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Integrated Care Centers for Delivery of HIV Care to Key Populations in India

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August 16, 2018



ELTON JOHN
AIDS FOUNDATION



National Institute of
Allergy and
Infectious Diseases

The First Evidence of AIDS in India



“Evidence for HTLV-III Infection in prostitutes in Tamil Nadu (India)”

Simoes et al. Indian J Med Res 1987; 85:335-8

YRGCARE (1993)

Vision

To prevent new HIV infections and to assist those living with the infection, live with dignity

Mission

To respond to the HIV prevention, care and research needs of the country



YRGCARE – Services offered



YRG CARE ID Laboratory (1994)



YRG CARE ID Laboratory (2016)



Specimen Storage



Microscopy



Hematology



Microbiology



Serology



Biochemistry

YRG CARE ID Laboratory (2016)



BACTEC - TB diagnosis



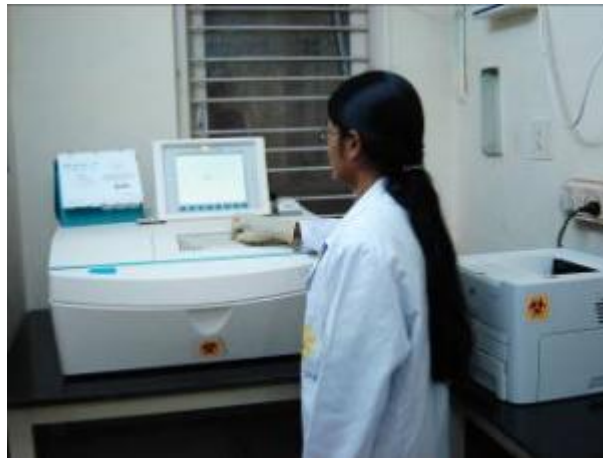
Flow Cytometry



Molecular Biology - Viral load



HIV/HCV PCR



Real-time PCR



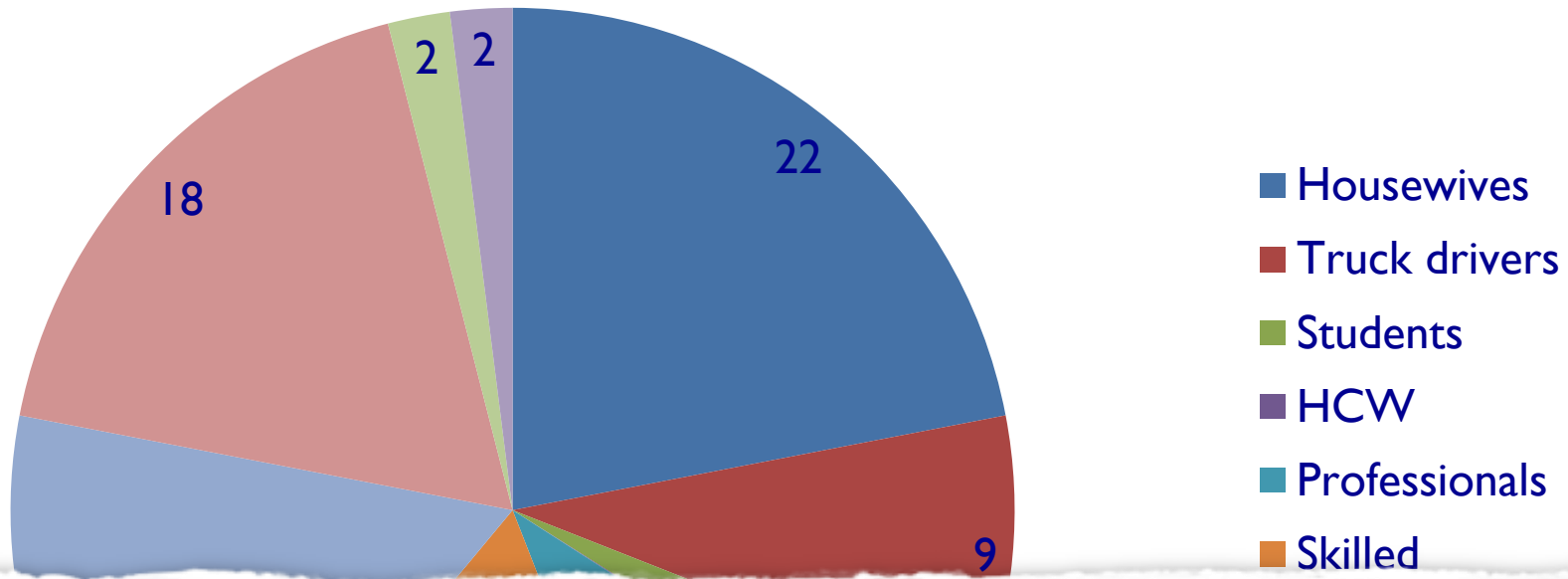
HIV/HCV genotyping

Activities at YRG CARE

- Over 30,000 clients tested for HIV

VCT at YRG CARE

VCT Client Profile



“Marriage, monogamy and HIV: a profile of HIV-infected women in south India”

Newmann et al. *Int J STD AIDS* 2000;11:250-3

Activities at YRGCARE

- Over 30,000 clients tested for HIV
- Over 20,000 patients registered
 - ~6000 patients on ART
 - ~300 children
- Research Portfolio:
 - Clinical trials: ACTG, HPTN, research (NIH/ICMR/DBT) trials
- Arranged Marriages for P



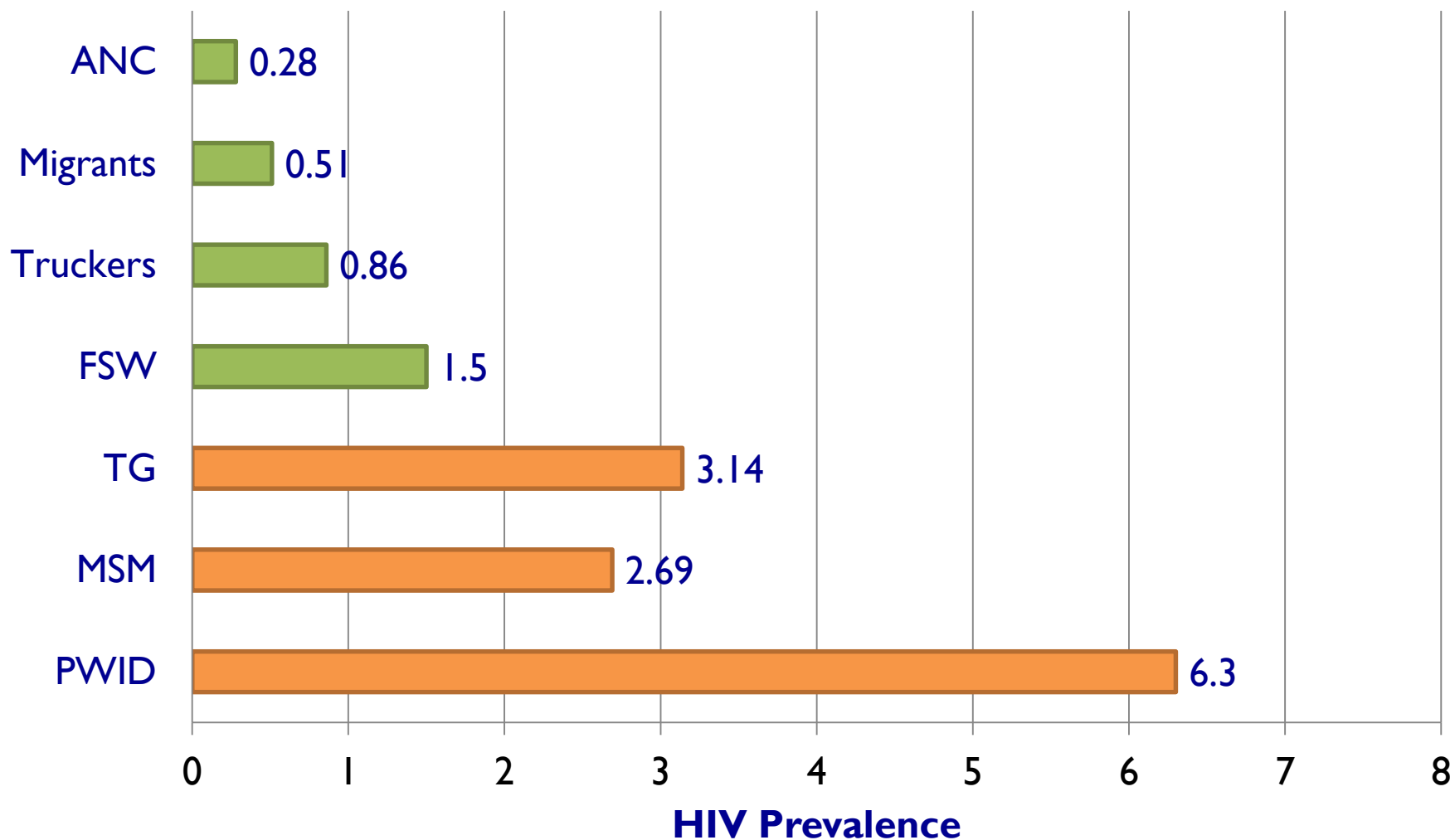
CME workshops at YRG CARE



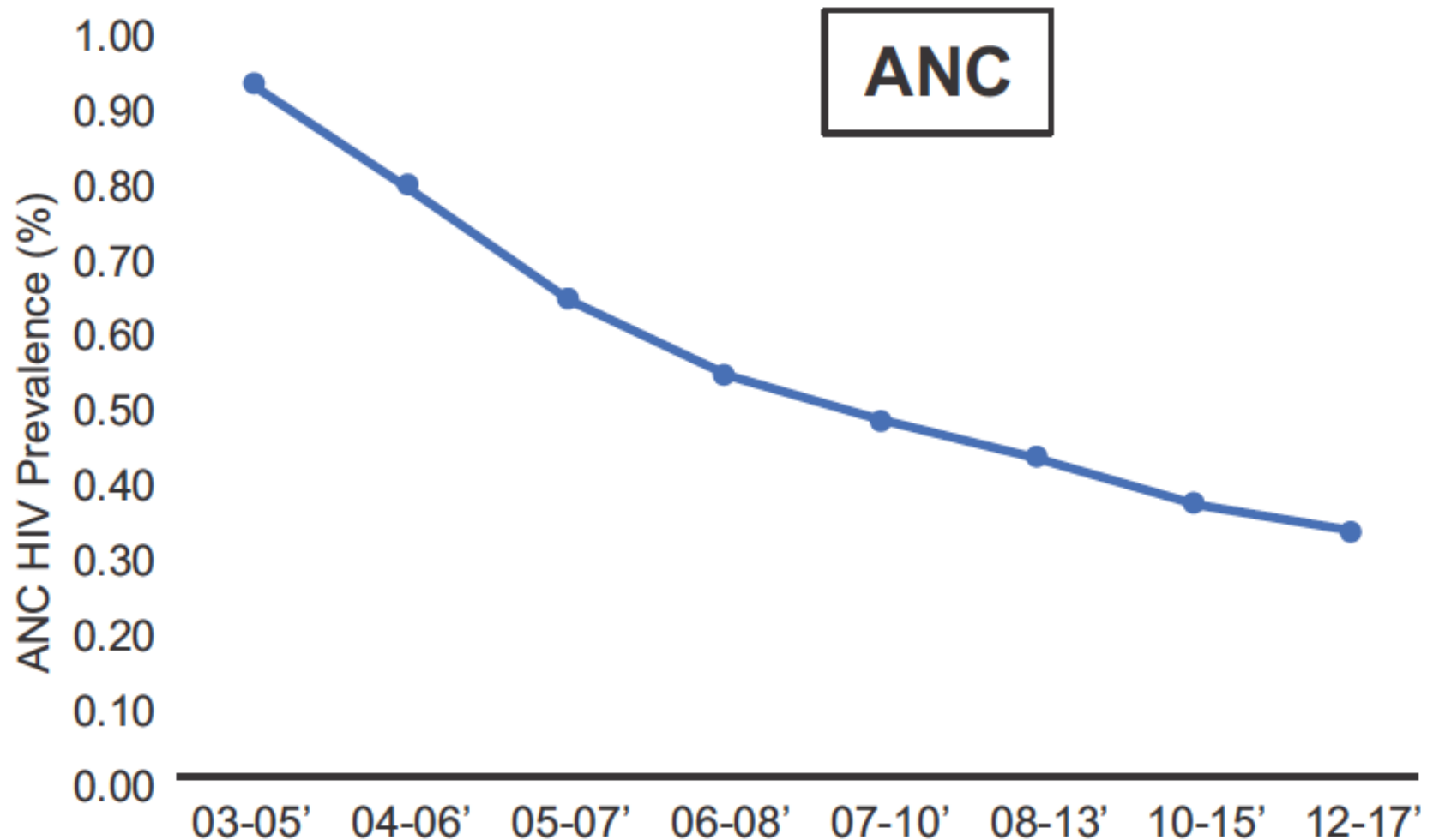
YRG CARE (2013)



