Hepatitis C and HIV Clinical Guidance Package

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Background

The opioid misuse epidemic in the United States has contributed to high rates of fatal and nonfatal drug overdoses as well as a range of negative health outcomes¹. A consequence of the opioid crisis is increased blood-borne infections, including viral hepatitis, human immunodeficiency virus (HIV), and bacterial and fungal infections. These infections are spread through contaminated injection drug equipment and unsanitary conditions. HIV is also commonly transmitted through sexual contact. Although less frequent, hepatitis C virus (HCV) can also be spread through sex with an HCV-infected person and through male-to-male sexual contact².

The number of people who inject drugs (PWID) in the United States was estimated at nearly 3.7 million in 2018. In 2022, Maine reported an estimated 54.3 drug overdose deaths per 100,000 people³. In 2023, there were an estimated 9,879 fatal and nonfatal overdoses. Rural communities like Maine are disproportionately affected by the opioid epidemic, have been most affected by overdoses, and are considered most vulnerable to the rapid spread of blood-borne viruses. Sharing needles, syringes, or other equipment (e.g. cookers, water, and cotton) to inject drugs puts people at high risk of transmission of HIV, HCV, and hepatitis B virus (HBV).

- PWID accounted for about 15% of people living with diagnosed HIV infection in the United States in 2022.
- Approximately 10% of people newly diagnosed with HIV in 2022 reported injection drug use.
- Among people diagnosed with acute HCV infection and information about injection drug use in 2015, 64% were PWID.
- Within 1 to 5 years of starting to inject drugs, 50% of drug users may already have been infected with HBV. About 6% to 10% of injection drug users who are infected with HBV become chronic active carriers who may infect others; they may also develop end-stage liver disease⁴.
- Among risk behaviors and exposures identified for reported cases of acute HCV infection in Maine (2022-2024), injection drug use is most reported.

Purpose of Resource Package

This clinical guidance package is designed for health care providers. It serves as a ready-to-use resource for providers and practices looking to increase HIV and HCV screening and treatment, promote prevention strategies for patients at risk, and improve patient care in a syndemic approach that addresses the intersectionality of HIV, viral hepatitis, sexually transmitted infections (STIs), and harm reduction.

A few notes on using this clinical guidance package:

- It only references previously established recommendations, mainly from the U.S. CDC and the American Association for the Study of Liver Diseases.
- It provides recommendations based on best practices. Clinical decisions should always be based on individual patient needs.

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- It is designed for adult patients only. Pediatric patients have unique needs that may not be adequately addressed here.
- There are links throughout the document that provide additional detail and external resources. These external resources will need to be accessed for comprehensive guidance, especially related to treatment. The best way to make use of this guidance package is on a device that has access to the internet.
- Citations are included in the Endnotes and may duplicate what has been referenced in the various links.



• Section 4: Follow up testing, treatment and linkage to care recommendations

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Section 1: Risk Factors for Routine HIV and HCV Screening

ASSESS FOR BEHAVIORS THAT INCREASE THE RISK OF HIV/HCV TRANSMISSION

- Identify if a patient engages in IV drug use, non-IV drug use, or certain types of sexual activity.
- Individuals who endorse certain behaviors are at increased risk for infection with HIV or HCV and should be tested more regularly.
- Universal <u>HCV</u> and <u>HIV</u> screening is recommended for everyone else, including pregnant persons.

Table 1: Behaviors associated with an increased risk of <u>HIV</u> and <u>HCV</u> transmission

D	oes the patient engage in IV and/or non-IV drug use?				
	 This includes, but is not limited to: Injection drug use Intranasal illicit drug use Use of glass crack pipes Sharing drug preparation equipment, such as cookers or filters, used to prepare injection drugs⁵ 				
	IF YES TO ANY, CONDUCT ROUTINE SCREENI	NG FOR HIV AND HCV			
E	Does the patient engage in certain types of sexual activity? Eliciting information about the types of sexual practices a patient has engaged in can help assess their risk for HIV, STIs and HCV. It can also help identify the best screening, treatment and prevention strategies.				
	 Anal or vaginal sex with someone living with HIV Male-to-male sexual contact Sex with more than one sex partner since their last HIV test Exchange sex for drugs or money Diagnosed with or treated for another STI Sex with anyone with the above risk factors or anyone whose sexual history they don't know 	 Sex with an HCV-infected person Male-to-male sexual contact (less common) 			
	IF YES TO ANY, CONDUCT ROUTINE SCREENING FOR HIV and STIS	IF YES TO ANY, CONDUCT ROUTINE SCREENING FOR HCV			
Н	Has the patient been incarcerated?				
	□ Spent any amount of time in a <u>correctional facility</u> such as a jail or prison ⁶ .				
	IF YES, CONDUCT ROUTINE SCREENING FOR HCV				

Testing should be provided to anyone who requests it without having to disclose the reason.

Resources on eliciting sexual exposures:

- National Coalition for Sexual Health: Sexual Health and your patients: A provider's guide
- <u>A Guide to Taking a Sexual History</u>
- How to Talk with Patients and Parents about Opt-Out Screening (with videos)

Resources on eliciting substance use behaviors:

- U.S CDC: Empathy: Talking to Patients About Substance Use Disorder
- U.S. CDC: <u>Remove Stigma: Talk with Your Patients about Substance Use Disorder</u>
- <u>Reducing the Stigma of Addiction:</u> What we say and do matters to patients with substance use disorder

Section 2: HIV, Viral Hepatitis and STI Screening Recommendations Summary

ONCE RISK BEHAVIORS HAVE BEEN ASSESSED, DETERMINE FREQUENCY OF SCREENING

- Determine if screening should be <u>routine</u>, at least once, or is not indicated.
 - Routinely assess for the presence of new risk behaviors since the patient's last visit.
 - A patient does not need to disclose any specific behaviors to be eligible for screening.
 - If the person is pregnant, screen for all pathogens listed.
- Identify prevention and risk mitigation steps based on behaviors.
- Vaccinate against hepatitis A and hepatitis B.
- Administer PEP/PrEP, if indicated.

