HIV Prevention Trials Network

Financial Incentives, Linkage to Care and Viral Suppression HPTN 065 (TLC-Plus) Study

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Outline of Presentation

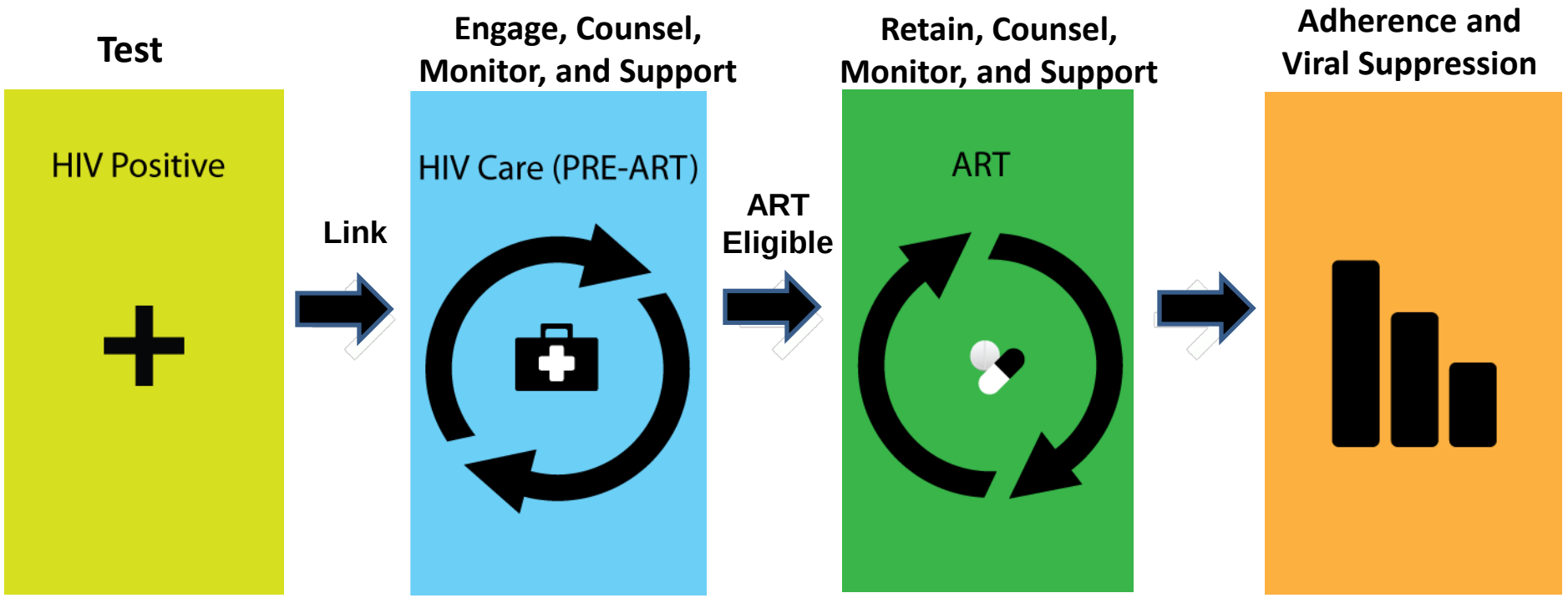
- Background and study rationale
- Methods
- Results
- Implications for future research
- Conclusions

Background

- Use of antiretroviral therapy (ART) has been shown to be efficacious for:
  - prevention of morbidity and mortality for PLWH
  - prevention of HIV transmission to others

- Achieving the potential of ART for treatment or for prevention is dependent on the *coverage and quality* of the HIV care continuum

HIV Care Continuum

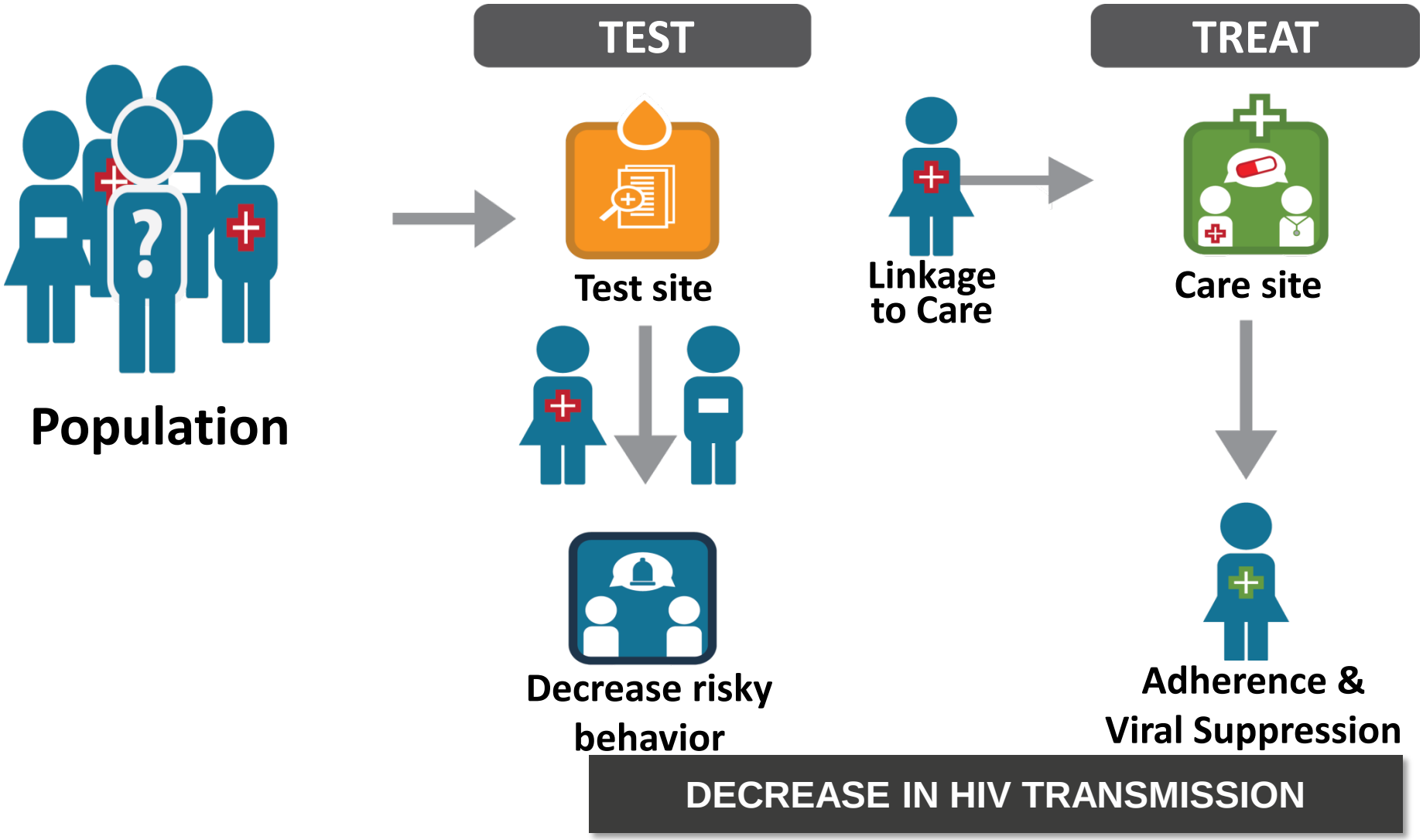


McNairy & El-Sadr, AIDS 2012

HPTN 065 (TLC-Plus) Purpose

To determine the *feasibility* of the test, link and treat strategy for prevention of HIV transmission in the US

Test and Treat Conceptual Framework



HPTN 065
Study Components

Expanded HIV Testing

- Social Mobilization
- Universal HIV testing in hospitals (ED & IP)

Linkage to Care

- $25
- $100

Financial Incentives

Viral Suppression

- $70

Financial Incentives

Prevention for Positives

Computer-based prevention intervention

Provider and Patient Surveys

Pre and post survey
- Providers
- Patients

Financial Incentive–Based Approaches for Weight Loss

A Randomized Trial

Kevin G. Volpp, MD, PhD
Leslie K. John, MS

Contex
lic healtl

Financial Incentives for Extended Weight Loss: A Randomized, Controlled Trial

Leslie K. John, MS[1], George Loewenstein, PhD[1,2], Andrea B. Troxel, ScD[2,3], Laurie Norton, MA[2,4,5], Jennifer E. Fassbender, MS[3], and Kevin G. Volpp, MD, PhD[2,4,5,6]

A Mixed-Methods Randomized Controll Trial of Financial Incentives and Peer Networks to Promote Walking Among Older Adults

A Randomized, Controlled Trial of Financial Incentives for Smoking Cessation

Kevin G. Volpp, M.D., Ph.D., Andrea B. Troxel, Sc.D., Mark V. Pauly, Ph.D., Henry A. Glick, Ph.D., Andrea Puig, B.A., David A. Asch, M.D., M.B.A., Robert Galvin, M.D., M.B.A., Jingsan Zhu, M.B.A., Fei Wan, M.S., Jill DeGuzman, B.S., Elizabeth Corbett, M.L.S., Janet Weiner, M.P.H., and Janet Audrain-McGovern, Ph.D.

