Addendum to Research Methodology

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There are three main ways in which the field of research methodology has changed since this article was written. First, Evidence Based Medicine (EBM) has grown from an up-and-coming movement within medicine to become the dominant approach to healthcare research and practice. As the evidence-based practice movement has matured, systems of grading the quality of evidence have become more nuanced and more comprehensive -- spearheaded by the international Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group.

Second, there has been a significant shift in the way that research is organized. Change started in the public sector, with a worry about the apparent failure of massive public sector investments in basic science to make their way into innovative therapies. The suggestion was that more attention needed to be paid to the processes of research, and the ways in which potential "translational chasms" in moving from basic science to a potential clinical application (T1), crossing from a potential to an acceptable clinical application (T2), and in moving from the marketing approval of a new drug or device to its actual adoption in clinical practice (T3) could be bridged. The result has been a renewed attempt to look at health research systems in the round -- and see where the overall blockages are, and where there is potential for greater efficiencies through public-private partnerships.

The last and potentially most far-reaching change has been the rise of Open Science. Open Science is a broad movement, which aims to open up access to scientific

research processes, data and publications. The percentage of healthcare research that is published as open access has increased massively, catalyzed by a combination of the rise of prestigious open access journals such as the Public Library of Science (PLoS), research funder requirements for open access availability, and a sea-change in researchers' attitudes. The current frontier is open access to scientific data through curated and publicly accessible data repositories -- with fields such as genomics leading the way.

A number of reasons are cited for improving access to data, for example by Nielsen and by the Royal Society. Data collection is expensive, and it is wasteful for researchers unnecessarily to have to repeat work that has already been done. Greater openness is also argued to be required out of concern for the corrigibility of research. The data are what warrant the claims made in a scientific research paper, and it is difficult for other researchers to check the accuracy of these claims unless they are granted access to the underlying data. Access to research data has also been opened up as an ethical issue -- both through the idea that citizens have a right to access knowledge that has been produced by public funding, and through an increasing realization of the preventable harms that have resulted through the lack of publication of clinical trial data -- as detailed for example by Goldacre.

Further reading

Butler, Declan 2008. "Translational Research: Crossing the Valley of Death". *Nature* 453: 840-842.

Goldacre, Ben 2012. *Bad Pharma: How drug companies mislead doctors and harm patients*. London: Fourth Estate.

GRADE Working Group. Materials available from http://www.gradeworkinggroup.org/index.htm

Greenhalgh, Trisha 2010. *How to Read a Paper: the Basics of Evidence-Based Medicine*. Fourth edition. Oxford: WileyBlackwell.

Nielsen, Michael 2011. *Reinventing Discovery*. Princeton, NJ: Princeton University
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Royal Society 2012. *Science as an Open Enterprise: Open data for open science*.
London: The Royal Society. Available from
http://royalsociety.org/policy/projects/science-public-enterprise/

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