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PUTTING IT ALL TOGETHER

THE BUILDING BLOCKS TO CREATE THE 21ST CENTURY HEALTH CARE DELIVERY SYSTEM

For the past three years, industry leaders have been meeting to discuss possible strategies to reengineer the health care system.[1] This year they have focused on four building blocks that make up the system: financing, regulating, purchasing, and providing. (See SLIDE 1.) The first is the financing of a system that would provide basic universal coverage, being developed by Victor Fuchs. The second, still in the research stage, involves the establishment and integration of a regulatory body or bodies to oversee the system. The third is the evolving realities of purchasing. Finally, there is providing and the evolution of the delivery system. The first two still require intense research and political opportunity. On the third and fourth, the purchasers and the delivery system, we are well underway.

Financing and regulation I'll discuss briefly at the outset. Then we will take up purchasing and finally the delivery system.

THE FINANCING OF BASIC UNIVERSAL HEALTH INSURANCE

Although the time does not seem ripe for moving ahead with a strategy for universal coverage, to not include it in a vision for a 21st century program would be derelict. One of the most thoughtful proposals is being developed by Ezekial Emanuel and Victor Fuchs. (See SLIDE 2.) Called "An Efficient, Equitable Approach to Universal

[1] JFK School of Government Health Care Delivery Program at http://www.ksg.harvard.edu/cbg/hcdp/

Coverage,"[2] it would establish a semi-autonomous agency similar to the Federal Reserve with commissioners serving a term not coterminous with the President. Rather than setting interest rates to minimize inflation and maximize employment, the agency would balance the setting of a basic health benefit against the cost of a dedicated value-added tax. The job of balancing a tax against basic benefits in an agency protected from political interference has much appeal.

In the Fuchs plan, those who wish to obtain more health care could purchase supplemental coverage with after-tax dollars. This proposal would be different from the HSA passed as part of the Medicare Reform Act. The HSA as written is triply tax-free (going in, earnings on available dollars in account, and coming out for medical uses). In the Fuchs plan, the general budget would be freed of the existing tax losses, e.g., corporate and Medicaid. Given the tax implications, one gives universal basic insurance coverage, the other in reality is limited to people with sufficient incomes to invest, similar to 401(k)s. (Although companies as well as individuals can make deposits, the end result could be like a 401(k) but with the catastrophic coverage requirement.)

In setting the basic benefit, staff would monitor productivity—balancing advances in quality that have significant value from those that do not. Just as the determination of productivity affects the Fed's monetary policy, health care productivity would affect the scope of basic benefits. Such a balance might well send producers of drugs and devices to reduce costs or significantly improve quality—measured quantitatively. The agency would use data from semi-autonomous agencies, including the FDA, CDC, and ARCQ to determine the best balance of cost and quality.

A GOVERNMENT REGULATORY SYSTEM

Introduction

[2] Ezekiel Emanuel and Victor Fuchs, "An Efficient, Equitable Approach to Universal Coverage," presentation of preliminary plan to Harvard University Kennedy School of Government Health Care Delivery Policy Program, Scottsdale, Arizona, February 2004.

In remarks to the Boston Economic Club, Alice Rivlin noted,

> *Just about everybody has concluded that a high-performance economy has to be one in which the dominant motivation behind economic activity is a pursuit of personal gain. What is not widely recognized is that the easy part of a free-market economy is the market part. The hard part is creating the public policy environment within which the market can operate effectively….*
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> *First, if markets are to work, there have to be rules of the game about property rights, bankruptcy, contracts, and not injuring others in specified ways. Second, there have to be social, environmental, and other public policies in place to handle the fact that people and companies operating in their own interests tend to load costs onto others when they can and leave behind those unable to fend for themselves. And third, there are genuine public goods – armies and navies, police, roads, parks, and public health services – that private investors operating on their own will not provide.*[3]

Metaphors

It is not that we do not have effective regulatory agencies for many key industries—we do, and they address safety and quality, standards, standard reporting, transparency, grievances, arbitration and tort law. Industry and government efforts have transformed whole industries—the FAA and NTSB ensure the safety and efficiency of civilian air transportation, the SEC and Congress, by allowing the integration of the financial services industries, permitted multiple silos to be merged. (See SLIDE 3.)

