.

People with HIV taking an integrase inhibitor as part of their HIV treatment had a 49% higher risk of developing type 2 diabetes. More research is needed to understand the mechanism that raises diabetes risk in people taking integrase inhibitors, say researchers who carried out an international cohort study to look at the relationship between HIV treatment, weight gain and diabetes risk.

**Cardiovascular Disease**

**Diagnosis and treatment for high blood pressure need to be funded as part of HIV treatment programmes**

Keith Alston | 26 July 2023 | Estimated reading time 5 minutes

High blood pressure more likely to develop in people taking an integrase inhibitor and tenofovir alafenamide (TAF).

The development of high blood pressure (hypertension) after starting antiretroviral treatment in sub-Saharan Africa is common but can be managed with monitoring and low-cost generic drugs. Professor reinas Venter of the University of the Witwatersrand told the 19th International AIDS Conference (IAC 2023) that the findings from the study with TAF are important. "We need to fund hypertension screening and treatment in our antiretroviral programmes," she said.

**Weight gain & body fat**

**Switches away from integrase inhibitors do not reverse weight gain, studies find**

Keith Alston | 27 July 2023 | Estimated reading time 6 minutes

Pressure needed for studies of new weight loss drugs in people with HIV.
First person may be cured of HIV after stem cell transplant without CCR5 mutation

A man dubbed the ‘Geneva patient’ appears to be the latest person cured of HIV after a stem cell transplant for cancer treatment. Unlike the other five known cases, however, he received stem cells from a donor who does not have a rare mutation that prevents HIV from entering cells. The man continues to have undetectable HIV 20 months after stopping antiretroviral therapy (ART).

“What has happened to me is wonderful and magical,” the Geneva patient said in a press statement. “We can now focus on the future.”
Thank you
email: roger@nam.org.uk
twitter: @RogerPebody
www.aidsmap.com
STI / HIV 2023
WORLD CONGRESS

COMMUNITY ADVOCACY /
IMPLEMENTATION UPDATES

Charles (Charlie) Peterson
Pronouns: he/him; él; il
Manager, Community Engagement & Clinical Research Education
University of Illinois at Chicago (UIC)
DIVERSITY, EQUITY, INCLUSION (DEI)

- Approach key communities with respect, intentionality, and purpose
- Recognize that you are encroaching on communities’ safe spaces
- Acknowledge the intersectionalities, social inequities of health, traumas, and different lived experiences that communities may have
- Know that all people look for inclusive healthcare, where they feel seen and understood, where their needs are met, and lived experiences are affirmed
- Diversified community stakeholders provide many perspectives into and critical knowledge regarding key populations, thereby increasing the quality of healthcare initiatives
DIVERSITY, EQUITY, INCLUSION (DEI)

• “We are more than a finger-prick”
• “We are not a checkbox”

• In healthcare settings, noticing inclusion from allies, from organizations, from people who come from our communities, helps inspire confidence and trust
STRENGTHENING COMMUNITIES

• Joseph Tucker, MD, PhD, from University of North Carolina at Chapel Hill, talked about pay-it-forward models that work well in Asia
  • Increase community interconnectedness / connectedness
  • Help cover 20 – 60% of STI testing costs
  • Kindness spreads in social networks
  • Receive/Give model
    • Receive (free healthcare service)
    • Donate
      • Write a message on a postcard to motivate others to get tested
      • Give money
STRENGTHENING COMMUNITIES

- Jagadīśa-Devaśrī Dācus from Northwestern University’s Institute for Sexual and Gender Minority Health and Wellbeing (ISGMH) discussed key population-led approaches
  - Identified by the communities themselves: needs-based, demand-driven, and client-centered
  - Co-created between these communities and public health agencies, located in areas with high need, and offer stigma- and discrimination-free comprehensive services’
Strengthening Communities

We need to shift the paradigm from community engagement to community leadership in the HIV response. Key populations cannot only be service recipients.

Rena Janamnuaysook, transgender woman advocate

Shift from community-driven to community led
STRENGTHENING COMMUNITIES

Educate community and advocates on the importance of testing, different options available, and the pipeline.

