Ethics of Case Report Publications

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A couple of years ago I reviewed a book[1] about institutional review boards (IRB) overstepping their mandate. The book, privately published by a Family Medicine professor at Baylor, was entitled, "From Oversight to Overkill."[2] It noted a problem that I, too, have complained about, of IRBs extending their intended role of protecting research subjects, to protecting their institutions. The book argued that many lives have been lost due to unnecessary delays in research trials due to a variety of unimportant issues. My focus here is different, but related, namely, medical journals requiring informed consent, under the guise of protecting personal information when individual cases are described, even when there is no revealing information.

Here is the example that triggered this column. "Among my current 44 Parkinson's disease (PD) patients treated with clozapine, a 74-year-old woman was treated with filgrastim for three months due to persistent severe neutropenia (absolute neutrophil count 600) which began 11 months after starting clozapine while taking 75 mg/d. She has not required it for the past nine months despite no change in medications." I also described two additional patients with similar degrees of "identification." The editor reported that he contacted the editor of another journal and both agreed that I would need consent from the patients or that I had to alter the description to make them less identifiable. The editor suggested, "a broad summary, stating something like, "among 44 PD patients taking clozapine in my clinic, four have had clinically significant neutropenia, xx required filgrastim…" How this differed from my presentation still escapes me. I was unable to identify one of the three patients when I looked for contact information to get the approvals. Luckily, the staff member in my office who handles the clozapine remembered who it was. I recalled the other two as these issues were recent and we had spoken a few times recently. I could not have identified them from my manuscript, even though I follow them myself, without a nurse or physician assistant. Identifying any of these patients, even in my office using our electronic medical records (EMR), would have been impossible without reading thousands of records. My staff didn't know who the other two were.

All three were happy that they could contribute to a medical report on PD. The request for consent did not cause any problem. The letter to the editor was approved for publication. Although it contained only a small amount of data it actually is important, since data in this particular area are very sparse and my letter was in response to a report, also with very limited data, that suggested a much reduced need for monitoring clozapine than my limited data suggested. At a time when European drug agencies are reviewing monitoring requirements for clozapine, these small data are useful. So, why should there be impediments to reporting? Even if someone had access to my EMR they would be unable to identify these patients. If I couldn't identify all three using my EMR and I knew them all well, how could anyone else? I follow a couple of thousand similar patients. If one of these patients was paranoid, or didn't like me, that case could not be published in its proper context, reducing its value. I can easily imagine other situations where subject refusal would make the project useless.

I believe that the initial notion of obtaining informed consent for case reports started in 1999 with a case report in the *New England Journal of Medicine* (NEJM).[1] Perhaps it occurred earlier, but the fact that the NEJM published the report without requiring the consent indicates that if the issue had been raised prior, it was not a standard procedure

I recall the episode because it attracted attention in the news, and the senior author was a distinguished neurologist in whose laboratory I had been a research assistant 20 years prior. The NEJM article was a case report published as a letter to the editor about the street drug, Ecstasy, causing parkinsonism.[3] There were no identifiable data but the "personal health information" of age, gender

and having been seen in Michigan were. However, the patient sent an irate letter to the journal, apparently without a request to remain anonymous. "I find it hard to believe that physicians at an institution like the University of Michigan would submit such a letter about me without telling me beforehand and then using incorrect information to make their claim."[4] The response, which noted that the information labeled as incorrect, that he had smoked marijuana, was provided by his friend, sitting with him in the office, and not contradicted at the time. "Our patient believes that he should have been informed about our letter before we sent it to the *Journal*. We followed the current practice for publishing clinical observations, which does not include a requirement to inform the patient about the submission. Moreover, we assiduously protected the patient's confidentiality. We did not identify him by name, we published no photographs of him, and we provided no information that would enable any reader to determine his identity."[4]

It is rare that a medical report provides actual identifying information. Only in cases where one might plausibly identify the patient should consent be required for publication. In my field of movement disorders written consent, or blurring of the face, is always required for the videos we publish. It is rare otherwise for this to be necessary. Obviously, journal editors see things differently. Will we need consent to discuss cases at conferences? ❖

References

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