



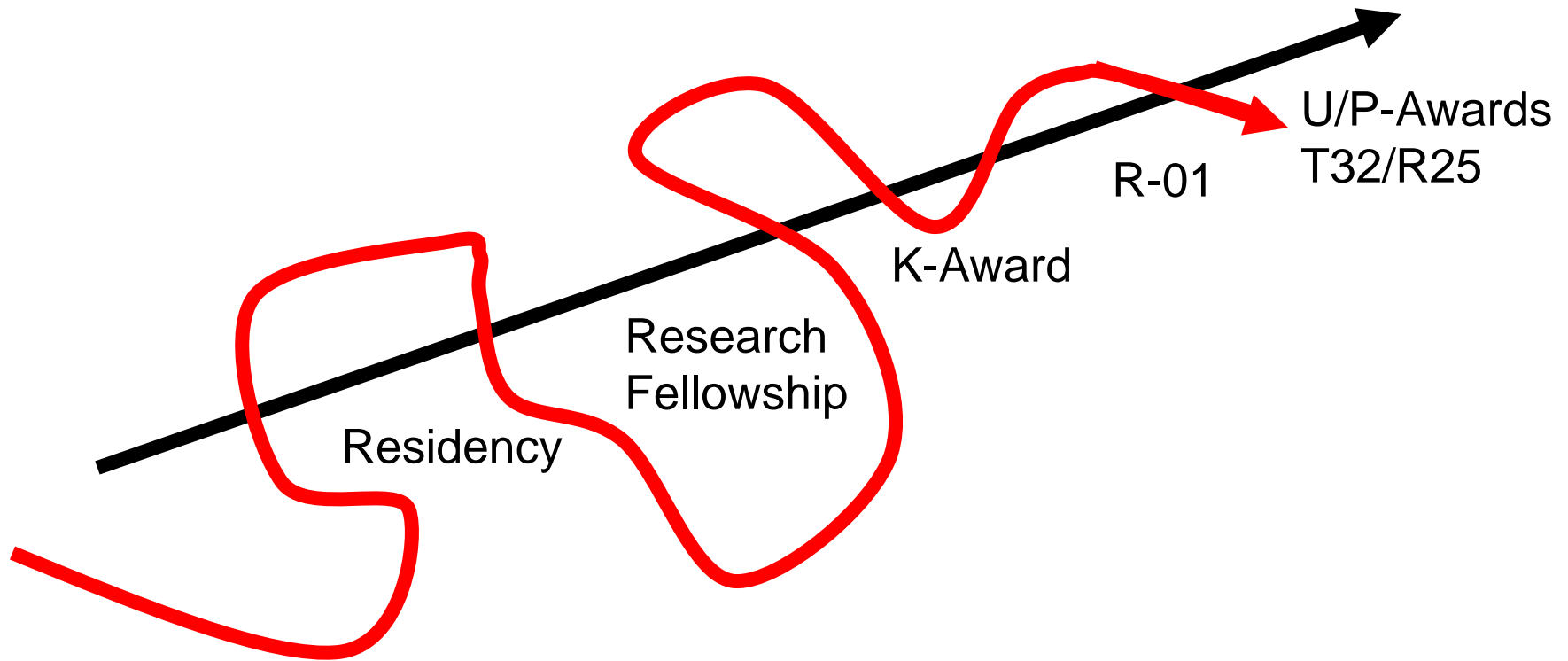
Care Integration and Cascade Research: Lessons Learned from the BRAVO Vietnam Trial

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RAMS Presentation December 16, 2019

