Management of Patients with Chronic Liver Disease Admitted to Hospital as an Emergency.

NIHR 132969

Detailed Information about The Study And Privacy Notice

What is the purpose of this research?

Liver disease is a major and increasing health problem in the UK. However, people with it often don't know that they are affected until it causes sudden severe health problems and they need to be admitted to hospital as an emergency. People admitted in this way are often very ill, and a quarter of them die within 2 months of coming into hospital.

The care they get when they are in hospital, and after being discharged, varies greatly across the country. This has major effects on how long they survive; survival of those who live in the most deprived areas is half that of those who live in the most well-off ones. We want to understand how and why where people live, and what care is available to them affects the way they are treated - and their survival.

We will study the key points in the 'journey' that people with liver disease follow when admitted to hospital for the first time. We want to understand why some but not others are treated by specialists or admitted to Intensive Care Units, and how this changes depending upon what staff and facilities are available. We also want to see how differences in outpatient care after discharge make a difference. If we can work out what care has the best survival, we can begin to make sure that all people with liver disease get access to the best care, wherever they live.

How will these research questions be answered?

The research project we are undertaking will investigate how we can best care for unwell people with chronic liver disease. The title of the Project is 'Management of People with chronic liver disease who are admitted to hospital as an emergency' or 'MAP-CLD' for short. There are two major parts to this project: one involves observing care of people with liver disease in different hospitals, and interviewing them and the staff looking after them. This is described elsewhere [*link to ethnography section*]. The other part of the project is a clinical epidemiological project that will examine information from a linked dataset with information about many thousands of people with chronic liver disease treated by the NHS in England. This is described in detail below.

What is Data Linkage?

In England the NHS records information about patients whenever they attend their GP or are seen/admitted to hospitals. Civil registration data (births and deaths) is recorded by the Office for National Statistics and is available to the NHS. This information is stored in various different databases controlled by a wide variety of NHS healthcare providers. Similar systems are in place in Wales, Northern Ireland and Scotland, but they are not included in this research.

When we undertake medical research studies we usually need to find out what happens to those people ('research participants') taking part in research after they have entered the research study. The usual way to do this is for a member of the research team to see or contact the research participant to directly gather further information. This is sometimes difficult to do, particularly for very large research projects that run over a long time period, and may not be possible if some of the participants have died.

Because the NHS records and stores information about people in electronic databases, researchers can ask for approval to access this information as an alternative to getting the information directly from research participants. Care has to be taken when doing this to make sure peoples' personal information is protected and not used without their permission.

To be able to access electronic healthcare data to add to a research study, or just to join two different databases together, we have to 'link' the electronic data. This is what we mean by 'data linkage'. In healthcare research we commonly use 'NHS numbers', date of birth, sex and postcode for this. Because NHS numbers are unique to any one person, if we have two databases that contain NHS numbers we can link the information for each individual from one database with the information from another database.

We plan to use electronic healthcare data made available from NHS Digital (the NHS data 'warehouse') and two other sources in our current research. We will analyse these data at the London School of Hygiene and Tropical Medicine (LSHTM) in London. The data that will be made available to the research team at the LSHTM will be de-identified. This means that the dataset does not include the patients' name, NHS number, date of birth or address. However, it will retain the date of death of those people who have died because this is required in the analyses that are planned. More details of what we plan to do and how we will protect peoples' personal information is given in the 'privacy notice' below.

What is the purpose of this privacy notice?

This privacy notice has been published because the research we are performing involves analysing NHS health information from records of people with liver disease who have previously been admitted to hospital. It is important that information about this work and its results are made publicly available.

What data will be used?

NHS Digital will identify the *patient identifiers* (NHS Numbers, dates of birth, sex and postcodes) of people with liver disease who have been admitted to a hospital as an emergency across England in the period 2007-2020. The *clinical data* relating to their care in and outside the hospital will be extracted and stored separately from the patient identifiers within NHS Digital. Data from Scotland, Norther Ireland and Wales will not be used.

