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### DOT-C

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# **DOT-C: A Cluster Randomised Feasibility Trial Evaluating Directly Observed Anti-HCV Therapy in a population receiving opioid substitute therapy from community pharmacy**

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Running Head:

Hepatitis C Testing and Treatment in Community Pharmacies

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## **Abstract:**

### Background

Direct-acting antiviral therapy (DAAs) for hepatitis C infection (HCV) have a much smaller burden of treatment than interferon-based regimes, require less monitoring and are very effective. New pathways are required to increase access to treatment amongst people prescribed opioid substitution therapy (OST).

### Method

An exploratory cluster randomised controlled trial with mixed methods evaluation was undertaken to compare the uptake of dried blood spot testing (DBST) and treatment of people with genotype 1 HCV infection in a conventional service pathway versus a pharmacist-led pathway in a population receiving OST.

### Results

Pharmacies randomised to the conventional pathway obtained 58 DBST from 244 patients (24%): 15 new reactive tests and 33 new negative tests were identified. Within the pharmacist-led pathway, 94 DBST were obtained from 262 patients (36%): 26 new reactive tests and 54 new negative tests were identified. Participants in the pharmacist-led pathway were more likely to take a DBST ( $p=0.003$ ). Of participants referred for treatment through the conventional pathway, 4 patients from 15 with new reactive tests (27%) attended clinic for assessment. In the pharmacist-led treatment pathway, 20 patients from 26 with new reactive tests (77%) attended for assessment blood tests. Participants in the pharmacist-led pathway were more likely to proceed through the assessment for treatment ( $p=0.002$ ). One participant completed treatment through the conventional pathway and three patients completed treatment through the pharmacist-led pathway. The process evaluation identified key themes important to service user completers and staff participants.

### Conclusion

The study provides evidence that testing and treatment for HCV in a pharmacist led-pathway is a feasible treatment pathway for people who receive supervised OST consumption through community pharmacies. This feasibility trial therefore provides sufficient confirmation to justify proceeding to a full trial

## Introduction

Hepatitis C (HCV) is a blood-borne viral infection (BBV) causing liver disease. Around 0.8% of the Scottish population are chronically infected with HCV (Scottish Intercollegiate Guidelines Network, 2013). A recent Public Health England report highlighted that less than 3% of those known to be infected with HCV are being treated and less than half of those infected are known (Public Health England, 2016). The largest single infected group are those on opioid substitution therapy (OST) (Arain, 2014). Research suggests around 40% of people receiving OST have HCV (Aspinall, 2015; Edlin 2005)

The world-wide burden of HCV infection has been estimated as 71.1 million infections (62.5—79.4), with the largest group being genotype1 (Polaris Observatory HCV Collaborators 2017). The increased morbidity, mortality and economic impact of the infection are of concern to both industrialised and developing countries (Lavanchy, 2009).

The paradigm shift resulting from the introduction of Directly Acting Antiviral drugs (DAAs) has changed the narrative around HCV, with a realisation that HCV could be eliminated in people who inject drugs (Lima, 2015). There is optimism that the use of DAAs offers a high chance of clearance of HCV infection from the population (Grebely, 2014). Treating all patient groups with HCV would yield substantial benefits (van Nuys, 2014) but there are concerns that the infrastructure and treatment capacity to deliver the required health outcomes are not generally available or of insufficient scale (Leask, 2016).

Treatment uptake for HCV amongst people who inject drugs is currently low (Weissing, 2014) and prospective patients may have a number of barriers to overcome in order to access care (Fernandez-Montero, 2014). There are identified deficiencies in the extent of screening and diagnosis of at-risk populations, as well as improvements required in access to treatment initiation and clinical monitoring (Artenie, 2015): People who inject drugs may find it difficult to consistently attend medical clinics (Papatheodoridis, 2014). However, the delivery of HCV testing and treatment through community-based care pathways has been shown to be feasible (Wade, 2016) and Dried Blood Spot Testing (DBST) has been demonstrated to increase the uptake of testing from high-risk populations (Coats and Dillon, 2015).

Creating the complex interventions necessary to eliminate HCV requires that well-designed cross-disciplinary programmes are put in place (Suther and Harries, 2015) using different strategies to increase screening, testing and diagnosis (Brouard et al, 2015). The potential of community pharmacy practices to make a greater contribution to the health of their local populations has been recognised for some time (Anderson et al, 2009). Pharmacists have

long had a major role in delivering OST to this group of patients with a high prevalence of HCV (Anderson, 2007) and pharmacist involvement in delivering HCV treatment through multi-disciplinary clinics has been described for some time (Kolor 2005, Arora 2011)

The Tayside region of Scotland has sequentially developed integrated HCV treatment services over the last two decades, moving from standard secondary care-based hospital outpatients, onto nurse-supported treatment services, then to a HCV managed care network (MCN) including a widespread dry blood spot testing programme in drug services and development in our outreach services across the region. This most recent development includes providing treatment within drug services and prisons (Tait 2016). The network aims for wide involvement in BBV testing and follow-up, with healthcare professionals such as drug workers, GPs, prison nurses and social workers taking the opportunity to discuss referral and treatment with patients.

A cluster randomised feasibility trial was therefore designed to optimise the research design and consider whether a pharmacist-led testing and treatment pathway could be both effective and successful, before being more widely implemented (Bowen et al 2009). The study was designed with a mixed methods approach to evaluate: whether people who receive OST for pharmacies could be recruited to the study; whether pharmacies could successfully complete all elements of the testing and treatment pathway; which elements of the pathway work well and which elements are less successful; to make an estimate of the effect size in terms of how many participants complete each stage of the pathway (Eldridge et al 2016; Arain et al 2010).

