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Title:
Community attitudes to emergency research without prospective informed consent: A survey of the general population

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Abstract: (233/250 words)

Objective: To give voice to the general public's views of prospective and retrospective (deferred) consent in the emergency research setting.

Design: A cross sectional, stratified population based, telephone survey was conducted in April to July 2016. A questionnaire consisting of standardised health and demographic details, and seven specifically designed, and pilot tested questions, five closed and two open text, based on literature review and previous surveys in the field. Quantitative and qualitative techniques were used in data analysis.

Setting: Centrally coordinated national telephone survey in Australia, the 2016 National Social Survey coordinated by Central Queensland University

Participants: Data for 1,217 adult (18+ years) participants were included in the analysis, with a response rate of 26%. The sample demographics were broadly representative of the Australian population.

Results: The majority of respondents were supportive of research in emergency circumstances without prospective informed consent. However, the type of research and level of risk influence its acceptability. Common themes in qualitative analysis included: the critical or life threatening nature of the illness being researched, and the potential harms and benefits of participation.

Conclusions: This research provided the first opportunity for the community to contribute to discourse about prospective and retrospective (deferred) consent in the emergency research setting in Australia. Further work is needed to determine

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community expectations of how this process can be optimised and implemented, and to identify potential situations where this may not be acceptable.

Background

Research in Australia is performed under guidelines issued by the National Health and Medical Research Council (NHMRC),[1] based on the principles of the Declaration of Helsinki (DoH).[2, 3] , While these documents stress the importance of prospective, voluntary informed consent, the uniqueness of emergency research, and the subsequent ethical, clinical, and legal dilemmas that arise because of it, particularly in terms of respecting patient autonomy, are well recognized in updates of the DoH and the NHMRC *National Statement* (table 1). Advancement of medical knowledge relies on quality research in this unique clinical area.

Prospective informed consent may not always be possible in emergency research. There may be situations where the participant lacks capacity to provide informed consent because of the condition for which they need treatment (e.g. cardiac arrest). Similarly, for time critical interventions, there may not be sufficient time to obtain consent from proxy or surrogate decision maker (SDM), or it may be unfeasible to do so.[4-7]

Within the emergency research environment, tension exists between two key areas; 1) the general primacy of autonomy and respect for persons as evidenced by the requirement for informed consent prior to participation in any research; versus 2) the need for research into emergency treatment and ensuring researchers do not deny patients natural justice and freedom of choice by automatically excluding patients from research if they are unable to provide prospective consent.

While the DoH and the *National Statement* have gone some way in highlighting important issues with consent in these circumstances,[1, 2] one key voice is missing; that of consumers of emergency services who may be impacted by emergency research, and their preferences about consent practices. In this study we have sought to understand how research without prospective consent in emergency research settings

is perceived by the general public.[8] The study was initiated as a critical first step to address the gap in knowledge, and to start a conversation about including views of the community in development of research guidelines.

The aims of this study were to (i) Understand the general public's views about prospective and retrospective (deferred) consent in emergency research and (ii) Identify whether there is a discrepancy between research guidelines and the views of the general public.

Methods

Study design

A telephone-based survey of the general adult population, and analysis of results in the context of relevant national and international documents and standards relating to prospective and retrospective consent in the emergency research setting.

Study population

The survey was part of the 2016 National Social Survey from June 12, 2016 to August 2, 2016. Coordinated by Central Queensland University (CQU), the survey aimed to obtain public opinion and high quality data on a range of topics, of a representative sample of the community in terms of demographics and geographically.[9] Australia was delineated into state and territory areas for telephone interviewing. Dual frame random digit dialling was employed with 50% of the sample contacted on mobile phones. The target population was all persons greater than 18 years, who could be contacted by land based or mobile telephone service. A computer program drew the sample, and a standardized protocol identified eligible respondents.

Survey instrument

The survey comprised a standardized introduction, demographic and core health questions, and specific research questions developed by the research team based on a review of existing literature and input from clinical and research colleagues and laypersons. Themes, scenarios and questions were informed by the review, including existing surveys and qualitative research.[10-20] The survey was pilot tested by trained interviewers on 40 randomly selected households. Interviewer comments regarding question order, clarity and content as well as frequency distributions of responses were reviewed, and questions modified.

