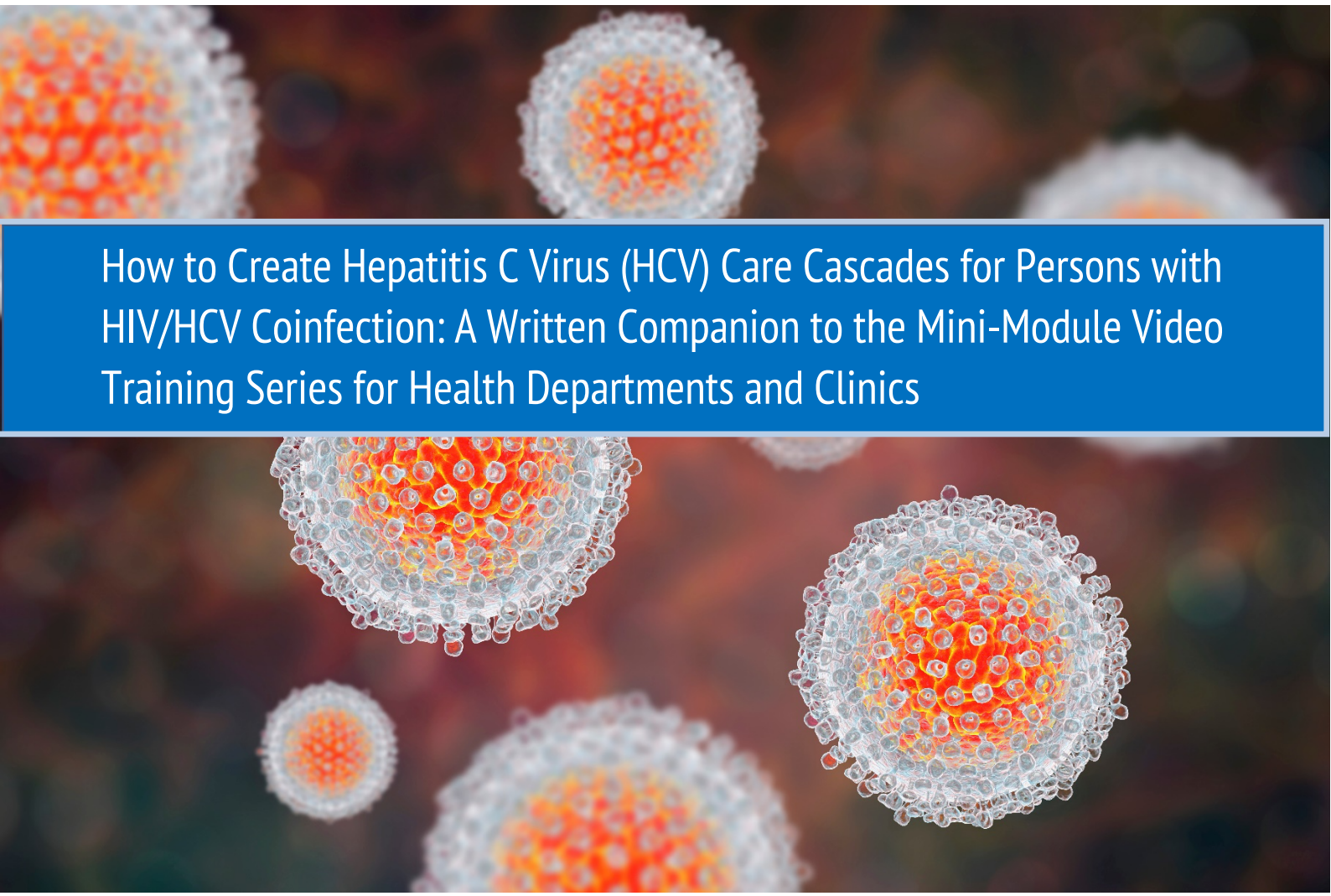


How to Create Hepatitis C Virus (HCV) Care Cascades for Persons with HIV/HCV Coinfection: A Written Companion to the Mini-Module Video Training Series for Health Departments and Clinics

Yale School of Medicine, AIDS Program

Ralph Brooks, MS
Data Manager

Lisa Nichols, MPH
Program Manager

Katarzyna Sims, PhD
Instructional Design and eLearning Manager

Merceditas Villanueva, MD
Director, AIDS Program

Maximilian Wegener, MPH
Epidemiologist

Arizona Department of Health Services

Alena Pittman
Senior Epidemiologist, MSC

Michigan Department of Health and Human Services

Geoffrey Brousseau, MPH
Viral Hepatitis Unit Manager

Adam Hart, MPH
Viral Hepatitis Epidemiologist & Surveillance Coordinator

Macey Ladisky, MPH
Viral Hepatitis Prevention Coordinator

Glossary of abbreviations

CDC- - Centers for Disease Control and Prevention

CEA - - Cost-Effectiveness Analysis

D2C - - Data to Care

ELR - - Electronic Lab Reporting

HCV - - Hepatitis C Virus

HIV - - Human Immunodeficiency Virus

RWHAP - - Ryan White HIV/AIDS Program

SVR - - Sustained Virologic Response

Table of Contents

Introduction

Background

Chronic hepatitis C viral (HCV) infection is a major cause of liver damage, (including cirrhosis), liver cancer, and death. Persons with HIV and HCV co-infection have worse clinical outcomes compared to those with HCV mono-infection. Since late 2013, well-tolerated and highly effective direct-acting antivirals (DAAs), have revolutionized the treatment of HCV. The DAAs enable individual cures and the avoidance of long-term consequences of HCV infection as well as the achievement of the public health goal to eliminate HCV.[1]

Strategic Planning Efforts

National and global strategic plans have been created with goals of eliminating HCV through enhanced testing and treatment.

The U. S. National Viral Hepatitis Strategic Plan outlines 5 major goals pertinent to viral hepatitis:[2]

Goal 1:	Prevent New Viral Hepatitis Infections
Goal 2:	Improve Viral Hepatitis–Related Health Outcomes of People with Viral Hepatitis
Goal 3:	Reduce Viral Hepatitis–Related Disparities and Health Inequities
Goal 4:	Improve Viral Hepatitis Surveillance and Data Usage
Goal 5:	Achieve Integrated, Coordinated Efforts That Address the Viral Hepatitis Epidemics among All Partners

HCV Elimination

The Centers for Disease Control and Prevention (CDC) HCV Guidance for Jurisdictional Hepatitis C Elimination Strategic Planning 2021 is a roadmap for health department jurisdictions to achieve HCV elimination.[2] It articulates detailed objectives for each goal within the National Viral Hepatitis Strategic Plan with sample strategies. While all the goals are important, we developed this training specifically to implement the objectives of Goal 4, Improve Viral Hepatitis Surveillance and Data Usage. Specific objectives include:

Objective 4.1	*Improve public health surveillance through data collection, case reporting, and investigation at the national, state, tribal, local, and territorial health department levels*
Objective 4.2	*Improve reporting, sharing, and use of clinical viral hepatitis data*
Objective 4.3	*Conduct routine analysis of viral hepatitis data and disseminate findings to inform public health action and the public*

Sample strategies are outlined in each objective including:

- *Develop a hepatitis C viral clearance cascade surveillance system consistent with CDC guidance to monitor HCV elimination progress and to inform quality improvement efforts.*

- *Use the hepatitis C viral clearance cascade to identify and engage patients in need of HCV RNA testing, linkage to care, initiation of treatment, and confirmation of cure.*

The HCV Viral Clearance Cascade

The importance of a HCV clearance cascade lies in its utility to track population-level progression from HCV diagnosis to cure.[3] The CDC's HCV clearance cascade provides standardized methodology based on laboratory reporting which can include public health surveillance data.[4] The viral clearance cascade also provides insight into testing and treating gaps making it a vital tool in addressing and monitoring progress towards HCV elimination.[4]

The cascade provides an initial step for health department jurisdictions to assess the population level status of HCV elimination and identify gaps along each step of the cascade.[4] This is essential to developing innovative approaches to achieve HCV elimination.[4]

What is Data to Care?

One of the goals for the creation of the viral clearance cascade is the application of Data to Care (D2C) strategies.

