Understanding reinfection risk of Hepatitis C in people who inject drugs: A Qualitative Study

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Abstract

Background: Given the ambition of the World Health Organisation (WHO) to eliminate Hepatitis C (HCV) as a public health concern by 2030, clarity on the factors contributing towards the reinfection of HCV in people who inject drugs (PWID) need better understood. In 2018, NHS Tayside implemented the ADVANCE trial which found no significant differences in the efficacy of Direct Acting Anti-Viral (DAA) treatment in curing HCV in PWID when different treatment regimens were compared: (1) directly observed therapy; (2) fortnightly dispensed and (3) fortnightly dispensed with a psychological intervention. Despite NHS Tayside diagnosing 90% of PWID with HCV and initiating treatment in 92% of these, there are still cases of reinfection following a successful cure. The objective of this study was to gain an improved understanding of the psycho-social factors associated with the reinfection of HCV in patients who participated in the ADVANCE trial.

Methods: Semi-structured interviews were conducted with 6 patients who had received HCV treatment via the ADVANCE trial. All patients self-reported as having no further HCV infections following their cure. To further develop the grounded theory and to obtain some comparative data between those who do and do not become reinfected, 6 healthcare staff were recruited to offer their experience in supporting those who do become reinfected. A constructivist grounded theory methodology was used to analyse the data.

Results: The core category of “Identity Shift” was developed. The identity shift which occurs can be explained through five theoretical categories: (1) Good Healthcare Relationships; (2) Re-establishing Place in Society; (3) Hierarchy of Substance Use; (4) Shifting Locus of Control and; (5) Socially Responsible Patient.

Conclusion: The positive identity shifts which occur in this study are thought to be protective of HCV reinfection. The findings of the study also provide evidence that DAA treatment can support patients to achieve non-clinical outcomes and Sustained Virologic Response (SVR), despite concerns around the impact that a less intensive treatment regimen would have. Providing longer-term clinical care to patients also appears to be important in maintaining HCV cure and a recovery orientated identity.

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Declaration

I declare that, except where explicit reference is made to the contribution of others, this thesis embodies the results of my own research and was composed by me.

This thesis has not been submitted for any other degree at the University of Stirling or any other institution.

Signature: Katie Heslop

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List of Acronyms and Abbreviations

ADVANCE - A Direct obserVed therApy versus fortNightly CollEction study for HCV treatment

BBV – Blood Borne Virus

DAAs – Direct Acting Anti-Virals

DOT – Directly Observed Therapy

HCV – Hepatitis C

IEPS – Injecting Equipment Provision Site

IPA – Interpretative Phenomenological Analysis

IMB - Information-Motivation-Behavioural

NHS – National Health Service

OST – Opioid Substitution Therapy

PI – Principal Investigator

PWID – People Who Inject Drugs

SVR – Sustained Virologic Response

TasP – Treatment as Prevention

WHO – World Health Organisation

Chapter 1 – Introduction

Chapter one provides a literature review which gives an overview of Hepatitis C, the advancements seen in treatment, the increased roll out of treatment in NHS Tayside, Scotland and the issue of reinfection. The researcher employed a structured search strategy using Medline, PsychINFO, CINAHL and EMBASE. These databases were chosen as they provide access to literature from the fields of medicine, nursing, psychology and health which were all relevant to the present study. The literature search was completed between October 2022 and February 2023 with no language or date restrictions used. Subject headings and free text terms were used in relation to Hepatitis C, treatment, reinfection, Tayside and Scotland.

The literature review is followed by an introduction to grounded theory methodology, the main research aims of the present study and an overview of the structure of the thesis.

1.1 Overview of Hepatitis C and Treatment

Hepatitis C (HCV) is a blood borne virus (BBV) causing inflammation of the liver and is most commonly transmitted through the sharing of injecting equipment by people who inject drugs (PWID), with 98-99% of infections directly attributed to drug injecting behaviours (Scottish Government, 2019). In many instances there are no physical symptoms of HCV in the first six months of infection (NHS, 2021b), however, in up to 80% of cases, acute HCV will develop into chronic HCV (Dietz & Maasoumy, 2022). Where symptoms do develop, they often include high temperature, fatigue, loss of appetite, nausea, stomach pain and jaundice (NHS, 2021b). Due to delay in symptom presentation, the disease is often advanced and more challenging to treat when people present themselves to healthcare services (Scottish Government, 2019). Chronic HCV can have a more significant impact on the body and quality of life with liver cirrhosis, liver failure and liver cancer all being complications associated with an untreated HCV infection (NHS, 2021a).

With an estimated 1.5 million new infections annually and the global prevalence of chronic HCV reaching 58 million (WHO, 2022b), it is an important public health concern, with PWID being disproportionately affected (Degenhardt et al., 2017). In Scotland, 57,300 people between the ages of 15 and 64 routinely misuse substances, meaning Scotland has a higher incidence of problem substance use, when compared to other European countries (Scottish Government, 2022). The prevalence of HCV in Scotland (between 500 and 1500 people annually) is also associated with drug injecting behaviours (Scottish Government, 2019). When investigating the population level prevalence of HCV, Palmateer et al. (2021) found that the incidence of HCV in PWID fell from 37% in 2010 to 32% in 2018. Despite this reduction, the prevalence of disease remains high with an estimated 21,000 active infections in Scotland (Scottish Government, 2019). Sharing needles and drug preparation equipment is likely to contribute towards infection rates seen in this population so the provision of safe injecting equipment and Opioid Substitution Treatment (OST) has evidence of being effective in reducing virus transmission (Midgard et al., 2016).

To tackle the prevalence of HCV, the WHO published its Global Health Sector Strategy on viral hepatitis, focusing on chronic Hepatitis B and C and reaffirmed its ambitions in eliminating HCV as a public health threat by 2030; reducing the number of new infections in PWID to 2 per 100; and increasing diagnosis and cure rates to 90% and 80% respectively (WHO, 2022a). The Scottish Government (2019) initiated its own ‘Hepatitis C Action Plan’ and stated its vision for eliminating HCV as a major public health concern by 2024. Elimination, by definition, would consist of 5000 or less active HCV infections in Scotland. If achieved, this would supersede the 2030 target set by the WHO. Central to achieving the ambitions set out by the WHO and the Scottish Government was engaging PWID in harm reduction services, increasing the number of people receiving HCV treatment, tailoring the delivery of treatment to the needs of patients, addressing the barriers experienced by populations who are most at risk of infection and identifying and engaging undiagnosed and diagnosed people in HCV services. Current standard treatment recommendations for HCV are Direct-Acting Antiviral (DAA) tablets prescribed over a period of 8-12 weeks (Dietz & Maasoumy, 2022). The introduction of DAAs marked a transition away from the previous treatment via Interferon. This was seen as an important advancement in the treatment of HCV due to the significant reduction in side effects, improvement in cure rate and less burdensome treatment regime (Donaldson et al., 2022; Hickman et al., 2019). Despite the advancements in pharmaceuticals, a recent systematic review found that PWID have continued to experience barriers in accessing treatment. The perception from healthcare providers that PWID will become reinfected, will not adhere to treatment and will respond poorly to treatment have been noted as reasons for withholding treatment from this population (Pedlar et al., 2020). PWID beliefs around the severity of HCV illness; side effects of treatment; lack of social support and stigmatisation from healthcare providers were all barriers associated with accessing treatment (Pedlar et al., 2020). Being treated with dignity and respect, at their own pharmacy and by their own drug worker were factors outlined by people prescribed OST as being important contributors to them engaging in HCV testing in a Scottish study. This study also identified less travel distance to the testing facility and reduced waiting time to receive test results as being important (Radley et al., 2019). By expanding HCV treatment to community settings and primary care, barriers PWID experienced in accessing treatment reduced and adherence to treatment improved (Abdelwadoud et al., 2021).

1.2 Hepatitis C Treatment in NHS Tayside

With a population of 417,000, NHS Tayside is a health board in Scotland covering the geographical areas of Angus, Dundee, Perth and Kinross and treats 7% of Scotland's Hepatitis C infected population (Scottish Government, 2019). Within this population, it is estimated that 1 in 149 people will either inject drugs or be receiving OST, of which 30% will have a chronic HCV infection (Scottish Government, 2019). In Tayside, HCV testing and treatment is available in community pharmacies, prisons, GP practices, Injecting Equipment Provision Sites (IEPS) and substance misuse services (Byrne et al., 2020). To reduce the incidence of disease, the provision of HCV treatment was expanded by the health board, through an enhanced Treatment as Prevention (TasP) programme (Byrne et al., 2022). TasP aims to reduce onward HCV transmission by reducing the overall prevalence of disease in the population through successful treatment (Scottish Government, 2019; Martin et al., 2013). Over a three-year period (January 2017 – April 2020), more than 700 HCV treatments were given, which resulted in the diagnosis of 90% of PWID with HCV and the initiation of treatment in 92% of these (Byrne et al., 2022), which is consistent in achieving the target outlined by the WHO.

1.3 ADVANCE Hepatitis C Study

To further this work, NHS Tayside designed and implemented the ADVANCE study in 2018 which aimed to determine whether the efficacy of HCV treatment via DAAs would be affected by changes to form of delivery elements. One hundred and twenty-nine participants were randomised into one of three different treatment regimens (1) DAAs via directly observed therapy (DOT); (2) DAAs via fortnightly provision and (3) fortnightly provision of DAAs with a psychological intervention (Beer et al., 2022). Participants in the DOT group were required to attend the Injecting Equipment Provision Site (IEPS) on a daily basis so that their consumption of medication could be observed. Participants in this group were provided with medication to take on the days that the IEPS was closed. Participants in the fortnightly provision group were given a prescription to last two weeks. Participants in the fortnightly provision and psychological intervention group were given fortnightly prescriptions and a single, one-hour, one-to-one session with a Specialist Nurse or Health Psychologist prior to receiving their prescription of DAAs.

The psychological component of the intervention explored and enhanced participants' personal and social motivation to adhere to the treatment through the provision of a 'Hepatitis and Me' booklet which was based on the Information-Motivation-Behavioural (IMB) Skills Model of Adherence. The IMB Skills Model of Adherence assumes that the acquisition of knowledge, motivation and behavioural skills will result in the initiation and maintenance of health promoting behaviours (Fisher et al., 2003). In this model, knowledge directly relates to facts about the behaviour. In the context of ADVANCE, participants were provided with information about the treatment regime which was both personalised to the individual and generalised for all participants (Beer et al., 2022). Motivation refers to the attitudes an individual holds about initiating a health promoting behaviour as well as the social support they receive when engaging in behaviour change (Fisher et al., 2003). The 'Hepatitis and Me' booklet contained exercises which elicited participants' personal and social motivations for engaging in treatment (Beer et al., 2022). Behavioural skills are described in the model as the individual's self-efficacy and ability to engage in the behaviour (Fisher et al., 2003). ADVANCE incorporated action plans into their psychological intervention arm to improve the behavioural capability of participants (Beer et al., 2022).

On completion of treatment, there were no significant differences between groups for the efficacy of treatment in successfully curing HCV. Sustained Virologic Response (SVR) was consistently high across all three treatment groups (1) 92.86% in DOT; (2) 87.88% in fortnightly provision and (3) 94.29% in fortnightly provision plus psychological intervention (Beer et al., 2022). The ADVANCE study demonstrated that PWID do not need to be under DOT for treatment to be adhered to and to be successful. Fortnightly dispensing from the IEPS is also consistent in achieving some of the factors that have been outlined as being important in promoting access to treatment within this population, including a reduction in travel time and treatment being delivered in community settings by drug workers known to the patients (Radley et al., 2019).

1.4 Reinfection of Hepatitis C in PWID after successful treatment

Despite the advancements seen in HCV diagnosis and treatment, there are still global incidents of reinfection amongst PWID (Askar et al., 2022; Akiyama et al., 2020). A meta-analysis of thirty-six studies with a combined person-years follow up of 6,311, investigated the prevalence of HCV reinfection in PWID (Hajarizadeh et al., 2020). Highest incidence of reinfection was found in people who were not receiving OST but had recently used drugs (6.6 per 100 person-years) followed by people who had recently injected drugs (6.2 per 100 person years). The lowest incidence was seen in those not using drugs and receiving OST (3.8 per 100 person-years). In NHS Tayside, Byrne et al., (2022) found a reinfection rate of 15.20 per 100 person-years indicating that further work needs to be done to understand and mitigate risk factors associated with reinfection.

The prevalence of continued risk-taking behaviours, such as continued injecting drug use, place limitations on the benefits seen from scaled up HCV treatment due to the subsequent effect this has on reinfection rates in high-risk groups (Midgard et al., 2016). In addition, the reduction in side effects and a less burdensome treatment regime seen in DAA treatment is thought to influence reinfection rates. Treatment delivered via Interferon required regular contact with healthcare professionals, providing opportunities for behaviour change interventions to be delivered to maintain SVR on completion of treatment (Midgard et al., 2016). When investigating reinfection in Scotland, Yeung et al. (2022) reported increased incidence of reinfection since the introduction of treatment via DAAs. They also found that treatment being delivered in prison and community settings, drug related hospital admissions during treatment or in the 3 years after treatment and being aged 35 and under on the commencement of treatment were all factors associated with reinfection.

