



# Countering threats to AIDS research at NIH: What happened and what you can do

Feb. 2, 2016

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#### Overview

Kenyon Farrow, US and Global Policy Director, Treatment Action Group



#### **About Treatment Action Group**

Treatment Action Group is an independent research and policy think tank focused on activism to accelerate research, treatment, access, and community information to prevent, treat, and cure HIV and its most common coinfections, hepatitis C virus (HCV) and tuberculosis (TB).

www.treatmentactiongroup.org





## Today's Agenda

- Overview
  - > Kenyon Farrow, US and Global Policy Director, Treatment Action Group
- History and Outlook of the Office of AIDS Research
  - > Mark Harrington, Executive Director, Treatment Action Group
- NIH/NIAID HIV research: So much to get excited about
  - > Carl Dieffenbach, Ph.D, Director of the Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases (NIAID)
- SOCIAL-BEHAVIORAL RESEARCH and HIV: INTERVENING for the VULNERABLE
  - Wendy Davis, Ed.D, Senior Manager and Senior Associate at Center for AIDS Research, Prevention Core, Johns Hopkins University Bloomberg School of Public Health
- Building and enhancing a coordinated research & practice community
  - ➤ Jose Bauermiester, M.P.H., Ph.D, Director of the Center for Sexuality and Health Disparities (SexLab), *University of Michigan School of Public Health*
- A&Q •



### History and Outlook of the Office of AIDS Research

Mark Harrington, Executive Director,

Treatment Action Group





# NIH/NIAID HIV research: So much to get excited about

**Carl Dieffenbach, Ph.D**, Director of the Division of AIDS (DAIDS), *National Institute of Allergy and Infectious Diseases (NIAID)* 



#### **Outline of Presentation**

- NIH priorities
- HIV prevention research
- NIH therapeutics research
- Cure research
- Co-morbidities
- Future vision

#### THE NIH DIRECTOR

#### Statement on NIH Efforts to Focus Research to End the AIDS Pandemic

**August 12, 2015** 

#### **High-priority areas of HIV/AIDS research are those that:**

- Reduce incidence of HIV/AIDS, through the development of better PrEP and safe and effective vaccines
- Develop the next generation of HIV therapies with improved safety and ease of use
- Discover and develop a cure for HIV/AIDS
- Improve prevention and treatment of HIV-associated co-morbidities and co-infections
- Foster cross-cutting areas of basic research, health disparities research, and training



#### **HIV Prevention**

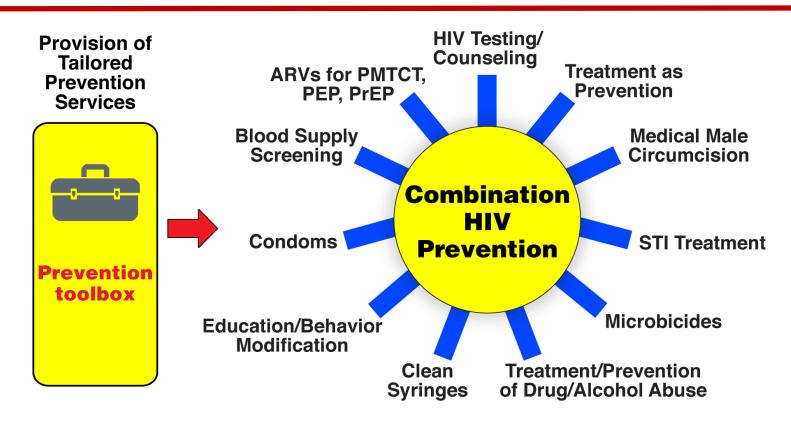
- Vaccines
- Improving PrEP

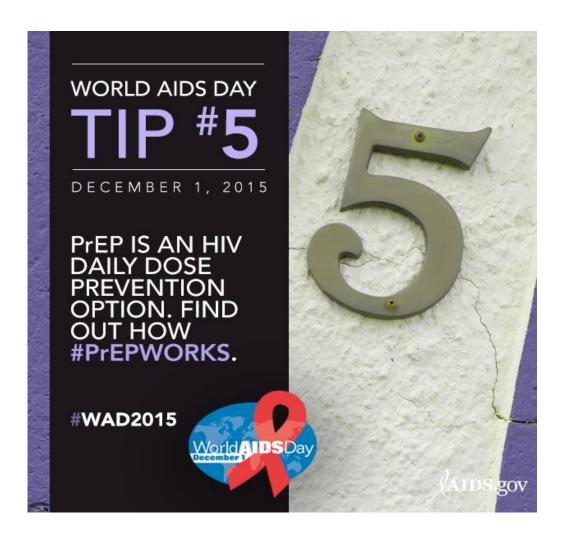
# Alternative Strategies and Parallel Tracks to HIV Vaccine Development

