

Unlocking the research potential of the GP electronic care record

The electronic records of patients registered with UK NHS general practices contain a wealth of data and have the potential to make a major contribution to medical science.^{1,2} Representing over 95% of the entire population and often spanning several decades of an individual's life, they include a summary of key health events and a detailed record of activities relating to prevention, prescribing, and investigation. The use of GP records for research is not new. The General Practice Research Database (GPRD) has for more than 20 years provided high quality routine data from practices covering approximately 8% of the UK population, and other similar resources such as QResearch® and The Health Improvement Network have extended this to around 20% of the population. The potential extension of coverage to a much larger proportion of the population should bring major rewards in terms of the representativeness of the data and the ability comprehensively to identify patients with specific clinical characteristics, including those with rare conditions. It will also offer major improvements in the monitoring of new medications.

WHAT IS THE CPRD AND HOW WILL IT BE USED?

The Clinical Practice Research Datalink (CPRD) was launched in April 2012 with a remit to extend coverage to the entire UK population and to add additional services for record linkage and embedded clinical trials.³ Hosted by the Medicines and Healthcare products Regulatory Agency and jointly funded by the National Institute for Health Research (NIHR), the CPRD benefits from extensive expertise developed through both the GPRD and the Research Capability Programme, and will provide researchers from approved organisations with access for research purposes to anonymised patient data extracted from a wide range of linked clinical datasets. General practice care records will be central to ensuring comprehensive population coverage, while further data will be available from other sources including hospital records and cancer and death registries. It is likely that linkage will be additionally extended to experimental data sets such as UK Biobank.⁴ The CPRD has the potential to enable important research questions to be

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answered through the analysis of routinely collected observational data drawn from a range of sources and on a much larger scale than was previously possible. Furthermore, its unique clinical trials support facility will not only enhance the work of NIHR but also offer major advantages to the UK and global life sciences industries.

CPRD AND THE HEALTH AND WEALTH AGENDA

Clinical trials are essential to the UK economy for two reasons. First, the UK pharmaceutical sector invests £3.3 billion each year in research and development and provides employment for 25 000 people.⁵ Secondly, the NIHR spends in excess of £1 billion each year on supporting research to improve the quality and effectiveness of NHS care. Nonetheless, several key life sciences research facilities have recently closed in the UK, due in part to difficulties recruiting and following research subjects.⁶ The CPRD will deploy an advanced information technology infrastructure to underpin the conduct of feasibility counts, recruitment, consent, and long-term follow-up within NHS health record systems. Its high speed search facility will enable the rapid identification of the anonymised records of subjects fitting the criteria for each approved research study. These will then be linked back to the full records in the patients' registered practice, where appropriate staff will be able to decide whether or not to approach them about recruitment to the study. If incident criteria are required, such as exacerbations

or newly presenting cases, software agents monitoring the data entered in the health record will be able to provide clinicians with alerts.⁷ Work currently being undertaken in the European Union's TRANSFoRM FP7 project in which the CPRD is a participant could also make it possible to integrate the storage of research and clinical data through solutions such as the E-Source, thus avoiding the problems of duplication of data entry.^{8,9}

LEARNING THE LESSONS FROM MAJOR IT PROJECTS

The CPRD has real potential to lead the world in this field and to provide the UK and global life sciences industries with a uniquely valuable resource to support their clinical trial activities. It will be developed in partnership with established suppliers of electronic health record systems and the Information Centre for Health and Social Care, and therefore will not require a national procurement exercise of the kind that proved so problematic with Connecting for Health. Nonetheless, comprehensive national deployment is likely to present a major socio-technical challenge because of the complexity of the issues which it raises.¹⁰ For example, although the provision of explicit consent by patients for the use of their data for research purposes ('Opt in') is generally regarded to be best practice, it is clear that this is not a realistic option if the CPRD is to achieve comprehensive record coverage. 'Opt out' may be acceptable to the majority of patients and healthcare professionals,

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but it is likely that some will be opposed to this.¹¹ Concerns have also been expressed about confidentiality, although the excellent track record of stewardship of GP data by the GPRD with no breaches of privacy in 25 years should provide firm reassurance about this.

The CPRD presents additional challenges due to the extension of record linkage beyond general practice to other data sets in health and social care, and will be well served by the more robust approach to confidentiality and data security recently approved by the NHS Information Governance Board. Due account will also need to be taken of concerns about the quality of the information given to patients, technical aspects of data protection, and the use of the data for commercial purposes, but several influential, independent groups have recently provided opinions on these issues. The Academy of Medical Sciences was broadly in favour of increased data sharing because of the impact on clinical studies and the ‘unparalleled opportunities for enhancing such research’.¹² A consensus statement developed by the Wellcome Trust and endorsed by the British Medical Association and Royal College of General Practitioners suggested three key guiding principles:

- patient confidentiality and privacy must be safeguarded;
- GPs and healthcare professionals should play the role of patient’s advocate; and
- public awareness and understanding of the use of records in research should be improved.¹³

THE CHALLENGES FOR GENERAL PRACTICE

The CPRD is being deployed against a background of many changes in the health and social care systems in the UK. Although those in England may seem the most radical, all administrations will need to consider how best to ensure that their data sharing arrangements are compliant with the Wellcome principles. The CPRD will only achieve its real potential if it achieves access to the great majority of patient records in general practice, and it is critical

that practices across the country embrace the opportunity and constructively engage with this project. The government has made clear its commitment, and has included a new provision within NHS Constitution for the anonymisation of all data collected during the course of patient treatment and its use to support research and improve patient care. There is also good evidence that most patients expect their clinical records to be made available for research purposes. Practices should therefore feel confident in exercising their choice to sign up, for failure to do so would significantly detract from the ability of this initiative to achieve its full potential in benefiting patient care.

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Provenance

Commissioned; not externally peer reviewed.

DOI:10.3399/bjgp13X668023

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