In preparing to undertake this study, work was undertaken using a co-production approach in partnership with OST patients (Radley et al, 2016) and has developed the intervention through using the views of patients and staff to identify barriers and facilitators to effective care (Radley et al, 2017). The DOT-C study utilises the existing pharmacy environment and therapeutic relationships to smooth the pathway into HCV therapy and co-administer OST with anti-HCV therapy under the supervision of the pharmacist. The conventional care pathway requires referral and attendance of the patient at another site and treatment according to the established standard of care. This feasibility study therefore aims to address questions about increasing testing and uptake of treatment, through a simplified community pharmacist-led care pathway for patients with genotype 1 HCV and to incorporate these colleagues into the work of the MCN.

## **Methods**

Trial design:

An exploratory cluster randomised trial of directly observed anti HCV therapy versus conventional care in HCV positive patients attending a pharmacist delivered OST program.

*Study protocol:* Ethics approval was received for this study (15/ES/0086) from East of Scotland REC2 on 2 July 2015. Caldicott Guardian approval was given on 25 July 2015

#### Participants:

Approximately 2,200 patients are prescribed OST within the Tayside region of North East Scotland. Around 85% of these patients receive daily supervision of their OST consumption through the 92 community pharmacies. At least 40% of these patients will be infected with HCV, 40% of infections are Genotype 1 virus (Hutchinson et al, 2006).

#### *Trial inclusion criteria*

Pharmacies were eligible to participate in the study if they could offer DBST for HCV or be trained to do so. Pharmacies required around 30 patients to ensure adequate recruitment.

Patients were eligible to be consented to the study if they were prescribed OST with supervised administration by a pharmacist and had a reactive DBST. Only genotype 1 patients were included. Genotype 3 patients were excluded because of the requirement to provide interferon-based regimes at the time of the study.

#### Randomisation:

Eight pharmacies were randomised into two groups: conventional care and pharmacist-led care. Randomisation was carried out using <http://www.randomization.com>. The subjects were randomized into one block using the seed 12576 along with the number of subjects per block/number of blocks and (case-sensitive) treatment labels. The pharmacy provided the level of randomisation, so patient allocation was dependent on the pharmacy attended.

#### Interventions:

All pharmacy staff involved with the study received training on good clinical practice, study procedures and documentation. Patients confirmed as having genotype 1 HCV infection were assessed for suitability for treatment with ledipasvir 90mg/sofosbuvir 400mg (Harvoni<sup>®</sup>, Gilead) (EMC, 2016).

#### *Conventional care pathway*

In these pharmacies, the pharmacist opportunistically discussed with the patient the possibility of HCV infection and provided verbal and written information about testing and or treatment. If the patient consented and had not been recently tested, a DBST was taken and sent to the local laboratory. In Tayside, the DBST reports Anti-HCV, Hepatitis B surface

antigen (HBsAg) and Anti-HIV. DBSTs reactive for anti-HCV are confirmed through venepuncture and PCR to determine genotype and viral load.

The local laboratory sent back the result of the DBST to the pharmacist, with results for HCV, hepatitis B and HIV (NHS Tayside MCN, 2012). The identity of each patient approached and the result of their DBST was recorded on a screening log. For patients with a reactive DBST, a standard referral letter was sent to the treatment centre and an appointment letter issued, inviting the patient to attend a clinic. For patients admitting to a recent HCV test, a standard referral letter was also sent to the treatment centre as described above. For patients attending the appointed clinic, assessment and treatment was carried out as normal within the standard of care.

#### *Pharmacist-led pathway*

In these pharmacies the pathway was identical to the conventional pathway, except that patients with a reactive DBST were assessed by the pharmacist for treatment. For consenting patients, the pharmacist completed a pre-treatment checklist of co-morbidities, medical history and concomitant medication. The patient was invited to attend a local phlebotomy service and have a panel of blood tests taken including markers of liver fibrosis (Castera, 2012) and viral parameters (genotype and load). The pharmacist used a Fib 4 test result to identify patients that required further assessment and input from the hospital-based multi-disciplinary team (Sterling 2006). Patients with a score of 3.25 or above were excluded from the study and referred to the multi-disciplinary team. These bloods were part of standard care for HCV treatment and are not research specific (i.e., they were also part of the conventional pathway). If the pharmacist identified no contra-indications to HCV therapy, the patient was commenced on treatment. Prescriptions were written by a pharmacist independent prescriber. In patients with potential contraindications or queries about suitability, the pharmacist contacted the central clinical co-ordinator for medical review. Unsuitable patients were referred for assessment outside the study, through the conventional care pathway. Patients received daily HCV treatment at the same time as their OST, (usually on 5 or 6 days, so a modified version of DOT). For weekend doses (when the patient self-administered), the pharmacist and patient made a brief if-then action plan (an implementation intention) and coping plan (to overcome anticipated barriers) (Gollwitzer and Shearer, 2006).

#### Outcomes:

Participating pharmacies were asked to test all consenting and eligible patients from the cohort who attended the pharmacy. Trial outcomes were (1.) The proportion of OST patients accepting the offer of testing, (2.) the proportion of patients undertaking assessment for

treatment, (3.) the proportion of patients completing treatment. The study endpoint was when all patients had completed the study care pathway or had dropped out.

#### Analysis of data:

We have summarised study data as means (standard deviations), with t tests or chi squared tests used, respectively, to compare between-group baseline parameters. The outcomes from the participant flows were assessed by chi squared and non-parametric significance testing. Since this was a feasibility study, no sample size calculation was performed.

#### *Data collection*

Baseline information on age, sex, concomitant medication, co-morbidities and assessment outcomes was collected. Subsequent data was collected on a daily administration log which recorded attendance and any treatment side-effects. Participants completing treatment were invited for a blood test at twelve weeks to ascertain SVR. Recruitment commenced in November 2015 with the study being completed in September 2016.

#### *Process evaluation*

A logic model was constructed to explicitly identify targets for evaluation and data collection and is reported elsewhere (Radley et al, 2017). The evaluation examined the processes involved with effectiveness of implementation (Murray et al, 2010).

