

## Supplementary information

### Appendix A: Study Information Letter



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«Title» «GP\_First\_Name» «GP\_Last\_Name»  
«GP\_Location»  
«GP\_Business\_Address»  
«City» «State» «Post\_Code»

«Date»

Dear «Title» «GP\_Last\_Name»,

#### Re: Pilot project of active hepatitis C case management for new notifications in Tasmania

The simplicity of new treatments for hepatitis C make it possible for Australia to become one of the first countries to eliminate hepatitis C. **Despite the new treatments becoming available on the Pharmaceutical Benefits Scheme in 2016, half of Australians living with hepatitis C remain untreated<sup>1</sup>.**

In accordance with Guidelines under the *Public Health Act 1997*, hepatitis C is a notifiable condition to the Director of Public Health. Public Health Services (Department of Health (DoH), Tasmania) and the Burnet Institute (Melbourne) are conducting a pilot project to determine if a new model of engaging General Practitioners (GPs) who provide care for diagnosed patients will increase treatment uptake (University of Tasmania HREC H0018418).

The project compares current DoH processes following a notification of hepatitis C (standard of care) with active engagement of GPs to provide enhanced case management (new model of care). All GPs in Tasmania who have diagnosed hepatitis C during the study period will be eligible to participate in the project and will be randomly assigned to either the new or standard model of care. This new model will be delivered by a DoH Clinical Nurse Consultant (CNC) who will contact the diagnosing doctor by phone and provide support, as needed, to facilitate hepatitis C pre-treatment testing, treatment, and post-curative support. The Clinical Nurse Consultant will also offer direct patient contact if requested by the GP. A follow-up evaluation phone call will be made to all participating GPs twelve weeks after the initial hepatitis C notification to assess whether enhanced case management results in increased uptake of hepatitis C treatment.

DoH records indicate that you recently requested testing that has resulted in a hepatitis C notification and you have been randomised to participate in the **new model/standard model of care**.

Our CNC Rachel Barter will contact you soon to invite you to participate in this project which we hope you will consider. Verbal consent will be sought on initial phone contact by Rachel. Your involvement will contribute to

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<sup>1</sup> Burnet Institute and Kirby Institute. Australia's progress towards hepatitis C elimination: annual report 2019. Melbourne: Burnet Institute; 2019.

a rigorous evidence base for future practice, improve the opportunity for Tasmanians living with hepatitis C to be cured and assist us achieve our hepatitis C elimination goal.

If you wish to talk to Rachel Barter beforehand, please contact her on 6166 0634 or [rachel.barter@health.tas.gov.au](mailto:rachel.barter@health.tas.gov.au).

Yours sincerely,

**Dr. Mark Veitch**  
Director, Public Health  
Tasmanian Director of Public Health

**Dr. Joseph Doyle MPH PhD FRACP FAFPHM**  
Infectious Diseases Physician  
Deputy Director, Disease Elimination Program  
Burnet Institute

## Appendix B: GP questionnaire

This is the GP Form which will collect data on the GP and will randomise the GP using the REDCap tool online. This needs to be filled in only once for every GP.

A randomised controlled trial of active case management to link hepatitis C notifications to hepatitis C treatment in Tasmania  
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## GP Form

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GP ID (REDCap assigned) \_\_\_\_\_

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GP ID\_TNDD (as assigned by TNDD) \_\_\_\_\_

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Name of GP \_\_\_\_\_

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What is the postcode of the clinic where this GP works? \_\_\_\_\_

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Alternative postcode \_\_\_\_\_

---

**Please provide some information for GP ID [record\_id]**

Please confirm that all eligibility criteria for GP have been met ☐ Yes  
☐ No

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Group to which GP has been randomised ☐ Standard of Care  
☐ Intervention

---

Has GP been reached yet? ☐ Yes  
☐ No

---

Please confirm that GP consents to participate in the study ☐ Yes  
☐ No

---

Please close this form and do not use this GP ID anymore.

---

Please provide reason why GP is not willing to consent 
☐ Time constraints  
☐ Privacy issues  
☐ Know enough about HCV  
☐ Patient already referred to a specialist  
☐ Patient no longer attends practice, transferred  
☐ Patient is lost to follow up  
☐ Declined to give a reason  
☐ Other

---

Please specify 'other' \_\_\_\_\_

---


Does GP have previous experience in HCV care? ☐ Yes  
☐ No

---

Have you ever written a DAA script? ☐ Yes  
☐ No

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Please close this form and do not use this GP ID anymore.

