Participant Information Sheet: National Musculoskeletal Audit and Research Database

Understanding the National Musculoskeletal (MSK) Audit and Research Database
The National MSK Audit and Research Database aims to improve the quality and equity of care for patients presenting to primary care (General Practices) and community MSK services with musculoskeletal pain including back, neck, joint or muscle problems.

Who is the researcher responsible?
Professor Jonathan Hill, a primary care researcher at Keele University, is the lead investigator for the National MSK Audit and Research Database.

Who is sponsoring and funding the project?
This research is sponsored by Keele University (reference RG-0359-22) and funded by Pfizer Ltd and the British Society of Rheumatology (BSR).

What is the purpose of the database?
The research database supports the routine collection and sharing of data from care providers for patients presenting to primary and community care with MSK conditions. The information collected is anonymised and stored in a research database to help researchers understand how MSK conditions affect people, how treatments help people, and to understand and improve care provision for people in the future.

What research questions are being asked?
The research database is designed to enable scientists to ask multiple questions about MSK conditions. Researchers can apply to Keele University to ask a specific question from the national MSK research database. Applications are peer reviewed by the Keele research database management team, and if suitable, a data sharing agreement is put in place to enable the researchers to answer their questions.

What do I have to do if I agree to my data being used?
We are not asking you to do anything extra to your usual care. The questionnaires that you complete for your care provider have been selected because they help your clinician understand your condition and how it is affecting you. The questionnaires are all recommended for routine use in the NHS. Agreeing to take part in the audit and research database simply supplies permission for your data to be used to answer research questions in the future.

Who can see my personal data?

Information you enter into the patient survey system will be visible to your treating clinical team. In addition, the research team at Keele University will be able to see your information but with your personal identifiable information removed except for a unique patient identifier (your NHS number), your postcode, and your date of birth. They may use your NHS number to match your survey data to other NHS databases to provide more information about your health.

How will my identity be protected?

The team at Keele University will then create a new database with all personal and identifiable data removed. The process of making this new dataset fully anonymous includes:

• All patient identifiers except for a unique case id will be removed. A linkage key will be stored in a different location to the original dataset but will never be shared.

• Postcode will be converted into an index of multiple deprivation rank, and the original postcode removed.

• Date of birth will be converted to age and the date removed

How secure is the data storage?

Keele University is responsible for the manner in which your data are processed. The information you enter is stored in a digital format only. Information is held in an encrypted format in a secure Microsoft server. Keele University processes the data, using a secure cloud-based data storage solution within Microsoft SharePoint at Keele University. All data repositories are encrypted, and password protected. All people with access to the data sign confidentiality agreements and are trained in the responsibilities of data protection. The data will then be shared with an additional data processor (the West Midlands Secure Data Environment Team based at University Hospitals Birmingham (NHS based)). Once the data is transferred to the West Midlands Secure Data Environment the personal data at Keele will be deleted. Data within the West Midlands Secure Data Environment will be held in a secure environment, where only the Data Custodian and assigned personnel will have access to the data. No data will be shared outside the environment area and processes will be put in place to ensure that only relevant individuals will have access to personal data and that this is kept separately to the anonymised research database.

What linkages will take place?

We join the national MSK database to other national databases to help researchers understand the impact of MSK conditions in more detail. The linkages join up information on, prescribing, hospital admissions, and use of NHS care. Databases that may be linked are:

• England: NHS Digital (on behalf of PHE and the Office for National Statistics)

• Northern Ireland: Health and Social Care Business Services Organisation and Northern Ireland

• Scotland: National Health Service Central Register and National Services Scotland

• Wales: NHS Digital (on behalf of Public Health Wales and the Office for National Statistics) and NHS Wales Informatics Service.

Who else might access my data?
No one else can access data that could identify you. The de-identified database may be shared with other researchers that have had their research question approved by the Keele National MSK Audit and Research Database team. These researchers could be people in academic institutions, or in industries involved in the development of treatments for MSK conditions. No data will be made available to health insurers.

What are the benefits of agreeing to take part?
The main reason for taking part is to help researchers answer questions that will help other people with MSK conditions in the future.

Who has reviewed this study?
All research in the NHS, is reviewed by an independent group of people, called a Research Ethics Committee - to protect your rights, dignity and wellbeing. This study has been reviewed and given favourable opinion by Central Bristol Research Ethics Committee, 23/SW/0059.

What if there is a problem?
There are no risks (in terms of safety or physical harm) involved in participating in the research database. If you have a concern or a complaint about any aspect of the research database, you should ask to speak to the researchers at Keele University who will do their best to answer your questions. The researchers contact details can be found at the end of this information sheet. Please call 01782 732950.

If you remain unhappy and wish to complain formally, you can make a formal complaint through the NHS complaints procedure. Details can be obtained through the Patient Advisory Liaison Service at your hospital.

What will happen if you want to withdraw your data from the database?
Under the Data Protection Act 2018 and the General Data Protection Regulation (GDPR) 2018 you have rights as an individual which you can exercise in relation to the information we hold about you. If you decide to opt-out from sharing your data after your data has entered the secure database we will use a unique identifier available in the depersonalised dataset to enable re-identification and erasure of your data from the database, preventing its use in future research. Fully anonymised data that has already been made available to academics within the secure data environment for approved analyses will not be able to be re-identified.

How can I find out the results of research?
Study results are published in medical journals, and summary versions are made available online by Keele University.   The results of the study will be presented at conferences. The study results may also be used to improve NHS services and inform public health policies.

Further information and contact details.
For further information please contact Keele University Clinical Trials Unit on 01782 732950 or visit www.keele.ac.uk/nationalmskaudit

Thank you for taking the time to read this Participant Information Leaflet and for considering taking part in the National MSK Audit and Research Database.