

01

BIGG ELIMINATION TRIBUTE PROJECT | MODULE 2

# Building Provider Capacity for HCV Prevention Program Integration

## Screening & Diagnosis- Dx



# Introductions

- Caring Ambassadors Program
- Jill Wolf, LCSW - Hepatitis C Program Director
- Co-created with Chicago Recovery Alliance (CRA) and adapted from a training conducted in October 2019

We are grateful to Abbvie and Gilead for their support of this training and education program. We are also thankful to the Chicago Department of Public Health by way of the Centers for Disease Control for supporting us with seed money that contributed to the initial curriculum development.



03

# In honor of Dan Bigg

- Executive Director of Chicago Recovery Alliance for 25 years
- Created system for Syringe Service Program access and Naloxone Distribution
- Awarded The Norman E. Zinberg Award for Achievement in the Field of Medicine
- Fierce HCV Elimination Advocate
- Awarded 2017 Chicagoan of the Year
- Known as the 'Godfather of Naloxone'



Photo Credit: Nigel Brunsdon



# Overall Project Goal

To build the capacity, confidence, and knowledge to integrate responsive hepatitis C (HCV) screening, testing, linkage-to-care/cure, and support programs into existing infrastructures.





# Modules

Module 1 - Prevention & Education



Module 2 - Screening & Testing



Module 3 - Vaccination



Module 4 - Staging



Module 5 - Treatment



Module 6 - Cure



Module 7 - Wellness & Support



# HCV Screening & Testing

The purpose of this module is to break down the various HCV testing options minding the necessary legal documents and reporting codes



# Screening & Testing Objectives

## Participants will be able to:

- Explain the process of HCV screening and testing
- Utilize tools to modify existing protocols or services to ensure HCV testing programs are comprehensive and follow all administrative reporting codes
- Modify existing testing services to support the components of HCV counseling sessions



# Screening & Testing - Nothing About Us Without Us

08





# Screening & Testing – CDC

09

## **CDC Recommendations for Hepatitis C Screening Among Adults in the United States.**

**Universal hepatitis C screening: Hepatitis C screening at least once in a lifetime for all adults aged 18 years and older, except in settings where the prevalence of HCV infection (HCV RNA-positivity) is less than 0.1%**

Schillie S, Wester C, Osborne M, Wesolowski L, Ryerson AB. CDC Recommendations for Hepatitis C Screening Among Adults – United States, 2020. MMWR Recomm Rep 2020;69(No. RR-2):1–17. DOI: <http://dx.doi.org/10.15585/mmwr.rr6902a1>external icon

