

reviews that were positive increased substantially from the previous year. And the percentage of students who attended class shot up from about 30% to 80% — even though class attendance was optional.

Evidence is accruing that online instruction is effective and scalable. For example, Stanford's computer science department has shifted several courses to instruction using 10-to-15-minute video segments with embedded quizzes to engage learners and test their comprehension. Professors use class time to challenge students with hands-on exercises, and class attendance has increased substantially. Off campus, three computer science courses, offered free, have been viewed by more than 350,000 enrollees from around the world.

Freeing up class time does seem to make a difference. In a recent study, researchers compared two sections of an undergraduate physics course that had a large enrollment.³ The first section used the traditional lecture model and was taught by a Nobel Prize-winning physicist. In the second section, which was led by

teaching assistants, students grappled with real physics problems as they might be encountered by a practicing physicist. The students in the second, active-learning section were more engaged (as assessed by their course ratings) and more likely to attend class, and their scores on a course test averaged 74%, as compared with 41% among students in the traditional lecture section. A meta-analysis published by the Department of Education has concluded that “on average, students in online learning conditions performed modestly better than those receiving face-to-face instruction,” with larger effects if the online learning was combined with face-to-face instruction.⁴

That's the vision that we want to chase: education that wrings more value out of the unyielding asset of time. There are limits to the amount we can lengthen class periods and the additional homework we can assign, but we can use our limited time in ways that boost engagement and retention. Imagine first-year medical students learning critical biochemical pathways by watching short videos as many times as neces-

sary in the comfort of their personal learning space. Knowledge acquisition is verified by repeated low-stakes quizzes. Then, in class, the students participate in a discussion that includes a child with a metabolic disease, his or her parents, the treating clinician, and the biochemistry professor. The relevant biochemistry — so dry on the page of a textbook — comes to life. The lesson sticks.

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Looking beyond Translation — Integrating Clinical Research with Medical Practice

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One area of amazing recent medical advances has been childhood cancers, for which survival rates have quadrupled over the past four decades and now exceed 80%. This progress has been driven not only by the introduction of novel therapies but also by the remarkable level of patient and physician participa-

tion in the clinical research process. The robust clinical trial enterprise for this patient population may offer a model for improving outcomes in other age groups, populations, and conditions. The success stems largely from the Children's Oncology Group, a cooperative clinical research group that includes more than 5000 U.S.

pediatric cancer specialists. Ninety percent of U.S. children with cancer receive care in centers affiliated with this network, and more than 60% of children with cancer are enrolled in clinical trials. This engagement permits rapid evaluation of new therapies, including delineation of appropriate subpopulations, which

informs both the use of current therapy and the design of future trials.

By comparison, very few adult patients with cancer are enrolled in clinical trials, and there's a lack of meaningful engagement by many key stakeholders, especially patients, community physicians, and health care policymakers. The situation is similar for other diseases: only 5 to 10% of all eligible adult patients are engaged in clinical research, and challenges in recruiting patients delay the completion of many trials. Participation rates are even lower among the elderly, women, and minority groups. The process of generating medical evidence is therefore slow and inefficient. Trials are rarely comprehensive enough to address the many treatment comparisons and clinical decisions that patients and providers must contend with. Moreover, the generalizability of trial insights is often threatened by the narrow settings and populations addressed. In fact, most treatments that patients receive lack adequate scientific evidence of efficacy.¹

Why is the clinical research enterprise — so fundamental to improvements in health outcomes — faltering? The separation of medical practice and clinical research into silos lacking adequate communication is partly to blame. Over the past decade, much has been made of bridging this divide by translating research into practice. Prominent examples of such efforts include the National Institutes of Health Roadmap for Medical Research, the creation of Clinical and Translational Science Awards, and the congressional authorization of the National Center for Advancing Translational

Sciences. These initiatives have facilitated or may yet facilitate many important scientific advances. However, efforts at “translation” often don't make it to broad-scale implementation, and important research findings often fail to be translated into effective care.

To accelerate the pace and spread of scientific discovery, we must look beyond the initial translation and integrate clinical research with medical practice, creating a patient-centered, science-driven health care enterprise. But there are barriers to doing so.

