Waiver of informed consent in prehospital emergency health research in Australia

WAIVER OF INFORMED CONSENT IN PREHOSPITAL EMERGENCY HEALTH RESEARCH IN AUSTRALIA

Amee Morgans
Research Fellow, Department of Community Based Emergency Health and Paramedic Practice, Monash University
Correspondence to Amee Morgans: Amee.Morgans@med.monash.edu.au

Informed consent is a vital part of ethical research. In emergency health care research environments such as ambulance services and emergency departments, it is sometimes necessary to conduct trial interventions or observations without patient consent. At times where treatment is time critical, it may be impossible or inappropriate to seek consent from next of kin. Emergency medicine is one of the few areas where the process of informed consent can be waived to allow research to proceed without patient consent. This article will explore the ethics of informed consent in the prehospital emergency research context. This will include an overview of current Australian guidelines for ethical research, and recent changes in law internationally which have affected the conduct of international emergency health research. An overview of the ethical reasoning behind the waiver of informed consent in emergency research is presented, also addressing issues relating to emergency health research such as proxy consent, unconscious patients, and patient decision making capacity. The unusual circumstances encountered in the prehospital ambulance environment will also be discussed, including the dependent and coercive relationship between patients and ambulance professionals, and a lack of alternatives for care and transport for patients who refuse consent. The conflict arising from differences in medical culture and values between patients and health care professionals will also briefly be discussed. It will be argued that, while emergency care research should not require informed consent due to the restrictions of time and dependent nature of the relationship between patient and health professional, emergency health researchers still have a responsibility to consider the patients' perspective when considering the ethical issues of an emergency research project, particularly in the prehospital environment.

A health emergency is a situation where a patient requires health care in a timeframe restricted by impending ill health or death. This often begins in the 'prehospital' environment such as in the patient's home, or in a public place. Health emergencies in the prehospital environment sometimes involve Ambulance Paramedics, who provide front line emergency health care with limited resources.

The area of emergency health research is a very important one because, when a health condition becomes time critical, early intervention and improved medical care has a higher potential to improve patient health outcomes, including reducing morbidity (Herlitz 2002). It is important, however, to remember that emergency patients are highly dependent on medical care and, as such, are a vulnerable population with diminished autonomy deserving extra protection (Biros et al. 1995). Emergency patients may face several additional areas of vulnerability in terms of language, age, gender, culture or disability (Moreno et al. 1998). It is important to note that this article pertains to informed consent for inclusion in *research*, not consent for *medical treatment*. Informed consent for medical treatment in the Australian context is addressed in a recent publication by an Australian paramedic (Steer 2007).

Prehospital research comes in many forms and in many settings. Areas of research relating to ambulance paramedics involve trialling health care interventions and drugs, clinical trials, social and behavioural research and the epidemiological examination of health records. According to the international Cochrane Collaboration which registers and indexes research protocols and meta-analyses, the volume of emergency health research being conducted has increased exponentially over the past twenty years, resulting in the establishment of the Cochrane Prehospital and Emergency Health Field to specifically address this field of research (Cochrane Collaboration 2010). A common research consideration in any type of emergency health study is the issue of informed consent. Even simple studies using de-identified medical records or observation of patient behaviours with no researcher interaction can still threaten the privacy of the patient in some cases (Office of the Health Services Commissioner 2002), and call into question the duty of care of providers of health care to inform the patient of any situational factors which threaten the patient's autonomy and rights to privacy.

This article will explore the issues of informed consent for research in emergency health situations. The process of informed consent will be explored, including the role of patient, carer and community consent, and decision making capacities of those parties involved. This article aims to examine the issues surrounding informed consent in the emergency health field from a patient, researcher and healthcare provider perspective to offer some insight into the conduct of emergency health research in Australia.

