Classification: Official

NHS England

Hepatitis C Clinical Network Specification

Publication reference: PRN231105

Contents

Executive Summary

Hepatitis C Virus (HCV) Clinical Networks ('Operational Delivery Network', or ODN) are commissioned to plan, manage and oversee all clinical pathways for HCV in a given geographical area. The network builds and supports partnership working among a diverse range of providers including those outside the NHS. It oversees the venue, methodology and amount of testing taking place and the subsequent pathway to (and success of) clinical treatment.

ODNs are commissioned as a series of Trust-based network 'Hubs' across England, and each of those network Hubs will manage relationships and delivery with a defined set of Trust-based 'Spokes'.

Pathway management ranges from partnership development, overseeing appropriate coverage and quality of services through to clinical treatment delivery and evaluation.

1. Clinical Networks

Specialised services Clinical Networks are a vehicle for specialty level collaboration between patients, providers and commissioners. They should have clear lines of governance and accountability with Integrated Care Boards (ICBs) including providers and provider collaboratives, and to NHS England (NHSE) Regional Teams, to ensure local ownership, alignment and a local mandate.

All networks have an important role in delivering the triple aim, supporting:

- better health and wellbeing of everyone,
- better quality of care for all patients, and
- sustainable and efficient use of NHS resources

23 Hepatitis C Clinical Networks (also known as 'HCV Operational Delivery Networks', or ODNs) are commissioned to coordinate and oversee patient finding and treatments for HCV. In addition a specialist Paediatric ODN is commissioned to improve and increase the treatment of children from age 3 by providing advice and guidance to other clinicians.

HCV ODNs are commissioned by NHSE regional teams in partnership with those ICBs whose population is served by the network. As a function of the national HCV Elimination Programme, there will be a continued close relationship with the national HCV team within NHS England Specialised Commissioning.

All HCV ODNs will work in partnership with local systems to ensure effective delivery for the local patient population and the opportunity to 'mainstream' activity when HCV elimination has been achieved.

This specification sets out the appropriate scope for the work of Hepatitis C Clinical networks. This will inform the development of the annual workplans developed in conjunction with the network's commissioners. No network will, or could, focus on all aspects of the scope described, at one time.

In describing the appropriate scope for networks, these specifications refer to the work of the network board and the network's members, supported by the network team. Networks are not expected to assume the legitimate accountabilities and responsibilities of providers who are accountable for meeting the needs of the Service Specification. However, network responsibilities inevitably overlap with those of providers, because networks aim to improve the ways in which services are delivered operationally and shape how they develop and because providers are members of networks.

2. Hepatitis C Elimination Strategic Context

- Hepatitis C is an inflammation of the liver caused by the hepatitis C virus (HCV)
- The virus can cause both acute and chronic hepatitis, ranging in severity from a mild illness to a serious, lifelong illness including liver cirrhosis and cancer
- The hepatitis C virus is a bloodborne virus and most infections occur through exposure to blood from unsafe injection practices, unsafe health care, unscreened blood transfusions, injection drug use and sexual practices that lead to exposure to blood
- Globally, an estimated 58 million people have chronic hepatitis C virus infection, with about 1.5 million new infections occurring per year
- WHO estimated that in 2019, approximately 290 000 people died from hepatitis C, mostly from cirrhosis and hepatocellular carcinoma (primary liver cancer)
- Antiviral medicines can cure more than 95% of persons with hepatitis C infection, but access to diagnosis and treatment is low internationally
- There is currently no effective vaccine against hepatitis C

Hepatitis C virus (HCV) causes both acute and chronic infection. Acute HCV infections are usually asymptomatic and most do not lead to a life-threatening disease. Around 30% (15–45%) of infected persons spontaneously clear the virus within 6 months of infection without any treatment. The remaining 70% (55–85%) of persons will develop chronic HCV infection. Of those with chronic HCV infection, the risk of cirrhosis ranges from 15% to 30% within 20 years.

In England, the Hepatitis C (HCV) Elimination Programme is working to eliminate HCV before the World Health Organization goal of 2030, by supporting a drive to get at-risk patient groups tested and treated to a point where HCV can be declared eliminated as a public health threat.

