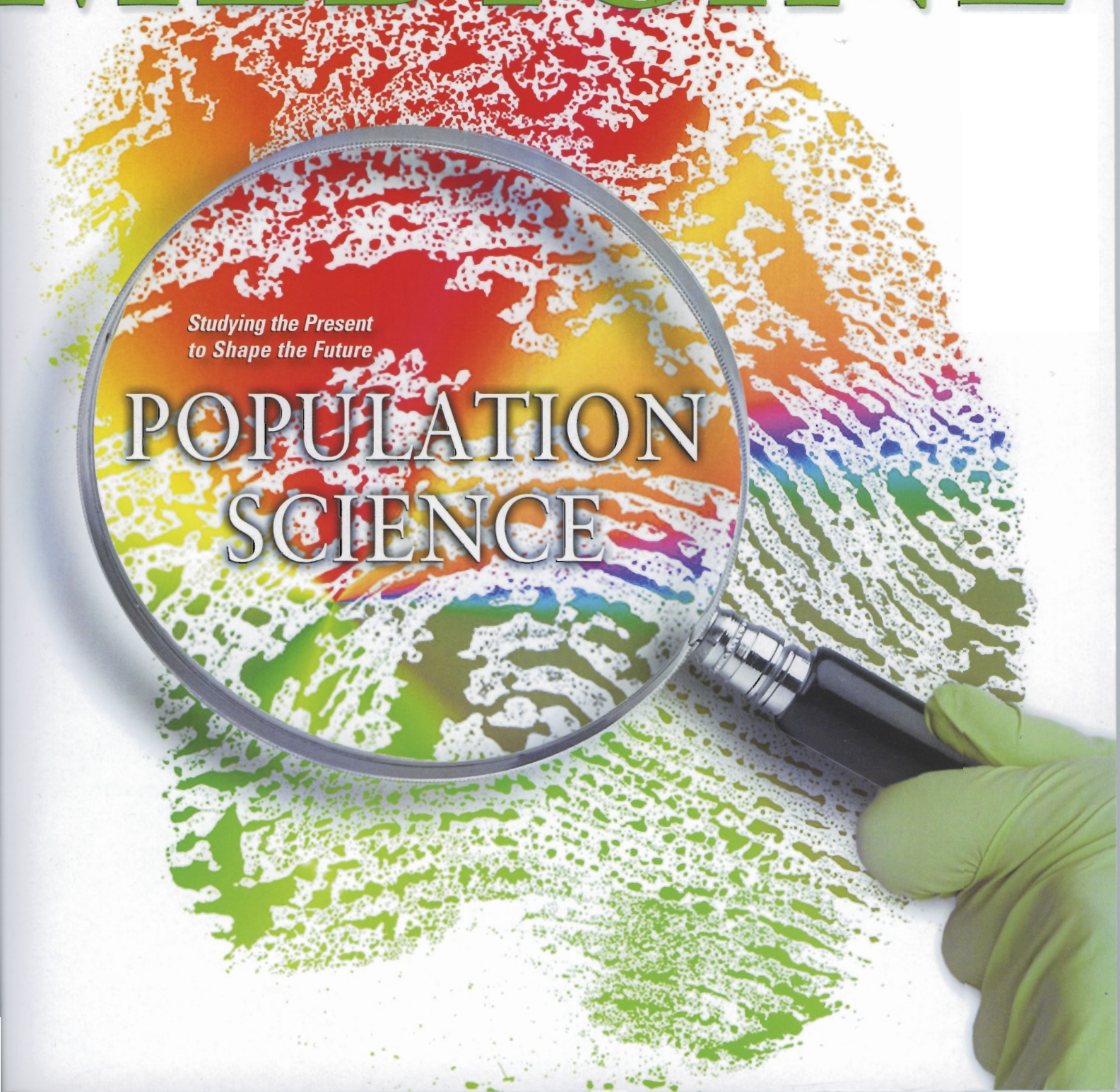
A PUBLICATION FOR ALUMNI & FRIENDS OF UMDNJ-ROBERT WOOD JOHNSON MEDICAL SCHOOL

Robert Wood Johnson MEDICINE

SPRING 2011



Studying the Present to Shape the Future

POPULATION SCIENCE


AABB NEWS
NEJM 2009
NEJM 2009
NEJM 2009
NEJM 2010
NEJM 20
TRANSFUSION

BY
LYNDA
RUDOLPH
PHOTOS BY
JOHN EMERSON

CLINICAL COMPARATIVE EFFECTIVENESS RESEARCH:

How Will It Work, and How Will We Use It?

"Clearly CCER makes enormous sense. The challenge is doing it so we get solid results," says Jeffrey L. Carson, MD, Richard C. Reynolds Professor of Medicine and chief, division of general internal medicine.

As part of the American Recovery and Reinvestment Act, the federal government allocated $1.1 billion for clinical comparative effectiveness research (CCER). The goal of CCER is to compare the effectiveness of different treatments for different illnesses. Although there is no disagreement that there must be a better way to learn what treatments, drugs, and procedures work best, questions surrounding CCER are already stirring the pot in Washington and in academic communities across the country.

"Clearly CCER makes enormous sense," says Jeffrey L. Carson, MD, Richard C. Reynolds Professor of Medicine and chief, division of general internal medicine. "The challenge is doing it so we get solid results." Most physicians agree that CCER is a huge step in the right direction, but the concept has its limits regarding both how it will be implemented and how large a role it will play in decision making.

"As a patient, it's important to know what your options are so you can make the right decision," says Grace Lu-Yao, PhD, MPH, professor of medicine and member, The Cancer Institute of New Jersey.

