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IT-enabled personalized healthcare

Improving the science of health promotion and care delivery

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By Jim E. Adams, Edgar L. Mounib and Amnon Shabo

To succeed in transforming healthcare, many countries will need to move to more personalized healthcare (PHC). Successful migration must encourage innovation, provide access to more complete patient information and incorporate advanced clinical knowledge into clinical decision making. Therefore, PHC will require a much more open, robust health information technology (HIT) environment than exists today. We have identified five major HIT-related challenges, as well as recommendations to foster HIT-enabled PHC.

Executive summary

Healthcare systems around the world are making great strides in technological, scientific and clinical innovations. Even so, many countries, even those with reputations for excellent care, are struggling to address increasing costs, poor or inconsistent quality and inaccessibility to timely care. Many believe that fundamental transformation is required for what are becoming increasingly unsustainable healthcare systems.[1]

Three factors contribute to the unsustainability of healthcare: fragmentation, waste and inadequate science for health promotion and care delivery. Issues with fragmentation and waste are indeed daunting; they are a key focus of current U.S. health reform efforts, for example. Receiving less attention is inadequate science – more explicitly, problems involving the science of health promotion and care delivery. These issues impact both quality and costs, with estimates for unwarranted care – just one part of inadequate science – ranging from US$250 to $325 billion per year in the United States.[2] This paper focuses on these inadequate science problems, which present significant barriers to realizing the vision and promise of PHC.

PHC could help address difficulties associated with the science of health promotion and care delivery by using broader and deeper patient information and applying more complete clinical knowledge to help promote patient-centered health and predict, prevent, aid in early detection of, treat and manage diseases. Through improved science, PHC has great potential to improve quality and reduce overall costs of health promotion and care delivery. However, it is incredibly information and knowledge intensive even compared to today's complex needs, which already exceed human cognitive capacity. Access to and appropriate use of burgeoning volumes of patient information and clinical knowledge will require a powerful health information technology (HIT) environment.

A much more open, robust, flexible, standards-based HIT environment will be required to enable personalized healthcare. This environment must be capable of capturing, storing, analyzing and appropriately sharing information about individual patients and patient populations. It must be capable of rapidly generating new clinical knowledge, managing that knowledge and easily incorporating the knowledge into clinical processes and workflows for decision making for health promotion and care delivery.

This environment also must facilitate appropriate interactions among constituents, whether they involve patients communicating with their care delivery teams, communications among care providers or researchers working across traditional organizational, industry or country boundaries. However, these capabilities were not top priorities when today's HIT systems were designed and implemented. Today's systems were designed primarily to facilitate administrative functions such as billing and payments and to automate specific clinical encounters such as a doctor's appointment or hospital inpatient stay.

To realize the vision of PHC, five interdependent HIT-related challenges must be overcome:

1. Lack of an interoperable HIT environment for care delivery and research
2. Prevalence of tightly coupled applications and data
3. Inadequate data and knowledge standards
4. Insufficient analytics capabilities
5. Absence of a clinical decision-making foundation.

These challenges are much more difficult to address than the HIT-related issues associated with healthcare's fragmentation and waste problems. They are also more complex than the IT-related problems faced in other industries. Solutions will require sophisticated use of existing IT-related capabilities, as well as the development of new approaches.

While a robust HIT environment is necessary for PHC implementation, it is certainly not a panacea for success. Other hurdles, including those relating to policy, funding, education and ethics, must also be cleared. However, perhaps the first step is ensuring stakeholders have a clear understanding of PHC and its implications, followed by recognition that it must be a key part of the solution.

"Estimates suggest that as much as US$700 billion a year in healthcare costs do not improve health outcomes. It occurs because we pay for more care rather than better care. We need to be moving towards a system in which doctors and hospitals have incentives to provide the care that makes you better, rather than the care that just results in more tests and more days in [the] hospital."

Peter Orszag, director of the White House Office of Management and Budget, during a National Public Radio interview[3]

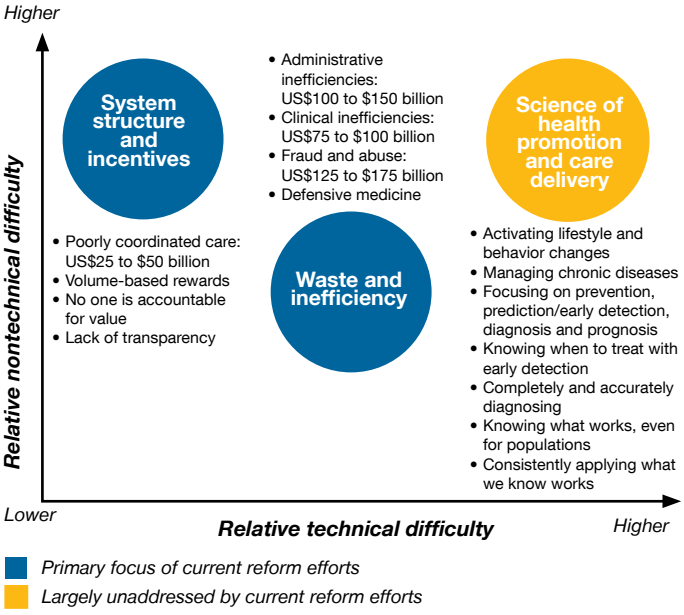
Table of Contents

The need for PHC

Many healthcare systems today are not really "systems" at all. They are fragmented, resulting in poorly coordinated patient care and lack of accountability for overall costs and quality. It's estimated this fragmentation costs the United States US$25 to $50 billion annually.[4] The accompanying lack of transparency into costs and quality makes it difficult to be an informed healthcare services consumer. The U.S. system further exacerbates these problems through a reimbursement system that rewards volumes of procedures, particularly major acute interventions, instead of value.

Many healthcare systems also suffer from tremendous waste (spending that can be eliminated without reducing the quality of care) resulting from clinical and administrative inefficiencies.[5] In the United States, clinical waste includes factors such as inefficient, error-prone, labor-intensive processes (costing US$75 to $100 billion per year); duplicate diagnostic testing due to unavailability of results; and defensive medicine, coupled with high levels of fraud and abuse (estimated to be US$125 to $175 billion per year).[6] And administrative inefficiencies are estimated to cost US$100 to $150 billion per year.[7]

Again, these fragmentation and waste issues are at the heart of current U.S. health reform efforts (see Figure 1). However, this paper's focus is on problems involving the science of health promotion and delivery, which receive far less attention. To achieve affordable, high-value healthcare that can appropriately tailor health promotion and care delivery to meet the needs of each individual – in other words, PHC – these inadequate science problems must be addressed in large part.



Sources: IBM Global Business Services; IBM Institute for Business Value.

Figure 1: **HIT investments addressing structure and waste problems can be beneficial but insufficient to address science problems.**

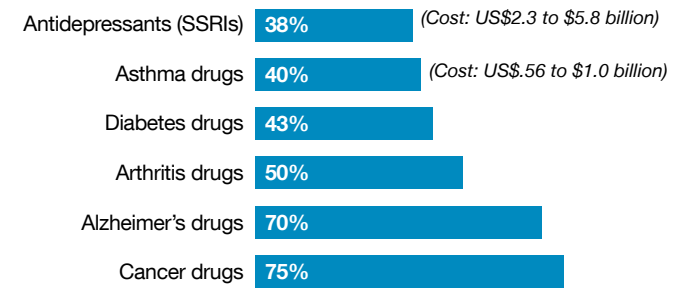
Science of health promotion and care delivery

The problems associated with the science of health promotion and care delivery involve a number of largely unanswered questions:

- *How can individuals be motivated to make better health and healthcare choices?* Some diseases, such as cystic fibrosis or Huntington's disease, can be attributed directly to genetic variations and sometimes to a variation of a single gene. The great majority of disorders, however, such as cardiovascular disease, diabetes or cancer, are caused by complex interplay among multiple genes and nongenetic factors such as lifestyles and environment. Approximately 80 percent of coronary artery disease, up to 90 percent of type 2 diabetes, and 30 to 70 percent of cancers could be prevented or significantly delayed through lifestyle changes such as proper diet, adequate exercise, limiting alcohol consumption and not smoking.[8] Even so, the United States is experiencing a diabetes epidemic with 24 million diabetics and 57 million prediabetics.[9]
- *What can be done to better manage the growing the number of people with chronic diseases?* Chronic disease accounts for about 75 percent of the costs of U.S. healthcare; yet, much of the system remains oriented to providing acute care.[10] Managing chronic conditions requires a number of activities beyond acute care such as coordinating care appropriately among clinicians; ensuring that the right preventive, diagnostic and therapeutic interventions occur at the right time; monitoring and improving patient adherence to treatment regimens; activating lifestyle changes; and monitoring outcomes over time.
- *What can be done to promote a greater focus on and effectiveness of prevention and prediction/early detection both in individuals and throughout the healthcare system?* It is estimated that 56 percent of the chronically ill are not receiving appropriate preventative services.[11]
- *As early detection capabilities improve with tools such as advanced imaging, how does one learn more about which factors detected require treatment or ongoing monitoring and which do not?* For example, researchers are still learning which types of prostate and other cancers need to be treated aggressively and which types can be monitored or treated less aggressively.
- *How can doctors ensure complete and accurate diagnoses?* The rate of diagnostic error is up to 15 to 20 percent, and the cases physicians see as routine and unchallenging are often the ones that end up being misdiagnosed.[12]

- *What can be done to increase knowledge about which diagnostic and therapeutic approaches work in real-world settings?* It is estimated that only about 25 percent of care decisions are supported by evidence – and existing evidence-based knowledge tends to be fragmented and inaccessible.[13] For chronic conditions, prominent researchers estimate that evidence-based guidelines exist for 20 to 33 percent of healthcare spending.[14] Yet only about one-tenth of 1 percent of U.S. healthcare spending is devoted to determining what works best.[15]
- *What can be done to more consistently apply what is known to work?* Despite having only limited clinical knowledge, patients in the United States receive only 50 percent of recommended preventive, acute and long-term healthcare.[16] Additionally, even if perfect and complete clinical knowledge existed to address these questions about the science of health promotion and care delivery, the current health information technology (HIT) environment could not help enable the consistent incorporation of this knowledge into clinical decision making.

A simple example to illustrate the problems with the science of care delivery involves how different drugs affect different individuals. Major drugs are ineffective for many due to differences in the way patients metabolize the drugs and the difficulty of identifying which disease might be causing a particular set of symptoms that are widely shared among multiple diseases (see Figure 2). Drugs designed for Alzheimer's disease, for instance, are effective for just 30 percent of the patient population – but doctors are unable to identify the 30 percent in advance.[17] Prescribing the drugs to everyone identified with Alzheimer's is expensive and increases the risks for side effects. Better clinical knowledge would enable a clinician to say to a patient, "This drug is 100 percent effective for 30 percent of the population and, based on our testing, we know that you are part of that 30 percent."



Source: Spear, Brian B., Margo Heath-Chiozzi and Jeffrey Huff. "Clinical application of pharmacogenetics." *Clinical Trends in Molecular Medicine, Volume 7, Issue 5*. May 1, 2001.

Figure 2: **Major drugs are ineffective for many.**

The fragmentation, waste and science problems contributing to the unsustainability of healthcare systems are related. If improvements are not made in the science of health promotion and care delivery, then other steps might be taken to lower costs, which could negatively affect quality. For example, in an attempt to reduce waste or to address fragmentation by coordinating care, decisions might continue to be made without an understanding of what preventive, diagnostic or therapeutic interventions are the most effective or cost-effective for patient populations or subpopulations. Innovation could also be stifled if decisions are made to not pay for new, perhaps initially more expensive, diagnostic or therapeutic capabilities due to a lack of understanding of the associated benefits or the total costs associated with not paying for the new capabilities (for example, ineffective treatments based on an inaccurate or incomplete diagnosis). In short, improving the science of health promotion and care delivery is critical to high-value health reform but has received insufficient attention thus far.

