

HCV Surveillance System Evaluation Guidance

Purpose

The purpose of this guide is to provide a resource for jurisdictions interested in completing a surveillance system evaluation for hepatitis C virus (HCV). A systematic evaluation may support health departments in better understanding efficiency and limitations of current surveillance data systems, identify areas for improvement in current data sources, and identify internal and external sources/systems that may supplement existing systems for tracking hepatitis C virus (HCV) care continuum metrics. Note that evaluations may be done on any piece of the surveillance system and are not exclusive to a comprehensive review.

Methodology

This evaluation plan was modeled after the Centers for Disease Control and Prevention, Program Evaluation Framework¹; leveraging a Strengths, Weaknesses, Opportunities, and Threats (SWOT) Analysis to organize findings. Jurisdictions may consider conducting an assessment of HCV surveillance systems through in-person or virtual key informant interviews with identified staff and partners. The purpose of key informant interviews is to collect information from a wide range of persons who have first hand knowledge about HCV surveillance, data collection, and workflows; therefore, epidemiologists, disease intervention specialists, nurses, management, and outside partners should be considered for interview. These experts, with their particular knowledge and understanding, can provide insight on successes and challenges and give recommendations for solutions. If possible, an outside consultant or staff unassociated with the HCV program should facilitate key informant interviews.

For this approach to be most effective, detailed and progressive key informant interviews should take place. It is recommended to utilize a SWOT analysis for each interview in order to support identifying strategies and recommendations for system improvement and related resource needs. Each category is as follows:

- **Strengths**: Characteristics of protocols, resources, systems, that *support and enhance* HCV surveillance. Examples may include existing financial and personnel resources, protocols that are efficient and address barriers to data collection, or exceptional communication between different teams.
- **Weaknesses**: Characteristics of protocols, resources, systems, that are *barriers to supporting and enhancing* HCV surveillance.
- **Opportunities**: Internal and/or external factors could help *improve and streamline* HCV surveillance.
- Threats: Internal and/or external factors that can impede and hinder HCV surveillance.



Interview Format & SWOT Analyses Tables:

The following general formal can be followed for each key informant interview. See Appendix A for a detailed interview template.

- Introduction: Evaluation facilitators should:
 - Introduce themselves;
 - Provide background and establish the purpose for the interview;
 - Explain confidentiality and why their cooperation is important in collecting the information needed;
 - Ask for permission to record the interview for note taking purposes;
 - Describe what will happen with the collected information and how the health department and partners may benefit.
- **Key interview questions**: Questions will draw upon the informant's expertise and unique viewpoint. See below tables for details.
- Probing questions: Probing questions encourage participants to reflect more deeply on the meaning of their comments. These questions are also useful at getting people to think about the cause or root of the problem being discussed.
- **Closing question**: Evaluation facilitators should provide an opportunity for the key informant to give any additional information or comments, as well as for their recommendations or solutions in addressing any barriers or challenges discussed.
- **Summary**: If time permits, evaluation facilitators should summarize the major comments heard throughout the interview and thank them for their time. Provide facilitator emails for any additional comments or questions from key informants.

Key informant interviews may focus on one or more of the following topic areas, pending the jurisdictions evaluation needs, Additionally, questions and topics may change as dictated by interviews. See Appendix B for SWOT tables with detailed interview questions broken out by focus areas.

- Programmatic
 - Organizational structure and logistics
 - Communications and infrastructure
- Case Investigation and data collection
- Surveillance and data management
 - Data sources and flow (in)
 - Use of surveillance data
 - Epidemiology, analytics, and outputs
- Outside partner(s)
- State Department of Health
- Local Health Departments



Initiation of Key Informant Interviews

Evaluation facilitators should coordinate scheduling with identified key informants and provide a summary of questions prior to the interview. Key informant interviews are anticipated to be an hour each and it is suggested that only evaluation facilitators be present in order to ensure honesty and confidentiality. Consider recording interviews for note-taking purposes; however recordings should be discarded after the project concludes. Subsequently, evaluation facilitators may reach out to staff to address additional questions via email, as needed.

Supplemental Document Gathering

Evaluation facilitators should collect and review critical documents to support project assessment. Documents may include organizational charts, written protocols and procedures, and aggregate surveillance data; documents will be requested as needed.

