

Ethical considerations for nurses undertaking research with a potentially vulnerable population with chronic kidney disease

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Abstract

This paper discusses the ethical issues that nurse researchers need to consider when undertaking research with a potentially vulnerable population of people who have a diagnosis of chronic kidney disease (CKD). People with CKD may be considered vulnerable because, firstly, the presence of uraemia may impair their cognition which can affect decision-making and secondly, gate keeping by health professionals and/or family may affect their access to research participation. The purpose of identifying vulnerable populations is not to exclude them but to ensure that full consideration is given to allow their maximum participation within the requirements of ethical research. It is important that the process of recruitment is transparent and informed from the perspectives of the potential participant, the researcher and the health facility. This paper applies the principles of informed consent and vulnerability for those with CKD, using the ethical framework that underpins the National Health and Medical Research (NHMRC) National Statement (2007) of autonomy, beneficence/non-maleficence, social justice and respect and provides practical strategies to increase recruitment and retention.

Keywords

Nursing research, ethics, chronic kidney disease, vulnerability, decision-making.

Introduction

Research is only ethically acceptable when the potential benefits of research findings outweigh any risks to the participants involved (NHMRC 2007). Like all researchers, nephrology nurses, who engage in research, need to accept responsibility for the design and conduct of ethically sound research that contributes to a better understanding of the social welfare and wellbeing of the recipients of nursing care (NHMRC, 2007; Breimaier *et al.*, 2011; Moreno-Casbas *et al.*, 2011; O'Byrne & Smith, 2011). This paper evolved from a review of the nursing literature on the ethics of research with vulnerable populations undertaken by one of the authors (SC) in preparation for an ethics application to an Australian human research ethics committee (HREC). The purpose of this paper is to inform potential nurse researchers about how to ethically protect the rights of, and manage the risks to, individuals with chronic kidney disease (CKD) who are invited to participate in research studies. The ethical principles outlined by the NHMRC (2007) guidelines of autonomy, non-maleficence, beneficence, social justice, and respect are outlined. The ethical challenges related to informed consent are described including recognition of the role of gate-keepers and respect for the person's right not to

participate. Finally, some practical strategies are offered which may increase the recruitment and retention of people with CKD into much-needed research studies.

Increasing the confidence of nurses to design and undertake ethically responsible research, will increase the possibility that nurses will nominate themselves as primary investigators, and increase the likelihood that findings from their research will be translated to the practice environment to support evidence-based nursing practice (Breimaier *et al.*, 2011; Moreno-Casbas *et al.*, 2011; O'Byrne & Smith, 2011). Although, this paper presents a principles-based analysis of the ethical issues in qualitative nursing research, contextualised to the sphere of nephrology nursing, the strategies can be extrapolated to other research paradigms and nursing specialities.

Background

An established tenet of ethically responsible research is that researchers ensure that the wellbeing of research participants is of paramount importance (NHMRC, 2007). Knowledge acquisition is subordinate to participant wellbeing (Dobratz, 2003). Nurse researchers must ensure that participants who choose to participate in research do not suffer any medical,

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social or psychological damage or harm (Quest & Marco, 2003; Kavanaugh *et al.*, 2006; NHMRC, 2007; McCauley-Elsom *et al.*, 2009; Mkandawire-Valhumu, Rice, & Bathum, 2009).

Therefore, nurse researchers need to critically analyse their research methods so that the study is undertaken in an ethical manner that upholds and promotes scientific rigour without marginalising potentially vulnerable populations whose health, nursing is mandated to protect (Arraf *et al.*, 2004; Rischbieth & Blythe, 2005; NHMRC, 2007; Mkandawire-Valhumu *et al.*, 2009; Johnstone, 2011). Attention to the ethical considerations of informed consent, and the use of participatory approaches to data collection, maintains the participants' dignity and creates a positive environment conducive to improved recruitment and retention of both marginalised and vulnerable populations (Arraf *et al.*, 2004; Eyler & Jeste, 2006; Kavanaugh *et al.*, 2006; McCabe & Holmes, 2007; Smith, 2007).

Role of HRECs and guidelines for ethical conduct

Research on humans in Australia is governed by Australian common law and nurse researchers are required to consider a number of important issues when preparing to conduct research studies (NHMRC, 2007; Driscoll *et al.*, 2008; Staunton & Chiarella, 2008). Only research that is considered to be ethically responsible will be permitted to proceed. All research proposals must be submitted to a human research ethics committee (HREC) where the proposal undergoes a rigorous ethical review (Driscoll *et al.*, 2008). HRECs in Australia perform two roles when reviewing research proposals. The first is to review the integrity of the research design. This assists to maintain the robustness of the research findings. The second, more important role, is the protection of the health and welfare of those people who consent to participate in the research (Rischbieth & Blythe, 2005; Smith, 2007; Johnstone, 2011).

