## Drug Treatment Service (DTS) Hepatitis C Micro Elimination Criteria for People in Structured Treatment Within the Defined Population

June 2024

An update to August 2022 agreed criteria - August 2022. For review June 2026.

Drug Treatment Service (DTS) Hepatitis C Micro Elimination Criteria for the People in Structured Treatment Within the Defined Population has been developed and funded by Gilead Sciences Ltd in collaboration with representatives from Gilead-partnered DTS providers and The Hepatitis C Trust.

# Achieving elimination through collaboration

## **Table of Contents**

1.	Disclaimer	Page 3	
2.	Provider Forum Members and Mission Statement	Page 3	
3.	Provider Forum Charter		
4.	. Introduction		
5.	DTS Hepatitis C Micro-Elimination Criteria	Page 6	
	<ul> <li>a. Criteria 1</li> <li>b. Criteria 2</li> <li>c. Criteria 3</li> <li>d. Criteria 4a</li> <li>e. Criteria 4b</li> <li>f. Criteria 4c</li> </ul>	Page 7 Page 8 Page 9 Page 10 Page 12 Page 13	
6.	Exemptions from Micro-Elimination Criteria	Page 14	
7.	Abbreviations and Terminology	Page 15	



#### Disclaimer

This document has been developed by the Gilead Hepatitis C Drug Treatment Service Provider Forum, a coalition of Gilead-partnered drug and alcohol services in England in collaboration with Gilead Sciences Ltd and The Hepatitis C Trust.

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#### Gilead Hepatitis C Drug Treatment Service Provider Forum partners:

(In alphabetical order)

- Change Grow Live
- Gilead Sciences Ltd
- The Hepatitis C Trust
- Humankind
- NHS Addictions Provider Alliance (APA) / HepCULater
- Turning Point
- With You
- Via















#### **Mission Statement**

The Provider Forum is united in our commitment to eliminate hepatitis C for drug and alcohol service users in England, driving change through collaboration and fostering a healthier, stigma free community for our service users.



#### **Provider Forum Charter**

The Gilead HCV Drug Treatment Services Provider Forum is united in our shared commitment to eliminate Hepatitis C in England. Recognising the urgency of this public health challenge to achieve this goal ahead of the World Health Organisation target of 2030, we pledge to work collaboratively, leveraging our collective expertise and resources.

#### Principles:

- 1. **Shared mission**: Through collaboration and shared best practice, we will eliminate Hepatitis C in drug and alcohol services in England, a disease that disproportionately affects our most vulnerable service users.
- 2. **Integrated approach:** We commit to a comprehensive and integrated strategy that combines best practice support for individuals affected by drug and alcohol use, lived experience, NHS clinical expertise and pharmaceutical innovations.
- 3. **Equity and access:** We will work to address health inequalities by delivering equitable access to testing, treatment and support services, ensuring that all communities have the opportunity to benefit from HCV elimination.
- 4. **Innovation and research:** We will foster innovation through joint research initiatives, exploring new pathways and improving existing interventions to reduce stigma and increase access to care for those affected by hepatitis C.
- 5. **Education and awareness:** We will jointly develop and implement educational campaigns to raise awareness about hepatitis C, reducing stigma and promoting prevention.
- 6. **Data sharing and monitoring:** We commit to transparent data sharing and collaborative monitoring mechanisms to track progress, assess outcomes and continually refine our strategies.
- 7. **Service users**: We recognise the importance of centering service users and those with lived experience, incorporating their insights, feedback, wants and needs into everything we do.

#### Actions

- 1. **Best practice sharing:** Share and publish research to advance best practice interventions to achieve HCV elimination in drug and alcohol services.
- 2. Capacity building: Work together to enhance the capacity of drug and alcohol services, ensuring they are well-equipped to address the unique needs of individuals affected by hepatitis C.
- 3. Capability building: Develop and deliver standards and training programmes for our service staff and partners, fostering a multiagency approach to hepatitis C testing and treatment
- 4. Awareness campaigns: Launch joint awareness, testing and treatment campaigns to educate our services users and support them into effective pathways for testing and treatment
- 5. **Policy advocacy:** Develop and advocate for supportive policies and local, regional and national levels to create an enabling and sustainable environment for hepatitis C elimination.

By signing this charter, we affirm our collective dedication to eliminating hepatitis C in drug and alcohol services in England. Through collaboration, innovation and a shared commitment to improving the lives of our service users, we aspire to create a legacy, transforming lives and building a hepatitis C free future for all.