Semi-structured interviews were conducted with (i) 6 service users and (ii) 8 professionals taking part in the study, with all 8 pharmacies represented. The service users who had completed treatment or who had been asked to attend for assessment blood tests were interviewed where possible. Interviews were conducted using topic guides developed in line with the research aims and programme theory. All interviews were recorded as digital audio files and transcribed in full for thematic analysis (Richie and Spencer, 1994). Transcripts were inductively analysed to identify themes emergent from the interviews. These data contributed to the assessment of feasibility and acceptability (including barriers and facilitators), that had been gained from this and previous work (Radley et al, 2016, 2017).

#### *Resource utilisation of conventional and pharmacist-led pathways*

The stages and inputs contained within the conventional treatment pathway were defined through discussion and agreement within the multi-disciplinary team. The stages and inputs contained within the pharmacist-led pathway were defined by the study protocol and reviewed and agreed by the study team.

#### *Cost collection methods*



NHS Reference costs, published micro-costing studies, and Personal Social Service Research Unit costs (PSSRU) (Shepherd et al, 2007), were used for the unit costs of managing patients while on treatment.

Monitoring costs refer to the costs of monitoring the patient while they are treated with DAA therapy. Monitoring unit costs were predominantly taken from a micro costing (NHS Reference Costs, 2015) and were inflated to 2014/2015 costs using the Hospital and Community Health Services (HCHS) Pay and Prices Index (Stevenson, 2012 et al). NHS Reference Costs were also consulted as a possible source for this analysis. Although these sources were broadly aligned, more detailed costing data was available, which was essential for this analysis (NHS Reference costs, 2015; Curtis and Burns, 2015).

The unit costs used to estimate the total monitoring costs and service costs for each pathway are displayed in Table 4. Service costs refer to the costs of services (e.g. pharmacist time, nurse time, consultant time) provided to the patient while they are treated with DAA therapy. Unit costs were predominantly taken from PSSRU Unit Costs of Health and Social Care 2015. Unit costs are calculated from NHS reference costs and have been updated using the HCHS pay & prices inflator (Shepherd et al, 2007).

#### *Assessment of pathway costs*

Using the pathway map, monitoring and services costs were summed to cost both the conventional and Pharmacy Pathway. Service unit costs were multiplied by the staff time taken to complete that activity to provide the cost per activity.

## **Results**

### Baseline parameters:

There was no significant difference between the age distributions of participants in the conventional pathway (m=38, sd = 7) and in the pharmacist-led pathway (m=37, sd = 8);  $t(504) = 1.65, p = 0.100$  (Table 1). Chi Square testing showed no significant differences for sex ( $p < 0.4$ ) or the hepatitis C test status parameters between the two participant groups ( $p < 0.7$ ). The testing and treatment status of both groups at baseline were compared. Mann Whitney U Testing demonstrated no significant differences between the hepatitis C testing parameters ( $U_{stat} > U_{crit} \alpha = 0.05$ ).

### Recruitment and participant flow:

Of 506 patients attending the 8 pharmacies for OST, 175 were identified as having no record of a previous test (35%) for HCV (Table 2) through a data linkage exercise linking OST prescription records with laboratory testing records. Pharmacies randomised to the

conventional pathway obtained 58 DBST from 244 patients in receipt of OST (24%). Of these, 15 new reactive tests and 33 new negative tests were identified. The pharmacists also tested 2 participants who were known positives and repeated tests on 8 participants who had been tested in the last twelve months.

Within the pharmacist-led pathway, 94 DBST were obtained from 262 patients in receipt of OST (36%). Of these, 26 new reactive tests and 54 new negative tests were identified. The pharmacists also tested 4 participants who were known positives and repeated tests on 10 participants who had been tested in the previous twelve months. The difference between these variables was significant ( $p < 0.003$ ). Participants in the pharmacist-led pathway were more likely to take a DBST.

Variability in uptake of testing per site was also assessed to evaluate the relationship between number of tests and numbers of OST patients attending each pharmacy (Table 3). A significant difference was identified between pharmacies in the conventional pathway ( $p < 0.002$ ). A significant difference was also identified between pharmacies in the pharmacist-led pathway ( $p < 0.00002$ ). The uptake of testing of OST patients was therefore shown to vary significantly between different pharmacies participating in the trial in both pathways.

#### Outcomes from testing and treatment:

When a DBST was found to be reactive, participants had either to attend an appointed clinic in the conventional pathway or attend a local phlebotomy service in the pharmacist-led pathway (Table 2). Of the participants referred through the conventional pathway, six from fifteen patients attended at clinic for assessment (27%). Of the participants assessed for treatment in the pharmacist-led pathway, twenty from twenty six patients attended for assessment blood tests (77%). A Chi Square test of independence was performed to examine the relationship between numbers of participants proceeding through the assessment for treatment. The difference between these variables was significant ( $p < 0.002$ ). Participants in the pharmacist-led pathway were more likely to proceed through the assessment for treatment. Of note, a larger number of genotype 3 patients were seen in the pharmacist-led arm, than the conventional pathway arm (7 versus 1), and these patients were therefore unable to proceed to treatment in this study.

In this study, one participant completed treatment through the conventional pathway and three patients completed treatment through the pharmacist-led pathway. A number of reasons for exclusion from treatment were responsible for patient attrition from the

pathways, including spontaneous clearance of HCV and identification of a genotype 3 HCV infection. A flow chart of patient disposal is presented in Figure 1

#### Process evaluation

Interviews were held with participants who had either completed the pathway or who had tested positive but not yet attended for assessment blood tests. Examples of quotations are set out in Figure 2.