Reinfection of HCV results in increased cost to the individual's health and the healthcare system due to the need for multiple courses of treatment to be delivered (Hajarizadeh et al., 2020). It is evident that continued injecting drug use and non-adherence to using sterile injecting equipment are risk factors associated with reinfection. However, less is known about the psychosocial factors contributing to these high-risk behaviours. As such, understanding the psychosocial determinants of continued injecting drug use following successful HCV treatment is important in informing the development of treatment pathways which encourage SVR and consequently reduce the overall prevalence of HCV.

1.5 Research Aims

The purpose of this research is to develop an improved understanding of the psychosocial factors associated with the reinfection of HCV in PWID after successful treatment, by qualitatively exploring the lived experience of participants, specifically PWID and healthcare staff involved in their care. By taking a qualitative, rather than quantitative approach, it is anticipated that a more in-depth understanding of the experience of participants will be obtained. The complex nature of injecting substance use and HCV reinfection means that semi-structured interviews may be the most appropriate methodological choice due to the opportunity it presents in being able to gather rich data.

The research has three overarching aims:

1. To identify the factors associated with the reinfection of HCV in PWID after successful HCV treatment.
2. To develop a theory-based understanding using the data obtained from participants, in relation to why people do or do not go on to become reinfected with HCV after successful treatment.
3. To inform healthcare and treatment pathways for people with HCV to prevent reinfection after successful treatment.

1.6 Theoretical Framework

The exploratory nature of this research project, to obtain an improved understanding of the psychosocial factors underpinning HCV reinfection risk in PWID, meant that grounded theory was selected as the most appropriate theoretical framework. Due to its efficacy in conducting research within applied areas such as health psychology, Interpretative Phenomenological Analysis (IPA) was also considered. However, because the focus of IPA is on understanding individual experience rather than social processes it was felt that it would be less effective when analysing the social elements of engaging in the sharing of injecting equipment. As grounded theory is often used in research where the purpose is to understand the social processes which underpin a particular phenomenon, this approach was considered more appropriate. Further, as the purpose of the project was to obtain a theoretical understanding of reinfection risk in PWID, and grounded theory is a methodology which has a specific purpose of developing a theoretical framework to explain a phenomenon, this methodology was considered most consistent with achieving the desired outcome of the study.

Grounded theory is often used in a field where a problem exists but there is a limited understanding of why it occurs (Flick, 2018). Through simultaneous data collection and analysis, a progressively more focused theoretically based understanding of a problem can be developed (Bryant & Charmaz, 2007). Glaser and Strauss (1967), define the key features of grounded theory as: (1) the use of theoretical sampling; (2) simultaneous data collection and analysis; (3) constructing codes based on data and not preconceived hypotheses; (4) constant comparison of data at each stage of analysis to further the development of theory; (5) memo-writing to record researchers' thoughts and (6) conducting a review of literature after the analysis has been completed. The methodology associated with grounded theory has changed over time with the two founders diverging in their approaches to analysis and a third, constructivist, approach being added (Table 1). The three approaches have similar methodologies but there are important philosophical differences which researchers need to consider before embarking on a grounded theory research project (Birks & Mills, 2022).

The Glaserian (1978) grounded theory approach, often viewed as 'classical grounded theory' is considered as the most consistent with the original grounded theory methodology of Glaser & Strauss (1967). Glaser (1978) views researchers as being completely objective in their analysis of data and states that they will take a passive approach to analysis whereby the researcher will allow the data to tell its own story. Glaser (1978) believes that theory will only emerge from the data and that external influences will not affect the outcome of the analysis, whereas Strauss and Corbin (1990) argue that the construction of theory will be influenced by factors external to the data. Despite Strauss and Corbin (1990) accepting the less objective stance of the researcher in their approach, they developed a systematic approach to conducting grounded theory which attempts to reduce any biases from the researcher. Kathy Charmaz introduced the constructivist approach to grounded theory in a chapter featured in Smith et al., (1995). This approach of grounded theory has similarities with Strauss and Corbin (1990) due to their shared understanding of the role that the researcher has in analysing and interpreting the data. The constructivist methodology states that the researcher is not independent from the theories they develop as they will bring their own perspectives, consciously or unconsciously, to the analysis (Smith et al., 1995). As such, Charmaz and Strauss and Corbin (1990) believe that there can be multiple explanations for a studied phenomenon depending on the interpretation of the data by the researchers (Singh & Estefan, 2018). Glaser (1978) believes that there can only be one theoretical explanation of a problem.

Table 1.

Differences in the approaches to conducting grounded theory

Concept	Glaser (1978)	Strauss & Corbin (1990)	Charmaz
Role of researcher	Positivistic – the researcher is objective in their analysis of the data.	Postpositivist – the researcher is less objective in their analysis of the data but will limit subjective analysis through detailed methodological procedures.	Constructivist – the researchers' experiences and views will shape the analysis of the data.
Literature review	The researcher should only review literature outwith the main topic area prior to analysis.	The researcher should do a brief literature review prior to analysis.	Assumes that the researcher will have knowledge on the topic prior to beginning analysis, including that from reviewed literature.
Hypotheses	There should be no hypotheses or preconceived ideas prior to conducting research.	Hypotheses will be tested against codes and categories that are emerging from the data.	Hypotheses will be tested against codes and categories that are emerging from the data.
Approaches to coding	Induction (all relevant codes will emerge from the data).	Induction and Deduction (collecting further data to test previous codes)	Induction, Deduction and Abduction (re-examining data to intuitively or creatively explain unanswered or unexpected observations).
Analytical methods	1. Open coding.[1] 2. Selective coding. 3. Theoretical coding.	1. Open coding. 2. Axial coding.[2] 3. Selective coding.	1. Initial coding. 2. Focused coding.[3] 3. Theoretical coding.

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[1] Breaking the data into discrete parts and engaging in constant comparative analysis of incidents within and between transcripts to develop initial codes.

[2] Beginning to put the fractured data back together by making connections between concepts derived during open coding stage of analysis.

[3] Synthesising large amounts of data by using the most frequently occurring and significant codes from the initial coding stage of analysis to categorise the data.

The Principal Investigator (PI) of this research project has a family history of injecting substance misuse and associated BBV infections. It is therefore reasonable to assume that this experience may result in the PI having a more subjective grounding in the data. The objective nature of analysis proposed by Glaser (1978) and Strauss and Corbin (1990) are not thought to be appropriate methodologies for this study due to the researcher's personal knowledge of the topic being analysed. As Charmaz acknowledges that theory is built through the researchers' own experiences and perspectives, this study will take a constructivist approach to data analysis.

1.7 Structure of the thesis

This thesis will describe one empirical piece of research pertaining to the topic of reinfection of Hepatitis C in people who inject drugs.

- Chapter 2 will provide an overview of the methodology used to conduct and analyse the interviews of PWID and the healthcare staff who support them.
- Chapter 3 will outline the results obtained from the interviews conducted with patients and healthcare staff.
- Chapter 4 will discuss the implications of the findings from the interviews conducted with patients and healthcare staff. Limitations and suggestions for future research will also be discussed.

Chapter 2 – Methodology

2.1 Overview of methods

The aim of this research was to obtain an improved understanding of the psycho-social factors associated with the reinfection of Hepatitis C (HCV) in people who inject drugs (PWID) after successful treatment. A constructivist grounded theory approach was used to qualitatively explore the lived experience of patients.

The study followed the timeline outlined in Figure 1. The initial stages of the project focused on the recruitment of patients who had received treatment via the ADVANCE trial to see whether there were any differences between those who did and did not become reinfected with HCV. Due to challenges with recruitment, it was not possible to recruit any patients who had become reinfected with HCV following treatment. As such, it was not felt that the data was representative of those who did become reinfected. To obtain some comparative data, an ethical amendment was submitted to allow the participation of healthcare staff who deliver care to those who have become reinfected. The latter stages of the study therefore focused on gaining an improved understanding of the patients who had become reinfected with HCV following treatment by exploring the views of healthcare staff. This chapter will describe the methods used.

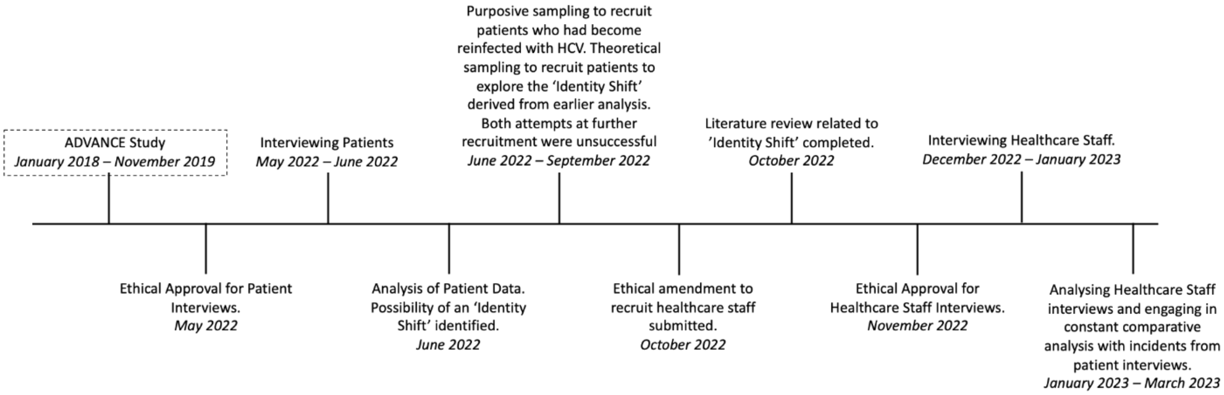


Figure 1. Research timeline

2.2 Patients

2.2.1 Participants

The study aimed to recruit a sample size of 15 participants. To make comparisons between those who had and had not become reinfected, there was a recruitment target of 7-8 participants from each group (reinfected following the ADVANCE trial and not reinfected). The study inclusion and exclusion criteria are described in Table 2.

Table 2.
Inclusion and Exclusion criteria of patients.

Inclusion Criteria	Exclusion Criteria
• Adult (aged 18 or over) • Previously engaged in successful HCV treatment delivered by NHS Tayside. • Able to provide informed consent. • English speaking. • Living in Tayside.	• Unable to provide informed consent. • Aggressive or violent behaviour. • Under 18 years of age. • Unable to communicate in English. • No previous engagement in HCV treatment in NHS Tayside.

Six patient participants were successfully recruited for the study. Their demographic details are outlined in Table 3.

Table 3.
Patient Demographics.

Pseudonym	Gender	Age	Self-reported injecting behaviour	HCV reinfection after ADVANCE?	ADVANCE treatment arm
John	Male	34	No	No	FD
David	Male	41	No	No	FD+PI
Jack	Male	56	No	No	DOT
Callum	Male	43	Yes	No	FD
Zoe	Female	36	No	No	DOT
Daniel	Male	43	No	No	DOT

Abbreviations: DOT – Directly Observed Therapy; FD – Fortnightly Dispensed; FD+PI – Fortnightly Dispensed + Psychological Intervention

2.2.2 Recruitment

The recruitment of patients began in May 2022, with all six of the participants who took part in interviews participating in June 2022. A further 3 patients expressed an interest in participating but after three unsuccessful attempts at contacting them, they were deemed to no longer be interested in participating and no further attempts were made to recruit them. In September 2022, the active recruitment of patients was concluded as the IEPS were unable to identify any further patients who were interested in taking part.

Participants were recruited using purposive and theoretical sampling strategies to participate in semi-structured interviews. Purposive sampling is used to recruit participants who are known to have the characteristics needed for the study. Consistent with this sampling method, participants were identified from a national clinical database of 110 patients who had previously completed HCV treatment via the ADVANCE trial in NHS Tayside. The database was accessed by clinical staff who work within the IEPS. Using this method, six patients who had received treatment in the ADVANCE study were recruited. These patients had maintained their sustained virologic response (SVR) following treatment and had not become reinfected with HCV. Guided by the principles of theoretical sampling, whereby participants are recruited based off of their perceived ability to provide data that will meet the analytical needs of the developing grounded theory (Birks & Mills, 2022), the Principal Investigator (PI) amended the interview schedule following these interviews to explore a suggested identity shift that occurred in these patients following treatment for HCV. Despite efforts from the staff within the IEPS, it was not possible to explore this identity shift with patients due to challenges in recruitment. Further, the PI also requested staff from the IEPS to engage in further purposive sampling with the aim of recruiting patients who had become reinfected with HCV to ensure that their experience was reflected in the grounded theory. Again, due to challenges in recruitment it was not possible to recruit any patients who had become reinfected with HCV following successful treatment from ADVANCE. It is thought that this is due to them presenting less regularly at the IEPS and therefore being harder to inform about the study.

Although the preference would have been to recruit patients who had become reinfected, the PI made the decision when it was apparent that this was not possible, to submit an ethical amendment to allow the inclusion of healthcare staff within the research. It was felt that the recruitment of healthcare professionals who work within the IEPS and provide support to people who do become reinfected with HCV was appropriate, as they would be able to offer some insight into the experience of this group. In addition, the interviews with healthcare staff were also thought to be a good opportunity to further explore the developing theme of "identity shift" amongst patients who had received HCV treatment.

2.3 Healthcare Staff

2.3.1 Participants

The study had a recruitment target of 10 healthcare professionals. The inclusion and exclusion criteria are noted in Table 4.