Information and knowledge: Key for high-performance healthcare system

Better information and knowledge provided in large part through HIT can help address all three sets of factors – fragmentation, waste and inadequate science – plaguing the U.S. and many other health systems. We believe improving the science of health promotion and care delivery will require a much more powerful HIT environment than one required to address the fragmentation and waste factors – but the clinical cost and quality benefits could be considerable. Fortunately, the HIT-related investments made to address fragmentation and waste factors can lay the foundation to continue to improve the science of health promotion and care delivery. For example, the electronic data generated by today's electronic health records (EHRs) can be used to some degree to generate knowledge required for better clinical decision making.

Many countries are investing to improve their HIT environments. In the United States, the Health Information Technology for Economic and Clinical Health (HITECH) Act, part of the American Recovery and Reinvestment Act (ARRA) of 2009, has allocated tens of billions of dollars toward enhancing the HIT environment, particularly implementing EHRs and health information exchanges (HIEs) and supporting comparative effectiveness research to identify what works for which patients under what circumstances.[18] Even though almost all agree that HIT investments are needed, concerns have been expressed relating to different aspects, such as the government's ability to implement the provisions of the HITECH Act, the criteria for physicians or hospitals to receive funding and the benefits that may ultimately accrue.

HIT-related investments addressing fragmentation and waste can lay the foundation to continue to improve health promotion and care delivery.

As governments and organizations invest in HIT, key questions arise, which this study seeks to answer:

- What are the scope of and vision for PHC, and how can PHC improve the science of health promotion and care delivery?
- How does PHC differ from today's predominant health promotion and care delivery approaches?
- How can PHC help address the cost and quality problems with today's healthcare systems?
- Are current HIT-related initiatives and investments sufficient to enable the continued migration to PHC? If not, what key challenges exist and how can they be addressed?
- What are the recommendations for key stakeholders?
- Will the HIT environment being funded by the U.S. HITECH Act enable or inhibit progress toward PHC?

PHC scope and vision

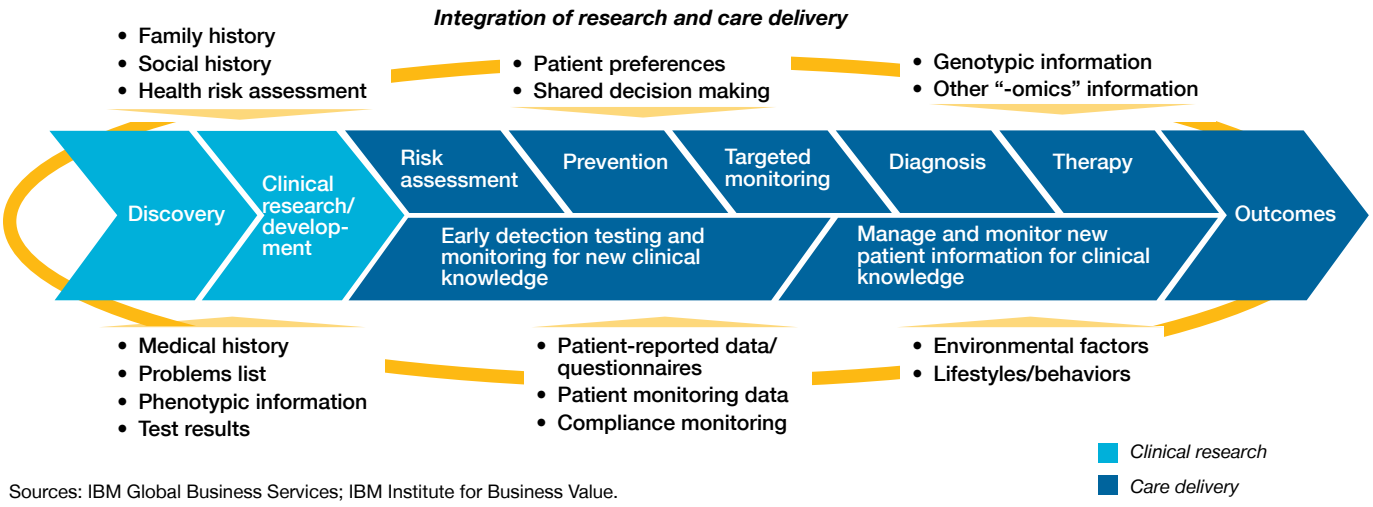
In 2008, the U.S. President's Council of Advisors on Science and Technology (PCAST) defined personalized medicine (PM) as "the tailoring of medical treatment to the individual characteristics of each patient. It does not literally mean the creation of drugs or medical devices that are unique to a patient, but rather the ability to classify individuals into subpopulations that differ in their susceptibility to a particular disease or their response to a specific treatment. Preventive or therapeutic interventions can then be concentrated on those who will benefit, sparing expense and side effects for those who will not."[19]

For this paper, we will use this definition of personalized medicine as a foundation for our broader term: personalized healthcare, or PHC. PHC expands on this PM definition in four key areas. First, PHC is broader than PM in scope. Although diagnosis and preventive or therapeutic interventions for disease are critical in both PM and PHC, PHC also appropriately emphasizes health promotion and ongoing monitoring and management of patients (see Figure 3). These additional areas become increasingly important with the growing prevalence of chronic disease.

Second, PHC is broader than medicine based on "-omics." While PM is frequently and appropriately associated with genomics (the study of genes and their function), proteomics (the study of the full set of proteins encoded by a genome), epigenomics (the study of chemical compounds that modify, or mark, the genome in a way that tells it what to do, where to do it and when to do it) and other types of "-omics," much can and needs to be done, as we will discuss later, to personalize healthcare as knowledge of "-omics" expands.[20]

Third, PHC requires closely linked research and care delivery. Clinical knowledge must continuously be generated, managed and appropriately incorporated into future decision making both for the individual and for similar patients and individuals. Also, clinical data must be appropriately and securely available for research to advance the understanding of disease and treatment outcomes.

Fourth, it must be participatory – individuals must be strong participants in their own health and healthcare. The interplay of multiple factors affects an individual's health, including lifestyles and behaviors, unique human biology or genetic makeup, the environment and medical care received. Individuals make many health-related decisions outside the clinical care setting, such as lifestyle choices or whether to adhere to treatment regimens. Additionally, individuals should participate appropriately in some clinical decisions through mechanisms such as advance directives or shared clinical decision making for conditions for which there is no one best treatment option.



Sources: IBM Global Business Services; IBM Institute for Business Value.

Figure 3: **PHC tailors preventive, predictive, diagnostic and therapeutic activities to the specific characteristics of each patient.**

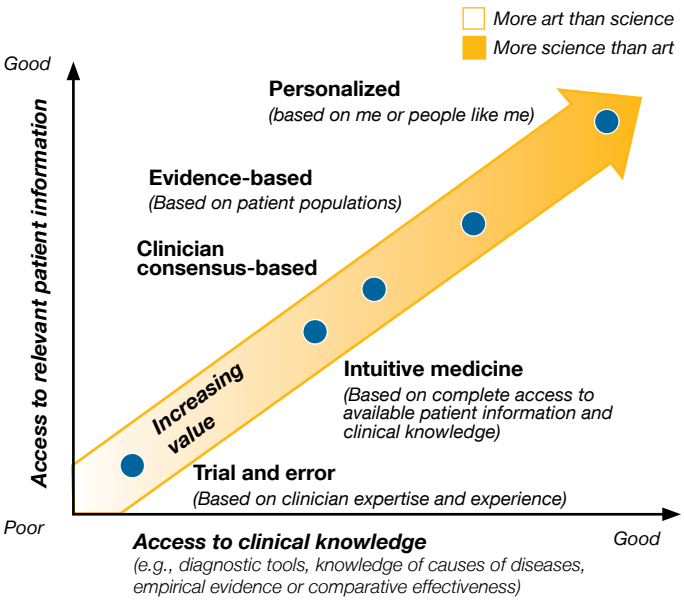
In short, PHC helps address the problems with the science of health promotion and care delivery by using more individualized patient information and clinical knowledge to help promote patient-centered health and predict, prevent, aid in early detection of, treat and manage diseases.

Delivering PHC

Very little health promotion and care delivery today would be considered PHC. Good decisions by patients and clinicians about health promotion and healthcare depend heavily on two critical factors: access to relevant patient information and the ability to apply the best clinical knowledge. The first includes a broad array of information, such as a patient's family history, lifestyle, previous medical history, personal preferences and – increasingly – individual genetic information. The second involves knowledge that has been gained about how to promote health, prevent disease, predict risk, diagnose completely and correctly, and treat and manage patient conditions successfully.

Unfortunately, medicine generally has been practiced with far too limited availability of both patient information and clinical knowledge. It is helpful to visualize the evolving practice of medicine toward PHC as illustrated in Figure 4. The large diagonal arrow indicates a progression from practicing medicine based on the knowledge and experience of individual practitioners; through intuitive or consensus-based approaches when evidence is sparse; to evidence-based approaches grounded in large populations (sometimes referred to as a "one-size-fits-all" approach); and, finally, to PHC based on personal choices, where appropriate, and evidence developed from smaller populations (also called subpopulations) as similar to the individual patient as possible.

PHC can help address problems associated with the science of health promotion and care delivery.



Sources: IBM Global Business Services; IBM Institute for Business Value.

Figure 4: **The ability to personalize healthcare requires better access to a wider variety of relevant patient information and clinical knowledge.**

Much of care delivery today is based on "trial and error" – the expertise and knowledge of the individual clinician, with limited access to relevant patient information and clinical knowledge that is not already "in the clinician's head." This approach, which is based more on art than on science, has led to many costly problems, including incorrect or incomplete diagnoses, use of ineffective interventions and failure to use effective interventions. This frequently is not a shortcoming of individual physicians. Rather, until recently, longitudinal patient information was not systematically captured and stored

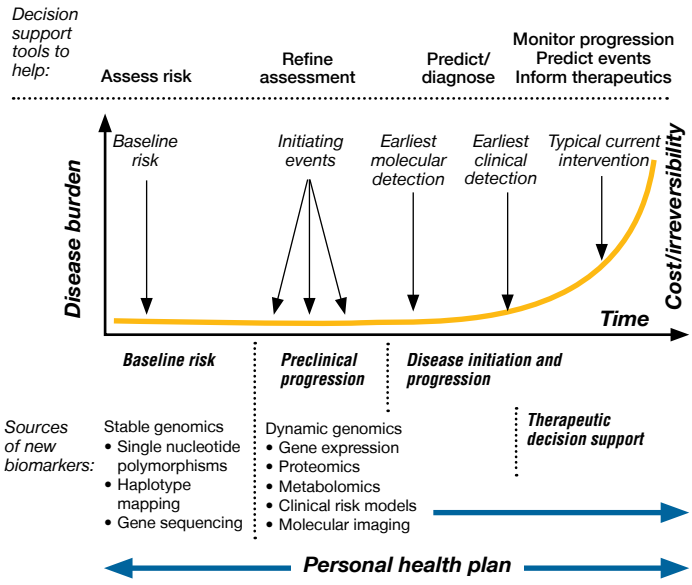
in a way that was efficient or readily available to caregivers. Further, insufficient tools exist to ensure clinicians have access to the latest clinical knowledge – and those that do exist may not contain the latest knowledge, given the pace and dynamism of today's scientific discovery.