Using the NHMRC (2007) guidelines for ethical conduct for human research (the National Statement) as a framework for ethically responsible research, the four major principles of autonomy; beneficence/non-maleficence; social justice and respect are outlined below.

Autonomy

Respect for a person's autonomous choices means respecting their ability to make decisions that reflect their own self-interest and wellbeing (Ryan & Deci, 2000; Arraf *et al.*, 2004). Within this principle is the concept of informed consent and respecting the person's right, not to participate. Humans are known to be curious, vital and self-motivated and, as such, are moved to make decisions that foster their own wellbeing (Ryan & Deci, 2000). The challenge for the researcher is to maximise the potential participant's sense of power and autonomy in the decision-making process of determining whether to participate in the particular research project (Mkandawire-Valhumu *et al.*, 2009). Potential participants are entitled to be given as much accurate information as possible so that they can: grasp the meaning of the information; independently weigh the risks and benefits to themselves; and make an autonomous decision to participate or not that is free of duress (Ryan & Deci, 2000; Quest & Marco,

2003; Rischbieth & Blythe, 2005; Eyler & Jeste, 2006; NHMRC, 2007; Smith, 2007; Mkandawire-Valhumu *et al.*, 2009).

Informed consent

There are four elements in the decision-making process to provide an informed decision to participate in a research study: understanding; appreciation; reasoning and choice (Eyler & Jeste, 2006). Understanding involves more than the potential participant gaining knowledge about the study. It also involves the researcher entering into a reciprocal relationship with that participant to allow them to comprehend and analyse the information being provided. This responsibility of nurse researchers is an integral component of nursing's approach to research. Appreciation involves the potential participant's awareness of the relevance of the information for their own personal wellbeing and is subject to emotional factors that influence that person's belief system or world view. Reasoning is the ability of the potential participant to weigh the risks and benefits of their participation in the study. It requires sufficient cognitive processes and capacity so that complex information can be memorised and analysed at the same time. Choice involves the potential participant being able to communicate to others their decision in a clear and unambiguous way and is strongly linked to positive feelings of autonomy (Deci & Ryan, 2000; Arraf *et al.*, 2004).

Nurse researchers, who adopt an empathic ethical position that enables them to inform potential participants of the possibility that the study will produce clearly articulated and meaningful outcomes to allay future suffering and/or improve nursing practice, are more likely to succeed in recruitment (Moore & Miller, 1999). For consent to be judged as valid it must be free from power dynamics such as coercion (Eyler & Jeste, 2006; NHMRC, 2007; Smith, 2007; Mkandawire-Valhumu *et al.*, 2009; Tait, 2009). Coercion can be interpreted in two ways: firstly, the researcher needs to ensure that they do not overemphasise any benefits of the research. If potential participants have an unrealistic expectation of the research benefits to themselves, they may consent to participate from a premise of therapeutic misconception (NHMRC, 2007). Secondly, nurse researchers need to be aware that potential participants may feel some degree of coercion if a request to participate originates from a health professional who provides their treatment or care. The person with CKD is in a chronically dependent relationship for their ongoing kidney health care and this relationship often continues for an extended period of time (Davison, Murtagh & Higginson, 2008). A request for potential participation may add undue stress on the kidney health care relationship as the person with CKD may feel that their kidney health professional will be angry with them if they decline to participate in the research (Quest & Marco, 2003; NHMRC, 2007; Smith, 2007; Mkandawire-Valhumu *et al.*, 2009; Tait, 2009). To avoid this potential stressor, an independent recruiter such as a research assistant (who does not provide treatment or care) should be employed to explain the research study, obtain informed consent and enrol potential participants into research studies (Quest & Marco, 2003; NHMRC, 2007).

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Importantly, potential participants must be given sufficient time to consider all risks and benefits, and ask questions of the researcher as well as discuss their participation with others such as family members, kidney health professionals or community elders if they wish to do so (NHMRC, 2007). It is important that potential participants should be made to feel that their contribution to the research is valued and that they are not being used solely as an object of study (Eyler & Jeste, 2006; NHMRC, 2007; McCauley-Elsom *et al.*, 2009; Tait, 2009). One mandatory requirement of informed consent is that the benefits and risks of the research need to be clearly outlined for potential participants in a participant information sheet (PIS) in language that is easily understandable to lay people (Rischbieth & Blythe, 2005; NHMRC, 2007).

