To waiver or not to waiver? The dilemma of informed consent in emergency department suicide prevention research

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CASE REPORT

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Abstract

Ethical issues are inherent in research with vulnerable populations; researchers are encouraged to view these issues as challenges rather than obstacles. This paper details the request of a suicide prevention research collaboration to collect data in specific circumstances involving the waiver of consent. The conflicting multi-ethics committees' responses to this request are examined, with the purpose of highlighting the resultant impact of delayed multi-site ethical approvals. Implications of the committees' responses for this research in terms of being able to address the original stated project aims of improving future acute health service provision to suicidal individuals are discussed.

Key Words
Research, suicide, self-harm, ethical dilemma, emergency department, self-discharge.

Background

Deliberate self-harm (DSH) is a strong risk factor for future suicide[1-4] and approximately 12% of non-psychiatric emergency department (ED) admissions acknowledge suicidal ideation.[5] The ED has the opportunity to potentially prevent suicide among these patients by identifying those at risk, providing immediate intervention to reduce risk, and implementing strategies to encourage patients to engage with treatment.[2,6] To date, however, there is almost no evaluative research reporting evidence-based data on the potential effect of such interventions among these patients. This paper outlines the research protocol for a short intervention.

The Suicide Prevention in the Emergency Department (SPED) project aims to reduce future suicide in an identified at-risk and vulnerable group of people who present at EDs with an episode of DSH, suicide attempt, and/or reported suicidal ideation. SPED was conceptualised as an intervention which could be implemented within current arrangements for service delivery within EDs in Australia.
The evaluation aims to provide evidence regarding the effectiveness of a psychosocial intervention (SPED) for low-moderate risk patients who are discharged directly home from the ED. The evaluation involves a quasi-experimental design across four Victorian metropolitan hospital EDs, where participants are randomised to receive SPED or standard care. The approval of three separate ethics committees has been required, with a fourth ethics committee receiving the application as a registration only.

Previous authors have discussed the difficulties involved in defining 'vulnerability',[7-9] the ethical considerations and challenges associated with conducting research with populations considered to be vulnerable,[7,9-12] specifically with suicidal populations,[1,13-19] and multi-centred research with vulnerable populations.[20] This paper adds to the existing body of literature by detailing a unique data collection request that elicited conflicting responses from each of the three ethics committees consulted. This request was to collect a limited data set where direct consent of participants was unable to be obtained. The ethics committees' various responses to this request caused significant delays in ethics approvals and in the implementation of the SPED project and evaluation.

This paper details the research collaboration's rationale and justification, and discusses the implications of the ethics committees' responses for the research in terms of being able to address the original stated project aims of improving future acute health service provision to individuals at risk of suicide. The intended purpose of outlining these specific circumstances is to assist future researchers faced with similar situations.

Case details

As part of the overall ethics applications, ethics clearance was sought to allow the separate collection of data on two sub-populations. The first sub-population comprised those patients who presented to the ED after a suicide attempt or an episode of DSH or suicidal ideation, but who discharged themselves prematurely prior to completion of a comprehensive psychosocial and risk assessment. These patients could not have consented to either study participation or data collection because they had already left the ED prior to a worker being able to approach them for consent. Previous research suggests that this sub-population are at significantly increased risk of repeating self-harming episodes, or indeed, of successfully completing suicide.[2,21-23]

The second sub-population was those patients who may be at risk of repeating harming episodes or completing suicide who underwent assessment in the ED but who did not consent to participate in the study. Importantly, this second sub-population was never formally asked to participate. When the researcher was not present in the ED and an eligible person presented, the assessing mental health clinician handed them a brochure about the study. These patients in this second sub-population were those who refused the brochure. There may have been several reasons for refusing the brochure, such as that the clinicians did not discuss the study with these patients, they had other patients to attend to, and that many patients once assessed were anxious to leave the ED (particularly if this was at night).

For these two sub-populations, permission was sought to collect aggregated, non-identifying data limited to the following variables:

- basic demographic data (sex, age, marital status, suburb, ethnicity);
- reason for presentation/diagnosis;
- previous ED presentations with similar presenting issues; and
- discharge status i.e. self-discharge; discharge before seen; discharge self with only partial treatment received etc).

Approval was sought for the collection of this data from existing participating hospital electronic database records only. The hospital databases of interest were the administration systems that were used to record patients' details during each hospital presentation. More detailed information, such as medical, nursing and allied health progress notes which form part of the medical record were excluded from the request (i.e. the request excluded access to patients' medical records). At the time, in the participating hospitals, these notes were all hand-written into a patient's medical file and were not only excluded from the request but could not be accessed via the databases.

It was planned that all data would be de-identified, through use of a de-identifying research identification number to code data collection and delineate these two sub-groups. It was intended that this data be collected and analysed by a research assistant who would not be employed in any other role or associated with any other aspect of the SPED project. The purposes of collecting this data were as follows.

