The Complexity of America’s Health Care Industry

White Paper #5: The Increasing Complexity of The Field of Medicine

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In previous NWHA White Papers, we reviewed several factors that contribute to the complexity of the health care industry, which in turn makes health care an especially difficult industry for IT. These included:

- A look at how health care, as a “services-based” business differs in important ways from a “product-based” business.¹
- An overview of the unique role physicians play in the health care industry.²
- A review of the challenges of working with patients who often don’t participate in, or in many cases even understand their own health challenges.³
- The difficulties of formally measuring returns from health care IT investment and making judgements about the quality of the services provided in the health care industry.⁴

In this White Paper we look at several issues which impact the entire field of medicine, creating an overall level of complexity that simply isn’t found in any other industry. We cover themes related to:

1. The increasing complexity of decision making in the field of medicine;
2. The increasing integration of research and clinical practice;
3. Challenges from the burdens of government regulation.

1. **The increasing complexity of medical decision making**

Several years ago, Dr. Bill Stead, Vice Provost for Health Affairs at Vanderbilt University, developed an iconic representation of the challenges faced by clinicians in reaching diagnostic and therapeutic decisions about their patients. In particular, Dr.

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¹ Next Wave Health Advisors, White Paper #1, *Health Care Services; Difficult to Define, Difficult to Measure*, 2015
² Next Wave Health Advisors, White Paper #2, *Complexity in Health Care: The Unique Role of the Physician in the Health Care Industry*, 2015
³ Next Wave Health Advisors, White Paper #3, *Patients are Challenging Consumers*, 2015
Stead observed these challenges are only going to become greater. The graph, presented in Figure 1, is intended to be descriptive at a high level and is not based on any actual analysis of how many data points actually enter into any particular decision. However, it is easily comprehended, 25 years ago, it was the facts about the clinical phenotype that were used predominantly in a clinician’s decision making, including the determination of disease and as the basis for a recommended treatment. When a patient’s genotype starts to be considered, the amount of data to be reviewed on behalf of a patient increases significantly. With the advent of “genomic” medicine in which the patient’s genomic expression patterns enter the analysis, and genomic medicine probes deeper into structures and pathways of cells literally at the molecular level, the number of facts needed to reach a decision escalates significantly.

Figure 1. Increasing Facts per Decision as Medicine become more focused on Genomics

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5 From the clinical perspective, a phenotype is essentially a representation of observable characteristics, such as physical properties, including observations of behavior, data from clinical analysis such as lab tests, etc. A genotype is a representation of the genetic makeup of an individual.
As biomedical knowledge in general is enhanced more and more by discoveries based in genetics and genomics, the individual clinician’s ability to process this knowledge becomes more and more difficult.

Some of the explosion in data sources stems from the rapid increase in new laboratory testing capability. As indicated in Figure 2, over the past decade, the growth in number of unique laboratory tests has expanded exponentially, while the number of laboratories performing those tests has remained relatively constant. In other words, even with a constant supply of testing facilities, the amount of information available has increased substantially.

![Figure 2. Growth in Numbers of Unique Laboratory Tests](chart.png)

Clayton Christensen has provided some insight into this challenge by identifying three major stages of medical practice which in some ways represent ways to improve the processing of medical knowledge, particularly with the increasing use of ever more specific understandings of disease, treatment and outcomes.
Christensen distinguishes these stages as follows:

**Intuitive medicine** – care for conditions can be diagnosed only by their symptoms and only treated with therapies whose efficacy is uncertain. By its very nature, intuitive medicine depends upon the skill and judgment of capable but costly physicians.

**Empirical medicine** – occurs when a field has progressed into an era of “pattern recognition”—when correlations between actions and outcomes are consistent enough that results can be predicted in probabilistic terms.