Table 4.
Inclusion and exclusion criteria of healthcare staff

Inclusion Criteria	Exclusion Criteria
• Adult (aged 18 or over) • Provide care to patients from the IEPS who have HCV. • Able to provide informed consent. • English speaking.	• Under 18 years of age. • Unable to provide informed consent. • Unable to communicate in English. • No direct involvement with patients who have HCV.

Six healthcare staff were recruited to participate in the study. They had a range of roles - Health Psychologist (n=1), Lead Nurse for Harm Reduction (n=1), Operations Manager (n=1), Specialist Nurse in Blood Borne Viruses and Harm Reduction (n=3).

2.3.2 Recruitment

The recruitment of healthcare staff began in November 2022. One interview was conducted in December 2022, with the following five taking place in January 2023 before ethical approval lapsed at the end of the month. Healthcare staff were recruited using theoretical sampling methods as the purpose of their participation was to further the development of the grounded theory by exploring their thoughts on: (1) the potential "identity shift" which occurs in patients who do not become reinfected and; (2) to provide an improved understanding of the psycho-social factors surrounding patients who do become reinfected with HCV. Figure 2 provides a summary of the overall recruitment of patient and healthcare staff.

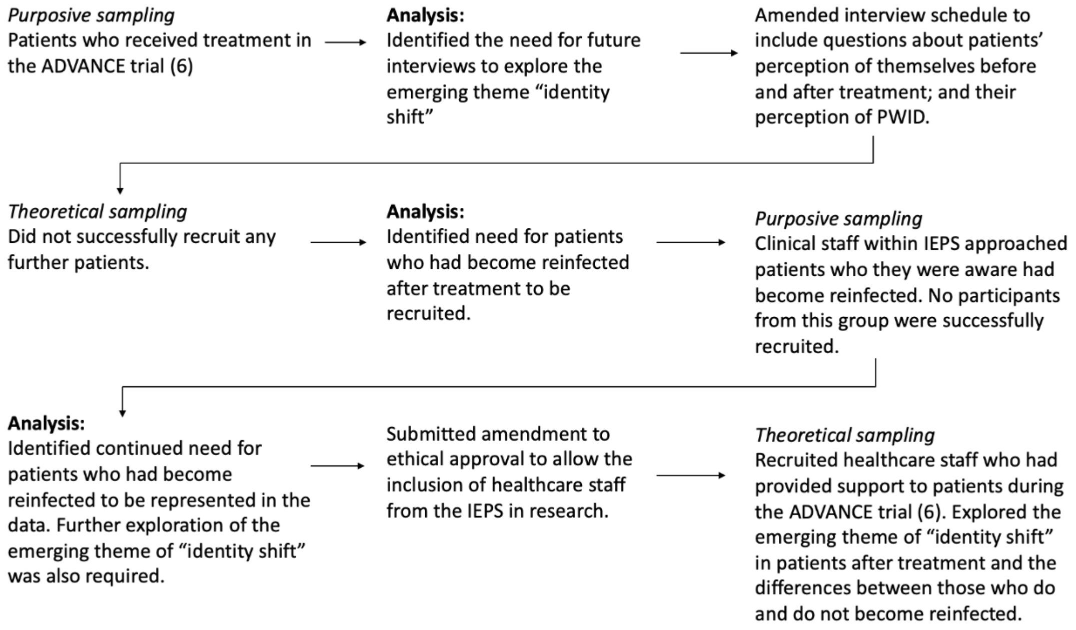


Figure 2. Theoretical and purposive sampling of participants

2.4 Procedure

2.4.1 Patient Interviews

The initial approach to participants was made by staff within the IEPS who were familiar with the patients and had an established relationship with them. As the initial approach was made via the IEPS, it was only possible to recruit patients if they responded to this contact. If a potential participant showed interest in participating, then they were introduced to the PI in one of two ways: (1) in person if the PI was onsite at the IEPS; or (2) they gave their consent to the IEPS for the PI to phone them to introduce themselves. When introductions were facilitated in person, the PI provided the participant with the participant information sheet. Where introductions were facilitated over the phone, staff within the IEPS would provide participants with the participant information sheet prior to the phone call. The PI explained the study verbally to all participants during their first introduction. Participants were given the option of participating in the study on the same day or at a time convenient in the future. If a participant did not attend their pre-booked appointment, then three further attempts were made to contact them to rearrange. Where this was not successful, it was assumed that the potential participants no longer wished to participate and no further attempts to recruit them were made.

Data was collected using semi-structured interviews and lasted between 20 and 60 minutes. To increase covid-19 safety and to give participations options, they were offered to participate in either face to face or remote interviews. Four of the patients participated in a face-to-face interview and two opted for a telephone interview. If conducted face-to-face, interviews took place in a clinical room at the IEPS. Interviews were digitally recorded using an audio recorder and were transferred to a password-protected laptop to be transcribed.

Patients were asked about their experiences of having HCV and receiving treatment in addition to their thoughts on sharing injecting equipment. The semi-structured interviews also explored patients' mental health, social norms and self-efficacy (APPENDIX A).

2.4.2 Healthcare Staff Interviews

An advertising leaflet was sent, via email, to staff at the IEPS by a senior harm reduction nurse on behalf of the PI. Potential participants were invited to contact the PI directly to express an interest in participating. Participants who expressed an interest in participating were provided with a copy of the participant information sheet and were given the opportunity to ask any questions about what their participation would involve. If they wished to proceed, an interview was scheduled. Three of the participants opted for their interview to be conducted via Microsoft Teams. The further three participants requested a face-to-face interview which took place within offices at the IEPS.

The interviews with healthcare staff followed the same procedure as the interviews with patients. Interviews lasted between 20 and 60 minutes and focused on their thoughts on the treatment provided, impact of treatment on patients, patients' perception of their self-image, reinfection risk factors and the role of support in preventing reinfection (APPENDIX B).

2.5 Consent and Confidentiality

All participants were provided with a copy of the Participant Information Sheet and were given a verbal explanation of the study. Once participants were satisfied that they had been given an adequate explanation of the study and were given the opportunity to ask any unanswered questions, they were invited to participate in the interview. Patients were able to participate in the interview on the same day or at a time convenient in the future. Healthcare staff were given a minimum of 24 hours between being provided with the participant information sheet and participating in the interview. Informed consent was obtained at the time of interview. All participants were informed that they could withdraw from the study at any time, without giving reason or penalty

All participants were assigned a pseudonym to protect their confidentiality. To avoid the identification of individual participants in the published results, identifiable information was not transcribed from interviews. All electronic and paper records were stored securely with access limited to the research team. With the exception of the PI, the research team were blind to the identities of each of the participant transcripts.

2.6 Analysis

Consistent with Charmaz's (2014) grounded theory approach, the data was analysed through three distinct methods of coding: initial coding, focused coding and theoretical coding. As the healthcare staff had been recruited via theoretical sampling, with the purpose of furthering the development of the grounded theory, the patient and healthcare staff data was analysed together and written up as one study. This was achieved by engaging in constant comparative analysis, where incidents from the patient data were compared to incidents within the staff data (and vice versa). Throughout all of the stages of analysis, the PI engaged in memo-writing to capture the process of generating theory (Figure 3). This supported the PI in making connections between concepts within the data.

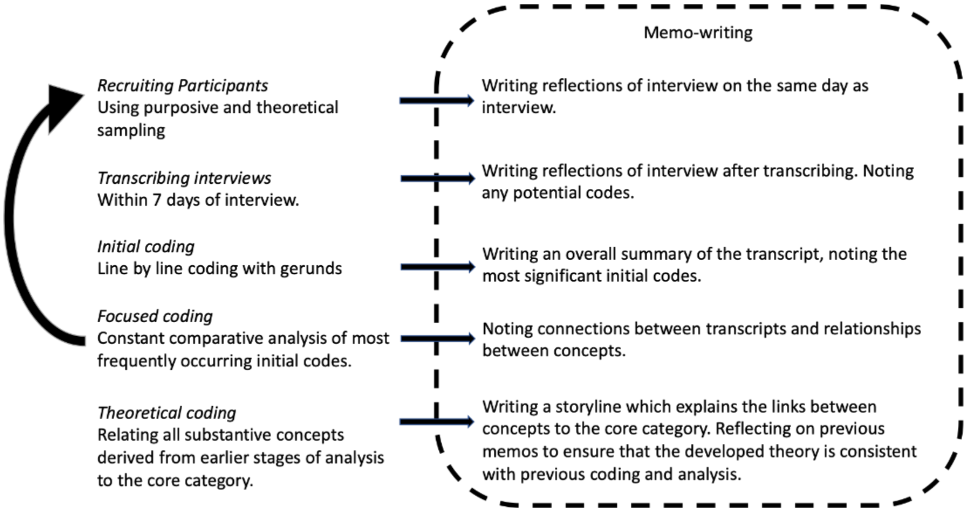


Figure 3. Process of data analysis.

2.6.1 Initial Coding

The PI undertook line-by-line initial coding with gerunds (..ing’ words). Coding with gerunds was chosen as it can be effective in detecting action processes described by patients within the data and can subsequently preserve their experience in the grounded theory. As suggested by Charmaz, (2014), the PI asked questions of the data whilst completing initial coding in order to remain critical and think more analytically (Table 5).

Table 5.
List of questions to ask the data during analysis (Charmaz, 2014).

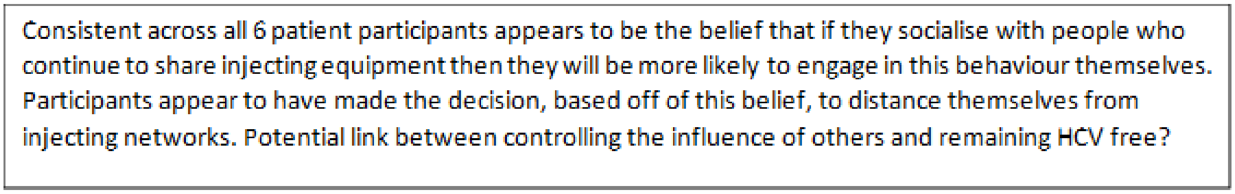
Questions
1. What process(es) is at issue here? How can I define it?
2. How does this process develop?
3. How does the research participant(s) act while involved in this process?
4. What does the research participant(s) profess to think and feel while involved in this process? What might his or her observed behaviour indicate?
5. When, why and how does the process change?
6. What are the consequences of the process?

2.6.2 Focused Coding

The most significant and frequently occurring initial codes were then scrutinised and assessed in the focused coding stage of analysis. During constant comparative analysis, the PI compared the initial codes within and between transcripts and grouped similar ones together under an action-based gerund which explained the quality that they had in common – e.g., “recognising progress in self.”

Constant comparative analysis aided theoretical sampling and gave the PI direction to explore with participants in future interviews. As discussed previously, the interview schedule was changed so that future interviews could explore the concept of an “identity shift” with participants. The codes which were derived from later interviews were compared with existing codes to develop focused codes. Theoretical saturation was reached when no new theoretical insights were identified through the constant comparison of the transcripts during the focused coding stage of analysis.

Memo-writing within the focused coding stage of analysis concentrated on understanding the different focused codes that were generated and what underpinned each of them (Figure 4). Memos also documented the links between transcripts and relationships between concepts. The PI denoted the potential connections with diagrams to begin the process of theorising the data.



Consistent across all 6 patient participants appears to be the belief that if they socialise with people who continue to share injecting equipment then they will be more likely to engage in this behaviour themselves. Participants appear to have made the decision, based off of this belief, to distance themselves from injecting networks. Potential link between controlling the influence of others and remaining HCV free?

Figure 4. Example memo from focused coding stage of analysis.

2.6.3 Theoretical Coding

To understand and report how the focused codes linked together, theoretical coding was undertaken. The theoretical coding stage of analysis comprised of the theoretical sorting of the data and theoretical diagramming.

Theoretical sorting. The analytic memos which were written at earlier stages of analysis were organised to create and refine theoretical links between concepts. Theoretical sorting was achieved using two methods. In the first instance the PI physically mapped out the memos to experiment with different arrangements and relationships between concepts. By comparing memos and grouping related memos together, it became more evident which concepts fitted together and how they were related to one another. Secondly, the PI used the story-lining technique outlined in Birks and Mills (2022) whereby the PI wrote a storyline which explained the relationships between concepts. This was consistent with their organising of the memos and helped to form the grounded theory.

Theoretical diagramming. Once the relationships between concepts were established through theoretical sorting, the PI drew diagrams to provide a visual representation of the concepts and their relationships to one another (Figure 5).

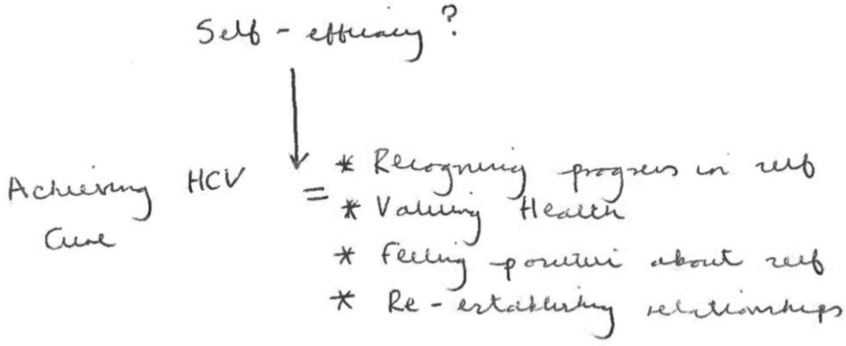


Figure 5. Example of theoretical diagramming from theoretical coding stage of analysis.

