THE UNIVERSITY OF CHICAGO
MEDICINE & BIOLOGICAL SCIENCES

Connecting the Dots:

From Testing to Linkage to Rapid Start

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Disclosures

- Served on an advisory board for Gilead Sciences, unrelated to current presentation
- No other financial disclosures
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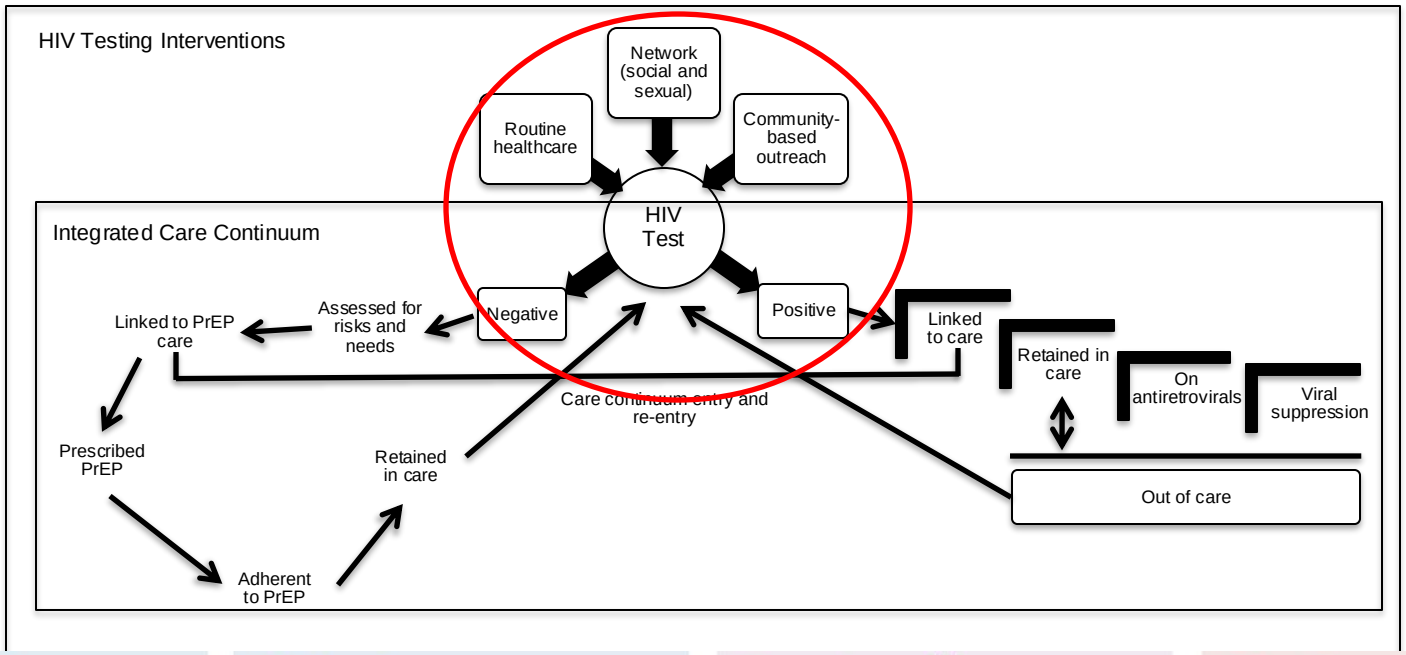
Objectives

- Recognize the importance of HIV testing and accurate diagnosis
- Understand evidence, guidelines, and implementation of rapid initiation of antiretroviral therapy
- Identify symptoms of acute HIV infection

HIV Testing as Care Continuum Entry



Diagnosed

received a diagnosis of HIV

Linked to care*

visited an HIV heath care provider within 1 month (30 days) after learning they were HIV positive

Received or were retained in care*****

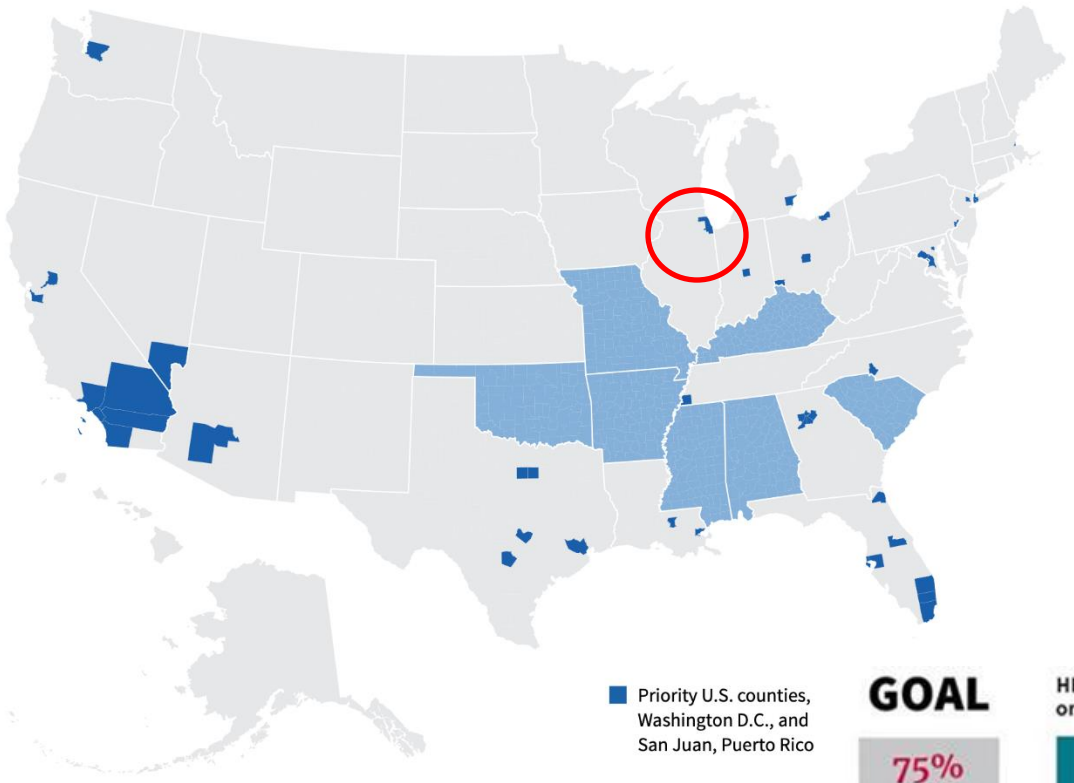
received medical care for HIV infection

Viral suppression

their HIV "viral load" – the amount of HIV in the blood – was at a very low level.