WHAT IS ROUTINE OR PERIODIC SCREENING?

Who:

- All persons with ongoing risk factors, while risk factors persist.
- All persons who have engaged in risk factors since their last test, even if the person has no ongoing risk factors.

How often:

- <u>At least annually</u>.
- <u>Up to every 3-6 months</u> for people with ongoing risk factors.
- More frequent testing may be recommended during periods of elevated transmission (i.e. outbreaks).

	Risk-Based Screening		Pregnant	Universal
	see <u>S</u>	<u>ection 1</u>		
	Sexual exposures	IV and non-IV drug use		
	S	CREENING RECOMMENDATIO	NS	
HIV	Routine screening	Routine screening ⁱ	Every pregnancy ⁱⁱ *Syphilis testing in	At least once for all patients 13-64
HCV	May be recommended ⁱⁱⁱ		pregnancy is <u>legally</u> <u>required</u> in Maine	At least once all patients 18 and older
Syphilis	Routine screening Syphilis screening Algorithm (PDF)	Not indicated		Not indicated
Chlamydia	Routine screening	Not indicated		Not indicated
Gonorrhea	Routine screening	Not indicated		Not indicated
HBV	Routine screening	Routine screening		At least once

ⁱ Key Populations: <u>Identification and Management of HCV in People Who Inject Drugs (AASLD)</u>

ⁱⁱ CDC pregnancy screening recommendations for <u>HIV</u>, <u>HCV</u>, <u>STIs</u>, <u>HBV</u>.

^{III} Although less common, certain sexual behaviors indicate screening for HCV including but not limited to: sex with an HCVinfected person, male-to-male sexual contact (especially HIV-infected male to male sexual contact). Anal sex may damage the lining of the rectum and make it easier to pass the HCV through the blood.

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		Maine. See Maine State Law reg	
Risk mitigation	Discuss safer sex practices and referrals Section 3: <u>Risk mitigation</u> recommendations	Discuss harm reduction practices and referrals Section 3: <u>Risk mitigation</u> recommendations	If pregnant patient endorses risk behaviors refer to Section 3: <u>Risk</u> <u>mitigation</u> <u>recommendations</u>
Vaccination	-	ensive list of prenatal vaccination	
Other risk mitigation services	 for anyone with risks of acquises or drug use. People who have a sexul partner living with HIV People who have not conhaving sex People who have been of past 6 months People who share needled drug equipment Guide to prescribing Pre-Ex Guide to prescribing Pre-Ex Through sexual contact Through sexual contact Through sexual assault 	led as an HIV prevention option puiring HIV infection through al partner or an injection nsistently used condoms when diagnosed with an STI in the les, syringes, or other injection posure Prophylaxis (PrEP) d for HIV post-exposure ve had possible exposure to on drug equipment	
Referrals for additional services	prevention) See <u>Referrals section (sexual disorder).</u>	l health, harm reduction, menta	al health, substance use

Tests to order

THE FOLLOWING TESTS SHOULD BE ORDERED TO DETERMINE IF THERE IS AN ACTIVE INFECTION

- Order the following tests based on the recommendations above.
- All recommended tests should be performed during the same visit, if possible.

Pathogen	Test to order	Specimen Type	Notes
HIV	 HIV 1/2 antigen/antibody (Ag/Ab) combination assay, with reflex to supplemental HIV- 1/HIV-2 antibody- differentiating test if the Ag/Ab test is positive <u>AND</u> Quantitative HIV RNA (viral load) depending on results of initial test 	Blood draw Finger prick or oral fluid for rapid point-of- care test	If the patient is unlikely to return for the results of the initial lab-based test, consider using a rapid point-of-care test or collect all samples needed to diagnose HIV in a single visit. When using point-of-care sampling as the initial screening test, confirmatory testing requires obtaining an additional sample (blood draw). For more information about HIV testing guidelines see <u>HIV - STI Treatment</u> Guidelines
HCV	 Hepatitis C antibody (anti-HCV) <u>with reflex</u>^{iv} to RNA (HCV RNA). 	Blood draw Finger prick for rapid point-of-care test or dry blood spot testing ^v .	Collect all samples needed to diagnose hepatitis C in a single visit and order HCV RNA testing automatically when the HCV antibody is reactive. This automatic testing streamlines the process because it occurs without any additional action on the part of the patient or the clinician. <u>HCV RNA point-of-care tests were FDA</u> <u>approved in 2024.</u>
HBV	All the following: Image: HBV surface antigen (HBsAg) Image: HBV core antibody (anti-HBc) Image: HBV surface antibody (anti-HBs)	Blood draw	CDC now recommends use of the triple panel test. Any periodic follow-up testing can use tests as appropriate based on the results of the triple panel.

^{iv} Reflex means that when the HCV antibody test is reactive, the laboratories should automatically perform NAAT testing for HCV RNA detection.

^{iv} A dried blood spot (DBS) is collected by fingerstick and is an alternative to venipuncture for collecting blood. After performing a fingerstick, drops of blood are placed on a specialized collection card and then air dried before shipping to the laboratory for analysis. DBS testing is not widely available. Contact Maine CDC for more information on access to DBS.

Syphilis	 Nontreponemal test (e.g., Venereal Disease 	Blood draw	Use of only one type of serologic test (nontreponemal or treponemal) is
	Research Laboratory	Finger prick or	insufficient for diagnosis. There are two
	[VDRL] or rapid plasma	oral fluid for	different <u>algorithms</u> frequently used to
	reagin [RPR] test)	rapid point-of-	diagnose syphilis, both of which are
	AND	care test	acceptable.
	 Treponemal test (e.g., 		
	the T. pallidum passive		
	particle agglutination		
	[TP-PA] assay, various		
	EIAs,		
	chemiluminescence		
	immunoassays [CIAs]		
	and immunoblots, or		
	rapid treponemal		
	assays).		
Chlamydia	Chlamydia trachomatis	Urine (first-	Determine which site to test:
	NAAT	pass ^{vi}), vaginal	Testing should be performed for all sites
		swab (may be	where the patient reports engaging in
		self-collected),	sexual contact.
		or other	• Patients with vaginas: vaginal swab,
Gonorrhea	Neisseria gonorrhoeae	bodily fluid	cervical swab or a urine sample. Self-
	NAAT, POC NAAT, or		collected vaginal swabs may be
	culture. NAATs and POC		considered as an alternative to
	NAATs allow for the		provider-collected swabs.
	widest variety of FDA-		• Patients with penises: first-pass urine
	cleared specimen types.		sample or male urethral swabs.
	Collection methods and		• Testing is not limited to vaginas or
	specimen types vary by		urethras and may also include
	NAAT manufacturer;		oropharynx and/or rectal testing.
	consult the product		Taking a thorough patient history is
	insert.		important in order to identify which sites
	AND		should be tested.
	In case of suspected or		
	documented treatment		
	failure, perform both		
	culture and		
	antimicrobial		
	susceptibility.		