Intuitive medicine differs from "trial and error" medicine in that the clinician has complete access to available patient information and relevant clinical knowledge. Even so, knowledge about many diseases or combinations of diseases is not sufficient to standardize the approach to diagnosis and treatment. Therefore, the clinician must depend largely upon personal expertise, skills and intuition (insights and judgment, for example) to determine what is wrong (frequently based on symptoms) and how best to treat with therapies whose efficacies are uncertain.[21]

When the level of evidence, particularly of diagnostic and therapeutic intervention effectiveness, improves significantly, real strides can be made in the overall quality of care. Evidence-based approaches, which gather information from large populations, can increase the likelihood of effectiveness, though they cannot guarantee the outcome. The same treatment can result in different outcomes among different patients due to difficulty in accurately diagnosing diseases based primarily on symptoms or due to different responses from patients to similar treatments. For example, one patient may respond well to a certain treatment, another may respond poorly, a third may have an adverse reaction and a fourth may not respond at all.

As health promotion and care delivery move into the realm of PHC, they continue to evolve to more of a science than an art, with clinician decisions based on patient preferences and evidence gathered from subpopulations as similar to the patient as possible. As a result, PHC is more precise for diagnosis, and treatment of disease is more predictable. With PHC, enough patient information and clinical knowledge exist to diagnose a disease – ideally as early as possible based on cause rather than on symptoms – and treatments exist to treat the causes of the disease, not just the symptoms.[22] Additionally, PHC can help tailor other health-related activities such as health promotion, prevention or care management for the individual, thereby improving the outcomes.

When appropriately applied to an individual with a disease, PHC can significantly improve the ability to assess risks, understand events that initiate a disease and detect those events molecularly (perhaps long before clinical detection is possible) and to tailor treatments specifically for that individual (see Figure 5). This approach can improve the likelihood of preventing or reversing the disease, thereby reducing overall costs associated with the disease (see sidebar, *Applying PHC to breast cancer*).



Sources: Ralph Snyderman, M.D.; IBM Global Business Services; IBM Institute for Business Value.

Figure 5: **PHC has potential to provide better risk assessment and prediction, earlier detection, earlier treatment and targeted treatments.**

Applying PHC to breast cancer

Consider the case of breast cancer: Women with the BRCA1 or BRCA2 genes are at a significantly higher risk for the disease.[23] That information, gathered through genetic testing and combined with information about family history and personal lifestyle, provides a baseline for assessing a particular individual's degree of risk. If the risk is high, then the individual may require earlier or more frequent screenings or may be more willing to take preventive steps such as maintaining a healthy weight, exercising, eating well, limiting alcohol consumption and not smoking.

The next step involves early detection. More information about the molecular pathways through which tumor cells circulate is being uncovered, with the hope that tests can be developed to diagnose the disease before traditional tests typically can. Meanwhile, clinical detection is constantly improving, through the detection of lumps and mammography – possibly including magnetic resonance imaging (MRI) or positron emission tomography (PET) scans for high-risk patients – and, increasingly, molecular biomarkers (a characteristic that can be objectively measured and evaluated as an indicator of biologic processes) that indicate disease onset prior to any phenotypic or physical symptoms.[24] Once the disease is detected, current therapies typically include surgery, radiation or chemotherapy.

Next, capabilities now exist to aid in therapeutic choices. Overexpression of the HER2 gene in breast cancer patients, present in about 30 percent of patients, has been associated with a poorer prognosis and a higher potential for recurrence of the cancer. The overexpression can be suppressed by the use of the drug Herceptin® (trastuzumab).[25] Similarly, by evaluating 21 separate gene expressions, the Oncotype DX® test can calculate the level of risk of the cancer returning within ten years and thus aid clinicians in making decisions regarding chemotherapy.[26]

PHC with and without "-omics"

Despite the strong potential of "-omics," as illustrated by the breast cancer example described in the sidebar, a working personalized healthcare system is by no means entirely dependent on them for its success. However, including "-omics" information and clinical knowledge can improve both the individual clinician's and the system's effectiveness. We describe five ways to provide PHC by leveraging information and knowledge available today and how each can be enhanced with "-omics" information and knowledge:

1) Incorporate patient preferences into decision making. Individuals can make their preferences known through tools such as advance directives, which can include "Do Not Resuscitate" agreements and instructions regarding life-sustaining treatments such as cardiopulmonary resuscitation (CPR), dialysis, artificial nutrition and mechanical ventilation. Additionally, clinicians and patients can participate in shared decision making. Physicians and other clinicians may increasingly be interpreters of information and facilitators of decisions rather than sole decision makers. In cases where there is no obvious best choice, clinicians can present information about benefits, risks and costs of treatment alternatives, and the patient can make decisions based on his or her personal values and convey these decisions through tools such as informed consent.

Use of "-omics" will provide much more complete knowledge about the risks inherent in various diseases, as well as the effectiveness of various treatments. This knowledge about baseline risk and preventive or therapeutic intervention effectiveness will enable patients to collaborate even more closely with clinicians to make vital care decisions with greater confidence.

2) Improve prediction and early detection.
Predictive modeling can help answer the question, "What might happen next?" Geisinger Health System uses predictive modeling for congestive heart failure (CHF) using nongenomic data contained in its EHR to identify patients who may develop CHF. Roughly half of the patients were diagnosed 6 to 24 months before a diagnosis would typically have been determined, giving an opportunity to avoid the disease or lessen the impact.[27]

Data from patient monitoring equipment can also be useful in predictive modeling. Analyzing such data can help identify high-risk patients earlier, perhaps avoiding emergency visits or even hospitalizations.

Employing "-omics" techniques could enable more accurate and earlier preclinical detection of a disease through proteomics and complementary technologies such as molecular imaging. Added benefits could include reduced total cost for detection and treatment since diseases could be treated at a less severe stage and improved potential to reverse diseases such as diabetes by detecting them at an earlier stage (see Figure 5).

3) Support clinical decision making.
EHRs can store large amounts of clinical information about individual patients. However, that information can be difficult to locate, organize and use – particularly if it is outside the context of why it was originally captured. By using tools to better integrate key data and then presenting them visually in the appropriate decision-making context, clinicians can better understand and use them. Geisinger found that physicians use 50 percent more data in making clinical decisions regarding rheumatology when the information is organized and displayed properly.[28]

More complete information, including genetic information, will increase the need for tools to help identify and visualize the relevant information in a way that aids clinical decision making. The need for better clinical decision support systems for clinicians and expert team members such as geneticists will also increase significantly as the volume and complexity of the data used for clinical decision making increase.

4) Develop multiple channels for delivering care.
New knowledge about preventing, predicting, diagnosing, treating and managing diseases will likely expand the variety of delivery approaches and channels. Obviously, care delivery cannot be personalized unless patients are willing to receive such care, perhaps through more convenient and cost-effective venues than today's ambulatory or inpatient facilities. Thus, it will become more important to offer a wide range of care delivery channels – from e-mail, e-visits and e-consultations to retail clinics, specialized treatment facilities, telemedicine and remote monitoring.

The increased use of "-omics" information and knowledge could help tailor channels based on better understanding of diseases and their causes, as well as effective prevention, detection and treatment options. For example, cancer treatment today is organized largely by body organ. In the future, treatment may be organized instead by molecular pathways, creating new delivery channels or treatment centers.[29] Also, as knowledge of diseases at the molecular level continues to evolve, more treatment locations or channels, such as outpatient care or home-based care, may become viable for diseases that today must be treated in more expensive and intensive acute care settings.

5) Help activate and sustain lifestyle and behavior changes. As chronic diseases become more prevalent, the role that lifestyle and behaviors play on health continues to grow in importance – both in maintaining good health and managing a condition once it is diagnosed. Just as patients respond differently to treatments, they also are motivated by different approaches. To date, helping motivate individuals to make and sustain lifestyle and behavior changes has not been a focus of many healthcare systems across the world and remains an area of great interest with a scarcity of knowledge.

Better information about genetic dispositions for disease and the genetic causes of disease can further this effort in multiple ways. If an individual knows that he or she has genetic factors that increase risk for certain diseases, that knowledge could help motivate lifestyle changes to prevent the disease. Additionally, genetic factors may impact an individual's ability to make lifestyle changes. For example, early evidence indicates that certain genes may make smoking cessation more difficult.[30] Knowledge of these genetic factors could influence selection of approaches for helping the individual make and sustain changes.

The value of IT-enabled PHC

PHC holds the potential to vastly improve the quality of healthcare and the way it is delivered, while potentially reducing its overall cost (see Figure 6). As previously stated, PHC can help provide the right treatment to the right person at the right time through earlier and more precise diagnosis and cost-effective treatments – which may then improve patient compliance with treatment regimens. PHC has the potential to improve the cost effectiveness of many of today's high-cost or low-benefit activities.

Both prevention and disease management (DM) must be cornerstones of any high-value healthcare system. While there are many benefits associated with both, cost effectiveness is a subject of considerable debate. We believe that more complete patient information and improved clinical knowledge could greatly improve the cost effectiveness of prevention and disease management – and could even generate net cost savings.

In hopes of preventing disease, for example, clinicians currently screen broad sections of the population to determine whether particular individuals have a specific disease. With PHC, preventive activities such as selective screenings could be conducted based on clinical utility – in other words, with better knowledge of risks and benefits – better matching preventive activities with individual risk profiles.

Similarly, today's disease management efforts have not consistently yielded the cost and quality benefits desired. Better information and knowledge, however, could enable specific management approaches tailored to each individual or subpopulation of individuals, depending on their conditions, preferences and goals to improve both the results and the cost effectiveness. For example, a clinician could more cost-effectively work with a patient to prevent him or her from becoming a Type 2 diabetic or work with a diabetic to better manage the condition, rather than have a patient progress unimpeded to the point of needing kidney dialysis and foot amputations, ideally significantly reducing the total costs of care over the duration of the condition.

PHC has the potential not only to improve the quality of healthcare, but also the overall costs and the cost-effectiveness of many of today's high-cost or low-benefit activities.

	With today's information	With IT-enabled PHC
Diagnosis	• 15 percent are inaccurate or incomplete • 20 percent of fatal illnesses misdiagnosed	• Better ability to distinguish among diseases with similar symptoms • Better ability to diagnose based on cause rather than by symptoms • Ability to reinterpret patient data based on new clinical knowledge
Treatment effectiveness	• Evidence for maybe one-third of what is done • Where evidence exists, it is "one size fits all" • Lengthy delays to incorporate latest clinical knowledge into practice • Poor patient compliance	• Ability to generate and incorporate more and finer-grained evidence • Tailored interventions • Better knowledge of when not to treat • Better monitoring of patients and compliance
Prevention to avoid disease or compress morbidity	• Screenings for broad populations • Behavior changes hard to make and sustain	• Selective screenings based on clinical utility • Stronger evidence of risk and better knowledge of what helps drive sustainable behavior changes with similar people
Disease management	• Difficult to identify which patients will benefit most from different types of active management	• Risks stratification based on clinical, environmental and genomic information to identify patients with maximum benefit
Technology	• New technology drives up costs (e.g., overuse or misuse)	• Evidence-based treatment plans, including diagnostics, required

Sources: IBM Global Business Services; IBM Institute for Business Value.