We have begun to undertake the research that would give health care a government agency that could address issues now handled by a wide variety of SROs or by Medicare and Medicaid as a part of their responsibilities. Since quality and safety have been on the top of our agenda most recently, the metaphor we have used is the

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[3] Alice M. Rivlin, "Challenges of Modern Capitalism," *Regional Review,* Federal Reserve Bank of Boston, Volume 12, Number 3, Q3, 2002, remarks to the Boston Economic Club on April 17, 2002.

Federal Aviation Agency. Similar to health care, the civil air transport system depends on complex interrelated activities to reach the level of safety required and regular and unscheduled monitoring to keep the system safe. Civil air transport has only gotten safer over the past 25 years. While there are those who say the consequences to the air transport team are more catastrophic than to health professionals, there is much we can learn from their procedures and policies. Perhaps the most important one is that the ancillary agency, the National Transportation Safety Board, does not report to the FAA. The NTSB has a well-staffed capability not only to understand accidents, but to continuously test ways to improve the system, which has led to both safer and more efficient transportation.

Another metaphor is found in the Federal Reserve System, where the Fed as a semi-autonomous agency, in addition to setting interest rates, carries out significant supervision and regulation. What makes it relevant is that it shares the function with the Executive Branch Office of the Comptroller of the Currency, and with state banking commissioners. Health regulation is also spread throughout the federal and state governments. How does the banking system remain strong and open and responsive to public need? An example is the Community Reinvestment Act.

Also within the financial world, we have the SEC, which includes FASB where standard vocabulary and reporting are maintained. Although an SRO, its standards reinforce transparency and performance comparisons. Another agency of the SEC is the National Association of Security Dealers, the SRO that licenses dealer-brokers and—perhaps of greater interest to us—carries out an arbitration function to determine cause and appropriate compensation before ending in court.

It is our goal to develop a model for a health care system regulatory agency. As Alice Rivlin remarked, balancing a market system and public policy is a dynamic and necessary function in the 21st century world.

In addition to the metaphor approach, we are doing research on recent strategies to improve regulatory results. They include performance-based, management-based, and risk-based regulation.

PURCHASING HEALTH INSURANCE

The inclusion of HSAs in the Medicare Prescription Bill (Medicare reform bill) is perhaps the most important legislative change in the past 30 years (since HMOs). (See SLIDE 4.) Along with consumer-defined health plans already being offered by a number of firms, small and large, it signals changes in the purchasing structure. Jack Rowe from Aetna reports steep growth in uptake and that United Health Group has tripled its membership.[4]

From Third Party to First Party

This shift in the insurance structure coincides with the burden of premium increases shifting from companies to employees and retirees. Most labor negotiations now involve maintaining health benefits rather than wages. In Medicare payments, Part B increased 6.2 percent while CPI payments increased only 2.6 percent.[5] From the late 1990s to the present, the average employee contribution went from 10 percent to 30 percent, while large numbers of companies either decreased or eliminated retiree supplemental benefits.[6]

From Defined Benefit to Defined Contribution

Some have suggested that the pattern in health care insurance looks similar to that seen in retirement benefits. Not suddenly—but over a number of years—corporations (except those that are unionized) shifted from defined benefits to defined-contribution

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[4] J. Rowe, Harvard Interfaculty Program for Health Systems Improvement Stakeholders Meeting, Boston, MA, Harvard Faculty Club, February 25, 2004.

[5] A.H. Munnell and A. Sunden, *Coming Up Short: The Challenge of 401(K) Plans*, Washington, DC: The Brookings Institution, 2004 (forthcoming).

[6] Kimberly Blanton, "Unhealthy Increases: Employees At Small Firms Hit Harder By Health Plan Costs," *Boston Globe,* February 18, 2004, D1.

retirement funding. The 401(k) plan offered a strategy for tax-free contributions from employees that rolled over and were portable.

