

Appendix C: Data Protection and the UK Renal Registry in 2002

C:1: Introduction

The political and social context of data management has changed since the UK Renal Registry was established. In particular, there has been growing concern that the NHS should become more 'patient centred'. In addition, the benefits of data collection for science and research are no longer assumed to be self-evident but need to be demonstrated outside the medical arena. Whenever patient identification is a necessary component of research or data collection, it has become important to obtain informed consent.

This has ethical and legal considerations. Although the formal position has evolved with the Data Protection and Human Rights Acts of 1998, certain circumstances have suggested the need for further legislation. Very large research exercises, for example, make consent impractical to obtain, the condition of some patients makes consent impossible, and the bias introduced by selective refusal/omissions might make data un-interpretable.

C:2: European law – Directive 95/46/EC

This law relates to the protection of individuals with regard to the processing of personal data and the free movement of such data.

Member States shall prohibit the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, and the processing of data concerning health or sex life.

Paragraph 1 shall not apply where processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health care services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy.

European Union law therefore excludes the collection of medical information from the data protection laws.

C:3: The Health and Social Care Act 2001 (England & Wales)

In England & Wales, Section 60 of the Health and Social Care Act 2001 provides discretionary powers to the Secretary of State ensuring that patient-identifiable information needed to support essential NHS activity can be used without the individual consent of patients. These powers can be used only to support medical purposes that are in the interests of patients or the wider public, when consent is not a practicable alternative and when anonymised information will not suffice. The decisions are to be reviewed annually. An effort towards obtaining consent or the development of patient anonymity is expected of any group seeking to use Section 60.

The Patient Information Advisory Group (PIAG) has been established as the advisory mechanism to the Secretary of State. Because of the numerous activities that might require consideration, it has been anticipated that broad classes of exceptions will be formulated, with only a limited number of applications requiring detailed PIAG consultation. The Registry hopes that one such class might encompass generic, Registry-type, data collection. The UK Renal Registry has submitted its application to PIAG for the consideration of exemption from the need to seek individual patient consent.

C:4: The Registry case

The Registry is the cornerstone of the monitoring of RRT in Britain. The involvement of all UK renal units is confidently expected within the next few years. This has been mandated by advice from the Department of Health to health authorities. The Registry is funded by a capitation fee from health authorities, endorsed by the Department of Health. The annual reports are the basis of assessment for health provision, management and outcomes in renal disease nationally. The accurate demographic and quality performance data will be one foundation of the Renal National Service Framework (NSF), which is currently under development. The evidence of treatment distribution is critical to ensure the developing NHS agenda on equity of patient access. These clinical data are the basis of national comparative audit and quality improvement initiatives that are equal to, or in advance of, any developments in other medical specialities. It is hoped that these benefits of the Registry will be recognised as being sufficiently important to invoke the term ‘essential NHS activity’, thus enabling the Secretary of State to use his discretionary powers (Section 60, Health & Social Care Act).

There are over 39,000 patients on the Registry database. Some will have been identified retrospectively after an acute presentation; others may have been unable to give consent through incapacity of one kind or another. The need for patient identification hinges on the need to track the course of treatment between renal dialysis and transplant units. If any compelling example of this need were required, the demise of the previous European Renal Registry occurred in part because of the intractable difficulties of following patients during transitions of treatment, with a huge ‘lost to follow-up’ cohort.

The Renal Registry will lie at the heart of the Renal NSF and supplies crucial information to government about an expanding and resource-intensive service. Patient identification is required for data validation.

C:5: The way forward

The principles of data protection are scrupulously observed at the Registry, and only those directly involved in data validation and analysis have access to patient-identifiable material.

It is nevertheless necessary to explore how individual patient consent can best be obtained. This might involve a single Registry-solicited enrolment at the start of renal treatment. It is also important to establish, perhaps from data already available, what bias would be introduced were selective refusal to consent a factor. The suggestion that receiving NHS treatment for renal disease should carry an obligation to individuals to provide consent is not

widely supported. A formula for satisfying all the ethical and legal issues may yet develop from other experience of the practicalities of NHS data collection. It should be noted that other applications of the Registry database would have to be examined on their merits, and the availability of the data for all purposes, such as the identification of patients for research, cannot be assumed.

The current Renal Registry data collection has continued in the confidence that existing data protection procedures, apart from consent, are well established and that the case for exception under Clause 60 provisions will have a *prima facie* validity. The Registry submitted to PIAG, and while further clarification on some issues was awaited by PIAG, the Registry was given permission to continue data collection. It is hoped that the Registry's new role in monitoring the NSF will strengthen its submission, in conjunction with the support of patient groups, the Department of Health, the NHS Information Agency and the Royal College of Physicians, while the possibility of obtaining consent is examined further within the discipline.