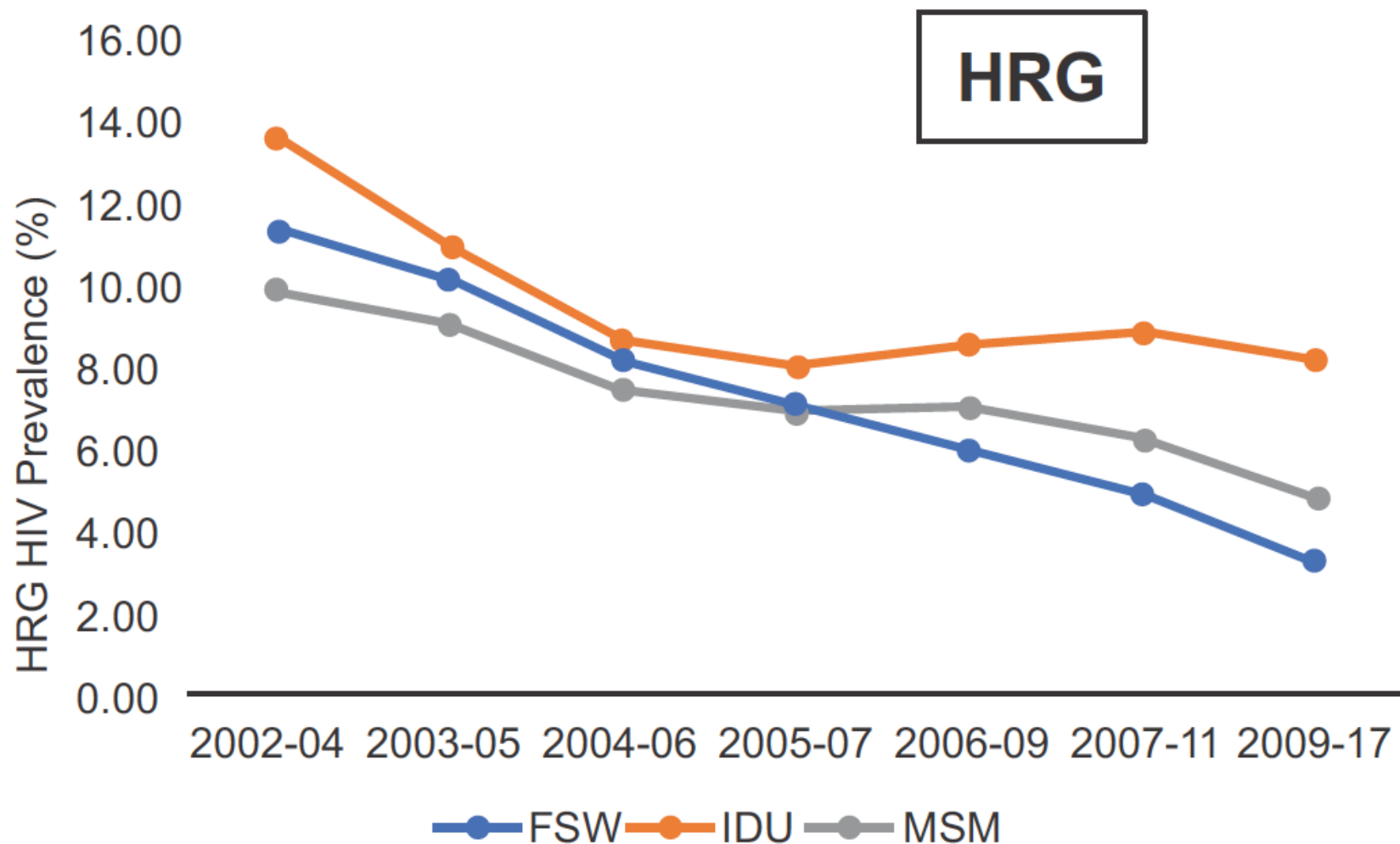
HIV Prevalence in India (2016-17)



HIV in general population



HIV in key populations

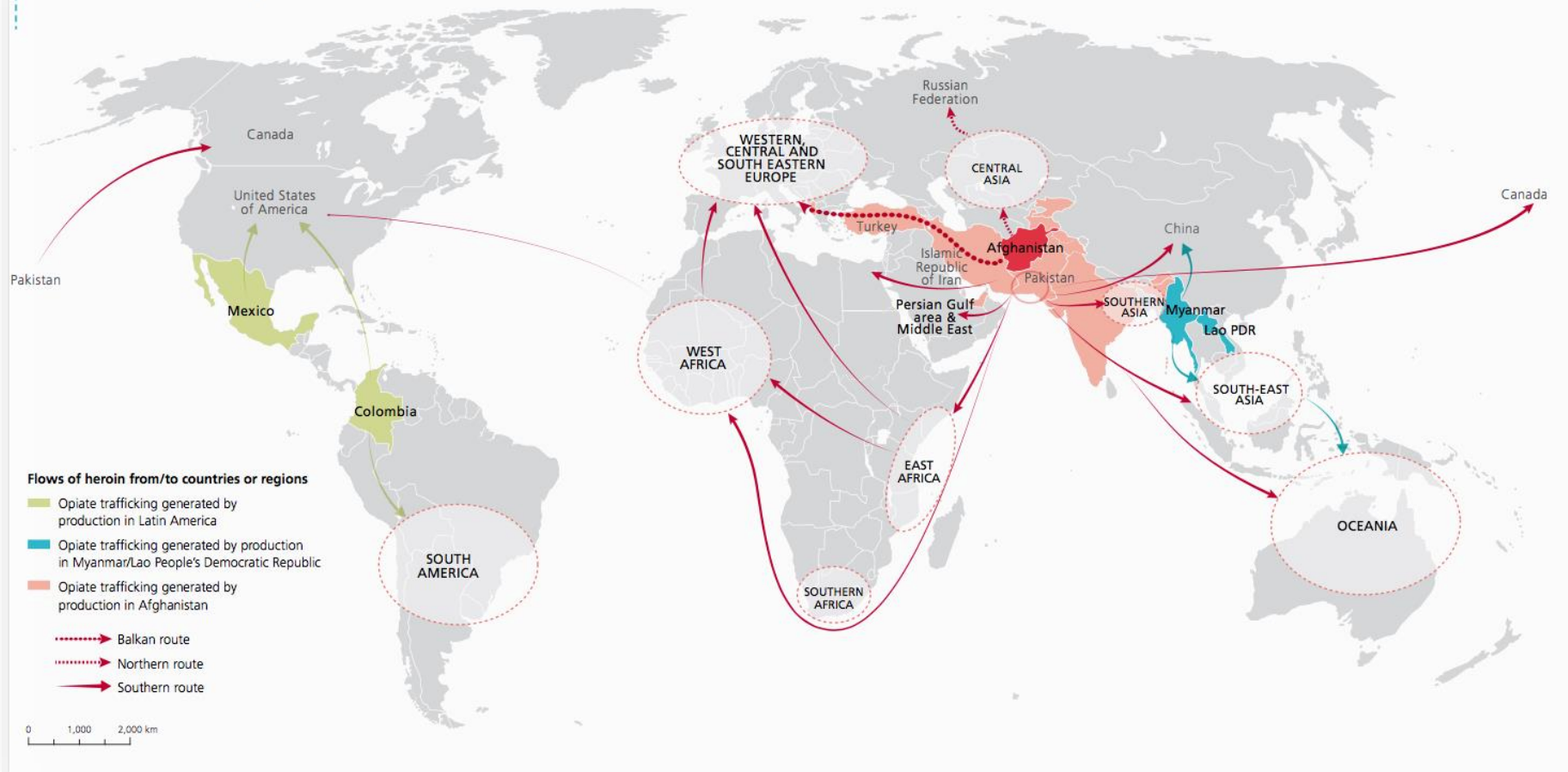


PWID in India

- Globally, India is the largest consumer of opiates

Injection Drug Use & India

Main trafficking flows of heroin



PWID in India

- Globally, India is the largest consumer of opiates
- Geographic distribution of PWID epidemics
 - Oldest epidemics in the Northeast (NE)
 - Emerging epidemics in the North
- Historically, PWID have had poor service access
 - Among 2075 IDUs in Manipur, Nagaland & Maharashtra
 - 6-25% had ever had an HIV test
 - 2-32% had heard of ART
- Stigma, discrimination and harassment common
- Fragmented service delivery

MSM in India

- ~2.3 million high risk MSM in India

Section 377 of IPC

Chapter XVI, Section 377 (1860)

“Unnatural offenses: Whoever voluntarily has carnal intercourse against the order of nature with any man, woman or animal, shall be punished with imprisonment for life, or with imprisonment of either description for term which may extend to ten years, and shall also be liable to fine.”

MSM in India

- ~2.3 million high risk MSM in India
- Estimates of same-sex behavior prevalence as high as 10%
- Historically, MSM have had poor access to services
 - Among 4597 MSM from AP, MH, TN and KN
 - 13-50% had ever had an HIV test
 - 6-18% had ever heard of ART
- Stigma, discrimination and harassment common
- Fragmented service delivery

Research Question

“Can the provision of essential services for HIV prevention/treatment under a single roof in a stigma-free environment improve service utilization among disenfranchised populations (MSM/PWID) in the Indian setting?”

Study Overview: The NCA Study

- **Cluster randomized trial:**
 - Intervention nested between two serial cross-sectional samples of the community
 - ClinicalTrials.gov identifier: NCT01686750
- **Primary objective of trial:**
 - Impact of integrated delivery of HIV prevention and treatment services in a non-discriminatory setting on uptake of HIV testing among PWID and MSM in India

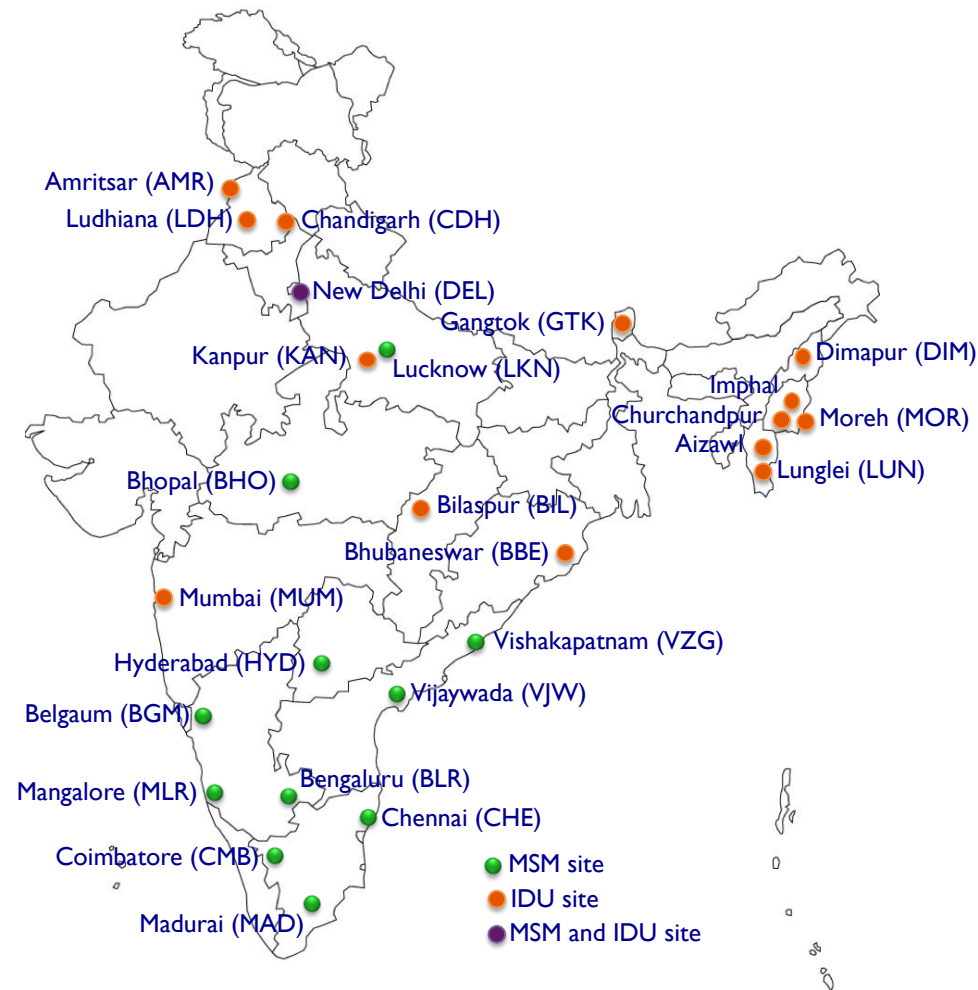
Study Design

Baseline
assessment in 27
sites

2012 (Q3) - 2013

Baseline assessment

- 27 sites in 26 cities were selected



Baseline assessment

- 27 sites in 26 cities were selected
- In each city, RDS was used to recruit ~1000 PWID/MSM
- RDS is a chain-referral strategy to recruit hard-to-reach populations
- Initiated by “seeds”
- Each seed and recruit given 2 coupons
- Study Procedures:
 - Informed consent
 - Biometric capture (to identify duplicates/contamination)
 - Electronic interviewer-administered survey
 - Blood draw
 - Rapid HIV testing on site
 - HCV antibody and HCV RNA on stored plasma specimens
 - Provide referral coupons to recruit peers

