

STEP C FREE OUTCOMES REPORT

STEP-C Free - Support to Treatment by Engagement with Peers Hep C Free

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Micro-Elimination of HCV by Pathway Optimisation utilising Point of Care Testing and Peer Support. A collaboration (joint working) project between NHS Forth Valley - Sexual Blood Borne Virus Managed Care Network and Gilead Sciences Ltd.

1. Background

Scotland has been striving to eliminate Hepatitis C (HCV) since the National Hepatitis C Action Plans began in 2006, evolving into the Sexual Health and Blood Borne Virus Frameworks from 2011 to the present. The next multi-year framework is being developed by the Scottish Government and Public Health Scotland (PHS). The NHS Forth Valley Sexual Health and Blood Borne Virus Managed Care Network (FVSHBBVMCN or FVMCN) is committed to achieving HCV elimination status by 2024-25. However, the COVID-19 pandemic has disrupted progress, particularly among the most at-risk populations.

NHS Forth Valley (NHSFV) has established effective pathways for testing and treating patients who naturally engage with healthcare services. However, there remains a significant unmet need for chaotic drug users and other hard-to-reach groups, who do not benefit from existing pathways. These groups would benefit the most from a "treatment as prevention" strategy, reducing community transmission and contributing to the elimination of HCV.

Workshops held in December 2021 and February 2022 aimed to address these challenges by mapping the barriers in existing care pathways and exploring potential solutions. Facilitated by David Fitton-Weir from Gilead Sciences and attended by community partners, key workers, and individuals with lived experience, the workshops confirmed that certain client groups, particularly those disengaged from traditional services, are not being adequately reached. Key groups identified included:

- People currently using drugs but avoiding statutory drug treatment or harm reduction services.
- Clients attending homeless shelters or Salvation Army properties.
- Chaotic drug users in rural areas with limited access to Injecting Equipment Provision (IEP).
- Individuals known to the drug recovery networks but disengaged from services despite being at risk of HCV.

FVMCN already had evidence of success through its Peer Support Worker model, which had been jointly supported by Gilead Sciences and NHSFV. This model demonstrated that peer-

led community engagement is a critical resource for accessing and supporting clients through the treatment pathway.

The workshops also highlighted delays in testing turnaround times, particularly the 6-8 week wait for dried blood spot (DBS) test results. Even before COVID-19, results took two weeks, which was causing significant delays in starting treatment. The need for rapid point-of-care testing (POCT) using a Cepheid machine became evident as a solution to expedite the testing and treatment process.

JOINT WORKING

It was agreed that a joint working project would be the best way to execute this project to leverage the experience and expertise both parties to optimise the care pathway and provide innovative solutions to complex problems. During the concept phase of the project, the ABPI Joint/collaborative working toolkit (published in the ABPI Code of Practice 2021). This guide provided structure to the project and was referenced throughout the project to ensure compliance with the ABPI code of conduct. A checklist of 'red;' and 'amber' questions was adhered to as set out in the ABPI "Collaborative working criteria" in the planning phase of the project to ensure that joint working was appropriate. All questions in the criteria were met and reviewed by appropriate legal and public health stakeholders in Gilead Sciences Limited and NHS Forth Valley, respectively. The ABPI defines joint working as follows:

"Joint working between one or more pharmaceutical companies and the NHS and others which is patient centred and always benefits patients is an acceptable form of collaborative working providing it is carried out in a manner compatible with Clause 20 and other relevant requirements of the Code. It must be clear in the documentation that the project is a joint working project and account must be taken of relevant best practice guidance on joint working between the NHS, the pharmaceutical industry and other relevant commercial organisations."

The project initiation document set out the benefits to patients, NHS and Gilead Sciences Ltd. As follows:

Outcomes for Patients:

- Easier access to Testing, significantly reduced waiting time, compared to 8-week DBS result delay
- Immediately placed into shortened pathway once Cepheid result known
- Treatment starts within few days as opposed to 10 weeks
- The new pathway will allow access to test, treat and support for client groups who don't currently engage with standard pathways
- Peer worker will significantly increase support and harm reduction messages to hard to engage groups
- Easier and seamless testing will positively encourage those testing negative to undergo regularly repeat process if further risk activity is identified.

