

Managing HIV and Hepatitis C Outbreaks Among People Who Inject Drugs

***A GUIDE FOR STATE AND LOCAL
HEALTH DEPARTMENTS***

March 2018

Version 1.0

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Division of HIV/AIDS Prevention



Contents

ABBREVIATIONS	III
ACKNOWLEDGMENTS	IV
FIGURES	V
BACKGROUND	1
OUTBREAK PREPAREDNESS AND DETECTION	3
Chapter 1 Introduction to outbreak detection and response among people who inject drugs	3
Chapter 2 Planning for an outbreak response	5
Chapter 3 Detecting an HIV or hepatitis C virus outbreak among people who inject drugs	11
OUTBREAK INVESTIGATION	21
Chapter 4 Introduction	21
Chapter 5 Developing a case definition	23
Chapter 6 Contact tracing and partner services	24
Chapter 7 Testing at venues frequented by people who inject drugs	29
Chapter 8 Overview of HIV laboratory testing and identification of acute infections	34
Chapter 9 Overview of hepatitis C virus laboratory testing and cluster investigations	37
OUTBREAK RESPONSE	39
Chapter 10 Management structure	39
Chapter 11 Engaging law enforcement	42
Chapter 12 Role of community-based organizations and community partners	44
Chapter 13 Coordinating HIV care and treatment	45
Chapter 14 Coordinating hepatitis C virus care and treatment	51
Chapter 15 Establishing a syringe services program	56
Chapter 16 Treatment of substance use disorders and recovery services for PWID	61
Chapter 17 Setting up a one-stop shop	70
Chapter 18 HIV pre- and post-exposure prophylaxis	74
Chapter 19 Other considerations—hepatitis B virus infection	77
REFERENCES	78
APPENDICES	82
Appendix A Glossary	82
Appendix B Procedure for the collection, processing, and shipment of serum and plasma specimens to CDC for sequence analyses and detection of HIV infections	84
Appendix C GHOST	86
Appendix D Indiana State management of an outbreak response	87
Appendix E Compilation of guide web links	92

Abbreviations

AASLD	American Association for the Study of Liver Diseases
Ab	antibody
ADAP	AIDS Drug Assistance Program
Ag	antigen
CBO	community-based organization
CDC	Centers for Disease Control and Prevention
CLIA	Clinical Laboratory Improvements Act
DAA	direct acting antiviral
DIS	disease intervention specialists
EIS	Epidemic Intelligence Service
EMAC	Emergency Management Assistance Compact
FDA	Food and Drug Administration
GHOST	Global Hepatitis Outbreak and Surveillance Technology
HBV	hepatitis B virus
HCV	hepatitis C virus
HIV	human immunodeficiency virus
HRSA	Health Resources and Services Administration
ICS	incident command system
IDSA	Infectious Diseases Society of America
ISDH	Indiana State Department of Health
LEO	law enforcement official
MAT	medication-assisted treatment
MOU	memorandum of understanding
MSM	men who have sex with men
NASTAD	National Alliance of State and Territorial AIDS Directors
NAT	nucleic acid test
NGS	next-generation sequencing
PCR	polymerase chain reaction
PEP	post-exposure prophylaxis
PrEP	pre-exposure prophylaxis
PWID	people who inject drugs
RNA	ribonucleic acid
SAMHSA	Substance Abuse and Mental Health Services Administration
SSP	syringe services program
STD	sexually transmitted disease
STI	sexually transmitted infection
US	United States

Acknowledgments

This guide was developed by staff from the Centers for Disease Control and Prevention, Indiana State Department of Health, Kentucky Department for Public Health, National Alliance of State and Territorial AIDS Directors, Tennessee Department of Health, Virginia Department of Health, and the Wisconsin Department of Health Services.

Kathy K. Byrd, MD, MPH

Centers for Disease Control and Prevention

Nasima Camp, MPH, CHES

ICF

Erika Chapman, MPH, CPH, CHES

Indiana State Department of Health

Greg Corby-Lee, BS

Kentucky Department for Public Health

Susie Danner, BA

Centers for Disease Control and Prevention

Karen Diepstra, MPH

Virginia Department of Health

Diana Jordan, RN, MS

Virginia Department of Health

Yury Khudyakov, PhD

Centers for Disease Control and Prevention

Magalie Lerman, BA

National Alliance of State and Territorial AIDS Directors

Alexander Millman, MD

Centers for Disease Control and Prevention

Robyn Neblett-Fanfair, MD

Centers for Disease Control and Prevention

John Nichols, BA

Indiana State Department of Health

Alexa Oster, MD

Centers for Disease Control and Prevention

Philip J. Peters, MD

Centers for Disease Control and Prevention

Karen Sams, BASc

Kentucky Department for Public Health

Lindsey Sizemore, MPH, CPH

Tennessee Department of Health

Lauren Stockman, MPH

Wisconsin Department of Health Services

Dennis Stover, MS

Indiana State Department of Health

William M. Switzer, MPH

Centers for Disease Control and Prevention

Eyasu Teshale, MD

Centers for Disease Control and Prevention

James Vergeront, MD

Wisconsin Department of Health Services

Jennifer Walthall, MD

Indiana State Department of Health

Paul J. Weidle, PharmD, MPH

Centers for Disease Control and Prevention

Gayle Yocum, MSW

Kentucky Department for Public Health

We thank the following persons for their assistance in developing this document: John T. Brooks, Ashley Carter, Aaron Harris, Heather Hauck, Thomas Kresina, Elaine Martin, Samantha Mathieson, Marie Morgan, Rendi Murphree, Anne Rhodes, Michael Rickles, Susan Robilotto, Julie Shaffner, John Weiser, Lauren Yerkes.

A checklist of considerations for management of HIV and hepatitis C outbreaks among people who inject drugs is available at: <https://www.cdc.gov/hiv/pdf/programresources/guidance/cluster-outbreak/cdc-hiv-hcv-pwid-checklist.pdf>

Suggested citation: *Centers for Disease Control and Prevention. Managing HIV and hepatitis C outbreaks among people who inject drugs—A guide for state and local health departments.* March 2018. Available at: <https://www.cdc.gov/hiv/pdf/programresources/guidance/cluster-outbreak/cdc-hiv-hcv-pwid-guide.pdf>

Figures

FIGURE 3-1	MOLECULAR HIV CLUSTER AND ITS UNDERLYING TRANSMISSION CLUSTER AND RISK NETWORK	14
FIGURE 8-1	CDC RECOMMENDATIONS FOR HIV TESTING IN LABORATORIES	34
FIGURE 9-1	SUGGESTED HCV TESTING ALGORITHM DURING A SUSPECTED HCV OUTBREAK AMONG PWID	37
FIGURE 9-2	SUGGESTED HCV TESTING ALGORITHM DURING ONGOING TRANSMISSION AND CONTINUOUS HCV INTRODUCTION AMONG PWID	38
FIGURE 10-1	GENERAL INCIDENT COMMAND SYSTEM ORGANIZATION	39
FIGURE 17-1	EXAMPLE OF A ONE-STOP SHOP	71

Background

The United States is in the midst of an opioid misuse epidemic involving prescription drugs, as well as heroin and other synthetic opioids (e.g., fentanyl). This crisis has led to increases in drug overdose deaths, admissions for substance use treatment, and neonatal abstinence syndrome. Deaths caused by drug overdoses increased from 6.2 per 100,000 in 2000 to 14.7 per 100,000 in 2014, and admissions to substance-use treatment facilities increased from <1 per 10,000 in 1999 to approximately 4 per 10,000 in 2009.^{1,2} In addition, the incidence of neonatal abstinence syndrome increased from 1.5 per 1,000 births in 1999 to 6.0 per 1,000 births in 2013.³

In 2014, an estimated 1.9 million persons had substance use disorders involving prescription pain relievers, and 586,000 persons had substance use disorders involving heroin.⁴ Precise data on the number of people who inject drugs (PWID) in the United States is lacking; however, estimates for the numbers of PWID in 2011 ranged from 500,000 to 1 million persons.⁵ In addition, the prevalence of injection drug use has increased; heroin injection increased 63% during 2002–2013.⁶ Part of the increase in injection drug use stems from prescription opioid abuse: 4 of 5 new heroin users started by misusing prescription opioids.⁷ Prescription opioid abuse is contributing to increases in drug injection in communities not previously considered at high risk of injection-related infections.

The opioid epidemic has also increased the number of PWID in the United States and thereby substantially increased the risk of transmission of blood-borne viruses, including human immunodeficiency virus (HIV), hepatitis C virus (HCV) and hepatitis B virus (HBV) through use of shared equipment. Unsafe injection of drugs, such as by sharing injection equipment (e.g., syringes, cookers, water, and cotton) to inject or split drugs, contributed to an increase in new HCV infections from 1,232 to 2,436 from 2011 through 2015.⁸ Although PWID make up 1%–3% of the total population, injection drug use accounted for approximately 6% of new HIV diagnoses in 2015; infections attributable to the combined risk of male-to-male sexual contact and injection drug use accounted for another 3% of diagnoses.^{5,9} Among persons diagnosed with acute HCV infection and information about injection drug use in 2015, 64% were PWID.⁸

Rural communities are disproportionately affected by the opioid epidemic and have been most affected by overdoses, new acute HCV infections, and are considered most vulnerable to rapid spread of HIV and HCV if introduced among uninfected communities of PWID.¹⁰ Identifying jurisdictions particularly vulnerable to an HIV or HCV outbreak can guide public health efforts to detect, prevent, and respond quickly to, potential outbreaks. Although numbers and rates of acute hepatitis C infections are proportionally greater in rural communities, significant increases have also been recorded in urban counties.^{11–16}

The potential for rapid spread of HIV among this new population of PWID was realized during a 2015 outbreak in rural Scott County, Indiana. In January 2015, disease intervention specialists (DIS) reported 11 new cases of confirmed HIV infection epidemiologically linked through injection drug use; by comparison, only 5 HIV infections had been diagnosed in this county in the prior 10 years (2004–2013).¹⁷ By November 2015, 181 new cases of HIV had been diagnosed; 92% of infected persons were coinfecting with HCV. The impact of injection drug use can be far reaching, and PWID have a wide range of needs that may complicate their ability to follow the treatment and prevention recommendations essential to controlling an outbreak. Lack of medical care capacity for HIV and HCV infection as well as limited local resources for prevention and treatment of substance use disorder may have allowed this outbreak to spread faster and further than it would have had these resources been present.¹⁷ Controlling the outbreak involved establishing these services, especially provision of antiretroviral therapy for HIV infection. Additional activities that further aided control included use of advanced HIV and HCV molecular technologies to characterize the network of PWID, rapid deployment of DIS teams to conduct contact tracing and HIV and HCV testing throughout the affected community, and use of the state's emergency preparedness resources to coordinate a multitude of other services (e.g., insurance enrollment, care coordination, vaccinations).

Advanced planning can facilitate an effective coordinated response for communities faced with the possibility of similar future outbreaks of HIV or HCV among networks of PWID. This document is intended to help health departments prepare for such an outbreak. The document provides guidance on how to plan for an outbreak of HIV or HCV among PWID including considerations for developing an outbreak response plan to minimize the impact of the outbreak on the community and stop further transmission. The document also outlines strategies to detect and investigate a possible outbreak.

HIV or HCV outbreaks can be defined as follows:

An increase in diagnoses above what is normally expected in a geographic area or population during a particular period **AND** evidence of **recent transmission** of HIV or HCV among case-patients.

Outbreak preparedness and detection

Chapter 1: Introduction to outbreak detection and response among people who inject drugs

What is an outbreak?

HIV and HCV infection affect every community. If adequate testing and surveillance are available, a baseline prevalence of these infections can be established. Establishing baseline prevalence helps estimate the number of new diagnoses expected in a community. An outbreak refers to an increase in the number of new diagnoses in excess of the number expected in a particular geographic area or population during a particular period. The related term *cluster* refers to new diagnoses that may be grouped by similar epidemiologic features (grouped by place and time) or matching viral sequences (a molecular cluster). HIV or HCV outbreaks can be defined as follows:

An increase in diagnoses above what is normally expected in a geographic area or population during a particular period **AND** evidence of **recent transmission** of HIV or HCV among case-patients.

Recent transmission typically refers to transmission of HIV or HCV within the previous six months.

What is outbreak response?

Outbreak response is a process used by public health programs to investigate and intervene when an outbreak is suspected or confirmed. The ultimate goal of an outbreak response is to interrupt transmission and to prevent future infections. Responding to an HIV or HCV outbreak may require augmenting and redirecting resources, engaging a large and diverse group of partners and stakeholders, building upon collaborations and developing targeted communication messages for specific groups. Increased resources are usually needed to respond to the increased number of new diagnoses and to identify the root causes of the outbreak.

Who is responsible for detecting and responding to an outbreak?

State and local health departments have jurisdiction and responsibility for HIV and HCV prevention in their communities. Depending on state law, either the state or local health department has legal authority to lead an outbreak response in the jurisdiction. However, because an outbreak response may require substantial resources, a state or local health department may find it difficult to manage an outbreak response while maintaining adequate staffing and coverage for other public health activities. Thus, health departments might request assistance from other agencies, including neighboring local health departments, the state health department, neighboring state health departments, and federal agencies

Outbreak preparedness provides health department staff with general direction about how to initiate a response when and if an outbreak occurs.

(including the Centers for Disease Control and Prevention [CDC]) to assist with the outbreak response. CDC can assist with an outbreak response when requested by a state health department, another federal agency, or a sovereign entity (e.g., American Indian/Alaska Native tribe, U.S. territory, or foreign country).

Why prepare for an outbreak?

Outbreak preparedness provides health department staff with general direction about how to initiate a response when and if an outbreak occurs. A response plan for a specific outbreak may be a modification of a health department's general outbreak plans. Areas that are vulnerable to HIV or HCV outbreaks (e.g., areas with high numbers of drug overdose deaths, prescription opioid sales) should consider having HIV and HCV specific outbreak response plans.

Preparedness also establishes relationships in advance with potential key staff and partners who may be engaged if an outbreak occurs. For an outbreak of HIV or HCV infections among PWID, key staff and partners include those with expertise in policy, communications, law, finance, insurance enrollment, and health care access.

Standing outbreak response plans cannot predict all the issues pertinent to a specific outbreak. However, planning for the more predictable aspects of an outbreak allows more time to respond to an outbreak. For example, given that lack of access to sterile syringes may be an important aspect of an outbreak among PWID, it is important that health departments establish contact with resources that can quickly provide sterile syringes.

Planning is essential to a prompt, effective response to an outbreak.

State and local health departments should establish the criteria for an HIV or HCV outbreak in their jurisdiction and the threshold at which the outbreak response plan is to be initiated.

Chapter 2: Planning for an outbreak response

Planning is essential to a prompt, effective response to an outbreak. Specifically, planning can improve the outbreak response of HIV and viral hepatitis prevention programs by allowing time to assign authorities, draft policies, and outline procedures for managing a public health response. The final product of planning is an outbreak response plan. Below are issues to consider when developing an outbreak response plan including readiness prior to an outbreak and planning for the detection of and response to an outbreak.

Issues to consider in planning: readiness prior to an emergency

Determining what prompts an outbreak investigation

When creating an outbreak response plan, state and local health departments should establish the criteria for an HIV or HCV outbreak in their jurisdiction and the threshold at which the outbreak response plan is to be initiated. Not all outbreaks require activation of a comprehensive outbreak response plan.

Determining who is responsible for investigating and responding to an outbreak

State and local health departments are responsible for leading responses to HIV and HCV outbreaks in their jurisdictions. When assembling an HIV and HCV outbreak response team, identifying the people or teams responsible for the following activities should be considered:

- Leadership, management, and oversight of outbreak activities*
- HIV or HCV surveillance activities
- Contact investigation and epidemiologic investigation
- Data management
- Provision of HIV or HCV testing and transport of laboratory specimens
- Laboratory testing
- Control and prevention measures
- Coordination of HIV or HCV treatment
- Coordination/provision of hepatitis A and hepatitis B vaccination services
- Coordination/provision of risk-reduction services
- Coordination/provision of substance-use treatment services
- Coordination with external partners and agencies
- Risk communication and communication with media
- Health education
- Other support activities, such as logistics and liaison with law enforcement

An Epi-Aid is a short-term field investigation and technical assistance provided by an Epidemic Intelligence Service (EIS) officer and other CDC subject matter experts.

*For complex outbreaks or for outbreaks in which multiple jurisdictions or agencies are involved, health departments might consider using an incident command system (ICS). (For an example of how an ICS can be used during an outbreak response, see [Chapter 10](#) and [Appendix D](#).)

Planning for additional staff or resource assistance during an outbreak

Depending on the size and complexity of the outbreak, additional staff may be required to support the outbreak response. An outbreak response plan includes an outline for requesting assistance from other agencies and determining when additional assistance is necessary, such as from neighboring local health departments, the state health department, and CDC. Deciding when to request assistance first requires determining the current health department capacity and at what point, before or after exceeding this capacity, to request assistance.

A memorandum of understanding (MOU), between state health departments or between local health departments within a state, can be used to request assistance from other states or jurisdictions. Ideally, an MOU should be in place before an outbreak occurs and should specify the resources that can be shared between states.

Requesting technical assistance

Health departments that need HIV technical assistance can contact the CDC Division of HIV/AIDS Prevention, Prevention Program Branch Project Officer or HIV Incidence and Case Surveillance Branch Project Officer. Health departments can also contact CDC-INFO (<https://www.cdc.gov/cdc-info/about.html>), a CDC contact center established to answer public inquiries. CDC-INFO can be reached by phone at 1-800-CDC-INFO (232-4636) or by email at www.cdc.gov/info.

For viral hepatitis technical assistance, health departments can contact the CDC Division of Viral Hepatitis, Prevention Branch Project Officer or Surveillance Branch Project Officer. Alternatively, health departments can contact CDC-INFO or email ViralHepatitisOutbreak@cdc.gov.

(For information about how to request CDC laboratory assistance, see [Chapter 8](#) and [Chapter 9](#))

Requesting an Epi-Aid

Public health authorities can request short-term epidemiologic assistance—an Epi-Aid—to respond to an urgent public health problem. An Epi-Aid is a short-term field investigation and technical assistance provided by an Epidemic Intelligence Service (EIS) officer and other CDC subject matter experts. The purpose of an Epi-Aid is to assist local partners in rapidly controlling the public health problem. An Epi-Aid can increase the technical capacity and the size of the workforce responding to the public health problem and can simplify access to CDC subject matter experts and laboratory resources. The requesting public health authority maintains overall leadership of the investigation.

Who can request an Epi-Aid?

A variety of public health officials (e.g., state, territorial, or local public health authorities) can request an Epi-Aid. When a local jurisdiction within a state requests an Epi-Aid, CDC ensures that the appropriate state-level health officials, if not already aware, are informed of the request.

How to request an Epi-Aid

- A state or local public health authority contacts the CDC subject matter expert or the EIS program office to request an Epi-Aid.
- The CDC subject matter expert contacts the EIS program (or vice versa) to discuss the request. If CDC can support the Epi-Aid, the CDC subject matter expert notifies the requesting authority.
- Once notified that CDC can support an Epi-Aid, the requesting authority emails an invitation to the CDC subject matter expert contact or to the EIS Program Chief at EpiAid@cdc.gov.
- Once the emailed invitation is received, the EIS program decides whether to approve and activate the Epi-Aid.

(For more information about Epi-Aids, see <https://www.cdc.gov/eis/downloads/requesting-epi-aid.pdf>)

(For information about how to request disease intervention specialist (DIS) support from CDC, see [Chapter 6](#))

Developing communication plans

During an outbreak, coordination of information among staff and all partners is essential. Plans should be developed to disseminate pertinent information internally (within programs) and between agencies and external partners. A plan should also be developed for communicating with the media. (For general guidance on how to develop an outbreak communication plan see, https://www.nphic.org/toolkits/outbreak/item/download/3962_0ffb487900a79d136ba77b5920da168d)

Educating staff

Before an outbreak, and on an ongoing basis, staff should be educated about core strategies for preventing HIV and HCV transmission among PWID. An outbreak response plan should specify staff training. For example,

- HIV and HCV testing, including screening for acute HIV infection
- Partner services, including contact tracing
- Community education, including condom distribution
- Risk-reduction services, including syringe service programs and medication-assisted treatment
- Mental health and substance use treatment
- HIV and HCV treatment

Planners should identify local providers and clinics that can provide HIV or HCV care and treatment, establish the capacity of the health department and local clinics to provide care and treatment, and develop protocols for referring affected persons to care.

Health departments should consider developing protocols for referring affected persons to mental health and substance use treatment as part of the response plan.

- HIV preexposure prophylaxis and HIV postexposure prophylaxis
- Viral hepatitis prevention including vaccination for hepatitis A and hepatitis B
- Scientific ethics and patient privacy and confidentiality
- Communication with the media
- Other training related to engagement with the community (e.g., cultural competency)

Identifying access to treatment

Planners should identify local providers and clinics that can provide HIV or HCV care and treatment, establish the capacity of the health department and local clinics to provide prevention care and treatment (i.e., number of persons with HIV or HCV a provider or clinic can reasonably treat), and develop protocols for referring affected persons to care. Health departments that provide care and treatment should determine the threshold for referral to sources of care outside the local health department and potentially outside the local area. Areas with limited access to HIV or HCV providers should develop a plan for rapid access to HIV and HCV prevention and treatment services. This plan may include the use of telehealth technology or bringing providers from outside the local area to work alongside local providers. Health departments might also develop an outline for assisting persons with enrollment in insurance plans.

Identifying access to substance-use treatment services

PWID may need screening and referral to mental health and substance-use treatment services. Health departments should consider developing protocols for referring affected persons to mental health and substance use treatment as part of the response plan. The following are pertinent considerations:

- Number and location(s) of mental health providers and substance-use treatment centers
- Type of facility services (e.g., inpatient treatment, intensive outpatient treatment, individual and group counseling)
- Average number of treatment slots available at any given time
- Number of medication-assisted treatment providers in area
- The maximum number of persons that can be treated by these providers

Partnerships during an outbreak

When developing an outbreak response plan, health departments should consider identifying potential community and government partners, their resources, and their capacity to provide services and resources during an outbreak. Potential community partners include community based organizations (CBOs), health care providers, hospitals, mental health

An outbreak response plan should include an outline of how health department resources will be used to detect an outbreak.

providers, substance-use-treatment providers, pharmacies, and risk-reduction providers. Potential governmental partners may include leaders in local government, law enforcement, jails and prisons, emergency management agencies, and county hospitals. In addition, health departments should consider involving these groups in the development of the outbreak plan. (For information about working with law enforcement and CBOs, see [Chapter 11](#) and [Chapter 12](#))

Practicing for an outbreak

After an outbreak response plan has been developed, one way to test an outbreak response plan is by conducting an exercise in which the team discusses, in an informal setting, a simulated outbreak scenario. Such an exercise helps the team assess the plan, policies, and procedures and clarify staff roles and responsibilities. The plan can then be revised on the basis of the strengths and weaknesses identified during the exercise.

Issues to consider in planning: detecting an outbreak

Detecting an HIV or HCV outbreak among PWID

Timely detection of an HIV or HCV outbreak is important to prevent further transmission of infections and minimize the magnitude of an outbreak. An outbreak response plan should include an outline of how health department resources will be used to detect an outbreak.

An outbreak response plan might include protocols for detecting an HIV or HCV outbreak using the following:

- Systematic analysis and review of case surveillance data
- Systematic analysis and review of molecular surveillance data
- Use of partner-services and contact-investigation data
- Enhanced surveillance, including additional specimen testing (e.g., pooled nucleic acid test [NAT], genotyping)
- Observations of staff in the health department, CBOs, and clinical settings
- Use of data to detect non-sterile injection drug use (e.g., rates of endocarditis as well as deep abscesses and other skin and soft-tissue infections)

(For information about detecting an HIV or HCV outbreak, see [Chapter 3](#))

Issues to consider in planning: responding to an emergency

Conducting the outbreak investigation

When the roles and responsibilities of health department staff and community partners have been determined before an outbreak, the outbreak response team can move quickly to confirm the outbreak, find cases, report findings, implement prevention and control measures, and monitor response to these interventions. (For information about conducting an outbreak investigation, see [Chapters 4–9](#))

Educating PWID

An HIV and HCV outbreak response plan should include education for PWID, who need to know how to prevent transmission of infection. Plans to educate the population should be part of an outbreak response plan. Education should cover (as permitted by law) medication-assisted treatment, safer injection practices and wound care, overdose prevention, hepatitis A and hepatitis B vaccination, and testing for HIV and HCV infection.

Referring affected persons for treatment

After an outbreak has been detected, affected persons require treatment. The list of treatment resources developed before the outbreak should be used to coordinate care (e.g., antiviral therapy, mental health treatment, substance use treatment). (For information about coordinating HIV and HCV treatment, see [Chapter 13](#) and [Chapter 14](#). For information about substance use treatment and recovery services, see [Chapter 16](#).)

Identifying access to sterile syringes

Planners should be aware of local syringe services programs and their capacity. Planners should review local laws and regulations regarding syringe services programs. Planners should also review syringe access laws and practices to determine if local pharmacies can be utilized to provide sterile syringes. In areas without ready access to sterile syringes, the response plan might specify the additional resources that would be needed to provide a syringe services program. (For information about establishing a syringe services program, see [Chapter 15](#).)

Deactivating and evaluating the outbreak response

Planners should include threshold criteria for reducing resources (when intense outbreak-related activities are no longer required) and for demobilizing resources. They should also prepare plans for an evaluation and review of the overall outbreak response.



Notes from the field

In 2016, the Viral Hepatitis staff, Tennessee Department of Health (with support from HIV, Sexually Transmitted Disease [STD], Immunizations, Hospital-Acquired Infections, Emergency Preparedness, and Surveillance Systems/Informatics staff), convened a working group that met bimonthly to discuss best practices for responding to an HIV/HCV outbreak. As a direct result of this working group, an HIV/HCV Outbreak Response plan was developed (<https://www.cdc.gov/hiv/pdf/programresources/guidance/cluster-outbreak/cdc-hiv-hcv-pwid-response-plan.pdf>). The Outbreak Response plan and its supporting documents establish a framework for the health department to prepare for, and respond to, an outbreak of HIV and HCV, describe the ongoing surveillance efforts for HIV and HCV, and outline the roles and responsibilities of Tennessee Department of Health staff in the event of (1) a transmission cluster investigation or (2) an outbreak investigation.