Eligibility Criteria

- Inclusion Criteria:
 1. Age > 18 years
 2. Not a duplicate by biometric verification
 3. Provides informed consent
 4. Has a valid RDS coupon unless “seed”
 5. **PWID**: Self-report of injection drug use (drugs for recreational purposes) in prior 24 months
 6. **MSM**: Self-identify as male AND report sex with another man in the prior year
- Exclusion criteria:
 1. Psychologically unfit to provide consent

RDS in Kanpur

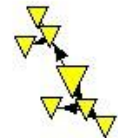
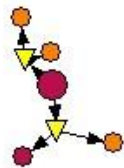
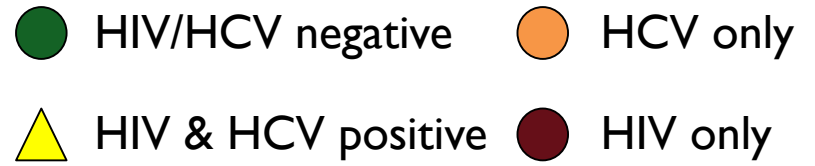


RDS in Kanpur

- HIV/HCV negative
- HCV only
- ▲ HIV & HCV positive
- HIV only

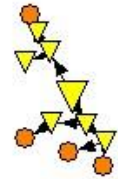
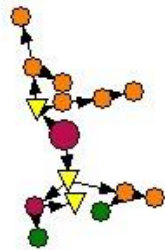


RDS in Kanpur

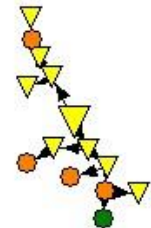
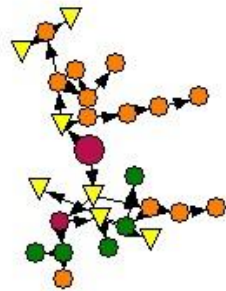
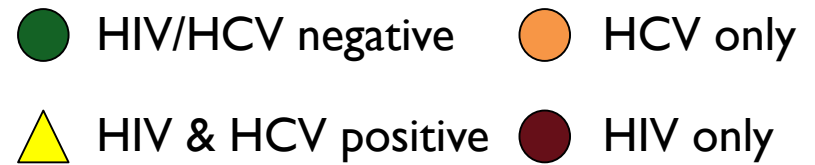


RDS in Kanpur

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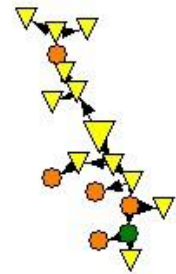
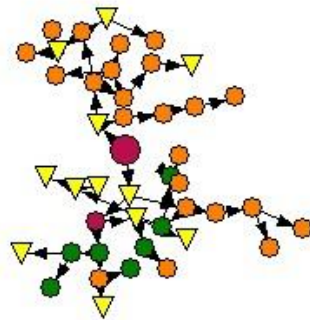


RDS in Kanpur



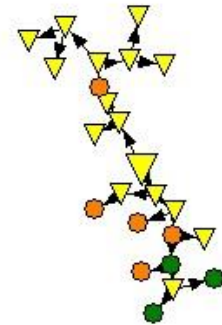
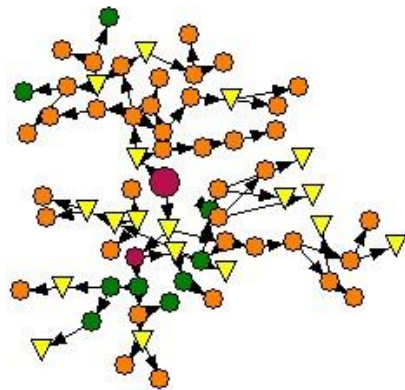
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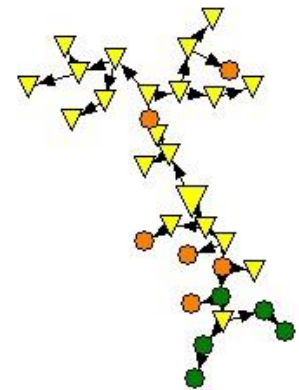
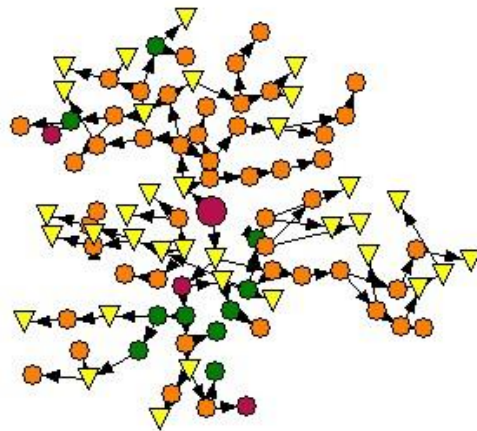
RDS in Kanpur

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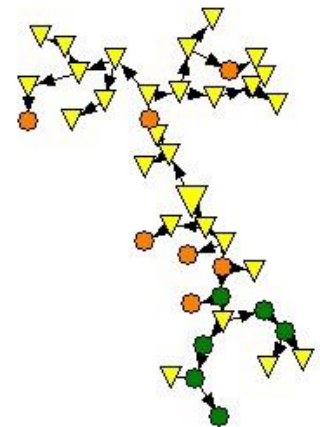
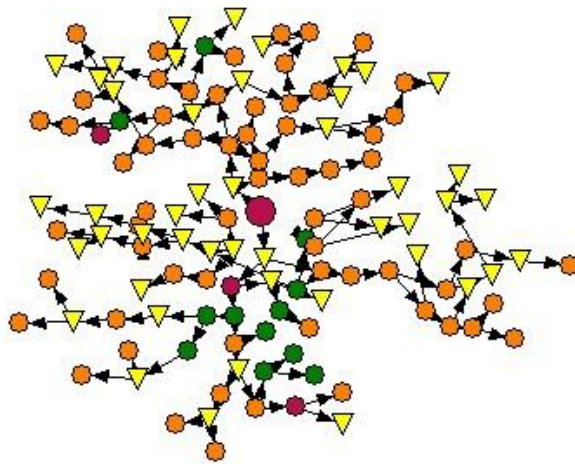
RDS in Kanpur

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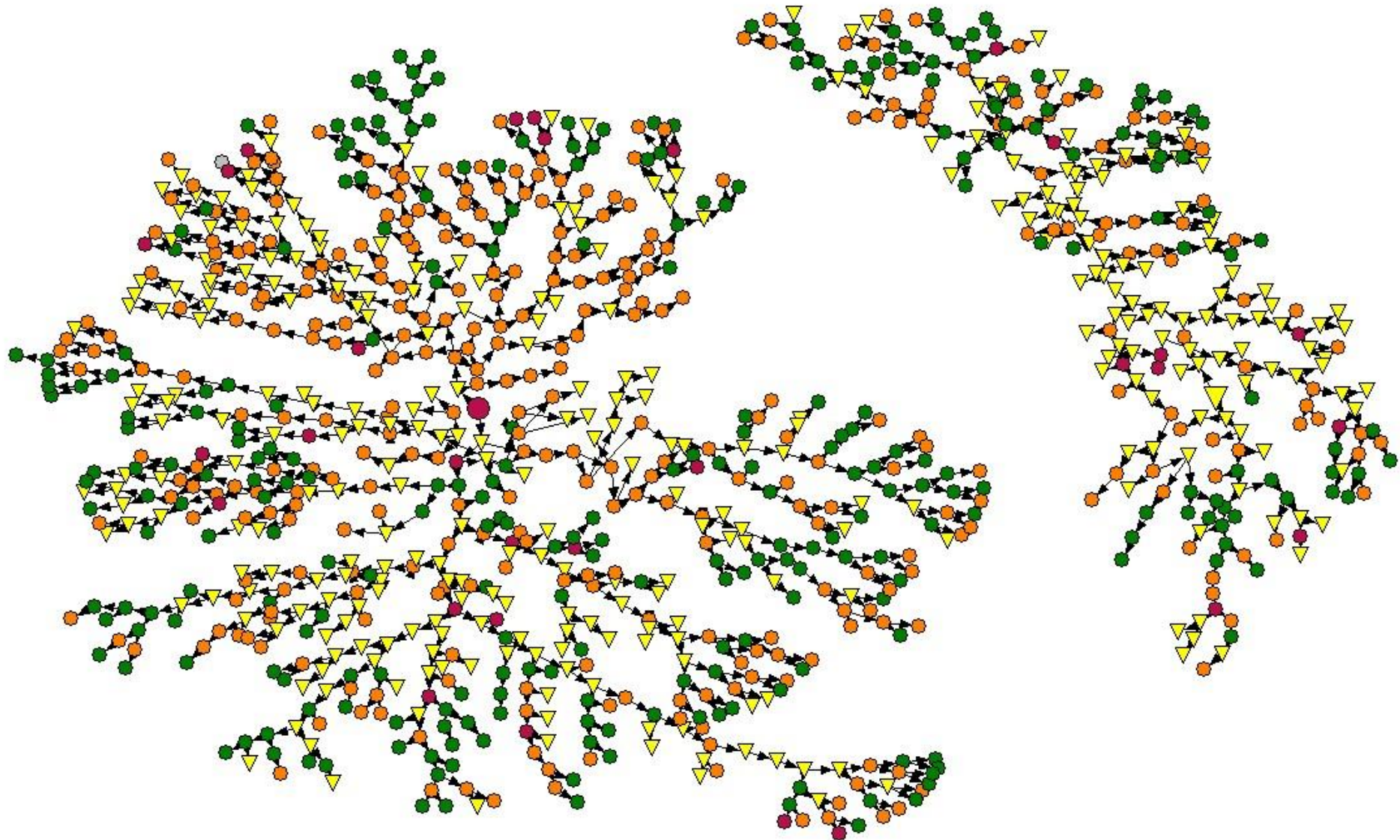
RDS in Kanpur

- HIV/HCV negative
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- HIV only

