Relationships & HIV Prevention: Lessons learned from research with African HIV serodiscordant couples

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NIH
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What we have learned in 10 yrs of research with HIV serodiscordant couples

- The seemingly impossible is possible
- Relationships change, even among ‘stable’ HIV serodiscordant couples
- Serodiscordancy is challenging for couples & providers but motivates prevention uptake
- Qualitative research is valuable adjunct to structured interviews
- There is high demand for HIV prevention among serodiscordant couples
HIV serodiscordancy: Common and challenging

- ~50,000 couples of unknown HIV status counseled and tested for HIV in 14 East & Southern African sites in 2 years
- Screened 6600 HIV discordant couples; enrolled 3408 couples with 90% retention at 2 years
- HIV discordance is common; 8-31% of all couples screened screened for Partners HSV-HIV Transmission Study
- In couples with a known HIV+ partner, 49% had an HIV-partner
- HIV serodiscordancy is difficult for providers to explain & for couples to accept

Lingappa PLoS One 2008
Partners in Prevention: HSV-2 Suppression to Prevent HIV Transmission

3400 HIV-discordant couples with HIV+ partner – coinfected with HSV 2

Randomize HIV/HSV-2+ persons w/ CD4 >250

Acyclovir 400 mg twice daily

Placebo twice daily

Follow couples for 1-2 years

Primary endpoint: HIV infection in HIV-negative partner (estimated 4% in placebo arm)

Secondary endpoint in HIV+: HIV disease progression (CD4<200, ART initiation, death)

Sites: Botswana (Gaborone), Kenya (Eldoret, Kisumu, Nairobi, Thika), Rwanda (Kigali), South Africa (Cape Town, Johannesburg, Soweto), Tanzania (Moshi), Uganda (Kampala), Zambia (Kitwe, Lusaka, Ndola)
Partners in Prevention HSV/HIV Transmission Study Baseline Characteristics

• 6543 HIV discordant couples screened; 3408 enrolled
• 67% of HIV+ partners were female
• 65% of participants ≤ 35 years old
• 75% married
• Average partnership 5 yrs duration, 90% cohabiting
• Median 5 sex acts in prior month & 29% reported unprotected sex
• 4% of HIV+ & 7% of HIV- partners reported outside partners
Partners PrEP Design

3900 HIV discordant couples (HIV+ partner CD4 >250, not on ART)

Randomize HIV- partners (normal liver, renal, hematologic function)

TDF once daily
FTC/TDF once daily
Placebo once daily

All receiving HIV prevention services

Follow couples for 24-36 months

1° endpoint: HIV infection in HIV-negative partner
Co-1° endpoint: Safety

Kabwohe, Kampala, Jin
Mbale, Tororo, Uganda

Eldoret, Kisumu, Nairobi, Thika, Kenya
Partners PrEP
Baseline Characteristics

- 7735 HIV serodiscordant couples screened, 4758 enrolled
- 62% of HIV- partners were male
- 56% of participants ≤ 35 yrs old; 11% <25 yrs old
- 98% married; 20% of men had >1 wife
- Median partnership 7 yrs duration; 5 months known discordancy
- Median 4 sex acts prior month; 27% reported unprotected sex
- Median of 2 children; 22% couples with no children
- 8% of HIV- partners reported outside partners
Sexual behavior: Within discordant partnership & outside partnerships
Partners in Prevention HSV/HIV Transmission Study: ‘Stable’ discordant partnerships change

- Sexual frequency decreases with time:
  - Sex in past month: 94% at enrollment & 73% at month 24 (p<0.001)

- Sex with an outside partner increases over time
  - 3% at enrollment to 14% at 24 months (p<0.001)
  - 5 fold more commonly reported by HIV- men than women
  - HIV- partners who had outside partners of unknown status were less likely to use condoms

- <5% reported concurrent partnerships

Ndase JAIDS 2012
Outside partnerships: HIV-negative women in Partners HSV/HIV Transmission Study