The Programme involves a close collaboration between NHS England, the Hep C Trust, Operational Delivery Networks (ODNs), the pharma industry, His Majesty's Prison and Probation Service (HMPPS), the Department of Health and Social Care (DHSC) and UK Health Security Agency (UKHSA).

The HCV Elimination Programme involves three pharmaceutical companies, Gilead, MSD and AbbVie, that have agreed to work together to identify and treat large numbers of infected

people. This is managed through NHS England's 'Strategic Procurement' of HCV direct acting antiviral (DAA) medication, whereby each supplier is awarded a defined share of the market (removing any competition to market their own drugs) and commits to deliver – in partnership with ODNs, other providers and the system a range of Elimination Initiatives.

Networks are expected to engage fully with the pharmaceutical companies as they would with any other delivery partner.

3. Network Scope

3.1 Scope

The entire Hepatitis C pathway within their local area is in scope for HCV Elimination Networks. Networks will lead the development of strategy and plans in any local area for patient finding activity, mass and targeted testing using a variety of methods appropriate to the setting and client group, managing access to treatment and the evaluation of the effectiveness of their services. The network team will work in partnership with hub and spoke providers, drug and alcohol services, prisons and probation settings, primary care, and Hepatitis C Trust peers, amongst others to effectively discharge their duties.

Networks operate on a 'Hub & Spoke' model with hub and spoke working in close partnership to contribute to the ODN's wider strategic goals. Network teams are hosted by a hub provider which receive additional funding for the network team and to support elimination initiatives across the network, ensuring that each spoke has sufficient resource (human and financial) and skill to deliver a comprehensive programme of patient finding, testing and treatment provision, contributing to the ODN Annual Plan.

The network 'board' or management group meets regularly, to plan and oversee the network's work. It is responsible for achieving the 'run rate' (target number of people to be found and treated) set by NHS England for the entire ODN.

Network partners must work together to meet the needs of the whole footprint recognising that different parts of the population may have different needs that require additional outreach or alternative approaches. Given that a large proportion of those who are infected with hepatitis C will attend community drug services it is essential that networks maintain a consistent presence in local addiction services to ensure that high rates of testing and treatment are maintained and that those found to be infected have ready access to therapy in a setting of their choice. A wide variety of treatment opportunities must be established in the network to ensure that covert discrimination does not develop. Sites where testing and treatment services should be readily available include prisons, probation services, sexual health services as well as homeless hostels and local sites that provide service to those who have no home.

3.2 Population Covered

The Networks responsible for Hepatitis C cover England only. Each Network has a defined geographical area in which to operate. Details of the Network configuration are available at Appendix One. The Hub is responsible for the oversight and treatment pathway of the entire ODN area; they may delegate some of this responsibility, work and resource to Spokes as agreed.

4. Network Aims and Objectives

4.1 Network Vision and Aims

The aim of the specialised Hepatitis C Operational Delivery Networks, for both adults and children, is to maximise the appropriate uptake and completion of HCV treatment, and to cure more people of infection. This will improve quality of life, prevent premature death, and reduce the risk of onward transmission. All of this will ensure England reaches its elimination goal in advance of the WHO 2030 target.

4.2 Unique position of Networks

HCV Elimination is, essentially, a programme to address health inequalities; the primary target audiences for elimination are those parts of society who experience some of the greatest levels of deprivation, most marked inequality and lowest levels of health-seeking behaviour (e.g. people who inject drugs, those engaged in the criminal justice system, the homeless and migrant communities).

As such, Networks have much to offer in terms of:

4.2.1 Better health and wellbeing of everyone

Networks are experienced in bringing care to communities that others find ‘hard to engage’; outreach provision into prisons, primary care, pharmacies and drug services remove the expectation that patients will be willing or able to travel to hospital-based services, whilst the HCV Community Van Programme and Peer Programme ensures that we can provide diagnosis, treatment and linkage to care for everyone who needs it.

4.2.2 Better quality of care for all patients

With a holistic approach to the pathway from patient-finding to sustained virological response (SVR) post-treatment, Networks have every opportunity to impact on the quality of each element of clinical and associated support. Embedded patient-led roles in every Network (through the Peer Programme) support this focus.

