Reviewer’s report

Title: Clinical Decision-Making and Secondary Findings in Systems Medicine

Version: 0 Date: 12 Feb 2016

Reviewer: Brent Mittelstadt

Reviewer's report:

This is a very well written and timely paper on ethical issues surrounding systems medicine or biomedical Big Data. The paper raises several ethical questions about the relationship between statistical research and algorithmic models of health, clinicians and patients. Big Data is influencing medicine from many angles, some of which are covered in this paper, including basic medical research, resource commissioning, risk stratification and clinical decision-making (for instance through clinical decision support systems). This paper rightly questions the validity of the epistemological assumptions of the big data approach, namely that statistical correlations are increasingly treated as actionable knowledge. Correlations have long driven population level decisions in medicine (e.g. epidemiology, resource commissioning), but the entrance into personalized medicine or decisions made that affect the individual in the clinic seems to be something new, quite apart from the role medical research plays in generating clinical best practice.

While the paper addresses an important topic, it would benefit from providing further context and unpacking some of the ethical questions in a number of places. The following points jump out:

p. 4 - The terms Personalized and Individualized Medicine are introduced but not explained. I have a different understanding of Personalized medicine than the others (less to do with omics, more with personal monitoring of health), so it would be helpful to include a brief explanation or history of the terms with some references.
p. 5 - The authors write "This approach, typically referred to as the big data approach, relies on statistical associations rather than mechanistic understandings." Typically according to who?

p. 7 - Line 134, an 'of' is missing.

p. 14 - Re: the discussion of the algorithm presenting the patient's body as a black box: this is certainly a risk, but there are ways around this. Decision aids, or algorithms, can be built to show the decision-making logic to the user. Similar issues are being tackled in work on discrimination detection in data analytics algorithms, and how to make classification and personalisation algorithms accountable (perhaps through auditing). It seems odd that systems medicine would actually create technologies that completely leave the clinician and patient in the dark; surely they would not be accepted at a clinical level and thus never spread (again, there is relevant background research on the diffusion of medical technologies and clinical evidence)? Existing clinical decision support systems seem to avoid this problem; how are they different from systems medicine?

p. 14 - The authors write "In order for medical care to be successful, clinicians must be able to be accountable for their clinical decisions, and patients must be given grounds for placing trust in the expertise of their providers." This is the crux of the paper; if we don't believe this premise, then there's no reason to take the ethical issues identified in the paper seriously. It should therefore be expanded. Why must clinicians be accountable? Could we not re-define the role of clinicians to remove the diagnostic element, meaning clinicians would become mere collectors of clinical observations and someone to provide support/advice to patients in making decisions, with diagnoses/treatments recommended by systems medicine? There's relevant work on medicine as a moral practice that covers why accountability, honesty etc. are so important to the success of medicine. Theories of virtue ethics in particular have been applied. I've included some relevant references below.

p.15 - Lines 319-20. Similar to the previous comment. If systems medicine merely provides recommendations, why can't the clinician bring in the missing human elements to the clinical decision-making process? It's not clear why we should assume that the entire clinical encounter would become automated by systems medicine.
If it's just a case of scale, can we just extrapolate from the ethics of risk stratification to ethics of systems medicine?

This is a very important point that is not stated enough. What is the source of this obligation?

Again, see the above comment about virtue ethics and re-defining the role of the doctor.

Beyond these specific issues, I was slightly disappointed some of the interested ethical questions identified throughout the paper weren't unpacked a bit further. Perhaps you can choose one or two to expand on, for instance questions on the acceptability of re-defining the role of clinicians to work with systems medicine (prior work on the ethics of automation and labor are relevant).

References:


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