Timely detection of an HIV or HCV outbreak is important to preventing further transmission and minimizing an outbreak.

Surveillance information determines the baseline level of HIV and HCV infection in a community and informs the expected number of new HIV and HCV diagnoses.

An increase in the reported number of new HIV or HCV diagnoses does not always indicate an outbreak; an increase in reported new diagnoses may reflect an increase in testing.

Chapter 3: Detecting an HIV or hepatitis C virus outbreak among people who inject drugs

How are HIV or HCV outbreaks detected?

Although HIV and HCV infections can be asymptomatic, which can cause delayed diagnosis, timely detection of an HIV or HCV outbreak is important to preventing further transmission and minimizing an outbreak. Health department staff may detect signs suggestive of an outbreak and should be encouraged to discuss their observations with the appropriate health department staff. Regular meetings and strong working relationships between prevention and surveillance staff can facilitate these discussions.

Outbreaks can be detected through the following activities:

- Routine and ongoing analysis of HIV or HCV case surveillance data to identify aberrant increases in diagnoses in a geographic area or population
- Identification of unexpected patterns in contact tracing investigations and partner services
- Analysis of molecular HIV surveillance data to identify clusters of closely related cases
- Astute observations by health care providers, health department staff, or community members

During the activities (above), health department staff should be alert for signs of more-than-expected HIV or HCV cases and evidence of transmission among persons with a recent diagnosis.

Case surveillance

Public health programs monitor new diagnoses of HIV and acute HCV infection by geographic area, population, and time in their jurisdiction. Some states also monitor new diagnoses of chronic HCV infection. This surveillance information determines the baseline level of HIV and HCV infection in a community and informs the expected number of new HIV and HCV diagnoses. An unexpected increase in the number of HIV or HCV diagnoses in a geographic area or population can be one of the first signs of an outbreak.

Similarities in patient demographics, reported risk factors, and recency of infection may also be early signs of an outbreak. In areas with a low reported incidence of HIV or HCV (e.g., rural communities), outbreaks can be more easily detected through case surveillance because any increase could indicate an outbreak. Improved timeliness of case surveillance reporting may improve a jurisdiction's ability to detect an outbreak.

An increase in the reported number of new HIV or HCV diagnoses does not always indicate an outbreak; an increase in reported new diagnoses may reflect an increase in testing, which may reflect diagnoses of persons with long-standing infection. In general, acute HIV infections (determined

HIV surveillance data should be monitored for increases in HIV cases reported with “history of injection drug use” as the transmission category.

through laboratory tests that can detect HIV antigen or ribonucleic acid [RNA]), recent HIV infections (determined through HIV recency tests) and HIV infections diagnosed for persons who tested HIV-negative in the preceding 6 months are clear indicators of recent HIV transmissions. Recent HIV transmissions, when detected, represent cases with early HIV infections. HCV infections in young persons are more likely to have been recently acquired.¹⁵

Monitoring surveillance reports for transmission category

HIV surveillance data (stored in the enhanced HIV/AIDS Reporting System) should be monitored for increases in HIV cases reported with “history of injection drug use” as the transmission category. An increase in the number of HIV reports in this category, compared to baseline data or an increase in these reports from neighboring communities, contiguous counties, and nonurban areas should be prioritized for investigation and follow-up. Analysis could also be conducted to assess increases in cases reported with combined history of “male-to-male sexual contact *and* injection drug use.” However, it should be noted that increases in cases with the transmission category of “male-to-male sexual contact *and* injection drug use” do not necessarily represent increased transmission through injection drug use. Men who have sex with men (MSM) are the population most severely affected by HIV and previous analyses suggest that sexual transmission is likely the primary transmission route for MSM who inject drugs.¹⁸ Public health staff should, therefore, first consider male-to-male sexual contact as the primary transmission route for persons with combined history of “male-to-male sexual contact *and* injection drug use.”

Although resources may not allow for complete identification of HCV risk on all reports, the HCV surveillance registry should be monitored for increases in the numbers of HCV-infected persons who reported injection drug use.

Contact tracing investigations and partner services

DIS are public health outreach workers who are responsible for locating, counseling, and educating persons with sexually transmitted and other communicable diseases—and their contacts. DIS work for local or state health departments or for federal public health agencies. Some DIS are trained in phlebotomy, rapid HIV and HCV testing, and advanced interviewing.

DIS routinely perform contact tracing investigations for all persons with newly diagnosed HIV infection; these investigations focus on providing services (including linkage to HIV care) for the HIV-infected person and outreach and testing for their partners or contacts who may have been exposed to HIV. These services are often referred to as *partner services*. While the full extent of partner services are generally not offered to persons with HCV infection, DIS can identify and locate contacts of persons newly infected with HCV during an outbreak investigation.

Molecular HIV surveillance provides another method that public health programs can use to detect outbreaks.

This method may be particularly helpful in areas with a high incidence of HIV infection, in outbreaks that cross jurisdictions, and in outbreaks in which persons are unwilling or unable to provide contact names or locating information.

A molecular cluster could be the first sign of an outbreak.

DIS, because they work extensively in local communities, are positioned to notice unexpected patterns or increases in HIV and HCV diagnoses. For example, DIS may notice that contact-tracing services are being conducted for two persons in a neighborhood without previous HIV diagnoses and that these persons have named the same syringe-sharing partners.

The following are other findings from a contact tracing or partner services investigation that may indicate an HIV or HCV outbreak:

- A high number of reported syringe-sharing contacts—suggesting a large and densely connected network of injection drug users
- Several HIV or HCV infections diagnosed among the named contacts of the index patient
- HIV or HCV infections diagnosed among social contacts of the index patient
- Same syringe-sharing contact named by more than one index patient

Someone in the health department (e.g., DIS program manager) should be responsible for routinely reviewing partner services results and looking for evidence of an outbreak. (For more information about contact tracing and partner services, see [Chapter 6](#))

Molecular surveillance

Molecular HIV surveillance provides another method that public health programs can use to detect outbreaks. This method may be particularly helpful in areas with a high incidence of HIV infection, in outbreaks that cross jurisdictions, and in outbreaks in which persons are unwilling or unable to provide contact names or locating information. Molecular HIV surveillance collects and analyzes HIV nucleotide sequence information generated through drug resistance testing performed as part of clinical care. If the HIV strains from two or more persons are similar, those persons may be in the same transmission cluster. HIV molecular analyses can help confirm, disprove, or detect connections among cases (which may be direct or indirect). A molecular cluster could be the first sign of an outbreak.

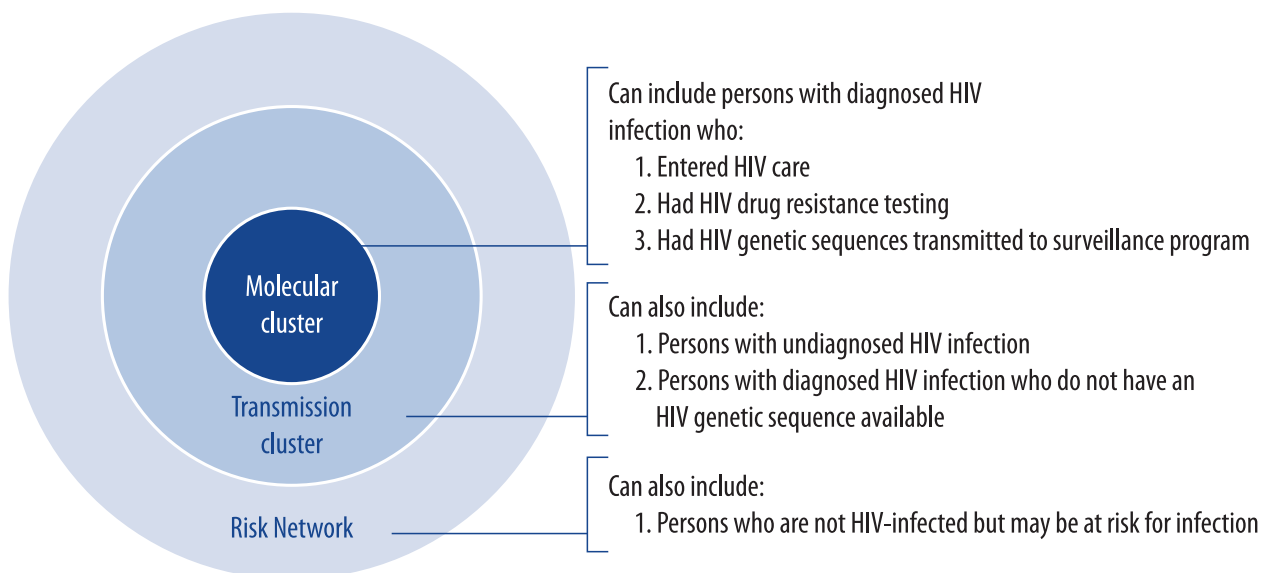
HCV molecular surveillance may become available in the future and could provide another method for detecting HCV outbreaks.

What is an HIV molecular cluster and how does it relate to a transmission cluster?

- A molecular cluster is a group of persons with diagnosed HIV infection who have genetically similar HIV strains. Persons whose viral strains are similar may be closely related by transmission. The ability to identify molecular clusters is therefore a tool for identifying transmission clusters that may represent possible outbreaks.
- Molecular clusters include persons with diagnosed HIV infection who entered care, who have HIV drug-resistance test results, and whose sequences were sent to the state/local HIV surveillance program for analysis.

- A molecular cluster is a subset of a transmission cluster ([Figure 3-1](#)). A transmission cluster can include
 - persons with diagnosed infection for whom a sequence for analysis is not available because they did not enter care; they entered care but did not have an HIV drug-resistance test; they entered care and had an HIV drug resistance test, but the sequence was not transmitted to the health department for analysis or was of poor quality and thus could not be analyzed
 - persons with undiagnosed infection
- The underlying risk network of the molecular cluster includes the persons in the transmission cluster as well as HIV-uninfected persons at risk of acquiring HIV.
- Molecular HIV surveillance data can serve as a proxy for an epidemiologic relationship but cannot reveal which cases are directly related by transmission or determine the direction of transmission. This is because it is possible to observe 2 persons with genetically similar HIV strains who are not necessarily directly linked by transmission; the relationship could be indirect, and unidentified persons could be involved in transmission relationships.
- Once a molecular cluster is identified, the molecular cluster can be characterized by using case surveillance information; however, the corresponding transmission cluster and risk network can be identified only through investigation (detailed in [Chapter 6](#)).

Figure 3-1: Molecular HIV cluster and its underlying transmission cluster and risk network



CDC has developed an analytic tool called Secure HIV-TRACE, which allows for state and local analysis of molecular surveillance data. Secure HIV-TRACE allows state and local health departments to define parameters for molecular cluster identification, such as the genetic distance threshold, to suit analytic goals locally while maintaining the ability to conduct analyses that are aligned with CDC approaches.

How are nucleotide sequence data generated and collected?

- Nucleotide sequence data are generated through HIV drug-resistance testing. This testing is recommended for all persons with diagnosed HIV infection at entry to HIV care to help HIV providers select an appropriate treatment regimen. The testing can also be ordered later (e.g., for a person who is receiving treatment but whose viral load is not suppressed or for a person whose antiretroviral therapy regimen is being changed).
- HIV genetic sequence data are routinely reported to the local/state HIV surveillance programs and to CDC through the National HIV Surveillance System. During 2013–2017, 27 U.S. jurisdictions participated in molecular HIV surveillance.
- Health departments report these data to CDC with case information collected by HIV surveillance programs (demographics, transmission category, CD4 results, viral load results), but without identifying information (e.g., name, street address).

How are molecular clusters identified?

The genetic sequence of HIV changes over time. Immediately following transmission of HIV between two persons, the genetic sequence of the HIV virus strain in the recipient will be nearly identical to strains found in the transmitting person. As time passes, however, the strains infecting each person will change independently of each other and will look more and more different. Therefore, persons whose viral strains are genetically similar may be closely related in transmission.

The nucleotide sequences of each strain is compared with every other HIV nucleotide sequence to identify pairs of sequences that are extremely similar (i.e., sequences between which the genetic distance, or difference, is very small). Pairs of cases with similar sequences are then connected to construct molecular clusters and identify clusters of very closely related cases.

CDC conducts quarterly analyses of national molecular surveillance data to identify clusters that, on the basis of the number of closely related cases, raise concerns about the recent, rapid transmission of HIV. When a cluster of concern is identified, CDC notifies the primary jurisdiction and securely transmits a cluster snapshot describing the cluster.

CDC has developed an analytic tool called Secure HIV-TRACE, which allows for state and local analysis of molecular surveillance data. Secure HIV-TRACE allows state and local health departments to define parameters for molecular cluster identification, such as the genetic distance threshold, to suit analytic goals locally while maintaining the ability to conduct analyses that are aligned with CDC approaches. Secure HIV-TRACE is available to state and local HIV surveillance program staff at <https://secure.hivtrace.org/>.

(For more information about molecular HIV surveillance, see <https://wwwdev.cdc.gov/hiv/pdf/funding/announcements/ps18-1802/CDC-HIV-PS18-1802-AttachmentE-Detecting-Investigating-and-Responding-to-HIV-Transmission-Clusters.pdf>)

Observations from health department staff and others in the community

HIV and HCV outbreaks are sometimes first detected through astute observations from health department staff. For example, public health nurses who provide HIV testing in a prison may notice that they have made several HIV diagnoses among new inmates from the same rural community, or a doctor in an emergency department may make several HCV diagnoses among persons being treated for skin and soft-tissue infections. Such observations call for further investigation to determine whether and how these persons are connected to each other and others in the community.

Enhanced surveillance for HIV and HCV outbreaks among PWID

HIV and HCV infections (acute and chronic) are nationally notifiable diseases. Local and state public health agencies play a vital role in monitoring HIV and HCV disease trends and outbreaks. Protocols to identify early HIV and HCV infection, to ensure case reporting, and to prioritize cases for follow-up investigation can be developed to enhance standard surveillance systems and ultimately, detect HIV and HCV infection clusters or outbreaks.

Although CDC directly funds HIV surveillance programs, funding for HCV surveillance varies among jurisdictions. Many health department surveillance programs receive a high volume of HCV laboratory test results but do not have staff or systems to investigate, review, or classify individual reports. If an HIV or HCV cluster is identified, surveillance data specific to the population at high risk can provide public health officials with the detailed information needed to allocate resources to affected persons and those at highest risk of infection.

What is enhanced surveillance?

Enhanced HIV and HCV surveillance supplements standard surveillance in order to monitor changes in HIV and HCV epidemiology, identify disease burden and the need for care and treatment in specific populations, and prevent new infections. Enhanced surveillance includes the collection of data that may not be collected by standard surveillance systems. Enhanced surveillance usually requires supplemental funding and staff for detection of HIV and HCV outbreaks, and includes collaboration among data managers, epidemiologists, and DIS. Information management systems and high-quality reporting systems, including laboratory-based reporting, are important components of enhanced surveillance.

Information to increase provider awareness

Increased provider awareness of the potential for an HIV or HCV outbreak among PWID is important for enhanced surveillance. A jurisdiction may consider releasing a public health advisory to call attention to the risk of HIV and HCV outbreaks among PWID in the jurisdiction. The advisory may describe the population at risk, explain testing recommendations, and explain the use of risk-based screening questions to identify persons for HIV and HCV testing. The advisory should also remind clinicians and laboratorians of the state requirements for the reporting of HIV and HCV infections. When an HIV or HCV outbreak is identified, an advisory should be repeated or a health alert issued.

Testing and reporting among populations at high risk

Enhanced surveillance may result in increased screening or case finding at clinics and community locations (e.g., syringe services programs, jails and prisons, substance-use treatment facilities, emergency departments, and other outreach sites). HIV and HCV rapid tests (results available within 20 minutes) have proven useful in increasing testing in hard-to-reach populations. Because these tests are not performed in a laboratory, they are not typically reported electronically to the health department. Staff from non-laboratory testing sites must have mechanisms in place to report reactive test results to the public health authority as statute and administrative code allow.

Prioritization of acute and early infections

Acute HIV infection is the period immediately after infection (approximately first 6 weeks after infection) when the virus is detectable by a NAT or antigen test but antibody response is immature or undetectable. Acute infection is the period of peak viremia and greatest risk of infecting others. During the acute period, nonspecific symptoms (fever, malaise, lymphadenopathy, and skin rash) develop in 50%–80% of acutely infected persons. (For more information about detection of acute HIV infection, see [Chapter 8](#))

Early HIV infection generally is considered the time up to 6 months after infection during which anti-HIV antibodies are detectable. Early infection can be detected based on testing history (a negative HIV test result ≤ 180 days before the first positive test result). (For HIV case surveillance definitions, see <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1.htm>)

The 2016 Council of State and Territorial Epidemiologists defines acute HCV as an onset of discrete illness consistent with acute viral hepatitis and jaundice or an alanine aminotransferase level of >200 IU/L. Laboratory criteria for diagnosis includes a positive test result for HCV antibody, NAT for HCV RNA, or presence of HCV viral antigen (For acute HCV surveillance definition, see <https://www.cdc.gov/nndss/conditions/hepatitis-c-acute/>; for more information about detection of acute HCV infection, see [Chapter 9](#))

An increase in HCV infections can indicate shared use of injection equipment, which may indicate that a community is at increased risk of an HIV outbreak.

Routine linkage of HIV and HCV registries to identify new HIV/HCV coinfections can help monitor for an increase in HIV transmission associated with injection drug use, as well as for recent HIV infection among persons with HCV infection.

Complete data on persons with acute or recent infection can enhance understanding of transmission-related factors. Complete data may include demographics, risk group for transmission, patient contacts (e.g., needle-sharing, sexual, social), and clinical and laboratory information. Interventions to prevent further transmission of HIV and HCV are considered most effective during acute infection (a highly infectious period). Although acute infection is an important focus for outbreak detection, a low incidence of acute HIV or HCV should not be interpreted as low overall prevalence of these infections; it is inherently difficult to capture all infections during the time-limited acute phase, especially when symptoms are nonspecific.

HCV reports for adolescents and young adults

Because most acute HCV infections are asymptomatic, many persons with newly acquired infection have not been tested or have not sought care. Data indicate that persons aged 15–29 years with diagnosed HCV infection are more likely than older persons to be newly infected. Furthermore, most HCV infections in the age group 15–29 are attributable to injection drug use.^{12–15}

Of all persons with newly reported chronic HCV, a subset of those aged <30 years should be followed-up to collect the following information: (1) demographics, (2) clinical and laboratory criteria information to classify cases according to the definitions of the Council of State and Territorial Epidemiologists, (3) risk factors for infection, (4) and risk factors for ongoing community transmission including information on potential networks of contacts. As resources allow, jurisdictions should routinely (e.g., monthly or quarterly) review HCV reports in any case-classification (e.g., probable, confirmed) from this age group. In addition, because of the delay in acquiring the information needed to confirm and finalize a case report, all cases in nonfinal status should also be considered for follow-up.

Collaboration between HIV and HCV surveillance programs

Coinfection with HIV and HCV is common among PWID: an estimated 50%–90% of HIV-infected PWID are also infected with HCV.¹⁹ HCV, compared with HIV, survives longer on surfaces and is more easily transmitted by injection drug use.^{20,21} An increase in HCV infections can indicate shared use of injection equipment, which may indicate that a community is at increased risk of an HIV outbreak.

HIV/HCV coinfection may be identified by using laboratory information available at the time of report. Routine linkage of HIV and HCV registries to identify new HIV/HCV coinfections can help monitor for an increase in HIV transmission associated with injection drug use, as well as for recent HIV infection among persons with HCV infection. An increase in new HIV infections among persons with HCV may indicate transmission from injection drug use.

Regular (e.g., monthly or quarterly) meetings of staff from HIV and viral hepatitis surveillance units (e.g., data managers, epidemiologists, and HIV

partner services staff) to share epidemiologic data may facilitate early recognition of clusters. Persons with shared contacts can be identified by collaborative review of individual-level data (e.g., syringe sharing partners, participation in the same sexual networks) and epidemiologic data such as persons with HIV and HCV whose demographic data are similar or who live in the same community.

Mapping databases

In many states, data on HIV, sexually transmitted infections (STIs), and viral hepatitis are stored in separate surveillance databases. Database mapping (the process of creating data element mappings between two or more distinct databases) ensures that data collected during an outbreak are disseminated to the appropriate databases throughout, and at the conclusion of, an outbreak. Regardless of the questionnaire or database used for the outbreak data collection, it is important to embed database-mapping elements in the outbreak questionnaire to ensure that outbreak data can be added to surveillance databases and ensure testing history for each patient. An example of an outbreak questionnaire is located within the Tennessee Department of Health HIV and HCV Outbreak Response Plan (<https://www.cdc.gov/hiv/pdf/programresources/guidance/cluster-outbreak/cdc-hiv-hcv-pwid-response-plan.pdf>). The questionnaire contains the data elements required in surveillance databases for each condition and can function as a key for database mapping of three specific surveillance databases (enhanced HIV/AIDS Reporting System, National Electronic Disease Surveillance System Base System, and the Patient Reporting Investigation Surveillance Manager).

Other data to consider

Behavioral surveillance data

Some jurisdictions collect HIV behavioral surveillance data. The objective of behavioral surveillance is to assess prevalence and trends in risk behavior for HIV infection including injection drug use.²² Information collected on drug injection practices (e.g., date of most recent injection, place where person gets needles, needle sharing, sharing of drug injection equipment) can be used to identify areas with a high prevalence of injection drug use and high-risk injection practices.

Inpatient or death certificate data

Areas that experience a high burden of hospitalization or mortality related to injection drug use (e.g., opioid overdose, heroin poisoning) can be identified by using statewide inpatient and death certificate data. Although the availability of data in these statewide databases often lag by 12–15 months, an analysis of mortality related to injection drug use may reveal areas in a jurisdiction that can be targeted for HIV and HCV testing and enhanced surveillance.

Syndromic surveillance data

Syndromic surveillance is a tool used by public health programs for early detection of outbreaks. The National Syndromic Surveillance Program makes current platforms available to state and local partners. Some jurisdictions have successfully used syndromic surveillance data to identify increases in emergency department visits related to injection drug use and opioid overdose. Jurisdictions already using such National Syndromic Surveillance Program platforms might consider using syndromic surveillance related to risk of HIV and HCV infection.

An outbreak investigation identifies the characteristics of affected persons in the outbreak and the characteristics of the underlying risk network.

An outbreak investigation includes the examination of current data and the collection of new data to identify factors associated with transmission.

Outbreak investigation

Chapter 4: Introduction

An outbreak investigation identifies the characteristics of affected persons in the outbreak and the characteristics of the underlying risk network—information that can guide intervention efforts to improve health outcomes and prevent additional infections. An outbreak investigation includes the examination of current data and the collection of new data to identify factors associated with transmission. The following are the goals of an outbreak investigation:

- Determine the extent of the outbreak and the risk network (e.g., undiagnosed cases, diagnosed cases not previously linked to the outbreak, persons at risk of infection)
- Identify factors associated with transmission
- Understand connections between cases
- Assess risk for ongoing transmission
- Determine the interventions that might stop the outbreak

Components of an HIV or HCV outbreak investigation

1. Create a case definition. A case definition should capture not only the cases that were identified initially (e.g., through molecular analysis or partner notification) but also cases that could be part of the underlying transmission cluster. (For information about developing a case definition, see [Chapter 5](#))
2. Identify available data sources (e.g., local surveillance data, partner services data, local STD and viral hepatitis data, Ryan White HIV/AIDS Program data, surveillance data from other jurisdictions, jail databases, social network sites).
3. Organize and display the information.
4. Review available data to address investigation-relevant questions.
 - a. Review partner services data to identify cases that meet the case definition and to assess the size of the underlying risk network.
 - b. Identify factors possibly associated with transmission.
 - c. Determine possible connections between persons with diagnosed infection.
 - d. Assess potential risk of continued transmissions from persons with diagnosed infection.
5. Increase case finding through contact tracing and increased HIV and HCV testing.
6. Collect additional information, including potential review of medical records and interviews, as needed.

7. Synthesize data.
8. Implement prevention and control measures.
9. Continue to synthesize information and refine intervention strategies as new information becomes available.

Creating a case definition is one of the initial steps in the investigation of a potential HIV or HCV outbreak and should account for the confirmed, probable, and possible cases in an underlying transmission cluster.

Chapter 5: Developing a case definition

Creating a case definition is one of the initial steps in the investigation of a potential HIV or HCV outbreak and should account for the confirmed, probable, and possible cases in an underlying transmission cluster. A case definition can be based on what is known—at the beginning of an investigation—from surveillance data, HIV and HCV testing data, contact tracing and partner services data, molecular analysis, and other sources. The following are examples of information that may be helpful in developing a case definition for an HIV or HCV outbreak.

- **Time of HIV or HCV diagnosis:** Establish the beginning of the outbreak. The beginning may be a specific date after which all new HIV or HCV diagnoses are considered potentially part of the outbreak (e.g., ≤1 year before the date the index case [the first identified case of a potential outbreak or cluster] was diagnosed), or it may be an arbitrarily chosen date (e.g., beginning of a calendar year). Given the date of recent HIV or HCV diagnosis, consider whether each person with a new diagnosis has a prior negative test result that confirms a new infection at the time of interest.
- **Geography:** Establish the region of interest. Determine whether persons who are potential cases reside in, visited, or had contact with residents of the region of interest during the time frame of interest.
- **HIV or HCV risk factors:** Determine whether persons who are potential cases report specific risk factors associated with the outbreak, such as injection drug use or sexual contact with PWID, during the time frame of interest.
- **Contact-tracing investigation:** Determine whether persons who are potential cases were named as a needle-sharing or sexual partner during a contact tracing investigation. Determine whether a person with newly diagnosed HIV or HCV infection named a needle-sharing or sexual contact whose infection is considered a possible, probable, or confirmed case in the outbreak.
- **Molecular analysis:** Determine whether HIV or HCV molecular analysis indicates similarity to the outbreak strain.



Notes from the field

During the 2015 HIV/HCV outbreak in Scott County, Indiana, the following case definition was developed: A laboratory-confirmed HIV infection newly diagnosed after October 1, 2014, in a person who either resided in Scott County, Indiana, or was named by another case-patient as a syringe-sharing or sex partner.¹⁷

Contact tracing is the identification, location, and follow-up of all persons who are needle-sharing or sexual partner(s) of persons with newly diagnosed HIV or HCV.

Contact tracing is essential to ending an outbreak. If contact tracing is not conducted thoroughly, transmission is likely to continue, which, in turn, will require continued response efforts.

