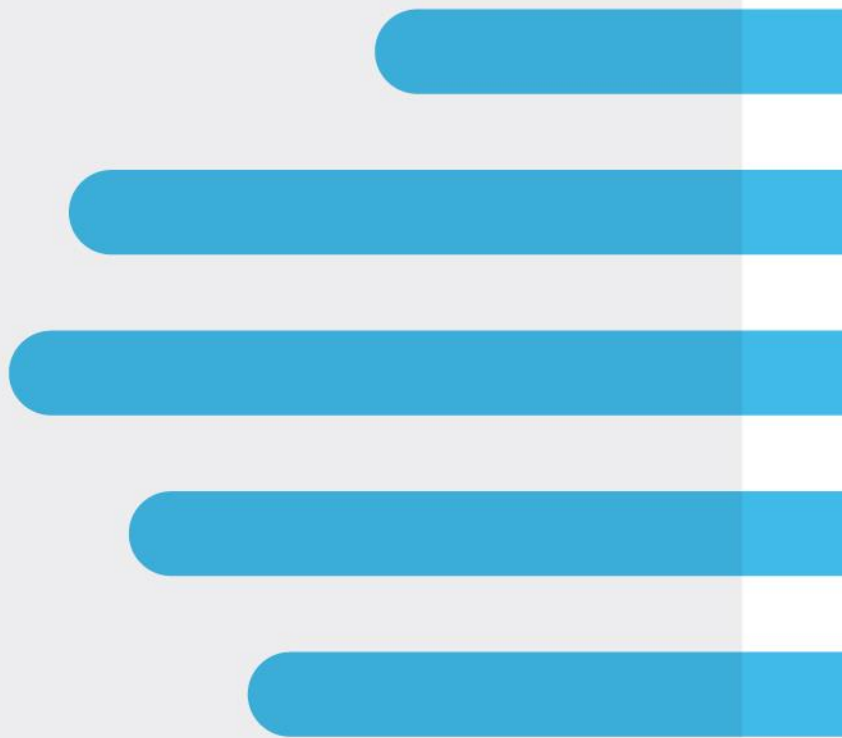


Patient Information

Research using patient information in Amyloidosis

July 2020



UNDERSTANDING COMPLEX DIAGNOSIS PATHWAYS AND TREATMENT PATTERNS IN AMYLOIDOSIS

NAC-HES DATA

The staff at the National Amyloidosis Centre (NAC), part of the Royal Free London NHS Foundation Trust, process information about you and your health, so that you can receive the right care and treatment. NAC has a collaboration agreement with IQVIA for the purpose of producing an enhanced dataset for use in medical research studies.

This enhanced dataset has been generated by linking NAC's data and the Hospital Episode Statistics (HES) data provided by NHS Digital ("NAC-HES Data"). The methodology used for this linkage was created by a trusted third party using secure encryption technology to link patient records without compromising patient confidentiality. This has also been approved and executed by NHS Digital. IQVIA Ltd and the Royal Free London NHS Foundation Trust are the data controllers of the NAC-HES Data.

As part of GDPR, a data controller "determines the purposes for which and the means by which personal data is processed. An entity is a joint controller when together with one or more organisations it jointly determines 'why' and 'how' personal data should be processed". In this case, for NHS Digital, HES data is considered to be personal data and any entity that provides input into the protocol which will use HES data needs to be added as a joint data controller as they are determining why and how the data will be used. So, in this case, this includes The Royal Free and IQVIA Ltd. as these entities are currently contributing to the development of the protocol.

ABOUT US

The Royal Free London NHS Foundation Trust is registered at the following address: Royal Free Hospital, Pond Street, London, NW3 2QG.

IQVIA Ltd ("IQVIA/we/our") is part of the IQVIA Inc. group of companies serving the combined industries of health information technologies and clinical research worldwide. IQVIA specialises in the provision of products and services including medical research and analytical solutions to healthcare and life sciences organisations. In the UK, IQVIA has collected and supported the research use of non-identified patient data for over 20 years.

IQVIA is registered in England and Wales as: IQVIA Ltd, registration number: 00634325. Our registered office is at 210 Pentonville Road, London, N1 9JY.

THE PURPOSE FOR WHICH NAC-HES DATA IS PROCESSED AND USED

Amyloidosis patients often go undiagnosed for a long period of time, with patients requiring multiple hospital visits before they are finally diagnosed. Therefore, there are still large gaps of knowledge about amyloidosis, especially when looking at specific subtypes of the disease.

Your de-identified information will support researchers in generating a better understanding about amyloidosis patients' use of the NHS and support the development of ways to improve diagnosis and treatment options for the disease. The results will also support the design of more efficient NHS services for amyloidosis patients, potentially lessening the burden on patients by helping to reduce repeat visits during a patient's diagnosis period, as well as supporting earlier diagnosis for patients. In heritable forms of the disease, the benefits identified may also help patient's family members to better understand the condition, which potentially may lead to earlier diagnosis. The results generated could

also provide evidence to support applications for novel therapies in this highly underserved disease area, potentially allowing patients in future to get access to new treatment options.