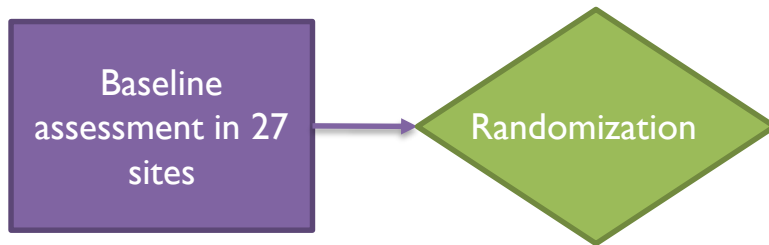


RDS in Kanpur

- HIV/HCV negative
- HCV only
- ▲ HIV & HCV positive
- HIV only



Study Design



Characteristics of PWID

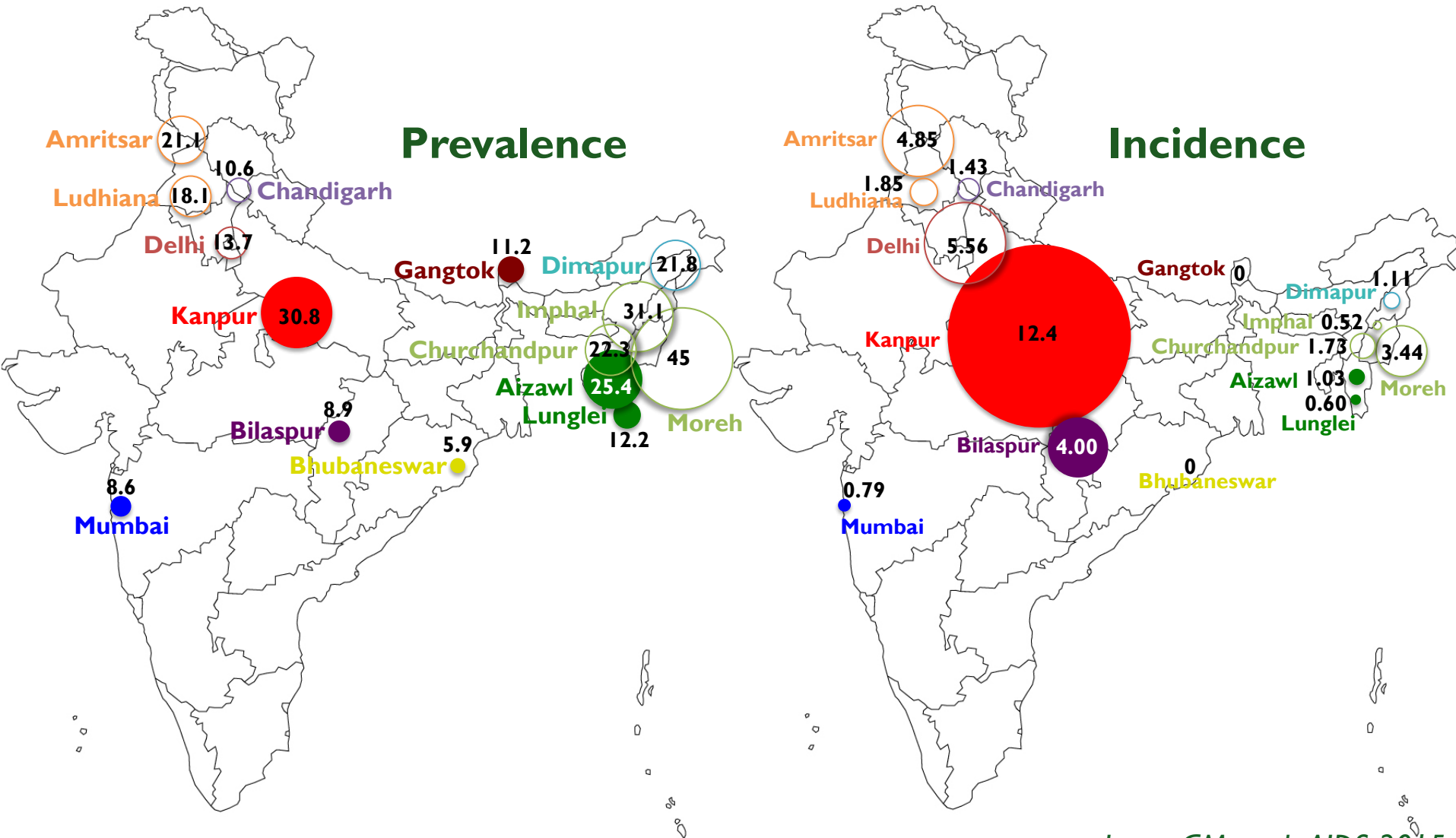
	Imphal, MN	Amritsar, PB	Kanpur, UP
Median age	34	27	34
Female	12%	1%	0.7%
≥High school education	33%	13%	9%
Married	56%	48%	41%
Injected*			
Heroin	98%	35%	15%
Buprenorphine	0.3%	65%	67%
Other pharmaceutical drugs	1%	7%	43%
Shared needle*	71%	40%	69%
Needle exchange*	15%	34%	6%
Opioid substitution*	15%	37%	2%

*Past six months

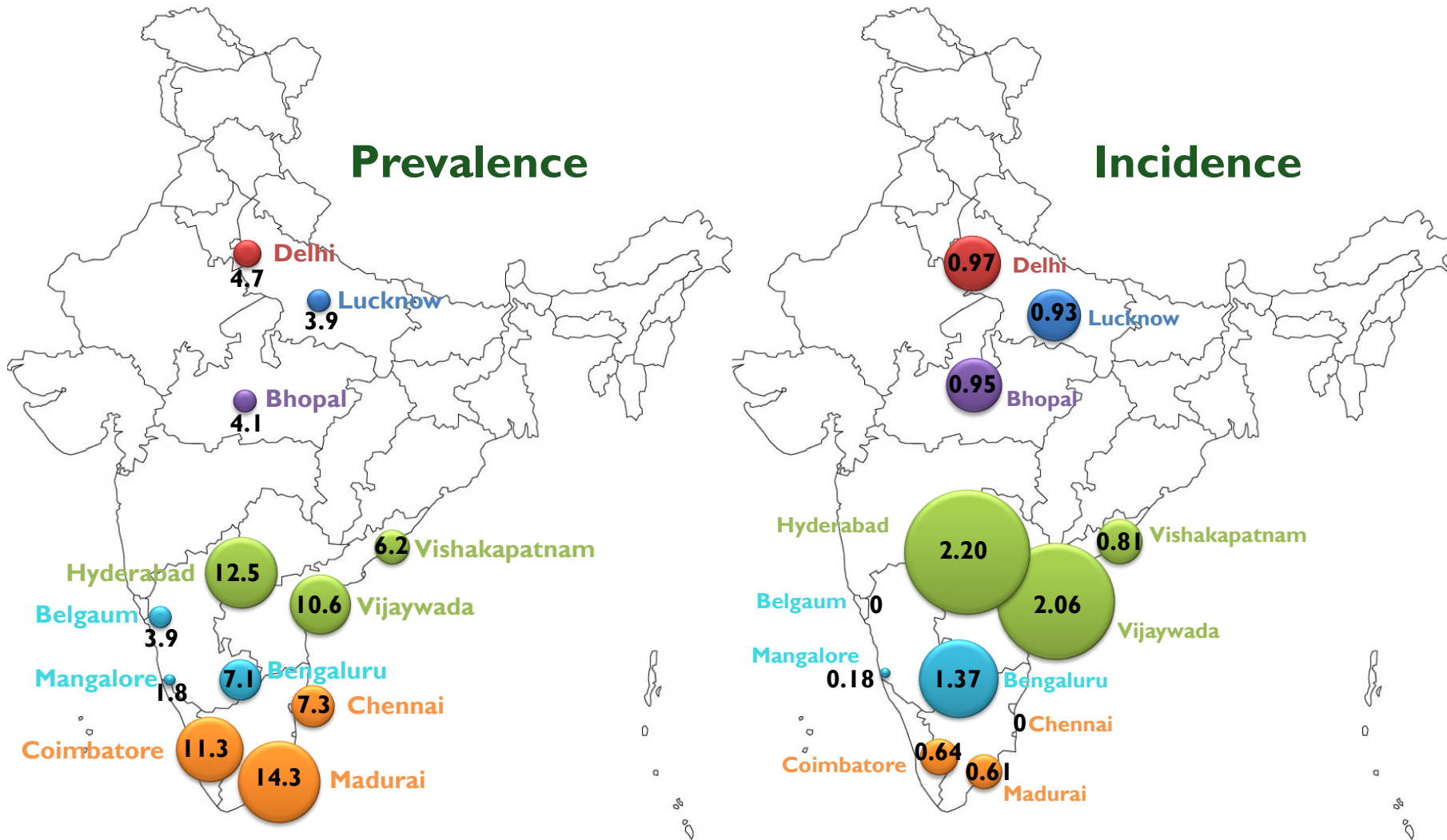
Characteristics of MSM

	Vijayawada,AP	Bangalore,KT	Chennai,TN	Delhi
Median age	27	29	25	22
Sexual identity				
Kothi	15%	12%	14%	13%
Panthi	52%	17%	23%	69%
Double-decker	21%	23%	16%	8%
Gay/MSM	<1%	4%	44%	1%
Married	37%	32%	21%	24%
Median lifetime male partners	20	10	12	5
Unprotected sex with a man last six months	47%	37%	46%	58%
History of sex work	33%	9%	12%	11%

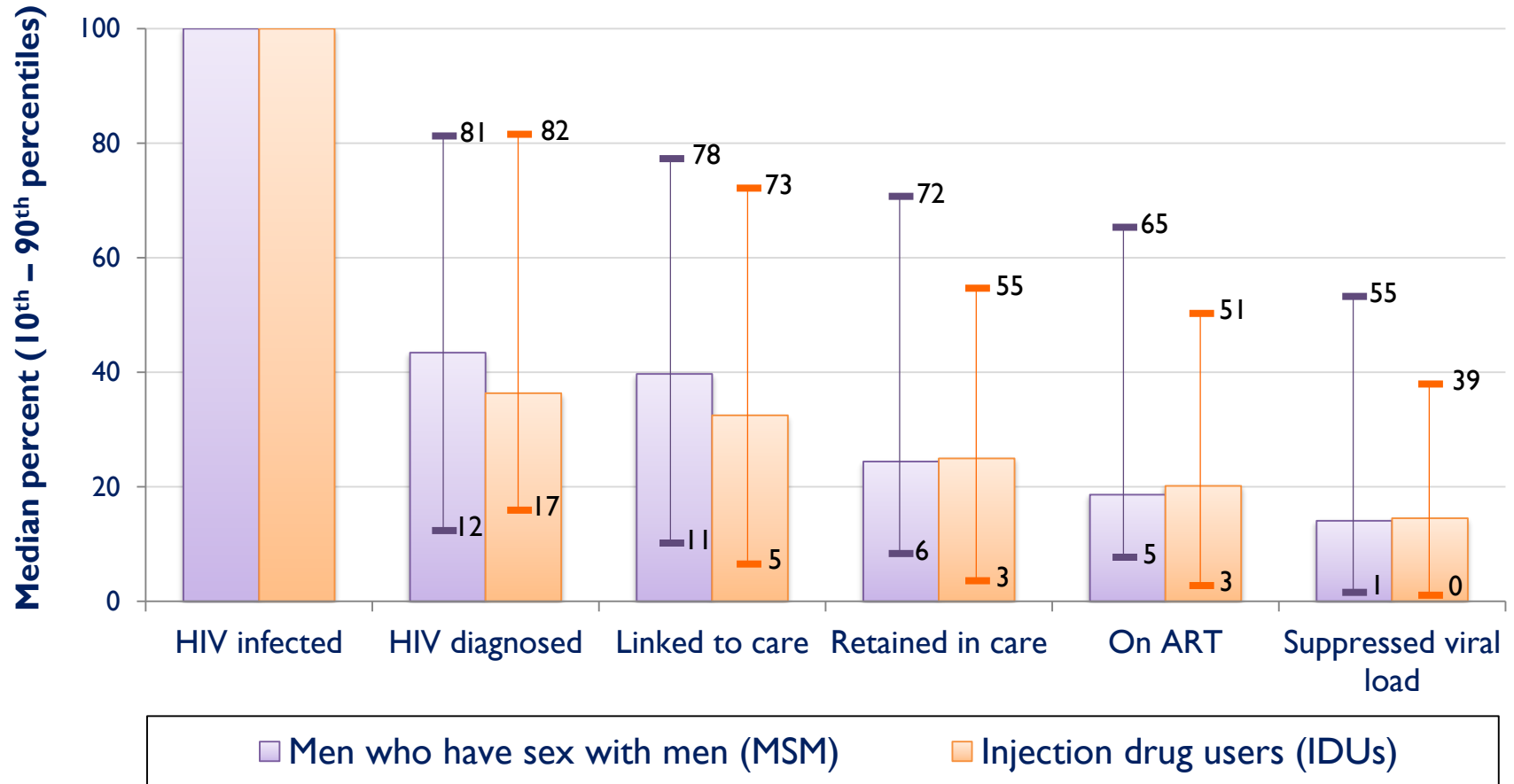
HIV prevalence and incidence among PWID in India (n=14,481)



HIV prevalence and incidence among MSM in India (n=12,022)