The patient-defined health plan and Health Savings Accounts seem to be moving in that direction with a few significant differences. First, these plans require catastrophic insurance with a minimum $2,000 deductible, but then include a cash deposit to patients and freedom in how they want to spend it. We propose three additional features: (1) is a carve in of additional dollars for those with chronic disease or high risk for it, (2) means-testing deductibility and cash doughnut hole, and (3) for patients who keep good habits of health promotion, disease prevention, and compliance with chronic disease protocol, reduced payment for both catastrophic insurance and a bonus cash deposit.

Economic researchers, in the field of behavioral economics (awarded a Nobel in 2001), have been studying participation in 401(k)s. The results have been very interesting. In a 401(k), there is a complicated array of choices: the voluntary sign up, matching contributions, asset allocations, and the ability to withdraw money when changing employment. The research demonstrates that “homus economus” does not, in real life, act rationally. In an article entitled "Libertarian Paternalism Is Not an Oxymoron," Cass Sunstein and Richard Thaler cite a study of 401(k)s in which participation soared when enrollment was automatic and opting out required effort, rather than the usual structure in which employees must opt in. The idea is that choices can be structured such that the default serves the goal, which in this case is increasing savings rates. No freedoms are abridged.[7]

If we are indeed moving to a similar system for health care, we have an enormous education job to do, even if we employ libertarian paternalism. What plan to take? (How much risk)? What doctor to choose? What tests to have? What treatment and by whom?

[7] Cass R. Sunstein and Richard Thaler, “Libertarian Paternalism Is Not an Oxymoron,” AEI-Brookings Joint Center Working Paper No. 03-2; U Chicago, Public Law Working Paper No. 43; U Chicago Law & Economics, Olin Working Paper No. 185.

Insights from the behavioral sciences are of increasing import because of the juxtaposition of Information Technology and Communication (ITC) and consumers' integration of the Internet into their daily behavior, and also the growing recognition of the importance of health promotion to disease prevention. The consumer is now able and expected to partner with providers to achieve an effective health care system. (See SLIDE 5.) How do population health, epidemiology, and behavioral economics come together to develop strategies that produce better health and medical care with the fewest "defects," opportunities missed, and treatment processes not followed?

We have also begun to segment the new partnership by division of responsibility according to the degree of health or medical care. Isham's work suggests a way to think about the progression of health needs and the transition of responsibility between patient and either health plan or care team.

As patient-defined plans and HSAs are rapidly being added to the offering, plans are using predictive risk techniques and disease management programs to control premium costs (not risk). The companies who do a better job clearly will be able to limit premium increases. Another example of libertarian paternalism is the changing use of disease management programs (for wellness, chronic disease, or catastrophic disease). A voluntary offering of employers up to now, a number of companies are requiring participation and demanding reduced costs from those companies providing these programs to insurers—a sign of employers' acceptance of these programs.[8]

Finally, based on the segmenting of consumer populations, plans are assembling networks for niche markets rather than only freedom of choice models. Results from a market survey segment health professionals by how they would prefer to relate to their patients. Recognizing differences and matching preferences is one of our ongoing research programs.

[8] Ibid.

THE PROVISION OF HEALTH AND MEDICAL CARE

Charged with satisfying the many conflicting needs of patients and caregivers, the health care delivery system must recognize that it is not the first to face major challenges to the way it operates. Other industries in this country have been forced to change, often because of competition from foreign companies that have been able to provide products at lower cost and higher quality. Customers have demanded that U.S. companies become more competitive or face the prospect of economic failure. While the pressures and the ultimate consequences to the health care delivery system are not identical to those of other industries, it is clear that the experiences of industries that have successfully adjusted can serve as a useful guide to the health care industry.

Two major changes have occurred in health care delivery. The first was organizational, consolidation to reduce overcapacity and to gain market power in negotiation with managed care companies. The second was the revelation that safety and quality of medical care are variable and that new studies continue to cast them as low. After the landmark study *Crossing the Quality Chasm,*[9] a wave of projects looked to improve various aspects of safety and quality. However, as we round five years, there is an emerging understanding that individual projects alone cannot improve the system to the extent needed.

