APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES™

Analysis. Answers. Action.

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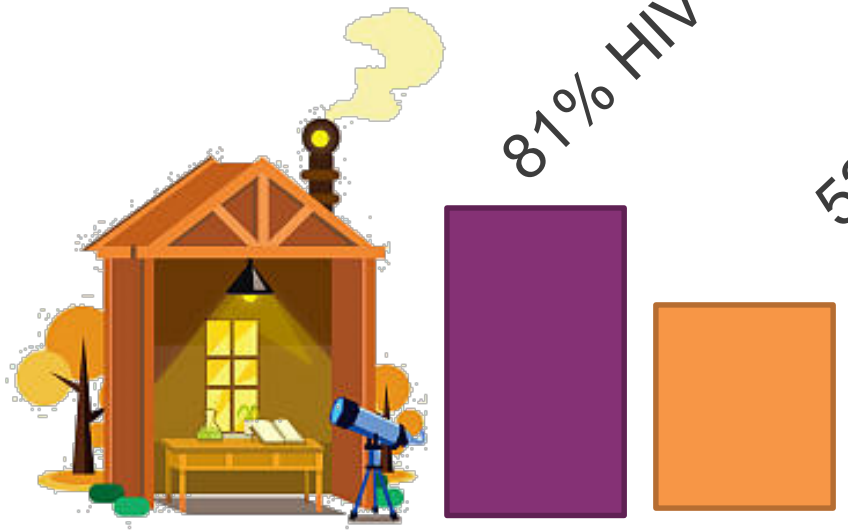
Discussion Panel: Integrated Testing and Screening

From Primary Care to Public Health

Anne Gaynor, PhD, Association of Public Health Laboratories
Vaneet Arora, MD, Kentucky State Public Health Laboratory
Lesley Miller, MD, Emory University School of Medicine
Liisa Randall, PhD Massachusetts Department of Public Health

Synergy is the creation of a whole that is greater than the simple sum of its parts

Why Integration?



81% HIV Testing

52% HIV & HCV Testing

APHL Survey Report

~66% HDs supporting HIV Testing also support HCV Testing

National HIV Prevention Inventory

https://www.nastad.org/sites/default/files/resources/docs/2019-nhpi-survey-report.pdf

Why Integration?

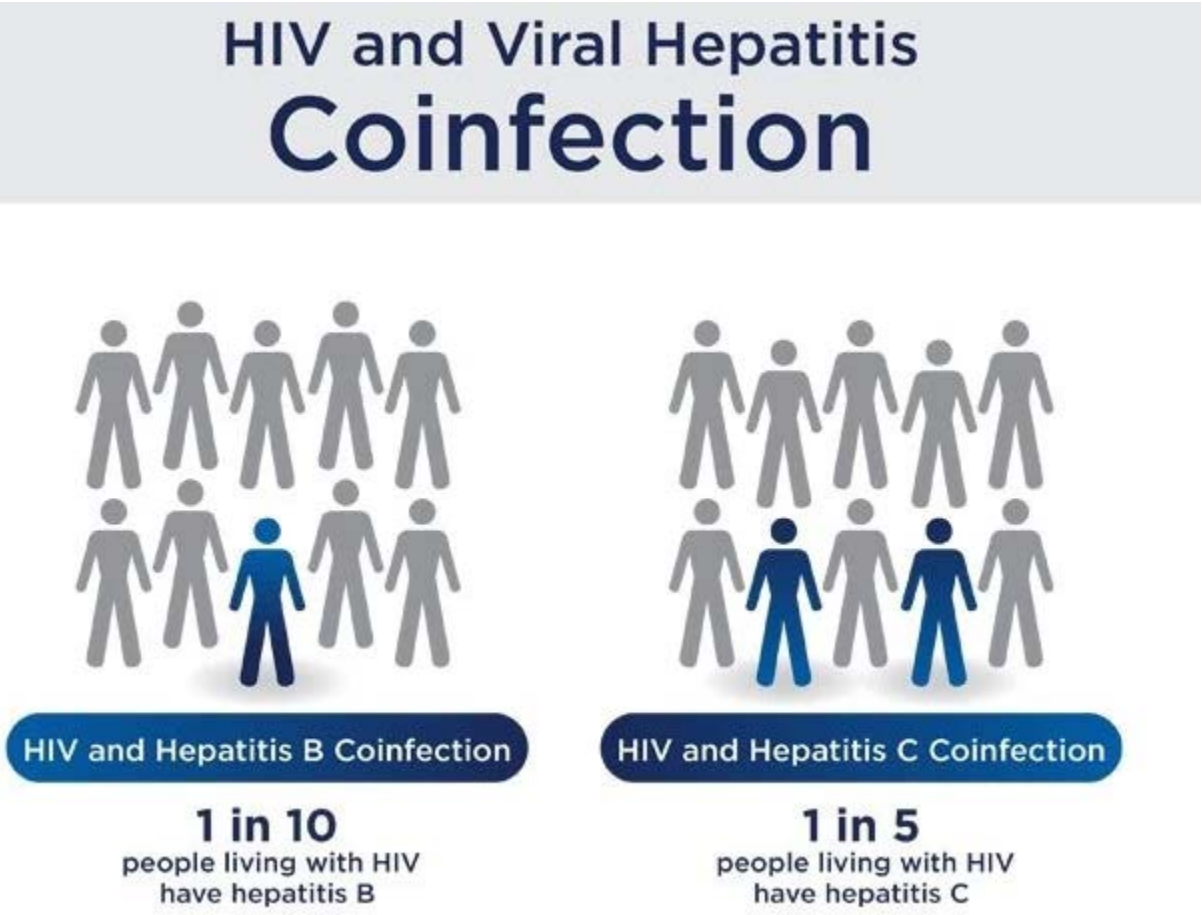


Image Credit: https://www.hhs.gov/hepatitis/blog/2019/01/16/new-hiv-hcv-coinfection-resources-for-providers.html

Where should there be integration?

- Ideally everywhere!

