Should Informed Consent Be Required to Publish a Case Report?

THE "PRO" SIDE

"Doctor's gory tale angers soldier's family"— so read the front-page headline in a national newspaper in the summer of 2007.[1] The article reported that a Canadian military physician had published graphic details of the medical treatment received by a mortally wounded Canadian soldier serving in Afghanistan. Friends and family of the soldier were outraged. The newspaper story[1] quoted the soldier's uncle as saying, "In my opinion, he breached doctor–patient confidentiality" and "The guy betrayed the trust of the Megeney family". Postings on the Web site of the magazine that published the original article included the following comments: "How awful to read about the death of your son and what the doctor did to him on the operating table in detail" and "Kevin's family is suffering enough. They don't need this."

Although published in a news magazine rather than a medical journal, the article engendered reactions that clearly illustrate the harms that can be caused by unauthorized publication of identifiable, confidential medical information. The military has now launched an investigation to determine whether the publication breached the National Defence Act. It certainly breached the principle of "doing no harm".

The Case Report

The case report has an important role in the advancement of medical knowledge. From Laennec's 1826 case report of a dissecting aneurysm[2] to the early reports of severe acute respiratory syndrome (now known as SARS),[3] the case report has provided important insights into the pathogenesis of disease, unusual or unexpected presentations of disease, and unreported medication side effects, as well as early warning of impending epidemics.

Intrinsic to the value of a case report are an accurate description of the patient's history, the results of the physical examination and laboratory investigations, and information about the treatment provided and the response to treatment. Depending on the case, the report might include sensitive information such as a history of childhood abuse, description of a physical deformity, or (as in the case of the Canadian soldier) a graphic description of the patient's final moments. To alter the details of the case to the point of true anonymity would alter the scientific value of the publication. Intrinsically, then, a case report provides information that could identify the subject.

It is important to recognize that the patient has provided this confidential information to the health care provider for the purpose of receiving health care, not for the advancement of medical knowledge. We must also recognize that although the physical chart belongs to the health care provider, the information in the chart is the patient's.[4]

The Past

In the past, case reports were published in hard-copy medical journals and were thus accessible to only a limited number of individuals. The likelihood of a medical journal subscriber being able to identify the patient described in a case was low. Publication of case reports without consent was no more justifiable then than it is now, but the risk of identification, and thus the potential harm, was lower. Recently, a number of factors have significantly increased the chance of identification of the subject of a case report.

The Present

Media and public interest in health care is increasing. Reports of medical matters have become a staple of the print and broadcast media. Reporters now attend major conferences and read professional journals to be able to report on the latest medical research. Virtually all major medical journals now offer online access to at least some of their content, and many of these journals are available to the public. Of particular significance to this discussion, the BioMed Central group now has an open-access online journal entitled the *Journal of Medical Case Reports*.[5] Anyone with access to the Internet can now read medical case reports from the comfort of their own home. One consequence of increased public access to medical publications is an increased probability of identification (including, but not limited to, self-identification) of the subject of a case report.

The Future

In the future, technological advances could further increase the chance of identification of the subject of a case report. In cancer care, DNA microarrays are being studied with the hope of allowing more individualized recommendations for chemotherapy.[6] As the science of pharmacogenomics advances, conditions such as Alzheimer's disease will also be treated in a more individualized fashion.[7] It logically follows that the more individualized the therapy, particularly for uncommon conditions, the more easily identified will be the subject of a case report and the greater the potential harm to that person.

This potential for harm extends beyond the subject of the report, as illustrated by the distress experienced by the soldier's family.[1] Harm can also occur from inadvertent acquisition of medical knowledge. For example, tests are now

available for the detection of several inherited diseases,[8] and in the future we will certainly have even greater ability to predict who is likely to develop a particular disease. This raises the possibility that a relative of the subject of a case report will find out from the report that he or she is at risk of the disease. There is potential for serious harm if individuals discover they are at risk of a serious illness and do not have access to appropriate genetic counselling.

Thus, the dilemma with case reports: publication of such reports benefits society by advancing medical knowledge, but, because a case report cannot achieve anonymity to the point of protecting the patient from the harms associated with being identified, publication should not take place without the patient's permission.

Publication Guidelines

The potential for such harms have been addressed by the International Committee of Medical Journal Editors (ICMJE) in its "Uniform Requirements for Manuscripts Submitted to Biomedical Journals".[9] These guidelines state that "Patients have a right to privacy that should not be infringed without informed consent. Identifying information, including patients' names, initials, or hospital numbers, should not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives written informed consent for publication." The requirements further state that "Complete anonymity is difficult to achieve, however, and informed consent should be obtained if there is any doubt." This is a sound policy.

Conclusions

The case report is a valuable tool in the education of health care professionals. We must recognize, however, that advances in information and medical technologies may increase the risk of identification, and thus the risk of harm, to the subject of a case report. Only in the direst of circumstances, for example a public health emergency, should the subject's fundamental right to privacy be violated. We must seek informed consent from the subject of a case report.