 $^{^{\}nu i}$ The first-pass part of the urine is the first 15-20 ml.

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Maine State Law regarding HIV and STI Screening

HIV testing when screening for other sexually transmitted infections

A Maine law passed in 2023 requires all health care providers to include HIV testing when conducting tests for other sexually transmitted infections (STIs). For example, when conducting testing for syphilis, gonorrhea, or chlamydia, providers should also discuss and seek consent from patients to conduct HIV testing as STIs can commonly occur together.

Full rule: <u>Title 5, §19203-G: HIV testing in conjunction with testing for possible sexually transmitted</u> <u>diseases and infections</u>

HIV screening during pregnancy and for newborns

Maine law requires health care providers to include an HIV test in the standard set of prenatal screening and medical tests. All pregnant people should be tested for HIV as early as possible in each pregnancy. A second test in the third trimester is recommended for those with ongoing risk. This rule also requires that a health care provider caring for a newborn should test the infant for HIV and ensure the results are available within 12 hours of birth if the health care provider does not know the HIV status of the birthing person. If a person declines to be tested for HIV based on this rule, this should be documented in the medical record.

Full rule: <u>Title 5, §19203-A: Voluntary informed consent required</u>

Voluntary informed consent for HIV testing

HIV testing must be voluntary and done only with a patient's knowledge and understanding that an HIV test is planned. The patient must be informed verbally or in writing that an HIV test will be performed unless the patient declines. The oral or written information given to the patient should include an explanation of what an HIV infection involves and the meaning of a positive or negative result. The patient must also be provided the opportunity to ask questions about HIV testing.

Full rule: Title 5, §19203-A: Voluntary informed consent required

Reporting of positive HIV and HCV results

Maine law requires providers to report all positive HIV and HCV tests to the Maine CDC within 48 hours of diagnosis. This reporting can be done by electronic lab report; by fax to 1-800-293-7534, or by phone to 1-800-821-5821.

Full rule: <u>10-144</u> (PDF)

Syphilis screening during pregnancy

Maine law requires healthcare providers to test pregnant persons for syphilis. It also allows healthcare professionals to provide expedited partner therapy for sexually transmitted infections (STIs).

Full rule: Title 22, §1231: Blood sample for laboratory test

Expedited Partner Therapy Implementation Rules

Maine law requires that health care professionals offer counseling to patients who are infected with a sexually transmitted infection (such as, but not limited to, chlamydia and/or gonorrhea) and must provide written materials developed by the Maine CDC Infectious Disease Prevention Program for their partners who will receive Expedited Partner Therapy (EPT) either as a prescription to be filled or as medication to be taken. These materials are intended to assist health care professionals in counseling and providing EPT to their patients and their partners.

Full rule: Title 22, §1242: Expedited partner therapy

Section 2.1: HIV AND HCV Pregnancy Screening Recommendations

SCREEN ALL PREGNANT PERSONS

- Determine if screening should be routine or one-time during each pregnancy, depending on if the person is at increased risk.
- Screen for all listed pathogens.
- Test type does not differ for pregnant persons.

Population to screen	Recommended
	Screening
First prenatal visit (regardless of timing)	
All pregnant women, every pregnancy	
An pregnant women, every pregnancy	
	Syphilis
All pregnant women less than 25 years of age	Chlamydia
AND	Gonorrhea
Pregnant women >25 years at increased risk due to:	
Sexual exposures	
 IV- and non-IV drug use exposures 	
 Late entry to prenatal care (first visit during the second trimester or 	
later) or no prenatal care, unstable housing or homelessness.	
Third trimester (repeat screening)	
Pregnant women at increased risk due to:	Syphilis *at 28
Sexual exposures	weeks
 IV- and non-IV drug use exposures 	HIV *at 36 weeks
 Late entry to prenatal care (first visit during the second trimester or 	Chlamydia
later) or no prenatal care, unstable housing or homelessness.	Gonorrhea
At delivery	
Pregnant women at increased risk due to:	Syphilis
Sexual exposures	
 IV and non-IV drug use exposures 	
 Late entry to prenatal care (i.e., first visit during the second trimester 	
or later) or no prenatal care, unstable housing or homelessness.	
AND	
Pregnant women not screened during pregnancy	
Pregnant women with signs and symptoms of hepatitis (HBV and HCV	
only)	
Pregnant women who deliver a stillborn infant (Syphilis only)	

Section 2.3 HCV Testing Sequence and Interpretation

Below is the U.S. CDC recommended testing sequence for diagnosing current (active) hepatitis C infection. Note this testing sequence does not distinguish between an acute infection and a chronic infection with hepatitis C. The testing sequence consists of initial HCV antibody testing (using either a rapid or laboratory-conducted assay), followed by HCV RNA testing for all persons with a positive HCV antibody test. It is important to note that routine HCV testing and treatment is cost-effective, even when linkage to HCV treatment after testing was poor and the rate of HCV reinfection among injection drug users was high.