Theoretical sorting and diagramming resulted in the generation of five theoretical categories which were all related to the core category of "Identity Shift". The PI then completed a literature search to explore the five theoretical categories in more detail. The literature surrounding self-efficacy, social identity, locus of control and social norms appeared to align closely to the data obtained from participants and helped to provide explanatory power to the concepts and validated the grounded theory which was developed in the present study.

2.6.4 Reflexivity

Consistent with constructivist grounded theory, the PI maintained their reflexivity as a researcher by engaging in the memo-writing process. By recording thoughts and rationale about analytical decisions in memos, they were not only useful in developing the grounded theory, but they assisted the PI in maintaining an audit trail. Further, the PI consulted a secondary reviewer, who had expertise in grounded theory methodology, to maintain quality in the analytical process and to ensure that there were no disputes regarding how the data was categorised. The secondary reviewer blindly audited the analysis at the theoretical coding stage. They reviewed the assignment of quotes from participants to each code and examined the links that the PI had made between concepts. They were satisfied with the coding of the data into categories when they reviewed and made no suggestions for change.

2.7 Ethical approval

This study was sponsored by the University of Stirling and received a favourable ethical opinion from NHS Wales REC 4. The original ethical approval, for the recruitment of people who inject drugs, was obtained on the 10th of May 2022 (APPENDIX C). A favourable ethical opinion to the substantial amendment which was made to allow the recruitment of healthcare staff who provide direct care to HCV patients at the IEPS, was granted on the 16th of November 2022 (APPENDIX D).

2.8 Methodological Challenges

2.8.1 Recruiting patients who had become reinfected

A considerable methodological challenge of the research was being unable to recruit patients who had become reinfected with HCV following treatment. When this issue first became apparent the PI requested that staff within the IEPS engaged in purposive sampling by contacting patients that they knew to have become reinfected. This process continued from June 2022 – September 2022 but was not successful in recruiting any further patients to participate in the study. Obtaining the perspective of people who do become reinfected was an integral aspect of the research. When it became apparent that it was unlikely that any patients from this population would be recruited, the PI considered alternative methods of ensuring that their experience was represented in the data. This resulted in an ethical amendment being submitted which allowed healthcare staff, who supported patients from the IEPS, to be recruited to participate in the study. As healthcare professionals who work within the IEPS provide care and treatment to people who do go on and become reinfected with HCV it was thought that they would be able to provide some knowledge on the experiences of this group and factors that they believe contribute towards the reinfection.

2.8.2 Conducting remote interviews

Conducting interviews with patients via telephone was also challenging as they were sometimes unavailable at the mutually agreed and scheduled time. This resulted in some rescheduling. In addition, it was harder to control the environment that the patient was in when they were participating in the interview. In one instance it was apparent that there were several distractions in the location that the patient was participating from. When phoning participants to schedule the interview, the PI attempted to overcome this by requesting that the participant chose a time and place that would allow them privacy to take part in the study. The scheduling phone call was also a good opportunity to try and build some rapport with patients. Although it was more challenging to do this via telephone than in person, the quality of the interviews did not appear to be compromised.

2.9 Methodological Strengths

2.9.1 Stakeholder Involvement in the Research

The research protocol for the present study was written in collaboration with members of the team who were involved in the development and delivery of the original ADVANCE trial. These experts included a Health Psychologist who works within drug and alcohol recovery; a Professor of Hepatology and Gastroenterology; and a Clinical Psychologist with a specialist interest in addictive behaviours and complex trauma. Their input in forming the research protocol and the most appropriate methodology to use, given their knowledge of the participant population, was invaluable and helped to reduce the barriers that patients may have experienced in participating in the research and the IEPS may have experienced in supporting its implementation.

Although the data was obtained through semi-structured interviews with a pre-determined interview schedule, the interview was left open for any comments by the participants at the end in case the schedule had not covered something that they deemed to be important. This helped to ensure that participants were able to raise any topics or issues of relevance to them.

2.9.2 Conducting remote interviews

Although conducting remote interviews was noted as a methodological challenge, they also proved to be a methodological strength as it provided flexibility to patients and healthcare professionals in how they participated in the study. As one of the barriers noted by PWID in accessing treatment is travel time to the location that treatment is delivered, it was important to the PI that participation in the interview was not dependent on patients travelling to the IEPS, particularly when travel costs were not going to be reimbursed. Further, conducting interviews via telephone and video call also meant that there was less burden on the IEPS in finding a physical space for the PI to conduct in-person interviews in. As the IEPS has a large footfall, this was considered a methodological strength as clinical space was required less frequently by the PI.

Chapter 3 – The Identity Shift of Patients following Treatment

Chapter three outlines the results obtained from the interviews conducted with patients and healthcare staff, described in Chapter two. This chapter will present five theoretical constructs which emerged from the patient and healthcare staff data and discuss how they relate to the core category of "identity shift". Each of the categories outlined in this chapter were discussed by patients and healthcare staff so the developed grounded theory is supported by both populations.

3.1 Identity Shift

A greater degree of stigma can be experienced by people who engage in behaviours that are deemed as being less acceptable by society (Johannson et al., 2017). People who inject drugs (PWID) are often seen as having a flawed character and fewer morals than those who do not use drugs (Donaldson et al., 2023). The findings of the current study also indicate that there is further stigmatisation within the substance use population whereby PWID are stigmatised by non-injecting drug users.

The core category of "Identity Shift" emerged from the data where being cured of HCV represented an important turning point for patients in terms of their engagement in injecting substance use and their self-identity. As social identification is a significant determinant of wellbeing (Haslam et al., 2009), the identity shift which occurs is thought to be protective in reducing the risk of the reinfection of HCV amongst patients who have successfully achieved their cure. The data from the present study indicates that where this identity shift is not present, patients will be more susceptible to reinfection.

An important component of the identity shift occurring may be an increase in self-efficacy. Self-efficacy appeared to provide a foundation on which PWID felt able to exert an internal locus of control and distance themselves from injecting drug networks, which consequently had an impact on the likelihood of them engaging in behaviour that would increase their HCV reinfection risk. Further, healthcare professionals commented on the impact they felt achieving a HCV cure had on the self-efficacy of their patients and the resulting impact this had on them being able to re-establish their place within society and pursue a recovery orientated identity.

The "Identity Shift" is clarified and expanded in five subcategories: (1) Good Healthcare Relationships; (2) Re-establishing Place in Society; (3) Hierarchy of Substance Use; (4) Shifting Locus of Control; and (5) Socially Responsible Patient (Figure 6).

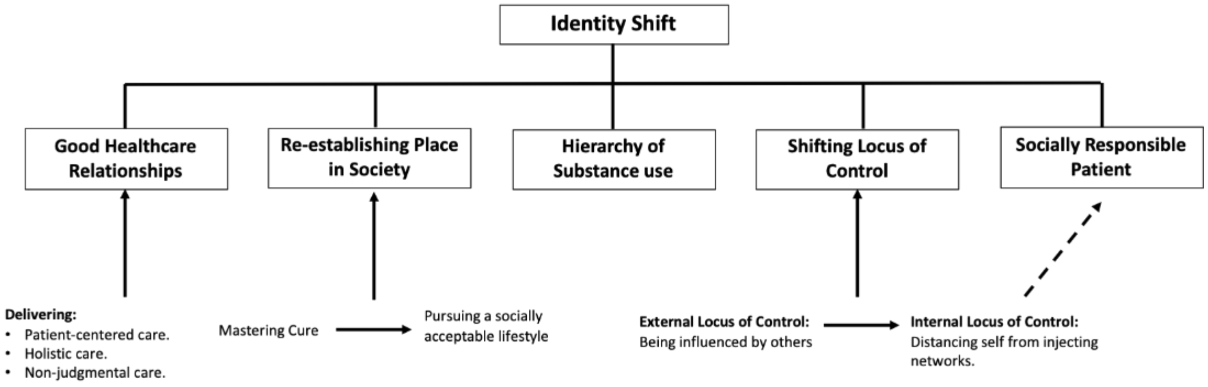


Figure 6. Category tree outlining the five different categories of identity shift.

3.2 Good Healthcare Relationships

People who use substances can experience stigma from healthcare professionals which can impact on the quality of care and treatment they receive (van Boekel et al., 2013). One participant shared their experience of a phone call they had with a health professional:

> "I remember nothing but absolutely insulting and cheeky on the phone saying I miss appointments, saying I'm this, I'm that, I've got a cheek when I'm doing … taking this. I'm like, I'm like … "are you speaking about the right, the right

> person?" I say, "you know what, I don't want your help if you're going to insult me the way you have."" (Participant 6, Male).

The healthcare professionals who participated in the present study also reflected on the stigma that PWID experience from the healthcare system and the impact that this can have on their self-efficacy and perception of their own abilities:

> "They often have a perception of themselves that I can't do that. They're told, they've been told for so long that they're too chaotic for this, and too, you know, too unready for this, and they're not stable enough for that. That will have a knock-on negative effect of thinking, "well that must be true because they're the professional and they're saying that."" (Participant 8, Healthcare Staff).

Being stigmatised by the healthcare system is acknowledged in the literature as being a barrier to PWID accessing care, whereby they engage in a decisional balance to weigh up the benefits of engaging in treatment against the barriers of being judged by the person delivering the care (Austin et al., 2022). Stigma can degrade an individual's self-worth and impact their ability to initiate treatment:

> "I think they just, psychologically, not in a state that they can address it, and I think that's the consequence of stigma." (Participant 10, Healthcare Staff).

The healthcare staff within the IEPS who were interviewed for the present study appeared to understand the barriers that PWID experienced in accessing healthcare and it was evident that a priority for this group was to ensure that patients felt comfortable accessing their care. They appeared to do this in three different ways: (1) delivering patient-centered care; (2) delivering holistic care; and (3) delivering non-judgmental care. Each of these themes will be discussed and illustrate how they contribute to PWID being more likely to engage with healthcare and reduce their reinfection risk. The healthcare staff data will be presented first to provide context for the patient perception of the actions taken to enhance their care.

3.2.1 Delivering patient centered care

Staff from the IEPS acknowledged that traditional models of delivering care where patients are given an allocated appointment which they must attend to receive care, were not always appropriate for the substance use population and that adaptions should be made to improve accessibility and reduce barriers:

> “I think there's, there's other mitigating factors that led the patient not being able to receive that healthcare. Such as meeting appointment times. And, and, and structure and rigidity of appointment services and availability whereas I think we have an open-door policy. It certainly helps.” (Participant 10, Healthcare Staff).

As the ADVANCE trial showed no significant differences in the success of treatment when daily and fortnightly dispensing were compared, the staff felt that this provided adequate evidence that treatment could be tailored to their patients' needs. They reflected on the benefits this could have in improving adherence to treatment:

> “We've had some individuals who we’ve tried 2 or 3 times to get treatment started properly, and we've never got quite past the first week of the first 2 weeks because dispensing to them on a weekly basis just didn't work. We were having to phone them every week to try and get hold of them to remember to go to your chemist today to pick up your medication. But once they had it, they were able to take it at home when they were brushing their teeth in the morning so it’s about finding out what's right for the individual” (Participant 8, Healthcare Staff).

Patients also reflected positively on the benefits of the IEPS having an open-door policy, both in terms of having a safe space they could receive support but also to support them in overcoming challenges associated with adhering to their treatment:

> “Knowing this service was here, I could drop in at any time if I had any questions about the treatment that I was doing … yeh it made me feel confident. It always makes me feel confident coming in here, you know. They bring out the best in you.” (Participant 1, Male).

As reduced population reinfection rates are reliant on patients presenting themselves to healthcare services if they suspect they have contracted the virus, delivering healthcare in an accessible manner is central to being able to achieve this. Patients reflecting on the ease at which they can access care from the IEPS, due to their doors open policy, is promising in terms of reduced reinfection of HCV.

3.2.2 Delivering holistic care

Staff also recognised that patients who attended the IEPS had a variety of needs which extended beyond harm-reduction and HCV treatment. The IEPS responded to this by delivering care which supported the wider needs of patients who attended the needle exchange:

> “We were able to give them a couple of buildup drinks for a part of their study [ADVANCE] and get them a food parcel. Someone was going away thinking this is, this is great. And then we were also trying to support with well-being packs for like winter warmer packs, giving coats, hats, gloves and we were giving new starter packs to guys who are being liberated from prison, so we were doing things like TV's, toasters, kettles.” (Participant 9, Healthcare Staff).

By addressing the wider holistic needs of patients, staff felt that it would have a positive impact on the likelihood of a patient engaging in further health promoting behaviours:

> “There's been lots of studies which evidence that if you can improve one health outcome for someone it’ll have a knock on positive consequential for other health outcomes. So, if someone goes and gets their teeth done when they've had rotten stumps before that and they can look in the mirror and think, “oh, I look good now.” That can have a really positive impact on how they feel about themselves and about what they want to achieve.” (Participant 8, Healthcare Staff).

