

Working with the:



# HEP C U Later

**Combined ODN & Drug Treatment Provider's  
Cepheid GeneXpert Census Report**

## Introduction and Background:

The Cepheid GeneXpert (Cepheid) machines were introduced by Merck Sharp & Dohme (MSD) as part of their elimination initiatives in 2019, and Operational Delivery Networks (ODNs) quickly saw the benefits of these machines.

Cepheid GeneXpert offers a point-of-care hepatitis C (HCV) Ribonucleic acid (RNA) test to check for an active HCV virus. This is done through taking a blood sample from a finger stick and running it in the machine. After one hour, the result and certificate are available. The benefits to patients are the ease of the test, which does not necessitate venous access, which can be problematic for some people, and the quick turnaround of results. For the ODN, it means shorter pathways and increased engagement from people as a result. There is also a benefit to all stakeholders with reduced administrative time, updating testing and result details in one go.

Originally, in 2019, MSD funded 9 machines, which was increased due to popularity and demand to 25 and then reduced as ODNs gained their own machines; there are currently 5 MSD-funded machines. As part of the Elimination Programme, NHS England (NHSE) have gave ODNs several opportunities to purchase their own machines, and most ODNs took up this offer.

Hep C U Later has had MSD-funded machines since 2021, and since then, we have developed our offer to NHS Addictions Provider Alliance members, along with the ODNs. This includes training sessions, best practice guides, videos, case studies, Standard Operating Procedures (SOP) and a cartridge waste minimisation project.

As a result of our experience and learning, in 2025, Hep C U Later facilitated an online Cepheid GeneXpert census across the ODNs and Hepatitis C Drug Treatment Provider's Forum. The overall aim of the national survey was to assess how they were being used and fundamentally where the data was shared and recorded.

This report combines the analysis of the ODN Cepheid Census and the Drug Treatment Cepheid Census to highlight best practices and make recommendations.

A total of 18 ODNs and 6 Drug Treatment Providers responded to the Cepheid census, covering a wide geographical spread, including hospitals, ODNs, drug treatment providers, and prisons. The survey explores the distribution and use of Cepheid GeneXpert machines for hepatitis C diagnostics, data recording processes, governance considerations and interoperability challenges. The response was encouraging and has provided a wealth of information about the use of the machines, standard operating procedures (SOPs), and the various information flows.



