- 1 The potential epidemiological impact of COVID-19 on the HIV/AIDS epidemic and the cost-
- 2 effectiveness of linked, opt-out HIV testing: A modeling study in six US cities
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1 **Research in context**

2 Evidence before this study:

3 The ongoing COVID-19 pandemic presents multifaced challenges to health providers in delivering 4 HIV-related prevention and treatment services, as well as to people living with HIV (PLHIV). We 5 searched the PubMed database for literature published up to June 15, 2020, with the terms ("HIV" 6 [Title/Abstract]) AND ("COVID-19" OR "SARS-CoV-2" OR "coronaviruses" [Title/Abstract]) AND 7 ("USA" OR "United States" OR "US"). We identified several observational studies and 8 commentaries on how the COVID-19 pandemic has disrupted the HIV continuum of care and 9 prevention. One survey study examined impacts of the disruptions caused by COVID-19 on 10 sexual partnering and access to HIV prevention and treatment services among U.S. men who 11 have sex with men. Another study conducted in Chicago, IL, also found declining HIV care 12 engagement among PLHIV given the financial stressors and changes in healthcare delivery. 13 However, none of the reviewed papers provided any direct evidence of the epidemiological impact 14 of the COVID-19 pandemic on HIV incidence. In a recent editorial, we argued that SARS-CoV-2 15 testing and contact tracing may provide a unique opportunity to also conduct widespread opt-out 16 (i.e. routine offer which the client may decline) HIV testing. The potential public health benefit and

17 cost-effectiveness of this hypothetical strategy is not known.

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19 Added value of this study:

20 Using a dynamic compartmental HIV transmission model calibrated for six US cities, this modeling 21 study is the first, to our knowledge, to directly estimate the potential epidemiological impact of 22 COVID-19 on the incidence of HIV under a range of possible levels of temporary service 23 disruptions and behavioural changes due to COVID-19. We extend this analysis to determine the 24 number of HIV infections that would be averted with the addition of linked opt-out HIV testing at 25 various implementation levels and the cost-effectiveness of such a strategy, accounting for the 26 effects of service disruptions and changes in risk behaviour. Despite requiring an up-front 27 investment, implementing this one-time HIV testing campaign that is linked with SARS-CoV-2 28 testing would be cost-saving in the long term across all cities.

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30 Implication of all the available evidence:

31 Linking HIV testing to SARS-CoV2 testing might reduce HIV incidence through linking individuals

32 who test positive to HIV care and mitigate racial/ethnic disparities in HIV incidence and access to

33 HIV treatment that have been highlighted and exacerbated by COVID-19 in the US. Although

34 scarcity of healthcare resources, including labour force shortages, may present challenges, this

35 strategy might have substantial public health benefits with relatively small incremental upfront

investments. 36

1 Abstract

Background: Widespread viral and serological testing for SARS-CoV-2 may present a unique opportunity to also test for HIV infection. We estimated the potential impact of adding linked, opt-out HIV testing alongside SARS-CoV-2 testing on HIV incidence and the cost-effectiveness of this strategy in six US cities.

6 Methods: We calibrated a dynamic compartmental HIV transmission model to match the 7 epidemiological characteristics of six US cities (Atlanta, Baltimore, Los Angeles, Miami, New York 8 City, Seattle). For each city, we constructed three sets of scenarios: (1) sustained current levels 9 of HIV-related treatment and prevention services (status quo); (2) temporary disruptions in health services and changes in sexual and injection risk behaviours at discrete levels between 0%-50%; 10 11 and (3) linked HIV and SARS-CoV-2 testing offered to 10%-90% of the adult population in addition 12 to scenario (2). We estimated cumulative HIV infections between 2020-2025, as well as 13 incremental costs, guality-adjusted life years, and incremental cost-effectiveness ratios of linked 14 HIV testing over 20 years.