Trained interviewers conducted the survey seven days a week, including outside of traditional working hours. A minimum of five call attempts was made to selected numbers. The survey consisted of an introductory statement in lay language regarding research in the emergency department setting in a situation where prospective informed consent was not possible and five closed and up to two open questions depending on responses (see Appendix 1 for survey text). It was emphasized that the hypothetical research project had received approval from a hospital human research ethics committee. Respondents were asked their level of support for a research project that commenced before consent could be obtained, and factors that might influence their decision, their level of support for the same situation in children, the best timing to be informed about participation in a study, and whether it was acceptable to use data without consent in the situation where a participant in a research study dies prior to consent being obtained.

Analysis

Data were analysed using SPSS Version 24 (IBM Corp. Armonk, NY). Standard descriptive statistics were used to describe participant characteristics. Associations between age, sex, education level, country of birth, and location and responses to survey questions 1-3 were explored (ANOVA for numerical variables; chi-square tests for categorical variables). Full text responses to open ended questions were exported to NVivo for Mac (QSR International Pty Ltd. Version 11, 2016) and coded

according to themes. A process of data weighting was applied to adjust for over and under representation of certain groups due to non-response and non-coverage. Un-weighted results are presented and sensitivity analysis was used with weighted analysis to ensure the robustness of the data to the general population.

Ethics

The survey was approved by the Human Ethics Research Review Panel at CQUniversity (Project: H14/09-203,NATIONAL SOCIAL SURVEY 2016).

Results

Quantitative results

We included 1,217 complete responses, representing a response rate of 26%. Half were male (49.5%), the majority married (65.3%), half were > 55 years (49.3%), three quarters born in Australia (72.1%) and just under half (45.7%) had university or higher education (Table 2).

Responses to survey questions are summarized in Table 3. In emergency research when prior informed consent was not possible, 62.1% indicated support, with a further 32.3% indicating they might support, depending on the circumstances. Only a small proportion of respondents (8.4%) indicated that it would not be acceptable to include participants without consent in any study. The type of research influenced acceptability, with a quarter of respondents indicating this was only acceptable when comparing two standard types of treatments. There was less support for inclusion of children in research without prior consent, however 76.5% of respondents believed it was acceptable in some form (Table 3). A high proportion (84.8%) of participants thought it was important or very important to be told about participation in a study as soon as they were able to understand. Two thirds of respondents indicated that use of data without consent would be acceptable in the event of a patient's death. Of demographic data collected, only age was associated with responses to questions 1-3,

with participants >45 years more likely to support research with deferred consent than younger people ($p<0.01$).

Qualitative results.

Participants who responded they might support research without consent "depending on the circumstances" were asked for an open text response to what circumstances or factors might influence their decision. Qualitative data are summarised in Table 4. Themes included clinical factors, the perception of personal benefit, patient factors, surrogate decision makers, trust in medical teams, altruism, and deferred consent (Table S1). Some appeared to confuse concepts of research and clinical care, and indicating support if interventions have previously been proven in randomised trials.

Responses to the open question about the most appropriate time to seek consent in the case of a death during a research study highlighted the complexity of the issue (Table 5). Responses described themes of specific circumstances and families' capacity to deal with the situation and giving families sufficient time to grieve.

Discussion

This is the first population-based survey in Australia of opinions regarding participation in emergency research with alternatives to prospective informed consent. Designed to be representative of the population, we found high levels of support for participation in emergency research in the specific and rare circumstance where prospective informed consent was not possible. Factors influencing support included the life threatening nature of the condition studied and time critical nature of the intervention. Support extended to the involvement of children in research, albeit with a slightly reduced proportion. These finding were consistent across all participant demographics except for age where there was some variation between unconditional support and support based on circumstance.

Previous estimates of support for research in emergency settings without informed consent are wide.[11-13, 16, 18] Most studies in the U.S. and Canada, with various methodologies have found the majority of participants support for research without prospective consent, with point estimates ranging from 64% to 84%.[12, 13, 21-23] In the context of a trauma trial Simms et al found high levels of support (67-85%),[18] whereas in a stroke trial Goldstein et al found fewer (55%) willing to be enrolled.[16] The lowest support for emergency research without consent was reported in a U.S. study where only 35% of respondents agreed that it was acceptable to enrol patients into emergency research without consent when no study details were included.[11] This rate improved to more than half if told there might be a direct benefit to the participants, or specifically applied to their personal involvement in the research[11]. Qualitative research has generally indicated support for research without prospective consent.[24-26] Differences in support may be attributable to varying populations or context[10-13, 15, 16, 18-20, 27] including specific research scenarios such as neurological emergencies,[25] stroke,[16] trauma,[18, 21] or those designed to specifically fulfil U.S. "community consultation" requirements for a planned clinical trial.[11, 21, 24]