Effect of a structural intervention for the prevention of intimate-partner violence and HIV in rural South Africa: a cluster randomised trial

Paul M Pronyk, James R Hargreaves, Julia C Kim, Linda A Morison, (

Effect of a cash transfer programme for schooling on prevalence of HIV and herpes simplex type 2 in Malawi: a cluster randomised trial

Should we pay the patient? Review of financial incentives to enhance patient compliance

Antonio Giuffrida, David J Torgerson

Randomized trial of lottery-based incentives to improve warfarin adherence

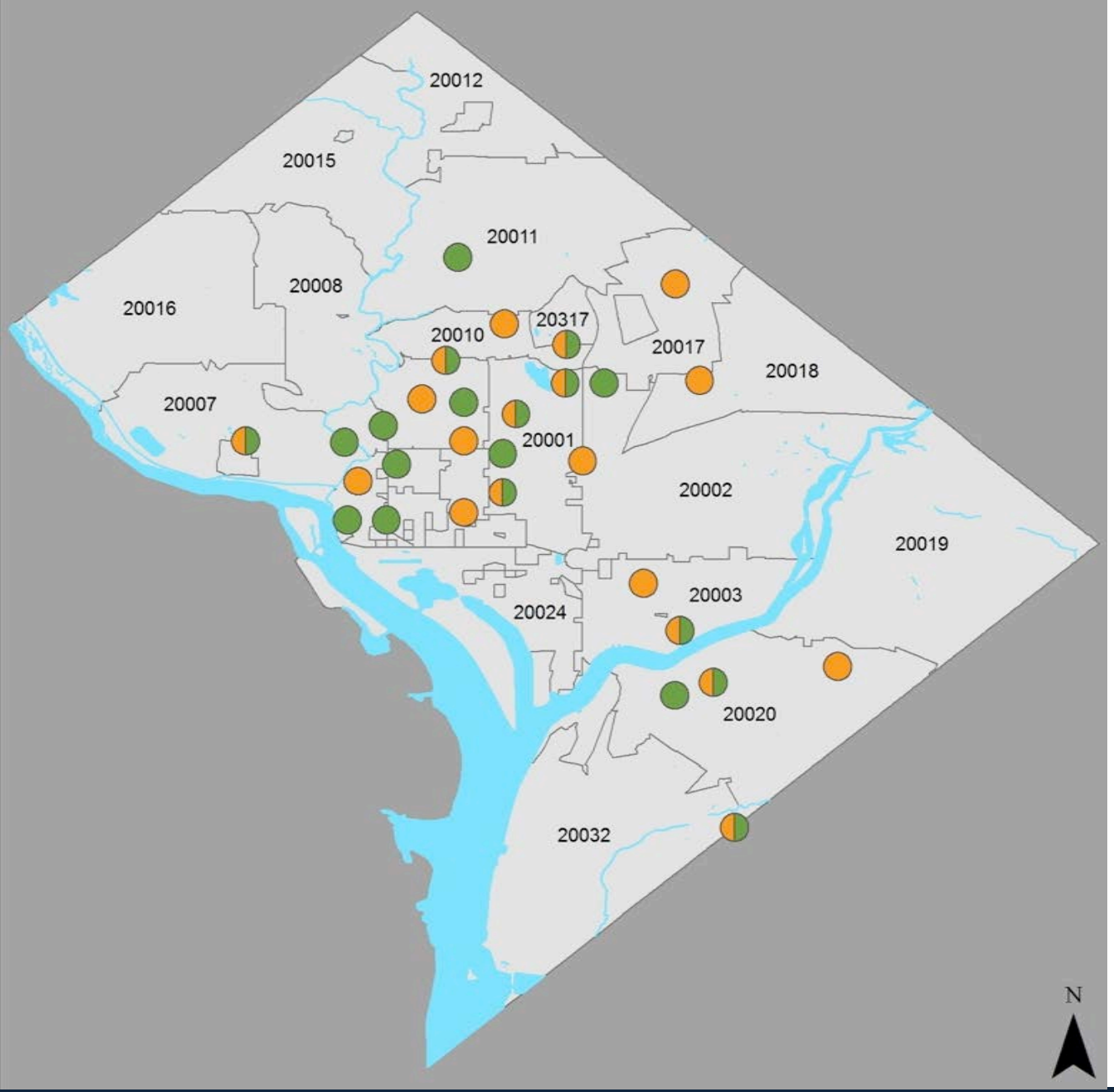
Stephen E. Kimmel, MD, MSCE,[a,b,c] Andrea B. Troxel, ScD,[a,c] George Loewenstein, PhD,[c,d] Colleen M. Brensinger, MS,[a] Jane Jaskowiak, BSN, RN,[a] Jalpa A. Doshi, PhD,[b,c] Mitchell Laskin, RPh,[e] and Kevin Volpp, MD, PhD[b,c,f,g] *Philadelphia, and Pittsburgh, PA*

Objectives

- Determine the feasibility and effectiveness of financial incentives (FI)
  - On **linkage to care (L2C)** of HIV-positive individuals from HIV test to HIV care sites within three months

    and
  - On **viral suppression (VS)** (<400 copies/ml) in patients in HIV care


Bronx
Test / Care Sites
18
20
INTERVENTION
COMMUNITIES:
Bronx, NY
Washington DC
DC
Test / Care Sites
19
19

