

The potential role for sociologists in designing RCTs and of RCTs in refining sociological theory

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Randomized controlled trials (RCTs) allocate individuals or clusters of individuals to different groups which exposing them to new, existing or no interventions. This allows the testing of hypotheses about resulting differences in outcomes. Randomisation prevents systematic bias in allocation and aims to minimise chance imbalances (though even with large samples, never completely succeeds). Deaton and Cartwright's first key point for a sociological audience is that RCT research should stop at reporting whether a given intervention is effective. Estimates from one population cannot be assumed to apply to others, so RCT findings are not directly generalizable. Deaton and Cartwright suggest many reasons for this; these boil down to the fact that there will be differences between a trial and other populations or settings in the array, prevalence and/or strength of moderators. Moderators are variables that directly measure or act as a proxy measure for some factor modifying the effect of allocation receive an intervention on an outcome. Moderators can explain differences in effect between sub-groups within a trial or explain differences in the effect found in one trial and that found in another trial or that which would be found were the intervention delivered elsewhere.

We have previously discussed this issue using the example of peer-education to reduce transmission of HIV and other sexually transmitted infections among men who have sex with men.[1] Peer-education was reported as effective in reducing infections among men in small US cities during the early 1990s but ineffective for men in a larger Scottish city during the late 1990s. It may have been that the intervention was simply poorly delivered in Scotland, but another reason concerns moderators. In the early 1990s USA, lack of information was very prevalent and within the trial might have strongly moderated intervention effects, so that the least-informed men benefiting most from the intervention. In the later Scottish context, lack of information may have been rarer (so that the overall effect on the intervention was less), and might not have been as strong a within-trial moderator as it likely was in the US (for example, if individuals unaware how to reduce sexual risk were more likely to be guided in risk reduction by sexual partners who were aware) again reducing the overall effect of the intervention. And in the later context, novel moderators might have arisen, such as use of new psychoactive drugs in sexual encounters, which might undermine the benefits of peer education.

Deaton and Cartwright review ways to address this sort of problem so the results of one trial might be more useful in predicting what effects might be found elsewhere. One option is to reanalyse the original trial data, reweighting strata defined by within-trial moderators to take account of different prevalence of moderators in the new context. This requires evidence about prevalence of these factors in the new population. But modelling is much harder where moderators differ not only in their prevalence but in their strength between contexts, or with cases of new moderators. We rarely have evidence about the range of strength of moderators from meta-regressions conducted within systematic reviews. Even where we do, we will not know which point in the range will apply to our new context. For a new moderator, such as new psychoactive drugs in the example above, we might estimate its strength by looking at evidence from observational research, for example about how use of such drugs interacts with knowledge as a determinant of risk of HIV transmission. But this will be largely guesswork because it will draw on research that is not about interventions. Deaton and Cartwright acknowledge that models like these will offer limited predictive power in new settings because they don't theorise how interventions work and how this will vary with context. Hence, Deaton and Cartwright make another key point, that generalisation from RCTs is best made on the basis of theory about context affects intervention outcomes.

But Deaton and Cartwright say little about what such theory should look like. They do not draw a sharp distinction between 'theories of change' that explain specific interventions and 'theories of problem' that explain the occurrence of the phenomena to be addressed. This suggests they see the

task of intervention research as enabling refinement not merely of intervention-specific theories of change, but of more general theories. Just as a drug trial might inform general understandings of physiology or pathology, so can social experiments inform general social theories.

We agree with this implied focus on general theory and think sociology can contribute to this endeavour. Sociology is useful first in defining the appropriate format of theory. Critical realist sociologists view mechanisms as causal processes that can trigger events, not mechanically and unvaryingly, but contingently dependent on interactions with other mechanisms operating in a context.[2] In the realm of evaluation, this has led to interventions being theorised in terms of how the mechanisms that an intervention aims to trigger will interact with context to generate outcomes.[3] Realist evaluators argue that evaluations should test hypotheses about context-mechanism-outcome configurations to assess what works, for whom, under what conditions.

Second, sociology is useful in clarifying what mechanisms involve. Deaton and Cartwright suggest that in the field of economics, from which they draw many of their examples, behaviour is theorised as being enabled or constrained by money. Sociologists would broaden this to theorising agency as being enabled and constrained by various social structures, such as the formal and informal rules and rituals that shape social interactions.[4] This helps to open the 'black box' so that mechanisms are understood as something more than just arrows connecting variables. This should sensitise evaluators to the contingency of mechanisms, dependant not only on context but also the agency of those providing and receiving interventions. Mechanisms are portable concepts that are an indispensable part of causal explanation. They are ontologically distinct from variables and thus amenable to sociological analysis.[5] But drawing on sociology to inform the detailed contents of theory can be challenging. Sociological theory rarely takes the form of abstracted formulations of causal inter-connections between defined phenomena, instead taking the form of: broad views of ontology; thick descriptions of phenomena or processes as ideal types or constellations of meaning; sensitising lenses; or theories of broad processes of historical transformation.[6-9]