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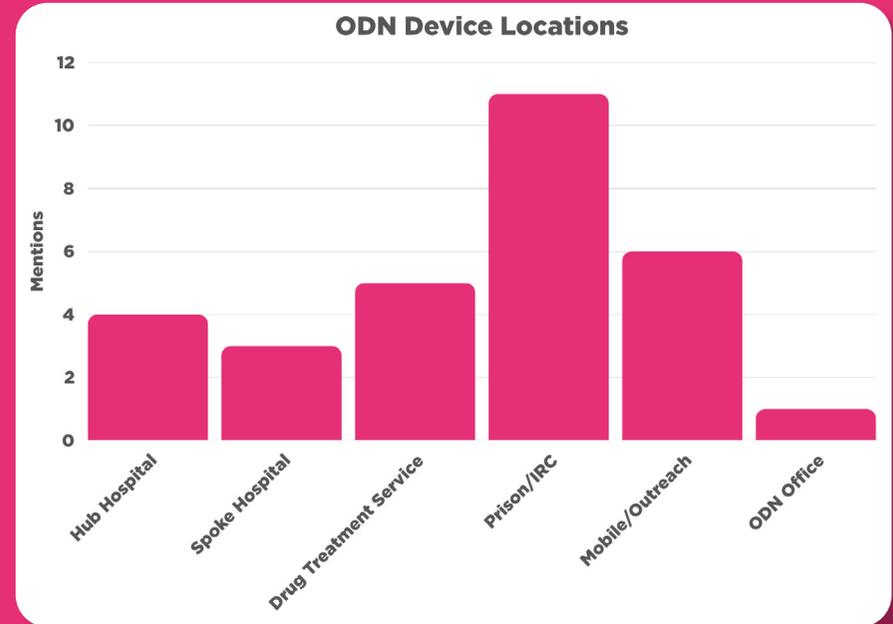
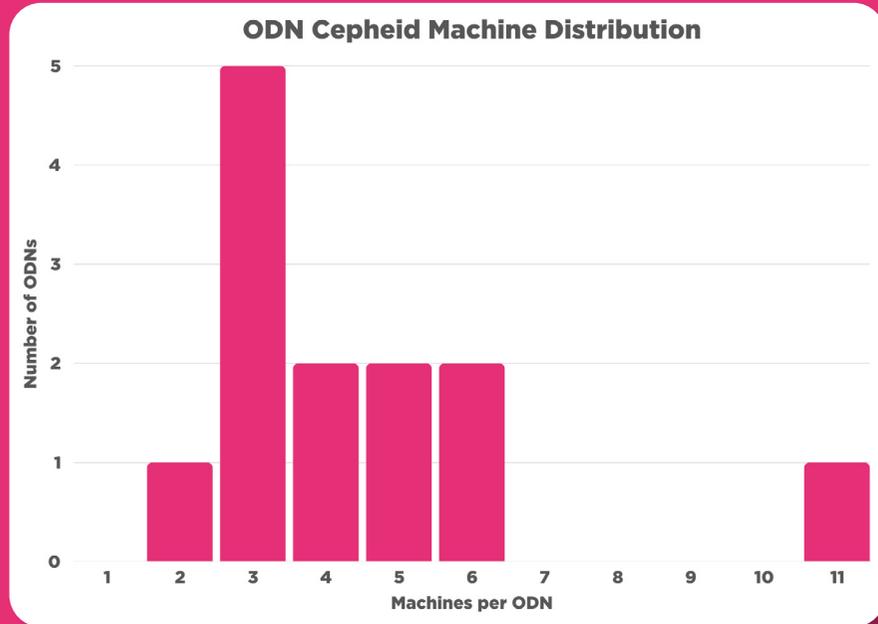
The census concentrated on HCV; therefore, questions were not focused on whether the machines were used for HIV or hepatitis B. This may have been a limitation in the depth of data which could have been received, particularly in relation to the machines located on community vans and immigration removal centres.

Learn more about Cepheid GeneXpert machines on Hep C U Later's dedicated webpage, including videos, policies which can be adapted, best practice case studies, and tools for professionals: [Cepheid GeneXpert Machines - HEP C U Later](#)