Rather there is recognition that the system itself is in need of change. In a recent *New York Times* article entitled "Running a Hospital Like a Factory, in a Good Way," Don Berwick is quoted, saying whether in industry or in health care, "quality strategy gives a unified vocabulary for thinking about production as a system with a focus on customers."[10] With the emergence of a common vocabulary for clinical, economic, and managerial aspects of the system, the possibility of success in transforming the system is greatly improved.

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[9] Committee on Quality of Healthcare in America, Institute of Medicine, *Crossing the Quality Chasm,* Washington, DC, National Academy Press, 2001.
[10] Andrea Gabor, "Running a Hospital Like a Factory, in a Good Way," *New York Times,* February 22, 2004.

Two more trends bode well for the future. In the past five years, major advances in the social and behavioral sciences and in the information technology and communications industry have occurred and have important implications for health care delivery.[11] Second, economists have made great progress in understanding the measurement of productivity in service industries. Work by Jack Triplett and Barry Bosworth confirms that the great spurt in productivity is in the service industries.[12] Building on advances in productivity measurement in services, we can accelerate our research into health care productivity.

LOWER COST AND HIGHER QUALITY = PRODUCTIVITY

If we wish to design a health care delivery system to achieve quality and efficiency, we must be able to measure quality and efficiency. With a system in place to track and measure productivity, lowering costs and improving quality could become a reality. (See SLIDE 6.) In the report *At What Price?,* published by the NRC in 2002, there is a chapter entitled "The Special Case of Medical Services." In it Ernie Berndt outlines the reasons medical care is not like any other service industry. He raises the key question of whether the BLS should measure the medical CPI based on medical inputs or medical outcomes. With the advances in service industry research, and the evolution of medical care to include evidence-based medicine and disease management, significant data sources on outcomes are becoming available. On the quality side, health services researchers and insurance companies are developing and testing measures for outcomes of episodes of illness and chronic conditions. The claims data of insurance companies have been rearranged into condition or episode "groupers." These advances make it possible to test the recommendation that Ernie Berndt made:

> *BLS should select about 15 to 40 diagnoses from the ICD (International Classification of Diseases), chosen randomly in proportion to their direct medical treatment expenditures and use information from retrospective*

[11] S. Zuboff, *The Support Economy: Why Corporations are Failing Individuals and the Next Episode of Capitalism,* Viking: New York, NY, 2002.
[12] Barry P. Bosworth and Jack E. Triplett, "Services Productivity in the United States: Griliches' Services Volume Revisited," Brookings Institution, Washington, DC, September 2003.

claims databases to identify and quantify the inputs used in their treatment and to estimate their cost. On a monthly basis, the BLD could reprise the current set of specific items (e.g., Anesthesia, Surgery, Medications) keeping quantity weights temporarily fixed. Then, at appropriate intervals, perhaps every year or two, the BLD should reconstruct the medical care index by pricing the treatment episodes of the 15 to 40 diagnoses—including the effects of changed inputs on the overall cost of those treatments. The frequency with which these diagnosis adjustments should be made will depend in part on the cost to BLS of doing so. The resulting MCPI price indexes should initially be published on an experimental basis. The panel also recommends that the BLS appoint a study group to consider, among other things, the possibility that the index will "jump" at the linkage points and whether a prospective smoothing technique should be used.[13]

Just recently, the Bureau of Economic Analyses let a contract to begin testing the recommendation. Simultaneously, a number of individual efforts are underway in academic centers.

Of equal import, because health care delivery is a service industry, there have not been the usual productivity measures and metrics against which engineering design, development, and improvement can be targeted. Productivity brings together the measures of costs and improvements in quality and social benefit. The application of productivity measurement techniques, together with engineering experience and application, represents a particularly fertile interdisciplinary area of research.

As SLIDE 6 shows, it is possible to take conditions (the 15 priority conditions to begin) and, adjusting them for severity both clinical and functional, examine the full

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[13] Charles L. Schultze and Christopher Mackie (eds.), *At What Price?: Conceptualizing and Measuring Cost-of-Living and Price Indexes,* Washington, DC: National Academies Press, 2002.

resources used in caring for each condition. In our research, these will be derived from three sources: claims data; clinical data; and disease management protocols.