4.3 Network Objectives

The service overseen and delivered by the network must:

- Deliver a uniform standard, high-quality service to adults and children with hepatitis C throughout England. A national paediatric ODN either provides treatment to children over 3 years old or supports adult ODNs to carry this out safely and effectively.

- Provide equitable access across the ODN geographical footprint. The network is responsible for ensuring this coverage, even outside of the hub catchment area.
- Establish a managed network of services responsive to local epidemiology and prevalence. This will include working effectively in partnership with other healthcare providers and local organisations from all sectors (e.g. Primary Care Services, Local Authorities, service for People Who Inject Drugs, Health & Justice, charities for the homeless and people who misuse substances).
- Report objective measures and timely data to demonstrate the treatment being provided.
- Utilise the Patient Treatment Registry alongside the Patient Testing Registry to record tests and treatment numbers.
- Contribute to tailored services to meet the needs of specific vulnerable populations across the ODN geographical footprint. This also includes working adaptively and innovatively to find patient groups that have not previously had extensive levels of testing. The groups might include the homeless and uprooted populations, asylum seekers, and people born in countries with endemic HCV infection.
- Ensure people with hepatitis C are given sufficient, appropriate and high-quality information, support and advice throughout the testing and treatment pathway, including access to peer support.
- Allow more people to have access to clinical trials of new drugs, with consequent improvement in outcome and effective use of NHS resources in the long term.

4.4 Network Functions

All networks will have responsibilities in each of the key functions identified below. The balance of functions will be agreed locally taking account of the network scope, local need and network maturity.

Service delivery: *the network's role in planning and managing capacity and demand*

The ODN (at both Hub and Spoke level) will:

- Plan and manage capacity and demand for patient finding, testing & diagnosis, treatment and follow-up / SVR. As a minimum, the Elimination Initiatives to ensure patient finding and delivery should include (but not be limited to) those detailed in Section 6.
- Publish suitably detailed 'patient pathways' including details of referral pathways, waiting times management and minimum standards. It is anticipated that different pathways will operate for different patient populations to ensure that all affected by hepatitis C have access to services that meet their needs.
- Ensure that people with a new reactive HCV test, wherever they are tested, are offered a full assessment, carried out by an appropriately trained practitioner with specialist expertise in HCV, at the earliest possible opportunity and no later than 2 weeks after receiving a positive HCV RNA test result.
- ODNs are responsible for ensuring all data in relation to testing and treatment for HCV submitted by network members is of high quality and complete. The network team should work with network member organisations to respond to ad hoc data requests to support the national analysis programme and thereby ensure the continuation and success of the programme.

Resources: *the network's role in stewardship of resources across whole pathway and minimising unwarranted variation*

- Carry forward of Elimination Initiative funding is approved on a case-by-case basis, and decisions communicated to ODN colleagues in writing.
- Ensure that treatment pathways across the Network area are consistent and maximise efficient, timely access from diagnosis through referral to treatment.
- Ensure appropriate use of high-cost treatments, managing a pathway that prioritises VAT-free access and a nationally defined market share for prescribing.
- Work with other related networks to share learning and target resources for best effect and improved patient access.

Workforce: *the network's role in ensuring flexible, skilled, resilient staffing*

- Networks will be expected to maintain an appropriate level of flexible, skilled, resilient staffing, suitable to their needs and the drive to deliver the elimination programme.

Quality: *the network's role in improving quality, safety, experience & outcomes*

- Networks should have an active workstream and regular senior reviews of workplans to improve quality, safety, experience & outcomes.

Collaboration: *the network's role in promoting working together across organisations at local, system and national level*

- Networks should be able to evidence working together with individuals and organisations at system level.
- Network actively participates in and supports national network meetings, sharing experience and learning.
- Benchmark services against national peers and share best practice.

Transformation: *the network's role in planning sustainable services that meet the needs of all patients*

- Networks should plan sustainable services that meet the needs of all patients.