HIV care continuum

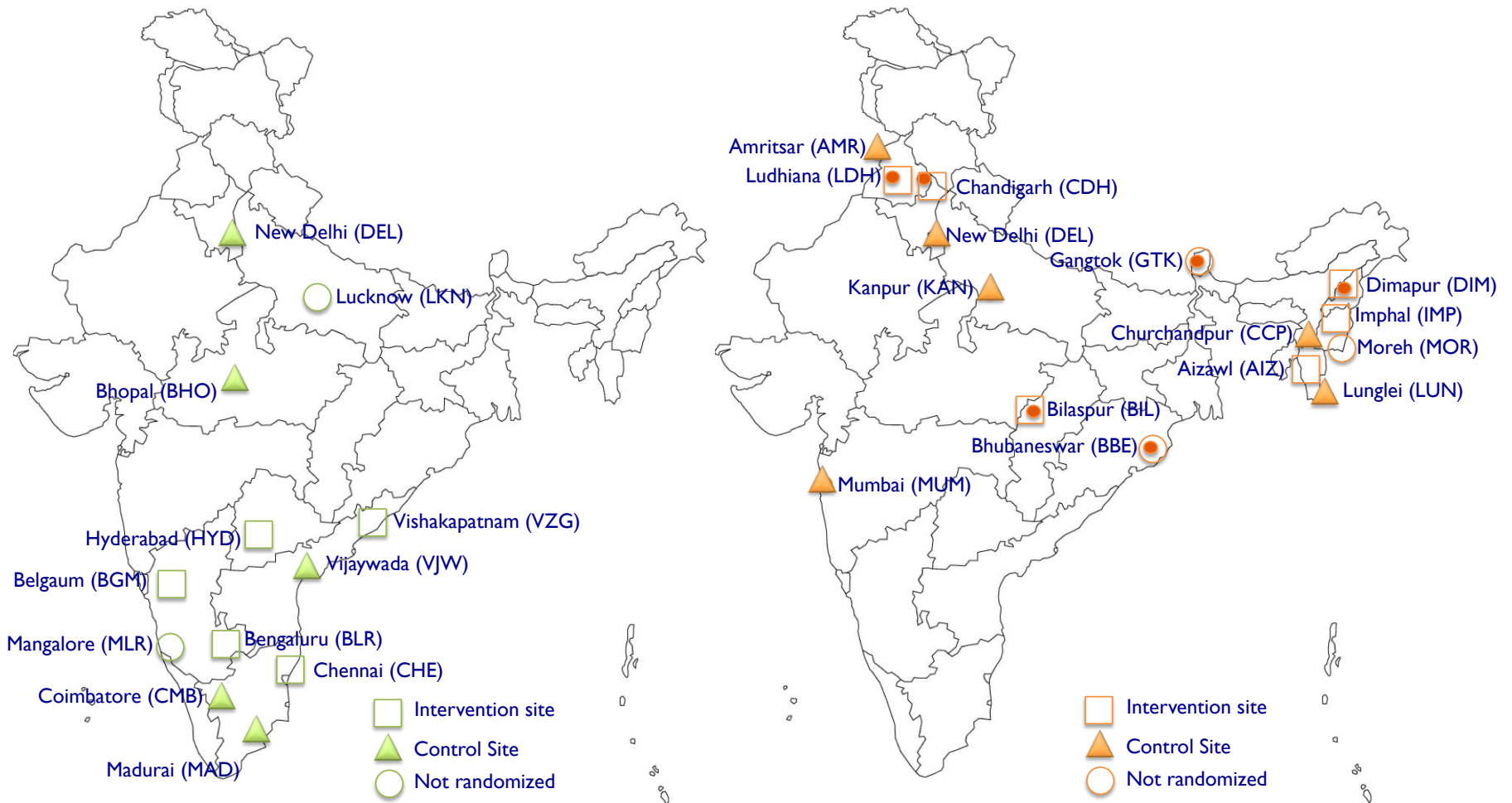


HIV+ MSM: n = 1146; HIV+ PWID: n = 2906

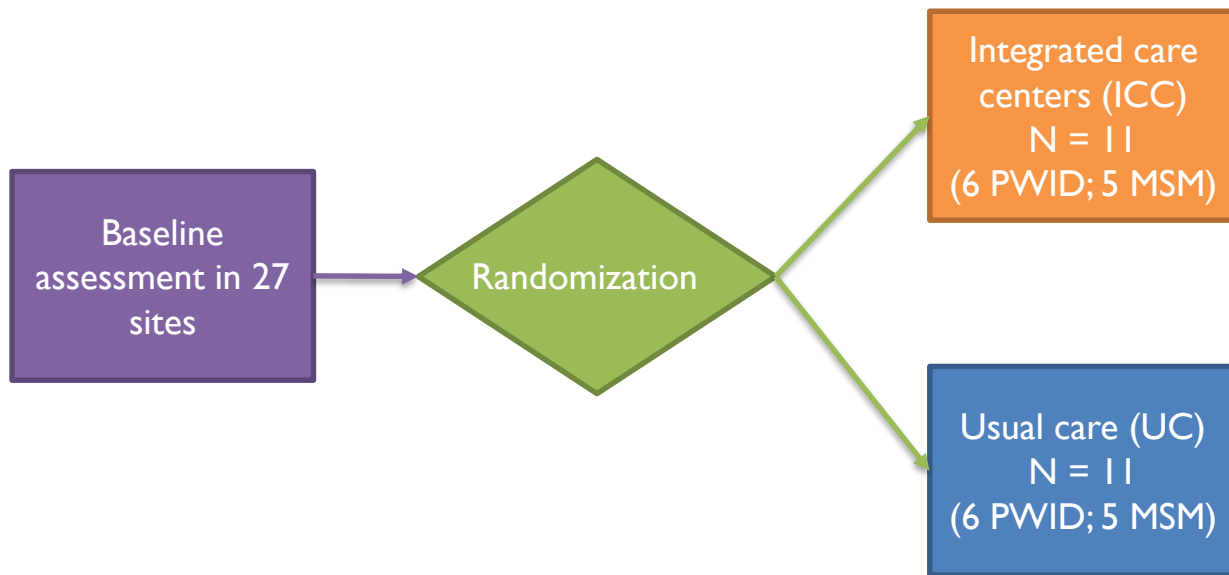
Randomization

- Stratified restricted randomization was used to distribute sites between ICC and UC at 1:1 allocation ratio across 22 sites
- Stratification:
 - MSM vs. PWID
- Restrictions:
 - Recent HIV testing at baseline < 5%
 - HIV Prevalence < 2%
 - Geographical restrictions:
 - No more than 3 ICCs in the Northeastern states
- HIV prevalence and geography to account for stage of epidemic

Randomization



Study Design



Integrated Care Centre (PWID)



TB Testing & Treatment

- Sputum collected on site but tested in govt center
- TB drugs from DOTS program dispensed on-site

Needle exchange

Field-based & on-site

STI syndromic management

Government sponsored

General medical care:

Glucose screening, blood pressure monitoring, doctor available for general health problems

HCT: rapid testing performed on-site; positive results confirmed at govt center



ART: delivered through a link model (ARVs provided by government but peer health worker picks up meds so clients can receive directly from ICC)

STAFF:

- 1 site coordinator
- 2 nurses (OST, STI Treatment, TB screening & treatment)
- 1 doctor (general medical care, HIV care, ARV prescription)
- 2 counselors
- Multiple outreach workers

Opiate substitution
(delivered either in Government hospital or NGO)

Condoms

Counseling: Individual & group/ substance use, alcohol, adherence, couples, family etc

Integrated Care Centre (MSM)



TB Testing & Treatment

- Sputum collected on site but tested in govt center
- TB drugs from DOTS program dispensed on-site

NSEP/OST

If needed

STI syndromic management

Government sponsored

HCT: rapid testing performed on-site; positive results confirmed at government center



ART: delivered through a link model (ARVs provided by government but peer health worker picks up meds so clients can receive directly from ICC)

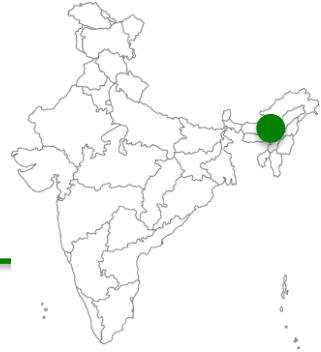
General medical care:

Glucose screening, blood pressure monitoring, doctor available for general health problems

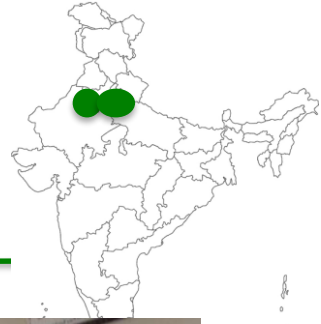
Condoms

Counseling: Individual & group on substance use, alcohol, adherence, couples, family, etc.

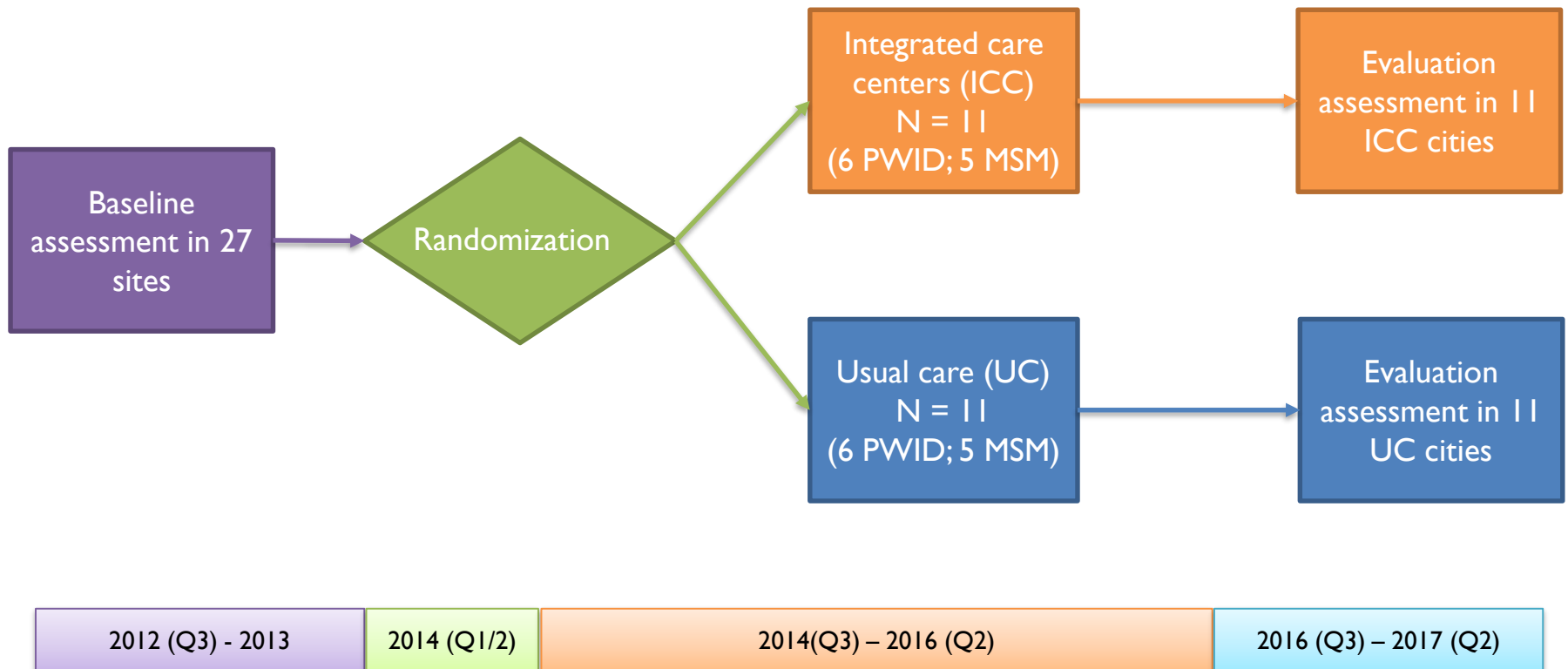
ICC in Imphal, Manipur (NGO-based)



ICCs in Chandigarh and Ludhiana (Government-based)



Study Design



Evaluation assessment

- Samples of 1000 PWID/MSM recruited in each of the 22 study communities (11 ICC and 11 UC) using RDS
- RDS was conducted from the same site as baseline or nearby (same area) if baseline site was unavailable
- Same “seeds” as baseline were used or similar if the “seeds” from baseline were not available
- Eligibility criteria identical to baseline
- Study procedures and survey identical to baseline

Study outcomes

- Primary outcome:
 - Self reported recent HCT (past 12 months) at the community-level
- Secondary outcomes:
 - Care continuum outcomes
 - Prevalence of viremia
 - Cross-sectional HIV incidence
 - Risk behaviors (UAI, needle sharing, etc)
 - Stigma

Statistical Methods

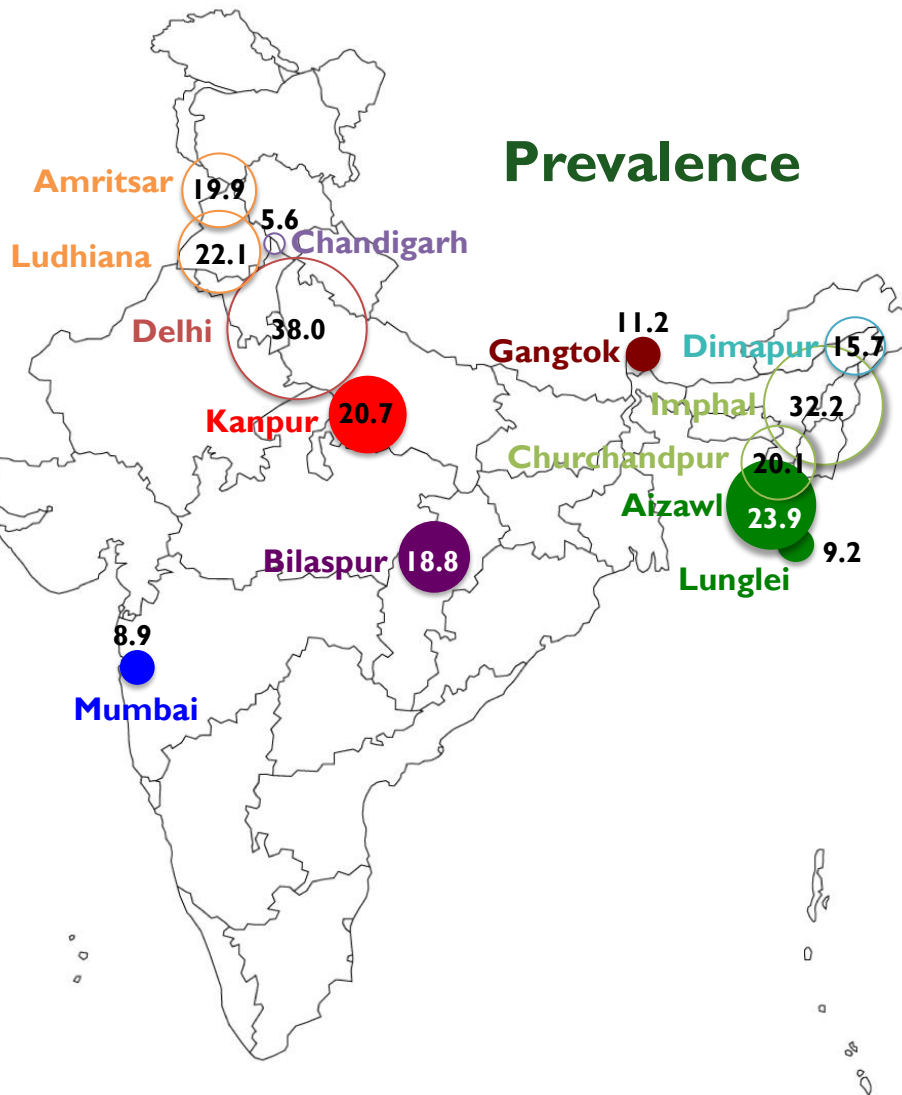
- Analyses incorporated RDS2 weights and excluded “seeds”
- Primary analyses estimated cluster-level prevalence ratios (PR) for ICC vs. UC at evaluation adjusted for baseline
- Pre-specified analyses:
 - Unweighted analyses
 - Individual-level restricted to ICC sites only comparing those who did and did not use ICC
 - Individual-level with random intercepts for site and arm (ICC vs. UC)
- Post-hoc analyses:
 - Interaction between penetration of ICC and recent HCT at community-level