Who Should Be Involved

To successfully complete key informant interviews, internal and external staff and partners who support every level of HCV surveillance should be involved. Further, staff who support different data systems and disease surveillance should be involved to ensure resources and processes that already exist within the department for other diseases are considered for HCV surveillance.

Staff key informants may include the following, however additional staff/partners may be identified throughout the project:

- Hepatitis management and staff, including:
 - Disease Intervention Specialist(s) (DIS)
 - Public health nurse(s)
 - Nurse manager(s)
- Harm reduction program staff
- Informatics/data systems management and staff
- Epidemiology and surveillance staff
- Community partners

Results and Final Report

A SWOT analysis alone should not be considered a method to diagnose the success or challenges of the program. The evaluation facilitators should meet regularly throughout the key informant data collection stage to review and aggregate results, using the SWOT framework as a guide. Themes and hypotheses will be identified throughout the process. Additional evaluation considerations may be included in the analysis and final assessment, including the simplicity, flexibility, data quality, representativeness, timeliness, etc. of the surveillance system. This evaluation may be limited in scope to address certain aspects of the surveillance system, including positive predictive value, sensitivity and other more numeric evaluations, however, broader statements and indications may be alluded to.



After key informant interviews and document reviews have been completed, the evaluation facilitators should meet to review the overall SWOT and established broad themes. A final report will be written to provide recommendations and considerations for optimizing the HCV surveillance system. The final report will help highlight areas for improvement to maximize external opportunities and internal strengths while minimizing external threats and internal weaknesses. Recommendations may be made for additional resources and technical assistance opportunities. Next steps may require consultation with other health departments, NASTAD, other disease program areas, and other technical assistance resources. Internal health department collaboration should decide on the priorities and attainable arenas for growth.

Appendix A

Key Informant interview template

60 minute virtual key informant interview template

Introduction and Overview (5 minutes)

Purpose. Thank you for taking the time to speak with us today. Our names are, and we are he	ping to
facilitate an evaluation of's HCV surveillance system. As indicated in the outreach email, the	goal of this
evaluation is to better understand efficiency and limitations of current surveillance data systems, ider	ntify areas for
improvement in current data sources, and identify internal and external sources/systems that may su	pplement
existing systems for tracking local hepatitis C virus (HCV) care continuum metrics. To do this successfu	lly, we are
collecting information from a wide range of people who have first hand knowledge about HCV surveil	lance, case
investigation, reporting, and workflows.	
Confidential. What you share with us today will go into a report that will be provided to We	may share

suggestions, feedback, and concerns that you provide you in the report, but will not include any identifying information about you, and your individual comments will remain confidential. So, please speak freely, even if what you have to say is negative, or if you don't know the answer to a question.

Voluntary. If you do not feel comfortable answering any given question at any time, please let us know and we will skip it. Nothing that you tell us today will affect your individual working relationships with the health department or any other organizations. We have some questions prepared, but please feel free to add anything that we miss along the way.

Recording. While we will be taking some notes, we would like to audio-record this conversation for note-taking review and recall. We will not share the recording with anyone at or associated with the health department, and it will be erased once all the notes are compiled for the report. Do you all agree for this conversation to be recorded?

Questions. Thank you. What questions do you have before we begin?



[START RECORDING]

Key Interview Questions & Discussion (50 minutes)

Questions:

The below questions will be asked based on interviewee expertise; not all questions will be asked during each interview.

Organizational Structure/Logistics

- What are the program goals?
- What are the SOPs/protocols in your role?
- How are you held accountable in the work that you do?
- Are job roles and deliverables explicitly defined? What do staff check-ins look like?
- What training opportunities are available for staff working with HCV?
- How many FTEs are working on HCV? How many are full time? Where do they work (physical locations)?
- Is there fragmentation of activities? Do staff also work on other disease conditions?
- How is the staff capacity to workload? Are there additional staff needs that could be accommodated by collaboration within the health department?
- Do you fund/partner with any external organizations for HCV activities? What are the activities?