- How to integrate will depend on your…
  - Venue/Setting
  - Population
  - Client Preferences
  - Resources
  - Policies and Regulations

Integration

INTEGRATIN

HIV AND HC

TESTING

NASTAD

TABLE 2

COMPARISON OF TESTING STRATEGIES

Comparison Categories	Laboratory-Based Testing (using CDC-recommended serum/ plasma algorithms)		Point-of-Care Rapid Testing (using CLIA-waived tests)	
	HIV	HCV	HIV	HCV
Approximate window period	2-3 weeks	8–11 weeks	3-5 weeks (blood specimens)[2]	8–11 weeks
Able to detect acute infection	✓ Yes	Yes, when interpreted in conjunction with clinical information such as symptoms	✗ No	Yes, when interpreted in conjunction with clinical information such as symptoms
Able to distinguish between HIV-1 and HIV-2	✓ Yes	Not applicable	✗ No	Not applicable
Final results	All tests in algorithm may be performed on one specimen		Negative results from single test/ specimen; Positive results require supplemental testing with second specimen	
Testing for multiple infections	✓ Yes, multiple tests may be performed on single specimen		✗ No, separate specimens needed for other tests	

Laboratory Testing Integration

Table: FDA-Approved HIV, HAV, HBV, HCV, and STD Diagnostic or Monitoring Assays by Manufacturer and Platform*

	Manufacturer	Platform	HIV	HAV	HBV	HCV	Chlamydia, Gonorrhea, Syphilis
Serologic Assays	Abbott	Architect	HIV Ag/Ab Combo	Anit-HAV IgG, Anti-HAV IgM	Anti-HBs, HBsAg Qual, HBsAg Qual Conf., Anti-Hbc, Anti-HBc IgM,	Anti-HCV	Syphilis TP
	Bio-Rad	EVOLIS	HIV Combo Ag/Ab EIA, HIV-1/HIV-2 Plus O EIA	MONOLISA Anti-HAV EIA, MONOLISA Anti-HAV IgM EIA	MONOLISA Anti-HBs EIA, MONOLISA Anti-HBc, GS HBsAG EIA 3.0, GS HBsAG Confirmation 3.0		Syphilis IgG
		BioPlex 2200	HIV Ag-Ab				Syphilis Total & RPR assay
		Manual	HIV Combo Ag/Ab EIA, HIV-1/HIV-2 Plus O EIA, Geenius HIV-1/2 Supplemental Assay	MONOLISA Anti-HAV EIA, MONOLISA Anti-HAV IgM EIA	MONOLISA Anti-HBs EIA, MONOLISA Anti-HBc, GS HBsAG EIA 3.0, GS HBsAG Confirmation 3.0		
	Ortho-Clinical Diagnostics	VITROS Eci/EciQ	Anti-HIV1+2	Anti-HAV IgM, Anti-HAV Total	Anti-HBc, Anti-HBC IgM, Anti-HBe, Anti-HBs, HBeAg, HBsAg	Anti-HCV	
		VITROS 3600	Anti-HIV1+2, VITROS HIV Combo	Anti-HAV IgM, Anti-HAV Total	Aniti-HBc, Anti-HBC IgM, Anti-HBs, HBsAg	Anti-HCV	
		VITROS 5600		Anti-HAV IgM, Anti-HAV Total	Anti-HBc, Anti-HBC IgM, Anti-HBs, HBsAg	Anti-HCV	
	Roche	Cobas e 411		Elecsys Anti-HAV IgM, Anti-HAV Total	Elecsys Anti-HBc Total, Anti-HBc IgM, HBsAg, HBsAg Confirmatory, Anti-HBs	Elecsys Anti-HCV II	Elecsys Syphilis (Treponemal)
		Cobas e 601		Elecsys Anti-HAV IgM, Anti-HAV Total	Elecsys Anti-HBc Total, Anti-HBc IgM, HBsAg, HBsAg Confirmatory, Anti-HBs	Elecsys Anti-HCV II	Elecsys Syphilis (Treponemal)
		Cobas e 602	Elecsys HIV Combi PT	Elecsys Anti-HAV IgM, Anti-HAV Total	Elecsys Anti-HBc Total, Anti-HBc IgM, HBsAg, HBsAg Confirmatory, Anti-HBs, HBeAg	Elecsys Anti-HCV II	Elecsys Syphilis (Treponemal)
	Siemens	ADVIA Centaur XPT	HIV Ag/AB Combo, EHIV 1/O/2 Enhanced		Anti-HBs2, HBc IgM, HBc Total,	HCV	Syphilis (Treponemal)
		ADVIA Centaur XP/CP	HIV Ag/AB Combo, EHIV 1/O/2 Enhanced		Anti-HBs2, HBc IgM, HBc Total, HBsAg, HBs Ag Confirm.	HCV	Syphilis (Treponemal)
		IMMULITE 2000/Xpi			Anti-HBs, Anti-HBs Quant., Anti-HBc IgM, Anti-HBc Total, HBsAg, HBsAg Confirm.		Syphilis Screen (Treponemal)
Molecular Assays	Manufacturer	Platform	HIV	HAV	HBV	HCV	STD
	Abbott	m2000	RealTime HIV-1 (Viral Load)		RealTime HBV (Viral Load)	RealTime HCV (Viral Load), RealTime HCV Genotype II	RealTime CT/NG
	Roche	cobas 6800/8800	cobas HIV-1 (Viral Load)		cobas HBV (Viral-Load)	cobas HCV (Dual-Claim)	
		cobas 4800					cobas 4800 CT/NG
		cobas AmpliPrep	COBAS AmpliPrep/COBAS Taqman HIV-1 Test, v2.0 (Viral Load)		COBAS AmpliPrep/COBAS Taqman HBV Test, v2.0 (Viral Load)	COBAS AmpliPrep/COBAS Taqman HCV Test, v2.0 (Dual Claim)	
		Manual			COBAS Taqman HBV Test (Viral Load)	COBAS Taqman HCV Test (Viral Load)	
	Hologic	Panther	Aptima HIV-1 Quant (Viral Load)		Aptima HBV Quant (Viral Load)	Aptima HCV Quant Dx (Dual-Claim)	APTIMA Combo2 for CT/NG, APTIMA CT, APTIMA GC, APTIMA TV
		Tigris					APTIMA Combo2 for CT/NG, APTIMA TV
		Manual	Aptima HIV-1 RNA Qual (Diagnosis)			Aptima HCV RNA Qual (Diagnosis)	
	Siemens	VERSANT				VERSANT HCV Genotype 2.0 (LiPa)	