Outcomes for NHS

- Improve access to testing and treatment for hard to reach and marginalised groups, improving health inequalities and reducing burden of long-term chronic disease in disadvantaged populations
- Significantly increase the use of “Treatment for Prevention’ strategy in those groups with highest prevalence of Hepatitis C, thus reducing risk of secondary transmission and reinfection
- Will enable NHS Scotland target of Hepatitis C elimination to be reached by 2024-5 within Forth valley

Outcomes for the Gilead:

- Explore the use of alternative strategies for treatment delivery in a Scottish Health Board setting
- Gilead has a goal to become the chosen partner to lead improvements in health and healthcare for patients in the UK and Ireland disease/therapy areas in which Gilead operate. Involvement in this project is anticipated to further Gilead Sciences Ltd understanding of current and future HCV treatment pathways, including testing modalities, prevention/harm reduction, linkage to care and services – especially for difficult to reach patient.
- This project will allow Gilead a greater insight into where and how to engage with people living with HCV outside of the regular NHS touchpoints. To help Gilead understand what is important to patients with respect to their treatment journey, how they wish to be communicated with and how they may wish to be managed in the future.
- As geographies across the UK and Ireland get close to micro-elimination , the insights and learns from this pilot can support micro-elimination by means of sharing best practice

2. Project Aims

The **STEP C Free** project was designed to support **micro-elimination of HCV** in the NHS Forth Valley Health Board by optimizing testing, diagnosis, and treatment pathways and improving accessibility for hard-to-reach patients. Specific project aims included:

- **Reducing the time** from screening to treatment from over 10 weeks to less than one week.
- **Improving patient retention** by minimizing the number of steps between diagnosis and treatment.
- **Transitioning from DBS testing** to point-of-care screening using rapid HCV antibody tests and Cepheid GeneXpert HCV RNA tests.
- **Expanding peer support** networks to increase patient engagement and **enhancing CNS capacity** to deliver care.

- **Extending reach** beyond traditional clinical settings to engage high-risk populations in community venues, homeless shelters, and areas with poor access to harm reduction services.

3. Project Implementation

Project Design:

Following the pathway mapping workshops, a situational analysis was conducted to identify existing barriers and potential solutions. With buy-in from stakeholders and a clear understanding of the challenges faced by specific populations, the project was ready to launch with minimal lead time.

The project aimed to integrate a core team consisting of two peer workers with lived experience and a community BBV nurse specialist. These workers would provide outreach, screening, and support in non-healthcare community settings, ensuring that clients were engaged and supported throughout the testing and treatment process.

The project was implemented on July 1st 2023 and ran for 13 months until August 2024, following a 6 month planning phase (January 2023-June 2023), which established the following:

- STEP C Free project team comprising of 2 peer workers provided by the hepatitis C trust, funded from the project budget, 2 clinical nurse specialists from NHS Forth Valley, BBV Champion from NHS Forth Valley BBV MCN, and a pharmacist from NHS Scotland
- Testing protocol: HCV Rapid Antibody test, Cepheid GeneXpert mobile HCVRNA testing Unit, Dry Blood Spot tests (to test for other BBVs)
- Potential venues to hold testing events across Forth Valley
- Method of data collection



Testing and Treatment Model:

- Rapid HCV antibody tests were used to screen individuals in community settings. Clients who tested positive for antibodies were immediately tested with a mobile Cepheid GeneXpert module to confirm active HCV RNA infection.
- Positive results were provided within an hour, and peer workers facilitated immediate referrals to a community hepatology nurse for liver assessments, fibroscan tests, and further bloodwork (DBS for HIV and HBV).
- Those confirmed HCV RNA positive had treatment prescriptions lodged within a week, with peer workers supporting adherence throughout the treatment process. Peer

workers played a crucial role in managing social and logistical barriers to treatment, such as collecting medication or arranging transportation to clinics.



