

RESEARCH INTO COMMUNITY PERSPECTIVES ON HIV CURE SCIENCE

**PRE-CROI 2017 COMMUNITY CURE WORKSHOP
FEBRUARY 12, 2017**

PROPOSED OUTLINE

- Panobinostat + alpha-interferon HIV cure study update: ***Lynda Dee***
- Overview of community-based research; U.S. survey results: ***Karine Dubé***
- Perceived risks/benefits of HIV cure research: ***Jeff Taylor/Laurie Sylla***
- MDC focus groups: ***Laurie Sylla***
- Upcoming community based research: ***David Evans***
- Discussion and Q&A

PANOBINOSTAT + INTERFERON CURE STUDY UPDATE

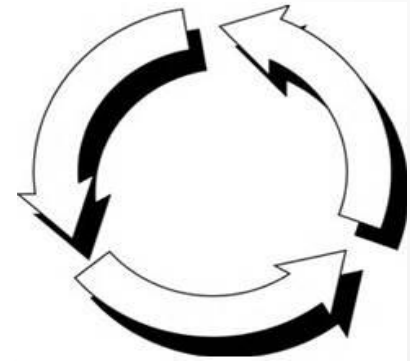
Lynda Dee

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PANOBINOSTAT + INTERFERON UPDATE

COMPETING STAKEHOLDER ROLES IN RISKY CURE
RESEARCH HEALTHY VOLUNTEERS WITH MANY SAFE &
EFFECTIVE OPTIONS:

FOOD AND DRUG ADMINISTRATION
CLINICAL RESEARCHERS & SPONSORS
COMMUNITY ADVOCATES



PANOBINOSTAT + INTERFERON UPDATE

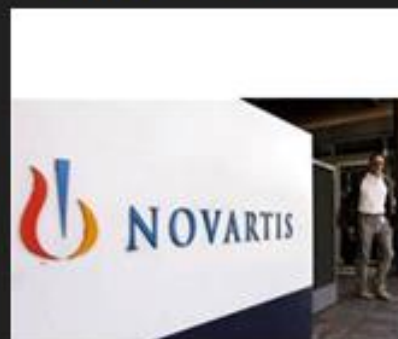
FDA
IND APPROVAL
SAFETY AND EFFICACY



RESEARCHERS
IND APPROVAL
NO DELAYS



NOVARTIS
PANOBINOSTAT
FULL FDA APPROVAL



PANOBINOSTAT + INTERFERON UPDATE

ROLE OF THE COMMUNITY

ETHICAL RESEARCH

CONDUCTED EXPEDITIOUSLY



PANOBINOSTAT + INTERFERON UPDATE

- **PANOBINOSTAT (FARYDAK): HIGHLY TOXIC/RISK OF HEART ATTACKS**
- **ONLY APPROVED AS SECOND LINE THERAPY IN CANCER PATIENTS**
- **PANOBINOSTAT & INTERFERON**
- **RISK OF HEMORRAGING**
- **ETHICAL IN HEALTHY PATIENTS?**
- **PROCEED EXPEDITIOUSLY?**

PANOBINOSTAT + INTERFERON UPDATE

- **COMPROMISE REACHED BY RESEACHERS AND THE FDA**
- **Stress echocardiograms to r/o clinically unsuspected cardio issues**
 - **Standard stress test**
- **Single, one week course of panobinostat +/-IFN**
 - **Three of four courses spaced four weeks apart**

PANOBINOSTAT + INTERFERON UPDATE

- **COMPROMISE REACHED BY RESEACHERS AND THE FDA**
 - **20 mg dose, the approved dose**
 - Cohort 1: n=8, 5 mg (6 with INF and 2 without INF)
 - Cohort 2: n=8, 10 mg (6 with INF and 2 without INF)
 - Cohort 3: n=15, 15 mg (10 with INF and 5 without INF)
 - **20 mg after the FDA reviews data from all three cohorts**
- **PROTOCOL UPDATE**
 - **No safety issues to date: Proceeding to Cohort 2**