NHS Blood and Transplant (NHSBT) will identify the *patient identifiers (*NHS Numbers, dates of birth, sex and postcodes) of people who are planned for or undergo liver transplants in the period 2007-2020. The clinical data relating to their care will be extracted and stored separately from the patient identifiers within NHSBT.

Three sources of data will be used:

1. NHS Digital, the secure data warehouse for the NHS, holds data for hospital admissions, outpatient care and deaths. We will use datasets that include 'Hospital Episode Statistics'

(HES)-Admitted Patient Care, HES-Outpatients, HES-Accident and Emergency, HES-Emergency Care Dataset, HES-Critical Care and HES-ONS mortality.

2. The Intensive Care National Audit and Research Centre (ICNARC), holds data on admissions to intensive care. We will use the dataset from the Case-Mix Programme (CMP).

3. NHSBT hold data on people who are planned for or undergo liver transplants. We will use the dataset from the UK Liver Transplant Registry.

Only the *clinical data* provided by these sources will be available to the team at the LSHTM carrying out the research. This clinical data includes dates and codes that specify location of care given by the NHS, and codes that detail the sorts of care that have been delivered in hospital, in intensive care and, if relevant, about liver transplantation. It will **not** include identifying information such as name, NHS number, date of birth or address. However, it will retain the date of death of those people who have died because this is required in the analyses that are planned.

How will the data be combined?

Data from NHS Digital, NHSBT and ICNARC are not routinely combined together in the NHS. All three sets of data are held by separate organizations and cannot be combined without special safeguards and permissions. None of these organizations currently hold these data in a combined format for the medical research.

The patient identifiers (NHS numbers, dates of birth, sex and postcodes) of the relevant people identified by NHS Digital will be sent electronically and securely to ICNARC without any clinical data. ICNARC will then link the records of people in the ICNARC data to the records of the people in the NHS Digital data.

The patient identifiers (NHS numbers, dates of birth, sex and postcodes) of the relevant people identified by NHSBT will be sent electronically and securely to NHS Digital without any clinical data. NHS Digital will link the records of people in the NHSBT data to the records of the people in the NHS Digital data.

To make this research possible, ICNARC, NHSBT and NHS Digital will remove **all** identifiable data from the clinical datasets before sending them to the research team at LSHTM in a process called 'de-identification'. This deidentified clinical data will then be sent by a secure electronic link to the research team who will combine the three sets of data together. This process of de-identification allows the research team to join the three clinical datasets together effectively without any patient identifiers being transferred to them.

How can three de-identified sets of data be joined together?

NHS Digital, NHSBT and ICNARC use the individual's NHS number, sex, date of birth and postcode to identify people in their datasets. NHS numbers are unique to an individual and, together with other patient identifiers, can be used to link together individual records from each set of data. To protect people's identity this can be done in such a way that whoever is creating the link cannot identify any of the people in any of the datasets.

The process that will be used to join the clinical data together is over three separate phases and is as follows:

Stage 1 - NHS Digital will create and add a unique identification code to the records for each person identified as having an emergency admission with liver disease (this code is the 'pseudonym').

It will then create two sets of data from this dataset.

- The clinical dataset will have all identifiable data removed (name, address and postcode, date of birth, NHS number etc.) leaving just the information about in-patient and out-patient care and survival and the unique identification code for each person in the dataset. This will be sent to the research team at the LSHTM through a secure electronic link.

- The dataset of patient identifiers created by NHS Digital will be a list of NHS numbers, dates of birth, sex and postcodes for all the people in their data set together with the unique identification code for each of them. This dataset of patient identifiers will be sent to ICNARC by a secure electronic link.

Stage 2 - ICNARC will receive the list of NHS numbers, dates of birth, sex and postcodes and unique identification code from NHS Digital. They will use the NHS numbers, dates of birth, sex and postcodes to add information from the data they control for intensive care admissions and liver transplants, respectively, to the list.

Once complete, the NHS numbers will be removed from the dataset, leaving just a list of information for each person with just the unique identification code attached. NHSBT and ICNARC will then send this to the research team at the LSHTM by secure electronic link.