Chapter 6: Contact tracing and partner services

What is contact tracing?

Contact tracing is the identification, location, and follow-up of all persons who are needle-sharing or sexual partner(s) of persons with newly diagnosed HIV or HCV. Once located, contacts are offered testing and treatment. Rapid identification and testing of partners can reduce further transmission.²³ Contact tracing is therefore essential to ending an outbreak. If contact tracing is not conducted thoroughly, transmission is likely to continue, which, in turn, will require continued response efforts.

Contact tracing is most commonly conducted by DIS but can be conducted by other health care professionals, including nurses and medical providers. Persons infected with HIV or HCV are interviewed to elicit information about sexual or needle-sharing partners in the previous 12 months so that those partners can be confidentially notified of their possible exposure.

Either the newly diagnosed person (index patient) or health department staff (e.g., DIS) can notify sex- and needle-sharing partners of the index patient. If health department staff notifies the partners, they inform partners of their exposure without identifying the index patient. If index patients wish to inform their partner(s) themselves, DIS can provide coaching to assist with this process. Regardless of whether all partners identified by the index patient are located and notified, compiling a list of all persons identified by the index patient enables the DIS to maintain an accurate record of all persons at risk of infection.

What are partner services?

Partner services comprise a group of services (e.g., prevention counseling, testing for HIV or other STIs, testing for viral hepatitis, linkage to medical care, and linkage or referral to other prevention services such as substance use treatment and mental health services) offered to persons with newly diagnosed HIV infection and his or her partners.

Partner services, although particularly useful during an outbreak, are also conducted outside the outbreak setting. Health departments use surveillance data (individual and aggregate) to identify persons with newly diagnosed infection as candidates for partner services. As mentioned in [Chapter 3](#), partner services data can be used to identify potential outbreaks.

Cluster interviewing and social network strategy of testing

Persons with newly diagnosed HIV or HCV may be reluctant or unable to share partner contact information (e.g., when names of partners are unknown). Thus, it may be useful to collect information about social network contacts. The process of eliciting contact information for persons other than the index patient's partners, who might also be at risk of infection, is referred to as *cluster interviewing*. Cluster interviewing, or the related *social network strategy* for HIV testing, may be useful adjuncts

Cluster interviewing, or the related social network strategy for HIV testing, may be useful adjuncts to traditional contact tracing.

to traditional contact tracing.²⁴ When using the social network strategy, HIV-positive and high-risk HIV-negative persons recruit persons from their social, sexual, or needle-sharing networks for testing.²⁵ This strategy can be useful because it includes eliciting partner and social contact information even if someone tests negative.

(For more information about the social network strategy for HIV testing, see <https://effectiveinterventions.cdc.gov/en/HighImpactPrevention/PublicHealthStrategies/SocialNetworkStrategy.aspx>)

Steps to effective contact tracing and partner services

- Interview index patient (HIV or HCV) to solicit a list of all syringe-sharing and sexual partners within the previous 12 months.
- Counsel index patient about reducing the risk of transmitting HIV or HCV infection.
- Locate, contact, and interview all of the index patient's contacts to test for HIV or HCV infection.
- Locate, contact and interview all of the index patient's contacts for other possible contacts (associates of the source and index patient) and screen those persons for HIV and HCV.
- Counsel contacts about reducing their risk of acquiring HIV or HCV.
- Provide treatment or referral for treatment for persons who test positive for HIV or HCV.
- Follow-up persons with diagnosed HIV or HCV to encourage them to seek care and treatment.
- Follow-up, as necessary, to retest persons whose initial test may have taken place during the window period, but who have continuing exposure to HIV or HCV.

(For more information about HIV partner services, see <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5709a1.htm> and <https://effectiveinterventions.cdc.gov/en/HighImpactPrevention/PublicHealthStrategies/PartnerServices.aspx>)

Determining the capacity of DIS staff to conduct contact tracing

DIS are the backbone of contact tracing investigations and partner services. A large outbreak, however, might quickly surpass the capacity of a health department's DIS staff.

Ideally, a health department determines the capacity of its DIS staff before an outbreak occurs:

- Maximum number of open cases (short- and long-term or mixture of short- and long-term cases) that staff can manage at any given time
- Amount of travel time required to locate and follow-up persons with diagnosed infection

The state can request additional DIS support from CDC or from other states.

After determining current capacity, a health department should establish the point at which to request additional DIS staff.

During an outbreak, a health department may increase DIS capacity by shifting internal staff (e.g., by deploying current staff who previously worked as DIS).

Requesting additional DIS to support an outbreak

If responding to an outbreak starts to exceed the state's current DIS resources, the state can request additional DIS support from CDC or from other states. Before requesting additional DIS support, a state should consider the following:

- How many DIS are needed, and how long will additional DIS support be needed?
- What skill sets are needed? Will responding DIS need advanced interviewing skills, phlebotomy skills, ability to conduct rapid HIV or HCV testing?
- What are the expectations of responding staff? What are the expected responsibilities and duties, work hours, and command structure (i.e., to whom will the DIS report)?
- How will travel and other costs be funded?
- What are the health department's plans after responding DIS leave?

Requesting additional DIS from CDC

The following are steps for requesting DIS from CDC during an outbreak:

- A state public health authority contacts its CDC contact. The CDC contact may be the HIV or viral hepatitis project officer or program consultant, Regional Management Official, or other CDC contact assigned to work with the state.
- The state public health authority summarizes what is known about the outbreak, what has been done to address the outbreak, and why additional DIS are needed.
- The CDC contact, along with the state official, contacts the Field Services Branch, Division of STD Prevention, CDC, to discuss the state's needs.
- The state epidemiologist or STD Program Director or Manager makes a formal request for CDC DIS assistance to the Field Services Branch, Division of STD Prevention, CDC. The request can be in the form of an email and should include a brief background (what is currently known about the outbreak). Requests for CDC DIS assistance go through the Division of STD Prevention regardless of whether the outbreak involves an STI.

The Emergency Management Assistance Compact (EMAC) is a mutual aid agreement between all 50 states, the District of Columbia, Puerto Rico, Guam, and the U.S. Virgin Islands.

During a governor-declared state of emergency, states can use EMAC to request personnel, equipment, supplies, and services from other states to assist in the emergency.

A memorandum of understanding (MOU), between state health departments or between local health departments within a state, can be used to request DIS assistance from other states or jurisdictions.

Requesting additional DIS through the Emergency Management Assistance Compact

The Emergency Management Assistance Compact (EMAC) is a mutual aid agreement between all 50 states, the District of Columbia, Puerto Rico, Guam, and the U.S. Virgin Islands. During a governor-declared state of emergency, states can use EMAC to request personnel, equipment, supplies, and services from other states to assist in the emergency. Public health resources, including DIS, Public Information Officers, epidemiologists, and data managers, can be requested through EMAC. Requesting and assisting states and territories agree to legally binding terms, by which the requesting state is responsible for reimbursing costs to the assisting state. EMAC legislation allows for interstate recognition of credentials, licenses, and certifications.

The following are the steps for requesting DIS or other public health resources through EMAC:

- The governor of the affected state declares a state of emergency.
- The affected state determines the resources (and skills) needed and sends a request to State Emergency Management personnel.
- EMAC is activated.
- State Emergency Management personnel route the request to other EMAC states to find the requested resources.
- Potential assisting states determine availability of resources and collect offers of assistance within the state.
- Requesting and assisting states agree on estimated costs.
- State Emergency Management Agency personnel from the requesting and assisting states complete the EMAC Request for Assistance form (REQ-A), a legally binding agreement between states that includes all terms of the agreement, including cost reimbursement.
- Resources are deployed to the requesting state.

(For more information about EMAC, see <http://www.emacweb.org/>)

(For a sample completed EMAC form, see http://www.amchp.org/programsandtopics/CHILD-HEALTH/projects/newborn-screening/Documents/Template-NBS-Req-A-section1_EMAC.pdf)

Memorandums of understanding between state health departments

Because EMAC can be used only after a state of emergency had been declared, states may need another mechanism for requesting DIS support, between states, during an outbreak. An MOU, between state health departments or between local health departments within a state, can be used to request DIS assistance from other states or jurisdictions.



Notes from the field

To assist with an HIV and HCV outbreak among PWID in rural Indiana in early 2015, the Indiana State Department of Health made an EMAC request for personnel to aid in contact tracing, HIV rapid testing, phlebotomy, and patient interviews. DIS from nine state health departments were provided to Indiana in staggered deployments over approximately three months to assist in the outbreak response. Upon arrival at the command center, deployed DIS received an initial briefing that included an overview of the drug driving the outbreak, refresher training in phlebotomy, training in data systems, and outbreak documentation. Between April–November, state, EMAC, and CDC DIS located 536 persons who were linked to the outbreak: of these, 468 were assessed for risk, tested for HIV, and if HIV-infected, linked to care.

Before and during an HIV or HCV outbreak, testing at venues where large numbers of PWID seek medical treatment or other care can improve screening rates among this population.

Because SSPs primarily serve PWID, they are ideal sites for HIV and HCV testing among this population.

Chapter 7: Testing at venues frequented by people who inject drugs

Before and during an HIV or HCV outbreak, testing at venues where large numbers of PWID seek medical treatment or other care can improve screening rates among this population. High-risk testing venues can be clinical sites, nonclinical sites, and outreach sites; the sites may be operated by a variety of organizations including state and local health departments, CBOs, and healthcare organizations. Testing at high-risk venues is particularly useful during an outbreak but is also useful before an outbreak occurs—when routine or targeted testing can help identify an increase in HIV or HCV cases. Regardless of the type of testing venue, the following testing principles should be followed:

- Testing should be voluntary (free from coercion).
- Clients should be informed of HIV or HCV testing and have the option to opt-out.
- Testing should maintain the confidentiality and privacy of the client.
- All persons tested positive for HIV or HCV should be linked to care.
- Positive HIV and HCV test results should be reported to the health department, as required by local and state laws and regulations.

Syringe services programs

Syringe services programs (SSPs) provide access to sterile needles and syringes. SSPs can provide a variety of other services, including HIV and HCV screening. Because SSPs primarily serve PWID, they are ideal sites for HIV and HCV testing among this population. In addition, the fact that many SSP clients are repeat clients allows multiple opportunities for testing.

Jails and prisons

Each year, 24%–36% of persons who inject heroin are jailed or imprisoned.²⁶ Rates of reincarceration are especially high for persons with substance use disorders. The repetitive imprisonment of persons with substance use disorders makes correctional facilities useful venues for HIV and HCV testing. Both routine and targeted testing of these populations can be used. Discussions of HIV and HCV testing and care—how to conduct testing, how to manage the care of infected persons, how to transfer a person’s care to a community provider upon release—should include on-site medical staff, community HIV and HCV clinical care providers, and local health department staff. Additionally, if a person was receiving HIV or HCV treatment before incarceration, a plan is needed to coordinate the treatment during incarceration with the care that had been provided in the community.

Testing in substance-use treatment facilities provides an opportunity to address the role of drug use in increased risk of HIV and HCV infections.

Substance-use treatment facilities

Although the estimated percentages of PWID in substance-use treatment programs vary widely (1%–39% in large metropolitan areas²⁵), these programs, by providing testing, can contribute to the prevention of HIV and HCV infections and to the care of infected persons:

- Testing provides an opportunity to address the role of drug use in increased risk of HIV and HCV infections.
- Substance-use treatment facilities can serve as an entry point to medical care for a person with HIV or HCV infection and can improve adherence to medical treatment regimens.
- Knowledge of a client’s HIV or HCV status can help providers of substance use treatment choose medications to help prevent interactions between the drugs used to treat substance use disorders and the medications used to treat HIV and HCV infection.

Substance-use treatment programs can be inpatient (in a hospital or a in a separate facility) or outpatient. Inpatient programs may be better equipped to provide testing. Outpatient substance-use treatment programs, many of which are operated by small CBOs, may need assistance from the local health department or a larger CBO focused on HIV and HCV testing. Methadone maintenance programs typically require daily or otherwise frequent contact with clients, including contact for intense behavioral counseling, and are thus ideally positioned to offer routine HIV and HCV testing at program intake, and to offer repeat testing for persons at continued risk of infection.

Emergency departments

Emergency departments are useful as testing venues because HIV and HCV prevalence is high among persons who access care at emergency departments. According to the results of studies conducted in urban emergency departments, 0.1%–7.8% of emergency department populations are HIV-positive, and 10%–14% are HCV-positive.^{27–34} Emergency departments may offer rapid or laboratory-based HIV and HCV tests and provide results before the patient is discharged. Emergency departments may be part of a health system that has on-site clinics for HIV or HCV care, and may be able to refer to substance use treatment.

Sexually transmitted disease clinics

Injecting drugs can reduce inhibitions and increase engagement in high-risk sexual behaviors such as trading sex for drugs or money, sex with multiple partners, and sex without a condom. PWID, who are at increased risk of STIs, may seek treatment at STD clinics,³⁵ which routinely perform HIV testing. During an HIV/HCV outbreak among PWID, risk-based HCV testing can be considered. In addition, all persons who test positive for HIV should be tested for HCV and HBV.²¹

An outbreak investigation might reveal other places where PWID congregate; these places can be considered as potential testing sites.

Other testing sites

Testing can also be conducted at non-fixed settings such as mobile outreach vans. Mobile outreach brings testing to PWID where they reside or where they can otherwise be found. Another testing venue to consider is homeless shelters. Persons experiencing homelessness are more likely to engage in behaviors, including injection drug use, which put them at higher risk of HIV and HCV infection.^{36,37} Lastly, an outbreak investigation might reveal other places where PWID congregate; these places can be considered as potential testing sites.

Testing in nonclinical settings

The following are important considerations and procedures for nonclinical sites:

- Familiarity with state and local laws regarding HIV counseling, use of rapid HIV tests, confirmatory testing of preliminary positive test results, informed consent, laboratory requirements, confidentiality, and training and authorization of health care personnel who may administer HIV tests and provide HIV counseling.
- Familiarity with state and local laws and regulations regarding reporting of HIV and HCV test results to the health department, and notification of sex or needle-sharing partners. Staff at nonclinical sites should have all forms and tools needed for reporting and notification.
- Determination of the certification needed to provide testing. For example, if the plan is to use waived rapid HIV tests, obtain a certificate of waiver under the Clinical Laboratory Improvements Act of 1988 (CLIA), or establish an agreement with a laboratory to work under its current CLIA certificate.
- Protocols for data security and confidentiality and quality assurance.
- Determination of training for nonmedical personnel who perform testing. Training should include specimen collection, test administration, reading of test results, documentation, quality control procedures, client interactions, patient privacy and confidentiality, and HIV and HCV test counseling procedures.
- Consent: Clients whose behavior is significantly altered by the influence of drugs or alcohol cannot provide consent.
- Provision of counseling and testing: Pretest- and posttest-counseling is not required (especially in persons who have tested for HIV and HCV before) but if provided, the counseling and testing should be conducted in a private location where client confidentiality can be ensured.
- Confirmation of rapid HIV and HCV tests: A positive result from a rapid test requires confirmatory testing. The facility will need to have arrangements with a laboratory for confirmatory testing. If confirmatory tests are conducted at an outside laboratory, the site

should establish procedures for collection and transport of specimens, obtaining confirmatory results, and how to inform clients of the confirmatory test results. Alternatively, the facility can choose to immediately refer a person with one or more positive rapid tests result to a clinical provider.

- **Linkage to medical care:** Establish relationships with local providers to quickly refer persons with an HIV or HCV diagnosis. (For more information about identifying HIV and HCV providers, see [Chapter 13](#) and [Chapter 14](#))

(For more information about HIV testing in nonclinical settings, see https://www.cdc.gov/hiv/pdf/testing/cdc_hiv_implementing_hiv_testing_in_nonclinical_settings.pdf)

(For more information about HIV counseling and prevention, see <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5019a1.htm>)

(For more information about HIV testing laws and confidentiality see <http://hivlawandpolicy.org/state-hiv-laws>)

Additional considerations for testing in jails and prisons

- **Who to test:** Although routine opt-out screening is the most comprehensive testing strategy, limited resources may restrict implementation. Other testing strategies include risk-based, clinical screening, demographic screening, or multiple approaches. During a local outbreak (in a population residing in a facility where routine testing is not conducted), risk-based screening enables focus on an affected population and the effective allocation of resources.
- **When to test:** Because many persons are released from jails within 48–72 hours, the testing period is limited. Use of rapid tests and protocols for referring persons with preliminary positive rapid test results can be considered in jail settings. Because prison incarcerations tend to be longer, prison systems can test at the initial medical evaluation and can consider rapid and conventional lab-based testing strategies.
- **Confidentiality:** Maintaining the confidentiality of incarcerated persons is imperative to protect persons who test positive, particularly those who test positive for HIV. Concerns about privacy and fear of stigma prevent testing. Facility providers should be familiar with state and local laws regarding confidentiality and disclosure of an inmate's status to public health authorities and others (e.g., parole officer, sexual or needle-sharing partners) and should inform inmates about confidentiality and reporting laws.
- **Clinical care:** Appropriate clinical care and support services should be provided to inmates with diagnosed HIV or HCV. Jail inmates may be released before they receive confirmatory test results, so it is important to promptly notify them of final test results; those who tested preliminary positive should be linked to care upon release. For longer-stay inmates, a post-release care plan should be developed.

(For more information about HIV and HCV testing in correctional facilities, see <https://www.cdc.gov/hiv/pdf/group/cdc-hiv-correctional-settings-guidelines.pdf> and <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5201a1.htm>)

(For information about Tips and Tools for providing transitional care coordination, see <https://careacttarget.org/library/tools-tips-providing-transitional-care-coordination>)

(For information about HIV testing laws and confidentiality, see <http://hivlawandpolicy.org/state-hiv-laws>)

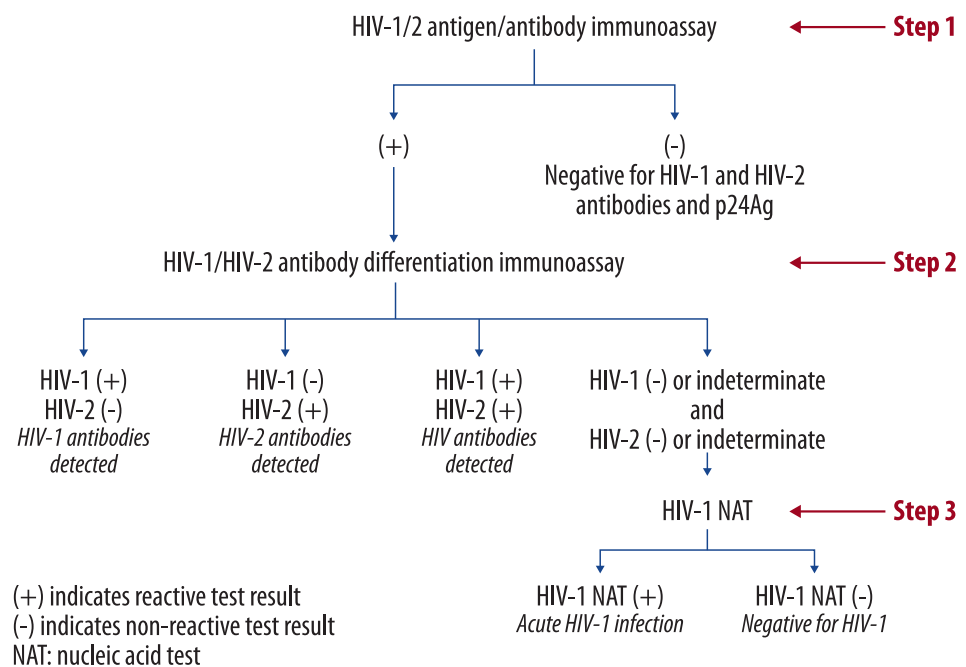
Serologic screening and confirmation of HIV infection should be conducted by local or state health departments, using the algorithm recommended by CDC/Association of Public Health Laboratories.

Chapter 8: Overview of HIV laboratory testing and identification of acute infections

State or local health department HIV laboratory testing

Increased testing will be required to assess the full extent of the possible outbreak. Serologic screening and confirmation of HIV infection should be conducted by local or state health departments, using the algorithm recommended by CDC/Association of Public Health Laboratories (<https://stacks.cdc.gov/view/cdc/50872>) (Figure 8-1).³⁸ For health departments who do not have the resources to perform HIV diagnostic testing, CDC can assist in testing specimens.

Figure 8-1: CDC recommendations for HIV testing in laboratories



Antigen/antibody immunoassay

The first serologic assay in the HIV testing algorithm is an antigen (Ag)/antibody (Ab) test that can detect both the HIV-1 p24 gag antigen and antibodies to HIV proteins (step 1, Figure 8-1). Assays that can detect p24 antigen allow for earlier detection of HIV because they can detect the virus before the body has mounted an immune response. During the eclipse period (the period between infection and the first detection of virus in the blood by any test, on average about 11 days after infection), no currently available test can diagnose infection.

HIV-1/HIV-2 antibody differentiation immunoassay

Reactive specimens from Ag/Ab testing are tested with a supplemental assay that detects and differentiates HIV-1 and HIV-2 antibodies

In an outbreak setting, the preferred specimen for rapid testing is fingerstick whole blood instead of oral fluid.

During an outbreak investigation, persons who initially tested negative, by any test, should be retested 3–6 weeks after the initial test.

(step 2, [Figure 8-1](#)). Specimens testing reactive for HIV antibodies in the supplemental assay are considered HIV-1, HIV-2 or HIV-positive depending on the specific seroreactivity observed in the test. Specimens testing negative or indeterminate in the supplemental test should be tested using an HIV-1 NAT to diagnose possible acute HIV-1 infection (step 3, [Figure 8-1](#)).

Persons with a negative HIV-1 NAT result (step 3, [Figure 8-1](#)) and an HIV-2 indeterminate result or an HIV indeterminate antibody differentiation immunoassay result (step 2, [Figure 8-1](#)), should be tested with a different validated supplemental HIV-2 test (antibody test or NAT) or the algorithm should be repeated in 2 to 4 weeks, starting with an Ag/Ab immunoassay.³⁹

HIV nucleic acid testing for specimens with negative antigen/antibody test results

To identify infection during the window period (period between HIV infection and when a test can reliably detect infection—this period includes the eclipse period), specimens that are nonreactive to an Ag/Ab immunoassay can be pooled and then further tested by a NAT.^{40–42} One approach is to pool HIV Ag/Ab-nonreactive specimens into intermediate pools of 16 specimens and then combine the 16 intermediate pools into a master pool of 256 specimens. Master pools are tested for HIV-1 RNA; if the result is positive, the individual specimens in the pool are tested.

HIV point-of-care (rapid) testing

Point-of-care testing using Food and Drug Administration (FDA)-approved, CLIA-waived rapid HIV tests can be used to screen for infection. In an outbreak setting, the preferred specimen for rapid testing is fingerstick whole blood instead of oral fluid. Although rapid tests provide immediate results in the field, the sensitivity of rapid tests is lower than that of Ag/Ab assays using plasma/serum.^{39,43–45} Preliminary positive rapid test results must be confirmed following the diagnostic algorithm recommended by CDC/Association of Public Health Laboratories ([Figure 8-1](#)) by either the organization conducting the rapid test or by another healthcare provider. Persons with preliminary positive rapid test results can be immediately linked to medical care; a person's visit to a healthcare provider does not have to be delayed pending confirmatory testing.

Serum/plasma is required for HIV Ag/Ab assays and for serologic screening for HCV. Serum/plasma is also needed for the HIV recency and phylogenetic testing performed at CDC (described below).

Retesting for HIV during an outbreak

During an outbreak investigation, persons who initially tested negative, by any test, should be retested 3–6 weeks after the initial test.⁴⁵ Re-testing can begin with rapid tests or with laboratory-based testing. Results of retests may identify infections that were missed because initial tests were performed during the window period.

CDC HIV laboratory testing

Testing for recent HIV infection and determining whether those infections are genetically linked is important for characterization of the potential outbreak and for determination of public health prevention strategies.¹⁷ Determining new infections and transmission links can also provide helpful information on transmission dynamics (who is infecting whom and how) and the effectiveness of specific interventions. In general, “recent infection” is defined by a laboratory-based recency assay and usually occurs within 6 months of infection but this timeframe depends on the recency assay used.

Laboratory assistance from CDC

The Laboratory Branch, Division of HIV/AIDS Prevention, CDC can assist an outbreak investigation as follows:

- Determine whether HIV infections are recent (new, or incident) or longstanding (prevalent, or long-term) by using antibody avidity-based serologic recency assays.
- Perform HIV sequencing on plasma/serum specimens, and analyze HIV sequences to
 - determine whether viral transmission linkages are internal to the outbreak (between persons in the outbreak) or external to the outbreak by comparing the sequences with local and global reference sequences
 - identify recency of infections by comparing sequences from persons in the investigation. If two or more sequences share nucleotide identities < 0.5% this can indicate recent and rapid transmission since little time has elapsed for the viruses to have measurably evolved
 - identify evidence of antiretroviral drug resistance, which can complicate treatment strategies

Combining the results of these analyses with contact-tracing and other epidemiologic and laboratory data (e.g., viral load, CD4 count) can enhance understanding of outbreak transmission (HIV and HCV) and thus contribute to effective prevention efforts.

During an investigation of a suspected HCV outbreak among PWID, the CDC testing guidance for identifying HCV infections in the general population should be supplemented by testing HCV antibody–negative specimens using a pooled NAT technique.

After HCV antibody–positive and antibody–negative specimens have been tested by NAT, all reactive NAT (positive) specimens are tested using next-generation sequencing and CDC’s Global Hepatitis Outbreak and Surveillance Technology for detection of cases sharing similar HCV strains and for the identification and visualization of transmission networks.

Chapter 9: Overview of hepatitis C virus laboratory testing and cluster investigations

The epidemiology of HCV infection in PWID communities will usually be characterized as either: (1) recent introduction of a single HCV strain into the community or (2) ongoing transmission with repeated introduction of HCV infections into the community. HCV laboratory testing during an outbreak prioritizes the detection of new HCV cases.