Adapted from McNulty, Schneider et al. AIDS 2018;. and Horn et al. J Int AIDS Soc. 2016; 19(1): 21263.
https://www.iapac.org/fact-sheet/hiv-care-continuum/

Ending the HIV Epidemic



Priority U.S. counties, Washington D.C., and San Juan, Puerto Rico

GETTING TO ZERO ILLINOIS

GOAL

75% reduction in new HIV infections in 5 years and at least 90% reduction in 10 years.

HHS will work with each community to establish local teams on the ground to tailor and implement strategies to:

- **Diagnose** all people with HIV as early as possible.
- **Treat** people with HIV rapidly and effectively to reach sustained viral suppression.
- **Prevent** new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs).
- **Respond** quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.

https://files.hiv.gov/s3fs-public/ending-the-hiv-epidemic-flyer.pdf

Opt-Out Testing in HealthCare Settings: Expanded Testing and Linkage to Care Program

- Implement healthcare-based HIV testing activities at sites located in geographies with high rates of STIs, HIV, and morbidities/mortalities from HIV

- Routine opt-out HIV testing per CDC recommendations
  - All patients ages 13-64 are tested for HIV, regardless of risk factors
  - 4th or 5th generation testing technologies

CCHE The Chicago Center for HIV Elimination

AT THE FOREFRONT UChicago Medicine

Opt-Out Testing in HealthCare Settings: Expanded Testing and Linkage to Care Program

- Partnerships:
  - In 2011, South Side Healthcare Collaborative:
    - South and West sides of Chicago
    - Primarily communities of color
  - In 2019, program expansion and partnerships occurred beyond the City of Chicago:
    - Added West and South suburban clinical testing sites as sub-partners (Cook County report)
  - Community of practice around HIV testing
    - Data feedback
    - Best practices
- Partnership with CDPH:
  - Leverage annual surveillance reports to identify areas most vulnerable to HIV and align testing & LTC activities with the community's greatest need

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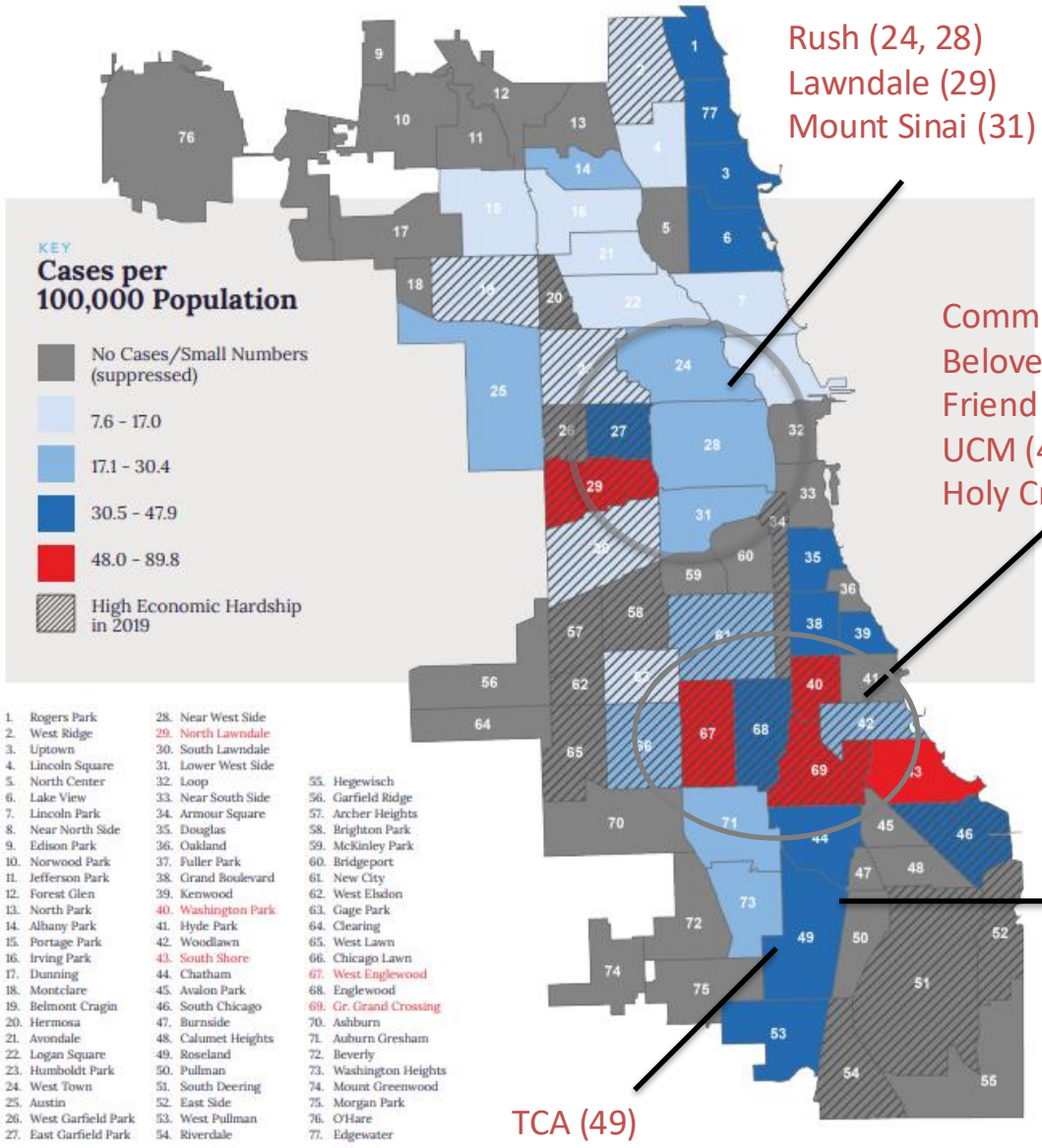
FIGURE 1.2

Rate of HIV Infection Diagnoses by Community Area

Chicago, 2021



1. Rogers Park
2. West Ridge
3. Uptown
4. Lincoln Square
5. North Center
6. Lake View
7. Lincoln Park
8. Near North Side
9. Edison Park
10. Norwood Park
11. Jefferson Park
12. Forest Glen
13. North Park
14. Albany Park
15. Portage Park
16. Irving Park
17. Dunning
18. Montclare
19. Belmont Cragin
20. Hermosa
21. Avondale
22. Logan Square
23. Humboldt Park
24. West Town
25. Austin
26. West Garfield Park
27. East Garfield Park
28. Near West Side
29. North Lawndale
30. South Lawndale
31. Lower West Side
32. Loop
33. Near South Side
34. Armour Square
35. Douglas
36. Oakland
37. Fuller Park
38. Grand Boulevard
39. Kenwood
40. Washington Park
41. Hyde Park
42. Woodlawn
43. South Shore
44. Chatham
45. Avalon Park
46. South Chicago
47. Burnside
48. Calumet Heights
49. Roseland
50. Pullman
51. South Deering
52. East Side
53. West Pullman
54. Riverdale
55. Hegewisch
56. Garfield Ridge
57. Archer Heights
58. Brighton Park
59. McKinley Park
60. Bridgeport
61. New City
62. West Elsdon
63. Gage Park
64. Clearing
65. West Lawn
66. Chicago Lawn
67. West Englewood
68. Englewood
69. Gr. Grand Crossing
70. Ashburn
71. Auburn Gresham
72. Beverly
73. Washington Heights
74. Mount Greenwood
75. Morgan Park
76. O'Hare
77. Edgewater

Data Source: CDPH, Enhanced HIV/AIDS Reporting System (as of 09/26/2022), City of Chicago GIS Shapefiles, and U.S Census.

