Is Consent Required For Publication of Medical Errors?

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Abstract

Publication of information about medical errors is critical to error prevention and shared learning among health professionals and institutions. While some countries have error reporting systems in place, journal publications are still essential reference tools for learning about error, and editorial policies about when to publish errors are needed, as these provide important guidance to journal editorial boards.

While there is a *prima facie* moral requirement to obtain consent to publish patient information, publication without patient consent may be justified if certain criteria are met. Justification will involve consideration of a variety of principles, rules and conditions grounded in ethics, law and policy. Except in exceptional circumstances of overriding importance to public health, a patient's personal information should not be published over the patient's refusal. But what constitutes "exceptional circumstances of overriding importance to public health"? We argue that medical error is one such circumstance and present an argument in favour of a specific policy stance on publication of medical errors.

INTRODUCTION

Current literature about medical error reflects a debate about how "error" should be defined in medicine (Quality Interagency Coordination Task Force 2000; Grober and Bohnen 2005). Regardless of the exact definition, publication of information about medical errors is critical to error prevention and shared learning among health professionals and institutions. While some countries have error reporting systems in place, the systems are not always utilized by, or accessible to, healthcare providers who need to know about errors. These reporting systems will hopefully reach their full potential in the future as sources of education and warnings related to error, and will undoubtedly contribute to the development of acceptable definitions. In the meantime, journal publications are still essential reference tools for learning about error, and editorial policies regarding when to publish errors are needed, as these provide important guidance to journal editorial boards and authors.

In general, and regardless of whether or not an article is about error, there is a *prima facie* moral requirement to obtain consent to publish patient information. Alternatively, publication without patient consent may be justified if certain criteria are met. Justification will involve consideration of a variety of principles, rules and conditions grounded in ethics, law and policy, most often including the following:

- Will an onerous degree of effort be required to contact the patient to obtain consent?

- Is it impossible or unreasonable to obtain consent from the patient's next of kin?
- Would a reasonable person in the patient's position object to publication?
- Is there a risk that the patient will be identified, to others or to the patient himself or herself, and have appropriate efforts been made to minimize the risk?

Except in exceptional circumstances of overriding importance to public health, a patient's personal information should not be published over the patient's refusal (Singer 2004).

But what constitutes "exceptional circumstances of overriding importance to public health"? We argue that medical error is one such circumstance and present an argument in favour of a specific policy stance on publication of medical errors. As described below, the characteristics of medical errors are consistently of such overriding importance to public health that with a few specific exceptions, waiver of the requirement to obtain patient consent for the purpose of publication may be justified, even over the objection of an individual patient. These characteristics exist within a social context of public attention and concern about the need to make errors known to the public as a preventative measure.

RATIONALE

a) Underlying Principles

The argument in favour of publication of medical errors is grounded in the following underlying principles:

- The primary focus of publication is the error, not the individual who was the subject of the error.
- Medical errors, by definition, are not intentional and are predominantly caused by one or more system failures that if remedied can prevent future errors or mitigate harm from the error.
- Publication of a medical error provides the greatest public benefit when it occurs within a policy climate and culture of prevention, not of blame and liability.
- The public benefits of reporting of medical errors are well established and accepted.
- The interests of individual patients must always be balanced against the interests of other patients, including future patients.

b) Patients and Professionals Want to Know About Medical Errors

As patients' awareness of medical error increases, so do patients' expectations that they will be kept informed upfront, not only through disclosure of errors, but also through shared learning for the purpose of overall quality assurance and enhancement of the healthcare system. Patients and their families endorse reporting of errors to agencies, organizations and hospital committees focused on patient safety (Hobgood et al 2002; Evans et al 2004). Patients who have suffered an error want to know that the practitioner and institution have learned from the error and that they have plans for preventing similar errors in the future (Gallagher et al. 2003). Experts in patient safety maintain that "effective systems to assure and improve safety involve a culture in which the reporting of error or apparent error is a valued and positive act, which leads not to blame but to curiosity and study" (Berwick 1998).

Among healthcare professionals and institutions, root cause analysis of medical error that is performed according to correct methodology can facilitate full and frank discussion and lead to identification of contributing factors. Successful experiences can be widely shared. The increase in publications describing medical errors illustrates a new ethos of openness and shared accountability (Gandhi 2005; Bernstein 2003a, 2003b).

c) Methods for De-identifying Personal Information Are Effective

Error reporting programs can provide information with aggregate level protection (n>3) and can present event information that is de-identified with respect to the patient, reporter and health service organization (Leape 2002; Runciman et al. 2001). Medical error, when the case comes through an anonymous error reporting system, is an exception to the usual requirement to obtain patient consent. Extra efforts to anonymize can be made. Consent to publish is one form of respect for patients; where general notice is given as part of a reporting and analysis system, this is also respectful of patients.

d) All Patients Are Entitled to Protection from Similar Medical Errors

It is well established in ethics and law that while physicians' primary responsibilities are to their patients, they nevertheless have responsibilities to others, particularly with regard to foreseeable risks of harm. This places limits on requirements for confidentiality. In the case of medical error, recurrence is predictable, and timely information to the rest of the medical community is a way of preventing harm to other patients. Publication of articles about the error serves to satisfy the moral responsibility to mitigate risks and begin the process of searching for preventative measures.

