



<b>Title</b>	<b>Challenges of Recruiting a Vulnerable Population in a Grounded Theory Study</b>
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<b>Citation</b>	<b>Challenges of recruiting a vulnerable population in a grounded theory study. <i>Nursing and Health Sciences</i> (2001), 3, 205–211</b>
<b>Issued Date</b>	<b>2001</b>
<b>URL</b>	<b><a href="http://hdl.handle.net/10722/57055">http://hdl.handle.net/10722/57055</a></b>
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## Research Article

# Challenges of recruiting a vulnerable population in a grounded theory study

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### Abstract

Recruitment is a crucial and fundamental part of research and one that poses various degrees of difficulty. This is particularly so when the area of research is one that is either highly sensitive, or that involves participants who are deemed to be particularly vulnerable. This article explores the inherent tensions in matters of participant recruitment among meeting the demands of institutional ethics committees, satisfying the concerns of clinicians in the field and the need to maintain methodological rigor. A postgraduate research student's experience of these tensions underpins the discussion. The article concludes with an outline of the student's strategies and resolution of these issues.

### Key words

ethics, grounded theory, informed consent, primary selection, recruitment, rigor, theoretical sampling, vulnerability.

## INTRODUCTION

A postgraduate student sought to conduct a study that focused on the support given by lay carers to critically ill patients during their hospitalization in the Intensive Care Unit (ICU) and up to 3 months later. The methodology proposed for the study was grounded theory (Glaser & Strauss, 1967; Strauss & Corbin, 1998). The student and his supervisors were cognizant of the vulnerable nature of the participant group and made extensive efforts to accommodate the concerns expressed by ICU clinicians through the study's recruitment criteria. Despite this, the institutional ethics committees, to which the study proposal was submitted, expressed numerous reservations about the proposed recruitment process for participants. The student, while seeking to address these concerns, was also conscious of the need to maintain methodological rigor within his study. This paper explores the tensions and responses in satisfying the concerns of clinicians in the field, complying with the

demands of institutional ethics committees and the need to maintain methodological rigor. These issues and experiences may be of interest to other grounded theory researchers in the field.

## LITERATURE REVIEW CONCERNING RECRUITMENT

While social and psychological researchers seldom provide exact information about their recruitment methods or discuss the implications of these methods in depth (Patrick *et al.*, 1998), the difficulties of recruitment in nursing research studies that utilize clinical trials are widely acknowledged (Buckeldee & McMahon, 1994; Kelly & Cordell, 1996; Motzer *et al.*, 1997; Steger, 1997; Ross *et al.*, 1998; Wilson & Rose, 1998). The difficult issues in recruiting participants for intervention research (Pletsch *et al.*, 1995), survey research (Patrick *et al.*, 1998) and practise-based research in the community (Carey *et al.*, 1996) have also been addressed. In short, these issues are: lack of trust between potential participants (e.g. ethnic minorities and the elderly) and recruiting researchers; cost-effectiveness of recruitment methods; and difficulty in retaining recruited participants in the study. Furthermore, Raudonis (1992) explored the ethical

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Received 11 June 2001; revised 5 August 2001; accepted 20 August 2001.

challenges in recruiting hospice patients as a vulnerable population for clinical research. However, except for a study conducted by Higgins and Daly (1999), the issues and attendant challenges related to recruiting patients in a critical care setting have not been discussed widely.

### **The research question**

Seeing patients recovering from a critical situation is part of the working experience of intensive care nurses. During the recovery process, social support is widely accepted as beneficial to the patients (Jung, 1984). However, one particular episode concerning the impact of support from a layperson on a comatose patient made a deep impression on the researcher and this led to the researcher's interest in undertaking a graduate research study. Several years ago, a young man was admitted to an ICU in status epilepticus attributable to a sudden onset of viral encephalitis. He was heavily sedated and mechanically ventilated in an attempt to control his convulsions. During the first week of his admission, he developed rhabdomyolysis and acute renal failure for which he received hemodialysis. Adult respiratory distress syndrome (ARDS) and multisystems failure followed. Sedatives were gradually ceased when continuous electroencephalogram (EEG) monitoring indicated stabilization. Unfortunately, the patient remained unconscious for over a month despite all possible medical intervention. The prognosis for a full recovery was deemed to be very poor. Nevertheless, the patient's fiancée provided him with continuous support from his first day of admission. She came every day to talk with, sing to, touch and hold the young man, and to help with his care. She also provided emotional support to the patient's parents. After a few months the patient eventually recovered from his coma and was discharged with only residual weakness in his lower limbs. Although this was only one instance, it caused the researcher to ask what it is about layperson support that impacts upon critically ill patients. What are the laypersons' and patients' perceptions and expectations of support during the process of recovery from a critical illness?