This map represents 90% (575/639) of total new HIV infection diagnoses. The economic hardship index utilizes multiple indicators to measure economic conditions of Chicago Community Areas. High hardship index scores indicate worse economic conditions.

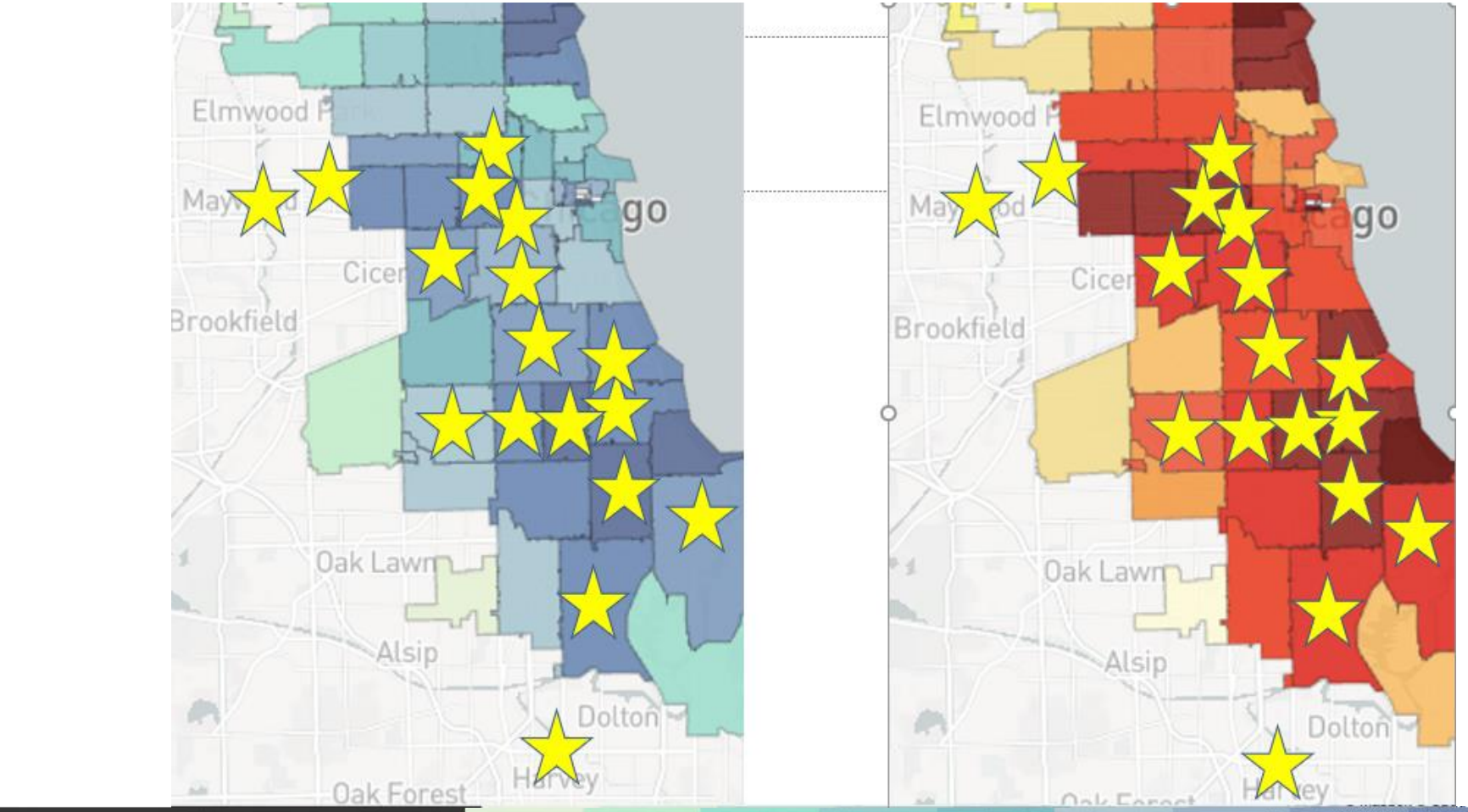
Rush (24, 28)
Lawndale (29)
Mount Sinai (31)

Michael Reese (33)
UIC (28)

Community Health (68, 24)
Beloved (68)
Friend Family (40)
UCM (42)
Holy Cross (66)

Chicago Family (66, 50, 52, 49, 46, 89)

TCA (49)



*Rates displayed are the number of cases per 100,000 population

AIDSVu.org

Opt-Out Testing in HealthCare Settings: Expanded Testing and Linkage to Care Program

Year	# Sites	Tests	Positive Tests (%*)	Newly Positive (%*)
2011	3	11,855	90 (0.76)	43 (0.36)
2012	10	27,311	135 (0.49)	67 (0.25)
2013	10	36,287	173 (0.48)	77 (0.21)
2014	12	30,858	230 (0.75)	118 (0.38)
2015	12	65,063	297 (0.46)	122 (0.19)
2016	14	86,143	463 (0.54)	189 (0.22)
2017	14	121,102	537 (0.44)	191 (0.16)
2018	13	104,424	483 (0.46)	166 (0.16)
2019	13	123,730	458 (0.37)	137 (0.11)
2020	14	112,713	656 (0.58)	169 (0.15)
2021	14	133,737	893 (0.67)	168 (0.13)
2022	14	141,691	847 (0.60)	174 (0.12)
2023	14	150,180	755 (0.50)	156 (0.10)
TOTALS		**1,145,094**	**6016 (0.53 %) About 1:190 Tests**	**1,777 (0.16%) About 1:640 Tests**

*Percentage of positive and newly positive tests out of all tests performed.