<table>
<thead>
<tr>
<th></th>
<th>Enrollment</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Age ≤25</td>
<td>Age &gt; 25</td>
</tr>
<tr>
<td>N observations</td>
<td>255</td>
<td>842</td>
</tr>
<tr>
<td>Any Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study partner</td>
<td>92%</td>
<td>91%</td>
</tr>
<tr>
<td>Outside partner</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Concurrent (both)</td>
<td>1%</td>
<td>0%</td>
</tr>
</tbody>
</table>

- Sexual frequency with primary partner decreases during follow-up
- Slight increase in outside partners, appears to be due to relationship dissolution with primary partners
- <1% of women reported having concurrent partners

Ndase et al JAIDS 2012
### Outside partnerships among HIV-negative women in Partners PrEP Study

<table>
<thead>
<tr>
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<th>Enrollment</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Age ≤25</td>
<td>Age &gt; 25</td>
</tr>
<tr>
<td>N observations</td>
<td>696</td>
<td>4051</td>
</tr>
<tr>
<td><strong>Any Sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study partner</td>
<td>96%</td>
<td>96%</td>
</tr>
<tr>
<td>Outside partner</td>
<td>3%</td>
<td>10%</td>
</tr>
<tr>
<td>Concurrent (both)</td>
<td>3%</td>
<td>9%</td>
</tr>
<tr>
<td><strong>Any unprotected sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study partner</td>
<td>31%</td>
<td>26%</td>
</tr>
<tr>
<td>Outside partner</td>
<td>2%</td>
<td>4%</td>
</tr>
<tr>
<td>Concurrent (both)*</td>
<td>1%</td>
<td>3%</td>
</tr>
<tr>
<td><strong>Frequency of sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study partner– median (IQR)</td>
<td>5 (3, 10)</td>
<td>4 (2, 8)</td>
</tr>
<tr>
<td>Outside partner – median (IQR)</td>
<td>3 (2, 10)</td>
<td>4 (2, 7)</td>
</tr>
</tbody>
</table>

- Younger women less likely to have outside & concurrent partnerships at enrollment
- Sexual frequency decreases & condom use increases with primary during follow-up
One quarter of HIV infections acquired from outside partners

- Viral sequencing of transmission pairs
- 27% of transmissions from ‘outside partner’ in Partners in Prevention HSV-HIV Transmission Study (Campbell, PLoS One 2011)
  - Unlinked transmissions occurred with longer time in study
  - Male seroconverters were more likely to have acquired HIV from an outside partner
  - No difference by region or subtype
- 25% of transmissions from ‘outside partner’ in Partners PrEP Study
Condoms are difficult to negotiate in HIV serodiscordant couples

- 28 in-depth interviews & 8 FGDs among HIV serodiscordant couples in Thika & Nairobi
- Desire and expectation to have children is a major factor
- Misconceptions about HIV serodiscordance
  - Couples who have been together for years and remain serodiscordant without condoms think they are ‘resistant’ to HIV
- Male reluctance, alcohol use, lack of adequate knowledge about condoms

“...the husbands insist that even before they knew their status they were never using condoms. Therefore, they will not use them. Hence, many have become pregnant. It is challenging to use condoms.”

Ngure K, AIDS Care 2012
Social harms
Low incidence of social harms
Partners in Prevention HSV/HIV Transmission Study

• Low incidence
  – 2.7% among HIV+ women, 2.2% among HIV- women
  – 0.9% among HIV+ men, 0.7% among HIV- men

• Correlates of IPV among women: HIV+, unmarried, living with partner, unprotected sex that month

• Consequences of IPV: Relationship dissolution in 23% of women & 36% of men reporting IPV

• IPV incidence decreased during follow-up

• IPV was not associated with HIV seroconversion

Were, et al JAIDS 2012
Fertility intentions, pregnancy & contraception
Fertility intentions

- Fertility intentions are common in couples:
  - In those with CD4 >350 and not on ART, 36% of HIV infected women and 28% of HIV infected men had fertility intentions.