Interpretation of Results

HCV Antibody	HCV RNA	Interpretation	Further Action /Counseling	Treatment
Positive	Positive	Current, active HCV infection	Provide appropriate counseling regarding active HCV infection	Link the individual to treatment
Positive	Negative	Prior exposure to HCV; no current HCV infection. Consistent with spontaneous clearance or prior HCV treatment.	Individual remains susceptible to HCV, provide appropriate counseling regarding harm reduction	No treatment is required
Negative	Positive ^{vii}	Acute HCV infection. HCV likely acquired in the past 3 months.	Provide appropriate counseling regarding active HCV infection	Link the individual to treatment
Negative	Negative	No HCV infection	Individual remains susceptible to HCV. Provide appropriate counseling regarding harm reduction	No treatment is required

^{vii} Individuals who have a negative HCV antibody test in the setting of a recent exposure to HCV may possibly have acute or very early HCV infection. In this situation, an HCV RNA test should be ordered and, if positive, would indicate acute or very early HCV infection. Given the potential fluctuations of HCV RNA levels early after infection, a follow-up HCV RNA level is indicated for individuals with a recent (within 6 months) exposure to HCV if the HCV RNA is negative.

Section 2.4 HIV Testing Sequence and Interpretation

The CDC and APHL HIV testing algorithm utilizes an <u>HIV-1/2</u> antigen-antibody immunoassay as the initial test, followed by an HIV-1/2 differentiation assay for positive test results. This HIV testing algorithm provides for a more accurate diagnosis of acute HIV-1, a more accurate diagnosis of HIV-2, fewer indeterminate results (due to a shorter window period), and a faster turnaround time than previous approaches. Although the use of this algorithm will enhance earlier detection of acute HIV-1 infection, no single test is capable of detecting HIV immediately following HIV acquisition during the window period. The same



patient blood sample should be used for the initial screening test and the HIV differentiation assay.

Interpretation of Results

HIV Ag/Antibody	HIV-1/HIV-2 ^{viii} differentiation assay	HIV- 1/HIV-2 RNA	Interpretation	Further Action /Counseling	Treatment
Negative	N/A	N/A	No infection with HIV-1 or HIV-2, unless the individual undergoing testing has acquired HIV within the past 30 days.	If acute HIV is suspected, then perform an HIV-1 RNA test.	No treatment
Positive	Positive for HIV-1 Negative for HIV-2	N/A	HIV-1 infection	Provide appropriate counseling regarding active HIV infection	
Positive	Negative for HIV-1 Positive for HIV-2	N/A	HIV-2 infection	Provide appropriate counseling regarding active HIV infection	Provide/ link to
Positive	Positive for HIV-1 Positive for HIV-2	N/A	HIV-1 infection and HIV-2 infection coinfection	Provide appropriate counseling regarding active HIV infection	treatment
		HIV-1 RNA is positive	Acute HIV-1 infection	Provide appropriate counseling regarding active HIV infection	
Positive	HIV-1 negative/ indeterminate Negative HIV-2	HIV-1 RNA is negative	No HIV-1 or HIV-2 (initial reactive immunoassay result was a false-positive). Alternatively, in a person with risk factors for acquiring HIV-2, these test results could indicate acute HIV-2.	Follow-up testing with HIV-2 NAAT should be considered if an individual has epidemiologic risk factors for exposure to HIV-2.	No treatment

^{viii} AIDS is caused by 2 known types of HIV: HIV type 1 (HIV-1) and HIV type 2 (HIV-2). Both types are similar in viral morphology, overall genomic structure, and its ability to cause AIDS.

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Section 3: Talking Points and Recommendations for Risk Mitigation

DISCUSS RISK MITIGATION WITH ALL PERSONS WHO ENDORSE RISK BEHAVIORS

- Regardless of HIV and HCV results, this is an opportunity to discuss steps to reduce transmission of HIV, HCV, HBV, and STIs through prevention methods.
- Provide information about how to reduce the risk of transmission during sex, if applicable.
- Provide information about how to reduce the risk of transmission during IV and non-IV drug use, if applicable.

Recomme	Recommendations and talking points to discuss with patient based on behaviors		
	Safer Sex	materials	
	People with sexual exposures		
Talking Points	Condom Use: Consistent external or internal condom use is	Chlamydia Fact Sheet	
Taiking Points	recommended during vaginal, anal, and oral sex to reduce the		
	risk of HIV, STIs and unintended pregnancy.	Gonorrhea Fact Sheet	
	 Lubrication: Water- or silicone-based lubricants are 	<u>Conomiea ract sheet</u>	
	recommended to reduce friction and lower the risk of condom	EPT Chlamydia Handout	
	breakage.	(PDF)	
	 Barrier Methods: Dental dams or condoms are recommended 		
	for oral sex to reduce STI transmission risk.	EPT Gonorrhea Handout	
	 Regular Testing: Routine STI, including syphilis and HIV testing, 	(PDF)	
	is recommended based on individual risk factors and exposure.	<u>(+ 0+)</u>	
	Testing helps with early detection and treatment.	EPT Patient Guide (PDF)	
	Monogamy or Reduced Partners: Maintaining a monogamous		
	relationship or limiting sexual partners reduces exposure to	HIV and STI Prevention	
	potential STIs.	Options: PrEP, PEP, and	
	 Open Communication: Promote honest communication about 	Doxy-PEP Explained - Q	
	STI status, sexual history, and boundaries with partners.	Care Plus	
	□ Substance Use:		
	 Avoid using substances before or during sexual activity to 	Doxy-PEP patient	
	maintain safer decision-making.	<u>handout</u>	
	 Provide referrals for substance use resources if needed 		
	including harm reduction supplies, counseling, or treatment	Doxy PEP FAQs	
	for a substance use disorder (SUD)		
	Use inclusive and non-judgmental language to create a safe	Maine CDC Hepatitis A	
	space for discussions about sexual health.	Flyer, Pocket Card	
	Partner Notification:		
	 Support confidential partner notification systems to 	<u>TellYourPartner.org</u> –	
	encourage testing and treatment among potentially exposed	Anonymous partner	
	partners.	notification texting	
	 Contact a Maine CDC Disease Intervention Specialist to 	service.	
	assist with partner elicitation and notification.		