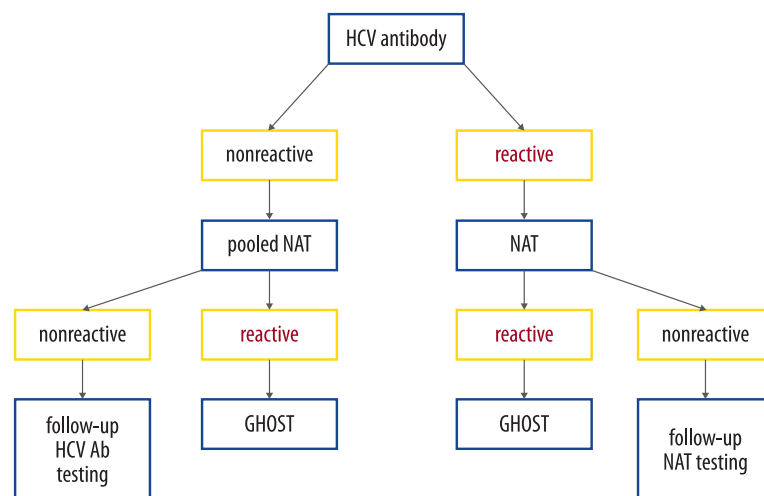
Detection of acute infections

During an investigation of a suspected HCV outbreak among PWID, the CDC testing guidance for identifying HCV infections in the general population (<https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6218a5.htm>) should be supplemented by testing HCV antibody–negative specimens using a pooled NAT technique (as described for HIV infection in [Chapter 8](#)). This will identify persons during the acute phase of HCV infection, before the development of HCV antibodies ([Figure 9-1](#)).

Identification of transmission clusters

The suggested HCV testing algorithm during a suspected or ongoing HCV outbreak among PWID involves pooled NAT techniques, next-generation sequencing (NGS), and use of CDC’s Global Hepatitis Outbreak and Surveillance Technology (GHOST), a cloud-based, public health research tool. After HCV antibody–positive and antibody–negative specimens have been tested by NAT, all reactive NAT (positive) specimens are tested using NGS and GHOST for detection of cases sharing similar HCV strains and for the identification and visualization of transmission networks ([Figure 9-1](#)). All reactive NAT specimens collected during a suspected outbreak investigation can be submitted to CDC for NGS/GHOST testing. Alternatively, state public health laboratories equipped with NGS can use GHOST after receiving the required training. (For more information about GHOST and training required to access GHOST, see [Appendix C](#))

Figure 9-1: Suggested HCV testing algorithm during a suspected HCV outbreak among PWID

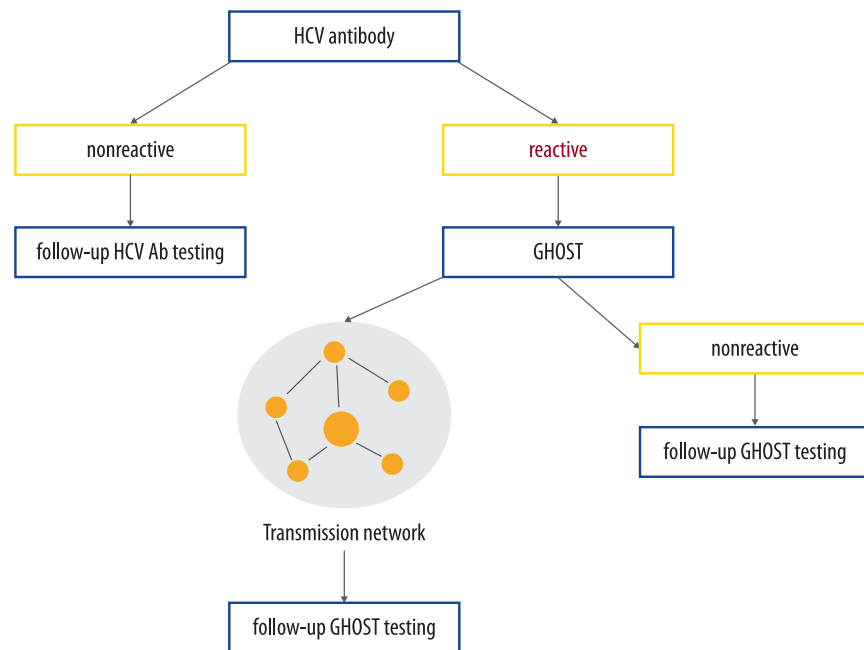


In general, PWID communities should be monitored to identify new infections. Whenever possible, monitoring should include follow-up testing of persons with nonreactive NAT (negative) results depending on the estimated risk of HCV infection, population size, and available resources.

Laboratory testing for ongoing transmission with continual HCV introduction

In PWID communities with a history of HCV infection, NGS/GHOST testing, using only HCV antibody–positive specimens and repeat serologic testing may be considered (Figure 9-2). In PWID communities with established HCV infection, molecular investigation is focused on identification of HCV transmission network(s) to facilitate targeted public health interventions. If possible, persons who test HCV antibody-positive should be followed-up with testing by GHOST; persons who test HCV antibody-negative should receive a second test for HCV antibody or NAT a few months after the initial negative result. If resources allow, persons previously tested reactive by GHOST should have follow-up GHOST testing to identify re-infection with new HCV strains.

Figure 9-2: Suggested HCV testing algorithm during ongoing transmission and continuous HCV introduction among PWID



Follow-up testing

In general, PWID communities (expected to be at high risk of HCV infection and reinfection) should be monitored to identify new infections. Whenever possible, monitoring should include follow-up testing of persons with nonreactive NAT (negative) results depending on the estimated risk of HCV infection, population size, and available resources. If an HCV outbreak is evident (multiple persons diagnosed with acute infection), the follow-up interval for testing PWID with HCV antibody-negative or nonreactive NAT results should be short (e.g., 1–2 months). If an HCV outbreak is not evident (few or no persons are identified with acute infections), the follow-up interval for testing PWID with HCV antibody-negative or nonreactive NAT results may be longer (e.g., 6 months).

For complex outbreaks or outbreaks that involve multiple jurisdictions or agencies, health departments can consider using an Incident Command System (ICS) to manage the outbreak response.

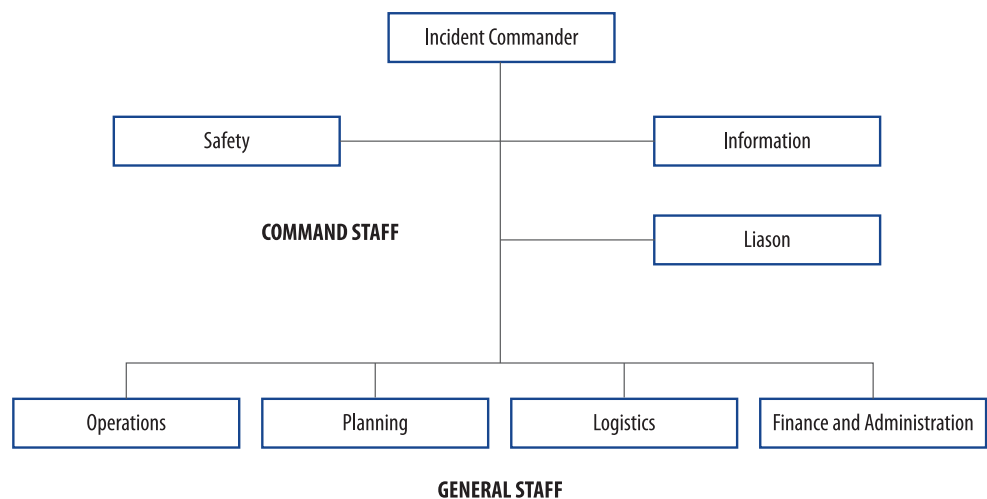
Outbreak response

Chapter 10: Management structure

Incident Command System

For complex outbreaks or outbreaks that involve multiple jurisdictions or agencies, health departments can consider using an Incident Command System (ICS) to manage the outbreak response. An ICS facilitates coordination during an outbreak by using a common organizational structure (i.e., clearly defined roles and responsibilities) and terminology ([Figure 10-1](#)).

Figure 10-1: General Incident Command System organization



Incident Commander

The incident commander has overall responsibility and authority for the response. The incident commander directs and manages all response operations, develops response objectives, and approves response plans. The incident commander also defines the organization of the ICS by determining which command posts and functional sections are required for the response and by designating persons to perform those functions. Roles not designated by the incident commander are assumed by the incident commander.

Command Staff

The command staff is designated to carry out staff functions needed to support the incident commander. The command staff typically comprises a public information officer, a liaison officer, and a safety officer but may include others as required and assigned by the incident commander.

Public Information Officer

The public information officer develops and releases accurate, accessible, and timely information about the incident to the news media, response staff, and partner organizations. The public information officer determines, according to the direction of the incident commander, limits on the release of information and keeps an eye on media information that may be useful in response planning.

Safety Officer

The safety officer recommends and establishes measures for ensuring staff health and safety. The safety officer also develops a site safety plan and reviews response plans for safety implications.

Liaison Officer

The liaison officer is the point of contact for assisting and coordinating activities between the incident commander and other agencies and groups. The liaison officer also develops and maintains a list of partner agencies and their representatives and monitors incident operations to identify current or potential interagency conflicts.

Other command staff personnel

Depending on the nature of the response, additional responders may be needed. These responders, typically part of the command staff, may include agency representatives and technical specialists.

Agency Representatives

An agency representative, a person assigned (from another agency) to support the response, should be authorized to make decisions on behalf of the parent agency in matters that directly affect the agency's involvement in the response.

Technical Specialists

Some responses may require the use of technical specialists who have specific skills pertinent to the response. Technical specialists may be assigned wherever their services are needed.

General Staff

The general staff is responsible for the functional aspects of the response (e.g., planning, logistics, finance, and administration). Each of these responsibilities remains with the incident commander until delegated to another person. When response operations, planning, logistics, and finance and administration are established as separate functions under the incident commander, they are managed by a section chief and can be supported by other functional units.

Operations section

The Operations section conducts all activities directly relevant to the response and is responsible for implementing response strategies.

A unified command is established for multijurisdictional responses or for responses that require resources from multiple agencies.

Operations can comprise multiple groups and functions and can span multiple components of an agency.

Planning section

The Planning section collects, evaluates, and disseminates strategic response information. The Planning section supervises the preparation of the response plan, develops situation reports and executive summaries, establishes information requirements and reporting schedules, and schedules tactics and planning meetings throughout the response. The Planning section is also responsible for the management of incident documentation and tracking of resources.

Logistics section and Finance and Administrative section

The Logistics section provides all materials, services, and facilities. The Finance and Administrative section is responsible for all financial, administrative, and cost analysis aspects of the response, including ensuring that response plans operate within the financial limits of the response.

Modular structure of ICS

The organizational flexibility of an ICS allows adaptation to match the size and complexity of the incident. Response efforts can be expanded or contracted, and only the parts of the structure that best meet the needs of the response are activated. For example, some responses will not require activation of the Planning, Logistics, or Finance and Administration sections; other responses require activation of some or all of these sections.

Unified Command

Although a single incident commander typically leads a response, the ICS can be expanded into a unified command. In general, a unified command is established for multijurisdictional responses or for responses that require resources from multiple agencies. Jurisdictions may differ by geographic area (e.g., 2 or more counties or states), governmental level (e.g., local, state or federal), or functional responsibility (e.g., public health, medical care, law enforcement). A unified command usually consists of the incident commanders and other agency representatives (who have the authority to make decisions regarding their agency's participation), who work together to form a single command structure. These persons are jointly responsible for the management and direction of response activities (e.g., development and implementation of objectives and strategies, integration of agency operations, planning for tactical activities, and commitment of resources).

(For more information about the ICS, see <https://training.fema.gov/emiweb/is/icsresource/index.htm>)

(For an example of how an ICS was adapted for use during an HIV/HCV outbreak response, see [Appendix D](#))

Law enforcement officials can provide valuable assistance in identifying and addressing an HIV or HCV outbreak among PWID.

Chapter 11: Engaging law enforcement

Public health and law enforcement partnerships

Law enforcement officials (LEOs) (e.g., sheriff and police department officers and staff, county or jurisdictional prosecutors), who are often aware of substance use patterns in the local community, can provide valuable assistance in identifying and addressing an HIV or HCV outbreak among PWID.

Health department-LEO relationships are mutually beneficial. For example, health officials can provide sharps containers, tongs, and gloves to prevent accidental needle sticks and in some jurisdictions health officials can provide first-responders with naloxone for rapid response in situations involving an acute overdose. LEOs can help health officials develop safety plans. The following are examples of beneficial partnerships between public health officials and LEOs.

Community assessment

LEOs can provide an overview of the PWID communities in the outbreak area and assist in linking cases and supporting epidemiologic investigations.

Engaging key community stakeholders

LEOs can assist in identifying and engaging key community partners who may be able to encourage PWID engagement in public health interventions such as HIV and HCV testing, linkage to care, and participation in SSPs. In addition, staff members from SSPs—by offering to pick up publicly discarded syringes, a service that LEOs are often asked to perform—can build LEOs' support for SSPs.

Testing, treatment, and linkage-to-care during incarceration and at reentry to the community

Public health officials can work with LEOs to ensure that jails and state prisons have HIV and HCV testing and treatment plans and that these sites have linkage-to-care plans for persons reentering the community.

Incarceration and reentry

Public health officials can advise jails and prisons about how to maintain the confidentiality of inmates with HIV or HCV. To prevent stigma and mistreatment, it is important to maintain confidentiality regarding an inmate's positive HIV or HCV status. Special care should be exercised when dispensing medications. During reentry to the community, it is important to ensure that the public health care coordinator work with the person to ensure continuity of medical and other care services.

SSPs

LEOs can encourage PWID to engage with an SSP, thus helping develop trust in the work of the LEOs and that of the SSP. Providing information and encouragement to PWID is important in ensuring the success of newly established SSPs.

The North Carolina Harm Reduction Coalition has published a 2-page infographic entitled Law Enforcement Guide to Syringe Exchange Programs. Although the infographic is tailored to the needs of LEOs, it can be modified to meet the needs of a specific community (<http://www.nchrc.org/assets/Syringe-Exchange-resources/LEO-Syringe-Exchange.pdf>).

Engaging field staff

Productivity and staff safety benefit when street-assigned police officers, DIS, and community health workers know one another. For example, if DIS are conducting contact tracing and are in the home of a PWID during a search or an arrest, it is helpful for LEOs to know that the DIS are public health officials.

Establishment of a security plan

LEOs can assist in establishing operations and safety protocols in the incident command center, SSPs, testing sites, and other prevention sites to ensure the safety of staff and participants.

CBOs complement the HIV and HCV prevention efforts of state and local health departments by providing prevention services, education, and outreach.

During an outbreak, CBOs can provide services that may be beyond the capacity of local and state health departments.

Chapter 12: Role of community-based organizations and community partners

Community-based organizations (CBOs)

A CBO is a public or private nonprofit organization that is representative of a community or a significant segment of a community and that provides education or related services to persons in the community. CBOs complement the HIV and HCV prevention efforts of state and local health departments by providing prevention services, education, and outreach. CBOs are particularly useful in engaging hard to reach populations (e.g., PWID; lesbian, gay, bisexual, and transgender persons; homeless persons).

During an outbreak, CBOs can provide services that may be beyond the capacity of local and state health departments. For example, CBOs may be able to provide mobile HIV and HCV testing, hepatitis A and hepatitis B vaccination, linkage-to-care services for persons with recently diagnosed infection, and risk-reduction services (e.g., operation of an SSP where allowed by law). Because CBO services can overlap with prevention and health care services offered by other public health and health care providers, coordination between CBOs and public health providers is necessary to ensure that evidence-based interventions are being used and that outbreak-response goals are met in accordance with the outbreak response plan. In addition, when CBOs are used to augment HIV or HCV testing during an outbreak, mechanisms should be in place for the immediate reporting of positive test results to the health department.

Before an outbreak, health departments should identify local CBOs, understand the services they provide, and establish a plan for CBO assistance. Health departments may establish an MOU with CBOs and may identify a contractual funding source to pay for CBO assistance during an outbreak. The MOU should detail the services the CBO is expected to provide, the duration of the commitment, and the expectation that the CBO abide by the health policies, laws, and regulations of the state and local jurisdiction.

Including CBO staff in health department trainings and outbreak exercises can increase CBOs' preparedness and help prevent inefficiencies and redundancy of service delivery during an outbreak.

Community partners

Partnerships with local community partners (e.g., local clinics, hospitals, pharmacies, universities) can help ensure that additional resources and personnel are available to assist during an outbreak.

For persons with diagnosed HIV infection, linkage-to-care offers antiretroviral therapy, which provides health benefits and decreases the possibility of further transmission.

During an outbreak, other services besides direct medical care may be needed including medical case management, substance abuse treatment, mental health treatment and assistance procuring health care coverage.

Clinical consultation is available from the National Clinician Consultation Center (<http://nccc.ucsf.edu/>) or at (800) 933-3413.

Chapter 13: Coordinating HIV care and treatment

For persons with diagnosed HIV infection, linkage-to-care offers antiretroviral therapy (recommended for all persons with diagnosed HIV), which provides health benefits and decreases the possibility of further transmission. Persons in care are offered additional behavioral support (e.g., risk-reductions interventions to further reduce transmission).⁴⁶

Although HIV care and treatment may be specialized, HIV care can be managed by various providers: infectious disease specialist, internist, family medicine practitioner, or pediatrician.⁴⁷ Under a comprehensive care model, one physician provides HIV and primary care. In settings without HIV experts, it is advisable for a provider who is new to HIV treatment to consult with an HIV specialist to establish best practices for evaluating patients, choosing antiretroviral therapy, determining frequency of medical visits, selecting appropriate laboratory monitoring, and providing prophylaxis and treatment of opportunistic infections. Clinical consultation is available from the National Clinician Consultation Center (<http://nccc.ucsf.edu/>) or at (800) 933-3413.

Guidelines for treatment of persons living with HIV, including guidelines for antiretroviral treatment of adults and adolescents, antiretroviral treatment of children, antiretroviral treatment of pregnant women and prevention of mother-to-child HIV transmission, and guidelines for treatment and prophylaxis of opportunistic infections for adults and for children are available at AIDSinfo (<https://aidsinfo.nih.gov/>).

HIV program staff in most state health departments are aware of the network of local HIV care providers to whom they can refer persons. During an outbreak, other services besides direct medical care may be needed including medical case management, substance abuse treatment, mental health treatment and assistance procuring health care coverage. If an HIV/HCV outbreak occurs in a part of the state without specific HIV health care or support services, a creative approach will be needed to identify available local care and treatment services that can be supported by HIV medical provider experts outside the immediate region. Resources to improve HIV service capacity are available; becoming familiar with these resources prior to an outbreak will help jurisdictions expand services more quickly.

(For Recommendations for HIV prevention with Adults and Adolescents with HIV, see <https://stacks.cdc.gov/view/cdc/44064>)

Where to find HIV care providers and training resources

Before or during an outbreak, health departments can locate HIV care and treatment services in their state and develop capacity in areas where needed. The following are sources of HIV care and treatment service providers and resources for increasing the capacity of HIV care providers:

- The Health Resources and Services Administration (HRSA) HIV/AIDS Bureau Ryan White HIV/AIDS Program (<https://findhivcare.hrsa.gov/index.html>) can help persons living with HIV access medical care

The Ryan White HIV/AIDS Program, administered by the HRSA HIV/AIDS Bureau, funds and coordinates with cities, states, and local community-based organizations to deliver HIV care, treatment, and support for low-income persons living with HIV.

through an online locator that includes doctors and clinics.

- The HRSA Bureau of Primary Health Care’s Health Center Program (<https://findahealthcenter.hrsa.gov/>) can help persons living with HIV access medical care through an online locator that includes doctors and clinics.
- The National Clinician Consultation Center (<http://nccc.ucsf.edu/>) works to improve patient health outcomes by building the capacity of health care providers through expert clinical consultation and education. The center includes experienced HIV-treatment physicians, clinical pharmacists, nurses, and nurse practitioners from the University of California, San Francisco, who provide rapid expert consultation on the management of HIV/AIDS, perinatal HIV, preexposure prophylaxis, and the management of postexposure prophylaxis for HIV, HBV, and HCV.
- The HIV Medicine Association (<http://www.hivma.org/Home.aspx>), an organization of medical professionals who practice HIV medicine, maintains an online directory of members who are accepting new patients.
- The American Academy of HIV Medicine (<http://aahivm.org/Default.aspx>) provides credentialing for practicing clinicians (HIV Specialist), non-practicing clinicians (HIV Expert), and eligible HIV-specialized pharmacists (HIV Pharmacist). The academy maintains a directory of certified specialists. The academy also provides educational resources for clinicians including workshops and webinars.
- The AIDS Education and Training Center (<https://aidsetc.org/about>) is the training arm of the Ryan White HIV/AIDS Program. The center is a national network of HIV experts who provide locally based, tailored education, clinical consultation, and technical assistance to health care professionals (both prescribing and non-prescribing providers such as case managers) and health care organizations. The training centers can provide instruction to health care providers with no experience treating patients with HIV through education and mentoring programs such as through Project Echo models.

Health Care Coverage for HIV care

Health care coverage for HIV related provider visits, laboratory monitoring, and monthly medications is important. Typical options include public health care coverage (e.g., Medicaid or Medicare) and private insurance; for persons who have neither, HIV care can be accessed through the Ryan White HIV/AIDS Program.

The Ryan White HIV/AIDS Program, administered by the HRSA HIV/AIDS Bureau, funds and coordinates with cities, states, and local community-based organizations to deliver HIV care, treatment, and support for low-income persons living with HIV. The Ryan White HIV/AIDS Program statute indicates that the program is the “payor of last resort” which means that Ryan White HIV/AIDS Program funds can only be used for services

The Ryan White HIV/AIDS Program AIDS Drug Assistance Program (ADAP), a state and territory-administered program, provides FDA-approved medications to low-income persons living with HIV who have limited or no health coverage from private insurance, Medicaid, or Medicare.

not covered by other federal or state programs, or private insurance. The majority of Ryan White HIV/AIDS Program funds support primary medical care and essential support services. A smaller but equally important portion is used to fund technical assistance, clinical training, and the development of innovative models of care. HRSA also administers the Community Health Center Program which provides primary health care, including HIV care.

The Ryan White HIV/AIDS Program AIDS Drug Assistance Program (ADAP), a state and territory-administered program, provides FDA-approved medications to low-income persons living with HIV who have limited or no health coverage from private insurance, Medicaid, or Medicare. ADAP serves as an important source of ongoing access to HIV medications. ADAP funds may also be used to purchase health insurance for eligible persons and for services that enhance access to, adherence to, and monitoring of prescription medication.

Many pharmaceutical companies have patient-assistance programs that provide prescription medications at no charge for qualifying persons. A case manager or pharmacist experienced at securing medications through these programs can assist the clinical provider.

(For more information about the Ryan White HIV/AIDS Program, see <https://hab.hrsa.gov/about-ryan-white-hivaids-program/about-ryan-white-hivaids-program>)

(For more information about HRSA's Community Health Center Program, see <https://bphc.hrsa.gov/about/>)

The HIV care team

Ideally, the HIV care team includes an HIV-expert who manages the patient's HIV primary care needs and identifies needs for subspecialty care, but the team can be managed by a variety of providers who consult with HIV experts through referrals or by co-management via telehealth. Other specialists may be needed to manage comorbidities such as HBV, HCV, malignancies, heart disease, metabolic disorders, mental illnesses, substance use disorders, and obstetric-gynecologic care. Dental (oral health) care is also an important component of HIV care.

(For information about HIV clinical care guidelines and resources, see <https://hab.hrsa.gov/clinical-quality-management/clinical-care-guidelines-and-resources>)

Care coordination

In clinics, the HIV care team should include staff to help coordinate care. These staff might include case managers, social workers and patient navigators. Although roles for various care coordination staff might differ between jurisdictions, staff should be designated to assist the following:

- Maintaining communication with other providers to coordinate access to psychosocial support, reproductive and gynecologic services, alcohol or drug treatment, medication-assistance programs, prevention counseling, and other services

Because adherence to antiretroviral therapy is critical to achieving HIV viral suppression, the care team should regularly identify barriers to adherence and provide adherence support.

It is prudent for the provider to establish a relationship with one or more community pharmacists who will dispense antiretroviral and other medications and monitor refills, provide adherence support, patient education, and reconcile medications. The pharmacist can identify medication-related problems in the community, and provide ongoing feedback to the provider.

- Support access to social services, including housing, transportation, mental health, and legal assistance
- Linkage to HIV care and support to help keep persons engaged in care

Medication management

Persons should begin antiretroviral therapy as soon as possible after diagnosis. Because adherence to antiretroviral therapy is critical to achieving HIV viral suppression, the care team should regularly identify barriers to adherence and provide adherence support. Adherence support can be provided by multiple members of the care team including, nurses, case managers, peer educators, and pharmacists.

Guidelines for antiretroviral therapy provide a comprehensive schedule for laboratory monitoring during antiretroviral therapy. Before therapy, a set of tests, readily available from most commercial laboratories, should be performed. Ideally, the results of an HIV medication–resistance test are known before treatment begins. However, a regimen, selected in consultation with an expert HIV provider and based on resistance patterns in the community, can be started before the results are known and if necessary, adjusted in response to the test results.

Medication management is critical for primary HIV care. In many comprehensive HIV clinics, a clinical pharmacist with HIV expertise works alongside other service providers to assist with medication management, including identification of drug-drug interactions, support of patient adherence, and reconciliation of medication profiles. In settings without an HIV-expert clinical pharmacist, consultation can be sought through a Ryan White HIV/AIDS Program clinic or another HIV care provider.

It is prudent for the provider to establish a relationship with one or more community pharmacists who will dispense antiretroviral and other medications and monitor refills, provide adherence support, patient education, and reconcile medications. The pharmacist can identify medication-related problems in the community, and provide ongoing feedback to the provider.

Considerations for medication management for PWID

Conventional antiretroviral therapy includes medications that are taken once or twice daily. For some regimens, a single fixed-dose combination tablet is all that is needed. PWID may experience adverse effects from antiretroviral therapy because of underlying hepatic, renal, neurologic, psychiatric, gastrointestinal, and hematologic disorders; these comorbid conditions need to be considered when selecting antiretroviral medications for this population. Other considerations for PWID are drug-drug interactions with medications used for substance use treatment (e.g., methadone, buprenorphine). Additionally, for HCV co-infected persons, it is important to consider drug-drug interactions between medications for HCV infection and antiretroviral therapy. Assistance from an HIV-

expert physician or HIV-expert pharmacist may be needed: many drug-drug interactions are complex and continue to evolve as new medications become available.