Population health: *the network's role in assessing need, improving inequalities in health, access, experience and outcomes*

- Networks will be proactive in assessing need, improving inequalities in health, access, experience, and outcomes. To fulfil this expectation, Networks should ensure adequate liaison with patient and community groups, local Public Health specialists, and other partners. Full use should be made of data and information which can assist in the promotion and improvement of population health, such as outcome, deprivation, and access data. Plans should be in place to explicitly reach communities likely to be disproportionately affected by HCV, or who may be less likely to exhibit health-seeking behaviour.

4.5 Annual workplan

The Network will agree an annual workplan with its commissioners. This will reflect national, regional and local priorities.

The Network will publish an annual report, as a minimum, detailing its activities, accounts and delivery against the agreed annual plan. Where requested, and where there are specific interventions or issues relating to HCV or the services / Elimination Initiatives in an ODN area, a quarterly report may be requested and the national team will expect to be able to meet quarterly with the ODN to review progress and plans.

5. Governance

5.1 Accountability

Hosting

Networks are hosted by NHS Trusts; usually attached to or integrated into Hepatology or Infectious Diseases specialties.

Networks and their boards are independent of the host, with their own governance and accountability directly to the commissioner. The host is not accountable for the delivery of the network's functions and where the host is a network member, they will have the same roles and responsibilities as other members and will exert no undue influence as host of the network.

The network host will be selected by the Commissioners following an open and defensible process that maximises value for money, which would include consideration of opportunities for sharing infrastructure. The responsibilities of each party will be set out in a formal hosting agreement.

Network funding provided to the host is ring-fenced for the network and cannot be used by the host for other purposes, and is not subject to host cost improvement targets.

Accountability and responsibility

Network footprints reflect patient flows, provider scale and catchments so will often cut across ICB and regional boundaries. Governance arrangements must provide clear accountability to commissioners at system level (with emerging links to all relevant ICBs) and region as appropriate for both network delivery and commissioning responsibilities. Arrangements to achieve this should be clearly documented within the network's terms of reference.

Networks delivering HCV Elimination will continue to be accountable to NHS England via the retained services governance process, with ICB input via this route.

Networks will be responsible to commissioners for the management of local pathways and delivery of locally agreed targets.

The network will also be accountable to the regional team of NHSE, which will manage the flow of national finance and NHSE relationships with the Trust generally. Detailed HCV-specific relationships will be directly between the Trust, Network and national Elimination Team.

Network plans and deliverables should be agreed with the national Elimination Team. Networks will be expected to provide regular reports and have regular reviews with NHSE national team.

A single network plan and deliverables should be agreed for each network with their commissioners. Networks will be expected to provide regular reports and have regular reviews with their commissioners.

The network's authority to act on behalf of its commissioners and members will be set out clearly within the network memorandum of understanding (MOU) and where necessary clarified within the agreed annual plan.

5.2 Network governance and architecture

Members and stakeholders

Networks are required to have a formally constituted governing body or board, which is accountable to the network's commissioner for delivery of the network's agreed programme, with a line of sight to all ICBs whose patients use the services of providers within the network.

Network boards should include balanced representation from member organisations and other relevant stakeholders, including patient representatives and third sector organisations. Clinical representation should cover the whole multi-disciplinary team and pathway of care.

Network meetings and strategic planning should always include patient representation, and consideration should be given to ensure that the membership reflects principles of equality, diversity an inclusivity.

The Board

The board should meet on a regular basis and operate under the oversight of a suitable chair with agreed terms of reference. The chair will normally be the network clinical lead, who is accountable to NHS England at regional and national level, with line management through the Trust medical director.

5.3 Risk Management and risk sharing

HCV networks manage risk within a system of national, regional and system level arrangements. Networks support risk identification, assessment, mitigation and may facilitate any agreed response.

Specific local risk management arrangements and governance processes should be managed locally through MOUs/ SOPs etc which are clear and signed off. Escalation processes for risks within a system should be clear and explicit, with any quality concerns escalated through agreed systems and regional processes.

