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PARTICIPANT INFORMATION SHEET

UK Myasthenia Database (UKMyDb)

We'd like to invite you to be included in our UK Myasthenia Database. Before you decide, it is important that you understand why the database is being created and what it would involve for you. Please take time to read this information and discuss it with others if you wish. If there is anything that is not clear, or if you *would like more information, please ask us.*

What is the UK Myasthenia Database?

The UK Myasthenia Database (UKMyDb) is a UK-wide data collecting collaboration between the clinical teams looking after patients with Myasthenia Gravis (MG), Lambert-Eaton Myasthenic Syndrome (LEMS) and Congenital Myasthenic Syndromes (CMS). It will store information about the diagnosis, assessment and management of people with MG, LEMS and CMS living in the UK. The database will make it possible to give researchers controlled access to anonymised data from a large number of people. The creation of this database is funded and supported by Myaware and sponsored by the University of Oxford.

What is the purpose of the study?

The information we collect will help to:

- Have accurate data on the number of people with myasthenia in the UK in order to improve care.
- Identify patterns in myasthenia in different populations in order to improve diagnosis and treatment.
- Plan and develop services for better management of myasthenia.
- Undertake audits and produce reports that help improve the clinical care of patients at a regional and national level.
- Identify areas for future research and support research to improve our understanding of myasthenia as well as improve care of patients.

Why have I been invited?

You have been invited because you have a diagnosis of either MG, LEMS or CMS. We are aiming to include all patients with a diagnosis of myasthenia who are under the care of specialists in NHS hospitals in the UK, regardless of how long they have had the diagnosis or how severe their illness is.

Do I have to take part?

- No. Taking part is entirely voluntary.
- You can withdraw from the database if you change your mind at any time. You do not need to give a reason. If you do withdraw, your previously anonymised data will be retained, but all other information will be erased.
- Withdrawal will not affect your clinical care.
- To withdraw from the database, please speak with your doctor or specialist nurse and they will help.

What information will be collected and how?

We will record information including:

- Your NHS number.
- Your date of birth.
- Your weight and height.
- Your ethnicity.
- How long you have lived in the UK.
- When your myasthenia symptoms started and when you were diagnosed, as well as what symptoms you had at the beginning and if you have any ongoing symptoms.
- Any related hospital admissions, what caused them and how you were treated.
- Age at diagnosis, results of antibody testing, gene testing, imaging and neurophysiology.
- Details of other related relevant conditions (e.g. Thymoma, other cancers or autoimmune diseases).
- Details of other medical conditions (e.g. diabetes, heart disease or stroke).
- Details of treatments past and present, and how well your responded to them.
- Details of other medication that you may be taking, such as heart medications.

This is the information normally collected when you attend each clinic visit, and you will not need any extra assessments or tests as part of this project. We plan to collect and save information each time you are assessed in clinic for as long as possible. The information collected will likely expand with time but will always be limited to information gathered at standard clinic visits. You can ask for more detail about what information we collect at any time.

Who collects the information?

The hospital staff– usually this is a doctor or nurse. Various members of the team that cares for you, including junior doctors, medical students or administrative staff may help with data entry. All information will be stored on a secure system which is password protected.

When will we collect the information?

Initial data entry will begin as soon as possible once you have agreed to participate. Following this, your information will be updated following every clinic visit.

How will we collect the information?

We will collect the information from your medical records and test results. Some information may also be entered directly during or immediately following any time you see your medical team.

What will happen to me if I decide to take part?

You will not need to do anything and there will be no need for extra clinic visits.

Are there any possible disadvantages or risks from taking part?

There will be no physical risk to you as we are only collecting existing information. This information will be stored on secure servers run by the University of Oxford with all access monitored and protected by individual usernames and passwords. There is always a risk of data security being compromised, but this risk is extremely low and many processes are in place to ensure that this does not happen.

What are the possible benefits of taking part?

You will not benefit directly from your information being included in the database; however it is anticipated that this data will help optimise standards of care throughout the UK.

The database is expected to make a valuable contribution to current and future research that will help develop a better understanding of myasthenia. This may benefit you as well as others with myasthenia in the future.

It is possible that the information held on the database could also help in producing new / better treatments in the future by helping researchers design more informative trials while also helping us to monitor the effects of newly licenced treatments over time.

Will my General Practitioner/family doctor (GP) be informed of my participation?

Your GP will not be routinely informed as being part of the database will have no impact on the clinical care of your myasthenia or any other condition you see a healthcare professional for.

Will my taking part in the study be kept confidential?

Every effort will be made to keep your data secure. The details that directly identify you, such as your name, date of birth and NHS number, will not be visible to anyone other than your clinical team and the Oxford team who manage the database.

The database is created using the REDCap system. This is secure and has been used worldwide for similar projects. All access is controlled by a username and password. Your full information will be visible to the medical team responsible for your care and a core group of the team at Oxford who are responsible for creating and maintaining the database. Other medical teams around the country will not be able to view any of your information.