### **Aims and design of the study**

The study had three broad aims: first, to identify, describe and provide a theoretical analysis of the critically ill patient's perception of the impact of support from, interactions with and expectations of his or her principal lay support person (PLSP) during

the recovery process; second, to identify and describe this phenomenon from the perspective of the patient's PLSP; third, to identify a substantive theory that describes and explains this support from the PLSP during the patient's experience of critical illness. As lay support for critically ill patients is a perceptible, multifaceted and multidimensional social phenomenon and little is known about it (Hughes, 1980; Minnis, 1985; Chenitz & Swanson, 1986; Hupcey & Morse, 1995; Rier, 2000), the study employed a grounded theory approach (Glaser & Strauss, 1967; Strauss & Corbin, 1998). Methods of data collection in this study included interviews with and observation of the patients and the PLSPs who provided support during the period of hospitalization and up to 3 months later.

### **Clinicians' concerns**

Before the ethics application was submitted to the two relevant institutional ethics committees, the proposal was submitted to and discussed with the Nursing Unit Manager (NUM) of an ICU where it was proposed the study would take place. This was done to secure the NUM's approval, in principle, for the research to be carried out in this unit, and to secure an agreement to provide assistance to the researcher. Furthermore, the proposal was discussed with the ICU management committee, a multidisciplinary membership of senior ICU staff in the unit. The principal concerns of clinicians in the ICU were to uphold patients' rights to autonomy in relation to informed consent and to protect patients from physical and psychological harm.

### **The demands of the ethics committees**

Having satisfied the concerns of the clinicians (see later discussion relating to how this was achieved) and having received their support for the study, a proposal was submitted to the Health Service and the University Ethics Committees. Both of these committees expressed concerns about the process through which participants would be recruited. Specifically, these concerns were as follows.

- Clinical nursing staff whom the researcher had proposed would assist in the recruitment of participants for the study might, because of their potential nursing relationship with the patient and the patient's PLSP, influence their participation in the study.
- Coercion of participants might take place if the researcher was not kept 'at arms length' in the

recruitment process. Furthermore, the concurrent role of the researcher as clinician in the ICU might also influence the potential participants' decision-making when providing consent. Role confusion and conflicts of interest are not uncommon for qualitative researchers (Archbold, 1986; Swanson, 1986; May, 1991; Mundall, 1988 & Pickett *et al.*, 1994, cited in Burr, 1996).

- Obtaining consent from unconscious patients was impossible and so it was impossible for unconscious patients 'to be informed about the research or to determine their wishes about it' (National Health and Medical Research Council, 1999).

### **The need for theoretical sampling in grounded theory**

Primary selection is the preferred strategy for 'theoretical sampling' (Glaser & Strauss, 1967; Glaser, 1978; Strauss & Corbin, 1998) and this sampling technique is an integral part of maintaining methodological rigor in grounded theory research. As Morse (1991) suggests, in qualitative research methods (e.g. grounded theory, ethnography, participant observation and phenomenology) the preferred strategy for sampling is primary selection because, 'in order to ensure that the sample meets the criteria for appropriateness and adequacy, the *researcher must have control over the composition of the sample*'. Primary selection means that the researcher recruits participants for the study. The justification for this strategy is that, when he or she is responsible for primary selection, the researcher is able to maintain control over who is selected for data collection according to his or her first-hand knowledge of the subject, what information is required for appropriateness and adequacy in the study and who would be most useful to talk to and willing to participate. This level of control is important for theoretical sampling because it enhances relevant data input for the 'constant comparative method of qualitative analysis' (Glaser & Strauss, 1967; Strauss & Corbin, 1998) integral to grounded theory. However, in order to ensure that vulnerable participants are protected and to maintain participants' autonomy in terms of informed consent, ethics committees are generally reluctant to allow the researcher to recruit participants to the study based on the strategy of primary selection. There is a concern that primary selection might result in coercion of potential participants to take part in the study. This concern is further emphasized in instances where participants are from a particularly vulnerable group, for example if they are from an ICU.

## **DISCUSSION**

### **Resolving clinicians' concerns**

In order to maximize the ICU clinicians' input to the study and to ensure due consideration of their concerns, considerable time was allowed for them to discuss the study with the researcher, negotiate resolutions to problems raised, relay these to the ICU management committee and ultimately discard or agree with the suggested resolutions. It was, nevertheless, essential to gaining the clinicians' support for the study that the process should take place in an unhurried fashion. Given the short length of stay (LOS) of patients in ICU, for similar reasons it was also necessary to carry out this process of discussion with the staff of several general wards to which ICU patients were likely to be transferred.