GUIDELINES FOR ETHICAL RESEARCH INVOLVING HUMANS IN AUSTRALIA

The guidelines for research ethics in Australia are well documented and used by human research ethics committees when considering research project proposals for ethics approval. Section Four of the *National Statement on Ethical Conduct in Research Involving Humans* (Commonwealth of Australia 2007) considers research involving persons highly dependent on medical care and includes the areas on emergency, neonatal, intensive care, terminal care and unconscious patients, all of which may be applicable to the emergency healthcare context. The guidelines for ethical research are very clear on the research project requirements the committee needs to consider. These are briefly prefaced below.

The opening section of Chapter One clearly states for a Human Research Ethics Committee (HREC) to approve any proposed research project in including any of these emergency health participants, the project must fulfil a set of four major requirements:

1. RESEARCH MERIT: The project must be of significant potential merit. This is the first key factor affecting research project approval. The burden of participation must be outweighed by the potential benefit of the study.
2. JUSTICE: although it may seem unfair to conduct research on people who are in emergency care situations, where the research merit principle is fulfilled, there must be fair access to participation opportunities.
3. RESPECT: where communication is impaired it may be possible to offer information and seek consent in a non verbal or non-written way.
4. BENEFICENCE: The benefit of the research must justify any risks of harm or discomfort to participants. Furthermore, in the section 4.4.6; which addresses the beneficence principles specifically for emergency care research, the guidelines state that the nature of emergency health research means that informed consent may not be possible, therefore a waiver of consent can be granted by committees where the research merit principle is fulfilled and there is a reasonable expectation of benefit of the study.

If these research conditions are considered by a HREC and it is decided that the project has merit and has been designed to align with these ethical principles, The *National Statement* also includes a guide for ethics committees considering a waiver of informed consent for research proposals on this population, and then a process for those projects given a waiver of informed consent to follow:

Section 2.3.4: Waiver of Consent

2.3.5 Only an HREC may grant waiver of consent for research using personal information in medical research, or personal health information. Other review bodies may grant waiver of consent for other research.

2.3.6: Before deciding to waive the requirement for consent (other than in the case of research aiming to expose illegal activity), an HREC or other review body must be satisfied that:

a) involvement in the research carries no more than low risk to participants;

b) the benefits from the research justify any risks of harm associated with not seeking consent;

c) it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records);

d) there is no known or likely reason for thinking that participants would not have consented if they had been asked;

e) there is sufficient protection of their privacy;

f) there is an adequate plan to protect the confidentiality of data;

g) in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media);

h) the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled;

i) the waiver is not prohibited by State, federal, or international law. (Commonwealth of Australia 2007, 24).

These ethical guidelines show clear opportunity for emergency health research to be approved by ethics committees, even in situations where consent to participate cannot or will not be given. This is referred to as a waiver of informed consent, which can only

be granted in specific situations, including medical emergency (Irvine et al. 2002) and in the interests of public health, for example quarantine situations, where individual autonomy is superseded by community need (Foex 2001).

Once a waiver is granted by an ethics committee, the research must follow a process to minimise the potential harm of not seeking consent. Where a research project seeks consent from the patient or patient's proxy (including his/her next of kin or legal representative), the researcher must take steps to minimise the risk of stress or emotional impact affecting the participant's ability to understand the information or provide consent. The researchers must also ensure that the relationship between people dependent on care and their carers does not impact the decision to participate. Where the researcher is also the treating health professional consent for research should be sought by another independent person.

Where consent is not being sought from the participant or his/her legal representative, then a waiver of informed consent should only be granted where: it is reasonable to believe the patient would normally have consented, all risks to the participant are minimised, and the project is not culturally or morally controversial. Where the project is a health intervention, the research may only be offered a waiver of informed consent where the research has a reasonable possibility of benefit compared to standard care and the risk of participation is justified by the potential benefit, and inclusion is not contrary to the interests of the patient. If all these conditions are fulfilled then an ethics committee can grant HREC approval with a waiver of informed consent, provided that the participant or their legal representatives are informed of their inclusion after their participation, and offered the opportunity to consent to their inclusion, and offer the option of withdrawal without any reduction in care.

