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The challenges of gaining ethics approval for ethnographic research in the pre-hospital setting

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Introduction

The process of ethics approval for social research remains a challenge in areas such as the provision of out-of-hospital Emergency Medical Services (EMS). Research in this setting has traditionally focused on structured clinical trials rather than social research. In Australia the delivery of out-of hospital EMS is not nationally regulated and may be provided by health practitioners variously calling themselves Paramedics, Industrial Medics, Medics, Ambulance Officers, Emergency Medical Technicians, and Patient Transport Officers (Paramedics Australasia, 2011).

This paper is based on research with currently employed paramedics within the S.A. (South Australian) Ambulance Service. The aim of the research is to explore how paramedics identify, assess and manage psychiatric presentations in the community. The research was based in the Emergency Department (ED) and ambulance arrival area **(the ramp)** at a major

tertiary teaching hospital. The research covered the dispatch, arrival, point of assessment, and the transfer of care of psychiatric patients by paramedics.

This paper explores the challenges of gaining ethics approval for conducting this ethnographic study in the out-of hospital EMS setting. It focuses on the emergent nature of the research process and the logistical challenges of meeting prior informed consent. These experiences highlight continuing challenges when attempting ethnography within an area that is not familiar with the research methodology.

Ethics committees and pre-hospital research

The purpose of this paper is to explore the logistical difficulties and the theoretical differences which contributed to the challenges in gaining ethics approval. The paper outlines the strategies used in this particular case to overcome those challenges and suggests areas to consider when using ethnography in this or similar settings. In the past the structure and regulatory nature of ethics review bodies has been largely based on the traditional biomedical model of clinical trials (Murphy & Dingwall 2007). While this has changed and qualitative methods are accepted as an important paradigm in research, qualitative methods and theoretical frameworks still encounter barriers in gaining ethics approval. This is particularly so for ethnographic studies.

The paper is divided into three sections: first, an outline of the need for the research, second, the underlying methodological approach of ethnography, and a brief overview of the study. The third section provides a case study of the difficulties encountered in gaining ethics clearance from a Joint University and Hospital Human Research Ethics Committee (HREC). The challenges encountered in the process of ethics approval occurred in two important areas: ethnography as an emergent process which requires continual negotiation and relationship building, and the concept of prior informed consent which includes the nature of risk and harm in ethnographic research. As the case illustrates, a number of the suggestions of the ethics committee are counter to the nature of ethnographic research.

Senior management from the South Australia Ambulance Service and the Emergency Department were involved from the beginning of the study prior to ethics approval being sought. They participated in the development of the research design with consideration to access, information dissemination, gaining consent, the potential sample size and workload, all of which was included in the original proposal.

The need for the research

The emergency delivery of care by paramedics to people experiencing a mental illness or 'psychiatric presentation' has only recently received attention in the literature (Shaban 2009). As a result of emergency departments becoming the point of entry for treatment for mental health patients, emergency health professionals are being forced to take on greater responsibility for providing both primary and acute mental health care. Eppling (2008) directly attributes the increased emergency department utilization by mentally ill patients to the decrease in funding for mental health services, including limited outpatient and clinical services, as well as a decreasing number of psychiatric beds and the closure of entire psychiatric programmes.

In Australia there has been a significant increase in ambulance attendance to individuals suffering mental illness. This increase is particularly evident in the urgent but not immediately life-threatening ambulance dispatch category, category 2. The Queensland Ambulance Service Audit Report (Queensland Government & The Queensland Ambulance Service 2007) demonstrated that growth for presentations coded psychiatric, abnormal behaviour and suicide attempts for the year 2003/ 2004 to 2006/2007 was 97.4% (3594 in 2003/2004 to 7094 cases in 2006/2007). Roberts & Henderson (2009) found a similar increase in South Australian Ambulance psychiatric caseload from 1.78% of ambulance workload in 2001/2002 to 2.41% in 2005/2006. From July 2006 to mid May 2007, 6169 psychiatric cases out of a total of 219 429 dispatches were identified as psychiatric, comprising 2.73% of workload.

Given the paucity of qualitative research in this specific area of practice, ethnography has a key role in informing and documenting paramedic practice, strategies and 'on-road' experience.

