

***“Study Designs and Analytic Strategies for Environmental and Policy Research on Obesity, Physical Activity, and Diet”***

April 8, 2008, Washington, DC

***Promising study designs for environmental and policy research and evaluation***

Ana Diez-Roux, MD, MPH, PhD. Associate Professor of Epidemiology, University of Michigan

Key points:

- There are different types of evidence, each of which may be relevant depending on what the ultimate goal is (“evidence typology rather than hierarchy”).
- Study design is important, but it is not the only predictor of the quality or relevance of the evidence. Useful evidence can be gleaned from imperfect studies.
- Particularly for policy-relevant questions, external validity is as important as internal validity
- Multiple types of studies are relevant to understanding effects of the built environment on health
- Randomized trials have obvious advantages in terms of confounder control and avoiding unsupported extrapolations that sometimes occur when inferences are drawn from observational studies. Key challenges in applying randomized trials to investigate built environment effects include: (1) What should we randomize to? There is still considerable uncertainty regarding what factors are the most relevant and worth testing in randomized trials. Under these circumstances rigorous observational studies continue to be useful. (2) Feasibility of implementing randomized trial (feasibility of randomization of appropriate units, diffusion or contagion effects, sample size) (3) When a randomized trial is feasible, the conditions may be so “atypical” that generalizability to real-world scenarios may be limited.
- Observational studies often have great flexibility and can be more exploratory. They are most appropriate for initial phases of research. Limitations include (1) the fact that causal inference is sometimes questionable (2) studies generally focus on characteristics on attributes rather than policies or interventions. There is a need for rigorous analytical approaches and sensitivity analyses to potential methodologic problems (e.g. multilevel spatial analyses, propensity score matching, marginal structural models, instrumental variable approaches, sensitivity analyses to exposure definitions). The simplifications and assumptions of observational studies may sometimes be appropriate, we need methodologic work to determine under what circumstances they are and under what circumstances they are not.
- Natural experiments may sometimes allow for improved causal inference. An advantage is that they focus on real world policies /interventions and are therefore of high relevance. A key challenge is developing the partnerships necessary to take advantage of natural experiments in a timely fashion. Sometimes, natural experiments to address the questions of most interest may simply not exist.
- Simulation/systems approaches imply a move from describing associations to modeling the processes that generate them. They allow prediction of effects under conditions different from those observed and accounting for feed back loops and adaptation of people and environments over time. An important caveat is that the validity of the conclusions is contingent on the validity (and realism) of the model. An important additional benefit of simulation approaches is that the process of building these models can highlight policy-relevant areas where we need more data.

Conclusions:

- Complementarity of different types of evidence
- Experimental evidence is not always necessary for action
- Sometimes we need to act in the presence of incomplete evidence (in fact we are already acting...)
- Key is that we learn from the results of these actions

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Recommendations:

1. Draw on (and synthesize) multiple sources of evidence (“Match the question with the design” )
2. Develop systematic ways to capitalize on natural experiments
3. Emphasize both external and internal validity
4. Act on incomplete evidence but evaluate those actions rigorously (e.g. “policy surveillance”)
5. Explore utility of systems/simulation approaches