- Fertility goals are important to couples
  - “… We just said even if we have the virus, we will still get the baby. I went and the coil was removed and I stopped using the condom.” [23 year-old HIV- woman].
  - “…I wanted to get a child to prove to him that it is not only the negative who can bear children.” [35 year-old HIV+ woman].
  - Risk of HIV transmission is frightening and couples strongly desire strategies to decrease their risk.

Mujugira et al. JAIDS 2013
Ngure et al. AIDS Care 2012
“My intention was a child but I was very afraid”: Fertility intentions & HIV risk perception

- Qualitative research in Thika, Kenya site with 36 HIV serodiscordant couples
- Desire to conceive overrode their HIV transmission concerns
- Reasons for desiring pregnancy:
  - Satisfying desired family size, naming children for relatives, desire for biologic children, stability of partnership, sociocultural pressures

Ngure et al, AIDS Care 2012
Pregnancy incidence in Partners PrEP Study

<table>
<thead>
<tr>
<th></th>
<th>≤ 25 years</th>
<th>&gt;25</th>
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<tbody>
<tr>
<td>Person years</td>
<td>520</td>
<td>3166</td>
</tr>
<tr>
<td>Pregnancies</td>
<td>136</td>
<td>253</td>
</tr>
<tr>
<td>Incidence (per 100 PY)</td>
<td>26.1</td>
<td>8.0</td>
</tr>
</tbody>
</table>

- Much higher pregnancy rate in younger women
- Pregnancy testing conducted monthly
### Contraceptive use among women in Partners PrEP study

<table>
<thead>
<tr>
<th></th>
<th>No children at enrollment</th>
<th>Children at enrollment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>≤ 25 years</td>
<td>&gt;25</td>
</tr>
<tr>
<td>Visits</td>
<td>1035</td>
<td>1525</td>
</tr>
<tr>
<td>Oral, injectable,</td>
<td>32%</td>
<td>21%</td>
</tr>
<tr>
<td>implants, IUD, surgical, or diaphragm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Higher contraceptive use after first child.
- Younger women more likely to use contraception before first child.
HIV prevention preferences
Not all HIV+ persons are willing to use ART early

- Mixed methods work in Thika, Kenya among 772 members of HIV-1 serodiscordant couples in the Partners PrEP Study (funding NIH R21 NR012663)

**Survey question:** Would you be willing to start antiretrovirals before your CD4 count reaches 350 if it would lower your chance of giving HIV to your partner?

![Survey Results]

**Top concerns about initiating early ART for HIV-1 prevention:**
- Side effects (51.4%)
- Stigma (20.8%)
- Pill burden (19.4%)
- Potential for earlier development of antiretroviral resistance (18.1%)

Heffron et al. JAIDS 2012
Choice of PrEP vs. ART in couples

- Mixed methods work in Thika, Kenya among 772 members of HIV-1 serodiscordant couples in the Partners PrEP Study (funding NIH R21 NR012663).

Survey question:
If you had 2 new choices for HIV prevention for your partnership and they both worked very well, which would you choose: PrEP or early ART?

Heffron et al. JAIDS 2012
What does it mean to patients to start ART?

• Qualitative work: meaning of ART is death – not a great message to build on for programs.…. (Curran et al., AIDS 2013)

“You know the mentality that is there when you take the ARVs, it means you are at the lowest stage and that is why people fear ARVs.”

“Like me, if I am given ARVs I will think I am nearing the grave.”
Kenyan HIV serodiscordant couples’ attitudes regarding early ART initiation

• Motivators:
  – Preserving health, immunity, keeping virus in check
  – Avoiding stigma from opportunistic infections and visible signs of AIDS
  – Ability to work and care for family

• Concerns
  – Side effects, which could lead to inadvertent disclosure of HIV
  – Life-long adherence
  – Stigma
  – Partner reactions to ART
  – ART initiation signifies the final stage (whereas co-trimoxazole signified earlier stage)
ART initiation in Partners PrEP

- In a trial with CD4 monitoring every 6 months, counseling of ART benefits, & active linkage to HIV care, 40% of HIV+ partners had not initiated ART 6 months after referral.
- Higher CD4 counts, asymptomatic HIV disease, and alcohol consumption predicted ART non-initiation.