Trauma-informed approaches need to be used for underserved & underrepresented communities.
Greater visibility helps others take STI messaging seriously

Follow the HIV model of incorporating community voice into messaging and advocacy

Add community members to planning councils to give greater voice

Add community input into trials to ensure clinical studies are inclusive
INNOVATION & IMPLEMENTATION

The current system puts nearly all the burden on the clinical healthcare system

Paradigm shift towards decentralization

Self-testing / Point-of-care testing
Artificial intelligence applications (diagnostic / screening tools, chatbots)
INNOVATION & IMPLEMENTATION - SELF TESTING

• Joseph Cherabie, MD, from Washington University in St Louis, highlighted several self-testing benefits, namely
  • Convenience (more than 50% of patients preferred home kits and preference was irrespective of insurance status)
  • Speedy results
  • Reduction of person-to-person interaction
    • Stigma reduction
INNOVATION & IMPLEMENTATION - SELF TESTING

• Potentially less time consuming, as it can quicken visits or can be done at home
• Increases screening rates
• Bypass systemic barriers (lack of internet/computer/phone, travel concerns)
• Targeting of key populations (areas of greater need)
• Lead-in to telehealth / tele-PrEP
Remote options have the potential to help people navigate healthcare more easily in areas where same-sex relations are criminalized or there is heavy stigma.
INNOVATION & IMPLEMENTATION – SELF TESTING

• A Preventx presentation showed that home testing led to the diagnosis of a similar number of STI infections (chlamydia, gonorrhea, Hep B, Hep C, HIV) to what clinic diagnoses would have been
• And that home testing kits (online postal self-sampling, OPSS) were being ordered a lot (2.2 MM kits), with a very high kit return rate (~1.8 MM)
• More options allow for greater reach, more testing and more diagnoses
• Trickle up effect (testing, data collection, etc), permitting better-informed healthcare industry decisions
**INNOVATION & IMPLEMENTATION – AI DIAGNOSTIC / SCREENING TOOLS**

- Lei Zhang, PhD, from the Melbourne Sexual Health Centre, talked about AI screening tools for STI detection
- Yudara Kularathne, MD, spoke about HeHealth, occupying a similar niche
- Both platforms were:
  - Confidential, private
  - Accessible from mobile devices
  - Provided fairly good identification of STIs (71 – 83% accuracy / 86% and higher, respectively)
  - Continual AI learning/improvement
- HeHealth delivers personalized instructions based on local guidelines.
- While these apps are in their infancy, more data and more users lead to greater accuracy, making them a potentially invaluable tool in the future
INNOVATION & IMPLEMENTATION - CHATBOTS

• Chatbots tap into artificial intelligence and can be used for initial conversations with clients
  • Planned Parenthood has developed Roo
  • This bot can answer questions about:
    • Sexual health
    • Relationships
    • Growing up
INNOVATION & IMPLEMENTATION - CHATBOTS

- Tom Nadarzynski, PhD, from University of Westminster mentioned additional issues
  - Bots can be used to reach marginalized communities without judgement, without stigma
  - Offer a safe space to discuss private, vulnerable topics
  - Relevant, personalized answers
- CONS: systemic barriers (digital inequality, not human, not diagnostic, only accurate if human provides honest answers)
We must recognize that people are sexual beings.

Additional steps suggested were to create environments where people feel comfortable discussing STIs.

Integrate STI services with Primary Care, sexual/reproductive health, and HIV services.

Facilitate POC diagnostics and other affordable technologies.
CARE IMPROVEMENT

- STI testing should be targeted: racial/ethnic minorities, sexual/gender minorities, rural/remote areas, persons under- and uninsured (Alison Footman, PhD - AVAC)
- Make STI/HIV tests at locations like Emergency Departments opt-out.
- Acknowledge the traumas that lead to current medical distrust to not sound culturally tone-deaf (intergenerational, historical)
- Recognize that healthcare is not necessarily a priority for people, especially when living paycheck to paycheck
- Communities sometimes lack education (ambassadors/champions), which needs addressing
- The Community Group Design-a-Thon mentioned that a reframing or a gain-framing of STI messaging is needed. Essentially, move away from risk messaging, and reposition the discussion of STIs in discussions about sexual pleasure, sexual health, sex normalization and positivity
DISCUSSION