Ethnographic method and the study design

Ethnography is well established as both a process and a product, not only as a research approach that illuminates our understanding of human experiences and its meaning, but also for its capacity to highlight the researcher's lived involvement within the field of study (Tedlock 2003). Ethnography provides multiple sources of data to facilitate a contextual understanding of participants' experiences and culture. The open-ended nature and flexibility of ethnographic research design and its ability to respond to emerging insights and developments is well suited to the exploration of paramedic culture and everyday practices (O'Neil 2002). The rich description generated in the process of ethnography provides the ethnographer with the opportunity to see the actions, motivations, communication and

functions of the individual or the 'society' under study in new and different ways. The insight may provide new ways of connecting old concepts or develop new concepts from data that might not have been captured before, such as paramedic practice when attending people with mental health problems. The rich description developed from observation, interviews and document analysis enables paramedics' actions and how they view those actions to be captured and placed in the wider context of culture. Another argued benefit of insightful descriptions is the ability to remove the thinking and observation from previous frameworks, which may have been used routinely to construct what is considered 'reality', to open them to different possibilities.

The potential sample at the time of the study was 479 emergency operational personnel (paramedics). The observations occurred over an 11-month period between 2009 and 2010 in the triage area of the emergency department and arrival area for the ambulances also known as 'the ramp'. The data from observations were collected in the form of written field notes later transferred to computer for analysis. Twenty brief unstructured interviews were planned to be conducted with the paramedics on the ramp with negotiations made for a second longer interview. Short interviews with the emergency department staff were planned regarding the handover process from paramedics and intended to involve only those staff who were directly involved in the handover of the patient.

Gaining ethics approval

In Australia all HRECs are registered through the Australian Government National Health and Medical Research Council and are guided by national standards which include those stated in the National Statement on Ethical Conduct in Human Research (Australian Government 2007). The National Statement under section 5.1.30 requires that the composition of a HREC should consist of no less than eight members with specific qualifications and expertise. The National Statement outlines the relevant ethical principles and values, such as informed consent, beneficence, justice, confidentiality and malevolence which guide the HRECs when reviewing research proposals.

In this study the challenge in gaining ethics approval related to the nature of the observations and interview process. The emergent nature of ethnographic research makes defining expected outcomes difficult in comparison to the more pre-defined procedures of strict clinical trials. The amount and detail of the data provided by the participants will vary and is dependent on the relationship between the researcher and the participants. This developing relationship means that the researcher cannot, at the outset, define the full risks

and benefits of the research to participants because they do not know what may be divulged or how open the participants will be (Parker 2007). This requires the ethics process to be viewed as a continual dynamic process and not as a once-off contractual agreement with clear structured steps.

The logistics of conducting initial interviews and negotiating a second longer interview with paramedics was a continual process involving extended time in the field. Assurances that the research would not impinge unduly on staff time and workload were required from the researcher. The original proposal indicated that interviews would be conducted in negotiation with participants and would cease if operational requirements dictated. The HREC strongly recommended that the beginning of the next shift for the emergency department staff provided the best opportunity to conduct the interviews because of decreased early morning workload in the emergency department and the fill-in support of senior staff. In reality this was difficult and almost unworkable because of the changing rosters of the staff, the ability for emergency department staff to recall the case after many different presentations during a shift, and being able to negotiate a time which took almost as long as the interview itself. As the research process became understood and the relationship developed with paramedics and the emergency department staff they controlled when the interviews would occur. Murphy & Dingwall (2007) encapsulate this development and ownership of the process when they describe the participants as 'hosts'. The term emphasizes the relationship between the researcher and those participating. Ethnographers are guests in someone else's environment, which has associated expectations of conduct. These expectations are sometimes clear, if not always explicit, but in many cases are developed with careful negotiation and relationship building which takes time and presence in the field. This relationship building, unlike clinical trials, often cannot be fully articulated in the initial proposal and design.

The interviews with paramedics were based broadly around the research question, but in accordance with ethnographic research principles allowed the paramedics to introduce and explore the actions and meanings of their practice in their own cultural context. The ethics committee viewed the interview questions as a structured question and answer process instead of an open guide to an essentially unstructured interview. Staff availability and workloads were raised as logistical concerns in relation to observation and completion of the interview questions. In response to these concerns two detailed letters were provided which addressed the purpose of the questions, how they were going to be used and provided examples regarding ethnographic methods and data analysis. This was in addition to copies of

previous ethnographic research conducted in the mental health field already included in the original research proposal. Additional concerns were raised by the ethics committee about the ability to track refusal or completion rates and what would happen if the interviews were not completed. This required explanation that ethnography was not numbers dependant and the interview and observation analysis were based on the data obtained not what was missed. The researcher met with the Chair of the ethics committee to discuss concerns and the final result was that the interview questions with minor rewording and modifications were accepted. This enabled the interviews and observation process to remain unstructured in line with ethnographic tenets. During the meeting the Chair of the HREC confirmed that they had not considered the waiving of the consent from the patients as a concern because of the fact that the study was focusing on the practices and beliefs of the paramedics. The structure of the findings under themes, the use of pseudonyms for the paramedics and emergency department staff, no identifying date or time within the case studies, and no use of either paramedics' or patients' names also factored into the HREC's decision to waiver the patients' consent. Although the original application had addressed the issue of consent from the patients themselves, there was an expectation that this might be one of the challenges raised by the HREC, but it turned out it was not their main concern.