RV144 approach

Structure-based vaccine design approach (bNAbs)

# **Tailored Prevention Using HIV Prevention Toolkit**

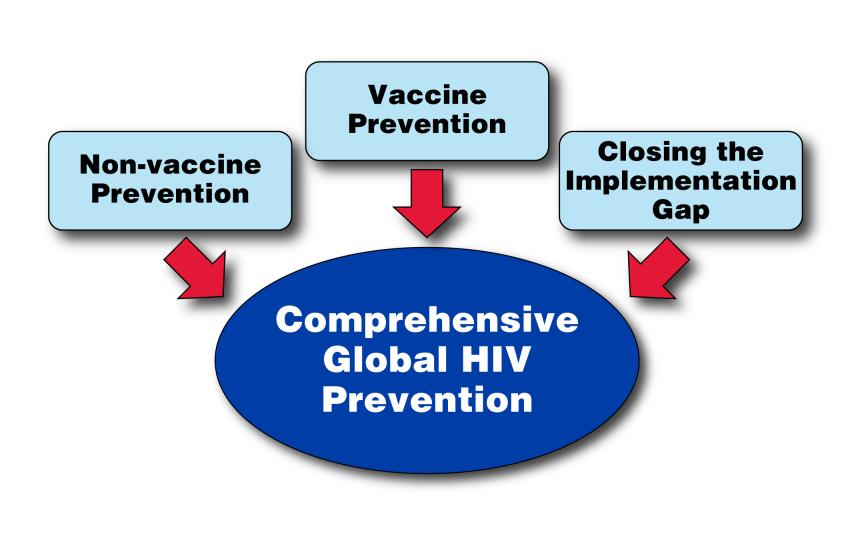




#### **Novel Drugs and Formulations**

- Sustained release/longacting formulations
  - Develop a pipeline of formulations for prevention and therapeutic indications
  - Improve access and adherence to therapy
  - Address needs of particular populations
- Evaluation of two drug combinations
- Clinical development of broad neutralizing antibodies

- Types of formulations
  - Injectable/implantable
    - Every other month to three times a year
  - Oral
    - Pills once a week



# Treating HIV-Infected Individuals: A "Trifecta" of Pivotal ART Studies

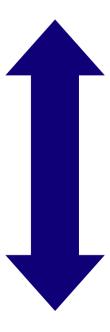
SMART Episodic ART inferior to continuous ART

HPTN 052 Early ART reduces HIV transmission to uninfected sexual partner by 96%

■ START Early ART reduces serious illness/death by 57%

# Treatment Treatment versus is Prevention Prevention

#### **Biomedical Interventions**



**Behavior and Adherence** 

### Cure

nature vol. 16 No. 6 immunology

# HIV Reservoirs as Obstacles and Opportunities for an HIV Cure

T-W Chun, S Moir and AS Fauci

"A better understanding of the pathophysiologic nature of HIV reservoirs and the impact of various interventions on their persistence is essential for the development of successful therapeutic strategies against HIV or the long-term control of infection.."

# Towards an HIV Cure: Addressing the HIV Reservoir

**Eradicate the reservoir** 

Control viral rebound – Sustained virologic remission

#### **An HIV Cure**

- Simple tertiary care not needed
- Safe not worse than current treatment
- Scalable relevant to millions of people

#### **Co-morbidities**

# Randomized Trial to Prevent Vascular Events in HIV



Randomized Trial to Prevent Vascular Events in HIV





#### **TB** and **HIV**

- Facilitate development of new drugs and regimens
- Shorten therapy
- Explore novel treatment strategies
- Improve diagnosis of TB and TB drug resistance
- Develop TB vaccines
- Treat latent TB infection