15 Findings: In the absence of linked, opt-out HIV testing, we estimated a best-case scenario (50% 16 reduction in risk behaviours and no service disruptions) of 6,733 fewer HIV infections between 17 2020-2025 (16.5% decrease), and a worst-case scenario (no behavioural change and 50% 18 reduction in service access) of 3,669 additional HIV infections (9.0% increase) across cities. If 19 HIV testing could be offered to 10%-90% of the adult population, we estimated that a total of 576-20 7,225 (1.6%-17.2%) new infections could be averted. The intervention would require an initial 21 investment of \$20M-\$218M across cities; however, the intervention would ultimately result in 22 savings in health care costs in each city.

Interpretation: Although COVID-19-related disruptions in HIV-related services may increase or decrease HIV incidence, a campaign in which HIV testing is linked with SARS-CoV-2 testing could substantially reduce HIV incidence and reduce direct and indirect health care costs attributable to HIV.

27 Funding: US NIH-NIDA Grant No. R01-DA041747

1 Introduction

The COVID-19 global pandemic is placing an increased burden on the health care system while 2 3 creating widespread challenges and disrupting the delivery of routine medical services. In major 4 urban centers of the United States, COVID-19 might exacerbate the burden of HIV in 5 disproportionately affected populations with existing health challenges, especially Black and 6 Latinx Americans.^{1, 2} The reported reductions in access to health services due to the COVID-19 7 pandemic such as routine HIV testing, initiation or continuation of antiretroviral therapy (ART) for 8 people living with HIV (PLHIV), pre-exposure prophylaxis (PrEP) for men who have sex with men 9 at high-risk of HIV infection, medications, and harm reduction services for people who inject drugs 10 (PWID)³⁻⁷ may prompt increases in HIV transmissions, further challenging national efforts toward 11 the 'Ending the HIV Epidemic' goals.⁸

12 At present, there is limited evidence on the clinical relationship between SARS-CoV-2 and HIV. 13 Several studies have suggested no increased risk of COVID-19 disease among those stably engaged in HIV care.⁹⁻¹⁴ Furthermore, COVID-19 physical distancing recommendations may also 14 15 decrease sexual and drug injection risk behaviour, thus reducing the risk of HIV transmission.⁶ 16 However, if hospitals and clinics reach their capacity, disadvantaged populations such as PWID 17 may experience even greater barriers to medical care for COVID-19.¹⁵ Self-guarantine, physical 18 distancing and other public health measures, the economic repercussions of the epidemic, and 19 mental distress have disrupted access to syringe services programs, access to 20 pharmacotherapies including medication for opioid use disorder (MOUD), and other support 21 needed by people with opioid use disorder (OUD),¹⁶ potentially putting this already 22 disproportionately affected population at higher risk for HIV infection and drug overdose mortality. 23 Likewise, disruptions in social services such as housing, food, and social counselling could 24 complicate risk behaviour management and medical care provision for all PLHIV.

25 In a recent editorial, we argued for opt-out HIV testing to be linked to SARS-CoV2 testing and 26 contact tracing efforts that have been proposed as a central component of a COVID-19 public health strategy in the United States.¹⁷ Although recommendations from the US CDC and the US 27 28 Preventive Services Task Force currently recommend opt-out HIV testing for adults in all healthcare settings^{18, 19} to assist with reaching the goal of universal one-time testing of adults, 29 30 population-level testing remains low;^{20, 21} and even before the COVID-19 pandemic began, an 31 estimated 14% of PLHIV in the US had undiagnosed HIV.²² With evidence that HIV testing interventions are often cost-saving,²³⁻²⁷ increasing HIV testing has been shown to provide great 32 value on its own. Pairing SARS-CoV-2 viral and serological testing with testing for HIV (and 33 34 potentially other sexually transmitted and blood-borne infections like hepatitis C virus) not only 35 has the potential to provide profound health benefits, but may in part offset the immense costs of 36 such an approach in the long-term.

We aimed to estimate the potential impact of widespread, linked, opt-out HIV testing combined with SARS-CoV2 testing on the HIV/AIDS epidemics in six US cities, as well as the costeffectiveness of such a strategy, accounting for a variety of hypothesized effects of COVID-19 on HIV risk behaviours and access to HIV treatment and prevention services.