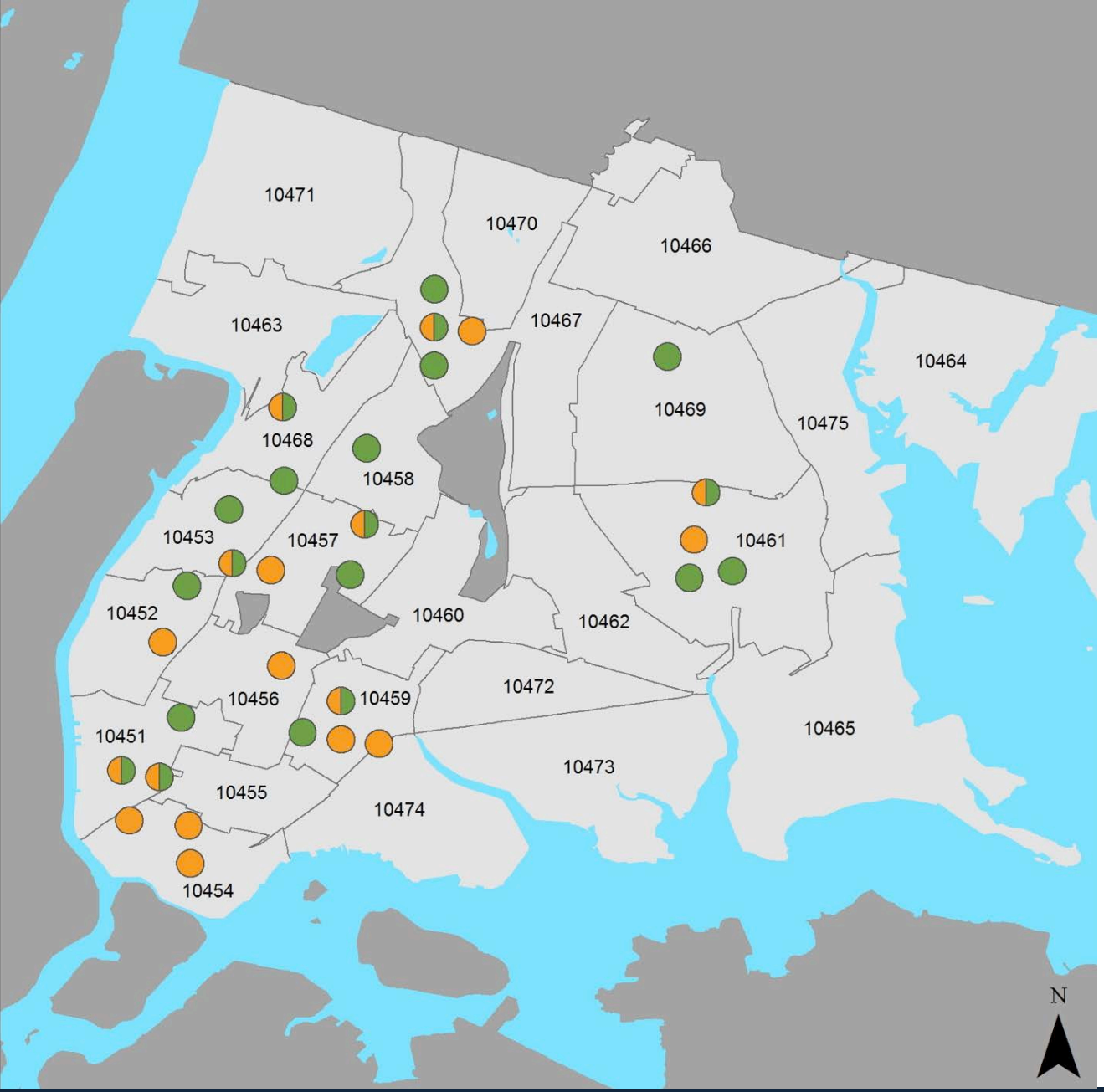


Washington, DC Test / Care Sites

19

19

- Test site
- Care site
- Test and Care site



Bronx, NY
Test / Care Sites

18

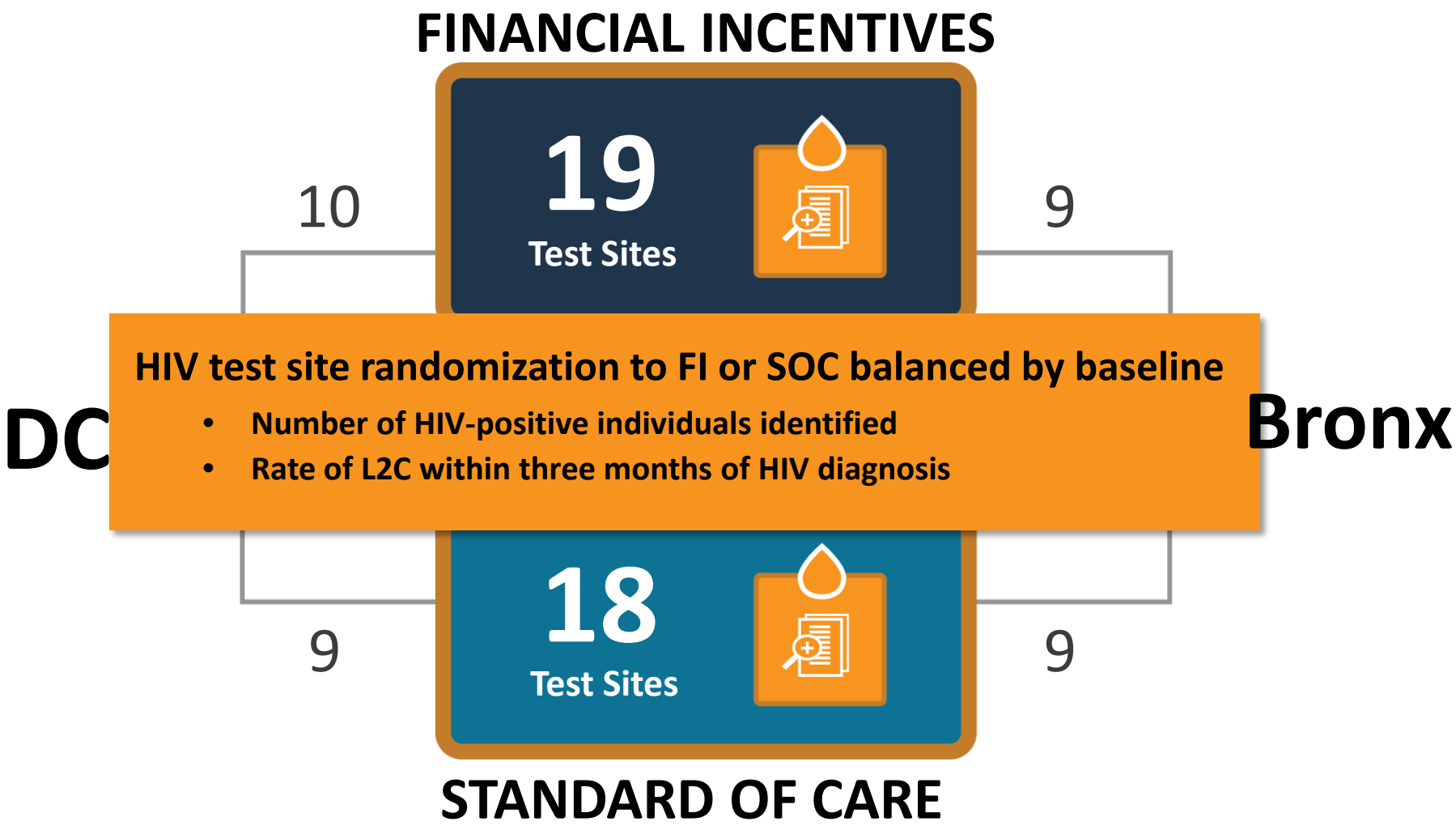
20

Test site

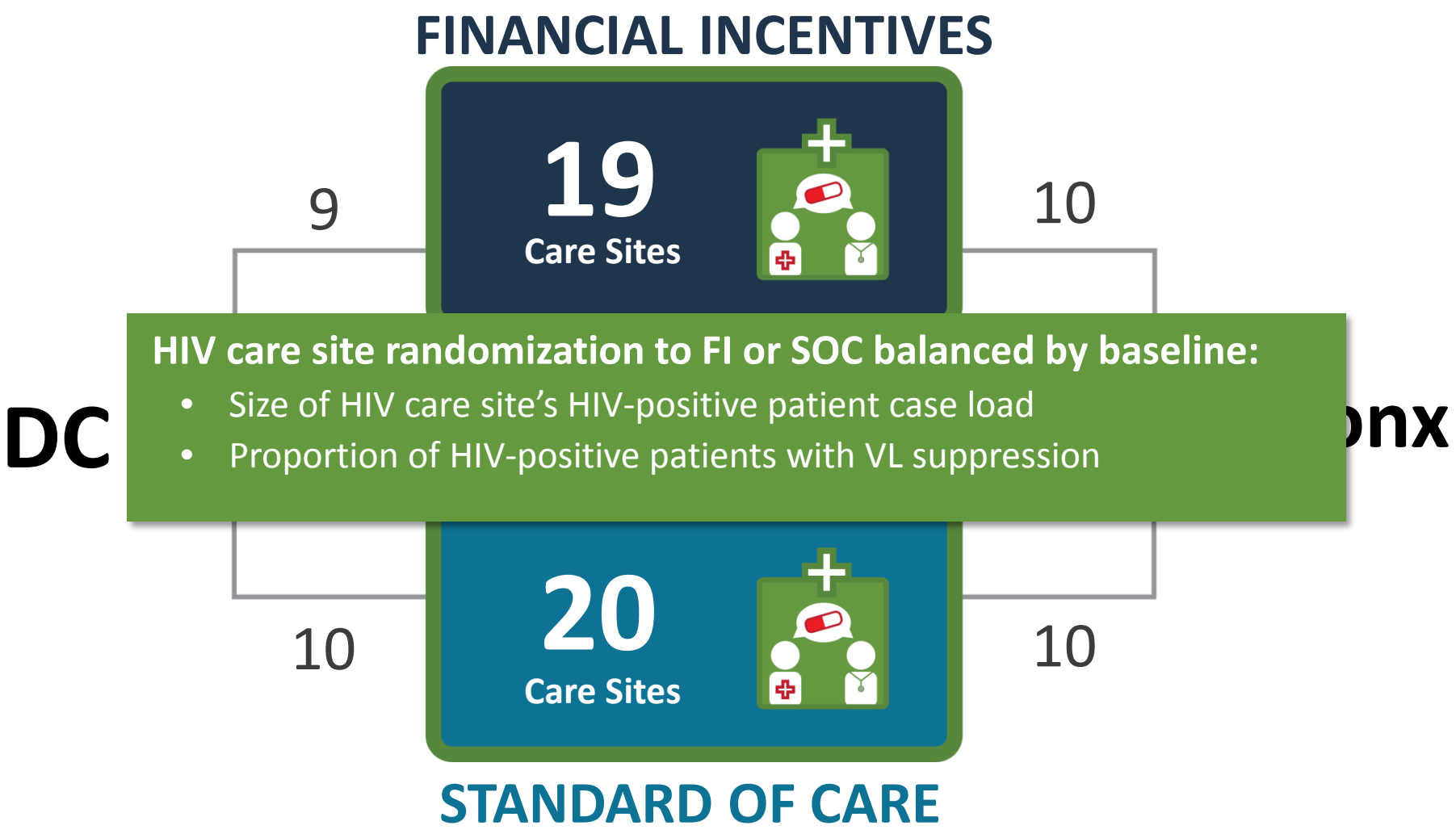
Care site

Test and Care site

HIV Test Site Randomization (L2C)



