Epidemiologic Studies, Warts and All, Are Our Best Chance

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Despite some bad press, epidemiologists are in high demand these days. Epidemiologic studies play an increasingly important role in health policy decisions, and recent legislative developments in the United States—concerning comparative effectiveness research and the regulation of approved drugs—are accentuating this tendency. This issue of EPIDEMIOLOGY includes a collection of invited commentaries that highlight some areas in which observational research is becoming central, along with some crucial challenges.

Hamburg, from the Food and Drug Administration (FDA), describes epidemiologic research as an integral part of FDA activities.[1] Her description of the key role assigned to epidemiologists within the agency may come as a surprise to many who view the FDA as centered around randomized clinical trials. However, one of FDA's goals is to quantify the benefit-risk of approved drugs in real-world settings—a goal often beyond the abilities of randomized clinical trials. As Hamburg explains, epidemiologists need to participate in the development and monitoring of postapproval study requirements and, more generally, in regulatory decision making.

Lauer and Hodes, from the National Institutes of Health (NIH), discuss the decades-long support of epidemiologic studies by NIH, the Agency for Health Research and Quality (AHRQ), the Veterans Administration, and other agencies.[2] They expect this support to increase, given the renewed focus on comparative effectiveness research in recent legislation.

Both commentaries mention some successes of epidemiologic research supported by NIH and the FDA, but some apparent failures also. In particular, Lauer and Hodes[2] offer some cautionary examples about the pitfalls of observational analyses for cardiovascular disease. Interestingly, their examples seem unrelated to residual confounding, the most widely cited weakness of observational studies. Rather, one apparent failure (antiarrhythmic drugs) resulted from equating clinical prediction with etiologic inference and the other (estrogen plus estrogen hormone therapy) was the consequence of using an analytic approach that did not match the goals of the study. Neither example implies a fatal flaw in observational data.

The commentary by Madigan and Ryan[3] presents a recent initiative to improve the analysis of observational data for comparative effectiveness research and drug safety: the Observational Medical Outcomes Partnership (OMOP). OMOP is a private-public collaboration chaired by the FDA and managed through the Foundation for the NIH. OMOP's goal is to compare the performance of various methodologies for drawing inferences from observational databases. Madigan and Ryan describe the ongoing and future research activities of OMOP and invite interested epidemiologists to participate in this initiative.

Finally, Reiter and Kinney[4] tackle one of the greatest challenges in epidemiologic research for health policy: data sharing. Their commentary reviews the relative advantages and disadvantages of various methods to share data without breach of confidentiality. A

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better knowledge of these methods may lead to a more transparent system in which the same observational data can be analyzed independently by several groups.

Epidemiologists have often succeeded at delivering correct answers to questions about the benefit-risk of medical treatments in the real world.[1,2] Appropriate methodologic training[3] and adequate access to high-quality data[4] may help increase the success rate. Because there is no alternative to epidemiologic studies, we better keep improving them.

REFERENCES

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