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Commentary on 'The ecological design'

Lisonkova et al. show an association between a country's preterm birth rate, stillbirth rate and neonatal death rate based on country-level data. This type of study, which presents associations between country-level data rather than individual-level observations, is an *ecological study*. When the research goal is to make inferences about individuals, ecological studies—which do not link observations at the individual-level—are prone to special biases not present in individual-level (e.g. case–control or observational cohort) studies of the same populations (Robinson, *Am Soc Rev* 1950;15:351–7; Goodman, *Am Soc Rev* 1953;18:663–4; Greenland et al., *Am J Epidemiol* 1994;139:747–60; Freedman, *Encyclopedia of Social Science Research Methods*, Los Angeles, CA, USA: Sage Publications; 2004, p. 293). The *ecological fallacy* occurs when one falsely assumes that relationships at the group level hold at the individual level.

Robinson was perhaps the first to outline the limitations of using ecological data to infer individual-level relations. He presented research on state-level data from each of the 48 US states in 1930. Comparing the percentage of the population who are literate (in English) to the percentage of the population who are foreign-born, he found a positive correlation of 0.53. This indicated that states with more foreign-born residents had higher literacy rates, which was true. The ecological fallacy occurs when one draws the conclusion that foreign-born *individuals* are more likely to be literate in English; at the individual level, the correlation was −0.11, with individuals born outside the USA less likely to be literate in English. The ecological correlation of 0.53 occurred because foreign-born individuals were more likely to immigrate to states in which native-born citizens were highly literate.

Ecological studies are practically appealing (Morgenstern, *Modern Epidemiology*. 3rd edn. New York: Wolters Kluwer/Lippincott Williams & Wilkins, 2008; p.511–31) and can sometimes yield important insights about individuals (Greenland, *Int J Epidemiol* 2001;30:1343–50). Furthermore, some (Wen et al., *J Clin Epidemiol* 1999;52:7–12) have suggested that ecological studies may minimise confounding by indication, which occurs when the treatment under study is preferentially allocated to those who need it most and who are therefore at a higher risk of the outcome (Joffe, *Pharmacoepidemiol Drug Safety* 2000;9:37–41). However, in the absence of individual-level data, determining whether aggregate-level associations accurately reflect individual-level relations is notoriously difficult (Greenland et al., *Am J Epidemiol* 1994;139:747–60). The assumptions required for ecological studies to minimise confounding by indication are often heroic, and rarely justified (Joffe, *Pharmacoepidemiol Drug Safety* 2000;9:37–41; Naylor, *J Clin Epidemiol* 1999;52:

1–5). Even if the assumptions needed to minimise confounding by indication are met, confounding in general is more difficult to control in an ecological study (Morgenstern, *Modern Epidemiology* 3rd edn, New York: Wolters Kluwer/Lippincott Williams & Wilkins; 2008, p.511–31). Hence, confirmation of individual-level trends identified using ecological data alone would, at the very least, require additional research based on individual-level data. Ideally, such inferences should be confirmed using *multi-level* data that combine the best of both worlds (Greenland, *Int J Epidemiol* 2001;30:1343–50; Diez-Roux, *Am J Public Health*, 1998;88:216–22; Subramanian et al., *Int J Epidemiol* 2009;38:342–60). When making decisions about individuals, ecological results should be viewed with caution until such confirmation is made. ■

Disclosure of interest

The authors have no conflicts of interest to disclose.

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