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	Discuss PrEP and PEP to p	revent HIV infection	Hotlines:
	-	ure prophylaxis (PrEP) for individuals	National HIV/AIDS
	at high risk of HIV expo		Hotline: 1-800-CDC-
		oost-exposure prophylaxis (PEP) as an	INFO (232-4636)
	· · · · · · · · · · · · · · · · · · ·	tool after potential HIV exposure	National Domestic
	PEP	PrEP	Violence Hotline: 1-800-
	 PEP is medicine that prevents HIV after a possible exposure. PEP is for emergency situations only. PEP must be started within 72 hours (3 days) after exposure. Discuss Doxy PEP to prevent bisexual, and other men vertication of the started second secon	 PrEP PrEP is medicine that greatly reduces your chance of getting HIV from sex or injection drug use. PrEP is for people without HIV who may be exposed to HIV through sex or injection drug use. Most insurance plans and state Medicaid programs cover PrEP. ent other STIs: **For all gay, who have sex with men (MSM) and /) with a history of at least one 	799-SAFE (7233)
Services to provide during the visit	 benefits and harms of usin of oral, vaginal, or anal sex Prescribe PrEP and PEP, if ind 	icated: d PrEP Guidance (for HIV prevention)	
	 Screening and Treatment: Screen for asymptomatido not present with symptom 		
	 Encourage adherence to complications and further tra 	prescribed treatments to prevent nsmission.	
	Expedited Partner Therapy (E		
	 EPT is the clinical practi patients diagnosed with Healthcare providers ca medications to take to t the partner(s). 		
	More information: EPT Vaccination: Advocate for vac	guidelines and resources. ccines such as hepatitis A and	
	hepatitis B to protect against	•	
	Birth Control: Provide compre		
	birth control methods at this		

	If a referral is necessary, see list of free or low-cost STI services in	
	Maine: STD Data - HIV, STD, and Viral Hepatitis Program - Division	
	of Disease Surveillance - Maine CDC: DHHS Maine	
	or bisease surveinance - Marie ebe. Britis Marie	
	Harm Reduction	
	People who inject drugs	
Talking Points	Avoid sharing needles, syringes, or other drug equipment.	How to use nasal
	Even cooker/cotton sharing can contribute to transmission.	<u>Naloxone</u>
	Be careful not to get someone else's blood on your hands,	
	needles, syringes, or other injection equipment.	OD-ME App for
	Dispose of syringes safely after one use. People can put them	overdose rescue
	in a sharps container or another container like an empty	<u>education</u>
	bleach or laundry detergent bottle. Keep all used syringes and	
	needles away from other people.	Safe(r) Drug Use 101
	Avoid using substances before or during sex to maintain safer	
	decision-making.	<u>Hotlines:</u>
	Use in the presence of other people or have a safety net. If it	Massachusetts
	is not possible to be physically with someone, there are free,	Overdose
	trusted and anonymous options that use volunteers to stay on	Prevention Helpline
	the phone with you and call emergency services if needed.	(also serves Maine):
	Test your drugs with fentanyl test strips.	(800) 972-0590 or
	Have Naloxone (for overdose reversal) on hand. To search for	Home - Safespot
	organizations that distribute free naloxone, visit: Get Maine	Overdose Hotline.
	Naloxone – Find Narcan [®] / Naloxone in Maine or Find	
	Naloxone in Maine – Maine Drug Data Hub	
	Start small and go slow. This will allow you to test the strength	
	of the drug and how you respond to it. If you are injecting,	
	start with a small amount (maybe less than half of what you'd	
	typically use) and wait 20 seconds to see how you feel. You can	
	always take more, but you can never take less. If it feels off,	
	consider using less or not using it.	
	Consider alternatives to injection. Smoking or using a pipe,	
	snorting, swallowing, "booty bumping" are all forms of harm	
	reduction. While smoking is not harmless, it does reduce	
	concerns like infections and wounds at the injection site,	
	transmission of HIV and hepatitis C, soft tissue infections,	
	abscesses, vein damage, and endocarditis.	
	Vaccination: Advocate for vaccines such as hepatitis A and	
	hepatitis B to protect against infections.	
Services to	Connect patients with community resources, including harm	1
provide during	reduction or syringe services programs, to ensure access to	
the visit	sterile syringes and to address other social and behavioral	
	health needs. Syringe service programs are located across	
	Maine: Syringe Service Programs MeCDC Maine DHHS	
	If syringe services programs are not easily accessible, provide	
	prescriptions for syringes or information about	
	nonprescription pharmacy sales.	

Referrals for safer sex, harm reduction and other services

Prior to completing a patient referral: Ensure the proper releases are signed for connection to infectious disease or other health care provider as well as to medical case management.

Mental Health and Substance Use Disorder

• <u>Treatment Connection</u>: Over the past several years, Maine DHHS has worked to adopt a new online treatment referral resource called "Treatment Connection" that is available to clinicians, patients, and family members of those seeking treatment for SUDs and/or MH conditions. This resource is available through an online platform or telephone and can be used by clinicians, patients, or family members to locate SUD and MH treatment providers throughout the state; the online tool is a fully searchable database that can be used to locate available SUD and MH providers by zip code, town/city, or statewide, as well as the type of service required.

To locate a facility, go to: <u>www.treatmentconnection.com</u>. These facilities have been reviewed by the state government where it is located. Additional restrictions may apply if seeking treatment outside of your state of residence.

- <u>The Overdose Prevention Through Intensive Outreach Naloxone and Safety (OPTIONS) initiative</u>: Whether you want to make a change related to your own substance use, or you are exploring resources and services for a loved one, your local OPTIONS Liaison is someone you can trust to help you navigate. Liaisons are substance use professionals plugged into a network of local resources for harm reduction, treatment, and recovery, as well as other services. They offer judgment-free guidance, understanding that everyone's path is unique and not every service is a good fit for every person. Get in touch now and read more about the ways to find support below. Find OPTIONS Liaisons by County: <u>OPTIONS Liaisons Options</u>
- Suicide & Crisis Lifeline: 988 Suicide & Crisis Lifeline (simply dial 988).
- <u>MaineMOM</u>: MaineMOM improves care for pregnant and postpartum people with opioid use disorder and their infants by integrating maternal and substance use treatment services. Information about MaineMOM service locations and how to refer to services can be found at <u>MaineMOM.org</u>.
 <u>Services Include</u>:
 - Offer a team-based approach to care, including a perinatal provider, substance use counselor, patient navigator, nurse care manager, behavioral health clinician, and recovery coach.
 - Provide pregnant and parenting individuals with a treatment plan for counseling, recovery support, and treatment, including medications.
 - Provide coordination and a plan for supportive prenatal, delivery, and postpartum care, including family planning.
 - Coordinate referrals for other services a person might need during and after pregnancy like health care, housing, or transportation.

