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REPUBLIC OF KENYA
MINISTRY OF HEALTH

Yale

Testing and Linkage to Care for Injecting Drug Users (TLC-IDU)

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NIDA R01DA032080

Presented by John Lizcano

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Context

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- Kenya first in sSA to implement gov't-run NSP country-wide in 2013
  - Estimated 18,000 PWID; on Coast, 17% incident infections, 4% nat'l
  - **Seek**
    - Respondent-Driven Sampling (RDS) to find PWID
  - **Test**
    - Offer rapid HIV and HCV test at NSP service sites (N=10)
  - **Treat**
    - Offer point of care (POC) CD4 assay if HIV+
  - **Retain**
    - If HIV+ and CD4+ at treatment threshold provide peer case manager (PCM) for linkage to care
    - Conditional cash transfer to participant & PCM

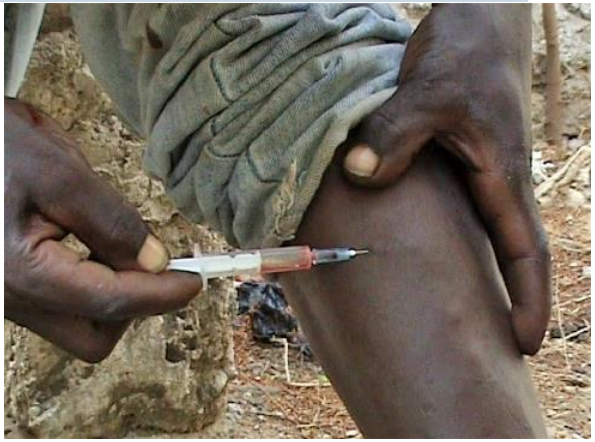

Photo: Jimmy Kamude/IRIN
Flash blood magnifies HIV risk of sharing needles

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Study Intervention Components

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- **NSP program (by KANCO, Global Fund, MDM):**
  - Sterile syringes; supplies for safer injection; peer educators to demonstrate safer injection; risk reduction and safer sex counseling; condoms; referrals for addiction tx/OST; prioritized ART (tx slots) for CD4+ cell count <500/mm3

- **Study-specific elements:**
  - Point of care CD4 testing to determine who needs ART
  - Peer case managers to support HIV care access and ART initiation among PWIDs testing positive and clinically eligible
  - Conditional cash transfers to HIV+ eligible patients and peer case managers for successful linkage to care/ART initiation

Study Design

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- Evaluate Gov't of Kenya NSP intervention (time-series analysis)
  - number needles, HIV incidence, community viral load

- Evaluate linkage to care study components (stepped-wedge design)
  - randomized intervention roll-out sites and control sites: testing and data capture over time

Approach

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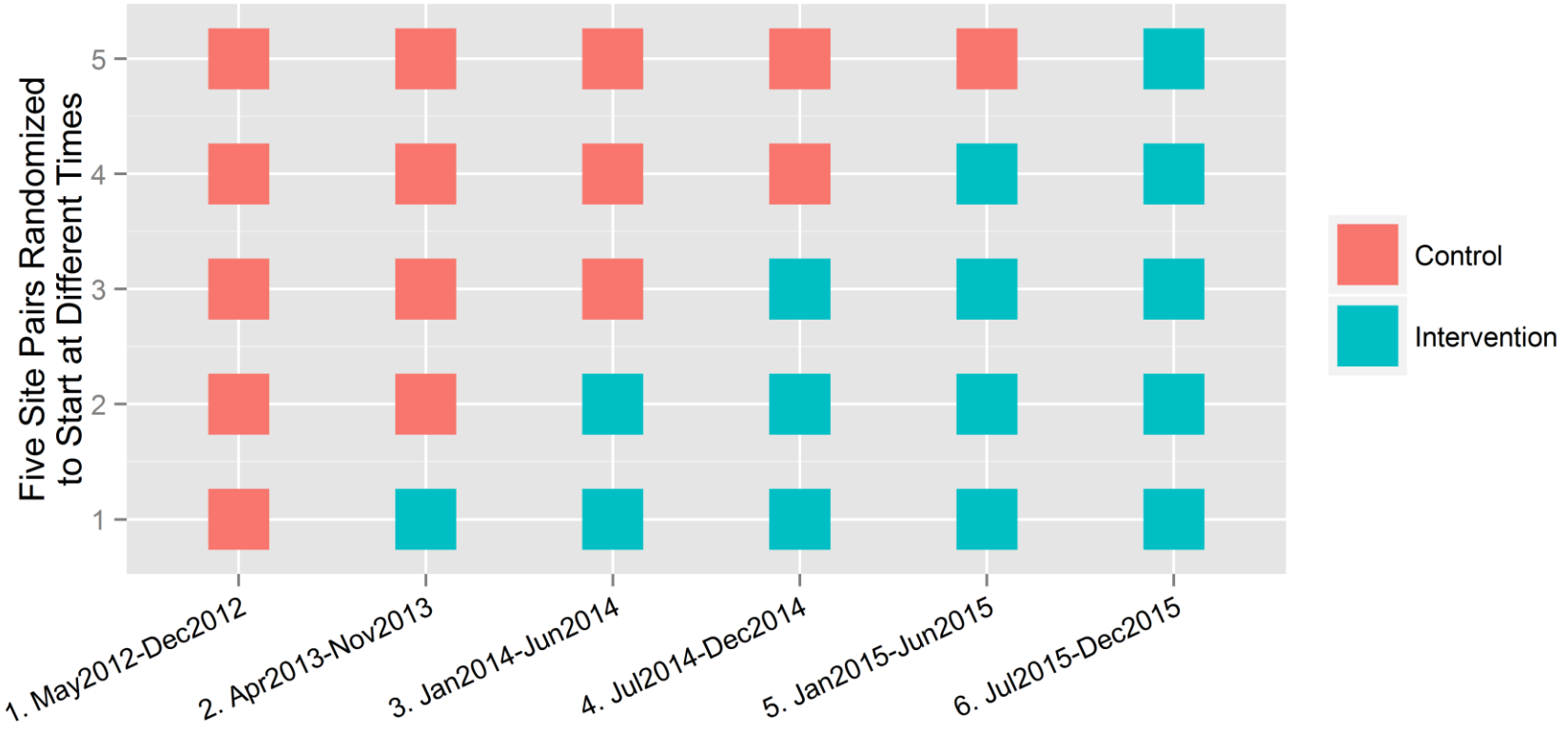
- Ten sites, respondent-driven sampling, stepped wedge, repeated surveys, HIV testing, viral load



Biometrics & Data Management

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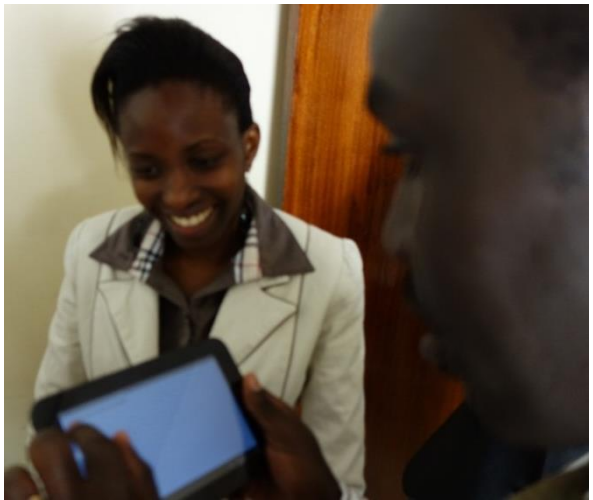
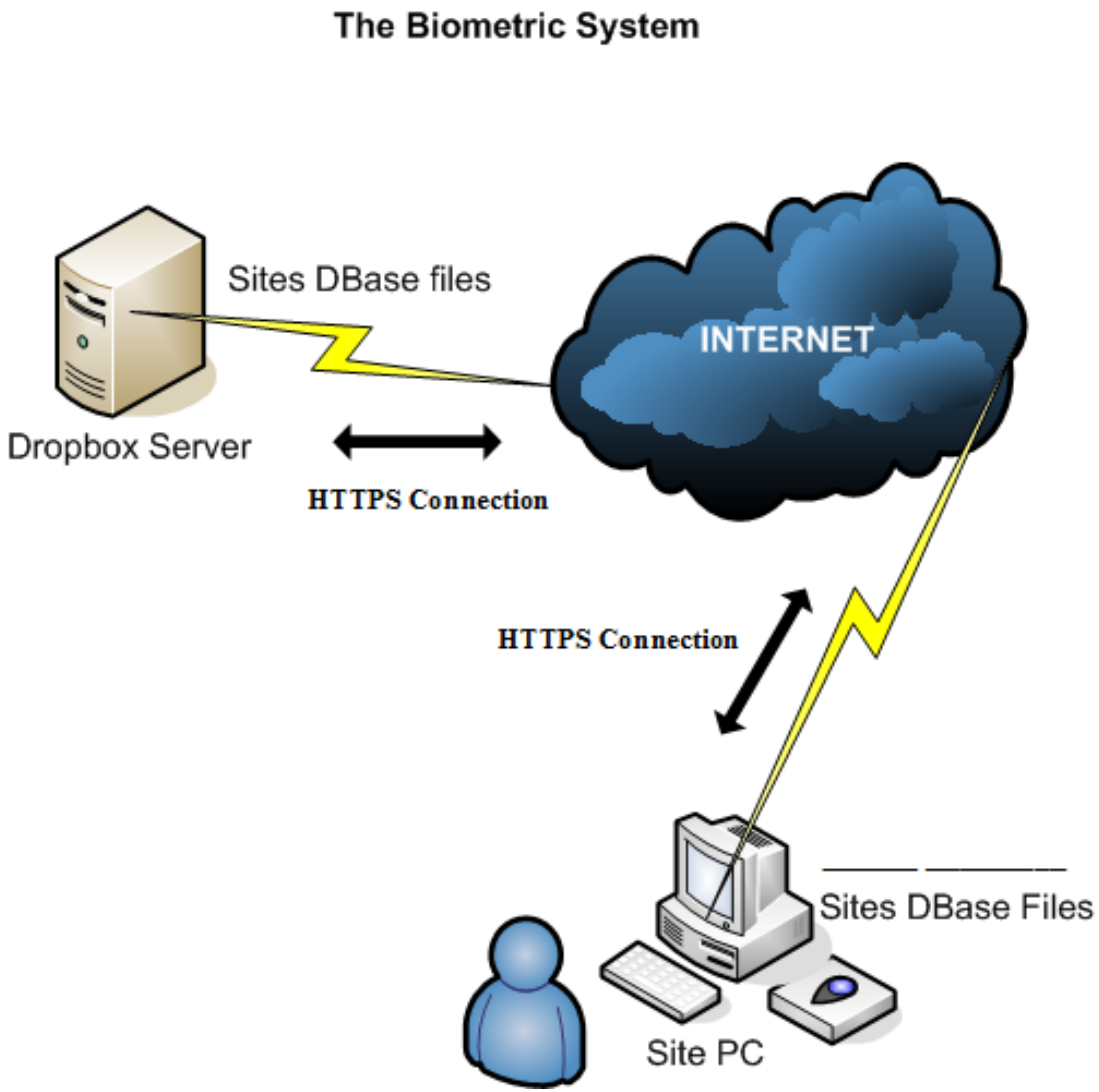
Eliminates double enrollment in time wave