PANOBINOSTAT + INTERFERON UPDATE

- **THANKS**

- **FDA**

- **DAN KURITZKES**

- **RICHARD JEFFERYS**

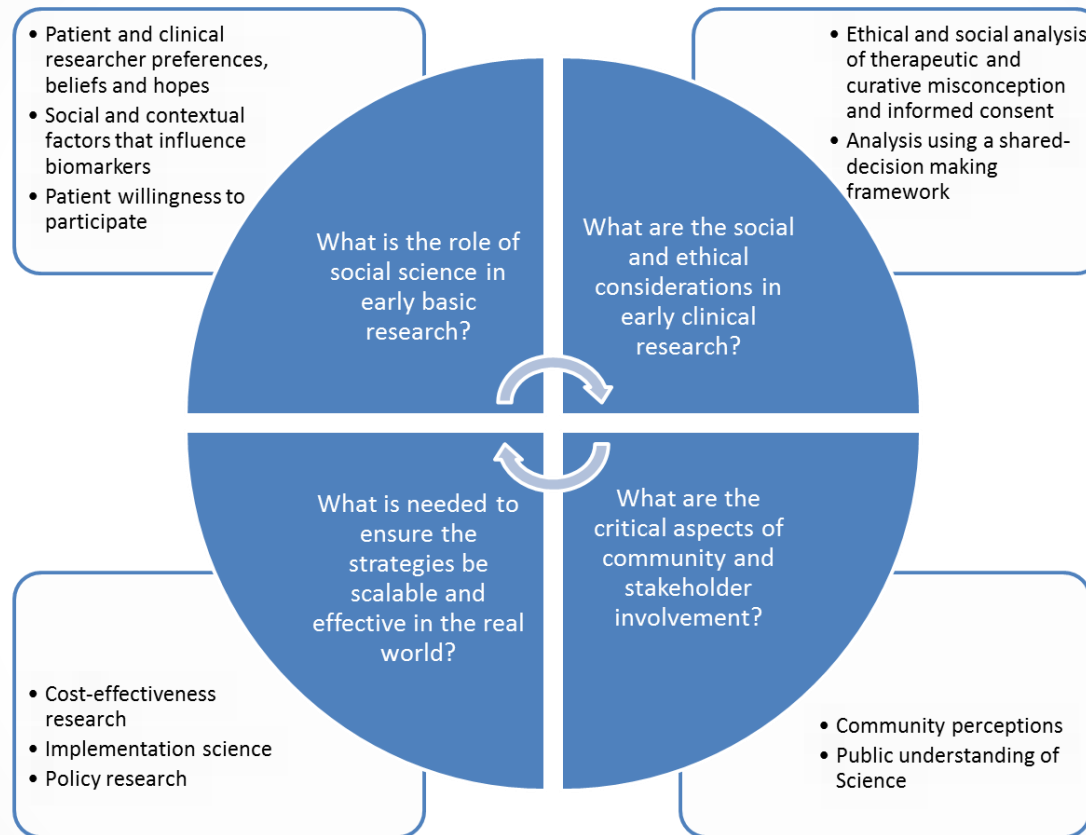
RESEARCH INTO COMMUNITY PERSPECTIVES ON HIV CURE SCIENCE



Karine Dubé

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INTEGRATING THE BIOMEDICAL AND SOCIAL SCIENCES AGENDA AROUND HIV CURE



Grossman CI *et al.* Towards a Multi-Disciplinary HIV Cure Research. Integrating Social Science with Biomedical Research *Trends in Microbiology* 2016

Willingness to participate and take risks in HIV cure research: survey results from 400 people living with HIV in the US

Karine Dubé^{1*}, David Evans^{2,3}, Laurie Sylla⁴, Jeff Taylor⁵, Bryan J Weiner^{1,6}, Asheley Skinner^{1,7}, Harsha Thirumurthy¹, Joseph D Tucker^{8,9}, Stuart Rennie¹⁰ and Sandra B Greene¹

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QUALITATIVE DATA ANALYSIS

- **KEY INFORMANT INTERVIEWS (N = 36):**

- ❖ 12 persons living with HIV (PLWHIV) (≥ 18 years old; 7 males, 5 females; from survey subset)
- ❖ 11 clinician-researchers (8 academic centers in the United States; various HIV cure research modalities)
- ❖ 13 policy-makers/bioethicists/regulators of HIV cure research (from different agencies)

- **FOCUS GROUPS (N = 11):**

- ❖ 4 in Seattle area (**Laurie Sylla**): women, LT survivors, Latino gay men, young adults
- ❖ 2 in Los Angeles (**David Evans**): women and mixed
- ❖ 2 in San Diego/Palm Springs (**Jeff Taylor**): women and older MSM
- ❖ 3 in North Carolina (**Karine Dubé**): 2 mixed (mostly African-Americans); 1 couple

RESEARCH ARTICLE

'Well, It's the Risk of the Unknown... Right?': A Qualitative Study of Perceived Risks and Benefits of HIV Cure Research in the United States

Karine Dubé^{1*}, Jeff Taylor², Laurie Sylla³, David Evans^{4,5}, Lynda Dee⁶, Alasdair Burton⁷, Loreen Willenberg⁸, Stuart Rennie⁹, Asheley Skinner^{1,10}, Joseph D. Tucker^{11,12}, Bryan J. Weiner^{1,13}, Sandra B. Greene¹