#### Introduction

HCV is one of the main causes of liver disease in England. NHS England has implemented a national HCV elimination programme to eliminate HCV before 2030, and announced the ambition for England to be the first major country in the world to eliminate HCV by  $2025^1$ .  $\approx 90\%$  of HCV infection in England is attributed to injection drug use (IDU), highlighting the critical role of drug and alcohol services in testing for HCV and linking to care those with active HCV infection.  $^2$ 

In September 2020, Gilead Sciences set up The Hepatitis C Drug Treatment Services (DTS) Provider Forum as a unique collaboration between NHS England, The Hepatitis C Trust and the largest providers of DTS in England with a united approach to achieve HCV elimination in DTS: Turning Point, NHS Addictions Provider Alliance (APA), Change Grow Live (CGL), Humankind and With You. Via became a partner of the Provider Forum in 2021. Partnered DTS are commissioned to test service users for HCV and refer them to treatment.

In May 2024, as a benchmark against an individual service's HCV elimination efforts, the Forum reached an updated consensus on criteria for achieving Micro Elimination within a DTS site superseding criteria previously agreed in June 2022. In broad terms, Micro Elimination is the achievement of HCV elimination within a specific location or small population: for DTS, this means that there aren't many patients left with active HCV infection at the site. It is achieved by breaking down national elimination goals for individual population segments or specific settings, for which treatment and prevention interventions can be delivered more quickly and efficiently using targeted methods.<sup>3</sup>

This document sets out the detailed criteria for Micro Elimination of Hep C within a DTS that has been collaboratively established through an extensive and careful review process, and by consensus agreement from the Hep C DTS Provider Forum partners. It is important to note that there are caveats around the criteria, and that the criteria are not intended to be a definitive definition of elimination, but to serve as aspirational targets to local and individual DTS as we work towards our shared ambition to achieve Hep C Elimination in DTS, in England and globally.

Abbreviations and terminology can be found at the end of this document on page 15.



# Drug Treatment Service (DTS) Hepatitis C Micro Elimination Criteria for the People in Structured Treatment Within the Defined Population

Before setting out the criteria for Micro Elimination, it is important to note that:

- 1. The criteria refer to a sub-set of the total client population. It is acknowledged that the criteria will not include all clients and only applies to active clients in structured treatment.
- 2. It is intended that the criteria are to be reviewed and refined on an ongoing basis, and not serve as a definitive definition of elimination in an area and/or service.
- 3. It is expected that as part of any definition of elimination, services undertake a robust quality assurance process which includes reporting against numbers of clients excluded from the definition.
- 4. Reassurance should be provided by the service that clarifies ongoing and future work to address the needs of clients excluded from the definitions.
- 5. Date of meeting the criteria would be reported, and review against the criteria is expected on a 6-monthly basis in order to maintain elimination status.

	Definition
Criteria 1	100% of clients in structured treatment are offered a Hep C test.
<u>Criteria 2</u>	100% of clients in structured treatment who have a history of injecting and have been triaged more than 30 days ago; have a valid Hep C Test Date (equal or prior to Reporting Month End date) and result recorded (ever).
<u>Criteria 3</u>	90% of clients*§ in structured treatment, who have a history of injecting (and are deemed to be at risk), and have been triaged more than 30 days ago, have a Hep C Test Date (in the last 12 months up to the Reporting Month End date) & result recorded.
<u>Criteria 4</u>	90% of clients* in structured treatment with Positive Hep C test result PCR (RNA) status (recorded at the last CIR if present or triage) have commenced treatment† Or: 90% of Service Users with positive hepatitis C AB status and PCR (RNA) status are cleared of hepatitis C. Or: 90 % of clients* in structured treatment with Positive Hep C PCR (RNA) status ever have commenced treatment or have completed it.

<sup>\* 2%</sup> tolerance is permissible



 $<sup>\</sup>S$  Excluding assessed as not appropriate to offer

<sup>&</sup>lt;sup>†</sup> Accountability for patient starts and reporting patient starts sits with the Operational Delivery Network. The service will commit to ensuring a robust referral mechanism and support stakeholders in seeking and implementing a local and/or national mechanism for obtaining and reporting accurate patient start data based on a patient start date defined as date of prescription.

100% clients\* in structured treatment are offered a hepatitis C test.

