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**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](http://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.**

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**Keele’s National MSK Audit and Research Database: Privacy Statement**

Living with musculoskeletal conditions can be hard and affect you in many ways. By answering some questions about your health and wellbeing, your musculoskeletal healthcare team can get a better understanding of how you are feeling and coping.

This data is collected by your Healthcare Provider using an online platform to help collect this information and share it with your musculoskeletal team.

The online system collects information to support routine holistic care for patients with musculoskeletal conditions.

This aims to improve the care provided to people by helping musculoskeletal teams understand symptom burden and disease severity. Your healthcare provider uses the data gathered to inform individual patient care, and together with Keele University, to additionally conduct research, audit, and service evaluation. Keele University, the British Society of Rheumatology (BSR), and your healthcare provider are joint data controllers for the information provided.

***Sources of information***

Patients are registered on the online platform by their musculoskeletal service administrator or clinician. Information about symptoms, wellbeing and health are submitted online by the patient. If data are used for research purposes, linkage with other NHS databases may occur. Further information about data linkage is available in the research database protocol.

Data are gathered by patients and clinicians via a secure web-based platform. The information is held on a secure server.

Security and confidentiality are maintained through use of restricted access with passwords and security agreements. All individuals who access personal identifiable data are your healthcare provider employees, who access the information for the purposes of clinical care. Where data are used for research and clinical audit, they are pseudonymised and users are unable to identify patients from the information at their disposal.

***What will we do with the information you provide to us?***

All the information provided will only be used for the purpose for which you provided it, or to fulfil business, legal or regulatory requirements if needed.

Keele University, BSR, and your electronic survey provider will not share any information provided to us to any third parties for marketing purposes.

Information is held in secure data centres in the EEA which comply with the Data Protection Act (2018) and the General Data Protection Regulation (2018).

All data are held on a restricted server. Staff at healthcare provider sites can access data for their site only. Staff at Keele University and within the West Midlands Secure Data Environment team are responsible for processing the data to create a pseudonymised dataset for research.

Data may be used to monitor the delivery of Keele’s National MSK Audit, Research Database, and service evaluation. Aggregated data may be used to publish research at various levels (e.g. by patient group or pain site).

Where data are requested for research purposes, an application is made and approved via Keele’s National MSK Audit and Research Database team.

***What information are we collecting?***

Keele’s National MSK Audit and Research Database does not collect more information than is needed to fulfil the requirements of the programme and we will not retain it longer than is necessary.

The information we ask for is used either to maintain a record of your care or to contact you, provide information to support and inform clinical care, or for Keele-approved research purposes. We process:

1. Demographic data including age and gender.
2. Care data including diagnosis and treatment.
3. Routine patient reported outcomes such as the musculoskeletal health questionnaire (MSK-HQ).
4. Routine patient reported experience measures.

***Use of data processors***

Data processors are third parties who process data for us. We have contracts in place with our data processors. This means they cannot do anything with the information unless we have instructed them to do it.

Our data processors will not share any information with any organisation other than us. They will hold it securely and retain it for the period we instruct.

The data processors we use are:

• Provider of the British Society of Rheumatology (BSR) electronic patient reported outcome measure (ePROMs) platform (Net Solving)

• Other Providers of online data collection platforms commissioned by musculoskeletal healthcare providers to capture patient survey data

• Academic partner for curation of the pseudonymised data Keele University (National Musculoskeletal Audit and Research Database).

• West Midlands Secure Data Environment (WMSDE) commissioned by Keele University to securely store/host the Research Database.

***How long is the data retained for?***

Information added to patient’s clinical records is retained in line with the Records Management Code of Practice for Health and Social Care (2016).

***Patient’s Clinical Care***

All health and social care providers are subject to a statutory duty to process information about a patient for their clinical care. This includes medical diagnosis, the provision of health care or treatment, performance against national targets, local clinical audit and service improvement. Keele University therefore applies for following lawful basis for processing personal data:

Article 6(1)(e) – Necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller.

In addition, as this National MSK Audit and Research Database processes special category data (such as health data), and therefore must process this data under an additional legal basis. Keele University applies the following legal bases for processing this data:

Article 9(2)(h) – Necessary for the purposes of preventative or occupational medicine, for assessing the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or management of health or social care systems and services on the basis of Union or Member State law or a contract with a health professional.

And

Article 9(2)(i) – Necessary for reasons of public interest in the area of public health, such as protecting against serious cross- border threats to health or ensuring high standards of healthcare and of medicinal products or medical devices.

Keele’s National MSK Audit and Research Database

For any research conducted using Keele’s MSK Research Database data, applications are reviewed by Keele’s National MSK Audit and Research Database Management Team and are processed under the following legal basis:

Article 6(1)(a) - the data subject has given consent to the processing of his or her personal data for one or more specific purposes;

And

Article 9(2)(a) – the data subject has given explicit consent to the processing of those personal data for one or more specified purposes, except where Union or Member State law provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject;

Data from patients who have not explicitly consented to the research database within the online data collection portal will not be processed/shared with Keele University for any research purposes.

***Confidentiality***

All information received via Keele’s National MSK Audit and Research Database is treated as confidential. Identifiable information is only processed for the purpose of informing individual clinical care and treatment by the healthcare provider. All other information is processed in a pseudonymised format, initially retaining NHS number, postcode, and date of birth, until data are linked within the secure data environment at which point a new dataset is developed where individual patients are then only identifiable using coded patient lists which are held separately to the dataset within the secure data environment.

The Keele National MSK Audit and Research Database team, clinicians, or researchers will not publish information which can enable individuals to be identified, nor allow third parties to access the data.

The confidentiality and security of information is maintained in the following ways:

* In all publications, the statistical information is reviewed to ensure the risk of identification is minimised, and where necessary small numbers are supressed.
* All publications include aggregated data at a relevant level.

Your Rights

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.

Rights for individuals are:

* The right to be informed.
* The right of access.
* The right to rectification.
* The right to erasure.
* The right to restrict processing.
* The right to data portability.
* The right to object.
* Rights in relation to automated decision making and profiling.

For more information on your rights as an individual, visit  [Information Commissioner's Office (ICO)](https://ico.org.uk/)

***What if I do not want my information used?***

As a patient, you can choose not to provide data to the National MSK Audit and Research Database. Please tell your healthcare professional that you do not want to take part.

If you would not like your data to be used for research purposes, please let your healthcare professional know. You can also choose to not have any of your confidential patient information used in research and planning via the NHS opt-out service (https://www.nhs.uk/your-nhs-data-matters/).

***Complaints or queries***

Keele University and the BSR take data protection and privacy requirements seriously. If you have any concerns, questions or wish to make a complaint you can contact us using the information at the bottom of this notice.

You can also complain to the Information Commissioners Office directly:

Information Commissioners Office
Wycliffe House
Waterlane
Wilmslow, Cheshire SK9 5AF
0303 123 1113
[http://ico.org.uk](http://ico.org.uk/)

Changes to this Notice

We keep our privacy notices regularly under review. This privacy notice was last updated in February 2023.

Contact Us

Keele University’s Data Protection Officer can be contacted at: dpo@keele.ac.uk.

The BSR’s data protection officer is Caroline Wilson, and can be contacted on cwilson@rheumatology.org.uk