In our own field of public health, even when interventions aim to improve health by transforming institutions and systems, interventions often draw on psychological not sociological theory.[10] For example, the Gatehouse Project aimed to reduce adolescent risk behaviours, such as violence and smoking, by rendering schools more participative and engaging. But its underlying theory derived from Bowlby's theory of attachment, substituting the school for the mother and the adolescent for the baby.[11] This sheds little light on institutional mechanisms that might render schools more engaging and healthy.

In contrast, our own RCT of a school-level intervention to reduce bullying and promote healthy behaviours (INCLUSIVE) was inspired by the Gatehouse Project, but drew on the sociological theory of human functioning and school organisation and Bernstein's educational sociology.[12, 13] Drawing on these general theories, INCLUSIVE's theory of change proposed that bringing together staff and students to learn social and emotional skills, review school policies and transform school disciplinary practices would erode 'boundaries' between them, and increase the extent to which schooling was 'framed' around student needs. In turn, this would increase student 'commitment' to school, particularly among socio-economically disadvantaged students, for whom risk behaviours, such as violence and smoking, are enacted partly to generate social status when formal markers of academic status are unavailable. Use of sociological theory improved the intervention, for example by ensuring activities aimed to transform whole-school systems and involved disadvantaged students. It also enabled the trial to examine hypotheses about how mechanisms play out differently in different schools, such as whether the intervention was more effective in schools with more disadvantaged students. This should render the RCT more useful, both for informing public-health decision-making but also in refining sociological theories of how schools engage students: for

example, by exploring whether schools' failure to engage socially disadvantaged students is modifiable as Bernstein's work would suggest, or intractable as the work of Marxist scholars would imply.[14]

The theory of human functioning and school organisation is an example of 'mid-range' sociological theory. Advanced by Merton, mid-range theory aims to understand tractable empirical phenomena (such as schools promoting student health) rather than more abstract concepts (such as the systems beloved of functionalist sociology[7]).[15] Merton and Popper both called for sociology to test such theory by carrying out experiments, but these have not produced lasting programmes of research.[15, 16] What experimentation there has been in sociology has generally not engaged with theory and has waned in recent decades.[17]

There are practical reasons why RCTs will often be unable to assess sociological theories, for example where these focus on political or inter-personal mechanisms or longer-term transformations not amenable to randomisation. However, we think that the example above illustrates that RCTs could play a greater role in assessing and refining some elements of some sociological theories. The reluctance of sociologists to use RCTs might reflect RCTs being wrongly criticised as 'positivist'. Such critiques suggest that trials a) pursue an empiricist strategy of building knowledge solely from sensory data; b) reduce theory to assemblages of variables; and c) fail to recognise that social science must differ from natural science in engaging with how those being researched interpret the world.[18-20] Regarding a), like Deaton and Cartwright, we would advocate RCTs instead being used hypothetico-deductively to test and refine theory. Regarding b), as argued above, we believe that to offer insight and predictions for novel contexts, theory must engage with dynamic, contextually contingent and not directly observable mechanisms. Regarding c), RCTs of social interventions need not restrict themselves to testing hypotheses using quantitative data, but can also include nested qualitative research based on analysis of research participants' interpretations, in the service of refining theories.[12]

Finally, we believe there to be an important role for sociological analysis in designing trials. As Deaton and Cartwright note in their discussion of configurational causation, stratification by subgroup in randomisation can enhance the credibility of moderator analyses. Exactly which subgroups are most salient, especially in complex social systems, is not merely an epidemiological question in respect of heterogeneity in the average treatment effect. Rather, it is a question about how we theorise whether intervention effects will be similar or different between subgroups. All of these relate to a sociological understanding of both intervention and problem.

Like Deaton and Cartwright, we think that trials are often but not always the best way of testing hypotheses concerning the causal effects of social interventions and refining theory about the social world. We would strongly support a greater involvement of sociologists in experimental research on social interventions to ensure trials benefit from the expertise of sociologists in theorising and researching social mechanisms, but also so that RCT evidence can be harnessed comparatively, alongside evidence from other designs, in assessing and refining some aspects of sociological theory. A key trend in the use of evidence to support policy has been a move away from single, definitive trials to comparative learning across trials, whether by meta-analysis and meta-regression or realist synthesis. This trend is useful not just in countering the view that a single RCT can supply the one definitive answer, but also in the opportunities it presents for theoretical development: development that sociologists are well placed to lead.

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