



Is the “well-defined intervention assumption” politically conservative?



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The potential outcomes framework has gained traction and is now, arguably, the prevailing methodological perspective in epidemiology. While it has not yet fully permeated the applied literature, the current generation of epidemiology students is trained in this approach and it dominates the methodological literature. This perspective requires a reframing of epidemiologic questions and the retooling of many epidemiologic methods. The traditional hallmarks of study validity—no confounding, selection bias or information bias—are being supplanted by exchangeability, positivity and well-defined interventions (Hernán, 2005; Hernán and Taubman, 2008). Here we examine how the requirement to study well-defined interventions impacts the kinds of questions asked by epidemiologists.

To meet the “well-defined intervention” requirement, exposures must be factors that can be conceptualized as treatments in a randomized controlled trial. They must be manipulable under the Stable Unit Treatment Value (SUTVA) assumption (Rubin, 1986), i.e., there must be only one version of the treatment and there should be no interference between units. For example, if a particular drug had both an oral and an injectable version and these versions would have different effects for a single individual, the first aspect

of SUTVA would be violated if the different versions of treatment were not distinguished in the study. The second aspect of SUTVA would be violated if couples were included in a study and an individual benefitted from an intervention on his/her partner. If SUTVA is violated, each individual in the study could have a different response depending on the version of treatment he or she receives or who else in the study receives that treatment. Such individuals' potential outcomes are unstable and therefore the causal effect is not precisely estimable. The potential outcomes framework is strongly promoted under the assumption that it will provide the surest route to useful public health interventions and policies.

This framework gives priority to thinking about intervening on the world rather than explaining it, to controlling the world rather than understanding it (Kaufman et al., 2003); it has been tied to renewed calls for “consequentialism” (Naimi et al., 2014). An emphasis on action resonates with a progressive strain articulated in the “epidemiology wars” (e.g., Shy, 1997). It addresses the charge that epidemiology had neglected its mandate to focus on actions that will improve the public's health.

The potential outcomes perspective has already had positive effects on the field: it clarified many basic epidemiologic concepts, spurred the development of new methods for confounder control and re-invigorated attention to mediation and interaction. Most profoundly it has legitimated the use of the term “causation” in epidemiology. So much benefit flows from this underlying shift that it is hard to overstate its import.

The potential outcomes framework has moved along a common trajectory of new ideas, from skeptical assessment to acceptance; it is now in the dissemination phase. This framework is currently promoted not only as a way to conduct etiologic epidemiology research but as the *only* way. From a sociological perspective one might say it has gained discursive hegemony. For example, Kaufman et al. (2003) argue that the activity of causal inference from a potential outcomes perspective “... is designed not to describe the world as it exists, but rather how it would change under some defined, generally hypothetical, intervention ... epidemiologists are firmly committed to this activity by virtue of the field being situated within the larger domain of public health. This disciplinary identity fixes intervention as the primary focus of

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epidemiologic research”, p. 2398. Or even more directly, [Hernán \(2005\)](#) dismissed exposures that are not well defined as “fishy causal concepts” of no use to scientists or policy makers. These statements are unambiguous: we must frame our causal questions in terms of well-defined interventions for them to have any relevance.

Adopting this framework represents a fundamental shift that “has implications for how we see the world and ... determine what types of questions can be answered in a useful way for public health purposes and what kinds of questions are beyond our capacity to answer” ([Glass et al., 2013](#), p.3). As the potential outcomes framework becomes branded, disseminated, and implemented, it seems prudent to contemplate the consequences of its adoption for the field. What are the types of questions that are privileged? What are the questions that are left out and what are the implications of their omission? To open the conversation, we pose a provocative claim—that a price may be paid for the clarity that this approach provides, and that price is a conservative articulation of social constructs and a conservative approach to intervention and social change. The potential outcomes framework, while certainly change-oriented in its emphasis on intervention, implicitly embraces and endorses a *particular theory of change* – one that privileges certain actors and types of action, and promotes a particular understanding of “pragmatism,” i.e., possibilities within existing systems. While this theory of change has its place, we argue that the relegation of all other theories of change, and attendant causal questions, to the dust bin of futility may undermine our ability to imagine and prepare for more radical approaches to public health problems.

