

## **Reengaging patients with previously diagnosed Hepatitis C in to care**

<b>Running title:</b>	<b>Reengaging patients with previously diagnosed Hepatitis C in to care</b>
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<b>Sponsor:</b>	<b>NHS Greater Glasgow &amp; Clyde</b>
<b>Funder:</b>	<b>Health Protection Scotland</b>

This study will be performed according to the UK Policy for Health and Social Care Research (March 2018) and WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI Ethical Principles for Medical Research Involving Human Subjects 1964 (as amended).

## **Reengaging patients with previously diagnosed Hepatitis C in to care:**

### **Background:**

Greater Glasgow and Clyde has a large number of patients who have previously been in contact with hepatitis C services, but failed to engage with treatment.

New direct acting antivirals allow for all patients to be treated with interferon free regimens with high rates of sustained viral response (SVR), which is associated with a reduction in liver and all cause mortality.

Little is known about the most effective way to re-engage patients who are lost to follow up. Anecdotally colleagues in other health boards have found phone calls more effective than letters. It is unclear whether these anecdotal results can be generalised to a large health board, where there are a larger cohort of staff involved in HCV care, and it is unlikely to be feasible for every patient to be called by someone who has previously seen them. In other health care settings the use of incentives has been used to improve engagement, and this is currently being evaluated in Glasgow in the context of HIV testing uptake amongst a cohort of people who use drugs in Glasgow city centre. Historically lost to follow up patients in GG&C have been sent letters inviting them to make an appointment at several points in the past (as standard care). However these efforts took place prior to the availability of more effective treatments, and unfortunately the outcomes were not robustly recorded.

The Scottish HCV clinical database is a public health surveillance system, that is coordinated and funded by Health Protection Scotland (HPS) on behalf of Scottish Government for the Sexual Health and BBV Framework. The establishment of this system received ethics approval and patients are informed and can opt out if they don't wish their data to be included.

### **Aims:**

To evaluate the impact of a letter, phone call and incentive in re-engaging patients with hepatitis C care.

### **Outcomes of interest:**

#### **Primary outcome of interest:**

- Attendance for assessment of liver disease within 4 months of being sent invitation letter.

#### **Secondary outcomes of interest:**

- Commencing treatment within 6 months of being sent invitation letter.

**Methods:**

**Patient identification:**

The local copy of the Scottish Hepatitis C database holds data regarding patients referred to secondary care for treatment of their hepatitis C, and holds ethics approval for research on treatment and patient outcomes. This will be used to identify patients with hepatitis C infection that is untreated, treatment has been unsuccessful, or the patient has been treated but the outcome is unknown (due to non attendance for blood tests). The database has been cross checked with virus lab results, to ensure infection status is up to date. Finally, the patient data has been checked by NHS GG&C information team, to exclude patients who are deceased, or whom are no longer resident in NHS greater Glasgow and Clyde based on updated details obtained from SCiStore.

**Inclusion criteria:**

Patients (16 years and over) who have previously engaged with Hepatitis C services in Glasgow but who are either untreated, have been treated unsuccessfully, or have been treated but have not attended for blood tests to check for treatment success.

**Exclusion criteria:**

Patients with HIV.

Patients no longer resident within NHS Greater Glasgow and Clyde area.

**Allocation to contact groups:**

Patients will be randomly distributed into 3 groups:

- 1) Letter: Will be sent letter 1 (appendix)
- 2) Letter plus telephone call: will be sent letter 2 (appendix) and be followed up with a telephone call from the treatment centre if no contact has been received after 4 weeks
- 3) Letter plus incentive: will be sent letter 3 (appendix)

**Process:**

Patient letters will be sent out by GG&C public health.

For all 3 groups the letter will be sent with the small Hepatitis C Scotland booklet "Hepatitis C treatments have changed".

Letters will identify include the telephone number for the identified treatment centre which will be either, the last known treatment centre or a more local treatment centre were appropriate based on current residence.

Each treatment centre will be given access to an excel spreadsheet containing the list of patients sent letters and which group they are in. This will be password protected and stored on a secure shared drive on the NHS GG&C server.

Each centre will update the spreadsheet if a patient makes a call and if an appointment is made. They will also update the spreadsheet if the patient attends. Data on whether the patient commences treatment will be obtained from the HCV Database.

For the group in the phone call evaluation, the centre will be asked to make an attempt to call the patient if there has not been a response between week 4 and 6 after the letter is sent out. 2 attempts will be made on separate days. If there is no response then and the number has an answerphone, then a message will be left saying "This is the [name of hospital] phoning, we wrote to try and arrange a clinic appointment with you, please phone us back on [unit phone number] to make an appointment".

The outcome of this attempt will include whether the phone number recorded in the patient's electronic record was valid, whether contact was made with the patient and as for other groups. whether the patient made an appointment.

For the group in the incentive arm, along with the letter, a colourful A5 flyer will be included (appendix) that will explain what "love2shop vouchers" are, and how they will get them. For patients in group 3, the clinic staff will provide the £20 vouchers when patient attends for assessment. These will be bought by funds from Health Protection Scotland and distributed to the treatment centres by Public Health.