Mujugira JAIDS 2014
PrEP Adherence & sexual behavior
Sustained use (and non-use) of PrEP: Partners PrEP Study

At Month 1, ~80% had tenofovir detected

Donnell et al JAIDS 2014
Sustained use (and non-use) of PrEP: Partners PrEP Study

75% of those who had tenofovir at Month 1 continued PrEP at month 12
Sustained use (and non-use) of PrEP: Partners PrEP Study

- Those who had no tenofovir at Month 1 had no tenofovir throughout.
- Plasma TFV <40 ng/ml associated with not having sex with HIV+ partner.
Adherence patterns in 29 seroconverters on active PrEP arms

- Declining adherence over time in 29 seroconverters; 5 had plasma TFV >40 ng/ml at last time point prior to seroconversion
Partners PrEP: Ancillary study on intensive adherence measures

1147 HIV uninfected partners enrolled
  • Median unannounced pill count adherence = 99%
  • Median MEMS adherence = 92%
  • Low adherence associated with no sex in the prior month

14 HIV infections were observed:
  • 14 in 333 person-years among placebo participants
  • 0 in 616 person-years among PrEP participants (p<0.001)

High adherence in setting of active adherence monitoring & support was associated with a high degree of reduction in risk of HIV acquisition

“What’s Love Got to Do With It?”
PrEP Adherence in HIV Serodiscordant Couples

• In-depth qualitative interviews of 60 Partners PrEP Study participants about adherence experiences, barriers, and facilitators

• “Discordance dilemma” after learning serodiscordant status
  – Competing priorities of desire to avoid acquiring HIV and advantages of preserving the relationship

• PrEP is seen by HIV- partners as a potential solution to HIV discordance

• Adherence support is often received from HIV+ partners

• When discord in the relationship, adherence suffers

Ware et al JAIDS 2012
PrEP adherence & sexual activity

- 96 HIV- participants in Thika Kenya site did daily SMS surveys for 60 days about sex & PrEP
  - 48% reported unprotected sex at least once
- Sex was highly correlated with PrEP adherence
  - Participants reporting more sex were less likely to report PrEP non-adherence
  - Missed doses were correlated with sexual abstinence
- Better ability to predict when they would not have sex (NPV 80%) than when they would (PPV 57%)
  - Would present challenge with intermittent PrEP dosing

Curran AIDS Behav 2013
Risk compensation among those receiving PrEP

• In the Partners PrEP Study, no increase in unprotected sex in serodiscordant couples, STIs, or pregnancy after July 2011 (when placebo stopped and all received active PrEP)

Average frequency of unprotected sex, \( \leftarrow \) before & after \( \rightarrow \) July 2011

Mugwanya et al., Lancet ID 2013
Implementation of ARV-based prevention among HIV serodiscordant couples
Both PrEP and ART protect against HIV
- ART is clearly the priority for HIV+ partners with lower CD4 counts (and, when possible, for all persons with HIV)
- Not all HIV+ partners will choose to or can start ART immediately

Staged use of PrEP, as a bridge to ART, might be one effective and cost-effective public health strategy
- (Hallett et al. PLoS Med 2011; Mitchell et al. STI World Congress 2013)
Partners Demonstration Project

- Subset of Partners PrEP Study sites in Kenya and Uganda
- Open-label demonstration project among new, high-risk HIV-1 serodiscordant couples
  - Provide PrEP, provide ART – assess interest, uptake, and sustained use (adherence)
  - Quantitative and qualitative research to better understand facilitators, preferences, and barriers
Demonstration project approach – PrEP as a bridge to ART and viral suppression

Recruit higher-risk HIV-1 serodiscordant couples

Offer/refer for ART for HIV-1\(^+\) partners according to current national guidelines