1 Methods

2 Model description

We used a dynamic, deterministic compartmental HIV transmission model to replicate the citylevel HIV microepidemics in Atlanta, Baltimore, Los Angeles, Miami (Dade County), New York City, and Seattle (King County). A detailed account of the underlying evidence synthesis, calibration, and validation are available in prior publications.^{28, 29}

7 The model tracked HIV-susceptible individuals through infection, diagnosis, treatment with ART, 8 and ART dropout. In each city, the adult population (aged 15-64 years) was grouped by biological sex (male, female), HIV transmission risk group (MSM, PWID, MSM-PWID, and heterosexual 9 persons), race/ethnicity (Black/African American [Black], Hispanic/Latinx [Hispanic], and non-10 11 Hispanic White/others [White]), and sexual risk behaviour level (high-risk vs. low-risk). The model 12 captured heterogeneity in the risk of HIV transmission, aging (via differential maturation and 13 mortality rates for PLHIV and the general population across cities), and observed racial/ethnic 14 disparities in access to health and prevention services, including HIV testing, ART, syringe service 15 programs (SSP), MOUD, and targeted PrEP for high-risk MSM.

16 Racial/ethnic- and risk-behaviour-specific linkages to HIV care and use of PrEP, SSP, and MOUD 17 were drawn from local, state and national surveillance sources.²⁸ We estimated stratified, regional 18 ART initiation and persistence rates through separate analysis of HIV Research Network data.³⁰ 19 In the absence of comprehensive city-level HIV testing data,²⁸ we back-calculated HIV testing 19 rates from high quality race/ethnicity- and risk behaviour-specific surveillance data for new 19 diagnoses published by local public health departments.²⁹ We accounted for in-migration of 12 PLHIV and overall population growth, also stratified by race/ethnicity.²⁸

23

24 Hypothetical scenarios on changes in risk behaviours and reductions in access to services

We estimated the potential impact of the COVID-19 pandemic on number of HIV infections in comparison to the status quo scenario for each city between 2020-2025. The status quo scenario was defined as maintaining all access to care constant at 2015 levels, with PrEP at 2017 levels and no changes to sexual or injection risk behaviours over time.³¹

29 In alternative scenarios, we assessed a range of possible health service disruptions levels due to 30 COVID-19, defined as 0%, 25%, and 50% reductions in access to all forms of HIV care, treatment and prevention services, including HIV testing, ART initiation, ART engagement, PrEP uptake, 31 SSP, and MOUD.⁷ We also considered possible reductions of 0%, 25% and 50% in the number 32 33 of sexual partners and the number of shared injections due to physical distancing 34 recommendations, and estimated the potential impact of all combinations of these discrete levels 35 of health service disruption and change in risk behaviours. These conditions were assumed for a 12-month period from March 1st 2020 to February 28th 2021, with conditions returning to pre-36 37 COVID-19 levels thereafter. These timeframes were chosen with the assumption that an effective 38 vaccine will be developed and ready for use in early 2021.

39

40 Linked HIV and SARS-CoV-2 testing

We also estimated the preventive benefits of linked opt-out HIV testing compared with the aforementioned COVID-19 scenario with possible disrupted health services and changes in sexual and injection risk behaviours. We assumed that the SARS-CoV-2 testing would be offered to 10%, 25%, 50%, 75%, and 90% of the adult population in each city between June 1st and February 28th 2021, and that of those, 65.9% would accept opt-out HIV testing, consistent with acceptance rates reported in a randomized clinical trial set in the emergency department of an
 urban teaching hospital and regional trauma center.³²

3 To maximize its potential reach, we assumed linked HIV testing could be offered alongside viral, 4 antigen, or antibody testing for SARS-CoV-2, using oral swab or fingerstick point-of-care HIV 5 testing, oral specimen or dried blood spot sample collection for remote laboratory testing, or 6 phlebotomy for serological laboratory testing. We applied the costs of the highest-cost testing 7 technology (oral swab point-of-care test: \$17.63 for a non-reactive test, and \$102.16 for a reactive 8 test [Appendix Tables A1-A3]) to generate a conservative estimate for the cost-effectiveness of 9 the strategy. The HIV testing cost included personnel time and material costs using fourthgeneration HIV assays and equipment.³³ These costs were adapted from the estimated costs for 10 HIV testing in emergency department settings.³⁴ We assumed reactive results would be reported 11 to public health authorities for follow-up, and we did not include the cost of these follow-up 12 13 activities.

