

Raw Data: Research and Health Care Goals Differ

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LETTERS

edited by Jennifer Sills

Raw Data: Access to Inaccuracy

IN "RAW PERSONAL DATA: PROVIDING ACCESS" (POLICY FORUM, 24 January, p. 373), J. E. Lunshof and colleagues argue that donors should have access to raw data derived from their contribution to research or clinical repositories. Fairness, reciprocity, and respect for autonomy are compelling ethical reasons for access, if not for one major problem: the intrinsic inaccuracy of most research data.

Even the best-documented population studies cannot guarantee

accurate data for individual participants. Limited research budgets force researchers to decide between assessing a few variables at high quality or many variables at lower quality, and they typically choose the latter. More data means more research opportunities, and suboptimal data quality is perfect enough when conclusions are drawn for populations at large. Yet, the data cannot be used to inform about individual participants.



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IN THEIR POLICY FORUM "RAW PERSONAL data: Providing access" (24 January, p. 373), J. E. Lunshof *et al.* suggest that more should be done to enable persons who had their genome sequenced, either as research subjects or as patients, to actively access their raw data. They argue that routinely providing them with personal access codes to those data would be a matter of transparency and respect for autonomy. We think Lunshof *et al.* underestimate the dangers of actively handing out data that we know are not fully reliable and can lead to misinterpretation.

In our view, the proposed policy would be at odds with the responsibility of health professionals.

In health care, clinical utility should have priority over social utility. An appeal to reciprocity between donors and users of genomic data does not change this argument. Patients are not the same as data donors. If patients become data donors by consenting to have their data stored in research registries, they should be aware that they have entered a different relationship, in which they primarily contribute to the benefit of future patients.

Lunshof *et al.* ignore the crucial difference between health care and research when they criticize the recent recommendations of the European Society of Human Genetics

To illustrate the moral obligation for granting access, the authors draw an excellent analogy with money banks, but the example actually undercuts their point. Money banks would never provide customers access to their bank accounts if they had even the slightest doubt about the accuracy of the balances. Inaccurate account data not only harm individual customers, who then remain uncertain about their financial position, but also destroy public trust in money banks. This is a risk that banks would not even think of taking, and scientists should not either.

High-quality online genome data interpretation tools, health professionals, and other independent experts cannot make sense of data when they cannot rely on the quality. A disclaimer concerning data accuracy, as the authors propose, does not solve that problem. If researchers respect their participants, take them seriously, and want to do more good than harm (1), they do not give them all they have, but give something valuable in a responsible way (2). And that is not merely access to data.

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1. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Ethical Principles and Guidelines for the Protection of Human Subjects of Research (1979); www.hhs.gov/ohrp/humansubjects/guidance/belmont.html.
2. J. P. Evans, B. B. Rothschild, *Genet. Med.* **14**, 358 (2012).

(ESHG). To avoid the unnecessary generation of incidental findings, these recommendations advise the use of targeted forms of testing if that is sufficient to address the patient's problem (1). According to Lunshof *et al.*, this is problematic as it "systematically precludes the possible discovery of complex genetic causation." We disagree: Discovery is the aim of research, not of health care. Conflating these aims risks turning patients into research subjects without their consent.

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Ant against ant

974



Turning microtubules inside out

981

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References and Notes

1. C. G. van El *et al.*, *Eur. J. Hum. Genet.* **21**, 580 (2013).
2. The authors are writing on behalf of the ESHG Public and Professional Policy Committee.

Response

WE FULLY AGREE WITH A. C. J. W. JANSSENS and W. K. Dondorp *et al.* on the importance of considering very carefully what conclusions from analysis of raw data should be returned to data donors. However, that is very different from enabling patients and research participants to access the raw data. The two processes serve different purposes: The returning of findings aims at providing research participants and patients (and their doctors) with analytically valid, clinically relevant, and, if possible, clinically actionable information. Indeed, in this situation, the professional responsibility of health care professionals is a particular one.