THE ETHICAL CONSIDERATIONS OF THE WAIVER OF INFORMED CONSENT FOR EMERGENCY HEALTH RESEARCH

The ethics of the decision to waive informed consent is based upon the balance of beneficence (seeking the best health outcome for patients), whilst still respecting patient autonomy (represented in their right to make their own decisions about treatment and participation in research). However, there is some merit to the argument that if a patient cannot consent to participation, then the research should be conducted with another participant group or in another setting which allows consent (Moscati 2002). There is also the possibility of a HREC approving a two stage consent procedure, where researchers can seek preliminary consent to participate despite the patient's inability to offer full in-

formed consent, and then seek a confirmation of informed consent at a later stage when the patient or legal representative has had time to make an informed choice.

The Australian ethical guidelines for research involving humans in emergency health outlined above ensure that the ethical principle of beneficence is maintained, by allowing research which is reasonably likely to be of equal or greater benefit than the standard treatment (for example, where the intervention's benefits may be demonstrated in animal studies but not yet demonstrated in humans) to proceed, without delaying implementing the intervention to attempt to get patient consent. Conducting emergency health research whilst still respecting patient autonomy in the form of informed consent is constrained by two factors; the potential impairment of the patient's decision making capacity and the need to deliver the research intervention in the shortest time possible. Additionally, the desire to waive consent in emergency health also acknowledges that asking for patient consent in medical emergencies could be seen to be an unfair burden on an already vulnerable patient (Kowey and Ornato 2000). The decision making capacity of any patient experiencing a health emergency can be affected by many factors, including medication, stress, emotion, and the illness or injury that has caused the emergency. A recent article which examined the ethics of informed consent for medical treatment by ambulance paramedics presented six major barriers to informed consent for medical treatment in the prehospital environment (Steer 2007) which are also faced when seeking informed consent for research participation. In brief, these are summarised as extreme time pressure, extreme emotion, information deprivation, resource limitations, conflict at the scene (for example between paramedics and patients, but also between family members and patients) and impaired judgement. These unique circumstances mean that informed consent in the prehospital emergency ambulance environment needs to be specifically addressed as a different set of circumstances to the in-hospital emergency environment, which generally has greater ability and resources to assess and manage patients, additional support to include carers in the decision making process and is and less dependent on one medical practitioner.

The unique prehospital emergency health research situation has resulted in a recent extensive modification of the waiver of informed consent laws in emergency health research in the US (United States Government Printing Office 2000) to restrict emergency research without patient consent. This presumes that emergency patients as a population can give informed consent, and if they cannot, then they are ineligible to be included in research studies. This is based on the logical presumption that not all ambulance cases have patients with impaired consciousness, and some may therefore be eligible to offer informed consent. To consider whether patients can give informed consent, the process

of informed consent must be explored in the context of a health emergency. To be considered true informed consent, five key elements must be present (Foex 2001).

The first key element of informed consent is a **disclosure** of the information about the proposed trial, including possible positive and negative outcomes. This is difficult to do in a timely manner, and delays the implementation of the research intervention while it is explained. This is a concern in emergency health research, as the 'window of opportunity' for some interventions is restricted by the progress of the patient's condition. Due to the extreme pressure of time encountered in many prehospital cases, (Steer 2007), using explanatory statements in emergency health research is not always feasible. Furthermore, exactly how much information the patient needs to be given to understand the risks and benefits of the proposed research has been debated (Braunack-Mayer 2002). Patient education has been explored in chronic and preventative health situations, and even when patients were informed about their life threatening health situations in a non emergency environment, their understanding and tendency towards compliance can still be problematic (Campbell et al. 1995). Therefore simply giving potential participants an information sheet about a proposed trial may not supply them with sufficient knowledge about the proposed research project. Knowledge levels and patient preferences about informed consent to participate in research were investigated in a small Swedish study of 31 heart attack patients. The study found that despite extensive informed consent processes during the trial's enrolment, two weeks after the trial began the participants had retained little understanding of the trial and their participation. When asked about their preferred informed consent procedure, patients wanted a concise verbal explanation with family present, rather than written information and signed consent, and were concerned about having to sign papers whilst acutely ill or medicated. Patients and carers also preferred medical professionals to make clinical decisions for them, and found the consent procedure was a further burden in a time of great anxiety. This research suggests that even when consent is informed, the understanding and retention of information by both patients and legal representatives, particularly while patients are acutely unwell or medicated, was compromised. Despite these barriers to the full disclosure of information, improvement of information delivery to a simple, understandable format would enrich the provision of information to patients and may allow consent for inclusion in a research trial to be sought where research concepts are relatively uncomplicated. Alternatively, it may also be possible for patients to consent to a deferral of their decision to a medical professional. In some respects, this would seem a paternalistic approach to health care decision making, however, the patient has the right to choose to defer their medical de-

