Patient Opt-out policy (National Data Opt-out)

Introduction

The RA collects confidential patient information without common law patient consent in England & Wales under permissions granted by the Health Research Authority's Confidentiality Advisory Group (HRA CAG) under section 251 of the NHS Act 2006 (s251). The RA holds two sets of permissions under s251 for its processing; the first set is for non-research purposes to allow for the collection and processing of data for the UK Renal Registry's (UKRR) national audits of patients diagnosed with Chronic Kidney Disease Stage II-V, and patients at risk of Acute Kidney Disease (HRA CAG reference: 16/CAG/0153). The second set is for research purposes allowing for the use of data collected under the non-research permissions to also be processed and shared for the purposes of research which improves the treatment and outcomes of renal patients (HRA CAG reference: 16/CAG/0042).

As well as the data collected under s251, the RA collects confidential patient data, with patient consent,

a) To collect and process patient measures data collected through the "Your Health Survey" questionnaires;
b) for the purposes of providing services through the PatientView web portal and application; and
c) to populate the National Registry of Rare Kidney Diseases (RaDaR).

While these data flows are collected under a different common law legal basis, the data itself is collected from the same sources and in some cases using the same methods for both consented and non-consented datasets.

A stipulation of processing confidential and personal patient information without patient consent, both under the permissions granted by HRA CAG and the requirements of the Data Protection Act (2018) is that patients must be provided with the opportunity and the means to opt-out of their data being processed. Renal patients can opt-out of their confidential information being processed either by informing their renal centre or by recording their preferences via the National Data Opt-out.

The National Data Opt-out program is a system by which all health and social care service users in England can register their preferences regarding how their confidential information is used outside of their direct care. By 1st April 2020, all organisations that process confidential patient information for secondary purposes (i.e. not for the direct care of the patient) must evidence how they comply with the opt-out program.

A-Z Policies and Procedures for Information Governance

Principles

The RA is responsible for ensuring that the National Data Opt-Out is applied to data flows within its own internal data processing or where it shares confidential data with third parties such as for the purposes of linking with informatics services.

The RA will check its datasets against the national data opt-out database at key gateways within its processing such as where the data are to be used for purposes outside of audit, specifically research.

The RA expects organisations which submit data to the UKRR to have applied the national data opt-out, as appropriate, prior to transferring data to the UKRR. Said organisations (renal centres and/or NHS laboratories) hold the primary responsibility for applying the national data opt-out for any data flowing out of their controllership.

The National Data Opt-out program will not apply to data collected and processed for the purposes where patients have provided their common law consent for their confidential information to be processed, such as:

a) Your Health Surveys
b) Patientview; and
c) RaDaR

For the purposes of this document, all references to patients providing consent or wishing to opt-out of their data being processed shall also refer to instances where said consent or wish is provided by a patient's legal guardian or proxy on behalf of a patient who is either too young or deemed to lack the mental capacity to consent or opt-out themselves.

Implementation

Chronic Kidney Disease (Stages II-V) and dialysed Acute Kidney Injury

Submission of Data – The inward flow of data is subject to the National Data Opt-out. As such the NHS Trusts/renal centres are responsible for removing patient identifiers for patient who have opted-out prior to submitting data to the UKRR. Following this approach, the UKRR will be able to accurately report the incidence and prevalence of renal replacement therapy (RRT), chronic kidney disease (CKD), and dialysed acute kidney injury (AKI) without holding patient identifiers on opted-out patients. Guidance on how renal centres can de-identify patient records for submission can be found in the here.

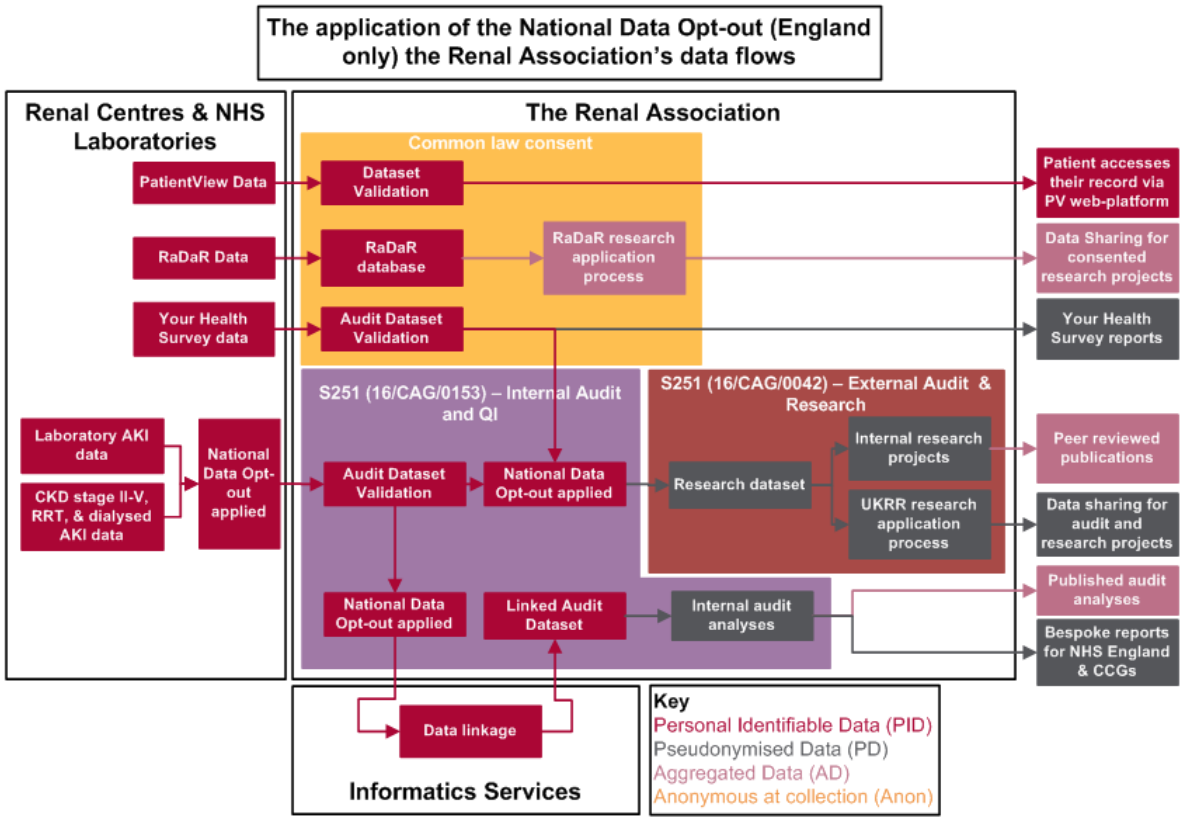
Processing for Audit – With the National Data Opt-out having been applied and recorded during the submission of data to the UKRR, the data submitted will be processed for audit purposes, with opted-in patients having their data processed in a pseudonymised form, as the data of opted-out patients will be processed with identifiers removed.

