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Credibility and geometry of the evidence: Are recommendations and decisions based on appropriate clinical studies?

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Evidence-based medicine has made major advances in moving health care away from dependence on the whim of expert opinion. Randomized controlled trials and meta-analyses have become the most highly-cited articles in the health sciences literature and they have assumed a pivotal role in guiding recommendations for practice and medical decision making. These are welcome changes that have helped offer a scientific justification to the messy art of medical care. However, the application of evidence-based medicine is still threatened by the poor conduct, analysis and reporting of many clinical trials; and by the setting of research agendas that focus unilaterally on specific treatment agents (e.g. blockbuster drugs) rather than trying to obtain balanced evidence on all treatment options available. Randomized trials are mostly designed, conducted, and written up by the industry and their teams. The talk will discuss empirical data from meta-epidemiological studies that suggest that a large number of clinical studies seem to arrive at false results and conclusions. I will discuss aspects of quality and the difficulty to address quality of studies post-hoc, unless the detailed protocol, raw data, and analyses plans are available. I will also present empirical data on how the geometry of the evidence (the totality of randomized comparisons between different available treatments on the same condition) is often illogical and potentially misleading. Single trials and meta-analyses focus on specific agents, and the clinical trials along with their accompanying reviews, and editorials serve mostly as advertisements to promote sales. Conversely, one is interested in understanding the relative merits of all the different treatments that are potentially available. Newer methods, including analyses of network geometry (evaluation of diversity, co-occurrence, and homophily), and multiple treatment meta-analyses, can be useful in identifying gaps and irregularities or inconsistencies in the evidence; generating estimates of the relative benefits and harms of all treatment options; and feeding some reliable information to recommendations and health care decision making. Randomized trials should be designed in the future taking into account the totality of the prior evidence on the management of the condition of interest, and their design should be entrusted to non-conflicted stakeholders with a prime interest for the public good. Ideally, research agendas should be even constructed prospectively considering the totality of the evidence that is to be accrued from the clinical trials being considered. Selection of clinically-important outcomes and sufficient follow-up in pragmatic trials could also enhance the utility of the evidence. Finally, raw data from randomized trials should be readily available in public access.

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