#### **Optimistic, Long-Range Vision**

- The therapeutic armamentarium will continue to improve with the development of formulations requiring only 4-12 doses per year
- PrEP will also evolve to 4-12 doses a year
- Cure research is an expanding research area, defined by the quality of the concepts coming forward
- Roles of broadly neutralizing antibodies in prevention, cure and therapy will be evaluated
- Additional prevention tools will also be developed
- These tools will help control the HIV pandemic



# SOCIAL-BEHAVIORAL RESEARCH and HIV: INTERVENING for the VULNERABLE

Wendy Davis, Ed.D, Senior Manager and Senior Associate at *Center for AIDS Research*, Prevention Core, Johns Hopkins University Bloomberg School of Public Health



### Points for today's presentation

- CFAR defined
- Social-behavioral research defined
- National priorities
- A research/activism agenda
- The added value of implementation science



#### Center for AIDS Research (CFAR)

- NIH funded
- 20 centers, all connected to academic institutions
- "emphasize interdisciplinary collaboration ...between basic and clinical investigators as well as behavioral scientists to support translational research"
- Cores (social/behavioral, clinical, laboratory, etc.)
- Community participation



### Social-behavioral research exemplars

- Formative research (qualitative interviews; mapping; assessing needs and services)
- Community mobilization/empowerment (education and employment; stigma; social support)
- Networks and social norms
   (social media and communication; social and sexual networks)
- Structural/multi-level (social determinants; institutions; venues)
- Training (health care professionals; capacity building)



#### **National Priorities**

# NIH HIV/AIDS Research Priorities and Guidelines for Determining AIDS Funding

Notice Number: NOT-OD-15-137

**Key Dates** 

Release Date: August 12, 2015

# **NATIONAL HIV/AIDS STRATEGY** for the **UNITED STATES**:

**UPDATED TO 2020** 







#### "High Priority AIDS Research: SBR" per Auerbach

#### High Priority research topics for support using AIDS-designated funds

- •Reducing incidence of HIV/AIDS including: developing and testing promising vaccines, developing and testing microbicide and pre-exposure prophylaxis candidates and methods of delivery, especially those that mitigate adherence issues; and developing, testing, and implementing strategies to improve HIV testing and entry into prevention services.
- •Next generation of HIV therapies with better safety and ease of use including: developing and testing HIV treatments that are less toxic, longer acting, have fewer side effects and complications, and easier to take and adhere to than current regimens. Additionally, implementation research to ensure initiation of treatment as soon as diagnosis has been made, retention and engagement in these services, and achievement and maintenance of optimal prevention and treatment responses.
- •HIV-associated comorbidities, coinfections, and complications including: addressing the impact of HIV-associated comorbidities, including tuberculosis, malignancies, cardiovascular, neurological, and metabolic complications, and premature aging associated with long-term HIV disease and antiretroviral therapy.

#### "High Priority AIDS Research: SBR" per Auerbach

- Cross cutting areas: Basic research, health disparities, and training including:
  - Research to reduce health disparities in the incidence of new HIV infections or in treatment outcomes of those living with HIV/AIDS.
  - Research training of the workforce required to conduct High Priority HIV/AIDS or HIV/AIDSrelated research.



## NATIONAL HIV/AIDS STRATEGY per Brooks

# RIGHT PEOPLE

(gay, bisexual, MSM; black women and men; Latino men and women; PWID; youth 13-24)

# RIGHT PLACES

(Metropolitan areas; Southern United States)

# RIGHT PRACTICES

(HIV testing and linkage to care; support for PLHIV; viral suppression; PrEP)



### "Social and Behavioral" per Brooks

### Supporting Behavioral Health

- Preventing HIV infections: Step 1B calls for effective behavioral interventions that facilitate people to remain engaged in HIV care, on PrEP, and other clinical models that improve the care continuum
- Improving Care: Step 2B calls on increasing and improving health workforce, including supporting screening and referral for substance use and mental health services for people living with HIV
- Reducing Disparities: Step 3B calls for adopting structural interventions to improve co-occurring conditions using a biopsychosocial approach to address intersecting issues, like intimate partner violence