##### *How did participants feel about treatment in pharmacies?*

The transcripts of participant interviews demonstrated positive perceptions of treatment in pharmacies. Interviewees clearly thought that pharmacies were a good place to receive care and valued the positive relationships built with pharmacy staff. Lack of money meant travelling to a local hospital was a barrier to clinic attendance. Pharmacies however were viewed as part of the local community. Participants were apprehensive about experiencing stigma and discrimination if people knew of their HCV infection.

Participants noted that treatment with DAAs initially made them feel sick and tired, although this quickly faded. On completion of the course of treatment participants expressed positive views about their future and described plans to move their life on.

##### *What feedback on implementation was received from staff?*

Interviews were held with a member of staff from each pharmacy in both pathways. Both pharmacists and pharmacy support staff were interviewed. Examples of quotations are found in Figure 2.

Staff interviewees had clear views about what factors led to successful implementation. Staff considered that strong leadership and involving all the pharmacy team were necessary prerequisites for success. The intervention was less successful in areas where this was lacking. The degree of enthusiasm for new roles and positive relationships with patients were also important. Where the testing and treatment service was seen as the sole responsibility of the pharmacist, the pharmacies managed to complete fewer tests. Pharmacist availability was a limiting factor where this occurred. Less tests were completed in pharmacies where the staff felt under pressure because of dispensing work load. Where the service was seen as a team responsibility, the service was more successful and the intervention was able to cover a greater number of patients. Positive relationships with patients were a key factor. Where these relationships were weaker, the acceptance of testing and the progress into treatment was less successful. In pharmacies with strong patient relationships, the service was seen as part of the range of ways that the health of the

patients was improved. There were some initial anxieties expressed about potential contact with infected blood, but respondents said that these fears soon faded. The patient assessment was felt to be straightforward and easy to accomplish.

Staff appreciated that participants often needed time to come around to the idea of being tested and entering treatment. The need for off-site phlebotomy was recognised as a weakness in the care pathway.

#### Resource utilisation of conventional and pharmacist-led pathways

The different levels of input and intervention in the conventional and pharmacist-led pathways are demonstrated in Figure 3. The total cost of the conventional Pathway was estimated at £933 (£643 service cost, £290 monitoring cost), and the cost of the Pharmacy Pathway was estimated £238 (£143 service cost, £95 monitoring cost) (Table 4). Therefore, utilising solely the pathway costs, the difference in the cost per patient was £695 (£499 service cost, £195 monitoring cost). The costs associated with the pharmacy setting are around one quarter of the cost of treating a patient in a conventional setting (assuming the same cost of DAA treatment). In terms of staff capacity, the pharmacy pathway model uses four hours less service resources than the conventional pathway (6.66 hours with conventional pathway versus 2.66 hours with pharmacy pathway).

## Discussion

### Main study findings

This feasibility study provides evidence that community pharmacies can successfully provide DBST to patients attending for OST and that progression to treatment is feasible. More participants accepted a DBST in a pharmacist-led pathway than in the conventional pathway, where there was no requirement to attend a hospital clinic for treatment. Interviews with participants identified a number of explanatory factors for this. This study found that more participants undertook assessment for treatment in the pharmacist led pathway, where the care pathway was delivered entirely in the pharmacy. Both patient and staff experiences and views demonstrated how the pharmacist-led pathway overcame some of the barriers that prevent people prescribed OST accessing testing and treatment.

### Strengths and weaknesses of the study

The criteria set out for evaluating the success of the feasibility trial included whether people who receive OST for pharmacies could be recruited to the study; whether pharmacies could successfully complete all elements of the testing and treatment pathway; which elements of the pathway work well and which elements are less successful; to make an estimate of the

effect size in terms of how many participants complete each stage of the pathway (Arain 2010). The study has provided evidence that these criteria can be met: OST patients can be recruited and pharmacies can guide patients through all stages of the pharmacist-led pathway.

The need to attend for off-site phlebotomy led to some loss of potential patients in the pharmacist-led pathway and this weakness should be addressed in the design of the final pathway for full trial, with perhaps the inclusion of peripatetic phlebotomy services visiting pharmacies. This study demonstrated that three participants could access treatment in the pharmacist led pathway compared to one participant in the conventional pathway. However, a series of further aspects also provide encouragement that a significant effect size is present, including the reduced losses at clinic attendance stage in the pharmacist-led arm. Notably, demonstration of a larger effect size in the pharmacist-led arm was impaired because of a larger proportion of patients spontaneously clearing infection and a great number of genotype 3 patients being identified in this arm, which at the time of the study could not be treated with interferon free regimens.

Some variation in uptake was observed between pharmacies in both pathways. Additional factors may explain this variation, such as the degree of enthusiasm of the pharmacy staff for new roles, the relative burden of dispensing workload in the pharmacy and the leadership shown by the pharmacist. This variance may be addressed through growing acceptance of this service as part of what a pharmacy should offer.

A further limitation is the access of pharmacies to electronic laboratory results services. Although, these are now being implemented into pharmacies in some areas, this resource is not yet widely available. The consequence of this, as identified in this study, was that some patients received duplicate blood tests. Additional variables such as length of time of OST and the dispersal of co-morbidities and BBV co-infection may also act as confounders. The use of pharmacies as study sites precluded assessment of medical notes to assess these factors systematically, but the DBST taken from clients assessed Hepatitis B and HIV co-infection, as well as HCV. The exclusion criteria for the study required that such patients were directly referred to the standard care pathway. A further large scale study is now being implemented to fully assess the potential of this pathway.