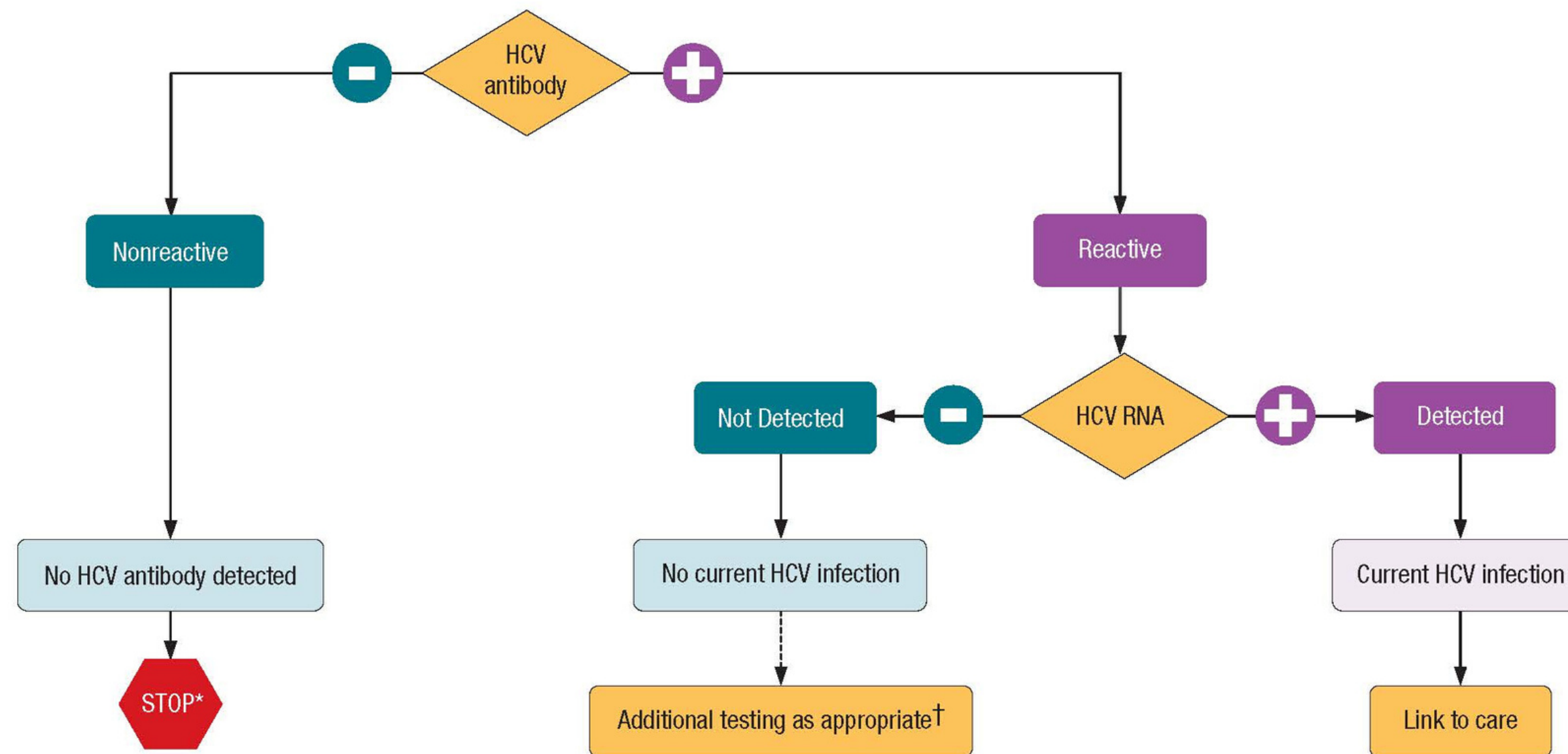


# Screening & Testing - CDC Testing Algorithm

## Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection



U.S. Department of  
Health and Human Services  
Centers for Disease  
Control and Prevention



\* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

† To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

Source: CDC. Testing for HCV infection: An update of guidance for clinicians and laboratorians. MMWR 2013;62(18).



# Screening & Testing – CDC Testing Algorithm

11

## Interpretation of Results of Tests for Hepatitis C Virus (HCV) Infection and Further Actions



U.S. Department of  
Health and Human Services  
Centers for Disease  
Control and Prevention

TEST OUTCOME	INTERPRETATION	FURTHER ACTIONS
<b>HCV antibody nonreactive</b>	No HCV antibody detected	Sample can be reported as nonreactive for HCV antibody. No further action required.  If recent exposure in person tested is suspected, test for HCV RNA.*
<b>HCV antibody reactive</b>	Presumptive HCV infection	A repeatedly reactive result is consistent with current HCV infection, or past HCV infection that has resolved, or biologic false positivity for HCV antibody. Test for HCV RNA to identify current infection.
<b>HCV antibody reactive, HCV RNA detected</b>	Current HCV infection	Provide person tested with appropriate counseling and link person tested to care and treatment.†
<b>HCV antibody reactive, HCV RNA not detected</b>	No current HCV infection	No further action required in most cases.  If distinction between true positivity and biologic false positivity for HCV antibody is desired, and if sample is repeatedly reactive in the initial test, test with another HCV antibody assay.  In certain situations,§ follow up with HCV RNA testing and appropriate counseling.

\* If HCV RNA testing is not feasible and person tested is not immunocompromised, do follow-up testing for HCV antibody to demonstrate seroconversion. If the person tested is immunocompromised, consider testing for HCV RNA.

† It is recommended before initiating antiviral therapy to retest for HCV RNA in a subsequent blood sample to confirm HCV RNA positivity.

§ If the person tested is suspected of having HCV exposure within the past 6 months, or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.



## Screening vs. Testing

For the purpose of hepatitis C diagnosis in an ideal setting and situation...

