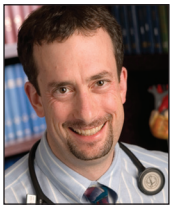
John Spertus, MD

The Clinical Director of Outcomes Research at Saint Luke's Mid America Heart Institute discusses the importance of measuring outcomes, as well as the many benefits of creating and implementing risk models to support a personalized approach to providing health care.



How has Saint Luke's Mid America Heart Institute become a national leader in researching and defining patient outcome measures?

When I came out of fellowship, I was already very interested in patients' experiences with their heart disease. I had developed something called the "Seattle Angina Questionnaire," which patients complete to describe their symptoms, function, and quality of life when dealing with coronary artery disease. When I began looking for a job, I was very impressed that Saint Luke's was already interested in studying and tracking the outcomes of patients undergoing angioplasty. They had a large database, and they wanted to augment it with information about patients' experiences with care. I realized that this would provide a good opportunity to start my research, as it already had an infrastructure in place and was committed to studying patient outcomes.

During the last 18 years, Saint Luke's has continued to strive for a better understanding in terms of what they could do to provide the greatest benefit to patients—in essence, they have always embraced the concept of being a "learning health care system" that continues to better understand its care and to try novel strategies to deliver better care in the future, based upon what they have learned from the past. Thus, our team has been allowed use of the entire health system as a wet lab to come up with better strategies to provide patient care.

It has been an exciting environment to work in because, although I love doing research, I do it because I ultimately want to improve health care delivery and patient outcomes. I found that this was a place where I could bring ideas into practice more rapidly than at very traditional, large, academic medical centers, which typically have a lot more bureaucracy and an ingrained, less flexible culture. Saint Luke's remains a very fertile ground for innovation and working to improve health care delivery, and that is why I ended up here. We've been able to excel due to the culture and commitment of the community, allowing data to drive new opportunities to improve care.

How can trial outcomes research be bridged into real change in the design of future trials?

Randomized controlled trials (RCTs) are considered the gold standard in medical evidence. From these trials, we build guidelines. Our thinking in regard to trial design has evolved in two ways. First, we were concerned that the selection criteria in RCTs may prevent including patients who may derive greater benefits, or risks, from novel therapies. This is why we do a lot of observational registries to better understand the potential benefits of therapies in a broader spectrum of patients. Second, when an RCT is reported, the average benefit across the entire population is conveyed, but not all patients are average. Some patients benefit a lot, and some are actually harmed. As health care changes, and we want to be more cost effective and provide better value to the health care system, we must tailor our treatments to those who benefit the most and not treat those who don't benefit or are harmed. With this approach, we not only save money but also improve outcomes.

With this in mind, I started working with people who conduct clinical trials to model the heterogeneity of treatment benefit and use prediction models to anticipate which patients will benefit most from a specific treatment and who will not. More importantly, we can use those outcomes to engage patients in shared medical decision-making so that they can understand why they are, or are not, being treated; we can be respectful of their personal goals and values. When we choose not to use an expensive therapy, it's not rationing care—it's explaining to people what we are doing, why we are doing it, what benefit we expect them to receive, and sharing in the decision-making process. We believe (and have shown that) this will lead patients to feel much more satisfied with their care.

Do you (or your colleagues at Saint Luke's) currently use the ePRISM tool (Health Outcomes Sciences) in daily clinical practice? What benefits has this tool provided, and what barriers are there to implementing such a system?

The ePRISM tool allows physicians to execute a prediction model (a complex multivariable regression model)

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with patient-specific data to allow us to estimate outcomes for each individual patient. We can use that information to counsel patients, help select treatment, and engage in shared decision-making. This has been a very exciting project and innovation for us because it allows us to provide personalized medicine in routine clinical care. Although there have been web-based tools that have been around for a long time that can also estimate risks from multivariable models, nobody really uses them in routine clinical care; nobody is going to interrupt his or her conversation with a patient to go onto the web and run a tool/calculator. But if we can integrate such a tool into the routine clinical workflow, the data are consistently available as part of providing care to the patient.