Tracks mobility, repeat services over time, incidence





Key Outcomes

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- **Successful linkage to care**
  - # days between first test positive and first visit with HIV provider
- **Time to ART initiation**
  - # days between first test positive and ART initiation
- **'Community Viral Load'**
  - Specimens at each site/waves over time from all PWID who tests HIV+, to document changes in infectivity (median viral load)
  - Using Dried Blood Spot (DBS) for VLs
- **Additional biomarkers added:**
  - Phylogenetic analysis at the end of Wave 3
  - HCV on Wave 6

Viral Phylogenetics

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- Provides data for assessing the relationship between the HIV viruses from different participants

- Will give additional information about possible transmission patterns among participants of the TLC-IDU study and their parenteral, sexual, and social networks, by comparing genetic characteristics

- Will provide valuable information about mutating HIV viruses and drug resistance, of which there is little known in Kenya especially among the PWID population

Phylogenetics Approach

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- DBS, 1 specimen per participant per lifetime of the study on HIV positive participants
- 347 specimens collected since end of wave 3
  - 9 on wave 3
  - 212 on wave 4
  - 96 on wave 5
  - 73 on wave 6
- Specimens get frozen at - 80 after collection, shipped to US

- Dr. Davey Smith, UCSD, is currently working on analysis of the specimens

Hepatitis C Virus

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- Global pandemic affecting 185 million people worldwide
- Undetected and untreated, chronic HCV infection can result in cirrhosis, hepatocellular carcinoma, liver failure and death
- HCV prevalence varies across regions worldwide. Africa has the highest estimated HCV prevalence in the world at 5.3% (common genotypes are 1, 4 and 5)
- However not enough is known about HCV in sub-Saharan Africa, where an increasing number of people who inject drugs (PWID) live and are becoming HIV- as well as HCV-infected.

HCV Approach

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- To establish HCV prevalence, ALL study participants get tested using SD Bioline HCV test
  - Immunochromatographic rapid test for qualitative detection of antibodies specific to HCV in serum, plasma or whole blood
  - Collect about 10 uL of capillary blood (by finger prick) and place it on the device with 4 drops of reagent.
  - Results in 5 to 20 minutes
- If the rapid HCV test is reactive, we collect about 6ml of venous blood for confirmatory test
- All reactive participants are confirmed by Qualitative RNA
- Counseled and referred per nat'l standards

Implementation Challenges

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- Politics
  - Structural situation (e. g. change and decentralization of the government).
- Cultural
  - Initial community opposition
- Legal
  - Police crack-downs (ongoing)
    - E.g., president of Kenya was in Coast early Sept 2015 and gave order of more police crack-downs. PWIDs currently hiding, slowing recruitment
- Resources
  - Competing demands
    - Some religious leaders wanted drug rehab instead

"Where do they expect them to inject themselves? Their bodies are ruptured and rotten as a result of constant use of the needles. Besides, [drug] peddlers and barons will have a field day, for they'll know their products will be on demand, and that's not acceptable."

- NGO leader& mother of PWID

Implementation Challenges

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- Changing context, ethical exigencies
  - Funders (e.g., KANCO and Global Fund) and implementing partners wanted to start NSP programs as fast as possible and all at once in all sites since this was a life-saving intervention. Needed for HIV epidemic control. However, it constrained stepped wedge research design timeline

Therefore de-coupled 1) NSP program evaluation (time series analysis) and 2) study linkage to care elements to let each program roll-out NSP naturally, continuing linkage to care on the planned stepped-wedge schedule.

Will still be able to evaluate the Government of Kenya's syringe and needle exchange/IDU treatment program

Implementation Challenges

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Intervention Issues

- Point Of Care CD4
  - Reliability – Not trusted by HIV Clinics in the beginning
- Peer Case Management
  - Finding suitable Peer Case Managers
  - High turn-over
  - Commitment
  - Appropriate Follow-up
- Conditional Cash Transfer (CCT)
  - Some participants trying to cheat the system
  - Once no longer getting CCT, some participants stopped ARVs

Challenges with Participants

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1. Follow-up of participants challenging as are highly migratory
2. Participants sometimes do not attend appointments since:
   - Time to attend HIV clinic is limited – busy "hustling" to sustain drug needs
   - Simply forget appointment date and time
3. Participants non-adherence
4. Storage of HIV meds very difficult as some are homeless
5. Stigmatization from those who are not on medication, hence some prefer not to take medication

Challenges with Participants

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6. Some feel HIV is not a major concern due to:
   - Feeling of hopelessness in life
   - There are other higher risks like mob justice
7. Police Raids
8. Some clients believe ARVs will reduce drug “highness”, hence they stop taking the ARVs
9. Withdrawal symptoms
10. Reliability of self-report
11. Rapid saturation of RDS recruitment chains

Challenges at CCC/HIV Clinics

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1. Discrimination and stigma from some clinic staff
2. Participants not accepted because of geographical area
3. Some clients get discouraged
4. Clients usually get impatient if they feel they have been kept waiting for too long
5. Reliability of POC CD4 – Initially not trusted by CCC staff
6. CD4 retesting - some clients feel discouraged when told to repeat the CD4 count tests, delaying ART
7. Limited human resources

Challenges at Site level

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- Work dynamics with host sites (our study sites are pragmatic-not set up specifically for TLC-IDU)

- Study site capacity
  - Different funding streams
  - Potentially different package of services

- Productivity levels of staff and sites
  - Number of participants
  - Number of good quality samples

- Leadership challenges

Challenges with Testing and collection

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- Viral Load
  - Collecting right amount of blood, using DBS filter paper correctly, appropriate packaging and shipment of specimens
- Phylogenetics
  - Collecting right amount of blood, using DBS filter paper correctly, appropriate storage and shipping mechanism
  - Degradation of DNA during the shipping process, making it difficult for analysis
- HCV
  - A few participants refusing to be tested, using the rapid test kit, collecting venous blood for confirmatory test, getting venous blood in timely manner to lab for plasma separation

Recruitment and Demographics

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	Period One	Period Two	Period Three	Period Four	Period Five	Period Six
Screened	1946	1739	1265	1336	1460	1677
Enrolled	1785	1489	1186	1286	1395	1659
Median Age	30	31	31	31	32	32
% Male	86.8	87.9	90.9	88.3	89.4	88.6
% Married	15.5	17.3	15.9	15.9	15.7	13.1
% Nairobi	37.1	41.4	43.4	47.7	46.2	49.2
% Coast	62.9	58.6	56.6	52.3	53.8	50.8
% Homeless	20.1	25.3	24.9	30.5	24.7	15.5
% Participated Before	0.0	34.5	57.8	62.4	63.4	61.4

4897 unique enrolled PWID; **3903** participated in >1 period;
8800 total interviews of enrolled PWID

Years Injecting

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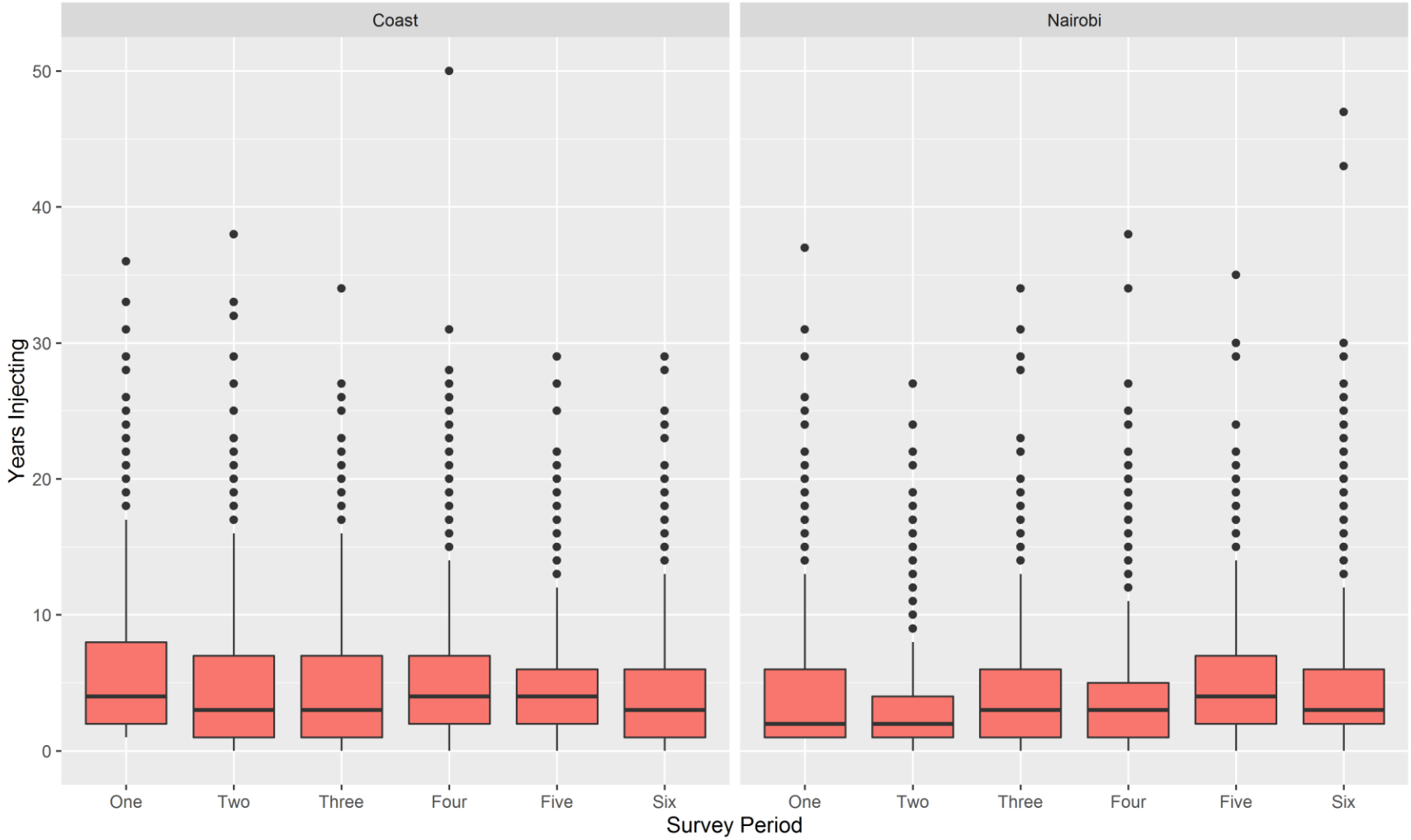