Receiving holistic care from the IEPS was reflected on by patients in their interviews. This was in relation to addressing both social and mental health needs:

> “It’s a wonderful place. I mean, for people with, not necessarily just drug problems, you know what I mean. They help with my mental health; you know what I mean. They really do help with my mental health … I could be walking along with my head down, and I think, you know what I’ll pop into the [IEPS]. And I’ll go out that back door with my head up.” (Participant 1, Male).

By providing holistic support to patients, rather than focusing solely on harm reduction, reinfection risk may be reduced as patients might be more likely to present at the IEPS when they are experiencing challenges in maintaining their recovery and abstaining from behaviours that may put them at increased risk of reinfection.

3.2.3 Delivering non-judgmental care

The staff within the IEPS acknowledged their role in delivering HCV treatment and harm reduction to their patients but also understood the importance of delivering it in a non-judgmental manner:

> "I mean my job, our job is to you know, make sure that we've reached elimination of hepatitis C and that we can maintain that. We don't do that by ostracizing patients and making them feel uncomfortable when they come into a clinical environment. So, it's about trying to make sure that this is their safe space." (Participant 8, Healthcare Staff).

Staff perception of successfully delivering non-judgmental care was supported by patients with them commenting positively on the support they receive:

> "You got made to feel welcome. They... you were'nae judged when you come in here. Your made to feel welcome" (Participant 3, Male)

Delivering care in a non-judgmental manner can provide a reassuring point of access back into treatment which reduces the likelihood of onward transmission and increased risk of the reinfection of others:

> "And again, those who have become reinfected, there has been again that kind of no wrong door, people have came back." (Participant 9, Healthcare Staff).

3.2.4 Engaging with healthcare

By delivering a healthcare experience which encompassed non-judgmental, holistic and patient centred care, the staff within the IEPS were able to establish relationships with the patients and reduce some of the barriers they experienced in accessing and maintaining access to healthcare. The ethos of staff working within the IEPS was commented on positively by the patients who accessed support from them:

> “Honestly, the guys in there are, everybody inside the [IEPS] are absolutely brilliant and mean nothing but, they just try and help you as much as they can. They’re fantastic. (Participant 6, Male).

Due to the stigma and sensitive nature associated with some of the health concerns that PWID may have, staff felt that it was important to establish relationships with them so that they felt more comfortable discussing their needs:

> “I think they've got such good relationships with us as well, the team. That they feel that we're obviously invested in helping them. So, they feel here is obviously quite a safe place to come” (Participant 12, Healthcare Staff).

By feeling more able to discuss their needs, reinfection risk may be reduced as patients are more likely to discuss the behaviours that they in engage in which increase their reinfection susceptibility.

Further, by establishing relationships with patients, healthcare staff also felt that if a BBV test came back as positive for HCV then it would be easier to initiate the conversation around treatment and support them to engage in it. This staff member compared the current service to previous experience:

> “They didn't know us. They didn't know what gastroenterology was and they hadn't, so there was no relationship there. So that was the reason for me basing myself here as well. It was to make sure I can start to form those relationships. And when a dry blood spot test came back as positive, we were able to then straightaway say “Oh, here’s [name not transcribed], he’ll do your bloods. He'll get you on your Hep C treatment” (Participant 8, Healthcare Staff).

Feeling able to continue engaging in healthcare to ensure that they had remained free of HCV infection was also cited as being important to patients:

> “I'm just so glad that I know that I've got a place where even like, I give them blood every couple of months, just to make sure. Just to make sure I’m all clean which I am.” (Participant 6, Male).

As motivation can be a key determinant in individuals initiating and maintaining behaviour change, patients continuing to access the IEPS to check their HCV status may be an important indicator in their continued abstinence from behaviours that increase their reinfection risk.

3.3 Re-establishing Place in Society

The findings of this study suggested that treatment represented an important turning point for patients where they were able to pursue a socially accepted lifestyle by building their self-efficacy through achieving their HCV cure.

Figure 7. Theoretical diagram outlining the relationship between obtaining HCV cure and pursing a socially accepted lifestyle.

3.3.1 Mastering Cure

The ADVANCE trial provided patients with the opportunity to engage in treatment to obtain a positive health outcome. The healthcare staff within the present study reflected on the impact they felt obtaining a HCV cure had on the self-efficacy of patients as a result of completing a difficult task successfully:

> "I think it's, hepatitis treatment it's, is a, is a badge to say, "yeah, I've done that, and I achieved that" and that could be something really positive which someone who, who may in some cases not have many other achievements which they're proud of." (Participant 8, Healthcare Staff).

As the old Interferon treatment had a number of well known, adverse side effects, many of the patients reflected on the apprehension that they had about engaging in the treatment as they assumed the treatment provided in ADVANCE would have been the same:

> "See what put us off before? Up in the jail and that. See my mates, they were taking that needle thing, ken? You had to use a, had to stick a needle in their stomach or something. I was like "ugh." And then I seen a couple of my mates come off the bus and I says to them "what's the matter with you?" He looked terrible, he says "I'm going through that hepatitis treatment."" (Participant 3, Male).

> “All of them were aware of the horror stories of interferon treatment, and some of them had experienced it. Some of them hadn't but thought that it was still around.” (Participant 7, Healthcare Staff).

Despite patients going into treatment with concerns about side effects, they all commented on the ease of treatment in comparison to their expectations or previous experiences with interferon. By successfully achieving an outcome that they had perceived to have been difficult due to their pre-conceived ideas around the adverse side effects of treatment, they may have experienced an improvement in self-efficacy.

> “No side effects, apart from a slight headache from the tablets. That was it. No side effects, no injections, no blood tests. Well, the final blood test obviously but you know, with the interferon I had to provide a blood sample every month … A lot easier and it was a lot shorter as well because the interferon I was on for 21 months.” (Participant 4, Male).

Despite treatment being easier than patients had expected it to be, healthcare staff still felt that patients were proud of themselves for achieving their cure as it required commitment, often during challenging social circumstances:

> “It's something that they've done themselves ... it's them who's come back to us either every day for their tablets or every fortnight for their tablets. You know in amongst their chaotic… some, some of them had obviously chaotic lifestyles. You know they took that ownership and they wanted to complete treatment … And like I say, it's great and everyone when you tell them that they're cured, they are delighted. It's the best news.” (Participant 12, Healthcare Staff).

As ADVANCE had three treatment arms, two of which involved the fortnightly dispensing of medication, healthcare staff also commented on the positive psychological impact that being given responsibility to take the medication as prescribed had on patients:

> “It was their feedback that I thought was the more interesting to take into consideration because they felt empowered, they felt as if they were given respect with the responsibility of having to take a tablet every day.” (Participant 10, Healthcare Staff).

3.3.2 Pursuing a Socially Accepted Lifestyle

Consistent with the findings from a systematic review conducted by Donaldson et al., (2023), the patients in the present study began to see themselves more positively and described having a meaningful role within society where they felt trusted and valued as a result of abstaining from intravenous substance use:

> “And since the drug use had stopped, well when I say the drug use had stopped, I mean mainly heroin which was the one which took us right down. I've had a job, a trusting job, in Tesco call Centre, which became Tesco Direct which was dealing with people's master cards, setting up accounts, you know, so I felt really trusted and confident.” (Participant 1, Male).

Patients also discussed being able to re-establish relationships that were lost as a result of their substance use:

> “When I started taking drugs and hepatitis and all this stuff, they kind of just turned their back and just said “ken what? It's nothing to do with us. If you want

> fixed, fix yourself.” ... So now that I have got better, they have been, my sister has been speaking, my brothers been speaking.” (Participant 6, Male).

It also appeared that engaging in HCV treatment and achieving a positive outcome in relation to their health encouraged patients to think differently about their longevity and wellbeing:

> “I’m in my 40’s now so the life expectancy of somebody who's on a daily prescription is gonna be about 50 or something. I don’t wanna die. I’d like to see my granddaughter growing up and... I want to live longer.” (Participant 2, Male).

The social redemption described by patients in the present study is suggested to be protective of reinfection risk due to its consistency with a ‘non-addict’ identity. It is suggested that the positives derived from HCV cure, such as improved health, re-established relationships and having a more meaningful role within society encourages PWID to maintain their recovery and reduces HCV reinfection risk.

3.4 Hierarchy of Substance Use

Patients commented on the hierarchy of substance use, whereby those who no longer administered their substances intravenously, but continued to engage in non-injecting substance use, engaged in downward social comparison where they evaluated themselves at a higher social ranking within the substance use population by feeling superior to those who continue to engage in intravenous drug use:

> “Because injecting, I see heroin as a dirty drug. And it is a dirty drug.” (Participant 2, Male).

Of the patients who participated in the study, only one self-reported that they continued to engage in injecting substance use after HCV treatment. Despite continuing to engage in intravenous substance use, they now attend the IEPS regularly to ensure that they have clean injecting equipment to avoid reinfection. During the interview, they commented on their experience of being on the receiving end of downward social comparison from PWID as a result of contracting HCV:

> “Well, I was shunned by my friends that I told so basically, I kept it quiet apart from a few people right. And eh, they were eh, how should I put it? Um sort of looked down at you ... It's like, yeh aye you know nothing but a dirty junkie. You know what I mean, and all that. It wasn’t good.” (Participant 4, Male).

Engaging in injecting substance use can be seen as morally unacceptable and can impact on the moral status of an individual (Plumridge & Chetwynd, 1998). This was reflected on by healthcare staff in the present study who indicated that people who do not inject drugs will think negatively of those who do, due to the moral implications of being an injector:

> “It's a degree of degradation where people would still maintain that they've got self-value, they've got enough moral compass not to inject. And I think, try not to use the word in inverted commas ‘dirty,’ people within the drug community will further stigmatise people who use drugs by injecting. And I think, whilst its socially acceptable to use drugs, not all drugs are acceptable within communities to be injected.” (Participant 10, Healthcare Staff).

The findings from the interviews indicate that patients who have received treatment for HCV and have not become reinfected as a result of changing their injecting behaviour, engage in downward social comparison, whereby they have achieved a positive identity shift where they perceive themselves as being superior to those who continue to inject their drugs, and indeed themselves in their previous identity as a PWID. A desire to maintain this social standing is thought to reduce the likelihood of HCV reinfection.

3.5 Shifting Locus of Control

Participants within the present study described a process, consistent with shifting the locus of control, where they recognised the control they had over engaging in groups whose social norms were consistent with injecting substance use.

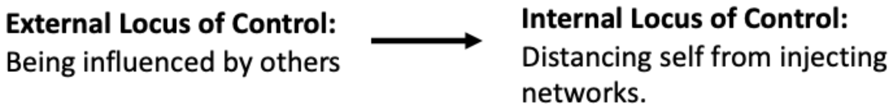


Figure 8. Theoretical diagram outlining the process of individuals distancing themselves from injecting networks through a shift in locus of control.

3.5.1 External Locus of Control and being influenced by others

Individuals who have an external locus of control are likely to attribute the reasons for behaviours and outcomes to an external force such as influential people, luck or fate (Nießen et al., 2022). During interviews, participants often reflected on the influence of others in determining their behaviours. Patients spoke about this in terms of their initial introduction to injecting substance use whereby the choice of whether to engage in this was removed due to the influential nature of others, suggesting that they did not hold themselves accountable for their initiation to intravenous drug use:

> “I've never injected myself or anything like that in my arms and she's like “oh I could inject you, and it’ll be fine, you’ll be fine, you’ll be fine.” and I thought because I loved the girl and I thought maybe if I’m on the same wave length as her, we’ll get on a lot better. So, I’m like “yeh just go ahead.” and she did just injected in my arm.” (Participant 6, Male)

The influence of others extended beyond the patients' initial introduction to intravenous drug use. Participants reflected on the concerns that they had in relation to being influenced by others to re-engage in injecting substance use despite a period of abstinence:

> “It's so hard for me to say no ... It's so weird. It's like I've got a voice in my head telling us not to do it and voice saying, ‘just do it, just do it.’” (Participant 6, Male).

The findings from the present study suggest that an individual's self-efficacy moderates their ability to manage the influence of others and exert an internal locus of control:

> “I’m confident. I think I can do it; I think I can do it. I’m easily led though. I can, all it takes is to bump into the wrong person.” (Participant 2, Male).

The views of patients in feeling that their substance use was influenced by other people was also supported in the interviews conducted with healthcare staff who work in the IEPS:

> “Some people might not define themselves as sharers, but then in that moment, at that time it just happened, and this is translatable to any behavior really, you know we can all relate to situations in which we do something that we wouldn't usually do and then because of, of feeling part of a group, getting peer pressured, feeling like I'm actually enjoying myself, I'll just do it and we perform a behavior that we wouldn't usually.” (Participant 7, Healthcare Staff).

The findings suggest that an external locus of control is more consistent with HCV reinfection due to the individual not believing that they have any control over virus transmission. As such, they do not appear to have the self-efficacy to remove themselves from situations that put them at more risk of contracting HCV.

3.5.2 Internal Locus of Control and the process of distancing self from injecting networks

Although participants spoke about the influence of others in initiating their sharing or injecting substance use behaviour, a shift in locus of control appeared to occur which was protecting participants from becoming reinfected following the ADVANCE trial. Participants appeared to have more self-efficacy in their ability to exert some control over situations and people that were likely to influence their reinfection risk, namely distancing themselves from injecting networks:

> "I stopped, stopped eh associating with people where I'd end up sharing needles." (Participant 4, Male).