Has the GP been reached at the 12 week evaluation phone call?

☐ Yes

☐ No

Is GP lost to follow up? (after 3 contact attempts over a 30-day window)

☐ Yes

☐ No

Number of HCV notifications associated with GP?

☐ One

☐ Two


☐ Three

☐ Four

☐ Five

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## Appendix C: Notification questionnaire

This is the Notification form, which will record information about each eligible Notification GPs can have multiple notification during the study period.

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*A randomised controlled trial of active case management to link hepatitis C notifications to hepatitis C treatment in Tasmania*  
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### Notification form

GP ID (REDCap assigned) \_\_\_\_\_

**This is the Notification form, which will record information about the eligible Notification. GP: [record\_id], [gp\_name] Arm: [treat] GP consent: [gp\_consent] Please only fill in Notifications Forms if GP has consented to participate in our study! This needs to be specified in the GP Form**

Enter Notification ID \_\_\_\_\_

Enter Resident (Patient) ID \_\_\_\_\_

WARNING: Notification ID cannot be the same as Patient ID.

What is the lab notification received date on the notification? \_\_\_\_\_

Is this notification a confirmed or repeat notification?

☐ Confirmed (Ab+)  
☐ Confirmed (PCR+)  
☐ Repeat (Ab+)  
☐ Repeat (PCR+)

WARNING: Since this notification is a [notification], please check whether patient [patient\_id] has already enrolled in the study with another notification.

☐ No, patient [patient\_id] is new to the study  
☐ Yes, patient [patient\_id] has already enrolled in our study with same GP [gp\_name]  
☐ Yes, patient [patient\_id] has already enrolled in our study with DIFFERENT GP

Is there a related Notification ID to this [notification] notification?

☐ Yes  
☐ No

What kind of notification is the related Notification ID?

☐ Confirmed PCR+  
☐ Repeat Ab+  
☐ Repeat PCR+  
☐ Confirmed Ab+

Enter related [related\_id\_2] Notification ID \_\_\_\_\_

WARNING: The related notification ID cannot be the same as the current notification ID.

WARNING: The related notification ID cannot be the same as the patient ID.

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What is the date of the related notification? \_\_\_\_\_

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Is GP same for [related\_id\_2] Notification ID [related\_id\_3]? ☐ Yes ☐ No

---

Is the other GP participating in this study? ☐ Yes ☐ No

---

Enter GP ID \_\_\_\_\_

---

WARNING: same ID as GP ID.

---

**1. Clinical summary for Notification ID [notification\_id]**

**Please fill in at time of lab notification received date: [lab\_date]**

	detected	not detected	not tested	testing to follow (test ordered)	Unknown
Hepatitis C Antibody (Anti-HCV)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hepatitis C Virus by Nucleic Acid Testing (PCR or HCV RNA)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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WARNING: This combination is not correct.

---

What is RNA test date on the notification? \_\_\_\_\_

(Note that for a repeat PCR the lab date is the same as the RNA date)

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**2. Enhanced Form**

**For Confirmed (Ab+) notifications only**

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Has enhanced form been sent back by GP? ☐ Yes ☐ No ☐ Unknown ☐ N/A

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What is the Enhanced Form date (date reviewed by DoH)? \_\_\_\_\_


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Has this person had a negative hepatitis C antibody test within the past 24 months? ☐ No ☐ Yes ☐ Unknown

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Date of last negative test \_\_\_\_\_

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Confirmation that this infection was notified previously Interstate and to the National Notifiable Diseases Surveillance System? ☐ Yes, record as Previously Notified Interstate  
☐ No, Confirmation Status remains Confirmed

---

**Has patient had any of the following risk exposures (please tick all options that apply for each risk exposure)**

	Yes (within last 2 years)	Yes (over 2 years ago)	No	Unknown
Injecting drug use	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Imprisonment	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sexual partner of opposite sex with HCV	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sexual partner of same sex with HCV	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Household contact with HCV	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Perinatal transmission	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Tattoos	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Acupuncture	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ear or body piercing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Occupational needlestick/biohazard injury in non- healthcare worker	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Non-occupational needlestick/biohazard injury (other than IDU)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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**3. Patient information of Patient [patient\_id]**