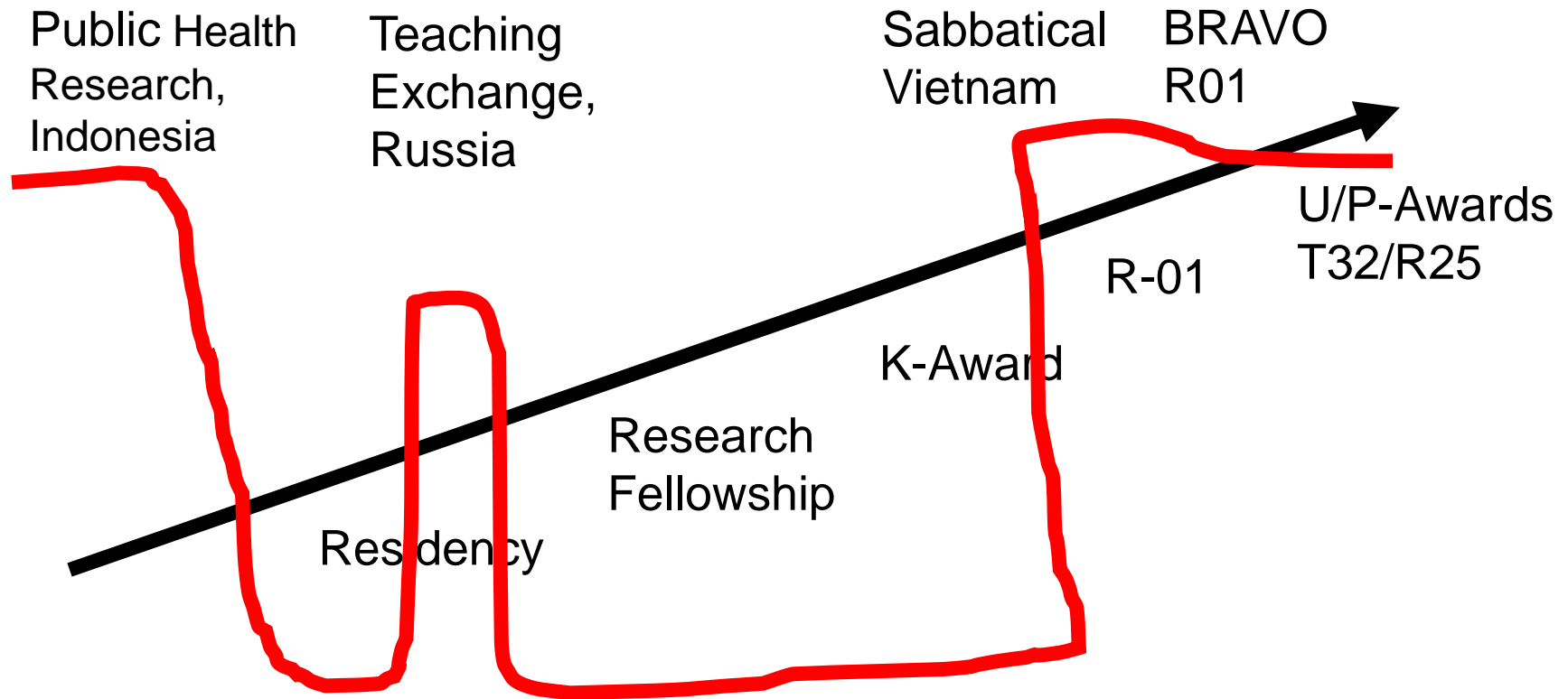
Disclosures

- Dr. Korthuis has no financial disclosures
- Funder: National Institutes of Health, National Institute on Drug Abuse (R01DA037441)
- Dr. Korthuis serves as principal investigator for NIH-funded trials that receive donated study medication from Indivior (Buprenorphine/naloxone) and Alkermes (extended-release naltrexone)

Clinician Researcher Trajectory



International Work – Finding a Time and Place



International Work

- How would you like to incorporate international work into your research career?
- What are the up-sides?
- What are the risks?

Considerations for International Research

- Is the setting aligned with your research career goals?
- Is there a potential pathway to funding?
- Relationships
 - Need strong in-country collaborator
 - Meet people at CPDD International Forum and other meetings to form collaborations
 - Is the timing right for your partner/family?
 - Do you have your institution's support?

