



Response to Invited Commentary

Roger et al. Respond to “Future of Population Studies”

Véronique L. Roger*, Eric Boerwinkle, James D. Crapo, Pamela S. Douglas, Jonathan A. Epstein, Christopher B. Granger, Philip Greenland, Isaac Kohane, and Bruce M. Psaty

* Correspondence to Dr. Véronique L. Roger, Mayo Clinic, 200 First Street, SW, Rochester, MN 55905 (e-mail: roger.veronique@mayo.edu).

Initially submitted January 7, 2015; accepted for publication January 9, 2015.

In 2013, the National Heart, Lung, and Blood Institute (NHLBI) assembled a working group from its Advisory Council and Board of External Experts to make recommendations to the NHLBI Council about future directions for the epidemiologic study of heart, lung, blood, and sleep diseases. The working group made 7 recommendations to the NHLBI Council and invited a broad dialogue with the scientific communities and all relevant stakeholders (1). The commentary by Vasani and Folsom (2), which expressed general agreement with the recommendations, provided additional perspectives.

CHARTING THE SCIENTIFIC ROADMAP

As Vasani and Folsom noted, the charge from the NHLBI centered on processes. Consequently, the recommendations are intentionally pragmatic. Recommendation 1 is to convene a forum to identify and prioritize the scientific questions to be addressed. We agree with Vasani and Folsom regarding the need to engage relevant stakeholders, including the participants, patients, and their families, in deliberations on future research directions. This engagement is even more critical as data collection migrates to electronic approaches that link study-specific data with electronic medical records and claims, which raise critical privacy and confidentiality issues.

JOINING FORCES WITH OTHERS IS IMPERATIVE

The challenges faced by epidemiologic studies of heart, lung, blood, and sleep diseases are not unique to NHLBI, and Vasani and Folsom support the plea for widespread alliances across the National Institutes of Health and across the broad scientific and stakeholder communities (under recommendation 2). Although the need for resourcefulness and partnerships has been recognized (3), optimizing collaboration across various relevant entities remains a challenge. The current fiscal constraints might catalyze the deployment of such collaborations and partnerships.

BIG DATA AND EPIDEMIOLOGY

Contemporary epidemiology faces an unprecedented proliferation of information, including genomic, proteomic/metabolomic, clinical, societal, and environmental data. Claims data from insurers and clinical data from electronic medical records are increasingly used to ascertain outcomes in cohorts (4). The multiplicity, diversity, and size of data sources generate “big data” challenges. Because the concept of big data elicits a powerful vision of an open door to new information, new connections, and new discoveries, it has generated widespread enthusiasm.

The charge to the working group implied that big data present big opportunities for epidemiology and that seizing such opportunities would yield new discoveries and more efficient science. However, making use of these very large data sets presents numerous highly complex challenges that must be approached deliberately. A constructive critical appraisal is crucial when evaluating the validity and reliability of new data sources and determining how to apply them to epidemiologic research (recommendation 2). Although we agree that epidemiology cannot be reduced to a data-collection science, the information age is fundamentally reconfiguring how research data are defined, generated, collected, and analyzed. Accuracy of measurements and inferential rigor are core components of epidemiologic research, and a robust engagement of epidemiologists in the new field of data science is indispensable to the proper use of big data (5). One example of the imperative for epidemiologists to do so is the misconception surrounding the use of electronic medical records for research. Indeed, migrating to electronic storage does not remove limitations inherent to medical record data, which are collated during health-care events and driven by clinical practice, care-seeking behaviors, and billing needs. Hence, these data remain subject to numerous biases, including incomplete documentation by providers, the economic incentives for selected coding practices, and confounding by indication. Further, as paper records vanish

from hospital and clinics, accessing electronic data for research could become more rather than less challenging and will present new retrieval and privacy challenges that have yet to be fully inventoried and resolved.

Finally, Vasani and Folsom judiciously raise questions about funding strategies in times of constrained resources and underscore the difficulties of measuring return on investment. The cohort consortium (recommendation 6) is envisioned as the operational vehicle to address these issues and navigate these times of transition.