1. To make comparisons between consenting study participants and both of these sub-populations to understand the impact of any selection bias with respect to the generalisability and applicability of research findings.
2. To generate a profile of these two patient cohorts (premature discharges from ED and persons who are assessed in the ED but were not formally approached to provide consent to enter the study) to allow future service interventions to be designed with the aim of better targeting such at-risk patients.

Importantly, the request to collect this data and the justification for collecting the data were documented in each of the three ethics applications with identical wording. The responses of the three ethics committees to this request are detailed below.

Ethics committee #1: Conditional approval was granted immediately, one month after the application was submitted, pending amendment to the terminology utilised in the protocol to categorise participants. It was requested that the terminology of 'non-consenting participants' be modified to 'non-participants'. This was modified and the application resubmitted. An additional four months elapsed from this conditional approval before final ethics approval was granted (approximately five months from the original submission date).

Ethics committee #2: Two separate and additional

clarifications were sought by the Committee over a period of five months requesting further justification for the collection of identifiable data without the consent of the participants, stating the following: "For the Committee to approve access to identifiable data, the public interest in the proposed research must substantially outweigh the public interest in respecting individual privacy".

Through two separate re-submissions, sufficient justification was eventually provided for the Committee to grant clearance for this request. Seven months had elapsed from the original submission date.

Ethics committee #3: Significant additional information was requested by the Committee to process this request, as per the following: "The Committee agreed that this request fell outside the scope of the current project and did not meet guidelines for waiving consent. Please review application and amend as necessary".

Amendments with justification were made and resubmitted; however permission for this data collection to proceed was ultimately denied. Ethical approval for the rest of the project was granted within three months of the original submission, conditional to any reference regarding waiver of consent being removed from the research protocol. The Committee's final approval letter stated: "As discussed this request does not meet the requirements for waiving consent and is not appropriate from an ethical or legal standpoint".

Patient consent

Due to the nature of this article, consent from specific individuals was not required and the identification of the services involved has been protected. It is the intention of this paper to highlight the responses to these ethical issues broadly rather than identify and critique the ethics committees' responses individually.

Discussion

The US Belmont Report[24] summarised three critical ethical principles that underpin biomedical and behavioural research involving human research participants: respect for persons, beneficence, and justice. These three principles have been widely accepted since publication of the Belmont Report and are embedded in Australia's National Health and Medical Research Council's statement on ethical conduct in human research. [25]

The application described in this paper was particularly related to the concept of beneficence; i.e. consideration that the greater public good may outweigh the risk to study participants. Ethics committees utilise the ethical principle of beneficence as one of the principles which form the basis for their decisions to approve or restrict research participation.[12] They may advise researchers to drop aspects of their research in which they seek to recruit vulnerable groups or where the risk to participants outweighs any consequent public good. One possible effect where beneficence is used to justify exclusion of vulnerable populations from research is where such exclusion leads to research results being diluted; in turn affecting any benefits of the research to specific groups in society.[11]

In the case of SPED, the request to waive informed consent rested on the merit and integrity of the research in terms of its potential benefits to improved social welfare,[25] and the evaluative argument that these benefits could only be realised where generalisability of the study findings was established.

Regarding the research merit and integrity, SPED was a further development of a pilot programme (WASPS; Western Area Suicide Prevention Strategy) which in the six-month follow-up period was associated with a significant reduction in self-harm presentation recidivism (Private communication, A/Prof Lynette Joubert). The waiver request was therefore justifiable by the potential benefits to society from possible reductions in self-harm and presentations to EDs, and by improved individual autonomy through improved well-being for future individuals presenting to the ED with self-harm.

Regarding generalisability, the formal logic has been known since Peirce[26] described his quantitative induction in the 1880s. Suchman[27] argued, over 40 years ago, that the evaluation of specific programmes has no generalisability due to the constraints of the study sample. Lavori et al[28] explicitly pointed out that generalisability was a function of either replicability or equivalence where equivalence is defined as being able to demonstrate that the study population is representative of the broader population to which study findings might be applied. Meeting Lavori et al's[28] requirement of equivalence is problematic. Although Lavori et al[28] argued that the only way of meeting this requirement was for there to be random sampling from the underlying population, (quite apart from random allocation to treatment) this is not always possible.

These theoretical issues were operationalised in the SPED programme through requesting a waiver of the requirement for informed consent of the two sub-populations described above. The primary argument related to the merit of the research in terms of the potential lethality of the condition

of DSH, i.e. potential suicide. In order to properly evaluate the effectiveness of the SPED intervention with respect to its merit and generalisability, it must be determined whether those not receiving the intervention (whether through premature discharge from the ED or not having been formally approached to provide consent to enter the study) have similar characteristics to those in the experimental group. Thus the justification for the application was based on verification; that is, to generate a profile of presenting cases to compare study participants with the underlying population. This is necessary to report any bias that might affect the interpretation of the study findings, to validate its research merit and achieve generalisability. In the case of SPED, generalisability is particularly important since the study findings may be used to justify either further roll-out of the programme to other hospital EDs or the development and roll-out of similar programmes elsewhere. The request was believed justifiable on these grounds given that it would be making an evidence-based contribution in a field that is currently lacking in quantitative evidence.