In addition to distancing themselves from injecting networks, patients reflected on forming new relationships with groups who were not associated with substance use. This appeared to support patients being able to regain part of their former identity:

> "I started going to the church at lunchtimes and stuff … and because of going to these places and getting just a bit of extra support, meeting new friends and stuff like that everything has just changed a lot. I just feel like, I feel like I felt like 10 years ago when I was working in a Volkswagen garage." (Participant 6, Male).

The healthcare staff within the present study felt that the patients who were less likely to become reinfected were those who had managed to distance themselves from injecting networks:

> "I would say the people who have accessed and sustained in recovery activities, in my experience, have not been the ones who became reinfected. The guys who went back to the, their traditional ways within the community, still engaging with

> the same peers are the ones we see coming back through our door reinfected."
> (Participant 9, Healthcare Staff).

3.6 Socially Responsible Patient

Linked to having an internal locus of control is the subcategory of becoming a "socially responsible patient" whereby patients recognised the potential control they had over reducing the likelihood of other people becoming infected with HCV.

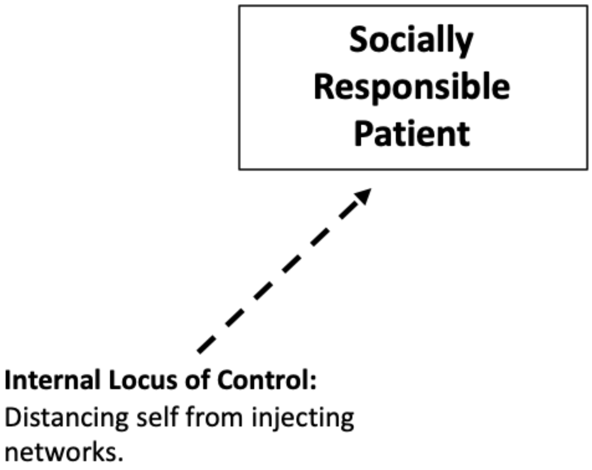


Figure 9. Theoretical diagram outlining the relationship between internal locus of control and being a socially responsible patient.

Consistent with the systematic review conducted by Jones et al., (2014), participants in the present study spoke about the responsibility they felt as a person who had a diagnosis of HCV to prevent onward transmission. In some cases, this sense of responsibility resulted in them undergoing treatment:

> "Just because I've got, I've got a young son ay? And if I cut myself and he had a wee cut he would have got it and all. I don't want anybody to catch it or that."
> (Participant 5, Female).

However, social responsibility extended beyond initiating treatment. For some participants, obtaining a cure represented a sense of stability and resulted in them feeling that their lived experience could be useful in supporting others to reduce their substance use, sharing behaviours and consequently, reinfection risk:

> “That’s the drug use. That’s but, I’ve never done that for a while now. Eh I do come and use the exchange but that’s for someone that who’s a bit lazy. It's a family member. I don’t like them doing it, but he will continue to use the same needle. Ehm and it gets blunt. I’ve actually caught him sharpening it, you know what I mean. So, I was like no I’ll come in, I’ll go into the [IEPS].” (Participant 1, Male).

In other instances, being aware of their HCV infection caused patients to reflect on their role in transmitting the virus and protected those that they were sharing equipment with by injecting last. Thus, reducing the likelihood of reinfection:

> “There was definitely this image that I found from my study on kind of a, a socially responsible injector because they had Hepatitis C. They had the responsibility to let other people know that they had Hepatitis C. And, and to let other people inject safely before them, even though other people didn't know their status.” (Participant 7, Healthcare Staff).

Despite the sense of social responsibility resulting in patients engaging in HCV treatment and using their lived experience to support people, there are instances where the desire to be more socially responsible makes patients more vulnerable to reinfection:

> “Just because I live in [place not transcribed] which is full of, you see needles on a daily basis sort of thing, it’s always me out with a bottle, getting them in a bottle.

I’ve always got a sin bin of my own … I’m taking a chance, taking a risk. But I will put this needle in a sin bin and with the sin bin, I’ll come here [IEPS] and tell them “Look this is where I got it”. Eh, yeh, so just trying to do my bit.” (Participant 1, Male).

Chapter 4 – Implications for Practice

Chapter four will build on the results outlined in the previous chapter by discussing the implications they have on the delivery of healthcare and future prevention of the reinfection of Hepatitis C. This chapter will also discuss the limitations of the study and directions for future research in addition to providing a reflective account from the PI on the research process.

4.1 Discussion

The findings from the study indicate that patients who undergo HCV treatment and do not become reinfected following a successful cure have experienced a shift in identity. The identity shift which occurs can be explained through five theoretical constructs: (1) Hierarchy of Substance Use; (2) Shifting Locus of Control; (3) Socially Responsible Patient; (4) Re-establishing Place in Society; and (5) Good Healthcare Relationships. These findings are consistent with elements of Self-Efficacy Theory, Locus of Control, Social Identity Theory and Social Norms. The Grounded Theory developed in the current study does not stipulate that an individual must experience all five of the theoretical constructs above to be considered as experiencing a shift in identity. Rather, the experience of at least one of these constructs would be an example of an identity shift occurring in an individual. Due to identity being a significant determinant of wellbeing (Haslam et al., 2009), each of these identity shifts are thought to be protective of an individual engaging in behaviours that would make them more likely to become reinfected with HCV.

Each of the patients who participated in the study had not become reinfected with HCV following the treatment they received in the ADVANCE trial. The desire from the patients who had participated in the present study to relinquish their identity as a PWID was evident through all interviews as they often made comparisons between their present circumstance and their life prior to being cured of HCV, with the former being more positively appraised than the latter. There was also evidence of patients who no longer self-reported as being a person who injects drugs, assigning themselves a superior identity to people who continued to inject drugs through the process of downward social comparison (Festinger, 1954).

Social Identity Theory offers explanation as to how people view their position within a group or society and proposes that they do this, in part by comparing themselves to others (Tajfel & Turner, 1979). Festinger (1954) outlines that people will compare their own values, achievements and abilities against others who hold similar characteristics to themselves in order to understand their own worth. Upward and downward comparison occurs when individuals compare themselves to someone that they deem to be superior to them (upward social comparison) or someone that they deem to be inferior to them (downward social comparison) to define where they fit within a group (Festinger, 1954). The likelihood of an individual engaging in behaviours that may harm their health, such as injecting substance use, can also be determined by social identity (Haslam et al., 2009). This process was evident in the present study.

When engaging in downward social comparison, patients who are abstaining from intravenous drug use, would make derogatory comments about PWID using terms such as “disgusting”, “junkie” and “scumbag”. This finding was supported by the interviews conducted with healthcare professionals who reflected on the hierarchy which exists within the substance use population whereby those who use drugs, but do not administer them via injecting, stigmatise PWID due to the moral implications of being an injector. This is consistent with Social Comparison Theory (Festinger, 1954) whereby people will focus on the positive characteristics of the group that they belong to but will focus on the negative characteristics of an out-group. By comparing themselves to PWID in this way, they are distancing themselves from the social norms of this group. This may reduce their likelihood of becoming reinfected with HCV as engagement in risk taking behaviour is often associated with conforming to the normative behaviours of a group (Haslam et al., 2009). As the process of downward social comparison allows an individual to rank themselves as having a higher social identity to those that they are comparing themselves to, the desire to maintain this superior social ranking may also be a motivating factor in their continued abstinence from injecting drug use or the sharing of injecting equipment.

Locus of Control (Rotter, 1954), the extent to which individuals believe that they are responsible for their own actions, was described by participants during interviews. Often when Locus of Control is discussed in relation to health, those with good health outcomes attribute the reasons for this to their own behaviour. Whereas those who have poorer health outcomes tend to attribute the reasons for this to the behaviour of other people (Giblett & Hodgins, 2023). The findings of the present study were consistent with this whereby “External Locus of Control” was discussed with reference to the influence of others in sharing injecting equipment and becoming infected with HCV. However, “Internal Locus of Control” was more closely associated with engagement in the health protecting behaviour of abstaining from sharing by recognising the role they had in controlling the influence of others by distancing themselves from injecting networks. Self-efficacy is also consistently found to be higher in those who have an internal locus of control (Nießen et al., 2022). This view is further supported by a systematic review which found that self-efficacy is considered to be one of the biggest factors determining whether an individual can engage in self-management behaviours to achieve positive health outcomes (Holmes et al., 2014).

When reflecting on the period in their life where patients engaged in injecting substance use and became infected with HCV, they described an external locus of control where they were forced to do and engage in behaviours that they did not want to, rather than having any active control over the decisions they made. However, following their HCV cure, patients described having a much less passive identity and attributed the reason to them not becoming reinfected to “staying away” and no longer associating with people who would encourage needle sharing. Not only did participants discuss exerting an internal locus of control to distance themselves from injecting networks, but they also referenced establishing relationships which supported their engagement in recovery activities. By removing themselves from groups whose social norms were consistent with injecting substance use to networks which have an identity that is consistent with recovery, the patients within this study were behaving in accordance with the Social Identity Model of Recovery (Best et al., 2016). Key to achieving this identity shift is patients recognising that by changing the social norms that surround them to ones that are not consistent with injecting substance use, they are less likely to become reinfected with HCV. This finding was consistent with previous literature which found that people were more likely to share injecting equipment if they had a stronger identification with PWID (Malaguti et al., 2022). Furthermore, Beckwith et al., (2019) found a positive correlation between a ‘recovery identity’ and the number of groups within an individual's network whose normative behaviours were to be abstinent from substance use.

People who inject drugs are often seen by others as having lower morals and a flawed character (Plumridge & Chetwynd, 1998). This belief is often internalised and associated with negative health outcomes (Johannson et al., 2017; Brener et al., 2021). However, some of the patients within the present study challenged this stereotype and embodied the qualities of a socially responsible patient. The main motivations to behave in accordance with a socially responsible identity appeared to be to reduce the risk of transmitting their HCV infection to someone else and to reduce the overall risk of Hepatitis C transmission, regardless of the source of the virus. Patients did this in several ways: (1) engage in HCV treatment; (2) volunteer their time as a peer supporter; (3) remove used injecting paraphernalia from public places; (4) collect sterile injecting equipment from the IEPS for other people; and (5) by injecting last if sharing equipment. Being a peer supporter and having a more socially responsible role within recovery support, has been found to be protective of the peer supporters' own recovery (Scannell, 2022) but has also been associated with people who use substances experiencing an identity shift whereby they move from seeing themselves as a patient to someone who is in recovery (Dugdale et al., 2016). Living in accordance with a recovery identity and experiencing the positive effects on psychological wellbeing derived from supporting others to reduce their substance use, may reduce the likelihood of an individual's relapse into behaviours that would make them more susceptible to becoming reinfected with HCV. However, the positive effects derived from being more socially responsible in one's substance use may be limited if they increase their own risk of reinfection by protecting others. It was difficult to determine from the data gathered when the identity shift, to a more socially responsible patient, occurred. As discussed above, some patients described a sense of responsibility from the point they discovered they had an active infection. In other instances, it wasn't possible to establish the point at which the identity shift occurred. However, it is thought that the emergence of social responsibility is related to an individual developing an internal locus of control where they recognise that their behaviour can have an impact on the reinfection risk of other people.

Self-efficacy is an important construct to discuss as the data from the participant interviews suggested that treatment represented a turning point whereby patients emerged with increased levels of confidence as a result of obtaining a cure. Albert Bandura (1997) considers mastery experiences, the successful engagement in a challenging task, to be one of the most influential sources of self-efficacy. As patients had, in many instances, anticipated treatment to be challenging due to their own beliefs around adverse side effects, achieving a successful cure was considered to be consistent with engaging in a mastery experience. Further, individuals who receive less support in the achievement of a task will attribute more of the success to their own competence and ability. Whereas individuals who received a greater degree of support will credit those who assisted them in their success (Bandura, 1997). Depending on the outcome of randomisation within the clinical trial, some patients from the ADVANCE study were given more responsibility for achieving their cure through the fortnightly dispensing of medication. By giving patients more independence in adhering to their medication, this could have enhanced their mastery experience and the acquisition of self-efficacy as a result.

As treatment was easier than anticipated, and less burdensome than the former interferon treatment, this could have negatively altered a patient's perception of their achievement. However, improvement in self-efficacy through participation in mastery experiences is not always consistent with the greater expenditure of effort or increased degree of difficulty, particularly when adults are considered. Adults can associate high investment of effort into the achievement of a task with having less ability due to the increased time needed to achieve the overall goal. Consistent with ADVANCE, investing less time and effort in the achievement of a task can signify high ability and as such can improve an individual's self-efficacy due to less effort being needed to obtain the outcome (Bandura, 1997). Indeed, engaging unsuccessfully in a task that is very challenging, such as interferon treatment, would be counterproductive and have an adverse effect on self-efficacy.

As in the literature, engaging in HCV treatment has been found to facilitate the shift to a ‘non-addict’ identity in the present study (Rance & Treloar, 2014; Jones et al., 2014; Newman et al., 2013) as the process of completing treatment and obtaining their HCV cure appeared to improve the self-efficacy of patients and provided a foundation on which they began to relinquish their identity as PWID. Following cure, patients pursued a more socially accepted lifestyle where they re-established relationships, valued their health and felt valued by others by ceasing their engagement in injecting substance use. This is consistent with the findings of Madden et al. (2018)

who found that patients reflected on the positive impact that achieving a HCV cure had on enhancing relationships and pursing a new identity.