These advances in technology and in understanding health care as a service industry ready us for an organized transformation of the health care system that is focused and rigorous.

FIRST PRIORITY: ESTABLISHING COST AND QUALITY IMPROVEMENT IN HEALTH AND MEDICAL CARE (PRODUCTIVITY)

The Genomic Analogy

Think of productivity measures as the gene library where, rather than genes being tested against disease implication, our condition library contains severity-adjusted conditions (both clinically and functionally) and the evidence-based best demonstrated process for achieving outcomes that include the clinical, technical, function, service, and trust.

This construct of productivity brings together in the same vocabulary the issues of equality, safety, and costs. As quality and safety problems appear with painful regularity, costs of care are continuing to increase at rates multiple of the CPI, making the transition to “productivity metrics” a fundamental and critical next step in creating a viable delivery system. Again, to use the genome analogy, simply knowing what is in the library does not move the operation of the system to a new place. Just as genomics is exploding into interdisciplinary systems biology, productivity metrics must move the delivery system ahead.

Embracing Productivity and Systems Engineering

In engineering there already exist tools and techniques, broadly grouped as systems engineering, that have been used in other industries for many years. While medicine is a special case, the general knowledge and specific applications create the opportunity for a system focus for the delivery system, with engineering tools and techniques being married to the delivery of care. A soon-to-be-released study jointly developed by the NAE and IOM, calls for the establishment of a permanent program that combines the advances in productivity with the tools of information technology and techniques from engineering.

COMPLEX INTERDEPENDENT SYSTEMS

To bring order and improvements to health and medical care delivery, the report proposes using the approach of engineering to complex interconnected systems as a framework to carry out the next stages of translation to practice. (See SLIDE 7.) Once again recognizing medicine as a special case, the report separates the complex interconnected system into four levels: the patient; the front line team; the organization; and the environment.[14]

The Patient

Fifty years ago, with the post-World War II construction of a nation of community hospitals, the patient was brought to the site where all modalities of care could act upon him, and a single chronological comprehensive record was kept as documentation of the diagnosis, the plan of treatment, and the result of that treatment. The doctor was the process and plan designer and the nurse the foreman. The patient was the passive recipient of the care.

It was then that we embarked on the knowledge quest that created such expansion that medicine was divided into increasing sub-specialties in order to keep someone up to date on the rapidly advancing knowledge and practice. Soon after, the advent of HMOs sought savings through the reduction of unnecessary hospitalizations and length of stay.

Fifty years later, medicine has moved from the hospital as a place where care was concentrated to a myriad of sites with no coordinator or overall designer. The patient has

[14] E.B. Ferlie and S.M. Shortell, "Improving the Quality of Health Care in the United Kingdom and the United States: A Framework for Change," *Milbank Quarterly* (2001): 79: 281-315.

gone from “passive” to “active,” both as coordinator of his own care with no easy way to do so and as active participant in diagnosis and treatment decisions.

Imagine we recreated the nurse call button as a home-based or portable device. We would return the connectivity to 7x24x365. You ask where we will get the nurses to respond to the population at large when we are faced with a nursing shortage today. Advances in the coordination, analyses, decision supports, and data collection devices of such micro size and cost enable us to turn the home into an ICU. Not only does that improve timely oversight of critical parameters, but it allows decision support to respond and take appropriate action itself. And to anticipate the question—that does not take away from the unique skills of the doctors and nurses to interpret symptoms and signs to make appropriate decisions for each patient. The growth of evidence-based medicine and the ability to undertake mass customization of a standard plan—by matching patients’ complete data against a decision base—moves the production of routine but complicated medicine into the modern era.

This year alone will see enormous advances in remote monitoring, biosensors, asynchronous language systems, the net and the web, and now ultra-wideband wireless networks that will greatly enhance our capabilities to gather and transmit *information*. New capabilities will be fully realized within an information infrastructure that collects data and then connects it to all the other nodes required for health care delivery.

Not only will this improve the quality of care, it will also address the documented growing dissatisfaction of patients with the quality of their interaction with the care system.