CDC defines D2C as a public health strategy that uses HIV surveillance data, pharmacy fill data, clinic appointment data, and other treatment and care data sources to identify persons with HIV who are not in care, link them to appropriate medical and social services, and ultimately support the HIV Care Continuum (Data to Care (hyperlink)).[5]

D2C is a collaborative endeavor among health departments, medical providers, and clinics, and it is applied as part of a wide-ranging strategy for linkage to and re-engagement in care activities. It is part of the National HIV/AIDS Strategy 2021-2025.[5]

The D2C Approach can be expanded to further the goals of HCV Elimination.

Training Approach

This written companion developed as a result of a two-year (2020-2022) HRSA-funded project HRSA-20-077 "Leveraging a Data to Care Approach to Cure Hepatitis C within the Ryan White HIV/AIDS Program (RWHAP)".[6] The focus within the training is on persons with HIV and HCV coinfection.

The grant supported collaboration with seven health department jurisdictions and Yale Team HepC (**Y**ale **Te**chnical **A**ssistance for **M**icro elimination of **He**patitis in **P**eople with HIV **C**o-Infection) who served as the technical assistance provider for the project. The project had two major components:

1. Creation of health department jurisdictional HCV clearance cascades
2. Outreach and linkage to HIV Clinics

We developed a training platform to accomplish these two components.

The Mini-Modules Approach

We developed an eLearning platform consisting of short (2-4 minutes) videos (mini-Modules) on core topics related to the development and use of the HCV viral clearance cascade. The advantages of using videos are that they are:

- Brief
- Practical
- Interactive

This written companion is meant to **complement** the on-line mini learning modules *(TargetHIV website: https://targethiv.org/spns-hcv-dtc*) and is NOT meant to be a verbatim transcript of the modules.

It describes the process of creating a viral clearance cascade specifically for individuals with HIV/HCV co-infection. It offers a practical step-by-step explanation on how to build a surveillance-based viral clearance cascade for this priority population which can be expanded for use in persons with HCV mono-infection.

It also describes a specific D2C approach, namely, the process of "case conferencing" whereby health departments can partner with individual clinics to create clinic-based HCV care cascades.

A formal Implementation Manual entitled "Leveraging a Data to Care Approach to Cure Hepatitis C" which gives further details on project outcomes is also available on the TargetHIV website https://targethiv.org/spns-hcv-dtc.

Goals & Objectives

- Explanation of tools and methodology for HCV and HIV database cleaning and matching.
- Creation and utilization of the viral clearance cascade.
- Implementing the Case Conference approach with individual clinics to promote Data to Care strategies
- Lessons learned and practical tips for replicating this approach for health department jurisdictions.

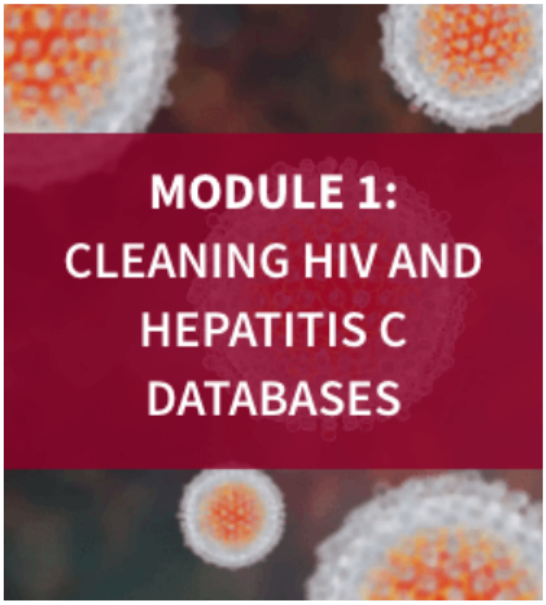
Target Audience

This document supports public health department and clinic staff, and is intended for:

- ☑ Epidemiologists
- ☑ Project coordinators
- ☑ Surveillance data analysts
- ☑ Case managers (clinic and non-clinic based)
- ☑ Clinic and community-based health nurses
- ☑ Clinic managers
- ☑ Clinic data managers
- ☑ Providers (physicians, physician assistants, APRNs)

Mini-Modules

CLEANING HIV AND HEPATITIS C DATABASES



Module 1

Video 1.1: Ensure Data are Unique, Complete and Accurate

Video 1.2: Resolve Hepatitis C Paper Lab Result Backlog

Cleaning the HIV and HCV surveillance data is a necessary step before matching HIV and HCV databases and creating the clearance cascade. This process involves a thorough examination and review of the data available through the reporting system and ensuring that the data are unique, complete, and accurate.

One of the best practices for HCV surveillance is creating an electronic system for the systematic collection and storing of HCV laboratory test results and other case data such as demographic, risk, and clinical information for unique (de-duplicated) persons.

Disease surveillance systems vary across jurisdictions. The Connecticut Department of Public Health uses CTEDSS (Connecticut Electronic Disease Surveillance System) to collect information about reportable diseases including HCV. The Arizona Department of Health Services uses Arizona's Medical Electronic Disease Surveillance Intelligence System (MEDSIS) to collect HCV data.

DATA MUST BE UNIQUE

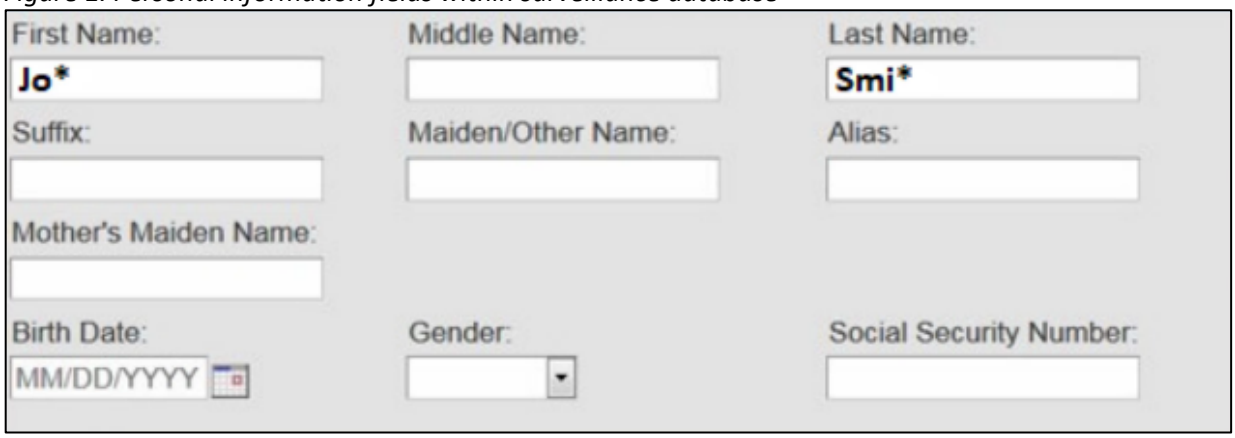
When entering the data into the systems either from ELR (Electronic Laboratory Reporting) or paper, any duplicates found for any patient entry need to be reconciled. Reviewing patients' information ensures that the patient is not included in the database under a misspelled name, incorrect Social Security Number, or incorrect date of birth (**Figure 1**).

How to review patients' information:

Conduct a quick search using the following personal information fields located on the lab report such as:

1. Date of birth
2. Social security number
3. Last name
4. First name

Figure 1. Personal information fields within surveillance database



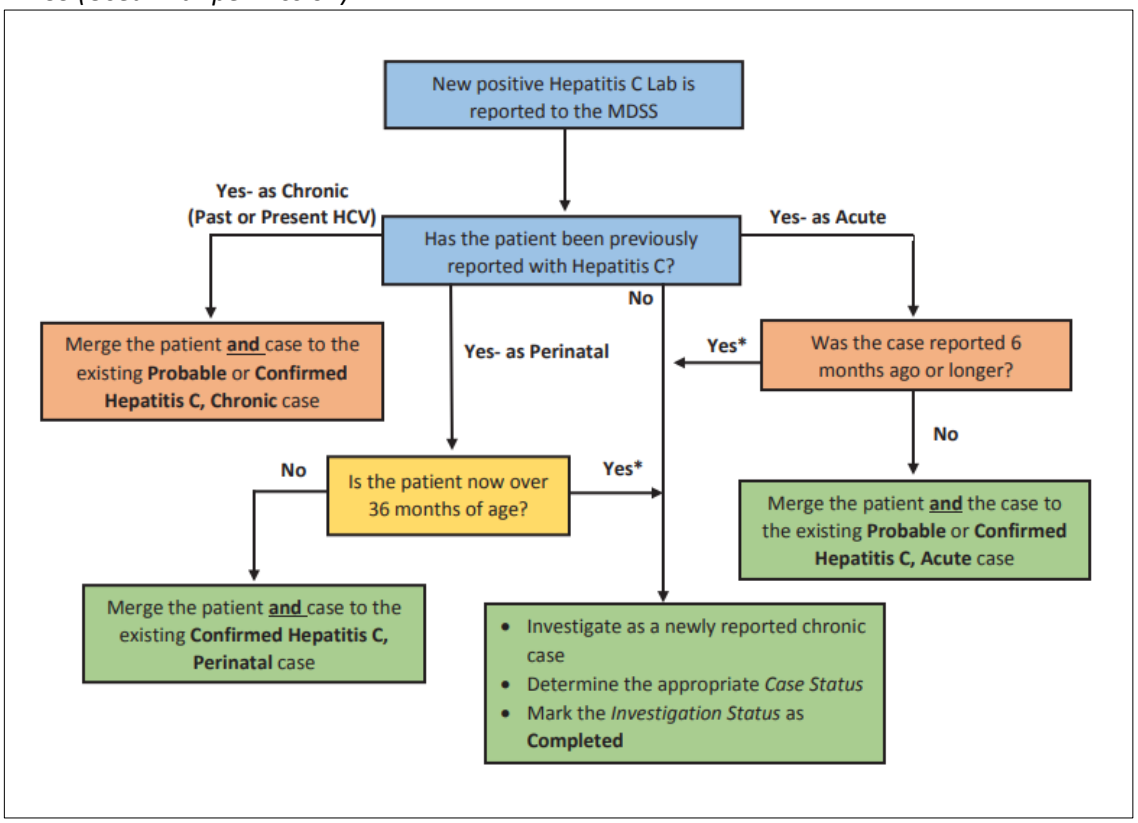
Special wildcard characters (*) that rely on partial entries or values are often used when conducting a database search. The wildcard for name, for example, relies on partial name for matching (**Figure 1**).

If a patient appears more than once in the database, you may follow your jurisdiction's policy on deduplicating the patient's entries.

As an example, the Michigan Department of Health and Human Services offers instructions for deduplication in their manual for their surveillance system, the Michigan Disease Surveillance System (MDSS)

The flow in **Figure 2** from Michigan's MDSS shows that an individual can only be reported and calculated once in their lifetime including for perinatal HCV. If the same person tests positive for HCV and is older than 36 months of age, a new chronic case should be created.

Figure 2. Deduplicating Hepatitis C Reports in Michigan Department of Health and Human Services, MDSS (Used with permission).



If surveillance staff comes across a different person in the database who also appears more than once when performing the database search, they should reconcile this individual before entering data for the laboratory results.

DATA MUST BE COMPLETE

There are minimum recommended fields for doing the database match between HIV and HCV surveillance, specifically for project reporting case conferencing.

The minimum recommended fields for doing the match are:

- ☑ First name
- ☑ Last name
- ☑ Date of birth
- ☑ Gender
- ☑ Social security number if available

The following variables should be included on the final matched dataset that come from both HIV and HCV surveillance:

- ☑ Race
- ☑ Ethnicity
- ☑ Age
- ☑ Birth sex
- ☑ Gender
- ☑ Residence
- ☑ Deceased status
- ☑ Date of last HIV visit
- ☑ HIV lab type
- ☑ HIV lab result
- ☑ HIV lab collection date
- ☑ Hepatitis C lab type
- ☑ Hepatitis C lab result
- ☑ Hepatitis C lab collection date

DATA MUST BE ACCURATE

One of the examples of the lack of data precision is when a person is defined as chronically infected in the HCV surveillance database, but they do not have the appropriate labs to confirm this, such as no PCR positive result for cases added after 2016, or no elevated signal-to-cutoff (S/Co) ratio prior to 2016.

Another example is the discrepancy between the formats of the entered quantitative and qualitative results. For example, if a person is entered into the database with a qualitative negative result but their quantitative result, which was collected on the same day, shows <100 IU per milliliter, they may need to be reevaluated since a negative result is usually <15 IU per milliliter

Summary

Cleaning patient data reported in the HIV or HCV database can be summarized in 3 steps:

STEP 1

Follow the process for data cleaning and standardizing laboratory reports, making sure that data are **unique**.

STEP 2

Evaluate laboratory reports for **completeness** and **accuracy**.

STEP 3

Identify and analyze possible **duplicate** laboratory report, and person entries.

RESOLVE HEPATITIS C PAPER LAB RESULT BACKLOG

If the jurisdiction is experiencing an HCV paper lab result backlog, only those labs that contain new information should be entered. This means that any labs that have been previously entered into the system should not be entered.

EXAMPLE: Let's imagine that there is a person by the name of John Smith with an HCV antibody positive paper lab.

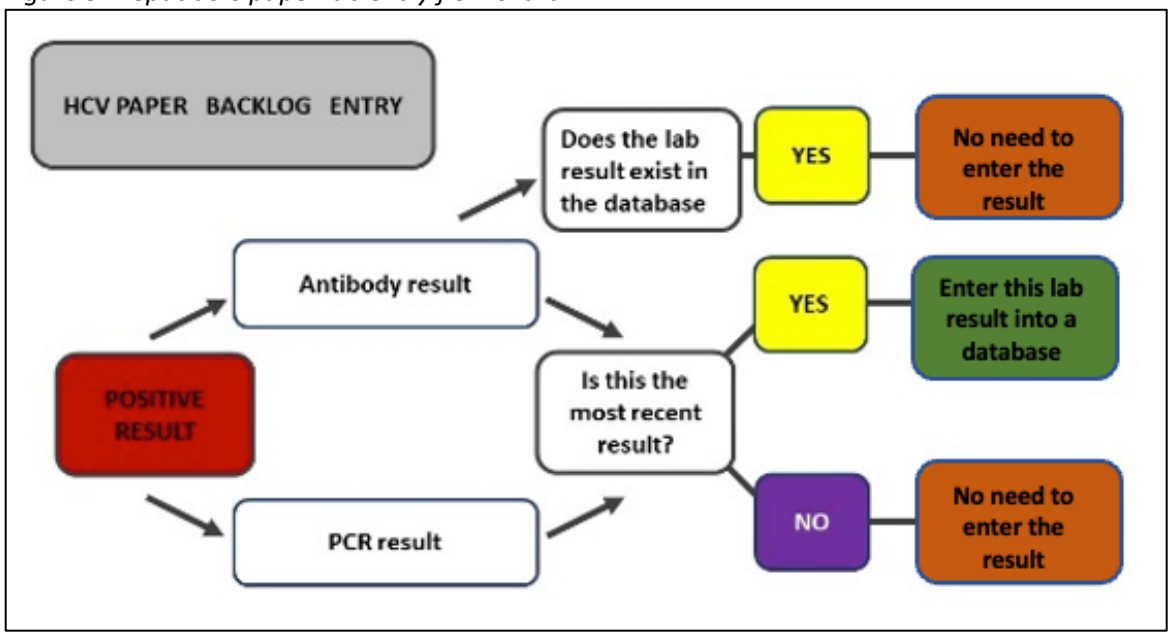
Search for John in the database using the following steps (see **Figure 1**).

1. Search last name as it appears on the report.
2. Search last name using wildcards (*) in case John is in the database under a misspelled name. For John Smith, this will be SMI*.
3. Search date of birth.
4. Search Social Security number, if available, or even last four digits in case it is entered wrong in the database.

If the database shows that John already has, for example, a recorded positive HCV antibody lab or a positive PCR result with no antibody result, then **do not enter** these additional results in the database.

If the scenario is different and John has a positive PCR paper lab result, verify the results in the database to see if any positive PCR results have been recorded that are more recent. If there is a more recent positive PCR result in the database, **do not enter the paper results.** If the PCR result is the most recent, **enter it into the database**. Please see **Figure 3** for simplified flow of this process.