Questions / Answers

cp3o@uic.edu
STI & HIV 2023 WORLD CONGRESS:
CLINICAL & BIOMEDICAL UPDATES

Aniruddha (Anu) Hazra, MD
Assistant Professor, Section of Infectious Diseases & Global Health
Director of STI Services, Chicago Center of HIV Elimination
Medical Director, DCAM Sexual Wellness Clinic
University of Chicago Medicine
Howard Brown Health Center

@AnuHazraMD
**MINOCYCLINE FOR MYCOPLASMA GENITALIUM**

- M. genitalium is a cause of non-gonococcal urethritis, cervicitis, PID, and adverse obstetric outcomes

- Main available classes of antimicrobials:
  - tetracyclines
  - macrolides
  - streptogramins
  - fluoroquinolones

- Macrolide-resistance exceeds 50% in many regions globally, and the prevalence of fluoroquinolone resistance mutations is >30% in some regions of the Asia-Pacific

- There is a need for alternative to quinolones if they fail or are contraindicated

Vodstricil L, et al. O4.5 - Efficacy of minocycline for the treatment of Mycoplasma genitalium
MINOCYCLINE FOR MYCOPLASMA GENITALIUM

- Minocycline is a tetracycline which is widely available and affordable

- Limited data on the efficacy of minocycline for treating M. genitalium from case reports and a small series of 35 patients

- Retrospective review of patients with macrolide-resistant M. genitalium who were treated with minocycline at the Melbourne Sexual Health Centre (MSHC) between February 2020 - May 2022

- Microbial cure was defined as a negative TOC within 14-90 days after completing minocycline

Vodstricil L, et al. O4.5 - Efficacy of minocycline for the treatment of Mycoplasma genitalium
MINOCYCLINE FOR MYCOPLASMA GENITALIUM

- 60/90 patients (66.7%, 95% CI: 56.0%-76.3%) experienced microbial cure within 14-90 days of completing minocycline

- >95% adhered to the 14-day regimen

- Predominantly mild adverse effects reported, most common was dizziness (9%)

- Minocycline is a nonquinolone alternative, that will cure 2/3 macrolide-resistant infections

Vodstricil L, et al. O4.5 - Efficacy of minocycline for the treatment of Mycoplasma genitalium
High prevalence of acyclovir resistant HSV (up to 25%) in immunocompromised people

Remianing therapy is IV foscarnet, extremely toxic requires close monitoring

Those that cannot tolerate foscarnet have no other options currently

Pritelivir is a small molecule with novel MOA, inhibiting viral helicase-primase complex

Birkmann A, et al. O5.5 - Pritelivir for the treatment of resistant HSV infections in immunocompromised patients: update on an ongoing Phase 3 trial and Early Access Program
In Phase 2 studies, Pritelivir reduced viral shedding and clinical lesions.

Demonstrated superiority to valacyclovir in suppression of HSV shedding.

Birkmann A, et al. O5.5 - Pritelivir for the treatment of resistant HSV infections in immunocompromised patients: update on an ongoing Phase 3 trial and Early Access Program

Protocol amendment in preparation to replace foscarnet with standard of care

AIC316-03-II-01 (PRIOH-1): PHASE 3 (NCT03073967)
Trial on Efficacy and Safety of Pritelivir Tablets for Treatment of Acyclovir-Resistant Mucocutaneous HSV Infections in Immunocompromised Subjects

RANDOMIZED, OPEN-LABEL, MULTICENTER TRIAL

**Primary endpoint:** All lesions healed at Day 28 (secondary endpoint: Day 42)

**Pritelivir 100 mg PO QD (following a loading dose) or foscarnet 40 mg/kg IV TID or 60 mg/kg IV BID (Part C)**

**Immunocompromised subjects with mucocutaneous HSV Infections:**

- **Part C**
  - Acyclovir-resistant pritelivir vs. foscarnet, randomization 1:1

- **Part D (fully recruited)**
  - Acyclovir and foscarnet resistant or foscarnet intolerant

- **Part E**
  - Acyclovir susceptible

- **Part F**
  - Acyclovir resistant who failed on Standard of Care
In 2022, Massachusetts DPH identified a novel strain of multidrug-non-susceptible Neisseria gonorrhoeae with:
- reduced susceptibility to ceftriaxone, cefixime, and azithromycin
- resistance to ciprofloxacin, penicillin, and tetracycline

The identification of two non-susceptible cases prompted MDPH officials to recommend broadening surveillance further across the state.

