

# Hepatitis A vaccination coverage amongst people with Chronic Liver Disease in England (HEALD): protocol for a retrospective cohort study

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<b>Registration date</b> 12/10/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/01/2025	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Hepatitis A outbreaks in the United Kingdom are uncommon. Most people develop mild-to-moderate symptoms that resolve, without sequelae, within months. However, in high-risk groups, including those with underlying chronic liver disease, hepatitis A infection can be severe, with higher risk of mortality and morbidity.

The UK's public health body, the Health Security Agency and the English guidelines organisation, the National Institute of Health and Care Excellence, recommend pre-exposure hepatitis A vaccination given as two doses to people with chronic liver disease, regardless of its cause. There are currently no published reports of vaccination coverage in people with chronic liver disease in England, or internationally.

The study aims to describe hepatitis A vaccination coverage in adults with chronic liver disease in a UK primary care setting. To compare liver disease aetiology, sociodemographic characteristics and comorbidities in people who are and are not exposed to hepatitis A vaccine.

### Who can participate?

Data used for the study will include all the individuals in England.

### What does the study involve?

During the study GP data will be retrospectively analysed to get an understanding of hepatitis A vaccination coverage in adults with chronic liver disease in a UK primary care setting, comparing liver disease aetiology, sociodemographic characteristics and comorbidities in people who are and are not exposed to hepatitis A vaccine.

### What are the possible benefits and risks of participating?

The results of the study will give a better understanding about how to administer the hepatitis A vaccine to people with chronic liver disease in the English population in the future.

Where is the study run from?

Nuffield Department of Primary Health Care Sciences of the University of Oxford (UK)

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

March 2022 to August 2024

Who is funding the study?

GlaxoSmithKline (Belgium)

Who is the main contact?

Prof. Simon de Lusignan, [simon.delusignan@phc.ox.ac.uk](mailto:simon.delusignan@phc.ox.ac.uk)

## Contact information

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Scientific

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**Additional identifiers****Clinical Trials Information System (CTIS)**

Nil known

**Protocol serial number**

GSK ISS: 14309

**Study information****Scientific Title**

Hepatitis A vaccination coverage amongst people with Chronic Liver Disease in England (HEALD): protocol for a retrospective cohort sentinel network database study

**Acronym**

HEALD

**Study objectives**

This study fills this gap reporting hepatitis A (Hep A) vaccine coverage in people with chronic liver disease (CLD), with a focus on whether there are disparities as to which people with CLD receive Hep A vaccination.

The study aim is to report Hep A vaccination coverage in people with CLD in English primary care and the predictors of receiving a single dose or full vaccination course. With the following objectives:

1. To report Hep A vaccination coverage in people with CLD by:
  - a. Sociodemographic characteristics (e.g. age, gender, ethnicity, deprivation, obesity, smoking, alcohol consumption)
  - b. CLD disease type (e.g. alcoholic liver disease, chronic hepatitis B and C, Non alcoholic fatty liver disease).
  - c. CLD complications (e.g. renal disease, ascites, liver failure and transplant, cardio-metabolic disease)
  - d. Comorbidities and exposures (e.g. Cambridge Multimorbidity Score (CMMS), bile duct and colon cancers, at least three doses of COVID-19 vaccine, flu vaccination).
2. To report the predictors of one- and two-doses of Hep A vaccination in people with CLD.

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

approved 09/06/2022, Central University Research Ethics Committee (CUREC) at the University of Oxford (Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB, United Kingdom; +44 1865 616577; ethics@medsci.ox.ac.uk), ref: R80951/RE001

## **Study design**

Retrospective cohort study

## **Primary study design**

Observational

## **Study type(s)**

Other

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

People with chronic liver disease, including alcohol-related liver disease (ALD), chronic hepatitis B infection (CH-B), chronic hepatitis C infection (CH-C), and non-alcoholic fatty liver disease (NAFLD)

## **Interventions**

Using data from the Primary Care Sentinel Cohort (PCSC) of the Oxford-Royal College of General Practitioners (RCGP) Research and Surveillance centre (RSC) for the period between the 1st January 2012 and 31st December 2022. Data will be extracted retrospectively at the time of the start of the study.

## **Intervention Type**

Other

## **Primary outcome(s)**

Number of doses of hepatitis A vaccination measured using patient records at a single time point

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

There are no secondary outcome measures

## **Completion date**

31/08/2024

# **Eligibility**

## **Key inclusion criteria**

We will include adults registered in general practices within the RSC network, with a diagnosis of CLD, as defined by our ontology, within the period between the 1st January 2012 and 31st December 2022. The following inclusion criteria will be applied:

People registered in the RSC general practices, aged 18 years of age and older, with a diagnosis of CLD. Our ontology for CLD includes: Alcoholic liver disease (ALD), chronic hepatitis B (CH-B),

chronic hepatitis C (CH-C), non-alcoholic fatty liver disease, Wilson's Disease, haemochromatosis, autoimmune hepatitis (AIH), primary sclerosing cholangitis (PSC) and primary biliary cholangitis (PBC).

**Participant type(s)**

Population

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

13875

**Key exclusion criteria**

1. Patients with recorded contraindications to the Hep A vaccine (confirmed anaphylactic reaction to a previous dose of Hep A containing vaccine, or to any of its components).
2. Records of administration of post-infection or risk-of-infection immunoglobulins.

**Date of first enrolment**

06/06/2023

**Date of final enrolment**

06/06/2023

**Locations****Countries of recruitment**

United Kingdom

England

Wales

**Study participating centre**

**Clinical Informatics and Health Outcomes Research Group, Nuffield Department of Primary Care Health Sciences at the University of Oxford**

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## Sponsor information

### Organisation

University of Oxford

### ROR

<https://ror.org/052gg0110>

## Funder(s)

### Funder type

Industry

### Funder Name

GlaxoSmithKline Biologicals

### Alternative Name(s)

GSK Belgium, GlaxoSmithKline Biologicals SA, GlaxoSmithKline Biologicals SAS, GlaxoSmithKline (GSK) Biologicals, GSK Biologicals, GSK

### Funding Body Type

Private sector organisation

### Funding Body Subtype

For-profit companies (industry)

### Location

Belgium

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository, at the ORCHID database hosted by the Nuffield Department of Primary Care Health Sciences at the University of Oxford (<https://orchid.phc.ox.ac.uk/>)

### IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>	version 5.2	04/12/2024	17/01/2025	No	No
<a href="#">Protocol (preprint)</a>		05/09/2023	15/09/2023	No	No