- Screening = Rapid HCV antibody screening test
  - if reactive/positive...
- Testing/Confirmatory = serologic (blood) testing - HCV viral load, PCR, or RNA

1. Laws and Consent
2. Reporting Requirements
3. CLIA Waivers
4. PSO - Physician Standing Orders
5. Quality Control
6. Types of Screening & Testing
  - a. Rapid, point-of-care
  - b. Whole blood/venipuncture/serologic

### Laws and Consent

- Consent is recommended - best performed in an 'opt-out- model'
  - Since HCV is reportable, it is best practice to inform patients
- Consent is NOT required - this is often conflated with HIV testing

### RESEARCH ARTICLE

### Open Access

## Patient acceptance of universal screening for hepatitis C virus infection

Phillip O Coffin<sup>1\*</sup>, Anne M Stevens<sup>2</sup>, John D Scott<sup>1</sup>, Joanne D Stekler<sup>1</sup> and Matthew R Golden<sup>1</sup>

### Abstract

**Background:** In the United States, about 70% of 2.9-3.7 million people with hepatitis C (HCV) are unaware of their infection. Although universal screening might be a cost-effective way to identify infections, prevent morbidity, and reduce transmission, few efforts have been made to determine patient opinions about new approaches to screening.

**Methods:** We surveyed 200 patients in August 2010 at five outpatient clinics of a major public urban medical center in Seattle, WA, with an 85.8% response rate.

**Results:** The sample was 55.3% women, median 47 years of age, and 56.3% white and 32.7% African or African-American; 9.5% and 2.5% reported testing positive for HCV and HIV, respectively. The vast majority of patients supported universal screening for HCV. When presented with three options for screening, 48% preferred universal testing without being informed that they were being tested or provided with negative results, 37% preferred testing with the chance to “opt-out” of being tested and without being provided with negative results, and 15% preferred testing based on clinician judgment. Results were similar for HIV screening.

**Conclusions:** Patients support universal screening for HCV, even if that screening involves testing without prior consent or the routine provision of negative test results. Current screening guidelines and procedures should be reconsidered in light of patient priorities.



## Reporting Requirements & Considerations

- National Notifiable Diseases Surveillance System (NNDSS)
  - Requires the reporting of hepatitis A, B, and C - process and specifics are determined by each individual State
    - Illinois as an example:
      - HCV is a reportable condition under the Control of Communicable Disease Code of Illinois, Title 77, Chapter 1, Subpart C, Section 690.200 and Subpart D, Section 690.452
      - Report all Positive/reactive screening/tests - antibody, PCR, etc
      - Negative/non-reactive screening/tests are helpful to determine positivity rates - consider reporting negative tests to provide the 'N'

# Screening & Testing – Things to Consider

Hepatitis C Provider Reporting Form - Chicago Department of Public Health

2160 W Ogden Ave, Chicago, IL 60612 | 312.746.6388 (fax)

Hepatitis C is a reportable condition under the Control of Communicable Disease Code of Illinois, Title 77, Chapter I, Subpart C, Section 690.200 and Subpart D, Section 690.452. Disease reports can be faxed to 312.746.6388 or submitted electronically using the Illinois National Electronic Disease Surveillance System (INDESS) through the Illinois Department of Public Health (IDPH) web portal (<http://portalhome.dph.illinois.gov/>).

The health department requires additional information for the individual listed below. Please complete this form and return it to our office no later than 7 days from when this was received.

If you have any questions please contact: \_\_\_\_\_ at (312) \_\_\_\_\_

PATIENT INFORMATION

Patient's name: \_\_\_\_\_  
first last

Parent's name (if patient is a child): \_\_\_\_\_  
first last

Address: \_\_\_\_\_  
street apt

\_\_\_\_\_  
city state zip code

Telephone 1: \_\_\_\_\_ Telephone 2: \_\_\_\_\_  
☐ home ☐ cell ☐ work ☐ home ☐ cell ☐ work

DEMOGRAPHICS

Date of birth: \_\_\_\_/\_\_\_\_/\_\_\_\_

Status (check one):

- ☐ Alive  
☐ Deceased → date: \_\_\_\_/\_\_\_\_/\_\_\_\_  
☐ Unknown

Sex/gender (check one):

- ☐ Male  
☐ Female → is patient pregnant? ☐ Yes ☐ No  
☐ Transgender

Race (check all that apply):

- ☐ American Indian or Alaskan Native  
☐ Asian  
☐ Black or African American  
☐ Native Hawaiian or Pacific Islander  
☐ White  
☐ Unknown

