
RA guideline statement on planned/ongoing data collections and Information Governance in the context of the COVID-19 outbreak

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Background

There is clinical urgency to plan services to provide best care for patients with kidney disease during the current COVID-19 pandemic. Faced with this challenge large numbers of people in the wide kidney community are actively involved in data-collection to guide that care. The UK community is in a fantastic position to maximise learning on the clinical course and outcomes of patients who have COVID-19 and kidney disease. This will translate to the best possible care and management of affected patients.

Basic principles

Despite the unprecedented nature of the COVID-19 pandemic it is crucial to retain the trust of kidney patients by continuing to follow the basic principles of good information governance.

This guideline outlines the basic principles of Information Governance (IG) that should be adhered to even though we are in the midst of the epidemic. These are summarised in a flow chart (Figure 1).

In particular, anyone submitting data needs to remain conscious of their personal and organisational responsibilities, and there are very high fines for IG breaches and violations of the General Data Protection Regulation (GDPR). Any data collection involving identifiable patient data and without individual patient consent needs particular care and consideration, but even the use of “pseudonymised” (patient level) data needs to be carefully assessed. The IG rules have been relaxed somewhat until September 2020 to enable home-working/remote access to patient data, as well as timely data-collection to facilitate management of the outbreak, and we outline below what this means for us. Renal Association members who have read this guidance but wish further advice at this unprecedented time can contact the Renal Association (RA) data protection officer (Tom Gray at Tom.Gray@renalregistry.nhs.uk).

Local data collection for local service delivery for patients with kidney disease

In principle, any local (centre-specific) data collection to guide local service planning is appropriate and covered under audit, provided it is proportionate to the need. For example, the collection of centre-specific numbers of affected COVID patients to project patient transport needs in the weeks to come is acceptable.

However, if data are collected for research i.e. to generalise beyond the population studied (for example to predict outcomes according to patient characteristics) then there must be appropriate ethical permissions in place to do this work. Whether an analysis should be considered audit or research can be checked using the intuitive and easy to follow Health Research Authority online tool (www.hra-decisiontools.org.uk/research/)

National data collection for risk prediction in patients with kidney disease to enable clinical decision-making during the epidemic

Any type of risk prediction intended to guide decision making in clinical care (i.e. chances of survival, predicting the need of RRT etc) or that is intended to enable service delivery during the epidemic needs robust and representative data. Without this the conclusions cannot be reliably used to inform the care of future patients.

In order to increase the chances that a data-collection will be robust to inform care, the RA have convened a national group of data-collection chaired by the academic vice president (Prof Neil Sheerin). Anyone considering a data collection at a national level is encouraged to contact the chair of the group to allow co-

ordination and support for robust studies and to reduce overlap. Please contact Beth Crosby at the RA (Beth.Crosby@renalregistry.nhs.uk).

Anyone considering a new data collection should also consider whether the same question could be answered better, or with less burden by using linkage between existing data-sources. The benefit of using national data from routine data sources (e.g. COVID test results held at Public Health England, PHE) is that this provides a representative sample of patients, whilst local data collection, especially when clinical work is very busy and a large list of information is requested, is likely to be incomplete and biased to a non-random subset of patients.

The UKRR is leading on linkage analysis for the RA, and has already submitted IG amendments (under s251) to enable the UKRR to have the legal basis to do linkages with PHE and the intensive care audit (ICNARC) to carry out risk prediction work to guide service delivery. Questions on the work to establish a robust linked data-source for audit and care-planning is welcome to contact the UKRR medical director (Dr James Medcalf at james.medcalf@nhs.net).

Once this permission is in place, the UKRR will submit appropriate IG for further research with the data it holds, and would welcome discussions with researchers interested in doing research on this data-source so that permission can be sought collectively to do this. Researchers interested in exploring this should contact the RA informatics research director (Prof Dorothea Nitsch at Dorothea.Nitsch@lshtm.ac.uk).

Incidence of Acute kidney injury or other kidney outcomes in patients with COVID

The UKRR has permission to hold data on patients with AKI, CKD and on RRT. Therefore, questions regarding the incidence of AKI, CKD and RRT in people with COVID-19 infection cannot be answered by the UKRR alone, as the UKRR has no legal basis to hold data on all people with COVID-19 infection, or all people who are admitted to intensive care.