In addition, IQVIA may use some of this information for other reasons, for example, to help us to protect and improve the health of the general public, to train staff and to carry out medical and other health research for the benefit of patients. IQVIA is currently involved in a medical research study, within amyloidosis, which will use this information in a de-identified form.

IQVIA Ltd., IQVIA Technology Services processes The Royal Free Data on the basis of legitimate interests in supporting medical research and because it is necessary for the above scientific research purposes, subject always to appropriate safeguards. The Royal Free London NHS Foundation Trust are processing the data in line with their goals to carry out the task in the public interest. Technical and organisational measures are in place to ensure only non-identified data is used.

All directly identifiable details (name, address, post code, telephone numbers, NHS number, full date of birth) are removed from your information before being used for research, and all information will be checked for identifiable details by an automated process before any researchers have access.

WHO IS THE DATA MADE AVAILABLE TO?

Your information from the NAC will be linked with other NHS data for the purpose of this research. In order to do so your NHS number will be shared from the NAC to NHS Digital, the national provider of information, data and IT systems for health and social care. This is the NHS entity that looks after your health and care information.

The research will be conducted by researchers from IQVIA which does not and will not have access to any identifiable personal details, only non-identified information as outlined above. All researchers receive extensive training on data handling and security to ensure all non-identified information is protected. You will not be identified in any published results.

A list of published research from this study can be found at <https://www.rwebibliography.com/> or please contact Edmund Drage on telephone number +44 2030755784 or email Edmund.Drage@iqvia.com for a paper copy.

DATA RETENTION

IQVIA holds linked NAC-HES Data records from 2000 to 2017. For studies using patient data to be scientifically sound, all information relating to a patient's past medical events should be considered as this will influence their doctor's decision and affect their current care. Historical data on patient contact with secondary care is important because the lead up to diagnosis of many conditions, particularly rare diseases, can be complex and lengthy. In addition, longitudinal data are increasingly important in, for example, studying chronic conditions, when, a long history is required so that trends and signals can be detected, and early risk prediction tools can be designed. Availability of sufficient data and research can drive health policy changes or adoption of new guidelines for healthcare providers, thus leading to improved outcomes for patients.

IQVIA retains data in accordance with UK Medical Research Council (MRC) guidelines which recommend basic research data and related material be retained for a minimum of 10 years after the study has been completed. This is to support good research practice which requires research studies to be reproducible.

<https://mrc.ukri.org/documents/pdf/retention-framework-for-research-data-and-records/>

SECURITY

IQVIA has implemented an Information Security Management System. IQVIA Limited is accredited to the ISO 27001 standard and IQVIA Ltd has an NHS approved Information Governance Toolkit (IGT) assessment and has submitted a NHS data security and protection toolkit (DSPT) assessment.

IQVIA stores the NAC-HES Data records on secure servers located in the UK only. IQVIA have put in place appropriate security measures to prevent unauthorised access to or disclosure of the NAC-HES Data. Access to the data is strictly controlled and limited internally to authorised personnel. External use and access are governed by data sharing agreements detailing confidentiality and the terms on which the data is shared, used, stored and accessed.

CONSENT AND PATIENT RIGHTS

Patients have the right to opt out of their data being included in the NAC-HES Database. Patients are informed by means of posters in their GP practice that their data is collected for scientific research and they can opt out at any time by notifying their GP practice. Any patients who have withdrawn their consent from the NAC data collection are removed together with all their records from the NAC database and subsequently from the NAC-HES data that IQVIA holds. Royal Free London NHS Foundation Trust is responsible for collecting patient consent for the NAC database.

For patients who have opted-out: the NHS number will be sent to NHS Digital for processing to ensure that no records related to your hospital stay(s) are used in the study. This will not affect your care in any way.

Patients also have the right to request rectification or restriction of processing of their personal data held by their GP practice, or to object to the processing of such personal data, as well as the right to data portability. Patients would need to contact their GP practice to exercise these rights.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. Personal data will not be transferred to any third countries or international organisations. No automated decision making will be included, including profiling for this specific study.

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available on the UCL website
- by contacting Royal Free London NHS Foundation Trust : Julian Gillmore on telephone number: +44 207433 2816 or email j.gillmore@ucl.ac.uk .
- by asking one of the research team

If you wish to raise a query or make a complaint in relation to this study, please contact the ICO using the following telephone number: 0303 123 1113

CHANGES TO THIS NOTICE

IQVIA may update this notice from time to time. IQVIA encourages you to review this notice periodically to stay informed about how IQVIA is using and protecting NAC-HES Data. If IQVIA plans to use personal data for a new purpose, IQVIA will update the privacy information and communicate

the changes to individuals before starting any new processing. Any changes to this notice take effect immediately after being posted or otherwise provided by us.

CONTACT DETAILS

Questions and comments regarding this notice and use of your information should be addressed as follows:

To IQVIA: Edmund Drage on telephone number: +44 2030755784 or email Edmund.Drage@iqvia.com or email eu.dpo@iqvia.com.

To the National Amyloidosis Centre, and, Royal Free London NHS Foundation Trust: Julian Gillmore on telephone number: +44 207433 2816 or email j.gillmore@ucl.ac.uk.