Consent and end-stage kidney disease: improving the consent processes in dialysis

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Abstract

People with end-stage kidney disease (ESKD) receiving dialysis require monthly blood testing and annual registry data collection. Consent for these tests and data collection has historically been verbal. Accreditation surveys prompted a decision to review consent processes within this large Australian renal service. A quality initiative was introduced, requiring written consent for ESKD treatment including dialysis, data collection and blood tests. Medical staff complete an ESKD treatment consent form including consent for routine pathology with all new patients, to the renal unit. Feedback regarding the implementation of this quality initiative from both medical and nursing staff has been positive.

Keywords

Dialysis, consent, end-stage kidney disease, quality.

Background

People with end-stage kidney disease (ESKD) receiving dialysis require frequent health-related episodes of care over undefined periods of time. This differs from episodic, acute hospital admissions and other more long-term hospital interventions, such as chemotherapy and clinical trials, which are performed over defined time frames. Integral to dialysis treatment for all people with ESKD is a schedule of monthly blood tests. Medical information regarding people receiving dialysis treatment and transplants is submitted to the Australian and New Zealand Dialysis and Transplant Association Registry (ANZDATA) on a regular basis. Currently, at a large Australian renal service, all people with ESKD sign a written consent form for routine blood testing and ANZDATA collection on commencement of dialysis treatment. This system was implemented in response to changes to the privacy legislation and has been in place for several years. Consent for dialysis treatment has historically always been verbal. Renal unit staff reported that accreditation surveyors were requesting evidence of consent and a review time frame for consent for dialysis and its associated procedures such as routine pathology and data collection. This prompted a decision to review local consent processes relating to dialysis. Initially the aim was to implement, concurrently, a system of written consent to receive treatment for ESKD with a system of annually updating written consent for routine blood testing and ANZDATA collection for all dialysis and transplant patients. The aim of this paper is to report a quality improvement project undertaken to improve the process of consent for dialysis treatment in one large Victorian renal service.

Literature review

A literature review was conducted to ensure that any systems changes would be supported by evidence. Literature was sourced via online medical journal databases and within a hospital library as far back as 2002, looking at international literature from major English-speaking countries (for example, the United Kingdom). Search criteria included: consent for medical treatment, time frames for medical consent and legal aspects of medical consent. There exists a significant amount of international literature defining medical consent, none of which recommended a defined time frame for consent once given. To enable changes to reflect relevant legal aspects, the review was limited primarily to literature from Australia.

Consent for medical treatment can be defined as “the voluntary agreement by an individual to a proposed procedure, given after appropriate and reliable information about the procedure, including the potential risks and benefits has been conveyed to the individual” (Department of Health and Ageing, NHMRC, 2008). Consent can be seen as a two-way process of shared and informed decision making between health professionals and patients (Kerridge et al., 2009).

Consent should be freely given with no pressure placed on the patient. The patient should be given an explanation of the risks associated with the procedure subject to consent. Any given consent is specific only for the proposed procedure and should be given by someone who has the cognitive ability to do so. The issues around medical consent for people with cognitive impairment is a vast topic and beyond the scope of this work. The patients’ understanding of the proposed procedure or treatment should always be assessed (Breen et al., 2010; Kainer & Fetherstonhaugh, 2010; Kerridge et al., 2009; Royal College of Nursing, 2005; Staunton & Chiarella, 2008; Victorian Healthcare Association, 2009).

A patient gives implied consent when they arrive for and do not resist the procedure being undertaken (Kerridge et al., 2009).
Informed consent is almost always directed towards major procedures which carry significant risks (Breen 	extit{et al}., 2010). For example, in Western Australia, consent must be gained in writing by law for the following: surgical, medical, radiological, oncology, and endoscopic procedures requiring general, regional or local anaesthetic or intravenous sedation; administration of blood transfusion and blood product; invasive procedures where there significant risk; administration of high risk or new medications and clinical trial participation (Staunton 	extit{et al}., 2008).

In Victoria, the second most populated state in Australia, there is no legal requirement for obtaining informed consent (Breen 	extit{et al}., 2010). However, the Victorian Charter of Human Rights requires that consent for medical treatment be full, informed and voluntary. The charter also requires that patients who are competent be given enough information to enable a decision to be made and be able to understand the information (Victorian Healthcare Association, 2009). Written consent for major procedures involving significant risk is observed as standard practice by health providers with local policies and procedures in place.

Informed consent is an ethical issue where competent adult patients have a right to make autonomous decisions about what is done to them providing it does not impinge on the rights of others. Informed consent can then be applied to low-risk or non-harmful interventions as well as those which are high risk (Victorian Healthcare Association, 2009). This supports an individual’s right to be informed and empowered, and should be considered given the ever-growing focus and trend towards increased consumer participation in health care.

Breen 	extit{et al}. suggest that informed consent is not enshrined in Australian law (Breen 	extit{et al}., 2010). There no guidance in relation to how long consent, once given, remains valid (Breen 	extit{et al}., 2010). Literature available defining the duration of consent either makes vague statements or refers only to time-limited medical procedures. For example, Queensland Health states in its policy statement on informed consent for invasive procedures that “consent is valid for 12 months or as long as the patient is able to recall the information” (Queensland Health, 2007). Other literature states that consent must be as close as possible to the intervention (Victorian Healthcare Association, 2009). In long-term, large clinical trials, consent is considered an ongoing requirement that needs to be updated when there are material and/or significant changes to the research (Royal College of Nursing, 2005; Wendler & Rackoff, 2002). None of these scenarios fit the unique consent review needs of a person receiving dialysis, but there is general agreement that patients need to have an ongoing understanding of the treatments and procedures that they are involved in.