Section 4: Follow-up testing, treatment and linkage to care recommendations

FOR PATIENTS WHO TEST POSITIVE FOR HIV OR HCV

- Initiate treatment **OR** rapidly link to care to reduce viral load, improve patient outcomes, and prevent further transmission.
- Primary care providers can treat HIV and HCV.
- Evaluate the presence of any coinfections (especially HIV, HCV and HBV) prior to initiating treatment.
- Initiate treatment **OR** rapidly link to care if the patient is positive for any STIs, including gonorrhea, chlamydia, or syphilis.
- Report positive results to Maine CDC.

Reporting Requirements

Report any positive **HCV**, **HIV**, **HBV**, **Chlamydia**, **Syphilis or Gonorrhea** test to Maine CDC by electronic lab report; by fax to 1-800-293-7534, or by phone to 1-800-821-5821. See full <u>Notifiable Diseases and Conditions</u> <u>List</u>.

Link patient to care immediately

If necessary, provide a referral for patients. Linkage to care is a crucial early step in successful HIV/HCV treatment and is typically defined as **the completion of a first medical clinic visit after an HIV/HCV diagnosis.** Without timely linkage to care, individuals with HIV and/or HCV miss an opportunity to benefit from treatment at the earliest stage feasible.

HCV

- Maine CDC has linkage to care coordinators to assist patients with accessing care for hepatitis C.
 - <u>Hepatitis C Linkage to Care Form</u>: This form is for people who have questions about hepatitis C testing and treatment, and for anyone who would like help connecting to care for hepatitis C (or at: <u>Hepatitis C Link to Care Form</u>).
 - You can also contact Maine CDC Hepatitis C Navigator at: <u>helen.price-wharff@maine.gov</u> or <u>disease.reporting@maine.gov</u>.

ΗIV

- Use the following resources to find an HIV care provider when a referral is needed:
 - o American Academy of HIV Medicine
 - o <u>HIV Medicine Association</u>: 703-299-1215
 - <u>HIV/AIDS Hotline</u>: 800-851-2437 (Maine)
 - Ryan White HIV/AIDS Program: 877-646-4772
 - o <u>HIV.gov</u>

HIV Clinics in Maine

Clinic Name	Location	Contact Information
MaineHealth Adult Specialty	48 Gilman St.	(207) 661-4400
Care (formerly MMP Gilman	Portland, ME 04102	MaineHealth Adult Specialty Care -
Clinic)		Gilman St - Portland MaineHealth
Greater Portland Health	Multiple locations throughout	(207) 874-2141
	Portland, South Portland, and	Ryan White Program
	Westbrook.	
Northern Light Eastern Maine	417 State Street	(207) 973-4377
Medical Center	Webber East	Northern Light Infectious Disease Care -
	Bangor, ME 04401-6639	Northern Light Health
MaineGeneral Horizon	21 Enterprise Drive	(207) 248-0460
Program	Augusta, ME 04330	HIV & AIDS Services Maine
		MaineGeneral
Central Maine Medical	10 High Street,	(207) 795-2729
Center	Lewiston, ME 04240	Central Maine Infectious Diseases -
		Central Maine Healthcare
Regional Medical Center at	43 South Lubec Road	(207) 733-1090
Lubec, Northern Maine HIV	Lubec, Maine 04652	Northern Maine HIV Program - Regional
Program		Medical Center at Lubec
		https://www.rmcl.org/services-and-
		programs/northern-maine-hiv-program/

HIV Case Management in Maine

Case Managers help their clients navigate complex systems and coordinate referrals.

Organization	Coverage area	Contact Information
Andwell Health Partners	Androscoggin, Oxford, Franklin	(207) 777-7740
		710 Main Street, Lewiston, ME
		Andwell Health Partners
Frannie Peabody Center	Cumberland, York	(207) 774-6877
		30 Danforth Sr. Suite 309, Portland, ME
		Frannie Peabody Center
Health Equity Alliance	Washington, Hancock, Penobscot,	(207) 990-3626
	Piscataquis, Somerset, Aroostook	Bangor, Ellsworth, Machias, and Presque
		Isle, ME
		Health Equity Alliance
MaineGeneral Horizon	Androscoggin, Franklin, Kennebec,	(207) 248-0460
Program	Knox, Lincoln, Oxford, Sagadahoc,	21 Enterprise Drive, Augusta, ME
	Somerset, Waldo	HIV & AIDS Services Maine
		MaineGeneral