### Summary of Responses:

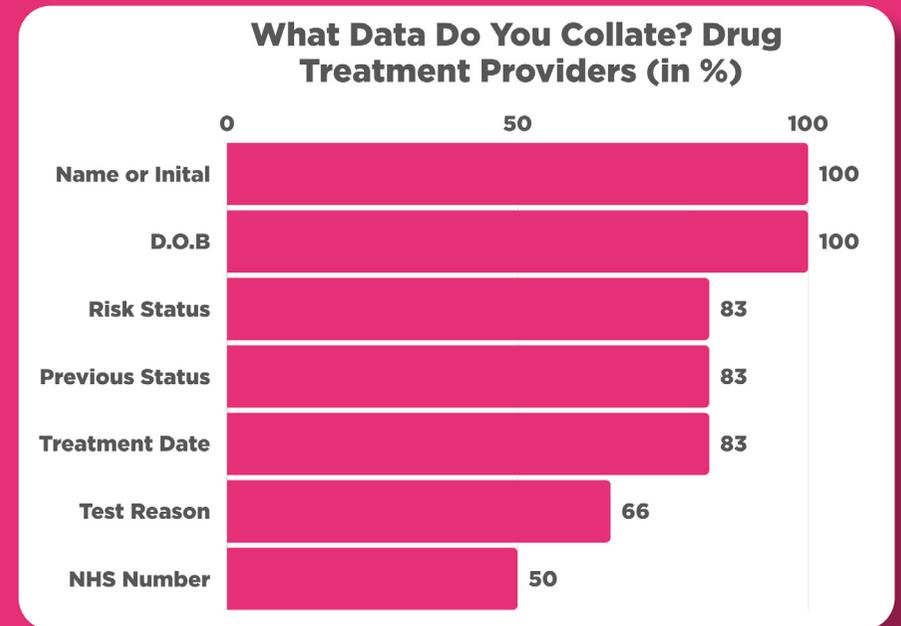
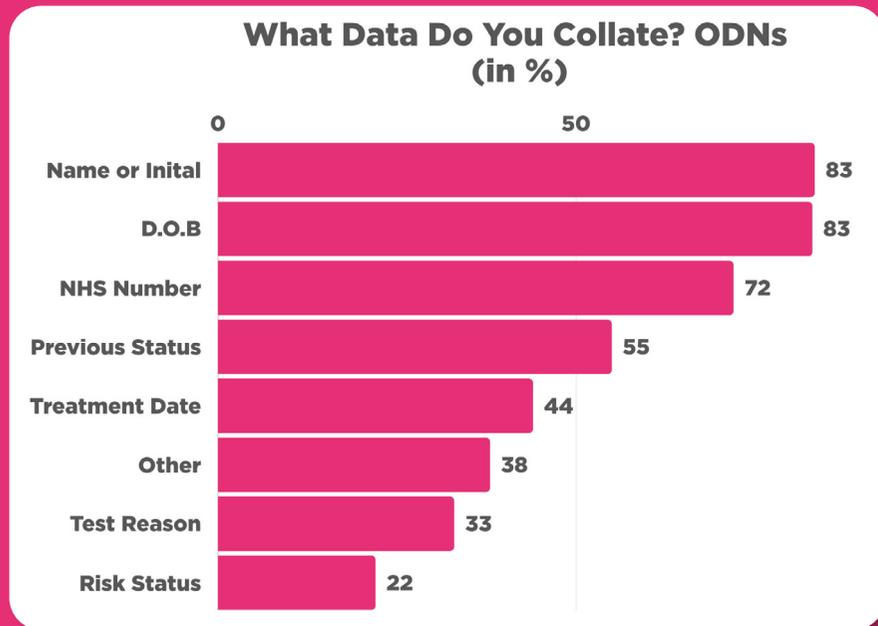
Out of the 18 ODNs who responded, there are a total of 60 Cepheid GeneXpert machines in use. Most ODNs reported having between 1 and 5 machines, with one ODN having 10 machines. Most ODNs have machines placed within prison estates, and one ODN reported that they had 4 machines at their local Immigration Removal Centre. Within drug treatment services, who responded 3 services owned a Cepheid GeneXpert machine, and 3 had access to one via their ODN. There is a recognition that some ODN and Drug Treatment Providers did not respond, and therefore, there may be additional machines in use. However, the responses gained were sufficient to be analysed into themes and make recommendations.

The most frequently used ODN settings for Cepheid GeneXpert machines included prisons, hospitals, mobile/outreach, and drug treatment services.



Most ODNs collected detailed patient data when using Cepheid GeneXpert machines, as detailed in the table below. The most commonly collected data included name/initials, date of birth, NHS number, previous hepatitis C status, and treatment start date, if known.

The drug treatment providers reported collecting the following data: name or initials, date of birth, risk status, test reason, previous hepatitis C status, and treatment date, if known. All results were recorded in the person’s local drug treatment electronic patient record.



Key differences between ODN and drug treatment service data collection include:

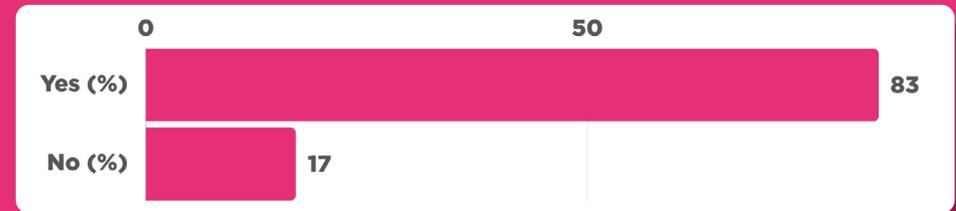
1. ODNs had a higher rate of collecting NHS numbers. Drug treatment services do not routinely collect NHS numbers when a person begins treatment for drug or alcohol use, and instead, they use unique patient identifiers. At a recent consultation, changes to the National Drug Treatment Monitoring Service (NDTMS – the mandated data collection across all community drug and alcohol treatment services) were proposed to commence collecting NHS numbers on a non-mandatory basis from 2027.
2. Drug treatment services recorded a higher rate of previous hepatitis C status, test reason, treatment date, and risk status compared to ODNs. This is likely due to ‘business as usual’ recording within the NDTMS data set and agreed processes in recording these details into the Cepheid GeneXpert machine when carrying out a test, likely the result of consistent training.