Times Injecting on an Average Injecting Day

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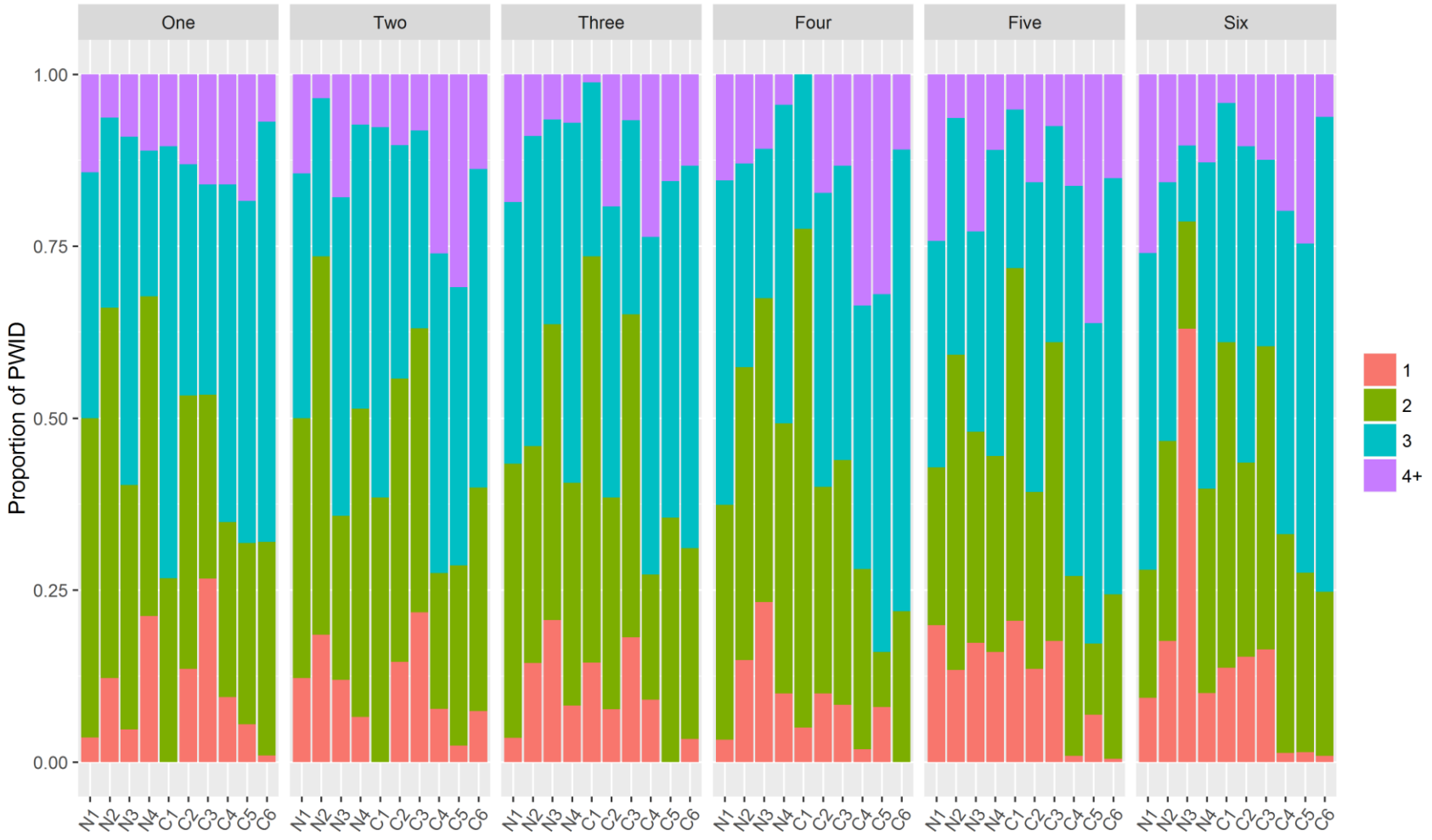

Injection Equipment Sharing

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	Period One	Period Two	Period Three	Period Four	Period Five	Period Six
% Receptive sharing of the most recent needle/syringe	10.6	4.0	2.3	2.6	3.3	3.0
% Receptive sharing of cooker, cotton, or water at last injection	39.0	13.2	7.3	10.0	11.0	13.3
% Ever frontload/backload	31.7	31.4	22.8	24.0	14.0	10.5
% Ever flashblood	2.8	3.3	1.4	1.5	1.7	0.5

HIV Testing Results

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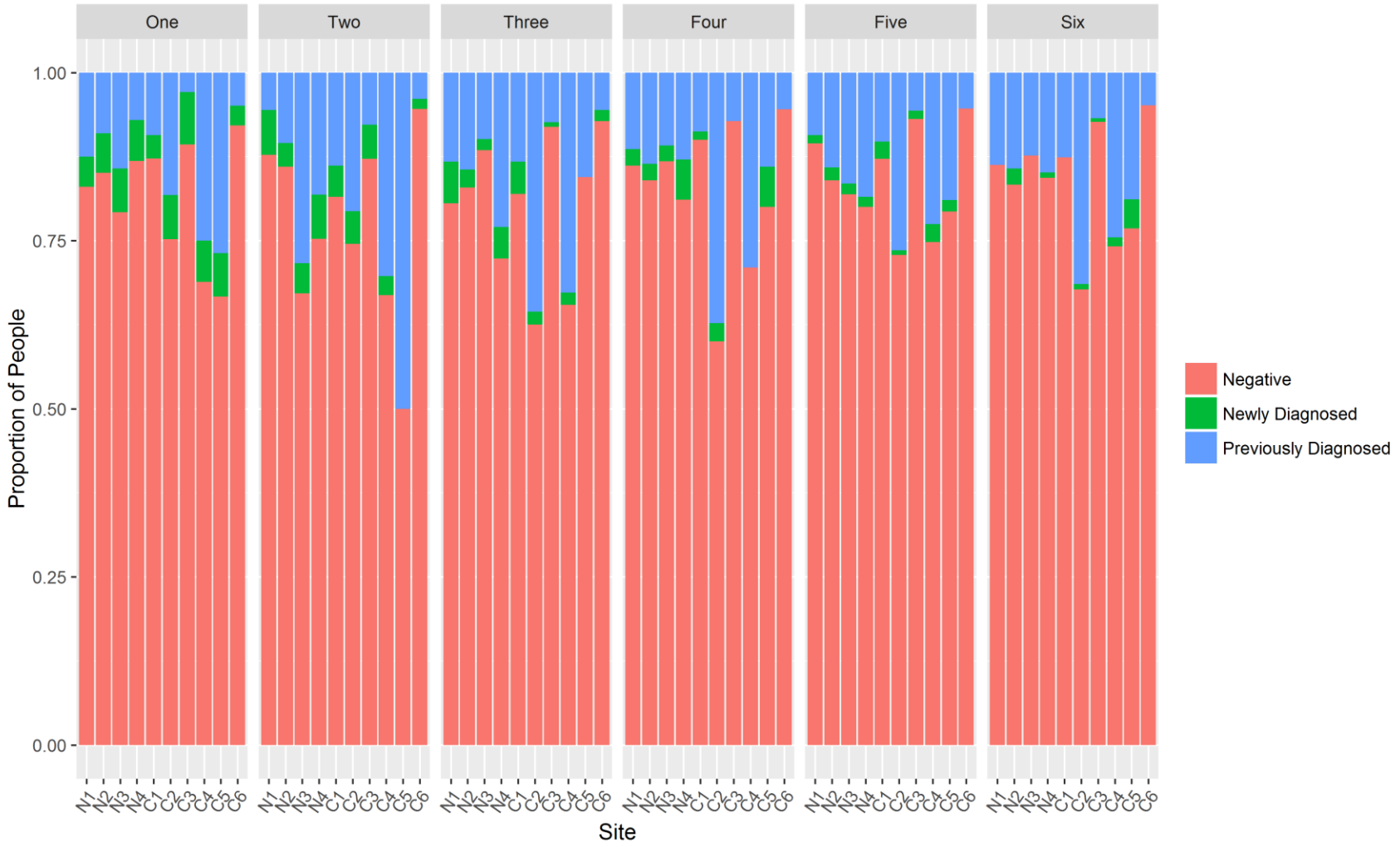