<u>The Front Line Team</u>

One of the most clearly articulated descriptions of the front line team is described in an article “Microsystems in Health Care” by Nelson et al.[15]

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[15] E.C. Nelson et al., “Microsystems in Health Care: Part 1. Learning from High-Performing Front-Line Clinical Units,” *Journal of Quality Improvement,* 28(9):472-497, September 2002.

What is a front line team? A clinical microsystem is a small group of people who work together on a regular basis to provide care to discrete subpopulations of patients. It has clinical and business aims, linked processes, and a shared information environment, and it produces performance outcomes. Microsystems evolve over time and are often embedded in larger organizations. They are complex adaptive systems, and as such they must do the primary work associated with core aims, meet the needs of internal staff, and maintain themselves over time as clinical units.

Since the publication of *Crossing the Quality Chasm*, there has been significant work on the attributes of the team. Ed Wagner has thoughtfully laid out the progress they have made in improving performance of the team. He concludes that progress has reached a much improved but still only adequate stage. To our thinking, it is time for research and experimentation to transition to the next stage using engineering practices and tools. Imagine that after reviewing a patient's data, both from the patient's input and the data in the EMR, the team has available a protocol for the diagnosis and care of the patient (as well, at Mayo, of the last 400 cases with similar findings), makes customizing changes, and sends the protocol forward for execution.

It is here that flexible manufacturing techniques can ensure that no handoffs are dropped and no results data escape review. The team member would have a "cockpit" available for monitoring the patient's condition. Thus, many safety and quality problems would be significantly decreased if not eliminated, as the team or the accountable individual would be aware of the patient's condition around the clock. As in avionics, sophisticated programs monitor raw data, assess it for any important change and limit transfers to the team member to important information. This system would employ knowledge in pursuit of care quality and safety.

The Organization

It is at the level of the organization that flexible manufacturing is carried out. The organization's overall climate and culture for productivity, as well as corporate decision-making and human resource practices, create the "learning organizations."

The Environment

With standardized vocabulary and reporting, the environment is able to use data for many things, from post-introduction surveillance of drugs and devices, to front-line signals for detection of bioterrorism incidents. The CDC could trace communicable diseases; policy makers would be able to model and simulate the impact of legislative and regulatory actions.

How are these complex interdependent systems managed? Engineering tools and techniques have successfully made such systems more productive in terms of quality and cost.

ENGINEERING IN THE SERVICE OF MEDICINE

Within the framework of complex interdependent systems, we can divide engineering contributions into two large opportunity sets:

- Information Technology and Communications
- Engineering tools and techniques (See SLIDE 8.)

At each level of the system the backbone is the information system. A number of information technology companies are moving to this next generation. They have taken concepts from other industries and adapted them to medicine. While they still have the same front-end systems, they have much more sophisticated capabilities, which at present few health care systems can use.

INFORMATION TECHNOLOGY AND COMMUNICATIONS

Health care delivery is almost entirely dependent on information, which today is housed in a myriad of silos. So many errors and missed opportunities come from not knowing key information. Handoffs between silos are very difficult and fraught with unreliability. (See SLIDE 9.)

ITC advances in power, ubiquity, and declining cost are making the tradeoff between capital expense and productivity (both cost and quality) too significant not to be one focus of the national effort. The advances in microsystems and biosensors make it possible to collect patient data at long distance, continuously, and at low and declining cost.

Microsystems: Making Every Room an ICU

> *While improvements in handling information could have dramatic effects on making the health-care system more efficient and on eliminating errors, much more will be needed to meet the challenges that will confront us during the coming decades. We will somehow have to provide much better monitoring and diagnostics to substantially more patients, and we will have to do it with fewer nurses and physicians. Microelectronics, by itself, can only interface with other electronic systems, occasionally displaying data for interpretation by physicians. While software to distill data into conveniently readable forms and suggest treatments may emerge, just as systems for checking drug interactions are emerging today, none of these systems will fully meet the challenges of the health care system unless we can obtain better data in the first place.*
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> *In parallel with developments in microelectronics, there has been a move to develop sensors based on the same technology. The resulting integrated sensors have evolved to microelectromechanical systems (MEMS), and combined with microelectronics and wireless interfaces are now emerging to form wireless*