As intimate family relationships negatively predict the occurrence of substance misuse (Kliewer et al., 2006; Molero et al., 2019) re-establishing these relationships could be protective in an individual engaging in behaviours that would make them more susceptible to becoming reinfected with HCV. Furthermore, Zeng et al., (2021) established that although positive relationships with family are consistent with having greater coping strategies, this is moderated by self-efficacy. As the findings from the present study indicate that patients experience increased self-efficacy as a result of engaging successfully in HCV treatment, the combination of this and the re-establishment of close family relationships could provide an enhanced level of protection against HCV reinfection. Inversely, those who remain distant from their family and have low self-efficacy may be less likely to develop coping strategies to help them maintain their abstinence from riskier injecting practices and make them more susceptible to reinfection. A health-valuing attitude has also been found to buffer the likelihood of an individual engaging in substance misuse (Reifman et al., 2001; Ritt-Oslon et al., 2004). Following HCV treatment, the patients in the present study spoke about valuing their health more than previously, which may be one of the factors protecting them from engaging in injecting drug use and consequently their absence of future HCV infections.

The findings of the present study indicate that patients continued to attend the IEPS on completion of their HCV treatment due to the non-judgmental and welcoming attitudes of staff. As such, it is thought that one of the factors contributing to reduced reinfection risk seen within the population of patients who participated in this study is the feeling of being less judged when accessing healthcare in relation to their BBV risk, injecting needs or wider health. This was consistent with the systematic review conducted by Jones et al., (2014) which found that having a relationship with healthcare staff within substance misuse services was important in predicting the likelihood of a PWID presenting themselves for testing. As the Treatment as Prevention (TasP) programme of NHS Tayside relies on people presenting themselves for testing in order to reduce the prevalence of un-detected virus and therefore infection risk, the fact that patients continued to attend the IEPS on completion of treatment to get follow-up BBV tests should be seen positively in terms of reducing transmission of HCV and other blood borne viruses.

4.2 Implications for Practice

Self-efficacy, distancing self from social norms that encourage injecting substance use and living in accordance with a ‘recovery identity’ were all associated with reduced risk of reinfection.

The present study recognises that not everybody who has a history of misusing substances has the opportunity to re-establish relationships with family and friends or to engage in new relationships which would allow them to distance themselves from injecting drug networks without experiencing a significant degree of social isolation. As such, the role of peer supporters within the substance use population is important in facilitating social contact and building a network around the individual which has a recovery orientated identity. In addition to there being a significant degree of evidence around the positive benefits that being a peer supporter can have on those in that role (du Plessis et al., 2020) it has also been shown to have a positive effect on those receiving the support by providing connections to the wider recovery community and community in general (Scannell, 2022). The present study suggests deploying peer supporters who have successfully achieved and maintained their HCV cure to support people who have newly completed treatment. It is thought by doing this that the initiation of an identity shift can be attained as the identity surrounding the individual is consistent with being in recovery and maintaining abstinence from behaviours that are likely to increase reinfection risk.

This thesis acknowledges the value that peer supporters can have in providing access to a recovery network. However, it also demonstrates the value of providing patients with longer-term clinical care. The patients from the present study have continued to engage in the services provided by the IEPS since the treatment they received from ADVANCE (January 2018 and November 2019). It is therefore suggested that their SVR is, in part, as a result of their continued engagement in harm reduction and the holistic support offered by the IEPS. This highlights the need for the funding of longer-term professional care and the benefits this could have on reduced HCV reinfection.

Fostering the attainment of self-efficacy in patients through the care delivered by healthcare providers also appears to be important in facilitating the protective identity shift which occurs. Engaging in the mastery experience of achieving a HCV cure seemed to be integral to this, and there may be other mastery experiences within the process of recovery which have the same effect. Setting goals with patients around the things they want to accomplish and supporting them to develop action plans to aid the successful completion of set goals may be effective in improving self-efficacy in the same manner that achieving their HCV cure was. Evidence also indicates that self-efficacy can be built by giving patients roles of responsibility such as that of a peer supporter (du Plessis et al., 2020)

Furthermore, this study emphasised and illustrated the benefits that can be derived from delivering care that is non-judgmental and patient centred. As such, healthcare at all levels should be delivered with the same ethos to not only encourage PWID to initiate the engagement in treatment but to provide a reassuring point of access back into treatment if reinfection is suspected. This will support the overall TasP by identifying active infections in the community more efficiently.

4.3 Strengths and contributions of the Research

The patients who participated in this study received their HCV treatment between January 2018 and November 2019. As all the patient interviews took place in June 2022, a notable strength of the research is the presentation of findings from patients who had maintained their HCV cure over a lengthy follow up period. The long term, qualitative, follow up with patients is thought to be novel and suggests that the core category of ‘Identity Shift’ which was developed in the present study is an outcome that patients can achieve and sustain beyond the close proximity of the end of treatment.

Further, patients have aspirations for treatment which extends beyond virus elimination such as behavioural changes to substance use, improvements in self-worth, enhancing relationships and achieving a positive identity shift (Harris & Rhodes, 2018; Madden et al., 2018). However, there were some concerns about the efficacy of achieving these non-clinical outcomes when treatment transitioned away from being interferon based due to DAA treatment requiring less intensive provision of care from healthcare professionals (Harris & Rhodes, 2018). The findings from the present study supports that non-clinical outcomes, which patients cite as being important to them, can be achieved in the era of DAA treatment. Notably, the patients who participated in the present study had been assigned to different treatment arms in the ADVANCE trial. This provided further evidence to support the view that less frequent contact with healthcare professionals may not negatively impact the psycho-social outcomes of patients as there were no apparent differences between patients who received directly observed therapy, fortnightly dispensed therapy or fortnightly dispensed therapy plus psychological intervention.

4.4 Limitations and recommendations for future research

The present study has some limitations which should be discussed. In the first instance, it was not possible to recruit patients who had become reinfected with HCV following treatment from ADVANCE, despite efforts to do so. As such, the developed grounded theory was not as representative of their views as would have been preferred. It is acknowledged that engaging a marginalised population in qualitative interviews can be challenging, particularly when they may experience stigma. It is therefore possible that patients who did go on to become reinfected were less likely to share their experience with a researcher due to concerns about being judged. Conversely, the patients who did participate in interviews had not become reinfected and may have been less concerned about being judged due to the fact they have been able to maintain their SVR. It is also possible that patients were less likely to express an interest in participating in the study when the recruitment was facilitated through an established member of staff from the IEPS. Patients may have wished to have participated more discretely, particularly if they wanted to share negative experiences of the treatment they had been provided.

One of the strengths of the support offered by the IEPS was the open doors policy to negate the need for patients to attend a pre-arranged appointment. As the Principal Investigator

(PI) was unable to base themselves within the IEPS due to other commitments it was not possible to offer this ‘drop-in’ facility to patients who wished to participate in the interview. Instead, they were invited to attend interviews on the days that the PI was onsite or at a pre-arranged telephone appointment. To improve recruitment in future studies, it may be beneficial for the PI to be located onsite more frequently. However, as grounded theory methodology recommends the recruitment of participants via theoretical sampling rather than methods of sampling which result in more equitable representation of participant groups in the analysis (i.e. those who have become reinfected and those who have not become reinfected), the lack of reinfected participants is not thought to have significantly compromised the development of the grounded theory. Consistent with grounded theory methodology and theoretical sampling, the present study submitted an ethical amendment to allow the inclusion of healthcare staff after it became apparent that further patients would not be successfully recruited. The interview schedule was amended to explore the developing concepts with healthcare staff.

Participants were given the option of participating in interviews in-person at the IEPS, on the telephone or via video call. Although this provided flexibility it was more challenging for the PI to establish rapport with those who participated via the telephone or video call. It was also difficult to ensure that participants had a private place to take part in the interview. Overall, the quality of interviews was consistent when remote and in-person formats were compared. However, there was one exception where the quality was compromised due to a number of distractions present at the location where one of the patients participated in the interview from.

In addition, the patients who participated in the study were all interviewed in quite quick succession (1 patient recruited on 23/06/22 and 5 recruited on 30/06/22). Consistent with grounded theory methodology, the PI had done very little research prior to conducting these interviews so that the knowledge they obtained was mainly derived from participants' experiences. As such, the schedule for these early interviews was broad so that the PI could gain an overall understanding of patient experience before exploring concepts which emerged. Because the six patient interviews happened over two interviewing days, with only a week in-between, it was more challenging for the PI to engage in constant comparative analysis as most of the analysis of patient data was done after they were all recruited and interviewed. As such, the overall theme of “identity shift” was only explored with the healthcare staff who participated in the interviews. Future developments of this grounded theory should therefore explore the “identity shift” with patients in more detail.

4.5 Reflections on the research process

Completing the research competency of my professional doctorate was the element of the qualification that I was most apprehensive about. On reflection, I believe that this was mainly due to most of my experience in health psychology, up until this point, consisting primarily of being a practitioner. However, by pursuing a research project that I had genuine interest in, I was able to see the role that research had in developing the delivery of healthcare and consequently improving health outcomes.

As with the other competencies, I noticed my confidence improve as the process of doing the research progressed. At first, I questioned whether my style of conducting the qualitative interviews was correct as I felt that I was offering too many reflections which may have led the participants to answer in a particular way. However, after listening back to the recordings when transcribing I was reassured by the fact that I hadn't led the participants but had instead validated some of the things they were saying to help put them at ease in the hope that it would encourage them to be more open in their responses.

When preparing to do this research project, it had been recommended to me by other students that I used a transcription service due to the time-consuming nature of transcribing. Although the process of transcribing was labour intensive, I am glad that I did it as it was invaluable in giving myself a good grounding in the data and in familiarising myself with the experience of participants. In addition, some of the memos that I wrote at this early stage of analysis proved to be the ones that became most useful and relevant at the later stages of analysis.

The process of analysing the data was challenging as I did not have any prior experience of conducting grounded theory analysis. Due to the different stages of coding and the constant comparative analysis it often felt that little progress was being made. However, towards the later stages of focused coding, it became evident that the time invested in memo-writing and comparative analysis was a good investment as it was much easier to make links between concepts to derive the overall theoretical categories and the processes behind them.

Overall, completing my research project was an enjoyable process which has encouraged me to pursue research opportunities again in the future. Prior to completing this project, my motivation for doing so was because it was a course requirement. However, through seeing the value and real-world applications of conducting research, it is a competency that I am pleased I developed and is one that I would not hesitate in using again in the future. Like the experience of the participants who underwent HCV treatment, this research project has felt like engaging successfully in a mastery experience. I feel more confident as a result and have noticed a shift in my identity from being a Practitioner Health Psychologist to a Scientific Practitioner Health Psychologist who will more readily undertake and conduct research in the future.

4.6 Conclusion

This study has developed a grounded theory which illustrates that identity shifts can occur in PWID to reduce their likelihood of becoming reinfected with HCV following a successful cure. By distancing themselves from groups whose normative beliefs and behaviours were consistent with injecting substance use, in addition to feeling more confident as a result of achieving cure, patients in the present study were able to live in accordance with a recovery orientated identity. This was consistent with being more socially responsible, exerting an internal locus of control, re-establishing relationships, valuing their health and engaging with health services.

The findings of the present study challenge the concerns raised in the literature about the efficacy of DAA treatment being able to support patients in achieving non-clinical outcomes due to less intensive interactions from healthcare professionals. However, the identity shifts which were described by patients in the current study suggest that these outcomes can be achieved in the era of DAAs, providing important implications for practice.

The long term, qualitative, follow up with patients suggests that the core category of ‘Identity Shift’ is an outcome that patients can achieve and sustain over a longer period of time. As the likelihood of an individual engaging in behaviours that harm their health are determined by social identity (Haslam et al., 2009), the identity shifts outlined in the present study are thought to protect patients from engaging in behaviours, such as the sharing of injecting equipment, that would increase their reinfection risk. Furthermore, the patients who participated in this study continued to engage in the services provided by the IEPS for a considerable period of time beyond achieving their cure. As such, this thesis suggests that the funding of longer-term clinical care for PWID may be key in maintaining a recovery orientated identity and reducing HCV reinfection risk.

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Appendices

Appendix A: Interview Topic Guide for Patient Interviews

Title: Understanding reinfection risk of Hepatitis C in people who inject drugs: A Qualitative Study

Chief Investigator: Dr Vivien Swanson Principal Investigator: Katie Heslop

Sponsor: University of Stirling

BROAD TOPICS TO DISCUSS AT INTERVIEW

1. **Hepatitis C and treatment: persons thoughts around their experience of having Hepatitis C and receiving treatment.**

An example question may be: Tell me a bit about your experience of receiving treatment for Hepatitis C.

2. **Needle sharing: persons thoughts and experiences around needle sharing, consequences of needle sharing and the support they receive from needle exchange services.**

An example question may be: What are your thoughts about needle sharing?

3. **Mental health: persons sense of their own mental health.**

An example question may be: How would you describe your mental health?

4. **Social norms: the influence of other people and organisations.**

An example question may be: Can you tell me about the supports you have around you?

5. **Self-efficacy: persons sense of confidence in being able to control cravings and remain hepatitis C free.**

An example question may be: How do you feel about your ability to manage cravings?