Ethnicity (check one):

- ☐ Hispanic  
☐ Non-Hispanic  
☐ Unknown

REPORTING FACILITY

Facility name: \_\_\_\_\_ Today's date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Provider name: \_\_\_\_\_ Phone number: \_\_\_\_\_

Reporter name: \_\_\_\_\_ Fax number: \_\_\_\_\_

Revised 1.29.2018

Page 1 of 2

TRANSMISSION RISK HISTORY (Check all that apply)

- ☐ Ever inject drugs  
☐ Heroin  
☐ Prescription (e.g. OxyContin, Methadone)  
☐ Other: \_\_\_\_\_
- ☐ Ever had a tattoo  
Most recent venue: \_\_\_\_\_
- ☐ Ever had a body part pierced  
Most recent venue: \_\_\_\_\_
- ☐ Ever incarcerated longer than 6 months  
Year of most recent incarceration: \_\_\_\_-\_\_\_\_-\_\_\_\_
- ☐ Ever on long-term hemodialysis  
Most recent location: \_\_\_\_\_
- ☐ Ever employed in a medical or dental field involving direct contact with human blood
- ☐ Ever a contact of a person who had Hepatitis C  
☐ Sexual  
☐ Household (non-sexual)  
☐ Other: \_\_\_\_\_
- ☐ Ever treated for a sexually transmitted infection (STI)  
\_\_\_\_ # of life-time sex partners
- Sexual preference (check one):  
☐ Heterosexual  
☐ Homosexual  
☐ Bisexual  
☐ Unknown

PATIENT HISTORY (Check all that apply)

Symptoms:

- ☐ Jaundice  
☐ Fever  
☐ Headache  
☐ Malaise  
☐ Anorexia
- ☐ Nausea  
☐ Vomiting  
☐ Diarrhea  
☐ Abdominal pain

Symptoms onset date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Hepatitis C care:

- ☐ Is the patient currently under your care for Hepatitis C?  
☐ If no, was a referral for Hepatitis C care made?  
Where: \_\_\_\_\_
- ☐ Has the patient ever received medication for Hepatitis C?  
Specify: \_\_\_\_\_  
Year: \_\_\_\_-\_\_\_\_

LABORATORY RESULTS

- ☐ Did the patient have a previously (unreported) diagnosis for Hepatitis C?  
Year: \_\_\_\_-\_\_\_\_

Test type	Test result	Test method	Reference Range	Specimen collection date
Antibody (anti-HCV)	<input type="checkbox"/> Positive <input type="checkbox"/> Negative			____/____/____
RNA	<input type="checkbox"/> Positive <input type="checkbox"/> Negative			____/____/____
Quantitative PCR				____/____/____
ALT		IU/L		____/____/____
AST		IU/L		____/____/____
Genotype	<input type="checkbox"/> 1 <input type="checkbox"/> 3 & <input type="checkbox"/> A <input type="checkbox"/> 2 <input type="checkbox"/> 4 <input type="checkbox"/> B			____/____/____
Signal to cut-off ratio				____/____/____
Surface antigen	<input type="checkbox"/> Positive <input type="checkbox"/> Negative			____/____/____

