Monitoring Effectiveness of HIV Programs in the Era of Implementation Science utilizing a sample of 27,000 Drug Users and Men who have Sex with Men in India

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Background

- Dramatic progress in delivery of HIV services in <u>resource-limited settings</u>
- Monitoring <u>effectiveness</u> of these programs is critical particularly in <u>hard-to-reach</u> populations
- <u>HIV incidence</u> is the <u>optimal</u> measure
 - Longitudinal HIV incidence is cumbersome
 - Novel cross-sectional assays available but require complicated testing protocols

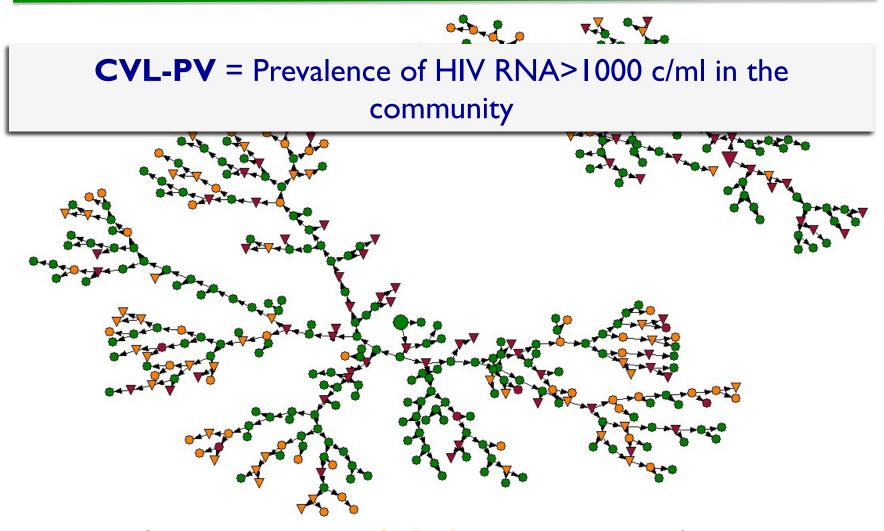
Study Objective

 To evaluate biological and self-reported measures that could serve as <u>surrogates</u> for HIV incidence using <u>population-based</u> samples from men who have sex with men (MSM) and people who inject drugs (PWID) across 26 cities in India.

Surrogates of incidence

- Biological measures
 - Community viral load (CVL)

Variations of CVL



GREEN = HIV negative; ORANGE = HIV+ and aware of status; MAROON = HIV+ and unaware of HIV status; \blacktriangle = HIV RNA > 1000 copies/ml

Surrogates of incidence

- Biological measures
 - Community viral load (CVL)
 - HIV prevalence
- Self-reported measures
 - PropART: Proportion of HIV-infected persons on ART
 - PropHCT: Proportion of individuals (excluding known positives) in the community who received HIV counseling and testing in the prior year
 - CommSERV: (number of HIV-infected currently on ART + number of HIV-uninfected who received HCT) ÷ population size

Methods

- ~1000 recruited per site across 27 sites (26 cities) in India using RDS (baseline assessment of cluster randomized trial)
 - MSM: 12 cities
 - PWID: 15 cities
- HIV incidence estimated using multi assay algorithm (MAA) that included BED, Avidity Index, CD4 count and HIV RNA
- <u>Correlation</u> between surrogates and incidence assessed using Spearman correlation coefficients
 - Correlation coefficients compared using STATA cortesti command
- <u>Association</u> between surrogates and incidence assessed using simple linear regression models (per one SD increase in surrogate)
 - R-squared, AIC/BIC used to compare across models