HIV Care Site Randomization for VS



Financial Incentives

- Approach
  - Conditional on linkage to care or viral suppression
  - For VS component:
    - all HIV patients in care on ART with VS qualify for FI, rather than only those initiating ART or those with unsuppressed VL
  - All individuals who qualified rather than use of lottery system
  - Minimize disruption/distortion of health services:
    - Site randomization
    - Only individuals testing HIV positive receive coupon at FI sites
    - Requirement for engagement in care at care site for eligibility for gift card for VS
- Amount of FI
  - Consultation with study community advisory group, providers and other stakeholders

Financial Incentives

- HIV test sites assigned FI:
  - Individuals found to be HIV positive received a L2C coupon
  - Coupons could be redeemed at HIV care sites within 3 months for:
    - $25 gift card for getting follow-up lab tests done and
    - $100 gift card at completion of provider encounter with development of care plan

- HIV care sites assigned FI:
  - Patients engaged in care and with VS (<400 copies/ml) received $70 gift card
  - A maximum of one gift card could be given every 3 months

Key Study Outcomes

- **L2C**: CD4/VL within 3 months of HIV+ test
- **VS:**
  - **Overall**: VL<400 copies/ml in patients in HIV care (i.e. with at least 2 CD4/VL in the last 15 months)
  - **VS at peak of intervention**: VL <400 copies/ml in the last quarter 2012 (18 months from start of intervention)
  - **Four subgroups were pre-specified for VS analyses**: Community (Bronx, NY/DC), baseline VS (<median/>median), size of site (<median/>median), type of site (hospital/community)
- **Continuity of care (CC)**: CD4/VL in at least 4 of last 5 quarters

HIV Surveillance System

Test Sites

Care Sites

HIV positive tests

CD4 and VL tests

Health Department HIV Surveillance System

Data aggregated by site

HPTN 065 Database

Statistical Methods

- **L2C:** All cases Oct 2011 – Dec 2012; logistic regression weighted by number of HIV positive persons at site, adjusted for baseline L2C and accounting for correlation within a site

- **VS and CC**: All visits Jan 2012 – Mar 2013; linear regression for proportion VS, weighted by number of patients at site, adjusted for baseline VS and accounting for repeated site measures over time

- **VS at peak of intervention** (18 months): Oct – Dec 2012

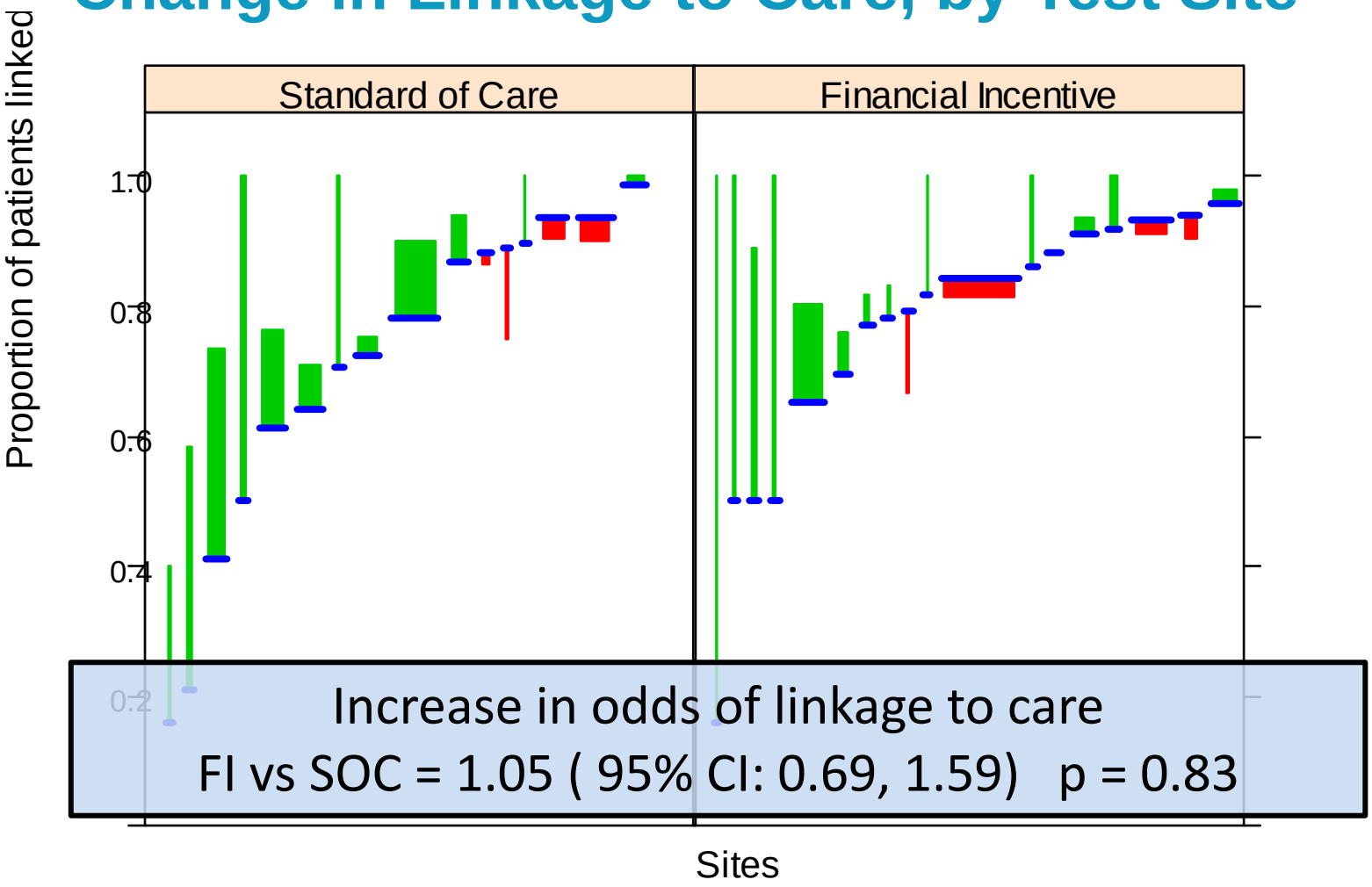
RESULTS

L2C Intervention

Characteristics	Bronx, NY	Washington, DC	Total
HIV+ Diagnoses (15 mo)	**357**	**752**	**1,109**
Men	63%	77%	**72%**
MSM	30%	60%	**48%**
Black	47%	68%	**60%**
Hispanic	49%	13%	**27%**
<25 years	16%	24%	**21%**
Coupons dispensed (24 mo)	**238**	**823**	**1,061**
Coupons redeemed	194 (82%)	644 (78%)	838 (79%)

79% (838/1061) of the coupons were redeemed for both the $25 and $100 gift cards

Change in Linkage to Care, by Test Site



Sites within each arm ordered by baseline L2C

Blue line is baseline L2C

Bar indicates mean change for each site: **green = increase**, **red = decrease**