Age \_\_\_\_\_

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Gender ☐ Male  
☐ Female  
☐ Other  
☐ Unknown

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In which LGA does the patient live?	<input type="radio"/> Break O'Day <input type="radio"/> Brighton <input type="radio"/> Burnie <input type="radio"/> Central Highlands <input type="radio"/> Central Coast <input type="radio"/> Circular Head <input type="radio"/> Clarence <input type="radio"/> Derwent Valley <input type="radio"/> Devonport <input type="radio"/> Dorset <input type="radio"/> Flinders <input type="radio"/> George Town <input type="radio"/> Glamorgan/Spring Bay <input type="radio"/> Glenorchy <input type="radio"/> Hobart <input type="radio"/> Huon Valley <input type="radio"/> Kentish <input type="radio"/> King Island <input type="radio"/> Kingborough <input type="radio"/> Latrobe <input type="radio"/> Launceston <input type="radio"/> Meander Valley <input type="radio"/> Northern Midlands <input type="radio"/> Sorell <input type="radio"/> Southern Midlands <input type="radio"/> Tasman <input type="radio"/> Waratah/Wynyard <input type="radio"/> West Coast <input type="radio"/> West Tamar <input type="radio"/> Unknown
Has patient had previous HCV treatment?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> N/A
Previous HCV treatment outcomes	<input type="radio"/> Patient had a sustained virological response (SVR) >12 weeks post treatment <input type="radio"/> Patient did not have a sustained virological response (SVR) >12 weeks post treatment <input type="radio"/> Unknown
<b>4. Contact with GP for this notification Please specify if any contact with GP. When: Intervention arm: 2 weeks - 3 months Control arm: 3 months (for intervention arm, information can be updated through 3 month period.)</b>	
Have you been able to contact the GP for this Notification?	<input type="radio"/> Yes <input type="radio"/> No (Please use a 30-day period to try to contact GP)
How many call attempts prior to reaching GP for this Notification?	(Please specify the total number. Leave blank if unknown.)
How many call attempts were made to reach GP for this Notification?	(Please specify the total number. Leave blank if unknown.)

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For GPs in the Control arm: has GP returned Enhanced Form (CRF) and/or did you call?

- ☐ GP had filled in our form and sent back  
☐ GP was called  
☐ Other (specify)  
 (Check all that apply.)

Other reason why enhanced form not returned

What is the reason this GP cannot be contacted for this notification?

- ☐ GP is no longer working at the practice  
☐ GP referred patient to specialist care  
☐ GP declined to be contacted  
☐ Practice no longer exists  
☐ Unable to access contact details for the GP  
☐ Other (specify)

Other (specify)

## 5. Assistance required

### Intervention arm only.

Please specify the assistance required by [gp\_name] for this notification.

What kind of assistance does the GP need in managing Hepatitis C care/ what questions do they have?

- ☐ Level 1: Information on the virus  
☐ Level 2: Further testing advice  
☐ Level 2: Conducting pre-treatment work-up assessment  
☐ Level 3: DAA prescription guidelines, including linkage to specialist consultation  
☐ Level 3: Advising on conducting post-cure management including methods of follow-up to manage risks; including harm minimization, reducing re-infection risk, opioid substitution therapy  
☐ Level 3: Linking/referral to resources for patients with cirrhosis or other concerns to specialist support for ongoing management  
☐ Level 4: Direct patient contact  
☐ Other  
 (Check all that apply.)

Please specify "other"

## 6. Calls and contact with GP or Patient

### Intervention arm only.

Please specify the calls that you have had with this GP over the 3 month period. Check all that apply

You can update this information any time during the 3-month intervention period

Call 1

Call 2

Call 3

Call 4

Call 5

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Choose moments of contact with GP or Patient ☐ ☐ ☐ ☐ ☐

Please specify the date of the first contact

Please specify duration of first call in minutes

(Please leave blank if unknown.)

Were prior call attempts made before successful contact? ☐ Yes ☐ No

Details of unsuccessful prior calls

Was this call with the GP or the patient? ☐ GP ☐ Patient

Please specify the date of the second call

Please specify duration of second call in minutes

(Please leave blank if unknown.)