As previously indicated, concerns raised by the ICU clinicians largely related to protection of patients from physical and psychological harm and autonomy in relation to informed consent. Because of this, the lengthy discussions with clinicians and ICU management resulted in an increase in the number of recruitment criteria originally proposed, from 9 to 15. More restrictive, as well as additional, criteria were demanded in order to exclude patients who could be disadvantaged by taking part in the study. For instance, the exclusion of patients who were in ICU as a result of trauma in which a person/people died was added to the study's criteria so as to prevent the chance of extra psychological stress for the patients and their PLSPs. Furthermore, patients who were taking any sedative medications at the time of consideration as potential participants were excluded so as to ensure informed consent.

### **Resolving the demands of institutional ethics committees and maintaining methodological rigor**

The issue of researcher role confusion was easily addressed by cessation of the researcher's clinical work in the ICU where it was proposed the study should take place. The concern relating to the recruitment of unconscious patients was more complex. However, in relation to unconscious patients, the National Health and Medical Research Council (1999) states that, 'because of their extreme vulnerability such persons should be excluded from all but the most minimally invasion observational research'. In this instance, the researcher intended to observe the interactions between the PLSP and the patient only during the time the patient was unconscious. Thus, consent for the unconscious patient could be

obtained from his or her PLSP, provided that this person was the 'person responsible' (Guardianship Board Tribunal, 1998) for the patient. The consent would be verified with the patient once he or she regained consciousness. If the patient agreed to take part in the study, he or she would be interviewed by the researcher. On the other hand, if the patient did not give consent to participate in the study and did not agree to the observation data being used, these wishes would be followed.

Because of the ethics committees' intention to ensure that an 'arms length' recruitment process was adopted in the study so that no coercion of participants could take place, the researcher accepted an alternative recruitment strategy, secondary selection. Thus, it was agreed that the NUM of the ICU and the unit social worker would act as intermediaries to identify whether or not a potential participant met the inclusion criteria and next introduce him or her to the researcher for informed consent. This change enabled the study to proceed. Although first-hand, direct control of sampling was limited as a result of secondary selection, the aim of theoretical sampling 'to maximize opportunities to compare events, incidents, or happenings to determine how a category varies in terms of its properties and dimensions' (Strauss & Corbin, 1998) for development of a rigorous theory was maintained. In this regard, theoretical sampling was conducted from within the database established from interviews and observation of secondarily selected participants who provided their consent to take part the study.

Even though there was a need to maintain methodological rigor as far as possible, in this case some compromise was necessary in order to satisfy the ethical demand of protecting autonomy in relation to informed consent of a particularly vulnerable population. When reflecting on this issue, the researcher considered secondary selection through intermediaries acceptable in this study. As Strauss and Corbin (1998) stated:

the ideal form of theoretical sampling might be difficult to carry out if a researcher does not have unlimited access to persons or sites or does not know where to go to maximize similarities and differences. Realistically, the researcher might have to sample on the basis of what is available.

### **Responses to the challenge of unsuccessful recruitment**

Resolving all the issues in the way discussed and gaining approval for the study from two institutional

ethics committees took a total of 5 months. A further 3 months were devoted to introducing the study to all staff in the ICU, as well as to the NUMs of the general wards to which ICU patients were likely to be transferred during their recovery. However, once the study commenced, no participant was recruited during the first 2 months.

Researchers such as Collins *et al.* (1984) and Steger (1997) have demonstrated that the longer and more restrictive the set of recruitment criteria, the more difficult it is to identify potential participants. Collins *et al.* (1984) suggest four strategies related to situation improvement when recruitment proves to be much slower and more difficult than anticipated. The suggestions include: (i) increasing the length of the recruitment period; (ii) replacing marginal sites; (iii) increasing the number of participating venues; and (iv) relaxing the inclusion criteria. However, these strategies have their own inherent problems. For example, Higgins and Daly (1999) spent 20 months recruiting 20 mechanically ventilated patients for their study; this indicates that an increased length of time for recruitment alone may not ameliorate problems with gaining participants. Furthermore, it was not a viable option to increase the length of the recruitment period in the present study, because of the time limit associated with postgraduate research. Nor was it appropriate to replace marginal sites, as there were a limited number of available sites within the specific geographical region. Nevertheless, the researcher in this study employed two of Collins *et al.*'s (1984) four criteria. Thus, the number of participating sites was increased to two. In addition, the inclusion criteria were carefully reviewed in collaboration with the clinical staff and ethics committees concerned, to enable less restrictive criteria while upholding ethical principles. The original set of inclusion criteria was revised in regard to the clarification, expansion and removal of closed, tight and over-restrictive statements. Examples of the changes were:

- 'Is not taking any sedative medication' was changed to 'may be a patient who is on sedatives for the purpose of mechanical ventilation and is expected to be weaned from both the sedatives and the ventilator'. This ensures that suitable patients with temporary and reversible mechanical ventilation will not be excluded from the study.