### Interpretation of findings

Previous pilot work from this programme has explored the context for delivery and the mechanisms that may lie behind the outcomes observed (Radley, 2017). Contextual factors have previously been identified by other authors, including: expectations and experiences of

stigma and discrimination; fears about confidentiality; the limited horizons of people receiving OST and the poverty they experience (Harris et al 2013, Wade et al 2016). Identified mechanisms that may influence uptake included the presence of established relationships with pharmacy staff; a pre-existing reason for attending the pharmacy for OST and the proximity of the pharmacy within the local community. The work undertaken in this study, has confirmed that the local nature of the pharmacy and the pre-existing reasons for attendance are key mechanisms in recruitment for testing and that good quality relationships between pharmacy staff and participants, supports recruitment (Edlin et al 2005). The barriers to completion of either of the care pathways were also confirmed: that participant may be anxious about what the results might mean for them, or mistrustful of the way they might be treated. Although the pharmacies provided a familiar environment within their local community, hospitals represented an unfamiliar setting. The health literacy required to navigate the journey from the participant's normal setting to attend multiple hospital-based appointments was a significant barrier (Arora et al 2011). For the pharmacist-led arm of the study, even the attendance at an external venue for a single phlebotomy appointment was a significant barrier, leading to patient loss from the pathway.

Treatment pathways that increase access and uptake of treatment of DAAs are required. Uptake of testing and treatment is currently low (Weissing, et al, 2014) and authors across the world have identified many common barriers that must be overcome by potential patients to treat the HCV infection (Wade et al 2016, Konerman and Lok, 2016)). There are identified deficiencies in the amount of screening and diagnosis undertaken for at-risk populations, as well as improvements required in access to treatment initiation and clinical monitoring (Artenie et al, 2015): The infrastructure to deliver sufficient treatment to enable eradication is not generally available or of sufficient scale (Leask and Dillon, 2016). People who inject drugs may find it difficult to consistently attend the medical clinics that are the mainstay of standard of care (Papatheodoridis et al, 2016). Delaying treatment because of funding problems risks patients being lost to follow-up (Fox and McCombe, 2016).

Creating the complex interventions necessary to eliminate HCV requires that well-designed cross-disciplinary programmes are put in place (Suther and Harries, 2016) using a variety of strategies to increase screening, testing and diagnosis (Brouard et al, 2015). The delivery of HCV testing and treatment through community-based care pathways has been shown to be feasible (Coats and Dillon, 2015).

There have been a number of different routes chosen to provide primary care-based treatment pathways. A targeted general practice-based screening intervention has been recommended, since low diagnostic yields limited the effectiveness of non-targeted

approaches (Anderson et al, 2009). Current work aims to produce a scalable general practice model (Roberts et al, 2016). Community-based, nurse-led care for HCV has shown been shown to be effective (Wade et al, 2015). The change away from interferon-based regimes should improve the proportion of people who are willing to undertake treatment (Lewis et al, 2016).

As well as the benefits that arise from harnessing the established OST care system already implemented in the pharmacy, such as improved regime adherence, there are further benefits gained through developing a new pathway designed to take advantage of DBST and the reduced burden of DAA treatment. The lower cost of primary care premises compared to hospital clinics as well as the simplified testing and monitoring requirements, is responsible for the lower estimated cost of the pharmacist-led pathway. These lower costs are likely to prove favourable even if current hospital-based standard of care pathways are also simplified and made more efficient. Although the conventional care pathway reported in this study required twelve attendances to complete treatment, other authors have reported pathways with up to eighteen stages (Arora 2011) With current pathways, the use of DAAs is cost-effective at all stages of liver disease (Leidner et al, 2015, Liu et al, 2012). With primary care based care pathways capable of recruiting greater numbers of people with HCV infection, cost-effectiveness of these medicines may increase further (Bennett et al, 2016). A coordinated programme delivered through a managed care network has increased the numbers of people accessing treatment and shortened the time for people with HCV infection to achieve an SVR (Tait et al, 2016). A multi-disciplinary approach to care has been demonstrated to improve care.

## **Conclusions**

This feasibility study provides further evidence that service users prescribed OST can access testing and treatment through a pharmacy. Use of a pharmacist-led pathway may remove some of the barriers that prevent OST patients accessing testing and treatment through conventional pathways.

A number of the identified barriers to the uptake of testing in this study were overcome through the local availability of the pharmacies and positive relationships with pharmacy staff. The use of community pharmacy delivered care has the potential to contribute to elimination of HCV in the United Kingdom. Further work to evaluate the outcomes associated with this service configuration is now on-going (NHS Research Authority, 2016).

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Reporting Guideline: Consort 2010 statement: extension to randomised pilot and feasibility trials <http://www.bmj.com/content/355/bmj.i5239.full>

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Contributor Statement:

AR: study conception, planning and design, protocol preparation, analysis and interpretation of data, manuscript preparation.

JT: acquisition of testing data, analysis of testing data, manuscript preparation

JFD: study conception and design, protocol preparation, manuscript preparation

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Mr Radley: Honorarium from Gilead and Research Grants from Gilead and Roche

Ms Tait: Honorariums and sponsorship from Abbvie, Bristol Myers Squibb, Gilead, Janssen, Merck Roche Sharp & Dohme and Roche

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Table 1: Baseline characteristics of trial population by group allocation

Characteristic	Conventional pathway (%)	Pharmacist-led Pathway	
Participants (n)	244	262	
Male	165 (68)	167 (64)	
Female	79 (32)	95 (36)	<i>p</i> =0.358
<b>Age (years)</b>			
20-24	3 (1)	7 (3)	
25-29	22 (9)	40 (15)	
30-34	65 (27)	64 (24)	
35-39	56 (23)	55(21)	
40-44	44 (18)	55(21)	
45-49	36 (15)	26(10)	
50-54	14 (6)	8(3)	
55-59	4 (2)	4(2)	
60-64	0	2(1)	
65-69	0	1	<i>p</i> =0.100
<b>Hepatitis C Status</b>			
Continued Follow-Up in Treatment	34 (14)	32 (12)	
Previous SVR Completed Treatment	20 (8)	21 (8)	
Last Test Negative	89 (36)	90 (34)	
No Record of Previous Test	80 (33)	95 (36)	
Referral, Did Not Attend	4 (2)	10 (4)	
Attended, Did Not Complete	14 (6)	14 (5)	<i>p</i> =0.622
Positive Test, No Referral	3 (1)	0	-