Fewer Newly Diagnosed Positives Over Time

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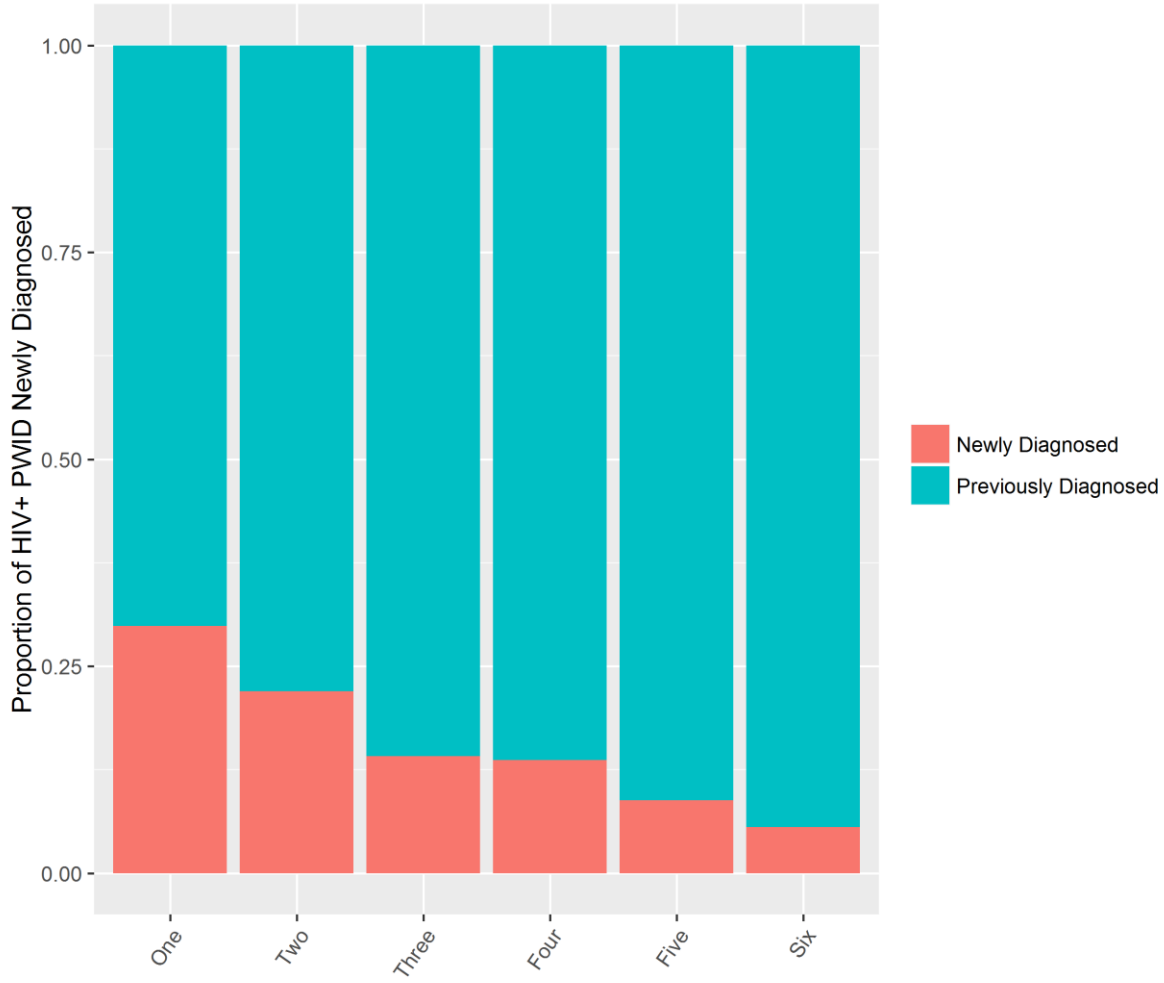
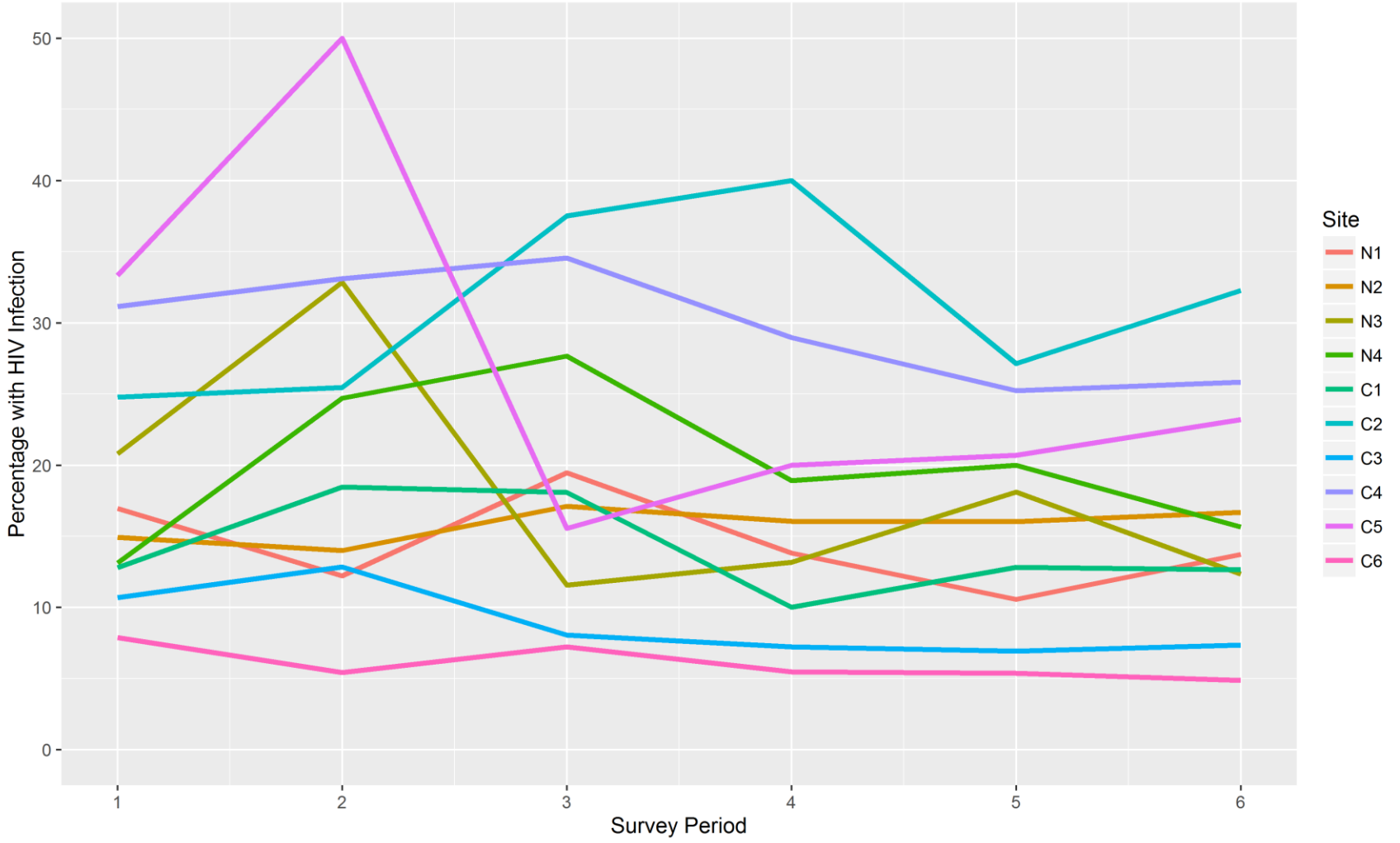


HIV Prevalence



Previously Diagnosed Taking HIV Medication

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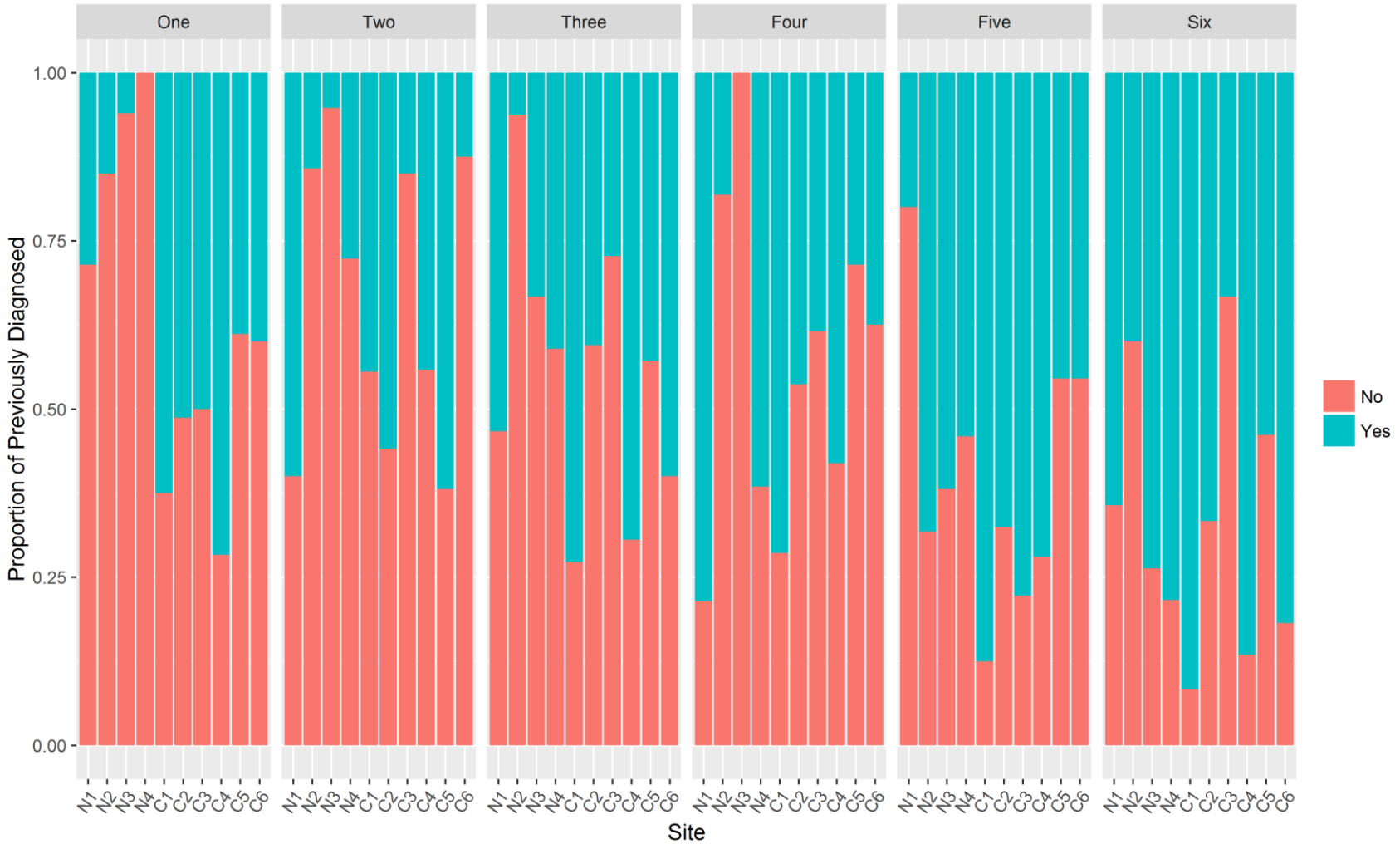

Period	One	Two	Three	Four	Five	Six
% Taking ART	41.0	34.5	46.1	45.4	59.7	68.1

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Viral Load among Participants with HIV Infection

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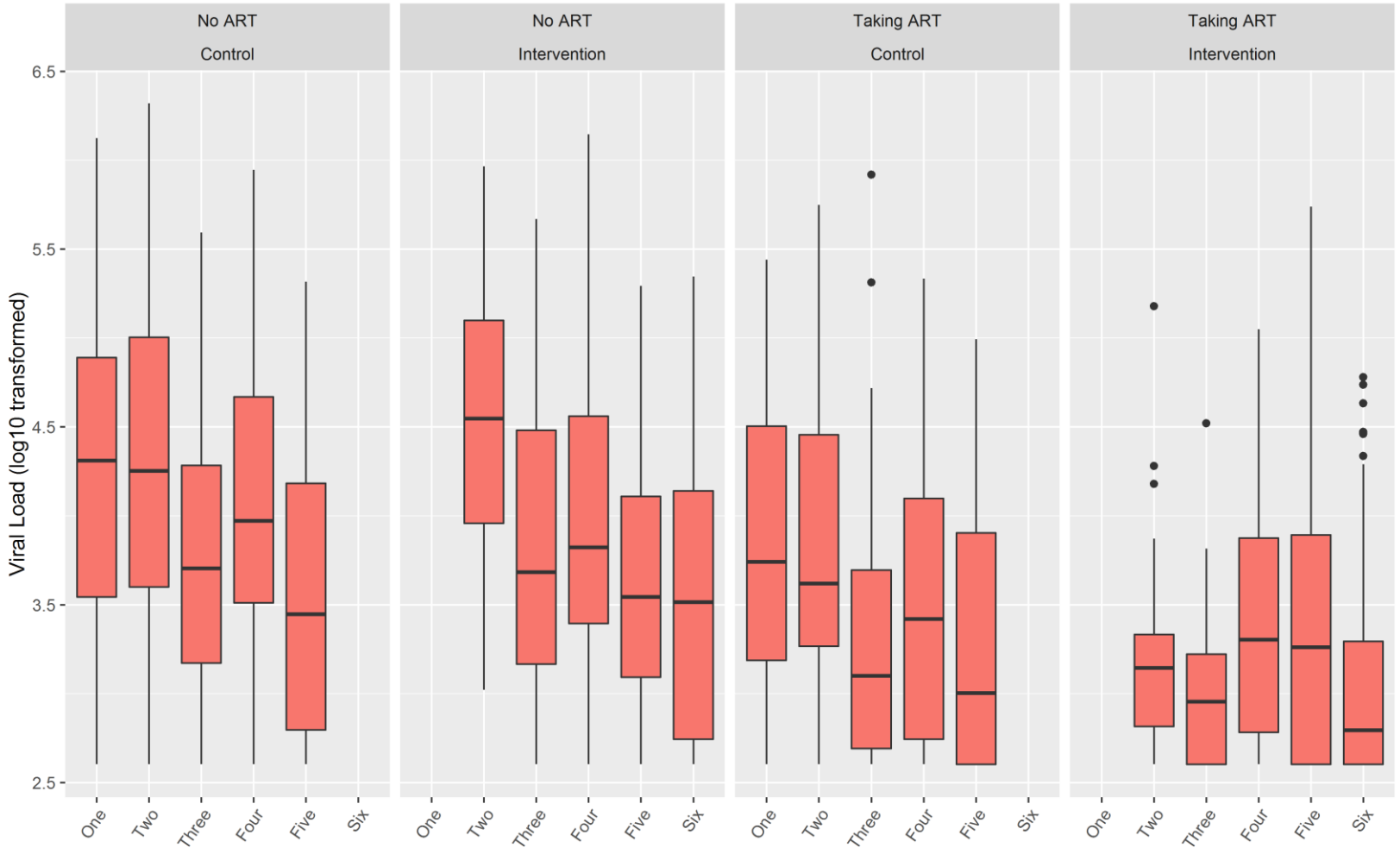