(For the Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents, see <https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf>)

(For the Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents, see <https://aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-oi-prevention-and-treatment-guidelines/0>)

Adherence considerations for PWID

Adherence to antiretroviral therapy is critical to achieving sustained HIV viral suppression, improved overall health and survival, reduced risk of drug resistance and reduced risk of transmission to others.⁴⁸ Adherence to antiretroviral therapy can be a challenge when treating a person who continues to use illicit drugs. However, antiretroviral therapy reduces morbidity and mortality even when adherence is suboptimal.⁴⁸ Substance abuse, mental illness, or other psychosocial problems should therefore not be considered a contraindication to starting antiretroviral therapy. Instead, the care team should include adherence support or referrals should be made for supportive services (e.g., substance abuse treatment, mental health treatment, case management) to address barriers to adherence.⁴⁸

Some PWID experience structural barriers to adherence related to homelessness. Although homeless persons, in general, may be at greater risk of antiretroviral therapy nonadherence, many can achieve levels of adherence comparable with those of the housed population and can benefit from antiretroviral therapy even if adherence is suboptimal.^{49,50} HIV care providers who have cultural competency with PWID can develop strategies to promote medication adherence (CDC's Compendium of Evidence-Based Interventions and Best Practices for HIV Prevention includes effective adherence interventions). Lastly, directly administered antiretroviral therapy (persons are observed while taking their medications) may be beneficial for PWID.

(For more information about CDC's Compendium of Evidence-Based Interventions and Best Practices for HIV Prevention, see <https://www.cdc.gov/hiv/research/interventionresearch/compendium/index.html>)

(For information about the Ryan White HIV/AIDS Program's Special Projects of National Significance which provide models of care and specific interventions, see <https://hab.hrsa.gov/about-ryan-white-hiv-aids-program/previous-spns-initiatives>)

Immunizations for persons living with HIV

Detailed information about immunizations for HIV-infected adults including PWID can be found at: <https://aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-oi-prevention-and-treatment-guidelines/365/figure--immunization>. All PWID should be vaccinated against hepatitis A,

hepatitis B, and tetanus if not immune or previously vaccinated. Live-attenuated vaccines should not be given to HIV-infected persons except under special circumstances. Other vaccines may be administered if the CD4+ cell count is >200 cells/ μ L.

Frequency of clinic follow-up

Guidelines for the frequency of monitoring laboratory tests and clinic follow-up can be found at: <https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf>. Continued viral suppression requires long-term retention in HIV care and adherence to antiretroviral therapy. Support services may be provided by care coordination staff. Attendance at clinic visits should be tracked through electronic health records, and a plan should be operationalized to provide reminders and follow-up for persons who miss visits.



Notes from the field

In Indiana, HIV-infected PWID may be eligible for HIV related services from the Indiana State Department of Health through Ryan White Parts A, B, and C funded programs, including ADAP. Linkage-to-care begins with care coordination programs in 22 locations in all 12 jurisdictions across the state. Care coordinators, funded by the state, are embedded in SSPs.

Care coordinators refer persons to HIV medical and support services and provide help accessing insurance premium and copay/deductible assistance. Care and treatment can include physician visits, medications, lab tests, and outpatient support services. Partner testing and counseling are also made available. Indiana has a decades-old high-risk pool insurance program (Health Indiana Plan 2.0), which was expanded through a Medicaid waiver in 2015. Care sites enroll persons through patient navigator services.

Depending on a patient's health coverage, medication assisted treatment for substance use disorders may be available through HIV Medical Services. Close partnerships with the designated state agency for mental health and substance-use-disorder programming and funding (Family Social Services Administration in Indiana) is key to a successful, comprehensive response.

Ensuring that HCV-infected persons are linked to care and begin curative direct acting antiviral (DAA) therapy is critical for reducing HCV-associated morbidity and mortality, and for reducing additional transmission risk.

Chapter 14: Coordinating hepatitis C virus care and treatment

Ensuring that HCV-infected persons are linked to care and begin curative direct acting antiviral (DAA) therapy is critical for reducing HCV-associated morbidity and mortality, and for reducing additional transmission risk.

The American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) recommend treatment for all persons with chronic HCV infection, except those with short life expectancies that cannot be remediated by treatment or transplantation.⁵¹

For persons with ongoing HCV transmission risk factors such as injection drug use, it is essential that they be linked to care with an addiction specialist or risk-reduction counseling services.

HCV care and treatment, although somewhat specialized, can be managed by a variety of providers (e.g., gastroenterologists, hepatologists, infectious disease specialists, or primary care providers). Depending on the individual provider and the clinical model used, HCV care can be provided in whole or in part in a primary care or a specialty setting. Some practices may have developed a primary care and specialist co-management model.

(For the AASLD-IDSA treatment guidance for persons living with HCV, including guidance for initial treatment, retreatment of persons in whom prior HCV treatment has failed, and guidance for persons with HIV-HCV coinfection, decompensated cirrhosis, see <http://www.hcvguidelines.org/>)

(For Recommendations for Prevention and Control of HCV infection and HCV-Related Chronic Disease, see <https://www.cdc.gov/mmwr/pdf/rr/rr4719.pdf>)

Where to find HCV care providers and training resources

Before or during an outbreak, health departments can locate HCV care and treatment services in their state and develop capacity in areas where needed. The following are sources of HCV care and treatment service providers:

- The American Liver Foundation has an online directory of health care providers and treatment facilities, including health clinics and substance-use-treatment clinics with capacity to evaluate and treat persons with liver disorders (<http://hepc.liverfoundation.org/find-a-healthcare-provider/>).
- HRSA Bureau of Primary Health Care's Health Center Program (<https://findahealthcenter.hrsa.gov/>) can help persons living with HCV access medical care through an online locator that includes doctors and clinics.
- State and local health departments may have a viral hepatitis prevention coordinator, who may be a resource for identifying clinics and providers in their jurisdictions (<https://www.cdc.gov/hepatitis/partners/hepatiscoordslist.htm>).

Health Care Coverage for HCV care

Health care coverage for HCV related provider visits, laboratory monitoring, and medications is important. Typical options include public health care coverage (e.g., Medicaid or Medicare) and private insurance. Case management services are important for helping low-income or uninsured HCV-infected persons obtain health care coverage for primary care and HCV care and treatment. Pharmaceutical companies have patient-assistance programs that can provide prescription medications at no charge for qualifying persons. A case manager or pharmacist experienced at securing medications through these programs can assist the clinical provider.

HCV care

HCV care and treatment can be delivered by a subspecialist or primary care provider. This will likely be influenced by factors such as the complexity of the patient's liver disease, provider's familiarity with HCV care and treatment, insurance reimbursement policies, and clinic practices and policies. Telehealth programs have been used in under-resourced areas to connect primary care providers with HCV specialists to assist management of HCV care and treatment. Other specialists may be needed to manage comorbidities such as HIV, HBV, other chronic liver diseases (e.g., cirrhosis), malignancies, kidney disease, metabolic disorders, mental illnesses, and substance use disorders.

Care coordination

Available care coordination services for persons with HCV vary by clinic, locality, and state. Care coordination staff might include case managers, social workers and patient navigators. Although the breadth of services may vary, care coordination services may include:

- Maintaining communication with other providers to coordinate access to psychosocial support, reproductive and gynecologic services, alcohol or drug treatment, medication-assistance programs, prevention counseling, and other services
- Support access to social services, including housing, transportation, mental health, and legal assistance
- Linkage to HCV care and support to help keep persons engaged in care

Medication management

Persons with chronic HCV infection should begin DAA therapy as soon as possible after diagnosis (ideally, persons with new infections should be monitored for spontaneous clearance for a minimum of 6 months before DAA therapy is initiated). The AASLD-IDSAs guidelines for HCV treatment provide a comprehensive schedule for laboratory monitoring during DAA therapy.⁵¹ Before therapy, the severity of liver fibrosis should be assessed. Persons with moderate or severe hepatic impairment (Child-Turcotte-Pugh

It is prudent for the provider to establish a relationship with one or more community pharmacists who will dispense DAA therapy and other medications and monitor refills, provide adherence support, patient education, and reconcile medications. The pharmacist can identify medication-related problems in the community, and provide ongoing feedback to the provider.

Given the possibility of spontaneous clearance after acute infection and the high efficacy of DAA therapy for treating chronic HCV infection, the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America recommends that persons be monitored for spontaneous clearance for a minimum of 6 months before DAA therapy is initiated.

B or C) should be referred to a health care provider with expertise in that condition and ideally to a transplant center. DAA therapy is typically given for 8–12 weeks. Sustained virologic response (or cure) should be assessed 12 weeks following the completion of the DAA treatment course.⁵¹

It is prudent for the provider to establish a relationship with one or more community pharmacists who will dispense DAA therapy and other medications and monitor refills, provide adherence support, patient education, and reconcile medications. The pharmacist can identify medication-related problems in the community, and provide ongoing feedback to the provider.

Considerations for medication management for HIV/HCV co-infected persons

For HIV/HCV co-infected persons, it is important to consider drug-drug interactions between DAAs and antiretroviral therapy. Assistance from an HIV-expert physician or HIV-expert pharmacist may be needed: many drug-drug interactions are complex and continue to evolve as new medications become available.

Considerations for medication management in an outbreak setting

Differentiating acute versus chronic HCV infection in an outbreak setting is important for determining the care of an individual patient. If acute HCV infection is suspected because of a possible exposure or clinical presentation, HCV antibody and HCV RNA testing are recommended. In approximately 20% of persons with acute HCV infection, the infection clears spontaneously.⁵¹ Spontaneous clearance generally occurs within 6 months after the estimated time of infection.⁵¹ Persons with spontaneous clearance should not be treated with DAA therapy.

Given the possibility of spontaneous clearance after acute infection and the high efficacy of DAA therapy for treating chronic HCV infection, AASLD-IDSA recommends that persons be monitored for spontaneous clearance for a minimum of 6 months before DAA therapy is initiated.⁵¹

In some situations, however, clinicians and public health officials may consider that the preventive benefits of early treatment outweigh the benefits of waiting for spontaneous clearance of the virus. These situations can include prevention of ongoing transmission (e.g., outbreak among PWID) or mitigation of severe clinical consequences. There are few data on the benefit of treating acute HCV infection with DAA therapy versus the benefit of delaying treatment initiation to monitor for spontaneous clearance of infection. As such, per expert opinion, if a decision is made to initiate HCV treatment during the acute phase, HCV RNA should be monitored for at least 12–16 weeks before treatment begins to allow for the possibility of spontaneous clearance.⁵¹ Finally, these persons should be linked to addiction specialists and risk reduction counseling, if appropriate.

(For guidelines on the initial treatment of HCV infection, see <http://www.hcvguidelines.org/full-report/initial-treatment-hcv-infection>)

Successful treatment for HCV infection does not result in immunity from future infections; therefore, persons who continue to engage in risky behaviors are at risk of reinfection.

(For the management of acute HCV infection, see <http://www.hcvguidelines.org/full-report/management-acute-hcv-infection>)

Considerations for PWID

Adherence to DAA therapy is essential to maximizing the benefit of curative HCV therapies. Persons whose substance use disorder is under control or in remission may be able to adhere to treatment well. Persons who continue to use illicit drugs require special consideration in terms of HCV treatment and prevention. All persons with HCV infection and ongoing substance use should be linked to an addiction specialist or risk-reduction counseling services. Some health plans require documentation of substance use counseling or a period of abstinence from drug and alcohol use before DAA therapy begins. For PWID, these requirements may constitute barriers to treatment access.

Although DAA therapy is highly efficacious and curative, successful treatment for HCV infection does not result in immunity from future infections; therefore, persons who continue to engage in risky behaviors are at risk of reinfection. The risk of reinfection should be considered when counseling PWID about HCV treatment and prevention. The risk of reinfection also underscores the importance of ensuring that PWID receive adequate addiction or risk reduction services to maximize the benefit of DAA therapy.

Immunizations for persons living with HCV

All persons with HCV infection who are susceptible to hepatitis A and hepatitis B infection should be vaccinated. Persons with cirrhosis should be vaccinated against pneumococcal infection.

(For the Advisory Committee for Immunization Practice guidelines for hepatitis A, hepatitis B, and pneumococcal vaccinations, see <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hepa.html>, <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hepb.html>, and <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/pneumo.html>)

Frequency of Clinic Follow-up

A quantitative HCV RNA viral load and other laboratory tests (complete blood count, creatinine, estimated glomerular filtration rate, hepatic panel) should be performed four weeks after starting DAA therapy.⁵¹ Additional clinical and laboratory monitoring may be required based on the specific DAA regimen, medical comorbidities, or other clinical indications. Virologic response should be assessed by a quantitative HCV RNA viral load test 12 weeks after the completion of DAA therapy.⁵¹ A sustained virologic response indicates that the patient is cured of the HCV infection. Persons with advanced fibrosis/cirrhosis, including those with sustained virologic response, will continue to require endoscopic screening for esophageal varices and periodic screening for hepatocellular carcinoma after completion of DAA therapy.

Sustained virologic response requires adherence to DAA therapy: support services may be provided by care coordinators or patient navigators in the community. Attendance at clinic visits should be tracked through electronic health records, and a plan should be operationalized to provide reminders and follow-up for persons who miss visits.

In 2016, the Consolidated Appropriations Act modified the restriction on use of federal funds for programs distributing sterile needles or syringes.

Before establishing an SSP, it is important to assess the needs of potential clients, their families, key stakeholders, law enforcement, and the community at large.

Chapter 15: Establishing a syringe services program

What is a syringe services program?

SSPs provide PWID with sterile needles, syringes, and other drug-preparation equipment; they also collect and safely dispose of used syringes. The terms *syringe services program*, *syringe exchange program*, *needle exchange program*, and *needle and syringe program* are often used interchangeably. Many use the term *syringe access* because studies have shown that access to new, sterile syringes and collection of used syringes from PWID helps prevent the spread of blood-borne pathogens, including HIV, HCV, and HBV.

History of SSPs

SSPs began in Amsterdam in 1983 in an effort to decrease HBV transmission among PWID. In 1987, the American Foundation for AIDS Research established the first legal SSP in the United States in Portland, Oregon.⁵² In 1988, another SSP, supported by the Pierce County Health Department and the American Foundation for AIDS Research, opened in Tacoma, Washington.^{52,53} Although it was legal to operate an SSP, the 1988 passage of section 300-ee-5 of the Public Health and Welfare Act, which prohibited the use of federal funds for SSP operations, limited the availability of these services. Since the establishment of the first SSPs, mounting evidence has shown that SSPs reduce HIV incidence and do not contribute to increased injection drug use.⁵⁴

In 2016, the Consolidated Appropriations Act (<https://www.congress.gov/114/bills/hr2029/BILLS-114hr2029enr.pdf>) modified the restriction on use of federal funds for programs distributing sterile needles or syringes. Federal funds still cannot be used to purchase sterile needles or syringes for injecting illegal drugs or for other devices used only for illegal drug injection. However, the 2016 act allows jurisdictions, after consultation with CDC and demonstrating need, to use federal funds for the following: SSP staff, supplies, syringe disposal services, provision of naloxone and for communication, outreach, planning, and evaluation activities.

Assessment

Before establishing an SSP, it is important to assess the needs of potential clients, their families, key stakeholders, law enforcement, and the community at large in order to eliminate barriers to implementation and to ensure that resources will be used by the persons for whom the program was developed. Prompt assessment is particularly important when establishing an SSP during an outbreak. The assessment should be conducted by persons well versed in SSP best practice to ensure realistic expectations of the groups assessed and to answer questions and address misconceptions about SSPs.

Restrictions on local and state funds should be assessed to determine whether they can be used for staff, supplies, and infrastructure and whether those funds can be used in conjunction with federal or grant funds.

The assessment should include the following:

- Review of applicable local, state, and federal laws and regulations
- Determination of the needs, wants, and nonnegotiable positions of the target population, key stakeholders, law enforcement, and the community at large
- Determination of measureable goals and objectives of the SSP
- A general method of service delivery, including the following specific considerations for operationalizing the SSP:
 - Structure of funding for staff, supplies, sharps disposal, and infrastructure
 - Role of local and commercial pharmacies in the distribution, exchange, or supply of sharps and other supplies

(For examples of assessment questions, see <http://www.in.gov/isdh/files/ISDH%20SEP%20Guidance%20Version%202%200%20FINAL%20-%2010-04-2016-EC.pdf>)

If the jurisdiction does not have the appropriate staff to complete the assessment, technical support can be obtained through the National Alliance of State and Territorial AIDS Directors (NASTAD), the Harm Reduction Coalition, or other jurisdictions that have operationalized SSPs.

Funding of the SSP

An important component of establishing an SSP is determining how the staff, supplies, and infrastructure (e.g., building or mobile unit) will be funded. Three federal agencies (CDC, HRSA and the Substance Abuse and Mental Health Services Administration [SAMHSA]) have issued guidance to grantees on how to obtain approval for use of federal grant funds to support approved SSP activities. (For the guidance documents, see <https://www.aids.gov/federal-resources/policies/syringe-services-programs/>)

Restrictions on local and state funds should be assessed to determine whether they can be used for staff, supplies, and infrastructure and whether those funds can be used in conjunction with federal or grant funds.

The North American Syringe Exchange Network operates a buyers club (offers bulk prices for the purchase of SSP supplies) and offers other services, such as technical assistance, to its members. (For information about the North American Syringe Exchange Network, see www.nasen.org)

Development of evaluation tools

Evaluation of the SSP is important to determine the efficacy of a newly established or emergently developed program. State and local HIV surveillance and epidemiology staff can help determine the most appropriate model and method of evaluation. For an SSP established to address an outbreak, evaluation tools and outcome reports provide an additional progress gauge and thus should be established, if possible.

Jurisdictions should use the information collected during the assessment phase, legal requirements, and program objectives and goals to determine the most appropriate evaluation model for their program. If possible, it is important to engage information technology and epidemiology staff in the development of evaluation tools to ensure that the tools are easy to use, assess, and modify and have the capacity for long-term use with minimal revision.

Operationalizing the SSP

The following questions are pertinent to planning the operation of an SSP in response to an outbreak:

- *What is the most appropriate location(s) for service delivery?* Is a fixed site, a mobile site, or a combination best for the target population and the surrounding community? Jurisdictions should consider the potential barriers to participation associated with choice of location. For example, if transportation to a location is not available and mobile delivery is not planned, how will potential participants access the SSP?
- *What hours will the SSP be operational?* Will the proposed hours meet the needs of the target population? For example, if most members of the intended population work full-time schedule (i.e., during the day), an SSP that operates only during regular business hours will be inaccessible.
- *Who will staff the SSP?* How many staff will be present at set-up, during operational hours, and during clean-up?
- *What are the staff qualifications and requirements?* For example, will staff be required to sign a confidentiality and security agreement, understand how to use data collection and basic evaluation tools, know the policies and procedures for handling an exchange, know emergency procedures for staff and participant safety and security?
- *If response personnel will staff the SSP, how will their response and SSP roles intersect?*
- *What is the most appropriate model for the SSP?* (For examples of models, see <http://www.in.gov/isdh/files/ISDH%20SEP%20Guidance%20Version%202%200%20FINAL%20-%2010-04-2016-EC.pdf>)
- *What services will be offered and how will these services be delivered?* For example, a process will be needed to deliver the following: syringe exchange, delivery of education in safe injection practices, wound care, HIV and HCV testing or referrals for HIV and HCV testing, and referrals for mental health and substance use treatment.
- *What supplies will be provided?* Determining which supplies are most appropriate for the targeted population during the assessment stage will ensure that supplies and their cost are limited to the items that are most used by the target population. The assessment should also determine whether supplies will be assembled into kits or whether

supplies will be available in an open-stock format (participants take what is most useful for them). In addition to syringes, other safe injection supplies should be provided. The following are examples of supplies:

- Newsprint or another barrier to create a clean injection space
- Tourniquets
- Alcohol prep pads
- Cookers
- Sterile water vials
- Clean cotton or other filter device
- Basic wound care/first-aid supplies such as antibacterial wipes, adhesive bandages, and pain reliever
- A graphic or a written reminder about safe injection practices
- Overdose reversal agent (i.e., naloxone)
- Condoms, dental dams, and lubricants
- Nondescript bags or other containers for transporting supplies discreetly
- *How will sharps be collected and destroyed?* A contract that includes the collection and destruction of sharps should be established with a reputable waste management entity.
 - Clients should be provided with individual containers for the return of used syringes.
 - A schedule and a process for the safe disposal of returned supplies should be established with the clients.

Technical assistance for the development of an SSP operational plan can be obtained from NASTAD, the North American Syringe Exchange Network, and jurisdictions with active SSPs.

Moving from outbreak response to routine service delivery

The development of an SSP to address an acute outbreak should be planned with ongoing, routine delivery of syringe services in mind. Evaluation tools, staffing plans, and other considerations should be established with the idea that the SSP will continue to serve the target population after the initial outbreak response.

(For more information about SSP development and implementation, see https://www.nastad.org/sites/default/files/055419_NASTAD-SSP-Guidelines-August-2012_0.pdf)

Other sources of sterile syringes

In most states, syringes can be purchased without a prescription at a pharmacy. The practice depends upon laws that regulate possession and sales of drug paraphernalia including syringes. Proof of identification and

Before an HIV or HCV outbreak, the health department should determine the local practices regarding syringe sales at pharmacies and discuss with pharmacists how to coordinate sales and collection of syringes with current or new SSPs.

age may be required to purchase syringes and the quantity of syringes that can be purchased at one time may be limited. Pharmacies may also be required to maintain a record of buyers. Nonprescription syringe sales at pharmacies are often left to the pharmacists' discretion and individual store policy. Before an HIV or HCV outbreak, the health department should determine the local practices regarding syringe sales at pharmacies and discuss with pharmacists how to coordinate sales and collection of syringes with current or new SSPs. The health department can identify the education and tools pharmacists may need to provide risk-reduction services and referrals for substance use treatment.

(For information about syringe distribution laws, see <http://lawatlas.org/datasets/syringe-policies-laws-regulating-non-retail-distribution-of-drug-parapherna>)

Comprehensive SSP

A comprehensive, multi-component, prevention program is the most effective approach for preventing the transmission and acquisition of HIV, HCV and other blood-borne infections among PWID.³⁵ SSPs are an important part of a comprehensive prevention program and are key to delivering health services to PWID, including HIV and HCV testing, hepatitis A and hepatitis B vaccination, risk reduction counseling, overdose prevention, and referrals to HIV or HCV primary care and substance use disorder treatment.

(For additional resources and tools for developing and implementing SSPs, see <https://www.cdc.gov/hiv/pdf/risk/cdc-hiv-developing-ssp.pdf>)

It is important for providers to measure the severity of a person's substance use disorder and to identify the substance(s) used. This information is needed to develop an individual treatment plan.

Medication-assisted treatment (MAT) is treatment for addiction that includes the use of medication along with counseling and other support. For persons with opioid use disorder, three medications have FDA approval for MAT: methadone, buprenorphine, and naltrexone.

MAT is the most effective treatment for opioid use disorder and is associated with retention in treatment, reduction in illicit opiate use, decreased craving, and improved social functioning.

Chapter 16: Treatment of substance use disorders and recovery services for PWID

PWID are at high risk for substance use disorders (as defined by the Diagnostic and Statistical Manual of Mental Disorders). It is important for providers to measure the severity of a person's disorder (measured on a continuum from mild to severe), and to identify the substance(s) used. This information is needed to develop an individual treatment plan. Treatment plans routinely include milestones and goals as measures of treatment progress. Optimal treatment plans comprehensively address the medical care and treatment needs as well as barriers to successful treatment outcomes. For mild substance use disorders, the treatment plan may be comprised of psychosocial counseling by a certified counselor and support services (e.g., clinical and case management, housing and transportation services, and mental health service) while moderate to severe substance use disorders likely require inpatient or outpatient medical care and treatment with additional social services. For opioid use disorders and alcohol use disorders, medication-assisted treatment (MAT) can be used as part of the treatment plan. (For information about principles of drug addiction treatment, see https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/podat_1.pdf)

Medication-assisted treatment

MAT is treatment for addiction that includes the use of medication along with counseling and other support. MAT is the most effective treatment for opioid use disorder and is associated with retention in treatment, reduction in illicit opiate use, decreased craving, and improved social functioning.⁵⁵ MAT is not the same as substituting one addictive drug for another. For persons with opioid use disorder, three medications have FDA approval for MAT: methadone, buprenorphine, and naltrexone.⁵⁶

Methadone

Methadone is a long-acting, opioid agonist (a drug that mimics the effects of naturally occurring endorphins by binding to opioid receptors) that prevents withdrawal symptoms for 24 hours or longer, reduces cravings for opioids, and reduces the euphoric effects of subsequent illicit opioid use. Methadone use for opioid use disorder is regulated and can only be dispensed in licensed and accredited opioid treatment programs. Methadone is dispensed in a controlled setting in which ingestion is directly observed.⁵⁷ Although methadone is usually administered as a single daily dose, dosages can vary widely. Side effects of chronic methadone therapy include constipation, mild drowsiness, excess sweating, reduced libido, increased sensitivity to pain, erectile dysfunction, and peripheral edema. Methadone, compared with buprenorphine, has a greater potential for lethal overdose (see below).

Methadone treatment

Methadone treatment for opioid use disorder requires enrollment in an opioid treatment program. Opioid treatment programs can either be private clinics (which require fee-for-service and may or may not accept health insurance), non-profit treatment programs or federal treatment programs administered through the Veterans Administration. Insured clients receive services that are reimbursed through private insurance or public healthcare coverage.

Opioid treatment programs require that a person have a diagnosis of opioid use disorder to enroll into a methadone treatment program; this diagnosis is obtained during the full physical examination that occurs as part of enrollment. A methadone maintenance program may enroll clients via appointment or through walk-in hours held very early in the morning. Because methadone requires daily adherence, methadone clinics often dispense medication for a few hours in the mornings. Opioid treatment programs can vary in the types of services and treatment modalities provided; clients should, therefore, choose a treatment program that provides services that match their needs.

Methadone maintenance is the first-line treatment for pregnant women with an opioid use disorder.⁵⁸ Maintenance treatment with methadone can have beneficial effects in addition to treatment of opioid use disorder: it has been associated with reductions in mortality rates and with reductions in the HIV transmission.^{59,60}

To locate methadone maintenance programs by state, see National Opioid Treatment Program Directory, maintained by the Substance use and Mental Health Services Administration (SAMHSA): <http://dpt2.samhsa.gov/treatment/directory.aspx>.