Managing the person's right not to participate

Potential participants using their autonomous power may choose not to participate in a study. Researchers have an ethical responsibility to ensure that people who have chosen not to participate have the same rights as those who have chosen to participate, and therefore do not suffer any disadvantage as a result of their refusal. The researcher needs to be aware that the potential participant is not required to give any reason or justification for their decision (NHMRC, 2007). Nurse researchers need to ensure that a decision to decline to participate will have no bearing on the potential participant's ongoing kidney health care. They also need to reassure the potential participant that this is the case (Stiles *et al.*, 2012). This can be achieved by maintaining a professional and caring nursing attitude along with reassurance that health care communication channels will remain open. Possible reasons why potential participants may decline to participate in research studies could include: not valuing the aims and purposes of the study; not feeling competent to fulfil all the participant responsibilities; or not expecting the research to yield any positive outcomes (Ryan & Deci, 2000). Of course, it might just be that they simply choose to exercise their right not to be involved.

Beneficence/non-maleficence

Respecting the principle of beneficence in the research context means that researchers will, to the best of their ability, do good; and it is closely linked to the principle of non-maleficence where the aim is 'above all, do no harm.' Nurses are able to recognise this principle within the context of 'duty of care' for competent professional nursing practice (Staunton & Chiarella, 2008, p. 32). The researcher needs to undertake an assessment of the risk/s to potential participants by gauging the likelihood and severity of the kinds of harm that may occur (NHMRC, 2007).

A risk can be defined as a potential for harm, discomfort or inconvenience (NHMRC, 2007) and may be deemed either psychological, physical or both. The concept of 'minimal risk' has been used to justify research studies where there is no direct benefit to the participant but alternatively there is no increased risk (Rischbieth & Blythe, 2005). The greater the risks to participants, the greater the ethical responsibility of the researcher to ensure those risks will be properly managed, and potential participants will be fully informed so that they clearly

understand the risks they may be taking on by participating in the research (NHMRC, 2007).

Psychological risks

In qualitative interviews there may be a risk of psychological distress or extreme anxiety from the disclosure of deeply personal information which may be potentially stigmatising, embarrassing or socially unacceptable (Arraf *et al.*, 2004; Kavanaugh *et al.*, 2006; McCauley-Elsom *et al.*, 2009). Participants may experience psychological harms such as feelings of worthlessness, guilt, anger, fear, embarrassment, humiliation, distress and an increase in anxiety levels resulting in episodes of crying from participation in interviews (Ryan & Deci, 2000; NHMRC, 2007). Nurse researchers need to have the confidence and skills to meet these emotional needs if a participant expresses such feelings (NHMRC, 2007; Mkandawire-Valhumu *et al.*, 2009; Breimaier *et al.*, 2011). Experienced counsellors should be made available and accessible to assist distressed patients and/or their families (Davison *et al.*, 2008).

Nurse researchers also need to consider their own wellbeing and be aware of their own emotional and ethical distress in some research situations. This is especially pertinent when participants reveal information that may have an impact on their health care. An example is the disclosure of a suicidal ideation during an interview. The nurse researcher needs to have a clearly outlined plan of action (risk mitigation for the participant) and a space for debriefing, either with the health facility counsellor or research supervisor (for the researcher) (Mitchell & Irvine, 2008). Interviews should be temporarily suspended if any participant becomes uncomfortable, fatigued or distressed. In certain circumstances, after consultation with all stakeholders, involvement of that participant may have to be permanently suspended so that the participant can then withdraw from the study. Ethically, the researcher must ensure that continuing support is given to the distressed participant by a nominated health care professional to moderate the harm that occurred (Arraf *et al.*, 2004).

Physical risks

Physical risks may be moderate in the form of a discomfort due to the pain associated with blood pressure measurement, while inconveniences include the time spent participating in research interviews or filling in forms or surveys (NHMRC, 2007). Nurse researchers must be aware that some physical risks can lead to harm if the level of the participants' stress increases. An example could be venepuncture. This intervention may be judged as an inconvenience by participants who donate blood regularly, but for those who are needlephobic it could be considered both a major physical and psychological harm due to the increase in pain and anxiety levels. Such differing effects across different participants highlight the need for highly individualised risk assessment, particularly when working with a potentially vulnerable group.

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Social justice

Respecting the principle of social justice involves consideration of fairness and equity to all potential participants during the recruitment phase, specifically in relation to the burdens and benefits of the research.