Figure 3. Hepatitis C paper lab entry flow chart

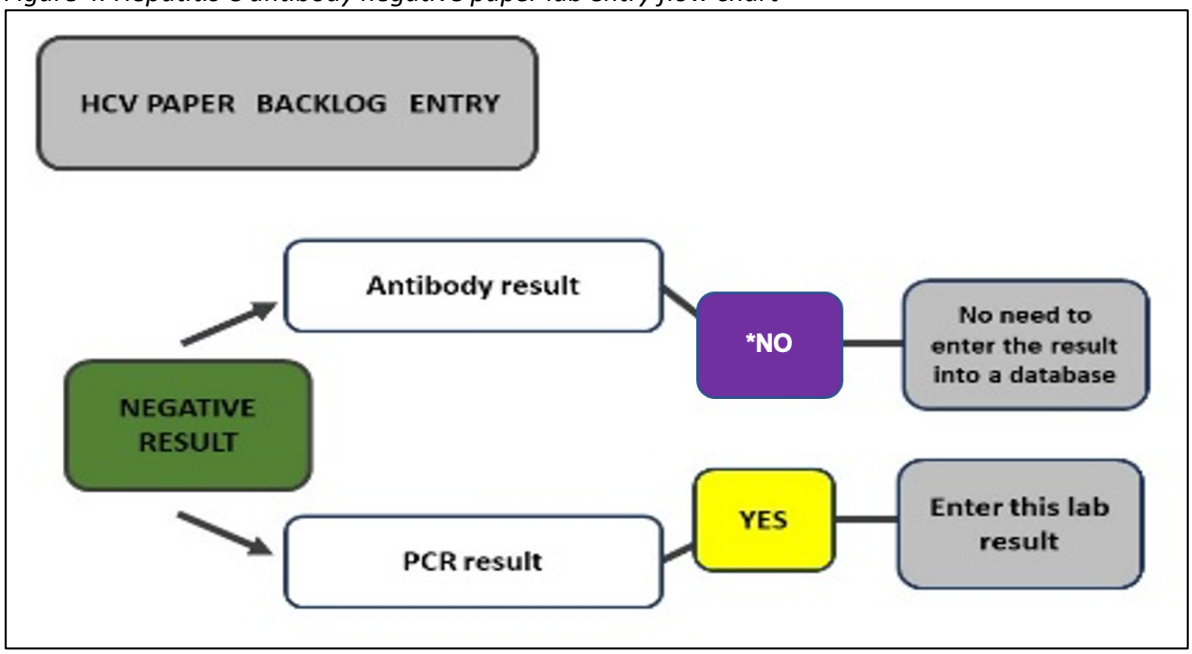


PATIENTS WITH HEPATITIS C ANTIBODY NEGATIVE PAPER LAB.

John's situation looks different if he has a negative HCV result. If John has a negative PCR paper result, then enter it into the database since all negative PCRs should be entered. Of course, this only applies if your jurisdiction collects negative PCRs.

If there is a negative antibody paper result for John but jurisdictional policy prohibits its entry, then do not enter it. Many jurisdictions do not track negative HCV antibody results. Please see **Figure 4** for a simplified flow of this process.

Figure 4. Hepatitis C antibody negative paper lab entry flow chart



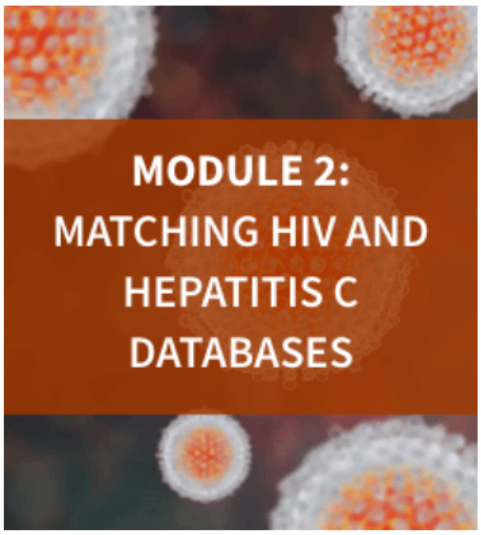
*If antibody negative results are reportable in your jurisdiction, then enter the result into the database – consult your jurisdiction's surveillance data policies

Summary

The data entry flow is different depending on whether a person's hepatitis C antibody paper lab result is positive or negative.

*If you discover that a person is not in the database, enter whatever lab you have into the database according to your jurisdiction's policy on lab types that are reportable.

MATCHING HIV AND HEPATITIS C DATABASES



Module 2

Video 2.1: Match Variables from HIV and HCV Databases

Video 2.2: Probabilistic and Deterministic Matching

Video 2.3: Determine if a Person is Deceased or Lives Out of State

PROBABILISTIC AND DETERMINISTIC MATCHING

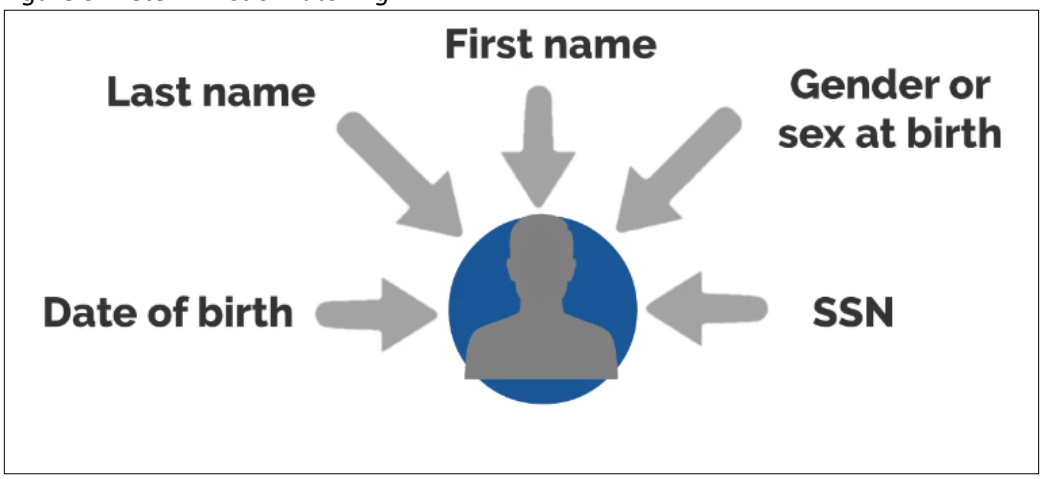
Two methods exist when performing data matching: deterministic and probabilistic.

Deterministic can be thought of as a more specific method while probabilistic is more sensitive.

Deterministic matching (**Figure 5**) involves using unique individual identifiers that are collected across multiple databases that can only be linked to a single person.[7] This method relies on accuracy of data input into each database.

For example, if there are slight variations in values for the matching variables or the values are missing, then a match will not occur even if the person is in both databases. Therefore, the variables must be identical.

Figure 5. Deterministic Matching



Probabilistic matching involves using probability estimates that measure the likelihood that a person who appears in one database is the same that appears in another even when some unique individual identifiers are not exact comparisons between the two databases. The most important takeaway from this method is that it allows for data entry errors and partial values, for example, partial or misspelled names, incorrect dates of birth, if someone changes their last name, etc. The actual process of matching is the same regardless of the method.

Many jurisdictions use probabilistic matching methodology; one of the recommended software programs that uses probabilistic methodology is Match*Pro (hyperlink).[8]

For probabilistic matching methods, many systems provide ways to determine if the matches are likely correct by assigning weights or scores to each matching variable. These weights can be categorized as exact match, uncertain match, or no match (**Figure 6**).

*Figure 6. Probabilistic Matching weights example from Match*Pro*

These results can be viewed by choosing the program's linkage results option.

Surveillance staff should consult their program's guide for specifics on weights and how to run the report. After these results are received, a manual review can be conducted to see if the undetermined matches are matches or not.

CHOOSING VARIABLES

The primary goal of matching is to determine if one person exists in both databases.

It is important to choose appropriate matching variables that most likely remain constant throughout a person's life to obtain as many matches as possible.

The variables we recommend are:

- ☑ First name
- ☑ Last name
- ☑ Date of birth
- ☑ Gender
- ☑ Social security number, if available

FORMATTING

The next step would be formatting all above listed variables so that they are identical in both HIV and hepatitis C databases.

EXAMPLE: for the variable "race" if the value 01 represents white and the value 02 represents black in the HIV database, then the same variable should represent white and black in the HCV database.

CODING MISSING OR UNKNOWN VALUES

Coding of missing or unknown values should be performed once formatting has been completed.

Consult organizational policy for programming standards for each missing and unknown value.

If no standard exists, one can be created. For example, unknown for unknown values, N/A for missing values. The same conventions need to be applied for both the HIV and hepatitis C datasets.