Denominator	Numerator
Those with a triage date <= reporting month end date and (T3/4 Discharge Date > reporting month end date or T3/4 Discharge Date is null).	Of those specified by the Criteria 1 denominator, the number of clients with Hep C Status
Triage Date Field = TRIAGED T3/4 Discharge Date Field = DISD (structured treatment discharge date)	Hep C Status Field = the last CIRHEPCSTAT (most recent one) if present or HEPCSTAT.  Set to:
N.B the above definition relates to using NDTMS extracts - for internal reports please consider those with psychosocial or pharmacological modality start date <= reporting month end date, psychosocial or pharmacological modality end date > reporting month end date or it is null. This is the NDTMS definition of a client in structured treatment.	Offered and accepted (Pre CDS-P) Offered and accepted - Had a hep C test Offered and accepted - Not yet had a test Offered and accepted but refused at a later date (Pre CDS-P) Offered and refused Assessed as "Not appropriate to offer" Deferred due to clinical reasons
	Additional points of note:  What does not count - is blank or not offered or other values.  Information from CIRs > than month end should be excluded.

<sup>\*</sup> NDTMS Consented clients in Structured Treatment Only (at the end of the reporting month).



100% of clients<sup>†</sup> in structured treatment who have a history of injecting (taken from INJSTAT) and have been triaged more than 30 days ago; and have a valid Hep C Test Date (equal or prior to Reporting Month End date) and result recorded (ever).

Denominator	Numerator			
Include Criteria 1 denominator, and additional criteria as follows:	Of those specified by the Criteria 2 denominator, the number of clients with:			
Injecting Status is one of: Previously injected but not currently injecting; or Currently injecting	Hep C Test Date Field = CIRHEPCTSTD if present or HEPCTSTD (from assessment)  Hep C Test Date >= 01/01/1993 and <= to			
Triage Date (TRIAGED) <= Reporting Month End Date - 30 days	reporting month end (Not included as counting against the target: Hep C test date before 1/1/93, no test date and Hep C			
N.B Effectively this looks at those that remain in treatment at month end that where triaged 30 days or more prior to allow for testing to be completed.	test dates in future (>reporting month end date))  Information from CIRs > than month end should be			
To confirm: Excluding any clients triaged with the last 30 days (to allow for their BBV tests to be completed)	And with:  Either Negative Antibody (Hep C antibody test status Field = CIRHCVAS if present or HCVAS (from assessment)) result  Or Positive Antibody (Hep C antibody test status Field = CIRHCVAS if present or HCVAS (from assessment)) result and Hep C test result PCR (RNA) status Field = CIRHCVPCR if present or HCVPCR (from assessment) equal to Positive, Negative (cleared by treatment), Negative (cleared naturally), or Negative (never infected)  Additional points of note: One client gets counted once; Most recent non-blank value for each of these fields: Hep C test date, Hep C antibody status and Hep C PCR status (from assessment or CIRs if present) Or Hep C test date linked with Hep C Antibody and Hep C PCR status (on the same CIR or from assessment)  Some clients may report that they have never had Hep C even though they are Ab+/PCR-, and it is not possible to confirm if they have naturally cleared the virus. What matters is that both their Ab and PCR status are known.			

<sup>\* 2%</sup> tolerance is permissible



 $<sup>^{\</sup>dagger}$  NDTMS Consented clients in Structured Treatment Only (at the end of the reporting month).

90% of clients\*† in structured treatment, who have a history of injecting (and are deemed to be at risk), and have been triaged more than 30 days ago, have a Hep C Test Date (in the last 12 months up to the Reporting Month End date) & result recorded.