The UKRR routinely links the data submitted from renal centres with informatics services in England to validate and enrich the database, improving the range and quality of analyses that are carried out on the data. These linkages require the sharing of patient identifiers with the informatics service(s) in

order to match with the data held in their database(s). Subject to the National Data Opt-out, the RA is responsible for ensuring that opted-out patients are not included in these processes. Patients who have not had their identifiers submitted by the renal centres will automatically be excluded from the linkage dataset. For all other patients, the RA will use the MESH technical solution made available by NHS Digital, either as part of the linkage process, when linking data with datasets held by NHS Digital, or prior to the sharing of identifiers when linking with other informatics services (NHS Blood & Transplant and Public Health England), removing any opted-out patients from the linkage file before sharing.

Processing for Research – In addition to the analyses that it carries out for audit, the RA also processes the data collected from renal centres in order to populate a research database. Extracts from this database are then used both by the RA and external institutions (based within the NHS or academia) to conduct research which improve the care and outcomes of patients with kidney disease.

Patients who have opted-out will not have their confidential information included in this database. To identify opted-out patients, the RA will use the MESH technical solution made available by NHS Digital, submitting all the NHS-numbers held in the audit database when the database is closed at the end of the collection cycle. Only patients with NHS-numbers returned to the RA via the MESH system will be transferred into the research database for internal and external research projects using pseudonymised data.



Laboratory Acute Kidney Injury

A-Z Policies and Procedures for Information Governance

The RA implements the National Data Opt-out to the Laboratory AKI data in the same way as it applies to the RRT, CKD stage II-V, and dialysed AKI datasets, as described above. NHS Laboratories submitting data for audit should apply the opt-out prior to submitting data for audit. Guidance on how NHS Laboratories can de-identify patient records for submission can be found here.

Your Health Surveys

The Your Health Surveys are collected as part of the Kidney Quality Improvement Programme (KQuIP). The surveys ask patients to answer questions regarding their symptoms, general health and how they manage their condition, in order for renal centres to improve the care provided to and improving quality of life of patients.

As part of completing the questionnaires the patients provide consent for their confidential information to be processed by the RA. This consent falls outside of the scope of the National Opt-out, meaning that patient confidential information will be processed for this purpose even if the patient has opted-out of their data being shared or processed for other secondary uses.

PatientView

Patient consent for their confidential information to be processed for the purposes of PatientView is outside the scope of the National Data Opt-out. As such in the event that a patient opts-out of their confidential data being processed for secondary uses but has signed up for PatientView, the renal centre must continue to submit data to the RA for the purposes of allowing the patient to use PatientView. The renal centre is responsible for ensuring that data is submitted in line with the patient's wishes.

RaDaR

Patient consent for their confidential information to be processed for the purposes of RaDaR is outside the scope of the National Data Opt-out. As such in the event that a patient opts-out of their confidential data being processed for secondary uses but has consented to participate in RaDaR, the renal centre must continue to submit data to the RA for the purposes of allowing the patient to participate in RaDaR. The renal centre is responsible for ensuring that data is submitted in line with the patient's wishes.

Summary of how the National Data Opt-out is applied to RA data sets

Data Flow	Common Law Legal Basis	Internal use of data for audit	Internal use of data for research	Outward flow of data for audit	Outward flow of data for research
RRT, CKD stage II-V and dialysed AKI	S251	✗	✓	✗	✓
Laboratory AKI	S251	✗	✓	✗	✓

Your Health Survey	Consent (audit) & S251 (research)	✗	✓	✗	✓
PatientView	Consent	✗	N/A	✗	N/A
RaDaR	Consent	✗	✗	✗	✗

✓ - The National Data Opt-Out applies

✗ - The National Data Opt-out do not apply

N/A – Data is not used for this purpose