2023 Demographics

	Male	Female	Transgender women	Unknown	Total
Overall	499 (68.0%)	224 (30.6%)	6 (0.8%)	4 (0.6%)	733
Existing	388 (68.2%)	175 (30.8%)	3 (0.5%)	3 (0.5%)	569
New	105 (66.9%)	48 (30.6%)	3 (1.9%)	1 (0.6%)	157
Unknown	6 (85.7%)	1 (14.3%)	0	0	7

2023 Demographics

	Black/ African-American	White	Multi-Racial	Asian	Native American/ Indigin-eous	Native Hawaiian/ Pacific Islander	Unknown/ No Race Reported	Total
Overall	560 (76.4%)	64 (8.7%)	11 (1.5%)	4 (5.5%)	3 (0.4%)	1 (0.1%)	90 (12.3%)	733
Existing	436 (76.6%)	49 (8.6%)	10 (1.8%)	3 (0.5%)	2 (0.4%)	1 (0.2%)	68 (12.0%)	569
New	119 (75.8%)	15 (9.6%)	1 (0.6%)	1 (0.6%)	1 (0.6%)	0	20 (12.7%)	157
Unknown	5 (71.4%)	0	0	0	0	0	2 (28.6%)	7

2023 Demographics

	Hispanic/Latinx	Non-Hispanic/Latinx	Unknown/No Ethnicity Reported	Total
Overall	99 (13.5%)	589 (80.4%)	45 (6.1%)	733
Existing	73 (12.8%)	463 (81.4%)	33 (5.8%)	569
New	26 (16.6%)	122 (77.7%)	9 (5.7%)	157
Unknown	0	4 (57.1%)	3 (42.9%)	7

2023 Demographics

Age	16 - 24	25 - 29	30 - 39	40 - 49	50 - 59	60+
Overall	63 (8.6%)	79 (10.8%)	227 (40.0%)	116 (15.8%)	125 (17.1%)	123 (16.8%)
Existing	26 (4.6%)	48 (8.4%)	174 (30.6%)	93 (16.3%)	112 (19.7%)	116 (20.4%)
New	35 (22.2%)	30 (19.1%)	50 (31.8%)	23 (14.6%)	12 (7.6%)	7 (4.5%)
Unknown	2 (28.6%)	1 (14.3%)	2 (28.6%)	0	1 (14.3%)	0

Expanded Testing and Linkage to Care Program

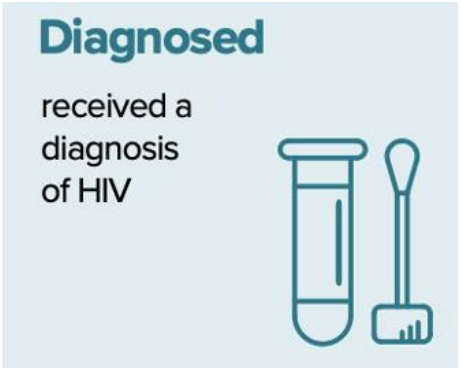
	CDPH			xTLC (n/%)			xTLC	
Year	Male	Female	Total	Male	Female	Total	Tests performed	Positivity rate
2011	812	176	988	26(3%)	9(5%)	35(3%)	11,867	0.29%
2012	869	176	1045	52(6%)	23(13%)	75(7%)	27,310	0.27%
2013	869	161	1030	51(6%)	26(16%)	77(8%)	36,270	0.22%
2014	810	138	948	82(10%)	30(22%)	112(12%)	44,498	0.25%
2015	756	133	889	84(11%)	32(24%)	116(13%)	65,073	0.19%
2016	717	156	873	133(19%)	55(35%)	188(21%)	91,860	0.20%
2017	627	132	759	133(21%)	43(33%)	176(22%)	93,575	0.19%
2018	609	126	735	111(18%)	47(37%)	158(21%)	104,125	0.15%
2019	533	100	633	146(27%)	35(35%)	181(28%)	123,664	0.15%
2020	545	81	627	137(25%)	30(37%)	167(27%)	112,713	0.15%
2021	534	103	637	126(24%)	42(41%)	168(26%)	133,737	0.13%
2022	514	113	627	120(23%)	49(43%)	169(27%)	141,691	0.12%
Grand total	8,196	1,595	9,791	1,201(15%)	421(26%)	1,622(17%)	986,383	0.16%

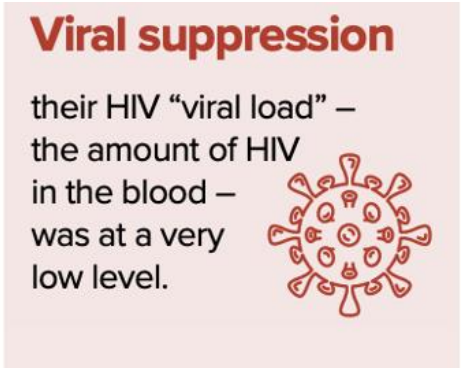
*n=number of individuals diagnosed with HIV, %= percent of CDPH diagnoses

HIV Testing and the Continuum of Care

- Benefits of faster linkage to care and ART

- Evaluation of NHAS linkage to care guidelines
  - Among those linked to care within 2–3 months after diagnosis, 58.2% and 72.7% achieved viral suppression within 12 and 24 months, respectively, lower than among persons linked to care within 1 month





CDC 2016; Jenness 2012; Pitasi 2020; Hall 2016

Early Antiretroviral Therapy (ART)

- Reduces morbidity and mortality
- Reduced risk of transmission to others
- Improved immunologic recovery
- Reduced HIV reservoir
- Reduced treatment delays

GETTING TO ZERO ILLINOIS

U = U
Undetectable means Untransmittable

Zolopa 2009; Lundgren 2015; Cohen 2016; Jain 2013; Ford 2018; New York State Clinical Guidelines Program 2015

Rapid Initiation of ART

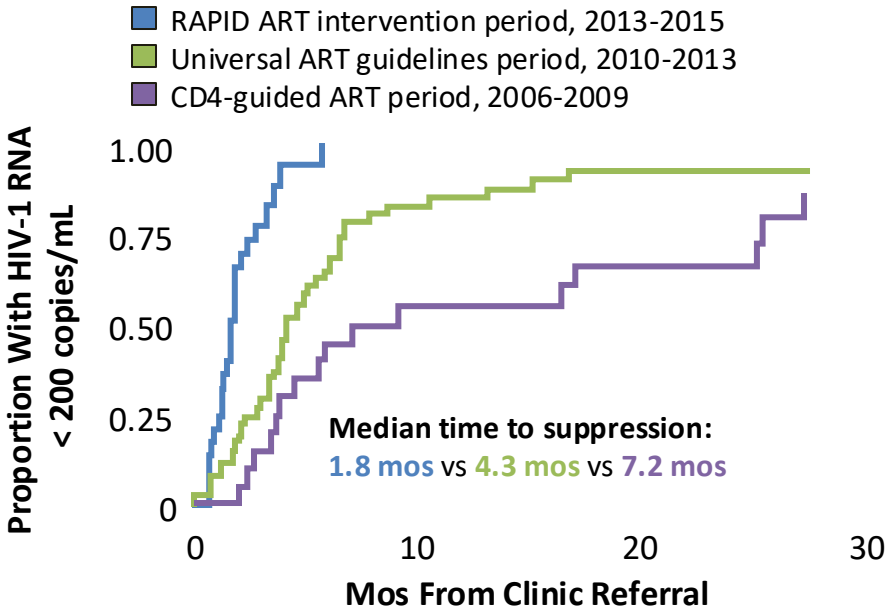
- Faster time to linkage **and** starting medication (same day, within 72 hours to 7 days):
  - Reduces loss to follow up
  - Faster viral suppression (including durable viral suppression)
  - Better retention in care
  - Trends towards less mortality
  - Expect less transmission to others