14

15 Cost-effectiveness analysis

16 Model-projected outcomes included quality-adjusted life-years (QALYs), total costs (in 2018 17 US\$), and new HIV infections. We described and compared the cumulative number of HIV 18 infections for each city between 2020 and 2025, matching the timeframe for the first target of the 19 US' Ending the HIV/AIDS Epidemic's strategy, and the cost-effectiveness analysis considered 20 outcomes until 2040 to capture long-term individual health benefits (i.e. delayed morbidity, 21 mortality due to ART engagement) and second-order transmission effects. We estimated 22 incremental cost-effectiveness ratios (ICERs) as the incremental cost per QALY gained for the 23 widespread HIV testing efforts compared with the hypothesized COVID-19 impact scenarios. Costs included those for HIV testing, ART, PrEP, and MOUD, other medical costs, and SSP costs. 24

In accordance with best practice guidelines of the Second Panel on Cost-Effectiveness in Health
 and Medicine, the cost-effectiveness analysis was conducted from the health-care sector
 perspective, including government, employer-paid, and out-of-pocket health-care expenditures.
 Both costs and QALYs were reported with a 3% annual discount rate.³⁵

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30 Role of the funding source

31 The funder of the study had no role in study design, data collection, data analysis, data

interpretation, or writing of the report. The corresponding author had full access to all the data inthe study and had final responsibility for the decision to submit for publication.

1 Results

Compared to the status quo of holding service levels constant, we estimated that the best-case hypothetical scenario of 50% reductions in sexual and drug injection risk behaviours and no disruptions in health service provision due to the onset of COVID-19 could result in a total of 6,733 fewer HIV infections between 2020-2025 for all six cities, a 16.5% decrease in cumulative incidence. Across cities, the relative reductions for this hypothesized scenario range from 14.3% in Los Angeles (1,683 fewer infections) to 20.4% in Miami (2,383 fewer infections) (Figure 1, Appendix Table A4).

9 In contrast, the worst-case scenario of no behavioural change and 50% reductions in health service provision could lead to a total of 3.669 additional HIV infections between 2020-2025 for 10 11 all six cities, a 9.0% increase in cumulative incidence compared to the status quo. The relative 12 increases ranged from 7.0% in Miami (821 more infections) to 15.7% in New York City (945 more 13 infections). Similarly, we estimated relative increases in HIV infections in all cities resulting from 14 no behavioural change and 25% health service reduction, ranging from 3.4% in Atlanta to 7.5% 15 in New York City. Comparing the change in HIV infections in the face of both behavioural change 16 and health service reduction due to COVID-19, we found the results were relatively more sensitive 17 to changes in HIV risk behaviours than disruptions in HIV-related services (Figure 1, Appendix 18 Table A4).

We estimated that linked, opt-out HIV testing alongside SARS-CoV2 testing and contact tracing
could reduce HIV infections between 2020-2025 in all six cities, ranging from 576-696 (1.6%1.7%) fewer infections with 10% offered HIV testing (16.5% accepting a test), up to 5,840-7,225
(16.3%-17.2%) fewer infections with 90% offered testing (59.3% accepting a test) (Figure 2,
Appendix Table A4).

24 At the city level, the smallest relative reduction in cumulative infections from linked opt-out testing 25 would be 1.0-1.2% (52-83 fewer infections) in New York City with 10% offered an HIV test, and 26 the largest reduction would be 25.9%-28.9% (609-719 fewer infections) in Baltimore with 90% 27 offered an HIV test. The relative reduction in HIV infections due to linked HIV testing was greatest 28 compared to the best-case scenario (50% reduction in risk behaviours and no health service 29 reduction) at all levels of testing intervention in Atlanta, Baltimore, and Miami, while Los Angeles 30 and New York City benefitted most compared to the worst-case scenario (no behavioural change 31 and 50% health service reduction). In terms of the range for the absolute number of infections 32 averted by the testing efforts, 10% testing would result in 19-23 (2.3%-2.4%) fewer infections in 33 Seattle at various levels of behavioural change and service reduction, while the impact of 90% 34 testing in Los Angeles would result in 1,601-2,070 (15.8%-16.1%) fewer infections (Figure 2, 35 Appendix Table A4).