1. Sources of conservatism

Before substantiating our claim that the well-defined intervention assumption is politically conservative, we need to clearly define our terms. By conservative we mean: “That conserves, or favors the conservation of, an existing structure or system” (Oxford English Dictionary). This can be juxtaposed with “radical,” which is defined as “going to the root or origin; touching upon or affecting what is essential and fundamental; thorough, far-reaching” (Oxford English Dictionary), or “focused on altering social structures” (Wikipedia). As we argue that the potential outcomes framework is conservative, we mean in the precise sense that it is more compatible with public health interventions that conserve rather than challenge existing social structures.

There are three sources of conservatism in the well-defined intervention requirement at the heart of the potential outcomes approach: (1) the direct effect of the requirement itself, (2) the encouragement of “randomized controlled trial (RCT) thinking,” and (3) the relationship that is promoted between research and policy.

1.1. The requirement itself

Narrowly defined constructs more easily meet the well-defined intervention criterion than broad social constructs. One can more easily imagine a well-defined intervention of a low fat diet or some other individual-level target rather than an intervention to reduce neighborhood inequality or corporate greed. Indeed, what makes social factors social is that they violate SUTVA—they are defined in terms of norms, social structures, and human interactions. In the strictest sense, any factor that has human agency is not well-defined as it cannot be a treatment in a randomized controlled trial ([Holland, 1986](#)).

Relatedly, as [Glass et al. \(2013\)](#) note, down-stream causes are more consistent with well-defined interventions than upstream

causes. One way to study social phenomena in a potential outcomes framework is to consider the downstream manipulable mediators of social constructs as the exposures of interest. For example, encouraging reading to children to improve cognitive development is proposed as a manipulable treatment downstream of low childhood SES. Similarly, encouraging employees to adopt better work-life balance is an intervention that more easily meets the “well-defined” criteria than challenging economic class relations. Mediators in this sense are examined as the manipulable intervention targets once again moving the intervention away from structural change. Notably, in the methods literature discussing well-defined interventions, examples most commonly involve providing beneficial factors, such as medication. Harmful factors are more difficult to frame as practicable well-defined interventions. For example, although one could imagine randomly assigning people to smoke cigarettes (although here too the mechanisms through which the assignment would be made would also seem to be important), what we really care about is the effect of removing smoking or preventing people from becoming smokers which must have a more narrowly defined mechanism in place to meet this criterion. For a causal effect to be well-defined and interpretable as an intervention effect would require identifying the mechanism of smoking removal (e.g., advertisements, fines, taxes) ([Greenland, 2005](#)). Thus instead of estimating the effect of smoking we would instead try to estimate the effect of some particular intervention to remove smoking. The well-defined intervention requirement therefore makes it more difficult to study and document the negative consequences of existing social arrangements.

Thus, trying to adhere to the well-defined intervention requirement itself has an elective affinity for more conservative interventions—interventions that are less social, less upstream, less system-changing.

1.2. Encouraging RCT thinking

The goal of the well-defined intervention criterion, in conjunction with exchangeability and positivity, is to create the conditions under which the causal effects we estimate in observational studies can be interpreted as estimates from conditionally randomized controlled experiments. Therefore, RCT thinking is central to this approach. The nature and strength of the idealized RCT is to change one thing while leaving everything else the same. It is about disconnecting human volition and institutional response, about uprooting the individual from the natural world, from social structures. It is about controlled assignment. In contrast, changing systems involves many moving pieces which makes it difficult to isolate one factor from the other. When we change a system, we change everything.

As [Oakes and Johnson \(2006\)](#) note, a hidden principle of potential outcomes is that they should be reasonable; they should focus, in Lewis' terms, on the “closest possible world”. In the neighborhood effects literature, overcoming the barriers to making neighborhoods meet criteria for potential outcomes (exchangeability, positivity, and well-defined intervention) could only be overcome by violating this principle, by “imagining a massive social revolution—what Lewis calls a miracle intervention”, p. 376. RCT thinking dissuades us from such imaginings. Estimating the effect of providing cultural competency training might be consonant with RCT thinking; estimating the effect of institutionalized racism is not.

This leads directly to the third point: the relationship that well-defined interventions encourage between research and policy.