Pilcher 2017; Coffey 2019; Halperin 2018; Colasanti 2018; Koenig 2017; Rosen 2016; WHO 2017; Saag 2018; DHHS 2019; Bacon 2020

Pilot Study: Rapid ART Program Initiative for HIV Diagnoses (RAPID) in San Francisco

- Same-day (RAPID) ART initiation, including access to HIV provider, labs, and counseling
  - Most RAPID protocol patients received INSTI-based regimens
  - No resistance-driven ART changes in RAPID protocol patients after GT became available (25% had transmitted mutations, 22% of which were major NNRTI mutations)
- RAPID protocol led to faster HIV-1 RNA suppression vs historical cohorts with different ART initiation strategies

Time to Viral Suppression in Patients Newly Diagnosed HIV+ at UCSF With RAPID vs Prior Periods



Pilcher. JAIDS. 2017;74:44.
Slide prepared by Dr. Gregory Hugn, Cook County Health, CORE Center

Slide credit: clinicaloptions.com

Recommendations for Rapid ART

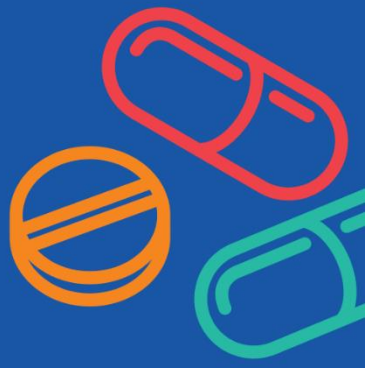
- DHHS
  - Recommended at time of diagnosis or soon afterward
    - Resource intensive
- WHO
  - Recommended for all PWH, including same day, if patient is ready
- IAS-USA
  - Start ART as soon as possible, including immediately after diagnosis, if patient is ready

*Rapid initiation defined as within 7 days of diagnosis. Priority should be given to patients with advanced disease.

DHHS Guidelines. December 2019; WHO Guidelines. July 2017; Saag. JAMA. 2018;320:379.
Adapted from slide prepared by Dr. Gregory Hugn, Cook County Health, CORE Center

Rapid ART

Starting antiretroviral therapy (ART) immediately after HIV diagnosis is recommended by U.S. federal guidelines. Rapid ART (aka immediate ART) can result in earlier HIV viral suppression, improved retention in care, and reduced HIV transmission.



INDICATIONS

Rapid ART is appropriate for:

- Individuals with a confirmed HIV diagnosis (i.e., HIV Ag, Ab, and/or HIV RNA viral load)
- Persons with suspected acute HIV infection, with or without confirmed HIV diagnosis (HIV Ag or Ab test results may be negative or indeterminate at the time of evaluation)

Rapid ART is not appropriate for:

- Persons with certain untreated opportunistic infections (OIs)—e.g., the CNS infections cryptococcal or TB meningitis; begin OI treatment before starting ART (consult with experts)

COMPRESSED HIV INTAKE

- Review of HIV test results
- Targeted health history
- HIV risk behaviors
- Date of last negative HIV test
- Use of PrEP or PEP
- Psychoemotional counseling, support
- HIV education (including ART benefits, possible adverse effects, adherence, preventing transmission)
- Targeted physical exam
- Benefits counseling, insurance enrollment or optimization

Baseline Labs

Offer ART

- If patient agrees and there are no contraindications, prescribe 30-day supply, give starter pack if available
- If patient declines immediate ART, follow up within 1-2 weeks, re-offer ART, continue HIV education

AIDS Education and Training Center Program. January 2023. AIDSETC.org

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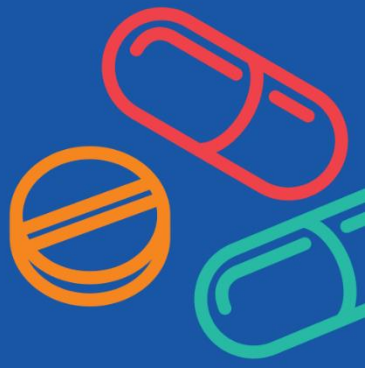


RECOMMENDED REGIMENS

These can be modified based on results of baseline labs.

- Dolutegravir (Tivicay), 50 mg once daily + [TAF/FTC (Descovy), TDF/FTC (Truvada), or TDF/3TC] 1 once daily
- Bictegravir/TAF/FTC (Biktarvy) 1 once daily
- Darunavir/cobicistat/TAF/FTC (Symtuza) 1 once daily

If **taking PrEP or PEP** at or since the time of HIV infection:

- Consider an enhanced regimen: boosted PI + integrase inhibitor + TAF/FTC (Descovy), TDF/FTC (Truvada), or TDF/3TC; seek consultation
- If on injectable cabotegravir PrEP, consider boosted PI + TAF/FTC (Descovy), TDF/FTC (Truvada), or TDF/3TC

If **pregnant** or trying to conceive (some antiretrovirals are notrecommended during pregnancy):

- Dolutegravir (Tivicay), 50 mg once daily + [TAF/FTC (Descovy), TDF/FTC (Truvada), or TDF/3TC] 1 once daily
- Other options may be appropriate; consult with expert

Abbreviations: 3TC: lamivudine; FTC: emtricitabine; PI: protease inhibitor; TAF: tenofovir alafenamide; TDF: tenofovir disoproxil fumarate; BID: twice daily

FOLLOW UP

Schedule a follow-up visit for 1-2 weeks, then at least monthly until well established in care