A novel strain of multidrug-non-susceptible Neisseria gonorrhoeae with reduced susceptibility to ceftriaxone, cefixime, and azithromycin, and resistance to ciprofloxacin, penicillin, and tetracycline, has been identified in a Massachusetts resident. Although cefixime 500 mg IM was effective at clearing infection for this case, this is the first isolate identified in the United States to demonstrate resistance or reduced susceptibility to all drugs that are recommended for treatment.

Enhanced surveillance has identified a second isolate that, based on its genome, likely has similarly reduced susceptibility to ceftriaxone and cefixime.

Identification of this strain, the same as what was recently reported in the United Kingdom and previously reported as circulating in Asia-Pacific countries, is a warning that N. gonorrhoeae is becoming less responsive to a limited arsenal of antibiotics.

**MDPH recommends that clinicians take the following action:**
- Ensure compliance with recommended treatment of cefixime 500 mg IM as a single dose for persons weighing <50 kg, (1 gram IM for persons weighing ≥50 kg), per 2020-21 CDC guidelines.
- Perform gonococcal culture from genital and extragenital sites for symptomatic patients, in addition to routine nucleic acid amplification testing (NAAT). Clinicians should consult with local clinical microbiology laboratories to determine how best to optimize gonococcal culture, for example by using non-nutritive swab transport systems (e.g., Amies agar gel).
INCREASED GONORRHEA CULTURE SURVEILLANCE IN MASSACHUSETTS

• 1st Case:
  - A patient presented to primary care with dysuria and no known STI exposure.
  - The clinician performed gonorrhea testing via urine culture and NAAT.
  - Per state regulation, isolates were sent to the State Public Health Laboratory (SPHL) where minimum inhibitory concentrations (MICs) demonstrated resistance and reduced susceptibility to all currently recommended drugs for treatment.

• 2nd Case:
  - Identified as a result of enhanced surveillance activities following the first case.
  - MDPH collaborated with local laboratories and CDC to undertake a retrospective molecular analysis on remnant NAATs.
  - Based on genomic analysis, it likely has similarly reduced susceptibility to ceftriaxone and cefixime.
INCREASED GONORRHEA CULTURE SURVEILLANCE IN MASSACHUSETTS

- Enhanced surveillance included:
  - Perform gonococcal culture from genital and extragenital sites for symptomatic patients, in addition to routine NAAT
  - Obtain risk history, including travel history, for all gonorrhea-positive cases
  - Perform test of cure using NAAT or culture, 14 days after initial treatment, at all previously positive mucosal sites
  - Perform test of reinfection with NAAT 3 months after treatment for patients previously treated for gonorrhea

- 224 cases with positive gonorrhea cultures were reported to MDPH between January 19 and May 18, 2023
# INCREASED GONORRHEA CULTURE SURVEILLANCE IN MASSACHUSETTS

<table>
<thead>
<tr>
<th>Age Categories</th>
<th>Cases with only NAAT n= 2,721 (%)</th>
<th>Cases with positive culture n= 224 (%)</th>
<th>Chi-square p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Younger than 15 years</td>
<td>7 (0.3%)</td>
<td>0 (0.0%)</td>
<td>0.3228</td>
</tr>
<tr>
<td>15-19 years</td>
<td>366 (13.4%)</td>
<td>23 (10.3%)</td>
<td></td>
</tr>
<tr>
<td>20-24 years</td>
<td>691 (25.4%)</td>
<td>47 (21.0%)</td>
<td></td>
</tr>
<tr>
<td>25-29 years</td>
<td>522 (19.2%)</td>
<td>46 (20.5%)</td>
<td></td>
</tr>
<tr>
<td>30-39 years</td>
<td>709 (26.1%)</td>
<td>64 (28.6%)</td>
<td></td>
</tr>
<tr>
<td>40-44 years</td>
<td>185 (6.8%)</td>
<td>17 (7.6%)</td>
<td></td>
</tr>
<tr>
<td>45+ years</td>
<td>241 (8.9%)</td>
<td>27 (12.0%)</td>
<td></td>
</tr>
</tbody>
</table>