Considerations for International Research

- Is the setting aligned with your research career goals?
- Is there a potential pathway to funding?
- Relationships
 - Need strong in-country collaborator
 - Who is working in that space?
 - Meet people at CPDD International Forum and other meetings to form collaborations
 - Is the timing right for your partner/family?
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Care Integration Research

- Most clinical trials of substance use disorder treatment have been conducted in specialty addiction treatment settings.
- Addiction Medicine providers are ideally suited for testing new treatments & models of care integration in diverse healthcare settings.
 - Primary Care
 - HIV Clinics
 - Jails
 - Hospitals/EDs
 - Skilled nursing facilities
 - Others?

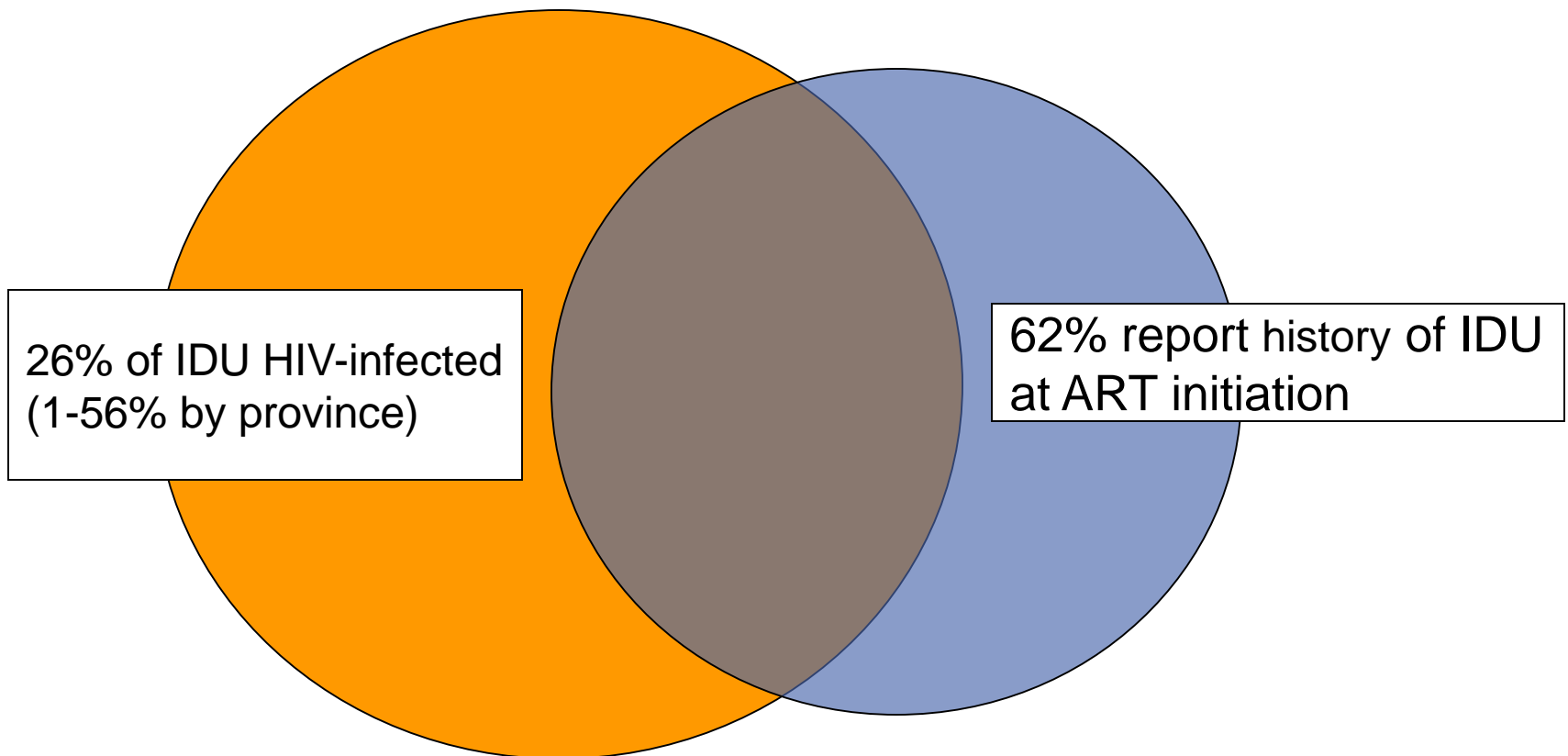
Needs Assessment:

- **Gathering evidence for your proposal**
- What type of preliminary data builds the best case for your grant application?
- How can what you're working on in the RAMS fellowship serve as preliminary data for a K or other award?
- What policy or public health gap can your ideas address?