integrated microsystems (WIMS). These microsystems (Wise, 1996, 2002) will merge sensors with embedded microcomputers and wireless transceivers in volumes of 1cc or less and operate at power levels below 1mW, consistent with long-term operation from batteries or even energy scavenging from the environment. They have the potential to turn every hospital room into an intensive care facility. They are small enough to be worn comfortably and unobtrusively, communicating with a bedside receiver that, in turn, communicates with monitoring stations and the larger health care facility. While present-day examples of such systems are still few and limited in performance, they are emerging. Blood oximeters, heart rate monitors, and temperature sensors are all candidates for WIMS use, and swallowable capsules for internally viewing the digestive tract have been reported. Wearable devices for blood pressure (hypertension), breathing patterns (sleep apnea) and other variables are certainly possible in the near term. The major challenges in this area are the interfaces with the body itself, but technology now appears ready to address an expanding array of such problems.

Swallowable capsules for all kinds of internal viewing and measurement could significantly improve our ability to diagnose a variety of conditions and could improve the quality of health care. DNA analysis chips are another example of technology that can be expected to have a broad impact. Such chips (Mastrangelo et al., 1998; Burns et al., 1998) will take advances in genetics into the hospital and even into the local doctor's office. They should produce substantial improvements in both diagnostics and preventative medicine. But although these developments will improve health care quality, their impact on costs will likely be indirect. There are also substantial issues of privacy to be dealt with.

Wireless integrated microsystems for health care are expected to be technically feasible within the coming decade, but in order to reduce costs, a complete system in which they can be used must emerge. Bedside receivers and wearable monitors could be a technical triumph but could also be an economic disaster for the *company producing them unless a larger system exists that can make use of such devices. Similar situations have existed for at least 20 years in the process control industry, where sophisticated sensors have been prototyped but have been very slow to be applied because controllers able to use their features have not existed. In the transportation industry, the entire control system of the automobile engine had to be redesigned to take advantage of microprocessors and electronic sensing. Thus, although an increasing number of wearable and implantable monitoring devices are possible, the larger system needs to be available to make use of them, and that calls for efforts (and coordination) at every level of the health care system.*[16]

ENGINEERING TOOLS AND TECHNIQUES

The second set of tools takes the data and information and transforms them in usable nodes of information for decision making, process design, fault correction, and optimal production. (See SLIDE 10.)

Examples of How Engineering Could Improve the System

Let us start at demand for care across the organization. One of the critical differences from other industries is the uncertainty of demand—how many, what sort, and how urgent. Modeling uncertainty is an example of using the tools of queuing theory in its many variants, to model scheduled, unscheduled, and urgent demand. Predicting demand has the potential to mitigate a number of problems. The Emergency unit has increasingly become the bottleneck into the delivery system. One can imagine—rather than patients calling endless phone numbers that turn out to be voice mail—enterprise systems where patients can indicate their need, either voice or internet response occurs appropriately for the problem and is smart response not "dumb." As that information comes in 7x24x365, the system is monitoring and testing the capacity to handle the

[16] T.F. Budinger, "Practical Biomonitoring using Wireless Technology," presented at NAE/IOM Workshop, "Engineering and the Health Care System," March 11-12, 2003; Also see Rob Stein, "Patients Find Technology Easy to Swallow," *Washington Post,* December 30, 2002, A1.

variety of problems. The key is always knowing the "state you are in," not only demand in the aggregate but what is actually happening at present in the organization.[17]

In the next level of engineering applications, such techniques as concurrent engineering are used to examine the needs and wants of all the stakeholders, including patients, first line team, and emergency response, followed by translation of these activities into actual computerized protocols. As we noted above, that is not cookbook, but rather as Toyota configures it, allows made-to-order iterations of the basic "design" (from evidence-based medicine). With knowledge of the predicted demand and what that demand will need from each level of the system, one turns to the organization's activities least utilized in health care delivery, namely CAM or in services Computer Aided "process management." The delivery system could use many techniques from other industries to optimize the functions that go into the diagnosis and treatment process.

