

Should medical researchers share their results with the volunteers in their studies?

June 6 2008

Every year, hundreds of thousands of Americans volunteer to take part in medical research studies, from simple health surveys to detailed analyses of their DNA or tests of experimental medicines.

But what happens after their participation is over? In many cases, volunteers won't ever hear from the researchers about what the study revealed. But other studies make a special effort to keep volunteers informed, via newsletters or Web sites.

A new review of the issue, published recently in the journal *Public Library of Science Medicine*, suggests that participants' desire to know the results of studies outweighs concerns by some bioethicists about the potential negative psychological consequences of sharing some results. Even when it's bad news, most study volunteers want to know.

So, should all medical researchers make an effort to communicate about their results with the volunteers who are so vital to their research? If they try to do so, what hurdles — ethical, privacy-related, financial or logistical — might complicate their efforts? Could sharing clinical research results with some volunteers actually upset them?

Such questions are addressed in the new paper, which was written by University of Michigan medical student David Shalowitz and Franklin Miller, Ph.D., of the Department of Bioethics at the National Institutes of Health. The research was funded by a grant from the U-M President's Initiative for Ethics in Public Life.

The paper reviews the landscape of knowledge on this issue, including commentaries on the potential positive and negative impacts of sharing results, and data from studies that evaluated the desires and reactions of research volunteers in specific clinical trials.

All in all, the article says, better data are needed on the ins and outs of sharing study results with research volunteers.

"It's a mixed bag," says lead author Shalowitz. "We found overwhelmingly that participants do want access to aggregate study results, and that to a lesser extent they want to know their individual results if they have relevance to their lives."

For instance, volunteers in a study looking for genes related to a particular disease might appreciate the opportunity to find out what their individual genetic test revealed. And they may be interested in learning what the entire study found.

But other people in the same study might not want to know their individual results, for fear of finding out that they have a higher risk of developing a particular disease.

One of the biggest hurdles that the authors found in both commentaries and studies of this issue, Shalowitz says, was the cost of contacting research volunteers and presenting trial results to them.

Presenting aggregate results in layman's language is not as difficult, he notes, as preparing individual reports for each volunteer, which can be very labor-intensive in a large study with hundreds or thousands of participants.

Then there's the ethical issue of whether and how to offer participants a way to communicate with the researchers about what they've been told –

for instance, by phone or e-mail if they're concerned about their individual test results.

And, for those who simply don't want to know their individual results or even the aggregate results, a system for opting out is needed.

These considerations might be addressed if researchers consider participant communications during the earliest planning of their study, including the funding request, Shalowitz says.

If the NIH and local Institutional Review Boards were to demand a plan for such communications as part of each study proposal, and perhaps provide staff who could facilitate such efforts, it would help researchers greatly, he adds.

In the end, the authors say, more research on the best approaches for contacting research volunteers, and the actual responses of volunteers to this issue, is needed.

"There's a need to develop a standard way of measuring these domains, so that systematic evaluations can be done," says Shalowitz. "We also need better evaluations of the best ways to communicate data to research participants. We need to change the current situation in which claims are being made about the benefits and risks of sharing results without data to back them up."

Source: University of Michigan

Citation: Should medical researchers share their results with the volunteers in their studies? (2008, June 6) retrieved 25 April 2024 from <https://medicalxpress.com/news/2008-06-medical-results-volunteers.html>

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