### Addressing Social Determinants of Health

- Improving Care: Step 2C calls for supportive patient-centered comprehensive care, including co-occurring conditions and challenges meeting basic needs such as housing, nutrition, childcare, social support, etc.
- Reducing Disparities: Steps 3A and 3B call for scaling up effective, evidence-based programs that address social determinants, especially among gay and bisexual men, Black women, and people living in Southern U.S.
- Public and private partners needed for effective scale up

## A social-behavioral research agenda

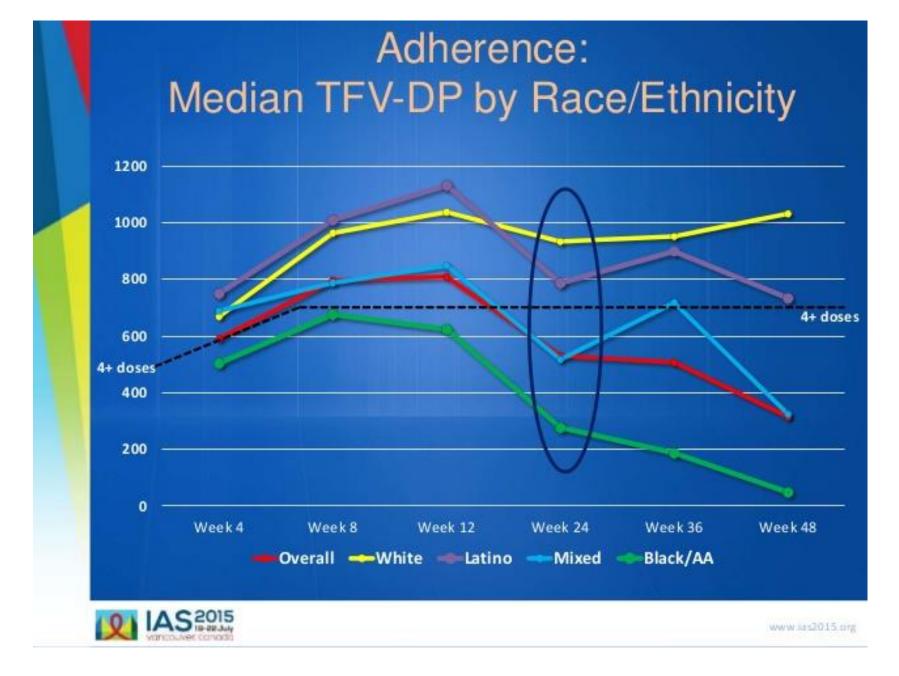
- Access to prevention services
- Improving adherence and engagement in care
- Addressing the impact of comorbidities, co-infections, and complications
- Reducing health disparities in incidence and treatment outcomes



### A research and activism agenda

- Access to prevention services
   Formative, structural, community mobilization, training
- Improving adherence and engagement in care Formative, structural, community mobilization, networks and social norms, training
- Addressing the impact of co-morbidities, coinfections, and complications
   Formative, structural, community mobilization, training
- Reducing health disparities in incidence and treatment outcomes
  - Formative, structural, community mobilization, networks and social norms, training





ATN 110:An HIV PrEP Demonstration Project and Safety Study for YMSM in the US

# The added value of Implementation Science

- Featured in NIH priorities, National Strategy
- Evidence based approaches for implementing evidence based interventions- science of the how
- Shorten bench to bedside
- Learn from other disciplines; mental health, primary care, nutrition, child welfare



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- Judith Auerbach, Professor, UCSF and Science and Policy consultant
- ATN 110: Sybil Hosek, Cook County Health and Hospital Systems



# Building and enhancing a coordinated research & practice community

Jose Bauermiester, M.P.H., Ph.D, Director of the Center for Sexuality and Health Disparities (SexLab), University of Michigan School of Public Health





### Traditional vs. CPR

TRADITIONAL CPR

Epid, Demographic Analysis Social analysis

Focus on weaknesses Focus on strengths

Goal is health outcome Goal is health & Community competence

Asks how can we motivate people Asks what are people's motives



# Challenges of Doing CPR

- Constraints and costs of doing CPR across different organizational cultures.
- Learning how to conduct research and work together in different ways.
- Challenge of ensuring community partners participate equitably in day-to-day research and governance decisions.