- **Accepts ART**
  - Offer PrEP for 6 months to HIV-1\(^-\) partner
  - Continue to counsel HIV-1\(^+\) partner on ART

- **Declines ART**
  - Offer PrEP to HIV-1\(^-\) partner

- **Not yet eligible for ART**
  - Offer PrEP to HIV-1\(^-\) partner
  - Follow HIV-1\(^+\) partner and refer for ART when eligible

ART Prioritization

PrEP as bridge to ART
Using a risk score to define couples at highest HIV risk

<table>
<thead>
<tr>
<th>Age of HIV-1 uninfected partner</th>
<th>20 years or less</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>21-30 years</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>More than 30 years</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Number of children</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>1-2</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>3 or more</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Male HIV-1 uninfected partner uncircumcised</td>
<td>Yes</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>0</td>
</tr>
<tr>
<td>Married and/or cohabiting</td>
<td>Yes</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>0</td>
</tr>
<tr>
<td>Unprotected sex within partnership, prior 30 days</td>
<td>Yes</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>0</td>
</tr>
<tr>
<td>HIV-1 plasma viral load, HIV-1 infected partner</td>
<td>50,000 copies or higher</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>10,000-49,999 copies</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Less than 10,000 copies</td>
<td>0</td>
</tr>
<tr>
<td>Total score</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

A score of 5 was associated with an HIV incidence of 5/100 pyrs

Kahle et al JAIDS 2013
Partners Demo Project Status

- Enrollment of 1012 high risk couples Nov 2012-August 2014
- High uptake of PrEP at enrollment: >90% of participants
- High adherence to PrEP based on MEMS and plasma TFV
- ART willingness is high among ART eligible participants at enrollment: >70% accept a referral or on-site ART
- PrEP discontinuation is feasible (typically when HIV+ partner on ART for 6 months)
- PrEP and ART can work together to provide couples with maximum protection against HIV transmission

Heffron R. CROI 2014 Poster # 949
Partners Demo Project: Sociocultural dimensions of ARV-based prevention

**PrEP**
The Partners Demonstration Project
The Bridging Strategy of Delivery

Couples’ Experiences of and Responses to...

**Couples Relationship Context**
- Relationship
  - “Discordance Dilemma”
  - Desire to Preserve the Relationship
  - Communication, Satisfaction
  - Trust, Commitment
  - Intimacy, Power
  - Fertility Intentions
- Individual Motives and Beliefs
  - Motive to Avoid HIV Infection
  - Perceived Risk of Acquiring HIV Infection
  - Motive to Accrue Social Capital

**Social, Cultural and Economic Context**
- Social Structure (e.g. gender inequality)
- Family & Community (e.g. stigma of HIV/AIDS)
- Health System (e.g. structure, organ.)
- HIV Policy in Uganda (e.g. treatment guidelines)
- Culture (e.g. culture of medicine)
- Economics (e.g. resource scarcity)
Preliminary findings from qualitative interviews in Uganda

- PrEP perceived to help HIV- partner stay HIV- and care for family
- Advice of health care providers is important
- Couples discuss decisions about PrEP & ART with each other
- Concerns about stopping PrEP
- PrEP offers a prevention strategy when ‘condoms can’t be managed’ & to have ‘live sex’

Ware, unpublished data
Preliminary findings from qualitative research in Partners Demo Project

- 24 couples in Thika, Kenya site
  - 9 had initiated PrEP, 9 had initiated ART, 4 had delayed ART, 2 had declined PrEP
- None had heard of TasP or PrEP before enrolling
  - Most reported that their decision to commence PrEP or ART was based on counseling from health provider
- PrEP and ART gives couples a way to cope with HIV discordance and a way to safely conceive

Ngure et al, unpublished data
Relationships & HIV prevention:
Lessons from HIV serodiscordant couples