### **Analysis:**

Data on intervention group and response to the letter will be amalgamated into a single spreadsheet containing all centres. Patients details will be used to create a standard linkage identifier and forwarded to Health Protection Scotland, as per current standard information governance around the database. HPS will link the data with HCV database information on baseline characteristics, analysis will be performed by Health Protection Scotland staff with appropriate information governance training required for this role.

Impact of telephone call and incentive on the primary and secondary outcomes will be analysed on univariate and multivariate analysis. Factors considered in the analysis will include: age, gender, former maximal alcohol intake, risk category for infection, presence of cirrhosis, previous treatment, previous hospitalisation episodes, and treatment centre.

### **Power and sample size:**

The samples size is estimated as 1000 patients. This is the number of patients with NHS Greater Glasgow and Clyde known to have HCV but who have been lost to care. No power calculation has

been used. All eligible patients will be contracted as it was considered , given the availability of new treatments, that it would not be ethical to not contact patients who may be eligible for treatment with these.

### **Definition of end of trial**

The study will end when the last patient completes their last study visit

### **Protocol amendments:**

Any change in the study protocol will require an amendment. Any proposed protocol amendments will be initiated by the CI following discussion with the Sponsor and any required amendment forms will be submitted to the ethics committee and sponsor. The CI will liaise with study sponsor to determine whether an amendment is non-substantial or substantial. Before the amended protocol can be implemented favourable opinion/approval must be sought from the original reviewing REC and Research and Development (R&D) office(s).

### **Insurance and indemnity:**

This study is sponsored by NHS Greater Glasgow & Clyde. The sponsor will be liable for negligent harm caused by the design of the trial. NHS indemnity is provided under the Clinical Negligence and Other Risks Indemnity Scheme (CNORIS).

The NHS has a duty of care to patients treated, whether or not the patient is taking part in a clinical trial, and the NHS remains liable for clinical negligence and other negligent harm to patients under its duty of care.

### **Funding:**

Funding for the study is being provided by Health Protection Scotland .



Letter 1:

Date

Dear x,

We are writing as you've previously been referred for consideration of treatment for Hepatitis C.

The good news is that hepatitis C is now easy to cure with a short course of once a day tablets, with none of the side effects of older treatments. We know that treated patients feel better and have fewer health problems.

**We'd like you to telephone us on xxxx xxx xxxx to book an appointment to arrange your treatment.** If you get the answerphone please leave your name, date of birth and a contact number and we'll phone you back.

If it's easier to attend another hospital, or one of our community treatment clinics, then we can arrange this for you too.

If you have had treatment elsewhere then please phone us so we can update your records.

Yours Sincerely

Dr x

Hospital

Letter 2:

Date

Dear x,

We are writing as you've previously been referred for consideration of treatment for Hepatitis C.

The good news is that hepatitis C is now easy to cure with a short course of once a day tablets, with none of the side effects of older treatments. We know that treated patients feel better and have fewer health problems.

**We'd like you to telephone us on xxxx xxx xxxx to book an appointment to arrange your treatment.** If you get the answerphone please leave your name, date of birth and a contact number and we'll phone you back.

If it's easier to attend another hospital, or one of our community treatment clinics, then we can arrange this for you too.

If you have had treatment elsewhere then please phone us so we can update your records.

If we don't hear from you after 4 weeks then we will try to contact you by phone to arrange an appointment– if you'd prefer we didn't, then please telephone us on the number above.

Yours Sincerely

Dr x

Hospital



Letter 3:

Date

Dear x,

We are writing as you've previously been referred for consideration of treatment for Hepatitis C.

The good news is that hepatitis C is now easy to cure with a short course of once a day tablets, with none of the side effects of older treatments. We know that treated patients feel better and have fewer health problems.

We know it can be tricky to prioritise hospital appointments if you're feeling well, so we'd like to **offer you a £20 Love2shop voucher** if you call us to make an appointment in the next 4 weeks and then keep your appointment.

Please telephone us on xxx xxx xxx to book an appointment to arrange your treatment.

If you get the answerphone please leave your name, date of birth and a contact number and we'll phone you back. You'll receive your voucher when you attend.

If it's easier to attend another hospital, or one of our community treatment clinics, then we can arrange this for you too.

If you have had treatment elsewhere then please phone us so we can update your records.

Yours Sincerely

Dr x

Hospital

£20 worth of Love2Shop vouchers are yours!



**When you call us to make an appointment in the next 4 weeks and then keep your appointment.**

Love2shop Vouchers are the UK's leading multi-retailer gift voucher. They can be redeemed in over 20,000 stores, restaurants and attractions, with over 150 top brands to choose from such as Argos, Boots, Debenhams, Halfords, HMV, Iceland, Matalan, Mothercare, New Look, PizzaExpress, River Island and TK Maxx. New brands added in 2018 include Topshop, Topman, Burton, Dorothy Perkins, Miss Selfridge, Evans, Outfit and Wallis.