Table 2: Participant Flow and outcomes

Population

Pool of 2,200 patients in Tayside receiving OST

Cohort

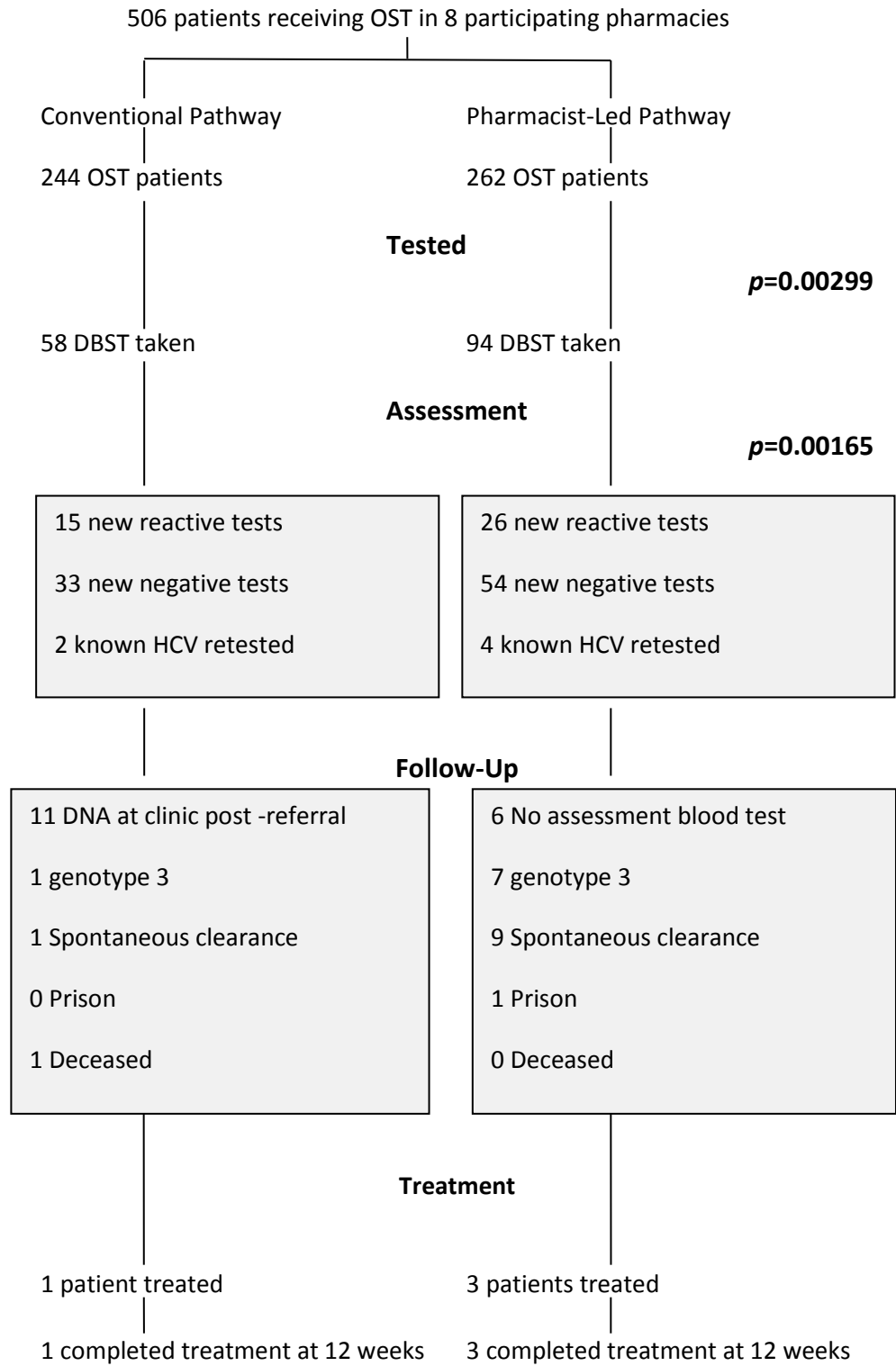




Table 3 Patient Outcomes – Uptake of testing and treatment by pharmacy site

Site	No. Patients	No record of previous test	DBST (%)	Known positives	Repeat test	New positives	New negatives
1	68	25	11 (16)	0	0	0	11
2	76	26	21(28)	2	2	7	10
3.	62	19	9(15)	0	3	2	4
4.	38	10	17(45)	0	3	6	8
<b>Totals</b>	244	80	58(24)	2	8	15	33
5	84	39	43 (51)	1	1	10	31
6	51	19	7(14)	0	0	2	5
7	86	21	20(23)	3	6	5	6
8	41	16	24(59)	0	3	9	12
<b>Totals</b>	262	95	94(36)	4	10	26	54



Figure 1: Percent Attrition of Patients with Reactive Tests for Conventional and Pharmacist-Led Pathways

