Emergency department patients' attitudes towards the use of data in their clinical record for research without their consent

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ABSTRACT

Background Health research often uses health information, a subcategory of personal information, collected during clinical encounters. Conditions under which such health information can be used for the secondary purpose of research are set out in state, national and international law. In Australia, consent is required or the relevant conditions for a waiver of consent must be met and approved by a human research ethics committee (HREC). Consent for use of health information for research is rarely sought at an emergency department (ED) presentation. Research often occurs after the index visit and gaining consent can be difficult. Waiver of consent provisions are frequently used, but acceptability of this approach to patients is unclear.

Objective To identify ED patients' knowledge and attitudes towards the use of health information for research, consent preferences and acceptability of waiver of consent.

Methods An online, anonymous survey of adult patients attending two large EDs in Melbourne, Australia.

Results 103 patients completed the survey. We found that 52% were unaware that health information might be used for research. A majority (77%) felt that HREC approval for use of health information without consent was acceptable. However, 36% would prefer to be contacted regarding consent.

Conclusion These findings suggest a lack of awareness that health information can be used for research and that waiver of consent is acceptable, but not necessarily preferred, in most of the ED patient population. Efforts to increase awareness and provide opportunities to express preferences about health information use for research are needed.

INTRODUCTION

Within medical research, it is generally a prerequisite for patients to give informed consent before they are enrolled to participate in a study. This principle is outlined in the World Medical Association's Declaration of Helsinki which sets down ethical guidelines for research involving humans.[1] These principles are echoed in the *National Statement on Ethical Conduct in Human Research* (National Statement), the document that guides research and research ethics in country. Informed consent is when a person makes a voluntary decision to participate with knowledge and comprehension of the risks and benefits involved and does so voluntarily.[2] This includes adequate understanding of the research purposes, aims and methodology. However, there are circumstances where the requirement for consent varies. These are often a result of practical, ethical or methodological concerns, whereby obtaining consent would be significantly impractical or harmful such as when de-identified data that have been collected for diagnostic purposes are seen to be of importance for advancing research or when data are used from social media.[3] In order for a human research ethics committee (HREC) in Victoria, Australia to waive the requirement for consent, it would need to consider and apply sections 2.3.6 and 2.3.7 of the National Statement and one or more of the following: Statutory Guidelines on Research issued under section 22 of the *Health Records Act 2001* (Vic),[4] Guidelines approved under section 95A of the *Privacy Act 1988* (Cth);[5] or Guidelines approved under section 95 of the *Privacy Act 1988* (Cth).[5] They require that involvement in the study is of no more than low risk to participants, that the benefits gained from the research outweigh any risks, that privacy and confidentiality are not jeopardised, that there is no reason to think that participants would not have consented had they been informed, and that the research complies with law. Waiver of consent can only be assessed and granted by a duly constituted HREC.[4]

Every year, there are millions of clinical presentations to Australian emergency departments (EDs). Each encounter results in large amounts of personal health information being produced and collected, from history of presenting complaint to investigations undertaken. The primary purpose of this information is delivery of medical care. However, another potential use of this health information is for research. In Victoria, Australia, this secondary purpose, including use without consent, is covered by legislation, specifically the *Health Records Act (Vic)* and additionally for private hospitals, the *Privacy Act 1988*.[4 5]

With research in the ED, the criteria outlined in waiver of consent are commonly considered to have been met. This is because most research happens after the patient's initial presentation with consent rarely gained at the time. Retrospectively attempting to gain consent for use of health information, sometimes years after the index ED presentation, is time-consuming, costly and work-intensive for researchers and may cause distress or anxiety to those approached for consent. There are other practical and ethical reasons both for and against the use of the waiver of consent provisions and some variation in requirements between jurisdictions, which we have reported previously.[6]