Width of bar is relative to number of patients testing HIV positive at site

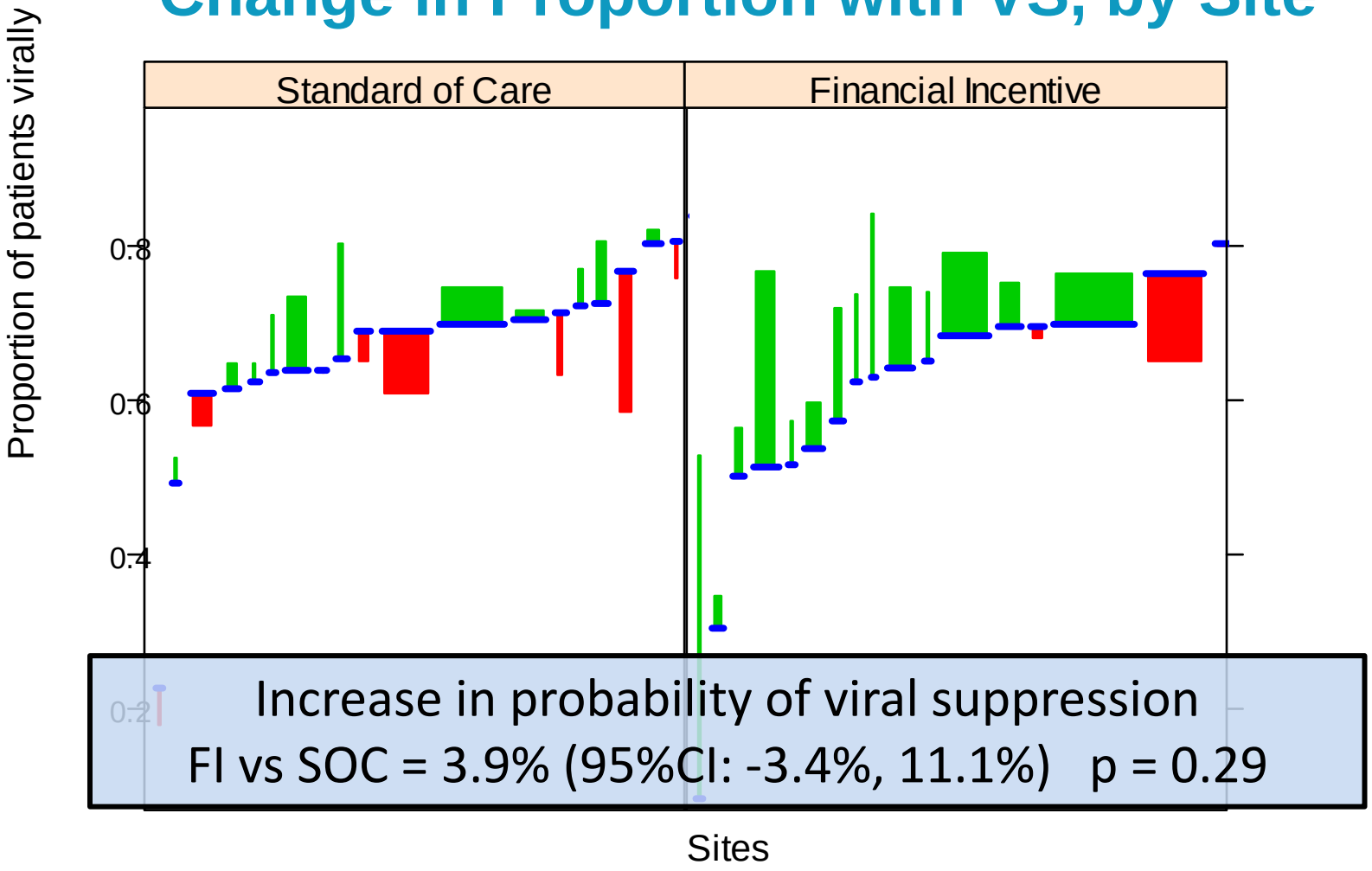
Mean HIV positives per HIV test site: 33, Geometric mean: 16 per site

VS Intervention

- Total of 19,185 patients in care (10,455 in Bronx, NY and 8,720 in DC)
  - At 17 hospitals and 20 community sites

- There were 9,641 patients eligible for gift cards
- There were 49,650 visits qualified for gift cards
  - **A total of 39,359 gift cards dispensed**

Change in Proportion with VS, by Site



Sites within each arm ordered by baseline VS

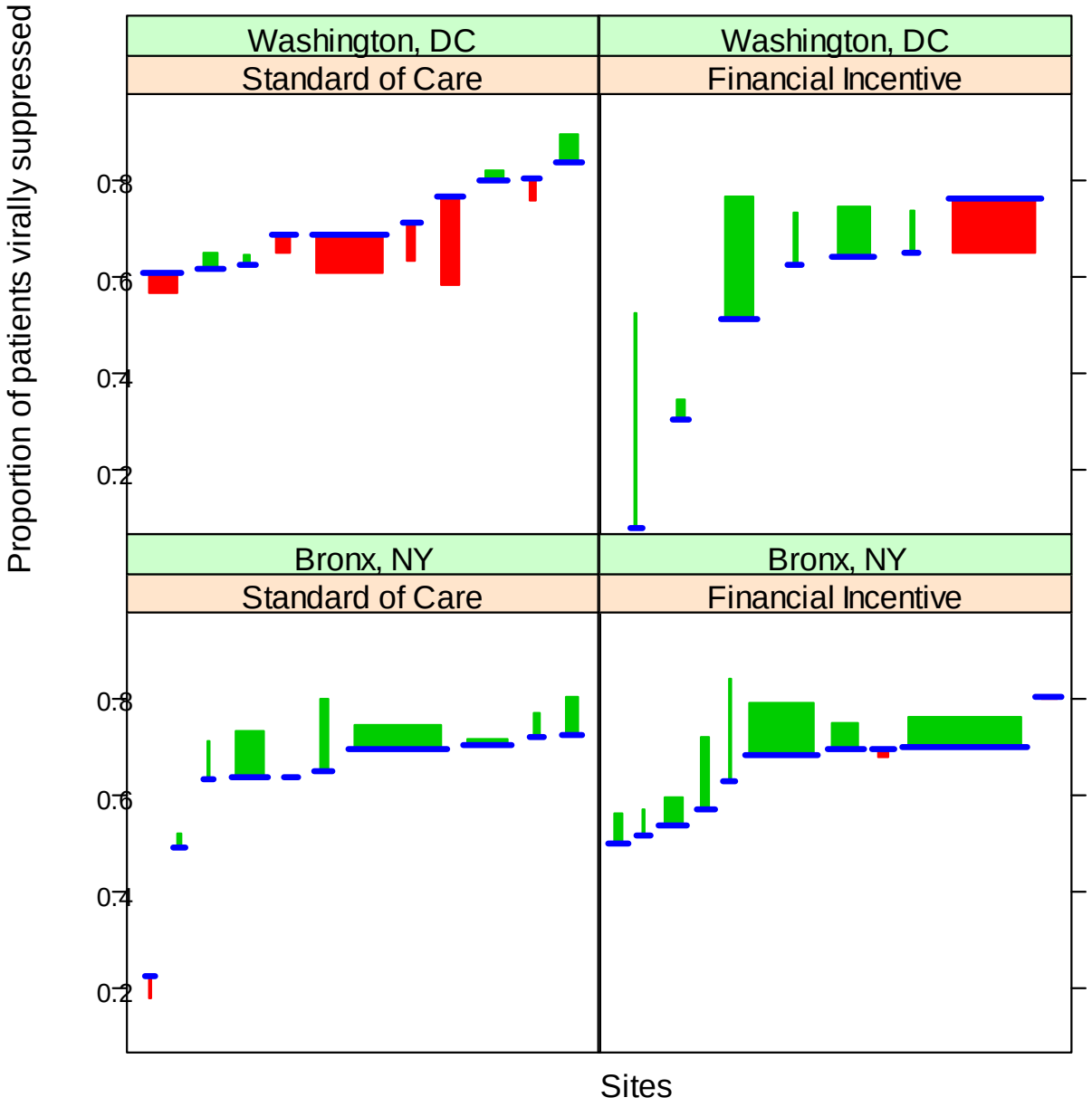
Blue line is baseline VS

Bar indicates mean change for each site: **green = increase**, **red = decrease**