If the HIV database has a standard way of presenting missing and unknown values and the HCV database does not, then the conventions from the HIV database should be followed.

CREATING A DATA SET

Once the match is accurate, a data set for the matched group can be created. This new data set will include the variables used for matching along with others from each database needed to conduct the final analysis.

The following variables are recommended in addition to the ones already mentioned for the match.

- ☑ Race
- ☑ Ethnicity
- ☑ Age
- ☑ Birth sex
- ☑ Gender
- ☑ Residence
- ☑ Deceased status
- ☑ Date of last HIV visit
- ☑ HIV lab type
- ☑ HIV lab result
- ☑ HIV lab collection date
- ☑ Hepatitis C lab type
- ☑ Hepatitis C lab result
- ☑ Hepatitis C lab collection date
- ☑ Last known ordering HIV provider
- ☑ Last known ordering HIV provider facility
- ☑ Last known ordering HIV provider phone number
- ☑ HIV transmission category
- ☑ Patient full address including street
- ☑ City-state, zip code
- ☑ Patient phone number

DETERMINE IF A PERSON IS DECEASED OR LIVES OUT OF STATE

During the process of matching the HIV and HCV databases, surveillance staff are asked to include a variable that identifies a patient's deceased status. Ensure that the values for this variable are not missing, and that it is possible to ascertain who is and is not deceased if the values are coded.

EXAMPLE: if the variable is titled deceased and includes values of 01 and 02, confirm that 01 either means yes, deceased, or no, not deceased, or vice versa.

Similar to identifying who was deceased on the matched list, staff should identify which persons are out of state.

Again, prior to the match, data staff are asked to include one variable that identifies the residential status of each patient. Ensure that the values for this variable are not missing. If the values are coded, it is possible to determine who is a state resident or not.

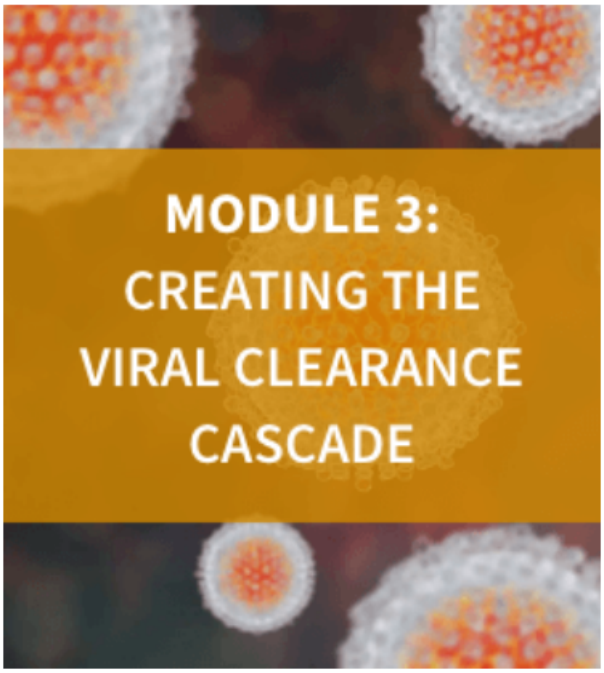
For example, if the variable is titled resident and includes values of 01 or 02, confirm that 01 either means yes, resident, or no, out of state, or vice versa.

It is also recommended that you follow your jurisdiction's policies for notifying other jurisdictions about any newly identified out of jurisdiction residents to prevent these persons from falling into testing or treatment gaps.

Summary

There are minimum fields for matching and reporting. The variables for HIV and HCV datasets must have the same values. Missing and unknown values must be coded, and new coding standards created if no standard exists in the organization.

CREATING THE VIRAL CLEARANCE CASCADE



Module 3

Video 3.1: Define HCV Case Status Based on Laboratory Result Dispositions

Video 3.2: Specify Elements of the Viral Clearance Cascade

Video 3.3: Use the Viral Clearance Cascade

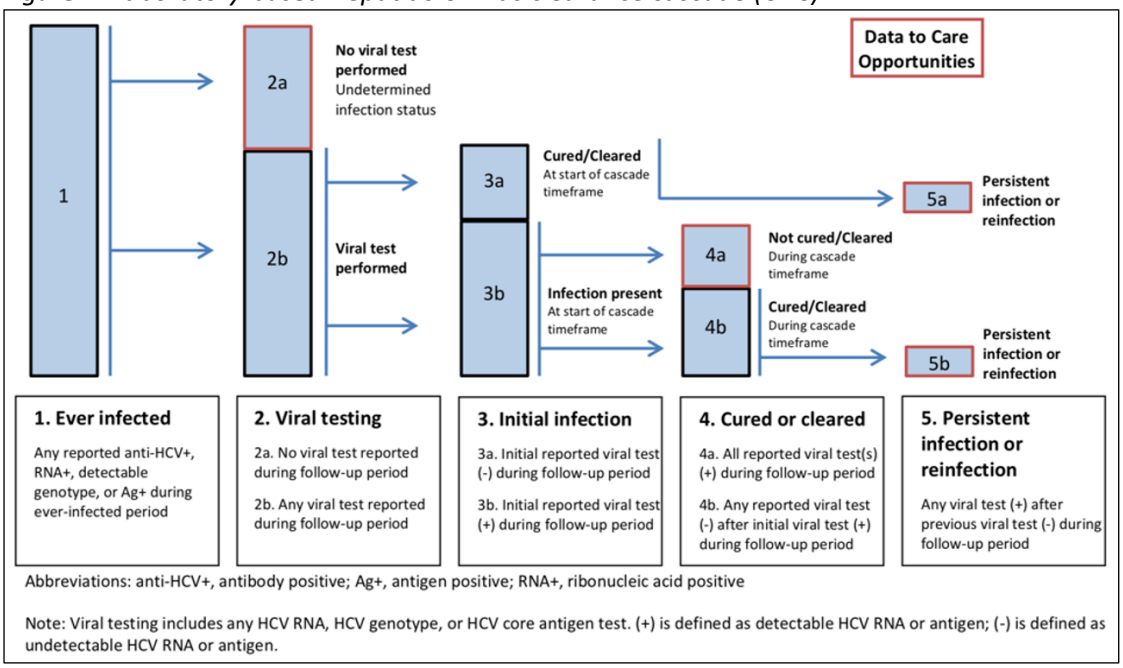
HCV VIRAL CLEARANCE CASCADE STEPS

The CDC developed a standardized, laboratory result-based HCV clearance cascade for public health jurisdictions. An example of HCV clearance cascade can be found in **Figure 7** which also shows the five key steps which make up the cascade along with details of these steps.[4] The five steps include:

1. EVER INFECTED
   - This starting point includes living residents of a jurisdiction with any reported anti-HCV+, RNA+, detectable genotype, or Ag+ during the ever-infected period
2. VIRAL TESTING
3. INTIAL INFECTION
4. CURED OR CLEARED
5. PERSISTENT INFECTION OR REINFECTION

Percentages for steps 2-5 are calculated using the previous step as the denominator. For example, the percentages of those with viral testing performed uses the ever-infected number as its denominator (2b/1); for the cured/cleared rate, the value for initial infection present is used as the denominator (4b/3b).