Despite the use of the waiver of consent provisions, there is scant evidence about patient

knowledge and attitudes towards this practice in an ED population. The research that does exist is focused on the enrolment of critically unwell patients that cannot consent and involves investigation of novel therapies. For these studies, the waiver of consent (or delayed consent) is generally viewed favourably if risks were minimal.[7–9]

Currently available research does not address whether participants would find it acceptable that health information from a non-critical ED encounter can be accessed retrospectively and without consent. Our objectives were to establish whether patients were aware that their health information could be used for research, without their knowledge or consent, and their attitudes towards this practice. A secondary aim was to identify patients' ideal consent preferences. Answers to these questions would inform researchers and HRECs about whether the assumption that there is no reason to believe that potential ED research participants, if asked, would not have consented to use of their health information (a required criterion for waiver of consent). Also, preferred consent approaches for this type of ED research would be identified.

METHODS

This was a prospective, opportunistic study. From October 2020 until April 2021 patients presenting to ED of two university-affiliated hospitals in Melbourne were invited to complete an online, anonymous survey. They were recruited by posters (see online supplemental material) in the waiting room and non-critical treatment spaces. They contained a website link and a quick response code to the survey. The survey was provided in English, Vietnamese and Arabic—the most common languages in the study EDs. Additionally, on discharge, patients were given a handout-sized copy of the poster. The survey was hosted on the Qualtrics platform (Qualtrics, Provo, Utah, USA) which provides confidential protection of data. Consent was implied if the survey was completed. Blank surveys were excluded. Patients aged under 18 years were excluded.

The survey

The survey addressed demographic details, awareness and expectations about and acceptability of use of health information for research without consent, and consent preferences for use of health information for research (see online supplemental material for a copy of the survey).

Analysis

The analysis was descriptive and performed on Microsoft Excel (Microsoft, Washington, USA). Categorical data will be presented as n (%). Omnibus χ^2 analysis was used to compare responses by age and gender groups.

Ethical approval

A specific requirement of the approval was that to avoid conflict of interest and potential coercion, clinicians were not permitted to encourage patients to complete the survey.

Impact of COVID-19

It had originally been planned to provide a pen-and-paper alternative to the online survey and to have independent data collectors within the ED. The restrictions imposed by the COVID-19 pandemic precluded both of these, with a potential impact on participation.

Table 1 Patient characteristics

Characteristics	All patients (n=103)
Age, years, n (%)	
18–29	32 (31)
30–39	21 (20)
40–49	18 (17)
50–59	19 (18)
60–69	5 (5)
Over 70	8 (8)
Female gender n (%)	58 (56)
Reason for attending n (%)	
Injury	20 (19)
Illness	42 (41)
Other	41 (40)
Nationality of main identification (%)	
Western*	74 (72)
African	2 (2)
Indian	4 (4)
Middle Eastern	1 (1)
Polynesian	3 (3)
Aboriginal or Torres Strait	2 (2)
Vietnamese	8 (8)
Other	9 (9)

Patient responses about use of health information are summarised in table 2.
*Western was specified as Australian, European, American, New Zealand.

RESULTS

There were 105 survey responses; 99 completed in English, 6 in Vietnamese and none in Arabic. There were no duplicate responses. Two responses were excluded as blank. One hundred and three responses were analysed.

Patient characteristics are summarised in table 1.

On Omnibus χ^2 test there was no difference in awareness that information might be used for research, expectation that information might be used for research, acceptability that information might be used for research, or contact preferences based on age or gender. We acknowledge however that our study was not powered for these analyses.

DISCUSSION

Despite the fact that there is extensive literature on the use of patient data without explicit consent, previous research into attitudes towards the use of the waiver of consent for use of health information for research in ED patients has either been in patients who are critically unwell when enrolled or been conducted using participants from the general (non-ED) population.[7–9] We believe our study is the first to attempt to investigate the attitudes of a general ED population towards the practice of using health information without consent for research in non-critical clinical situations.