5.4 Interdependent Relationships

The Operational Delivery Network must be able to demonstrate that it has well established links or an agreed plan, to work collaboratively with:

- Primary care and community pharmacy.
- Pharmaceutical partners.
- HCV virology including interpretation of resistance patterns, and access to viral load quantification results within 24 hours of sample receipt if required.
- Third sector services to support adherence, peer support and self-management programmes, including with the Hepatitis C Trust and the British Liver Trust.
- Alcohol and substance misuse services.
- UK Health Security Agency.
- Specialised hepatobiliary services, including liver transplantation services' for the management of Hepatocellular carcinoma (HCC).
- Formal pathways to support transition of paediatric patients to adult services as required.
- Local authority commissioners

- His Majesty's Prison and Probation Services (HMPPS).

Explicit links must be established with local Integrated Care structures (including Integrated Care Boards) and local addiction commissioners; these links should clearly be used to inform and advise the engaged parties on the most effective delivery and development of local provision / interventions, and facilitate their commissioning and delivery.

6. Resources

In order to discharge their duties HCV ODNs need the appropriate capacity and capability for clinical leadership, network planning and oversight and to support network led clinical activity.

As part of the annual planning process, commissioners must ensure that:

- the scale of resource made available to networks is sufficient to support the agreed programme of work
- networks have access to the data they need and the analytical capacity and capability to turn this into actionable improvement programmes

Typically each network will require:

- A Clinical Lead who is a consultant physician able to provide care directly, and to advise and support colleagues at other centres and in other services.
- An appropriate number of nurse specialists to deal with the number of patients being treated.
- An appropriate level of administrative staff to support the entire network. This will ensure best equity and access for patients locally. If this post is not effective at Project / Programme Management, and additional post of 'ODN Manager' is recommended.
- Dedicated pharmacist(s) to manage pharmaceutical needs of patients including adherence support, medication review, provision of specialist medications and advice about drug interactions.
- Lived experience or peer support workers

ODNs should also include additional external stakeholders, including partners from Drug (and Alcohol) Treatment Services, Cancer Alliances, the British Liver Trust, Community Liaison Officers, primary care staff, and others.

7. Deliverables, Service Indicators & Outcomes

1. Generic indicators of a well set up, well-functioning network
    - There is an appropriate network management team in post with the skills to deliver the specification

- The network board meets at least three times per year, is quorate, and minutes, actions and risks are recorded
- As appropriate to the network spec, there are regular network specialist Multi-Disciplinary Team (MDT) meetings (or equivalent)
- There are IT facilities in place that enable communication across the network, supporting image transfer and remote participation in the MDT.
- There is an annual workplan agreed with the network's commissioners
- There is an agreed plan for PPV engagement
- There is an analysis of the service needs of the population served by the network, a gap analysis and a plan, agreed with the network's commissioners to meet those needs
- There are network agreed patient pathways, procedures and protocols
- There is an analysis of workforce requirements and a plan, agreed with network members to meet these requirements
- There are arrangements (for example passporting) that enable workforce flexibility between providers within the network.
- There is an analysis of training needs, and an annual network training plan agreed with network members
- There is an analysis of the networks data and information needs and a plan, agreed with network members to meet these requirements
- There is a network agreed research strategy including access and participation in clinical trials
- The annual workplan includes at least one quality improvement initiative
- An annual report is produced, summarising the work of the network and its outcomes. The report includes a financial statement
- The network participates in the national network of networks

The Network will develop and operate a variety of Elimination Initiatives aimed at effectively patient finding in a variety of settings. There should be demonstrable evidence of action to identify and reduce health inequalities and to access patient groups who have traditionally been classed as difficult to engage. As a minimum, Network-prioritised settings should include:

- Drug Treatment Services
- Prisons
- Probation Services
- Primary Care
- Homeless services
- Specific populations (homeless, Eastern European, South Asian)

2. Nationally agreed indicators and outcomes for all networks of this specialty

Networks will also be expected to deliver nationally-driven Elimination Initiatives, as they develop. In 2023/24 these will include

- Testing in antenatal services
- Utilisation of the web testing portal
- Enhanced Primary Care Patient Finding
- ED testing (where not already in place)
- Forensic Mental Health Units
- Large employer programme / migrant workers

The primary indicator for the Network will be the annually set 'Run Rate' for treatment commencements. This will be reviewed by the national Team on at least a monthly basis, with the following levels of intervention.