Appendix B: Interview Topic Guide for Healthcare Staff Interviews

Title: Understanding reinfection risk of Hepatitis C in people who inject drugs: A Qualitative Study

Chief Investigator: Professor Vivien Swanson Principal Investigator: Katie Heslop

Sponsor: University of Stirling

BROAD TOPICS TO DISCUSS AT INTERVIEW

1. **Professional background**

Can you tell me about your involvement with the ADVANCE study?

2. **Hepatitis C and treatment: persons thoughts around patients experience of having Hepatitis C and receiving treatment.**

- *What are your thoughts on the treatment provided in ADVANCE?*
- *How do you think treatment impacted on your patients?*
  - *Health outcomes*
  - *Functioning*
  - *Psychological impact*

Any positive or any negative impacts?

3. **Needle sharing**

- *Can you tell me about patients' perception of their self-image?*
- *Do you think treatment had an impact on how your patients saw themselves?*
- *How do you think non-injecting drug users perceive themselves?*

4. **Reinfection: risk factors associated with reinfection**

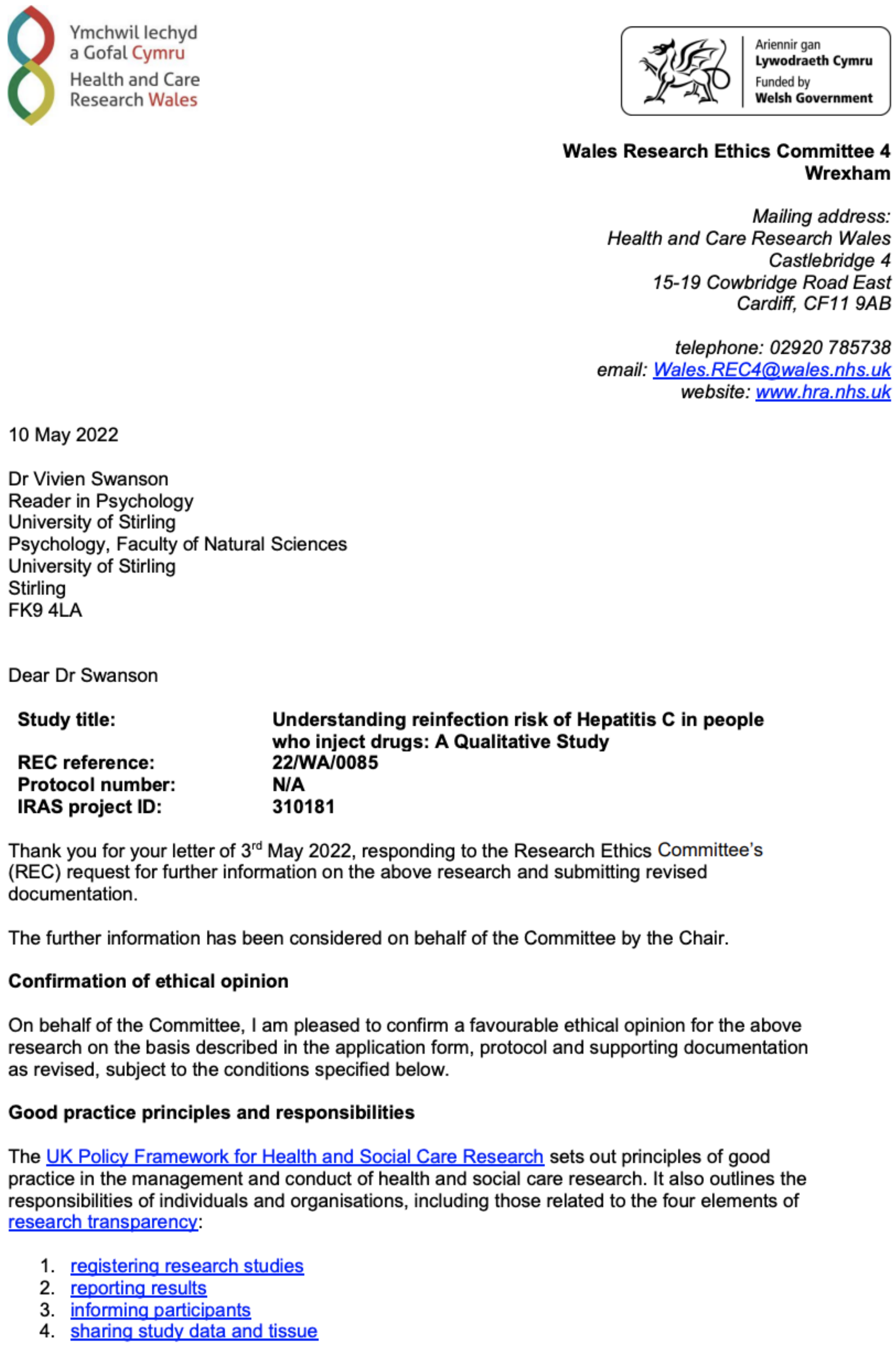
Do you think there are any differences between people who do and do not become reinfected with Hepatitis C after successful treatment?

5. **Social norms: the influence of other people and organisations.**

What formal (healthcare) support do you think is important in preventing reinfection?

What informal (non-healthcare) support do you think is important in preventing reinfection?

Appendix C: Favourable Ethical Opinion Letter for Part A of Study



Ymchwil Iechyd
a Gofal Cymru
Health and Care
Research Wales

Ariennir gan
Lywodraeth Cymru
Funded by
Welsh Government

Wales Research Ethics Committee 4
Wrexham

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telephone: 02920 785738
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website: www.hra.nhs.uk

10 May 2022

Dr Vivien Swanson
Reader in Psychology
University of Stirling
Psychology, Faculty of Natural Sciences
University of Stirling
Stirling
FK9 4LA

Dear Dr Swanson

Study title:	**Understanding reinfection risk of Hepatitis C in people who inject drugs: A Qualitative Study**
REC reference:	**22/WA/0085**
Protocol number:	**N/A**
IRAS project ID:	**310181**

Thank you for your letter of 3rd May 2022, responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as:

- clinical trial of an investigational medicinal product
- clinical investigation or other study of a medical device
- combined trial of an investigational medicinal product and an investigational medical device
- other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by the HRA (for more information on registration and requesting a deferral see: Research registration and research project identifiers).

If you have not already included registration details in your IRAS application form you should notify the REC of the registration details as soon as possible.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of materials calling attention of potential participants to the research [N/A]	1.0	03 January 2022
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [N/A]		17 January 2022
Interview schedules or topic guides for participants [N/A]	1.0	04 March 2022
IRAS Application Form [IRAS_Form_09032022]		09 March 2022
Letter from sponsor [N/A]		17 January 2022
Non-validated questionnaire [N/A]	1.0	04 March 2022
Other [Participant contact form]	2.0	13 April 2022
Other [Response to REC table]	1.0	29 April 2022
Participant consent form [Participant consent form]	2.0	13 April 2022
Participant information sheet (PIS) [Participant information sheet (PIS)]	2.0	29 April 2022
Research protocol or project proposal [N/A]	1.0	07 January 2022
Summary CV for Chief Investigator (CI) [N/A]		01 March 2022

Summary CV for student [N/A]		03 March 2022
Summary CV for supervisor (student research) [N/A]		01 March 2022

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 310181 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

SJ L Newman

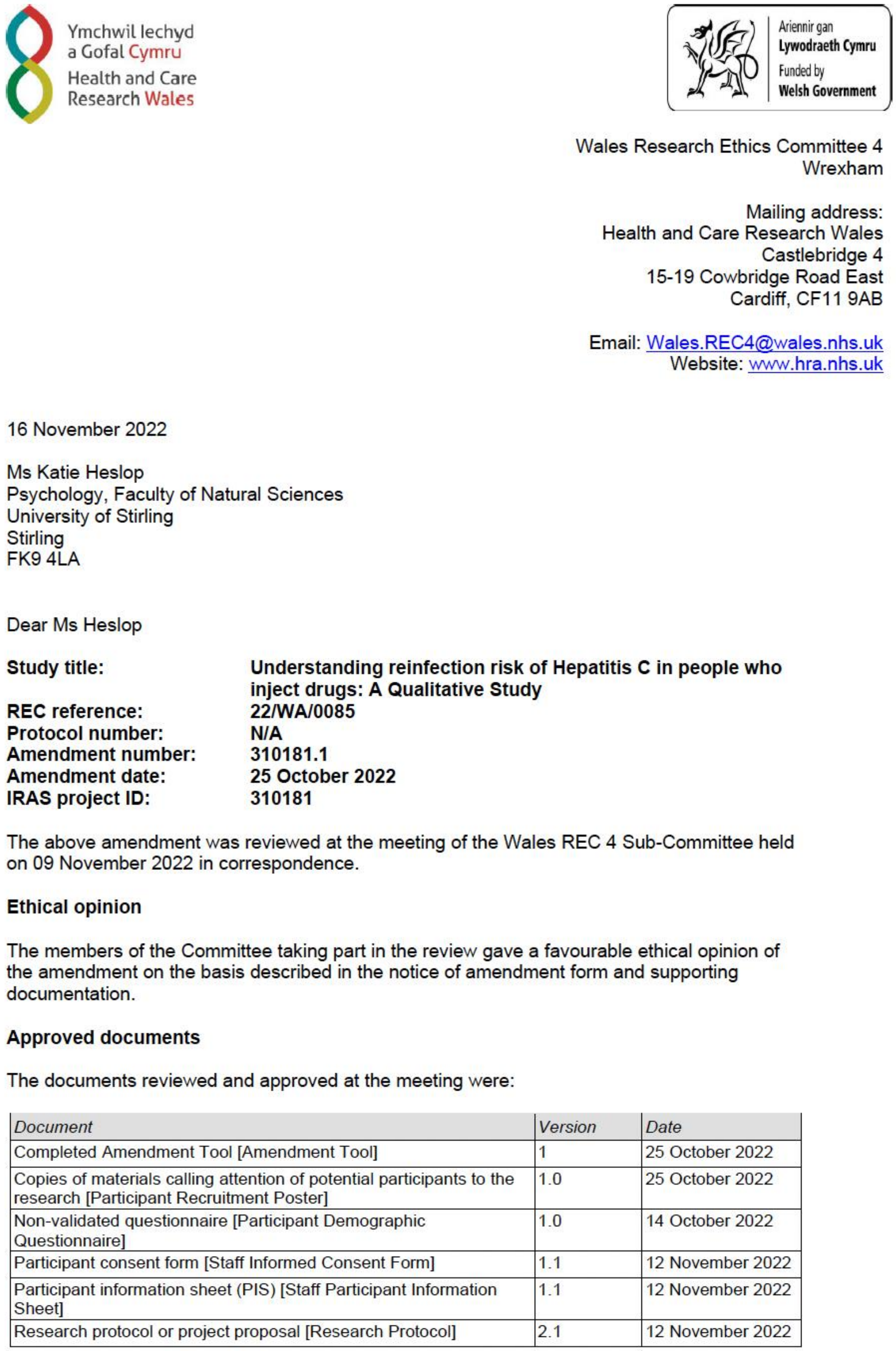
pp
Dr Julie Latchem-Hastings
Chair – Wales REC 4

Email: Wales.REC4@wales.nhs.uk

Enclosures: **After ethical review guidance for sponsors and investigators – Non CTIMP Standard Conditions of Approval]**

Copy to: Rachel Beaton
Lead Nation - Scotland: gram.nrspcc@nhs.scot

Appendix D: Favourable Ethical Opinion Letter for Part B of Study



Ymchwil Iechyd
a Gofal Cymru
Health and Care
Research Wales

Ariennir gan
Lywodraeth Cymru
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Welsh Government

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Email: Wales.REC4@wales.nhs.uk
Website: www.hra.nhs.uk

16 November 2022

Ms Katie Heslop
Psychology, Faculty of Natural Sciences
University of Stirling
Stirling
FK9 4LA

Dear Ms Heslop

Study title:	**Understanding reinfection risk of Hepatitis C in people who inject drugs: A Qualitative Study**
REC reference:	**22/WA/0085**
Protocol number:	**N/A**
Amendment number:	**310181.1**
Amendment date:	**25 October 2022**
IRAS project ID:	**310181**

The above amendment was reviewed at the meeting of the Wales REC 4 Sub-Committee held on 09 November 2022 in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Completed Amendment Tool [Amendment Tool]	1	25 October 2022
Copies of materials calling attention of potential participants to the research [Participant Recruitment Poster]	1.0	25 October 2022
Non-validated questionnaire [Participant Demographic Questionnaire]	1.0	14 October 2022
Participant consent form [Staff Informed Consent Form]	1.1	12 November 2022
Participant information sheet (PIS) [Staff Participant Information Sheet]	1.1	12 November 2022
Research protocol or project proposal [Research Protocol]	2.1	12 November 2022

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS Project ID - 310181:	**Please quote this number on all correspondence**

Yours sincerely

pp Mr Martin Rawson
Dr Julie Latchem-Hastings
Chair

E-mail: Wales.REC4@wales.nhs.uk

Wales REC 4

Attendance at Sub-Committee of the REC meeting on 09 November 2022

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mrs Maryanne Bray	Lead Research Midwife	Yes	
Dr Julie Latchem-Hastings (Chair)	Registered Physiotherapist	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mr Martin Rawson	Approvals Administrator