Suppressed (≤400) Viral Load

ART Initiation Eligibility

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CD4

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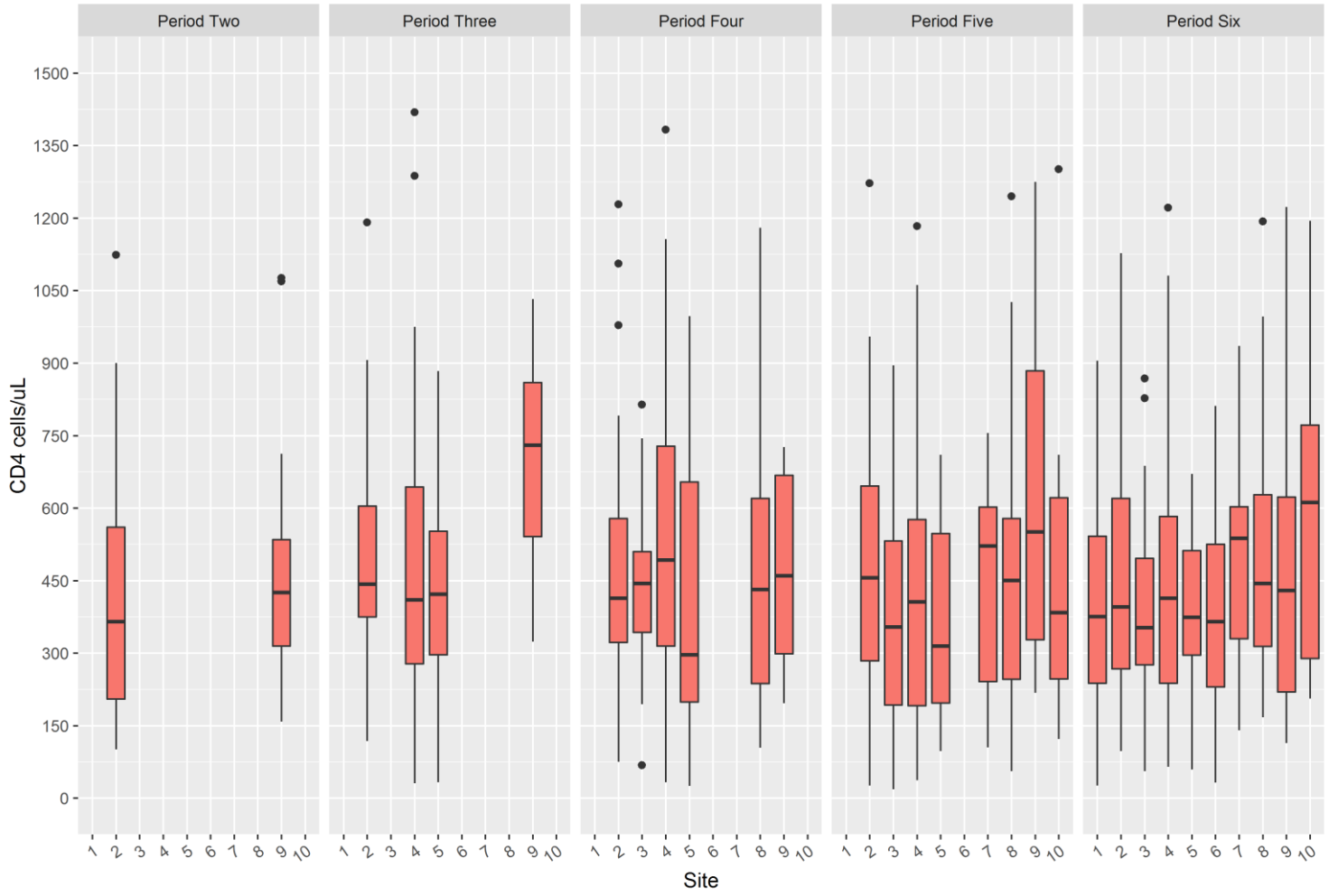

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HCV Results

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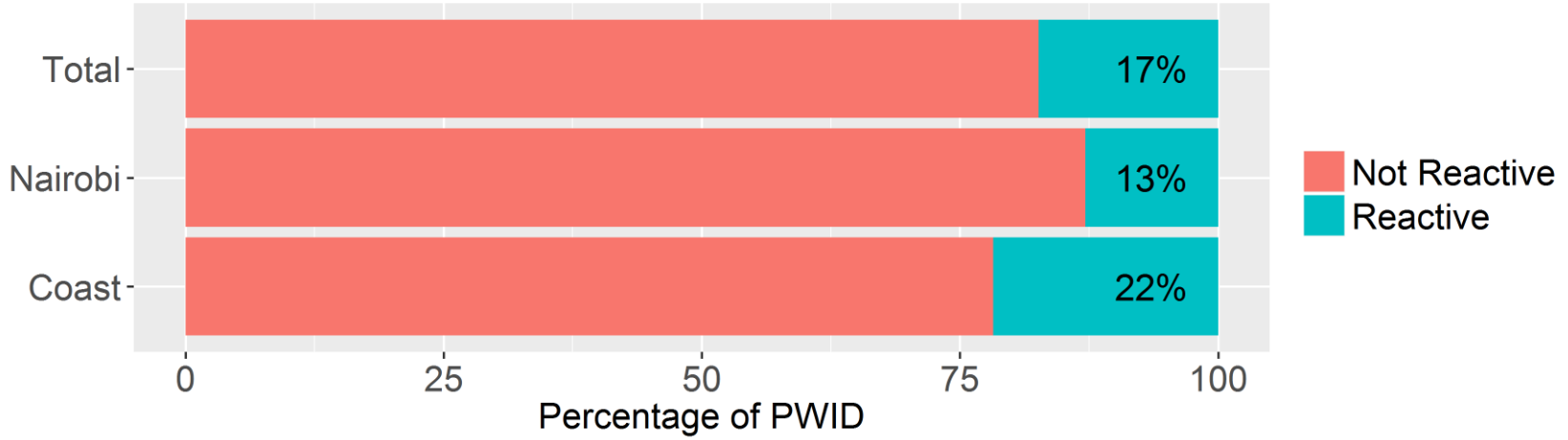
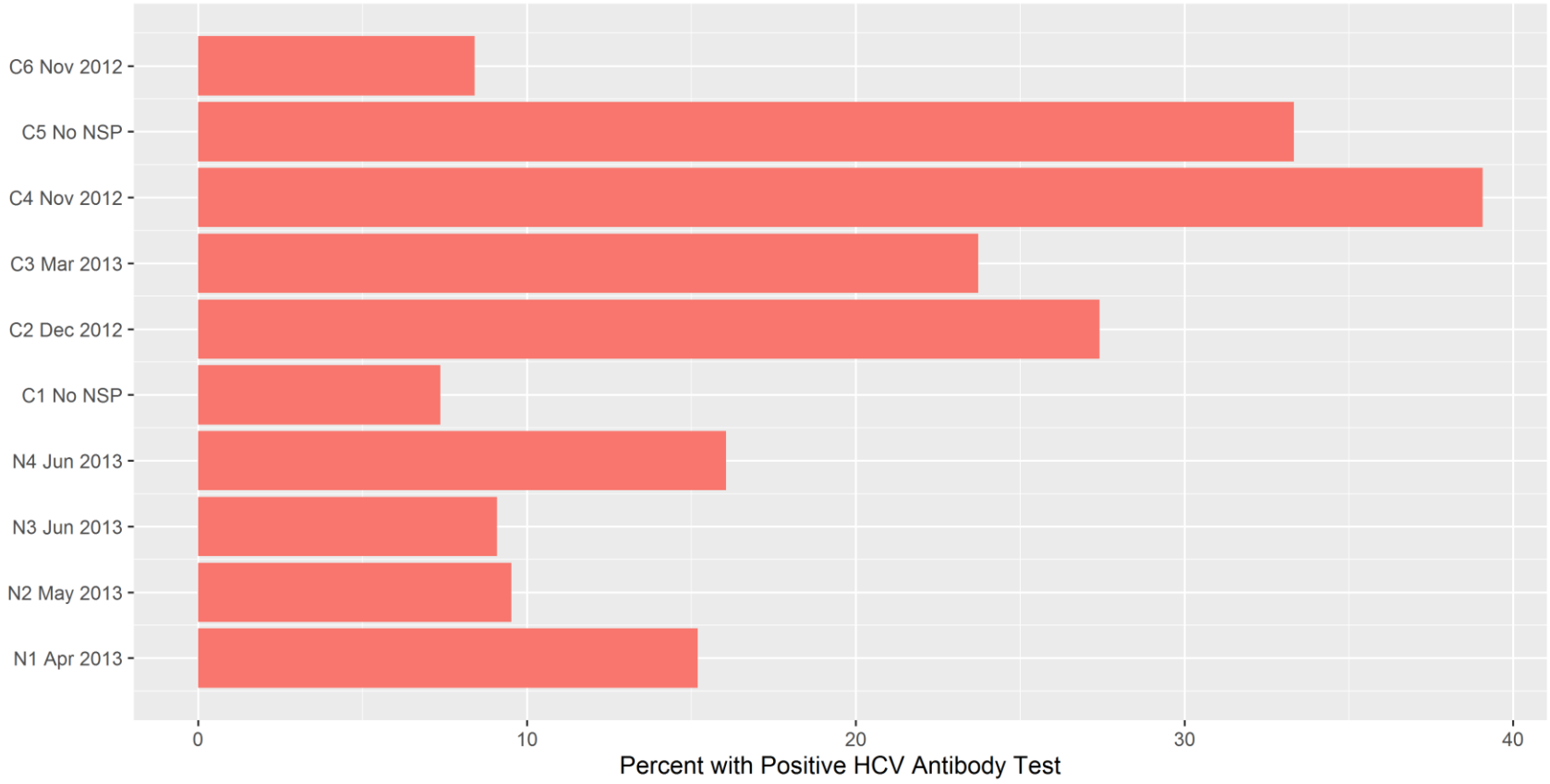
- 1658 participants tested (817 Nairobi/841 Coast)
- 288 have been reactive (105 Nairobi/183 Coast)
  - About 17.4% of total participants have been reactive using the SD Bioline rapid test for HCV