- Relationships are dynamic
- HIV serodiscordant couples are motivated to use HIV prevention strategies
  - Primary prevention strategies remain important; 25% acquired HIV from partner other than their study partner
  - Fertility desires are significant; couples need alternatives to condoms
  - Partner support important in PrEP adherence
  - Adherence data indicate majority have consistent use; non-use of PrEP associated with less risk
- Understanding motivators for HIV prevention is key
With great appreciation to the couples who tested together & participated in the Partners in Prevention HSV/HIV and Partners PrEP Studies
Partners in Prevention HSV/HIV Transmission Study Team

Sites: Nairobi, Kenya (Farquhar John-Stewart, Kiarie); Kisumu, Kenya (Bukusi, Cohen) Eldoret, Kenya (Were, Fife) Thika, Kenya (Mugo) Moshi, Tanzania (Manongi, Kapiga) Kampala, Uganda (Katabira, Ronald) Kigalii, Rwanda (Kayatenkore, Allen) Soweto, South Africa (Gray, DeBryn, McIntyre) Orange Farm, South Africa (Delany, Rees) Cape Town, South Africa (Coetzee) Gaborone, Botswana (Makhema, Essex) Lusaka, Ndola & Kitwe, Zambia (Inambao, Kanweka, Allen)

University of Washington Coordinating Center: Connie Celum (PI and Co-Chair), Jairam Lingappa (Co-Chair and Medical Director), Deborah Donnell (Statistician), Justin Brantley, Robert Coombs, Amy Dao, Shauna Durbin, Mira Emmanuel-Ogier, Lisa Frenkel, Carlos Flores, Harald Haugen, Renee Heffron, Ting Hong, Jim Hughes, Erin Kahle, Lara Kidoguchi, Meighan Krows, Matt Leidholm, Jai Lingappa, Toni Maddox, Angela McKay, Julie McElrath, Allison Mobley, Susan Morrison, Nelly Mugo, Andrew Mujugira, Vikram Nayani, Patrick Ndase, Apollo Odika, Hilda O’Hara, Dana Panteleeff, Jennifer Revall, Marothodi Semenya, Kathy Thomas, Ellen Wilcox

DF/Net (data center): Lisa Ondrejcek, Darryl Pahl, Jae Chong

CLS (laboratory oversight): Wendy Stevens, Charlotte Ingram, Ute Jentsch, Mukthar Kader, Nombulelo Gqomane, Feroza Bulbulia, Jan van den Heuvel

Bill & Melinda Gates Foundation (study funder): Renee Ridzon, Stephen Becker

HIV serodiscordant couples who tested, screened, & participated
Partners PrEP Study Team

- **Sites:**
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  - Jinja, Uganda (Makarere U, UW): Patrick Ndase (PI), Elly Katabira (PI), Fridah Gabona
  - Kabwohe, Uganda (KCRC): Elioda Tumwesigye (PI), Rogers Twesigye
  - Kampala, Uganda (Makarere U): Elly Katabira (PI), Allan Ronald (PI), Edith Nakku-Joloba
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  - Tororo, Uganda (CDC, TASO): Jim Campbell (PI), Jordan Tappero (PI), Aloysious Kakia

- **University of Washington Coordinating Center:**
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- **Adherence Ancillary Study:** David Bangsberg, Jessica Haberer, Norma Ware, Monique Wyatt, Steve Safren, Christina Psaros, Craig Hendrix, Namandjé Bumpus

- **DF/Net** (data center): Lisa Ondrejcek, Darryl Pahl, Jae Chong

- **CLS** (laboratory oversight): Wendy Stevens, Charlotte Ingram, Ute Jentsch, Mukthar Kader, Nombulelo Gqomane, Feroza Bulbulia, Jan van den Heuvel

- **ClinPhone/Perceptive Informatics** (randomization)

- **Gilead** (study drug donation): Jim Rooney

- **Bill & Melinda Gates Foundation** (study funder): Stephen Becker

- HIV serodiscordant couples who tested, screened, & participated
If you want to go fast, go alone.
If you want to go far, go together.
– African proverb