1.3. The relationship promoted between research and policy

The well-defined intervention requirement promotes a tight

relationship between causal questions and policy interventions, narrowing the types of problems to which and the audience to whom our work is addressed.

The tacit principle within epidemiology of studying reasonable potential outcomes moves us to consider interventions that can be developed within what Berk and Rossi (1999) call “policy space”, problems that policy makers see as important, with solutions that seem acceptable. This is one role for epidemiology that is extremely important and useful for strategic science or demand-driven research, i.e., responding to specific intervention questions that often arise after a general policy has been decided upon. This focus has the advantage of developing research that is practicable and is therefore useful within a reasonable time frame. However, it limits the focus to interventions that leave systems intact and change some element that is manipulable without doing “damage” to the system. In other words, it supports conservative policies.

This perspective on the relationship between causal questions and intervention questions also preferentially engages a narrow group of stakeholders — those who make policy or design interventions. This bypasses value-laden questions, much discussed in history, the sociology of science, and the “epidemiology wars” of the 1990’s (e.g., Shy, 1997), about the appropriate audience for our work (Bayoumi and Guta, 2012). Should we primarily address our research to—and identify professionally with—people in positions of power who determine the policy space (Chomsky and Foucault, 2006), or should we direct it toward grassroots social movements that are largely alienated from—and must apply pressure from outside—the policy space? That is, should the knowledge that epidemiologists produce be solely instrumental, helping to promote what is acceptable and practicable, or also be critical? (Burawoy, 2004) We suggest that, particularly with regard to social factors, the well-defined intervention view of “policy relevance” sidesteps these questions, in favor of a narrow consideration of how social policy is developed and how scientific evidence informs this process. The determination of what is relevant and plausible is thus presented as an objective, scientific exercise when in reality it is often also a political calculus.

By framing as valid only practicable interventions, the potential outcomes approach neglects, discourages, and dismisses more radical change. Such radical changes alter systems and structures of wealth distribution, social stratification, racialization, etc., and have myriad, locally relevant, large, fuzzy, and less predictable intervention effects. The well-defined intervention requirement moves epidemiology away from defining and uncovering the public health problems to be solved, to a focus on specific interventions for problems that are already identified, defined, and deemed reasonable by a narrow audience within the policy space.

2. Why Consider Structural Change?

One might well ask why epidemiology should consider structural changes and radical interventions. Conceptualizing, developing, and testing interventions within the policy space is difficult enough. Furthermore, these types of interventions can greatly improve the public’s health. Why is it not enough that epidemiology move toward practicable interventions? What use indeed are “fishy causal concepts”?

We want to give one example to explain why “reasonable” potential outcomes are insufficient. Ilan Meyer, a psychiatric epidemiologist currently at the Williams Institute at UCLA, conducted research for many years focusing on the negative health consequences of stigma and prejudice based on sexual orientation (Meyer, 1995, 2003). Meyer’s work focused on the application and testing of social stress theory to understand whether or not, and through what mechanisms, society’s valuation and treatment of

sexual minorities lead to mental health problems. His work emerged at a time when researchers did not recognize the now-documented fact that lesbians, gay men, and bisexuals have higher disorder prevalence and before public health discourse on health disparities was dominant. He did not (and could not) anticipate that his work would play an important role in the marriage equality debates years later. But in several court cases regarding the constitutionality of restricting marriage to a man and a woman, effectively banning same-sex marriages, his work became pertinent to legal and policy questions. For example, in California’s Proposition 8 trial, his work was cited as evidence of the harm to lesbian and gay individuals affected by California’s constitutional amendment banning gay marriages. This work, together with many other considerations, led the court to rule that banning same-sex marriage violates the U.S. Constitution.

This was not an exposure that was well-defined, the counterfactual was fuzzy, and the exposure was not a well-defined intervention: it could not be conceptualized in terms of an RCT. The evidence was based not on isolation under SUTVA but on explanation. Evidence for exchangeability derived from ruling out alternative explanations. His work on minority stress was not addressed to policy makers and did not provide answers to specific policy questions, instead it served to shape the discourse on health disparities related to sexual orientation defining them as related to social structures (IOM, 2011). The solutions implied by this work were therefore radical: to change the definition and valuing of sexual orientation, to change the public’s perception and understanding, and, as it turned out, to change the institution of marriage, one of the oldest and entrenched institutions in history. Etiologic research such as this, with long-term, broad implications and rippling effects, has policy relevance that is neither guaranteed nor predictable. As Meyer (2014) noted in a recent talk about his work: “this broad approach to policy is consistent with Mechanic and Aiken’s (1986) description of the role of social sciences in policy: ‘to percolate at the perimeters of policy making.’” Health effects will certainly not be the determining factor in these types of changes, but they can be an influential lever.