Support for emergency research without prior consent has not been consistently associated with participant characteristics. Individual studies have found associations with ethnicity and income,[28] catholic religion,[16] "non-white" race,[22] and gender.[20] Our study found persons aged over 45 years were more likely to support research without prior consent, but previous studies have not found a similar association.[12, 13, 18, 20, 22] One trauma study found decreasing acceptability of enrolment in the trial without prior consent with increasing age.[21] Differences may be due to social or cultural differences. Although no strong association has been consistently demonstrated with ethnicity or race, this may be influenced by the setting, e.g. in the US there may be historically related mistrust in medical experimentation from well-publicised misconduct.[29]

We found slightly less support for inclusion of children in this type of research, consistent with findings in a study enrolling both adults and minors (15-18 years).[21] In a survey of parents of children who had been effected by meningitis, including bereaved families, 67% were willing for their child to be included in a study without prospective parental consent, with most expecting to be told about involvement as soon as possible, or as soon as the condition of the child had stabilized.[15] Our data had similar levels of support.

Support for research without consent decreases with increasing perception of risk.[22, 23] This was congruent with themes in our qualitative analysis of text responses. Comprehension of risk is complex for doctors and patients, and can be affected by various intrinsic biases. A study in ED and geriatric clinics regarding exception from informed consent in a resuscitation study found high support for receiving an "experimental" medication on the recommendation of their doctor, but decreasing support as the rigour and robustness of a study design increased.[10] The perception of risk by participants in this case seems at odds with the actual chance of a risk eventuating, which is reduced with additional oversight and accountability of clinical trials.

Analysis of text responses suggested participants maintained preference for SDM if possible. SDM are often used in both clinical and research situations where patient consent cannot be obtained. However data suggest that SDM may not make decisions that reflect the preferences of patients,[13, 30] SDM may not be in the right frame of mind to make decisions about research, and perhaps most importantly SDM are often unavailable in time critical situations.[31] In circumstances where the therapeutic window is short, seeking SDM consent may delay treatment.[32]

The issue of retrospective or deferred consent in cases where the participant dies prior to consent is complex. Failure to include data has potential for substantial bias. In most circumstances consent would be sought for inclusion of data from next of kin.

However, in a paediatric trial in the UK using a deferred consent process, investigators found outcome was associated with obtaining consent.[33] Overall, only 72% of participants enrolled on an emergency basis obtained consent and were included in the analysis, with mortality 9% in consented patients and 18% in non-consented patients.[33] This is concerning and has implications for ethics committees to consider when approving such trials. In an adult study 81% thought data should be used if the patient died.[12] These results are again reflective of our results, but it is a complex area, and an individualized approach is probably necessary. A paediatric study found a distinction between bereaved and non-bereaved families, with bereaved families indicating a preference for disclosure of the trial after a child's death.[15] Our results indicated support for inclusion of these data, but in this complex ethical area, disclosure would be considered the standard process.

Currently within Australia research with a waiver of consent is permissible if certain conditions outlined by the NHMRC national statement are met (Table1). Our data and survey text responses suggest that these ethical guidelines are generally within acceptable community expectations. There are however, a small number of people who are not supportive, the reasons why, how this might be mitigated and the practical impact this may have needs to be explored.

Limitations

Our study had a number of limitations. The survey design had limited scope to explore reasons for respondent answers. The survey was based on hypothetical scenarios, and participants understanding of the concepts involved such as potential risk may be suboptimal. The response rate of 26%, although comparable with other surveys of this type, and reflective of the community attitude to surveys conducted in this fashion may introduce an element of selection bias. Consequently the findings may not be generalizable to the general Australian public. However, this should be balanced against the robust sampling methodology and large sample size, being broadly representative of the Australian population. The survey instrument was not a

validated tool, and limited by question number, detail, size and scope by resources available, but was specifically designed, based on previous surveys in the field and review of the literature. Other potential sources of bias include a social desirability bias in responses. It will be important to further explore issues identified here using other methodology e.g. interviews and focus groups.

Conclusion

In conclusion, our population survey in Australia found respondents supportive of research in an emergency setting conducted without prior consent in both adults and children. The type of research and the degree of risk involved influenced the level of support. Views expressed are reflective of current national and international guiding documents on research ethics and consent, and suggests that emergency and resuscitation researchers are operating within community expectations. Future research priorities should explore reasons behind and how emergency research processes can be improved.