Vietnam IDU-HIV Twin Epidemics

IDU Population
(n=336,000)

HIV-infected Population
(n=248,245)



Patient Survey

Attitudes toward treatment integration

- RA-administered surveys
- Convenience sample
 - 573 patients
 - 5 HIV clinics in Hanoi
- September-November, 2013



Patient Substance Use Discussions

	Overall	Hazardous Alcohol Use	Drug Use
Discussed drug use with HIV treatment staff in past year	21.1%	26.9%*	30.9%*
Discussed alcohol use with HIV treatment staff in past year	34.9%	61.8%*	46.4%*
Very comfortable discussing substance use with...			
Doctor?	68.9%	71.0%	69.4%
Nurse?	59.0%	57.0%	57.8%
Peer Educator?	62.0%	60.2%	62.5%

Patient Views of Integrating HIV and Addiction Care in Vietnam

	Overall	Alcohol	Drug
Agree care should be integrated	65.3%	68.3%	73.5%
Agree addiction care should be in HIV clinic	69.8%	69.9%	75.0%
Agree addiction care should be in separate clinics	26.4%	23.1%	33.8%
Agree addiction care should be by same provider	68.4%	67.2%	79.4%*
Agree addiction care should be by different providers	36.0%	37.6%	41.2%

p < .05

Needs Assessment

Conclusions

- Unhealthy alcohol and illicit drug use common in Vietnam HIV clinics
- Limited substance use discussions with HIV providers
- Majority of HIV-infected patients prefer to receive HIV and addiction care in same place from same doctor
 - Important minority prefer separate care