Figure 7. Laboratory-based Hepatitis C Virus clearance cascade (CDC) [4]



A jurisdictional data collection tool (automated Excel Spreadsheet) is available on *TargetHIV website:* *https://targethiv.org/spns-hcv-dtc*

Figure 8. Screen shot of the jurisdictional data collection tool

Matched Cohort Data Period Start	all prevelant cases	start of database (pos HCV ab or PCR)									
Matched Chort Data Period End								SVR% chronic	#DIV/0! 0		
"All LAB results through" date			<== Dropdown								
Submission Due date											
Category	ALL HIV+ (e.g. eHARs)		All HIV+/HCV+ Coinfected ("&")	& Deceased	& Out of Jurisdiction	& Ab+, no PCR	& Ab+, PCR-	& PCR+ [no PCR-]	& PCR+ --> PCR-	& PCR+ --> PCR- -->PCR+	Sum Check (should be zero)
Total patients in category											0
Race											
White / Caucasian											0
Black or African American											0
Asian											0
Native Hawaiian or Pacific Islander											0
American Indian / Alaska Native											0
Other											0
Unknown / Missing											0
TALLY CHECK (should be zero)	0	0	0	0	0	0	0	0	0	0	0
Ethnicity											
Hispanic / Latino											0
Non-Hispanic / Latino											0
Unknown / Missing											0
TALLY CHECK (should be zero)	0	0	0	0	0	0	0	0	0	0	0
Current Age Stats (all combined clients)											
Age (all combined clients), mean											0
Age (all combined clients), sd											0
Age (all combined clients), median											0
Age (all combined clients), IQR - Low (quartile 1)											0
Age (all combined clients), IQR - High (quartile 3)											0
Age (totals by category)											
<18 (as possible)											0
18-25											0
26-35											0
36-45											0
46-55											0
56-65											0
66-75											0
over 75 years											0
Unknown / Missing											0
TALLY CHECK (should be zero)	0	0	0	0	0	0	0	0	0	0	0

*From the target HIV website select "Tool: HCV D2C Co-Infection Clearance Cascade"

DEFINING HCV CASE STATUS BASED ON LABORATORY RESULTS

Laboratory results are ideally extracted from the HCV surveillance database. In some cases, alternative laboratory reporting databases may be used.[9]

The following dispositions (**Table 1**) correspond to the viral clearance cascade steps shown in **Figure 7**.[10]

Table 1. Disposition creation and steps in the HCV viral clearance cascade using HCV laboratory test results

HCV antibody	Subsequent HCV PCR test result	Disposition	Viral clearance cascade step
Positive	None reported	Antibody+ only	1, 2a
	Negative (≥1 PCR) on the same or a later date/specimen	Antibody+, PCR−	1, 2b, 3a
	Positive (≥1 PCR) on same or later date/specimen	Antibody+, PCR+	1, 2b, 3b, 4a
	Positive (≥1 PCR) on same or later date/specimen followed by 1 negative PCR	Antibody+, PCR+, PCR−	1, 2b, 3b, 4b
	Positive on same or later date/specimen followed by ≥2 negative PCRs	Antibody+, PCR+, PCR−	1, 2b, 3b, 4b
	Positive on same date/specimen followed by a later negative PCR followed by another positive PCR (and so on)	Antibody+, PCR+, PCR−, PCR+	1, 2b, 3b, 4b, 5
Negative	None reported	Antibody− only	Excluded
None reported	Negative (≥1 PCR) on the same or a later date/specimen	PCR− only	Excluded
	Positive (≥1 PCR) on same or later date/specimen	PCR+ only	1, 2b, 3b, 4a
	Positive (≥1 PCR) followed by 1 negative PCR on a later date	PCR+, PCR−	1, 2b, 3b, 4b
	Positive followed by ≥2 negative PCRs on a later date	PCR+, PCR−	1, 2b, 3b, 4b
	Positive PCR followed by a later negative PCR followed by another positive PCR (and so on)	PCR+, PCR−, PCR+	1, 2b, 3b, 4b, 5

The CDC also represented the cascade in a simplified version which eliminates steps 2a, 3a, 4a, 5a. An example of this simplified version can be found in an MMWR published by Wester et al in 2023.[9]

USING THE VIRAL CLEARANCE CASCADE:

The viral clearance cascade can be used as a dashboard to capture the current status and longitudinal trends of HCV care within a given jurisdiction. Importantly, jurisdictions can assess testing and treatment gaps along the cascade (**Figure 7**). Testing gaps found in step 2A include persons who have had a positive HCV antibody result with no record of any PCR testing. Treatment gaps found in step 4a include persons in the initial infection group who have no record of PCR negative result.

Addressing the gaps: Quantification of the testing and treatment gaps can lead to the following steps:

- Health department jurisdictions should ensure the accuracy of their HCV surveillance data, e.g., that there are no lab result backlogs (paper or ELR) needing to be entered.

- If data are available, perform demographic gap analysis to address potential disparities in access which can guide interventions.
- Health departments can partner with community stakeholders including RWHAP-funded community organizations.
- Health departments can consider adapting D2C activities including mobilization of Disease Intervention Specialists of field workers to promote care engagement.
- Health departments can facilitate specific partnerships with clinics, e.g., HIV clinics, to promote individual-level interventions that respond to individual barriers.

Another important note is that the viral clearance cascade can be applied to both mono- and co-infected HCV populations.

Summary

An HCV viral clearance cascade can be created by public health departments based on the CDC's standardized laboratory-based approach.

This approach can define testing and treatment gaps that can be addressed with targeted interventions.

The next section, Case Conferencing, will cover this clinic partnership approach in greater detail.

CASE CONFERENCING

Module 4

Video 4.1: The Case Conferencing Tool

Video 4.2: Create the HIV/HCV Co-infected List

Video 4.3: Implement the Case Conference

Video 4.4: Generate and Use the Clinic Care Cascade

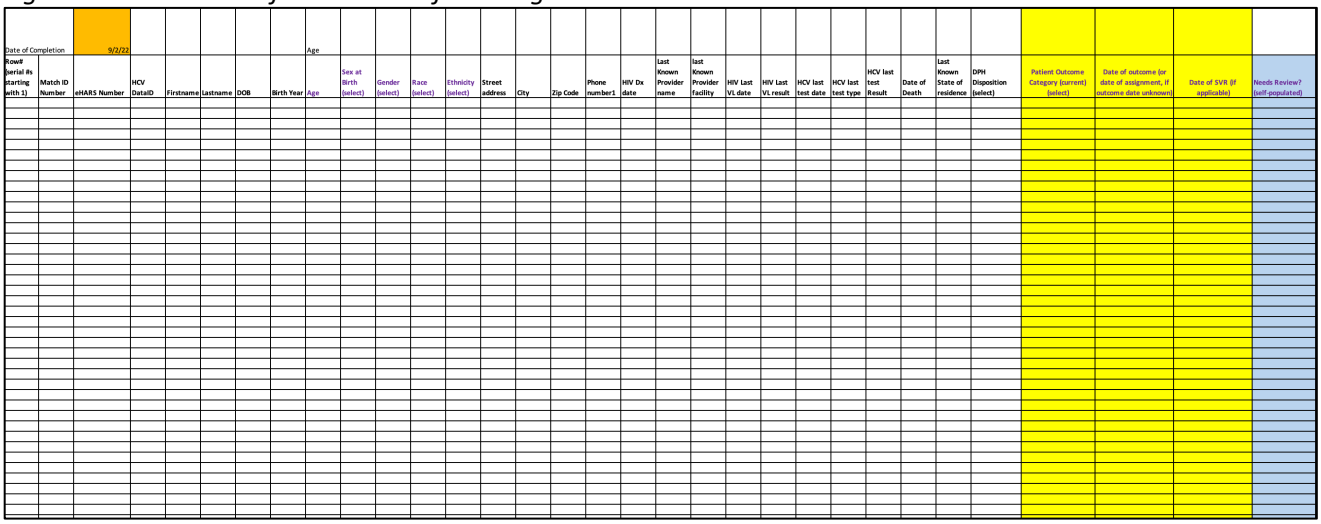
One approach for implementing Data to Care (D2C)[5] is through a case conference—a specific dialogue that occurs between health department and HIV clinic staff members. It is important for health departments to develop relationships with specific HIV clinics based on clinic size, location, and expertise. Some health departments have established relationships with selected clinics while others are still developing them. This relationship requires strategies for communication and a streamlined process for secure data exchange.

Yale Team Hep C has focused on the case conferencing strategy as the methodology for health department and selected HIV clinic communication and data sharing. The main purpose of case conferencing is to identify persons within each clinic who have not been treated for HCV, understand their barriers to treatment, and develop an individualized plan based on clinic-level and health department-level tools and strategies.

THE CASE CONFERENCING TOOL

Yale Team Hep C developed a case conferencing data tool that facilitates the communication and the data sharing between the health department and the clinic and is a key approach for D2C. This data collection tool (an automated Excel spreadsheet) is available on the *TargetHIV website:* *https://targethiv.org/spns-hcv-dtc*.