**Precision medicine** – the provision of care for diseases which can be precisely diagnosed, whose causes are understood, and which consequently can be treated with rules-based therapies that are predictably effective.⁶

Historically much of what we know about medicine has been acquired “intuitively”—based on the accumulated knowledge and experience of the clinician at the time of the encounter with the patient. However, as medical knowledge has progressed and the efficacy of certain interventions can be demonstrated, we will be moving along the continuum to clinical practice based more on empirically validated results—precision medicine.

On the down side, as the number and size of available data sources grow (illustrated in part by Figure 1 above); we can expect much overlap and conflicting information to occur. Absent strict management of terminology (which is the current situation), one physician's description of a patient’s illness may not match another’s, even though the underlying illness may be the same. The ability to query such vast amounts of information becomes not only difficult, but impossible in some cases. Even today, it is estimated between 30-60% of the genomic data currently stored in the federal government’s Genbank may be erroneous.⁷ Simply put, decision making in many areas of medicine is becoming much more difficult due to the explosion of data now being collected and made available to physicians.

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2. Increasing integration of research and clinical practice

Research and clinical practice have historically been quite separate domains: research was practiced in university settings, while clinical practice occurred in hospitals and physicians’ offices. In recent years, however, the boundaries between these arenas have been going away as new approaches such as “clinical research”, “research-driven practice” and “translational research” have become more commonplace. In addition, patients (especially those with life-threatening illnesses) are unwilling to wait the estimated seventeen years for the results from research to make their way into clinical practice. While there has been much progress in lowering this “two decade” time frame, the organizational separation between where research is carried out and where clinical care is delivered, continues to present barriers to moving as quickly as possible from scientific discovery to improved clinical outcomes.

There are, however, increasing concerns about the validity of some of the published articles and the clinical practices they engender, and concerns about the underlying accuracy of some of the scientific data on which new knowledge has been generated and shared, and our inability to determine what is “true” and what it not. Unfortunately, the track record of published research leading to improved clinical practice is itself challenged by what appears to be a number of research efforts that have turned out to be at best a mislabeling of data sources; at worst, outright fraudulent.

The National Cancer Institute makes available to cancer researchers a number of cell lines which have been cultured in the laboratory and shared to stimulate further research. However, it was recently discovered that one of the NCI’s 60 published cell lines labeled as “breast cancer” was actually an ovarian tumor cell

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8 Zoe Slote Morris, et. al., “The answer is 17 years, what is the question: understanding time lags in translational research”, Journal of the Royal Society of Medicine, v 104, n 12, December 2011.
line, not a breast cancer cell line, and as many as 300 papers may have been published with incorrect identification.9

In one of the largest known cases of academic misconduct, an anesthesiologist was accused of fabricating data and then publishing almost two dozen articles using the false data—articles which in some cases purported to change clinical practice.10

With this as background, it is no surprise the task of actually processing biomedical knowledge in order to arrive at a diagnostic or therapeutic decision is a significant challenge in itself. Likely, no other field is faced with such obstacles to clarity and direction (although understanding how one trades “derivatives” or what you actually do with “credit default swaps” is certainly a mystery to many!). Nevertheless, this is the context in which clinicians meet with patients every day, gather data on symptoms, review data from tests the patient has received, and move ahead not only with a diagnosis but in most cases, with a recommended treatment.

Translation of research findings into sustainable improvements in clinical outcomes and patient outcomes remains a substantial obstacle to improving the quality of care. Up to two decades may pass before the findings of original research become part of routine clinical practice.11

It is not sufficient that a new drug may be found in the laboratory to be efficacious in the treatment of a disease that leads to changes in clinical practice; complications come from all of the attendant collateral processes need to be developed, including dosage, identification and management of possible adverse reactions in some patients, educational materials, training of clinicians in the use of the new drug, etc. We want to get to the point that what was research data yesterday, becomes clinical data today, and the basis for predictive models for

diagnosis and treatment tomorrow. This process (outlined below) is circular, and once we are able to measure patient outcomes, this data becomes the basis for further scientific inquiry and discovery.¹²

![Diagram](image)