Hepatitis C Antibody Test Results by Study Site



Confirmatory HCV Results

Using Qualitative RNA:

- 181 were already analyzed at partner lab KERMI/CDC
  - 32 Negative (18%)
  - 149 Positive (82%)

- 107 currently being analyzed at partner lab KERMI/CDC

Accessed NSP in the Last 12 Months

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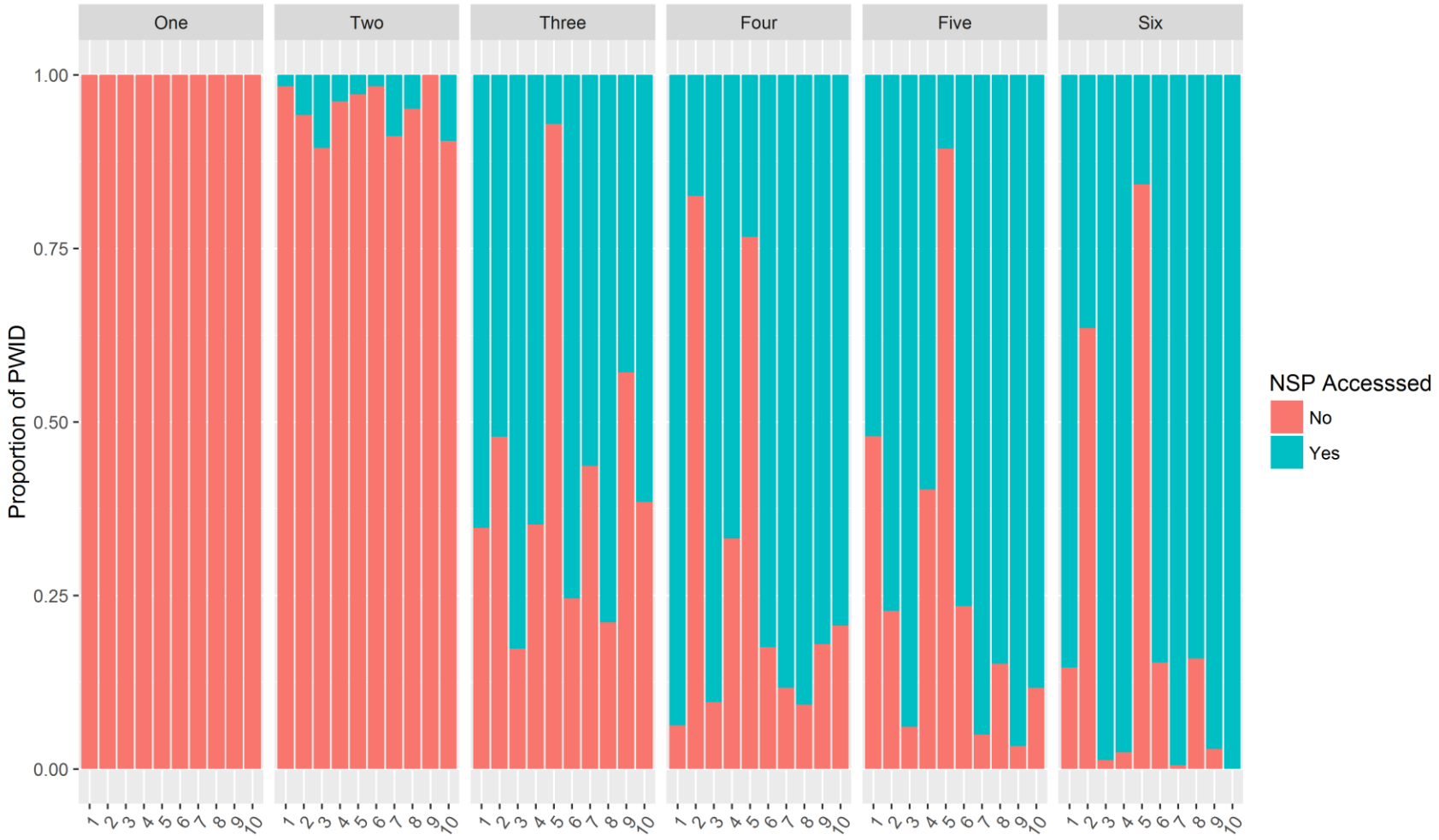

Average Times per Month Visit NSP

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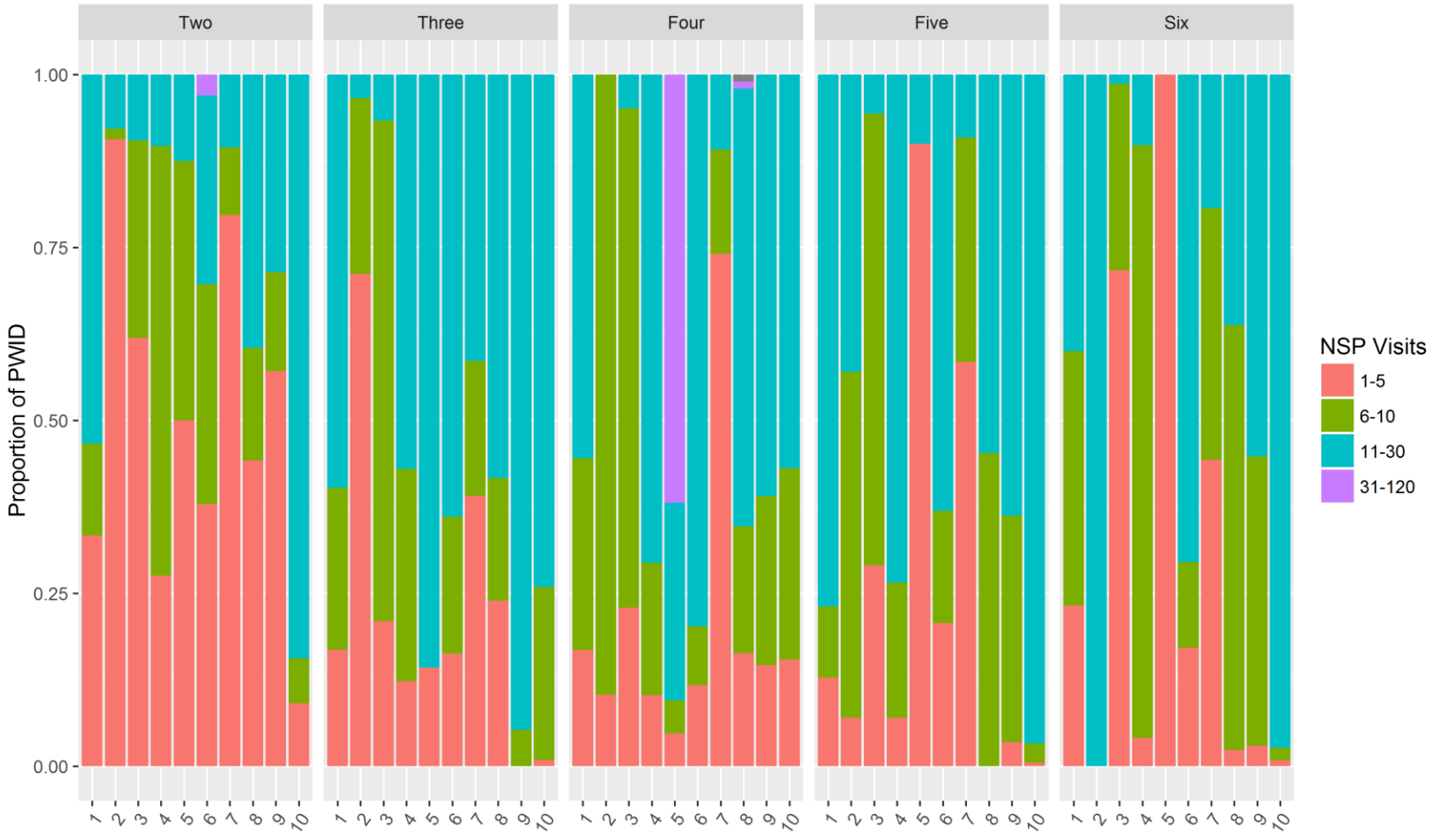

Services Received at NSP

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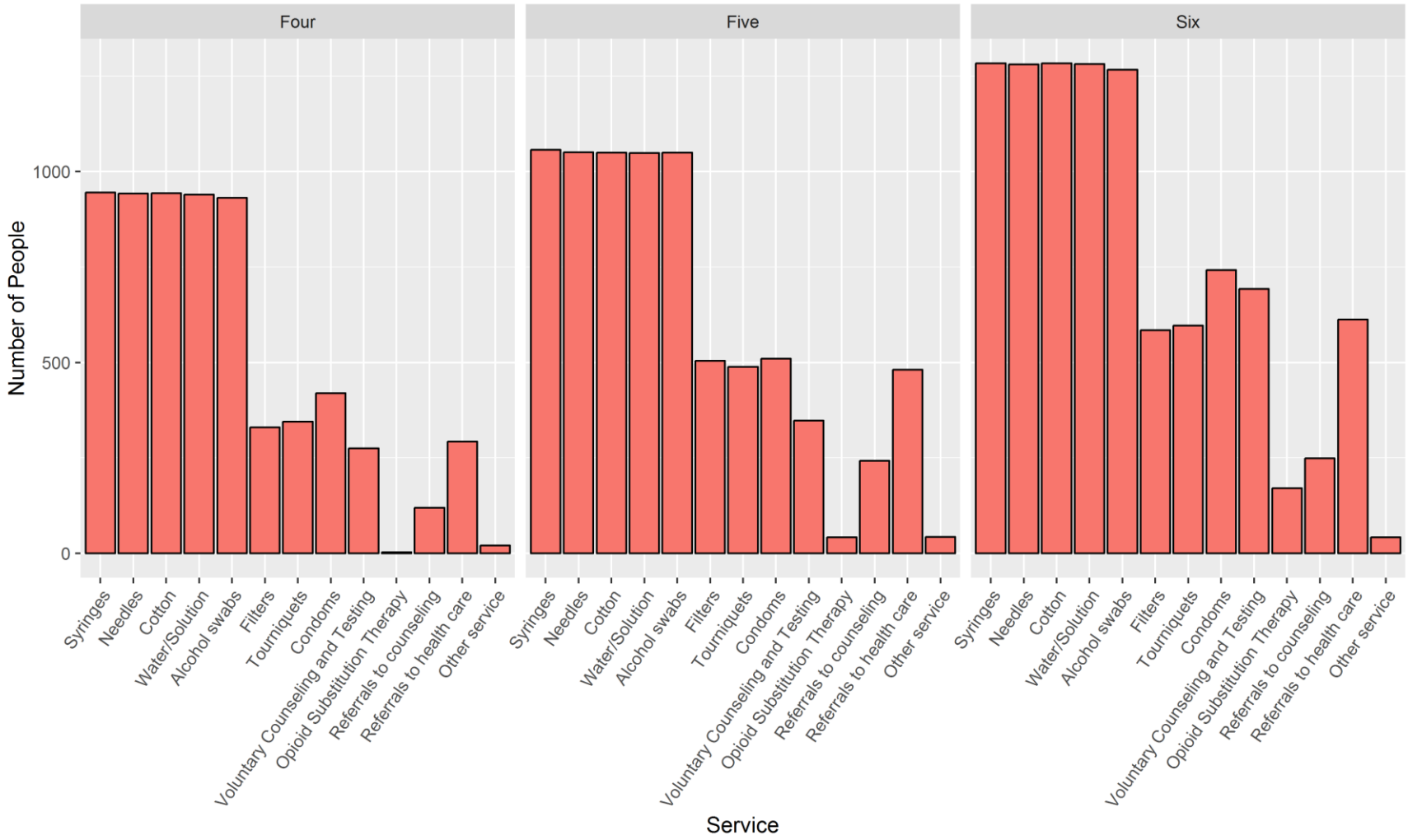

