Methods Papers

Commentary on the American Heart Association’s Pharmaceutical Roundtable-Spina Outcomes Center Papers

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Despite the critical role that health services and outcomes research should play in efforts to improve the quality of health care and address the unsustainable escalation in costs, federal support of these efforts has been complicated. Health services research has played a poor cousin to funding of traditional bench and clinical research; whereas the National Institute of Health’s 20041 roadmap emphasized translational research as a focus, and outcomes research as one avenue to achieve results, substantial funding has not followed. The Agency for Healthcare Research and Quality (AHRQ) has been the principal source of funding for investigators seeking support. Although the AHRQ received considerable increases in funding as part of the American Recovery and Reinvestment Act of 2009 and the Patient Protection and Affordable Care Act (PPACA), its history identifies the risk of infusing politics into science.2 The recent debate of the role of health services research and outcomes research as one avenue to diversify the support of research aimed at improving the delivery of health care.

In 2008, the American Heart Association (AHA), with funding from the AHA Pharmaceutical Roundtable (PRT) and a generous donation from David and Stevie Spina (David Spina is an AHA Board member), competitively awarded several large grants to support Cardiovascular Outcomes Research Centers. The purpose of the Outcomes Research Center program was to (1) fund cardiovascular and stroke research focusing on the end results, or outcomes, of health care; (2) provide a training program for health services research fellows; and (3) foster cross-institutional collaboration in cardiovascular care research. The successful applicants were Duke University, Saint Luke’s Mid-American Heart Institute of Kansas City, Stanford University/Kaiser Permente Center, and the University of California, Los Angeles. This issue of Circulation: Cardiovascular Quality and Outcomes includes 2 methods papers from the AHA/PRT-Spina Outcomes Research Centers. Cheng et al,5 from the UCLA/Kaiser Permente Center, report on a randomized, controlled trial (RCT) to improve care in vulnerable patients with recent stroke. Shah et al,6 from the Duke Center, report on an RCT that addresses secondary prevention in patients after acute myocardial infarction.

Several common themes in these studies merit mention. The first is that the investigators have chosen to address the implementation of evidence-based standards of care into practice. Despite professional education, public health campaigns, and direct to consumer marketing, there remains substantial opportunities to improve the use of secondary prevention services in high-risk individuals with cardiovascular disease.7 Realizing that education alone has not closed the gap, these studies test the ability of novel, nonphysician-based support to create sustainable behavior change. The second commonality is the choice of study design. The value of much of what is done in the delivery of medical care has not been subject to rigorous evaluation. These investigators have chosen to undertake an RCT in the real world, that is, using broad eligibility criteria, in real practice settings, with patients who look just like people. Although these types of studies are difficult to implement and manage, their results are much more likely to be generalizable. Third, both RCTs, like many comparative effectiveness trials, use active treatment in the usual care control arm. This design received significant lay and professional attention during the recent health care reform debate and the PPACA appropriates significant funding for comparative effectiveness research.2 Although this approach has substantial benefits in terms of ethical acceptance and generalizability, it also has a major limitation: Care in both the usual care and the intervention arms are complex and multifactorial. If there is a difference in outcomes, it will be impossible to know what worked. However, this is also true in most medical care, and so reflects real-world delivery.

There are notable differences between the two studies as well. The UCLA study addresses secondary stroke prevention in a diverse, low-income, vulnerable population after discharge from Los Angeles County public hospitals. Their novel support structure reflects this environment. The intervention is an adaptation of the chronic care model to a community-based care system and tests the impact that peer education sessions, supplemented with face-to-face care management support and self-management tools (including paper based report cards and,

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in a nod to technology, home blood pressure monitors), have on improving blood pressure control. The Duke study addresses secondary prevention for coronary artery disease in patients discharged from a large, suburban, tertiary-care hospital. Their intervention, which includes web-based educational material and personal health records, reflects the socioeconomic status of this population and is a nod to the future, where we will all be connected to our health through health information exchanges. Although these differences reflect the challenge of improving care in a country as diverse as the United States, both investigators are testing delivery models that implicitly acknowledge that the traditional, labor-intensive care delivery models of today must be tested against scalable, non–physician-based delivery models of tomorrow.

The mission of the AHA is to build healthier lives, free of cardiovascular diseases and stroke. The objectives of the AHA-PRT-Spina Grant, to discover and test new models of care delivery, develop tomorrow’s outcomes researchers, and foster multicenter collaboration clearly support this mission. At the midpoint of the initial grant period, the centers have shown remarkable progress in achieving these goals. One of the clear challenges before the AHA is finding a model that sustains and advances these efforts. The good news is that the success of their initial efforts should make this a less daunting task.

Disclosures

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References

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