AIDS Education and Training Center Program. January 2023. AIDSETC.org

Rapid Initiation of ART for HIV Infection

Figure 1. Protocol for Rapid Antiretroviral Therapy Initiation

Identify Rapid ART Candidates	Counseling and Education	Assess and Refer	Baseline Lab Testing	Initiate ART	Payment Assistance?	Follow-Up	Adjust ART
Candidates have: • A new reactive POC HIV test result, new HIV diagnosis, acute HIV, or known HIV, *and* • No or limited prior ARV use, *and* • No medical conditions or OIs that require deferral of ART initiation	• HIV diagnosis • Disclosure • Adherence • Side effects and management of • Management of lifelong medications	• Health literacy • Identify and address medical and psychosocial barriers to treatment and adherence • As indicated, refer for substance use treatment, behavioral health services, housing assistance	• Confirm HIV diagnosis • Viral load • Resistance testing • CD4 count • HAV, HBV, HCV testing • Metabolic panel • STIs • Urinalysis • Pregnancy test for individuals of childbearing potential	• Choose a preferred regimen based on patient characteristics and preference • Initiate ART immediately—preferably on the same day—or within 72 hours • Administer the first dose on site if possible	• Assess need for payment assistance • Refer patients with no insurance to NYS UCP • Provide resources for payment assistance	• Contact the patient within 24 to 48 hours by phone (or other preferred method) • Assess medication tolerance and adherence • If feasible, schedule in-person visit with medical care provider within 7 days • Reinforce adherence	• Change or adjust the initial ART regimen based on results of initial lab and resistance testing

New York State Department of Health AIDS Institute: www.hivguidelines.org

Implementation of Rapid ART

Patient experience:

(1) immediate ART encounters were seen as supportive
(2) immediate ART was sensible/logical
(3) immediate ART offered emotional relief from fears and agency over one's health

Successful programs:

(1) presence of an implementation champion;
(2) comfort and competence prescribing RAPID ART;
(3) expedited access to ART medications;
(4) expertise in benefits, linkage, and care navigation;
(5) RAPID team member flexibility and organizations' adaptive capacity;
(6) patient-centered approach; and
(7) strong communication methods and culture

Koester et al. BMC Infectious Diseases 2022
Christopoulos et al. Open Forum Infectious Diseases 2021

Key Components of Rapid ART Programs

- Provision of client-centered services
- On-site testing or strong partnerships with testing programs
- Warm hand-offs and accessible linkage coordinators
- Accessible education on beginning ART
- Accelerated access to a medical visit with an HIV provider
- Early and sustained access to ART
  - Pre-approved ART regimens and starter pack of medications
- Accelerated insurance/payor approval and clinic enrollment
- Follow-up with continued education, patient navigation, and supportive services

https://targethiv.org/ta-org/building-rapid-start

Open Forum Infectious Diseases

BRIEF REPORT

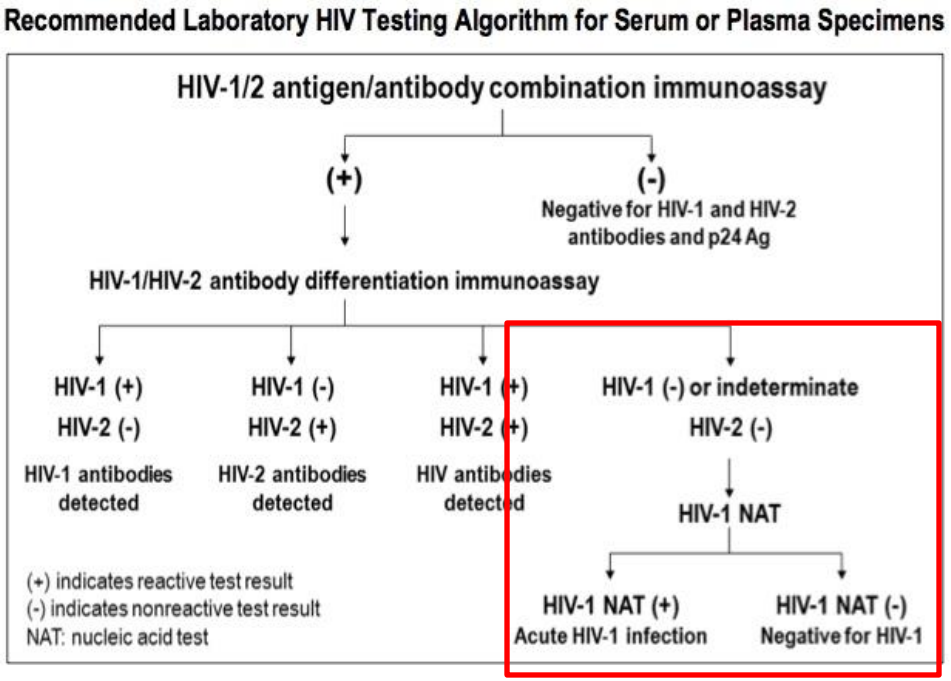
Reflex Human Immunodeficiency Virus (HIV) Type 1 RNA Testing Enables Timely Differentiation of False-Positive Results From Acute HIV Infection

Christopher Kaperak,[1] Dylan Eller,[2,3] Samantha A. Devlin,[2,3] André Hall,[2,3] Jessica Schmitt,[2,3] Eleanor E. Friedman,[2,3] Kathleen G. Beavis,[4] Kimberly A. Stanford,[5] David Pitrak,[2,3] and Moira C. McNulty[2,3,]

[1]Department of Medicine, University of Chicago Medicine, Chicago, Illinois, USA, [2]Section of Infectious Diseases and Global Health, University of Chicago, Chicago, Illinois, USA, [3]Chicago Center for HIV Elimination, University of Chicago, Chicago, Illinois, USA, [4]Department of Pathology, University of Chicago, Chicago, Illinois, USA, and [5]Section of Emergency Medicine, University of Chicago, Chicago, Illinois, USA

Background

- Discordant results of HIV screening typically require another blood draw to run the HIV-1 RNA viral load assay
- This can result in loss of follow up and inability to resolve if a discordant result is a false positive or acute infection
- Many HIV screening tests are performed on persons already diagnosed, some need re-linkage