Width of bar is relative to number of patients in care at the site

Mean number of HIV patients in care per site: 438, geometric mean: 243/site

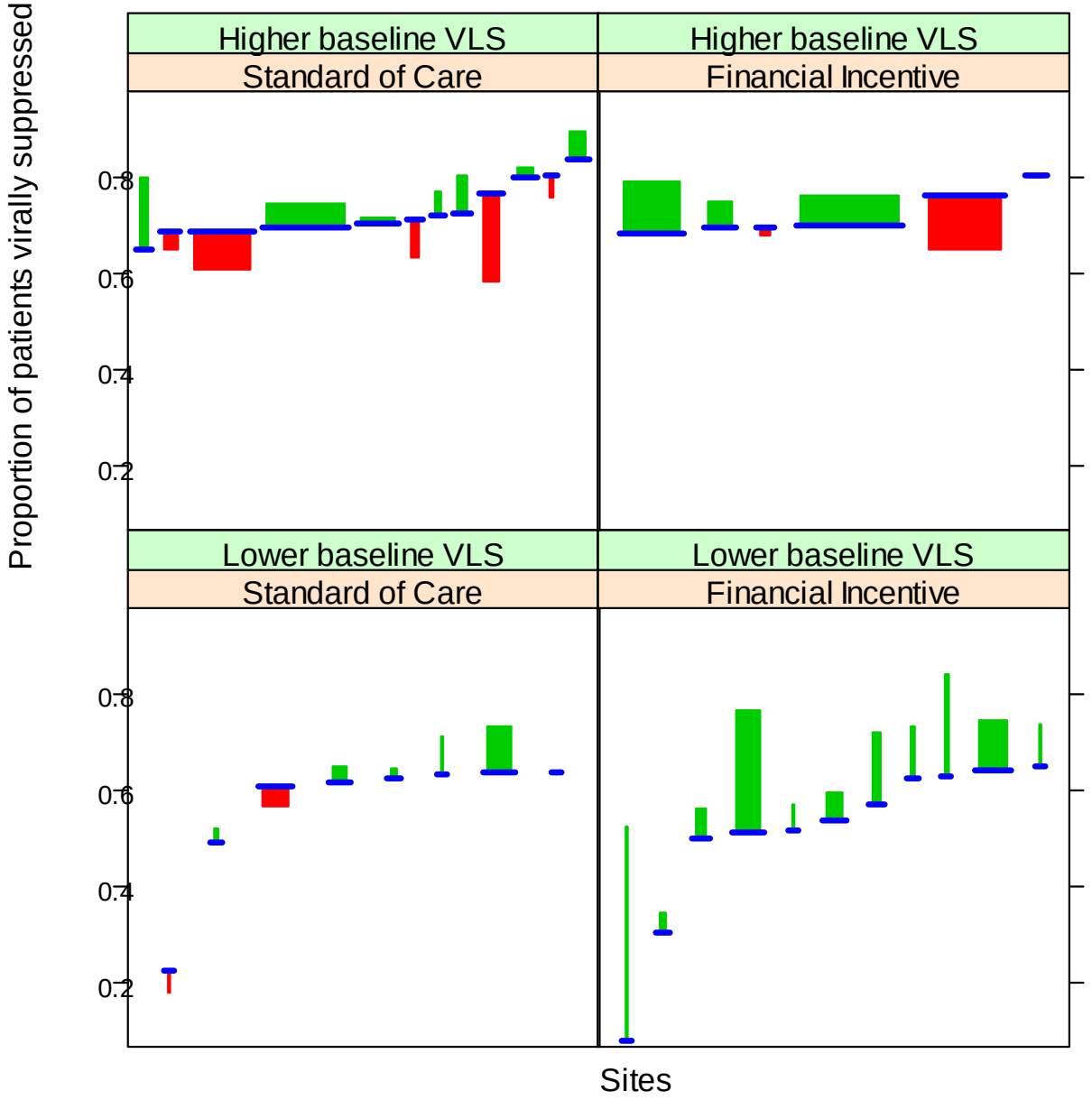
Change in Proportion with VS, by Community



DC: Increase in VS
FI vs SOC = 3.8%
95% CI (-6.7%, 14.3%)
p = 0.48

Bronx, NY: Increase in VS
FI vs SOC = 1.7%
95% CI (-1.3%, 4.7%)
p = 0.27

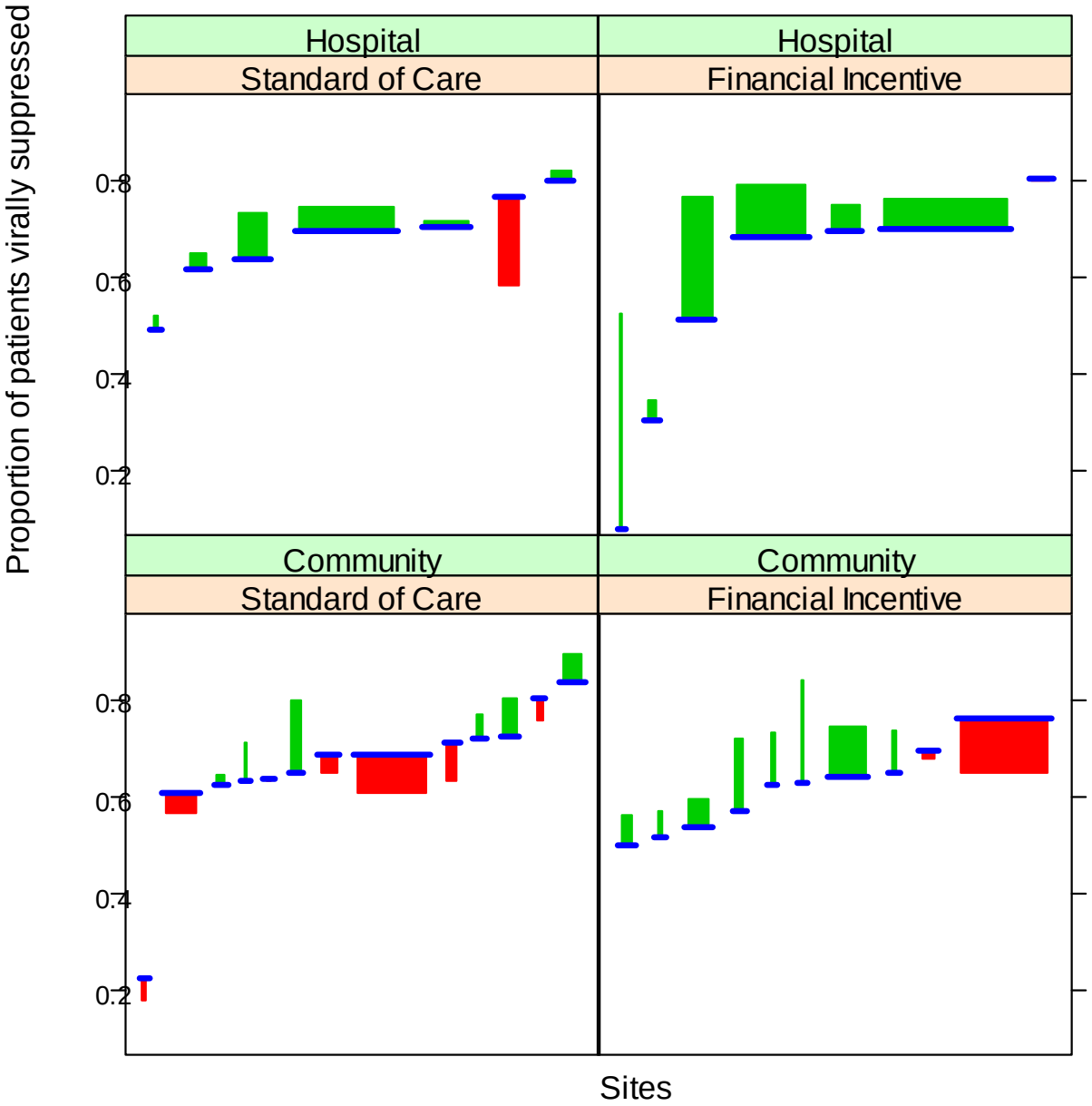
Change in Proportion with VS, by Baseline VS



≥65% with VS at baseline:
Increase in VS
FI vs SOC = 2.4%
95% CI (-5.7%, 10.6%)
P = 0.55

<65% with VS at baseline:
Increase in VS
FI vs SOC = 10.4%
95% CI (2.3%, 18.5%)
P = 0.012