Denominator	Numerator		
Include Criteria 1 and Criteria 2 denominators, and additional criteria as follows:	Of those specified by the Criteria 3 denominator, the number of clients with:		
Hep C Status			
<ul> <li>Hep C Status = the last CIRHEPCSTAT if present or HEPCSTAT (from assessment)</li> </ul>	Hep C Test Date >= to reporting month end date minus 12 months and <= to reporting month end		
Set to: • Offered and accepted (Pre-CDS-P)	Hep C Test Date Field = CIRHEPCTSTD if present or HEPCTSTD (from assessment)		
Offered and accepted - had a hep C test. Offered and accepted - not yet had a test. Offered and accepted but refused at a later date (Pre-CDS-P)	Not included as counting against the target: Hep C test date older than 12 months prior to reporting month end date or no test date or future date (>reporting month end date)		
<ul><li>Offered and refused.</li><li>Not offered</li></ul>	Information from CIRs > than month end should be excluded.		
<ul> <li>Deferred due to clinical reasons.</li> </ul>	excluded.		
<ul> <li>Null/Not set.</li> </ul>	And with		
N.B This effectively excludes those clients for whom Hep C testing is not appropriate, i.e., most recent Hep C status = Assessed as not appropriate to offer	<ul> <li>And with:</li> <li>Either Negative Antibody (Hep C antibody test status Field = CIRHCVAS if present or HCVAS (from assessment)) result</li> <li>Or Positive Antibody (Hep C antibody test status Field = CIRHCVAS if present or HCVAS (from assessment)) result and Hep C test result PCR (RNA) status Field = CIRHCVPCR if present or HCVPCR (from assessment) equal to Positive, Negative (cleared by treatment), Negative (cleared naturally), or Negative (never infected)</li> <li>Additional points of note: <ul> <li>One client gets counted once.</li> <li>Most recent non-blank value for each of these fields: Hep C test date, Hep C antibody status and Hep C PCR status (from assessment or CIRs if present)</li> </ul> </li> </ul>		
	Or		
	<ul> <li>Hep C test date linked with Hep C Antibody and Hep C PCR status (on the same CIR or from assessment)</li> </ul>		
	Some clients may report that they have never had Hep C even though they are Ab+/PCR-, and it is not possible to confirm if they have naturally cleared the virus. What matters is that both their Ab and PCR status are known.		

<sup>\*</sup> Excluding those assessed as not appropriate to offer

<sup>†</sup> NDTMS Consented clients in Structured Treatment Only (at the end of the reporting month).



There are three different methodologies that may be selected by an organization to measure criteria 4:

- **Criteria 4a:** 90% of clients\* in structured treatment with Positive Hep C test result PCR (RNA) status (recorded at the last CIR if present or triage) have commenced treatment†.
- **Criteria 4b:** 90% of Service Users with positive hepatitis C AB status and PCR (RNA) status are cleared of hepatitis C.
- **Criteria 4c:** 90 % of clients\* in structured treatment with Positive Hep C PCR (RNA) status ever have commenced treatment or have completed it.

Organisations must also maintain a focus on non-NDTMS consented clients.

#### Criteria 4a

90% of clients\* in structured treatment with Positive Hep C test result PCR (RNA) status (recorded at the last CIR if present or triage) have commenced treatment†.

#### Calculation:

Criteria 4a				
Denominator	Numerator			
Clients open in structured treatment at the end of the reporting period. (=criteria 1 denominator)	Of those specified by the Criteria 4 denominator, the number of clients with start date of HCV treatment falling within the reporting period.			
· · · · · · · · · · · · · · · · · · ·	HCV treatment start date is an internal (non-NDTMS) data point and can be confirmed by different routes:  Blueteq date			
may be taken from an internal non-NDTMS data point or from information provided by the treatment team. (You should check SVR status at 3 months post treatment).	<ul> <li>Written or verbal confirmation from ODN or other health or social care authorities e.g., GP or prison team</li> <li>Hep C nurses recording this information directly on the drug service system.</li> </ul>			
Clients who tested positive in the last 5 weeks before the end of the reporting period are excluded.	<ul> <li>Medication physically delivered to patient or patient informing you they started taking medication.</li> </ul>			
	Treatment start dates that are more than 30 weeks before the latest Hep C Test date should be excluded. These individuals need a review of their treatment.			
	For PCR Negative Service Users, 'SVR achieved date' may be taken from an internal non-NDTMS			



data point or from information provided by the treatment team. (You should check SVR status at 3 months post treatment).

Only clients in structured treatment at the end of the reporting period are included.

#### Additional Points of Note:

Services should provide assurance that they have worked closely with ODNs/treatment teams to highlight cases that may have been closed and are no longer tracked and where treatment responsibility now sits with the ODN/treatment team.

Treatment start and SVR information are carried over to new structured treatment episodes for each client. For example, if a client re-presents, the drug treatment service would still hold information about historic SVR.

Relevant General Practitioners should be informed where possible.

#### Additional Guidance for Criteria 4a

- The denominator and numerator conditions around triage, discharge, test and treatment start date include clients who have previously achieved Sustained Virological Response at Week 12 beyond treatment (SVR12)
- Organisations should identify and utilise use internal data points to identify clients who have achieved SVR12.