Figure 6: **PHC has potential to improve the quality and cost-effectiveness of many of today's current activities – and possibly even to reduce costs.**

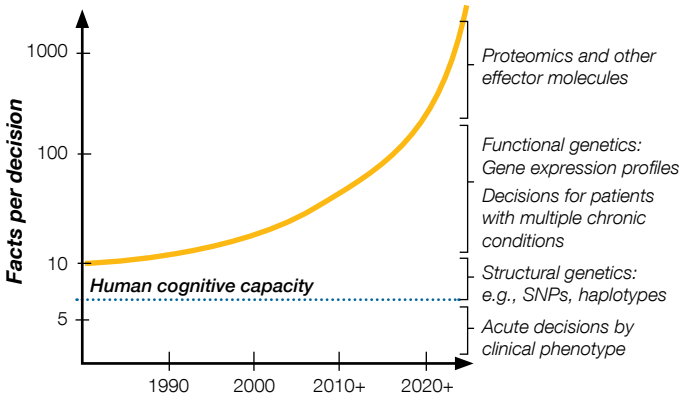
New technologies and treatments also present vexing cost and quality problems. Healthcare is one of the few areas in which new technologies often increase costs rather than reduce them. Cheaper diagnostic technologies, such as X-rays, may be replaced with much more expensive technologies, such as computerized tomography (CT) scans, and cheaper therapies may be replaced with more expensive therapies such as new surgical approaches or new, expensive patented drugs. Yet, knowledge is frequently missing or inaccessible to help practitioners understand whether or when the added benefit is worth the additional cost. Better patient information and clinical knowledge could help determine comparative effectiveness or cost effectiveness and then help develop and incorporate evidence-based diagnostic and treatment plans into care delivery processes.

Exceeding human cognitive capacity

While better patient information and clinical knowledge offer potential benefits, they also present a major obstacle to PHC. The amount, complexity and diversity of information and knowledge currently being generated will increase immeasurably as research into "-omics" continues. Even today's information and knowledge needed to make good clinical decisions are frequently well beyond the cognitive capacity of clinicians and patients. It has been estimated that the human mind typically can make use of no more than five to nine facts at a time when making decisions, such as about diagnoses or optimal treatment regimens.[31] Decisions involving patients with multiple chronic conditions may require the ability to process as many as 100 or

more facts – and even more than 1,000 facts when information regarding proteomics and other disciplines at the molecular level are added to the equation. No clinician can function optimally without the aid of a sophisticated HIT environment at this level of complexity (see Figure 7).

Through improved science, PHC has great potential to improve quality and reduce costs of health promotion and care delivery. But it is incredibly information and knowledge intensive – even compared to today's already complex needs – and exceeds human cognitive capacity. Access to and appropriate use of burgeoning volumes of patient information and clinical knowledge will require a powerful HIT environment.



Sources: William Stead, MD; IBM Global Business Services; IBM Institute for Business Value.

Figure 7: **A change in the nature of disease, plus an explosion of clinical information and finer-grained clinical knowledge, will challenge "expert- or experience-based practice."**

"Too often, U.S. healthcare overvalues local autonomy and undervalues disciplined science – not because of inattention or incompetence among doctors and nurses but because it is difficult for the human mind to keep up with the explosion of medical knowledge."

The New England Journal of Medicine article [32]

The current state of HIT

PHC will require a highly sophisticated HIT environment that can collect and analyze immense amounts of research and clinical information and knowledge and then present it in ways that clinical decision makers can easily use. Unfortunately, the current HIT environment is simply not up to such a task. It currently addresses administrative needs (such as health plan enrollment, physician or hospital billing and claims processing) better than it does clinical needs. Simplistically, the current environment can be divided into four major sets of components or layers: care delivery systems, research systems, administrative systems and infrastructure (see Figure 8).

Much of the hope for improving the current HIT environment rests on two types of digital patient records in the care delivery layer: EHRs – the primary object of HITECH Act funding – and personal health records (PHRs). Although these two terms are sometimes used interchangeably or even combined (the electronic personal health record), we view them as distinct entities.

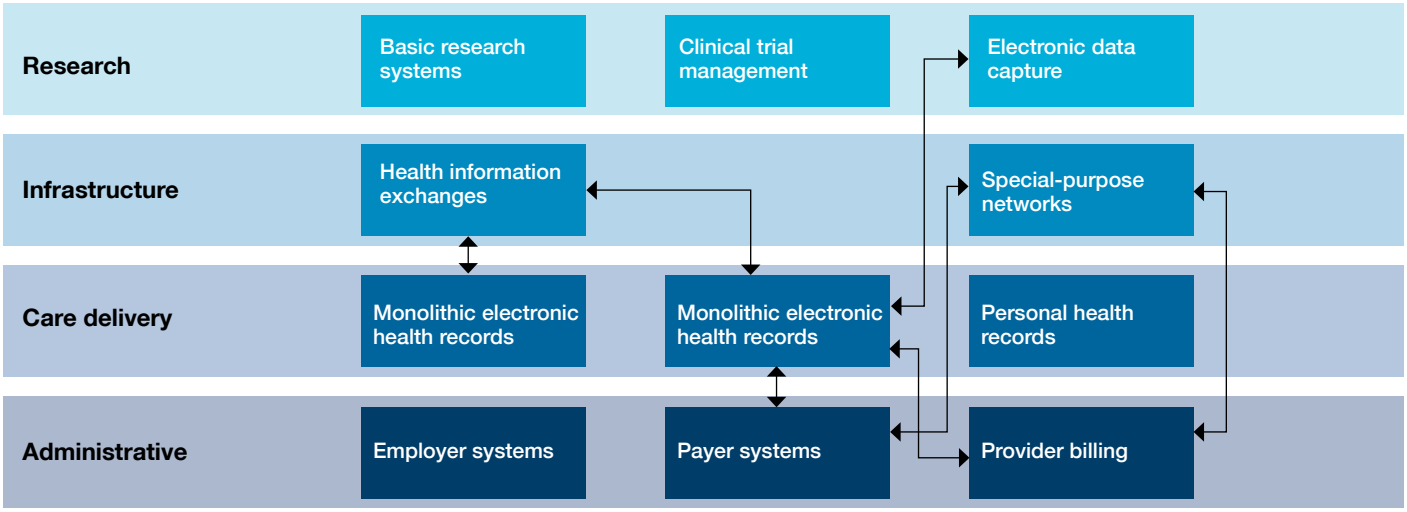


Figure 8: **The current HIT infrastructure does not lend itself to a learning, personalized, patient-centric healthcare system.**

While both are a "computer-accessible, interoperable resource of pertinent health information on an individual," an EHR is used primarily by a broad spectrum of clinical personnel involved in the individual's care, enabling them to deliver and coordinate care and promote the person's wellness.[33] A robust EHR system could include capabilities such as clinical documentation of problem, allergy and active medications lists; results viewing of laboratory, radiology or consultant reports; computerized provider order entry (CPOE) or e-prescribing; clinical decision support such as clinical guidelines, reminders and alerts; disease registries to help manage subpopulations of patients with similar diagnoses; portals to access the Internet; and tools to support exchange of health information with other clinicians or with patients (for example, reminders or electronic laboratory results). However, many of today's EHRs are used more to support coding of procedures and services and for billing functions than to provide advanced clinical functions such as CPOE, clinical decision support or disease registries.

Similar to the EHR, the PHR contains pertinent health information on an individual.[34] In contrast to the EHR, the PHR is managed by the individual and is intended to supply the information needed to help educate, empower and activate the individual to assume responsibility for his or her health and coordinate appropriately with health professionals.

The PHR may contain information that is not generally included in EHRs today, such as the individual's observations of daily living or exercise logs. PHRs are still in their infancy today, with only 7 percent of respondents to a recent survey having one.[35] Even so, a variety of organizations are offering PHR platforms or capabilities, including employers, health insurers (through payer-based health records), care delivery organizations (by allowing patients access to certain EHR information) and IT vendors such as Google Health and Microsoft.

Somewhat simplistically, today's infrastructure layer contains health information exchanges (HIEs), also a target of HITECH funding, and special-purpose networks to support functions such as claims submission or payments. An HIE facilitates the electronic movement of any and all health-related data according to an agreed-upon set of interoperability standards, processes and activities across nonaffiliated organizations in a manner that protects the privacy and security of that data and of the entity that organizes and takes responsibility for the process.[36] A 2009 survey identified 193 active HIE initiatives in the United States, with 57 being operational. Laboratory and medication data are the types most frequently exchanged.[37]

Low adoption of EHRs can be attributed to a number of factors, including the expense and technology competency required to purchase, implement and maintain them; the impact on clinical workflow; and concerns about interoperability.

A variety of research systems are also in use, including systems that manage clinical trials and electronic data capture systems designed to collect research data as part of a clinical study. Increasingly, there is a focus on capturing data from clinical trials directly from EHRs to avoid duplicate data entry, thereby improving accuracy and efficiency.

The administrative layer is perhaps the most mature layer of the HIT environment. It contains applications such as employer enrollment systems to support enrollment of employees into health plans, provider systems to support billing functions and payer systems to support claims processing and payments.

Even though these four layers of the U.S. HIT environment have been maturing over many years, adoption rates by clinicians for EHRs, one of the most critical applications for PHC, remain low – just 6 percent of hospitals, 20 percent of large physician groups and 8 percent of small groups have implemented advanced EHRs.[38] Low adoption can be attributed to a number of factors, including the expense and technology competency required to purchase, implement and maintain them; the impact on clinical workflow; and concerns about interoperability. The HITECH Act is intended to help address the problems with low EHR adoption in the United States. PHR adoption could also remain low without EHRs and, possibly, HIEs available to help easily populate the relevant PHR information.

Even when EHR and PHR adoption improves significantly, the HIT environment will still face five interdependent challenges to support the vision and promise of PHC.

Issues beyond the scope of this paper

While we believe that a patient-centric, high-performance PHC system must be built on a strong HIT environment, we recognize that many issues must be addressed concurrently but are beyond the scope of this paper.

These issues include a variety of policy concerns, such as privacy, informed consent, reimbursement, ownership of intellectual property, licensing and privileges for clinicians, standards for drug and device approval, and liability for using or not using evidence-based systems. Another set of issues involves educating stakeholders about PHC and the use of technologies that enable it. Clinicians and individuals will need to understand more about genomics, and caregivers must learn to accept computerized help and team-based care, for instance. Next, issues of how to fund these new systems and expectations regarding the return on investment from them will be central to successfully building them. And finally, there are serious ethical issues to face: Assuming such systems can be built, should they be? For example, what would be the societal, financial and environmental impacts if virtually everyone lived to be 110 years old?

Also, a number of technology-related topics such as the future of hand-held devices, servers, networks and storage devices; policy issues such as information retention, security and compliance and approved secondary uses of data; and technical issues such as how best to manage and secure huge volumes of data are best left to other more technical documents.

Toward a new HIT environment

PHC holds the potential to reduce costs while increasing the quality and continued innovation of health systems. To achieve this goal, a variety of policy, education, funding and social challenges must be addressed (see sidebar, *Issues beyond the scope of this paper*). At the same time, a much more open, robust, flexible standards-based HIT environment will be required. Additionally, not all of the technologies needed are readily available today. New general-purpose and healthcare-specific technologies need to be developed.[39]

This HIT environment must be capable of capturing, storing, analyzing and appropriately sharing information about individual patients and patient populations. It also must be capable of rapidly generating and managing new clinical knowledge and easily incorporating it into clinical processes and workflows for decision making related to health promotion and care delivery. This environment also must facilitate appropriate interactions among constituents. These capabilities were not top priorities when today's HIT systems were designed and implemented. Today's systems were designed primarily to facilitate administrative functions and to automate specific clinical encounters.

Five interdependent HIT challenges must be overcome for PHC to succeed:

1. Lack of an interoperable HIT environment for care delivery and research
2. Prevalence of tightly coupled applications and data
3. Inadequate data and knowledge standards
4. Insufficient analytics capabilities
5. Absence of a clinical decision-making foundation.

Challenge 1: Lack of an interoperable HIT environment for care delivery and research

The HIT environment (see Figure 9) will have to be more flexible, functionally rich and interoperable (the ability of different information technology systems and software applications to communicate; exchange data accurately, effectively and consistently; and use the information that has been exchanged) than today's highly fragmented HIT environment.[40] Each layer – research, infrastructure, care delivery and administrative – will need changes.