This moral responsibility has features in common with the legal duty to warn, which has been explored, for example, by Kleinman et al. (1997). Unlike cases that give rise to a duty to warn, cases of errors do not feature a threat of imminent harm by a particular patient to a specific third person that is unavoidable except by a physician's unauthorized disclosure. However, following identification of an error, there is a significant likelihood of serious and irreversible harm to some other patient and also likelihood that such harm will be mitigated through sharing of information about the error as widely as possible. This meets the test of proportionality. Given the extent to which personal information is de-identified when it is part of error reporting in most journal articles, any harm that may occur because of the publication will be less than the likely benefits of sharing.

Whether or not this moral responsibility gives rise to a specific legal obligation will depend on the laws of the jurisdiction in which the error occurs. Physicians, other healthcare providers and institutions will need to consult their regulatory bodies and applicable statutes to understand what actions may be mandatory or at least permissible.

IMPLEMENTATION

When a patient refuses to give consent to publication of an article about medical error, waiver of the requirement for consent to publication may be justified where there is no reasonably foreseeable risk that the patient will be identified as a result of the publication.

Where a reasonably foreseeable risk of identification exists, waiver of the requirement for consent may still be justified if public benefits, which as we have argued is likely to be significant in the case of medical error, are proportionate to the harm that may result from publication. This means that the decision to publish must include an adequate assessment of risk, including consideration of at least two dimensions of risk: remoteness and magnitude.

"Remoteness" refers to the likelihood that a patient might be identified. "Magnitude" refers to the degree of harm to the patient that would likely occur if they were identified. The decision to waive the requirements for consent to publish would need to satisfy both dimensions; that is, the harm that may result from identification of an individual must be both sufficiently remote and sufficiently minimal in magnitude to justify the risk. Where the magnitude of the potential harm is significant, even if the test for remoteness is satisfied, publication may not be permissible. For example, where there is a remote possibility that a person who is HIV-positive might be identified, publication would not be justified. In these cases, publication could proceed only if the patient's fully informed consent is obtained.

The journal publishing an article in which an error is disclosed should be entitled to rely on the assurance of the author that: 1) any duty to notify the patient or their representative that the error has occurred has been met; and 2) health professionals directly involved in the error, as well as the appropriate representative(s) of the institution at which the error occurred, have been given reasonable notice of the pending publication.

While healthcare providers may be justified in claiming that information about their professional activities (including the commission of a medical error) should only be published with their consent, we view this as a significantly different category of information from patient information. With regard to the professional who made the error, the report is about the person's professional activities and the interrelationship between human and system processes. It is "professional" or healthcare system information, not personal health information.

ASSOCIATED ISSUES

Remaining Concerns

Some readers may still be uncomfortable at the prospect of publishing articles about errors containing information that originates from a patient without involving that patient in some way. We want to be clear that in presenting our argument we advocate fully informing patients about the intent to publish an article about the error. If respect for patients does not occur through obtaining their consent, it should at the very least occur by sharing the anticipated publication with the patient and discussing with them the public interest that will be served and the efforts made to preserve confidentiality.

Additionally, even when patients are fully informed about a pending publication of error, publication of information without consent may still appear problematic where there is a chance that patients might be identified through the publication, unless complete anonymity can be guaranteed. It is true that even where the greatest care is taken to de-identify patient information, there may still be a risk that the patient will be identified. In other words, true anonymity cannot ever be guaranteed. Perfection is not required, however, nor necessary for a responsible editorial policy. What counts is that those involved in the publication have considered all the relevant features of the article and adequately answered the question of whether or not there is a reasonably foreseeable risk of the patient being identified through the publication. We believe that this is an appropriate test for publication and that it should be applied to articles about error. Where a reasonably foreseeable risk exists, the nature of the risk must be fully examined on a case-by-case basis.

Public Policy and Regulation

The enabling policy that we argue for means little if it is not supported by public policy and/or regulations that facilitate information flows. For example, in Ontario, a new health information privacy statute includes a provision that permits disclosure of patient information by a healthcare professional or hospital when necessary "for the purpose of eliminating or reducing a significant risk of serious bodily harm to a person or group of persons" (Personal Health Information Protection Act 2004). In the case of medical error reporting, the provision allows for an exemption from a requirement for consent by the disclosing physician or hospital where information about an error might identify an individual. However, the provision does not give carte blanche to publish identifying patient information; caution with regard to de-identification of patient data would still be best practice. Rather, it can be used to justify disclosure of information about error when there is a risk of residual identification of a patient.

CONCLUSION

There is a heightened level of interest in working together across boundaries and between organizations to enhance safety within our healthcare systems. Facilitating information sharing about medical error is one important way to realize this goal and in the course of pursuing safer practices, respect for individual patients will remain paramount. Respect for patients, however, comes in many forms, only one of which is expressed through obtaining consent. In light of the need to share medical error information and also consider the interests of patients who may become the subjects of the same error, respect for patients should include a meaningful opportunity to learn about the benefits of publication to all patients.

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