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Strengthening and opening up health research by sharing our raw data

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On 30 November 2011, a two-hour conference, "Horizon 2020: Investing in the common good," in the European Parliament in Brussels examined what it means to treat knowledge as a public good in policy making and how this should affect future 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 programme for research and innovation that was presented the same day.

The conference was organised with support from the Transatlantic Consumer Dialogue and Health Action International Europe. There were three presentations, followed by a response by the European Commission and an open discussion with the panellists, 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, Mariana Mazzucato, spoke about EU innovation policy in relation to risk taking and getting 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, Glyn Moody, focused on equitable licensing, open source research and access to scientific knowledge. I was the third speaker and I focused on the moral obligation and societal benefits of providing free access to all anonymised raw patient data from clinical research. This paper 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 randomised trials and more than 4,000 updated Cochrane reviews of these trials, doctors 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 about 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 their clinical trial data on oseltamivir (Tamiflu) and refused to share them with independent Cochrane researchers. We don't know whether oseltamivir decreases the risk of influenza complications, but it is not likely, as Roche would have published its studies if they showed this. There is total confusion (7) and the 2012 updated Cochrane review found a high risk of publication and reporting biases in the trial

programme of oseltamivir (8). The European Medicines Agency (EMA) stated that Tamiflu reduces influenza complications, whereas the FDA 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 an EU-funded placebo-controlled randomised trial in 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 OECD, the WHO, 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-funded and industry-funded research is an artificial and irrelevant one (1). As noted by The British House of Commons Health Committee, society's obligations towards the patients who participate in trials, and all other patients, must take precedence over commercial interests (9). Furthermore, the public is always a partner, contributing not only trial participants, but also the infrastructure needed for the research. And 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 also 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 doctors can only get access to biased information.

We must get access not only to the results but also to the raw data and the study protocols (1,10). A lot of research could be done 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 one 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 anti-competitive for the drug and device industries, as 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 go on 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 get access to clinical

study reports and the corresponding trial protocols of two diet pills at the EMA. The EMA consistently denied access, arguing it needed to protect the drug industry's commercial interests and didn't change its stance before the European ombudsman accused the EMA of maladministration by denying us access (10). We must ensure that all drug agencies adopt the same new openness policy that the EMA has now introduced.

Legislation is needed to make data sharing happen, as 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 done 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 optimise 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 alpha-1-antitrypsin for patients with this enzyme deficiency and lung disease, but before this was finalised, I was asked to review the randomised 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 doctors, patients and governments, then there is something fundamentally wrong with our priorities in healthcare.

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