cisions to a medical professional, or at least seek guidance to support their decision making.

The second key element of informed consent is **comprehension** of the information. Comprehension is usually confirmed by asking the patient to explain the information back to the researcher. Accurate comprehension depends on the researcher's ability to present the information in an unbiased manner. The language used to explain research concepts can be coercive, even when efforts are made to present all options even-handedly. For example, there has been some discussion in the literature about whether patients understand the concept of probability, which they confuse with possibility. For example, patients may prefer to believe that if the risk of death is 50%, they will be in the surviving 50%, technically known as 'optimistic bias' (Ji et al. 2004).

There is, therefore, some doubt whether patients can compare the risks and benefits of a trial intervention. In addition to understanding the risks and benefits, emergency health research usually involves complex medical and research language and understanding – such as a 'placebo controlled trial'. Even the potential for patients to confuse treatment with research, and the degree to which they overlap in a health emergency environment (Adams et al. 1992) can confuse patients. Asking patients to understand these complex medical research concepts during a health emergency is not only unfair, but will take time and may cause the patient additional distress. Therefore this research indicates that patients have the potential to confuse treatment and research and misinterpret, and therefore misunderstand, information related to emergency health research. Comprehension of information again comes down to simple information, clear explanation and opportunity to develop an understanding of the research, the potential risks and benefits and the patient's role as a voluntary participant. Adequate comprehension of all these concepts in the prehospital environment may be obtainable in the alert competent patient, however, there is limited time for consideration of all the factors and limited time also impacts on the opportunity for the patient to reflect on whether or not they truly wish to be involved.

Whether patients want to be involved in decision making in health emergencies was partially investigated in a survey of resuscitation consent with hospitalised patients. Of the 152 patients surveyed, 80% believed that the patients should have a say in end of life decisions, and 20% felt that it was the responsibility of the medical staff. Within the same study, 511 health care professionals were surveyed and 99% reported they believed patient should have a say in end of life decisions (Kerridge et al. 1998). These results are supported by other research (Chan 2004). These differences between medical professionals and patients show that the opinions of medical professionals do not always concur with

that of the patients. A qualitative survey compared physicians and patients views of medical risks, and found patients were willing to accept a low risk outcome of death, whereas physicians were not (Davis et al. 1996).

Whether deferral of decision making to health care providers is appropriate has been further investigated via an examination of conflicts between paramedics and patients. Within the prehospital health emergency environment, conflicts between patients and paramedics arose in 14.4% of 607 observed cases (Adams et al. 1992). A conflict was said to have occurred when the paramedics' perceived obligations were in conflict with the patients' wishes. Major areas of conflict were refusal of treatment or transport (27%) threatening circumstances (19%), limitation of resuscitation (14%), patient competence (17%), resource allocation (10%), confidentiality (8%) and truth telling (3%). The study concluded that the paramedics used a paternalistic approach to patient care but tended to err on the side of beneficence. A hypothetical example of this would be if paramedics wanted to convince the patient of the benefits of a particular outcome, such when they preferred to transport a patient with cardiac chest pain to a hospital with a cardiac care facility, when the patients wished to go to a smaller local hospital they are more familiar with. Conflicts between paramedic and patient are further complicated by the potential for liability, for example, for a patient taken to the smaller regional hospital at his or her own request, which could not provide adequate cardiac care, so that the patient died, in which case the paramedics could be considered negligent in their duty of care to the patient (Adams et al. 1992). These reported conflicts between medical staff and patients reflect the underlying priorities of paternalistic style of care, beneficence and autonomy, and further support the waiver of informed consent in emergency research in terms of seeking better health outcomes for patients. However it is also clear that patients wish to have a say in their emergency health care, and that the medical perspective of beneficence, manifested in prolonging life at all costs, is not always what the patient desires.