Stage 3 - The research team at the LSHTM will receive the de-identified data from NHS Digital, NHSBT and ICNARC. Because each set of data will have the same pseudonym for each person, the research team will then be able to link together the information from all three sources without requiring access to any identifiable data for any of the people in the research study.

How will personal data be protected?

The above process does not require any personal information other than the NHS number, postcode and date of birth to be transferred or shared between any of the organisations involved. NHS numbers, postcodes and dates of birth are only shared by NHS Digital with ICNARC and by NHSBT with NHS Digital in this process. No patient identifiers will be sent to the research team at the LSHTM. When NHS numbers, dates of birth and postcode are shared between NHS Digital, NHSBT and ICNARC, they will not be combined with any clinical information. All three organisations already hold these patient identifiers for all the people to be studied so they will not be receiving any information they do not already hold.

We can also confirm that no data will be transferred to any other organisations or countries and will not be used to undertake automated decision-making, including profiling.

How long will personal data be kept for?

The data will be kept at LSHTM for the shortest time possible in order to undertake this research. We expect the research to be complete by October 2024. Once the planned research is complete all data will be held for another two years and then safely deleted.

What other information is available?

More information about how your personal information is used by the other organizations involved in this research is as follows:

NHS Digital: https://digital.nhs.uk/about-nhs-digital/our-work/keeping-patient-data-safe/gdpr-register

ICNARC: https://www.icnarc.org/About/Information-Standards/Information-Security/Privacy-Policy

NHSBT: https://www.nhsbt.nhs.uk/privacy/

What if I don't want my data used in this research?

If you don't want your information to be used in this way in this or other future research projects then you can 'opt out'. This will not affect the care you receive from the NHS. More information can be found at the NHS Choices website (https://www.nhs.uk/your-nhs-data-matters/) where you can manage your NHS data choices including being able to opt out from research.

If you don't want your information to be used for this project, but would be happy for it to be used in other research then you can choose to 'opt out' of this project alone. To do this, please either email the project team at kch-tr.info-mapcld@nhs.net or write to us at MAP-CLD Project, Institute of Liver Studies, Kings College Hospital, Denmark Hill, London SE5 9RS. We can then make sure that your information is not used in the project.

Who has given approval for this research to go ahead?

Approval for this research has been given by from several authorities.

The Health Research Authority (HRA): This research involves the use of individual's medical records without direct consent. This is undertaken under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support'). Approval for this work has been granted by the HRA, on advice from the Confidentiality Advisory Group (CAG), an independent advisory group with lay representation. The research has also supported by the HRA having been reviewed and approved by the London Harrow Research Ethics Committee (REC).

NHS Digital: All data sharing agreements with NHS Digital are approved by the Independent Group Advising on the Release of Data. This group will have approved the release of data from NHS Digital as described here.

GDPR technical details

The UK General Data Protection Regulation (GDPR) governs data protection and privacy for individuals. As part of UK GDPR, we are required to provide some technical details about how we use your data in this research.

In this study, the following parties are involved

Organisation Name	Role	Function	Contact
NHS Digital	Controller	1. Creation of data group 2. Creation of Pseudonym Code 3. Provider of Pseudonym Code and NHS Number to NHS BT and ICNARC	DPO Name Jon Moore (enquiries@nhsdigital.nhs.net)
NHS Blood and Transplant	Controller	1. Provision of data based on NHS D List and sender of details to	DPO Name Katrina Smith (informationgovernanceteam@nhsbt.nhs.uk)
ICNARC	Controller	1. Provision of data based on NHS D List and sender of details to	DPO Name Lee Shailer (DPO@icnarc.org)
King's College Hospital	Controller	1. Oversight of Research Study	1.PI Name Professor William Bernal (william.bernal@nhs.net) 2. Nicholas Murphy-O'Kane, Data Protection Officer (Kch-tr.dpo@nhs.net)
London School of Hygiene and Tropical Medicine	Processor	1. Recipient of data from NHS D, NHS BT, and ICNARC 2. Complete analytic actions as directed by KCH	DPO Name Peter Wright (DPO@lshtm.ac.uk)