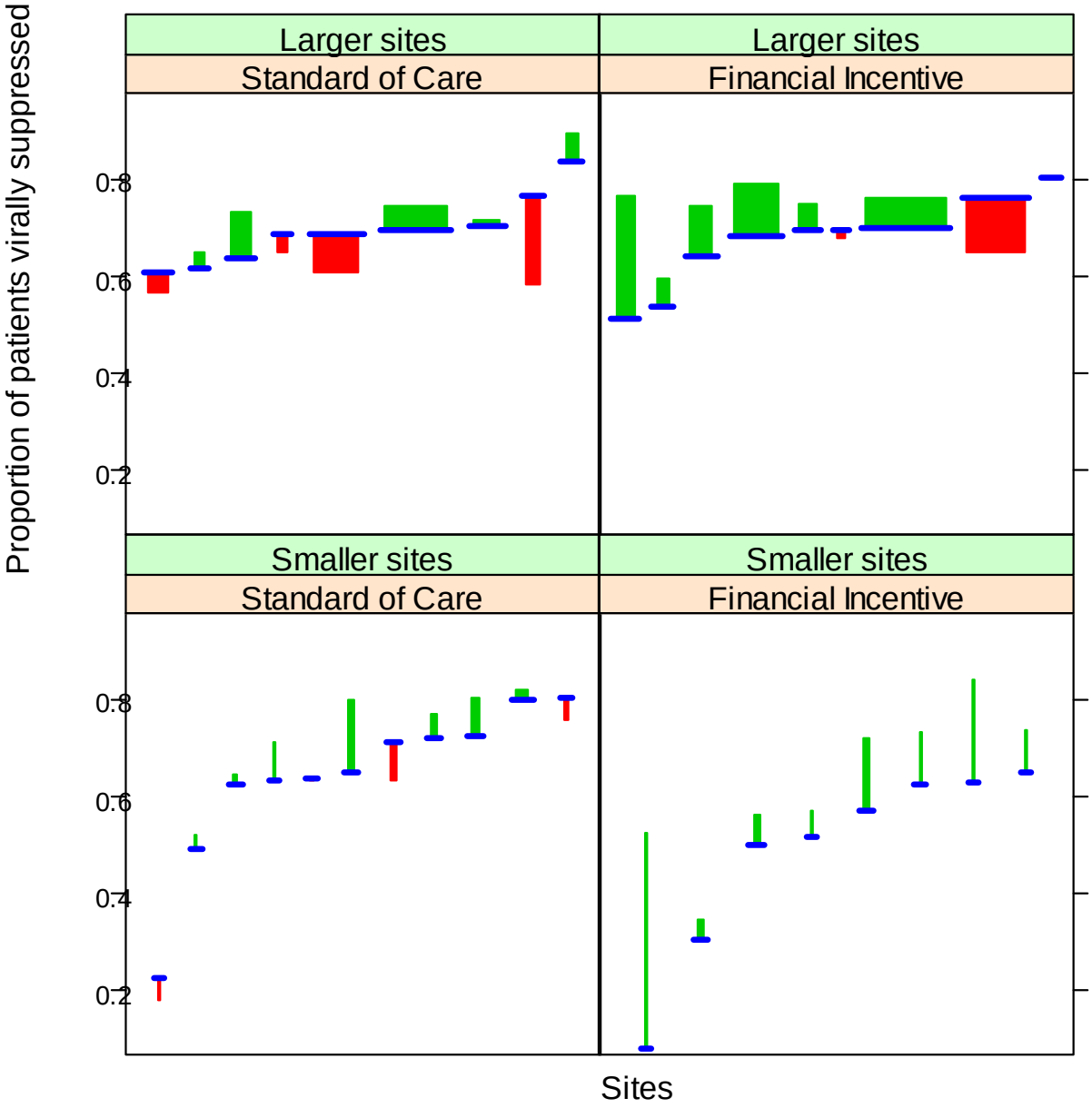
Change in Proportion with VS, by Site Type



Hospital Sites:
Increase in VS
FI vs SOC = 5.2%
95% CI (1.0%, 9.4%)
P = 0.015

Community Sites:
Increase in VS
FI vs SOC = 1.1%
95% CI (-8.3%, 10.4%)
P = 0.82

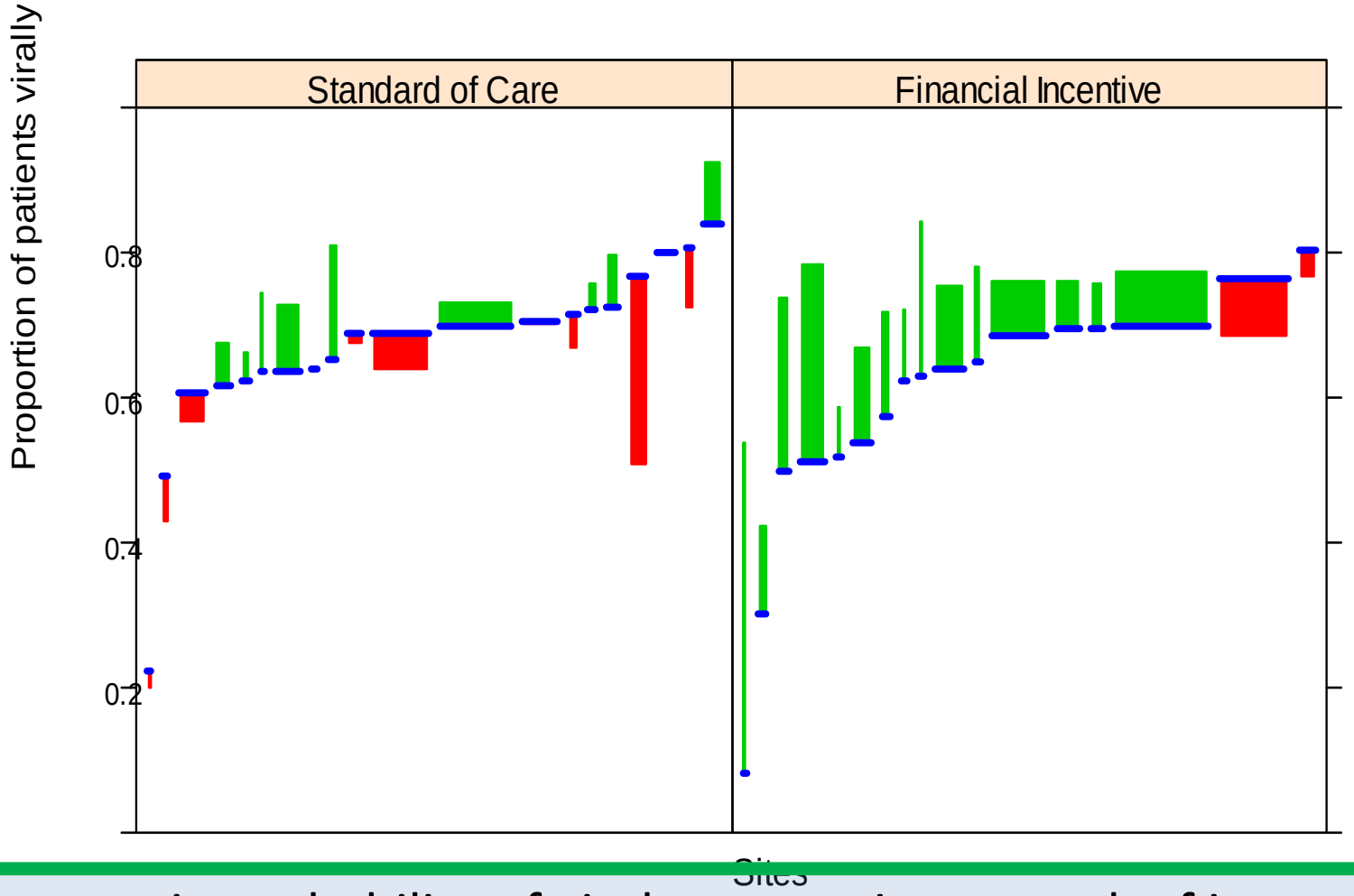
Change in Proportion with VS, by size of Site



≥186 patients in care:
Increase in VS
FI vs SOC = 4.7%
95% CI (-2.7%, 12.2%)
P = 0.21

<186 patients in care:
Increase in VS
FI vs SOC = 6.5%
95% CI (-0.7%, 13.7%)
P = 0.078

Peak of Intervention: Q4 2012
Change in Proportion with VS, by site



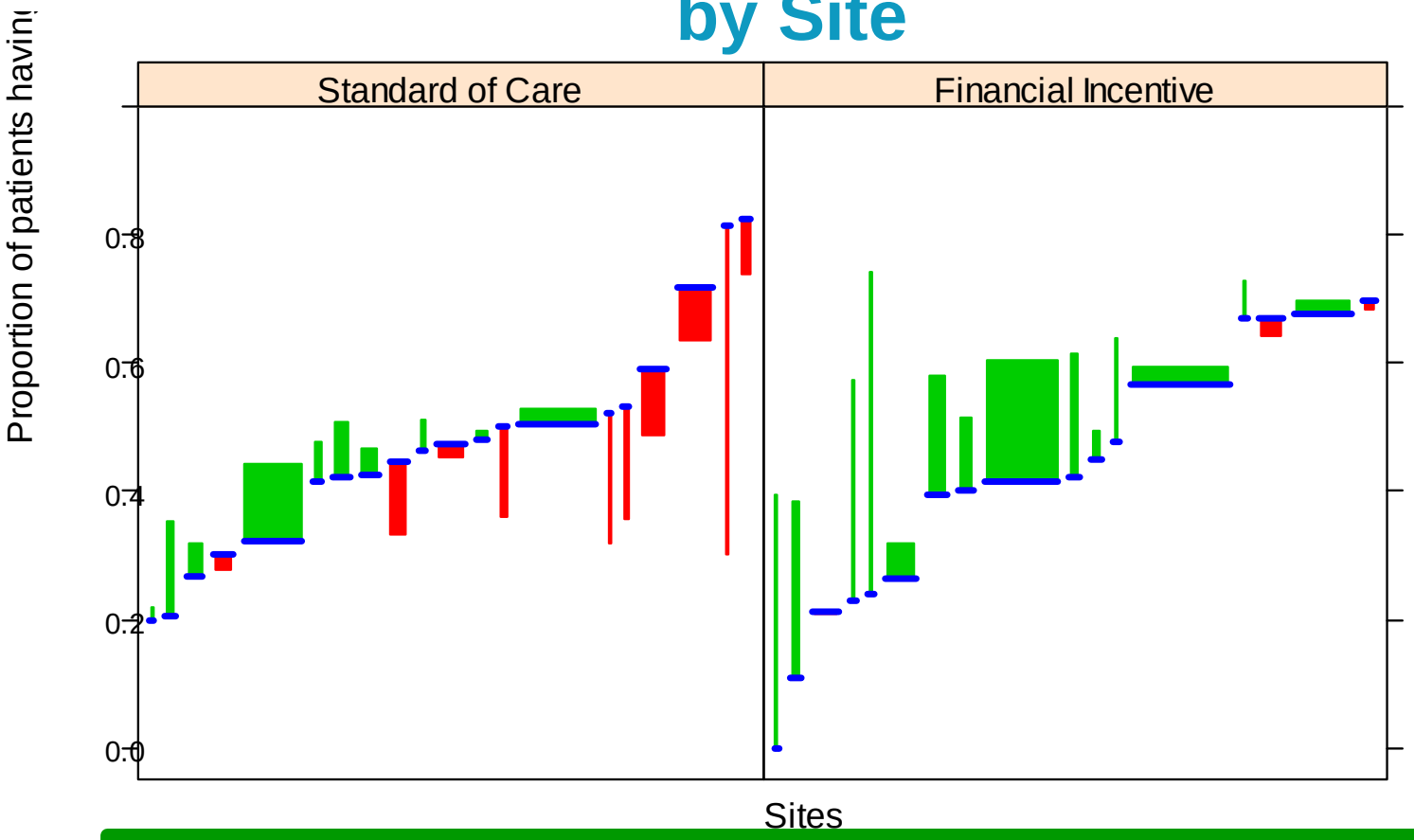
Increase in probability of viral suppression at peak of intervention