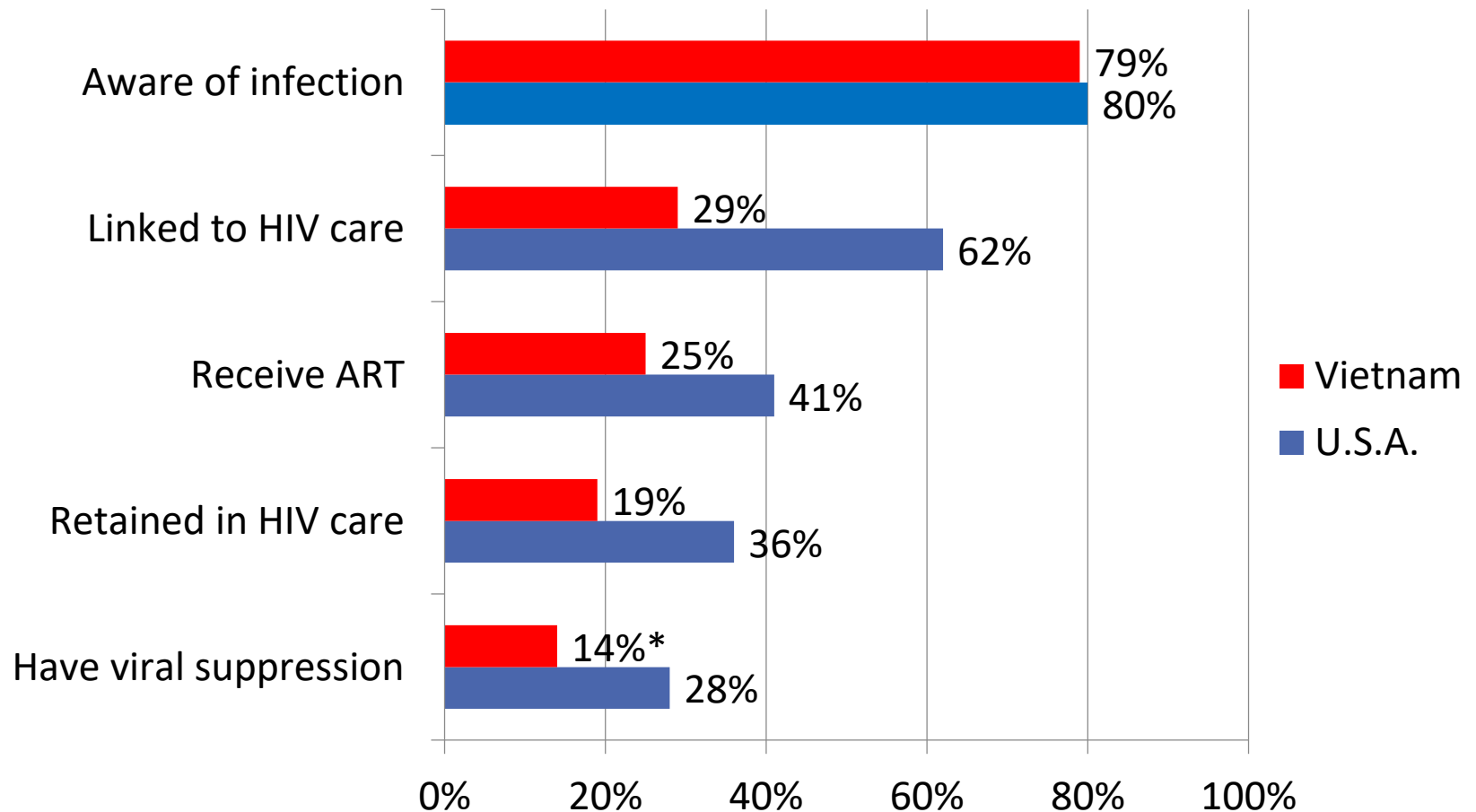
Rationale for HIV & Addiction Treatment Integration

- High prevalence of substance use in HIV clinics in many countries, but access is limited
- UNAIDS recommends buprenorphine or methadone treatment to help achieve 90-90-90 goals
 - 90% diagnosed
 - 90% on ART
 - 90% with HIV viral suppression

Care Cascade Research

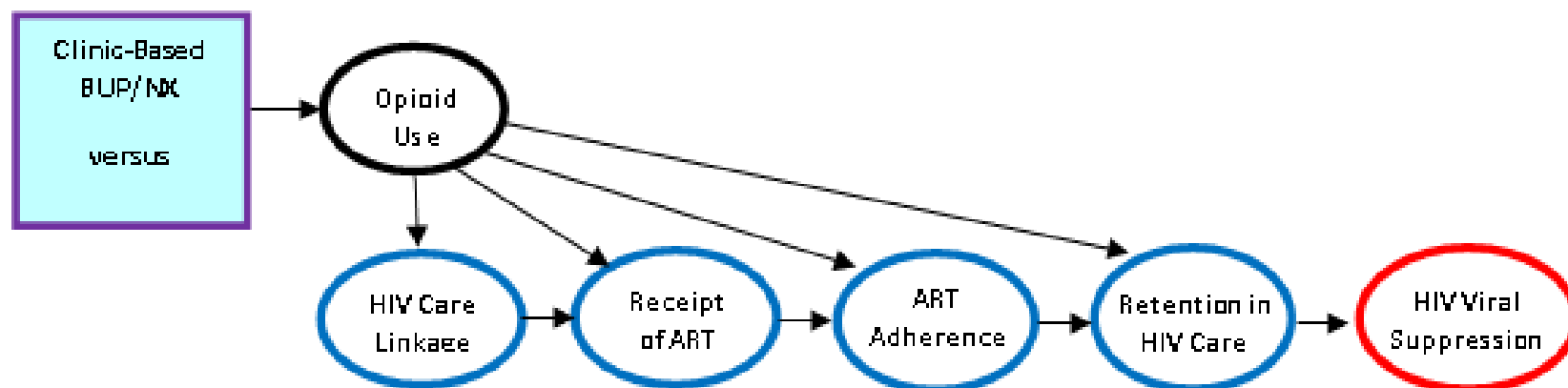
- Example of HIV in Vietnam (2013)

Percent of persons living with HIV who...