# Advantages of using community participatory approaches

#### Focuses on Issue of Concern to Community

- Increasing HIV/STI Prevention and Care Efforts
- Addressing structural inequities and disparities
- Using data to advocate for policy change

#### Improves the Research

- Adequate research formulation
- Data collection
- Recruitment and retention
- Dissemination

# A Timeline of CPR Projects

2009	
2010	Young Men's Study A University of Michigan & HIV/AIDS Resource Center (HARC) study
2011	uhip united for hiv integration and policy
2012	
2013	CONNECTED
2014	Welness Services AL GAMEA
2015	SPANDANCE MULTINE PROMOTOR  Promoting-placation by Fermitian the Committy  LINK Engage Thrive.
2016-	FIERCE VOETROIT.  SQUAB



### How has data been used?

- Build agency capacity to participate actively in research.
- Provide intersectional insight into the analyses.
- Share research findings with CBO staff, Board of Directors and client groups.
- Present research findings to other relevant groups, such as CABs, planning councils, and funders.
- Target specific areas of HIV education in outreach and testing efforts.
- Inform strategies to optimize service design, delivery and sustainability.



### Service Recommendations

#### Consolidation and interagency collaboration

Funding mechanisms to facilitate agency and programmatic sustainability

#### Increase in certain types of services:

- Peer-led programs
- LGBT and youth specific clinical services
- Centralized intake

#### Provider training

- Providers
- Curriculum at schools of medicine, nursing, etc.

Create a guide to open and accepting services and providers



### AIDS Partnership Michigan and HIV/AIDS Resource Center Announce Merger

Uniting to serve southeast Michigan through innovation, shared resources and expertise.











DETROIT and YPSILANTI, Mich., March 25, 2015 /PRNewswire-USNewswire/ -- In order to strengthen the response to HIV in Southeast Michigan, AIDS Partnership Michigan (APM) and HIV/AIDS Resource Center (HARC) have merged their organizations. Building on a history of collaboration and excellence, the merger of APM and HARC will ensure the sustainability of comprehensive HIV/AIDS prevention and care in their now 10-county area where 63% of people living with HIV reside.

#### A Strong History and Position for the Future

The organizations have worked together for more than 14 years through the HIV/AIDS Alliance of Michigan, AIDS Walk Michigan, the highly recognized StatusSexy community mobilization campaign, and through involvement as community partners of the University of Michigan Center for Sexuality and Health Disparities. Together, they provide HIV prevention and direct care services to almost 7,000 residents of Southeast Michigan.

"We are stronger together. Our Boards have worked for over a year to explore this opportunity and implement the merger. Our services have continued without interruption and are enhanced by the expertise and unique programming of each organization," said APM CEO William VanHemert who will serve as President and Chief Executive Officer of the merged organization.

"Our goal is to enhance our capacity in key areas, including programming, access to funding, community-based research, and delivery of HIV-related health care services. The constant is our commitment to compassionate HIV prevention and care services," said HARC President/CEO Jimena Loveluck. Loveluck will focus on expanding services and strengthening innovative approaches to address HIV as the Vice President of Community Research and Innovation.



### Translational Science

Integration of data into new and existing programs

Policy and Media Advocacy

Youth Internships

**Community Meetings** 

Dissemination of Policy Briefs

**Policy Dissemination** 





DETROIT — Researcher at the University of Michigan School of Public Health have released results of a study finding that young men who have experienced anti-gay discrimination in the workplace are more likely to have overall poorer health than those who had not experienced such discrimination, the <u>Gay, Lesbian, Bisexual & Transgender</u> News Network reports.



### Dissemination







### Fact Sheets



#### Mental Health

Sexual minorities, such as gay and bisexual men, are vulnerable to mental health issues because of homophobia, discrimination, and isolation. Psychological distress can lead to behavioral health issues and harmful coping mechanisms like substance use and sexual risk-taking. Stigma around accessing mental health remains a barrier for people seeking care. However, social support and access to sexuality- and gender-affirming mental health services can improve the mental health of sexual minorities.

The United for HIV/AIDS Integration in Policy (UHIP) study aimed to understand the structural factors shaping HIV/AIDS prevention and care in the Detroit Metro Area (DMA). The data below – Collectd and analyzed in 2012 from 50 stakeholder interviews and 429 online surveys with young gay and bisexual men and trans youth (ages 18-29) – highlight the issue of mental health in the lives of gay and trans youth in the DMA.