- 'Is not on antidepressants or antidepressant medications' was removed because there was no absolute evidence that patients on these drugs were likely to be cognitively impaired (Teri *et al.*, 1991; Allain *et al.*, 1992; Gray *et al.*, 1999). The use of the Mini Mental Status Questionnaire (MMS) (Folstein

**Table 1.** Comparison of original & amended inclusion criteria for the selection of ICU patients as potential participants

Original inclusion criteria for the selection of ICU patients as potential participants	Amended inclusion criteria for the selection of ICU patients as potential participants
<p>The patient (conscious and unconscious)</p> <p><i>Common criteria</i></p> <p>is not a paediatric patient is over 16 years old has been in the ICU for at least 48 h is able to communicate in English and has no hearing/speech impairment lives within the geographical regions of . . . (names removed for confidentiality)</p> <p>has an identified GP for follow up if required is not a routine postoperative patient</p>	<p>The patient (conscious and unconscious)</p> <p><i>Common criteria</i></p> <p>is over 16 years old has been in the ICU for at least 48 h is able to communicate in English and has no hearing/speech impairment lives within the geographical regions of . . . (names removed for confidentiality)</p>
<p>is not a victim of crime or in ICU as a result of trauma in which a person/people died</p> <p>is not on antidepressants or antidepressant medications</p> <p>is not taking any sedative medication</p>	<p>may be an elective postoperative patient (or a patient initially admitted to ICU for a minor procedure, e.g. insertion of central line) who has developed complication(s) that require him/her to remain in ICU for at least 48 h, or who was cared for initially in ICU and later developed unexpected complication(s) in the ward so was readmitted to ICU for at least 48 h</p> <p>is not a victim of crime or in ICU as a result of trauma in which a person/people died</p>
<p>has no neurological disease, cognitive deficit or psychiatric illness according to medical records</p>	<p>may be a patient who is on sedatives for the purpose of mechanical ventilation and is expected to be weaned from both the sedatives and the ventilator</p> <p>may have a neurological condition but may be a patient who does not have cognitive impairment or difficulty in receptive and expressive communication due to that condition (these patients must pass the MMS)</p>
<p>is not expected to die according to medical opinion</p>	<p>is not expected to die according to medical opinion</p>
<p><i>Additional Criteria</i></p> <p>In case of a conscious patient, he/she is oriented and was extubated for at least 48 h (if the patient was intubated before)</p> <p>In case of an unconscious patient, he/she must have a PLSP who is also the designated 'person responsible' who has the legal capacity to legal capacity to make consent to the study</p> <p>is able and mentally fit to give his or her direct consent 48 h after recovery from unconsciousness (must pass the MMS)</p>	<p><i>Additional Criteria</i></p> <p>In case of a conscious patient, he/she was extubated for at least 48 h (if the patient was intubated before)</p> <p>In case of an unconscious patient, he/she must have a PLSP who is also the designated 'person responsible' make consent to the study</p> <p>is able and mentally fit to give his or her direct consent 48 h after recovery from unconsciousness (must pass the MMS)</p>

GP, general practitioner; ICU, intensive care unit; MMS, Mini Mental Status Questionnaire (Folstein *et al.*, 1975); PLSP, principal lay support person.

*et al.*, 1975) was included prior to participants' interviews, to act as a test for cognitive function.

Thus, the set of inclusion criteria was reduced from 15 to 12 statements (Table 1).

As previously mentioned, a second ICU site at which to conduct the study was located. Clinicians at the new site agreed with the amended criteria, gave permission to access the unit and agreed to provide assistance. As there was no social worker at this new site it was agreed that nurses, who were involved in patient care but not in the study, should assist with recruitment. This decision had the support of the relevant ethics committees, which also supported the revised criteria and the inclusion of a second site. In granting approval for this amendment, both institutional ethics committees demonstrated their commitment to enabling the research to proceed and allowed for what Madjar and Higgins (1996) described as 'discretionary judgements' from expert clinicians in the field in terms of approaching potential participants and their families.

## CONCLUSION

The present study demonstrates that with a vulnerable population it is likely that tensions will arise among the issues of ethical demand, clinicians' concerns and the need for methodological rigor. However, despite the length of time necessary to negotiate all stakeholders' interests, with trust, consideration, collaboration and participation with colleagues, these issues can be resolved to allow original and important research to be conducted with a vulnerable population. The first participant in the study was finally recruited 16 months after the original research ethics application was formulated and submitted for approval.

## ACKNOWLEDGEMENTS

Vico C. Chiang gratefully acknowledges the funding of a Category 5 Scholarship from the New South Wales Nurses Registration Board, which assisted in conducting this study.

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