The linked opt-out HIV testing was estimated to produce gains of between 136-157 QALYs in Seattle with 10% offered an HIV test and up to 9,154-11,513 QALYs in Los Angeles with 90% offered an HIV test. At an estimated up-front cost ranging from \$1.4M-\$14.8M in Seattle to \$6.7M-\$70.2M in Los Angeles (with 10%-90% offered HIV tests), in addition to SARS-CoV2 testing costs alone, we found the linked opt-out HIV testing strategies were likely to be cost-saving over a period of 20 years for all cities at all testing levels compared to any comparator scenario for changes in risk behaviours and service access (**Appendix Table A5**).

1 Discussion

2 This study demonstrated that, in six US cities, if the COVID-19 pandemic adversely impacts HIV health service provision, increased numbers of HIV infections will likely occur, even if HIV risk 3 4 behaviors decline temporarily due to physical distancing recommendations. Furthermore, 5 implementing linked HIV testing alongside SARS-CoV-2 testing has the potential to reduce the 6 number of HIV infections by up to 17% over 5 years if 90% are offered HIV tests across all cities. 7 In addition, offering HIV testing with a SARS-CoV-2 vaccine, rather than with SARS-CoV-2 testing 8 (which could be implemented sooner because of the current lack of a vaccine), could be equally 9 effective. This HIV testing strategy would require a \$20M-\$218M incremental upfront investment

10 but would be cost-saving in the long term across all cities.

11 HIV testing has long been found to be an effective and cost-effective intervention in preventing 12 HIV transmissions and linking more PLHIV to HIV treatment.³⁶ Given its low unit cost, our 13 estimated cost-effectiveness for this proposed HIV testing intervention is consistent with our previous analysis²³ and other prior studies.³⁷ Population-level SARS-CoV-2 viral and serological 14 15 testing may provide a unique opportunity to conduct HIV testing, among other health promotion activities. Our analysis shows that this HIV testing strategy averted a relatively greater percentage 16 17 of HIV infections in Atlanta (which has low estimated HIV testing rates), Seattle, and Baltimore 18 (cities with higher levels of HIV treatment engagement). This finding demonstrates the potential 19 to enhance existing testing programs and the importance of subsequent HIV care and treatment

20 services to maximize the benefits after individuals receive a diagnosis.

21 The US CDC conducted over 3 million HIV tests annually, many as part of the 'Expanded Testing 22 Initiative',³⁸ and CDC-supported testing programs are associated with about one third of all HIV diagnoses in the nation annually.³⁹ Assembling and organizing the labor force to address COVID-23 24 19 has taken an all-encompassing effort in the six participating cities, but limited additional training 25 is required to include an offer for an HIV test.³⁴ Offering linked HIV testing may add relatively little 26 time to each contact, but implementation of HIV testing in practice may depend on local public 27 health initiatives. For instance, sample collection with a self-administered oral swab would allow 28 physical distancing, similar to how SARS-CoV-2 viral testing is currently being conducted, and 29 point-of-care HIV testing would provide immediate results (albeit with slightly lower sensitivity) 30 that may better facilitate subsequent linkage to care. Point-of-care HIV testing could also be 31 delivered with a fingerstick, which would require interactions with public health personnel. While 32 phlebotomy sample collection for HIV testing alongside serological SARS-CoV-2 testing would involve direct contact with patients and specimen handling, this option would allow for the 33 34 inclusion of other testing initiatives that may provide great public health benefits (e.g., HCV, 35 HbA1c); however, laboratory and personnel capacity for follow-up would need to be confirmed, as these inputs are likely to compete with resources needed for SARS-CoV2 testing, case 36 investigation, and contact tracing efforts. Specific combination implementation strategies may 37 38 therefore differ according to context, available resources and the needs of the communities served; we have only considered one such strategy in this analysis. Finally, whether linked HIV 39 40 testing - offered alone or in combination with other health promotion activities - would reduce SARS-CoV-2 test acceptance rates is also unknown and would require meaningful engagement 41 42 with public health personnel and the community throughout the process.