Were prior call attempts made before successful contact? ☐ Yes ☐ No

Details of unsuccessful prior calls

Was this call with the GP or the patient? ☐ GP ☐ Patient

Please specify the date of call 3

Were prior call attempts made before successful contact? ☐ Yes ☐ No

Details of unsuccessful prior calls

Please specify duration of call 3 in minutes

(Please leave blank if unknown.)

Was this call with the GP or the patient? ☐ GP ☐ Patient

Please specify the date of call 4

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Were prior call attempts made before successful contact?

☐ Yes  
☐ No

Details of unsuccessful prior calls

\_\_\_\_\_

Please specify duration call 4 in minutes

\_\_\_\_\_  
(Please leave blank if unknown.)

Was this call with the GP or the patient?

☐ GP  
☐ Patient

Please specify the date of the call 5

\_\_\_\_\_

Were prior call attempts made before successful contact?

☐ Yes  
☐ No

Details of unsuccessful prior calls

\_\_\_\_\_

Please specify duration of call 5 in minutes

\_\_\_\_\_  
(Please leave blank if unknown.)

Was this call with the GP or the patient?

☐ GP  
☐ Patient

Document other modes of communication with GP if applicable e.g. sending GESA guidelines or other links.

\_\_\_\_\_

## 7. Level of assistance provided

### Intervention arm only.

**Please specify the level of assistance provided to GP [gp\_name] for this notification at the end of 3-month period.**

Has assistance been provided to GP?

☐ yes  
☐ no

Level of assistance provided to GP [gp\_name] for this Notification

☐ level 1: information  
☐ level 2: testing, awareness, pre-treatment work-up  
☐ level 3: DAA guidelines, treatment support, post-cure management, referral to specialist  
☐ level 4: direct patient contact  
☐ other  
(Check all that apply.)

Please specify 'other'.

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During which call did you start the intervention?

☐ call 1  
☐ call 2  
☐ call 3  
☐ call 4  
☐ call 5  
☐ unknown

During the direct-patient call, what intervention has been done?

☐ Referral back to GP  
☐ Referred to online resources  
☐ Direct information to patient  
(Check all that apply.)

WARNING: This call has not been recorded above.

Has GP finished the intervention? (i.e. all required assistance has been provided to GP)

☐ Yes  
☐ No  
☐ Other (specify)

Other intervention outcomes?

\_\_\_\_\_

Why not?

☐ could not reach GP  
☐ GP did not want to be called back again  
☐ other  
☐ patient is lost to follow up  
☐ unknown

During which call did you finish the intervention?

☐ call 1  
☐ call 2  
☐ call 3  
☐ call 4  
☐ call 5  
☐ unknown

WARNING: This call has not been recorded above.

## 8. Outcomes

### Intervention arm and Control arm.

#### Please specify the outcomes (testing and treating) after 3 months

Please provide the date of recording information on the outcomes

\_\_\_\_\_

Has RNA test been ordered yet?

☐ Yes  
☐ No  
☐ Unknown  
☐ Yes, but by another GP  
☐ Yes, but by a specialist

What do you think is the number 1 barrier for not RNA testing this Notification?

☐ Patient lost to follow up (no longer engaged in care at this clinic)  
☐ Patient needed to be referred to specialist  
☐ Patient refused to undergo puncture  
☐ Unsuccessful attempts at blood draw  
☐ Other (specify)

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Please specify other barrier for no RNA testing

Have results come back yet?

- ☐ Yes  
☐ No  
☐ Unknown

What is RNA test date?

(Note that for a repeat PCR the lab date is the same as the RNA date)

What was the result of the HCV RNA test

- ☐ Detected  
☐ Not detected  
☐ Indeterminate

Were appropriate pre-treatment work-up blood tests collected e.g. full blood count (platelet count), liver enzymes (AST)

- ☐ Yes  
☐ No

What is the number 1 barrier for no pre-treatment work-up blood tests

- ☐ Patient is lost to follow-up  
☐ Patient declined blood draw  
☐ Patient was referred to a specialist  
☐ Patient transferred to another practice  
☐ Other (specify)

Other pre-treatment blood work up barriers

Has GP written a DAA script for this notification?

- ☐ Yes  
☐ No  
☐ Unknown

What is the number 1 barrier for not writing a DAA script?