Closing Gaps in HIV Care Continuum

Conceptual Model



HIV Clinic-Based Buprenorphine

BHIVES

Observational study in 11 HIV clinics (n=386)

- At 12 months, integrated treatment:
 - Decreased heroin/opioid use¹
 - Increased ART uptake²
 - Improved quality of care³, quality of life⁴

Pilot RCT

Single site pilot RCT of buprenorphine vs. methadone (n=93)⁵

- At 12 months, integrated treatment:
 - Decreased heroin/opioid use
 - No change in ART or viral suppression

¹ Fiellin JAIDS 2011

² Altice JAIDS 2011

³ Korthuis JAIDS 2011

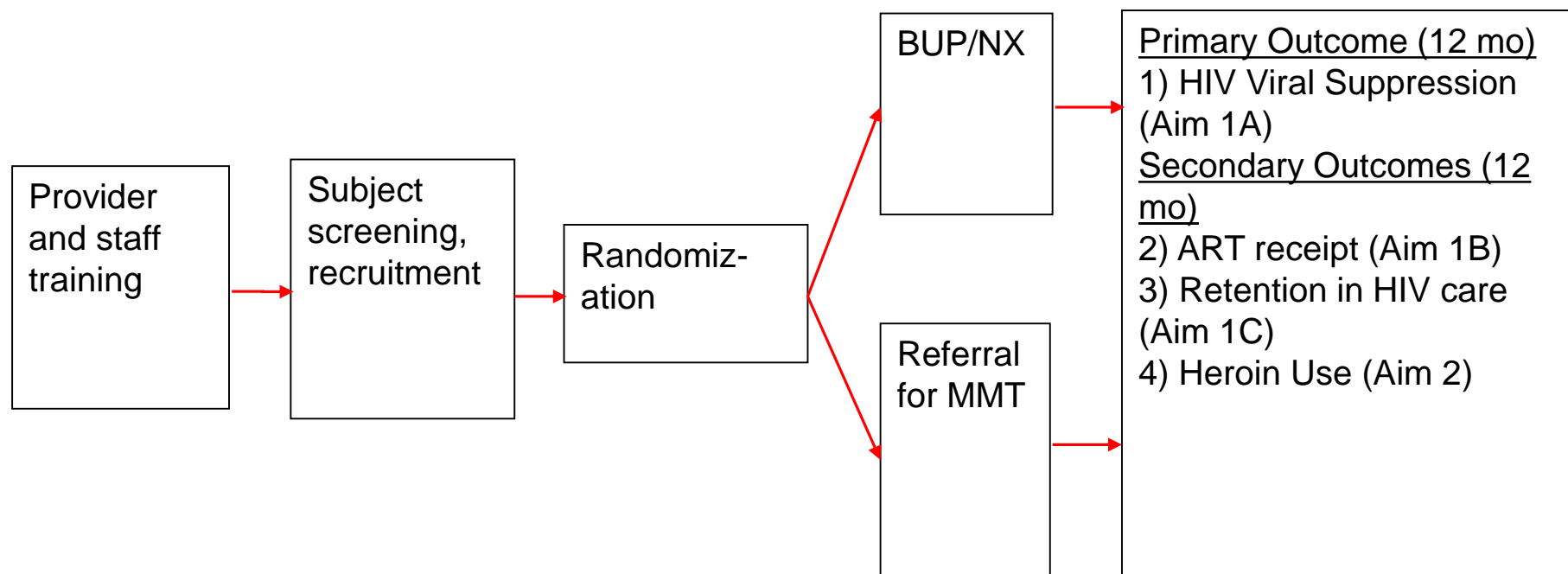
⁴ Korthuis JAIDS 2011

⁵ Lucas Ann Int Med 2011

Vietnam BRAVO Trial

Integrated Buprenorphine Care