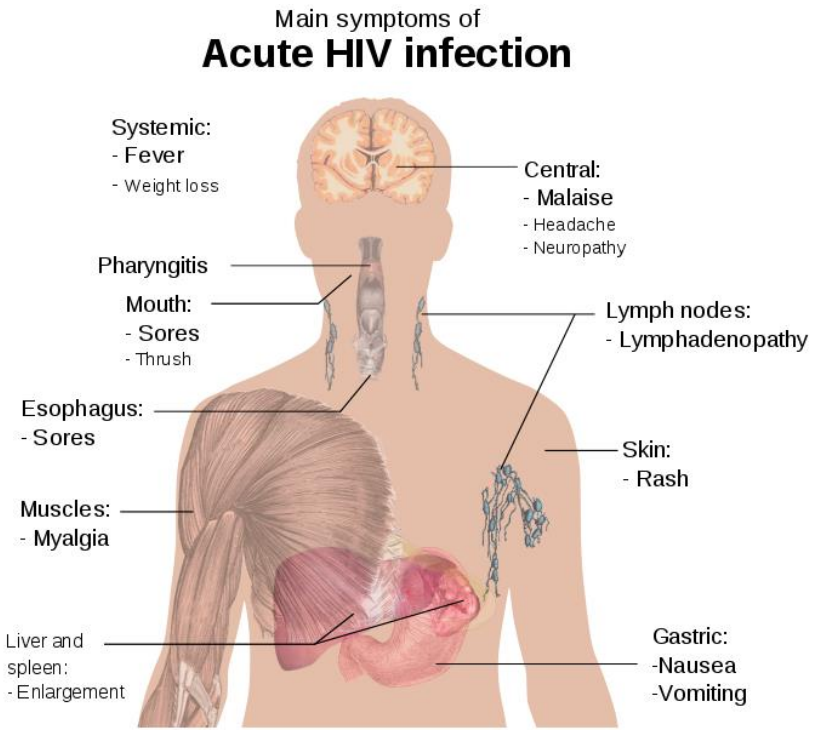
Acute HIV Infection

- Earliest stage of HIV infection associated with very high viral loads and risk of transmission
  - Also called the “window period” phase of seroconversion, where antibodies are not yet detectable
- Acute infection is defined as positive p24 antigen and viral load, but negative or indeterminate antibody detection
- Everyone has acute infection at some point
  - 50-75% of patients have symptoms of viral illness, but usually mild

CDC 2021; New York State Department of Health 2017; Pilcher 2004; Cohen 2010; Cohen 2011; Yerly 2001; Marzel 2015

Symptoms of Acute HIV Infection

- Symptoms
  - Fever
  - Rash
  - Sore throat
  - Swollen lymph nodes
  - Diarrhea
  - Body aches



Hoenigl et al., 2016

Significance

- Early detection of HIV is important for improving patient health outcomes and decreasing transmission
- Viral loads are very high in acute infection, especially if symptomatic, compared to chronically infected patients
- 8-10 times higher risk of transmission during acute infection compared to chronic infection
- ≥ 25% of new transmissions may be from patients with acute infection (Swiss cohort study)

CDC 2021; New York State Department of Health 2017; Pilcher 2004; Cohen 2010; Cohen 2011; Yerly 2001; Marzel 2015

Purpose

- Examine unconfirmed and discordant results before and after implementation of a reflex HIV-1 RNA assay following all reactive screening tests

- Report on discordant results, identification of acute infection, and time for linkage/relinkage to care before and after the introduction of reflex HIV-1 RNA testing.

Methods

- Data from the routine HIV screening program at the University of Chicago Medicine (UCM) were collected from 14 May 2014 to 30 June 2021

- Discordant test results: reactive screening assay followed by a negative or indeterminate antibody differentiation assay
  - Include confirmed false-positive results, unconfirmed results (patients who did not undergo HIV-1 RNA testing), and acute HIV cases

Results

Table 1. Human Immunodeficiency Virus (HIV) Test Results Before and After Reflex HIV-1 RNA Testing, 14 May 2014 to 30 June 2021

Year	All Patients Tested	Reactive HIV Screening Assay[a]	Confirmed True-Positive Results[b]	New HIV Cases (Acute Cases[c])	Existing HIV Cases	Existing Cases Needing Linkage	Discordant Results (Acute Cases[c])	Confirmed False-Positive Results	Unconfirmed Reactive Screening Assay	Median Days to Linkage (No. Linked)
2014	6924	56	46	20 (0)	26	11	10 (0)	3	7	31 (7)
2015	10 710	72	65	27 (0)	38	9	7 (0)	2	5	20 (9)
2016	9611	62	57	32 (7)	25	9	12 (7)	4	1	14 (5)
Subtotal	27 245	190	168	79 (7)	89	29	29 (7)	9	13	20 (21)
HIV-1 RNA reflex begins 28 September 2016										
2016	3139	25	17	8 (0)	9	2	8 (0)	8	0	14 (4)
2017	15 450	240	90	35 (5)	55	11	155 (5)	149	1	9 (21)
2018[d]	12 791	211	77	27 (3)	50	12	137 (3)	133	1	9 (19)
2019	27 860	288	186	56 (8)	130	32	110 (8)	101	1	12 (29)
2020	28 610	354	276	49 (12)	227	51	90 (12)	78	0	7.5 (46)
2021[e]	18 096	253	207	33 (7)	174	48	53 (7)	46	0	8 (28)
Subtotal	105 946	1371	853	208 (35)	645	156	553 (35)	515	3	9 (147)
Total	133 191	1561	1021	287 (42)	734	185	582 (42)	524	16	20 (168)

Abbreviation: HIV, human immunodeficiency virus.

[a]The "Reactive HIV Screening Assay" column is the sum of the "Confirmed True-Positive Results" plus "Confirmed False-Positive Results" plus "Unconfirmed Reactive Screening Assay" columns.

[b]The "Confirmed True-Positive Results" column reflects new HIV cases (a subset of which are acute cases) plus existing HIV cases.

[c]Acute cases are included in both the "New HIV Cases" column as well as the "Discordant Results" column since they are part of both categories.

[d]Includes data from 1 January 2018 to 30 September 2018 only.

[e]Includes data from 1 January 2021 to 30 June 2021 only.

Results – Prior to Reflex HIV-1 RNA Testing

- Total of 190 unique patients with reactive HIV screens
- 168 were confirmed true-positive (88.4%)
  - 79 new diagnoses [7 of which were acute]
  - 89 existing diagnoses
- 29 discordant results
  - 7 were acute cases (3.7%)
  - 9 were false-positive results (4.7%)
  - **13 tests were unable to be confirmed (6.8%)**
- These patients were either not able to be located or did not return for further testing at our institution
- In total, 108 people required outreach to link or relinkage to HIV care

Results – After Reflex HIV-1 RNA Testing

- 1371 reactive HIV screening assays in unique patients
- 853 were confirmed true-positive results (62.2%)
  - 208 new diagnoses [35 of which were acute]
  - 645 existing
- 553 discordant results
  - 35 acute infections (6.3%)
  - 515 confirmed false-positive (37.5%)
  - **3 unconfirmed (0.2%)**
- Unconfirmed tests mostly resulted from insufficient blood sample to run HIV-1 RNA and inability to contact or get patient back in for repeat blood draw
- Of reactive test results that were new, existing, or acute cases, 364 people required outreach to link or relinkage to HIV care

