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Research Meets Practice

by Robin Portman, Kevin Vigilante, and Brenda Ecken

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A nationwide cancer information network could use cross-boundary knowledge to promote a broader base of breakthroughs.

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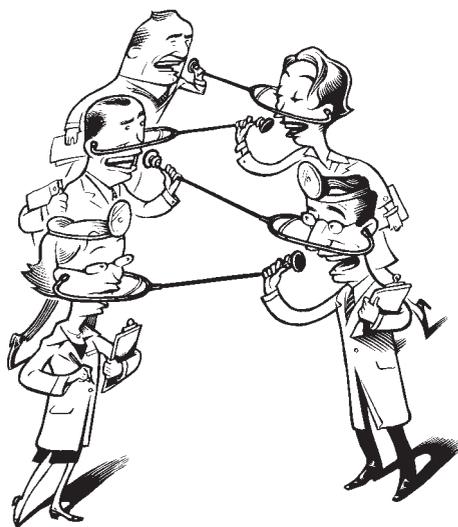
In Seattle and Baltimore, two university-based cancer research teams have competed for years. Isolated from each other, the teams have spent countless hours creating similar software tools intended to mine a variety of genomes for clues to cancer. Now they've each had a breakthrough: The two teams have separately discovered the same gene. But they've given the gene slightly different names, and they correlate it with different functions — one team associates it with the efficacy of a cancer drug, the other sees it as a marker for certain types of brain cancer. Linking these two observations would provide valuable insights for the drug-development process, but barriers to communication, both technical and cultural, prevent that crucial connection from being made.

Another story is unfolding in a small suburb outside Buffalo, N.Y. A cancer patient named William B. visits his oncologist to treat the stage 4 glioma that has invaded the left side of his brain. William asks his Buffalo-based doctor if he is aware of any experimental drugs or re-

search programs that might help him. The physician, already two hours behind schedule with 20 more patients to see before running back to the hospital, stares back at William blankly, says he will look into it, and scribbles a reminder in the paper chart. Of course he never follows up. So William never learns about the clinical trials at an academic medical center in Cleveland, where a doctor — we'll call her Dr. Kelly — is struggling to recruit a sufficient number of glioma patients to test the efficacy of a new investigational drug.

These two stories represent the rule, rather than the exception, in biomedical research. In the first case, expensive redundancy drives up the cost of taxpayer-funded basic research while information silos undermine the potential for scientific collaboration. In the second case, a patient is denied treatment that might have been beneficial while inefficiencies in recruiting research subjects drive up the cost of a clinical trial designed to test a promising new compound.

The second story also illustrates a particularly compelling challenge: how to build stronger links between



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medical research and medical practice. Doctors and their patients desperately need information on the latest therapeutic breakthroughs and clinical trials, but “bench scientists” and research physicians who run clinical trials rarely interact with community physicians. And yet the care that a patient receives represents the end of a long value chain to which each of these individuals, and many others, make important contributions.

Finally, both stories help explain the current stagnation in new drug research. The pharmaceutical industry and the National Institutes of Health (NIH) have each more than doubled their investments in research and development over the last decade. Yet despite this dramatic increase in spending, the number of new chemical compounds submitted to the U.S. Food and Drug Administration (FDA) annually has declined from approximately 45 in 1996 to approximately 25 in 2003, according to a March 2004 FDA report titled *Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products*. The shortfall in biomedical research won't be cured by infusions of cash; we've tried that. What is required is a fundamental change in the way research is conducted.

Collaboration and Communities

The National Cancer Institute (NCI), the lead federal agency for cancer research, is confronting these challenges through a paradigm-changing program called the Cancer Biomedical Informatics Grid, or caBIG. Launched by the NCI's Center for Bioinformatics in 2003, caBIG aspires to create an informatics network that connects cancer

researchers (and eventually all researchers) nationwide — a World Wide Web of cancer research.

Using common standards and an open source approach (one that encourages participants to join in designing and expanding the system), caBIG links data, research tools, scientists, and organizations in a virtual research environment. The goal is to create a voluntary forum in which the sharing of data produces research synergies and speeds the process of discovery. The most significant challenges are not technical, but cultural. For scientists to achieve the vision, former competitors will need to collaborate.

Today, research teams sequester precious data as they race to publish their findings in peer-reviewed journals. Those who publish first, and most often, are rewarded with grants, promotions, and tenure. Although competition certainly encourages productivity, the stagnation in discovery of new chemical compounds suggests that the benefits of isolated research do not outweigh the costs. Therefore, in addition to making information sharing technically feasible, the caBIG designers are seeking to prompt a dramatic cultural change in the cancer research community to make collaboration more likely. This will not occur through goodwill alone; incentives such as grant awards, academic promotion, and tenure are needed to break down the “information silos” that separated those researchers in Seattle and Baltimore.

