

# Viral hepatitis case-finding in primary care

<b>Submission date</b> 09/10/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 09/10/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 25/06/2020	<b>Condition category</b> Haematological Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Hepatitis B and C are blood-borne viruses that affect the liver. Long-term (chronic) infection with hepatitis B or C (HBV and HCV) is the leading cause of end-stage liver disease (cirrhosis) and primary liver cancer worldwide. In the UK, the rates of hospital admissions and serious complications due to hepatitis C (HCV) continues to rise year on year, with HCV now being the leading cause of liver transplantation in Europe and North America. Chronic infection with HBV and HCV seems more common in certain groups of people (at-risk groups), and due to several risk factors. Case-finding is the process by which at-risk individuals are identified and offered testing for viral hepatitis. As chronic infection typically causes few symptoms, it is important that those at-risk are offered testing to identify the virus early. Good effective treatment exists for both HBV and HCV, with several new treatments for hepatitis C released in the past year. Identification and treatment will eliminate or reduce the chances of disease progression, and this is the goal of case-finding. National and international guidance exists to support case-finding and insists on identifying those groups who should be offered testing for HBV and HCV in England. A key target of these recommendations is to increase testing in GP practices. As the majority of those infected with viral hepatitis lie in the community, offering testing to people in GP practices is priority. There is however no recommended strategy, and little research to guide GPs on how best to identify and offer testing to at-risk individuals in their practice. At the same time, most GP practices are finding it difficult to meet the existing service commitments, with no additional resources provided for case-finding. Developing and proving effective and acceptable case-finding strategies in GP practices is therefore a priority.

### Who can participate?

GP practices with suitable computer recording software and those with links to hepatology speciality services.

### What does the study involve?

In this study we will look at 3 different testing strategies for GP practices to identify and offer testing to individuals with increased risk of viral hepatitis, in comparison to current practice. GPs will be asked to identify and offer testing for viral hepatitis to their patients in one of three ways: systematic, opportunistic or new-patient testing, in comparison to a group of (control) GP practices undertaking usual testing practice. At-risk groups will be identified. In the Systematic arm of the study, we will identify at-risk groups within the GP practice, and write to offer them HBV and HCV testing. In the Opportunistic arm of the study, GPs will offer testing to at-risk

individuals who present to their GP for related, or unrelated consultations, and in the New-patient arm of the study, new patient registrations will be asked additional questions to identify risk factors that would merit a testing offer for HBV or HCV. Testing is optional, and we will record the uptake of testing in each arm, in comparison to testing uptake in the control GP practices.

**What are the benefits and risks of participating?**

The main benefit of the study is to help improve the detection of those infected with viral hepatitis, with the aim of treatment before complications arise. The study will also help improve our understanding of the number of at-risk individuals in GP practices, and in this population the actual numbers infected with viral hepatitis. We do not expect any undue risks for participants by taking part in this study. Testing will be at their wish, and participants will be given the opportunity for further discussions if they so wish before testing.

**Where is the study run from?**

The study will be conducted in local GP practices.

**When is the study starting and how long is it expected to run for?**

November 2014 to February 2015.

**Who is funding the study?**

Gilead Sciences Inc (USA)

**Who is the main contact?**

Dr Sanju Mathew

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## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Sanju Mathew

**Contact details**

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## Additional identifiers

**Protocol serial number**

17297

## Study information

**Scientific Title**

A feasibility study of case-finding strategies for the detection of Hepatitis B and C in primary care

**Study objectives**

National and international guidance recommends offering testing for hepatitis B and C to at-risk groups (case-finding). Identifying these individuals in primary care is a priority, with the majority of those infected known to remain undetected in the community. There is however little research to guide effective case-finding practice in primary care, with this taking a low priority in many practices.

In the following feasibility study we will prospectively assess three case-finding strategies in primary care, in comparison to standard (usual) practice. Through this we aim to develop and prove effective case-finding strategies for viral hepatitis (B & C) that can be adopted in primary care.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

14/EE/1159; First MREC approval date 25/09/2014

**Study design**

Non-randomised; Interventional and Observational; Design type: Screening, Qualitative

**Primary study design**

Interventional

**Study type(s)**

Screening

**Health condition(s) or problem(s) studied**

Topic: Primary Care; Subtopic: Hepatology, Primary care; Disease: All Diseases

**Interventions**

New-patient testing: New patient registrations will be asked additional questions relating to HBV and HCV risks.

Testing will be offered based on risk.

Opportunistic testing, At-risk patients will be offered HBV and HCV testing when presenting to GP practices for related/unrelated reasons

Systematic testing, GP practices will identify at-risk groups in their patient population using MIQUEST coding. Written invites will be sent to patients to offer HBV and HCV testing

Follow Up Length: 3 month(s); Study Entry : Other; Details: Practices will be recruited with the help of the PCRN team

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Uptake of testing for Hepatitis B / C; Timepoint(s): The uptake of testing in intervention arms compared to control (usual care). Over 3 months

### **Key secondary outcome(s)**

1. Acceptability of testing intervention; Timepoint(s): at end of testing period (3 months)
2. Positive cases for HBV and HCV; Timepoint(s): Over 3 months

### **Completion date**

16/02/2015

## **Eligibility**

### **Key inclusion criteria**

1. Practices will be selected with appropriate and eligible computer recording software
2. Practices with links to hepatology speciality services to provide support and onward referral
3. Practices with resource abilities to offer testing strategies

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Key exclusion criteria**

1. Practices without adequate computer records software
2. Practices without computer-linked results recording to laboratory services

### **Date of first enrolment**

10/11/2014

### **Date of final enrolment**

16/02/2015

## **Locations**

### **Countries of recruitment**

United Kingdom

England

**Study participating centre**  
**Faculty of Health and Medical Science**  
Guildford  
United Kingdom  
GU2 7XH

## Sponsor information

**Organisation**  
University of Surrey (UK)

**ROR**  
<https://ror.org/00ks66431>

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Gilead Sciences Inc (USA) - Grant Codes: 999/UK/13-05/CI/1010

## Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No