Figure 9. Screen shot of the case conferencing data tool



Date of Completion	9/2/22						Age																							
Row# (serial #s starting with 1)	Match ID Number	eHARS Number	HCV DataID	Firstname	Lastname	DOB	Birth Year	Age	Sex at Birth (select)	Gender (select)	Race (select)	Ethnicity (select)	Street address	City	Zip Code	Phone number1	HIV Dx date	Last Known Provider name	last Known Provider facility	HIV Last VL date	HIV Last VL result	HCV last test date	HCV last test type	HCV last test Result	Date of Death	Last Known State of residence	DPH Disposition (select)	Patient Outcome Category (current) (select)	Date of outcome (or date of assignment, if outcome date unknown)	Date of SVR (if applicable)	Needs Review? (self-populated)

* From the target HIV website select "Tool: HCV D2C Case Conferencing"

The case conferencing data tool is used to:

1. Track patients' clinical information and treatment outcomes.

2. Generate the clinic's HCV cascade of care for persons with HIV

3. Assist the health departments and clinics to develop a more personalized approach for advancing specific persons through the cascade, by including the person's needs and barriers in the discussion.

The case conferencing tool captures health department lab surveillance data and combines it with clinic care, treatment, and barrier information to create individualized treatment care and outreach plans for clients.

Of note, the case conferencing tool is in the Excel format which is easily adapted by clinics; this lowers the threshold for the skill needed to create a cascade, which can then be created without needing to write a program using complicated statistical software.

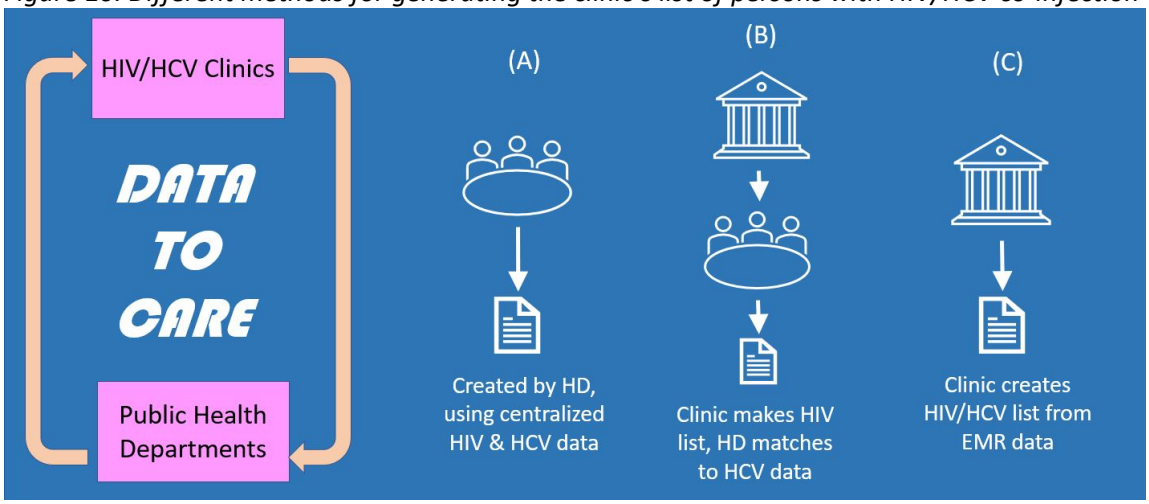
CREATE THE CLINIC HIV/HCV CO-INFECTED LIST

To populate the case conferencing tool, the first step is to identify the starting cohort based on timeframe. For example, people's receiving HIV clinical care from January 1, 2018 to December 31,

2018 can be a defined cohort that can be followed to see clinical outcomes at any timepoint. The HCV treatment status would utilize the latest available information at specified timepoints.

Creating a clinic's HIV/HCV list, i.e., defining the cohort for tracking, can be done in various ways. We propose three possible models (**Figure 8**) based on the degree of collaboration between the health department and participating clinic:

Figure 10. Different methods for generating the clinic's list of persons with HIV/HCV co-infection



Method A: Health Department Initiated

Jurisdictions that can generate persons with HIV data at the Health Department: health departments use CAREWare (or eHARS) to identify persons who received care during the defined timeframe and match that list to their HCV repository (surveillance). The health department can then populate the case conferencing data tool and share it with the clinics.

Method B: Clinic Initiated

This is a combined effort of health department and clinic, where jurisdictions require persons with HIV data to be generated by clinics: clinics will generate their persons with HIV list using a specified timeframe and send it to the health department who will match this list with their HCV repository (or projected generated coinfected list). The health department can then populate the case conferencing data tool and share it with the clinics.

Method C: Clinic Driven

Clinics can generate their own coinfected list of people receiving services during the selected timeframe using medical records and billing code reviews and send it to the health department. The health department will verify this list and populate the case conferencing data tool with this information and return the tool to the clinic.

The optimal model depends on the jurisdiction and the clinics, including any public health statutes governing data sharing limitations, as well as resource capacity at both the health department and clinics.

IMPLEMENT THE CASE CONFERENCING PROCESS

There are many ways by which a case conference can occur. Communication between the health department and clinic(s) can be via email, phone, face-to-face, or occur virtually. It is important to have a dedicated health department champion and a designated clinic champion(s) who have a structured meeting at an agreed upon frequency.

Best Practices:

- The clinic champion should be knowledgeable about HCV and able to interpret HCV lab results to accurately assign treatment status designations (e.g., nurse, medical assistant, physician) and correctly perform data entry.
- The case conferencing tool should be filled out ahead of the scheduled case conference discussion between the health department and clinic champions. The clinic champion should use medical records, clinic notes, and other patient level information to select the appropriate outcome from the drop-down list and indicate the date of the outcome in the case conference data tool. In cases where the patient is deceased or relocated, or if a lab result dictates the outcome, then these event dates (e.g., date of death) may be used instead.

Resolving Discrepancies in Data:

During the case conference, the health department champion and the clinic champion will review the data in the case conference tool. If the health department provides surveillance data that indicate the individual has achieved cure, and this is discrepant with the clinic's designation, then further chart review will be needed. If the clinic designates a person as "not treatment eligible" but the health department has data showing that the person is residing in the jurisdiction with a PCR positive result, the clinic can then change the designation to "treatment eligible".

During case conferencing, the clinic may identify a need for assistance from the health department DIS staff to locate and re-engage individuals who are out of care including identifying specific patient-level barriers to starting treatment.

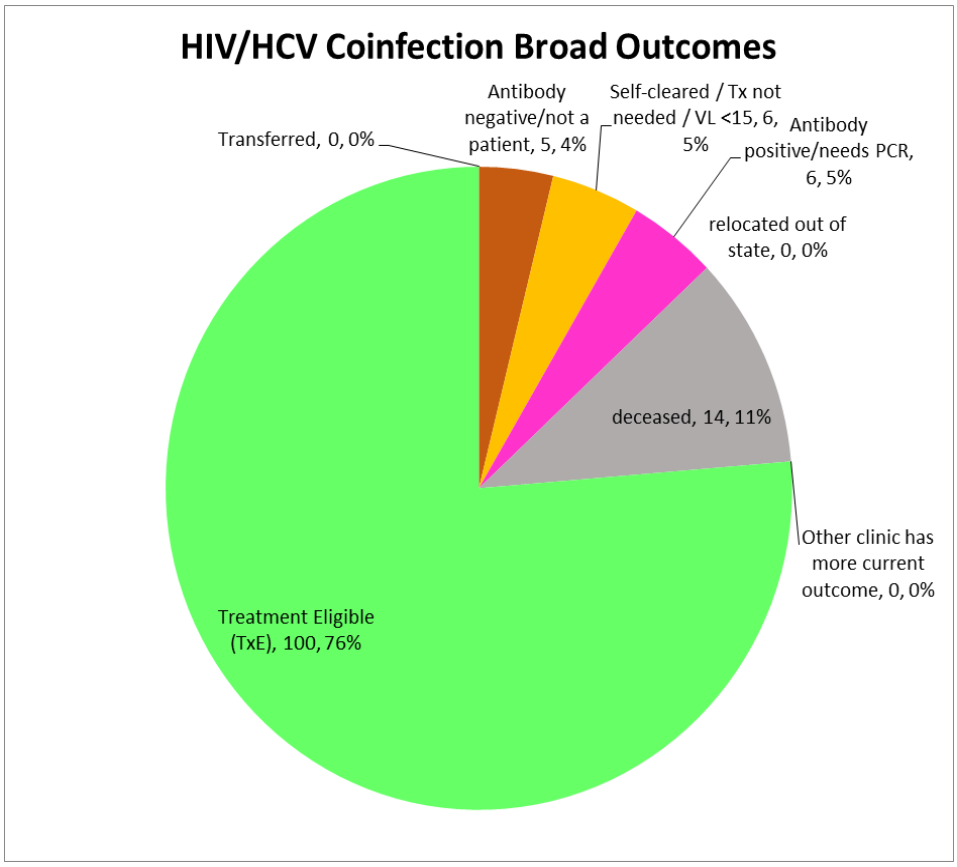
GENERATE AND USE THE CLINIC CARE CASCADE[11]

Once the case conference has occurred and person outcome status identified, the tool will automatically generate the clinic's HCV cascade of care.