The third element of informed consent is **voluntariness**. The voluntariness of informed consent in a health emergency is subject to several limitations, one of which is the potential for coercion. A health emergency is very frightening, and a conscious patient will contemplate the implications of the situation. People in general will hope for a positive outcome of a health emergency, making them vulnerable to coercion in the form of false hope (Simpson 2004). Because there is a more desirable outcome, people will generally believe that preferred outcome will occur for them, as shown in a study of patients suffering from life threatening cardiac illnesses (Cooper et al. 1999). In medical health emergencies, patients are highly dependent on medical care from paramedics, and therefore patients may feel that receiving health care depends on them complying with

the paramedics' requests. The potential for a dependent or coercive relationship is made even greater by the stress and emotional response to a health emergency and with reduced time to consider all options presented, therefore impinging on the voluntariness of consent. Unlike the in-hospital environment, there are no alternatives to ambulance paramedics seeking consent. The in-hospital environment allows for a research nurse or hospital staff member unrelated to treatment to approach patients or carers to seek consent to minimise this bias. The lack of alternative sources for emergency health care and transport to hospital make voluntariness problematic in the prehospital emergency health research setting.

The fourth element of informed consent requires that patients are deemed **competent** to make the decision. Patient decision making capacity is not routinely assessed in ambulance and paramedic practice, only level of consciousness. The Australian ethical guidelines above state that unconscious patients should be excluded from emergency research except for 'minimally invasive observational research, or in research designed *both* to be therapeutic for them and to improve treatment for the condition from which they suffer' (section 4.4.8, page 62). This policy guideline may exclude from research patients who are most at risk from death and impairment and who may therefore most likely to benefit from research (particularly in palliative care, where research trials are sometimes not able to promise a therapeutic benefit for the patient). It can therefore be argued that this stance sacrifices beneficence in the interests of respecting autonomy. There are many such illnesses that involve a loss of consciousness (such as diabetes, trauma, cardiac arrest, resuscitation, asthma, palliative care), all of which are important research areas, and moreover, these are the patients and populations most likely to benefit from optimisation of medical care (Olson 1994).

Excluding patients who are unconscious from emergency health research is also fraught with assumptions about consciousness and consent. The first issue is the definition of unconsciousness. In the Victorian Ambulance Clinical Practice Guidelines (Metropolitan Ambulance Service and Rural Ambulance Victoria 2001, 2009), and the Australasian Triage Scale (Australasian College of Emergency Medicine 2000), used in all Australian hospital emergency departments, the Glasgow Coma Score is used to determine the level of unconsciousness. The scale ranges from 1–15, with fifteen being completely alert and awake, and a score of seven being classified as unconscious. This scale alone indicates that there are varying levels of consciousness, so how conscious do patients need to be before they are capable of providing informed consent? Consciousness alone does not necessarily mean that patients are competent to make decisions about treatment or participation in research trials. It could be argued that paramedics could make an assessment

of decision making capacity, however, to date validated measures of decision making capacity generally only assess memory recall, and have been misused in research for the purposes of legal liability rather than assessing understanding (Welie 2001). The assessment of decision making competence has already been identified as a key opportunity for improvement in the ambulance paramedic skill set (Steer 2007). If decision making competence cannot be assessed in emergency health patients, then there is no assurance that participants were indeed competent to consent to their inclusion in research, and therefore their consent is invalid.