Overcoming Barriers:

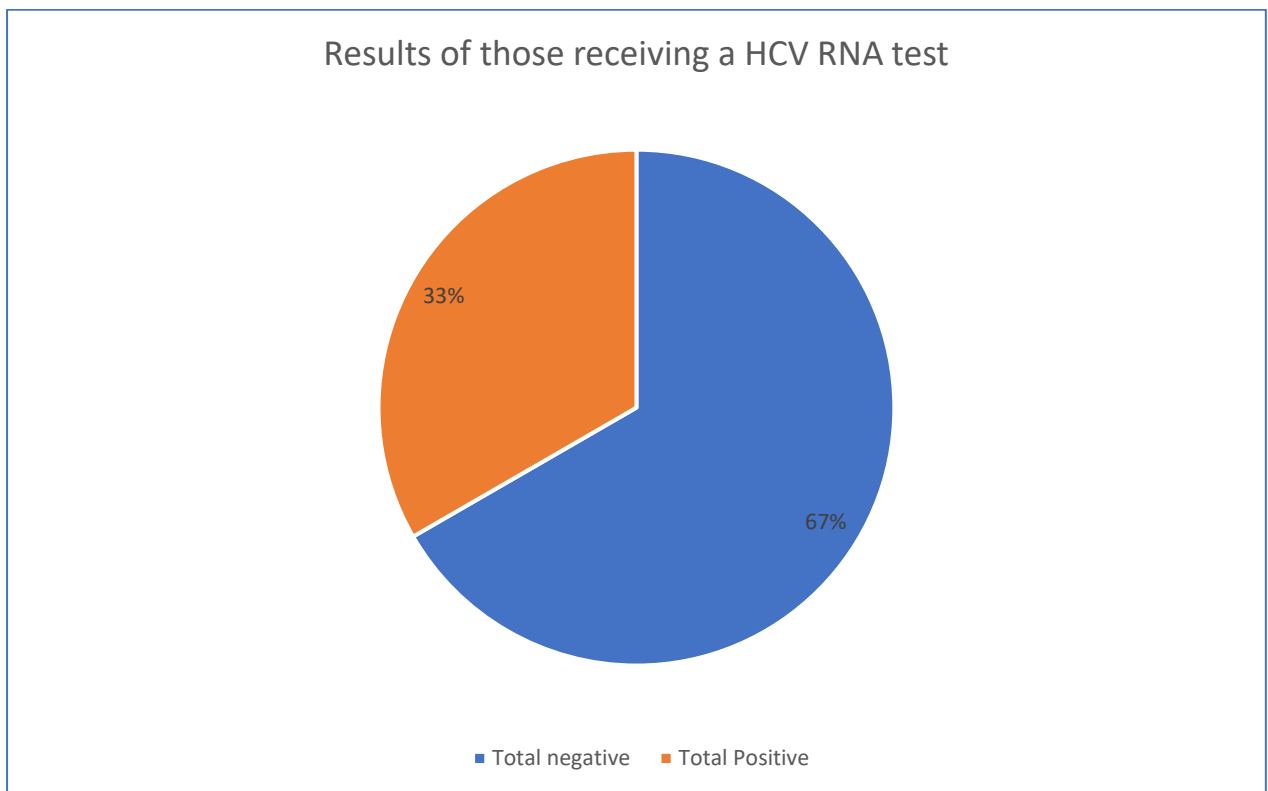
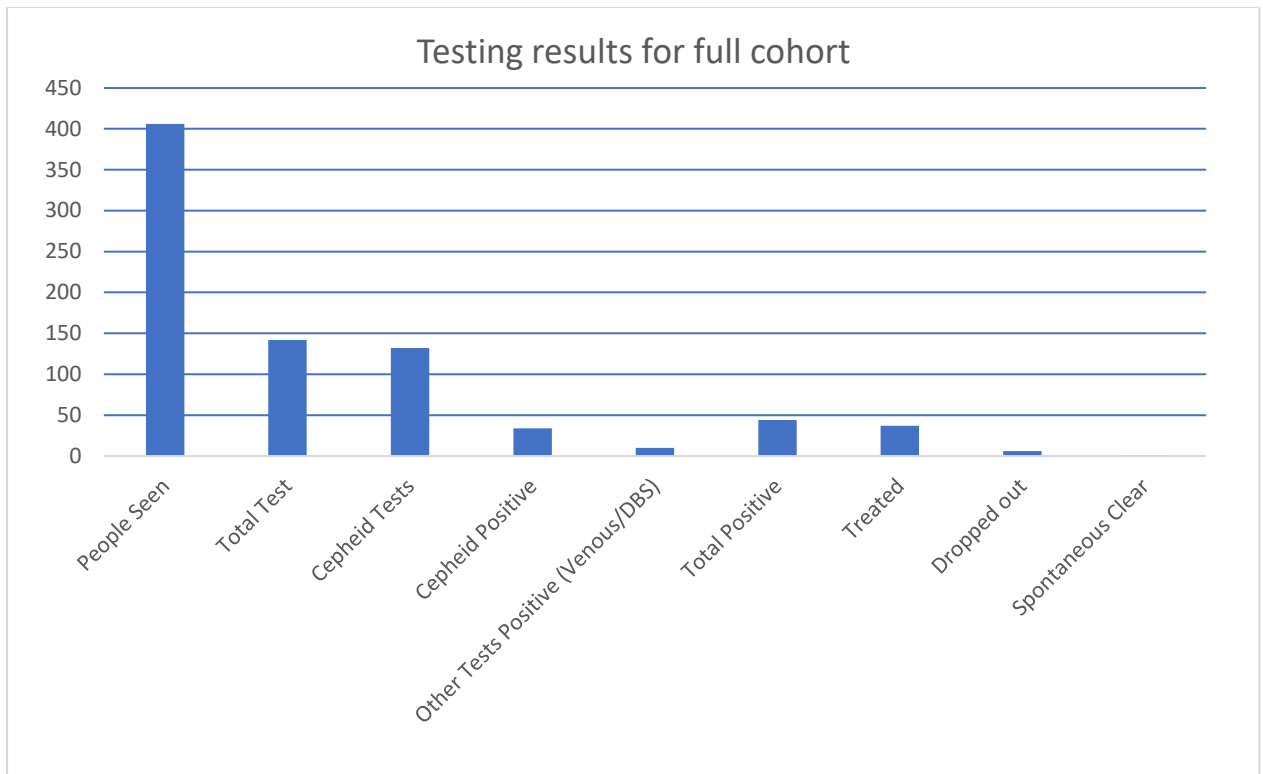
Peer workers provided emotional and practical support, helping to address social determinants of health, such as housing instability, mental health challenges, and financial insecurity. The inclusion of lived-experience peer workers enabled a non-judgmental, supportive approach that encouraged engagement from marginalized populations who may have otherwise avoided healthcare services.

