

Who Screens for Clinical Research?

How do they compare to the community at large?



Mary Latka, PhD MPH

Programme Director for HIV Prevention, The Aurum Institute

Assistant Professor, Mailman School of Public Health

Columbia University, NY, NY



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Background

- South Africa is a testing ground for many experimental HIV prevention products; home to much clinical research.
- Clinical trials use randomization to ensure internal validity
- However, the very design of clinical trials may limit generalizability (or external validity)
 - Multiple steps to entry
 - Specific eligibility criteria
 - Willingness to try experimental products
- Generalizability of trial findings may be especially at issue for microbicide trials which requires self-dosing among a select group.



Research Questions

- So who *are* the people in clinical research?
- Do they report higher or lower HIV-related risk behaviour compared with the larger community?
- Are they more or less likely to use products that can protect themselves from HIV / pregnancy, compared with the larger community?
- What does their profile of clinical research participants tell us about whether results from them might generalize to the larger community?



Outline

Methods

- How each sample derived
- Who are in the samples

Results

- Adjusted comparisons between clinic & community samples (HIV risk profiles; pregnancy issues)

Conclusions

- What does this mean for microbicide trials?



Methods

Where did the two samples
come from?



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Data on Hand to Explore these Research Questions

Panel study comparing two samples

Community Sample

- Done in 2008
- Representative sample of Rustenburg
 - Used STATS SA 2007 projection of 2001 census data to determine sampling frame.
 - 16 of 342 small area layer (SALS) / neighbourhoods sampled
 - Aerial maps of neighbourhoods updated via drive thru before sampling the household
- Targeted 512 persons; assumed 20% refusal
- **Final Sample: n=351 (31% refusal)**



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The second sample...

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Clinic Sample

- Case series: all who came to Rustenburg Research Centre to screen for a clinical study to estimate HIV incidence
- Ongoing: Nov 08 – now
- **Sample: n=672**

**Sub-set of Same Questions
Asked in both Surveys**



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More on the Samples.....

Community Sample

- Age range: 18-49
- Representative (no selection based on risk factors)
- 15% of sample non-Black
- (which reflects Rustenburg)

Clinic Sample

- Age range: 18-35
- Targeted recruitment of persons presumed at “high risk” for HIV
- 1.2% of sample non-Black

By design, samples expected to be somewhat different.

Therefore adjusted analysis done to make comparisons between clinic participants and demographic counterparts from the community.



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Domains Covered in Questionnaire

- Demographics
- Contraceptive use: Barriers & hormonal Any in L3mos
- Self-efficacy to convince partner to use condoms
- Pregnancy desires & STI history
- HIV Risk profile
 - STI symptoms
 - Partnering practices (New? Multiple? Concurrency?)
- HIV knowledge and beliefs (Fatalism; Gender Roles)



Who is in each sample?



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Demographics

Community Sample

- Median Age: 31 years
- % Black: 84.9%
- % Female: 59.8%
- Sr Secondary School: 61.5%
- Single with partner: 37.6%

Clinic Sample

- Median Age: 22 years
- % Black: 98.7%
- % Female: 59.1%
- Sr Secondary School: 82.4%
- Single with partner: 67.2%

**Clinic Sample: younger;
more likely to be Black, educated & have sex partner**



Sexual Risk Profile

Community Sample

- Males w/ multiple partners: **23.9%**
- Females w/ multiple partners: **3.5%**
- Always condoms with new partner: **83.3%**
- Ever condom regret? **12.4%**
- Genital sores L 3 mo: **6.5%**

Clinic Sample

- Males w/ multiple partners: **40.7%**
- Females with multiple partners: **16.4%**
- Always condoms with new partner: **59.23%**
- Ever condom regret? **38.9%**
- Genital sores L 3 mo: **13.4%**