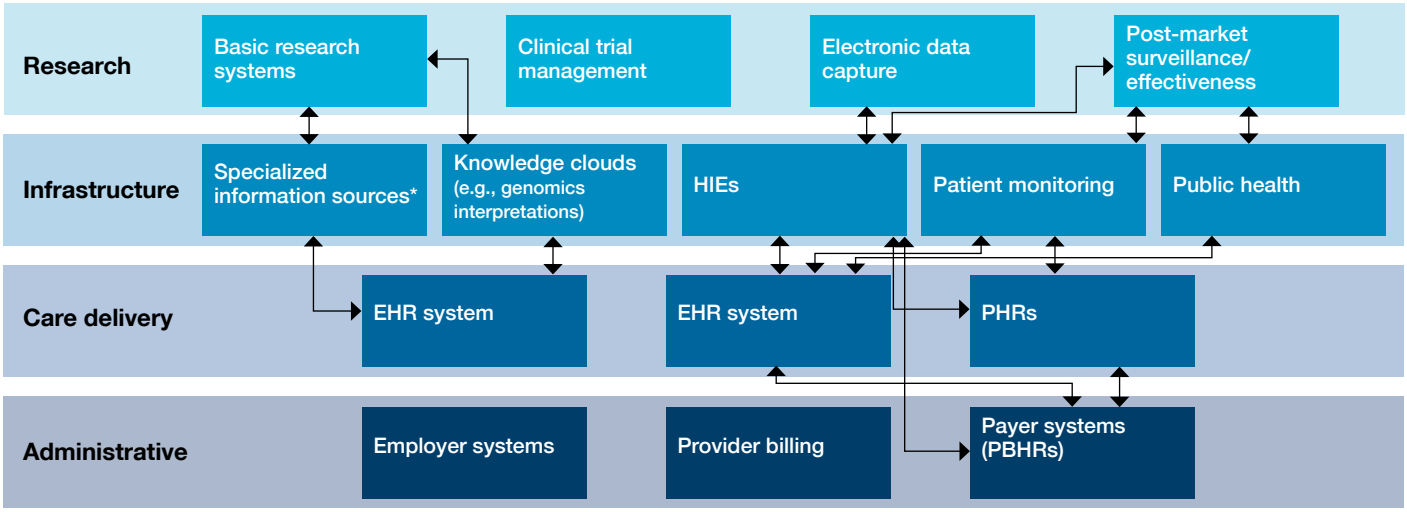
Research

The research layer will need a number of changes. First, basic research systems will need to facilitate research across traditional organizational and industry boundaries. Next, post-market surveillance of patients undergoing new treatments and ongoing monitoring of the effectiveness of the treatments is done only sporadically today and needs to become widespread. This could require much tighter links between research systems and EHRs or PHRs.

Infrastructure

The infrastructure layer will have to become much more functionally rich and even perform some of the services that historically might have been considered applications. Several capabilities must be added or enhanced to facilitate a wider variety and volume of information exchange among stakeholders.

Conceptual architecture of PHC-enabled healthcare IT environment



*Examples include genomics, biobanks and patient information.
Sources: IBM Global Business Services; IBM Institute for Business Value.

Figure 9: **A more interoperable, flexible, functionally rich HIT environment will be needed to cross the information and knowledge chasm to PHC.**

- *Specialized information sources or information "clouds."* A wide variety of critical data and information – including genomics and medical imaging, for instance – may be too sensitive, too specialized or simply too large to incorporate directly into EHRs. In this case, the information may need to be kept as a shared resource accessible through the Internet or a private network.
- *Specialized knowledge sources or knowledge "clouds."* The knowledge and skills required to interpret certain kinds of data, such as genomics or proteomics, will likely be specialized enough that it will need to be shared across multiple EHRs, facilities, organizations and care venues.
- *Patient monitoring.* Realtime patient monitoring and ongoing surveillance – regardless of location (in a hospital or at home, for example) – will be necessary to track current health conditions, adherence to treatment programs and longer-term outcomes.
- *Public health.* Systems will be required to track the overall quality and safety of treatments, as well as to manage public health reporting, such as disease outbreaks and the results of large-scale efforts to promote health and prevent disease.
- *Health information exchanges (HIEs).* Today's HIEs provide useful functions, such as exchanging lab or medication data and information about outpatient episodes or inpatient visits, frequently on a local or regional basis among organizations with trusted relationships.[41] As with other components, future HIEs may look quite different. They will likely need to facilitate the sharing of a much wider variety of information from specialized information and knowledge sources, such as PHRs or biobanks, among a larger group of entities (competing organizations, organizations outside the region or researchers, for example).

EHRs will need additional functionality and interoperability capabilities and will likely require a very different technology architecture.

Care delivery

For the care delivery layer, EHRs will need different capabilities, including access to specialized information or knowledge sources such as genomics information, specialized disease registries or biobanks and the ability to incorporate relevant data from patient monitoring devices.

EHRs also will need additional functionality and interoperability capabilities to support a broader scope of research efforts. EHRs can be beneficial for efficacy research and are essential for effectiveness research by tracking clinical outcomes over time, thereby more closely integrating care delivery and research (see sidebar, *Efficacy vs. effectiveness research*). Comparing effectiveness of alternative interventions or approaches to health promotion and care delivery – in other words, comparative effectiveness research – may be a tool for intelligent cost containment and identifying preferred therapies.[42]

These EHR research and care delivery capabilities will likely require a very different technology architecture. Today's "monolithic" EHRs can be difficult to change or to link with other systems within or external to the organization (departmental systems in a hospital or physician office systems, for example). To more fully support PHC and other requirements, future EHRs likely will have to be composed of a number of components or services that can work seamlessly together and can more easily be changed. EHR vendors likely will encounter major obstacles in "rearchitecting" EHRs from a monolithic to a more service-oriented architecture. These efforts could take over ten years to complete.[43]

Efficacy vs. effectiveness research

Efficacy research focuses on the extent to which a health care intervention is beneficial over the short term, often compared to a placebo, when administered in an idealized setting to a small group of carefully selected, highly compliant patients. Phase II and III clinical trials often focus on efficacy. Effectiveness research focuses on the extent to which a health care intervention works, possibly compared to other viable interventions, over the longer term when provided to a wide assortment of real-world patients, including those with multiple conditions, in diverse clinical settings across the country.

Today's nascent PHRs will need to become much more mature, functionally rich and interoperable, becoming the individual's window or portal to the healthcare world in a more patient-centric environment. Possible uses for the consumer-controlled PHR include interacting with clinicians (for example, conducting e-visits or scheduling appointments) or genetics counselors; capturing and analyzing information from remote monitoring devices and sharing relevant information with provider EHRs; helping monitor compliance to treatment regimens; connecting with patients who have similar conditions; capturing self-reported data such as observations of daily living; and linking to additional knowledge about diseases, disease prevention or general health promotion.

Administrative

Of course, the administrative systems must change to support this new environment. For example, as more information about the causes and treatments of diseases becomes available, payer/insurance systems and provider billing systems will need to support new ways of classifying diseases and new therapies or combinations of diagnostics and therapies. Also, for the near future, payer/insurance systems may have a broader range of information about individual patients than today's fragmented EHR systems. For example, payer systems may have information regarding medication prescriptions, visits to other care providers or potential gaps in care. This type of information needs to be shared with the EHR and PHR systems on a wider, more consistent basis than it is today.

Together, these changes to the HIT environment will help lay the foundation for a rapid-learning environment with better integration across care delivery and research.

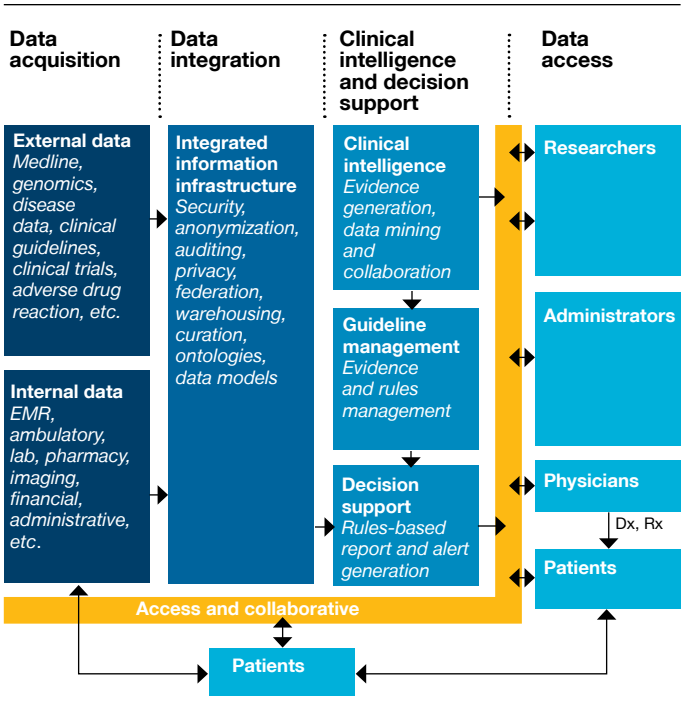
Challenge 2: Prevalence of tightly coupled applications and data

The new architecture previously described depends in large part on the ability of a wide range of applications and tools to gain access to necessary data. Somewhat simplistically, an application consists of three major layers. The presentation layer controls data input and output to the application user through technologies such as a PC screen, Internet browser or mobile device. The application layer contains the business or clinical logic (what laboratory tests need to run, for example) and work flow (who needs to approve or process a laboratory order, for example). The data layer contains the data used by the application.

In the current environment, applications and the data they depend on are typically very closely intertwined. The data generated by EHRs, for instance, often are not easily available to caregivers who don't have access to that EHR, to the patient or to researchers outside the care delivery organization who could benefit from appropriate access. Building tools to extract data from the originating application can be a laborious, costly and painful process. Only by decoupling or "liberating" such data from the applications that generate or create them can they be used throughout the HIT environment for care delivery or research – with appropriate data integrity, privacy and security capabilities in place (see Figure 10).

Making relevant data within the system available to key stakeholders would result in a number of benefits vital to a successful PHC system:

- Relevant information for a specific patient, regardless of when or where it was generated, could be combined to provide a more complete picture of the patient's health.



Sources: IBM Global Business Services; IBM Institute for Business Value.

Figure 10: **Data and applications must be decoupled for robust use of the data and for applications to draw upon multiple data sources.**

- Data for individual patients (including images and tissue samples) could be compared with data for a large number of other patients to help diagnose or determine the best treatment options.
- Doctors and researchers could collaborate across organizational boundaries applying data mining and analysis to the entire set of clinical patient information to develop disease-specific, personalized clinical decision rules for diagnosing and treating patients.

- Testing labs could develop expert systems integrated with the overall HIT environment to improve the quality and efficiency of diagnostic decisions.
- Advanced clinical decision rules developed by teams of researchers and physicians could be licensed or subscribed to by other hospitals and physicians around the world and incorporated into EHRs.

While the U.S. healthcare system generates huge volumes of data daily in care delivery, much remains locked up in isolated paper or electronic records. Opening them to a wide variety of uses, with appropriate privacy and security controls, could make the data truly valuable in improving the quality and efficiency of the system as a whole.

Challenge 3: Inadequate data and knowledge standards

The vision of interoperability, as described in challenge 1, depends in part on decoupling data from applications, as described in challenge 2, and making the data appropriately available throughout the system. However, without well-defined but appropriately flexible standards, improving interoperability among applications will continue to remain challenging.

