

Strengthening and Opening Up Health Research by Sharing Our Raw Data

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On November 30, 2011, a 2-hour conference, "Horizon 2020: Investing in the Common Good," in the European Parliament in Brussels, Belgium, examined what it means to treat knowledge as a public good in policy making and how this should affect future European Union (EU) funding schemes for research and innovation.

The conference aimed at exploring how EU funding can promote economically and socially sustainable innovation models with the aim of more openness, easier accessibility, and higher result-oriented efficiency. The conference was related to Horizon 2020, which is the EU's framework program for research and innovation that was presented the same day.

The conference was organized with support from the Transatlantic Consumer Dialogue and Health Action International Europe. There were 3 presentations, followed by a response by the European Commission and an open discussion with the panelists, the commission, and people on the floor (a video of the meeting is available at <http://www.greenmediabox.eu/archive/2011/11/30/horizon2020>).

The first presenter, Professor Mariana Mazzucato (University of Sussex, UK), spoke about EU innovation policy in relation to risk taking and obtaining the return, and she challenged the common, but false, assumption that the public sector has a limited role in economic growth and innovation. The second presenter, technology writer Glyn Moody, focused on equitable licensing, open-source research, and access to scientific knowledge. I was the third speaker and focused on the moral obligation and societal benefits of providing free access to all anonymized raw patient data from clinical research. This article is an almost verbatim reproduction of my talk.

Public investments in health research give a poor yield because there is too much ownership to the data and secrecy involved.¹ Furthermore, what gets published, if made publicly available at all, is often a highly selective and

misleading version of the true results. Although selective reporting violates the Declaration of Helsinki, it is not the exception, but the rule, both for industry-sponsored and academic research.²

This means that, despite the existence of hundreds of thousands of randomized trials and >4000 updated Cochrane reviews of these trials, physicians and governments cannot choose the best and most cost-effective treatments for the patients.

Selective reporting can have disastrous consequences for patients and for our national economies. One example is the rofecoxib (Vioxx) scandal. The drug maker Merck concealed, for many years, that its drug causes heart attacks, and the use of rofecoxib has probably caused ≈10 000 unnecessary deaths in the United States alone.^{3,4}

Another example is the mild 2009 influenza epidemic.^{5,6} The drug maker Roche had omitted publishing most of its clinical trial data on oseltamivir (Tamiflu) and refused to share them with independent Cochrane researchers. We do not know whether oseltamivir decreases the risk of influenza complications, but it is not likely, because Roche would have published its studies if this was shown. There is total confusion,⁷ and the 2012 updated Cochrane review found a high risk of publication and reporting biases in the trial program of oseltamivir.⁸ The European Medicines Agency (EMA) stated that oseltamivir reduces influenza complications, whereas the Food and Drug Administration stated that oseltamivir has not been shown to prevent complications. It seems that the European governments have wasted billions of euros on the purchase of this drug. We need a European Union-funded, placebo-controlled, randomized trial for patients at high risk for complications; planned and conducted independent of the drug industry; and possibly in collaboration with the US National Institutes of Health.

We should no longer accept selective reporting. By sharing all our research data, we could save billions of any currency every year and, at the same time, improve the health and longevity of the citizens and reduce the amount of harm they are exposed to.

International calls for sharing the results have come, for example, from the Organization for Economic Co-operation and Development, the World Health Organization, the US Congress, the European Commission, The Cochrane Collaboration, journal editors, and funders.¹

Calls for data sharing have mostly been restricted to publicly funded research, but the distinction between publicly and industry funded research is an artificial and irrelevant one.¹ As noted by The British House of Commons Health Committee, society's obligations toward the patients who participate in trials, and all other patients, must take precedence over commercial interests.⁹ Furthermore, the public is

The opinions expressed in this article are not necessarily those of the editors or of the American Heart Association.

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(*Circ Cardiovasc Qual Outcomes*. 2012;5:236-237.)

