



QRESEARCH PRACTICE INFORMATION SHEET

June 2003

Background

The University of Nottingham has been working in collaboration with EMIS to develop a new method, known as QRESEARCH, to make data from GP clinical computers available for research. This involves computer searches that are run centrally by EMIS. Data is anonymised within the practice and then extracted and aggregated to produce a database suitable for research.

Currently researchers wanting access to General Practice datasets for their research can undertake data collection using MIQUEST computer software. However, there are drawbacks because MIQUEST 'report style' searches needed for research may need to be repeated several times.

We have completed a pilot of QRESEARCH with 38 practices in the Trent Region and are now recruiting a national sample of 300-400 practices to be involved in a long-term national scheme. Full approval has been obtained from the Trent Multi-Centre Research Ethics Committee and the EMIS National User Group.

Why has my practice been invited to participate?

We are inviting all practices using EMIS Version 5 or above to take part.

Does the practice have to take part?

It is entirely up to the practice as to whether they wish to take part. Practices who agree to take part will activate the QRESEARCH module within their surgery system. The practice will only be included in the project once this activation has been done.

What will happen if the practice takes part in QRESEARCH ?

GP computer systems are currently connected to EMIS via the NHSNet for support and patching of system upgrades. EMIS will use this link to first upload key census related variables such as the deprivation score (called the Townsend Score) and a marker of rurality (called the Carstairs rurality score) into the patient's electronic record. These data items will be stored in the patients' record but will not be available on the patient's registration screen. The scores are derived from the national census and are linked to the electoral ward or enumeration district in which the patient lives. The scores are used in research to measure or monitor uptake and provision of health services.

The practice system will then generate an upload of the anonymised data and transmit this data via the NHSNet to a dedicated server within EMIS. The data is updated on a daily basis and this update does not interfere with the running of the practice or any back-ups. Practices can view the data extracted each day if they choose in accordance with guidance from the Committee of Standards of Data Extraction (COSODE).

EMIS will undertake a secure transmission of the aggregated data to the University of Nottingham, which is the single point of access to the data. To ensure maximum security, the data will be encrypted and will be stored on a stand-alone PC in the University of Nottingham. The University of Nottingham will be the only point of access to the data.

Can the practice withdraw from QRESEARCH at any time?

Practices can withdraw from QRESEARCH at any time and without giving a reason. If a practice does decide to withdraw, no further data from the practice will be included in future research projects. If a practice wishes to withdraw, it just selects the 'deactivation' option from the QRESEARCH module within their surgery computer system.

What are the benefits of taking part?

Practices will be contributing to the improvement of patient care through a good quality ethical research programme, carried out on large volumes of data. Practices will be able to run searches on their own system and compare their results with the anonymous aggregated searches obtained from the 300-400 QRESEARCH practices. Practices will be able to contribute to the decision about what feedback will be available by indicating preferences on our website (www.qresearch.org). We anticipate that our feedback will cover conditions NOT included in the New Contract as there are many other important diseases where comparative analysis may help benefit patient care. In addition, we will try to facilitate any of our practices who wish to undertake their own research project by discussing the project with them and providing advice on how to get the submission to the Scientific Committee ready.

QRESEARCH has been set up on a not-for-profit basis and there is no funding available to cover practice time. However, our pilot work shows that the amount of time involved in activating the upload is minimal.

We will provide voluntary guidelines on data recording for practices which will be consistent with advice given by other organisations, including PRIMIS and the NHS Information Authority.

Are there any risks to taking part?

We do not believe there are any significant risks to taking part in QRESEARCH. The main issue is security and confidentiality of the data collected and we have put systems in place to ensure maximum security of data. We have approval from Trent Multi-Centre Ethics Committee and have consulted widely with professionals with expertise in this area. All information will be held in accordance with the principles and conditions set out in the Data Protection Act 1998 and with proper safeguards to ensure confidentiality. No patient identifiable information will be extracted from your database and therefore patient identifiers will never be released by QRESEARCH. The identity of practices in QRESEARCH will be kept confidential. Although the practice identifiers will be known to EMIS and one member of the QRESEARCH team, no practice identifiable data will be released by QRESEARCH to a third party. All uses of the data, will require the approval of the National Advisory Board. Under no circumstances will a copy of the entire database be made available to any individual or organisation.

Trent Multi-centre Ethics Committee have advised us that all practices contributing to collection of anonymised data for research need to display a notice in their waiting room informing patients. The notice is attached to this information sheet. Patients who do not wish their data to be included in the upload are able to opt out by informing their General Practitioner who then assigns a specific EMIS Read code, which will cancel any future data collection from that patients' record. All data already collected from that patients record will then be deleted from the database.

What is the Advisory Board and what is its role?

The role of Advisory Board is:

- To oversee the general working of QRESEARCH including the handling of the data, the type of analyses undertaken and access to the database
- To agree and update the criteria and principles for access to the QRESEARCH database and oversee their application
- To advise on policy for accessing data (i.e. how quickly should researchers get data; how much should it cost)

- To offer general advice on professional issues to the QRESEARCH management team.