Number Needles Received Last Visit

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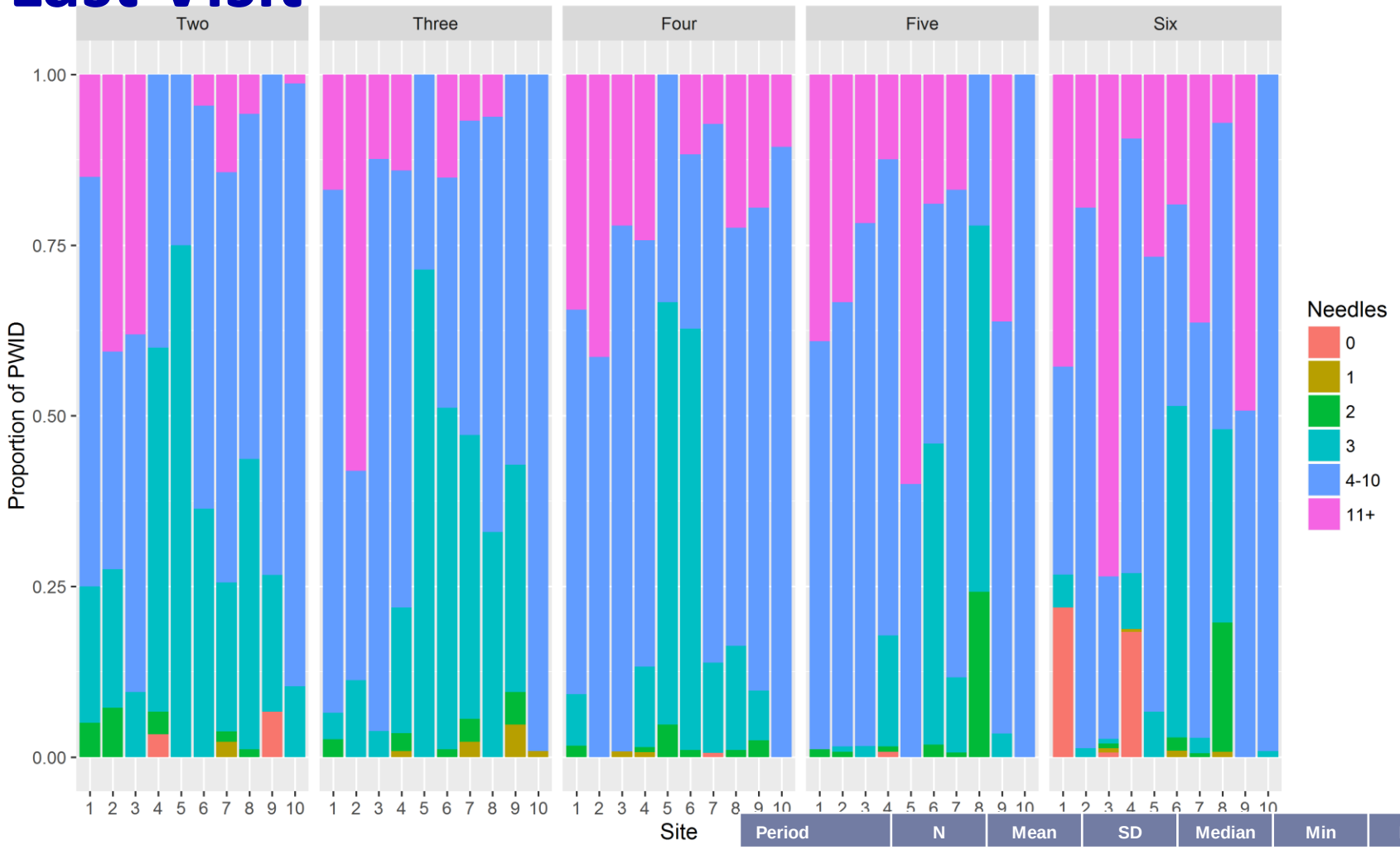

Period	N	Mean	SD	Median	Min	Max
Two	526	6.55	4.18	6	0	30
Three	770	7.29	4.20	6	0	40
Four	948	9.03	6.14	9	0	60
Five	1066	9.23	5.46	9	0	45
Six	1377	10.96	10.08	9	0	150

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Number Needles Returned Last Visit

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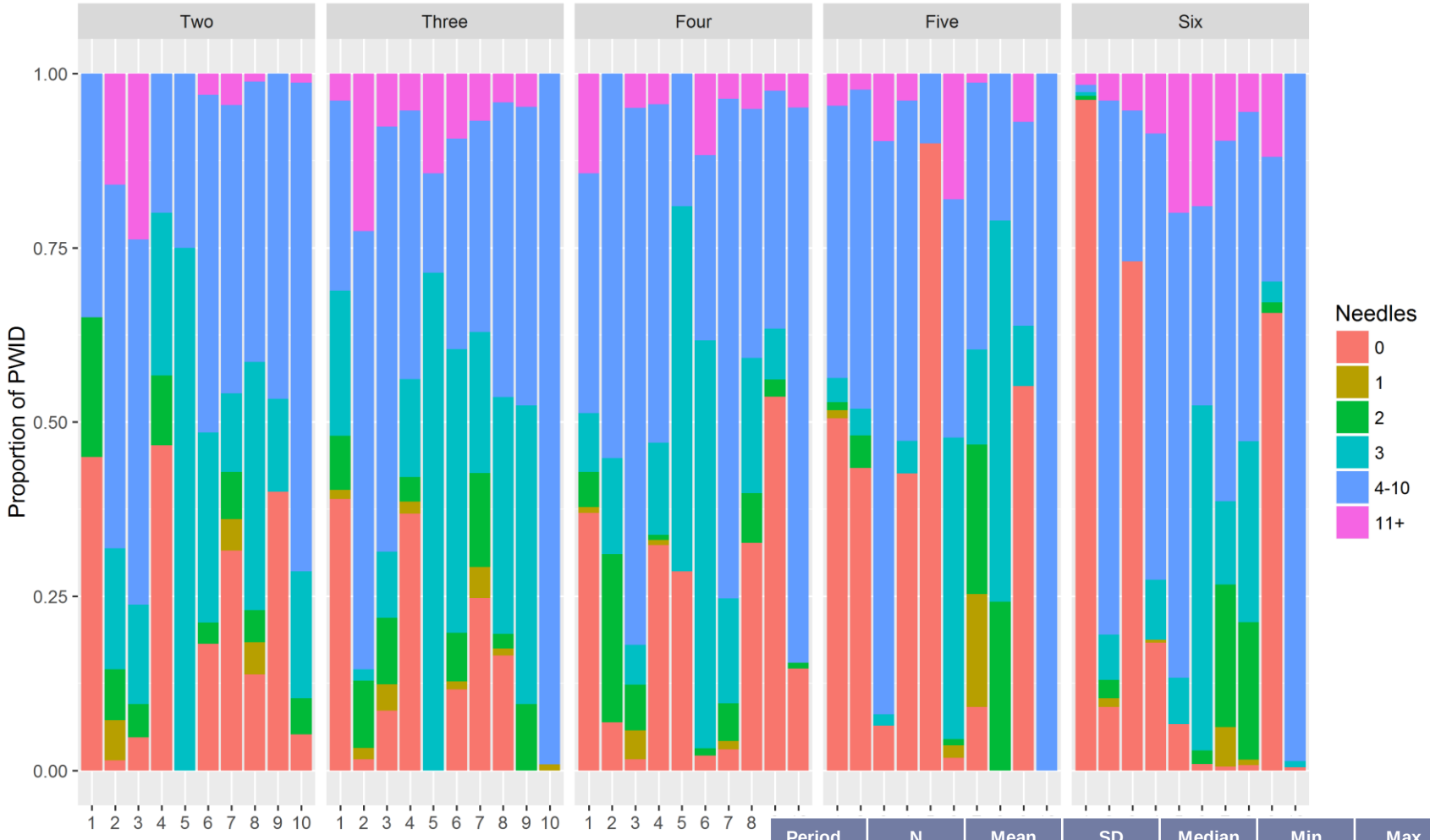

Period	N	Mean	SD	Median	Min	Max
Two	526	4.33	3.73	4	0	30
Three	770	4.97	4.09	5	0	40
Four	948	5.60	4.60	5	0	30
Five	1066	5.62	4.93	5	0	60
Six	1377	5.54	5.87	5	0	100

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Needles/Syringes Per PWID Per Month