We have primarily used this tool to create a new process of obtaining informed consent from patients. Every patient who goes through our cath lab receives a personalized consent form that not only describes the procedure in lay terms, but also embeds that patient's specific risk for bleeding, restenosis with bare-metal versus drug-eluting stents, mortality, and acute kidney injury. The patient is therefore more accurately informed about risks, and the physician can use these risk estimates to provide safer, more cost-effective care.

How can the American College of Cardiology risk-prediction models be applied in hospitals across the United States? What is the best way to disseminate this information and educate physicians in using a more personalized approach to treating their patients?

We have worked with the American College of Cardiology, which for years has built prediction models from its National Cardiovascular Data Registry (NCDR). For example, they have a very good bleeding model that predicts who is at low, intermediate, or high risk for bleeding. Patients who are at high risk for bleeding derive a lot more benefit from bivalirudin and radial access approaches than patients at low risk for bleeding. By running this model for every patient undergoing angioplasty, we know his or her risk for bleeding and can act accordingly. We did some previous work with the NCDR that showed, paradoxically, that physicians preferentially use bivalirudin in patients at low risk for bleeding, who benefit very little from the drug, and did not use it as often in patients with high bleeding risk, who would benefit greatly from the drug. We wanted to reverse that treatment pattern and preferentially treat the high-risk patients and less aggressively treat the low-risk patients.

At Saint Luke's, we recently published our results, wherein we reversed the risk-treatment paradox—preferentially treating high-risk patients more aggressively than low-risk patients—and our bleeding rate went down by 40%, while our hospital saved approximately $200,000 that year. It was gratifying to see that we saved money while improving the safety of angioplasty by using these risk models.

To extend our work, we recently completed a nine-center study of the ePRISM tool, and we reduced the bleeding rate across those nine centers by approximately 45%. This is a very good example of how personalized medicine can be used to improve the safety and cost effectiveness of care.

In terms of helping other hospitals to implement similar practices, we have spun off the ePRISM technology to an outside company, Health Outcomes Sciences, who is helping to offer this approach throughout the country. Approximately 20 hospitals have implemented the ePRISM tools, and some have had amazing results. Some are also extending this process beyond bleeding to address and improve acute kidney injury and stent choice, while others are starting to use different models, outside of cardiology, such as a tool to better treat patients with acute ischemic stroke with thrombolytic therapy. While I think that the ePRISM tool is particularly useful, other homegrown systems are also being developed based on these concepts, although it has been somewhat daunting to integrate these other tools into "every patient, every day."

How can interventionists make more judicious treatment decisions and avoid potential overuse of percutaneous coronary intervention in an environment of increasing focus on transparency and appropriate use criteria (AUC)?

The ePRISM tool is also equipped to run the AUC, and that can be very helpful. These criteria can be used to assist in medical decision making because you can know after angiography, but before angioplasty, that a patient has been deemed "appropriate," "maybe appropriate," or "rarely appropriate" for the procedure. However, there are some limitations to the AUC because you will inevitably come across a patient who is a "rarely appropriate candidate," according to the AUC, but who any competent doctor would treat with angioplasty. This is because the criteria are not refined enough to perfectly measure every patient factor or describe every possible clinical scenario.

Historically, we would treat blockages somewhat reflexively, even if the patient wouldn't benefit much. The AUC then serves to at least give physicians pause to consider whether angioplasty is necessary or if a more conservative medical approach might be the better course of action. In some cath labs, if there is a case that is deemed rarely appropriate but they think it should be performed anyway, they will seek a curbside consult from one of their colleagues to see if they agree. I believe that is a very positive, proactive way of trying to ensure that the benefits of the treatment outweigh the risks.

What types of additional care can be employed to overcome factors that lead patients to not comply with medicinal and follow-up protocols?