Revised 1.29.2018

Page 2 of 2

## CLIA Waivers from your State Department of Health

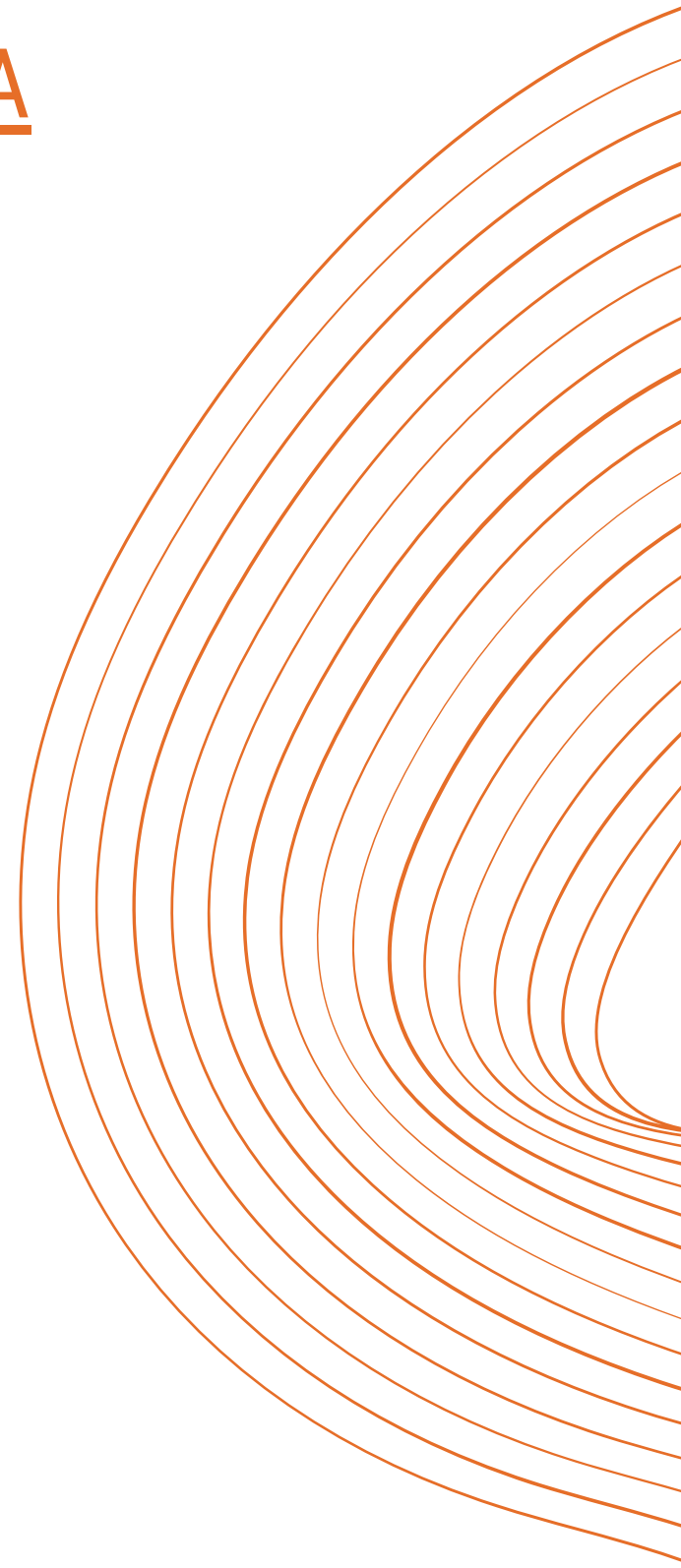
- Clinical Laboratory Improvement Amendment - (CLIA)  
"The CLIA definition of a laboratory is a facility that **performs testing** on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of human beings. **If you perform any testing** as defined by CLIA, you are considered as having a laboratory or as a laboratory."

\*This includes rapid antibody screening/testing\*



## CLIA Waivers from your State Department of Health

- The FDA states "a waived test is a simple laboratory examination and procedure that have an insignificant risk of an erroneous result."
- You must apply for a CLIA waiver using CMS - 116 Application \* Check your state for application #
- If you already have a CLIA waiver, hepatitis C testing must be added to your application
- You will need a CLIA certificate for EACH site where you perform a test UNLESS:
  - You have a mobile unit, or consistent change in locations, you may apply under a 'home base'
  - Non-profit or government laboratory using less than 15 waived tests
  - Locations are under the same building or campus



## Physician Standing Orders

- Why use them?
  - Streamlines and standardize care for all who meet criteria
  - Maximizes the full utility of all healthcare professionals
  - Empowers healthcare providers to conduct important screenings
- What are they?
  - Pre-written order/instruction and protocol from physician
- What does it allow for?
  - Other healthcare professionals (RN, PA, health educators, etc.) to share in patient care
  - A team to function at their fullest capacity

