The Promise of Big Data
Opportunities and Challenges
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Medicine is on the cusp of a remarkable transformative change fueled by the prospect of an acceleration and augmentation in knowledge generation and application. Medicine improved as it transitioned from being based on belief to becoming anchored in science. We were limited, however, in our ability to learn from clinical practice, even though natural experiments were occurring every day. Our methods tended to be reductionist, our data crude, our samples constrained, and our inferences speculative. This inability to learn quickly, easily, and meaningfully from everyday clinical practice is yielding to new capabilities and opportunities.

The shift is occurring as a result of advances in computational power and mathematical applications in concert with a rapid growth in the availability of data. Even changes in the last 5 years have produced breathtaking capabilities. We now have the computational heft to handle large, complex, high-dimensional data. We have mathematical applications that enable us to avoid the need to reduce the complexity of the data, maximizing the relevance of the data to patients seen in practice. And we have just experienced a remarkable advance in data availability through transformation of medical data and documentation into digital format.

A precision medicine future, with the generation of personalized estimates of risk of outcomes and response to various therapies, paradoxically depends on being able to analyze data from massive numbers of people. Only with such numbers can the heterogeneity of risk and response be revealed—and can each individual be understood in the context of the experience of people like them who have preceded them in the situation they are in. The knowledge of individual differences—and similarities—will provide opportunities for truly informed choices based on information that is more relevant, accurate, and meaningful.

To fully leverage this opportunity will require several key steps.

Training
Most researchers are not adequately training for a big data era. The basic principles of epidemiology, study design, and biostatistics, which form the core foundation for most clinical researchers, will remain important, but are not sufficient. There are additional areas of importance, including digital data, informatics, and machine learning. Skills in programming will be a core competency to understand the logic of the programs used to extract information.

Application
The production of the new knowledge is not enough to ensure that benefit is derived from it. The application of the knowledge produced from these data sources and methods will need to be optimized to promote benefit and minimize risk. The culture of medicine will need to evolve from a reliance on old methods of risk stratification, for example, to embrace computer-driven estimates that are linked to methods of producing information about net benefits of different strategies.

Replication
A major challenge of data-driven approaches is to ensure that the findings can be replicated. To depend on the estimates will require confidence that, time and again, they can be reproduced in different data sets, particularly for different subpopulations. The possibility of false-positive inferences—or estimates of risk that are not stable across data sets—is substantial.

Dissemination
The dissemination and communication of the knowledge and methods merits consideration. Our journals are ill-prepared to vet advanced analytics applied to massive data resources. In many cases, the approach may be difficult to evaluate by reviewers and editors. Of note, Circulation: Cardiovascular Quality and Outcomes is committed to finding reviewers, including technical experts, to evaluate novel technical approaches. Moreover, the result may be better suited to a dynamic presentation, rather than the static portable document format. In addition, the visualizations may not lend themselves to the 2-dimensional page. The results of research in this area may be better disseminated as a software product or application, with a paper that describes methods. There will be a need to develop platforms that enable this type of dissemination as part of a scientific contribution. Transparency is also important, even as there may be issues of proprietary algorithms and approaches.

Interoperability
Although data increasingly exist in digital format and provide remarkable opportunities for knowledge generation, obstacles...
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today as the pre-microbiology era was from what preceded
medicine is an information science will begin to spread. These
are likely to derive from work with mathematicians, statisti-
cians, and computer scientists. Such teams will bring together
data scientists and clinical scientists. The recognition that
medicines is an information science will begin to spread. These
tools will need to invest in learning each other’s culture, lan-
guage, and capabilities to forge collaborative activities where
the whole is truly larger than the sum of its parts.

Medicine already lags behind so many fields in its use of dig-
tal data. Our research and research funding is largely anchored
in a model that has been stable for decades. Our meetings and
journals largely remain bastions of traditional research and their
presentation. Our practices on the wards are moving slowly
toward the adoption of truly learning health system approaches.

And yet, we are at one of those amazing junctures in medicine
that will define a new future as profoundly different from
today as the pre-microbiology era was from what preceded
it. We may have the chance to see what was formerly unde-
cipherable. But the hazards of change are also great, and our
ability to tackle these challenges is far from guaranteed. We
will need ways to prove the value of these new approaches and
tools—and they should be subjected to the same scrutiny
as any new diagnostic or therapeutic intervention.

In this issue, we feature an array of insightful articles that
address different facets and applications with respect to big
data methods.2–11

The studies are not just about data size, but about approaching
the data in new ways. The publication of these contributions
signals a receptivity by Circulation: Cardiovascular Quality
and Outcomes to research done with massive data analyzed
in creative ways with important implications for practice and
policy. We are all hopeful that these new directions will yield
benefits for our patients and the public and inspire many of
our readers to consider similar approaches in their own work.
Be assured, research and clinical care are about to join the
digital, mobile, mathematical, personalized revolution. We all
need to ensure that the changes produce progress for people
and society.

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ific advisory board for UnitedHealth; and is the founder of Hugo, a
personal health information platform.

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