Finally, if participants have achieved all the previous steps in the process of informed consent, they must then decide whether to participate in the research trial, and have their **consent** recorded appropriately. To give valid consent, the researcher must be sure that patients understood that they had a choice whether or not to participate, and that declining to participate means that they will get standard treatment. In most cases, consent is indicated by signing a form, however, in some situations, this is not feasible. It is possible to seek unwritten consent; however, one complicating factor of unwritten consent is cultural differences in body language. For example, in many Asian countries, nodding implies that the person has heard and understood what has been said, and is used to prompt the conversation partner to keep talking, whereas in Australia, nodding indicates agreement, and can be interpreted as consent (Mkhize 2004). Therefore consent processes must be free of cultural or language biases, which can be assured with good research design and supporting documentation.

As previously argued, none of the five elements of informed consent are able to be adequately guaranteed in the prehospital health emergency environment. Successfully navigating the whole process of informed consent takes time, and therefore it could be argued even attempting this process is not appropriate for research in the prehospital health emergency situation *at all* due to the potential for delayed patient care and the impact of additional stress on an already vulnerable patient. If information provision and comprehension could be assured, and appropriate vehicles for recording consent could be developed, then three of the five elements of informed consent could be attained. However, the fact remains that the prehospital environment is uniquely impacted by the extreme pressure of time (in some cases where minutes make a difference to patient's health outcomes (Steer 2007), inability of paramedics to assess decision making competence, and a heavily dependent and coercive relationship between the paramedic and the patient.

So do we simply refuse to seek consent from patients for prehospital based emergency research? On one hand, it seems futile, as clearly, true informed consent cannot possibly

be obtained in most cases. How then can the patient's perspectives be considered without gaining informed consent in emergency health situations?

Alternatives to patient informed consent have been offered in different types of in-hospital research, such as retrospective or deferred consent. Even these options still involve conducting research on patients without their consent, and therefore still does not respect the patients' autonomy any better than the waiver of informed consent (Foex 2001). Some may argue that proxy consent may be suitable for gaining informed consent of family members for patients to participate in research trials. The Australian ambulance Clinical Practice Guidelines do not allow acceptance of proxy consent unless the patient is a minor or the proxy has an enduring power of attorney (Adams 1993). There is some dispute about whether proxies can make decisions for patients in health emergencies, when research has shown the majority of family members could not consent to resuscitation research due to their highly emotional state and the time required to impart understanding of the research trial and its implications within an appropriate clinical timeframe (Hsieh et al. 2001). Despite this, research also shows that when surveyed about consent for resuscitation, patients believe family members are an important resource in decision making (Kerridge et al. 1998). From the perspective of patient autonomy, gaining consent from a proxy does not improve patient autonomy, as the patients are still not in control of their own health, unless the proxy has been given a power of attorney by the patient. Furthermore, the concept of proxy consent is based on crucial assumptions; firstly, that the proxy will make better decisions on the patient's behalf than will medical professionals, and secondly, that the proxy has the patient's best interests at heart. In some cases, neither of these assumptions will be correct.

The international perspective on informed consent may offer some solutions to this ethical dilemma. Unfortunately, international guidelines on informed consent in health emergency research are inconsistent; both internationally and within individual states, health care systems, research ethics committees and hospitals (Edwards et al. 2004). In the US, approval for research is usually given in the form of case by case approvals, based on research protocols submitted to a Human Research Ethics Committee for approval prior to research commencement. Although the US used to subscribe to a waiver of informed consent system for all emergency health research, similar to the Australian system, the US federal government has extensively modified the guidelines about what types of projects are eligible for the waiver of informed consent (United States Government Printing Office 2000). There has been some suggestion of using a deferred/retrospective consent system (Kowey and Ornato 2000), however, this systems has the same legal li-

ability issues as the waiver of informed consent, and on that basis is unlikely to be approved.

The UK and Europe are experiencing the same issues with informed consent and legal liability, however, they have moved towards a community consent approach. This entails appointing a panel of survivors/carers/patients that approve the research in principle, and therefore offer community based consent. The US based regulations also require that community input should be sought prior to approval of the research proposal (American Medical Association 2003), and that results be made publicly available at the conclusion of the trial. No clauses in the Australian ethical guidelines require community consultation or transparency of results. A community based consultation and consent process would add a tier to the informed consent process to provide some element of patient involvement in the process of emergency health research, which is currently almost completely absent in the waiver of informed consent process.

