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Is waiver of consent for the use of health information for research acceptable to emergency department patients?

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ABSTRACT

Some emergency medicine research, especially retrospective studies using medical records review, rely on waiver of consent for use of personal health information (PHI) contained in clinical records. This is a secondary use of PHI and waiver of consent raises ethical, legal and practical issues. Granting of a waiver of consent is often (but not always) approved by a human research ethics committee and requires separate but inter-related consideration of the legal and ethical issues. In part, this involves a balancing of the public interest versus the risk to privacy and an evaluation of whether subjects would, mostly likely, have agreed to the use of their PHI had they been asked. To date, there is no robust data about whether use of PHI without consent for research would be acceptable to people who attend Australasian emergency departments for care.

MAIN TEXT

Scenario

An Emergency Department (ED) registrar has had a great research idea! In a trainee session at their hospital, guidelines for analgesia in patients with renal colic were discussed. Some doctors were comfortable prescribing non-steroidal anti-inflammatory drugs (NSAID) at the time of initial clinical assessment. Others expressed concern that if a patient had renal impairment, giving NSAID could worsen it. Unable to find published data about the proportion of renal colic patients with renal impairment at ED presentation, the registrar decides to address the question in a retrospective chart review study. The key information will be in medical records, but can it be used for research without patient consent?

Personal Health Information and Research

Health research is key to clinical progress. It is also the basis of evidence-based medicine, underpinning understanding of disease and clinical decision-making regarding diagnosis and treatment.[1] Personal health information (PHI) is integral to health research. PHI is specifically defined in Australian privacy law (Box 1).[2]

Significant amounts of PHI are collected from ED clinical encounters. The primary purpose of PHI is delivery of healthcare. Research is defined as a secondary purpose. In law, secondary use of PHI requires patient consent or, alternatively, compliance with conditions specified in applicable privacy law. Patient consent for use of their PHI for research is rarely sought at the time of ED encounters. Obtaining consent later, perhaps years after the index presentation, is arduous and time consuming. Waiver of consent is commonly relied upon for secondary use of PHI in Emergency Medicine research. Legislation prescribes that secondary use of PHI for research may be permitted under waiver of consent if defined criteria are met. These vary somewhat by jurisdiction (Box 2). There are important differences in the law between Australian states and importantly, the Commonwealth *Privacy Act* usually does not apply to public hospitals. These are governed by state-based privacy laws/principles. Waiver of consent involves ethical, legislative and practical issues which are discussed below.

There is little known about ED patients' knowledge about, or attitudes to, the use of their PHI for research and whether it is acceptable to them. The research that does exist is focused on the enrolment of critically unwell patients who cannot consent and usually involves investigation of novel therapies. For these studies, waiver of consent is generally viewed favourably by patients/next-of-kin if risks were minimal.[3,4]

Legislation

PHI is defined in Australia by the *Privacy Act* 1988 (Australia) [2](Box 1]), the *Privacy Act* 2020 (New Zealand) [5] and state-based privacy acts/principles (Box 2). Waiver of consent is also addressed in the *National Statement on Ethical Conduct in Human Research* (Australia) [6] and *National Ethical Standards for Health and Disability Research and Quality Improvement 2019* (New Zealand).[7]

In most jurisdictions, granting of waiver of consent is delegated to human research ethics committees (HRECs). This determination is in addition to, and importantly separate from, an evaluation of ethical aspects of the research. Some jurisdictions, for example Queensland, also require separate approval by a designated data custodian (Box 2).[8] The criteria for granting waiver of consent for use of PHI for research are that:

1. Involvement in research carries no more than low risk to participants;
2. The benefits of the research justify any risk of harm that may occur because of not seeking consent;
3. It is impractical to obtain consent;
4. There is no known or likely reason that participants, if asked, would not have consented;
5. There is sufficient protection of privacy;
6. There is a plan to protect confidentiality, including that no data that could potentially identify an individual is published;
7. There is a plan to communicate findings that might impact an individual's health to them (if relevant);
8. Any commercialisation of findings will not deprive participants of financial benefits to which they might have been entitled; and
9. The research complies with relevant law.[6]

The criterion regarding whether patients would have consented if asked is problematical. There is no evidence that ED patients are aware that their PHI might be used for research. In fact, research suggests that this is not the case.[9] Conversely, in a survey of a nationally representative

sample of Australians, 93% responded that the use of PHI for research was acceptable.[10] Whether this can be validly generalised to a population of Australasian ED patients is debateable because it is not known what proportion of respondents had experienced an ED visit. Specifically, there is no data about whether ED patients would agree to their PHI being used without consent for studies approved by HRECs.