In making this request, the researchers had made the judgement that beneficence and justice were more important in this context than autonomy, defined here as respect for the individual, which is usually operationalised in medical research through obtaining informed consent.[24,25] Although autonomy, so defined, usually outweighs beneficence and justice, the Belmont Report[24] and the current NHMRC guidelines[25] both allow that there may be circumstances where the principle of informed consent may not be obvious. Congruent with this position, the NHMRC guidelines permit waiver of consent under certain circumstances.

Section 2.3.6 of the National Statement on Ethical Conduct in Human Research[25] provides nine criteria for waiving consent, including low risk, beneficence and the impracticality of obtaining consent. All nine criteria must be satisfied for an ethics committee to approve the waiver of consent. In our view, the SPED request was consistent with these guidelines and met all nine criteria. In particular, the collection of the requested data would not cause any harm or risk to the individual given that the data would be collected in a de-identified form by an administrative research assistant not connected to the study in any other way, that analysis of the data would contribute to generalisability of SPED thereby meeting the requirements of beneficence should the SPED intervention have positive outcomes. There was no reason to suspect that these people would have refused participation in higher proportion than other potential participants, if they had the opportunity to be fully informed of the study, and that it was impractical to collect consent as outlined above (e.g. when the researcher was not present).

The advice received from the three ethics committees suggested that one committee accepted these arguments, one partly accepted them, and one rejected them. Upon reflection, it appears the specific criterion S2.3.6(d) that "there is no known or likely reason for thinking that participants would not have consented if they had been asked" was the criterion least overtly addressed in the application, and the most likely of these nine criteria where sufficient doubt may have existed for one committee to deny this request.

The ambiguous state of affairs prompted by the differing decisions by the HRECs has been previously reported in the literature, including McCauley-Elsom et al's[20] observation that multi-centred research involving multiple ethics applications to several ethics committees, each of which may request modifications to research design and methods that have already been approved elsewhere, may cause discrepancy across sites in research protocols that were originally intended to retain consistency.[20] In part, this situation may arise because researchers and ethics committees may hold different moral positions in relation to vulnerable populations. In Lakeman and FitzGerald's[15] surveyed responses of 125 ethics committee members addressing the risks, benefits, and ethical problems associated with suicide, all respondents apparently identified one or more potential benefits of undertaking research involving suicidal people: "In general, research involving people who might be suicidal could help scientists/clinicians to form a better understanding of suicide. In the case of service providers how to effectively reduce risk though design of service, models of service delivery and treatments".[15[p.14]]

Somewhat ironically, their investigation also uncovered that ethical problems and difficulties in obtaining approval to involve suicidal individuals in research have contributed to the current paucity of research that explores suicidal experience.[16,17] They postulated that both ethics committees and researchers varied in their moral positions in relation to suicide (moralist, libertarian or relativist perspectives as defined by Mishara and Weisstub).[17]

These issues are all pertinent to the experience of SPED where an identical data collection request was considered and reviewed by three committees, to the detriment of the study's outcome when this request was denied by one. In light of the arguments above, it would appear that

beneficence was weighted very differently by the three committees. The consequence of this situation is that waived consent for the collection of data for the two sub-populations is occurring in some study sites and not in others. The implication is that generalisability will not have been fully established. Should the SPED intervention have beneficial effects, there are implications for either continuing the project at existing sites, extending the SPED model to other EDs, or the development of new interventions based on the SPED model.

If replicated in the future, these issues may be averted by simple changes to the research design. For example, if de-identified data was collected from all presenters to ED with suicidal ideation and/or an episode of self-harm, the response from the ethics committee may be somewhat different. Indeed, one ethics committee postulated that if our original request had been submitted as a separate research project, not attached or affiliated to the SPED project in its current form, the request would have been approved without issue.

Additionally, recent developments in ethical research may also obviate these dilemmas with the implementation in 2006 of the Harmonisation of Multi-centre Ethical Review (HoMER); an initiative enabling the recognition of a single ethical and scientific review of multi-centre health and medical research within and/or across Australian jurisdictions.[29] Although many of the issues outlined in this paper would be eliminated where the ethics committees were participating HoMER committees, it is still the case some six years after this initiative that many institutions are non-signatories. It was unfortunate that HoMER participation was not available at the institutions involved with SPED. It seems likely, therefore, that where institutions are not HoMER signatories, the issues raised in this paper will remain.

In conclusion, our experience suggests that there needs to be a more consistent approach to how ethics applications in suicide are reviewed – a call which has been previously made by Lakeman and FitzGerald[15] who argued that there was a need to build a consensus relating to the key principles for ethical research practice in suicide.

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CONSENT

The authors declare that

1. All possible steps have been taken to safeguard the identity of the services involved.
2. This submission is compliant with the requirements of local research ethics committees.