One of the benefits of outcomes research is the ability to be creative about how we solve problems. In fact, I see outcomes research for a particular aspect of care having several steps: (1) describing the problem from observational data; (2) conceptualizing strategies to overcome the problem (sometimes this means modeling the heterogeneity of treatment benefit to better identify those who will benefit greatly [or be harmed]), as we did with PCI, and other times it is apparent that all patients may benefit from a different approach to care, and a structural intervention is needed; (3) implementing the strategy to improve care; (4) evaluating whether the intervention did improve care and outcomes; and (5) either refining the intervention or finding ways to disseminate the results so that other health systems—and patients—can benefit.

Improving patient adherence is in the early stages of this process, with ongoing descriptive research and a few interventions being developed. In our own practice, we are considering a range of strategies to address this problem but are just starting to work on this issue now. While we have identified this as one of the major problems that needs to be addressed, we are still searching for answers on how to fix it. We believe that these efforts will be particularly helpful to our health care system, as our hope is to minimize 30-day readmissions and improve transitions in care.

The two areas we are now working on most intensively are the use of dual-antiplatelet therapy after drug-eluting stents and advanced care planning for heart failure patients. For the former, we are starting to develop a shared decision-making tool for patients to choose between bare-metal and drug-eluting stents. Although bare-metal stents increase the risk of having to return for another procedure, they generally require a much shorter course of thienopyridine therapy, which is expensive, leads to increased bleeding and bruising, and can delay elective surgeries. We believe that if we can engage patients in actively choosing a bare-metal or drug-eluting stent after they are informed of their obligations to take dual-antiplatelet therapy, they will be more compliant with therapy because it is their choice to get a drug-eluting stent.

For heart failure, we are planning to implement a risk model that identifies patients being discharged who have a greater than 50/50 chance of dying or never regaining good quality of life. For these patients, we schedule an additional follow-up appointment with a palliative care team for the week after discharge. This "extra" visit will enable our health care team to help patients be more informed of their prognosis and to declare their treatment preferences so that we can better meet their needs.

Although some may be critical of the penalties for 30-day readmission rates from Medicare, I believe that this will challenge the health care system to think beyond hospital discharge to best help their patients, which is a step in the right direction.

What is your goal in training the next generation of outcomes researchers in the Postdoctoral Fellowship Training Program in Cardiovascular Outcomes Research? What are some of the tangible rewards that bring satisfaction to your work?

There is a growing demand, especially in the current environment of health care reform, for those who are able to think creatively about redesigning the way care is delivered for the greatest value. There are a plethora of positions available for cardiologists who are trained to conduct this type of research and have adequate understanding of the strengths and limitations of quality measures. We have a 2-year training program that is sponsored by the National Institutes of Health to train the researchers who can fill this national need.

Our fellows have been unbelievably successful and productive. Normally, a fellow might produce one or two papers over 2 years, whereas ours have been producing between 10 and 20 because there are so many interesting questions, so much data available, and because we have a very dynamic environment to work within. Once our fellows have mastered the skills of outcomes research, they can bring that skillset to other centers that are seeking this type of expertise. It is generally a very tough job market for cardiologists, but not for those with this kind of training because their research is aligned with the clinical mission of many health care systems, and they offer enormous value beyond just their clinical skills. It's very gratifying to see our training fellows move forward and prosper so much.

A great aspect of my job is that when I'm on service treating patients, I can provide hands-on help to 30 to 40 patients a week, and when I'm working on something like the ePRISM tool or a bleeding model, I can help improve the safety and outcomes for thousands of patients. I am passionate about engaging patients in treatment decisions and wisely using resources to maximally benefit all members of society. My work allows me to pursue this dream, and that is why I find it so gratifying. ■

John Spertus, MD, MPH, FACC, FAHA, is Daniel Lauer/Missouri Endowed Chair, Clinical Director of Outcomes Research, Saint Luke's Mid America Heart Institute in Kansas City, Missouri. He has disclosed that he has a small equity interest in Health Outcomes Sciences and owns the copyright for the Seattle Angina Questionnaire and the Kansas City Cardiomyopathy Questionnaire. Dr. Spertus may be reached at (816) 932-8270; spertusj@umkc.edu.