Murphy & Dingwall (2007) argue that extended time in the field makes the process of consent a negotiated and renegotiated process which presents a challenge to prior informed consent. Ethnographic consent is a relational and sequential process in response to an ever changing environment (Katz & Fox 2004). The practicalities of informing and obtaining consent from everyone who might 'enter' into the field of observation in a large and busy social setting such as an emergency department is an ongoing issue and remains one of the major ethical concerns for observational work (Mulhall 2003).

Prior informed consent is traditionally based on contractual agreements for short, defined episodic interventions typical of clinical trials which depend on providing the potential participants with information regarding foreseeable risks. In contrast to clinical research, the risks of ethnographic research are indeterminate and not always easy to communicate with accuracy in advance (Bosk 2004). In ethnography the consent may be initially tentative and within very strict boundaries. As the relationship builds with the ethnographer, the information participants provide may become detailed. The question then becomes: does initial contractual consent cater for this developing information sharing and access to participants? Addressing issues surrounding informed consent involved balancing the needs and concerns of the ambulance service (the stakeholders) and the ethics process.

The first issue was the logistics of gaining consent from paramedics on rosters and based in different geographical areas. A second consideration was the operational protocols such as 'clearing', when paramedics are either heading back to their station or ready to attend their next call, 'crib', which are the allocated breaks within their shift, and what happens if the paramedics need to leave to attend urgent cases. All required careful negotiation. Meetings set up with stakeholders and the ethics committee and maintaining regular contact assisted in addressing the majority of these issues.

Although paramedics were to receive information through their team leaders and via information sheets, both in hard copy and electronically prior to data collection, the ethics committee perceived coercion as an issue. Although paramedics are not routinely seen as a vulnerable group there were concerns that the initial information was not adequate to prevent paramedics feeling pressured into giving consent. Clear prior consent needed to be established and needed to be an 'opt in' rather than an 'opt out' process.

After careful negotiation through two letters to the HREC, email and telephone correspondence, with the Chair of the committee and stakeholders, three potential solutions were proposed. The first, to attend training and information days structured throughout the year for paramedics. Secondly, as an alternative, going to individual station team meetings to talk about the study or thirdly to have a 2-month recruitment period prior to observation and interviews based 'on the ramp', the arrival area of the emergency department. The 2-month recruitment period attempted to cover roster rotations and changes in paramedic crews prior to data collection. The first two approaches were not readily agreed to by the ambulance service because the attendance of the ethnographer at ambulance stations was problematic. This was due to logistics, station security and regard by paramedics of this space as their domain and a safe haven from the stresses of their work.

Agreement was finally reached after approximately 7 months of repeated negotiation on the 2-month recruitment period. It was agreed that during the recruitment period the researcher would be at the emergency department to talk to paramedics and provide hard copies of the information sheet and consent forms. If the paramedics wished to be involved in the study, the signed consent form could be handed to the researcher the next time both parties were at the emergency department. No interviews were conducted or field notes taken of handover at this time. Throughout the process verbal confirmation was continually obtained to ensure those that had signed a consent form still were willing to be involved.

Conclusion

These experiences highlight the continuing challenges with ethics surrounding emergent, collaborative and participant-driven research. The process revealed that within the framework and composition of HRECs which mainly deal with clinically based quantitative research, there is still a limited understanding of qualitative research methodologies. As the relevance of qualitative research to the provision of emergency medical care and clinical practice continues to evolve, the familiarity and expertise within these areas are significant when considering the composition of HRECs. To assist understanding of qualitative methodologies, HREC members could be provided with examples of national and international qualitative research within the emergency field. This greater understanding would assist HRECs to evaluate the ethical risks posed by the methods used or where the risk may outweigh the benefits.

The original discussions with industry were essential for understanding how to reach participants and for involving the stakeholders in the process. Gaining informed consent requires several strategies and creative thinking to achieve what in the long run in ethnography is a continual process. Ongoing negotiations with industry and the HREC require clear communication, goodwill between parties and ultimately one-on-one meetings to adequately address concerns from all involved. Finally, adequate explanation and supporting evidence of the methodology is needed when attempting ethnography within organizations which do not routinely use the research methodology.

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