

Observational epidemiology vs clinical trials: do we want to ask the wrong questions and answer them well, or to ask the right questions and answer them badly?

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"To understand causal effects, epidemiologists should put more effort into organizing large-scale randomized trials instead of traditional observational studies, which are inevitably crippled by confounding and other biases."

Before responding to this proposition, it is necessary to ask the question "which causal effects"? If the answer is "the types of causal effects that can best be answered by large-scale randomized trials" then the statement is tautologous and meaningless. If the answer is "the causal effects that are most important in public health terms and/or most interesting in scientific terms" then it becomes clear that randomized trials are not always the most appropriate technology for understanding such causal effects.

The appropriateness of any research methodology depends on the phenomenon under study: its magnitude, the setting, the current state of theory and knowledge, the availability of valid measurement tools, and the proposed uses of the information to be gathered. The major public health problems such as climate change and macro-level socioeconomic factors cannot be studied by randomized trials (not unless you have two planets or two governments). Even individual-level risk factors (e.g. smoking and diet) either cannot be studied with randomized trials (for ethical reasons), or cannot be studied well (for practical reasons). For example, many intervention trials of cardiovascular risk factors have failed not because the findings from epidemiologic studies were wrong, but because of the difficulties of ensuring effective interventions without any contamination of the non-intervention group. Other trials have failed because they adopted interventions (e.g. beta carotene) that were feasible, but were inconsistent with the epidemiologic evidence (e.g. consumption of green and yellow vegetables).

Many major sciences, including evolutionary biology, cosmology, astronomy, geology, and much of molecular biology, are inherently observational and randomized experiments have only a minor role. Epidemiology is in the same tradition. Epidemiologists should address the most important scientific public health questions, and use appropriate technology to address them. Sometimes this will involve a randomized trial; often it will not. To ask the wrong questions, simply because we can answer them with a particular method, is not only wrong in public health terms, but is also unscientific.