This principle is not to be confined to the actual participants but should include any who may be remotely affected by the research (NHMRC, 2007). Participants should feel that they are in a partnership with the researcher. This involves the researcher keeping the participants informed of the progress of the research and giving regular feedback such as sharing research findings. The sharing of research findings is an ethical initiative that allows participants the opportunity to comment on the researcher's interpretation of their world (Mkandawire-Valhumu *et al.*, 2009). As well, dissemination of research findings, both favourable and unfavourable, also allows for scrutiny of the research within the greater public domain (NHMRC, 2007).

Respect

Nurse researchers need to respect each individual's right: to make autonomous choices; to have their wellbeing protected; and to have their beliefs, customs, perceptions and cultural heritage recognised and appreciated. Embedded in this principle is an understanding and consideration of participants' potential vulnerability. Participants with diminished autonomy or vulnerability are entitled to have their decision-making capacity enhanced, or if this is not possible, the researcher needs to provide them with increased protection (Quest & Marco, 2003; Rischbieth & Blythe, 2005; NHMRC, 2007; McCauley-Elsom *et al.*, 2009; Tait, 2009). Importantly, respect involves maximising the potential participants' opportunity to make their own decisions about participation (Dobratz, 2003; Quest & Marco, 2003). The nurse researcher needs to convey a sense of hope and concern in all conversations by using respectful language that helps to maintain trust between the nurse researcher and participant. Trust is an integral component of the nurse-patient relationship (Bell & Duffy, 2009) and subsequently plays an important role within the nurse researcher-participant relationship.

Vulnerability and gate-keeping

Nursing research often focuses on vulnerable populations or on sensitive research topics (NHMRC, 2007). Sensitive research in nephrology may investigate the unique meaning of the CKD illness experience and particularly end-of-life, quality of care and decision-making (Davison *et al.*, 2008). Vulnerability in research is poorly defined but may be understood as situations where identified populations may be susceptible to, or at an increased risk of, physiologic or psychological harm because of their unequal power status with the researcher (Kavanaugh *et al.*, 2006; NHMRC, 2007; Smith, 2007; Mkandawire-Valhumu *et al.*, 2009). The purpose of identifying vulnerable populations is not to exclude them but to ensure that full consideration is given to allow their maximum participation within the requirements of ethical research (Quest & Marco, 2003; NHMRC, 2007). Research participants may be vulnerable due

to their health status such as mental illness (Kavanaugh *et al.*, 2006; Smith, 2007) or, because their freedom may be curtailed as they are under the authority of others in dependent power relationships (Quest & Marco, 2003; Smith, 2007; McCauley-Elsom *et al.*, 2009; Mkandawire-Valhumu *et al.*, 2009).

CKD, and in particular the impact of uraemia, is recognised as an independent risk factor for cognitive impairment and is known to affect decision-making capacity (Elias *et al.*, 2009). Therefore, there may be ethical implications, within the NHMRC framework of respect, in the capacity of people with CKD to provide informed consent for participation in research studies undertaken by nephrology nurses. Being diagnosed with CKD does not automatically render the person as vulnerable but if the disease affects the person's ability to maximise their autonomy and self-determination to make fully informed decisions, nurse researchers are required to consider that person as vulnerable and adopt procedures to ensure they have extra protection (Moore & Miller, 1999; NHMRC, 2007; Tait, 2009). Elias *et al.*, (2009) have suggested that people with mild CKD such as those with Stages 2 and 3 CKD are able to remember well-organised and specific plain language information but their ability to undertake higher order critical analysis and problem solving can be affected. Those with late Stage 4 and 5 CKD are more likely to have difficulties processing and remembering plain language research participant information (Elias *et al.*, 2009). To ensure that people with CKD are able to provide fully informed consent, nurse researchers may need to consider assessing the potential participant's ability to receive and analyse information prior to offering any information on the study (NHMRC, 2007).

People with CKD may be considered doubly vulnerable due to the effects of uraemia on cognition and gate-keeping by their kidney health professional and/or family. This gate-keeping may be because the kidney health professional and/or family believes that a potential participant's interests may be best served by not participating in a particular research study. External researchers who are not employees of the health service often require the involvement of health professionals (those providing treatment or care to the person with CKD) to gain access to the recruitment of potential participants, particularly marginalised vulnerable populations (McCauley-Elsom, 2009). Health professionals may potentially increase vigilance and act as paternalistic gate-keepers feeling justified in their efforts to protect the wellbeing of their patients, particularly those people who are seen as vulnerable (Dobratz, 2003). This judgement is often made without consultation with the outside researcher or potential participant (Moore & Miller, 1999; Smith, 2007; McCauley-Elsom *et al.*, 2009).