In addition, under privacy law, HRECs must evaluate whether the benefits of the research to the public outweigh the cost in the breach of privacy. It has been suggested that HRECs may lack the required expertise and knowledge to adequately assess whether research meets privacy law requirements and whether it is appropriate for the waiver of consent to be applied.[11] The decision about whether research provides more benefits to the public than risks to the individual is often subjective, despite guidance provided jurisdictional statutory guidelines.[11] This is exemplified by cases where HRECs have approved waiver of consent but it is denied by the data custodian or where, for the same study, some HRECs have granted a waiver and others have not (personal experience, the HEAD study [12]).

Ethical Considerations

There is significant ethical debate about waiver of consent and its interaction with the ethical principles of autonomy, beneficence and non-maleficence. Autonomy is the right to self-determination and is a cornerstone of not only medicine but also modern western society.[13] For example in healthcare, it governs the right for a person to choose treatments that are acceptable to them, to decline tests, to allow or disallow access to PHI and to choose to participate in research. Waiver of consent violates this principle by removing the ability to choose whether PHI should be included in research. This violation potentially risks damaging the patient-doctor relationship by eroding public trust. Further, if a person has a reasonable expectation that their PHI will be confidential and they discover that it has been used without consent for a purpose that they

do not know about, they might assume that other violations of trust may have occurred. This may negatively impact their healthcare. If waiver of consent results in distrust of the profession this may cause, conversely, a reduction in research participation.[14]

The ethical principles of non-maleficence (the avoidance of harm) and beneficence (the promoting of good) are interdependent and need to be balanced. Almost all medical interventions, research included, risk a degree of harm but the aim, and overall balance, must be in favour of doing good. It could be argued that waiver of consent has the potential to cause harm, through risk to privacy and confidentiality and erosion of trust, but this risk may be small compared to the degree of potential good yielded from the research. This cost to the individual might be justifiable if it is small and the benefits to the wider population are large. One conceptualisation of this is in the duty of easy rescue [15]. It is exemplified in 2020-1 by individuals self-quarantining during the pandemic to stop the spread of COVID-19.

Practical considerations

It would be a significant barrier to ED research if patient consent was required for use of PHI in retrospective studies. Similarly, asking all patients at the time of an ED attendance to provide blanket consent to the use of their PHI for research is impractical and violates the ethical principle of specific consent. It also risks confusion in patients about whether agreeing to the use of PHI for research is a requirement for being treated in ED. This is clearly not appropriate. The waiver of consent attempts to strike a balance between respecting patient's right to self-determination whilst also advancing the potential greater good gained from research.

Another lesser practical consideration is bias in a research sample if consent is required. Participants that consent to inclusion in research may differ from those who do not. At its extreme, this can result in findings that are inaccurate or incorrect. The waiver of consent eliminates this issue. Contacting people retrospectively requesting consent could also cause distress and anxiety that the waiver avoids. The cost and time

burden of seeking retrospective consent may challenge the feasibility of some research. The weight of these practical considerations compared to patients' right to autonomy is controversial.

Conclusion

Currently in Australia and New Zealand, research using PHI can be conducted under waiver of consent if defined criteria are met. Those criteria require a determination by HRECs (and data custodians) of whether patients are likely to have consented to use of their PHI if they were asked. There is little evidence to guide these determinations, and none specific to the ED patient population. Addressing this question by research would provide HRECs and data custodians with evidence on which to base their evaluation of requests for waiver of consent for emergency research and potentially improve transparency and trust in this process.

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Box 1: Definition of health information

The Privacy Act defines 'health information' as
(a) information or an opinion about: (i) the health or a disability (at any time) of an individual; or (ii) an individual's expressed wishes about the future provision of health services to him or her; or (iii) a health service provided, or to be provided, to an individual; that is also personal information; or (b) other personal information collected to provide, or in providing, a health service; or (c) other personal information about an individual collected in connection with the donation, or intended donation, by the individual of his or her body parts, organs or body substances; or (d) genetic information about an individual in a form that is, or could be, predictive of the health of the individual or a genetic relative of the individual.