*Note that this document was created to compile all HIV and HCV serologic and molecular assays by Manufacturer and Platform. We have also added any assays on these platforms that detect Hepatitis A Virus (HAV), Hepatitis B Virus (HBV), *Treponema pallidum* (Syphilis), *Chlamydia trachomatis* (CT), and *Neisseria gonorrhoeae* (GC). There may be other manufacturers and/or platforms that have assays that detect these pathogens but if they don't also have an HIV and/or HCV test available they were not included at this time. This document was supported by Cooperative Agreement # 5NU60OE000103 funded by the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC or the Department of Health and Human Services. Updated July 11, 2018.
For any questions please contact anne.gaynor@aphl.org.

www.aphl.org/vh
On the right side of the page under "Other Resources"

Routine HCV and HIV Screening at Grady Health System

Lesley Miller, MD
Associate Professor of Medicine
Emory University School of Medicine
Medical Director, Grady Liver Clinic

CDC HIV Diagnostics Conference

March 27, 2019

Disclosures

- Dr. Miller receives grant funding from Gilead Sciences (FOCUS Program) and Merck & Co. and participates on an advisory board for AbbVie

The FOCUS Program is a public health initiative that enables partners to develop and share best practices in routine blood-borne virus (HIV, Hepatitis C, Hepatitis B) screening, diagnosis, and linkage to care in accordance with screening guidelines promulgated by the U.S. Centers for Disease Control and Prevention (CDC), the U.S. Preventive Services Task Force (USPSTF), and state and local public health departments.

FOCUS funding supports HIV, HCV, and HBV screening and linkage to the first medical appointment after diagnosis. FOCUS partners do not use FOCUS awards for activities beyond linkage to the first medical appointment.

APPROXIMATELY

640,000

PATIENTS VISITS

GRADY IS THE LARGEST HOSPITAL IN GEORGIA

953 LICENSED BEDS

GRADY EMS RESPONDED TO MORE THAN

137,000

911 CALLS

25%

OF GEORGIA PHYSICIANS RECEIVED SOME OF THEIR TRAINING AT GRADY

6 GRADY NEIGHBORHOOD HEALTH CENTERS

141,000

PATIENTS TREATED IN THE EMERGENCY DEPARTMENT

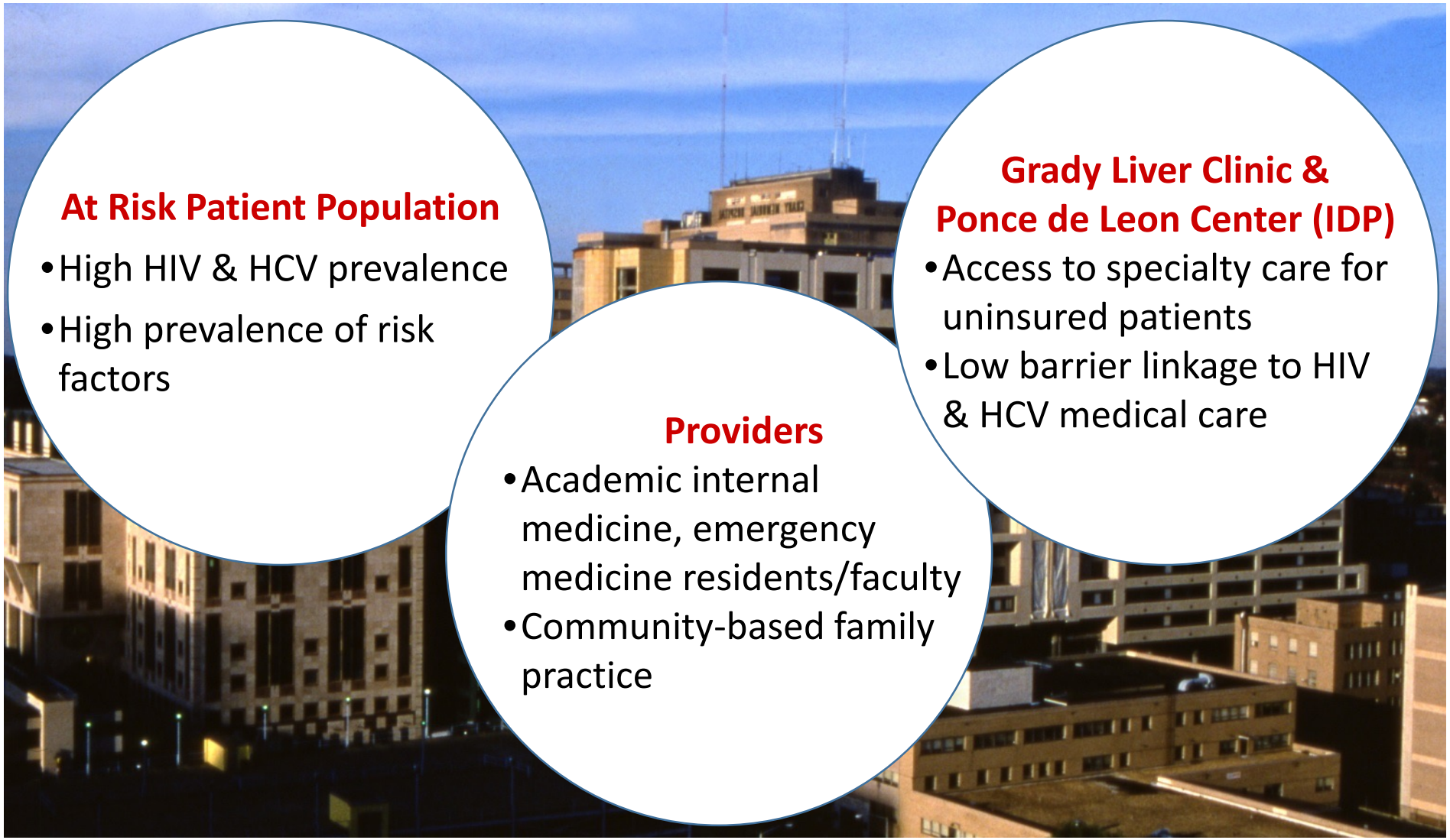
MORE THAN

6,000

EMPLOYEES

2017 Data

Importance of Routine HIV and HCV Screening at Grady



At Risk Patient Population

- High HIV & HCV prevalence
- High prevalence of risk factors

Providers

- Academic internal medicine, emergency medicine residents/faculty
- Community-based family practice

Grady Liver Clinic & Ponce de Leon Center (IDP)