- ☐ Patient is lost to follow-up at the practice  
☐ Patient has transferred to another practice  
☐ Patient was transferred to a specialist  
☐ Patient declined treatment  
☐ Other (specify)

Other reason for no DAA script

Has treatment already started?

- ☐ Yes  
☐ No  
☐ Unknown

What is the treatment start date?

What do you think is the number 1 barrier for not treating this Notification?

- ☐ Patient lost to follow up  
☐ Patient needed to be referred to specialist  
☐ Patient refused treatment  
☐ Other

Please specify other barrier for not treating

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Consent for a future follow up call (to assess  
sustained virologic response)

☐ Yes  
☐ No

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## Appendix D: Screening Log

Week	Effective Dates	Total notified test results	Weekly tally of Notified Test Results						Running tally (Eligible GP's)	Running tally (total not)	Exclusion Criteria											Weekly total ('must match excluded')	Running tally (exclusions)
			Yes/No (Ab+)	Lab dx (PCR)	Reflex	Eligible GP's	GP Prev Enrolled	Res ID related not.			Not based in Tasmania	Correct service	Special	Nurse Prac	Sexual Health	Family Planning	HIV	Hosp. based setting	Other				
W1	31/08/2020 - 06/09/2020	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W2	07/09/2020 - 13/09/2020	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W3	14/09/2020 - 20/09/2020	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W4	21/09/2020 - 27/09/2020	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W5	28/09/2020 - 04/10/2020	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W6	05/10/2020 - 11/10/2020	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W7	12/10/2020 - 18/10/2020	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W8	19/10/2020 - 25/10/2020	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W9	26/10/2020 - 01/11/2020	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W10	02/11/2020 - 08/11/2020	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W11	09/11/2020 - 15/11/2020	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W12	16/11/2020 - 22/11/2020	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W13	23/11/2020 - 29/11/2020	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W14	30/11/2020 - 06/12/2020	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W15	07/12/2020 - 13/12/2020	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W16	14/12/2020 - 20/12/2020	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W17	21/12/2020 - 27/12/2020	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W18	28/12/2020 - 03/01/2021	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W19	04/01/2021 - 10/01/2021	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W20	11/01/2021 - 17/01/2021	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W21	18/01/2021 - 24/01/2021	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W22	25/01/2021 - 31/01/2021	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W23	01/02/2021 - 07/02/2021	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W24	08/02/2021 - 14/02/2021	5	2	2	1	3	1	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0

## Appendix E: Sample size calculations

The sample size calculation is powered to cover a range of the most probable and realistic assumptions.

**1. Treatment uptake in standard of care arm:** Existing data estimates between 3-8% of people start therapy within three months (when our primary outcome will be assessed): data on national treatment uptake by specialists and general practitioners,[16] among people who inject drugs,[17] and in traditional referral to outpatient services all estimate treatment uptake of 8% or under at three months.[18] In this study, we will assume the higher (and therefore more conservative, biasing towards the null hypothesis) estimate of treatment uptake of 8% at three months in the control arm.

**2. Treatment uptake in intervention arm:** is estimated at 25% based on best estimates of intervention acceptance by GPs and follow up, RNA prevalence among those notified with HCV antibody, community treatment eligibility, and best estimate of intervention effect.

- **Acceptance and participation of general practitioners** is estimated at 90% at 3 months based on general practice acceptance of prescribing support (fewer than 10% of South Australian general practitioners declined SA Health support during remote follow up; unpublished data).

- **RNA prevalence** among those HCV-antibody positive has been measured 50-70% in surveillance data over the past 10 years.[19]

- **Community treatment eligibility** has been observed at 88% (10% cirrhosis, and 2% HIV or HBV coinfection or other serious comorbidities) in our Australian community treatment trials.[20]

- **Intervention of primary care support** is estimated to see 65% of eligible patients start on treatment at three months. We have informed this estimate based on pilot data from primary care support provided in Victorian models of support for general practitioners (91% treatment uptake among HIV-prescribers[21]; 74% treatment uptake in testing support models in community settings[22]; 71% follow up for treatment in a South Australian model of health department remote follow up, unpublished data). We have conservatively assumed a lower rate of treatment uptake among all eligible, viraemic patients of 65%.



Based on the most conservative of these assumptions, we estimate 25% (i.e.,  $0.90 \times 0.50 \times 0.88 \times 0.65$ ) of individuals in the intervention arm will commence treatment.