1 University of North Carolina Gillings School of Global Public Health, Chapel Hill, NC, United States of America, **2** Collaboratory of AIDS Researchers for Eradication (CARE) Community Advisory Board (CAB), Palm Springs, CA, United States of America, **3** defeatHIV CAB, Seattle, WA, United States of America, **4** Delaney AIDS Research Enterprise (DARE) CAB, Los Angeles, CA, United States of America, **5** Project Inform, Los Angeles, CA, United States of America, **6** AIDS Action Baltimore, Baltimore, MD, United States of America, **7** Multi-Decadal, Multi-CAB Member, Glendale, CA, United States of America, **8** Zephyr Long-Term Non-Progressors (LTNP) Foundation, Inc., Sacramento, CA, United States of America, **9** Department of Social Medicine, UNC Bioethics Center, Chapel Hill, NC, United States of America, **10** Duke Clinical Research Institute (DCRI), Durham, NC, United States of America, **11** UNC Institute of Global Health and Infectious Diseases (IGHID), Chapel Hill, NC, United States of America, **12** UNC Project China, Guangzhou, China, **13** Department of Global Health, University of Washington, Seattle, WA, United States of America

MDC FOCUS GROUPS

Laurie Sylla

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MDC FOCUS GROUPS

MOST IMPORTANT PERCEIVED BENEFITS



- Helping find a cure (soc 4-14X)
- Feel good contributing to cure research (ind. 3-6X)
- Helping others with HIV in future (soc 4-5.5X)
- Free lab work (ind 3-5.5X)

FACTORS AFFECTING WILLINGNESS

FOCUS GROUP DATA



- Incentives
 - Compensation
 - Study procedures
 - Study risks
 - Childcare/transportation/food
 - Inclusion/exclusion criteria
 - Safety plan
 - Clear, informed consent
- **Research Team**
 - Trustworthy
 - Respected research institution
 - Respectful of participants
 - Culturally competent
 - Multi-lingual
 - Accessible 24 hours
 - Tend to participant mental health
 - See whole person
 - Trauma-informed
 - Non-stigmatizing

**FUTURE RESEARCH INTO COMMUNITY
PERSPECTIVES ON HIV CURE RESEARCH**
David Evans

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FUTURE SOCIAL SCIENCES RESEARCH

Table 4. Future potential social sciences questions to inform study participation in biomedical HIV cure-related research

Meanings of cure

- ❖ What are the various meanings of HIV cure research and how can we reconcile patient-participants, clinician-researchers and policy-makers/regulators' perspectives?
- ❖ What are the various meanings of 'success' in HIV cure research (including intermediate outcomes)?
- ❖ What do potential participants understand about HIV cure research and how does that affect their willingness to participate?

Role of altruism

- ❖ What role do altruism, expectations, optimism and hope play in HIV cure research participation?

Research with prospective study participants

- ❖ How do demographic characteristics (such as age, gender, socio-economic status, nationality) relate to HIV cure understanding, acceptability and willingness to participate?
- ❖ How do people understand the purpose and risks of HIV cure studies?
- ❖ How does people's perceptions and experiences of their own health impact their willingness to assume risk in HIV cure studies?
- ❖ Discrete choice experiments borrowing from economic, cognitive psychology and decision-making literature – what are common trends in HIV cure research decision making (e.g. anchoring, judgmental heuristics and defaulting to patterns)?
- ❖ How can we increase recruitment of women and under-represented groups?
- ❖ Would asking for long-term follow-up of study participants feel better?
- ❖ How can we begin to study therapeutic (or curative) intent?
- ❖ What motivations to join HIV cure studies are ethical?
- ❖ How does long-term survival with HIV affect willingness to participate?
- ❖ What factors affect willingness to participate in studies?

Research with actual study participants

- ❖ **Would collaboration from biomedical HIV cure scientists, either retrospectively or prospectively as part of actual HIV cure studies (e.g. nested social sciences research), be required? What does HIV cure research mean for quality of life outcomes (such as Short-Form-36 Health Survey)?**
- ❖ What factors predict retention (or serial participation) in HIV cure studies?

Research with study decliners (more difficult)

- ❖ What are some of the reasons that cause people living with HIV to decline participation in HIV cure research?

Research with clinician-researchers and policy-makers

- ❖ How do clinician-researchers and policymakers view risks in HIV cure research?

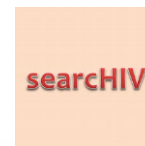
Research ethics questions

- ❖ What is an acceptable risk-benefit balance for potential HIV cure study participants?
- ❖ Are there groups who are more vulnerable than others in HIV cure research?
- ❖ How can HIV cure researchers best measure effective management of scientific uncertainty?

ACKNOWLEDGMENTS

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Jeff Taylor, CARE CAB
Laurie Sylla, defeatHIV CAB
Lynda Dee, AIDS Action Baltimore



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of NORTH CAROLINA
at CHAPEL HILL