- Access to specialty care for uninsured patients
- Low barrier linkage to HIV & HCV medical care

Evolution of Integrated HCV/HIV Screening

2013-16
Separate HCV and HIV Screening grants and programs

2016

- ***Combined programs***
- ***Expansion to neighborhood clinics***
- ***Creation of HCV Screening provider BPA***

2017

- ***Expansion to Inpatient Med/Surg***
- ***Bundled HIV/HCV inpatient BPA***

2018

- ***Expansion to Ambulatory Specialty Clinics***
- ***Bundled HIV/HCV outpatient triage BPA***
- ***Reflex RNA testing***

HCV/HIV Screening: Patient Pathway

ASSESS
- REGISTRATION: Smart algorithm to identify eligible patients

OFFER
- TRIAGE: RN/MA makes an opt-out test offer to eligible patients

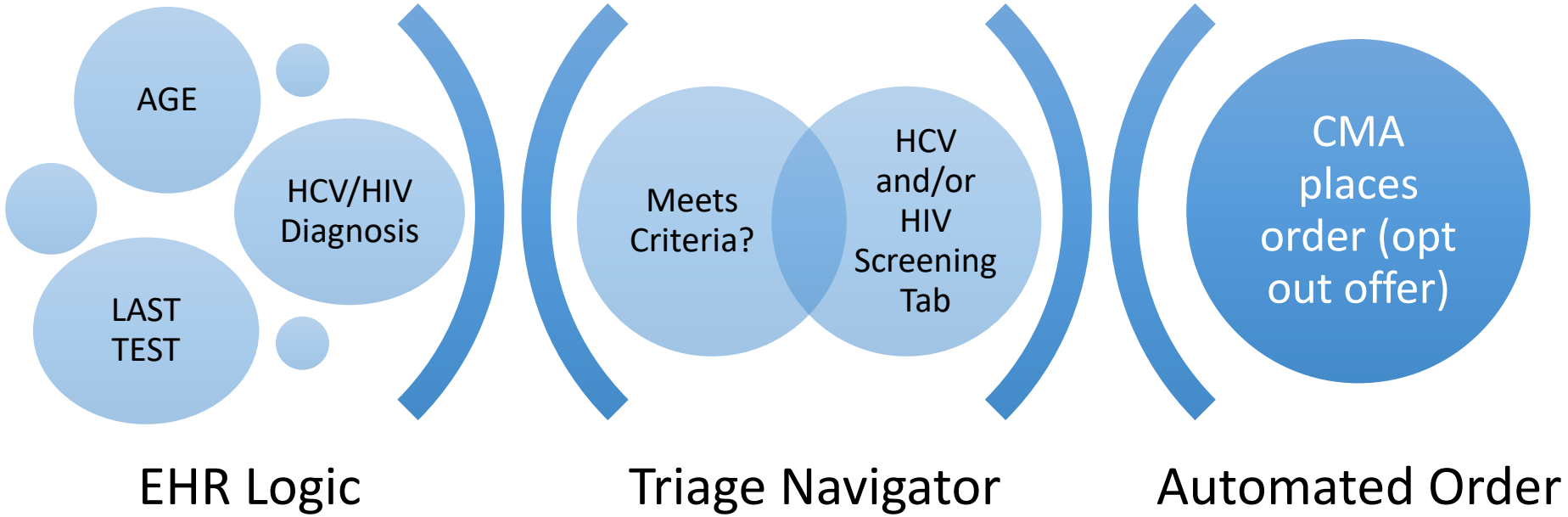
ORDER
- Order Signed: RN or Provider signs order

RESULTS
- Preliminary test results appear in EHR (HCV 24 h, HIV 3 h)

DISCLOSE
- HIV: MSW paged; collaborates with the provider to disclose
- HCV: Navigator or provider disclose after HCV RNA positive (1-2 weeks)

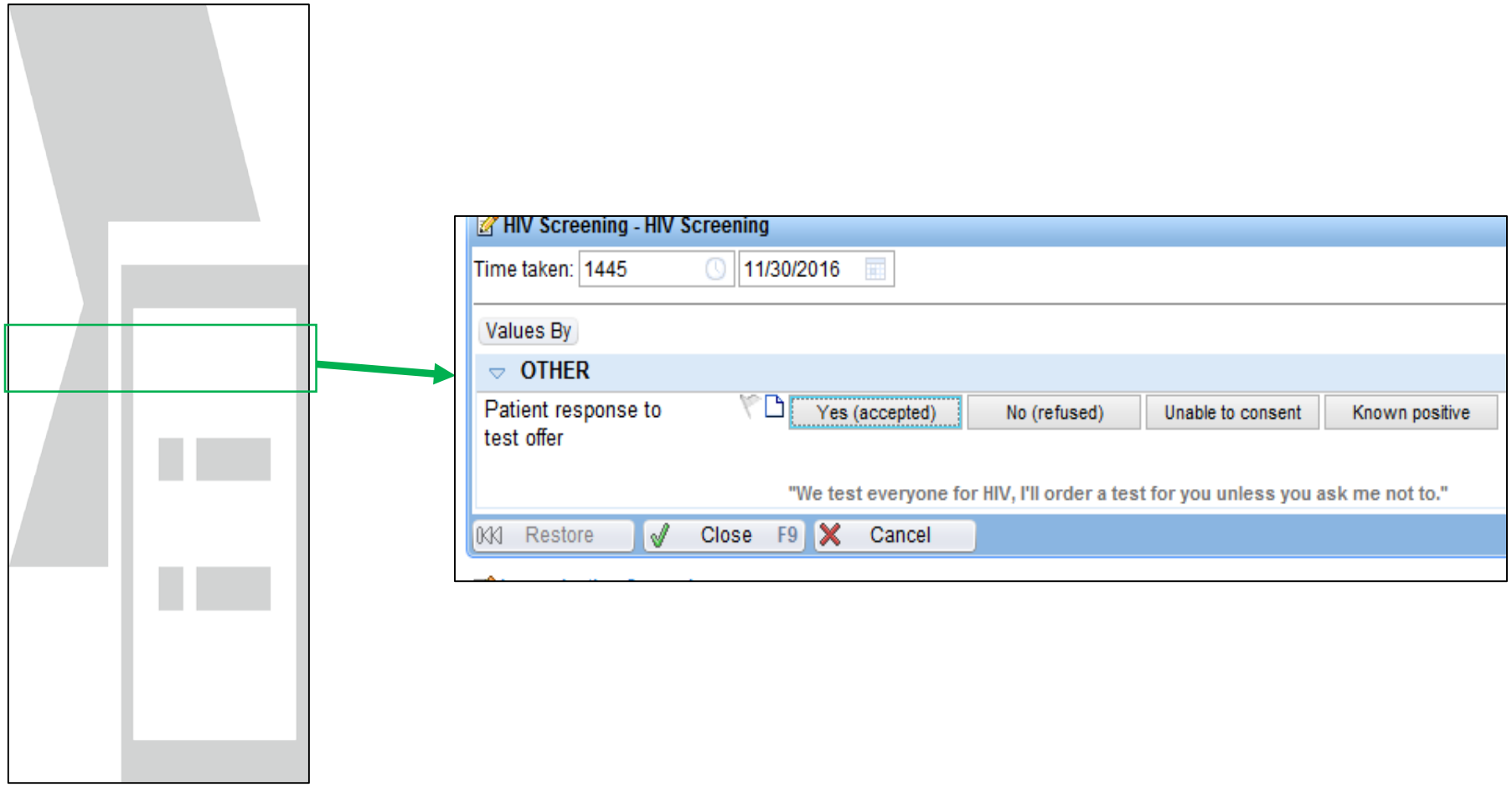
LINK
- MSW or navigator initiates linkage

