Int J Public Health (2017) 62:841–843
DOI 10.1007/s00038-017-0985-2

EDITORIAL

Population health intervention research: three important advancements

Till Bärnighausen[1]

Received: 13 May 2017 / Accepted: 16 May 2017 / Published online: 6 June 2017

On April 25th, 2016, editors of several major health journals issued the Ottawa Statement from the Sparking Solutions Summit on Population Health Intervention Research (henceforth Ottawa Statement), aiming to promote population health intervention research (PHIR) through editorial actions: issuing calls for papers and developing new journal sections on PIHR; appointing senior editors with expertise in PHIR; building reviewer capacity in PIHR; and encouraging the publication of rigorous PIHR studies irrespective of whether they demonstrated intervention success or failure (Di Ruggiero et al. 2017). The International Journal of Public Health is now endorsing the Ottawa Statement, further strengthening its commitment to publishing and promoting PHIR (Fuller and Potvin 2012; Henschel et al. 2012; Park and Sener 2017; Zota et al. 2016).

The action commitments in the Ottawa Statement are highly laudable and are likely to improve the quantity and quality of publication of PHIR results. However, journal editors could do even more to directly address the specific obstacles that PHIR faces because of its distinct characteristics. First, PHIR takes place in 'real life'. The Ottawa Statement defines PHIR as research that "is not clinical or laboratory-based", implying that PHIR takes place during the real-life delivery of interventions "within or outside the health sector" (Di Ruggiero et al. 2017). Second, PHIR is typically large-scale. The Ottawa Statement defines PHIR as "the use of scientific methods to produce knowledge about interventions that … have the potential to impact the health of populations and health equity" (Di Ruggiero et al. 2017). Ultimately, one of the main purposes of many types of health intervention research is to improve health—and, all else equal, improving the health of one person will also improve the health of the population the person belongs to. Implicit in the above definition of PHIR is thus a focus on research of interventions leading to health impact that is significant at the level of the population. In turn, significance of health improvements at the population level implies that the intervention under study addresses healthcare needs that affect large proportions of people in a population. Even interventions with large impact on health of individuals will be irrelevant at the population level if only few benefit and, conversely, even interventions with small health impact for the individual can lead to substantial population health gains when many are affected. To demonstrate population health impact and establish the distribution of impact across sub-populations, PHIR will thus typically be large in scale. Because of the real-life and large-scale nature of PHIR, the following three advancements could improve researchers' capacity to carry out PHIR.

Advancement I: a new relationship between governments and researchers

On the exposure side, governments' willingness to work with scientists to design policy and intervention strategies could generate powerful new opportunities for strong causal evaluation of population health impact (European Commission 2011; European Commission 2014). Governments could, for instance,

✉ Till Bärnighausen
till.baernighausen@uni-heidelberg.de;
http://www.klinikum.uni-heidelberg.de/PublicHealth

[1] Heidelberg Insitute of Public Health, Heidelberg University Medical School, University of Heidelberg, Im Neuenheimer Feld 130.3, 69120 Heidelberg, Germany

- Give scientists early notice of upcoming policy changes to allow baseline measurement of outcomes prior to the changes
- Start novel interventions earlier in some parts of a country than in others to generate contemporaneous control groups
- Allow randomization of policy innovations—e.g., randomly assign the intensity of a policy or the sequence of policy scale-up—for strong counterfactual analyses.

On the outcomes side, governments could increase the rigor of PHIR by working with scientists to improve the quality of routinely collected data and by making routine data publicly available.

Advancement II: a new framework for research ethics

Tailored ethical standards and oversight mechanisms for PHIR are not available, leaving scientists and governments with three unacceptable alternatives:

- First—forgo important research opportunities
- Second—try to squeeze through an ethical review and oversight process designed for clinical research, in particular for efficacy and safety trials for regulatory approval. The study processes required under this alternative will be unfit for many PHIR projects—e.g., written informed consent from entire populations—and violations of ethical standards are thus likely
- Third—try to circumvent ethical review altogether, e.g. by relabelling genuine research as 'monitoring & evaluation' or 'quality improvement'. Such approaches are likely unethical from the outset and preclude publication and use of the scientific results. A new global framework for ethical design and oversight of PHIR is thus needed.

Advancement III: recognition of the usefulness and causal strength of quasi-experiments and non-traditional experiments

In the view of many health researchers, there are only two categories of studies to investigate intervention impact: experiments—which are able to generate strong causal results—and non-experiments or 'observational' studies—which can only ever hope to suggest, but never prove, causal intervention impact. This view is enshrined in the WHO GRADE guidelines, but it is too narrow and especially limiting in the case of PHIR. Quasi-experiments, such as regression discontinuity or instrumental variable designs, can provide strong causal results and can be very useful to evaluate some types of population health interventions (Bärnighausen et al. 2017; Bor et al. 2014; Langlois et al. 2015; Sovey and Green 2010), in particular those listed as examples in the Ottawa Statement, "housing policies to reduce homelessness, immunization programs, and tax policy that discourages consumption of tobacco" (Di Ruggiero et al. 2017). Similarly, non-traditional experimental designs open up opportunities for rigorous PHIR when more traditional designs are not feasible. For instance, when an 'intervention' cannot be randomly assigned because it is thought to be harmful for health—such as the consumption of sugary drinks—experiments that randomize people to different levels of encouragement to reduce exposure can generate strong causal evidence on population health impact. And when traditional parallel-group designs are not feasible because of political or ethical concerns about withholding an intervention from the control group, stepped-wedge trials provide a feasible alternative, because everyone in the study will receive the intervention over the course of the study (Bärnighausen et al. 2014). Wider acceptance and use of quasi-experiments and non-traditional experiments, such as encouragement and stepped-wedge trials, would open up a range of opportunities for rigorous PHIR.

Expanding on the action commitments in the Ottawa Statement, journal editors could further PHIR through actions promoting the above three advancements—calling on governments to collaborate closely with scientists on policy evaluations and pointing to lost opportunities to learn about population health impacts when policies are implemented without accompanying PHIR; publishing normative articles on research ethics for PHIR; and appointing editors and recruiting reviewers who have expertise in quasi-experiments and non-traditional trials.

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