Food and Drug Administration, and pertussis experts should begin working on immediately.

In the interim, we need to use the vaccines we have (DTaP and Tdap [tetanus–diphtheria–acellular pertussis]) in the best ways possible. Of particular concern are the frightening rates of complications and death associated with pertussis in unimmunized young infants. The “cocooning” strategy — vaccinating people who have contact with infants — has been implemented but is often impeded by logistics. Immunizing pregnant women is fundamentally sound because it reduces the risk that the mother will acquire tetanus toxoid (i.e., Tdap) could result in increased local reactions.

Another approach would be to start DTaP immunization at a younger age, with shorter intervals between doses. This schedule could be started at birth, and the first three doses could be completed by 3 months of age. Notably, during the period of greatest reduction in pertussis incidence in the United States (1954–1974), the three-dose primary series was completed between 3 and 5 months of age.

In 2012, it is time to recognize the successes of the past and to implement new studies and direction for the control of pertussis in the future.

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Epidemic Pertussis in 2012

Getting the Methods Right — The Foundation of Patient-Centered Outcomes Research

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Health care in the United States has changed dramatically over the past several decades. Today, patients have more options than ever. Making the right choices, whether for prevention, diagnosis, or treatment, requires a critical appraisal of the potential benefits and harms of the options, within the context of the patient’s characteristics, conditions, and preferences.

Many of these choices are available thanks to advances in medical research. Yet most patients and many clinicians find research somewhat mysterious. They have difficulty sorting through the mountains of medical evidence to identify information that is reliable and actionable for their unique circumstances. Patient-centered outcomes research and comparative-effectiveness research promise to enhance decision makers’ ability to fully understand and weigh alternatives. But just as health care interventions and delivery strategies have advanced markedly in recent decades, so have research methods (see table). Without systematic guidance for the appropriate and efficient use of these methods, their rapid growth and complexity will only add to the confusion.
Selected Milestones in Health Care Interventions and Delivery Strategies and in Research Methods.

<table>
<thead>
<tr>
<th>Decade</th>
<th>Milestones in Health Care Interventions and Delivery Strategies</th>
<th>Milestones in Research Methods</th>
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<tbody>
<tr>
<td>1940s</td>
<td>Antibiotic agents (penicillin and streptomycin), kidney dialysis, general anesthesia, radiotherapy, first heart-pump machine, influenza vaccine, Papanicolaou (Pap) smear to detect cervical cancer, cortisone, intraocular lens implants for cataracts</td>
<td>First large-scale, randomized, controlled trial</td>
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<td>1950s</td>
<td>Cardiopulmonary resuscitation, kidney transplantation, vaccination against poliomyelitis, chlorpromazine for schizophrenia, Zeiss fluorescence microscope, antitubercular therapy, cardiac pacemaker, artificial heart valve, successful open-heart bypass surgery</td>
<td>Case–control methodology, Kaplan–Meier survival estimator</td>
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<td>1960s</td>
<td>Charnley’s hip replacement, coronary-artery bypass grafting surgery, heart transplantation, oral contraceptive pill, prenatal diagnosis of Down’s syndrome</td>
<td>Explanatory versus pragmatic trial concept, data and safety monitoring, growth of observational research methods committees</td>
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<td>1970s</td>
<td>Cure for some childhood cancers; neonatal intensive care; computed tomography; coronary angiography; quality measures in health care; ambulatory surgery; vaccinations against smallpox, measles, mumps, rubella, and pneumonia</td>
<td>Cox proportional-hazards model; meta-analysis; ascendency of randomized, controlled trials; statistical stopping rules</td>
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<td>1980s</td>
<td>Insulin therapies for diabetes mellitus, thrombolysis for heart attacks, antihypertensive drugs, magnetic resonance imaging, robotic surgery, permanent artificial-heart implant, deep-brain electrical stimulation system, first laser surgery on the human cornea, hepatitis B vaccine</td>
<td>Propensity score; large, simple trials; prognostic models (e.g., Framingham risk score), growth of decision and cost-effectiveness analyses</td>
</tr>
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<td>1990s</td>
<td>Coronary stents, triple therapy for the acquired immune deficiency syndrome, introduction of biologics, “physician extenders,” facial transplantation, vaccine against hepatitis A, first rotavirus vaccines</td>
<td>Evidence-based medicine, cumulative meta-analysis, reporting guidelines (CONSORT statement), ascendency of registries, electronic health records, Markov chain Monte Carlo sampling for Bayesian inference</td>
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<td>2000s</td>
<td>Human Genome Project completed, drug-eluting coronary stents, FDA guidance on patient-reported outcomes, minimally invasive techniques for surgery, human papillomavirus vaccine to prevent cervical cancer</td>
<td>Trial registration (ClinicalTrials.gov), comparative-effectiveness research, implementation science, large-scale genomic research, reproducible research</td>
</tr>
<tr>
<td>2010s</td>
<td>Genomics, epigenomics, individualized medicine, health information technology, emergence of telehealth, meaningful-use initiatives, Affordable Care Act becomes law</td>
<td>Patient-centered outcomes research</td>
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</tbody>
</table>

* Information on health care interventions and delivery strategies are from Le Fanu.² CONSORT denotes Consolidated Standards of Reporting Trials, and FDA Food and Drug Administration.

On July 23, 2012, the Methodology Committee of the Patient-Centered Outcomes Research Institute (PCORI) released for public comment (http://www.pcori.org/survey/methodology-report) the draft of its first report recommending selected standards for the conduct of research leading to evidence-based, patient-centered health interventions.² These standards underscore the importance of employing the right methods for patient-centered outcomes research. Indeed, a basic understanding, on the part of all health care stakeholders, of the methods underlying medical research findings is essential for several reasons.

First, patients’ health problems are increasingly complex. The aging of the U.S. population has been accompanied by increasing morbidity. The number of Americans who are 90 years of age or older has nearly tripled over the past three decades and is projected to more than quadruple over the next four. With increases in life expectancy at older ages, more people will have chronic health conditions. In 2010, a staggering 147 million Americans — approximately half of all adults — had at least one chronic illness.³ Obesity is now a major health threat. More than one third of adults and almost 17% of young people in the United States were obese in 2009 and 2010.⁴ Obesity increases the risks of many chronic conditions and complicates treatment, because obese patients are at higher risk for the toxic effects of therapies. With older patients who have more complex conditions, and with more complex therapies, the chances of differential responses to the same treatment increase markedly. Unless issues arising from compli-
For research to be meaningful, its methodologic foundation must be scientifically sound and patient-centered — and all stakeholders should be able to gauge the research’s quality and usefulness for decision making.
The federal system of the United States gives states substantial latitude and authority to regulate their economic affairs. With health care having grown from 13.8% of the national economy in 2000 to 17.9% in 2010, state governments have developed a major stake in ensuring that relentless growth in health care spending is controlled more effectively. In Massachusetts, for example, the costs of Medicaid for low-income residents and private health insurance for state employees account for approximately 40% of the state budget. Rising insurance premiums are also dampening wages in the private sector. A recently enacted Massachusetts law that seeks to control health care spending may therefore provide useful policy lessons for other states and the federal government.

Massachusetts is already a well-known venue for health care reform, with state leaders seeking to address two paramount challenges in the health care system.