Grady HCV/HIV EHR Testing Algorithm

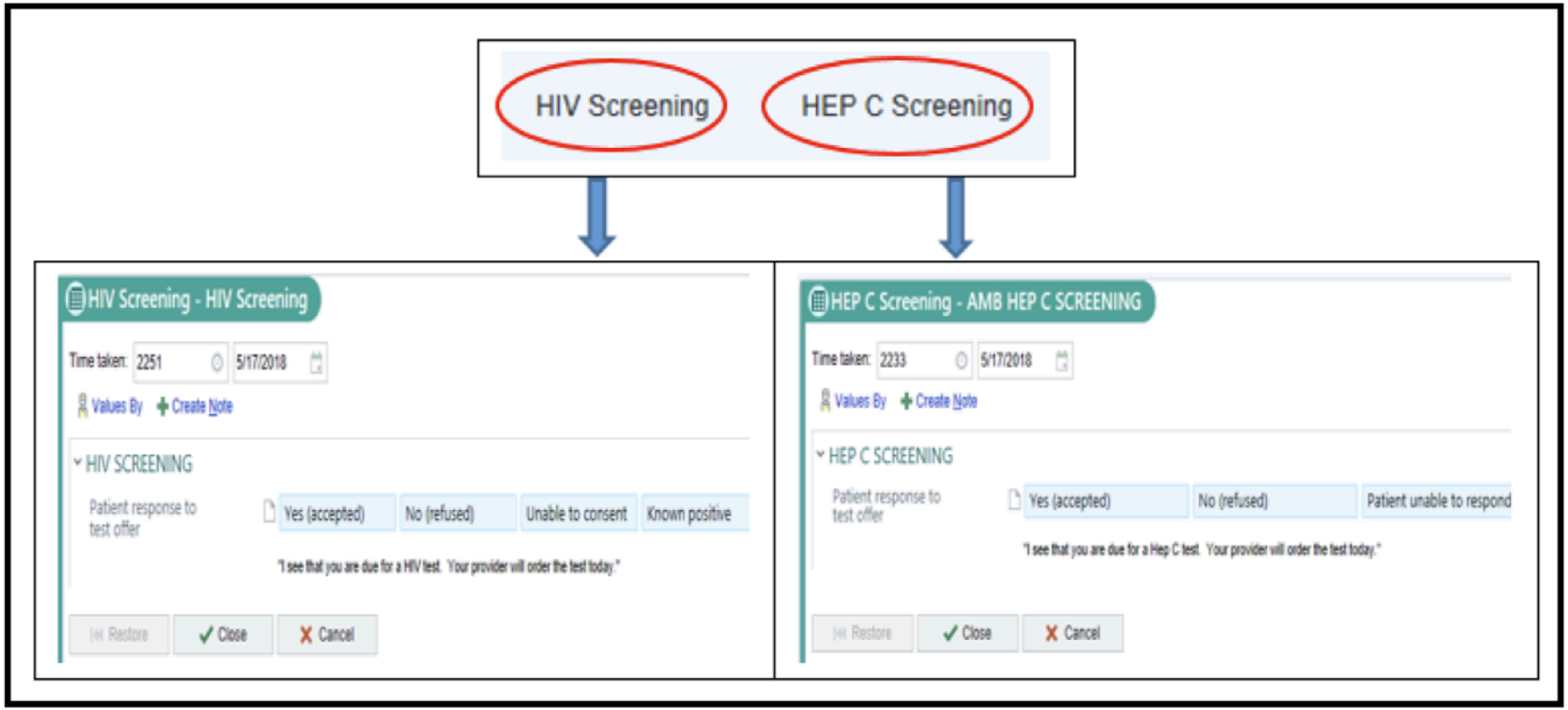


Triage: Test Offer

Only appears for patients eligible for an offer



HIV and HCV Screening Offer at Triage



"I see that you are due for an HIV and hepatitis C test today. Your provider will order the tests today."

Test Acceptance at Triage Triggers Provider BPA

Hepatitis C Focus

This patient agreed to a HEP C test. Please click Accept below to order the test.

Open SmartSet | Do Not Open | HCV AB with Reflex to HCV RNA-QUANT, PCR | Preview

Order FOCUS HIV Test

This patient accepted an HIV test. Please click accept below to order the test.

Add to unsigned orders: Focus:HIV-1/2 AB Screen

The following actions were applied automatically:

Initiated: Ghs ed focus hiv

Accept | Cancel

Inpatient HIV/HCV Screening Incorporated into Admission Order Set

Labs — Required

Chemistry Basic — 0 of 8 selected

Chemistry - Other — 0 of 6 selected

Focus HCV Screening

Patient meets criteria for Hepatitis C Virus screening.

- (•) HCV AB (2ND Generation) — Routine
- ( ) Patient declined testing
- ( ) Inappropriate for testing

HCV: Order is pre-selected. Change if patient declines/inappropriate to test.