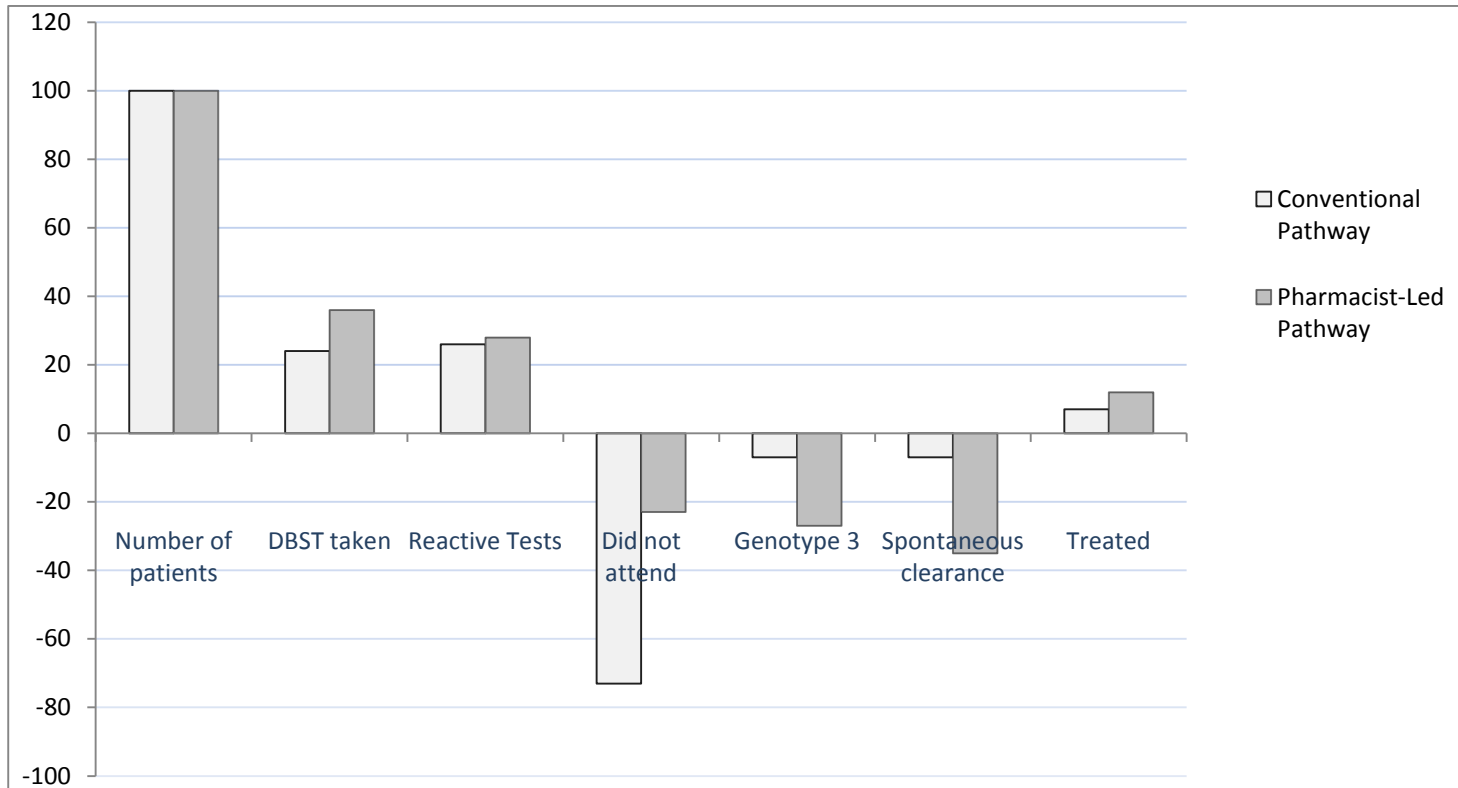


Figure 2: Examples of quotations from service users and staff participants

<b>Service Users</b>
<p><b>How did Hepatitis C affect your life?</b></p> <p><i>“I already knew I had Hepatitis C, I got diagnosed with it more than 10 years ago. I had always been waiting for the time ... my life just never seemed to get to a point where it was stable enough to do it”</i> <b>Participant 1, male</b></p> <p><i>“A couple of years ago I said to one of my pals there wus somethin’ wrang wi’ us, I was just tired, no strength to go any place”</i> <b>Participant 2, female</b></p> <p><b>What was your experience of treatment in the pharmacy?</b></p> <p><i>“I recognise that this is a big plus, being able to get a tablet every day at the chemist is so ease, so convenient”.</i> <b>Participant 4, male</b></p> <p><i>“When you got to the hospital sometimes you feel like you are being treated differently and I just found that in here(in the pharmacy) it was a more warmer environment and friendly”</i> <b>Participant 6 male</b></p> <p><b>Has completing treatment made any differences to you?</b></p> <p><i>“But I honestly feel different; I feel like my old self ken, I feel better”</i> <b>Participant 1, male</b></p> <p><i>“Going forward now it more just that, eh I want to go back to college and get into youth work if I can. I have a prospectus as home, so my future .. what I see is me hopefully doing something along lines”.</i> <b>Participant 2, Female</b></p>
<b>Staff</b>
<p><b>How did you feel about taking part in the study?</b></p> <p><i>“I was quite excited about it, quite looking forward to doing it, it was something quite different for pharmacies to do, we would get more involved with the methadone patients, so I was very interested and keen for it”.</i> <b>Staff Member 7, Female</b></p> <p><b>How did you manage the participants and help them to complete the pathway?</b></p> <p><i>“you build up your conversations and your style of conversations, the more you gain in confidence, the better the client feels and they also like to understand that we are learning and developing with them, they like to feel part of something too”.</i> <b>Staff member 3, Female</b></p> <p><i>“We did try quite a few times to get him to go but he kept said he would be going, in fact I think once he said he had gone but he wasn’t able to get tested, but I don’t know if that’s true or not”.</i> <b>Staff Member 5, Male</b></p>

