

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

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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.



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Disclaimer

This document has been developed by Gilead Sciences Ltd in collaboration with representatives from Gilead-partnered DTS providers and The Hepatitis C Trust, listed below.

Hep 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)

Turning Point

We Are With You

Westminster Drugs Project (WDP)

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 2025¹. ~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 We Are With You. Westminster Drugs Project (WDP) 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 June 2022, as a benchmark against an individual service's HCV elimination efforts, the Forum reached consensus on criteria for achieving Micro Elimination within a DTS site. 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.³

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 are available at the end of this document (page 10).

1. NHS England. Available at: <https://www.england.nhs.uk/2019/01/nhs-englands-plan-to-eliminate-hepatitis-c-decisively-backed-by-high-court/>. Accessed July 2022.
2. HSA. Hepatitis C in England 2022. Available from: http://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1057271/HCV-in-England-2022-full-report.pdf. Accessed July 2022.
3. Lazarus, JV. Semin Liver Dis. 2018; 38(3):181-192.

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
<u>Criteria 1</u>	100% of clients in structured treatment are offered a Hep C test
<u>Criteria 2</u>	100%* of those with a history of injecting have been tested ever with a known Ab status; if Ab+ then a known PCR status is required
<u>Criteria 3</u>	90% of current and previous injectors (at risk) have a Hep C test date within the last 12 months with a known Ab status; if Ab+ then a known PCR status is required [§]
<u>Criteria 4</u>	90% of HCV+ patients have commenced treatment [†]

* 2% tolerance is permissible

§ Excluding assessed as not appropriate to offer

† 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.

Criteria 1



of clients* in structured treatment are offered a Hep C test

Denominator	Numerator
<p>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)</p> <p>Triage Date Field = TRIAGED T3/4 Discharge Date Field = DISD (structured treatment discharge date)</p> <p><i>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.</i></p>	<p>Of those specified by the Criteria 1 denominator, the number of clients with Hep C Status</p> <p>Hep C Status Field = the last CIRHEPCSTAT (most recent one) if present or HEPSTAT.</p> <p>Set to:</p> <ul style="list-style-type: none"> • 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 <p>Additional points of note:</p> <ul style="list-style-type: none"> • What does not count – is blank or not offered or other values • Information from CIRs > than month end should be excluded

* 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

Criteria 2



of clients[†] 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)

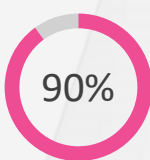
Denominator	Numerator
<p>Include Criteria 1 denominator, and additional criteria as follows:</p> <p>Injecting Status is one of:</p> <ul style="list-style-type: none"> • Previously injected but not currently injecting; or • Currently injecting <p>Triage Date (TRIAGED) <= Reporting Month End Date – 30 days</p> <p><i>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</i></p> <p><i>To confirm: Excluding any clients triaged with the last 30 days (to allow for their BBV tests to be completed)</i></p>	<p>Of those specified by the Criteria 2 denominator, the number of clients with:</p> <p>Hep C Test Date Field = CIRHEPCTSTD if present or HEPCTSTD (from assessment)</p> <p>Hep C Test Date >= 01/01/1993 and <= to reporting month end (Not included as counting against the target: Hep C test date before 1/1/93, no test date and Hep C test dates in future (>reporting month end date))</p> <p>Information from CIRs > than month end should be excluded</p> <p>And with:</p> <ul style="list-style-type: none"> • 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) <p>Additional points of note:</p> <ul style="list-style-type: none"> • 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) <p>Or</p> <ul style="list-style-type: none"> • Hep C test date linked with Hep C Antibody and Hep C PCR status (on the same CIR or from assessment) <p><i>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.</i></p>

* 2% tolerance is permissible

[†] 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

Criteria 3



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

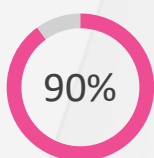
Denominator	Numerator
<p>Include Criteria 1 and Criteria 2 denominators, and additional criteria as follows:</p> <ul style="list-style-type: none"> • Hep C Status • Hep C Status = the last CIRHEPCSTAT if present or HEPSTAT (from assessment) <p>Set to:</p> <ul style="list-style-type: none"> • Offered 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 • Not offered • Deferred due to clinical reasons • Null/Not set <p><i>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</i></p>	<p>Of those specified by the Criteria 3 denominator, the number of clients with:</p> <p>Hep C Test Date >= to reporting month end date minus 12 months and <= to reporting month end</p> <p>Hep C Test Date Field = CIRHEPCSTD if present or HEPCTSTD (from assessment)</p> <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)</p> <p>Information from CIRs > than month end should be excluded</p> <p>And with:</p> <ul style="list-style-type: none"> • 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) <p>Additional points of note:</p> <ul style="list-style-type: none"> • 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) <p>Or</p> <ul style="list-style-type: none"> • Hep C test date linked with Hep C Antibody and Hep C PCR status (on the same CIR or from assessment) <p><i>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.</i></p>

* Excluding those assessed as not appropriate to offer

[†] 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

Criteria 4



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[†]

Denominator	Numerator
<p>Include Criteria 1 denominator, and additional criteria as follows:</p> <ul style="list-style-type: none"> Positive Hep C test result PCR (RNA) status Field = the last CIRHCVPCR if present or HCVPCR (from assessment) <p><i>N.B. – Exclude clients that tested positive in the five weeks before the end of the reporting month</i></p>	<p>Of those specified by the Criteria 4 denominator, the number of clients with start date of prescription of HCV therapy falling within the reporting period</p> <p>Operational Delivery Network (ODN) patient starts as defined by start date of prescription of HCV therapy (prescription start date as recorded on bluetec)</p> <p>Treatment start dates that are more than 30 weeks before the Hep C Test date (these individuals require review with ODN) or > reporting month end date should be excluded.</p> <p>Additional points of note:</p> <ul style="list-style-type: none"> 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.

* 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

[†] 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**

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
bluetec	high cost drug (HCD) management system (check spelling in document)
CDS-P	National Drug Treatment Monitoring System Core Dataset P
CGL	Change Grow Live
CIRHCVAS	Client Information Review Hepatitis C Result Antibody Status
CIRHEPCSTAT	Client Information Review Hepatitis C Intervention Status
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
WDP	Westminster Drugs Project