A
t the turn of the last century, physicians were largely
guided by lessons passed down in training, their own
personal experience, and the experiences of their colleagues.
Although this approach produced thoughtful clinicians, a
key limitation remained—even the busiest, most experienced
providers could see only so many patients, experience only a
limited number of outcomes, and often struggled to ascertain
the accuracy of diagnoses or the effectiveness of treatment.
These challenges to delivery of safe and effective patient care
were subsequently addressed by a growing focus on progres-
sively larger and better designed cohort studies and random-
ized clinical trials and later by distilling these insights into
clinical practice guidelines and appropriate use criteria to help
summarize the rapidly evolving medical literature.

Despite this exponential growth in well-conducted clini-
cal research, a barrier in applying these studies into clinical
care is that an individual patient may not obtain the average
benefit observed in a clinical trial. It is well recognized that
the heterogeneity of treatment effect across a population can
be obscured by focusing only on the mean treatment effect
in a population.1–3 Depending on a patient’s age, sex, comor-
bidities, and other characteristics, that patient may benefit
greatly from the same treatment that poses a significant risk
for another.4 Providers, after all, are concerned with delivering
the safest and most effective treatment for a particular individ-
ual, rather than a population of patients. Accordingly, a grow-
ing focus has been placed on developing and implementing
tools to identify which patients are likely to benefit from a par-
ticular treatment or strategy, those who may be harmed, and
those for whom balanced risks and benefits exist that should
prompt discussions between patients and providers about that
patient’s goals and preferences for care. To address this need,
there has been a proliferation of published clinical prediction
models to help tailor treatment to risk.

In this issue of Circulation: Cardiovascular Quality and
Outcomes, Wessler et al5 report findings from a rigorous
review of clinical prediction models in cardiovascular disease.
Examining over 20 years of contemporary literature, they found
≈800 models focusing on conditions across the entire spectrum
of cardiovascular disease. In fact, they found that the number
of new clinical prediction models has doubled each decade.
The growth of prediction models is encouraging, as the entire
profession seeks to better understand the outcomes of their
patients and how best to optimize these outcomes. Importantly,
however, they highlight many important challenges, including
the design, development, and testing of prediction models.

With respect to the design of clinical prediction models,
it is critically important that the results of the model would
alter a clinical decision. If a physician will not treat a low- or
high-risk patient differently, then what value is there in using
a model? With respect to development, the methods currently
published are clearly wanting. Only a modest number of publi-
cations reported adequate quantification of the model’s capac-
ity to discriminate the outcome of interest (just 63% reported
a c-statistic) and even fewer reported a measure of calibra-
tion to help readers understand how the model’s predictions
are compared with observed event rates (only 36% reported
a Hosmer–Lemeshow statistic or a calibration plot)—the lat-
ter being critically important in prospectively using models to
tailor treatment to risk. Moreover, only a minority of studies
reported either an internal or external validation of the model.
Another challenge, as the field strives to settle on the best
models for clinical care, is that few models reported—just
3%—compared alternative prediction models.

Perhaps most distressing is the lack of clinical applica-
tion of many of these models. Almost no studies have focused
on the effective implementation of these models in clinical
care—the principal goal of developing such tools. For exam-
ple, although few cardiologists complete a day without using
CHADS2 or CHADS2-Vasc models to predict stroke risk in
patients with atrial fibrillation, there are few studies examin-
ing whether the use of these models improves the outcomes
of patients with atrial fibrillation. One of the few examples of
prospectively using a risk prediction model in clinical care,
that we are aware of, is the use of the American College of
Cardiology’s prediction model for peri-–percutaneous coro-
nary intervention bleeding, which was associated with a 44%
reduction in the odds of bleeding.6,7 Implementing the best
prediction models and demonstrating improvements in care are
clearly a high priority for the profession and an important
step toward precision medicine.

Although the article by Wessler et al5 in this issue, and
the recent Prognosis Research Strategy (PROGRESS)8 and

The opinions expressed in this article are not necessarily those of the
editors or of the American Heart Association.

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Circ Cardiovasc Qual Outcomes is available at
http://circoutcomes.ahajournals.org
DOI: 10.1161/CIRCOUTCOMES.115.002038
Managing severe left main coronary disease, whereas another whose goal is to avoid returning to the hospital for additional procedures may strongly prefer bypass surgery. Using risk models to support these decisions represents the pinnacle of patient-centered care.

All of these potential applications of clinical prediction models demand continued creation and testing of these models. How will these efforts be incentivized and sustained? Although it is possible that some pharmaceutical and device manufacturers may fund these efforts so that they can create tools to support the use of their interventions at the time they publish the results of clinical trials, this has not yet been done. Professional societies, such as the American College of Cardiology and Society of Thoracic Surgeons, have built models, but these have been self-funded by-products of creating risk-standardized methods for comparing hospitals as part of a larger goal of improving quality. Governmental grants are unlikely to support such efforts, and the grant-writing effort often exceeds the workload in developing the models themselves. Although it is possible that models could be licensed and used to generate the resources needed to support their creation, this will prevent widespread access to potentially valuable models. Identifying funding mechanisms that support this important work is necessary for continued progress.

The future of clinical risk prediction models as a driver of more personalized care is promising. To realize this potential, it is critical that the outcomes research community continue to shift its focus from merely describing outcomes to creating models that can support the preferential use of treatments in patients who most benefit, while avoiding use in patients who do not benefit or might even be harmed. This will substantially increase the value of healthcare and is a priority for our field. Although the work of Wessler et al. to assemble and critically evaluate existing models is an important first step, defining how best to disseminate, to implement and sustain the best models is a top priority.

Disclosures

Dr. Spertus owns several patents on the ePRISM technology used to deliver clinical risk prediction models at the point of care and has an ownership interest in Health Outcomes Sciences, a company that distributes and supports the ePRISM software to hospitals. Dr. Salisbury reports no conflicts.

References


**Key Words:** Editorials ■ decision support techniques ■ patient care ■ physicians ■ risk assessment
Realizing the Potential of Clinical Risk Prediction Models: Where Are We Now and What Needs to Change to Better Personalize Delivery of Care?
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Circ Cardiovasc Qual Outcomes. 2015;8:332-334; originally published online July 7, 2015; doi: 10.1161/CIRCOUTCOMES.115.002038
Circulation: Cardiovascular Quality and Outcomes is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 1941-7705. Online ISSN: 1941-7713

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circoutcomes.ahajournals.org/content/8/4/332

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