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Circ Cardiovasc Qual Outcomes is available at
<http://circoutcomes.ahajournals.org>
DOI: 10.1161/CIRCOUTCOMES.112.965277

always a partner, contributing trial participants and the infrastructure needed for the research. In addition, taxpayers contribute substantially, both to research and by reimbursing drugs once they are on the market.

Respect for trial participants who often run a personal and unknown risk by participating in trials requires that they (and, therefore, the society at large that they represent) be seen as the ultimate owners of trial data. Research can only be a public good, if the public can see the data. It is an unacceptable double standard that trial participants are willing to share data about themselves with the investigators and sponsors when these people are unwilling to share the data with trial participants and others.

An incomplete knowledge base also leads to redundant research, and informed consent is an illusion when patients and their physicians can only obtain access to biased information.

We must obtain access to the results, the raw data, and the study protocols.^{1,10} Much research could be performed, at almost no cost, on existing data, making it unnecessary to collect new data. Furthermore, the incentive for bias, cheating, and fraud would be reduced when other researchers can check the data.

Data sharing would lead to tremendous benefits for patients, progress in science, and much more rational use of healthcare resources based on evidence we can trust.

The harmful consequences of data sharing are minor.¹ Obviously, anyone with an agenda could selectively interpret the data in a way that furthers this agenda. But, consider the alternative. Societies that have only 1 official version of the truth are not societies we would like to live in. Equally important, it is difficult to imagine a worse situation than the status quo, where people with vested interests so often distort the evidence for commercial or career gains, with no possibility for others to check what they have done.

Data sharing would not be anticompetitive for the drug and device industries, because all companies would be affected equally by it. It would lead to competition at a higher ethical level and has potential benefits for drug innovation. When failures with previous drugs or devices are kept secret, expensive development programs for similar drugs or devices can continue for years after they would have been stopped if the data had been known.

The European Commission has recommended that data sharing should mean that the data can be used for whatever purpose other researchers might find relevant, without needing to obtain permission from those who assembled the data.¹ Even so, it took the Nordic Cochrane Centre 3.5 years to obtain access to clinical study reports and the corresponding trial protocols of 2 diet pills at the EMA. The EMA consistently denied access, arguing it needed to protect the drug industry's commercial interests and did not change its stance before the European ombudsman accused the EMA of maladministration by denying access.¹⁰ We must ensure that all drug agencies adopt the same new openness policy that the EMA has introduced.

Legislation is needed to make data sharing happen, because guidelines and other voluntary agreements do not work, and

there should be appropriate sanctions to hold accountable those who refuse to share their data.¹

New research should not be performed unless the questions it proposes to address cannot be answered satisfactorily with existing evidence. Funding opportunities for clinical research should, therefore, not be limited to collection of new data but should always include systematic reviews of the research literature, which will also provide support for evidence based decision making to optimize the effectiveness of healthcare systems and reduce inequalities.

Systematic reviews can be extremely cost-effective. In 2008, a political majority in the Danish Parliament wanted to reimburse α -1-antitrypsin for patients with this enzyme deficiency and lung disease, but before this was finalized, I was asked to review the randomized trials. I produced a 10-page review in 4 weeks. There was no evidence that the drug worked, and the idea of reimbursing the drug was dropped, which saved Danish taxpayers at least 20 million euros each year. The review was later published as a Cochrane review.¹¹

If you disagree with what I have said about data sharing, then please consider this: If commercial or academic success depends on withholding data that are important for rational decision making by physicians, patients, and governments, then there is something fundamentally wrong with our priorities in health care.

Disclosures

Dr Gøtzsche's travel costs for the European Union meeting were reimbursed by the Transatlantic Consumer Dialogue.

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KEY WORD: ethics

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Circ Cardiovasc Qual Outcomes. 2012;5:236-237

doi: 10.1161/CIRCOUTCOMES.112.965277

Circulation: Cardiovascular Quality and Outcomes is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

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Print ISSN: 1941-7705. Online ISSN: 1941-7713

The online version of this article, along with updated information and services, is located on the World Wide Web at:

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