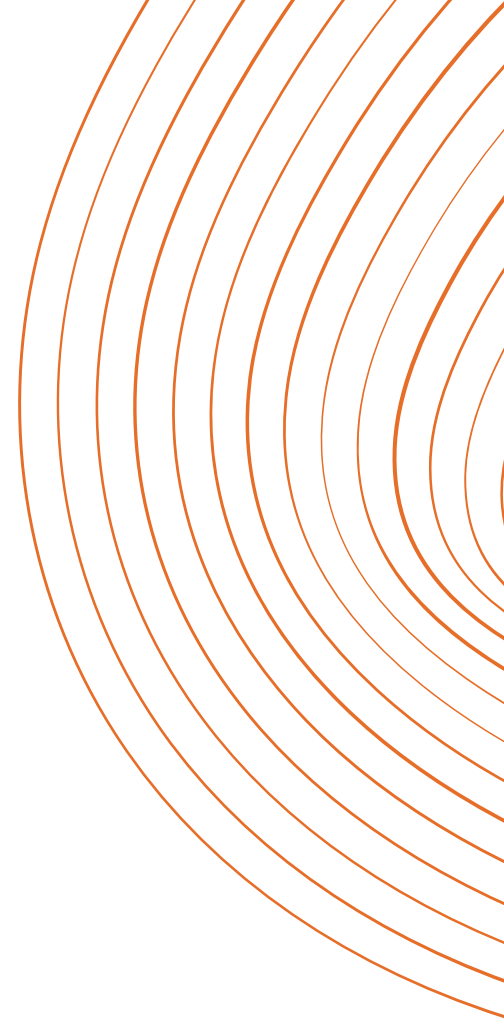
### Relevant PSOs

- HCV Testing
- HBV Testing
- HBV Vaccination
- Naloxone Distribution

## Illinois Physician Standing Orders for Naloxone

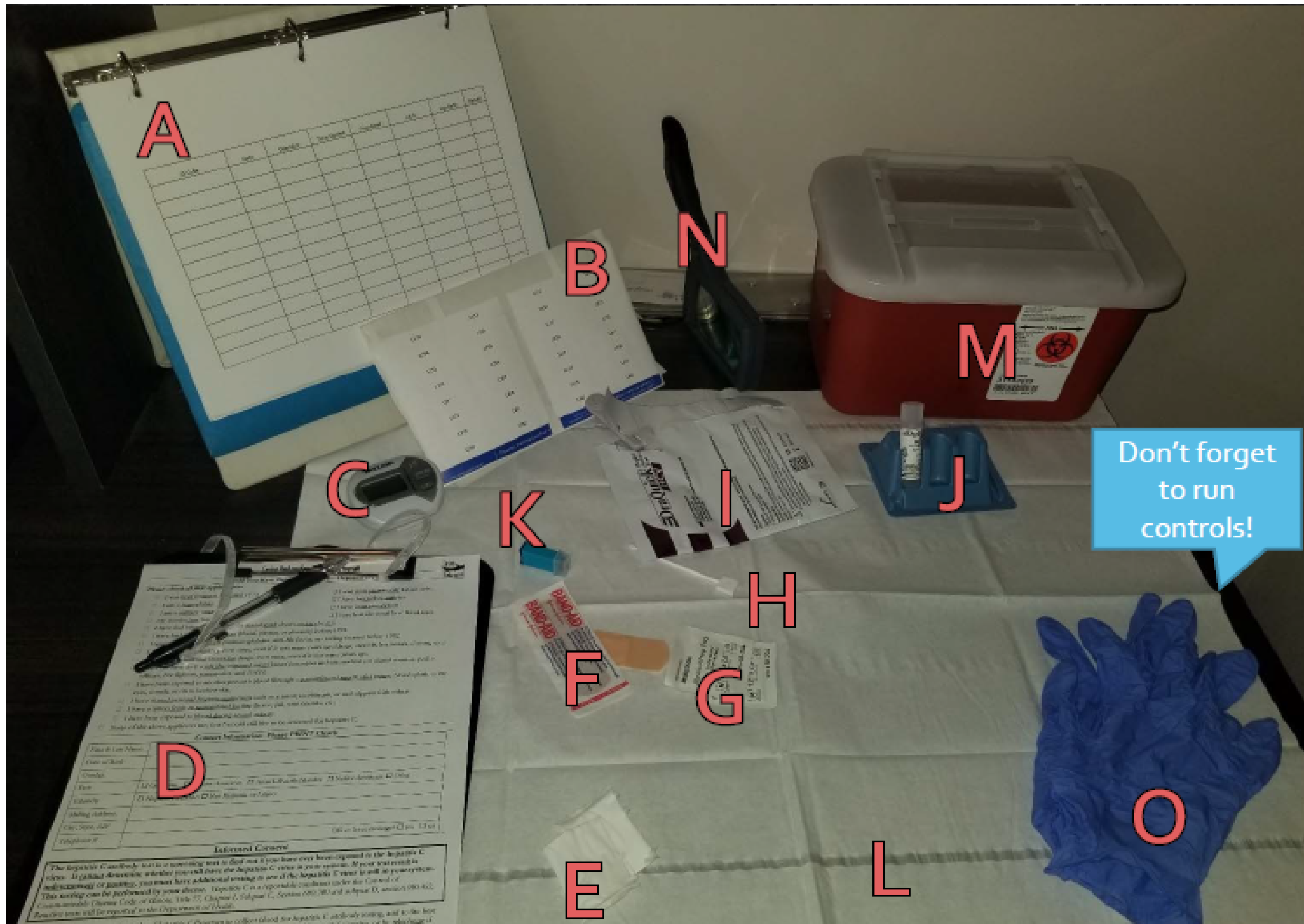
"The statewide Illinois Naloxone Standing Order authorizes trained, licensed pharmacists and overdose education and naloxone distribution (OEND) programs to dispense naloxone to anyone who requests it for the use of reversing a potential opioid overdose, even if they don't have an individual prescription for the medication. The order was issued by the Chief Medical Officer of the Illinois Department of Public Health on September 7, 2017 and will be renewed annually."





