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Editorials and Annotations

Editorial: The Tribulations of Trials— Intervention in Communities

We can all agree that the results of well-conducted trials are likely to provide the truest available reflection of the questions researchers specify in their protocols. But a gap exists between the constricted hypothesis of a tightly designed trial and the question at issue in the population at large. Thus trials may not provide the truest reflection of the questions researchers intend to pose and answer. Still, faith in the randomized controlled trial is so firm among epidemiologists, clinical scientists, and journals—not excluding this one—that it may justly be described as a shibboleth, if not a religion. Science, like freedom, dies of dogma; subversion is its lifeblood. We need a more rounded and complex perspective.

The modern trial had two great progenitors, Ronald Fisher and Austin Bradford Hill. Fisher, the theorist (of course, he was also a major figure in genetics and applied statistics) set out the principles of the design¹; Hill, the statistician/epidemiologist, showed how to apply those principles in the health and medical sciences.^{2,3} Both believed deeply in the value of the randomized trial. Their divergence from that point on, however, is illustrated by the pugnacious Fisher's attacks on the observational studies of Hill and Richard Doll on smoking and lung cancer.^{4,5(p11)}

Fisher was, of course, wrong. After 45 years of delving and testing, not even the tobacco industry can, straight-faced, call those results⁵ into question. Studies of smoking and its effects created a paradigm for modern epidemiology. That paradigm demonstrates where one can go when no trial is possible. Observational studies have a place as epidemiological armament no less necessary and valid

than controlled trials; they take second place in a hierarchy of rigor, but not in practicability and generalizability.

One can go further. Even when trials are possible, observational studies may yield more of the truth than randomized trials. In the population sciences, of which epidemiology is one, generalizability requires deep penetration of the world as it is, usually with an unavoidable loss of rigor. But as we reflect further on research into smoking prevention, we shall argue that rigor is not all.

In recent years, we have seen a number of well-conducted, large-scale trials involving entire communities and enormous effort. These trials have tested the capacity of public health interventions to change various forms of behavior, most often to ward off risks of cardiovascular disease. Although a few had a degree of success, several have ended in disappointment. Generally, the size of effects has been meager in relation to the effort expended. That was the case with one of the first such trials, the ambitious Multiple Risk Factor Intervention Trial (MRFIT).⁷ It is also the case with some recent trials, for instance, the Stanford Five-City Project,⁸⁻¹⁰ the Minnesota Heart Health Program,¹¹ and now the 26-work-site Take Heart trial¹² and the 22-city COMMIT trials,^{13,14} which have smoking-related cancers as the ultimate target. These were brave efforts. Each aimed to produce substantial effects, in large populations or communities taken as a whole, on forms of behavior that pose major health risks.

Editor's Note. See related editorial by Fisher (p 159) and articles by Glasgow et al. (p 209) and the COMMIT Research Group (p 183 and 193) in this issue.

The Journal has been the bearer of a fair amount of this not altogether welcome news. This issue carries the reports of the results of the Take Heart and COMMIT interventions. Both were well designed and well conducted. Take Heart had nothing but null results. COMMIT had one modest and partial positive outcome.

COMMIT especially sets a standard of care and precision that justifies the large resources deployed for a randomized controlled trial with cities as the obligatory analytic unit. It is a model of meticulous design, focused intervention, and careful analysis (excepting perhaps the partial neglect of adjustment for individual level effects^{15,16}). The results are certainly below the expectations of the sponsors.

Do we then conclude that human beings are obdurate? Is behavior too ingrained in the individual brain and psyche or embedded in the collective culture and social structure to be changed on a scale that matters? That is patently not the case. Over the past several decades, we have observed and measured—by means of simple descriptive studies that rank low in the hierarchy of science—startling, rapid, and unprecedented mass changes in smoking, diet, and exercise.

All these changes went against the dominant currents of the mid-20th century and those devils beckoning most of us to lust, gluttony, and sloth. They went against the grain of social norms embedded in the culture and reinforced, in the case of smoking, by individual addiction. And they went against the concerted efforts and commercial interests of the tobacco and food industries.

Nothing could be clearer: these changes were not miracles of chance. Entrenched norms yielded to the sustained efforts of the public health movement to counter them. Public health shaped the forces of social movements that actually accomplished the task of changing values and behavior through community organization and, ultimately, law and regulation.^{17(p157)}

If social change of this order can be achieved, why are we so often disappointed by the rigorous pursuit of the same objectives in intensive and localized controlled trials? The researchers themselves put many of the appropriate questions. Perhaps it is a matter of experimental design, even though we are mostly doing the best we know how to do. The interventions might be inappropriate in

form or manner or content and hence ineffective. Exposures might be too brief in duration or insufficiently intense to be effective. As in the deliberately low-intensity Take Heart trial, exposures might touch few people and so risk being ineffectual. Or effects might be deferred through a latent period and might not be observable in the short run of a few years. The comparison groups might, in a variety of obvious or subtle ways, be contaminated by exposures similar to those intended for the experimental groups, contamination that might neutralize the experiment. Or, as is often the case—although not in the studies that provoked this discussion—the communities might be too few; in such studies, the communities are the proper analytic units, and their number determines the statistical power of the design.¹⁴

These faults and weaknesses are to be found in various of the studies, but they are not so pervasive that one would expect so many disappointments. Taken together, the studies seem to complement each other sufficiently to avoid uniform failure on account of these alternative explanations. Indeed, COMMIT avoided the problems of contamination and insufficient units and many others, to little avail.