**Figure 3.** Steps from Scientific Discovery to Influencing Patient Outcomes

While the steps above are well laid out, it is the velocity with which the circle is moving that determines the actual time frame from discovery to care. Under the heading of “Using Information Technology”, the AHRQ has also made this observation:

*The potential for technology to translate research findings into sustainable health care improvements has long been recognized. Technology may be utilized to accelerate the implementation of research throughout organizations more rapidly than would occur if translation strategies depended on individuals or personal interactions.* ¹³

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Although the arrows in Figure 3 indicate a singular right hand circulation, the process of scientific discovery in the “real world” is not so uniform. In fact, the arrows circulate both ways: integration of research and clinical data can be improved by incorporating what we are learning through scientific discovery, and as well scientific discovery processes can be improved by linking them closely with clinical outcomes. The mechanism for making these linkages possible is the data itself: using data from scientific discovery processes to improve clinical care, and in turn using data on clinical outcomes to pose questions which might be able to be tested through scientific discovery.

One of major efforts to establish and validate the efficacy of clinical interventions has been supported by the Cochrane Collaboration, which uses close to 21,000 members organized into review groups in more than 100 countries.\(^\text{14}\) In a recent report on the conclusions from over a thousand reviews, it was determined in 49% of the cases, the evidence did not support either benefit or harm, and in 96% of the cases, more research was recommended.\(^\text{15}\) In short, it would appear about half the time clinicians continue to practice in the realm of “intuitive medicine”, we have a ways to go until medicine is more empirically based, and a long ways before clinicians are practicing “precision” medicine. For those asking whether medicine is being practiced as an art or a science, the documentation suggests we are still very much on the side of art.

The integration challenge is extraordinarily complex on its own, since it can take place both informally as well as more formally, or actually move from chance observations and intuition to structured clinical trials. Unfortunately, this approach relies more often on a “random event” process than one that has been created for predictable outcomes. So, the challenge becomes how to create access to data sources and relationships—“clinical” as well as “research”--so some of the

\(^{14}\) http://www.cochrane.org

“randomness” is taken out of the discovery process, in effect placing much less reliance on AHRQ’s “individuals or personal interactions”. There are several specific tasks which need to be defined and implemented in order to accomplish this:

- Letting clinicians and investigators know what data is being stored and where the data is located;
- Standardizing terminology and vocabulary in general so semantic challenges are minimized;
- Recognizing and protecting the rights of patients regarding how their data is being used.

Integrating research into clinical practice is no small challenge, yet it remains one of the major mechanisms for the improvement of clinical care. Introducing IT capabilities into this process is one way to both structure events more clearly and develop appropriate pathways for clinicians to follow in replicating the published results of the research community.

3. **Consistent burden of government mandates and regulations**

_Virtually no aspect of American health care escapes regulatory oversight._ Anyone who works anywhere in the health care system can attest to the overriding, and some might feel overbearing, influence of regulators. This is true for hospital administrators managing the delivery of health care services, physicians delivering those services, pharmaceutical executives planning the development of new drugs, pharmacists dispensing those drugs, medical directors making coverage decisions for health maintenance organizations, and even computer consultants planning a medical Web site. Outsiders, both in the government and in private accrediting and certifying organizations, have a major role in telling health care workers at all levels what to do.¹⁶

Many industries feel burdened by regulations imposed at the federal, state and local levels. Among these are regulations regarding employment, worker safety, taxes, the

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environment, intellectual property and consumer protection. Yet it can be argued the health care industry, particularly on the provider side, is more heavily regulated than any private business because it must follow all of the regulatory oversight every other industry faces, and in addition, operate under a number of health care-specific regulations.