Communications and Infrastructure

- What are the SOPs/protocols in your role? How often are these updated?
- How are you held accountable in the work that you do?
- Is HCV siloed from HBV, STD and/or HIV? What collaborations exist? Is there any coordination with HCV prevention and harm reduction efforts?
- Do people working on HCV internally meet regularly? What do these meetings look like?
- Does the program have regular meetings/communication with the state DOH?
- Does the program have any standing meeting with external partners, such as NASTAD or CDC?
- How do staff working on HCV receive communication on HCV protocols, including when there are any changes to these protocols?
- Is leadership well informed about HCV surveillance activities, needs, concerns?
- Do HCV surveillance staff have knowledge of other HCV activities, such as disease investigation, linkage to care processes, and prevention efforts?

Case Investigation & Data Collection

- Who conducts case investigations?
- What is the process for linkage to care?
- Who is responsible for case classification and reporting to CDC?
- How is case investigation information tracked and entered into the surveillance system? What other systems are used to track investigation information?
- How are cases that are followed up selected? Are these cases the most impactful?



- Is there any follow-up for perinatal HCV with providers/cases?
- Do any partners/external organizations conduct investigations on behalf of public health?
- How extensive are case forms? Are all questions necessary? Are any questions excluded?
- Any supplementation with other data sources?
- Do you work directly in the surveillance system? Do you create acute and chronic cases for an individual? Can you see other conditions for cases (HIV, STI, etc.)?
- Is it possible to access EMRs for chart review?
- Are you able to identify providers, clinics, or health systems that aren't reporting and/or providing case report information? Can they be contacted to streamline with automated or HD-based form completion?
- Any steps that could be streamlined/automated to maximize staff time (eCR, supplemental lab data, HL7 messaging)?
- Any areas for automation? (I.e. scannable forms and auto filling data systems)
- How is the cascade of case calculated? Which metrics are used? What system(s) supports this calculation?
- What does the continuum of care look like? What are the barriers and gaps to HCV screening, linkage, care, treatment, and cancer diagnosis/cares?

Data Sources & Flow (In)

- What labs are routinely reported? (HCV rapid screen, HCV antibody, HCV DNA, HCV genotype, LFTs, bilirubin)
- Do you receive negative labs? Which ones? If not, do other conditions receive negative results?
- How are labs processed? What proportion of labs received through ELR? Who is responsible for manual entry of labs/data?
- What proportion of labs received through ELR? Who is responsible for manual entry of labs/data?
- Any sense of completion of reporting for HCV labs?
- If ELR is not coming from everywhere, what initiatives are being done to onboard sites?
- Is ECR available?
- What data routinely comes in with labs, including demographics, pregnancy status, etc.?
- Are there data sources for race/ethnicity, address, country of origin, etc. other than labs that could be leveraged to supplement lab data?
- Do you collect any data on other platforms (REDCap, ClientTrack, etc.)? How is this data transmitted to CalREDIE?
- Does CalREDIE have linkages to any other data systems (vital records, Medicaid, Immunization registry, etc.)?

Surveillance & Data Management

- Is the HCV surveillance system case based or person based? Do you create acute and chronic cases for an individual? Can you see other conditions for cases (HIV, STI, etc.)?
- Are labs automatically appended to existing HCV cases for an individual?
- Is deduplication automated? Manual?
- Are negative laboratory results stored in the same system or in a different data repository?



- Does the program do any surveillance for perinatal HCV? What does this look like?
- Who assigns CSTE case status' for reporting to state/CDC?
- Is case statusing manual? In statistical software?
- How frequently is a case statused? Each new lab? Only until reported to the state/CDC?
- How frequently is data cleaning performed? What areas are routinely missing or in need of cleaning?
- What is the causality to data gaps? Internal protocols/barriers? External processes?

What is HCV Surveillance Used for

- Are there data-to-care activities that could arise from surveillance data?
- Does HCV surveillance data inform elimination planning/implementation? What elimination work could grow from surveillance?
- Can data identify barriers and gaps to HCV screening, linkage, care, and treatment?
- Are there additional uses for HCV surveillance data that are not achieved currently? What would be needed to achieve them? Why are they important?
- What reports are routinely run with HCV surveillance?