Now consider the case of William B., the patient in the second story, who is grappling with brain cancer — and a communication breakdown as well, though he doesn't know it. The inability to match William in Buffalo with Dr.

Kelly in Cleveland is both tragic and expensive. Currently, it costs an average of more than \$900 million to bring a new drug to market, with an average clinical trial budget of \$162 million. Approximately 16 percent of the clinical trial budget goes to patient enrollment: finding people like William whose diseases qualify them for participation in the experiments. Pharmaceutical company executives have ranked patient enrollment as the process with the greatest opportunity for improvement in their clinical research enterprise. This perspective is supported by the CenterWatch “State of the Clinical Trials Industry” report for 2005, which estimates that more than half of the delays in clinical trials can be attributed to patient recruitment problems.

Why is it so hard to find patients for trials? Because physicians don’t have the information they need for referrals. Only one-third of patients learn about clinical trials from their primary-care or specialty-care physicians. That’s hardly surprising, given the results of another CenterWatch study — “Will Physicians Refer Their Patients into Clinical Trials?” (March 2004) — in which 58 percent of physicians said they don’t refer their patients because they lack information on the treatment or trial, followed by 30 percent who said they didn’t have enough time to learn about and evaluate the trial, and 28 percent who said they were unsure where to refer their patients.

Intelligent Health-Care Records

Imagine a different scenario for William. Instead of a paper chart, his physician uses an “intelligent” electronic health record (EHR) that links to a research infrastructure

network such as caBIG. Smart applications scan William’s health data and note that he is 53 years old, that his liver and kidney functions are normal, and that his CAT scan reveals a brain mass measuring 4 centimeters in diameter. The biopsy report in the EHR confirms the diagnosis of glioma. The computer then scans a list of current clinical trials in NCI’s databases, whittles it

matched at low cost and almost without friction, but the trial is being monitored remotely without the need for paper files.

The benefits of building this type of intelligence into the health-care records system are obvious. Patients get access to the newest treatments; researchers can conduct trials more efficiently; and those who pay for these trials — largely

Biomedical R&D investments have doubled, while the number of new drugs each year has declined.

down to those relevant to glioma, and further examines inclusion and exclusion criteria for those trials — factors such as tumor size, duration of previous treatment, age, and kidney and liver function. The EHR recognizes that William may be eligible for at least three clinical trials that are still recruiting patients, including Dr. Kelly’s. A message appears on the computer screen in William’s physician’s office, stating William may be eligible for clinical trials at one or more NCI-designated cancer research centers. William’s physician clicks on one of the links, and a user-friendly recruitment process has begun.

Except for one or two trips to Cleveland, William receives his care and experimental medications from his current oncologist near Buffalo. Reports regarding tumor response and side effects of the treatment are automatically extracted from the EHR and sent to Dr. Kelly and the study nurse coordinator in Cleveland for review. Not only have William and Dr. Kelly been

the pharmaceutical industry and the taxpayers supporting NIH — can expect better results at a lower cost. In addition, the available pool of cancer patients for trial recruitment is richer and more easily identified.

Linking community oncologists with the research enterprise will enable them to become true customers of research, giving them ready access to the rapidly expanding body of medical understanding that can improve their practice. It has been well documented that there are disparities between new research evidence, particularly those involving effective medical interventions, and the general state of clinical practice. Outdated therapies persist despite new findings; advances in medical knowledge and treatment capabilities can take years to reach patients.

To be sure, physicians are supposed to base their practice on the evidence of new research studies, as published in the academic peer-reviewed literature. But there are thousands of journals publishing

many thousands of articles each year. It is almost impossible for busy clinicians to keep up with the abundance of new information coming from the scientific community. Physicians are often influenced more by the practice habits of local colleagues in their social networks than by the evidence-based literature. So although evidence-based medicine is the foundation of sound judgment and quality care, there are significant challenges to infusing this evidence into clinical practice.

If practitioners were linked with research networks and cutting-edge evidence, patients (and their insurers) could be reassured that they were receiving the most ap-

start the vision. Dr. Brailer modified existing conceptual frameworks to describe two important concepts that would facilitate the achievement of the president's goals — a national health information network (NHIN) and regional health information organizations (RHIOs). The NHIN can be thought of as a national infrastructure designed to support connectivity and information flow among health-care organizations, professionals, and citizens across the country. RHIOs are the local governance structures that foster EHR adoption and interoperability in communities.