A task as seemingly straightforward as sharing data about a person's gender depends in part on the development of common standards (or commonly agreed upon specifications) for how the data are structured and coded. Two different applications may have a similar structure – gender is represented by one character – but disagree on how data are coded. One application may allow "M" for male, "F" for female or "U" for unknown. Another application may support only the values "1" for female and "2" for male, making an accurate translation between the two applications impossible.

While many standards are in place, some areas do not have standards while others have conflicting standards (see Figure 11). For some areas, standards may be too restrictive, limiting their usefulness, while in other areas, standards may be too flexible, creating variability among and higher costs for implementations using those standards.

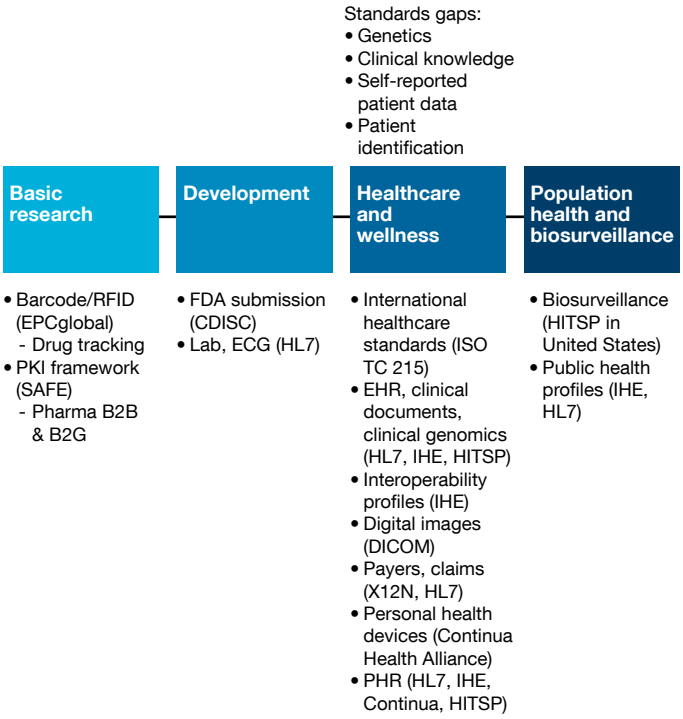
Existing standards

With regard to PHC, some essential standards have been or are being developed. For example, Health Level 7 (HL7) has developed Clinical Genomics specifications, which function as a bridge between clinical data standards and genomics. These two worlds of information are totally disparate at this point. The HL7 Clinical Genomics standards attempt to fuse them into a single coherent framework while keeping each of their underlying models in place.[44]

The Clinical Data Interchange Standards Consortium (CDISC) has developed standards for clinical trials and biological and clinical research.[45] Some of the CDISC standards have been incorporated into HL7 v3 (which is not yet widely adopted) to facilitate the exchange of data between healthcare providers and clinical trials sponsors.[46] Such standardized exchange can improve the costs and efficiency of clinical research.

While the U.S. healthcare system generates huge volumes of data daily in care delivery, much remains locked up in isolated paper or electronic records.

Examples of healthcare and life sciences standards and corresponding organizations



Sources: IBM Global Business Services; IBM Institute for Business Value.

Figure 11: **While HL7 is attempting to bridge the gap between genomic and clinical data, standards gaps still exist for clinical knowledge and for new types of clinical data such as self-reported data.**

Standards gaps: Genetics

Standards are largely lacking in a number of areas essential to PHC. In the area of genetic variations, for example, there is a need to represent variations in a standard way but remain flexible enough to accommodate new variations as well as new types of variations.

Standard gaps: Patient-recorded data

There are no standards for how a patient might record activities or observations of daily living such as sleep or eating patterns, level of exercise, mood and medication adherence, all of which are critically important to enabling PHC by improving health promotion and management of chronic conditions.

Standard gaps: Clinical knowledge

Perhaps the biggest challenge with PHC-related standards involves the lack of standards for coding clinical knowledge. Today, clinical knowledge, where available, is represented by constructs such as evidence-based guidelines for treating a disease. These guidelines are generally based on empirical evidence for populations of patients and don't address individual differences. They are typically for treatment of a single disease. Applying guidelines for each single disease may result in overtreatment or conflicting treatments for patients with multiple conditions.

Additionally, these guidelines are frequently paper based, making them difficult to incorporate into clinical practice. If the guidelines are incorporated into EHRs in forms such as care plans, order sets and reminders or alerts, they must be tailored to each vendor's EHR system – and perhaps each implementation of a vendor's system – and they may be challenging to implement and to maintain as knowledge changes.

The approaches described above to incorporate clinical knowledge into practice will become increasingly unworkable. As clinical knowledge is developed at an increasingly rapid rate for a growing array of intervention options to provide an expanding scope of potential preventive, acute and chronic services for increasingly fine-grained patient subpopulations, standards will be necessary to make clinical knowledge as interoperable as patient information.

Standards gaps: Patient identification

Patient identification presents another key problem involving standards. A key to PHC is access to more complete patient information. Frequently this information is scattered across multiple facilities or EHRs, each with a different patient identification approach. To aggregate patient information for administrative, care delivery or research purposes, the information must be linked with the right person. This is frequently done by probabilistic or deterministic matching techniques using demographic information. For example, with deterministic matching, a patient record under the name of "John Smith" could be matched with information in another EHR under the name of "Jonathan Smith" by using additional information such as address or date of birth. This method works well for smaller populations of patients but does not scale well as the number of individuals and the volume of and timeframe for data about each individual grow.

ASTM International has developed standards for individual health identifiers but these standards have not been implemented in the United States, primarily because of privacy concerns.[47] In short, privacy concerns will have to be balanced with the risks of failing to match patients, including poor patient care, higher costs and potential legal liability.[48]

Challenge 4: Insufficient analytics capabilities

As more and more standardized electronic data are appropriately made available to a variety of stakeholders, it will become possible to apply sophisticated analytics to that data, which will enable improved predictions about disease onset, more complete and accurate diagnoses, and the development and application of more successful treatment programs. The field of analytics is not new; indeed, it has been used extensively to analyze customer behavior and financial performance, as well as to optimize key business areas such as supply chain. Its use in healthcare, however, has been limited, particularly in clinical settings, in part because of a lack of complete, accessible and useable data.

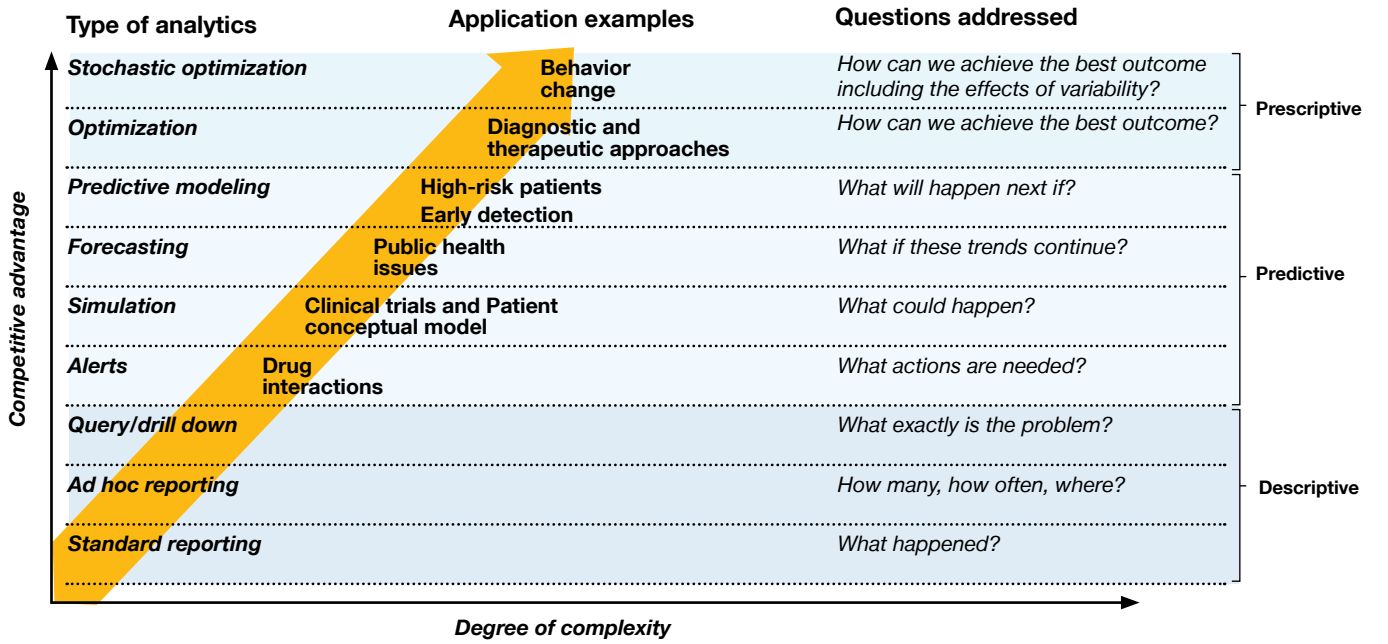
What might an advanced analytics system to support clinical decision making for PHC look like? There are three levels – descriptive, predictive and prescriptive – and various types of business intelligence and analytics capabilities within those levels (see Figure 12).

Descriptive analytics

At this level, available data are used to generate straightforward standard or ad hoc reports to help understand what happened and then drill down into the data for further clarification. For example, many hospitals produce standard financial or quality reports and then drill down into the data to better understand the performance of certain areas or how to improve clinical safety.

A number of challenges remain at this level for clinical data, such as natural language processing, which includes the coding or analysis of unstructured data (as found in a doctor's or nurse's notes). Similarly, the ability to analyze streaming data (from patient monitoring sensors in a hospital or remote setting, for instance) is still in its early stages.

Also, as knowledge about diseases and their causes expands, the standard ways of classifying diseases will have to change. For example, lymphoma was once considered one disease; today, over 50 different types have been identified, and each could require a different treatment approach.



Sources: IBM Global Business Services and IBM Institute for Business Value analysis; Davenport, Thomas H. and Jeanne G. Harris. *Competing on Analytics: The New Science of Winning*. Harvard Business School Publishing Corporation. 2007.

Figure 12: **Use of advanced analytics has the potential to impact key aspects of health promotion and care delivery.**

Predictive analytics

At this more complex level, the use of analytics can play a significant role in facilitating clinical decision making. It can alert clinicians to problems that might occur, such as adverse drug interactions, and simulate the results of clinical trials or how "virtual" patients might respond to alternative treatment regimens. Additionally, predictive modeling could be used to gather information about a patient and compare it with information from large patient populations to aid in the early detection of and prognosis for disease.

Predictive modeling could also be used to help identify patients most likely to benefit from early interventions or better management to avoid complications or the need for more expensive interventions in the near future. This could be particularly important in helping control overall costs. In the United States, for example, 5 percent of the population accounts for about 50 percent of healthcare spending.[49]

For the use of predictive analytics in healthcare to reach its full potential, new algorithms and tools are required, such as tools to simulate the results of specific interventions or link vast

volumes of patient data to finer-grained clinical knowledge. Also, tools will be needed to support a different type of logic. Clinical decision support today typically uses a deductive and deterministic approach for rules, alerts and reminders. In other words, if something is true for the overall patient population, it is assumed it could be true for a particular patient, providing a "one-size-fits-all" approach. Given the growing knowledge of patient heterogeneity – two patients exhibiting similar symptoms may not have the same disease or may respond differently to treatment – clinical decision support needs to also support inductive approaches (for example, matching a patient's information with a certain patient subpopulation and treating the patient based on what works best for the subpopulation) and probabilistic approaches (for example, if treatment A works for 78 percent of the patients and treatment B works for 52 percent, try treatment A first).