Ironically, academic medical settings are not always conducive to conducting clinical research. In the current economic environment, clinical trials are often seen as a costly distraction from the more lucrative mission of providing care. Absent a strong business case for clinical trials, academic centers have little incentive to invest in robust clinical trials infrastructure, so trials are typically conducted by a few extramurally funded investigators and the requisite systems are disassembled after each study. Instead of having informatics that integrates clinical trials into the fabric of clinical practice, institutions have separate research, accounting, and patient information systems, the use of which adds to the burden of research. Finally, there are cultural disincentives, as reflected in decisions of promotion committees that often value participation in clinical research activities less than basic or translational research.

Community physicians, who care for most U.S. patients, also face disincentives. One important hurdle is gaining knowledge of

the current universe of clinical trials that might benefit their patients. Engaging patients in clinical research — screening them for eligibility, explaining risks and benefits, obtaining consent, and negotiating with payers for coverage of care costs — is time-consuming and inadequately reimbursed, and experience and infrastructure are required for dealing with the regulatory environment. These disincentives have made community physicians reluctant to participate in clinical research, diminishing patient enrollment, threatening the relevance of trial results, and hindering the incorporation of new medical evidence into practice.

Overcoming the erosion of the clinical research enterprise will require major cultural, infrastructural, and economic change² — catalyzed by an informed and engaged public. Cultivating broad-based engagement will require effective use of social media networks and the involvement of advocacy groups and community organizations.

Essential cultural changes include a refocusing of medical education and training on multidisciplinary learning and the integration of clinical care and clinical research into a science of health care delivery. Current conceptual models that separate research from practice would have to be replaced by models combining research and care in a way that benefits present and future patients individually and collectively while protecting fundamental rights.³ Innovative methods for engaging patients and communities in every phase of the research process must be developed and deployed.⁴ Regional and national research networks, similar to the

Children's Oncology Group, could be built, linking community-based physicians with academic centers in a hub-and-spoke model grounded in integrated delivery systems.

Performance metrics must also be changed. Clinicians today are assessed according to the number of tests and procedures performed and the number of patients seen. Researchers are judged by the numbers of grants won and articles published. Neither set of metrics clearly leads to improved health outcomes. Integrated, "learning" health systems would result in novel metrics that focus on improving patient-centered outcomes, but they would also focus on active participation in research by multiple stakeholders to advance the same goals. Clinical departments, collaborating with community-based physicians and patient-advocacy groups, would have to prioritize entering patients in trials, and the value of research would have to be recognized in promotion decisions. This alignment of goals, incentives, and metrics would lead to better, more patient-centered clinical research and boost participation among both patients and clinicians, facilitating further improvements in health status.

Necessary infrastructural changes include the development of new mechanisms for recruiting, informing, and engaging patients using the electronic medical record, social media networks, centralized trial registries, and other means, which could substantially improve the efficiency of research. New research designs, such as

adaptive designs or those relying on Bayesian statistics or cluster randomization, should be studied and promulgated to reduce the patient-recruitment burden by minimizing sample sizes, to permit earlier detection of inadequate benefit in exploratory trials, and to facilitate comparison of care strategies. Improving efficiencies in the launching of trials will require contract offices skilled in negotiating nationally accepted templates for trial agreements, effective institutional review boards, and regulatory expertise. Community research councils will need to be formed to advise health-systems and research sponsors on the appropriateness of clinical research efforts from a patient and community perspective. Unified informatics and data-collection systems will be necessary to meet the needs of clinical research, finance, and patient care, replacing today's duplicate or triplicate systems.

Health care leaders should increasingly recognize the "business case" for this type of integrated learning health system. Health care reform initiatives, such as nonpayment for preventable complications, penalties for readmissions, and bundled payment schemes, will require health care systems to engage clinicians and researchers in understanding, measuring, and analyzing outcomes of the populations they treat. Creating an infrastructure integrating discovery and adaptive clinical research within the delivery system, so as to rapidly inform and improve patient care, will thus come to represent a com-

promising value proposition. We expect that payers will follow suit by adopting coverage policies facilitating patients' enrollment in clinical research and by sharing enrollee databases with health care institutions to permit outcomes analysis.

It's time to look beyond translation. Reengineering the health care enterprise to assimilate these cultural shifts, economic incentives, and necessary infrastructure will require major disruptive transformation,⁵ not simple translation. Anything less will continue to undermine medical advancement and keep us from turning today's biomedical promise into tomorrow's clinical realities.

Dr. Gabriel is chair of the Patient-Centered Outcomes Research (PCORI) Methodology Committee. The views expressed in this article are those of the authors and do not necessarily represent those of PCORI.

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