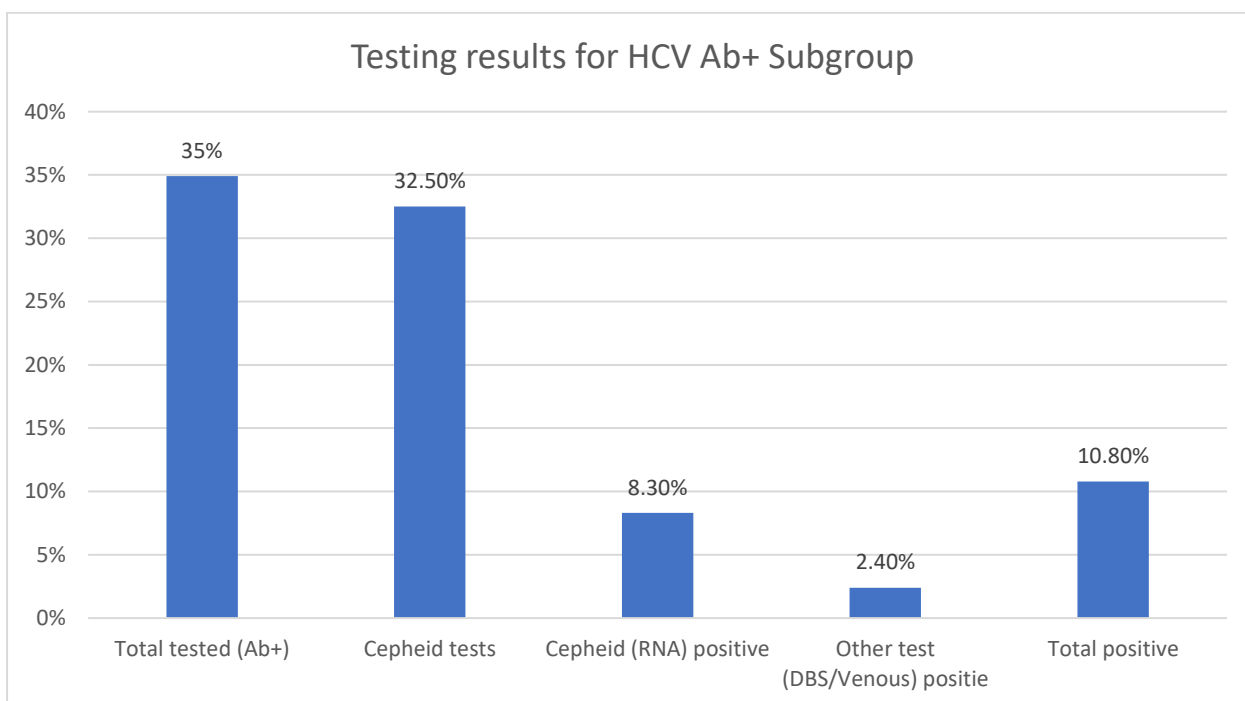
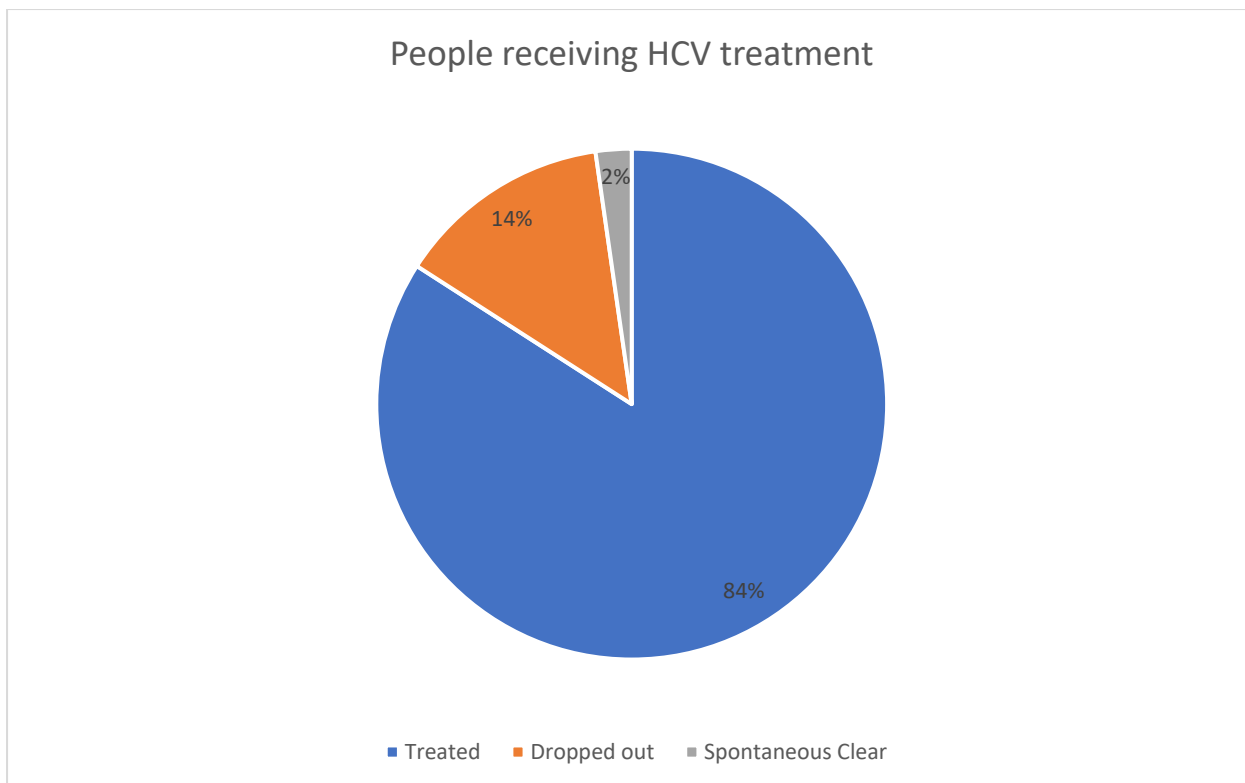
Additionally, Gilead's expertise and logistical support were crucial in developing the treatment pathway, including securing rapid medication delivery via community pharmacies and addressing staffing shortages that could affect treatment delivery.