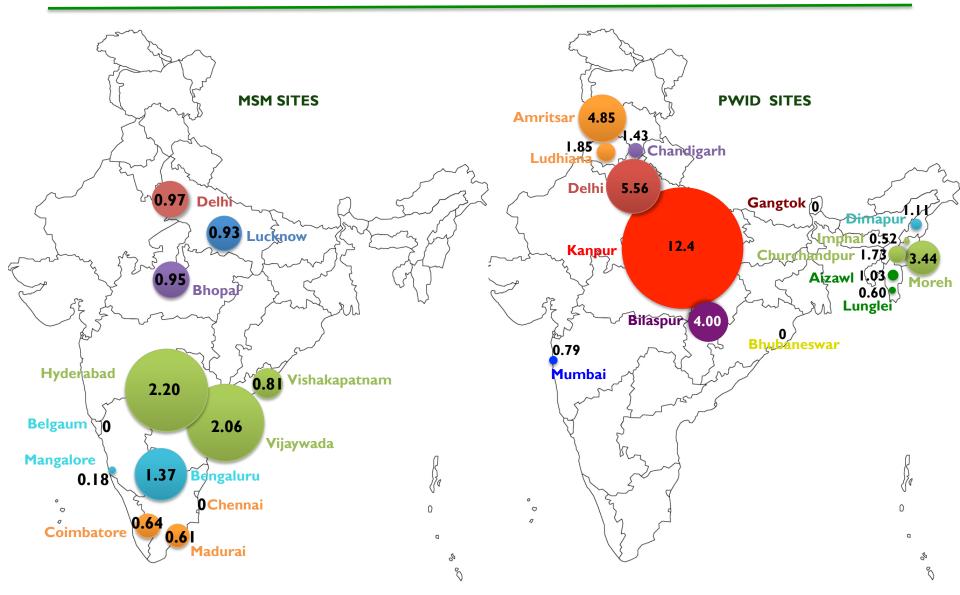
Results: Demographics

	MSM (12 sites; n= 12,022)	PWID (15 sites; n=14,481)
	Site median (Range)	Site median (Range)
Median age in years	25 (21 – 30)	29 (24 – 34)
Proportion male (%)	100	96.4 (76.7 – 99.9)
Education (%) Primary school or less Secondary school High school and above	17.6 (6.8 – 42.8) 41.7 (29.8 – 58.8) 31.5 (24.1 – 63.3)	33.7 (4.9 – 69.3) 46.6 (27.5 – 68.9) 21.3 (3.1 – 44.0)
Marital status (%) Currently married/living with partner Never married	35.0 (17.9 - 57.9) 62.4 (30.2 - 75.5)	47.5 (18.3 - 62.7) 41.9 (21.2 - 59.8)
Median income in Indian Rupees	6000 (4000-8000)	5000 (2000 - 7000)
Ever injected drugs (%)	1.2 (0.1 – 3.4)	100
Injected drugs in past 6 months (%)	0.9 (0.1 - 3.0)	91.1 (68.6 – 99.1)
Ever heterosexual sex, (%)	76.3 (62.6 - 86.2)	87.2 (75.1 - 94.7)
Unprotected heterosexual sex in the past 6 months (%)	45.1 (26.0 - 61.4)	40.5 (24.2 - 63.1)
Ever MSM behavior, n(%)	100	2.8 (0.7 - 12.8)
Unprotected MSM behavior in the past 6 months (%)	48.8 (35.8 - 73.7)	0.8 (0.1 - 3.1)

Surrogates of incidence

	MSM (n=12 sites)	PWID (n=15 sites)	Overall (n=27 sites)	
	Site median (range)	Site median (range)	Site median (range)	
CVL-AWARE (log ₁₀ copies/ml)	2.9 (2.5 - 3.8)	3.4 (2.5 - 4.7)	3.1 (2.5 - 4.7)	
CVL-POS (log ₁₀ copies/ml)	3.8 (2.7 - 4.4)	4.0 (2.6 - 4.6)	3.9 (2.6 - 4.6)	
CVL-PV (%)	4.8 (1.6 - 12.6)	13.7 (2.5 - 33.1)	8.3 (1.6 - 33.1)	
HIV prevalence (%)	8.6 (2.0 - 18.8)	19.7 (6.1 - 43.3)	13.1 (2.0 - 43.3)	
PropART (%)	39.6 (0 - 84.5)	28.2 (0 - 71.1)	36 (0 - 84.5)	
PropHCT (%)	29.9 (8.9 - 36.0)	25.0 (5.3 - 75.7)	27.5 (5.3 - 75.7)	
CommSERV (%)	30.6 (9.2 - 38.9)	29.7 (4.5 - 75.5)	29.9 (4.5 - 75.5)	

HIV Incidence



Community viral load (CVL) & Incidence

CVL Measure		Linear Regression ²			
CVL Measure	ρ' (P value)	Coefficient (95% Cl)	R-squared		
CVL – AVVARE	0.593 (0.001)	1.33 (0.40, 2.26)	0.266		
CVL – POS	0.505 (0.007)	1.19 (0.27, 2.12)	0.220		
CVL – PV	0.807 (<0.001)	1.54 (0.74, 2.34)	0.387		

"In New Delhi, reducing the prevalence of viremic individuals in the community from 15% to 11% would result in a corresponding reduction in HIV incidence from 4% to 3%"

Propriet	-0.255 (0.177)	-0.00 (-1.04, -0.12)	0.110
CommSERV	-0.296 (0.134)	-0.99 (-1.95, -0.03)	0.153

¹ Spearman correlation coefficient

² Regression coefficients from unadjusted linear regression models (expressed per standard deviation increase in explanatory variable, standardized within population ([MSM/PWID])

Statistical comparison of Spearman correlation coefficients for different surrogates and incidence

MEASURE	CVL- AWARE	CVL-POS	CVL-PV	HIV Prevalence	PropART	PropHCT	CommSERV
CVL- AWARE	×	0.901	0.035	0.433	0.308	0.103	0.107
CVL-POS		х	0.021	0.301	0.340	0.178	0.199
CVL-PV			×	0.002	0.029	0.005	0.006
HIV Prevalence				×	0.356	0.057	0.081
PropART					×	0.127	0.130
PropHCT						x	0.256
CommSERV							×

Note: Values reported are the p-values for the comparison

Conclusions

- Markers of <u>HIV treatment</u> access <u>better</u> correlated with HIV incidence than markers of HIV prevention access
- Prevalence of viremia in the community (a marker that incorporates HIV prevalence and the entire HIV care continuum) appears to be the <u>ideal</u> marker to evaluate the impact of HIV programs when incidence data is not available
 - Also may be a relevant outcome for implementation trials
- In settings where viral load testing is not feasible, self-reported ART use may be a robust marker of HIV incidence

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