What is “in the policy space” and what is not, is socially contingent. Sometimes the work has to be ready for the moment, the unpredictable moment in the future when the impossible seems possible, when the system can be moved, when structures can be changed, when the change can be radical and not conserving of the current system (Smith and Joyce, 2012). Does epidemiology not have a role in shaping the agenda, uncovering the unknown causes, naming the problems to be solved, and enlarging the policy space?

3. What is the Alternative to Well-Defined Interventions?

If one accepts the argument that the well-defined intervention assumption is politically conservative, and that limiting discussions of causation to this perspective can have a negative impact on the field, what is the alternative? Clearly it would be a step backwards from all the lessons learned from the potential outcomes framework to retreat to considering only associations. But if the valid estimation of causal effects requires well-defined interventions, then we seem to be stuck. There can be no evidence for structural changes, for social movements, for radically altering existing systems. Are there other approaches to causal inference that do not require well-defined interventions? Here we give of some possibilities for consideration and discussion. These alternatives are examined more fully in (Schwartz et al., 2011; Schwartz et al., under review).

There are counterfactual representations that allow an exposure to be identified as a cause even when the causal contrast does not

tell us what the effect of changing that cause might be. Indeed, we suspect that most causal contrasts actually warrant only this etiologic interpretation. Such causal contrasts help us to identify causes and provide us “with a rationale for wanting to change outcomes” (Glymour and Glymour, 2014, p. 489) even though they do not estimate an intervention effect. This etiologic interpretation is in line with Mackie's (1965) and Rothman and Greenland's (1998) definition of a cause and, we would argue, Pearl's (2014). Developing the identification of causes as a middle ground between surveillance and the estimation of causal effects allows the full force of causal thinking to inform the factors on which we decide to intervene. But the specifics of the interventions and their effects often require much more than the estimates that can come from our studies.

Assessments of randomized controlled trials within the social sciences (e.g., Sampson, 2008; Morgan and Winship, 2015) that emphasize the role of explanation rather than just intervention estimation also offer a way forward. Mediation is used to shore up causal inference rather than to change the intervention target (Hafeman and Schwartz, 2009; Morgan and Winship, 2015). That is, when predictions about mediational mechanisms are supported by the data, the results are not used to suggest that the mediator is the appropriate intervention target but rather give more credence to the entire causal model and its underlying theory. Evidence of mediation shores up our confidence that the exposure hypothesized to work through the mediator was, in fact, a cause.

Based on the identification of causes and accompanying explanation of those causes, we might then ask which way we should push the system to improve health rather than what would be the effect of changing this exposure from one value to another. This requires systems thinking, consideration of multiple outcomes, and unintended, long term consequences. It would imply consideration of multiple efforts for changing the system depending on local social and historical contingencies.

It would seem that this gives us a more realistic perspective on the relationship between the causal effects of our studies and intervention effects. This may be slower, less certain, less immediate (although this remains to be seen) but it will allow us to be better prepared for the moments in the future when policy spaces open.

To be clear, we are not arguing that all or even most epidemiologic research should be conducted in this way. We are only arguing that as the well-defined intervention requirement gains traction, it should not relegate all other types of causal questions to the ocean depths of “fishy causal concepts” or to surveillance or work that is of no use to anyone. There is utility in work within the policy space but work outside the policy space is critical. As Levins (1996) reminds us, it is worthwhile to ask why the world is the way it is and not a little different, (i.e., what RCT analogues ask), but it also necessary to ask why the world is the way it is and not very different.

As Oakes' (2006) explains, “unless one is willing to imagine an alternative world with vastly different socioeconomic forces and constraints,” the well-defined intervention assumption will be intractable for neighborhood effects and other social constructs. We submit that we are willing to imagine such a world, and that the field of social epidemiology should be willing as well.

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