Your data may be used for research purposes. If a research group wishes to access the data, they must first apply to Oxford team who are managing the database, stating their research proposal and why they need the data. They will also have to specify exactly what data they need for their research. This will then be discussed in a panel. If the panel agrees they will be provided with the data in an anonymised format. They will not receive information such as your NHS number and date of birth, or other details that may directly identify you. Anonymisation will be assessed and performed using appropriate UKAnon framework and ICO guidance to minimise any risk of re-identification further. The researchers will not be given access to the original database and will have to destroy any data they are given after 5 years, or apply for an extension. While every effort will be made to ensure you are not re-identified, it is difficult to make it impossible with rare diseases as there are a relatively small number of people with the disease. All data will be stored on University of Oxford's secure servers. The data will be downloaded in a pseudonymised format from the database at regular intervals both for use as a backup, and also to compare changes in the data over longer periods of time. 'Pseudonymised' means that the data will have a code on it that links to your identifiable details, but the data itself does not have identifiers.

This download will also be stored on University of Oxford servers. No strong identifiable information will be stored on private or non-secure devices. All files and folders will be password protected and any devices used for data entry will be required to meet strict security standards.

If any data is transferred to a third party for analysis, this will be done in a secure way in keeping with all relevant protocols.

Responsible members of the University of Oxford, regulatory bodies and the relevant NHS Trusts may be given access to data for monitoring and/or audit of the study to ensure that the research database is complying with applicable regulations.

Will I be reimbursed for taking part?

As there is no cost to you and no action will be required on your part, you will not be reimbursed for anything.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly.

We will be using information from your medical records in order to undertake this study and will use the minimum personally-identifiable information possible. We will keep identifiable information for 10 years after the research database closes. This excludes any research documents with personal information, such as consent forms, which will be held securely at the hospital that is responsible for the treatment of your myasthenia, in keeping with local policy.

The local NHS Trust will use your personal and clinical details held in the record to update the database, and to oversee the quality of the study. They will keep identifiable information about you from this study in keeping with local policy.

Can I see my own data?

Yes. If you want to see your own data, you will need to complete a short request form and give it to your medical team looking after your myasthenia. They will then arrange for your to be provided with a spreadsheet of your information. If you notice any errors in your data, please speak with your medical team to have it corrected.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at

https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting:
mohammad.ashraghi@ndcn.ox.ac.uk

What will happen if I don't want to continue to be included in the database?

Participation is completely voluntary. You are free to withdraw your consent at any time. If you wish to withdraw, please speak with your medical team. The medical care you receive will not be affected in any way.

We will not collect any more information or give it to researchers and will delete information that directly identifies you like your NHS number. Any information already given to researchers cannot be taken back, but none of this can be tracked back to you.

What happens to the results of studies supported by the research database?

It is expected that this database will lead to numerous scientific research publications over the coming years. You will not be identified in any of these. Some of the research being undertaken will also contribute to the fulfilment of an educational requirement (e.g. a doctoral thesis). Research findings may be presented at medical conferences. Some significant research findings may also be found on the Myaware website (www.myaware.org) or other public domains.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact the database manager, Dr Mohammad Ashraghi (mohammad.ashraghi@ndcn.ox.ac.uk) or you may contact the

University of Oxford Research Governance, Ethics and Assurance (RGEA) office on 01865 616480, or the director of RGEA email: ctrg@admin.ox.ac.uk.

Is there someone independent of the research team that I can contact about the study?

Yes. You can contact University of Oxford Research Governance Ethics and Assurance (RGEA) office on 01865 616480, or the director of RGEA, email rgea.complaints@admin.ox.ac.uk. RGEA is the sponsor office on behalf of the University of Oxford, and independent of its research teams. Alternatively, there is a person/department at your local hospital that you can contact: Name: [INSERT] Role: [INSERT] Email: [INSERT] Telephone number: [INSERT]"

How have patients and the public been involved in this project?

The UKMyDb is being funded by Myaware. A steering committee comprising myasthenia specialists from around the UK, Myaware trustees and patients with myasthenia have been involved in the design of the database and will continue to be involved going forward.

Furthermore, the wider patient population has been involved in numerous events hosted by Myaware where the database has been discussed and concerns addressed.

Who is organising and funding the study?

The creation of the UK Myasthenia Database is funded by the myasthenia charity Myaware. Their funding has allowed for the creation of the post of Oxford myasthenia clinical research fellow. This person is paid to create the database. Hospitals or members of medical teams participating in this project are not being paid.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by the Research Ethics Committee.

Participation in future research:

There are often studies that require specific patients to be recruited. Finding these patients can be difficult, particularly when looking at rare diseases. Sometimes, researchers may approach us to help them find suitable patients. If this happens, we can search the database for anyone suitable who has agreed to be approached about future research. If you were suitable, we could let your clinical team know that there is a study that you may be appropriate for. Your clinical team could then let you know and it would then be the decision of you and your doctors whether you want to be included.

You will only be contacted about studies that have received full ethical approval from the relevant governing bodies.

No contact details will be stored on this database and no contact information will be given to other parties, including research teams. If you choose not to be included in a study, you do not need to do anything.

Further information and contact details:

Please contact Dr Mohammad Ashraghi, mohammad.ashraghi@ndcn.ox.ac.uk

Thank you for reading this information