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Tables.

Table 1. Extracts from the Declaration of Helsinki and NHMRC national statement

Declaration of Helsinki (Section s30)	*"Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group. In such circumstances the physician must seek informed consent from the legally authorized representative. If the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee."*
NHMRC national statement (4.4.5)	*"In emergency research recruitment into a project often has to be rapid. Where the research involves emergency treatment…consent may be waived"*
NHMRC national statement (2.3.9)	*"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."*
NHMRC national statement (2.3.10)	*"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 (see paragraphs 2.1.6 and 2.1.7, page 18) 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."*
NHMRC national statement (4.4.1)	*"4.4.1 Research involving people who are highly dependent on medical care may be approved where:* *a) it is likely that the research will lead to increased understanding about, or improvements in, the care of this population;* *b) the requirements of relevant jurisdictional laws are taken into account; and* *c) either: (i) any risk or burden of the proposed research to this particular participant is justified by the potential benefits to him or her; or (ii) where participants have capacity to consent, any risk or burden is acceptable to them and justified by the potential benefits of the research."*

Table 2. Sample characteristics (N=1217)

DEMOGRAPHICS	**MALE**		**FEMALE**		**TOTAL**	
AGE	N	%	N	%	N	%
18-34 years	131	21.7	108	17.6	239	19.6
35-44 years	87	14.4	87	14.2	174	14.3
45-54 years	88	14.6	106	17.3	194	15.9
55 years and over	296	49.1	304	49.5	600	49.3
MARITAL STATUS						
Married/De facto	409	67.8	386	62.9	795	65.3
Separated/Divorced	50	8.3	72	11.7	122	10.0
Widowed	17	2.8	51	8.3	68	5.6
Single	123	20.4	102	16.6	225	18.5
COUNTRY OF BIRTH						
Australia	425	70.5	453	73.8	878	72.1
Other	176	29.2	157	25.6	333	27.4
HIGHEST LEVEL OF EDUCATION						
Primary schooling or below	9	1.5	13	2.1	22	1.8
Secondary/High School	172	28.5	170	27.7	342	28.1
Technical studies or further education	160	26.5	134	21.8	294	24.2
University or higher education	262	43.4	294	47.9	556	45.7
EMPLOYMENT STATUS						
Employed full-time	293	48.6	174	28.3	467	38.4
Employed part-time/casual	106	17.6	183	29.8	289	23.7
Unemployed	23	3.8	22	3.6	45	3.7

Retired/Pensioner	169	28.0	178	29.0	347	28.5
Student	9	1.5	16	2.6	25	2.1
Home duties	1	0.2	37	6.0	38	3.1
AUSTRALIAN STATE OR TERRITORY						
Australian Capital Territory	22	3.6	8	1.3	30	2.5
New South Wales	193	32.0	197	32.1	390	32.0
Northern Territory	4	0.7	6	1.0	10	0.8
Queensland	135	22.4	132	21.5	267	21.9
South Australia	40	6.6	37	6.0	77	6.3
Tasmania	7	1.2	11	1.8	18	1.5
Victoria	156	25.9	163	26.5	319	26.2
Western Australia	46	7.6	60	9.8	106	8.7
HOUSEHOLD INCOME						
Nil-$26,000 per annum	267	44.3	295	48.0	562	46.2
$26,001-$52,000 per annum	131	21.7	121	19.7	252	20.7
$52,001-$100,000 per annum	38	6.3	44	7.2	82	6.7
More than $100,000 per annum	37	6.1	18	2.9	55	4.5
No response	129	21.4	136	22.1	265	21.8

Note: Column percents are shown

Table 3. Participant responses to questions on deferred consent

Question	Response	N (%)
Q1: Would you support emergency research which has been approved by an ethics committee but involves starting treatment before consent can be obtained?	Yes, I would support this	756 (62.1)
	I might support this depending on the circumstances	393 (32.3)
	No, I would not support this	57 (4.7)
	Don't know/Unsure	11 (0.9)
Q2: What type of clinical research study would be acceptable for you to be automatically included as a participant, without your prior consent?	Any type of research would be acceptable	540 (44.4)
	Only a study comparing two standard forms of treatment	312 (25.6)
	Only a study comparing a standard treatment with a new form of treatment	199 (16.4)
	None - Inclusion without consent would not be acceptable for any study	102 (8.4)
	Don't know/Unsure	57 (4.7)
	No response	7 (0.6)
Q3: What type of clinical research study would be acceptable for YOUR CHILD to be automatically included as a participant, without your prior consent?	Any type of research would be acceptable	448 (36.8)
	Only a study comparing two standard forms of treatment	326 (26.8)
	Only a study comparing a standard treatment with a new form of treatment	157 (12.9)
	None - Inclusion without consent would not be acceptable for any study	204 (16.8)