Buprenorphine

Buprenorphine, a partial opioid agonist, reduces illicit opioid use when used in the long-term treatment of persons with opioid use disorder.^{56,61} Buprenorphine is available as a tablet for sublingual use (under the tongue) or as a sublingual film. Buprenorphine is initially given as monotherapy but later the regimen is changed to a combination preparation with naloxone (an opioid antagonist), unless the patient is pregnant. The combination preparation acts as a disincentive to crushing the tablets and dissolving them for intravenous injection or dissolving the film for injection, because use of the manipulated product can cause opioid withdrawal.⁵⁶ Before buprenorphine or buprenorphine-naloxone is initiated, the patient should have abstained from other opioids for long enough to be in a state of mild-to-moderate opioid withdrawal. Both buprenorphine and buprenorphine-naloxone are administered as a single sublingual dose of 4–24 mg per day. When the patient has been stabilized at a particular dose, the patient may receive a prescription for up to a 1-month supply, refillable for up to 6 months (similar to the prescription of other Schedule III controlled substances).

Buprenorphine is a partial opioid agonist. Unlike methadone, it can be prescribed in primary care settings.

Naltrexone is a non-narcotic opioid antagonist. It is frequently used in criminal justice and state-supported treatment programs that may be opposed to treatment using narcotic medications.

Side effects of buprenorphine can include sedation, headache, nausea, constipation, depression, diarrhea, runny eyes and nose, lack of energy, and insomnia. Buprenorphine-related deaths during maintenance therapy have occurred, primarily when buprenorphine is taken in combination with other substances, especially benzodiazepines and alcohol.⁶²

Buprenorphine treatment

In 2016, the FDA approved a long-acting subdermal buprenorphine implant for the treatment of opioid use disorders.⁵⁶ Buprenorphine implants provide a low, steady dose of the medication for 6 months. The implant is intended for use only in persons who have reached clinical stability with sublingual or buccal buprenorphine at a daily dose of ≤ 8 mg.

Buprenorphine, unlike methadone, can be prescribed in primary care settings.⁶³ Induction (the process to find the person's ideal daily dose) may be accomplished in the clinician's office under observation or at the person's home. Before prescribing, providers may require patient counseling and to determine the appropriate dose, may require multiple visits for urinary analysis.⁶⁴ Most buprenorphine providers require insurance reimbursement. Some ADAP programs cover buprenorphine and other substance use disorder treatment medications.

(For information about ADAP coverage, see <https://www.nastad.org/sites/default/files/ADAP-Formulary-Database-Users-Guide-FINAL.pdf>)

To prescribe or dispense buprenorphine, providers must receive a waiver (i.e., complete required training and apply for the waiver). A waiver limits the number of persons a provider can treat with buprenorphine.

Not all providers who have a buprenorphine waiver see patients. If no providers in your area have a buprenorphine waiver, contact local primary care providers, provide waiver information, and ask them to request a waiver so that they can provide buprenorphine. Providing buprenorphine and medical care for HCV and HIV at one location can reduce barriers to opioid maintenance therapy, increase retention in care, and improve HCV and HIV outcomes.⁶⁵⁻⁶⁷ When colocation is not possible, linkages between the primary health care sites to buprenorphine services can be established.

SAMHSA maintains a list of registered buprenorphine providers online (<https://findtreatment.samhsa.gov/>). Individual providers should be contacted to determine if treatment slots are available.

Naltrexone

Naltrexone, compared with opioid agonists such as methadone or buprenorphine, helps overcome addiction in a different way. Naltrexone is a non-narcotic opioid antagonist that can be used as part of a relapse prevention program. It is frequently used in criminal justice and state-supported treatment programs that may be opposed to treatment using narcotic medications. Naltrexone can prevent relapse because it blocks opioid receptors and the effect of opioid drugs (i.e., takes away the feeling of "getting high").

The suggested first-line treatment for opioid use disorder is an opioid agonist (methadone or buprenorphine) rather than an opioid-antagonist (naltrexone).

Persons who discontinue MAT and resume opioid use should be informed of the potential for an opioid overdose because of the loss of tolerance to opioids or misjudgment of a safe opioid dose to use at the time of relapse.

Oral naltrexone is taken as a single 50 mg tablet once daily. The medication can be started 3–6 days after the most recent use of short-acting opioids and 7–10 days after the most recent use of methadone or buprenorphine. A long-acting injectable form of naltrexone can be given every 4 weeks by deep intramuscular injection in the gluteal muscle at a set dose of 380 mg per injection. Side effects include hypertension, nausea, vomiting, abdominal pain, headache, insomnia, dizziness, anxiety, and decreased energy among others. The extended release form of naltrexone is favored over the daily pill, for convenience and adherence reasons. Naltrexone has not been found to be addictive or to have high potential for abuse.

Choosing between MAT options

There are few studies that compare the relative benefits of one MAT medication over another.⁵⁸ Selection of an MAT medication should therefore be made following a discussion, between provider and patient, of the risks and benefits of each medication. However, the suggested first-line treatment for opioid use disorder is an opioid agonist (methadone or buprenorphine) rather than an opioid-antagonist (naltrexone). Naltrexone may be a reasonable first-line alternative to opioid agonists for a highly motivated patient with mild opioid use disorder or for persons in occupations that do not permit treatment with an opioid agonist.⁵⁶ Buprenorphine is often preferred to methadone because buprenorphine can be prescribed and administered in primary care settings and has less potential for lethal overdose. Buprenorphine is also the preferred MAT option for teens over 16 years of age. Providers can consult with an addiction specialist to help choose a MAT option.

(For more information about MAT, see <https://www.samhsa.gov/medication-assisted-treatment>)

Other considerations

Before treating adolescents, federal, state, or insurance provider regulations should be verified to determine if MAT requires parental consent or notification prior to treatment. Persons who discontinue MAT and resume opioid use should be informed of the potential for an opioid overdose because of the loss of tolerance to opioids or misjudgment of a safe opioid dose to use at the time of relapse.

Detoxification

Detoxification is not treatment; detoxification is a set of interventions aimed at the management of acute intoxication and withdrawal.⁶⁸ Detoxification is also a form of palliative care (reducing the intensity of a disorder) for those who want to become abstinent or who must observe mandatory abstinence as a result of hospitalization or legal requirement.⁶⁸ Medically supervised detoxification may prevent potentially life-threatening complications in an untreated patient. However, detoxification without MAT may increase the risk of overdose among patients who have lost their tolerance to opioids and then resume use.⁶⁹ Detoxification is not required prior to

Naloxone is a fast-acting opioid antagonist that is used to reverse the effects of opioids and can be used as part of rescue from opioid overdose.

Outpatient services can include one-on-one counseling, group counseling, family therapy, educational groups, and psychotherapy.

Many MAT-prescribing doctors require that patients be engaged in outpatient treatment while taking MAT.

methadone or buprenorphine treatment, but is required for initiation of naltrexone for MAT.⁶⁸ Detoxification is not indicated for persons who have not used sufficient amounts of opioids to develop withdrawal symptoms or for persons whose time since last use is distant enough that they are no longer at risk of withdrawal. Methadone is the most frequently used agent approved for opioid detoxification, though buprenorphine is also approved for use. Although not FDA-approved for detoxification, clonidine (an α -adrenergic agent) is sometimes used during detoxification because it relieves most opioid withdrawal symptoms without producing opioid intoxication or drug reward.⁶⁸

(For more information about detoxification, see <http://store.samhsa.gov/shin/content/SMA15-4131/SMA15-4131.pdf>)

Naloxone

Naloxone is a fast-acting opioid antagonist that is used to reverse the effects of opioids and can be used as part of rescue from opioid overdose. Naloxone can be prescribed to persons who are considered at risk of opioid overdose, including those receiving MAT. Naloxone is approved by FDA to prevent overdose from opioids such as heroin, morphine, and oxycodone. Naloxone is an opioid receptor antagonist; it blocks opioid receptor sites, reversing the toxic effects of an overdose. Naloxone is administered when a patient shows signs of opioid overdose (e.g., loss of consciousness; unresponsiveness to stimulus; slow, shallow, erratic, or ceased breathing; vomiting; slow, erratic or no pulse; limp body). The medication can be given by intranasal spray or by intramuscular, subcutaneous, or intravenous injection. Candidates for naloxone include those who take high doses (>50 morphine milligram equivalents per day) of opioids for chronic pain, receive both opioids and benzodiazepines, use illicit opioids, receive rotating opioid medication regimens, or take certain extended-release or long-acting opioid medications. Side effects may include hypertension, tachycardia, agitation, convulsions, diarrhea, and nausea.

Outpatient and inpatient substance use treatment

Drug treatment programs can generally be classified into two types: outpatient programs and inpatient programs. Outpatient programs provide care or services at the program facility or clinic and allow the client to return to their home or other living arrangement after provision of services. Medical outpatient programs can provide individualized treatment plans for those with mild to severe substance use disorders. Inpatient programs require the client to live at the treatment facility and can provide services throughout the day. Medical inpatient programs provide care and treatment for individuals with severe substance use disorders as well as those with comorbid mental illness.

Inpatient treatment provides a contained, supportive environment for persons seeking recovery.

Outpatient treatment

Outpatient services can include one-on-one counseling, group counseling, family therapy, educational groups, and psychotherapy.⁷⁰ Many MAT-prescribing doctors require that patients be engaged in outpatient treatment while taking MAT. Currently, mental health and substance use counseling and other outpatient service are covered by private insurance and public healthcare coverage. Some outpatient services are also covered by Ryan White HIV/AIDS Program Part B funds. Persons seeking recovery may need assistance in identifying the type of coverage available to them.

SAMHSA's Behavioral Health Treatment Services Locator (<https://findtreatment.samhsa.gov/>) can be used to identify substance use and mental health treatment services. The tool combines outpatient and inpatient providers. Outpatient services vary in nature and focus (for more information, follow the website links). The tool can also be used to help providers present all available service options and discuss the advantages and disadvantages of each option so that provider and patient can make an informed decision together.

Inpatient treatment

Inpatient treatment provides a contained, supportive environment for persons seeking recovery. Room and board, counseling, and extra-curricular activities are provided for a specific period (specified in the patient's insurance plan). Not all public healthcare coverage covers inpatient treatment. The coverage offered by private insurance plans differs by provider and plan (e.g., one plan might cover a 1 month inpatient stay; another might cover only a few days). Many of the considerations that apply to outpatient treatment also apply to inpatient treatment. SAMHSA's Behavioral Health Treatment Services Locator can be used to identify inpatient programs in any given area. The Locator includes outpatient and inpatient providers. Follow the website links to find out more information.

Residential inpatient programs can be short or long term. Long-term residential treatment facilities provide care 24 hours a day, generally in non-hospital settings. A common residential treatment model is the *therapeutic community*. Therapeutic communities focus on the “resocialization” of the individual and use the program's entire community—including other residents, staff, and the social context—as active components of treatment. Other long-term residential programs include safe housing programs such as Oxford House (http://www.oxfordhouse.org/userfiles/file/purpose_and_structure.php) which provides democratically run, self-supporting, and low cost housing to persons in recovery.

(For more information about therapeutic communities, see <https://www.drugabuse.gov/publications/research-reports/therapeutic-communities/what-are-therapeutic-communities>)

Short-term residential programs provide intensive but relatively brief treatment based on a modified version of the 12-step approach of Alcoholics Anonymous®. The original residential treatment model consisted

of a 3 to 6 week hospital-based inpatient treatment phase followed by extended outpatient therapy and participation in a self-help group, such as Narcotic Anonymous®. Following stays in residential treatment programs, it is important for individuals to remain engaged in outpatient treatment programs or aftercare programs to reduce the risk of relapse.

Some inpatient and outpatient substance-use treatment facilities offer linkage to infectious disease prevention and care services. Treatment facility staff can be engaged, by health department staff, to further consider a client's need for infectious disease prevention and care, including testing and treatment adherence. Partnerships can be formed between health departments, CBOs, substance-use treatment facilities, and MAT clinics to provide infectious disease testing, linkage-to-care, health education classes, and naloxone distribution to all program clients who desire these services.

Recovery

SAMHSA defines recovery as a process of change through which individuals improve their health and wellness, live self-directed lives and strive to reach their full potential. SAMHSA lists four signs that lets persons know they are in recovery: person can address problems as they happen, without using illicit drugs, and without getting stressed; person has at least one person with whom they can be completely honest; person has personal boundaries and knows which issues are theirs and which ones belong to other people; person takes the time to restore their energy—physical and emotional—when tired. There are community and facility based services available for people in recovery.

Recovery-Oriented Systems of Care

Recovery-Oriented Systems of Care are coordinated networks of community-based services and support that builds on the strengths of individuals, families, and communities to achieve abstinence (<http://www.williamwhitepapers.com/pr/CSAT%20ROSC%20Definition.pdf>).

(For examples of Recovery-Oriented Systems of Care, see http://www.michigan.gov/mdhhs/0,5885,7-339-71550_2941_4871_4877_48561-113480--,00.html http://www.michigan.gov/documents/mdch/ROSC_FS_SUD_Agency_Directors_337044_7.pdf <https://www.dshs.texas.gov/substance-abuse/ROSC/>)

Spiritual programs

The most widely available form of recovery support is that offered by community-based peer-run 12 step programs such as Narcotics Anonymous® and Cocaine Anonymous®; both programs use the 12 steps of Alcoholics Anonymous®. Narcotics Anonymous® and Cocaine Anonymous® are non-drug specific programs. In-person, online, and phone meeting locators are available online for Narcotics Anonymous® (<https://www.na.org/meetingsearch/index.php>), Cocaine Anonymous® (<http://www.ca-online.org/meetings/>), and Alcoholics Anonymous® (http://www.aa.org/pages/en_US/find-aa-resources).

Secular Programs

Community-based secular alternatives to 12-step programs focus on sharing, cultivating life skills, and building peer recovery networks. Abstinence-based programs include organizations such as LifeRing® (<http://lifering.org/>), which offers meetings, and Oxford House™ (<http://www.oxfordhouse.org/userfiles/file/house-directory.php>), which offers sober recovery homes. Nonabstinence-based programs are a good fit for persons on MAT and others who define recovery as moderate use, not abstinence. Nonabstinence based programs include organizations such as SMART Recovery® (<http://www.smartrecovery.org/>) and Moderation Management (<http://www.moderation.org/meetings/>).

Recovery programs can also be facility-based. (For an example of a facility-based recovery program, see <http://marsproject.org/>)



Notes from the field

Historically, naloxone has been used only by trained medical personnel such as physicians and paramedics. Barriers to more widespread access include concerns about liability and regulatory issues. In the past few years, many states have launched initiatives to make naloxone directly available to patients. In 2016, the Wisconsin governor's office worked closely with the Wisconsin Department of Health Services to establish a statewide standing order for naloxone.

At the direction of the governor, a physician at Wisconsin Department of Health Services signed an order that allowed all pharmacies in Wisconsin to dispense naloxone, without an individual prescription, to anyone at risk or to anyone who would benefit from having naloxone on hand to respond to an overdose. The order was intended for pharmacies that do not have a medical provider on staff to write a prescription. The standing order further authorized pharmacists in Wisconsin to maintain supplies of naloxone and dispense them, along with instructions for use.

In addition to collaborating with state government to establish the statewide standing order, the Wisconsin Department of Health Services was involved in the following activities:

- Providing a list of required trainings for pharmacists to be eligible to use the statewide standing order
- Creating tools for pharmacists:
 - Posters to communicate the availability of naloxone at pharmacies
 - Screening checklist to identify persons who may benefit from naloxone (e.g., persons who have a prescription for a high dosage of an opioid or first-time users [persons who have never previously been prescribed opioids])
 - List of items that should be included in each naloxone kit
- Creating patient education materials:
 - How to administer naloxone and how to respond to an overdose
 - Patient resource guides for safe disposal options
 - List of resources for substance-use treatment

A key consideration during an outbreak is how to reduce the number of steps, visits, locations, and overall effort required to get care. If possible, planners should prepare to provide multiple services at a central location, or a one-stop shop.

Chapter 17: Setting up a one-stop shop

During an HIV or HCV outbreak, affected persons may require rapid provision of multiple care-related services. A key consideration during an outbreak is how to reduce the number of steps, visits, locations, and overall effort required to get care. If possible, planners should prepare to provide multiple services at a central location, or a one-stop shop ([Figure 17-1](#)). The one-stop shop model of HIV and HCV management addresses barriers to HIV and HCV testing, treatment, and addiction recovery for PWID and may be especially useful in rural settings. Addressing injection drug use and its complications holistically is often better than addressing disease treatment alone.

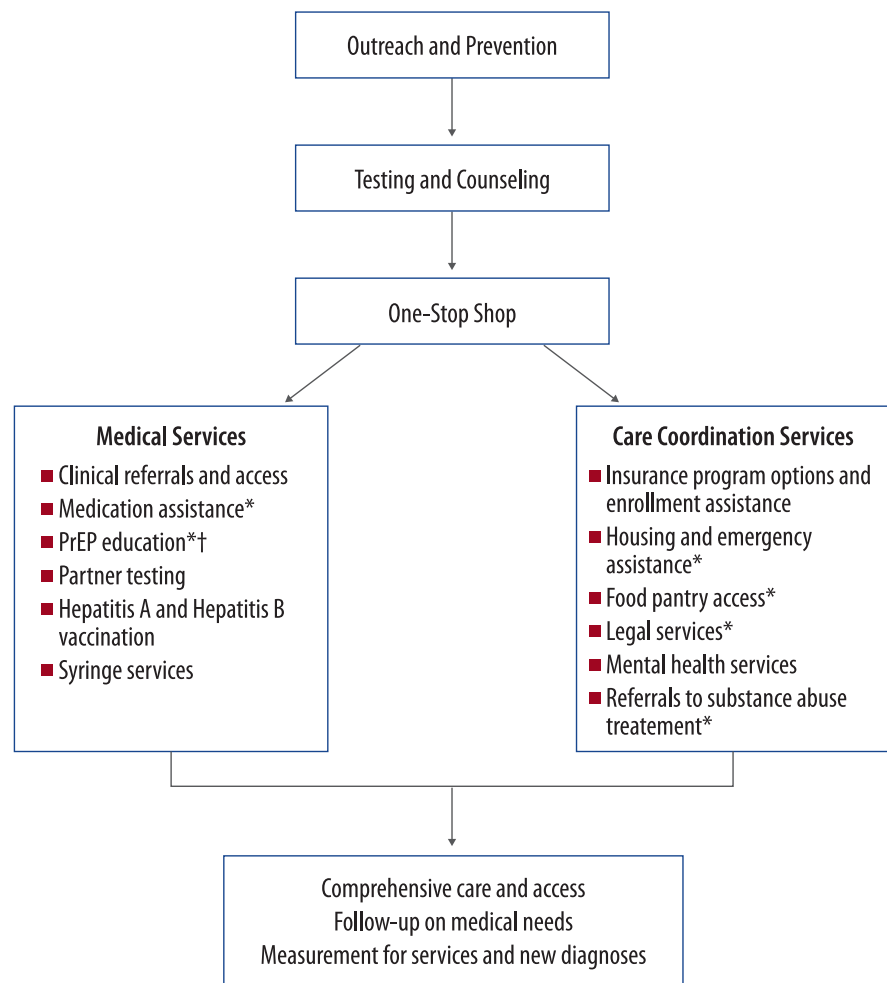
The following are important considerations in establishing a one-stop shop:

- **Location:**
 - Should be determined after discussions with local leaders and stakeholders.
 - Should be accessible and available to the target population and large enough to provide the intended services. Consider location walkability for areas where lack of transportation is a barrier.
 - Should be private enough that potential clients will not feel exposed when seeking services there.
- Determine the services the one-stop shop will provide. Potential services include the following:
 - Health insurance registration/enrollment.
 - Procurement of identification documents (e.g., driver's license, identification card, birth certificate), and any other records that may be a prerequisite to health insurance enrollment.
 - HIV and HCV testing.
 - Care coordination and referral for HIV and HCV prevention and treatment services.
 - Screening and referral for mental health and substance-use treatment.
 - Syringe services.
 - Opioid overdose prevention and treatment education and services (e.g., naloxone training and distribution).
 - Immunizations indicated for PWID (e.g., tetanus, hepatitis A, hepatitis B) as well as other routine immunizations (e.g., influenza).
- Determine how services will be promoted in the community.
- Set up processes for maintaining client confidentiality.
- Acknowledge clients' need for flexible schedules and services. For example, to accommodate injection practices, some clients may need

to visit the one-stop shop several times in order to take advantage of all the services they need.

- Maintain an active database of services provided.
- Strongly consider addressing the needs of family members during wait times. For example, toys for children, diaper-changing stations with supplies, snacks, and sufficient staff to talk with family members will enhance clients' experience and help to build rapport with staff.
- Determine whether the one-stop shop should continue after the outbreak has ended.

Figure 17-1 Example of a One-stop shop



*depending on capacity of care site

† pre-exposure prophylaxis



Notes from the field

In response to the unprecedented HIV outbreak in Scott County, Indiana, in 2015, the Indiana State Department of Health (ISDH) in collaboration with the Scott County Health Department established a one-stop shop.

The initial objective of the one-stop shop was to help clients apply for and receive approval for the Healthy Indiana Plan 2.0 insurance coverage, which would enable them to receive medical care and treatment. In addition, HIV and HCV testing, immunizations, and mental health and addiction counseling services would be offered. Many other services were added along the way.

The governor declared the outbreak a public health emergency, which enabled the Scott County Health Department to seek and gain approval to implement the first SSP in the State of Indiana. The Scott County Health Department opened an SSP 3 days after the one-stop shop opened. The SSP, albeit with a separate entrance, was located in the same building as the one-stop shop.

The first 60 days of the one-stop shop were managed through an incident command system. ISDH staff were on-site at the one-stop shop for 90 days to ensure sustainability. A recovery plan was initiated before demobilization of ISDH staff and transition of management of the one-stop shop to the Scott County Health Department.

To publicize the services, location, and operating hours of the one-stop shop, volunteers from the state Medical Reserve Corps distributed flyers door to door and set up mobile stations in affected neighborhoods. Signs were placed throughout the community—along roadways and in neighborhoods—and flyers were mailed to each home in Scott County.

Communications about the outbreak response and the one-stop shop—to the targeted population and the media—had to be considered and addressed throughout the response. To protect the privacy of visitors to the one-stop shop, the incident commander and ISDH decided not to allow media inside the shop during operating hours; press were invited to the shop at designated dates and times when the one-stop shop had closed for the day. In addition, the ISDH, Scott County Health Department, Scott County Sheriff, and Austin Police Department held weekly press briefings for the first 60 days of the response.

Federal, state, and local agencies, as well as community groups, faith-based volunteers, and private-sector partners, were involved in the one-stop shop. Their involvement allowed the continuation of the one-stop shop after the initial outbreak response concluded. Services continue to be provided once a week in the Scott County one-stop shop and the SSP (housed in the shop) offers services via a mobile unit multiple times throughout the week.

The following are the services that the one-stop shop provided and the agencies or organizations involved in providing the service:

- HIV and HCV testing (ISDH)
- Care coordination (ISDH and Scott/Clark County Health Department)
- DIS (made available through ISDH, CDC and EMAC)
- Immunizations (ISDH Immunization division)
- Insurance and presumptive eligibility (Family and Social Services Administration / Medicaid, Covering Kids and Families Indiana)
- Vital Records—birth certificates (ISDH)
- Indiana Bureau of Motor Vehicles—identification cards
- Job training (Indiana Department of Workforce Development)
- Food and shelter (Faith-based organizations, Housing and Urban Development)
- Transportation (ISDH, Scott County Health Department, local churches)
- SSP (Scott County Health Department)
- Mental health and substance use disorder services (Indiana Division of Mental Health and Addiction, LifeSprings Community Mental Health Center)
- Medical care, including STI and pregnancy screening (Foundations Family Medicine, AIDS Healthcare Foundation, Indiana University School of Medicine)
- Health messaging and education (ISDH Office of Public Affairs, CDC, Region V Midwest AIDS Training and Education Center)

Several factors became important in the implementation and rapid evaluation of the one-stop shop.

- Offering services (HIV testing, syringe exchange, and coordination) at a fixed and mobile location increased acceptance of services and enhanced the possibility of long-term connectivity to services.
- A concrete, well-coordinated media plan to protect the confidentiality of clients entering and exiting the one-stop shop helped build community trust and acceptance.
- The capacity to enter data through tablet, laptops, or phone service allowed ongoing analysis of process and outcome metrics.

PrEP is the use of HIV medications to lower the risk of getting HIV. Among PWID, daily use of PrEP reduces the risk of HIV by more than 70%.

Chapter 18: HIV pre- and post-exposure prophylaxis

PWID who test negative for HIV benefit from referrals to syringe services, substance-use treatment facilities, mental health services, and social services and may also benefit from biomedical HIV prevention.

Pre-exposure prophylaxis (PrEP)

What is PrEP, and why use it?

PrEP is the use of HIV medications to lower the risk of getting HIV. Among PWID, daily use of PrEP reduces the risk of HIV by more than 70%.⁷¹ At present, PrEP consists of a single pill (fixed-dose combination tablet of tenofovir disoproxil fumarate and emtricitabine) taken once daily. PrEP should be administered according to the current PrEP practice guidelines (<https://stacks.cdc.gov/view/cdc/23109>).

Who should be prescribed PrEP?

PrEP is indicated for PWID aged at least 18 years, without a diagnosis of acute or established HIV infection, who in the past 6 months have injected drugs not prescribed by a clinician and for whom at least one of the following is true: (1) shared any injection or drug preparation equipment; (2) received MAT (e.g., methadone or buprenorphine); or (3) is at risk of sexual acquisition of HIV). PrEP may benefit persons who, despite efforts to get them into drug treatment, continue to inject drugs. PrEP may also benefit persons using an SSP because users of these services may occasionally share needles or other injection equipment.

Laboratory testing requirements

To avoid prescribing PrEP for an HIV-infected person, clinicians should confirm that the person is HIV-negative and should repeat HIV testing every 3 months (i.e., before refilling a prescription for PrEP). Confirmation of HIV negativity includes assessment of renal function (creatinine clearance of ≥ 60 ml/min) and testing for HBV: decreased renal function and active HBV infection pose risk for the use of tenofovir disoproxil fumarate and emtricitabine.

