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ABSTRACT

A shift has taken place in the scientific community in recent years, away from the one-scientist/one-pathway model to Big Science initiatives. The concept of wide-scale collaboration among different disciplines and different institutions has driven the greatest advances. Personalized medicine is the dividend from investment in the most prominent of these Big Science initiatives, the Human Genome Project. But the scope of collaboration to support personalized medicine extends well beyond the scientists, and we must create a web of interaction among all the stakeholders.
In personalized medicine, there is no one organization—nor even one sector of the healthcare enterprise—that can be solely responsible for communications. This article highlights the spectrum of issues that impinge upon adoption of personalized medicine.

IMAGINE THIS SCENARIO

It's Monday morning. I'm at the doctor. I've come prepared with the results of a consumer-provided molecular diagnostic test that shows I have a higher genetic risk of developing Type II diabetes. To make sure my doctor gets a long-term view, I bring the results of traditional lab tests from the last 5 annual check-ups I've had, conducted in a different city, in a competing HMO. I throw my family history on my data stick for good measure. When the doctor arrives, I share all of this, and ask him what I should be doing. He does not have an electronic medical record for me. He does not have easy access to my primary care physicians in the other HMO. He looks puzzled as to why I would get a DNA test sold through the Internet. And he suggests that although my body mass index (BMI) is well within normal range, perhaps I should just lose a few pounds and not worry so much.

That imaginary appointment didn't take place this week, but it may well occur later this month or this year. Today, there are numerous molecular diagnostic products on the market,[1] available to be prescribed by physicians and conducted in CLIA-approved laboratories, or available to pro-active consumers through direct-to-consumer companies. These tests measure an individual's genetic risk for several different diseases, metabolic breakdown of certain pharmaceuticals, or the molecular sub-type and likelihood of recurrence of certain cancers. Also commercialized are several "companion diagnostic/therapeutic products" for identification and treatment of molecularly-defined forms of leukemia, breast cancer, colorectal cancer, and drug resistant forms of breast and colorectal cancer. A pipeline of other genetic biomarkers of potential clinical relevance is being submitted to the U.S. Food and Drug Administration (FDA) in response to the Guidance for Industry Pharmacogenomic Data Submissions that the Agency released in 2005.[2] Some of these biomarkers are likely to be embedded in future diagnostic or drug products.

Molecular Medicine (often referred to as Personalized Medicine), defined as the use of molecular analysis to better manage a patient's disease or predisposition toward a disease, and widely believed to be years away, is on the doorstep of the nation's health care system. Few, if any, traditional players in the life sciences and health care establishment are ready. Some organizations are willing to prepare, but are unsure of what steps to take.

Why has personalized medicine caught the system off guard? Unlike traditional medicine that that is geared to react and respond to the manifestations of a disease in progress, personalized medicine seeks to manage disease before the signs and symptoms appear, or to predict the response to treatment before the treatment is administered. It is a discipline that fundamentally depends on the calculation of risk based on the molecular, genetic, and environmental profile of the patient, as well as the actions

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that must be taken to reduce that risk. Our entire system of health care, including medical education, delivery of care, record keeping, billing, and payment, is based on the traditional model. To adapt to a new model of proactive care will require a transformation of the system and its culture.

In light of the dramatic transformation that virtually all aspects of our health care enterprise will undergo as a result of the shift to personalized medicine approaches, an effective strategy of communications will become the means to accelerate the preparedness of traditional players and the way to help organizations become more aware of and focused on their next steps. Just as the vocabulary, taxonomy, and systems of traditional medicine are evolving, it may be time for traditional communications in health care to give way to a new model, in order to become a key driver in the transition to personalized medicine.

WHY COMMUNICATIONS ARE SO CRITICAL IN THE AGE OF PERSONALIZED MEDICINE

The shift to personalized medicine will include the increasingly collaborative nature of biomedical research, a tighter linkage between basic researchers and clinicians, and a renewed emphasis on risk, predicted outcomes, and proactive care in the practice of medicine. Each of these interwoven trends has put communications at center stage.