Most industries face regulatory compliance from the following Federal agencies:\(^{17}\):

- Environmental Protection Agency (EPA)
- Occupational Safety and Health Administration (OSHA)
- United States Department of Agriculture (USDA)
- Department of Defense (DOD)
- Department of Homeland Security (DHS)
- Department of Justice (DOJ)
- Department of Labor (DOL)
- Federal Trade Commission (FTC)
- Internal Revenue Service (IRS)

In the health care industry, however, there are additional federal agencies with regulatory authority which focus specifically on health care. Within the massive Department of Health and Human Services (DHHS), these include:

- Department of Health and Human Services (DHHS)
- Agency for Healthcare Research and Quality (AHRQ)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare and Medicaid Services (CMS)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Services (IHS)
- National Institutes of Health
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- Office for Civil Rights (OCR)
- Office of Inspector General (OIG)

Outside of DHHS, we should also include the Veterans Administration (VA) and the National Science Foundation (NSF).

\(^{17}\) This listing comes from Robert I. Field, op. cit., Appendix B
At the state level, there are also regulatory departments who have oversight for health care, and in many localities, there are additional departments who exercise similar regulatory roles:

- Departments of Health (State and Local)
- Boards of Medicine
- Licensing Boards for Allied Health Professionals
- Departments of Welfare
- Departments of Insurance

In addition to the myriad of public agencies regulating health care, there are private organizations, which in particular, have authority over the licensing of health care organizations and the professionals who work in the field:

- Accreditation Council on Graduate Medical Education
- American Board of Medical Specialties (ABMS)
- Association of Schools of Allied Health Professions (ASAHP)
- Education Commission for Foreign Medical Graduates
- Federation of State Medical Boards
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
- Liaison Committee on Medical Education (LCME)
- Medical Specialty Societies
- National Board of Medical Examiners (NBME)
- National Committee on Quality Assurance (NCQA)
- United Network for Organ Sharing (UNOS)

Beyond the regulatory agencies focused on both business in general and health care specifically, legislative mandates have both stimulated health care IT investment and challenged many areas of health care (including hospitals, health systems, long care facilities, ancillary health organizations and clinicians). Most recently the HITECH legislation provided funding for the implementation of Electronic Health Records while at the same time through requirements for demonstrating "meaningful use", stipulated penalties for those who didn’t make the investment or weren’t able to meet the standards for compliance.18

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18 2009 Health Information Technology for Economic and Clinical Health Act (HITECH Act)
At the same time providers and provider organizations are attempting to work successfully within this regulatory environment, they are also facing mandates to update the practices they use for coding the care they provide. For a number of years, health care providers and payers have used the International Classification of Diseases, Version 9 (ICD-9), to report on inpatient diagnoses and procedures. This version of the coding standard contained over 20,000 code sets which have become integral to clinical practice. However, the federal government has mandated all health care organizations and providers upgrade to Version 10 of this classification, which will increase the number of codes to over 155,000. Coding a sprained ankle, for example, currently uses 5 coding options; this will increase to 45 under ICD-10. Angioplasty currently uses only one code; with ICD-10, the number of coding options increases to 1,170.19

A recent study reported physicians currently spend over 20% of their time “interacting with insurers on formularies, claims, billing, credentialing, pre-authorizations, and quality measures data”, a number which is certainly likely to increase,20 with a concomitant increase in physician workload.

IT companies investing in the health care industry may not be affected by every regulatory agency or legislative mandate or even regulations promulgated by federal, state and local agencies. The important point is their customers do feel the impact of all of this, must deal with this complex set of rules and regulations, and must consider them in the process of contemplating any IT investment.

IT companies seeking to be successful in the health care industry must understand the industry, and in particular the challenges which come from its uniqueness and complexity when compared to all other industries. While America spends trillions of dollars on health care, it can be a significant challenge for IT companies seeking to capture even a small part of this expenditure. Those who

take the time and make the investment in increasing their understanding of this industry will be rewarded, but the path is neither easy nor straight.

**Next Wave Health Advisors (NWHA)**

NWHA Advisors have long recognized the challenges of managing within a highly regulated environment. Over the years, they have been particularly successful in the development of IT strategies and in the implantation of IT systems which operate within the regulations of federal, state and local governments. IT companies working in the health care industry can take advantage of this expertise to improve not only their product offerings, but the success of the implementation of those products.