Demographic (Evaluation assessment)

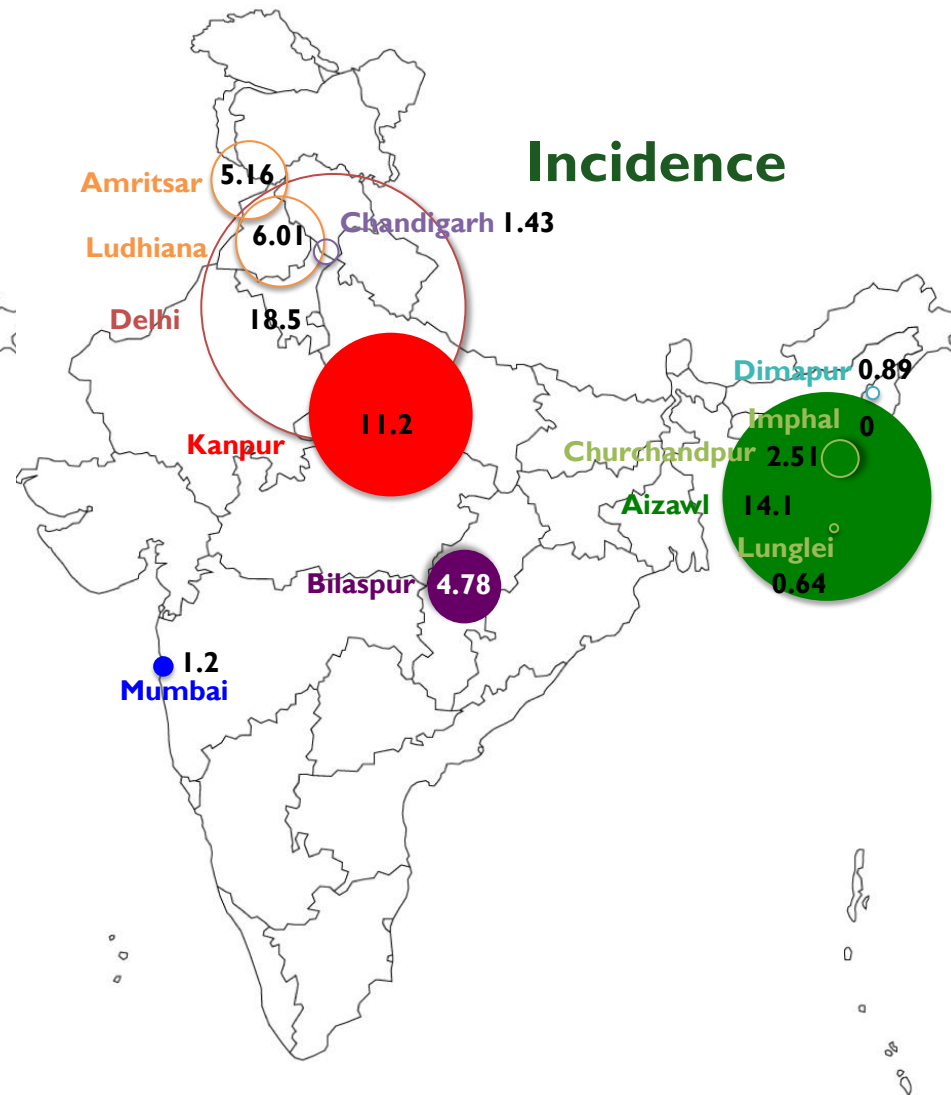
	PWID		MSM	
	UC	ICC	UC	ICC
Median age in years	29 (26 – 36)	28 (26 – 36)	28 (26 – 30)	31 (23 – 32)
Proportion male, (%)	98 (78 – 99)	98 (85 – 99)	100	100
Currently married, (%)	35 (27 – 49)	47 (28 – 63)	43 (33 – 67)	46 (36 – 87)
At least secondary-level education, (%)	51 (36 – 98)	74 (60 – 94)	84 (68 – 89)	84 (77 – 87)
Median number of male partners in past 6 months	--	--	1 (1 – 5)	1 (0 – 3)
Unprotected sex with a man in the past 6 months, (%)	--	--	57 (38 – 69)	32 (17 – 61)
Injected in the past 6 months, (%)	95 (58 – 98)	78 (27 – 90)	0.4 (0 – 5)	0.3 (0.1 – 0.5)
Type of drug ever injected, (%)				
- Heroin	77 (19 – 100)	63 (2 – 100)	--	--
- Buprenorphine/pharmaceuticals	82 (33 – 99)	75 (20 – 100)		
Shared injection equipment in past 6 months	34 (7 – 57)	28 (2 – 52)	--	--

HIV prevalence and incidence among PWID in India (n=11,745)

