

Chapter 18: The ‘Health and Social Care Act 2001’: section 60 exemption

Summary

The Registry has been granted a section 60 exemption by the Secretary of State under the Health and Social Care Act. This exemption allows the registration of identifiable patient information from renal units without first asking the consent of each individual patient, avoiding a breach of the common law on confidentiality.

This exemption is temporary and is reviewed annually. The progress towards collection of anonymised data or obtaining permission of the individual patient is monitored by the Patient Information Advisory Group (PIAG).

The first annual report on progress by the Registry towards anonymisation has been submitted to PIAG.

Introduction

The Registry falls under Schedule 3 exemption from the Data Protection Act 1998. This section within the Act relates to the processing of sensitive personal information. In Section 8 of Schedule 3, access to personal information is allowed for necessary medical purposes, but must be undertaken by either a health professional or a person who owes a duty of confidentiality equivalent to that of a health professional (such as health researchers or statisticians). In regard to the Renal Registry, “medical purposes” includes preventative medicine, medical diagnosis, medical research, the provision of care and treatment and the management of healthcare services. Under common law individual consent to collect identifiable data is still required.

The key patient identifiers collected by the Renal Registry are name, date of birth and postcode. Even without a name, date of birth and full postcode enable patient identification. The Registry currently requires these patient identifiable data for both data validation and

analysis, as follows:

a) Validation:

1. To avoid duplication of patients in the database, particularly when they transfer between centres often for transplantation. Matching of these items, together with a unique identifier allocated by the Registry when available, is currently essential.
2. To validate postcodes with the address fields, using a ‘postcoding’ package.
3. To use the above items to trace missing NHS numbers using the national tracing service.

b) Analysis (this is an indicative list):

1. To analyse data where age is a factor.
2. To assess geographical equality of access to treatment eg by local authority wards.
3. To assess the influence of social deprivation, by calculating deprivation scores from the validated postcode.

One option for full compliance would be to attempt to obtain permission for data transmission from each patient. This would have to be done by the renal units and would create a large and recurring workload. More importantly, it would lead to incomplete data collection, as some patients would refuse permission. In two recent medical studies^{1,2} only 33% of patients provided consent and it could be confirmed that outcomes in those groups were different from those patients where consent was not given. Such behaviour would render many of the Registry analyses invalid.

The alternative is for the Registry to develop processes to anonymise the data, whilst retaining enough information for purposes of validation and analysis. The Registry Committee has decided to take this course.

Path towards compliance

In the application to PIAG, the Registry set out a four-stage path towards full compliance.

It is government policy in England & Wales, that patient's NHS numbers will be used for all hospital episodes. The goal of the Registry is to use an encrypted NHS number as a patient marker. This will not allow identification of the patient. In parallel with this approach, a system will be developed to allocate the necessary characteristics to patients with regards to age, social deprivation and geographical area of residence such as local authority or health authority. It will then not be necessary to store the full postcode in the database.

1. Stage 1 –

1.1. Posters & patient information leaflets.

In the interim period, before anonymisation is achieved, formal consent for data transfer will not be necessary. However, patients must be fully informed about what is happening. With the support of the National Kidney Federation (of Patients Associations), the Registry will produce posters and information leaflets for distribution in renal units. These communications will describe the extent of the information that is stored regarding patients with renal failure and the fact that patient identifiers are only accessible to a small number of skilled and conscientious staff. It will also explain how that information is used and that all outputs are anonymous. Patients will be offered the opportunity to contact their local renal unit to withhold consent from sharing their patient identifiable record with the Registry if they wish to do so. Software is being installed on all renal unit clinical databases to enable this opting out to be recorded.

1.2. Move towards NHS numbers and deletion of patient names in the Registry database.

1.2.1. The Registry has altered its software to hold patient identifiable data items received from renal units in a separate database.

1.2.2. Where necessary data is incomplete, the Registry is using a 'postcode lookup application' to obtain a valid full postcode and then use the NHS

Strategic Tracing Service to obtain the NHS number. The Registry is advising renal units to update their patient demographic data to include the missing data.

1.2.3. The Registry will move towards deletion of the patient identifiable data from the temporary database at the time of the next submission of data (next calendar quarter) with the proviso that the renal unit is submitting data with a complete set of patient demographic data including the NHS number and the UK Renal Registry number.

1.2.4. The Registry will also apply this methodology to the records of deceased patients held in the database.

2. Stage 2 –

2.1. The National Programme for Information Technology (NPfIT) National Care Records Service (NCRS) is allocating an NHS number to every patient. When this becomes available from all renal systems, the Registry will modify the software application that handles pre-analysis characterisation of the patient and checking for duplicate records. All other patient identifiable data will be deleted once this pre-analysis activity has been completed.

3. Stage 3 –

3.1. The National Programme for IT is working on software for a secure encryption system for the NHS number. This encryption is consistent for the NHS nationally, so that record linkage can still be made even if the patient moves between Trusts/ Strategic Health Authority areas. The Registry will modify its software to handle the encrypted NHS number format. The renal software providers will have to modify software to link with the encryption software.

4. Stage 4 –

4.1. With the implementation of the electronic Integrated Care Records System (ICRS)

the local service providers (LSPs) will take responsibility for making the UK Renal Registry data available in the national dataset (SPINE) as a secondary use service (SUS). The UK Renal Registry will then become a user and not a custodian of anonymised patient data.

- 4.2. In partnership with the Department of Health (DoH) Datasets Development Programme, the Registry is currently seeking approval for the National Renal Dataset.
- 4.3. The Registry will work with local service providers to implement the Renal NSF Core Service. That includes the requirement for LSPs to provide the functionality for renal units to send data for the National Renal Dataset to the SPINE and for the National Application Service Provider to make this available in the

National Care Records Service Secondary Users Service. The data held will then be compliant with existing legislation and standards.

It is acknowledged by PIAG that some of the timescales may not be achieved due to as yet unresolved technical issues/lack of progress with the NHS IT infrastructure. All these issues will be reviewed annually by PIAG.

References

1. Tu JV, Willison DJ, Silver FL, Fang J, Richards JA, Laupacis A, Kapral MK. Impracticability of informed consent in the Registry of the Canadian Stroke Network. *N Engl J Med.* 2004 Apr 1;350(14):1414–21.
2. McKinney PA, Jones S, Parslow R, Davey N, Darowski M, Chaudhry B, Stack C, Parry G, Draper ES. A feasibility study of signed consent for the collection of patient identifiable information for a national paediatric clinical audit database. *BMJ* 2005 Apr 16;330(7496):877–9.

