U.S. HEALTH CARE

The Affordable Care Act as Translational Research

THE HISTORY OF MEDICINE AND PUBLIC HEALTH ILLUSTRATES A RECURRENT THEME: To develop solutions for myriad health problems, scientists must innovate. And the testing of a new product or strategy reminds us that to innovate is to experiment. This maxim forms the core of all medical research, public health interventions, and health policy innovations (1). In October 2013, the United States began the major national implementation of the Patient Protection and Affordable Care Act (ACA) (2)—the most substantial U.S. health care policy innovation since the initiation of Medicare (in 1966) and thus the nation’s largest-ever health care experiment. Here, we discuss the ACA’s role as translational research in order to promote a wider understanding of the role of experimentation in improving health at the public policy level.

A patient who enrolls in a clinical trial of a new drug is assured that the study design was carefully considered and that the study data will be continuously gathered, carefully monitored, and analyzed at prespecified milestones. This covenant matters because the ultimate goal of clinical trials is to improve medical care. The same is true of health policy innovations. There must be assurances that prior learning has been responsibly incorporated into the experiment, that risks are minimized, that there is a plan for analysis, and that there will be reasonably prompt application of the lessons learned.

Still, the notion that public policy innovations are experiments will raise some public anxiety and possibly political headwinds. In this context, it is important to acknowledge that the ACA is an incremental, rather than a radical paradigm-shifting, experiment. Unlike some proposals for health care reform made over the past 100 years, the ACA was built by using the current health care insurance system, with changes targeted at broadening access to health care through expansion of Medicaid and private insurance for individuals and small business owners and by changing how the private insurance market operates, such as prohibiting exclusion of individuals with preexisting medical conditions (2). The ACA also builds on a prior experiment conducted by the state of Massachusetts in its 2006 health care reform legislation, which, in addition to expanding coverage, included the creation of a marketplace (under the ACA, “exchanges”) in which a number of health insurance plans could be compared and purchased by those who do not have employer- or government-based coverage.

Although the ACA makes use of extant components and tested operations, it also uses some new approaches; therefore, the ACA appropriately includes detailed monitoring to determine whether specific features are meeting the goals of the legislation or should be modified. The objective is that the ACA take full advantage of this experimental opportunity to learn important lessons about health care effectiveness, delivery, and cost and to ultimately advance health care and health in the nation (3). Beyond its primary experiment of expanding access to health care, the ACA also includes targeted research projects directed at developing and testing new ways to improve care and contain costs so as to support midcourse improvements in health care delivery. In order to generate such knowledge without subjecting the entire public to radical experiments, the ACA supports local and state-based experimentation through creation of the Center for Medicare and Medicaid Services (CMS) Innovation Center and the Patient-Centered Outcomes Research Institute (PCORI). Both support translational research on the effectiveness and impact of America’s health system on care delivery and the public’s health.

The Innovation Center leverages CMS’s central role as the nation’s largest health care payor by developing and testing new payment and service-delivery models in pilot experiments. Whether for primary or hospital care, or health-system or state-sponsored care delivery, the focus is on identifying mechanisms for improving the coordination, quality, and efficiency of health care services. Examples include the evaluation of Pioneer and Advance Payment accountable care organizations (ACOs), “Right Care” initiatives for patients transitioning out of hospital care, and improvements in the coordination of benefits for patients who are dually eligible for Medicare and Medicaid (4). As a mechanism by
which this research can be translated into practice expeditiously, an important feature of the ACA is that if an Innovation Center pilot reduces cost while maintaining or improving care quality, once certified by actuaries, the U.S. Secretary of Health and Human Services can implement that approach as national policy.

Unlike the CMS Innovation Center, PCORI operates outside of the U.S. government, with a governing board made up of public and private stakeholders. Its research is intended to inform patients, care providers, and the public about the comparative effectiveness of treatments and care strategies, data that can then be weighed in the context of health care decisions. Strategies that demonstrate improvements in the quality, effectiveness, and value of health care then can be translated into widespread use (5).

Among all that might be said about the ACA, why do we point out that it is a translational medicine experiment? We do so because our nation needs a more authentic understanding of the role of experimentation—and translational research—in improving health, health care, and health policy.

Biomedical research is of great interest to, and strongly supported by, the American public (6). Yet, the general public has an incomplete understanding of the research process. We see evidence of this in the premature hopes, concerns, and actions spurred by 24-hour media coverage of early research results presented without adequate context. Perhaps because it does not focus directly on individual illnesses or disease risks, health care delivery research seems less able to capture the public’s imagination, even though access to state-of-the-art care affects all people. Just as medicine is advanced by translational research that turns biological insights into effective treatments, so is health care advanced—and public health improved—by translational research that moves new discoveries from clinical trials to clinical practice to policy development. Only by enhancing public understanding and support of the full spectrum of translational research will health care delivery and policy benefit from careful research and evaluation such as has led to the massive improvements in medical care of recent decades.

How then might scientists and clinicians help to ensure that the public views health policy innovation with the same high regard as that now reserved for conventional biomedical research? One way is to use the current stepwise experiment in improving access to U.S. health care so as to initiate a dialogue about the experimental nature of policy innovation. To this end, we emphasize that (i) across the entire spectrum of the translational research chain, experiments are needed in order to improve medical care and health, including those that improve the functioning of our health system, and (ii) as in all biomedical and health research, health care policy innovations should be built on a foundation of knowledge and experience so that, for individuals and the public, risks are minimized and benefits maximized.

The ACA follows tested approaches used in all clinical and translational research, and we stand to learn a great deal about ways to advance health care and wellness in the United States (3). This experiment deserves the explicit support of all in the biomedical research and clinical communities and, ultimately, understanding and support by the public. Only in this way will our nation truly experience the full promise of biomedical and health care research.

– Harry P. Selker, William H. Frist, Stuart H. Altman

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