Prescriptive analytics

The most challenging level of analytics is the ability to generate prescriptive recommendations within a clinical context. By analyzing all the available information, including patient data, clinical knowledge and research, the system would be able to offer advice on the best course of action for achieving the most desirable outcome, even when new, variable elements are factored in, such as changes in a patient's medical condition.

The practice of applying prescriptive analytics in a clinical setting is in its very early stages, so many challenges still exist. One such challenge involves knowing how to reinterpret static clinical data (for example, information about the patient's genome or family history) as relevant new clinical knowledge is developed and then possibly to initiate clinical workflows outside a patient visit. Another key challenge involves the use of analytics to help support behavior change in individuals, given the major role that lifestyles and behavior choices play in overall health status.

The future…

Across all levels, success with advanced analytics is highly dependent on the quality and completeness of the data subject to analysis, as well as the sophistication of the algorithms and models on which analyses depend. The full promise of PHC can be realized only with improvements in clinical data analysis – including genomic and proteomic information, phenotypic information such as lab results, patient self-reported data, medical images and tissue samples – in both research and real-world care delivery settings.

These clinical analyses can validate current clinical knowledge and generate new knowledge. Powerful standards, processes and tools – which are largely immature or lacking today – are necessary to help rapidly incorporate the clinical knowledge into practice.

Challenge 5: Absence of a clinical decision-making foundation

This fifth and final HIT challenge can be addressed once the previous four challenges have been resolved to a large degree. As discussed earlier, clinical decision making centers on assimilating relevant information about the patient and running that against relevant clinical knowledge within the context of a conceptual model for the patient. However, clinical decision making is too complex today to be done in one's head. Yet, that is what clinicians must do when relevant patient information and clinical knowledge are sparse or difficult to access in today's heavily paper-based system.

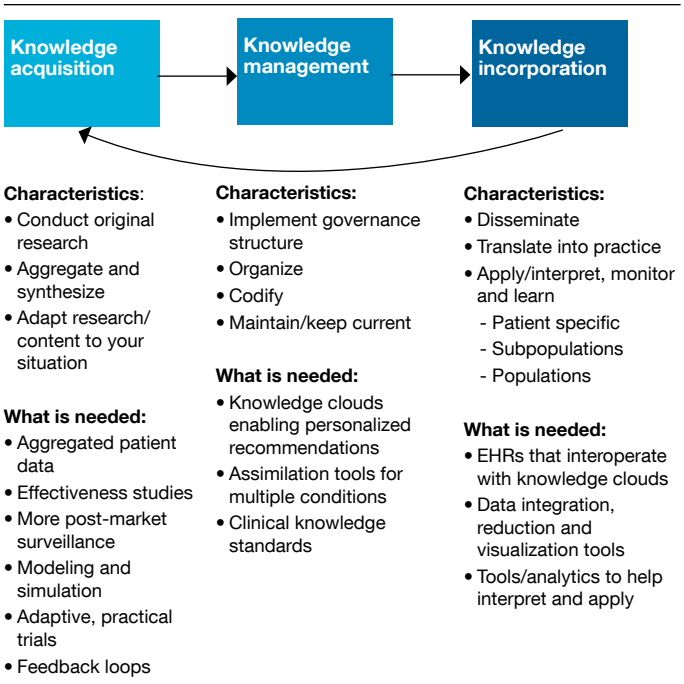
Even when EHRs help integrate (from multiple sources), reduce (include only relevant information) and visualize the patient information, much of the "heavy lifting" of determining what that information means and applying relevant clinical knowledge to diagnose and determine the best interventions

must be done in the clinician's head. Clinical decision support capabilities (i.e., care plans, order sets, reminders or alerts) frequently become useful only after the clinician has performed the "heavy lifting" correctly.

As the volume of clinical knowledge and its rate of development increase, "patient-centered cognitive support" will be necessary – that is, tools and systems that offer clinicians and individuals assistance in thinking about and solving problems related to specific instances of health and healthcare.[50] This support is essential for a healthcare system to become a rapid-learning one capable of incorporating new knowledge into clinical decisions.

The clinical knowledge lifecycle consists of three phases: acquisition, management and incorporation, which are linked together in a virtuous circle (see Figure 13). Knowledge is acquired through research and care delivery and must be organized and managed in ways that will make it useful to support clinical decision making. It is then disseminated back to clinicians and researchers, who use it and add to it in the course of their activities. It is a form of continuous learning that adds to total knowledge while consistently incorporating what is learned into daily practice.

Unfortunately, the current HIT environment is inadequate for all three phases. At present, it utilizes twenty-first century tools for generating information (for example, genetic sequencing or advanced medical imaging), twentieth century capabilities for turning that information into knowledge (for example, knowing which genetic variations are significant and what they mean), and nineteenth century techniques for managing that knowledge and enabling stakeholders to use it (for example, paper-based clinical knowledge such as evidence-based guidelines). What can be done to create a true knowledge-based learning system?



Sources: IBM Global Business Services; IBM Institute for Business Value.

Figure 13: **A learning healthcare system requires a robust, dynamic, coordinated effort supported by new research techniques and tools.**

Knowledge acquisition

Today's clinical trials, observational studies and literature reviews are not generating the knowledge necessary to enable a PHC system. Clinical trials need to more frequently become adaptive research trials, with the ability to change the direction of the trial based on knowledge gained during the trial. For example, if a drug is effective for only 40 percent of participants in a trial, it's important to understand why it is working and how to identify people for whom it will work in real-world settings. Research may also need to continue around the 60 percent for whom the drug failed to work adequately.

In addition, more emphasis on clinical effectiveness studies and post-market surveillance is needed to better understand the ongoing risks and benefits of treatments in real-world situations. Additionally, simulation studies could be used to help identify opportunities for new studies or to fill in information gaps when analyzing historical information that may not contain all the data needed for a study.

Currently, much patient data remain captive in isolated EHRs or paper-based medical records, making knowledge acquisition slow and difficult. Aggregated, standardized patient data can accelerate the pace of knowledge acquisition.

Knowledge management

Today, no clear standards exist for codifying clinical knowledge and evidence-based guidelines. Where clinical knowledge exists, it frequently remains paper based and limited to single conditions. Eventually, clinical decision makers may need to access specialized knowledge sources or "knowledge clouds" that will provide personalized recommendations based on individual data for patients with single or multiple conditions within the context of similar subpopulations.

Knowledge incorporation

At present, healthcare providers, including both physician practices and hospitals, determine how to incorporate research and clinical knowledge into their own clinical decision making and workflow, sometimes with the help of their EHR vendors. As discussed in the previous HIT challenge, rudimentary clinical decision support capabilities such as reminders and alerts are incorporated to support transactions such as provider order entry (checks for drug interactions, for example). Ultimately, providers will likely need EHRs that link into specialized knowledge sources that can provide cognitive and decision support. Better data integration, reduction and visualization tools will also be needed to aid both clinicians and patients in sorting through volumes of data to find the relevant nuggets and visualize the critical data to help identify viable options and support decision making.

Driving toward PHC

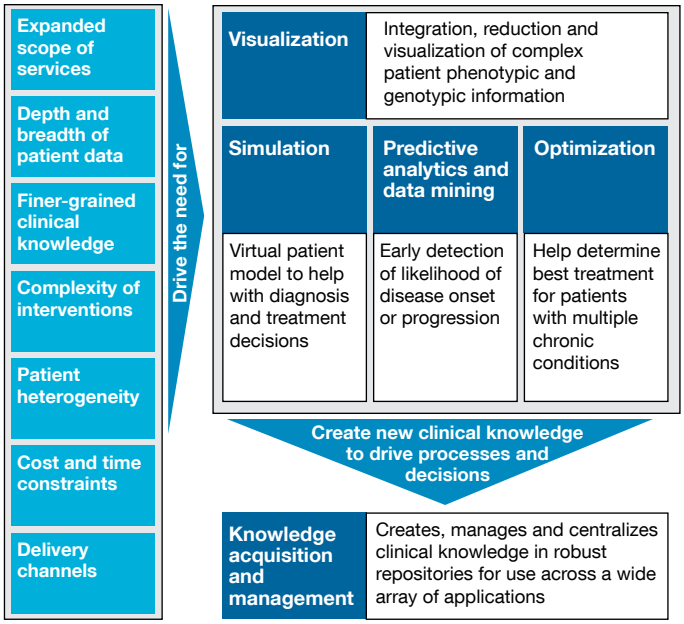
The analogy of taking a driving vacation in unfamiliar territory helps illustrate the journey from "trial and error" medicine to personalized healthcare. Worst case would be to take the trip based on past travel memories and anecdotes from others who have recently traveled there. This is akin to today's "trial and error" medicine. A map, though a major improvement, still requires knowing the location and best routes, analogous to assuming that a diagnosis is correct and the best therapeutic interventions are known, which is frequently not the case. Additionally, a map can become outdated and its use can interrupt driving, just as paper-based, evidence-based guidelines can become outdated or interrupt clinician workflows when referenced. A GPS system would be a further improvement; however, GPS use still may require location destination knowledge and may not easily accommodate en route plan changes. This is similar to having evidence-based guidelines based on patient populations incorporated into an EHR. They become part of the workflow and may work most of the time but not always – just as a wreck or change in plans can alter the best travel route.

The best solution for traveling in unfamiliar territory would be a trip planner that matches the travelers' interests (equivalent to patient information) and strong knowledge about various destinations (equivalent to robust clinical knowledge) to determine the best destinations (for example, diagnostic and therapeutic decisions) and then dynamically adapts to the rapidly changing environment during the trip (equivalent to adapting to changes in patient conditions or development of new clinical knowledge).

The PHC HIT environment will be much more sophisticated than this rough analogy to GPS navigation, and we recognize that clinicians are not always operating in unfamiliar territory. Yet, in an important sense, their purposes are the same – to achieve the optimal outcome by taking into account a variety of perhaps diverse and ever-changing data as effectively as possible. The vision for PHC cannot be achieved as long as healthcare decisions are still being made in the manner equivalent to driving without maps or with rudimentary GPS capabilities in unfamiliar territory. A robust clinical decision-making foundation capable of providing cognitive and decision support must be in place.

Clinicians face numerous challenges as they go about their daily routines – and data integration, reduction and visualization capabilities combined with strong clinical knowledge incorporation capabilities could aid them in meeting those challenges (see Figure 14). The goal, ultimately, is to develop systems that clinicians can use to better understand their patients' health and diagnostic and therapeutic options when needed – and patients can use to aid in the decision-making process. Those systems, in turn, should allow for the input of new data (changes in health status, treatment outcomes and the like) and clinical knowledge and then continue to improve clinical knowledge overall. Only at this point will there be an HIT environment that can fully support and enable the improvement of the science of health promotion and care delivery, migrating from today's all-too-frequent "trial and error" medicine – or even from intuitive medicine and evidence-based medicine – to PHC.

A robust HIT environment is necessary to further improve health promotion and care delivery.



Sources: IBM Global Business Services; IBM Institute for Business Value.

Figure 14: **Different analytics approaches can be combined to help provide cognitive support for clinicians and patients.**

Summary: Key capabilities to address HIT challenges

We have outlined not only the five interdependent PHC-related HIT challenges, but also some of the key capabilities required to address them (see Figure 15). These challenges are much more difficult to solve than the HIT-related issues associated with addressing healthcare fragmentation and waste problems and even more difficult than IT-related challenges faced in other industries. They will require both sophisticated use of existing capabilities and the development of new ones.

1	**Interoperability** • Specialized information and knowledge sources • EHRs for patient care and research
2	**Applications/data** • Exchange data easily and appropriately • Access specialized data or information sources
3	**Standards** • Genetics • Clinical knowledge • Patient-reported data • Patient identification
4	**Advanced analytics** • Simulations • Predictive modeling • Optimization
5	**Clinical decision-making foundation** • Knowledge acquisition, management and incorporation • Integration, reduction and visualization • Patient-centered cognitive support • Reinterpretation of static patient information • Long-term outcomes tracking

Sources: IBM Global Business Services; IBM Institute for Business Value.