The dangers, as perceived by Janssens and by Dondorp *et al.*, of communicating imperfect data and an uncertain interpreta-



tion to patients, are inherent to the clinical encounter and part of professional liability, as we emphasize in our Policy Forum. This responsibility is very different in enabling access to raw data. Moreover, in any context, personal risk assessments and the balancing with expected benefits are highly individual processes and not just a matter of professional expertise (1). It will need to be made very clear to those wanting to access their raw data sets that these may contain mistakes and inaccuracies, and that they may—in most cases—not be actionable in an immediate way. We expect that as a result, many patients and research participants will not actually access their raw data. But this

decision needs to be up to them. The same applies to personal raw data in other types of research, such as the social sciences, in which access to individual metadata has no practical utility for participants but serves transparency and is the cornerstone of a reciprocal relationship between participants and researchers.

Dondorp *et al.* raise the issue of conflating research and clinical care. They emphasize, first, that patients need to consent to become research participants and thus data donors. In practice, however, in many clinical settings, becoming a donor of research data or samples may occur by default, and individuals need to be aware of this and opt out if they do not want their data to be included (2). This underscores once more the asymmetrical relationship between patients on the one hand and clinicians or researchers on the other. Second, Dondorp *et al.*, referring to the need to restrict analyses to avoid the unnecessary generation of incidental findings, state that discovery is the aim of research and not of health care. However, such a dichotomy does not always correspond with the wishes of patients: Many patients want research to be done, for their own benefit and that of others, and they donate their data for research. In particular in genetics, patients and families, as partners in research, often seek the most comprehensive approach to find their disease-causing mutations (3, 4).

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2. K. B. Brothers *et al.*, *Per. Med.* **10**, 349 (2013).
3. E. A. Worthey *et al.*, *Genet. Med.* **13**, 255 (2011).
4. B. Maher, *Nature* **449**, 773 (2007).

CORRECTIONS AND CLARIFICATIONS

Letters: "Global warming and winter weather" by J. M. Wallace *et al.* (14 February, p. 729). The low-temperature record set at O'Hare Airport equates to -27°C , not -8°C . The PDF and HTML versions online have been corrected.

Reports: "Designing collective behavior in a termite-inspired robot construction team" by J. Werfel *et al.* (14 February, p. 754). A production error resulted in the omission of the end of the second sentence of the abstract. The sentence should read "Predicting high-level results given low-level rules is a key open challenge; the inverse problem, finding low-level rules that give specific outcomes, is in general still less understood." The PDF and HTML versions online have been corrected.

Reports: "An antifreeze protein folds with an interior network of more than 400 semi-clathrate waters" by T. Sun *et al.* (14 February, p. 795). The correct PDB code is 4KE2 (not 4EK2). The HTML and PDF versions online have been corrected.

News Focus: "Selling America's fossil record" by H. Pringle (24 January, p. 364). The date on which the GeoDÉcor Web site was accessed was incorrect; it was accessed on 6 December 2013, not in December 2014. The HTML and PDF versions online have been corrected.

Editors' Choice: "A question of balance" by H. J. Smith (3 January, p. 7). Lupascu *et al.* reported that in High Arctic tundra, warming alone decreases (not increases) the summertime CO_2 sink strength by up to 55%. The HTML and PDF versions online have been corrected.

Reports: "GRB 130427A: A nearby ordinary monster" by A. Maselli *et al.* (3 January, p. 48; published online 21 November 2013). Author B. Wiegand's name was incorrectly spelled "Weigand." The HTML and PDF versions online have been corrected.

Reports: "Pregnenolone can protect the brain from cannabis intoxication" by M. Vallée *et al.* (3 January, p. 94). In the author list, the dagger indicating that "These authors equally supervised this work" should be deleted from M. Vallée's name and added to G. Marsicano's name, indicating that G. Marsicano and P. V. Piazza were equal supervisors. The HTML and PDF versions online have been corrected.

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