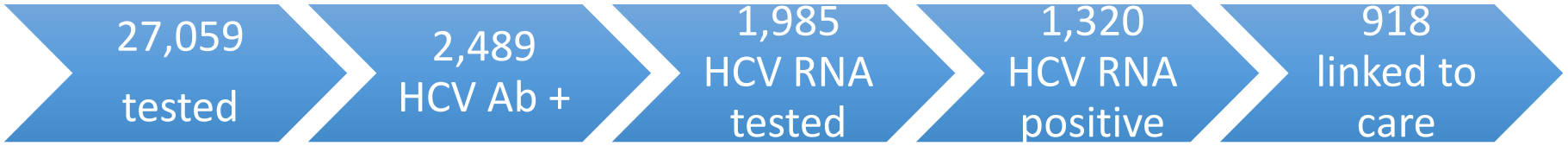
Focus HIV Screening

Patient meets criteria for HIV screening.

- (•) Focus:HIV-1/2 AB Screen
  - P If the patient is incapacitated and no surrogate available , consult Ethics Committee. , Routine
- ( ) Patient declined testing
- ( ) Patient unable to consent/inappropriate for testing

Grady HCV Care Cascade

October 2015-October 2018



- 9% prevalence
- 80% tested
- 66% viremic
- 70% linked

Grady HIV Care Cascade

July 2013-October 2018

- 0.7% prevalence

- 55% linked
- (68% adjusted*)

*Adjusted linkage to care excludes the following patients: deceased, incarcerated, moved, declined, provided incorrect contact information during registration or already in care (previously diagnosed).

Conclusions

- HCV and HIV testing and linkage to care are feasible and high yield in this safety-net health system
- Testing reveals high prevalence of both disease and successful linkage to care
- Bundling HCV and HIV testing increases efficiency and requires coordination, stakeholder investment and a focus on sustainability

Thank you

Massachusetts Department of Public Health
Bureau of Infectious Disease and Laboratory Sciences

Strengthening Testing and Linkage through Integration of HIV, HCV, and STI Testing in Massachusetts

Liisa M. Randall
Director, Office of Health Care Planning

2019 HIV Diagnostics Conference

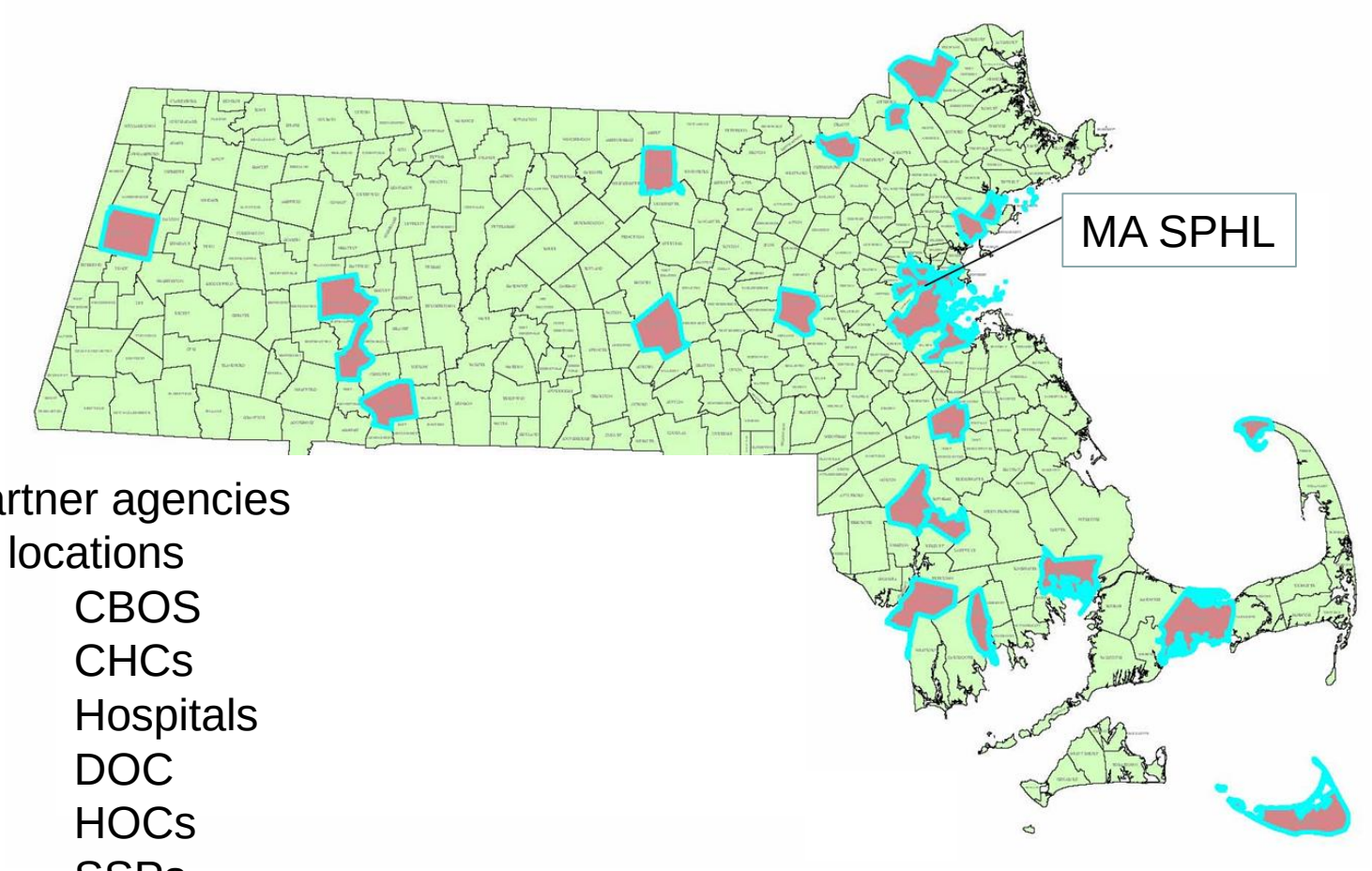
Context & Goals

- Public Health Laboratory
- Program
- Surveillance

Policy and Strategies

- Enabling policies
  - State appropriations
  - Retained revenue acct
  - Universal coverage
  - No treatment restrictions
  - IDDAP
  - Opioid
- SPHL capacity
  - Enhanced capacity
    - Automation
    - Co-testing
  - 3rd Party billing
- Integrated services
  - Targeted
  - Co-testing
  - Submission to MA SPHL
  - Accountable for outcomes
  - SSP expansion
  - Capacity building/TA
- Surveillance
  - MAVEN
  - Enhanced surveillance
    - ESP
    - TLC