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Biomedical research is undergoing a renaissance driven by the convergence of genomics and information technology and changes in the "sociology" of science—that is, the way scientists work together. Starting even before the watershed completion of the human genome sequence in 2003, there has been a rapidly expanding wave of "decoding" information about the genetic underpinnings of human biology and disease. While there exists only a small number of clinical products that can directly link their origins to genomic research, genomics touches upon almost every drug that is in development today, increasing our understanding of its mechanism and effects. Genomics and its conceptual offspring—proteomics, metabolomics, epigenomics, etc.—have become the wellspring of knowledge from which a new generation of health care products will emerge. Much of it is freely and completely accessible, through a plethora of government and academic websites. *The communications challenge: ensure that all who can benefit from these resources are aware of their existence and can find them easy to use. Support the development of standards that encourage interoperability of databases and algorithms.*

The marriage of information technology, medicine, and biology is beginning to bear fruit, making it possible for data to be shared widely and continually shrinking the distances among the global network of researchers and clinicians. The scale of scientific investigation has expanded with networks to link clinical data and phenotypes on thousands to potentially millions of patients and their genotypes with algorithms that can pry patterns from the data and make associations between disease, treatment, and molecular profiles. Actionable knowledge is beginning to emerge that would not have been possible if the data remained in isolated pockets of individual laboratories or in studies of smaller populations. A "web of connectivity" needed to conduct a true translational medicine process from bench to bedside is emerging, exemplified by the National Cancer Institute's cancer Biomedical Informatics Grid (caBIG™) initiative that seeks to connect the entire cancer spectrum of research, clinical, and patient communities.[3] *The communications challenge: ensure that collaborative IT resources attain a critical mass of participation by alerting all potential members of the "global" community. Foster a collaborative culture between research and clinical disciplines.*

Electronic health records (EHRs) will prompt a shift in the way that physicians gain access to and act upon information, in patient awareness and "ownership" of their health care, and in the way disease research is conducted. Government initiatives and legislation are mounting behind the effort to convert all clinical, pathological, and genomic patient information into exchangeable, portable electronic formats. The implementation of EHRs will create a basis for modernizations in the health care system such as e-prescriptions, telemedicine, and personalized medicine. The physician will have at his/her fingertips a wealth of information on the patient, from previous visits, laboratory tests, prescription history, family history, and molecular and genetic profiles. EHRs will also provide the impetus behind a more team-based approach to health care by linking physicians, nurses, pharmacists, clinical laboratories, and other providers in coordinating the care of each patient. *The communications challenge: provide appropriate packaging and delivery of medical information in EHRs to assist the physician in making informed clinical decisions. Facilitate a team-based approach to health care. Encourage health care organizations and physicians practices to adopt EHRs, and legislative initiatives that remove obstacles and provide incentives for adoption.*

Patients may also have easier access and ownership of their own EHRs, and a more comprehensive set of information upon which to make certain healthcare and lifestyle decisions. However, the availability of this information will not necessarily make it easier to understand, as the average consumer will encounter unfamiliar concepts in genetics and other medical data, and will be presented

with information from many, sometimes conflicting sources. *The communications challenge: help the consumer to interpret and act upon information presented in his/her EHR.*

The availability of a uniform system of electronic records on a large population of patients will be a treasure trove for research, particularly if those records contain data from molecular and genetic clinical tests. Many more large scale gene-disease studies will be possible through the linkage of clinical and research data, permitting the discovery of treatments for complex diseases, which could not be easily obtained from the study of smaller populations. *The communications challenge: encourage greater participation of the public in genetics research and improve the flow of information between laboratory and clinic.*

Cost and risk will gain prominence in health care decisions. Health care expenses—now at 16% of GDP—are predicted to wreak havoc on the economy and on our budgets and are believed to be unsustainable. A cultural and political shift may lead to increasing awareness among patients about the cost of their own health care. How much was the MRI, the blood test, or 15 minutes with the physician, and what can I do now to minimize costs later? This awareness may be prompted by restructured payment systems (e.g., high deductible plans), or just the rising costs of traditional plans.