The case conference data tool generates two charts – a pie chart and a bar graph.

The pie chart (**Figure 11**) is intended to identify those who are "treatment eligible" within the clinic sphere compared to the various subcategories of "non-treatment eligible" individuals. For example, those who are deceased, , have relocated, need PCR testing, have self-cleared, and those who have had their care transferred to another clinic are classified as not eligible for HCV treatment within the specific target clinic being considered (see Module 4, video 4). Incarcerated individuals are also in need of treatment but often during incarceration, they are beyond the reach of the clinic's staff. For this reason, they have been included among the "non-treatment" eligible categories. Mechanisms by which treatment might be supplied to them while incarcerated will vary by jurisdiction and may involve the Department of Corrections. Upon release, they would then return to treatment eligible status within the clinic cascade.

Figure 11. Case conferencing pie chart to identify HCV status of clinic patients with HIV/HCV coinfection

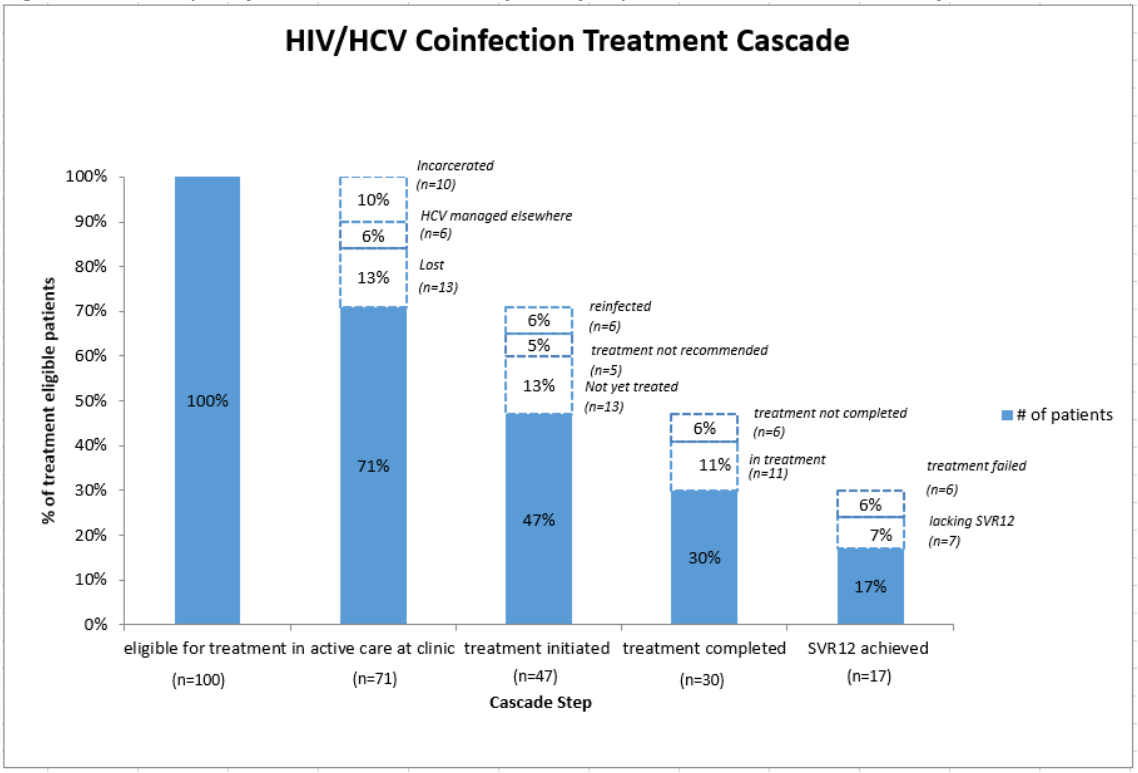


The case conference data tool also generates the clinic's HCV treatment cascade in a bar graph (**Figure 12**) for "treatment eligible" patients. These are reflected in five cascade steps:

- eligible for treatment,
- in active care at the clinic,
- treatment initiated,
- treatment completed,
- Sustained Virological Response at 12 weeks post treatment completion (SVR12)

An example of an individual clinic's HCV care cascade is shown in **Figure 12**.

Figure 12. Example of Clinic HCV cascade of care for persons with HIV/HCV coinfection



The cascade depicts various gaps in detail and highlight's granular knowledge possessed by specific clinics. There are three key gaps highlighted by the tool:

1) People with HCV Ab positive test result who lack PCR test result (see pink slice in Figure 9)
2) People who are "lost" to HIV care (see Figure 10)
3) People who are "not yet treated" (see Figure 10)

Clinic staff will need to develop individualized strategies, which may include collaborating with the health department or tapping into other resources to address patient level barriers identified (e.g., referral to substance use treatment), with the goal of moving people through the care cascade to HCV cure.

Summary

Data to care can be implemented by means of a case conferencing method involving individual clinics and health departments.

This ideally involves a champion from the health department and the clinic.

This approach can generate a clinic-specific HCV care cascade that can provide a starting point for personalizing treatment plans for persons who have not achieved cure.

REFERENCES

1. The Centers for Disease Control and Prevention (CDC). Division of Viral Hepatitis – 2025 Strategic Plan. 2020
2. HCV Guidance: Recommendations for Testing, Managing and Treating Hepatitis C. www.hcvguidelines.org
3. Thomas DL. State of the Hepatitis C Virus Care Cascade. *Clinical Liver Disease.* 2020;16(1):8-11. doi:10.1002/cld.915
4. Montgomery MP, Sizemore L, Wingate H, et al. Development of a Standardized, Laboratory Result-Based Hepatitis C Virus Clearance Cascade for Public Health Jurisdictions [published online ahead of print, 2023 May 4]. *Public Health Rep*. 2023;333549231170044. doi:10.1177/00333549231170044
5. Sweeney P, Hoyte T, Mulatu MS, et al. Implementing a Data to Care Strategy to Improve Health Outcomes for People With HIV: A Report from the Care and Prevention in the United States Demonstration Project. Public Health Rep. 2018;133(2_suppl):60S-74S. doi:10.1177/0033354918805987
6. Leveraging a Data to Care Approach to Cure Hepatitis C within the Ryan White HIV/AIDS Program (RWHAP) | *HRSA*. Accessed May 23, 2023. https://www.hrsa.gov/grants/find-funding/HRSA-20-077
7. Bosh KA, Coyle JR, Muriithi NW, Ramaswamy C, Zhou W, Brantley AD, et al. Linking HIV and Viral Hepatitis Surveillance Data: Evaluating a Standard, Deterministic Matching Algorithm Using Data From 6 US Health Jurisdictions. *American Journal of Epidemiology.* 2018;187(11):2415-2422
8. Match*Pro Software | National Institute of Health: National Cancer Institute https://seer.cancer.gov/tools/matchpro/
9. Wester C, Osinubi A, Kaufman HW, et al. Hepatitis C Virus Clearance Cascade — United States, 2013–2022. *MMWR Morb Mortal Wkly Rep.* 2023;72:716–720. DOI: http://dx.doi.org/10.15585/mmwr.mm7226a3.
10. Wegener M, Brooks R, Speers S, Nichols L, Villanueva M. Implementing a Surveillance-Based Approach to Create a Statewide Viral Clearance Cascade for Hepatitis C Among People with HIV and HCV Coinfection in Connecticut. *Public Health Reports*. 2023;0(0). doi:10.1177/00333549231172173
11. Brooks R, Wegener M, Speers S, et al. Creating a Longitudinal HCV Care Cascade for Persons With HIV/HCV Coinfection in Selected HIV Clinics Using Data to Care Methods. *Health Promotion Practice.* 2023;0(0). doi:10.1177/15248399231169792

ACKNOWLEDGMENTS

Collaborating Jurisdictions:

Arizona Department of Health Services

Connecticut Department of Public Health

Florida Department of Health in Orange County

Kentucky Department for Public Health

Michigan Department of Health and Human Services

Southern Nevada Health District

Puerto Rico Department of Health