Epidemiology, Analytics, & Outputs

- Are any data matches with HIV or other conditions regularly performed?
- What regular analyses are done with the data? What data sources are used for analysis?
- Is chronic HCV ever analyzed for trends over time? Do you have a chronic HCV prevalence estimate?
- What do you know about people living with HCV in your jurisdiction? What don't you know?
- What metrics are used to develop care cascades? Are there any barriers in developing these metics?
- Do you know how transmission is occurring in your jurisdiction?
- Are matches with cancer/death/birth regularly performed? What is done with that data?
- How long does data take to close? (I.e when is last year that is complete)?
- How are MMG/NNDSS provided to the state DOH/CDC?
- Do you create/maintain any HCV reports? Who are these shared with/where are they published?
- What are the expectations for manuscript and abstract preparation? Conference attendance?
- Are there any other special projects related to HCV that the epis work on?

Outside Partner Interview(s)

- What is your process for testing/treating for HCV?
- How do you identify new cases of HCV?
- What information do you provide to the health department (labs, LFTs, treatment, risk factors)?
- What barriers do you face with data collection and reporting?
- How do you report to the health department (REDCap, fax, email, other reporting portal)?
- What information would be helpful to receive from the health department regarding HCV? What formats would be beneficial?

State DOH Interview(s)



- Does the state conduct case investigations? What is the process for these?
- What is the state's relationship with outside partners (hospital systems, Medicaid, providers, CBOs)?
- What is the surveillance system that you use? What challenges/barriers exist? What works?
- How do you receive reports from the LHD?
- Is negative lab reporting mandated by the state? What about LFTs? Any other data?
- Is there someone at the state conducting case classification?
- Is there routine review for QA/QI in relation to state case status' and case investigation information?
- What are the LHDs strengths in data collection? What about weaknesses?
- How often do you communicate with the LHD?
- How are updates (case investigation changes, testing/treatment recommendations, etc.) communicated to the LHD?
- Does the state provide any surveillance/analytical support for HCV?
- How do you share surveillance data with LHDs?

LHD Interview(s)

- Does the LHD conduct case investigations? What is the process for these?
- What is the LHDs relationship with outside partners (hospital systems, Medicaid, providers, CBOs)?
- What is the surveillance system that you use? What challenges/barriers exist? What works?
- How do you receive reports from the State?
- Is negative lab reporting available to the LHD? What about LFTs? Any other data?
- Is there someone at the LHD conducting case classification?
- Is there routine review for QA/QI in relation to local case status' and case investigation information?
- What are the LHDs strengths in data collection? What about weaknesses?
- How often do you communicate with the State?
- How are updates (case investigation changes, testing/treatment recommendations, etc.) communicated to the State?
- Does the state provide any surveillance/analytical support for HCV?
- How do you share surveillance data with the State?

Probing questions : Can you tell me more about _	? Do you think there are other factors impacting or
contributing to? What do you think about	_? What barriers to you see in being able to successfully do your
job?	

Closing question: Is there anything else that you would like to add to this discussion? Do you have any additional recommendations, concerns, and/or input that you would like to share?

Summary & Conclusion (5 minutes)

Thank you so much for your insight; this has been great! Some of the major takeaways that we got out of this discussion are____. We will be interviewing more of your colleagues and partners over the next couple months and will be compiling a final report with our findings and recommendations. If we have any additional questions for you, we will reach out. Similarly, if you think of anything you would like to add or have any questions for us, please reach out via email.





Appendix B

Programmatic

	Organizational Structure/Logistics			
Inputs Example Questions	Roles &TrainingManageWhat a	; allocations . responsibilities g (on-the-job and academic) ement and supervision structure re the program goals? re the SOPs/protocols in your re	 Job role accountabili Workload allocations Physical locations of Partnerships with ex 	staff
	 How are you held accountable in the work that you do? Are job roles and deliverables explicitly defined? What do staff check-ins look like? What training opportunities are available for staff working with HCV? How many FTEs are working on HCV? How many are full time? Where do they work (physical locations)? Is there fragmentation of activities? Do staff also work on other disease conditions? How is the staff capacity to workload? Are there additional staff needs that could be accommodated by collaboration within the health department? Do you fund/partner with any external organizations for HCV activities? What are the activities? 			do they work (physical e conditions? that could be
Strengths Weaknesses Opportunities Threats			Threats	

Communications and Infrastructure			
Inputs	 Regular meetings and calls (attendance, which programs represented) Do staff participate in national HCV calls? 	 Cross programmatic/partner meetings Integration of activities Internal & external partnerships 	
Example Questions	What are the SOPs/protocols in your role? How often are these updated?		