FI vs SOC = 5.4% (0.4%, 10.4%) **P = 0.034**

Peak of Intervention (Q4 2012)
Change in Proportion with VS
FI vs SOC sites

	Increase in VS	95% CI	P value
Overall	**5.4%**	**0.4%, 10.4%**	**P=0.034**
Bronx	5.4%	-5.0%, 15.8%	P=0.28
Washington DC	3.9%	-0.1%, 7.8%	**P=0.054**
Sites higher baseline VS	3.5%	-3.7%, 10%	P=0.31
Sites lower baseline VS	**13.2%**	5.5%, 20.9%	**P=0.002**
Larger sites	6.0%	-1.0%, 13%	P=0.08
Smaller sites	**11.4%**	0.9%, 21.9%	**P=0.035**
Hospital-based sites	6.6%	-1.6%, 14.8%	P=0.10
Community sites	3.2%	-3.9%, 10.3%	P= 0.36

Change in Proportion in Continuity Care, by Site



Increase in proportion of patients with care continuity

FI vs SOC = 8.1% (2.4%, 13.7%) **p = 0.005**

Sites within each arm ordered by baseline CC

Blue line is baseline CC

Bar indicates mean change for each site: **green = increase**, **red = decrease**

Width of bar is relative to number of patients in care at site

Study Strengths and Limitations

Strengths

- Large community-based study, large number (80) of sites and included most of HIV-infected persons in care in the two communities
- Diversity of sites i.e. hospitals/community clinics, private/ public, small/large sites
- Use of HIV surveillance system to measure study outcomes
- Successful system established for distribution and accounting of FI

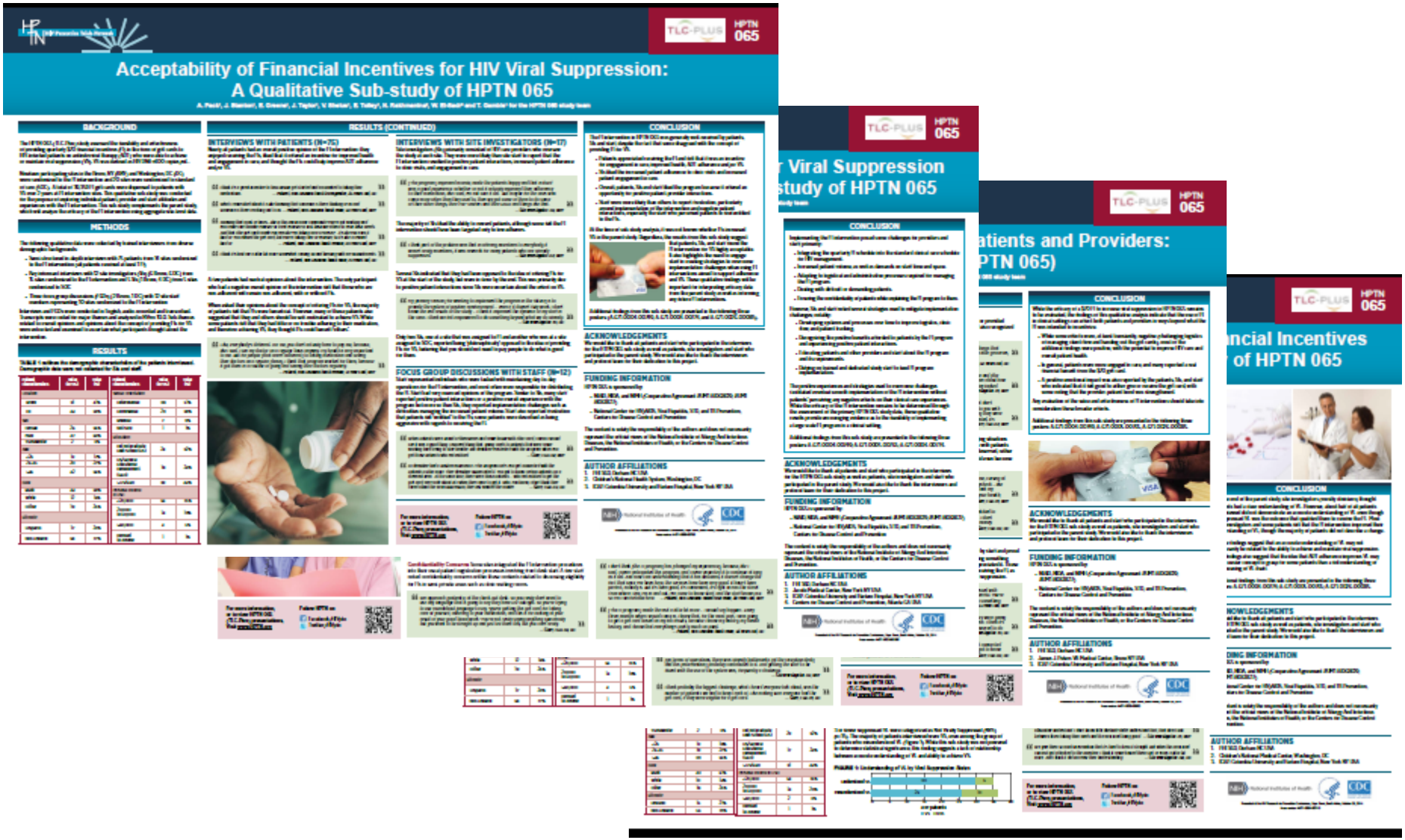
Limitations:

- Inability to distinguish patients by ART status in the surveillance system
- Reporting of lab data (CD4/VL) by place of residence rather than site of care (particularly in DC) and incomplete reporting for some sites
- Limited power for linkage to care component
- Change in ARV treatment guidelines during the course of the study

Summary

- HPTN 065 demonstrated feasibility of use of FI for L2C and VS and for measuring outcomes via HIV surveillance system
- Use of FI did not increase L2C, possibly due to limited power to detect an effect
- FI did not increase VS overall, however, FI significantly increased VS in certain settings
  - sites with lower baseline VS
  - hospital-based care sites
- At peak of intervention, FI significantly increased VS
- FI significantly increased continuity in care as evidenced by regular clinic attendance

Qualitative Assessments of FI HPTN 065



R4P Conference, 2014

Conclusions

- FI offer promise for achieving VS with possible need to target to specific populations and in certain settings
- Other FI studies have targeted non-adherers, low SES, assessed effect later after implementation
- Lessons learned from HPTN 065 can inform other studies evaluating FI
- Further analyses are planned to examine longer term effect of FI on VS
- Modelling is planned to estimate the impact of FI on VS at a population level based on HPTN 065 findings

Acknowledgements

- HPTN 065 study team
- Departments of health from New York City, Washington, DC, Chicago, Houston, Miami and Philadelphia
- Investigators at all participating HIV test and care sites
- Patients from participating communities
- HPTN 065 Community Advisory Group

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