Other plausible reasons for disappointing results of community trials do not reflect on their execution. One such reason is that, in the United States in particular, the very same changes aimed for in such matters as smoking, diet, and exercise are those that have been progressing apace in response to the social movement described above. Changes of this order could either nullify the effort to produce them by controlled intervention or render true effects of intervention undetectable.

Thus previous change could nullify efforts to intervene because the change is already at maximum. The degree of change attainable by the modes of intervention used might already have been reached by the progress of the social movement, leaving only the rump of hardcore smokers unable to quit. This explanation gains some support from the positive effects of COMMIT on light and moderate smokers in the absence of an effect on heavy smokers, but it looks weak because, in the society at large during the same period, substantial change continued.

Alternatively, effects could be present but remain undetected despite good design because of the rapidity of change.

Small effects nestling under the wings of large ones are difficult to elicit. The number of analytic units needed to meet the levels of statistical power to detect desired effects, estimated for a stable situation, could become insufficient as the pace of social change outruns the experiment. In the MRFIT trial, for instance, unanticipated favorable change in the randomized control group reduced power from an expected 90% to a mere 60%.¹⁸

Such suppression of actual effects by behavioral change makes community intervention trials the victims of successes with other forms of social intervention. Where the starting levels are high and stable and as yet untouched by a vigorous social movement, as has been the case in both Karelia^{19,20} and South Africa,²¹⁻²³ then intervention has been seen to produce effects. These effects are large enough to be persuasive even though the studies lack the strong design of more recent major undertakings.

Another reason for failure of even the best designs resides in the nature of the targeted behavior. The history of behavior change and its manifestations since 1950, when the smoke alarm was first raised, warns that the task is both difficult and slow. It also tells something about what the remedies for the failures might be. In the 1950s and early 1960s before-and-after observations, in what were essentially quasi-experiments about smoking behavior in populations, taught lessons we should not forget. The effects of large-scale if relatively brief interventions,²⁴ as well as of the release of two momentous reports on the consequences of smoking by the Royal College of Physicians in England²⁵ and the Advisory Committee to the Surgeon General in the United States,²⁶ although immediately appreciable, were short-lived.

It took time for evidence of sustained change to appear. Although in Britain the doctors in Doll and Hill's cohort study learned from the results and soon began to quit smoking,²⁷ cross-sectional prevalence surveys in the United States evinced no decline. Not until 1969 did the cohort analysis of Hammond and Garfinkel show men (but not yet women) quitting.²⁸

The nature of the change in habits that followed is instructive. First, it conformed with what those generations inducted into the cigarette smoking habit in growing numbers from World War I on already knew from personal experience; namely, that tobacco smoking for most is a persistent addiction that demands a trial of strength to break. As time went on, we

learned that as many as two thirds of those who sought help to quit—and were to that extent susceptible—were likely to fail. Second, the glacial pace of this initial change showed that it takes continuous effort and patience to build the momentum of a social movement that can halt and then turn back the epidemic; the long-awaited decline followed 2 decades of unremitting campaigning.

Few in the 1950s envisaged the possibility of a smoke-free environment as the socially acceptable norm it has become. The campaign began with epidemiologists and other public health professionals. By a characteristic process of informal diffusion,²⁹ it spread first to voluntary organizations and those who had been hurt by the epidemic. Finally, it gathered force enough to impinge on social policy through legislation, regulation, and taxation. A large array of studies, many published in the *Journal*, leaves no doubt about the substantial impact of each of these measures, whether the curbing of advertising, tobacco taxes in California, regulation and monitoring of sales to minors, or the restriction of smoking in workplaces and restaurants.

From this history we may reasonably draw four conclusions. First, to bring about notable change in ingrained behavior and have the change pervade populations, time is needed to ignite and build a social movement at nongovernmental levels. Second, once the movement is strong enough to induce policymakers to bring about formal policy change, change accelerates. Third, although community intervention trials may fail the expectations of their sponsors, their seemingly small effects are not incompatible with those of nonexperimental interventions sustained continuously over the years. Experimental interventions encompass only a segment of what a social movement brings to bear. The time, the stamina, and the funding required to broaden experimental interventions to an equal degree, however, are unlikely to be available. Fourth, we should not abandon community trials but should gather the knowledge necessary to refine them. For example, community trials should address especially the initiation of smoking by youth and the breaking of established addiction. But we have much to learn about how to change group behavior to accomplish such effects. Fu-

ture trials will need to draw on a deeper understanding, now lacking, of methods for bringing about social change. Creative, dedicated, and rigorous social research is essential to bring about this understanding. In this issue of the *Journal*, Edwin Fisher outlines the possibilities.³⁰ Meanwhile, the battle with tobacco interests is not over and, among youth, disquieting trends in smoking have appeared.³¹ There must be no let to social action against such known health hazards. □

Mervyn Susser
Editor

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