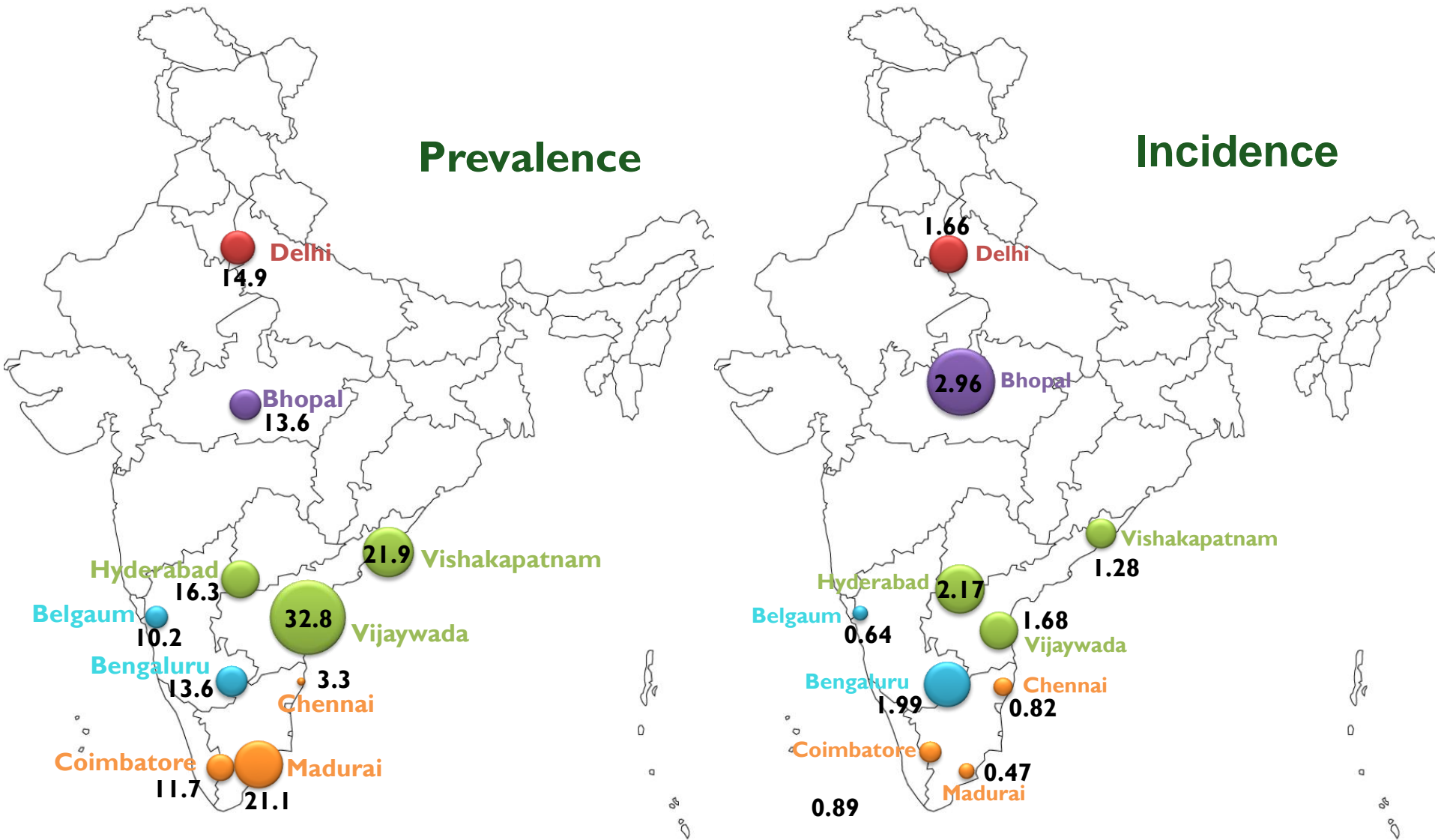
Prevalence



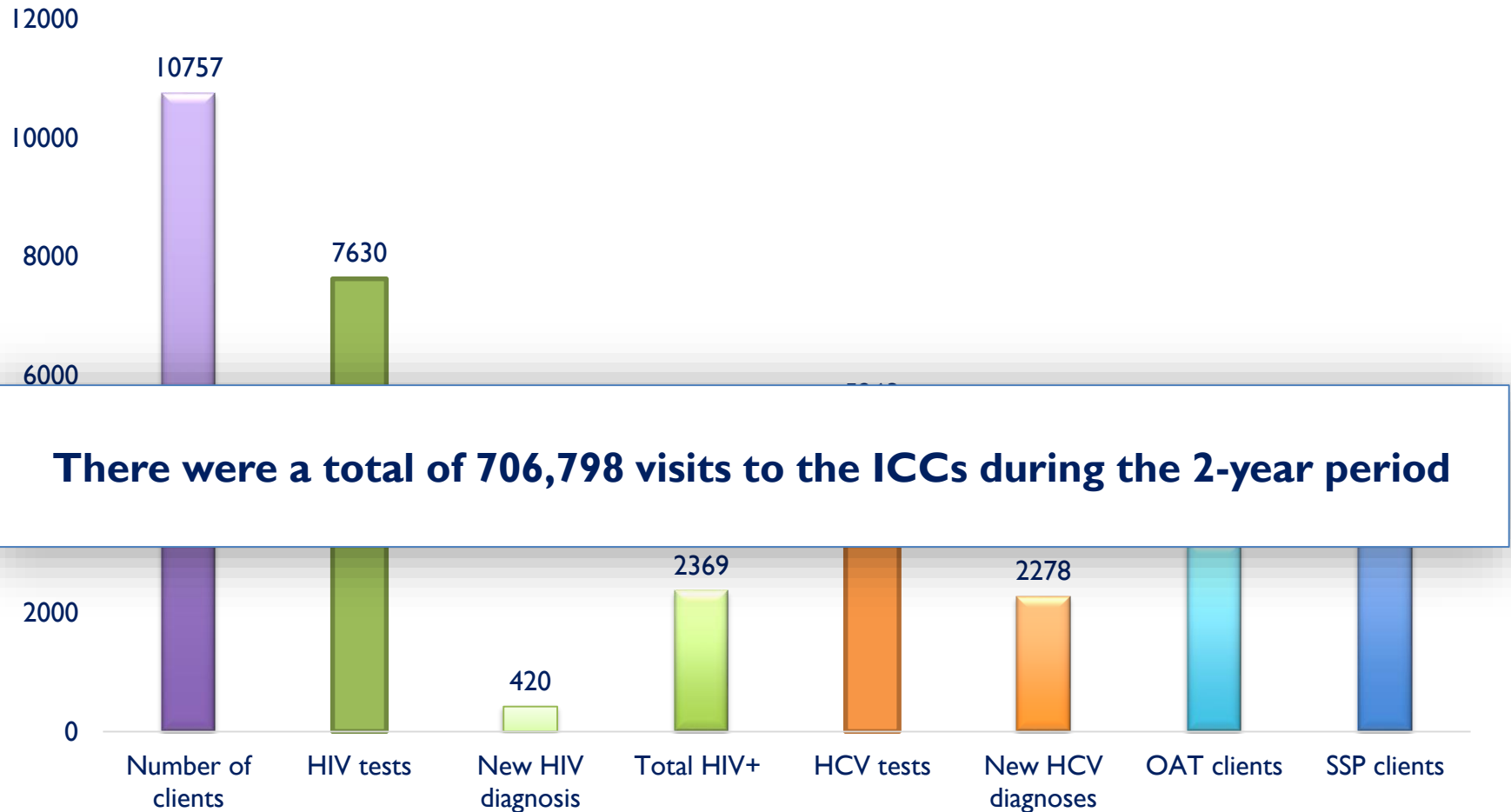
Incidence



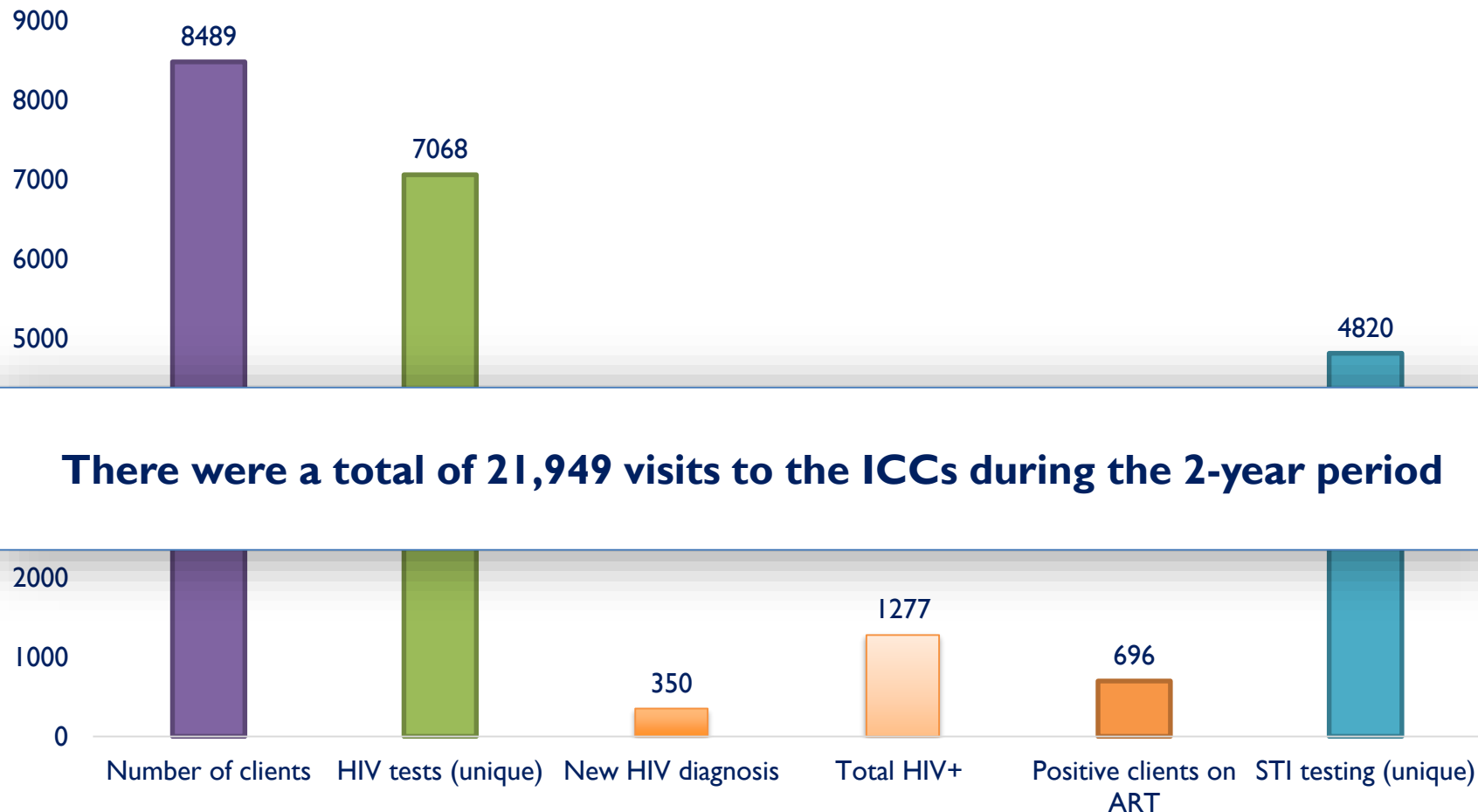
HIV prevalence and incidence among MSM in India (n=10,025)



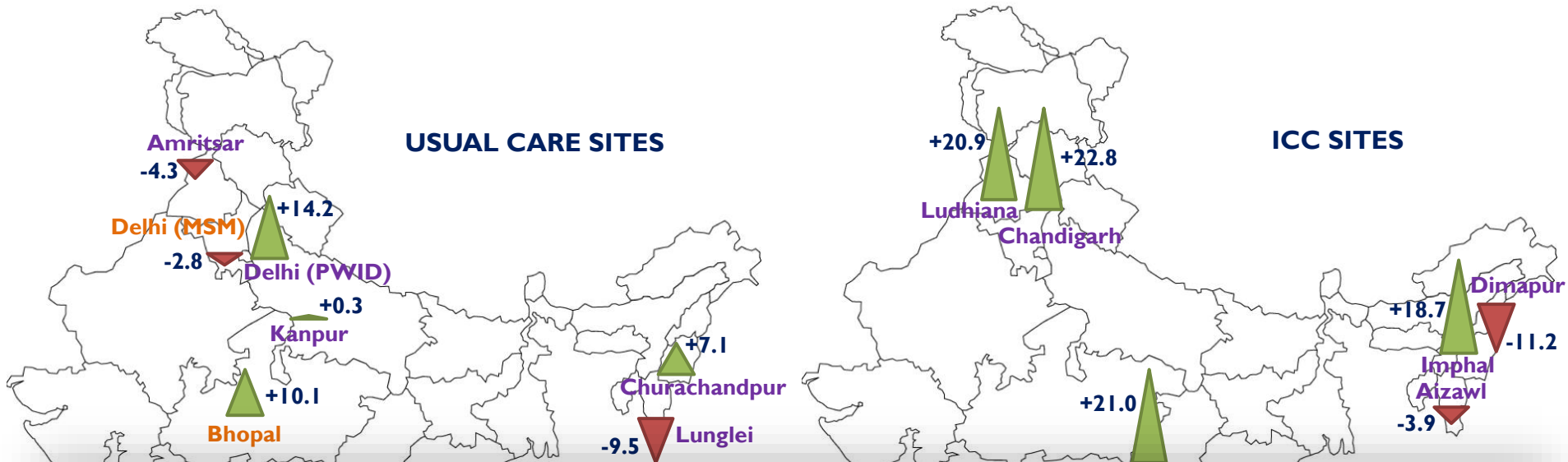
Service utilization at PWID ICCs



Service utilization at MSM ICCs



Change in recent HCT



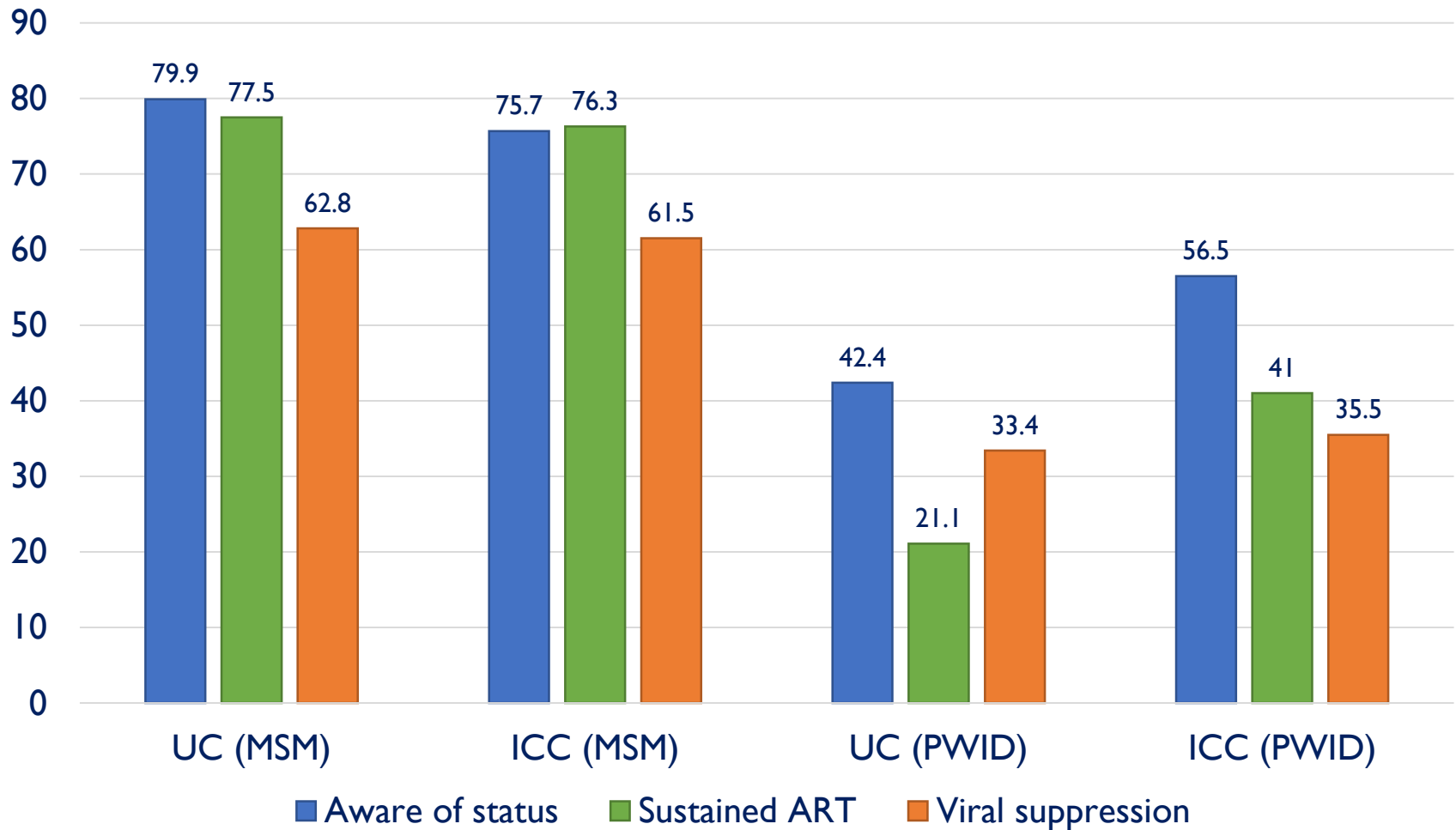
Median change in PWID (ICC vs. UC) = 10.9%