At the same time, risk will become a more ubiquitous concept in health care, particularly with the wider use of molecular and genetic profiling. As a hypothetical example, a person with a 30% risk of developing diabetes can reduce that risk to 15% by following certain lifestyle "prescriptions." Every action we take either raises or lowers a risk. By reducing our risk, we also reduce the cost of our health care. Health Internet sites such as www.yourdiseaserisk.com offered by the Harvard School of Public Health will take your personal data, calculate your risk for a host of diseases, and provide recommendations for what you can do to minimize that risk. The traditional approach of medicine focused primarily on the patient's current health status. Future medicine incorporating molecular and genetic testing will emphasize two major metrics: current health status and current risk. *The communications challenge: the public has generally not understood or applied the concepts of cost or risk in health care, which must now be communicated clearly and in order to frame a public dialogue that is receptive to genetic and other predictive testing as well as to the long term financial and health benefits.*

A medical education gap leaves the health care workforce ill-prepared for the changes to come. Physicians are the gatekeepers in health care decisions, but are generally not equipped with the knowledge or confidence to administer molecular and genetics-based personalized medicine. An anticipated growth in molecular and genetic diagnostic tests will present physicians with a large amount of information upon which to make critical clinical decisions. Concepts of personalized medicine must be incorporated into the medical educational system, from medical schools to continuing medical education courses, yet the current state of medical education has hardly begun to address this issue.[4] *The communications challenge: establish continuing medical education courses to prepare the current workforce and emphasize to medical education institutions the urgency of incorporating personalized medicine as a major component of their curricula for future health care professionals.*

Consumer demand drives a need for reliable information. Seventy million Baby Boomers, now or soon-to-be over age 60, seek to live not just longer, but healthier and more productive lives. When they fully understand and embrace personalized medicine, it will create an unprecedented level of consumer demand. When physicians feel they may incur liability for not offering a test that provides information on optimal care, the impetus toward adoption will be even greater. The Internet has long played a central role in consumer health information, but we are now witnessing the emergence of mainstream investments in Internet-based personal health services, such as Revolution Health. The risk of consumer or physician pull driven by a "free market" of health care information is that personalized medicine tests and treatments could be inappropriately prescribed. *The communications challenge: supporting consumer and physician demand for appropriate adoption of personalized medicine through accurate information and physician training.*

The list above only partially touches upon the financial, ethical, technological, and societal challenges that are converging in personalized medicine. These issues include addressing public concern for genetic privacy and legislative protections against genetic discrimination, communicating health and economic outcomes and benefits to healthcare payers and providers, and advocating for changes in Medicare and private insurer reimbursement to better support molecular diagnostics as the pathway to proactive, preventive medicine. Addressing all of these issues simultaneously in order to reach the ultimate destination of personalized health care is a complex and daunting task.

21ST CENTURY COMMUNICATION STRATEGIES TO MATCH 21ST CENTURY MEDICINE NEEDS

Many of these issues can be addressed by multi-faceted, multi-directional, and timely communications strategies. But what used to work perfectly well in health care communications may no longer be effective.

Table 1
A New Era of Communications

20th Century Communications	21st Century Communications
Print media	Digital media
Monolithic, one-way	Multi-sourced, multi-directional
Static	Dynamic
Authority-driven	Populist or consumer-driven

Traditional approaches to communication relied heavily

on print or broadcast media, usually focused on promoting a product or service. The communication was one way: an authoritative entity such as a corporation, government institution, or non-profit organization would make a judgment as to what the consumer needed to see or hear, and then delivered the message in a non-interactive format.

However, in order to accelerate the transition to personalized medicine, communications must now address not just the product or service, but also the entire spectrum of technological, business, societal, and legal issues. Furthermore, the model of one-way communication has been superseded by a multi-directional approach. Digital media have wrested control of the message from centralized authoritative sources, democratizing information through individual participation in dynamic environments such as interactive websites, blogs, wikis, social networking, and intranets.

In personalized medicine, there is no one organization—nor even one sector of the healthcare enterprise—that can be solely responsible for communications. Some policy organizations have made a yeoman start,[5] but their efforts represent just the tip of the iceberg of what is required.

Just as the biology that we are coming to understand is deeply complex and is organized beyond genes and proteins into intricate, adaptive systems and networks, communications for the new generation of health care must first look beyond mere product support and address a full spectrum of issues related to personalized medicine and make use of dynamic and multi-directional networking. For many, the shift in communication strategy is counter-intuitive: instead of trying desperately to "control" the message to each audience as most academic, government, and commercial organizations now do, it will be better to listen and respond dynamically in order to stay current with what will be a constantly evolving landscape of personalized medicine.