<sup>\*</sup> NDTMS Consented clients in Structured Treatment Only (at the end of the reporting month). Organisations must also maintain a focus on non-NDTMS consented clients.

<sup>†</sup> Accountability for patient starts and reporting patient starts sits with the ODN. The service will commit to ensuring a robust referral mechanism and support stakeholders in seeking and implementing a local and/or national mechanism for obtaining and reporting accurate patient start data based on a patient start date defined as date of prescription.

#### Criteria 4b

90% of Service Users with positive hepatitis C AB status and PCR (RNA) status are cleared of hepatitis C.

#### Organisations must also maintain a focus on non-NDTMS consented clients.

Criteria 4b				
Denominator	Numerator			
Include Criteria 1 denominator, and additional criteria as follows:	<ul> <li>AB +ve PLUS PCR (RNA) -ve (Cleared by Treatment)</li> </ul>			
<ul> <li>AB +ve PLUS PCR (RNA) +ve</li> <li>AND AB +ve PLUS PCR (RNA) -ve (Cleared by Treatment)</li> <li>AND AB +ve PLUS PCR (RNA) -ve (Cleared Naturally)</li> <li>AND AB +ve PLUS PCR (RNA) -ve (Never Infected)</li> <li>AND AB +ve PLUS PCR (RNA) Unknown**</li> <li>AND AB +ve PLUS PCR (RNA) Blank**</li> </ul>	<ul> <li>AND AB +ve PLUS PCR (RNA) -ve (Cleared Naturally)</li> <li>AND AB +ve PLUS PCR (RNA) -ve (Never Infected) *</li> <li>Additional points of note:</li> <li>Provider should develop and publish agreed exemption criteria and a robust process for agreeing exemptions.</li> <li>Services should develop a robust Data Quality Check Process</li> </ul>			
• i.e. AB +ve	<ul> <li>Relevant General Practitioners should be informed where possible.</li> </ul>			

<sup>\*</sup> Prior to CDS-P, some services used AB +ve PLUS RNA -ve (Never Infected) to denote RNA -ve (Cleared Naturally), hence assumed to be RNA -ve (Cleared Naturally)

#### Additional Guidance for Criteria 4b

- Date range = The time period applied to this calculation is the same as for all other NDTMS extract data i.e., any episode which is open during the NDTMS reporting month: those with a triage date up to and including the reporting month end date and T3/4 Discharge Date of null or greater than reporting month end date. This will include data from discharged episodes for any service users currently open to the service, where there is insufficient data in the current episode.
- There is evidence to suggest that many service users have been given the status of RNA -ve (cleared naturally), however, they have in fact been cleared by treatment. Hence the decision to include RNA -ve (cleared naturally) in the calculation. In addition, since the Micro-elimination Criteria are designed to show progress towards Micro-elimination of hepatitis C, not treatment, it is logical to include RNA -ve (cleared naturally).
- Some clients might be excluded from the calculation based on the agreed exemption criteria (see below).



<sup>\*\*</sup> RNA Unknown and RNA Blank included for service user safeguarding (clinical good practice)

#### Criteria 4c

90 % of clients\* in structured treatment with Positive Hep C PCR (RNA) status ever have commenced treatment or have completed it.

#### Calculation:

(PCR Positive started treatment + PCR Negative who achieved SVR) x 100.

% started or treated

All open clients who are PCR Positive now or have been recorded as Hep C PCR Positive on the service's CRMS ever

#### Organisations must also maintain a focus on non-NDTMS consented clients.

Denominator

Those with T3/4 Discharge Date > reporting month end date or T3/4 Discharge Date is null and a **Triage** Date (TRIAGED) <= Reporting Month End Date - 30 days

Triage Date Field = TRIAGED T3/4 Discharge Date Field = DISD (structured treatment discharge date)

N.B. - the above definition relates to using NDTMS extracts - for internal reports please consider those with psychosocial or pharmacological modality start date <= reporting month end date, psychosocial or pharmacological modality end date > reporting month end date or it is null. This is the NDTMS definition of a client in structured treatment.

Include additional criteria as follows:

- Positive Hep C PCR (RNA) test result ever (1 record per client). This can be the latest Hep C test result or Hep C test result from any point in the past, recorded on the service's CRMS. This can be recorded on any assessment (HCVPCR) or CIR (CIRHCVPCR) form, including previous episodes.
- N.B. Exclude clients that tested Hep C PCR positive for the first time in the five weeks before the end of the reporting month (this would be either a new PCR positive or a re- infection after achieving SVR)
- $\ensuremath{\text{N.B.}}$  Include not referred for Hep C treatment clients too.
- N.B. Some clients might be excluded from the calculation based on the agreed exception criteria (see below).