A NEW INSTITUTE LEADS THE WAY

The logistics of the initiative led to the creation of the Patient-Centered Outcomes Research Institute (PCORI). PCORI is not a government agency but a nonprofit organization, the goal of which is to help patients, clinicians, purchasers, and policy makers reach informed health decisions through the collection and analysis of research related to outcomes, clinical effectiveness, and appropriateness of different treatments and services.

PCORI has a 21-member Board of Governors, including Carolyn Clancy, MD, director of the Agency for Healthcare Research and Quality (AHRQ); Francis S. Collins, MD, PhD, director of the National Institutes of Health (NIH); and 19 additional members who were appointed in September by the acting comptroller general of the United States. The institute is charged with establishing a methodology, ensuring a peer review to assess scientific integrity, providing opportunities for public comment, and making the findings publicly available.

At the national level, PCORI will collaborate with other organizations to determine what drugs, devices, interventions, and procedures should be given highest priority on the CCER list. There are also questions regarding process that are yet to be answered. For example, in what form will the information be shared — meeting the mandate for transparency — while keeping in mind the need for patient confidentiality, and what method will be used to explain the results to the public?

Recent events have reinforced the importance of how the results are communicated. For example, when a new official position about mammographies was made public more than a year ago, the information was released in such a way that it became a spark for inflammatory comments that nearly obscured the important redefined protocol contained in the findings.

SPENDING LESS BUT ACHIEVING MORE

The objective in all of this is to improve health outcomes and help us learn how to spend more wisely. "There are obviously limited resources available for health care. If anything, this increases the pressure to reduce the cost of care," observes Frank Sonnenberg, MD, professor of medicine and director, clinical information systems at The Robert Wood Johnson Medical Group.

Dr. Sonnenberg describes how some diagnostics are ordered without enough reasons, saying, "Sometimes testing is done in physician offices on asymptomatic people without supporting evidence." One of the key problems is misaligned incentives: fee-for-service reimbursement encourages more, not less, spending on testing and procedures.

The fact that profits are based on fees for service rather than on the best care and outcome might seem to be illogical, but it is a long-standing tradition in the U.S. health care system. As a result, there has been a lot of thinking about how to pay physicians differently to promote more effective treatments. Ideas on the table include value-based provider payments, increasing reimbursements for the most effective treatments and for preventive services.

CCER could be used as a guide to determine what should be included in bundled payments. Once bonuses are tied to compliance with CCER-based metrics, the evidence-based practice could become a reality.

Redefining protocols, as well as paying physicians for effective treatments rather than just more treatments, could make a substantial difference in health care costs. The Commonwealth Report — from the private Commonwealth Fund, which promotes high performance in health care — found that if information about clinical and cost effectiveness of alternative treatment options was incorporated into insurance benefit design, it could result in $480 billion in savings over ten years, shared by all payers.

SHARING INFORMATION TO INCREASE EFFECTIVENESS

The ultimate goal of new guidelines as a result of CCER is to increase the use of effective care and decrease the use of ineffective care. Dr. Sonnenberg explains that occasionally — as is the case with Prostate Specific Antigen (PSA) testing and subsequent surgical procedures to remove the prostate — there is controversy about whether the commonly used procedure is beneficial.

"PSA tests have become very widely used to screen for prostate cancer, despite a lack of evidence that there is any long-term benefit, and the testing and treatment may do more harm than the disease," Dr. Sonnenberg says. "Studies have not consistently shown that screening populations with PSA has improved outcomes."

CCER can help determine to what extent procedures such as PSA tests are effective, if at all. This will inform providers so that dollars spent on ineffective care can be eliminated, leaving more to be spent on care that is both necessary and effective.

There are obviously limited resources available for health care. "If anything, this increases the pressure to reduce the cost of care," observes Frank Sonnenberg, MD, professor of medicine and director, clinical information systems at The Robert Wood Johnson Medical Group.

Assuming that giving the appropriate care saves money, how will the consumer look at this new movement? Will it appear that this is not as much about the best procedure or test as it is about the most affordable one? "As a patient, it's important to know what your options are so you can make the right decision," says Grace Lu-Yao, PhD, MPH, professor of medicine and member, The Cancer Institute of New Jersey.

"The most confusion in a patient's life — with potentially the most serious financial implications — typically comes at the point when he or she and his or her family members must make a decision about a path to take to resolve a health problem," Dr. Lu-Yao observes. When options are offered, CCER can make a difference

As a result of research, patients will learn not just the expected outcomes but also how the drug, device, or procedure will affect the quality of life. Even randomized clinical trials (RCT) have not provided that kind of information for patients' decision making. Paradoxically, outcomes evidence is inadequate in 18,000 RCTs published each year. The "end user" has been neglected in evidence collection in the past. "There is no one-size-fits-all in many cases," says Dr. Lu-Yao. "It's important for patients to know what is right for them."

A GAME CHANGER FOR DRUG AND DEVICE DEVELOPMENT

Another, equally important objective of CCER is to eliminate the translational gap in procedural development in health care. Clinicians and scientists agree that 20 years is too long to wait for research to go from bench to bedside. This initiative will undoubtedly change pharmaceutical, medical technology, and biotech businesses by shortening the process for developing drugs, devices, and equipment.

With transparency, there may be more opportunities than ever before for collaborations to develop the right solutions for a given disease or other health problem. On the other hand, CCER could affect the randomness of drug development. Once it is documented that certain drugs or types of devices or equipment are valuable only in nominal situations, it may be difficult to pursue or adopt them.

Given that the methodology and processes are developed with care and in collaboration with key stakeholders, this intersection of science and health care has the potential to advance decision making, inform physicians, transform the creation of drugs and devices, and empower consumers. And that is a win-win situation for everyone involved. M