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IMPLICATIONS FOR EVERY CONSTITUENCY IN THE HEALTH CARE SECTOR

Some considerations for the communication strategy of each sector are highlighted below.

Pharmaceutical industry: Few industries have received such bad press and unrelieved criticism. Virtually every media report on the pharmaceutical industry and personalized medicine implies or explicitly states that Big Pharma is apprehensive to move forward because of concerns about market segmentation into genetically defined populations. In response, the industry needs to be clearer about its huge scientific and financial commitment to genomic and proteomic technologies that are driving a new wave of pharmaceutical innovation and how, in fact, the industry is shifting its infrastructure and processes to accommodate the move toward personalized medicine for improved patient care.

Payers: Payers also suffer from an image problem and are widely perceived as dragging their collective feet to fend off the additional expense of a new generation of expensive molecular diagnostics. The truth is far more nuanced, and it includes the fact that while the industry requires outcomes studies demonstrating the cost effectiveness of a new technology, the data on personalized medicine approaches have been quite limited. Payers must demonstrate their commitment to the principles of personalized medicine, while advocating for public-private investment in outcomes studies and regulatory structures that encourage validation of personalized tests and treatments that reach the market.

Physicians: The medical genetics education of physicians, both in medical school and continuing education, is woefully incomplete. This fact is recognized by a small number of education providers and physician organizations, which have initiated programs to address this problem. As good as some of these programs can be, what is really needed is a pooling of resources and a shared vision for transforming medical genetics education across the entire system.

Patient advocates: Building on the model of HIV and breast cancer, patient advocacy groups have become increasingly savvy in both their scientific understanding of disease and their tactics to change policy and practice. Though not initially embraced by traditional health care organizations, these groups have increasingly become valued partners in the work to understand and treat disease. As knowledge of molecular and genetic risk factors grows, it becomes even more critical to have patients empowered by that knowledge so they may help drive adoption of personalized medicine and reimbursement policies that support their cause.

Policymakers: Each of the above stakeholders has a reason to communicate their needs to policymakers. For example, the pharmaceutical industry may have concerns regarding regulation; payers may wish to support more funding for outcomes studies; physicians may request incentives and the removal of obstacles for implementing electronic health records; and patient advocates might push for Medicare reimbursement of new tests and treatments. The policymakers themselves, along with government agencies, need to use strategic communications to integrate the mission and goals of a variety of initiatives supporting personalized medicine and engage in the broadest possible national dialogue on the issues, since large-scale genomics-based studies are very likely to have significant public health as well as individual health implications.

DIRECTING THE FLOW OF INFORMATION: THE NEW MODEL OF COLLABORATIVE HEALTH CARE

In personalized medicine, we have 21st century technology and tools that cannot be adequately delivered in a health care system that has its roots still firmly planted in the mid-20th century. Improving communication flow will be critical to bringing the delivery system up to date—fostering a culture of proactive care, connecting researchers and clinicians, and encouraging adoption of electronic health records. It is not just a matter of promoting products or shared databases, but also reinforcing a shared purpose among industry, policymakers, regulators, insurers, educators, hospitals, physicians, and patients.

A shift has taken place in the scientific community in recent years, away from the one-scientist/one-pathway model to Big Science initiatives. The concept of wide-scale collaboration among different disciplines and different institutions has driven the greatest advances. Personalized medicine is the dividend from investment in the most prominent of these Big Science initiatives, the Human Genome Project. But the scope of collaboration to support personalized medicine extends well beyond the scientists, and we must create a web of interaction among all the stakeholders.

Who is responsible for creating this web of interaction? No entity alone can inform the entire public around genetics and health. No single organization can take on the process of educating a new generation of genetics-savvy physicians. No one company can explain the entire emerging portfolio of diagnostic and therapeutic products. Each and every stakeholder has a role in delivering (and receiving) the message, a responsibility to function organically in a multi-directional flow of knowledge, and an opportunity to challenge and engage in a national dialogue, to achieve public consensus.

Today, in my doctor's office, would be a good place to start.

ENDNOTES

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5. See the Personalized Medicine Coalition (http://www.personalizedmedicine coalition.org), and the the Age of Personalized Medicine (http://www.ageof personalizedmedicine.org)