4. Results

Over the 13 month course of the project, the STEP C Free team engaged 406 individuals, offering rapid HCV testing in various community settings across Forth Valley. The detailed breakdown of results is as follows:

| Indicator | Value |
|------------------------------------|-------------|
| Total individuals tested (HCV Ab+) | 142 (34.9%) |
| Confirmed HCV RNA positive | 44 (10.8%) |
| Cepheid positive results | 34 (8.3%) |
| Other positive tests (Venous/DBS) | 10 (2.4%) |
| Total clients treated | 37 (84%) |
| Drop-out rate | 13.6% |
| Spontaneous viral clearance | 1 (2.3%) |





A majority of those treated were supported by peer workers who ensured that clients adhered to treatment regimens, collected medications, and attended follow-up appointments. Despite logistical challenges, the drop-out rate remained low, demonstrating the value of peer-led engagement in supporting treatment adherence.

5. Venue-Based Engagement

Testing and treatment were conducted in non-healthcare venues, ranging from homeless shelters to recovery communities. The success of the venue-based model demonstrated that placing services in familiar, non-threatening environments increased client engagement.

| Venue | People Seen | Cepheid Tests | Cepheid Positive | Other Tests Positive (Venous/DBS) | Treated | Dropped out | Spontaneous Clear |
|-------------------------|-------------|---------------|------------------|-----------------------------------|---------|-------------|-------------------|
| CADS North | 75 | 57 | 16 | 4 | 17 | 2 | 1 |
| no incentive | | | | | | | |
| CGL | 121 | 45 | 7 | 5 | 9 | 3 | 0 |
| no incentive | | | | | | | |
| Grangemouth Kersiebank | 57 | 7 | 1 | 0 | 1 | 0 | 0 |
| incentive | | | | | | | |
| The Pantry, Howgate | 45 | 0 | 0 | 1 | 1 | 0 | 0 |
| Incentive | | | | | | | |
| Alva Baptist Church | 10 | 0 | 0 | 0 | 0 | 0 | 0 |
| incentive | | | | | | | |
| Denny Flat | 9 | 0 | 0 | 0 | 0 | 0 | 0 |
| incentive | | | | | | | |
| The Sub, Langlees | 43 | 4 | 2 | 0 | 2 | 0 | 0 |
| incentive | | | | | | | |
| Tullibody Health Centre | 4 | 4 | 0 | 0 | 0 | 0 | 0 |
| incentive | | | | | | | |
| Salvation Army, Falkirk | 42 | 15 | 8 | 0 | 7 | 1 | 0 |
| incentive | | | | | | | |

6. Client Testimonials

“I think the support helped because in the first place, before that, I didn’t really have support from CADS. Then when I was gave your number, I felt like you encouraged me and didn’t judge me n that, know what I mean. Like having that made me feel horrible and dirty if you know what I mean, it’s made a big difference, coz a feel like I’ve got someone who is there for support and I can ask questions without feeling stupid or judged.” **Step C Free client**

“Being told I had hep was like a blow to the head, I didn’t know what to think what it even meant like, I had no clue and always thought, I’ll no get that. But after getting the result, I was introduced to Tommy and Lorraine and I’m no going to sugar coat the way I am with “professionals”, 28 years and I hate having to deal with them.” **Step C Free client**

“This is so needed, people struggle to get appointments with their GP’s and end up not bothering. It’s much better if you can go to them.” **Volunteer at The Pantry**

“We have met so many people as part of STEP C Free, who would never have come forward for testing or treatment, it’s just not on their radar. Getting food and getting by are much greater priorities. Healthcare needs to be much more visible and integrated into community settings, particularly for our most vulnerable people.” **Project staff member**



“It’s great you know , I would never go to the doctor, they canny be bothered with you and just want to get you out the door as quick as possible. I’m glad you came here and I really appreciate what you have done for us.” **Step C Free client**

“I really appreciated being able to meet people in an environment where they felt comfortable and were more open to undergoing testing and assessment for treatment. It also reduced the need for multiple clinic appointments and meant they could be quickly started on treatment. From a nursing view, seeing people in their own communities was definitely more in line with why I started my nursing career.” **BBV Nurse Specialist**

7. Limitations and Improvements

The purpose of the project was to demonstrate that by reducing the barriers to accessing testing and treatment, shortening the testing and treatment pathway and utilising the expertise of peers to engage, test and support through treatment, we could retain people in service and achieve successful outcomes from HCV treatment.