Integrated HIV/HCV/STI/TB Testing System: Massachusetts

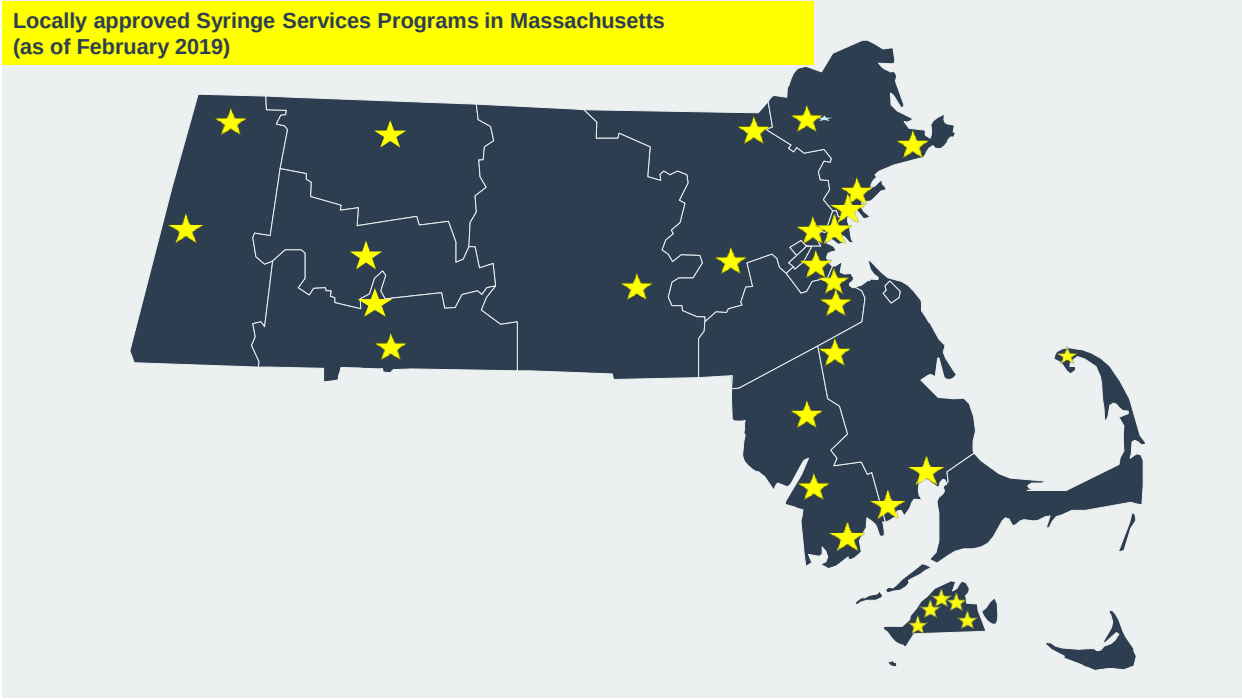


48 partner agencies
120+ locations

- CBOS
- CHCs
- Hospitals
- DOC
- HOCs
- SSPs
- SUD/OTP
- Mobile

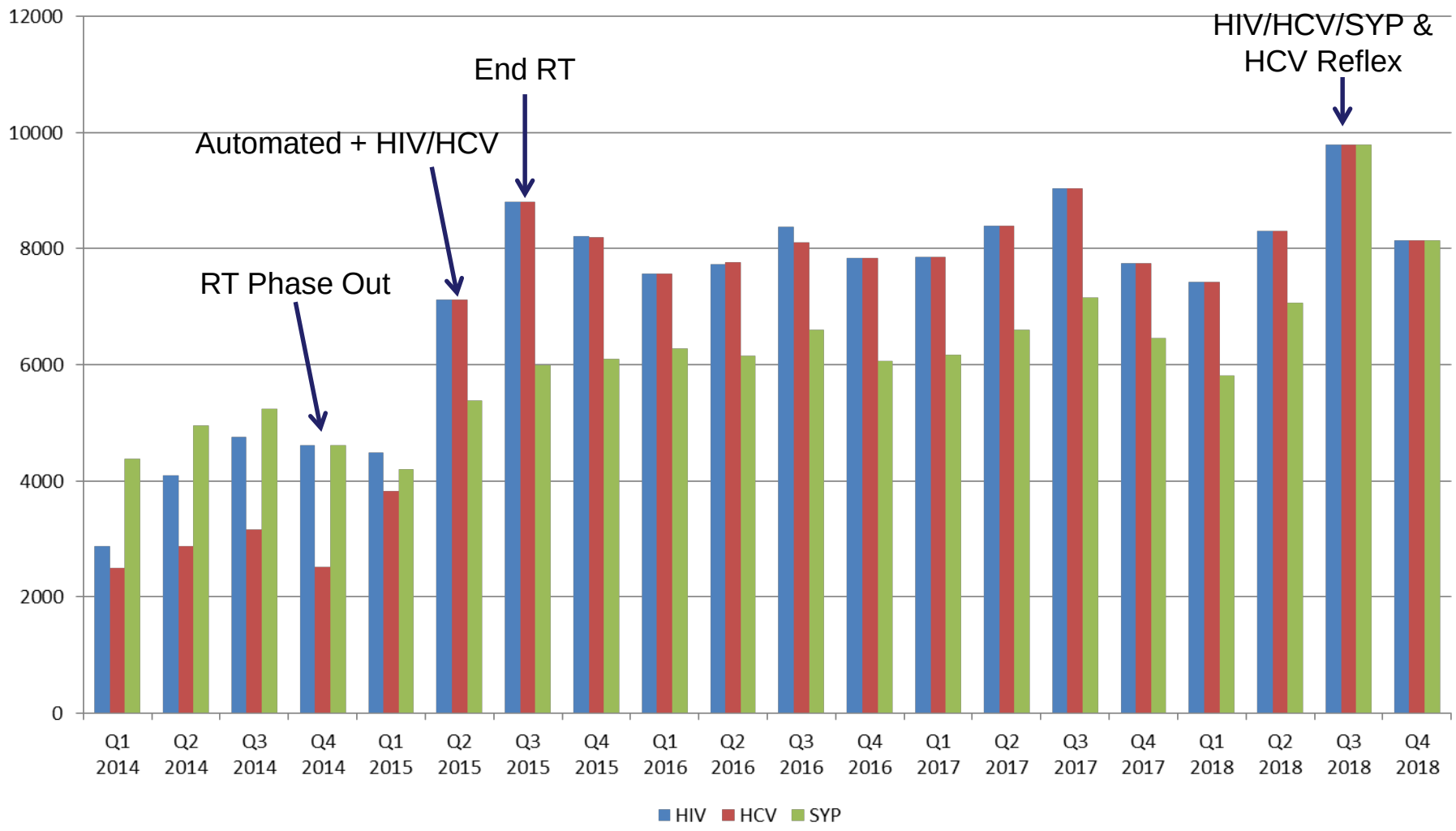
Syringe Services Programs

– Sterile injection equip.
– Syringe disposal
– Overdose prev., naloxone
– HIV/HCV/STI T&L
– Referral
  - SUD Tx
  - Prevention, support



https://www.mass.gov/syringe-service-programs

Implementing Integration: HIV, HCV, Syphilis Test Volume, 2014-2018



Data Source: BIDLS/MDPH. Current as of 3/5/19

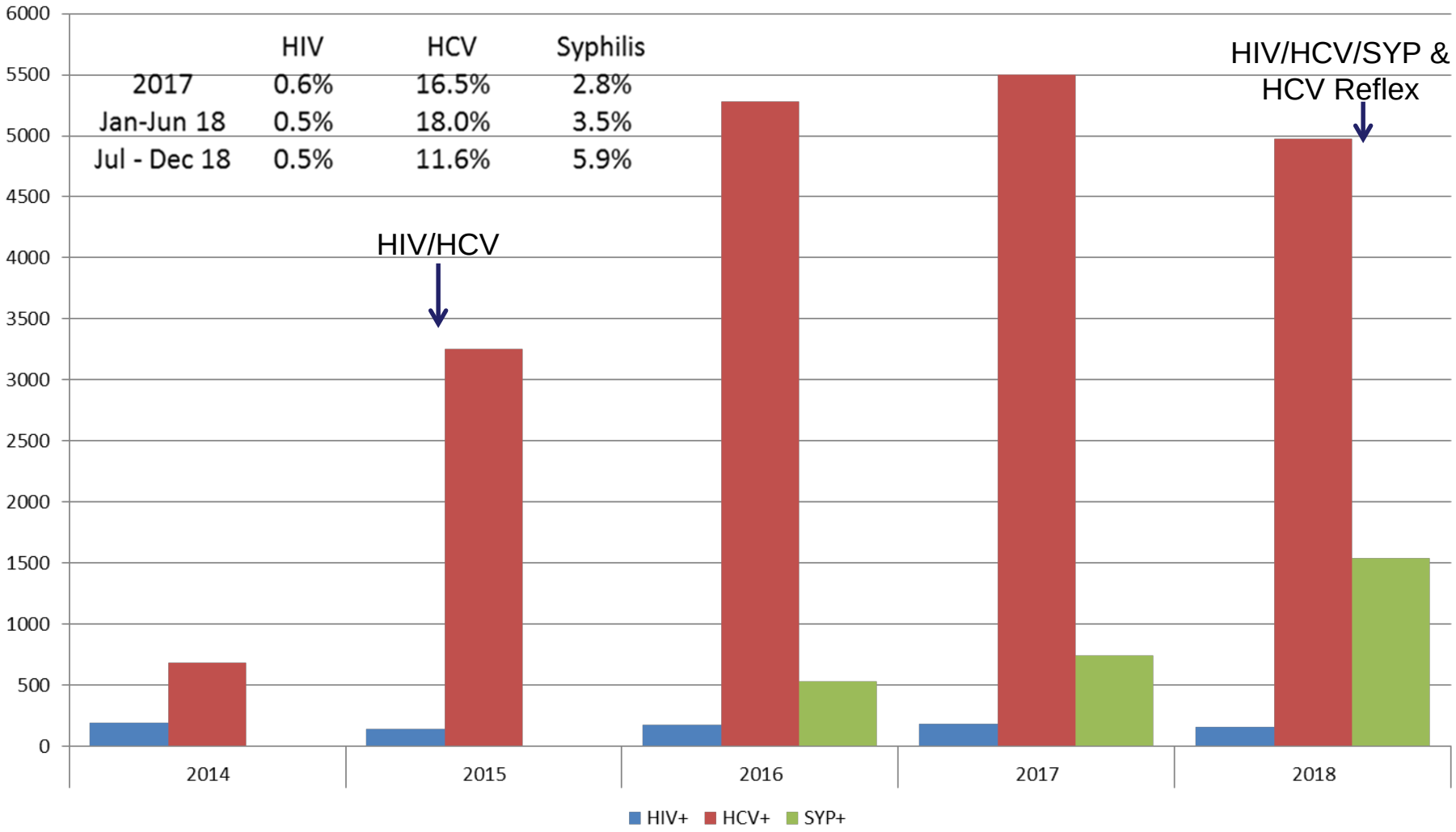
Impact of Integration: Testing Uptake 2014-2018

Increase:

- 106% overall
- 205% HCV
- 61% syphilis
- 63% PWID
- 48% MSM

Data Source: BIDLS/MDPH. Current as of 3/5/19

Impact of Integration: Infections Identified, 2014-2018



Data Source: BIDLS/MDPH. Current as of 3/5/19

Impact of Integration

- Increases uptake of testing
  - Related conditions
  - Priority populations
- Identifies infection
- Facilitates linkage
- Strengthens surveillance
- Enhances capacity

Lessons Learned

- Feasible
  - Leveraged existing capacity (lab, program)
  - Community-based implementation
  - Self-sustaining
- Facilitators
  - Enabling policies
  - Collaboration: PHL, Program, Surveillance
  - Capacity enhancement (lab, providers)

Future

- Refine strategies & tweak investments
  - Optimize targeting and yield
  - Support/facilitate intervention (e.g. PrEP, opioid prevention)
- Enhance clinical provider education/TA
- Continue to build PHL capacity

  HIV NAT, HBV, Other?

Liisa M. Randall, PhD
Director, Office of Health Care Planning
Bureau of Infectious Disease and Laboratory Sciences

Liisa.randall@state.ma.us