The table shows whether hepatitis C antibody testing is carried out before a Cepheid GeneXpert test within ODNs, or if the antibody status is known.

The ODN who replied No to this question have subsequently confirmed that most of the time the antibody status is known.

The 6 responses received from the drug treatment providers all stated that hepatitis C antibody testing was completed before, or the results were known ahead of time, using the Cepheid GeneXpert machine. One person detailed the challenges of not being able to record accurately on the NDTMS system if the antibody test was not completed before, and therefore, the records can appear incomplete.

One ODN who made use of an MSD-funded machine in the prison went straight to GeneXpert testing due to the quick turnaround in the prison population and the need to start people on treatment promptly. This has been highly effective and enabled many people to start treatment before leaving custody.



### Results, Recording and Data Sharing:



The census showed that overwhelmingly, the ODNs are only recording positive results, and that these were mainly recorded on the Arden and Gem Treatment Registry. Some ODNs reported they also recorded a sustained viral response (SVR) in this manner.

Results from the prison estate were routinely recorded on the electronic patient record, and the census indicated that this was perhaps the most thorough record-keeping. However, this information did not always make it back to the ODN or Arden and Gem due to systems not being compatible.

Some of the machines across the networks were managed by peers, mainly through the Hepatitis C Trust, and there was a lack of clarity from the census regarding what information was collected and where it was specifically recorded.

Several ODNs noted issues around client identifiers, subsequent difficulties matching these to people, and referred to NHS numbers being the gold standard for people to have their test and results recorded accurately.

Only 3 out of 18 ODNs submit data directly to UKHSA; another 4 cited that they do share details with UKHSA via Arden and Gem. Data submitted is variable and inconsistent across the networks. Submitted data often included hepatitis C RNA+ results, meaning anyone who had been tested post-treatment may not have their results linked to other health records.

This has been illustrated elsewhere in the system with primary care records, where people successfully completing treatment are still coded as having hepatitis C. ODNs who do not routinely share data cite barriers such as the lack of governance, lack of clarity on what should be shared, or system limitations.

The data sharing between drug treatment services and the ODNs was also highly varied, with a high number of ODNs reporting that drug treatment services did not routinely share data for people who had results of antibody positive/RNA negative. However, where in-house hepatitis C treatment was delivered (hepatology facilitating clinics in the drug treatment service), the exchange of information appeared to be more robust.

Overall, from the limited information back from Drug Treatment Providers referrals to the ODN for people who were hepatitis C RNA positive seemed to be very good, with excellent pathways detailed. How people were referred included direct referrals to hepatology or hepatology nurse specialists via email, through the use of standard referral forms, or via on-site clinics.

Rationales from ODNs regarding the gaps in test results being shared were cited as:

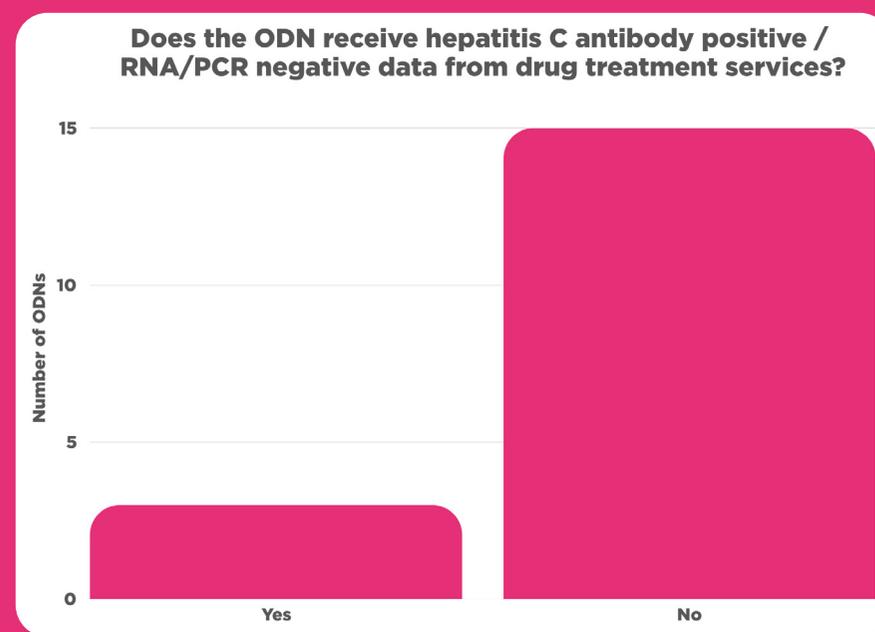
- **Missing consent**
- **Governance restrictions**
- **Lack of clarity on the purpose and need**

There was also recognition that dry blood spot test RNA results from some drug treatment providers do not routinely reach ODNs unless they were positive, meaning there are missed opportunities to record SVRs.