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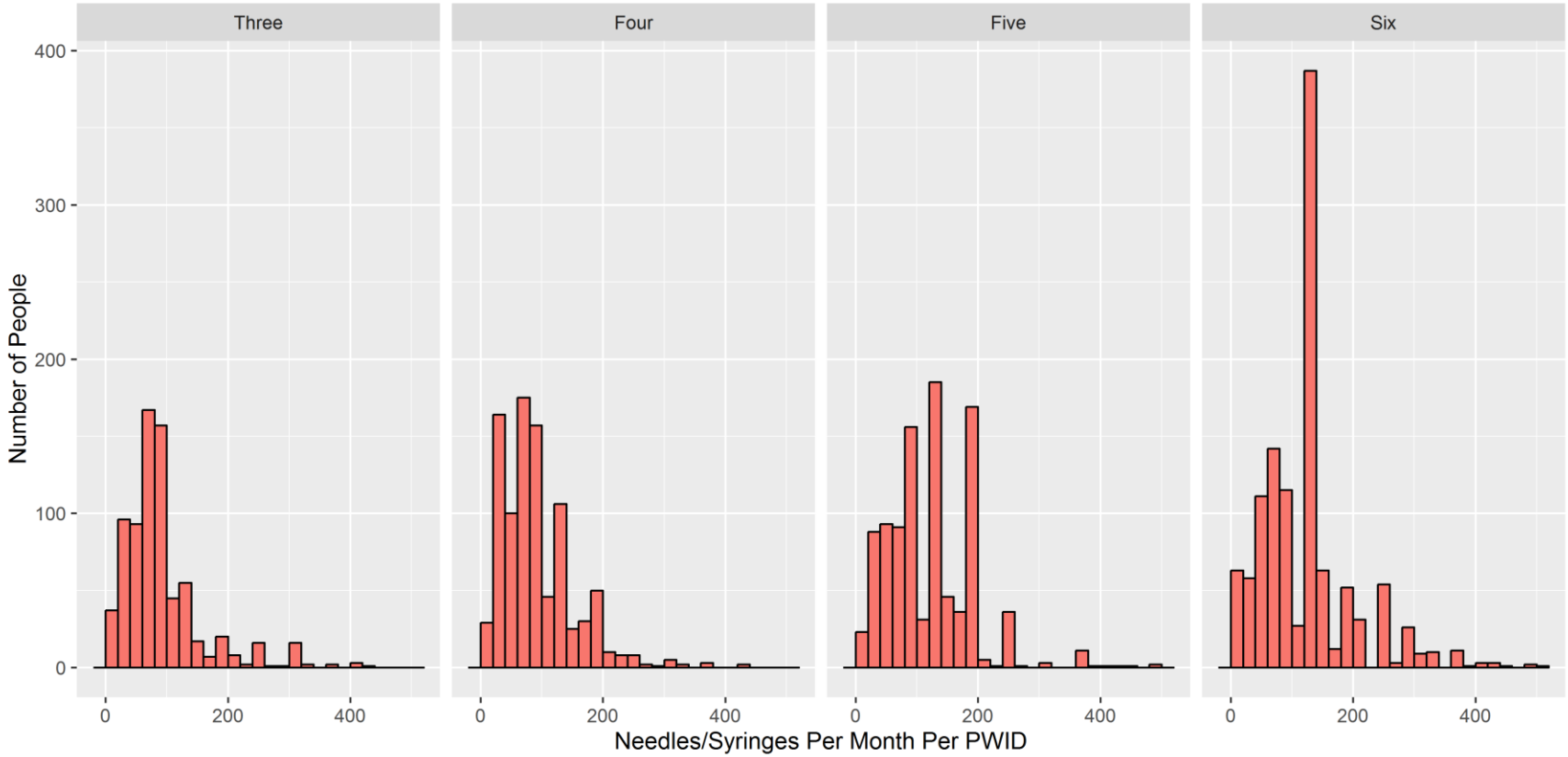

Period	N	Mean	SD	Median	Min	Max
Two	526	62	68	40	0	300
Three	770	85	68	72	0	600
Four	948	90	76	72	0	912
Five	973	119.32	94	120	9	1900
Six	1192	123.26	90	120	0	1200

NSP Program reports mean 1.5-28 per PWID/month)

Clinically Eligible Participants Initiating ART and Retained in Care

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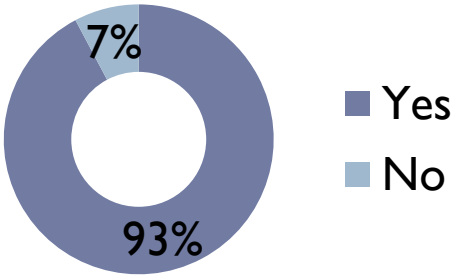
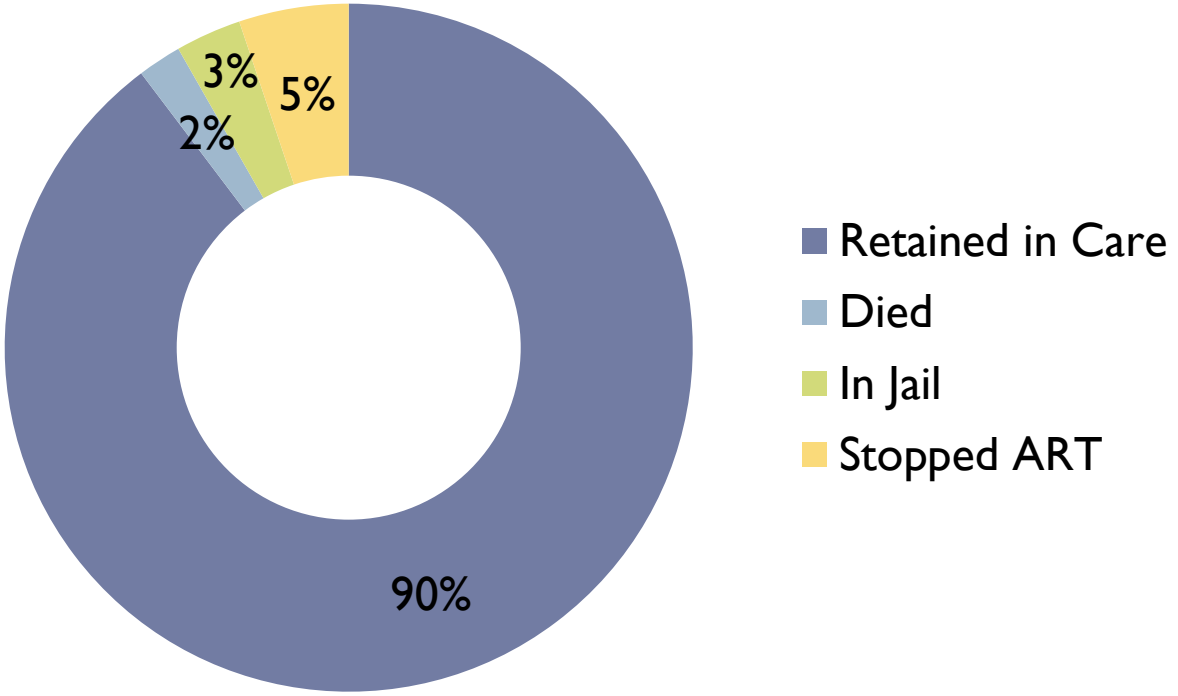
ART Initiation



90% of ART initiators not deceased or in jail retained

Retention



Eligible participants were linked to ART within 24 hours after testing. Initiation of ART took a maximum of 2 week

Western Kenya

- Two sites
- 130 enrolled in the first six weeks
- 98% male
- median age 30 years
- median years injecting 2.5
- Typically 2 injections per day most days of the month
- Receptive syringe sharing at last injection 6.2%
- Current HIV prevalence 8.5%
- 90% of those with HIV infection prescribed ART
- Current HCV antibody+ prevalence 2.3%

What Are We Learning About the PWID Cascade in Kenya

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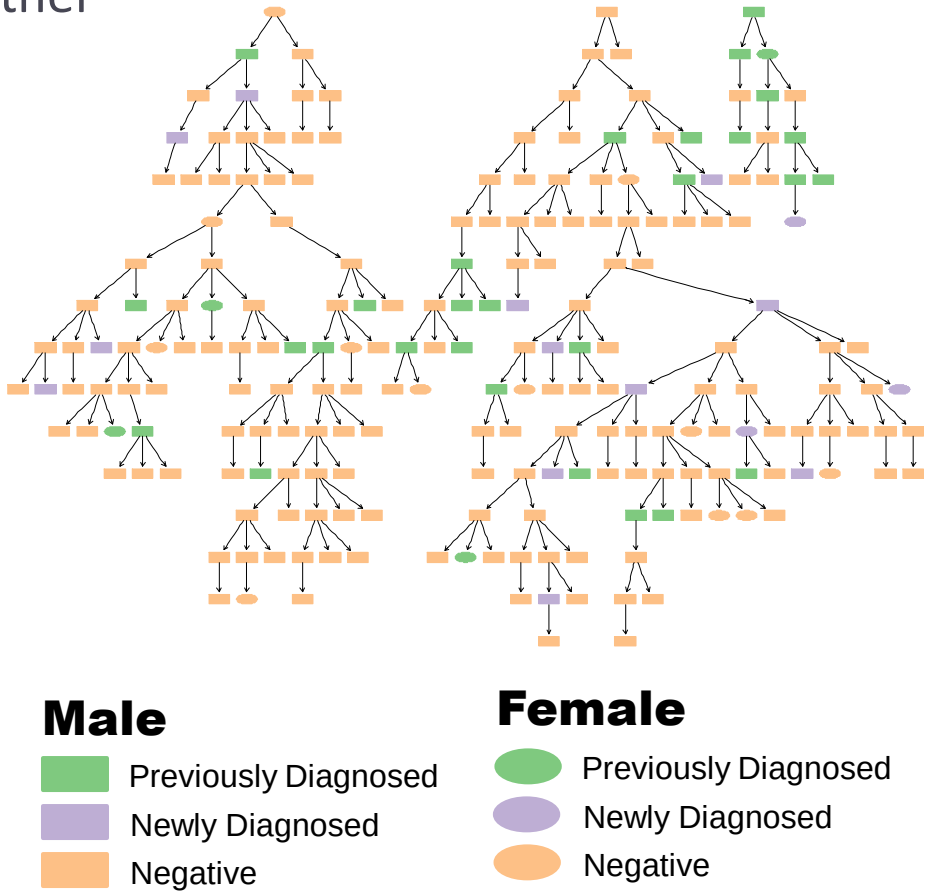
- SEEK - RDS
  - PWID readily able to recruit each other
  - Discordant HIV connected PWIDs
  - Saturation of chains
- TEST- PoC assays are helpful
  - Rapid HIV, CD4
  - Phylogenetics, Rapid HCV
- TREAT - linkage will see
- RETAIN - adherence will see
- SUPPRESS – will see



Conclusion

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- Evaluation of combination interventions using stepped wedge designs among PWID is not easy
  - Requires intensive training, motivated staff, appropriate QA/QC systems, good data management and appropriate leadership
  - BUT is feasible

- Implementation science gives us framework around anticipating and addressing challenges to:
  - Study design
  - Data capture
  - Policy dissemination & impact

Team Members

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- NASCOP/MOH KENYA
  - Peter Cherutich (co-PI)
  - Mercy Nyakowa, Paul Macharia, Daniel Fedha, Janet Muriithi, Emily Juma
  - Research Assistants (RAs)
  - Helgar Musyoki
  - Martin Sirengo
- Expert Advisors, CAB
  - Claris Obiero, Elizabeth Ngugi, Fred Owiti
  - Don Des Jarlais, Steffanie Strathdee
- YALE
  - Ann Kurth (co-PI)
  - John Lizcano
- NYU
  - Chuck Cleland
  - Scott Braithwaite
- NSP Implementers (NGOs), Site Partners, and Collaborating Labs.
- **Thanks to NIH – NIDA**
  - 1R01 DA032080
    - Redonna Chandler
    - Shoshana Kahana
    - Dionne Jones, PO

Implementers & Staff

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PCMs, RA & Participants

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All photos have consent