PrEP resources

- A brief guide about covering the cost of PrEP care is available at <http://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-paying-for-prep.pdf>.
- Infographics, videos, fact sheets, reports, and other educational materials about PrEP, including resources for health care providers, are available at <https://www.cdc.gov/hiv/risk/prep/index.html>.
- Clinical support services for providers who need consultation before initiating PrEP are available from the National Clinician Consultation Center (<http://nccc.ucsf.edu/clinician-consultation/prep-pre-exposure-prophylaxis/>) or through PrEPline: 855-448-7737, or 855-HIV-PrEP.

PEP is the use of antiretroviral medicines after a potential exposure to HIV to prevent HIV infection.

Persons who engage in behaviors that result in frequent, recurrent exposures that would require sequential or near-continuous courses of PEP should be offered PrEP at the conclusion of their 28-day PEP medication course.

Post-exposure prophylaxis (PEP)

What is PEP, and why use it?

PEP is the use of antiretroviral medicines after a potential exposure to HIV to prevent HIV infection. There are 2 types of PEP: nPEP (nonoccupational post-exposure prophylaxis) and oPEP (occupational post-exposure prophylaxis). A person takes nPEP when the potential exposure occurred outside of the work environment, such as after sex or injection drug use. oPEP is taken because of a potential on-the-job exposure to HIV such as after a needlestick injury.

The PEP regimen, which must be started ≤ 72 hours after possible exposure, consists of a 28-day course of a 3-drug antiretroviral regimen, taken once or twice daily. PEP should be administered according to the current practice guidelines (<https://stacks.cdc.gov/view/cdc/38856> and <https://stacks.cdc.gov/view/cdc/20711>).

Who should be prescribed PEP?

Clinicians should consider the following factors when determining whether to prescribe PEP.

1. Whether the source of exposure is known to have HIV infection
2. The potentially infected body fluid(s) to which the person was exposed
3. Exposure site or surface

Persons who engage in behaviors that result in frequent, recurrent exposures that would require sequential or near-continuous courses of PEP should be offered PrEP at the conclusion of their 28-day PEP medication course. Upon documentation of the person's HIV-negative status, PrEP can begin immediately.

Clinicians should make case-by-case determinations about prescribing PEP when the patient was exposed to infection from a person of unknown HIV status.

Laboratory testing requirements

Before PEP is initiated, persons should be tested by using an Ag/Ab test (or an antibody-based blood test). If rapid HIV blood test results are unavailable but PEP is otherwise indicated, PEP should be initiated without delay (can be modified if the patient is determined to be HIV-infected or discontinued if the source is determined not to be HIV-infected). Additional laboratory testing is recommended in the PEP guidelines to identify conditions that may affect the PEP regimen and to monitor for safety or toxicities. (For recommended additional laboratory testing, see <https://stacks.cdc.gov/view/cdc/38856> and <https://stacks.cdc.gov/view/cdc/20711>)

PEP resources

Clinical support services for providers needing consultation prior to initiating PEP is available from the National Clinician Consultation Center (<http://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/>) or the PEpline: (888)-448-4911.



Notes from the field

In Indiana, persons who test HIV-negative but who are considered at high risk of HIV infection are connected to providers for HIV PrEP education. These persons receive state services through the Special Populations Support Program, which is administered by the Division of HIV/STD, ISDH. The program is designed to deliver 2 distinct, but complementary, services: disease prevention and supportive care. The Special Populations Support Program employs certified HIV testing counselors who have been trained to perform comprehensive risk assessments, pretest counseling, testing, posttest counseling, and general outreach for PWID. Testing counselors conduct their activities in a variety of venues—wherever the target population can be found—including state treatment facilities sanctioned by the Department of Mental Health and Addictions. Any person who tests positive for HIV is referred to the program's support specialists who offer the person interventions designed to minimize substance use and maximize compliance with treatment plans. The specialists work closely with local HIV care coordinators to ensure that the person receives a full complement of care.

Chapter 19: Other considerations—hepatitis B virus infection

The prevalence of HBV infection among PWID is an estimated 12%.⁷² In recent years some states, that have experienced an increase in reported cases of acute hepatitis C associated with injection drug use, have witnessed an increase in reported cases of acute hepatitis B.⁷³ The prevention and control of HBV infection hinges on screening and linkage-to-care or vaccination. Current CDC guidelines recommend HBV screening for high-risk populations, including PWID, persons infected with HIV, and certain other groups.⁷⁴ Screening should include hepatitis B surface antigen, antibodies to hepatitis B surface antigen, and antibodies to hepatitis B core antigen.

(For a summary of the interpretation of HBV serology, see <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5708a1.htm>)

Persons who test positive for hepatitis B surface antigen may have acute or chronic HBV infection. These persons should receive counseling on how to reduce transmission and should receive hepatitis B–directed care and treatment. Persons linked to care can experience a reduction in HBV-associated morbidity and mortality and reduce the transmission of HBV infections.

The 3-dose hepatitis B vaccination series is highly effective in preventing HBV infection and is recommended for adults, including PWID, at risk of HBV infection.⁷⁵ The first dose can be administered at the time that HBV testing is performed.

References

1. Rudd RA, Aleshire N, Zibbell JE, Gladden RM. Increases in drug and opioid overdose deaths—United States, 2000–2014. *MMWR Morb Mortal Wkly Rep.* 2016;64(50-51):1378-82.
2. Centers for Disease Control and Prevention. Vital signs: overdoses of prescription opioid pain relievers—United States, 1999–2008. *MMWR Morb Mortal Wkly Rep.* 2011;60(43):1487-92.
3. Ko JY, Patrick SW, Tong VT, et al. Incidence of neonatal abstinence syndrome—28 States, 1999–2013. *MMWR Morb Mortal Wkly Rep.* 2016;65(31):799-802.
4. Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. (2015). Behavioral health trends in the United States: results from the 2014 National Survey on Drug Use and Health. Rockville, MD: Substance Abuse and Mental Health Services Administration. Available at: <https://www.samhsa.gov/data/sites/default/files/NSDUH-FRR1-2014/NSDUH-FRR1-2014.pdf>. Accessed April 20, 2017.
5. Lansky A, Finlayson T, Johnson C, et al. Estimating the number of persons who inject drugs in the United States by meta-analysis to calculate national rates of HIV and hepatitis C virus infections. *PLoS One.* 2014;9(5):e97596.
6. Jones CM, Logan J, Gladden RM, Bohm MK. Vital Signs: demographic and substance use trends among heroin users—United States, 2002–2013. *MMWR Morb Mortal Wkly Rep.* 2015;64(26):719-25.
7. Jones CM. Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers—United States, 2002–2004 and 2008–2010. *Drug Alcohol Depend.* 2013;132(1-2):95-100.
8. Centers for Disease Control and Prevention. Viral hepatitis surveillance—United States, 2015. <https://www.cdc.gov/hepatitis/statistics/2015surveillance/pdfs/2015HepSurveillanceRpt.pdf>. Published May 2017. Accessed November 28, 2017.
9. Centers for Disease Control and Prevention. HIV surveillance report, 2015; vol. 27. <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2015-vol-27.pdf>. Published November 2016. Accessed April 20, 2017.
10. Van Handel MM, Rose CE, Hallisey EJ, et al. County-level vulnerability assessment for rapid dissemination of HIV or HCV infections among persons who inject drugs, United States. *J Acquir Immune Defic Syndr.* 2016;73(3):323-31.
11. Centers for Disease Control and Prevention. Use of enhanced surveillance for hepatitis C virus infection to detect a cluster among young injection-drug users New York, November 2004–April 2007. *MMWR Morb Mortal Wkly Rep.* 2008;57(19):517-21.
12. Centers for Disease Control and Prevention. Hepatitis C virus infection among adolescents and young adults: Massachusetts, 2002–2009. *MMWR Morb Mortal Wkly Rep.* 2011;60(17):537-41.
13. Centers for Disease Control and Prevention. Notes from the field: hepatitis C virus infections among young adults – rural Wisconsin, 2010. *MMWR Morb Mortal Wkly Rep.* 2012;61(19):358.
14. Centers for Disease Control and Prevention. Notes from the field: risk factors for hepatitis C virus infections among young adults—Massachusetts, 2010. *MMWR Morb Mortal Wkly Rep.* 2011;60(42):1457-8.
15. Suryaprasad AG, White JZ, Xu F, et al. Emerging epidemic of hepatitis C virus infections among young nonurban persons who inject drugs in the United States, 2006–2012. *Clin Infect Dis.* 2014;59(10):1411-9.
16. Zibbell JE, Iqbal K, Patel RC, et al. Increases in hepatitis C virus infection related to injection drug use among persons aged ≤30 years—Kentucky, Tennessee, Virginia, and West Virginia, 2006–2012. *MMWR Morb Mortal Wkly Rep.* 2015;64(17):453-8.
17. Peters PJ, Pontones P, Hoover KW, et al. HIV infection linked to injection use of oxycodone in Indiana, 2014–2015. *N Engl J Med.* 2016;375(3):229-39.
18. Patel P, Borkowf CB, Brooks JT, et al. Estimating per-act HIV transmission risk: a systematic review. *AIDS.* 2014;28(10):1509-19.
19. Walsh N, Maher L. HIV and viral hepatitis C coinfection in people who inject drugs: implications of new direct acting antivirals for hepatitis C virus treatment. *Curr Opin HIV AIDS.* 2012;7(4):339-44.

20. Paintsil E, Binka M, Patel A, Lindenbach BD, Heimer R. Hepatitis C virus maintains infectivity for weeks after drying on inanimate surfaces at room temperature: implications for risks of transmission. *J Infect Dis*. 2014;209(8):1205-11.
21. Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents. Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. Available at: http://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf. Accessed June 26, 2017.
22. Gallagher KM, Sullivan PS, Lansky A, Onorato IM. Behavioral surveillance among people at risk for HIV infection in the U.S.: the National HIV Behavioral Surveillance System. *Public Health Rep* 2007;122 Suppl 1:32-8.
23. Centers for Disease Control and Prevention. Recommendations for partner services programs for HIV infection, syphilis, gonorrhea, and chlamydial infection. *MMWR Recomm Rep*. 2008;57(RR09):1-83.
24. Centers for Disease Control and Prevention. Use of social networks to identify persons with undiagnosed HIV infection—seven U.S. cities, October 2003–September 2004. *MMWR Morb Mortal Wkly Rep*. 2005;54(24):601-5.
25. McCree DH, Millett G, Baytop C, et al. Lessons learned from use of social network strategy in HIV testing programs targeting African American men who have sex with men. *Am J Public Health*. 2013;103(10):1851-6.
26. Boutwell AE, Nijhawan A, Zaller N, Rich JD. Arrested on heroin: a national opportunity. *J Opioid Manag*. 2007;3(6):328-32.
27. Galbraith JW, Willig JH, Rodgers JB, et al. Evolution and escalation of an emergency department routine, opt-out HIV screening and linkage-to-care program. *Public Health Rep*. 2016;131 Suppl 1:96-106.
28. Haukoos JS, Lyons MS, White DA, Hsieh YH, Rothman RE. Acute HIV infection and implications of fourth-generation HIV screening in emergency departments. *Ann Emerg Med*. 2014;64(5):547-51.
29. Henriquez-Camacho C, Villafuerte-Gutierrez P, Perez-Molina JA, et al. Opt-out screening strategy for HIV infection among patients attending emergency departments: systematic review and meta-analysis. *HIV Med*. 2017;18(6):419-29.
30. Hsieh YH, Kelen GD, Laeyendecker O, et al. HIV care continuum for HIV-infected emergency department patients in an inner-city academic emergency department. *Ann Emerg Med*. 2015;66(1):69-78.
31. Kelen GD, Hsieh YH, Rothman RE, et al. Improvements in the continuum of HIV care in an inner-city emergency department. *AIDS*. 2016;30(1):113-20.
32. Lyons MS, Kunnathur VA, Rouster SD, et al. Prevalence of diagnosed and undiagnosed hepatitis C in a midwestern urban emergency department. *Clin Infect Dis*. 2016;62(9):1066-71.
33. White DA, Anderson ES, Pfeil SK, Trivedi TK. Hepatitis C virus antibody testing: result availability at time of discharge for emergency department patients. *J Acquir Immune Defic Syndr*. 2016;71(3):e82-4.
34. White DA, Anderson ES, Pfeil SK, Trivedi TK, Alter HJ. Results of a rapid hepatitis C virus screening and diagnostic testing program in an urban emergency department. *Ann Emerg Med*. 2016;67(1):119-28.
35. Centers for Disease Control and Prevention. Integrated prevention services for HIV infection, viral hepatitis, sexually transmitted diseases, and tuberculosis for persons who use drugs illicitly: summary guidance from CDC and the U.S. Department of Health and Human Services. *MMWR Recomm Rep*. 2012; 61: 1-40.
36. Marshall BD, Kerr T, Shoveller JA, et al. Homelessness and unstable housing associated with an increased risk of HIV and STI transmission among street-involved youth. *Health Place*. 2009;15(3):753-60.
37. Kipke MD, Weiss G, Wong CF. Residential status as a risk factor for drug use and HIV risk among young men who have sex with men. *AIDS Behav*. 2007;11(6 Suppl):56-69.
38. Centers for Disease Control and Prevention and Association of Public Health Laboratories. Laboratory testing for the diagnosis of HIV infection: Updated Recommendations. Available at: <https://stacks.cdc.gov/view/cdc/50872>. Published June 27, 2014. Accessed January 24, 2018.

39. Centers for Disease Control and Prevention and Association of Public Health Laboratories. Technical update in HIV-1/2 differentiation assays. Available at: <http://dx.doi.org/10.15620/cdc.23447>. Published August, 12, 2016. Accessed November 13, 2017.
40. Hutchinson AB, Patel P, Sansom SL, et al. Cost-effectiveness of pooled nucleic acid amplification testing for acute HIV infection after third-generation HIV antibody screening and rapid testing in the United States: a comparison of three public health settings. *PLoS Med.* 2010;7(9):e1000342.
41. Sullivan TJ, Patel P, Hutchinson A, Ethridge SF, Parker MM. Evaluation of pooling strategies for acute HIV-1 infection screening using nucleic acid amplification testing. *J Clin Microbiol.* 2011;49(10):3667-8.
42. Westreich DJ, Hudgens MG, Fiscus SA, Pilcher CD. Optimizing screening for acute human immunodeficiency virus infection with pooled nucleic acid amplification tests. *J Clin Microbiol.* 2008;46(5):1785-92.
43. Masciotra S, Luo W, Youngpairoj AS, et al. Performance of the Alere Determine HIV-1/2 Ag/Ab combo rapid test with specimens from HIV-1 seroconverters from the US and HIV-2 infected individuals from Ivory Coast. *J Clin Virol.* 2013;58 Suppl 1:e54-8.
44. Masciotra S, Price KA, Sprinkle P, Wesolowski L, Owen SM. Performance evaluation of the CHEMBIO DPP(R) (dual path platform) HIV-1/2 assay in early and established infections. *J Clin Virol.* 2015;70:97-100.
45. Delaney KP, Hanson DL, Masciotra S, et al. Time until emergence of HIV test reactivity following infection with HIV-1: implications for interpreting test results and retesting after exposure. *Clin Infect Dis.* 2017;64(1):53-9.
46. Centers for Disease Control and Prevention, Health Resources and Services Administration, National Institutes of Health, American Academy of HIV Medicine, Association of Nurses in AIDS Care, International Association of Providers of AIDS Care, the National Minority AIDS Council, and Urban Coalition for HIV/AIDS Prevention Services. Recommendations for HIV Prevention with Adults and Adolescents with HIV in the United States, 2014. <http://stacks.cdc.gov/view/cdc/26062>. Accessed April 26, 2017.
47. Gallant JE, Adimora AA, Carmichael JK, et al. Essential components of effective HIV care: a policy paper of the HIV Medicine Association of the Infectious Diseases Society of America and the Ryan White Medical Providers Coalition. *Clin Infect Dis.* 2011;53(11):1043-50.
48. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Available at: <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>. Accessed February 24, 2017.
49. Bangsberg DR. Less than 95% adherence to nonnucleoside reverse-transcriptase inhibitor therapy can lead to viral suppression. *Clin Infect Dis.* 2006;43(7):939-41.
50. Bangsberg DR, Hecht FM, Clague H, et al. Provider assessment of adherence to HIV antiretroviral therapy. *J Acquir Immune Defic Syndr.* 2001;26(5):435-42.
51. The American Association for the Study of Liver Disease and Infectious Disease Society of America. HCV guidance: recommendations for testing, managing, and treating hepatitis C 2016. Available at: <http://www.hcvguidelines.org/full-report/management-acute-hcv-infection>. Accessed April 27, 2017.
52. Des Jarlais DC, Mathilde Krim, amfAR, and the prevention of HIV infection among injecting drug users: a brief history. *AIDS Patient Care STDS.* 2006;20(7):467-71.
53. Des Jarlais DC, Sloboda Z, Friedman SR, et al. Diffusion of the D.A.R.E and syringe exchange programs. *Am J Public Health.* 2006;96(8):1354-8.
54. Wodak A, Cooney A. Do needle syringe programs reduce HIV infection among injecting drug users: a comprehensive review of the international evidence. *Subst Use Misuse.* 2006;41(6-7):777-813.
55. Bart G. Maintenance medication for opiate addiction: the foundation of recovery. *J Addict Dis.* 2012;31(3):207-225.
56. Strain E. 2017. Pharmacotherapy for opioid use disorder. Available at: https://www.uptodate.com/contents/pharmacotherapy-for-opioid-use-disorder?source=search_result&search=narcan&selectedTitle=7~150. Accessed February 2, 2017.
57. United States Department of Health and Human Services, Substance Abuse and Mental Health Services Administration Center for Substance Abuse Treatment. 2011. Medication-assisted treatment for opioid

- addiction. Available at: <https://store.samhsa.gov/shin/content/SMA09-4443/SMA09-4443.pdf>. Accessed February 10, 2017.
58. American Society of Addiction Medicine. The National practice guideline for the use of medications in the treatment of addiction involving opioid use. Available at: <https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf>. Accessed November 28, 2017.
 59. MacArthur GJ, Minozzi S, Martin N, et al. Opiate substitution treatment and HIV transmission in people who inject drugs: systematic review and meta-analysis. *BMJ*. 2012;345:e5945.
 60. Sordo L, Barrio G, Bravo MJ, et al. Mortality risk during and after opioid substitution treatment: systematic review and meta-analysis of cohort studies. *BMJ*. 2017;357:j1550.
 61. Volkow ND, Frieden TR, Hyde PS, Cha SS. Medication-assisted therapies—tackling the opioid-overdose epidemic. *N Engl J Med*. 2014;370(22):2063-6.
 62. Tracqui A, Kintz P, Ludes B. Buprenorphine-related deaths among drug addicts in France: a report on 20 fatalities. *J Anal Toxicol*. 1998;22(6):430-4.
 63. Soeffing JM, Martin LD, Fingerhood MI, Jasinski DR, Rastegar DA. Buprenorphine maintenance treatment in a primary care setting: outcomes at 1 year. *J Subst Abuse Treat*. 2009;37(4):426-30.
 64. National Alliance of State and Territorial AIDS Directors. ADAP formulary coverage of substance use treatment, June 2016. Available at: <https://www.nastad.org/sites/default/files/Fact-Sheet-ADAP-Formulary-Coverage-Substance-Use-Treatment.pdf>. Accessed April 28, 2017.
 65. Altice FL, Bruce RD, Lucas GM, et al. HIV treatment outcomes among HIV-infected, opioid-dependent patients receiving buprenorphine/naloxone treatment within HIV clinical care settings: results from a multisite study. *J Acquir Immune Defic Syndr*. 2011;56 Suppl 1:S22-32.
 66. Norton BL, Beitin A, Glenn M, et al. Retention in buprenorphine treatment is associated with improved HCV care outcomes. *J Subst Abuse Treat*. 2017;75:38-42.
 67. Lucas GM, Chaudhry A, Hsu J, et al. Clinic-based treatment of opioid-dependent HIV-infected patients versus referral to an opioid treatment program: A randomized trial. *Ann Intern Med*. 2010;152(11):704-11.
 68. Center for Substance Abuse Treatment. Detoxification and substance abuse treatment. Treatment Improvement Protocol (TIP) Series, No. 45. HHS Publication No. (SMA) 15-4131. Rockville, MD: Center for Substance Abuse Treatment, 2006.
 69. Schuckit MA. Treatment of opioid-use disorders. *N Engl J Med*. 2016;375(4):357-68.
 70. Mee-Lee D, ed. The ASAM criteria: treatment criteria for addictive substance-related, and co- occurring conditions. Chevy Chase, MD: American Society of Addiction Medicine, 2013.
 71. Choopanya K, Martin M, Suntharasamai P, et al. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial. *Lancet*. 2013;381(9883):2083-90.
 72. Nelson PK, Mathers BM, Cowie B, et al. Global epidemiology of hepatitis B and hepatitis C in people who inject drugs: results of systematic reviews. *Lancet*. 2011;378(9791):571-83.
 73. Harris AM, Iqbal K, Schillie S, et al. Increases in acute hepatitis B virus infections — Kentucky, Tennessee, and West Virginia, 2006–2013. *MMWR Morb Mortal Wkly Rep* 2016;65:47–50.
 74. Weinbaum CM, Williams I, Mast EE, et al. Recommendations for identification and public health management of persons with chronic hepatitis B virus infection. *MMWR Recomm Rep*. 2008;57(RR-8):1-20.
 75. Mast EE, Weinbaum CM, Fiore AE, et al. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP) Part II: immunization of adults. *MMWR Recomm Rep*. 2006;55(RR-16):1-33.

Appendix A

Glossary

Acute HIV infection: The period immediately after infection (approximately first 6 weeks after infection) when the virus is detectable by a NAT or antigen test but antibody response is immature or undetectable. Acute infection is the period of peak viremia and greatest risk of infecting others.

Antibody avidity-based serologic assays: Antibodies produced following recent infection have low avidity or binding strength while, months following infection, antibodies mature to high avidity or high binding strength. Therefore, avidity assays can be used to assess low avidity (which indicates recent infection) versus high avidity (past infection).

Case surveillance: Monitoring new diagnoses of HIV and HCV infection by specific geographic areas, populations, and time periods.

Cluster: An aggregation of cases grouped in place and time that are suspected to be greater than the number expected, even though the expected number may not be known.

Community-based organization: A public or private nonprofit organization of demonstrated effectiveness that is representative of a community, or a significant segment of a community, and provides education or related services to persons in the community.

Contact investigation: The identification and follow-up of persons who may have come into contact with a person who is infected with HIV or HCV.

Direct acting antiviral therapy: Therapy with antiviral medications that target specific steps within the HCV life cycle resulting in disruption of viral replication and infection.

Disease intervention specialist: A public health outreach worker who is responsible for locating, counseling, and educating persons with sexually transmitted and other communicable diseases, and their contacts.

Early HIV infection: The time up to 6 months after infection during which anti-HIV antibodies are detectable.

Emergency operations center: The centralized base of operations during an emergency.

Genetic distance threshold: The level of genetic similarity between HIV nucleotide sequences, which is used to identify closely related pairs.

Incident command system: A command and control system delineating job responsibilities, organizational structure, and coordination of emergency response. ICS provides a common hierarchy within which responders from multiple agencies can operate during all types of emergency incidents.

Incident commander: The person responsible for the overall management of an emergency response.

Informed consent: Permission granted, for testing or treatment, with the full knowledge of the risks, benefits, and possible consequences.

Molecular cluster: A group of persons with diagnosed HIV infection who have genetically similar HIV strains.

Molecular surveillance: A laboratory-based method that can determine the genetic sequence of an HIV strain in a person. If the HIV strains from two or more persons are very similar then those persons may be in the same transmission network.

National Incident Management System: An integrated framework that defines the roles and responsibilities of federal, state, and local first responders during emergency events. Developed for

responders from different jurisdictions and disciplines to more effectively work together to respond to emergencies.

National Response Framework: A guide to how the nation responds to all types of disasters and emergencies. It is built on the template identified in the National Incident Management System and aligns key roles and responsibilities across the nation.

Nucleic acid test: A molecular technique used to detect a particular pathogen in blood, tissue or other body fluid. The test is based on detection and amplification of targeted regions of pathogen RNA or DNA. The term NAT includes any test that directly detects the genetic material of a pathogen such as polymerase chain reaction.

Nucleotide sequence: The order of nucleotides, the basic structural units of DNA and RNA, within a DNA or RNA molecule.

Outbreak: More diagnoses than expected within a geographic area or population during a particular time period and evidence of recent transmission among these case patients. The definition of an outbreak is not standardized but is relative to the local context.

Partner services: A broad group of services that are offered to persons with HIV and other STIs and their partners. Services include partner notification where past and present sexual and/or needle sharing partners are notified of a possible exposure. Services may also include prevention counseling, STI testing, hepatitis screening and vaccination, treatment or linkage to medical care, linkage or referral to other prevention services, and linkage or referral to other services (e.g., substance-use treatment and mental health services).

Point-of-care testing: Testing technology that allows persons to be tested for HIV or HCV and know their status during the same visit, usually in less than an hour. Also, referred to as “rapid” testing.

Post-exposure prophylaxis: The use of antiretroviral medicines after a potential exposure to HIV to prevent HIV infection.

Pre-exposure prophylaxis: A method for persons who do not have HIV but who are at substantial risk of getting HIV to prevent HIV infection by taking a pill every day. The pill contains two medicines that are used to treat HIV. When someone is exposed to HIV through sex or injection drug use, these medicines can work to keep the virus from establishing a permanent infection.

Rapid testing: Testing technology that allows persons to be tested for HIV or HCV and know their status during the same visit, usually in less than an hour. Analogous to “point-of-care” testing.

Recent HIV infection: The period of HIV infection that is defined by a laboratory-based recency assay and usually occurs within 6 months of infection.

Risk network: A group of persons among which HIV transmission has occurred and could be ongoing.

Sustained virologic response (HCV): An undetectable HCV RNA level 12 weeks after completion of therapy for hepatitis C.

Transmission cluster: A group of HIV-infected persons (diagnosed and undiagnosed) who have a direct or indirect epidemiological connection related to HIV transmission.

Appendix B

Procedure for the collection, processing, and shipment of serum and plasma specimens to CDC for sequence analyses and detection of HIV infections

A. Timing of specimen shipments to CDC

1. CDC can assist with laboratory testing of blood specimens during an outbreak investigation. Coordination and communication of specimen shipment with CDC is required to facilitate proper timeliness of the testing and results reporting, and depends on the preliminary assessment of the investigation. For example, if the potential outbreak appears limited in scope, all specimens can be collected and then shipped to CDC in a single shipment. In potential larger outbreak investigations, specimens can be collected and shipped weekly or bi-weekly to CDC. Other arrangements can be made with CDC as needed for the specific investigation.

