

Review Report: Should Research Use of Patients' Medical Information Require Approval of Attending Physicians?

Summary: In this brief paper, the authors consider an important dilemma that arises in public health research: though patients' ability to opt-out of (having their information used in) a study is the subject of much work in public health and research ethics, what's less-often scrutinized is whether medical professionals' consent should be required. That is, the authors ask whether medical professionals should, like patients themselves, have the ability to opt out of having their patients' medical records and the data therein used in retrospective observational studies. They ultimately conclude that the most feasible and ethically sound possibility is for research governance bodies to "Disclose information on the hospital's [homepage] or in leaflets...and give [this information to] medical professionals in the hospital concerned, [and] guarantee the opportunity to opt-out if they do not approve" prior to submitting the relevant information to the hospital's research ethics committee.

This paper deals with questions including: (1) Setting aside legal questions of intellectual property rights, whose interests—patients', physicians', hospital administrators', etc.--should be weighted most heavily in deciding how to use medical information? (2) Is opt-out consent *really* consent, given that we might be justified in assuming that most patients will not actually read the 'terms and conditions,' so to speak, of their treatment?

General comments:

- **all page numbers will refer to the page number given on the upper right-hand corner of the pdf**
- I really enjoyed reading this paper. I think the authors do a great job of drawing readers' attention to the "dual nature of medical records," (p. 4) which is often overlooked in favor of an almost-exclusive focus on patients' privacy rights. Understanding medical records in this dual way really helps to establish that they're dialogical, and that the physicians and other medical professionals who contribute to such records aren't mere collectors of information, but are themselves active participants in the creation of that information.
- The pragmatic force of this paper is also quite strong, as the authors compellingly make the case for why ethicists should be concerned about medical professionals' ability to opt-out of having their patients' data used in a study.
- One thing that I wondered while reading is whether there might be noteworthy differences between the *types* of consent that medical professionals (as opposed to patients) can actually give. Moreover, something that seems to be hinted at but not fully addressed is the different reasons that physicians might have for not wanting particular patients' data included in a research sample.

Specific points that might warrant further clarification:

- One thing that might read as a bit vague is the mention of "medical professionals in the hospital concerned" in option 3 on page 3.
 - First, I think that, semantically, there are two different readings of this sentence, and I wasn't entirely sure which was the authors' intention. Is the sentence

focusing on the concerned medical professionals in the hospital, or more generally on the medical professionals in the concerned hospital? In other words, it isn't totally clear to me what "concerned" is modifying here.

- The second, less nitpicky (ha) concern that might be raised here is the scope of the medical professionals concerned. Are we concerned primarily with attending physicians? It seems like the answer to this is no, given the difference between options 1 and 3. But still, are we concerned with attending physicians and residents/interns? What about registered nurses, or nurse practitioners, or physicians' assistants? Furthermore, what about LPNs/CNAs? I think that my question here can be more succinctly phrased as: *How do we determine which medical professionals have a vested concern in a particular 'piece' of patient data?*
- With respect to the latter point, it's also entirely possible that my own situatedness in the USA is coloring my reading here – it's possible that, simply by mentioning a specific geographical region in the italicized example on pages 2-3, this concern could be skirted, as I admittedly quite unfamiliar with who is in patient-facing roles in other parts of the world, including Japan. Or, the authors could avoid this concern by using language more specific than 'medical professionals,' perhaps referring exclusively to physicians, or something to that effect.
- I'm also a bit curious about the authors' claim on p. 4 that only physicians need be concerned that "refusal by 'opting out' may entail tangible or intangible sanctions." On the one hand, this makes perfect sense, given that the authors have already mentioned that the scope of their paper is retrospective observational studies, so the patients' data has already (presumably) been collected. However, there might be some warranted concern about long-term patients, or those who will return for some further/other treatment in the future, and whether having opted out of having their data included in research studies could feasibly worsen the quality of care they receive. Of course, this is quite the hypothetical, and the patients' concerns would still be markedly different from those of a physician who opts out of including his patients' data in a study.
- Lastly, also on p. 4, I'm wondering whether public health ethics *necessarily* "finds individual human rights (freedom) to be in opposition with the public interest of society." Though I think the two are quite often at odds, and though this may be unduly optimistic of me, I'm not sure that there isn't any way in which we can view a commitment to public interest as compatible with an expansive understanding of personal freedom.

Overall, I really enjoyed this paper, and look forward to seeing how it develops!