**Reported Sex/Gender**

<table>
<thead>
<tr>
<th>Sex/Gender</th>
<th>Cases with only NAAT n= 2,721 (%)</th>
<th>Cases with positive culture n= 224 (%)</th>
<th>Chi-square p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>1,813 (66.6%)</td>
<td>187 (83.5%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Female</td>
<td>904 (33.2%)</td>
<td>37 (16.5%)</td>
<td></td>
</tr>
<tr>
<td>Individuals of Transgender Experience</td>
<td>3 (0.1%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>Missing gender</td>
<td>1 (0.0%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
</tbody>
</table>

**Race/ethnicity**

<table>
<thead>
<tr>
<th>Race/ethnicity</th>
<th>Cases with only NAAT n= 2,721 (%)</th>
<th>Cases with positive culture n= 224 (%)</th>
<th>Chi-square p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Hispanic White</td>
<td>431 (15.8%)</td>
<td>84 (37.5%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Non-Hispanic Black</td>
<td>422 (15.5%)</td>
<td>48 (21.4%)</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>384 (14.1%)</td>
<td>54 (24.1%)</td>
<td></td>
</tr>
<tr>
<td>Non-Hispanic Asian</td>
<td>31 (1.1%)</td>
<td>13 (5.8%)</td>
<td></td>
</tr>
<tr>
<td>Non-Hispanic Other, AI/AN, Native Hawaiian PI</td>
<td>141 (5.2%)</td>
<td>9 (4.0%)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>1,312 (48.2%)</td>
<td>16 (7.1%)</td>
<td></td>
</tr>
</tbody>
</table>

* Chi-square test only includes males and females.

Elder H, et al. LB2.4 - Initial findings from increased gonorrhea culture surveillance in Massachusetts
Elder H, et al. LB2.4 - Initial findings from increased gonorrhea culture surveillance in Massachusetts
Since the clinical alert in January 2023, culture-positive symptomatic gonorrhea cases were distributed across the state and largely represented male individuals residing in moderately high or highly vulnerable census tracts.

The majority of culture-positive cases were reported by ID/Sexual Health and ER/Urgent Care.

Number and gender of sex partners and travel history were inconsistently documented.

Susceptibility testing revealed significant ciprofloxacin resistance but no further cephalosporin, macrolide, or aminoglycoside resistance.
ROLE OF AI IN STI SCREENING

Zhang L, et al. O8.2 - Artificial intelligence-assisted diagnostic tool for early detection of sexually transmitted infections
ROLE OF AI IN STI SCREENING

Zhang L, et al. O8.2 - Artificial intelligence-assisted diagnostic tool for early detection of sexually transmitted infections
DOXYPEP ADHERENCE IN CISGENDER WOMEN

- Doxycycline PEP did not reduce incident STIs among cisgender women in Kenya

- Some HIV PrEP studies lacked efficacy due to adherence

- Each quarterly visit participants reported on past 14 days
  - marked when she had sex and when she took doxyPEP

Stewart, J et al. O6.3 - Self-reported adherence to event-driven doxycycline postexposure prophylaxis for sexually transmitted infection prevention among cisgender women
**DOXYPEP ADHERENCE IN CISGENDER WOMEN**

Self-Reported Adherence
- 77% (579/755) coverage of last sexual exposure
- In 72.8% of the quarterly surveys, >80% of sexual acts were covered
- 64% (134/211) participants reported full coverage in at least 80% of weeks
- 78% of weekly SMS reported full coverage

Hair Drug Testing (subset of 50 participants assigned to doxyPEP)
- 56.0% (28/50) of participants had doxycycline detected at least once
- 29.0% (58/200) of all quarterly visits had doxycycline detected

Doxycycline hair testing indicated that 44% **assigned to doxycycline PEP may not have taken any doxycycline**.

Stewart, J et al. O6.3 - Self-reported adherence to event-driven doxycycline postexposure prophylaxis for sexually transmitted infection prevention among cisgender women
DEJÀ-VU ALL OVER AGAIN?

Striking similarities between HIV PrEP and DoxyPEP

- Novel biomedical intervention w/significant impact in priority populations
  - Concerns of anti-microbial resistance/misuse
  - Equity concerns regarding utilization and uptake
  - Data in cisgender women are lacking

So what’s different now?

- Signals of higher interest in Black and Hispanic/Latinx men

WE SHOULD KNOW AND DO BETTER
QUESTIONS?

@AnuHazraMD    a hazra2@medicine.bsd.uchicago.edu