GPRD

Ensuring the Confidentiality of Information on GPRD

Guidelines for Practice Managers

This practice is proud to contribute data to the General Practice Research Database (GPRD)

GPRD

GPRD is the world's largest and most extensively used database of its kind. It is used internationally for research into disease, drug safety and public health.

Patients' records from hundreds of practices in the UK are made anonymous so that research users cannot identify the patients or the practices. Added together, these anonymous records provide a vast amount of information for medical research.

GPRD is managed by the Medicines and Healthcare products Regulatory Agency (MHRA), a part of the Department of Health responsible for the licensing and safety of all medicines and medical products in the UK.

Our role

- We contribute data from this practice to the GPRD and are proud to do our bit towards this valuable database.
- Anonymity of individual patients and clinicians is assured in all cases.

Benefits

The practice receives

- Valuable feedback on the data we submit. This helps us to improve our record-keeping and the care of our patients.
- A small payment (10 pence per patient per year) towards the cost of the work involved.

A leaflet giving more detailed information about GPRD is available. If you would like a copy please ask a member of practice staff.

GPRD

MHRA

About this leaflet and supporting literature

This leaflet and the supporting poster and patient leaflet have been sent to you to help you comply with guidance from the General Medical Council (GMC), and advice from professional bodies about the law surrounding confidentiality of patient data.

All staff in the practice should be made aware of the issues raised in this leaflet since patients may ask them about the poster and other issues concerning the confidentiality of their records. A leaflet for patients is provided and we would also ask you to add a suitable sentence about the GPRD scheme to your practice leaflet and/or website.

This document provides Practice Managers with information to help them answer enquiries from patients about the General Practice Research Database and specifically about handling patient requests for information about withdrawal from the GPRD Scheme.

1. Background facts about GPRD

- The database is run on a non-profit making basis by the Medicines and Healthcare products Regulatory Agency (MHRA) in London.
- The MHRA's primary objective is to safeguard public health by ensuring that all medicines and healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and are used safely.
- The data on the database are used for large scale public health and medical research purposes. The types of study include epidemiology, drug safety, and prescribing analysis.

- GPRD has collected electronic data from general practices since 1987.
- GPRD's record on confidentiality is excellent. There have been no recorded breaches of confidentiality during the history of the scheme.
- GPRD's confidentiality procedures are at the highest appropriate level and fully approved as required.
- Guidance from the General Medical Council strongly encourages doctors to 'co-operate by providing relevant information wherever possible' to bodies such as the MHRA.

2. GPRD confidentiality policy statement

"The Medicines and Healthcare products Regulatory Agency seeks to ensure that the processes and procedures associated with the operation of the GPRD adhere to all applicable data protection legislation, as well as to guidance from medical, regulatory and professional bodies.

These processes and procedures are reassessed regularly and, where necessary, enhanced to ensure ongoing compliance with accepted best practices, with any risks of breach of confidentiality being reduced to the minimum possible."

3. GPRD procedures to safeguard patient confidentiality

Patient records are identified by only a number and a GP practice number that can only be reversed by your own practice software.

Your practice may only enable the option to allow an approved trusted third party to provide a mechanism so GPRD data can be linked to other NHS data, such as hospital records or those for specific diseases. Importantly, researchers never see any patient identifiers. A file from the GP computer system containing text is also removed but these data are accessed under extremely controlled circumstances and no original data are ever released to researchers.

GPRD operates confidentiality and security policies to the maximum level required.

The major components of GPRD's multi-faceted approach are presented in the table below.

Informing patients	• Communication of guidelines for practices on making information available to patients about research usage of anonymised data, including the provision of a poster and patient information leaflets
Data entry	• Recording guidelines which lay out procedures for practice staff to anonymise free text data using double backslash methodology. By placing a double backslash at the beginning of a free text entry, that entry will not be collected during the draw-down of data for GPRD.
Data transfer	• Adoption of the highest level of policy and methodologies to ensure all data are handled appropriately at all times.

Data loading	• Ability to exclude individual patients from data load, where the patient insists on opting out.
Data storage	• Complete separation between computers on which data are stored and those accessed by the users conducting research on the data.
Data access	• Data access conditional on signature of licence agreement with stringent constraints placed on use and onward communication of data and research. • Independent Scientific Advisory Board and ethical oversight of all research resulting in a publication from GPRD. • Exclusion of all free text from research users until each free text field is checked individually for presence of identifiable data. • Robust 'safe haven' approach to handling follow up of GP source records. • Latest security technologies (encryption, user authentication) applied at user interface.
Data linkage	• Your practice may enable data linkage using our Trusted Third Party. This methodology is appropriately approved and ensures researchers never access other than anonymised data.