#### ON RISK

24% reported depression and 17% reported anxiety diagnoses by a medical provider

#### ON RESILIENCE



About 60% of participants said,

"I am able to adapt to change."

"I can deal with whatever comes."

"I think of myself as a strong person."

1 in 5 participants said, "In the past week I felt..."

fearful depressed tense lonely



Over half of participants said, "In the past month, I felt nervous and stressed."



1 in 4 participants said,
"In the past month, I have had so many
problems that I could not deal with
them."

About 1 in 3 participants said,

"I think of myself as a strong person nearly all of the time."

About 3 out of 4 participants said,

"I am a person of worth and I have a number of good qualities."

The UHP academic community partnership included representatives from AIDS Partnership Michigan, the HIV/AIDS Resource Center, Detroit Latinities, Mutt Ellis Center, and the University of Michigan's Center for Sexuality & Health Disparities. This work was supported by the Ford Foundation and MAC AIDS Fund (Pir Bausemeister). The content is solely the responsibility of the authors and does not represent the filling livew of the funding agencies.

#### STAKEHOLDER PERSPECTIVES

"We focus so much on testing and care [for HIV/AIDS], and we're really not getting to the real, true root. And I firmly believe it speaks to mental health. 'Cause if I value myself, I don't want to endanger myself. I should believe in myself. I want to see the future. I believe in the future. All that's mental health."

Stakeholders shared their perspectives on mental health concerns among young gay and bisexual men and trans youth. Stakeholders include CBOs, local health departments, medical providers, LGBTQ and HIV specific organizations, and other community partners.

"What do you do when you're dealing with coming out, you just came out, you just lost your family, all this stuff going around in your mind and nobody to talk to...5o what do you do? You find allies in other places. I drink, I smoke, I do whatever I can to get my mind off of it."

"The MSM (men who have sex with men) of color community [...] particularly the Latino and Black community [...] it's not socially acceptable to see mental health care. You're supposed to go to your religion person or just to a family member. Getting folks to place where they understand that mental health, just like physical health, is something you need to take care of on a regular basis, is a huge obstacle and huge qoal."

#### POLICY RECOMMENDATIONS

On site mental health specialists at community organizations

> Implementing LGBT specific group based therapy

Patient navigators to help guide LGBT youth through the mental health care system

Field based mental health services like home based therapies.

#### ADDITIONAL RESOURCES

Affordable Care Act grants for support mental and behavioral health education and training for community organizations:

GLBTQI Mental Health: Recommendations for Policies and Services click here for PDF

Enhance current mental health programs with grants from the Substance Abuse and Mental Health Services Administration beta.samhsa.gov/grants

Parents Families, Friends, and Allies United with LGBT People

LGBT peer support groups for people with mental health issues like Rainbow Heights rainbowheights.org

For more information about the UHIP Project, go to sexlab.sph.umich.edu/uhip



### Lessons Learned

#### **CHALLENGES**

- 1. Learning research lingo and practice in order to be an active partner.
- IRB process can impact project timelines.
- 3. Understanding the important role of CBOs in participant recruitment and strategies.
- 4. Involving other staff in translating research results into practice.
- 5. Competing demands/rewards within academia and agency.

#### **BENEFITS**

- Put research findings into practice through service provider involvement and academic commitment to bring about positive change.
- Practice and service informed research to pose relevant and locally applicable research questions.
- 3. Built research capacity within CBOs.
- 4. Opportunities for new and stronger CBO partnerships.
- 5. Better research, science, and practice.



# Community Development

 Strengthened community partners' competitiveness in their grantseeking efforts and increased their capacity to do community-driven work.

- Shared opportunities for professional growth and national exposure.
- New relationships with other academic and community organizations in the area.



# Resource Sharing & Leveraging

- 1. Meet with agencies to offer summary of data and discussed how data could be helpful.
- 2. In-kind access/interpretation of data if desired.
- 3. Avoiding duplication of efforts.
- 4. Connect to Protect (C2P)
- 5. Michigan HIV/AIDS Research Corridor



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#### **Questions?**



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