Community based consent would have to be gained from a representative sample of people with extensive personal experience in dealing with the illness or situation being researched. At present, human research ethics committees do require lay members, however, these people are not necessarily experienced in the matter being considered, and may possess little more knowledge about the illness than is presented to them by the researchers. Therefore it is important for the community directly involved in the illness or situation to be consulted, which could be in the form of the support associations, survivor support groups, or patients and their families or carers themselves. Use of community based consultation would give the patients a voice in the emergency research process, currently absent in Australia.

In conclusion, it has been determined through careful examination of the informed consent process that informed consent does not seem a feasible research process in prehospital health emergencies due mostly to the issues of limited time and patients' questionable decision making capacity, even when conscious, due to the extreme anxiety and distress common to emergency health situations. This waiver of consent is supported in Australia by the National Statement on Ethical Conduct in Research Involving Humans (Commonwealth of Australia 2007), with the exception of unconscious persons in some cases. Within paramedic practice, paternalistic styles of care focusing on beneficence are most often used approaches to patient care, which conflicts with the principle of autonomy for patients.

One possible solution which has been identified internationally is the use of community consent procedures to allow some patient consultation and promote the importance of the patient's perspective when considering a research trial. It is the responsibility of a

Human Research Ethics Committee to assess a research proposal to determine it is of a high standard and is consistent with ethical research guidelines, however it is ultimately the researcher's responsibility to ensure research is conducted ethically; to maximize the benefits, whilst minimizing the risks and respecting the patient and carer perspectives.

These ethical research issues are common to all forms of medical research. The prehospital and emergency care setting is a research situation where patients are particularly vulnerable to violation of their rights. These issues are relevant to all research which requires informed consent, in addition to research where the participant and proxy understanding of the possible outcomes and potential harm is questionable. Most of all, these issues affect anyone who may one day find themselves in the emergency health situation, or having to make decisions about health on behalf of others.

REFERENCES

Adams, J. 1993. 'Ethical challenges in emergency medical services. A special contribution of the Ethics Committee, National Association of Emergency Medical Services Physicians'. *Prehospital and Disaster Medicine* 8 (2): 179–182.

Adams, J G; Arnold, R; Siminoff, L; Wolfson, A B. 1992. 'Ethical conflicts in the prehospital setting'. *Annals of Emergency Medicine* 21 (10): 1259–1265.

American Medical Association. 2003. *E-8.085 Waiver of Informed Consent for Research in Emergency Situations*. Washington: American Medical Association.

Australasian College of Emergency Medicine. 2000. Policy Document: The Australasian Triage Scale. 2000. Accessed 14 February 2003. Available from: http://www.acem.org.au/open/documents/triage.htm

Biros, M; Lewis, R; Olson, C; Runge, J; Cummins, R O; Fost, N. 1995. 'Informed consent in emergency research: Consensus statement from the coalition conference of acute resuscitation and critical care researchers'. *Journal of the American Medical Association* 273 (16): 1283–1287.

Braunack-Mayer, A. 2002. 'The ethics of participating in research'. *Medical Journal of Australia* 177: 471–472.

Campbell, D A; Yellowlees, P M; McLennan, G; Coates, J R; Frith, P A; Gluyas, P A. et al. 1995. 'Psychiatric and medical features of near fatal asthma'. *Thorax* 50 (3): 254–259.

Chan, H. 2004. 'Sharing death and dying; advance directives, autonomy and the family'. *Bioethics* 18 (2): 87–103.

Cochrane Collaboration. 2010. 'Prehospital and emergency health field'. *Cochrane Collaboration* (4 March 2010). Available from: www.cochranepehf.org.

Commonwealth of Australia. 2007. *National Statement on Ethical Conduct in Research Involving Humans*. Canberra: Commonwealth of Australia.