### **Cepheid 360 Software:**

Only 1 of the 18 ODN respondents to the census made use of the Cepheid 360 software; most ODNs reported within the census that they would like to know more about how it can support them. The ODN that used Cepheid 360 software reported finding it helpful. Some comments noted a reluctance to duplicate data entry when Arden and Gem were already established.

This poses potential limitations for the recording of some people who are re-tested (e.g., following interferon treatment, or someone treated out of area who is not listed on the local Arden and Gem access).



## What is Cepheid 360?

Cepheid C360 is a secure, hosted platform that collects and aggregates real-time disease and system surveillance information from any GeneXpert System. Cepheid C360 securely collects and aggregates, in dashboard format, real-time information from any GeneXpert System to enhance productivity and system performance.

## Standard Operating Procedures and Training:

Overwhelmingly, ODNs did not have Standard Operating Procedures (SOPs) or training materials, and those who did were unclear if they were allowed to share these outside of their NHS Trusts. Training was cited as being delivered by Hep C U Later or directly from Cepheid. ODNs had made use of the various Hep C U Later resources, which have been openly shared.

## Conclusions:

### Collaboration & Successes

- Positive patient acceptability of the Cepheid GeneXpert test - those with poor venous access were able to be tested and treated.
- Several organisations highlighted strong partnership working between hepatology teams, ODNs, Hep C U Later, The Hepatitis C Trust and harm reduction teams.
- Some regions strongly emphasised how the use of the Cepheid GeneXpert machines and the collaborative pathways have improved progress toward hepatitis C micro elimination. (Find out more about micro elimination [here](#)).
- There was a wide geographic deployment of Cepheid GeneXpert machines, enabling flexible outreach.
- Data collection captured people who had a hepatitis C RNA positive status and gave the viral load alongside this which has proven useful for clinical decision making.
- The Cepheid GeneXpert machines were considered an excellent resource for patient engagement and provided a quick turn-around of testing and results.



## Combined Insights & Themes

- Significant variation exists in how Cepheid GeneXpert testing is deployed across regions, and the census shows considerable variation in data pathways and recording.
- Prison and outreach-based Cepheid GeneXpert testing provides major coverage for people who might be at a high risk of hepatitis C. However, this information does not always get passed back to the ODNs.
- Governance and consent barriers are frequently being cited as limiting data flow to ODNs and UKHSA. However, there were good examples where data sharing was effective with the ODNs having data sharing agreements (such as MOU's) with UKHSA.
- Lack of connectivity from Cepheid GeneXpert devices to lab systems may be causing a reliance on manual spreadsheets.
- There is a very low adoption of Cepheid 360 across both ODNs and drug treatment services, which is likely due to organisations not being aware of the technology.

## Recommendations

Following the ODN and drug treatment provider Cepheid GeneXpert National Census, Hep C U Later have the following recommendations:



1. Develop standardised SOPs and data sharing frameworks across ODNs.
2. Seek consent to share results with UKHSA at the point of the test, and implement mechanisms to do this monthly or quarterly.
3. Provide national guidance on minimum data sets which can be used for Cepheid GeneXpert tests.
4. Improve integration between prison healthcare systems, community drug treatment and ODN data recording registries.
5. Build consistent data sets which are linked to patient clinical records including UKHSA.
6. Support the training and adoption of Cepheid 360
7. Further explore the data sharing of all RNA results from Drug Treatment to UKHSA / ODN / NHSE

**Hep C U Later would like to thank all of the ODNs and drug treatment providers who took part in the census, and Cepheid and MSD for providing Cepheid GeneXpert machines to some services (Cepheid GeneXpert machines provided as part of NHS England elimination tender).**

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