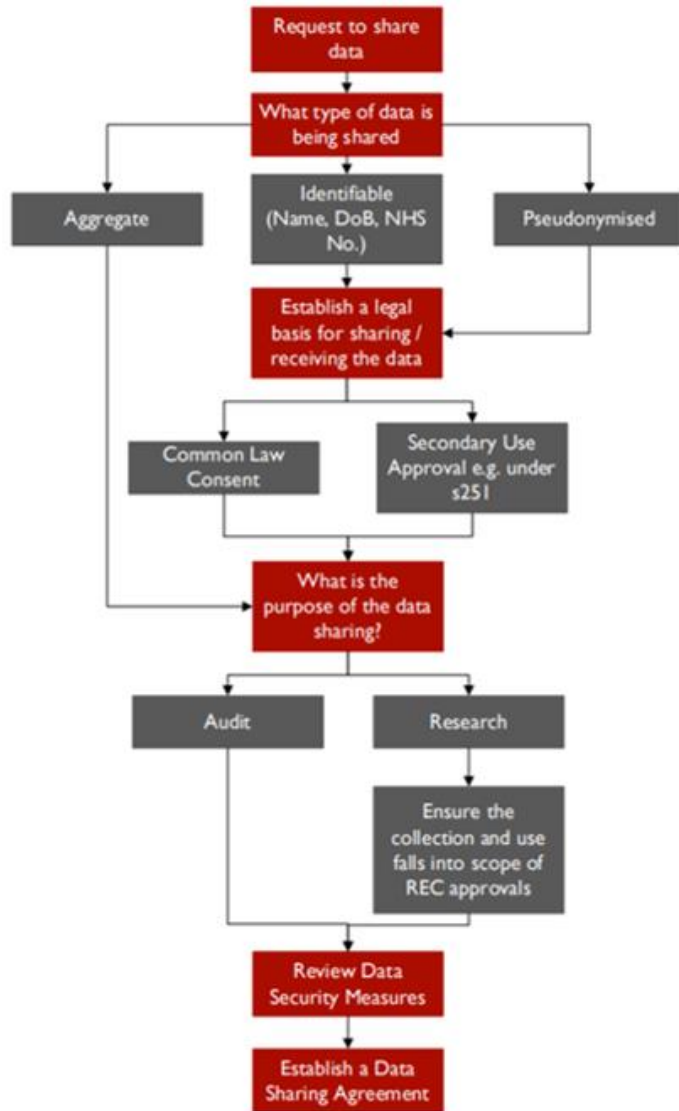
To address this the RA is aware of national efforts supported by the Secretary of State to establish data resources to answer such questions to which we will contribute to if and when the approvals are in place to analyse such national data.

National data collection for enrolment in research including clinical trials

In addition to data-collection for care planning and epidemiology research there are urgent national and international needs to identify people willing to take part in COVID-19 research.

There are several groups outside the kidney community, but the RA is in discussions with Thomas Hiemstra and colleagues in the Cambridge Clinical Trials Unit who are leading on the efforts to establish a national COVID cohort within which clinical trials will be nested. Crucially, this cohort will enable backfilling of data, as well as international data sharing. The RA believe there will be appropriate research governance in place to carry out research with these data, and a steering group overseeing data-sharing requests under a transparent process. In addition, there are plans for a mobile app that will enable clinicians to provide patient-identifiers that are submitted into an audited secure environment as required by IG rules. Anyone wishing to explore collaborations with the Cambridge group should contact Thomas Hiemstra and the Cambridge COVID-19 team at tfh24@cam.ac.uk.

Helping you decide



Decision 1 – What type of data is being shared?

Think about what data is necessary to complete the proposed task, only sharing what is strictly required to achieve the stated purposes and goals of the analysis/piece of work. Keep in mind the principle of data minimisation, limiting the amount of identifiers you share, and using aggregate data instead of pseudonymised data where possible.

Decision 2 – What is the legal basis to share data?

In order for an organisation to share or receive confidential patient information beyond their direct care, one or both organisations must either have the patient's consent to do so, or must have received permission to process data without patient consent from a national body.

- To collect data without consent for patients in England and Wales you must have permissions from the Health Research Authority – Confidentiality Advisory Group: <https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/>
- For patients in Scotland you must have permission from the Public Benefit and Privacy Panel: <https://www.informationgovernance.scot.nhs.uk/pbpphsc/>
- There is currently no formal method of granting permission for Northern Ireland, though if you provide evidence that you've been granted permission by another body the Department of Health NI will usually allow you to continue.
- You will also need to consider what your legal basis under the GDPR are: <https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/>

Decision 3 – What is the purpose of the data sharing?

Both organisations need to be clear on how the data is intended to be used as this will determine the permissions required to allow the data to be shared and processed i.e. Research will require ethical approval and specific research s251 permissions.

To help you if a project is audit or research please refer to the HRA's toolkit: <http://www.hra-decisiontools.org.uk/research/>

Decision 4 – Is there appropriate information security?

Both the sharing and the receiving organisation have a responsibility to ensure they have information security measures in place to protect the confidentiality, availability and integrity of the data. Key points to consider:

- Where will the data be stored? What protections will it have while stored?
- How will the organisations secure the transfer of the data?
- Who will have access to the data?
- How long will the receiving organisation keep the data for? Are there limits on how they can use the data?
- How will the organisation return or destroy the data securely when they no longer require it or are required to return it?

Decision 5 – Do you have a Data Sharing Agreement?

All the decisions made and the subsequent terms for the data sharing should be documented and signed off by both parties in a data sharing agreement. This will act as a record for both organisations for what data has been shared and/or is currently being held, as well as evidence of how the data sharing was justified.