The working group put forth recommendations to the NHLBI Council that recognize the need for constructive dialogue. We are grateful to Vasani and Folsom for contributing to this goal.

ACKNOWLEDGMENTS

Author affiliations: Department of Health Sciences Research, Mayo Clinic, Rochester, Minnesota (Véronique L. Roger); Division of Cardiovascular Diseases, Department of Internal Medicine, Mayo Clinic, Rochester, Minnesota (Véronique L. Roger); Human Genetics Center, University of Texas Health Science Center at Houston School of Public Health, Houston, Texas (Eric Boerwinkle); Division of Pulmonary and Critical Care Medicine, National Jewish Health, Denver, Colorado (James D. Crapo); Division of Cardiology, Duke University, Durham, North Carolina (Pamela S. Douglas); Department of Cell and Developmental Biology, the Institute for Regenerative Medicine and the Cardiovascular Institute, Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania (Jonathan A. Epstein); Division of Cardiology, Department of Medicine, Duke Clinical Research Institute, Duke University Medical Center, Durham, North Carolina, (Christopher B. Granger); Department of Preventive Medicine, Feinberg School of Medicine, Northwestern University, Chicago, Illinois (Philip Greenland); Department of Medicine, Feinberg School of Medicine, Northwestern University, Chicago, Illinois (Philip Greenland); Center for Biomedical Informatics, Harvard Medical School, Boston, Massachusetts (Isaac Kohane); Department of Epidemiology, Cardiovascular Health Research Unit, University of Washington, Seattle,

Washington (Bruce M. Psaty); Department of Medicine, Cardiovascular Health Research Unit, University of Washington, Seattle, Washington (Bruce M. Psaty); Department of Health Services, Cardiovascular Health Research Unit, University of Washington, Seattle, Washington (Bruce M. Psaty); and Group Health Research Institute, Group Health, Seattle, Washington (Bruce M. Psaty).

Conflict of interest: B.M.P. serves on the Data Safety and Monitoring Board for a clinical trial of a device funded by the manufacturer (Zoll Lifecor) and on the steering committee of the Yale Open Data Access project funded by Johnson & Johnson. C.B.G. reports personal fees from Boehringer Ingelheim, Bristol Myers Squibb, Pfizer, Gilead Sciences, GlaxoSmithKline, Eli Lilly, The Medicine's Company, Astra Zeneca, Daiichi Sankyo, Janssen Pharmaceuticals, Salix Pharmaceuticals, Bayer, and Hoffmann-La Roche, and grants from Armethon, Astra Zeneca, Boehringer Ingelheim, Bristol Myers Squibb, Pfizer, Daiichi Sankyo, Janssen Pharmaceuticals, GlaxoSmithKline, Medtronic Foundation, Merck & Co., Sanofi-Aventis, Takeda, and The Medicine's Company. All other authors declare no conflicts of interest.

REFERENCES

1. Roger VL, Boerwinkle E, Crapo JD, et al. Strategic transformation of population studies: recommendations of the working group on epidemiology and population sciences from the National Heart, Lung, and Blood Advisory Council and Board of External Experts. *Am J Epidemiol.* 2015;181(6):363–368.
2. Vasani RS, Folsom AR. Invited commentary: future of population studies—defining research priorities and processes. *Am J Epidemiol.* 2015;181(6):369–371.
3. Khoury MJ, Lam TK, Ioannidis JP, et al. Transforming epidemiology for 21st century medicine and public health. *Cancer Epidemiol Biomarkers Prev.* 2013;22(4):508–516.
4. Virnig B, Durham SB, Folsom AR, et al. Linking the Iowa Women's Health Study cohort to Medicare data: linkage results and application to hip fracture. *Am J Epidemiol.* 2010;172(3):327–333.
5. Khoury MJ, Ioannidis JP. Medicine. Big data meets public health. *Science.* 2014;346(6213):1054–1055.