Results

- With reflex HIV-1 RNA testing, reactive HIV screening assays were significantly more likely to be confirmed (either as true or false positives) compared to the period before reflex HIV-1 RNA testing was implemented (OR, 23.7 [95% CI, 6.7–83.4]; *P* < .0001)

- Newly diagnosed patients with HIV were linked to care significantly faster under reflex HIV-1 RNA testing (median difference, −7.6 days [95% CI, −12.7 to −2.6 days]; *P* = .003)

- Including HIV-1 RNA testing significantly reduced the number of patients needing to be contacted regarding discordant test results or to initiate linkage/relinkage to HIV care (OR, 0.7 [95% CI, .6–.8]; *P* = .001)

Discussion

- HIV-1 RNA reflex testing significantly decreased the number of discordant results and improved identification of AHI in a timely manner
- Resources to provide linkage to care and other important services
- Streamlined detection of true-positive HIV tests permitted growth of routine, opt-out HIV screening while allowing staff to prioritize contacting patients with true-positive results rather than tracking individuals with discordant results
- By removing the need for a second blood draw in most circumstances, reflex HIV-1 RNA testing has supported rapid linkage and initiation of ART

Discussion

- Reflex HIV-1 RNA testing generated better detection not only of people who were newly diagnosed with HIV but also people with HIV (PWH) who had lapsed in care

- Reflex HIV-1 RNA testing has enabled staff to better determine who may be out of care and prioritize relinkage efforts among PWH with elevated viral loads

- Supports the Diagnose and Treat pillars of the EHE initiative

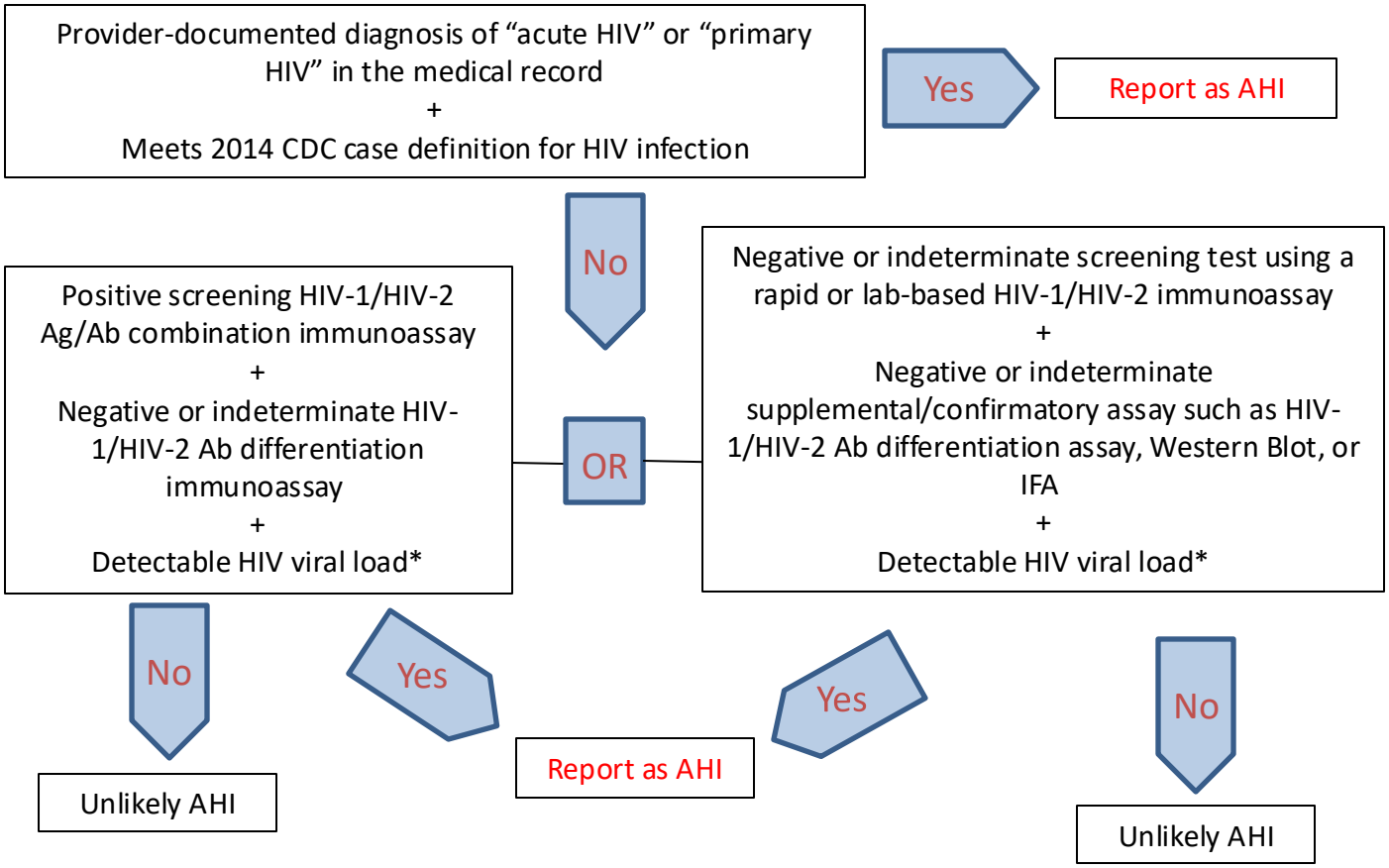
Limitations

- May be cost-prohibitive; needs formal cost analyses
- Single site; Larger studies will need to be conducted to see if these results are consistent across different settings and patient populations
- Retrospective study, changes in clinical guidelines and best practices over time emphasizing the importance of rapid initiation of ART likely impacted the time to linkage to care, not reflex HIV-1 RNA testing alone
- Additionally, it is possible that improvements in program and staff experience over time also contributed to reductions in time to linkage to care

Conclusions

- Can be considered in high incidence/prevalence settings and those like the emergency department
- Can improve timely diagnosis of HIV, enable guideline-based rapid linkage and initiation of ART, and reduce resources required to resolve discordant results
- Further work should include cost analysis to understand feasibility of such an approach across different healthcare settings

Revised Surveillance Case Definition for Acute HIV Infection



*Ideally nucleic acid test or HIV viral load is performed on the same specimen but no more than one month later.

https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1.htm

Conclusions

- Need multi-pronged approach for EHE
- Improve early diagnosis of HIV, with rapid linkage/ART
- Rapid initiation of ART is safe and effective, one part of approach for EHE
  - Leads to earlier viral suppression and supports retention/engagement in care
- Can be scaled up within existing HIV care and testing programs
- Barriers in implementation, but not insurmountable

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CCHE
The Chicago Center for HIV Elimination

AT THE FOREFRONT
UChicago Medicine

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Thank You!