 Do HCV surveillance staff have knowledge of other HCV activities, such as disease investigation, linkage to care processes, and prevention efforts? 				
Streng	gths	Weaknesses	Opportunities	Threats

Case Investigations and Data Collection

		Case Investigations	and Data Collection	
Inputs Example Questions	Case for Sentine Who composed with the sentine Who is the sentine How are sentine Any sure individuals is it por case recomple	ollow-up orms el events conducts case investigations? is the process for linkage to care is responsible for case classificate is case investigation information systems are used to track investigation information systems are used to perinatal H y partners/external organization each of the case forms? Are a pplementation with other data work directly in the surveilland lual? Can you see other condition sissible to access EMRs for chart u able to identify providers, cli eport information? Can they be etion?	• Linkage to care • Sampling technique • Fields/investigation e? tion and reporting to CDC? tracked and entered into the substigation information? elected? Are these cases the mo CV with providers/cases? Ins conduct investigations on beh If questions necessary? Are any of a sources? Ince system? Do you create acute ons for cases (HIV, STI, etc.)? It review? Inics, or health systems that aren is contacted to streamline with ac	st impactful? alf of public health? questions excluded? and chronic cases for an 't reporting and/or providing utomated or HD-based form
	 Any steps that could be streamlined/automated to maximize staff time (eCR, supplemental lab data, HL7 messaging)? Any areas for automation? (I.e. scannable forms and auto filling data systems) How is the cascade of case calculated? Which metrics are used? What system(s) supports this calculation? What does the continuum of care look like? What are the barriers and gaps to HCV screening, linkage, care, treatment, and cancer diagnosis/cares? 			systems) t system(s) supports this d gaps to HCV screening,
Stre	ngths	Weaknesses	Opportunities	Threats

Surveillance & Data Management

Data Sources and Flow (In)	
Data Sources and How (III)	



Inputs	 Reporting regulations Additional data sources (vital statistics, Medicaid, etc.) 	Data elementsELR and ECR detailsOther systems? How	, integrated 2		
Example	What labs are routinely reported? (HC')	·	_		
Questions	 bilirubin) Do you receive negative labs? Which of the ware labs processed? What proportion manual entry of labs/data? Any sense of completion of reporting for life ELR is not coming from everywhere, lise ECR available? What data routinely comes in with labse are there data sources for race/ethnicing be leveraged to supplement lab data? Do you collect any data on other platform. 	 bilirubin) Do you receive negative labs? Which ones? If not, do other conditions receive negative results? How are labs processed? What proportion of labs received through ELR? Who is responsible for manual entry of labs/data? Any sense of completion of reporting for HCV labs? If ELR is not coming from everywhere, what initiatives are being done to onboard sites? Is ECR available? What data routinely comes in with labs, including demographics, pregnancy status, etc.? Are there data sources for race/ethnicity, address, country of origin, etc. other than labs that could be leveraged to supplement lab data? Do you collect any data on other platforms (REDCap, ClientTrack, etc.)? How is this data transmitted to the HCV surveillance system? 			
Strengths Weaknesses Opportunities		Threats			

	Surveillance & Data Management			
Inputs	 Primary database for HCV Perinatal Hepatitis C program QA/QC processes Data cleaning processes System capacity Data security Case matching/deduplication Case statusing 		urity tching/deduplication	
Example Questions	• Is the HCV surveillance system case based or person based? Do you create acute and chronic cases			
S	Strengths	Weaknesses	Opportunities	Threats



What is HCV Surveillance Used for				
Inputs	 Coalitic commit 	HCV Prevention Programs Coalitions/technical advisory committees Syndemic programming Integration with other HD programs Integration with HIV, STI, harm reduction Perinatal HCV Reporting		
 Are there data-to-care activities that could arise from surveillance data? Does HCV surveillance data inform elimination planning/implementation? What elimination work could grow from surveillance? Can data identify barriers and gaps to HCV screening, linkage, care, and treatment? Are there additional uses for HCV surveillance data that are not achieved currently? What would be needed to achieve them? Why are they important? What reports are routinely run with HCV surveillance? 				
Strengths Weaknesses Opportunities Threats			Threats	