- ≥ 80%, no issues
- 71% to 79%, email or 'Teams' discussion to support any measures to accelerate patient finding and treatment commencement
- ≤ 70%, 'Teams' discussion and allocation of dedicated named member of national team, for a limited period, to achieve a mutually agreed set of objectives

Data on achievement against the set run rate will be made available every month, as a minimum.

3. The network's individual locally agreed annual workplan, which should build in metrics and indicators for each element.

The network board will agree an annual workplan with its commissioners which will include the expected in year deliverables along with the indicators that will demonstrate effective network operation.

8. Further support and information

- England.hepc-enquiries@nhs.net mailbox for all central concerns around the ODNs, the programme, and elimination initiatives.
- NHS Futures – please request access from the national team for the Hepatitis C Elimination Programme site.
- Hepatitis C testing and treatment dashboard https://www.gov.uk/guidance/hepatitis-c-testing-and-treatment-dashboard
- NHS Long Term Plan
- ODN Newsletter – circulated on the first Monday of each month to ODN members.
- Quality Accounts requirements – 2021/22 NHS England » Quality Accounts requirements 2021/22

The full suite of materials covering what clinical networks do, commissioning of specialised services clinical networks and the clinical networks operating model together with model materials for use by networks and their commissioners can be found on the Future NHS website here:
https://future.nhs.uk/NationalSpecialisedCommissioning/view?objectID=34094320

Access requires membership of the site and permission to access the workspace. This is straightforward for all NHS employees.

Appendix One – Map of Hepatitis C Networks

Hepatitis C Operational Delivery Networks and clinical leads

North

1. North East & North Cumbria
The Newcastle Upon Tyne Hospitals NHS Foundation Trust
Stuart McPherson

2. Greater Manchester & Eastern Cheshire
Manchester University NHS Foundation Trust
Javier Vilar

3. Cheshire & Merseyside
Royal Liverpool & Broad Green University Hospital NHS Trust
Paul Richardson, Libuse Ratcliffe

4. South Yorkshire
Sheffield Teaching Hospitals NHS Foundation Trust
Benjamin Stone

5. Humberside and North Yorkshire
Hull & East Yorkshire NHS Trust
Nicholas Easom

6. West Yorkshire
Leeds Teaching Hospitals NHS Trust
Mark Aldersley

7. Lancashire and South Cumbria
East Lancashire Hospitals NHS Trust
Ioannis Gikikas

Midlands & East

8. Leicester
University Hospitals of Leicester
Martin Wiselka

9. Birmingham
University Hospitals Birmingham NHS Foundation Trust
David Mutimer

10. Nottingham
Nottingham University Hospitals NHS Trust
Stephen Ryder

11. Eastern Hepatitis Network
Cambridge University Hospitals NHS Foundation Trust
William Gelson

London North West

12. West London
Imperial College Healthcare Trust
Ashley Brown

London Central North West

13. North Central London Viral Hepatitis Network
Royal Free London NHS Foundation Trust
Douglas MacDonald

London North East

14. Barts
Barts Health NHS Trust
Graham Foster

London South

15. South Thames Hepatitis Network (STHepNet) Kings
Kings College Hospital NHS Foundation Trust
Kosh Agarwal

London South West

16. St George's
St George's University Hospitals NHS Trust
Daniel Forton

South

17. Surrey Hepatitis Services
Royal Surrey County Hospital NHS Foundation Trust
Michelle Gallagher

18. Sussex Hepatology Network
Brighton & Sussex University Hospitals NHS Trust
Jeremy Tibble

19. Thames Valley Hep C ODN
Oxford University Hospitals NHS Trust
Jane Collier

20. Wessex Hep C ODN
University Hospital Southampton NHS Foundation Trust
Ryan Buchannan

21. Bristol and Severn Hep C ODN
University Hospitals Bristol NHS Foundation Trust
Fiona Gordon

22. South West Peninsula Hepatitis C ODN
Plymouth Hospitals NHS Trust
Matthew Cramp

23. Kent Network via Kings
Kings College Hospital NHS Foundation Trust
Kosh Agarwal

National

24. Paediatric
Birmingham Women's & Children's Hospital NHS Foundation Trust
Deirdre Kelly