There is a risk that potential participants may feel over-researched and it is the gate-keepers such as the health professionals and family that are most likely to possess information as to the other research projects the participant has agreed to participate in (Kavanaugh *et al.*, 2006; NHMRC, 2007). Family members may act as gate-keepers by restricting access to the potential participant, often due to the perception

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that “the person has suffered enough” (Moore & Miller, 1999, p. 1038). Clearly, there are positive and negative effects of gate-keeping and this illustrates the importance of a partnership of equals between the participant, researcher and health professionals focused on discovering new knowledge for the benefit of people with CKD. One strategy to prevent unwarranted paternalistic gate-keeping is for outside researchers to make repeated efforts to communicate and consult with the family and health professionals to fully address any concerns they may have with the research. This strategy ensures that all stakeholders are fully informed of the potential benefits of the research for changes in practice leading to improved care for future identified vulnerable populations (Smith, 2007). It also allows sufficient time for the gate-keepers to be comfortable with the researcher’s strict adherence to the principles of ethical research.

Now that the major ethical principles of research have been reviewed, the next section of the paper will address some practical strategies which may assist to increase the recruitment and retention of participants into important nephrology nursing research studies.

Practical strategies to increase recruitment and retention

Situational factors such as a noisy room and a rushed consent process do not assist potential participants to fully digest information about the study (Ryan & Deci, 2000; Eyler & Jeste, 2006). To resolve this issue, nurse researchers should ensure that a quiet room is available, where the potential risks and benefits of the proposed study can be outlined by the recruiter in a calm manner. Potential participants who have cognitive impairment (that is, from the effects of uraemia or, especially in older participants, from dementia) may become overwhelmed with too much information, and require repetitive explanation of the risks and benefits of the proposed study over a prolonged period of time, before they are able to provide their informed consent (Eyler & Jeste, 2006).

Distribution of a simplified ‘plain language’ participant information sheet at the first meeting between the researcher and potential participant, with gentle explanation at each subsequent contact, will increase the likelihood that potential participants will feel confident to ask questions of significant others such as family members, elders and/or kidney health care professionals so that all their concerns can be fully addressed (Eyler & Jeste, 2006; Kavanaugh *et al.*, 2006). Cognitive functioning during the CKD illness trajectory may vary. People with CKD who have had a sudden and rapid deterioration in kidney function, resulting in an acute episode of cognitive impairing uraemia, should be allowed to recover from their acute episode before being asked to participate in any research study.

The nurse researcher needs to display caring and supportive characteristics so as to acknowledge that the information the participant is sharing is important in the researcher–participant relationship. One action is for the nurse researcher to ensure the comfort of the participant before any interview commences. Flexibility in the scheduling of interviews is mandatory for

participants who have chronic illnesses such as CKD. The nephrology nurse researcher needs to acknowledge that the participant might feel too ill to participate on a specified day so the nurse researcher needs to be ready to arrange an alternative day and time for the interview.

Nurse researchers may experience role confusion if they are asked by the participant to provide educational information, particularly if undertaking a non-interventionist qualitative research study. In such circumstances, a pre-nominated health care professional should be contacted to provide this additional information after the interview, which then allows the researcher to remain in the role as a non-interventionist, ethically caring, and responsible researcher.

Conclusion

Nurses who engage in research with people who have CKD have a responsibility to design and undertake ethically responsible research. The key elements of the NHMRC (2007) framework require the nurse researcher to consider the values and principles of autonomy, beneficence/non-maleficence, social justice and respect in order to fulfil that ethical responsibility. There are competing interests between the researcher and the researched. The researcher is seeking new knowledge but needs the participant in order to procure that knowledge (NHMRC, 2007). The potential participant may have an interest in the discovery of new knowledge related to their condition but that knowledge may be of no real benefit to them. The effort and risk of participation may be more detrimental than any benefit of the new knowledge.

There is also a skewed power relationship between researchers and participants, especially where researchers are also health care professionals. For the nurse researcher, there is a continued need to research nursing questions within the CKD population so as to improve scientifically based nephrology nursing practice and people with CKD need to be able to participate in research that allows them a voice into their world. Increasing the confidence of nurses to undertake ethically responsible research studies and manage the issues that may arise during recruitment, data collection and analyses will build research capability and capacity. It will also increase the likelihood that important research findings will be translated to the practice environment.

Contributions

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