 Reports and summaries Special projects Cascade development Prevalence estimates Acute cases vs chronic 	Epidemiology, Analytics, & Outputs				
	Inputs	Special projects			
 Are any data matches with HIV or other conditions regularly performed? What regular analyses are done with the data? What data sources are used for analysis? Is chronic HCV ever analyzed for trends over time? Do you have a chronic HCV prevalence estimate? What do you know about people living with HCV in your jurisdiction? What don't you know? What metrics are used to develop care cascades? Are there any barriers in developing these metics? Do you know how transmission is occurring in your jurisdiction? Are matches with cancer/death/birth regularly performed? What is done with that data? How long does data take to close? (I.e when is last year that is complete)? How are MMG/NNDSS provided to state DOH/CDC? Do you create/maintain any HCV reports? Who are these shared with/where are they published What are the expectations for manuscript and abstract preparation? Conference attendance? Are there any other special projects related to HCV that the epis work on? 	-	 What regular analyses are done with the Is chronic HCV ever analyzed for trends estimate? What do you know about people living what metrics are used to develop care of metics? Do you know how transmission is occurred Are matches with cancer/death/birth remarked How long does data take to close? (I.e. where MMG/NNDSS provided to state Do you create/maintain any HCV reports the What are the expectations for manuscrip 	e data? What data sources are used for analysis? over time? Do you have a chronic HCV prevalence with HCV in your jurisdiction? What don't you know? cascades? Are there any barriers in developing these ring in your jurisdiction? igularly performed? What is done with that data? when is last year that is complete)? is DOH/CDC? is? Who are these shared with/where are they published? pt and abstract preparation? Conference attendance?		



Strengths	Weaknesses	Opportunities	Threats

$Outside\ Partner\ Interview(s)$

Outside Partner Interview(s)						
Inputs		l and reporting experience unity perspectives		EMR capacity knowledgeBarriers to data collection/reporting		
Example Questions	How dWhat iWhat iHow dWhat i	 What is your process for testing/treating for HCV? How do you identify new cases of HCV? What information do you provide to the health department (labs, LFTs, treatment, risk factors)? What barriers do you face with data collection and reporting? How do you report to the health department (REDCap, fax, email, other reporting portal)? What information would be helpful to receive from the health department regarding HCV? What formats would be beneficial? 				
Strengths		Weaknesses	Opportunities	Threats		

State DOH Interview(s)

 $These\ questions\ may\ be\ beneficial\ if\ the\ evaluation\ is\ for\ a\ local\ health\ department.$

State DOH Interview(s)			
Inputs	State surveillance systemState and Local HD relationships	State supportReporting regulations and authority	
Example Questions	 CBOs)? What is the surveillance system that you How do you receive reports from the LH Is negative lab reporting mandated by the Is there someone at the state conducting Is there routine review for QA/QI in relatinformation? What are the LHDs strengths in data coll How often do you communicate with the 	side partners (hospital systems, Medicaid, providers, use? What challenges/barriers exist? What works? D? ne state? What about LFTs? Any other data? g case classification? tion to state case status' and case investigation ection? What about weaknesses? e LHD? nges, testing/treatment recommendations, etc.)	



How do you share surveillance data with LHDs?			
Strengths	Weaknesses	Opportunities	Threats

LHD Interview(s)

These questions may be beneficial if the evaluation is for a state health department. It is recommended to interview a variety of LHDs, especially in larger jurisdictions where there may be a mix of urban and rural LHDs.

LHD Interview(s)					
Inputs		urveillance system and Local HD relationships	Local supportReporting regulation	ns and authority	
Example Questions	 What i What i How d Is negation Is therefore Is therefore What a How a committee 	hes the LHD conduct case investigations? What is the process for these? hat is the LHDs relationship with outside partners (hospital systems, Medicaid, providers, CBOs)? hat is the surveillance system that you use? What challenges/barriers exist? What works? hat is the surveillance system that you use? What challenges/barriers exist? What works? he do you receive reports from the State? he gative lab reporting available to the LHD? What about LFTs? Any other data? there someone at the LHD conducting case classification? there routine review for QA/QI in relation to local case status' and case investigation formation? hat are the LHDs strengths in data collection? What about weaknesses? hw often do you communicate with the State? hw are updates (case investigation changes, testing/treatment recommendations, etc.) hat are the State? he was a updated to the State? he state provide any surveillance/analytical support for HCV?			
Strengths		Weaknesses	Opportunities	Threats	