Figure 15: **Five interdependent HIT-related challenges must be addressed for PHC.**

Recommendations for stakeholders

As the struggle in the United States over healthcare reform makes all too clear, many different players have a stake in current and future healthcare systems – from individuals, caregivers and researchers to life sciences and medical device companies, to governments and payers. Aligning interests is a very difficult exercise, one that has so far proved insurmountable. However, if PHC is to become a reality, all players must make significant changes in how they address issues related to improving the science of health promotion and care delivery.

We have developed suggestions on how each stakeholder can help support the move to PHC in three critical areas: clinical knowledge, patient information, and health promotion and care delivery (see Figure 16). These suggestions are consistent with our key PHC themes: the tailoring of medical treatment to the specific characteristics of each patient; integrating care delivery and research; expanding the scope beyond "-omics" and beyond diagnosis and treatment to include health promotion, prevention, risk assessment, prediction, early detection and ongoing monitoring and management of patients; and expecting consumers to be strong participants in their health and healthcare.

	Clinical knowledge	Patient information	Care delivery
Life sciences	• Collaborate on research and appropriately share knowledge within and across disciplines and organizations. • Develop and use standardized core datasets for clinical trials. • Utilize standards-based clinical trial management systems and electronic data capture systems capable of incorporating multiple data types. • Develop an analytics environment capable of integrating phenotype and genotype, supported by robust biobanks with annotated clinical data.	• Conduct adaptive research trials that identify subpopulations of patients based on responses and then address the needs for key subpopulations. • Work collaboratively with providers to appropriately gain access to more patients and patient information.	• Fully utilize EHRs and PHRs to help develop and refine knowledge through automated clinical trials and post-market surveillance. • Develop knowledge that can be easily incorporated into automated cognitive and clinical decision support tools. • Work collaboratively with payers to improve clinical and financial success of new products that will help enable the PHC vision.
All care delivery organizations and clinicians	• Submit standardized public health and quality data and appropriately share data supporting research. • Invest in EHR systems that can easily incorporate clinical knowledge.	• Invest in standards-based EHRs and flexible architecture with ability to integrate external patient data and share data with other venues. • Incorporate patient and family preferences into clinical decision making. • Promote the patient adoption and use of PHRs.	• Take full advantage of available clinical decision support for diagnosis and treatment. • Where available, utilize patient-centered cognitive support. • Help initiate and sustain lifestyle and behavior changes in patients. • Develop multiple delivery channels.
Care delivery organizations and clinicians that conduct research	• Collaborate on research within and across disciplines. • Leverage data from core systems for research, where appropriate. • Implement EHRs and other systems that support clinical research during care delivery. • Help develop research and knowledge standards.	• Incorporate patient data from external sources (for example, genomics databases or biobanks). • Appropriately share patient information within and outside the organization for research purposes. • Separate data from applications. • Promote the patient adoption and use of PHRs.	• Incorporate research hypotheses into clinical care. • Help develop and utilize patient-centered cognitive support for research and care delivery.
Government (policy)	• Drive standards for clinical knowledge. • Fund basic technology research for cognitive and decision support. • Develop privacy regulations that balance individual privacy and research needs. • Support both population-based research and research for subpopulations. • Develop different standards of evidence for different types and uses of clinical knowledge.	• Harmonize standards and develop a common infrastructure for care delivery, research, quality reporting, public health, etc. • Develop intellectual property laws that appropriately protect but don't stifle innovation.	• Structure rewards and payments to appropriately reward evidence-based personalized healthcare, including combinations of services and treatments.
Payers/ insurers (including governments)	• Support knowledge generation about prevention, care coordination, treatment effectiveness, and ways of activating members and patients to make good decisions.	• Share relevant patient data with clinical decision makers. • Analyze patient data to help identify gaps or overlaps in care and safety issues.	• Empower clinicians and patients with access to actionable information and knowledge. • Implement reimbursement that facilitates the move to PHC.
IT vendors	• Participate in development and use of clinical knowledge standards. • Develop systems that can support clinical knowledge generation, management and incorporation.	• Make it easy to appropriately share data among applications and organizations. • Support coding or analysis of unstructured data.	• Provide strong data visualization capabilities. • Support embedded analytics. • Upgrade not only the functionality of products, but also the underlying technology architecture. • Enable mechanisms to integrate with external knowledge bases and "plug in" externally developed components focused on particular types of data (genetics) or disease areas.
Individuals	• Support appropriate secondary use of your information for clinical research. • Participate in clinical trials where you may be a profile candidate. • Participate in other research regarding post-market surveillance of therapeutic interventions or realtime analysis of your health as it relates to your care.	• Utilize PHRs and other personal health tools. • Document preferences in forms such as advance directives • Self report relevant information to your caregivers. • Monitor your own health and participate in remote monitoring where appropriate.	• Expect providers to utilize EHRs with robust decision support and electronic communications with patients and other providers. • Live healthy lifestyles and adhere to treatment regimens. • Participate in clinical decision making where appropriate. • Seek comparative information on providers and medical interventions.

Sources: IBM Global Business Services; IBM Institute for Business Value.

Figure 16: **Stakeholder-specific recommendations to enable PHC.**

HITECH Act funding for HIT

As these recommendations make clear, EHRs play a key role in enabling PHC. A significant portion of the money allocated to healthcare in the HITECH Act – estimates range up to US$44 billion – will be spent on the implementation and meaningful use of EHRs by physicians and hospitals. Opinions vary widely regarding whether the money is being well spent. Concerns range from the government's ability to implement the provisions in HITECH to the criteria that must be met to receive the funding to what the benefits ultimately will be.

It should be clear from the capabilities needed to address the five major HIT-related challenges that today's EHRs will not support the full vision of PHC (see Figure 17). EHRs will have to evolve significantly in functionality (the ability to provide cognitive support, for example) and technical architecture (to easily incorporate data and knowledge from specialized sources, for example) and may even require replacement. Even so, we believe implementing today's EHRs is an important step. Combined with other HITECH funding targets (HIEs and comparative effectiveness research) and with escalating EHR certification criteria, over time, today's EHRs could lay the foundation to continue to improve the science of health promotion and care delivery. We do not think it is feasible to go from today's heavily paper-based environment to IT-enabled PHC in one giant step – it will be a long journey to a rewarding destination.

Key challenge	Current U.S. status	Future needs
Interoperable HIT environment	• Laboratory and medication data • Continuity of care documents (CCD) for EHRs	• Broader and escalating criteria for EHRs • Interoperable clinical knowledge • Certification of specialized sources
Applications/ data	• Expensive customized interfaces • Difficult reuse of data	• Data and knowledge easily and appropriately shared or incorporated
Data and knowledge standards	• HL7 clinical genomics • CDISC	• Genetics (for example, genetic variations) • Clinical knowledge standards • Standards for patient-reported data
Advanced analytics	• General alerts • Retrospective data • Mostly descriptive analytics	• Patient-specific alerts • Realtime data • Predictive and prescriptive analytics
Clinical decision-making foundation	• Transaction-related decision support • "Meaningful use" criteria for EHRs for improving safety and quality • Limited outcomes tracking	• Cognitive and decision support for health promotion, diagnosis, care planning and care delivery • More sophisticated knowledge life cycle • Outcomes tracking for longer periods of time and for chronic conditions

Sources: IBM Global Business Services; IBM Institute for Business Value

Figure 17: **Sample of current HIT-related U.S. initiatives and future requirements to address challenges.**

Conclusion: The PHC journey

The road will be long and challenging to evolve from today's acute-care oriented, reactive, "find it and fix it" and all-too-frequent "trial and error" medicine to the full vision for PHC. While the vision may become clearer and clearer, conceptualizing the exact path and timing of actions needed to accomplish it is extremely challenging. As such, the journey will require numerous experiments, with rapid adoption of lessons learned through both successes and failures. Even so, it is a journey we believe must be taken, given the unsustainability of the health systems in many countries.

The United States must address specific issues, including fragmentation and waste. Equally important, the science of health promotion and care delivery must improve significantly– a challenge common to virtually all countries. Improving the science of health promotion and care delivery via PHC will require a much more powerful HIT environment than one required to address the fragmentation and waste factors. Fortunately, the HIT-related investments made to address fragmentation and waste factors can lay the foundation to continue to improve the science of health promotion and care delivery.

A robust HIT environment that addresses the five challenges is necessary but by no means sufficient for a successful journey to PHC. Other issues relating to policy, funding, education, culture and ethics must also be tackled. As all these issues are examined, some may question the costs associated with the PHC path. However, as countries and organizations continue to make significant investments in healthcare, they need to ask themselves: Should expenditures continue on waste, inefficiency and low-value care or, instead, should investments be made to enable the transformation to a more personalized, patient-centric, value-based, rapidly learning, affordable and sustainable healthcare system? Clearly, we favor the second option and believe that PHC is integral to comprehensive health reform.

About the authors

Jim E. Adams is Executive Director of the IBM Center for Healthcare Management, focused on global thought leadership for healthcare. Prior to joining IBM, he was a senior leader at Gartner and Healthlink and has served as a CEO, CFO and CIO in multiple industries. Mr. Adams serves on national healthcare committees and advisory boards for healthcare organizations and is a frequent speaker on the future of healthcare, healthcare IT and related topics. Mr. Adams can be contacted at *jim.adams@us.ibm.com*.

Edgar L. Mounib is the Healthcare Lead for the IBM Institute for Business Value. He manages the team's strategy-oriented research, exploring pressing issues facing healthcare systems and stakeholders. Mr. Mounib has over 15 years of experience in healthcare (providers and payers) and public health. He can be reached at *ed.mounib@us.ibm.com*.

Amnon Shabo (Shvo), PhD, works at the IBM Research Lab in Haifa and specializes in health informatics. He heads the Healthcare and Life Sciences Standards Program for IBM and holds leading positions in HL7, serving as a co-chair of the HL7 Clinical Genomics Work Group and a co-editor of the HL7 CDA R2 (Clinical Document Architecture) standard, the CCD (Continuity of Care Document) Implementation Guide and the Family History Standard. Mr. Shabo also specializes in longitudinal and cross-institutional Electronic Health Records (EHRs) and has been a pioneer of the Independent Health Record Banks (IHRBs) vision. He is currently leading IBM's contributions to the Hypergenes project (http://www.hypergenes.eu/), which is funded by the European Union to explore the genetic background of essential hypertension through genome-wide association studies. Mr. Shabo can be reached at *SHABO@il.ibm.com*.

Special content contributors

Samuel (Sandy) Aronson, Executive Director of Information Technology, Partners HealthCare Center for Personalized Genetic Medicine

Brett Davis, Senior Director, Personalized Healthcare, Oracle

Andrew Mellin, MD, MBA, Vice President for Predictive Care Solutions, McKesson Corporation

Julie V. Murchinson, Managing Director, Manatt Health Solutions

Ronald A. Paulus, MD, MBA, Executive Vice President, Clinical Operations and Chief Innovation Officer, Geisinger Health System

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Anna Fredricks, Senior Marketing Manager, Healthcare, IBM Sales and Distribution

Amy DuRoss, Vice President of Policy and Business Affairs, Navigenics

Felix W. Frueh, PhD, Vice President of Personalized Medicine Research and Development, Medco Health Solutions

Walter "Buzz" F. Stewart, PhD, MPH, Associate Chief Research Officer and Director, Center for Health Research, Geisinger Health System

Denny Van Liew, Senior Director of Global R&D Strategic Management Group, Pfizer

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