1. Phlebotomy, lab-based, whole-blood
  - a. hepatitis C antibody + reflex added to the other 'general' labs
2. Rapid, point-of-care (POC)
  - a. OraSure Screening/Test Kit
3. Quality Control & Technology
  - a. OraSure is the only manufacturer of rapid, POC HCV screening/test kits
    - i. Screens for antibodies
    - ii. 20 minute results
    - iii. FDA approved
    - iv. CLIA waived for single drop of blood

## SCREENING & TESTING - THINGS TO CONSIDER



A - Testing Log/Lab Record

B - Tacking Labels

C - Timer

D - Consent Form

E - Gauze

F - Band-Aid

G - Alcohol Swab

H - Specimen Loop

I - OraSure HCV Test Kit

J - Test Tube & Stand

K - Lancet

L - Absorbent pad/'chuck'

M - Sharps Container

N - Magnifying Glass

O - Gloves









# 25

## SCREENING & TESTING PARTS & PIECES OF HCV COUNSELING

1. Pre-Pretest
2. Pretest
3. Screen/Test
4. Lab
5. Post-test Counseling

\*Reference **Parts & Pieces: HCV Screening & Counseling**



# 26

## SCREENING & TESTING DIAGNOSIS & TESTING IN CLINIC

When screening through lab-based testing, there is no situation where a clinic should order an HCV antibody test only!

### Confirming Chronic HCV Infection:

- Hepatitis C Antibody with Reflex to HCV RNA, Quantitative, Real-Time PCR
- **Reflex testing saves time**, money, and reduces stress

### Once Confirmed with chronic HCV infection:

- Genotype
- CBC
- Hepatitis B - HBsAg, anti-HBs, anti-HBc (total)
- HIV



## SCREENING & TESTING WHAT'S CHANGED

- As of March 2020, the CDC & United States Preventative Services Task Force (USPSTF) recommends HCV screening in adolescents and adults aged 18 to 79 years
- Genotype testing is less important to determine treatment options b/c of pangenotypic DAA
- Increase in fatty liver disease (NAFLD) and so important to monitor this among G3 patients
- HCV testing including as part of HIV and opioid funding announcements
- COVID-19 - consider parallel testing with COVID-19
  - Treatment for COVID-19 may be harmful to the liver
    - may cause HBV flares - know your status!



## SCREENING & TESTING TOOLS & RESOURCES

- Parts & Pieces: HCV Screening & Counseling
- OraSure - Register for an account at
  - <https://orc.orasure.com/default.aspx?pageid=5046>
- CDC - Viral Hepatitis Program
- SAMHSA - TIP Manuals





# In conclusion...

29

## What's Next?

- Next Module is: Vaccination
- About 1 hour/1 CEU
- The purpose of the next module is to orient participants to the role of hepatitis A and B vaccination practices in the care of people living with HCV

## Obtaining CEU's & Attendance Certificates

- Don't forget to take the pre and post-test surveys to receive CEU's or Certificates of Completion!

## Access to Tools

Access to tools, resources, slides, and activities can all be found at <https://hepcchallenge.org/bigg/>

## Questions?

BiggInfo@CaringAmbassadors.org