If these obstacles can be overcome, implementing widespread HIV testing in the SARS-CoV-2
testing and vaccine response can help address the disproportionate impact of COVID-19 and HIV
on racial and ethnic minority and other disproportionately affected populations. A recent analysis
documented that counties where the majority of residents were Black experienced three times
the COVID-19 infection rate and nearly six times the death rate seen in counties where the

1 majority of residents were White.⁴⁰ Driven by long-standing systemic health and social inequities, 2 including the direct and downstream effects of systemic racism, lack of public health and 3 economic investment in minority communities, and mass incarceration, similar racial/ethnic disparities are observed in HIV disease burden in the United States.^{41, 42} We recently concluded 4 5 that even with tailored HIV treatment and prevention strategies implemented at ideal levels for each city, racial/ethnic disparities in HIV incidence will persist without addressing existing 6 7 inequities in access to healthcare.⁴³ Incorporating HIV testing and linkage to care within SARS-8 CoV-2 viral and serological testing, when done responsibly and with input from the most affected 9 communities, could be a promising approach to addressing these overlapping racial/ethnic health 10 disparities in the United States.

11 This study features several limitations in the structure of the model and the underlying evidence base that we have described in prior publications.^{23, 28, 29, 31} In addition, specific to this analysis, 12 13 the potential duration of the COVID-19 pandemic is unknown, and there is limited evidence of its 14 impact on the PLHIV population and level of HIV health service interruption in the US. If the level 15 of disruption in services is higher and lasts longer and/or the uptake of HIV testing does not achieve the ambitious levels we have proposed, the estimated additional number of HIV cases 16 17 that could occur would be even greater. Second, in the cost-effectiveness analysis, we only captured the increased cost of providing more HIV tests and subsequent treatment, and did not 18 19 consider additional costs that might be associated with implementing the linked HIV testing 20 intervention, such as potential costs for training personnel and other public health expenses for 21 linkage to care. In addition, many HIV and STD-focused staff in health departments have been 22 reassigned to support the COVID-19 response, and there may be limited human resources to add 23 HIV testing. However, we assumed the upper bound of possible incremental cost for linked HIV 24 testing, so our results are likely to be conservative, potentially offsetting some of the additional 25 costs and logistical obstacles. Furthermore, our results showed that the intervention was found to 26 be cost-saving across all cities and analyzed scenarios, further emphasizing its public health 27 value. Third, at present there are limited data on how the COVID-19 pandemic has affected risk 28 behaviours and delivery of HIV-related services to parameterize our model. To address this, we 29 simulated a range of possible levels of service disruptions and behavioural changes to better 30 capture the potential epidemiological impact of COVID-19 and benefits of adding the linked HIV 31 testing. Given the inherent uncertainty and exploratory nature of our results, we chose not to 32 conduct further deterministic or probabilistic sensitivity analyses.

33

Securing funding and ensuring successful implementation of SARS-CoV-2 testing are key hurdles to cross; however, linking HIV testing to SARS-CoV-2 viral and serological testing efforts could substantially reduce HIV incidence and the upfront costs of doing so would be offset over the long-term. Furthermore, the linkage in testing would provide an opportunity for the US to remain focused on its ambitious plan to end the HIV epidemic by 2030 and address racial/ethnic disparities in HIV incidence at a time when HIV prevention and treatment services have been disrupted.

1 Acknowledgments

2 This study was funded by the National Institutes on Drug Abuse (NIDA grant no. R01DA041747).

3 The findings and conclusions in this report are those of the authors and do not necessarily 4 represent the official position of the Centers for Disease Control and Prevention.

5 **Contributors**

6 XZ and BN conceptualized the study. XZ, EK and MP wrote the first draft of the article. EK, XZ, 7 MP and SC assisted with analyses and contributed to manuscript development. WSA, CNB, CDR,

8 DJF, BDLM, SHM, JM, LRM, BRS, SAS and BN aided in the interpretation of results and provided

9 critical revisions to the manuscript. BN secured funding for the study. All authors approved the 10 final draft.