	Don't know/Unsure	67 (5.5)
	No response	15 (1.2)
Q4: How important would it be to you that you are told about the study as soon as you were able to understand?	Very important	656 (53.9)
	Important	376 (30.9)
	Not very important	117 (9.6)
	Not at all important	54 (4.4)
	Don't know/Unsure	6 (0.5)
	No response	8 (0.7)
Q5: If a patient who was part of a research study dies during their time in an emergency department and information about their treatment could be used in the study, do you think it would be acceptable to use the data without the families' consent?	Yes	805 (66.1)
	No	371 (30.5)
	Don't know/Unsure	37 (3.0)
	No response	4 (0.3)
Q5b*: What do you think is the best time to approach the family in these circumstances to seek consent?	Immediately	151 (40.7)
	After a suitable period of time has passed	207 (55.8)
	Never	4 (1.1)
	Don't know/Unsure	8 (2.2)
	No response	1 (0.3)

*This question was only asked of participants who responded "No" to QRF5 (n=371).

Table 4. Factors that influence decision to provide conferred consent: Summary of responses to open-ended questions (by theme)

Question: What types of circumstances or factors would influence your decision? (Support for research before consent)	
Theme	**Supporting Quotes**
1. Clinical factors	*"if it was a life threatening situation I would support it"* *"if it was a matter of life and death"* *"if it is an emergency there is no time to get permission."* *"only if it is absolutely necessary, if it was life or death situation"* *"how severe the condition is would be the main factor eg if it's life threatening."* *"critical and the time factor."*

2. Perceived personal benefit	*"life or death, if it meant saving my life they can go ahead"* *"something beneficial where harm is minimal to the patient."* *"if there is any evidence if it would be helpful"* *"clear evidence that the medication was life saving"* *"it is critical that we have research programs, but there need to be checks and balances, patients safety is important trailed drugs can still have side effects. It's a curly one. If it's this treatment or nothing then that is ok."* *"I would want to know e.g. if it is a drug that it has been tested in a randomised trial "*
3. Patient factors	*"whether treatment known to offend cultural or religious customs"* *"hold old the patient is, like young children or adults"* *"i guess that people should have the right to not be involved in research if they don't want to."* *"if it was associated with blood transfusions i WOULD NOT want to be automatically included without consent."* *"whether treatment known to offend cultural or religious customs"* *"religious beliefs"*
4. Surrogate decision makers	*"if they can't contact a relative, and the patient is in a live or die situation"* *"cardiac arrest, stroke or CTA with no family present or family cannot be contacted."* *"if patient unable to consent relative not available"* *"If life or death and if no one can be contacted"*
5. Trust in medical teams	*"if the family cannot be contacted and the situation is an emergency -as i have faith in the medical community."* *"I suppose so long as it was monitored effectively, and the method of doing the research was thorough"*
6. Altruism	*"if it has been reviewed by ethics, of benefit or neutral to patient. and of greater good"*
7. Deferred consent	*"the patient or family would need to approve it later."* *"you could start the treatment but for it to be in a study you still to gain approval later on"* *"I think if it was not going to disclose information about patient"* *"if once given the information if the patient choose to withdraw from the research the information should be discarded"*

Table 5. Best time to seek consent to use data in the case of death: Summary of Responses (by theme)

In the case of a death as part of a research study, when is the best time to seek consent to use data already collected?		
Theme		Quote
1	Depends on circumstances	*"completely depends on the situation and on the family as well"* *"depends on circumstances"* *"would depend on circumstances (severity of the emergency, reaction of family)"* *"there are too many things to take into consideration: every situation is different"*
2	Time for grief	*"i feel when someone passes away you need time to grieve and i feel it would be disrespectful and too confronting for the families to deal with this immediately"* *"give the people a chance to deal with their grief"* *"once the family has had some time to let the death sink in. every family is different."* *"the family need to grieve and have closure first then discuss the issues"*