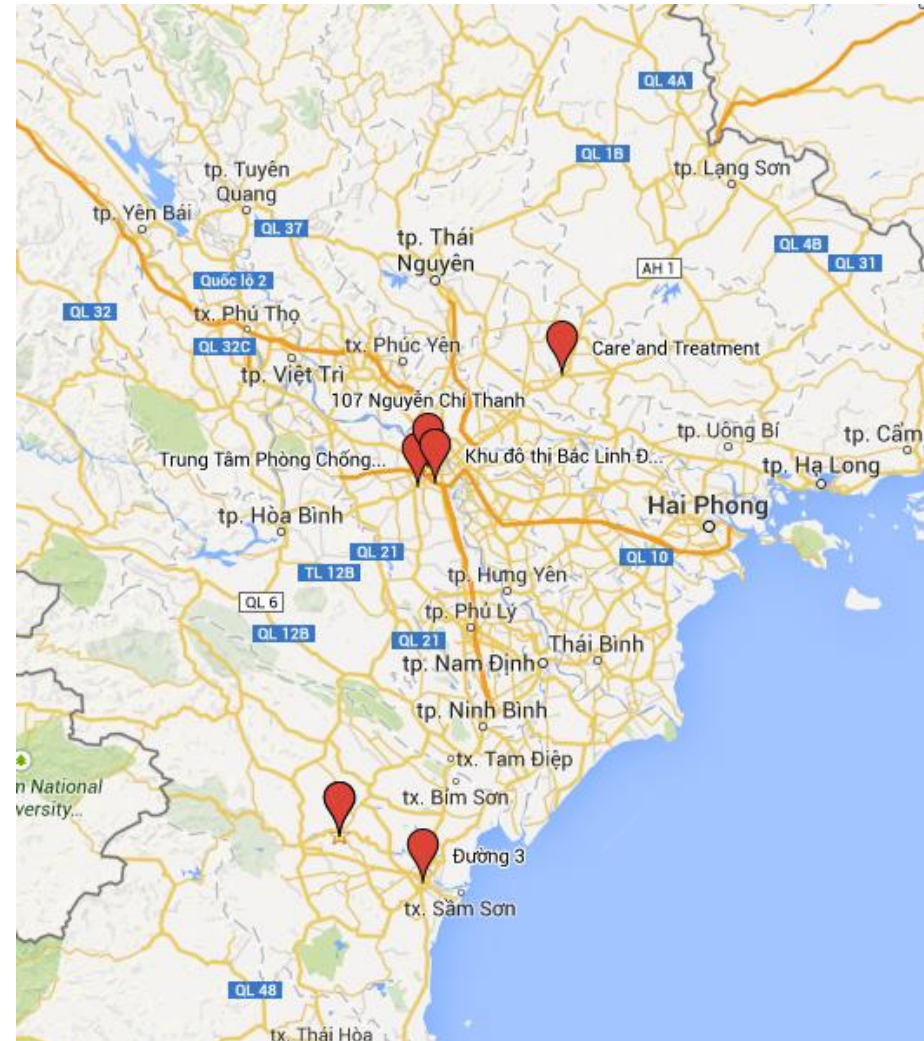
2014-2019



Preliminary Analysis: Intent to Treat at 6 months

Study Sites

- Ha Noi
 - Tu Liem OPC
 - Hoang Mai OPC
 - Dong Da District Health Center
 - Long Bien OPC
- Bac Giang
 - Bac Giang PAC
- Thanh Hoa
 - Thanh Hoa PAC



Intervention

Buprenorphine/naloxone

- Prescribed by HIV clinic doctor
- Directly observed therapy at clinic pharmacy
- 3 or 4 times per week dosing allowed after stabilization
- Medical management counseling from doctor
- HIV treatment

Methadone

- Referral to methadone clinic provider (on-site) for management
- Directly observed therapy
- Usual MMT care
- HIV treatment