Box 2: Privacy legislation and research ethics guidelines by jurisdiction

Country	State/territory	Legislation/ Standard	Applicability	Section(s)	Summary
Australia	National	*Privacy Act* 1988	Organisations but not State or territory authorities or instrumentalities (i.e. not public hospitals)	S 16B(3)	Requirements for use without consent: 1. the research is in the public interest or for public safety 2. the particular research purpose cannot be served by using de-identified information 3. it is impracticable to obtain consent 4. the use is in accordance with guidelines issued by the National Health and Medical Research Council and approved by the Information Commissioner under s 95A of the Privacy Act.
		National Statement on Ethical Conduct of Human Research, National Health and Medical Research Council	Public and private entities		Waiver of consent must be approved by a human research ethics committee. Requirements for waiver of consent: 1. the research poses no more than low risk to participants. Low risk is defined as research in which the only foreseeable risk is one of discomfort; 2. research benefits justify any risk of harm associated with not seeking consent; 3. consent is impracticable; 4. there is no known or likely reason for believing that participants, if asked, would not have consented; 5. there is sufficient protection of privacy and confidentiality; 6. where relevant and practicable, there is a plan to communicate to participants research findings that have significance for their welfare; 7. any possible commercial use of findings will not deprive participants of any financial benefits to which they would be entitled; and

					8. the waiver is not prohibited by law.
	ACT	*Health Records (Privacy and Access) Act* 1997- Schedule 1	Public and private entities	Principle 10(3)(a)	Requirements for use without consent: 1. the research is in the public interest 2. it is impracticable to seek consent 3. the research cannot be done using deidentified data 4. reasonable steps are taken to de-identify the data 5. no identifiable data is published
	Northern Territory	*Information Act* 2002	Public and private entities	Schedule 2 s 2.1(ca)	Covers all personal information not just PHI. Requirements for use without consent: 1. the research is in the public interest 2. no identifiable data will be published 3. it is impractical to seek consent 4. for PHI, use is in accordance with guidelines issued by the Information Commissioner
	NSW	*Health Records and Information Privacy Act* 2002	Public and private entities	Schedule 1 s 10(f)	Requirements for use without consent: 1. the research is in the public interest 2. the research cannot be done using deidentified data 3. reasonable steps are taken to de-identify the information 4. no identifiable information is published 5. the use complies with guidelines issues by the Privacy Commissioner
	Queensland	*Information Privacy Act* 2009	Public and private entities	Schedule 4 – s 2(c)	Covers all personal information not just PHI. Requirements for use without consent: 1. the research is in the public interest 2. no identifiable data will be published 3. it is impractical to seek consent
		Public Health Act 2005	Information held by a health agency	s 280	Access to identifiable or potentially identifiable confidential information without consent requires: 1. approval by an ethics committee 2. approval by the relevant data custodian 3. approval by the Director-General of Queensland Health
	South Australia	Premier and Cabinet Circular:	Public agencies	n/a	Research is not specifically addressed

		PC 012 – Information privacy principles instruction			
	Tasmania	*Personal Information Protection Act* 2004	Public and private entities	Schedule 1 s 2(c)	Requirements for use without consent: 1. the research is in the public interest 2. it is impracticable to seek consent 3. no identifiable information is published the user of the information is not likely to disclose it
	Victoria	*Health Records Act* 2001	Public and private entities	Schedule 1 s 2.2(g)	Requirements for use without consent: 1. The research is in the public interest 2. It is impractical to seek consent 3. The research cannot be done using deidentified data 4. Use is in accordance with guidelines issued by the Health Complaints Commissioner
	Western Australia	No legislation			
New Zealand	National	*Privacy Act* 2020	Public and private entities	s 22, IPP 10 (1)(b)(ii)	Personal information is to be used for research purposes and will not be publishable in a form that could reasonably be expected to an identify and individual.
		Health Information Privacy Code 2020	Public and private entities	S 5, Rule 10, (1)(e)(iii)	Specifies that approval by a research ethics committee, if required, must be obtained
		National Ethical Standards for Health and Disability Research and Quality Improvement 2019	Public and private entities	7.46-7.48	Requirements for a waiver of consent: 1. The nature, degree and likelihood of possible benefits outweigh the nature, degree and likelihood of possible harms. 2. That there are scientific, practical, or ethical reasons why consent cannot be obtained. 3. That appropriate data governance plans are in place. 4. The researchers have identified whether consultation is required, and if have undertaken it.

					5. That there is no known or likely reason to expect that the participant and/or individual(s) would not have consented if they had been asked.