We found that over half of people surveyed were unaware that information from their current or preceding visits to the ED could be used for research. One of the key assumptions of the waiver of consent provisions in Australia is that '*there is no known or likely reason for thinking that participants would not have consented if they had been fully aware of what the research involved*'.[3] This lack of awareness is a serious threat to the application of waiver of consent provisions. A strong case can be

Table 2 Summary of responses

Question	Response	N (%)
Did you know that information about your ED visit might be used for research?	No	54 (52)
	Yes	49 (48)
Would you expect that information about your ED visit might be used for research?	No	22 (21)
	Yes	80 (78)
	No response	1 (1)
Is it okay (acceptable) for a HREC to approve use of your health information without asking you to agree to it (consent).	Acceptable—it would be okay most of the time	52 (50)
	Somewhat acceptable—some concerns, but it would probably be okay	28 (27)
	Somewhat unacceptable—quite a few concerns, probably not okay	11 (11)
	Not acceptable—it would not be okay with me most of the time	8 (8)
	Don't know/have an opinion	4 (4)
What approach to obtaining your agreement (consent) for using your health information for research would you most like/prefer?	I would like to be contacted so that I can choose to opt out of a research project	19 (18)
	I would like to be contacted so that I can agree (give permission) for my health information to be used in a research project (opt in)	37 (36)
	If a HREC decided the research was okay and that my privacy and confidentiality were protected, I would prefer not to be asked for my permission/consent but would like to be notified that the research was being done	22 (21)
	If a HREC decided the research was okay and that my privacy and confidentiality were adequately protected, I would prefer not to be asked for permission/consent and I would not need to be notified of the research	21 (20)
	No response	4 (4)
If you answered that you would like to be contacted about the use of your data in research, how would you prefer to be contacted?	Email	39 (38)
	SMS/text message	38 (37)
	Not applicable/no response	26 (25)

ED, emergency department; HREC, human research ethics committee.

made that researchers who know that applications to use health information for research may be made, have a responsibility to inform those potentially affected by this. It is hard to argue that this is unreasonable or overly burdensome. For example, signs could be placed in patient waiting areas and this information could be included in any patient information materials that are provided, including discharge letters.

It is heartening that although participants of our study were largely unaware that their health information could be used for research, 78% expected that it would be. Further, most respondents reported that this was an acceptable approach, with only 19% opposed to it. It should be noted, however, that when asked how patients ideally would like to give their agreement most wanted to be contacted, either to be informed that their data were being used, or to opt in or out of the study.

Providing information about the potential use of health information for research in itself is insufficient to protect the rights of patients to consent to this use of their data. Mechanisms are also needed to allow patients to register their preferences regarding consent for use of their health information for research. Current ED patient management systems in Australia were designed for clinical care. They do not have the capability to document a patient's consent preferences about use of health information in research or to flag limitation/absence of consent to researchers. Such capability should be built into future systems.

These results highlight some of the bigger issues with the waiver of consent provisions and research, including the need to balance patients' right to privacy and autonomy when providing consent versus creating an environment where meaningful research can be undertaken with as few practical restrictions as possible.[10 11]

Our study has some limitations that should be considered when interpreting our results. The COVID-19 pandemic significantly reduced presentation numbers to ED reducing the number of potential participants. The requirement to use an online survey potentially may have resulted in a bias towards younger participants because elderly patients are traditionally less technologically knowledgeable and may have been unable to access the survey.[12] Unfortunately, due to COVID-19 restrictions, we were unable to facilitate the use of paper surveys to combat this. We also acknowledge the potential for volunteer bias that is inherently an issue with this study design. It is also possible that because there was no way to explain items included in the survey, participants' interpretation of questions may have varied, thus influencing the results.

CONCLUSION

Our results suggest a lack of awareness that health information can be used for research and that waiver of consent is acceptable, but not necessarily preferred, in most of the ED patient population. Efforts to increase awareness and provide opportunities to express preferences about health information use for research are needed.