Median change in MSM (ICC vs. UC) = 3.8%

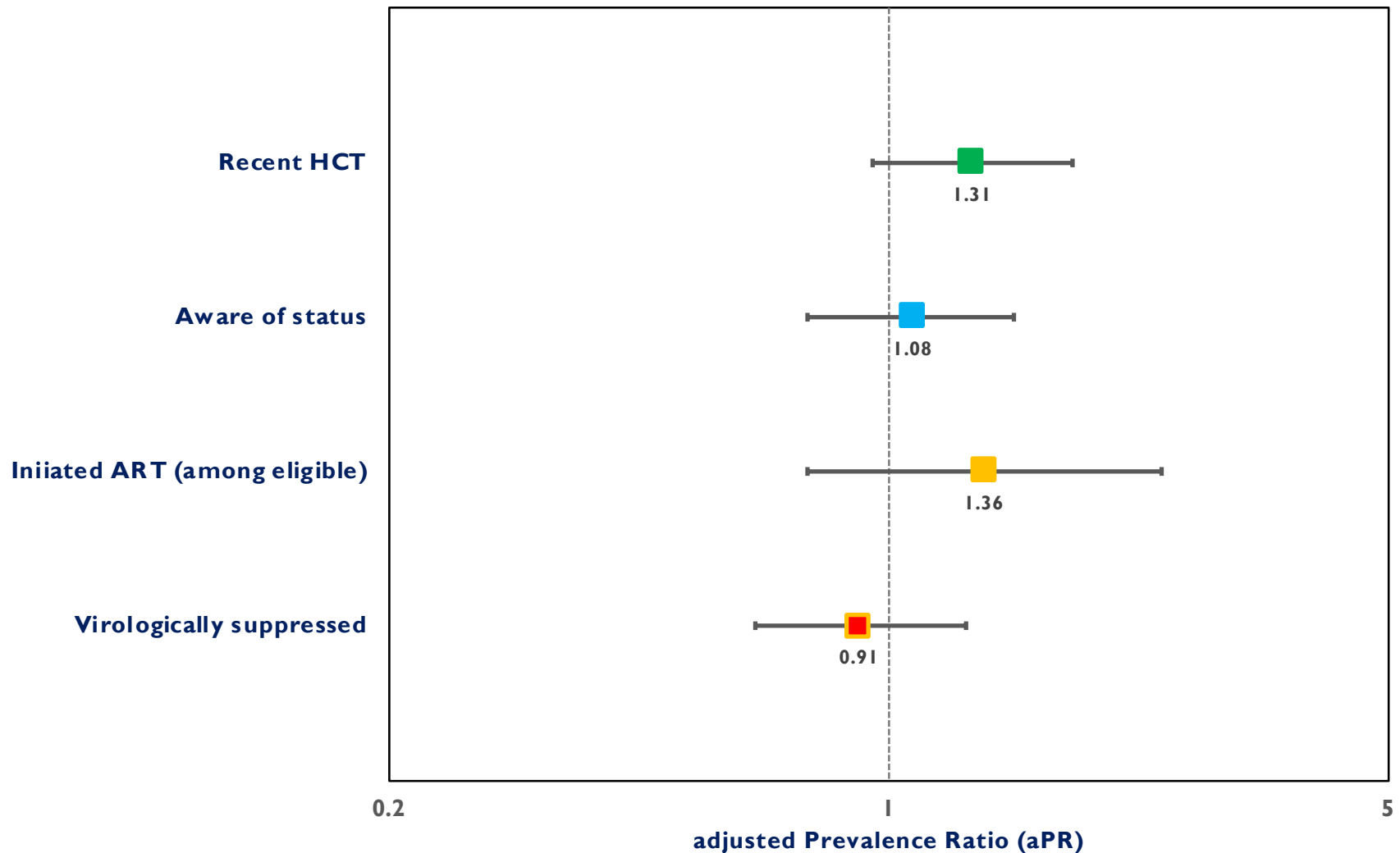
Difference in median % change (ICC vs. UC) = 7.7% (95% CI: -1.3, 16.6)



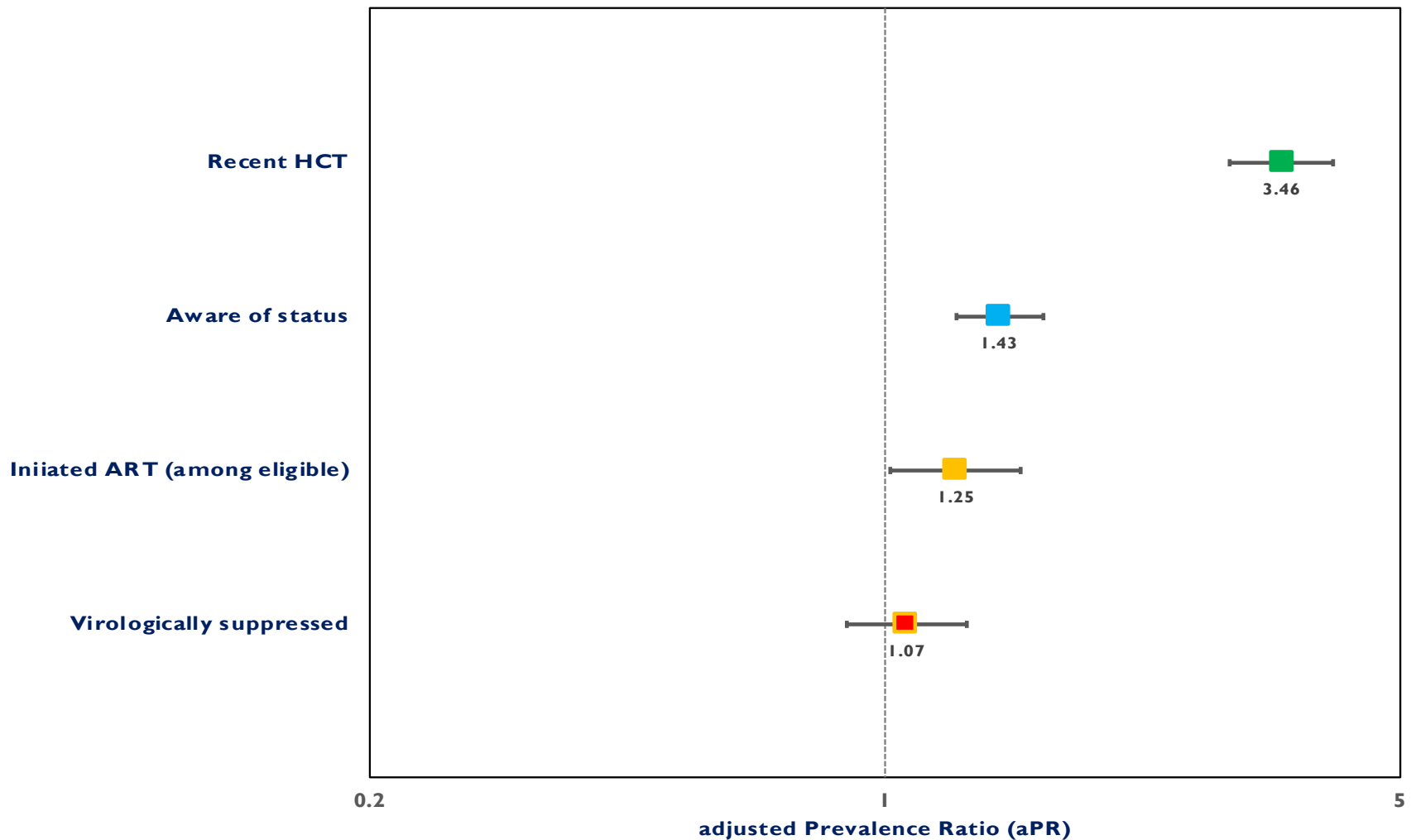
90:90:90 among PWID & MSM



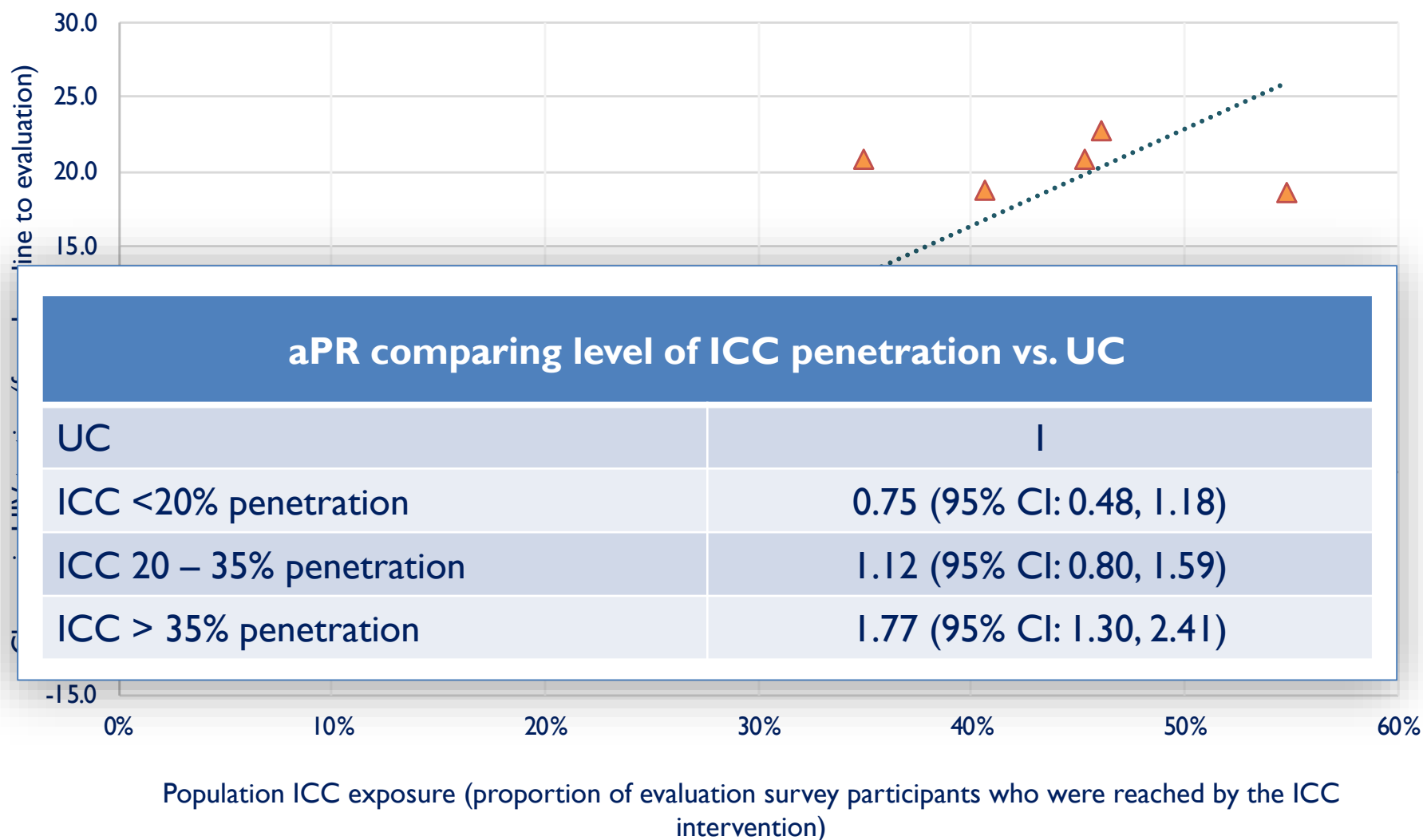
HIV Care Continuum (ICC vs. UC) at the community-level



HIV Care Continuum (ICC vs. UC) at the individual-level



ICC penetration vs. recent HCT



Limitations

- Primary outcome was self-report
 - High levels of misreporting at ICC sites
- High degree of variability in study populations
 - Affected power (intraclass correlation coefficient larger than anticipated)
- RDS to recruit samples
 - Limitations of RDS itself
 - Migration, death
- Impact of baseline RDS on control communities not quantifiable

Lessons learned

- ICCs improved testing by 31% at the community level but failed to achieve statistical significance at $p=0.05$
- At the individual-level, ICCs improved testing, awareness, linkage and initiation of ART
- More penetration = more impact
- People lie: Objective > self-report
- Improving HIV testing is the first step:
 - Viral suppression should be the goal (U=U)
- Access vs. Demand

Next steps



TB Testing & Treatment

- Sputum collected on site but tested in govt center
- TB drugs from DOTS program dispensed on-site

Needle exchange

Field-based & on-site

STI syndromic management

Government sponsored

Condoms

General medical care:

Glucose screening, blood pressure monitoring, doctor available for general health problems

Opiate substitution
(delivered either in Government hospital or NGO)

Counseling: Individual & group/ substance use, alcohol, adherence, couples, family etc

Incentivize pre-ART retention, ART initiation, ART refills, motivational counseling

ART: delivered through a link model (ARVs provided by government but peer health worker picks up meds so clients can receive directly from ICC)

Design of the ICC+

Baseline Assessment via cross-sectional sample using respondent-driven sampling (RDS) in candidate clusters (MSM=12; PWID = 15) (n=1000/cluster = 27,000)

Stratified, restricted Randomization

Intervention clusters (n=6 PWID, 5 MSM)

Implement Integrated Care intervention (ICC) for 2 years

Control clusters (n=6 PWID, 5 MSM)

Monitor environment-level changes

Matched pair Randomization

8 Prior Intervention clusters

PWID 1a

PWID 1b

PWID 2a

PWID 2b

MSM 3a

MSM 3b

MSM 4a

MSM 4b

ICC+ incentives

ICC only

8 Prior Control clusters

PWID 5a

PWID 5b

PWID 6a

PWID 6b

MSM 7a

MSM 7b

MSM 8a

MSM 8b

ICC+ incentives

ICC only

Viral suppression is the primary outcome

(MSM=10; PWID= 12)
(n=1000/cluster =22)

ICC+clusters (MSM=8; PWID= 8)
(n=1000/cluster; 16 clusters)

Camp Rainbow



Joint program between YRGCARE and Serious Fun, USA

Camp Rainbow



Camp Rainbow



Suniti Solomon Educational Fund



- Support medical education of underprivileged girls in the medical and basic science areas
- USD 600 covers the cost of tuition, hostel and mess fees and medical books for a girl for a year
- Currently providing support for ~10 girls

Acknowledgements

- Funding sources
 - NIDA
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- YRGCARE
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 - AK Srikrishnan
 - M Suresh Kumar
 - AK Ganesh
 - S Anand
 - P Balakrishnan
 - CK Vasudevan
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 - Lab Team
- Site Staff
- Participants