The need to provide patients with information about their treatment is also supported by literature on the topic of consent for clinical studies. Evidence shows that participants in clinical studies are frequently unable to retain study information for the duration of their involvement in the research, exhibiting poor memory for information disclosed during initial consent processes (Prentice 	extit{et al}., 2007). It can be assumed that this is also true for the long-term, open-ended nature of dialysis treatment.

**Quality activity**

**Initial actions**

A number of major Victorian metropolitan renal services provided feedback that, following accreditation surveys, a decision was made to implement a system of gaining written consent from all people commencing dialysis. Therefore, with the aim of also taking this approach in a proactive way prior to accreditation, a decision was made by the renal manager and renal quality coordinator to review all consent and information brochures currently in use when people commenced dialysis as the first step in implementing an improved process for gaining consent.

The existing pathology and data consent form, and the associated information brochure given to people commencing dialysis which explained both routine pathology and data collection was initially reviewed. This was performed by the quality coordinator, in consultation with the renal service manager, using information provided by the other large Victorian renal services that had already commenced a process of written consent for dialysis.

An initial draft of the patient information brochure and consent form was developed, including consent for treatment, pathology and data collection. The drafts were then circulated to senior renal unit medical and nursing staff for feedback, with the proposal that consent should be updated on a regular basis. This resulted in large amounts of feedback, highlighting a number of staff concerns. Nursing staff were happy to update consent for data and pathology, but not for treatment. Medical staff had significant concerns about the shift towards written consent for treatment which had not been done previously. The transplant staff expressed concerns about the logistics of consent with a continually expanding group of people who had received a transplant. All staff had concerns about the logistics of follow-up consent for the hundreds of people who were receiving renal dialysis or had received a transplant.

The patient information brochures provided the only positive feedback. As a result of the concern voiced by the renal unit staff, a decision was made by the renal service manager and quality coordinator to separate the process of consent for
treatment from the consent for pathology and data collection, and to have a staged implementation process.

Subsequent actions
The initial draft consent form was divided into two forms, one for pathology and data collection, to be implemented first, and the other for treatment, to be implemented at a later date. The draft pathology and data consent form was circulated for senior medical and nursing staff feedback. This was generally positive, although some concerns still remained in relation to the update of consent with such a large number of patients.

Having renal staff agreement on the pathology and data consent form, it now required hospital approval for inclusion in the electronic patient medical record. In line with internal health service processes, this approval was sought by submitting the form to the nursing documentation committee. Conditional approval was given on the form dependent on gaining additional approval from the hospital’s legal department and chair of ethics.

The legal department approval was given with the recommendation of a few minor word changes. Ethics, however, made a request for evidence of an ethics submission for ANZDATA collection prior to any consideration of approval. As ANZDATA is a quality database not geared towards research, this request was discussed amongst senior renal unit staff. A decision was made that the unit medical director would contact ANZDATA for advice on the request.

ANZDATA advice
ANZDATA provided the renal service with a letter of advice recommending an “Opt out” approach to consent, stating that this is consistent with the practice of clinical outcome registries across Australia. ANZDATA stated that this approach is recommended by the Australian Government Privacy Commissioner (2001) and the Australian Commission on Safety and Quality in Health Care (2008). With this approach, patient information is provided unless an individual patient makes a choice not to have their data submitted. It was decided to adopt this recommendation at the renal service.

Outcomes
The patient information brochure on ANZDATA and routine pathology collection has since been divided, with one brochure covering each topic. To keep patients informed about their right to opt out of ANZDATA collection, the ANZDATA brochure will be provided to all dialysis and transplant patients on a regular basis at a time frame yet to be determined. The consent form for routine pathology and data collection is no longer relevant, given the opt-out approach to ANZDATA which has been adopted.

Medical staff complete a written consent form for ESKD treatment including dialysis, transplantation and conservative care. Incorporated into the form is consent for routine pathology and additional blood testing in the event of possible blood and body fluid exposure.

The outcome of a complex process initially thought to be a simple quality initiative is that written medical consent for ESKD treatment, which received significant opposition at the start of the review process, is now being readily accepted by medical staff.

The scope of this project is limited to the context of Australian law and the law within the state of Victoria. Any application of this process to other states or countries should only be done with due consideration of the relevant laws. Financial and human resource constraints will limit the time frame decided upon for distribution of the information brochures given to the 770 people currently receiving dialysis and transplants from the renal service.

Conclusion
The introduction of a written consent form, to be completed with all people prior to commencing dialysis, introduces a systematic framework and a documentary record of a discussion about treatment options between a renal physician and person with ESKD. It will provide auditable evidence that the people with ESKD have been engaged in the decision-making process about their renal treatment, supporting a consumer-focused approach. The provision of information about routine pathology and data collection to all people who receive dialysis further supports the individual’s right to be informed, ask questions and make decisions concerning aspects of their care, including what happens to information about them, enhancing the quality of care received.

References
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