References

1. Freeman A. Doctor's gory tale angers soldier's family. *Globe and Mail* [Toronto] 2007 Aug 4;Section A: 1.
2. Doyle L. Three important early case reports on dissecting aneurysm of the aorta: one each from Dublin, Paris and York. *J R Soc Med* 1992;85(3):169-172.
3. Tsang KW, Ho PL, Ooi GC, Yee WK, Wang T, Chang-Yeung M, et al. A cluster of cases of severe acute respiratory syndrome in Hong Kong. *N Engl J Med* 2003;348(20):1977-1985.
4. *Medical records in private physician's offices.* Vancouver (BC): College of Physicians & Surgeons of British Columbia; 2006 [cited 2007 Aug 6]. Available from: https://www.cpsbc.ca/resources/file_repository/2006/04/03/25375_0604031212-164.pdf
5. *Journal of Medical Case Reports.* London (UK): BioMed Central Ltd; [cited 2007 Aug 2]. Available from: http://www.jmedicalcasereports.com
6. Guo QM. DNA microarray and cancer. *Curr Opin Oncol* 2003; 15(1):36-43.
7. van Delden J, Bolt I, Kalis A, Derijks J, Luefkens H. Tailor-made pharmacotherapy: future developments and ethical challenges in the field of pharmacogenomics. *Bioethics* 2004;18(4):303-321.
8. Wylie B, Burke W. Genetic testing. *N Engl J Med* 2002;347(23): 1867-1875.
9. Privacy and confidentiality. In: *Uniform requirements for manuscripts submitted to biomedical journals.* Philadelphia (PA): International Committee of Medical Journal Editors (ICMJE) Secretariat; updated 2006 Feb [cited 2007 Aug 1]. Available from: http://www.icmje.org/#privacy

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THE "CON" SIDE

In an era when we are attempting to change the "shame and blame" culture of health care to one of open, "non-punitive" reporting of medication errors, the need to obtain informed consent for publishing a case report for an adverse event is contradictory and unfathomable. After all, do we not want to encourage reporting of adverse events? The literature supports the contention that adverse events are already grossly underreported. For example, the US Food and Drug Administration received just 574 reports of adverse reactions to digoxin during a period when, according to Medicare records, admissions for digoxin-related adverse events totalled 202 211.[1] Another study identified that 523 cases of hyperkalemia attributable to an angiotensin-converting enzyme (ACE) inhibitor were reported in Ontario over a 7-year period,[2] but I suspect that we have had that many cases at our facility alone. Furthermore, given what we know about ACE inhibitor hyperkalemia, does anyone really believe that in Ontario we have on average just 2 cases per hospital site every 7 years? Requiring yet another step in the process will certainly not foster increased reporting of such events.

Although there are other venues for reporting adverse events, the detail in a case that has undergone the scrutiny of peer review before publication adds substantially to the quality of the information. Such published reports outline risk factors, temporal relations, and outcomes, allowing readers to make comparisons with the cases that they have encountered. Adverse reaction databases do not offer this level of detail. A situation that we encountered recently reinforces the value of publication of case reports. We had seen several cases of pleuropulmonary involvement involving ergot-derived dopamine agonists and reported the observation in this Journal.[3] However, it wasn't until one of our pulmonary medicine fellows explored the phenomenon more thoroughly, through a review of published cases, that an association was found between this adverse event and mesothelioma, probably a drug–disease interaction.[4] Without the published cases, it might not have been possible to identify the connection, as the information available in databases was not complete enough for the required analysis.

In my practice, I discuss adverse drug events frankly with my patients to avoid repeat exposures to the drug involved. For many patients, I would have little hesitation in asking their permission to report the event. For others, though, I would discuss the necessity of avoiding future exposure with substantially more caution, and I would never ask their permission to publish the case. It is often best to let sleeping dogs lie. Although our intent in publishing a case report is to prevent another patient's morbidity in the future, we can anticipate that some patients wouldn't necessarily support this approach; rather, it might legitimize, in the patient's eyes, a potential medicolegal issue. For example, what if the drug that the patient received had strong precautions or was relatively contraindicated? Certainly, such factors might fuel such a medicolegal course

Furthermore, I suspect that patients who were ultimately "saved" by the system that initially failed them (i.e., those who recover from an adverse event without long-term sequelae) would be more willing participants in publication. Patients who have experienced adverse events resulting in severe and persistent morbidity might be more reluctant to provide informed consent and allow publication. The situation would be even more delicate if the event was fatal, as it would be necessary to involve the patient's grieving family. I have dealt with family members after a fatal event and would not ask them for permission to write up the case at such a time. I suspect that I am not alone. The net result would be that we report only cases that are less severe, forgoing the ones that cause substantial morbidity and mortality. This situation would be similar to postmarketing studies: we "learn" what we already know and somehow feel better and safer.

So what is the advantage of obtaining informed consent? I can see little benefit, other than the fact that the patient is informed that the information is to be publicized. Specific patient identifiers are no longer permitted, so we are likely dealing simply with an issue of personal privacy. While I do respect an individual's right to privacy, it is important to look at the "big picture". Is medication safety a private, individual issue or a societal one? I would argue the latter. What if "another thalidomide" were introduced? Would any delay in reporting similar adverse consequences, in the most detailed, comprehensive way, be acceptable? Requiring informed consent to publish a case report is a step backward in achieving medication safety.

References

1. Moore TJ, Psaty BM, Furberg CD. Time to act on drug safety. *JAMA* 1998;279(19):1571-1573.
2. Juurlink DN, Mamdani M, Kopp A, Laupacis A, Redelmeier DA. Drug–drug interactions among elderly patients hospitalized for drug toxicity. *JAMA* 2003;289(13):1652-1658.
3. Macak I, Bayliff CD, McCormack DG. Bromocriptime-induced pulmonary disease. *Can J Hosp Pharm* 1991;44(1):37-38.
4. Hirani N, Bayliff C, McCormack DF. Diagnosis and management of pergolide-induced fibrosis. *Mov Disord* 2005;20(4):512-513.

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