Higher HIV risk profile in the clinic sample



Protective Method Use & Pregnancy Intentions

Community Sample

- Hormonal Injection: 30.6%
- OCPs: 12.7%
- Condoms: 49.0%
- Withdrawal: 5.6%
- Women: Pregnancy Desire Any Partner: 22.1%
- Ability to convince partner to use condoms: 48.4%

Clinic Sample

- Hormonal Injection: 23.9%
- OCPs: 11.4%
- Condoms: 64.7%
- Withdrawal: 22.8%
- Women: Pregnancy Desire Any Partner: 29.6%
- Ability to convince partner to use condoms: 39.2%

Clinic sample

- More condom users; but less confidence to use them
- Less hormonal use & in relationships desiring pregnancy



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Who is in each sample
controlling for demographics?

How does the clinic sample compare with
their demographic counterparts from the community?



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Comparing apples with apples...

Was the clinic sample a higher risk group ?

In the last 3 mos...	Community % yes	Clinic % yes	OR (95% CI)
Had new sex partner?	21.8	37.0	2.10 (1.32-3.34)
Had 2+ sex partners?	14.8	27.7	2.07 (1.27-3.37)
Thought SP had other partners?	22.7	39.4	2.76 (1.82-4.19)
Had STI symptoms?	12.7	19.5	2.00 (1.21-3.30)

Yes



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Comparing apples with apples...

What about condom use?

Was the clinic sample *more* likely to be condom users?

In the last 3 mos...	Community % yes	Clinic % yes	OR (95% CI)
Was a condom user?	63.0	64.6	1.00 (0.70-1.42)
Felt could convince partner to use a condom?	51.5	39.5	0.54 (0.39-0.76)

Clinic sample was no more likely to be condom users, and was less able to convince partner to use them



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What about pregnancy risk and desires?

How did the clinic sample compare with community?

In the last 3 mos...	Community % yes	Clinic % yes	OR (95% CI)
Had used injectables?	33.5	24.1	0.61 (0.41-0.89)
Partner wants (them) to fall pregnant?	7.0	12.8	
Among male participants (woman wants pregnancy)	6.3	8.1	1.37 (0.45-4.21)
Among female participants (man wants pregnancy)	5.7	15.4	2.22 (0.98-5.07)



**Clinic sample less protected from pregnancy;
Women under pressure from men to fall pregnant**

So What?



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What are the implications for Generalizability?

This clinic sample appears to be at greater HIV risk; yet less able to protect themselves through condom negotiation

- Important because many prevention products (microbicides) depend on ability of a person to negotiate their use.
- Lack of use in a trial hampers ability to test the product
- Presents challenge to trialists: the very people who need protection the most, may not be able to use products



What are the implications for generalizability?

This clinic sample was at greater risk for pregnancy

- Enter the clinical research setting less likely to be familiar with hormonal cx use
- Women, in particular, under pressure to fall pregnant
- Important b/c we know fertility intentions impact on barrier method use
- Challenge to trialists: need to avoid pregnancies in trials for safety reasons
- Once enrolled in a trial, the very women who need to avoid pregnancy, may be under more pressure to fall pregnant



Limitations

- Just one community
- Didn't have direct questions about propensity for product use
- No HIV testing in community – so direct comparison on prevalence not possible
- Clinic sample was screening for a cohort study, not a trial

Strengths

- Nothing special about our recruitment –so these finding might be generalizable to other places
- Exact questions repeated over time



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Conclusions

- We have a challenge:
 - People who screened for this clinical research study appear to be in ***greatest need of HIV protection***
 - But also are most vulnerable to it
 - People who screened for this clinical research study were **at risk of pregnancy**, but compared with their community counterparts ***less likely to be familiar with hormonal methods.***



Thank you!

Co-Authors:

Katherine Fielding(2), Candice Chetty(1), Fathima Moola(1),
Anna Meyer-Weitz(3), Petra Kruger(1)

1. The Aurum Institute, Johannesburg, South Africa
2. London School of Hygiene and Tropical Medicine, London, UK
3. School of Psychology, University of KwaZulu Natal

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