11 Declaration of interests

12 XZ, EK, SC, MP, WSA, CNB, CDR, DJF, BDLM, SHM, JM, LRM, BRS, SAS and BN declare no 13 competing interests.

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1 Figure 1. Potential impact of COVID-19-related disruptions in HIV services and changes in risk 2 behaviour on cumulative HIV infections between 2020-2025 in six US cities

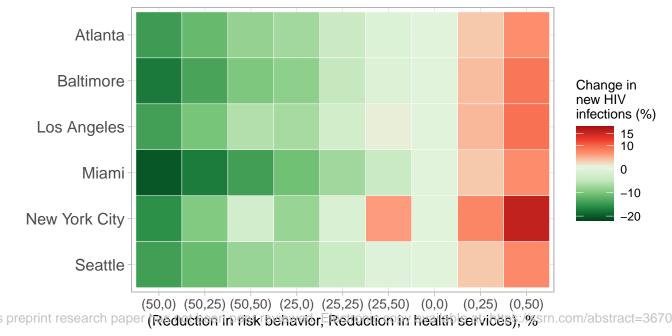
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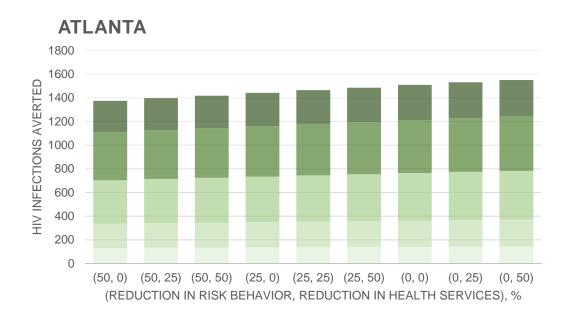
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- 5 Figure 2. Impact of linked opt-out HIV testing alongside SARS-CoV2 testing on averting HIV 6 infections between 2020 and 2025 in six US cities
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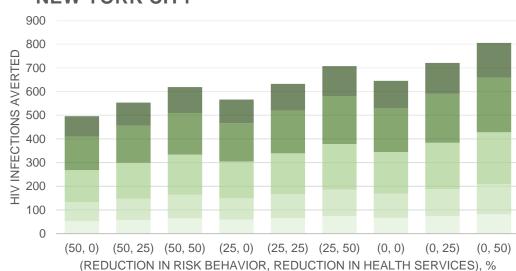
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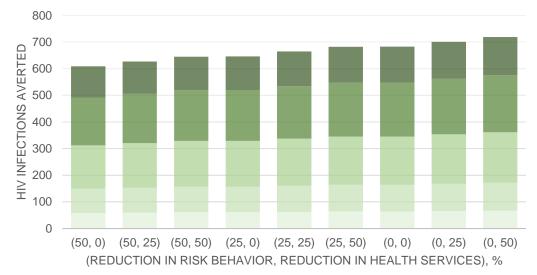


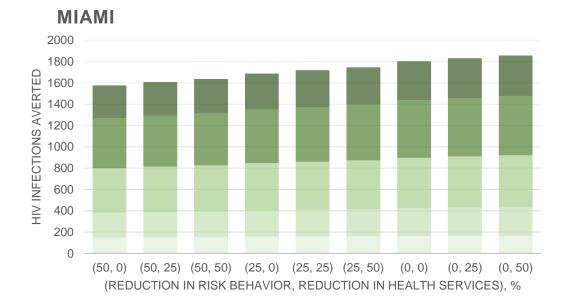
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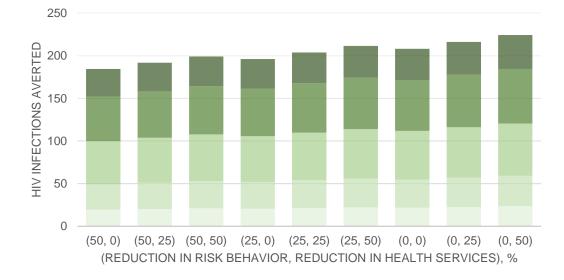




BALTIMORE







LINKED OPT-OUT HIV TESTING LEVELS 10% 25% 50% 75% 90%

SEATTLE

NEW YORK CITY