Figure 3: Conventional and Pharmacist-Led Pathways

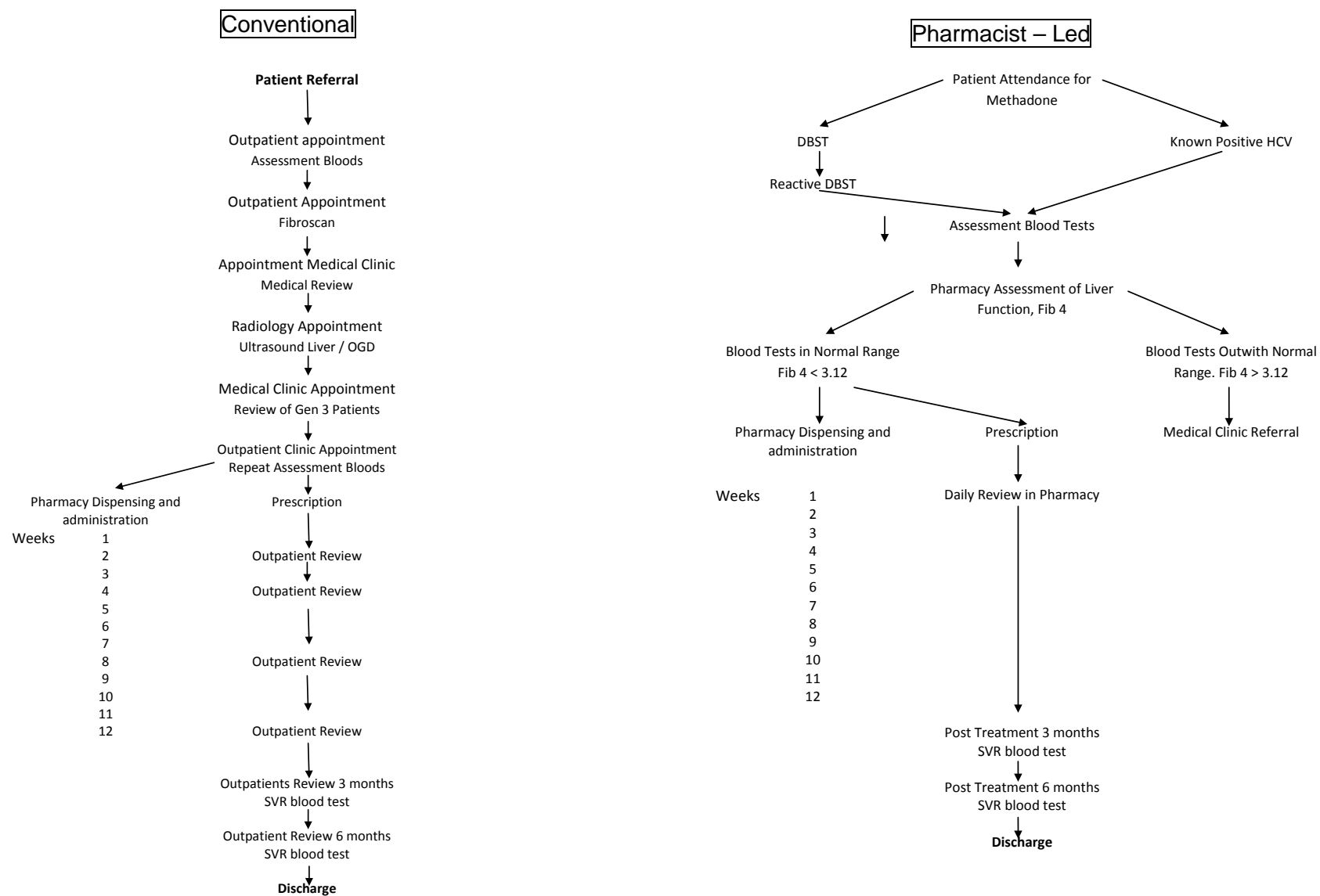


Table 4: Monitoring costs and service costs

Conventional Pathway Costing Results

Stage	Reason	Activity (Estimated Staff Time hrs)	Cost (per activity)
1	Dried Blood Spot Test	Specialist Nurse (0.33)	£41
		Dried Blood Spot Test	£40
2	Outpatient appointment	Specialist Nurse (0.66)	£83
		Liver Panel	£5
3	Outpatient Appointment	Ultrasonographer (0.5)	£20
		Fibroscan	£55
4	Appointment Medical Clinic	Consultant (0.5)	£69
		Liver Panel	£5
5	Radiology Appointment	Ultrasonographer (0.5)	£20
		Ultrasound Liver	£63
6	Medical Clinic Appointment	Consultant / Registrar (0.33)	£24
7	Outpatient Clinic Appointment	Specialist Nurse (0.5)	£63
		Liver Panel	£5
8	Prescription	Pharmacist Prescriber (8a) (0.5)	£36
9	Outpatient Review	Specialist Nurse (0.33)	£41
		Liver Panel	£5
10	Outpatient Review	Specialist Nurse(0.33)	£41
		Liver Panel	£5
11	Outpatient Review	Specialist Nurse (0.33)	£41
		Liver Panel	£5
12	Outpatient Review	Specialist Nurse (0.33)	£41
		Liver Panel	£5
13	Outpatient Review	Specialist Nurse (0.33)	£41
		SVR	£50
14	Outpatient Review	Specialist Nurse (0.33)	£41
		SVR	£5-
15	Discharge	Specialist Nurse (0.33)	£41
Total Pathway Cost			£933
Service Cost			£643
Testing Cost			£290

Pharmacy Pathway Costing Results

Stage	Reason	Activity (Estimated Staff Time hrs)	Cost (per activity)
1	Pharmacy Attendance for Methadone	Pharmacist (0.33)	£17
2	Dried Blood Spot Test in Pharmacy	Pharmacy Assistant (0.33)	£3
		Dried Blood Spot Test	£40
3	Assessment Blood Tests	Specialist Nurse (0.33)	£25
		Liver Panel	£5
4	Patient Assessment in Pharmacy	Pharmacist (0.5)	£25
5	Prescription	Pharmacist Prescriber (band 8a) (0.5)	£25
6	Outpatient Review (SVR test)	Specialist Nurse (0.33)	£25
		SVR	£50
7	Discharge from Service	Specialist Nurse (0.33)	£25
Total Pathway Cost			£238
Staff Cost			£143
Testing Cost			£95