B. General specimen and paperwork requirements

1. All specimens and paperwork should be coded without any personal identifiers.
2. Prepare an excel file listing the specimens with local IDs, specimen volumes, collection dates, and any local HIV and HCV test results. Email completed specimen excel file to Bill Switzer (HIV Laboratory, Diagnostics and Incidence Team Lead) at bis3@cdc.gov when the specimens are shipped to CDC.
3. HIV sequence analysis and recency testing requires a minimum of 1.0 mL serum or plasma.

C. Serum specimens

1. Collect 10–20 mL of whole blood using standard clinical venipuncture techniques.
2. Mix by gently inverting the tubes no more than eight times and allow the blood to clot by standing tubes vertically at room temperature for at least 30 minutes but not longer than 1 hour before centrifugation.
3. Place tubes in wet ice for no longer than 2 hours before centrifuging.
4. Centrifuge blood at least 15 minutes at 2200–2500 RPM at 4°C within one hour of collection.
5. Transfer 1.0 mL aliquots to pre-labeled screwcap cryovials on wet ice. Do not transfer red cells to the vial. Cap needs to be firmly screwed tight to prevent leakage.
6. Freeze aliquots at –20 to –80°C until shipped.

D. Plasma specimens

1. Collect 10–20 mL of ethylenediaminetetraacetic acid (EDTA) or acid citrate dextrose treated whole blood using standard clinical venipuncture techniques. Completely fill the labeled blood collection tube whenever possible to eliminate dilution from the anticoagulant or preservative.
2. Immediately mix the blood by gently and thoroughly inverting the tube five to ten times.
3. Centrifuge for at least 15 minutes at 2200–2500 RPM within one hour of collection.
4. Transfer 1.0 mL aliquots to pre-labeled screw cap cryovials on wet ice. Do not transfer red cells to the vial. Cap needs to be firmly screwed tight to prevent leakage.
5. Freeze aliquots at –20 to –80°C until shipped.

E. Specimen shipment

1. Place the samples in a shipping container following the instructions found at the CDC or the International Air Transport Association websites and ship on dry ice to the CDC Serum Bank STAT lab using an overnight, next morning delivery service. Specimens are shipped Monday–Thursday. CDC does not accept specimens on weekends and holidays.

CDC: <https://www.cdc.gov/laboratory/specimen-submission/shipping-packing.html>

2. Unless other arrangements are made, all shipments are to be sent to the following address. A project number will be provided by CDC if an Epi-Aid investigation is initiated.

CDC Serum Bank (STAT)
Centers for Disease Control and Prevention
1600 Clifton Road NE
Atlanta, GA 30329
“Attention: Project #”

Provide advance notice of the shipment by sending email notification to Bill Switzer (Email: bis3@cdc.gov) with the package tracking number when the samples ship. The email can also contain as an attachment the completed specimen excel file.

Appendix C

GHOST

What is GHOST?

GHOST is an acronym which stands for Global Hepatitis Outbreak and Surveillance Technology. The GHOST application, developed by the Division of Viral Hepatitis, CDC, integrates molecular, bioinformatics, and information technologies to detect HCV transmission and identify transmission networks. GHOST enables state and public health laboratories to independently conduct sustainable, real-time HCV molecular surveillance. Real-time molecular surveillance can be used to support outbreak response, investigations of endemic HCV transmission among populations at high risk, “cure-as-prevention,” and other strategies to stop HCV transmission.

How can GHOST be used to identify transmission links?

GHOST enables health departments and public health laboratories to conduct molecular surveillance and outbreak investigation by automating data processing—from raw NGS reads to the visualization of transmission networks. The output of GHOST is a graphic display of cases that are likely linked by transmission.

State public health laboratories and detection of HCV transmission networks

State public health laboratories equipped with NGS can conduct independent outbreak investigations and identification of transmission networks using GHOST. The laboratory protocol and bioinformatics tools for automatically detecting HCV transmission networks from NGS data are available at <https://webappx.cdc.gov/GHOST/>.

GHOST users must be authenticated to have access to the website. CDC provides hands-on laboratory training at GHOST workshops announced via the Association of Public Health Laboratories. All participants of GHOST workshops receive the necessary documentation and access to the GHOST website. Users may request contact information for GHOST authentication through the Division of Viral Hepatitis at CDC or the Association of Public Health Laboratories or by emailing GHOST@cdc.gov. Access is granted upon completion of workshop training or after completion of performance testing.

Appendix D

Indiana State management of an outbreak response

Multi-agency coordination

In response to emergencies that require the support of multiple agencies and jurisdictions, the State of Indiana and the Indiana State Department of Health (ISDH) utilize the Federal Emergency Management Agency's National Incident Management System and National Response Framework (https://www.fema.gov/media-library-data/1466014682982-9bcf8245ba4c60c120aa915abe74e15d/National_Response_Framework3rd.pdf). While commonly used during natural disaster response, these guidelines are designed to work for all types of hazards, and were central to Indiana's public health response to the 2015 HIV/HCV outbreak among PWID in Scott County. In order to effectively manage efforts of a multi-agency coordination system, the State of Indiana adapted its planning and response capability based upon the following operational constructs:

Executive Policy Group

Emergencies and disasters can produce issues which require prompt decisions to serve both short- and long-term emergency management needs. At times, these decisions require a high level of authority and leadership to work through governmental issues, state law and jurisdictional impacts. In order to ensure these decisions are made effectively, an Executive Policy Group is established to address issues which concern the safety and welfare of Indiana residents, property, and the environment.

The composition of the group consists of stakeholders with the authority to make policy-related decisions, but varies depending upon the type, size, and complexity of the event. These stakeholders may include, but are not limited to representatives from Indiana Department of Homeland Security, the Governor's office, Legislators, State Department of Health, Indiana National Guard, Indiana Department of Transportation, Indiana Department of Natural Resources, and the Indiana State Police.

Emergency Support Functions (ESFs)

The ESF structure used in the State of Indiana reflects the structure defined in the National Response Framework. An ESF is the grouping of governmental and some private sector capabilities into an organizational structure used to respond to an emergency event. Each ESF provides resources and services in their specialty area to support the response.

There are 15 ESFs within the National Response Framework including ESF #8—Public Health and Medical Services. The Indiana State Department of Health is the primary agency for the Indiana ESF #8. Per the Indiana Comprehensive Emergency Management Plan, the primary mission of the Indiana ESF #8 is to provide resources and personnel to support local jurisdictions to ensure the health and welfare of their residents, before, during, and after emergency or disaster events. ESF #8 provides assistance on public health issues necessary to protect the community and its citizens including mass casualty and fatality management, mental health services, medical supplies management and distribution, immunizations, epidemiological surveillance, laboratory services, environmental health, food safety, and long-term care.

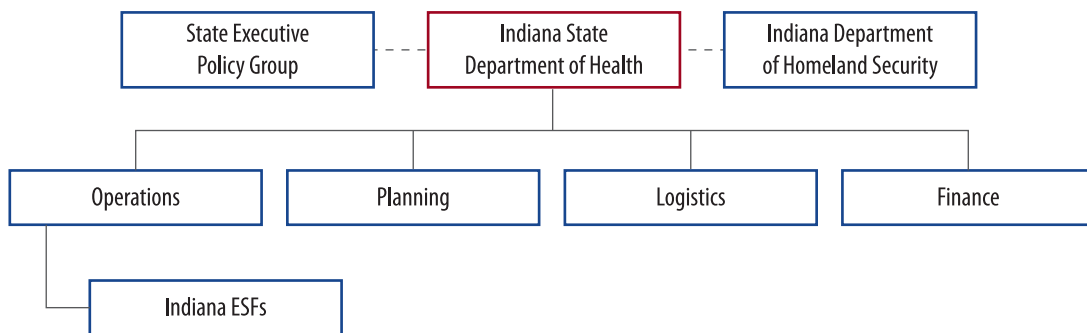
State Emergency Operations Center (EOC)

The Indiana State EOC is the physical location where multi-agency coordination occurs and is managed by Indiana Department of Homeland Security. The purpose of the State EOC is to provide a central coordination hub for the support of local, district and state needs. The State EOC can be configured to expand or contract, as necessary, to respond to the different levels of incidents requiring state assistance.

Organization and structure

The Indiana State Department of Health may act as the lead response agency during public health emergencies, disease outbreaks, or other public health and medical driven emergencies. [Figure D-1](#) represents a simplified organizational chart showing the State response structure with the ISDH as the lead response agency.

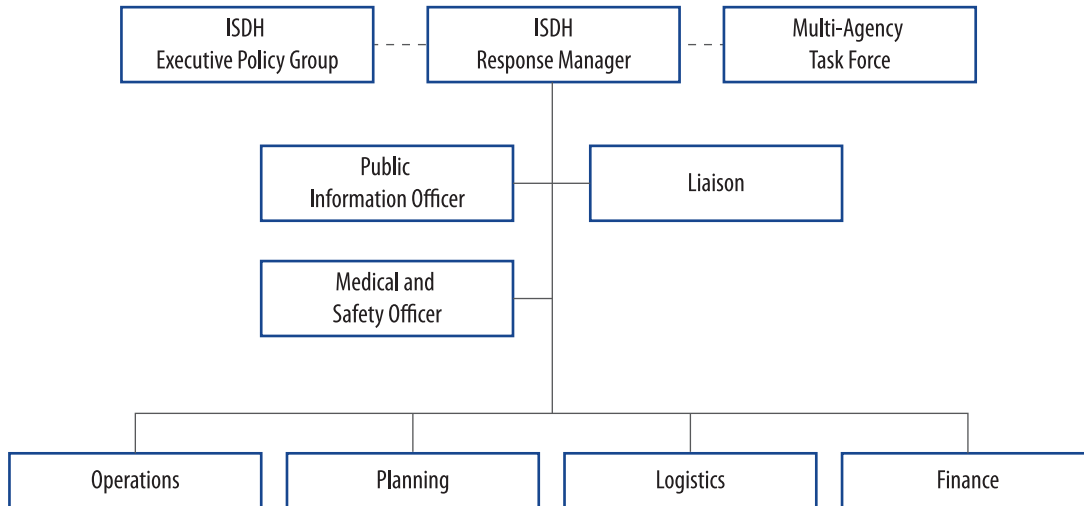
Figure D-1 Outbreak organizational chart with Indiana State Department of Health as the lead response agency



ISDH command structure

As the lead agency or support agency to a response, the ISDH implements a command structure to manage the response consistent with the National Incident Management System principles of the ICS. [Figure D-2](#) represents a simplified organizational chart showing the ISDH response structure within the agency.

Figure D-2 Indiana State Department of Health ICS command structure



ISDH Executive Policy Group

The ISDH Executive Policy Group is responsible for making the necessary executive decisions during a response. The ISDH Executive Policy Group is further responsible for communicating with the Indiana Governor's Office, State Executive Policy Group, or other executive level groups as established. The group consists of representatives from the Indiana State Health Commissioner and ISDH Executive Staff, as well as the directly impacted Division Directors.

Multi-agency task force

In most public health and medical responses, there is significant involvement from external stakeholders representing healthcare, public health, mental health, education, and other organizations and agencies, including those from the local affected area. The ISDH can convene a Multi-Agency Task Force as a mechanism to discuss response objectives and needs with a larger group of subject matter experts.

Response Manager

The Response Manager serves as the Incident Commander of the response, but is not deployed on-scene like a traditional Incident Commander. The term Response Manager is intentionally used to avoid confusion with the local response Incident Commander or a state deployment locally. The Response Manager is responsible for working directly with the ISDH Executive Policy Group and Multi-Agency Task Force as established. The Response Manager typically is served by the most pertinent Division Director, Assistant Commissioner, State Epidemiologist, or other Executive Staff. The Response Manager may have an additional Deputy Response Manager as needed. In some complex incidents, the ISDH Preparedness division may serve this role.

Command and General Staff

Public Information Officer: The ISDH Public Information Officer role is served by the ISDH Office of Public Affairs Division.

Medical & Safety Officer: This position is staffed in instances where dedicated medical and safety support is needed, and is usually staffed by an executive physician, nurse, or other person with medical and safety training.

Liaison Officer: There may exist multiple Liaison Officers performing different roles of liaisons to different groups. The following are examples:

State EOC & Homeland Security Liaison—Preparedness Division

Outreach & Education Liaison—Deputy State Health Commissioner

Operations Section Chief: Ideally this role is best served by a Division Director or Manager pertinent to the response subject, with the ability to oversee multiple division operational tasks. In some complex incidents, the ISDH Preparedness division may serve this role.

Planning Section Chief: This position is usually staffed by the ISDH Preparedness Division. The planning section may additionally include a Resource Unit Leader, Documentation Unit Leader, Situation Unit Leader, and Geographic Information System, as needed.

Logistics Section Chief: This position is usually staffed by the Preparedness Division. The Logistics section may include a Support Branch and Service Branch as needed.

Finance Section Chief: This position is usually staffed by the ISDH Finance Division.

ISDH Department Operations Center

The ISDH Department Operations Center is a physical location in which the multi-division coordination of the agency may take place. In most incidents, meetings and coordination occur in conference or virtually. However, during a large scale disaster, the Department Operations Center may be activated to support continuous coordination. The ISDH Department Operations Center is similar to the structure of the State EOC and the preceding ICS is utilized.

ISDH multi-agency coordination

In complex incidents, multi-agency incidents, or statewide disasters the ISDH Command Structure plugs into the State Response structure through multiple means. The ISDH ESF-8 Representative will serve as the main liaison to the State EOC and the Indiana Department of Homeland Security. The ISDH Executive Policy Group will have representation on the State Executive Policy Group as established. In responses in which the ISDH is not the lead agency but a support agency, the ISDH will support the Indiana Department of Homeland Security or other lead agency in the State response. The ISDH will work directly with the Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry, U.S. Department of Agriculture, or other ESF-8 Federal Partners throughout the response.

2015 Scott County HIV Outbreak

Role	Title	Division
Executive Policy Group	Executive Staff	Executive
Command Staff		
Response Manager	State Epidemiologist	ERC
Deputy Response Manger	HIV & STD Director	HIV & STD
EOC Liaison	Director of Planning & Response	PHPER
Medical & Safety Officer	Chief Medical Officer	Executive
Public Information Officer	Director of OPA	OPA
General Staff		
Operations	Director of Preparedness	PHPER
Planning	Director of Preparedness	PHPER
Finance	Finance Division	Finance
Local Command Staff		
Incident Commander	Director of LHD Preparedness	PHPER
Public Information Officer	Deputy Director of OPA	OPA
Local Liaison Officer	State Registrar	Vital Records
EOC Liaison Officer	Director of Planning & Response	PHPER
Safety Officer	Chief of Police	APD
Local General Staff		
Operations	Director of Training & Exercise	PHPER
<i>Vital Records Group</i>	State Registrar	Vital Records
<i>Immunizations Group</i>	Immunizations Director	Immunizations
<i>Mental Health Group</i>	Director of DMHA	FSSA
<i>Insurance Group</i>	Director of DFR	FSSA
<i>Care and Treatment</i>	Deputy State Health Commissioner	Executive
<i>DIS Group</i>	Local DIS	ISDH
<i>Identification Group</i>	Regional Manager	BMV
<i>Job Referral Group</i>	Regional Manager	DWD
<i>Exchange Group</i>	LHD Preparedness	SCHD
Planning	Senior Planning Coordinator	PHPER
Logistics	Director of Logistics	PHPER
<i>Support Branch</i>	Warehouse Supervisor	PHPER
<i>Service Branch</i>	Communications Manager	PHPER
Admin	Forms Coordinator	PHPER

Appendix E

Compilation of guide web links

Chapter 2

CDC-INFO <https://www.cdc.gov/cdc-info/about.html>

Information about Epi-Aids <https://www.cdc.gov/eis/downloads/requesting-epi-aid.pdf>

National Public Health Information Coalition outbreak communication guide
https://www.nphic.org/toolkits/outbreak/item/download/3962_0ffb487900a79d136ba77b5920da168d

Example of the Tennessee Department of Health HIV and HCV Outbreak Response Plan
<https://www.cdc.gov/hiv/pdf/programresources/guidance/cluster-outbreak/cdc-hiv-hcv-pwid-response-plan.pdf>

Chapter 3

Secure HIV-TRACE <https://secure.hivtrace.org/>

Detecting, investigating, and responding to HIV transmission clusters guidance
<https://wwwdev.cdc.gov/hiv/pdf/funding/announcements/ps18-1802/CDC-HIV-PS18-1802-AttachmentE-Detecting-Investigating-and-Responding-to-HIV-Transmission-Clusters.pdf>

Revised surveillance case definition for HIV infection—United States, 2014
<https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1.htm>

Case definition of acute HCV <https://www.cdc.gov/nndss/conditions/hepatitis-c-acute/>

Example of the Tennessee Department of Health HIV and HCV Outbreak Response Plan
<https://www.cdc.gov/hiv/pdf/programresources/guidance/cluster-outbreak/cdc-hiv-hcv-pwid-response-plan.pdf>

Chapter 6

Effective interventions: social network strategy of HIV testing
<https://effectiveinterventions.cdc.gov/en/HighImpactPrevention/PublicHealthStrategies/SocialNetworkStrategy.aspx>

Recommendations for partner services programs for HIV infection, syphilis, gonorrhea, and chlamydial Infection
<https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5709a1.htm>

Effective interventions: partner services
<https://effectiveinterventions.cdc.gov/en/HighImpactPrevention/PublicHealthStrategies/PartnerServices.aspx>

Emergency Management Assistance Compact website <http://www.emacweb.org/>

Sample completed EMAC form
http://www.amchp.org/programsandtopics/CHILD-HEALTH/projects/newborn-screening/Documents/Template-NBS-Req-A-section1_EMAC.pdf

Chapter 7

Implementing HIV testing in nonclinical settings: a guide for HIV testing providers
https://www.cdc.gov/hiv/pdf/testing/cdc_hiv_implementing_hiv_testing_in_nonclinical_settings.pdf

Revised guidelines for HIV counseling, testing, and referral
<https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5019a1.htm>

State HIV laws, state guidelines for healthcare workers with HIV, and youth access to STI and HIV testing and treatment information <http://hivlawandpolicy.org/state-hiv-laws>

HIV testing implementation guidance for correctional settings
<https://www.cdc.gov/hiv/pdf/group/cdc-hiv-correctional-settings-guidelines.pdf>

Prevention and control of infections with hepatitis viruses in correctional settings
<https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5201a1.htm>

Tips and tools for providing transitional care coordination
<https://careacttarget.org/library/tools-tips-providing-transitional-care-coordination>

HIV-related laws, guidelines for healthcare workers, and testing and treatment information
<http://hivlawandpolicy.org/state-hiv-laws>

Chapter 8

Laboratory testing for the diagnosis of HIV infection: updated recommendations
<https://stacks.cdc.gov/view/cdc/50872>

Chapter 9

Testing for HCV infection: an update of guidance for clinicians and laboratorians
<https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6218a5.htm>

Chapter 10

FEMA ICS Resource Center <https://training.fema.gov/emiweb/is/icsresource/index.htm>

Chapter 11

North Carolina law enforcement guide to syringe exchange programs infographic
<http://www.nchrc.org/assets/Syringe-Exchange-resources/LEO-Syringe-Exchange.pdf>

Chapter 13

The National Clinician Consultation Center <http://nccc.ucsf.edu/>

AIDSinfo website <https://aidsinfo.nih.gov/>

Recommendations for HIV prevention with adults and adolescents with HIV in the U.S., 2014
<https://stacks.cdc.gov/view/cdc/44064>

Ryan White medical care providers locator website <https://findhivcare.hrsa.gov/index.html>

HRSA's Bureau of Primary Health Care's Health Center Program online clinic locator <https://findahealthcenter.hrsa.gov/>

HIV Medicine Association website <http://www.hivma.org/Home.aspx>

American Academy of HIV Medicine website <http://aahivm.org/Default.aspx>

AIDS Education and Training Center website <https://aidsetc.org/about>

Ryan White HIV/AIDS Program
<https://hab.hrsa.gov/about-ryan-white-hiv-aids-program/about-ryan-white-hiv-aids-program>

HRSA's Community Health Center Program <https://bphc.hrsa.gov/about/>

HIV clinical care guidelines and resources

<https://hab.hrsa.gov/clinical-quality-management/clinical-care-guidelines-and-resources>

Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents living with HIV

<https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf>

Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents

<https://aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-oi-prevention-and-treatment-guidelines/0>

Compendium of evidence-based interventions and best practices for HIV prevention

<https://www.cdc.gov/hiv/research/interventionresearch/compendium/index.html>

Ryan White HIV/AIDS Program's Special Projects of National Significance

<https://hab.hrsa.gov/about-ryan-white-hiv-aids-program/previous-spns-initiatives>

Immunizations for persons living with HIV

<https://aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-oi-prevention-and-treatment-guidelines/365/figure--immunization>

Chapter 14

Recommendations for testing, managing, and treating hepatitis C <http://www.hcvguidelines.org/>

Recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease

<https://www.cdc.gov/mmwr/pdf/rr/rr4719.pdf>

American Liver Foundation online directory of listings of healthcare providers or treatment facilities for people with liver disorders <http://hepc.liverfoundation.org/find-a-healthcare-provider/>

HRSA's Bureau of Primary Health Care's Health Center Program online clinic locator <https://findahealthcenter.hrsa.gov/>

List of state Viral Hepatitis Prevention Coordinators <https://www.cdc.gov/hepatitis/partners/hepatitiscoordslist.htm>

Guidelines for the initial treatment of HCV infection

<http://www.hcvguidelines.org/full-report/initial-treatment-hcv-infection>

Guidelines for the management of acute HCV infection

<http://www.hcvguidelines.org/full-report/management-acute-hcv-infection>

Immunization recommendations for persons living with HCV

<https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hepa.html>

<https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hepb.html>

<https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/pneumo.html>

Chapter 15

The 2016 Consolidated Appropriations Act <https://www.congress.gov/114/bills/hr2029/BILLS-114hr2029enr.pdf>

Indiana State Department of Health syringe exchange program guidance for local health departments

<http://www.in.gov/isdh/files/ISDH%20SEP%20Guidance%20Version%20200%20FINAL%20-%202010-04-2016-EC.pdf>

CDC, HRSA and SAMHSA agency-specific guidance on use of federal funds for SSPs

<https://www.aids.gov/federal-resources/policies/syringe-services-programs/>

North American Syringe Exchange Network website www.nasen.org

Examples of SSP models

<http://www.in.gov/isdh/files/ISDH%20SEP%20Guidance%20Version%20200%20FINAL%20-%202010-04-2016-EC.pdf>

Syringe services program (SSP) development and implementation guidelines for state and local health departments (NASTAD) https://www.nastad.org/sites/default/files/055419_NASTAD-SSP-Guidelines-August-2012_0.pdf

Syringe distribution laws

<http://lawatlas.org/datasets/syringe-policies-laws-regulating-non-retail-distribution-of-drug-parapherna>

Resources and tools for developing and implementing SSPs

<https://www.cdc.gov/hiv/pdf/risk/cdc-hiv-developing-ssp.pdf>

Chapter 16

Principles of drug addiction treatment https://d14rmgrwzf5a.cloudfront.net/sites/default/files/podat_1.pdf

SAMHSA's opioid treatment program directory <http://dpt2.samhsa.gov/treatment/directory.aspx>

ADAP coverage database <https://www.nastad.org/sites/default/files/ADAP-Formulary-Database-Users-Guide-FINAL.pdf>

SAMHSA's Behavioral Health Treatment Services Locator <https://findtreatment.samhsa.gov/>

SAMHSA's medication-assisted treatment website <https://www.samhsa.gov/medication-assisted-treatment>

Detoxification and substance abuse treatment <http://store.samhsa.gov/shin/content/SMA15-4131/SMA15-4131.pdf>

Oxford House safe housing programs (overview)

http://www.oxfordhouse.org/userfiles/file/purpose_and_structure.php

Therapeutic communities model of residential treatment for substance use

<https://www.drugabuse.gov/publications/research-reports/therapeutic-communities/what-are-therapeutic-communities>

Recovery-Oriented Systems of Care <http://www.williamwhitepapers.com/pr/CSAT%20ROSC%20Definition.pdf>

Examples of Recovery-Oriented Systems of Care

http://www.michigan.gov/mdhhs/0,5885,7-339-71550_2941_4871_4877_48561-113480--,00.html

http://www.michigan.gov/documents/mdch/ROSC_FS-_SUD_Agency_Directors_337044_7.pdf

<https://www.dshs.texas.gov/substance-abuse/ROSC/>

Narcotics Anonymous® <https://www.na.org/meetingsearch/index.php>

Cocaine Anonymous® <http://www.ca-online.org/meetings/>

Alcohol Anonymous® http://www.aa.org/pages/en_US/find-aa-resources

LifeRing sober living® <http://lifering.org/>

Oxford Houses™ directory <http://www.oxfordhouse.org/userfiles/file/house-directory.php>

SMART Recovery® non-abstinence based treatment program for substance use disorder

<http://www.smartrecovery.org/>

Moderation Management® non-abstinence based treatment program for substance use disorder

<http://www.moderation.org/meetings/>

Example of a facility-based recovery program <http://marsproject.org/>

Chapter 18

Preexposure prophylaxis for the prevention of HIV infection—2014: a clinical practice guideline

<https://stacks.cdc.gov/view/cdc/23109>

Brief guide for covering the cost of PrEP <http://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-paying-for-prep.pdf>

PrEP infographics, videos, fact sheets, reports, and other educational materials

<https://www.cdc.gov/hiv/risk/prep/index.html>

National Clinician Consultation Center <http://nccc.ucsf.edu/clinician-consultation/prep-pre-exposure-prophylaxis/>

Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV—United States, 2016 <https://stacks.cdc.gov/view/cdc/38856>

Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis <https://stacks.cdc.gov/view/cdc/20711>

Chapter 19

Recommendations for identification and public health management of persons with chronic hepatitis B virus infection <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5708a1.htm>

Appendix B

Instructions for shipping laboratory specimens to CDC

<https://www.cdc.gov/laboratory/specimen-submission/shipping-packing.html>

Appendix C

Global Hepatitis Outbreak and Surveillance Technology website <https://webappx.cdc.gov/GHOST/>

Appendix D

National Response Framework

https://www.fema.gov/media-library-data/1466014682982-9bcf8245ba4c60c120aa915abe74e15d/National_Response_Framework3rd.pdf