Challenges in International Research

-Count of something going wrong

- Study Timeline Wildcards
 - Need for in-country political approvals
 - Need for importation license for study medication
 - Contracting with and study medication delivery to country
- Need for frequent site visits
 - Plan on spending twice as much time in-country as you think you'll need
 - Study Team AND medical provider assistance
- Build in financial/grants management safeguards

Implementation Lessons Learned

- Multiple addiction medicine trainings & technical assistance visits for stakeholders & providers are crucial
- 3x and 4x per week buprenorphine/nx dosing popular
 - Future possibility of take-home doses?
- Importance of peers and family members for recruitment & retention
- Importance of physical presence in international trials

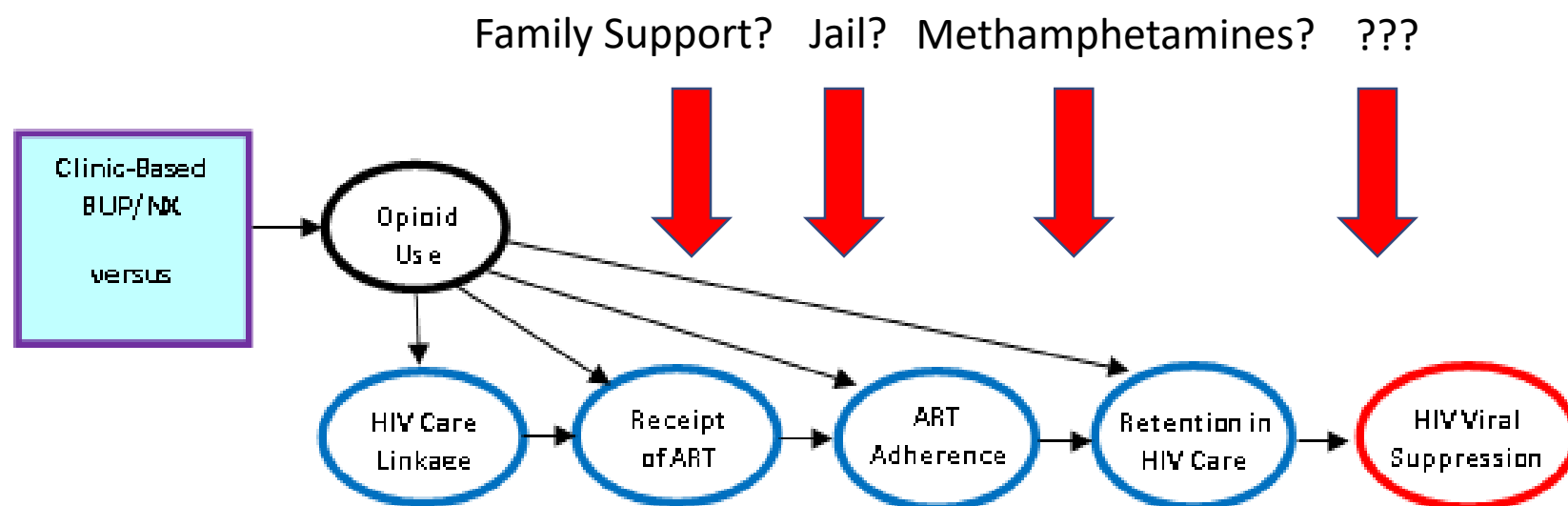
BRAVO Select Preliminary Results

How Do We Handle Unexpected Findings?

- Revisit analysis coding
- Review study procedures with research assistants
- Conduct qualitative interviews to understand findings
 - QUANT – qual
- Other ideas?

Closing Gaps in HIV Care Continuum

Conceptual Model - Revisited



Conclusions

- Heroin use decreased for both buprenorphine & methadone
- HIV care outcomes less favorable for buprenorphine than methadone due to less treatment initiation and retention.
- Integrating buprenorphine/naloxone into HIV primary care is feasible, but may require additional support to achieve UNAIDS 90-90-90 goals.
- Scale-up of buprenorphine may require greater support for retention.
 - Family support? Community health worker support?



Discussion