Contributors CS-S and AM-K were involved in the planning, conduct, including acquisition, analysis and interpretation of data, and the reporting of the study. They are also the joint guarantors and accept full responsibility for the aforementioned work. DZ was involved in the planning, interpretation of data and the reporting of the study.

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Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by the Melbourne Health human research ethics committee (HREC/20/WH/66336). Participants gave informed consent to participate in the study before taking part.

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v.4; 28 August20.

During your treatment in the Emergency Department, information about you, why you've attended and your treatment is recorded as part of your care.

Sometimes, researchers (including doctors) want to access that information for research. For example, they might be researching features of an illness or injury, how different doctors treat it or whether doctors follow published guidelines for treatment.

Research involving human subjects must be approved by a Human Research Ethics Committee. This is a committee made up of scientists, ethics advisors, lawyers and community members. It is the committee's job to make sure any research is being conducted according to ethical guidelines and law. This includes appropriate protection of your privacy and confidentiality.

We would like to understand how much you would like to be contacted about this type of research and whether you would want the opportunity to have your data included or not.

This survey only relates to research carried out by hospitals and universities. It does not include research undertaken by private companies.

This survey should take less than 5 minutes.

Participation is voluntary. By completing this survey, you give implied consent for the information you provide to be used.

No data that can identify you is collected.

Doing this survey will not change your care in any way. Your treating doctor will never know whether you participated or not.

Part 1: Demographics

Q1. What is your age group?	18-29, 30-39, 40-49, 50-59, 60-69, ≥70
Q2. What is your gender?	Male, female, other,
Q3. What is your ethic group?	Australian/European/US/NZ, Vietnamese, African, Polynesian, Indian subcontinent (India/Pakistan/ Sri Lanka/ Bangladesh), other (specify)
Q4. What has brought you to the ED?	Illness or injury or other (specify)

Part 2: Awareness and Acceptability

Q5. Did you know that information recorded about your ED visit might be used for research? Yes/No

Q6. Would you expect that information recorded about your ED visit might be used for research? Yes/No

Part 3: Acceptability

Research using already collected information is a trade-off between privacy and confidentiality and potential benefit to other patients and the broader community by improving health care.

This section asks about how **acceptable** it is to you for a Human Research Ethics Committee to not require your consent to access your health information.

Acceptability is not the same as what you would ideally prefer. It is what you think is reasonable given the safeguards described.

Q7. If research was approved by a Human Research Ethics Committee who were satisfied that your privacy and confidentiality were adequately protected and that individuals would not be identified, how **acceptable** would it be to you for the researchers not to require your consent to use the data?

A) Not acceptable/Not okay – it would not be okay with me most of the time

B) Somewhat unacceptable/ somewhat not okay – quite a few concerns, probably not okay

C) Somewhat acceptable/ somewhat okay – some concerns, but it would probably be okay

D) Acceptable/ Okay – it would be okay with me most of the time

E) Don't know or don't have an opinion

Part 5: Preferences

This section asks about **your preference** about release of your health information for research. Preference is what you would you like to happen in an ideal world.

Q8. What approach to obtaining your consent for using your data for this kind of research would you **most prefer**? (Choose one)

A) I would like to be contacted so that I can choose to opt out of a research project. This means that unless I opt-out, my health information would be automatically included in the research project.

B) I would like to be contacted so that I can agree (give permission) for my health information to be used in a research project (opt in). This means I would like to be asked for my permission any time my health information might be used for research.

C). If the Human Research Ethics Committee decided the research is in the public interest and that my privacy and confidentiality are adequately protected, I would prefer **not to be asked** for consent **but** would **like to be notified** that the research was being undertaken.

D). If the Human Research Ethics Committee decided the research is in the public interest and that my privacy and confidentiality are adequately protected, I would prefer **not to be asked** for consent and I **would not require notification** of the research.

Q9. If you would answered that you would like to be contacted about the use of your data in research, how would you prefer to be contacted?

- Mail
- SMS

- Email
- Combination
- Other (specify)

Thank you