Our stakeholder events and workshops highlighted areas where we needed to focus our efforts. Working collaboratively, we were able to secure accommodation to

host events within communities identified as most likely to have higher prevalence of HCV and were supported in these efforts by our colleagues in primary care, CGL, Salvation Army and local authority. The testing events were advertised widely in Substance Use Services, via our third sector partners and by distributing flyers to local shops and community pharmacies. The success of events was largely determined by the position of the venue in the community, footfall on days of the week when we offered testing and the offer of contingency management. Rapport within the community was also key to any success and involving someone who is recognisable and respected within the community has the ability to make a difference to how this is received. There remains a degree of suspicion within small communities and to try and counteract this, the intention was to remain at a single site, on consistent days, for a prolonged period of up to 2 months to try and develop strong community relationships. As the project progressed, it became obvious that people are more likely to access testing and treatment if offered at a time and in a place where they feel comfortable and are already accessing something which is of a higher priority in their daily lives and those settings should be the priority focus. Foodbanks, Recovery Cafes and Salvation Army cafes were all areas where we had the best engagement.

Due to the volume and bulk of equipment required to deliver rapid testing, assessment and treatment and to ensure the safety of staff, it became quite clear that the position of the accommodation within the venue had to be risk assessed for lifting and handling. This did not limit our ability to offer services within highlighted areas, however, we did have to ensure adequate numbers of staff to support the transport and set up of equipment. It is also worth bearing in mind that as the venues are non-healthcare, practices have to be adapted to ensure privacy, confidentiality and appropriate infection control, although there were no instances where it was felt any identified issues were insurmountable and a creative approach as often required. It also has to be added that community based services are generally very invested in ensuring that their community members have access to as many health and social benefits as possible.

As the project progressed, it became evident that some of the individuals we were seeing required a more holistic approach with environmental and social factors impacting their general well-being as much as their other co-morbidities. Our third sector partner agency Transform FV, who offer both Enhanced Assertive Outreach and Social Inclusion services, supported our events and were able to provide practical support to individuals including setting up bank accounts, transport to and from other Healthcare appointment, welfare checks and if required, IEP. This whole-person approach is essential for people who struggle to negotiate the complexities of healthcare and local authority services.

It is well recognised that the undiagnosed HCV population not engaging with Substance Use services is unknown and perceived to be a “difficult to engage” group. However, the STEP C Free project has demonstrated that if services are

tailored to optimise the touchpoints between healthcare and this cohort, then testing and treatment uptake is equitable with that of more traditional healthcare settings. STEP C Free is a model of care which could be replicated across a wide range of healthcare services and addresses and provides a creative solution to the barriers often faced by people who have difficulty in routinely accessing healthcare in a more standardised manner.

7. Conclusion

Despite the availability of routine HCV testing in Forth Valley, certain at-risk groups remained underserved. The STEP C Free project demonstrated that **peer-supported, point-of-care testing and treatment** in community settings can effectively reach these populations. The project's success lies in its rapid testing model, reducing client loss through immediate treatment initiation and expanding outreach efforts through trusted peer engagement.

By addressing both healthcare and social challenges, this model not only identified HCV-positive individuals but also ensured continuity of care through peer support. This holistic approach has proven successful in reducing transmission and promoting community health, suggesting that the STEP C Free model could be scaled and replicated in other areas.

The STEP C Free team is committed to refining this approach and working with stakeholders, including Public Health Scotland, to secure ongoing funding and expand the project. This initiative marks a crucial step towards HCV micro-elimination in Forth Valley, and its legacy will continue beyond 2024-25 through NHSFV's long-term commitment to providing integrated support for at-risk communities.