The full board will represent the key stakeholders in QRESEARCH and to gain and retain the respect of the public, the NHS, practices and the research community. Its membership will include representatives of the following organisations:

- The Royal College of General Practitioners
- The British Medical Association itself and its General Practitioners Committee
- EMIS National User Group
- A representative of the practices contributing data to QRESEARCH
- EMIS
- Patient representation
- The Research Ethics Committee
- University of Nottingham
- Chair of the Scientific Committee

In order to carry out the development and piloting of QRESEARCH we have appointed a pilot advisory board. Its membership, in addition to Julia Hippisley-Cox, Mike Pringle and David Stables, is Dr John Williams, Dr John Ford, Dr Dai Evans and Professor Azeem Majeed.

What are the requirements for the projects undertaken using QRESEARCH?

There will be two types of projects that will use QRESEARCH. The first type will be research projects and many of these will require a subset of QRESEARCH to analyse. Research projects undertaken using the QRESEARCH data will fulfil the following criteria:

- a) They have a named academic principal investigator and named co-investigators
- b) They will have a written protocol with a clear research question
- c) They will have current ethical committee approval for the project
- d) They will have a research sponsor and will meet the requirements of research governance
- e) They will agree to acknowledge the source of data in any publication or report (which will never identify any individual practices)
- f) They will guarantee their academic independence, including their ability to publish their findings regardless of the implications for any sponsor or funder
- g) The QRESEARCH Scientific Committee will need to give approval within the guidelines set out by the QRESEARCH Advisory Board before any analysis can occur and before the data can be supplied to the user.

The second type of project will require tables of data. These morbidity surveys will not require the release of a subset containing patient level data, but just analyses. The results of these analyses will be placed on the QRESEARCH website (www.qresearch.org). Applicants for tabular data will need to be approved by the Advisory Board.

Under no circumstances will QRESEARCH data will made available to pharmaceutical companies for pharmacosurveillance.

Will the identity of practices taking part in QRESEARCH be kept confidential?

Yes, the participation of the practice in QRESEARCH will be confidential. The Advisory Board, let alone any users of the QRESEARCH data will not know the identity of the practice. The practice will not be named in any report or publication.

What happens to the results of the research projects?

We expect researchers who use QRESEARCH data for their research to publish the findings in peer-reviewed journals. We will keep a list of all publications and this will be available to the practices on request.

Will all practices who volunteer be included?

If we have more than 400 practices included, then we will choose a geographically representative sample.

Who is organising the research and who are the guarantors?

The project is organised and guaranteed by Dr Julia Hippisley-Cox (Senior Lecturer) and Professor Mike Pringle, Division of Primary Care, 13th Floor, Tower Building, University Park, Nottingham, NG7 2RD.

Telephone: **0115 8466923** or **0115 8466901**

E-mail: **julia.hippisley-cox@nottingham.ac.uk** or **mike.pringle@nottingham.ac.uk**

QRESEARCH has been developed in conjunction with Dr David Stables, Medical Director of EMIS. Trent Multi-Centre Research Ethics Committee has approved the protocol. Anyone replacing these individuals will complete a QRESEARCH Confidentiality Declaration and notify Trent Multi-Centre Research Ethics Committee before receiving access to or involvement with QRESEARCH data.

Further queries

If you have any queries about QRESEARCH, then please contact either Dr Julia Hippisley-Cox or Professor Mike Pringle (as above) by e-mail or phone. Further details about QRESEARCH including the full protocol and documentation can be found on the QRESEARCH website (www.qresearch.org)

If you have any complaints about the way that QRESEARCH is being conducted, please contact either:

Professor Tony Avery

Head of Division of Primary Care, C floor, Medical School, Queen's Medical Centre, NG7 2UH.

Telephone: 0115 9709 387

E-mail: tony.avery@nottingham.ac.uk

Dr Dai Evans

EMIS National User Group, 2nd Floor, 2 Eslington Terrace, Jesmond, Newcastle upon Tyne NE2 4RJ.

E-mail: devans@emisnug.org

EXAMPLE NOTICE FOR PATIENTS

'SURGERY NAME' IS A RESEARCH PRACTICE.

We ask you for information about yourself so that you can receive proper care and treatment. We keep this information, together with the details of your care, because it may be needed if we see you again.

We may use some of this information for other reasons, for example, to help us protect the health of the public generally, to plan for the future, to train staff and to carry our medical and other health research for the benefit of everyone.

We are currently involved in some research studies that require anonymous information from patients' notes. You cannot be identified from this information.

If anything to do with the research would involve you personally, you will be contacted to see if you are willing to take part, you will not be identified in any published results without your agreement.

You have a right of access to your health records. If at any time you would like to know more, or have any concerns about how we use your information you can speak to: 'Person nominated by practice' tel: number

EVERYONE WORKING FOR THE NHS HAS A LEGAL DUTY TO KEEP INFORMATION ABOUT YOU CONFIDENTIAL