Section 4.1 Treatment guidelines: non-pregnant adults

	If patient is HCV+	If patient is HIV+	
KEY POINTS	 Hepatitis C can be cured in more than 95% of cases with just 8-12 weeks of well-tolerated oral-only treatment with direct-acting antiviral (DAA) agents. Except for pregnant people and children under 3 years clinicians should treat people with detectable HCV RNA in their blood with oral DAA therapy. There is no need to wait for potential spontaneous viral resolution. Current use of opioids or other injection drugs is not a contraindication to treatment.⁷ There is no medical reason to ensure abstinence (for any duration) prior to HCV treatment. 	 Antiretroviral therapy (ART) is recommended for all people with HIV, regardless of CD4 cell count. Help your patients adhere to ART by engaging in regular conversations at every office visit. Monitor your patients' viral load to confirm initial and sustained response to ART. 	
Treatment Guidelines Clinical Calcu	 Treat HCV infection: Simplified Pangenotypic HCV Treatment for Treatment-Naive Adults Without Cirrhosis Simplified Pangenotypic HCV Treatment Algorithm for Treatment-Naive Adults With Compensated Cirrhosis For more information about management of people diagnosed with acute or chronic HCV infection, see the <u>HCV Guidance</u>: <u>Recommendations for Testing, Managing, and</u> <u>Treating Hepatitis C</u> from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA). Jators 	 Rapid ART Initiation & Restart Guide: <u>Rapid</u> (<u>Immediate</u>) <u>ART Initiation & Restart: Guide for</u> <u>Clinicians</u> Adult & Adolescent ARVs: <u>What's New: Adult</u> <u>and Adolescent ARV HIV Clinical Guidelines</u>] <u>NIH</u> 	
 <u>Child</u> <u>Fibro</u> <u>Glom</u> 	<u>o Platelet Ratio Index (APRI)</u> <u>-Turcotte-Pugh</u> <u>sis-4 (FIB-4)</u> <u>nerular Filtration Rate (GFR)</u> <u>el For End-Stage Liver Disease (MELD)</u>		
	Patients with HIV and HCV coinfections		
Treatment guidelines	HCV Treatment Guidelines: Patients With		
	Patients who		
	Patients found or known to be HBsAg-positive sho meets <u>AASLD criteria for HBV treatment and initiat</u>		

22 | Maine Center for Disease Control and Prevention: Hepatitis C and HIV Clinical Guidance Package

	If patient is syphilis+, gonorrhea+ or chlamydia+		
Syphilis	 U.S. CDC: <u>Syphilis Treatment guidelines</u> Maine CDC: <u>Syphilis Treatment</u> <u>Recommendations</u> 	STI Tx Guide: STI prevention, diagnostic, and treatment recommendations (includes more clinical care guidance, sexual history resources, patient materials, and other features to assist with	
Gonorrhea	<u>Gonorrhea Treatment guidelines</u> *provide EPT Services	patient management.) Apple: Google Play:	
Chlamydia	<u>Chlamydia Treatment guidelines</u> *provide EPT Services		

Section 4.2 Treatment and follow up: pregnant persons

If patient is HCV +		
Pregnancy	Baseline liver function tests (LFTs) for comparison if concerns for preeclampsia	
management	Discuss the risks of ongoing use of alcohol	
implications	□ Screen for infectious diseases (Hepatitis B/A, sexually transmitted infections)	
	Amniocentesis suggested over chorionic villus sampling	
	Avoid prolonged rupture of membranes	
	Minimize the duration of fetal exposure to maternal fluids and blood	
	Changing the method of delivery <i>not</i> recommended	
	Perinatally exposed infants should be screened with an HCV RNA test at age 2	
	to 6 months to promote early diagnosis and linkage to care for this vulnerable	
	group.	
	Physical exam of the liver (normal in most patients)	
	□ Routine labs (baseline LFTs as above and INR, CMP, CBC with platelet count)	
	Refer to gastroenterology as indicated	
	For more information regarding perinatal hepatitis C:	
	Perinatal Hepatitis C Testing Recommendations (U.S. CDC)	
	 <u>Algorithm for Screening and Treating Hepatitis C in Perinatally Exposed Infants</u> (PDF) 	
	 Hepatitis C and Pregnancy- A Guide for Pregnant People with Hep C (PDF) 	
Infant feeding	Breastfeeding is supported unless risk of blood exposure (e.g., cracked/bleeding	
considerations for	nipples) or other potential contraindications (e.g., ongoing substance use, HIV +)	
people living with HCV		
Treatment (in the	There are no large-scale clinical trials evaluating the safety of direct-acting	
postpartum period)	antivirals (DAAs) in pregnancy.	
	For more information about the treatment of HOV in postportum women case	
	For more information about the treatment of HCV in postpartum women see: Algorithm for Screening and Treating Hepatitis C in Pregnant and Postpartum Women	
	(PDF)	

If patient is HIV +		
Pregnancy management implications	 All pregnant people with HIV should initiate antiretroviral therapy (ART) as early in pregnancy as possible, regardless of their HIV RNA level or CD4 T lymphocyte cell count, to maximize their health and prevent perinatal HIV transmission and sexual transmission. The selection of which ARVs to use during pregnancy should be made through shared decision-making between the health care provider and patient. <u>Overview:</u> 	
Infant feeding considerations for people living with HIV	 Shared decision-making between the health care provider and patient. Overview: <u>Recommendations for Antiretroviral Drugs Use During Pregnancy NIH</u> □ Health care providers should inquire routinely about infant feeding plans and/or breastfeeding desires, as well as the use of pre-masticated (pre-chewed or pre-warmed) food. Counseling against pre-mastication and discussion of safe infant feeding options should be provided. □ Individuals with HIV who are on ART with a sustained undetectable viral load should be counseled about the options of formula feeding, use of banked donor milk, or breastfeeding. Those who choose to breastfeed should be supported in this decision. Individuals with HIV who choose to formula feed should be supported in this decision. Providers should ask about potential barriers to formula feeding and explore ways to address them. Special Populations: Infant Feeding for People With HIV in the United States NIH □ In the case of a detectable viral load in a breastfeeding parent, breastfeeding should be stopped temporarily or discontinued and replacement feeding initiated while the viral load is rechecked, causes for the viremia are assessed, and, when applicable, adherence counseling is reinforced. Most experts recommend permanent discontinuation of breastfeeding when HIV RNA is ≥200 copies/mL. 	
Treatment (in the postpartum period)	□ ART should be continued after delivery. Because the immediate postpartum period poses unique challenges to ART adherence and retention in HIV care, arrangements for new or continued supportive services should be made throughout pregnancy and before postpartum hospital discharge. <u>Special</u> Populations: Postpartum Follow-Up of People with HIV NIH	

Financial Resources

Provide resources for assistance with paying for medical care and other needs, including:

- MaineCare special benefit waiver for people living with HIV
 - <u>MaineCare Benefits Manual</u> Maine Rules, Regulations, and Policy
 - MaineCare Preferred Drug List (PDL)
 - <u>The MaineCare Eligibility Manual</u> Office for Family Independence (OFI)
 - Nurse Coordinator: Michelle Pepin, 207-624-4008, <u>michelle.pepin@maine.gov</u>
 - Program Manager: Emily Bean, 207-624-4005, <u>Emily.bean@maine.gov</u>
- Ryan White Part B/AIDS Drug Assistance Program (ADAP)
 - Ryan White Part B administers the ADAP, which covers the cost of formulary medications and will pay for insurance coverage if the patient has none. Patients must have an income of 500% of FPL or less and complete an initial application with release, proof of income, and proof of residency. They recertify with proof of income and residency annually.
 - Financial assistance in the form of food vouchers, dental assistance, and assistance with rent/utilities is available for enrolled members who have an income of 350% of FPL or less and submit a complete application.
 - More information: (207) 287-3747, <u>RyanWhitePartB@maine.gov</u>, <u>www.maine.gov/dhhs/MaineRWB</u>
 - HIV Medication Assistance Programs: <u>HIV Medication Assistance Programs | AIDS</u> Education and Training Centers National Coordinating Resource Center (AETC NCRC)
- Insurance coverage for hepatitis-related services
 - <u>Navigating Health Insurance for Viral Hepatitis in Maine (PDF)</u>
 - <u>NASTAD Frequently Asked Questions: Insurance Coverage for Viral Hepatitis</u> <u>Treatment and Preventive Services (PDF)</u>
- Viral hepatitis patient assistance programs (for people who are un- or under-insured)
 - Gilead Epclusa, Harvoni, Vosevi, and Sovaldi; Generic Epclusa & Generic Harvoni: <u>Gilead Support Path® | Patients (mysupportpath.com)</u> : 1-855-769-7284
 - AbbVie—Mavyret: <u>MAVYRET Cost, Savings Card, and Insurance Information</u>: 1-800-222-6885, <u>Patient Assistance | AbbVie</u> to apply for patient assistance to cover medication costs.
- Other:
 - Medicine Assistance Tool: search engine for many of the patient assistance resources that the biopharmaceutical industry offers – <u>Medicine Assistance Tool</u>

Appendix 1: Hepatitis A and hepatitis B Vaccination Guidance

Advisory Committee on Immunization Practices (ACIP) recommends that the following people should receive hepatitis A and/or hepatitis B vaccination:

Criteria	Hepatitis A	Hepatitis B	
	Age and Risk-Based	Universal (everyone)	
Age	 Children/Adolescents All children ages 12-23 months. Unvaccinated children and adolescents age 2-18 years. 	 All infants Unvaccinated children younger than 19 years of age. Adults Adults 19–59 years. If not already vaccinated with hepatitis B vaccine (HepB), pregnant women should be vaccinated with HepB in pregnancy. Adults 60 years and older with known risk factors* for hepatitis B. 	
Risk/behavior	 International travelers. Men who have sex with men. People who use or inject drugs (all those who use illegal drugs). People with occupational risk for exposure. People who anticipate close personal contact with an international adoptee. People experiencing homelessness. 	 *For adults 60 years and older: People with a history of STIs or multiple sex partners. People with history of past or current HCV infection. People incarcerated or formerly incarcerated in a jail, prison, or other detention setting. Infants born to HBsAg-positive people. People born in regions with HBV infection prevalence of 2% or more. US-born people not vaccinated as infants whose parents were born in geographic regions with HBV infection prevalence of 8% or more. People who inject drugs or have a history of injection drug use. Men who have sex with men. Household contacts or former household contacts of people with known HBV infection. 	

		 People who have shared needles with or engaged in sexual contact with people with known HBV infection. People on maintenance dialysis, including in-center or home hemodialysis and peritoneal dialysis.
People at increased risk	 People with chronic liver disease. 	 *For adults 60 years and older: People with elevated liver
for severe	People with HIV infection.	enzymes.
disease from infection		• People with HIV infection.
Other	 Other people recommended for vaccination Pregnant people at risk for HAV infection or severe outcome from HAV infection. Any person who requests vaccination. People who are unvaccinated and exposed to HAV within the past 2 weeks (see postexposure prophylaxis recommendations below). Vaccination during outbreaks Unvaccinated people in outbreak settings who are at risk for HAV infection or at risk 	
	for severe disease from HAV infection.	

Key Points:

A single dose of hepatitis A vaccine has been shown to control outbreaks of hepatitis A⁸. Protective anti-hepatitis A virus antibody levels after a single dose of inactivated hepatitis A vaccine can persist for almost 11 years and increase or reappear after booster vaccination. In addition, a single dose of hepatitis A vaccine was shown to promote HAV-specific cellular immunity similar to that induced by natural infection. A second hepatitis A vaccine dose should be administered to complete the series when and if feasible.

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Time since	Age	Recommended prophylaxis
exposure		
<u><</u> 14 days	Less than 12 months	IGIM, 0.1 mL/kg ¹
	12 months-40 years	Hepatitis A vaccine ^{2,3,4}
	>40	Hepatitis A vaccine ^{3,4} , consider IGIM
>14 days	Less than 12 months	No prophylaxis
	12 months and older	No prophylaxis, but hepatitis A vaccine may be
		indicated for ongoing exposure ²

Hepatitis A Post-Exposure Prophylaxis Recommendations for non-Immune Individuals⁹

Note: Twinrix is not recommended for prophylaxis

More information on post-exposure prophylaxis for hep A: <u>Hepatitis - Disease Surveillance</u>

Epidemiology Program - MeCDC; DHHS Maine

Appendix 2: PEP and PrEP Guidance (for HIV prevention)

- PEP: Post-Exposure Prophylaxis (PEP) Toolkit
- PrEP: Prescribing PrEP: A Guide for Healthcare Providers

Appendix 2.1: Doxy-PEP Guidance (for STI prevention)

- Treatment: Interim Recommendations for the Use of Doxycycline for Post-Exposure <u>Prophylaxis (doxy PEP) for the Prevention of Certain Bacterial Sexually Transmitted Infections</u> <u>(STIs)</u>
- Prevention: Doxycycline as STI PEP: toolkit

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