Of those specified by the Criteria 4b denominator, the number of clients with the latest/most recent (based on the valid dataset - that is Hep C test date, Hep C antibody and Hep C PCR recorded on the same form - either assessment or full/partial CIR) Hep C PCR status Negative (Cleared naturally) (NDTMS option 5), Negative (cleared by treatment) (NDTMS option 4) or only PCR Positive (NDTMS option 1) with start date of prescription of HCV therapy which is no more than 30 weeks before today's date.

Operational Delivery Network (ODN) patient starts as defined by start date of prescription of HCV therapy (prescription start date as recorded on Bluetec)

Treatment start dates that are more than 30 weeks before **today's** date (these individuals require review with ODN) or > reporting month end date should be excluded.

Additional points of note:

- The expectation is that the Hep C treatment start date should be after the latest PCR+ test date however it is recognised that in some cases when patients don't reach SVR or where clients are re-tested during treatment this may not be the case. Services should make effort to review such cases and quality assure.
- Services should provide assurance that they have worked closely with ODNs to highlight cases that may have been closed and are no longer tracked and where treatment responsibility now sits with the ODN.
- Relevant General Practitioners should be informed where possible.



#### **Exemptions from Micro-Elimination Criteria**

These are service users who have been identified by the service as being exempt from the 4 micro-elimination criteria.

The rationale for a service user being deemed exempt normally falls into one of three categories:

- 1. Service user is under palliative care
- 2. Service user is under the care of hospital/has a current severe illness
- 3. Service user is at a high risk of disengaging from drug and alcohol service (and all reasonable attempts have been made to engage them

There should be a full procedure around any service user being exempted as well as the monitoring of their exemption status. Using the exemption criteria is normally rare for services and the numbers are not expected to exceed single figures for any service. The process for agreeing that someone is exempt is a robust, auditable and collaboratively agreed process. For example:

A process for agreeing proposed exemptions is:

- 1. Service is close to achieving micro-elimination (criteria 4b close above 80% for example).
- 2. A review is held of those service users falling outside ME criteria with the lead for the service.
- 3. A record of reason for exemption is made.
- 4. A process for review by appropriate service staff is put in place with competency for agreeing exemption status as valid or not.



#### Abbreviations and Terminology

AB+ Antibody positive. A reactive or positive hepatitis C antibody screening test

checks for

infection with the hepatitis C virus. However, this may not mean that an individual still has the virus, only that they have had the virus at some point. If an antibody screening test is reactive/positive, a further HCV RNA PCR test

should be carried out to make a definitive diagnosis of HCV

BBV Blood-Borne virus(es), e.g., HIV, HBV, and HCV

Blueteq High-cost drug (HCD) management system

CDS-P National Drug Treatment Monitoring System Core Dataset P

CGL Change Grow Live

CIRHCVAS Client Information Review Hepatitis C Result Antibody Status CIRHEPCSTA Client Information Review Hepatitis C Intervention Status

Τ

CIRs Client Information Reviews

Denominator Group of people to whom the criteria apply

DISD Episode Discharge Date
DTS Drug treatment services

HBV Hepatitis B virus HCV Hepatitis C virus

HCVAS Hepatitis C Result Antibody Status
HEPCSTAT Hepatitis C Intervention Status
HIV Human immunodeficiency virus

IDU Injecting drug use(r)
INJSTAT Injecting status

NDTMS National Drug Treatment Monitoring System

NHS APA NHS Addictions Provider Alliance

Numerator How many people have met the criteria using the fields as specified in

Denominator (%)

ODN Operational Delivery Network. ODNs are focused on coordinating patient

pathways between providers to ensure access to specialist resources and expertise, e.g., viral hepatitis assessment and treatment services are

delivered by hepatology, infectious diseases, and gastroenterology specialists

PCR Polymerase chain reaction. A PCR test is designed to detect and measure

RNA

RNA Ribonucleic acid (RNA) is a nucleic acid present in all living cells. An RNA test

detects and measures viruses, such as hepatitis C, in the blood

SVR Sustained virologic response. Patients who achieve SVR are considered to be

'cured' of having HCV

T3/4 Tier 3 and 4