Currently, RHIOs tend to focus on connecting community

flow is important today, it will become even more important as care becomes increasingly customized to an individual's genetic characteristics. Today we create drugs for populations that are differentiated mostly by the disease or condition they happen to have — arthritis, hypertension, elevated cholesterol, non-Hodgkin's lymphoma. For often unclear reasons, drugs work better for some than others and produce side effects that vary from person to person. This variability is probably due in some cases to subtle differences in genetic characteristics of the individuals taking these drugs, and, in the case of cancer patients, genetic differences of the cancer tissue. As research reveals the underlying genetic differences that drive the different responses to the same drugs, compounds that are tailored to the genetic characteristics of individuals will be created.

This will improve drug efficacy and safety while creating challenges in clinical trial recruitment. In the future, our fictional oncologist, Dr. Kelly, may not be looking merely for glioma patients with normal liver and kidney function. She may be looking for glioma patients with certain genetic characteristics. Instead of choosing from the universe of existing glioma patients, which is already a relatively small population, she will be looking for a subset, say the 20 percent of glioma patients with certain genetic characteristics that correlate with a higher response rate to the drug she is testing.

In this environment it will be vital to use national networks to identify patients for clinical trials. Without such networks, the costs of recruitment will continue to climb

Informal social links between physicians and researchers will accelerate the pace of discovery.

propriate care for their medical condition. Evidence-based medicine would also reduce variability in practice and contribute to improvements in the quality of care in other ways. Physicians are more likely to refer patients to clinical trials when research results will be readily shared with the referring physicians.

All of this is technically feasible, and yet, like so many other forms of innovative infrastructure, a "research web" connecting laboratories to community physicians remains a vision for the future. But progress toward this goal is accelerating. In 2004, President George W. Bush called for the widespread adoption of electronic health records by 2014. He also appointed Dr. David Brailer as the national coordinator for health information technology in an effort to jump-

doctors, hospitals, labs, and pharmacies in the service of everyday care. Their role in supporting research is often overlooked.

But it wouldn't take much to extend the RHIO concept to include the creation of "research RHIOs." These local organizations could focus on connecting the network of community caregivers with the network of cancer researchers, using caBIG as their medium. (Of course, these projects would have to be careful to safeguard the privacy of patients and would need to comply with privacy rules mandated by the U.S. government's 1996 Health Information Portability and Accountability Act.)

Personalized Medicine

Although decreasing friction in research and clinical information

and will become increasingly disproportionate to the size of the market for which a given drug is relevant. In some cases, the costs of development will become prohibitive and the drug will not be produced. In other cases, the cost of the drug will be significantly higher than it otherwise would have been, and will create added financial stress for organizations already buckling under the pressures of health-care costs. The promise of personalized medicine will not be fully realized until information networks link researchers with community caregivers and the patients they serve.

Weak Ties, Strong Science

In the process of linking scientists and practitioners through an informatics network, not only is the transfer of information being facilitated, but vital social ties between individuals and social systems that previously had no reliable links are being created. Such “weak links,” or casual and informal social ties and connections, are easily fostered by electronic networks and have been shown to be effective in exposing people to types of information they are unlikely to encounter in their usual social environments.

For example, sociologist Mark Granovetter studied job referrals in the early 1970s and found that attractive opportunities were unlikely to come from close friends and coworkers, who travel in the same social circles. By linking researchers in different “ivory tower institutions” with one another, and then linking them with community-based medical caregivers “in the trenches,” this new network will facilitate a web of weak social ties.

This should be the broader objective of any new research-

oriented electronic network: to enable the sharing of information and knowledge across different disciplines and thus create a more robust network in the research and practitioner communities. Although the Internet has provided a way for highly motivated actors to forge weak social ties with one another, there can be time and effort barriers that make it difficult for beleaguered physicians like William’s doctor to identify researchers doing highly specialized clinical trials. In other cases, as with the research teams in Seattle and Baltimore, information systems that speak different scientific dialects prevent scientists in different social networks from sharing information with one another. Bringing these communities together in the service of science and patients promises to provide synergies in both domains that could not have otherwise been achieved.

William was looking for a simple answer to a simple question: How can science help me live longer? His doctor probably knew that somewhere in the large social system of medical researchers, someone could answer that question, but, unfortunately, he was not aware of a mechanism to find that person. Properly constructed information tools and connections could have provided that answer and linked the researcher with the practitioner. Such episodes of interdisciplinary social linkage can be life-changing for people like William, and over the long term can accelerate the pace of basic scientific discovery. +

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