Evaluating Prescribing Safety Indicators in Clinical Decision Support

Patient Privacy Notice

What is this study about?

Patients can sometimes be harmed by their medication because of inappropriate prescribing. To help doctors and other practitioners to prescribe more safely, computer programs are implemented in many general practices to aid clinical decision making. During the prescription process, these programs automatically check the patient's electronic health record for potential factors that could influence safety of the medication being prescribed. These include, for example, use of other medications and other diagnoses. An alert is sent to the prescriber if the prescription is identified to be potentially hazardous to the patient. We aim to understand the effect of the implementation of one of these computerised clinical decision support systems, OptimiseRx, on rates of hazardous prescribing in general practices, and of hospitalisation and death. We will also evaluate if OptimiseRx is cost-effective for the NHS.

This study is Work Package 2 of the National Institute of Health Research (NIHR) Programme Grant for Applied Research (RP-PG-1214-10005): "Avoiding patient harm through the application of prescribing safety indicators in English general practices" (acronym: PRoTeCT). The programme is a collaboration between the University of Nottingham, University of Manchester, University of Dundee, and University of Edinburgh. Work Package 2 is led by the University of Manchester.

What data will we use for this study?

We will use data from ResearchOne http://www.researchone.org/, which is a database of non-identifiable clinical and administrative data drawn from the electronic patient records currently held on the TPP SystmOne clinical system.

Your healthcare provider may use the TPP SystmOne clinical system to maintain your electronic patient record. All English general practices using SystmOne are invited to contribute data to the ResearchOne database, which was set up to facilitate medical research and to benefit public health. In order for any data to be included in ResearchOne, the data controllers for health and care providers on SystmOne must decide to opt-in. Providers can choose to opt-in or opt-out at any time. Units who have direct contact with patients are provided with posters to display so that patients are aware that their non-identifiable data is to be used for research purposes. For any individuals who do not wish their de-identified data be held for research purposes, all SystmOne users who provide data to ResearchOne can easily record this dissent as a flag on the patient record. Any change to the patient status will be reflected within seven days at the next database update.

If any of your healthcare providers has opted-in and you have not requested your records to be excluded for research purposes, then this anonymous data will be stored on ResearchOne. All data stored in the ResearchOne database is non identifiable and no information that could identify you or your healthcare providers is available to researchers. This means that no identifiable details such as name or address are brought into the database. Similarly no textual information is transferred in order to maintain patient confidentiality.

For this study, we will use data from general practices contributing to ResearchOne, irrespective of whether they have implemented OptimiseRx. For practices that have implemented the software, we will compare the trends in hazardous prescribing in the time before the implementation with the period after. Data from practices which have not implemented OptimiseRx will be used for comparisons.

TPP will extract the data from ResearchOne for this study. In order to assess whether the implementation of OptimiseRx has led to changes in rates of hospitalisation and death, as well as costs to the NHS, we will also use linked secondary care and death records from NHS Digital. We have obtained approval from the Confidentiality Advisory Group of the Health Research Authority for TPP to transfer the patient pseudonyms, date of birth and gender to NHS Digital, so that NHS Digital can extract the secondary care and mortality records of the relevant patients for this study. No patient identifiable information, including the NHS numbers, will ever be transferred from ResearchOne or NHS Digital to the University of Manchester. We will only have access to de-identified and anonymised data.

In accordance with the General Data Protection Regulation (GDPR) data minimisation principle https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/principles/data-minimisation/, we will also only request the data that are needed for this study. This would include records of prescribed medications, diagnoses, and laboratory results that are relevant to the hazardous prescribing indicators in our investigation.

Who is responsible for the data?

The University of Manchester and University of Nottingham (PRoTeCT programme lead) are joint controllers of the data for this study.