4. GMC guidelines on consent

An important component of the guidelines for data collection schemes is the provision of enhanced information to patients. The GMC provides the following guidelines, for circumstances when patients' records are made available to research organisations such as the GPRD:

"In all such cases you must be satisfied that patients have been told, or have had access to written material informing them:

a. That their records may be disclosed to persons outside the team which provided their care.
b. Of the purpose and extent of the disclosure, for example, to produce anonymised data for use research, epidemiology or surveillance.
c. That the person given access to records will be subject to a duty of confidentiality.
d. That they have a right to object to such a process, and that their objection will be respected, except where the disclosure is essential to protect the patient, or someone else, from risk of death or serious harm"

Source: GMC Guidelines

In order to comply with these guidelines the MHRA is providing posters and patient information leaflets to every practice which contributes to the GPRD. Copies are enclosed with these guidelines. The posters should be displayed in the practice, probably in the waiting room. The practice manager, or other nominated staff member, should store the stock of leaflets and give a copy to those patients that request further information.

If you need further copies of the poster or leaflet please contact us at GPRD Freepost, LON10978, London SW8 5YY, or telephone 020 7084 2383.

5. Withdrawal of consent

As a result of reading the poster or leaflet, a patient may choose to withdraw consent for their records to be collected as part of the GPRD scheme.

If possible, patients should be discouraged from withdrawing their consent. There are substantial public health benefits gained from the data, and there would be significant damage to the value of the data caused by the withdrawal of even a small number of patients from the scheme.

6. Procedure to follow should patients choose to withhold consent

Should a patient be adamant that they do not want their records to be included in the scheme their medical records can be marked to ensure they do not form part of the draw down of records for inclusion in the GPRD.

To comply with the patient's wishes, click in the box marked 'Consent refused for GPRD Data Collection' under the 'Consent' tab on the Registration Details screen in Vision. This will prevent that individual patient's data being collected as part of the draw down of data for inclusion in the GPRD.

If you have any questions please do not hesitate to contact the GPRD Helpdesk on 020 7084 2383.

Examples of the research that GPRD is used for

The following are some of the medical papers that have resulted from research using the GPRD:

1 **What is the harm-benefit ratio of Cox-2 inhibitors?**
van Staa TP, Smeeth L, Persson I, Parkinson J, Leufkens HG.
Int. J Epidemiol. 2008 Apr;37(2):405-13. Epub 2008 Feb 8.
This aim of the study was to determine the balance of potential harm and benefit related to Cox-2 inhibitors' exposure. The results showed that the benefit of Cox-2 inhibitors in reducing the frequency of upper GI events may be offset by their cardiovascular harm, particularly in patients with risk factors for cardiovascular disease.

2 **Epidemiology of childhood fractures in Britain: a study using the general practice research database.**
Cooper C, Dennison EM, Leufkens HG, Bishop N, van Staa TP.
J Bone Miner Res. (2004) Dec; 19(12): 1976-81. Epub 2004 Sep 20.
A study of fractures in children, aged 16 or under, in the UK showed that fractures were more frequent in boys, with fractures most likely at age 14, than in girls, with fractures most likely at the age of 11.

3 **Dopamine agonists and the risk of cardiac-valve regurgitation.**
Schade R, Andersohn F, Suissa S, Haverkamp W, Garbe E.
N Engl J Med. 2007 Jan 4;356(1):29-38.
This study showed the use of the dopamine agonists pergolide and cabergoline was associated with an increased risk of newly diagnosed cardiac-valve regurgitation.

4 **Risk of myocardial infarction and stroke after acute infection or vaccination.**
Smeeth L, Thomas SL, Hall AJ, Hubbard R, Farrington P, Vallance P.
N Engl J Med. 2004 Dec 16;351(25):2611-8.
This study showed that acute infections are associated with a transient increase in the risk of vascular events.

5 **MMR vaccination and pervasive developmental disorders: a case-control study.**
Smeeth L, Cook C, Fombonne E, Heavey L, Rodrigues LC, Smith PG, Hall AJ.
Lancet. 2004 Sept 11-17;364(9438):963-9
The study showed that MMR vaccination is not associated with an increased risk of pervasive developmental disorders.

An extensive bibliography can be found at www.gprd.com

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