Cooper, A; Lloyd, G; Weinman, J; Jackson, G. 1999. 'Why patients do not attend cardiac rehabilitation: Role of intentions and illness beliefs'. *Heart* 82 (2): 234–236.

Davis, M A; Keerbs, A; Hoffman, J; Baraff, L. 1996. 'Admission decisions in emergency department chest pain patients at low risk for myocardial infarction: Patient versus physician preferences'. *Annals of Emergency Medicine* 28 (6): 606–611.

Edwards, S; Ashcroft, R; Kirchin, S. 2004. 'Research ethics committees: Differences and moral judgement'. *Bioethics* 18 (5): 409–427.

Foex, B. 2001. 'The problem of informed consent in emergency medicine research'. *Emergency Medicine Journal* 18 (3): 198–204.

Herlitz, J. 2002. 'Consent for research in emergency situations'. *Resuscitation* 53 (3): 239.

Hsieh, M; Dailey, M W; Callaway, C. 2001. 'Surrogate consent by family members for out-of-hospital cardiac arrest research'. *Academic Emergency Medicine* 8 (8): 851–853.

Irvine, R; McPhee, J; Kerridge, I. 2002. 'The challenge of cultural and ethical pluralism in medical practice'. *Medical Journal of Australia* 176 (4): 174–175.

Ji, L.-J; Zhang, Z; Usborne, E; Guan, Y. 2004. 'Optimism across cultures: In response to the severe acute respiratory syndrome outbreak'. *Asian Journal of Social Psychology* 7 (1): 25–34.

Kerridge, I; Pearson, S; Rolfe, I E; Lowe, M. 1998. 'Decision making in CPR: Attitudes of hospital patients and healthcare professionals'. *Medical Journal of Australia* 169: 128–131.

Kowey, P; Ornato, J. 2000. 'Resuscitation research and emergency waiver of informed consent'. *Resuscitation* 47 (3): 307–310.

Metropolitan Ambulance Service and Rural Ambulance Victoria. 2001. *Time Critical Guidelines* (Clinical Practice Guidelines). Melbourne: Metropolitan Ambulance Service and Rural Ambulance Victoria.

Metropolitan Ambulance Service and Rural Ambulance Victoria. 2009. *Time Critical Guidelines* (Clinical Practice Guidelines). Melbourne: Metropolitan Ambulance Service and Rural Ambulance Victoria.

Mkhize, N. 2004. *Indigenous Selves and Ethical Decision Making: Towards Dialogue Between Universalism and Communalism in Ethics*. Paper presented at the 7th World Congress of Bioethics, Sydney, Australia. 9th – 12th November 2004.

Moreno, J; Caplan, A L; Wolpe, P R. 1998. 'Updating protections for human subjects involved in research. Project on Informed Consent, Human Research Ethics Group'. *Journal of the American Medical Association* 280 (22): 1951–1958.

Moscati, R. 2002. 'Protection of human subjects in prehospital research'. *Prehospital Emergency Care* 6 (2 Suppl): S18–S23.

Office of the Health Services Commissioner. 2002. *Health Records Act 2001 (Vic): Statutory Guidelines on Research*. Melbourne: Office of the Health Services Commissioner.

Olson, C. 1994. 'The letter or the spirit: Consent for research in CPR'. *Journal of the American Medical Association* 271 (18): 1445–1447.

Simpson, C. 2004. 'When hope makes us vulnerable: A discussion of patient healthcare provider interactions in the context of hope'. *Bioethics* 18 (5): 428–447.

Steer, B. 2007. 'Paramedics, consent and refusal – are we competent?' *Journal of Emergency Primary Health Care* 5 (1): 1–10.

United States Government Printing Office. 2000. *Code of Federal Regulations, Title 21; Food and Drugs; Part 50 – Protection of Human Subjects*. Washington: United States Government Printing Office.

Welie, S. 2001. 'Criteria for patient decision making (in)competence: A review of and commentary on some empirical approaches'. *Medicine, Health Care and Philosophy* 4 (2): 139–151.

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