The data will be processed by research staff at the University of Manchester only. For more information please contact:

Professor Niels Peek (niels.peek@manchester.ac.uk) - Chief investigator

Dr Pearl Mok (pearl.mok@manchester.ac.uk) - Researcher responsible for the study data

Mr Alex Daybank (dataprotection@manchester.ac.uk) - Data Protection Officer.

What is the legal basis of processing the data?

The legal bases for processing these data are:

GDPR Article 6 (1e):

"Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller."

GDPR Article 9 (2j):

"Processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject."

Section 251 of the NHS Act 2006:

Section 251 was established "to enable the common law duty of confidentiality to be lifted to enable disclosure of confidential patient information for medical purposes, where it was not possible to use anonymised information and where seeking consent was not practical, having regard to the cost and technology available" https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/why-confidential-patient-information-used/#:~:text=Section%20251%20of%20the%20NHS%20Act%202006%20came,that%20required%20the%20use%20of%20identifiable%20patient%20information. Although the University of Manchester will not have access to any identifiable patient information for this study, we have obtained approval from the Confidentiality Advisory Group of the Health Research Authority for Section 251 support to enable ResearchOne to transfer the patient pseudonyms, gender, and date of birth of the patients to NHS Digital, and for NHS Digital to share non-identifiable data with the University of Manchester for analysis.

How we protect the data

The University of Manchester will only receive de-identified data from ResearchOne and NHS Digital, and these data will not be shared with any other parties or organisations. The data will only be used for this study and will not be combined with other information in a way that could identify any patients. Only aggregated results from the analysis will be reported and no record level data will be produced. This means that the outputs cannot be used to identify patients or sensitive information.

The data will be stored in the University of Manchester Research Data Storage Service, which is the recommended location for storing sensitive or critical University data. Only authorised researchers at the University employed for this study will have access to the data. A valid University of Manchester IT account is required to login to the system, and account credentials are unique to each member of staff and only the account owner knows the password. All staff are also trained in data protection and abide by all principles of the GDPR and Data Protection Act (DPA) 2018, as per the University policies and standard operating procedures, retention schedule, and privacy notices.

How long we keep the data

Data received by the University of Manchester will be destroyed within a five-year period, in accordance with our agreement with TPP and NHS Digital. Data generated by the study analysis will be stored for a minimum of five years following the end of the study or until all relevant publications relating to the research project have been published. This aligns with the University of Manchester Data Retention policy. These data will remain within the University's Research Data Storage Service until destruction.

Rights of individuals

The GDPR provides the following rights for individuals:

- The right to be informed - you have the right to be informed about the collection and use of your personal data.
- The right to access – the right to access and receive a copy of your personal data, and other supplementary information.
- The right to rectification – your right to have inaccurate personal data rectified, or completed if it is incomplete.
- The right to erasure –your right to have personal data erased.
- The right to restrict processing – the right to request the restriction or suppression of your personal data.
- The right to data portability – your right to obtain and reuse your personal data for your own purposes across different services.
- The right to object - the right to object to the processing of your personal data in certain circumstances.
- Rights in relation to automated decision making (i.e. making a decision solely by automated means without any human involvement) and profiling (automated processing of personal data to evaluate certain things about an individual).

For more information, see https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/.

As the University of Manchester only have access to de-identified data, we cannot identify any individuals in the data we hold. If your healthcare provider contributes data to ResearchOne and you would like to exercise any of these rights, please contact your healthcare provider. For more information, see:

- http://www.researchone.org/everybody/
- ResearchOne patient information leaflet http://109.228.3.129/wp-content/uploads/2013/01/Patient-Information-Leaflet_V1-2.pdf

Contact us

If you would like to contact us for more information about how we process and protect the data for this study, please email Dr Pearl Mok pearl.mok@manchester.ac.uk.

Complaints

Should you wish to report a complaint or if you feel that we have not addressed your concern in a satisfactory manner, you can complain to the Information Commissioner's Office (ICO) by visiting https://ico.org.uk/make-a-complaint/ or by calling their helpline on 0303 1231113.