By knowing both expected demand and current use, one can use engineering techniques to access the people or machines needed to respond. The object is to optimize the assets available to produce the most defect-free outcome in the shortest time and with the most efficient use of resources. One critical aspect of the optimization is to know what assets are not available because of breakdown or being occupied elsewhere. A process management system continues updating and rerouting in real time the patients throughout the system.

The other means by which Toyota achieves such high quality of production is engaging the front line worker in understanding the goals of his or her function, understanding the current state of the function, and working as part of a team to accomplish the function. If there is a breakdown, the team is equipped to work around or to immediately inform the system of the breakdown, such that incoming work can be

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[17] J. Birge, personal communication.

rerouted. At Toyota, workers are encouraged to forward ideas for improving either reliability or efficiency.[18]

Finally there is continuous monitoring of performance, of failures in supply chain, of deficits in capacity, and in the data being shared with workers, supervisors, managers and top management and the back office functions of enterprise management.

BARRIERS TO IMPLEMENTATION

There is clearly an underlying assumption in industry that is not true in the health care delivery system. In industry, fully integrated enterprises carry out these activities. It is no wonder that the first generation systems that have been most successful in applying these principles are such integrated systems—Kaiser, Mayo, and the VA. These systems are all beginning to move to the next level. They are undertaking major new projects to take advantage of what has been learned both inside and outside their enterprises, and to leverage the great advances in ITC and design, analysis, and control.

As an aside, one of the major issues facing the system is that reimbursement is predicated mainly on individual input units. Technologies that are developed to increase accuracy, but do not contribute to the outcome, attribute their demand for higher prices to the higher "quality" of both the machines and the labor. Experimental reimbursement systems that are predicated on diagnosis and treatment of conditions (not inputs) and measured by the outcomes of quality, from clinical, to functional, to "trusting," to service, are coming into testing now.

The transition to this way of thinking can have a critical influence on technologic innovation in health care. Rather than continuing to reward the development of more sophisticated equipment which garners greater reimbursement, a productivity driven system becomes a more rigorous version of technology assessment. Technology has to

[18] K. Bowen, "Decoding the DNA of the Toyota Production System," *Harvard Business Review,* September 1, 1999.

demonstrate real quality improvement to gain reimbursement. Examples could include the "automated" bath for elderly patients, the aforementioned turning a room and the home into an ICU, and patient-friendly devices to encourage compliance—the needleless insulin dosing, the simplest effective treatments such as diuretics for hypertension, or healthy habits rather that surgical procedures for heart disease.[19]

Given the maturation and integration of ITC, the biosensors and microsystems that accompany them, and the steeply decreasing costs of IT, the major hurdle is the reengineering of large numbers of jobs, all of which are codified as professionals (independent thinking), each in a narrow area of knowledge.

ESTABLISHING A NATIONAL PRODUCTIVITY AND SYSTEMS ENGINEERING RESEARCH AND DEVELOPMENT PROJECT

It is our strong belief that we must establish a permanent research and development effort with engineers and health professional housed together, adjacent to laboratories for home-, office-, and hospital-based prototype development and finally testing and scaling. (See SLIDE 11.)

Progress also rests on changing medical education and training. Two core transitions in belief are necessary—one, that caring for patients in teams, and not as individuals, is not losing one's professionalism, and two, that using protocols and algorithms are not cookbook medicine.

Fortunately, we have seen the beginning of experimental efforts to build research laboratories for care delivery. Clinical research physicians and engineers are beginning to enter strategic partnerships with industry to develop the programs that should one day

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[19] James Brooke, "Machida Journal; Japan Seeks Robotic Help in Caring for the Aged," *New York Times,* March 5, 2004; Daniel Rosenberg, "Medical-Device Makers Striving To Perfect the Needleless Injection," *Wall Street Journal,* March 18, 2004, D4; Gina Kolata, "New Studies Question Value of Opening Arteries," *New York Times,* March 21, 2004.

exist at medical schools.[20] As in the biosciences, the setup must be permanent for advances in both engineering sciences and medical device technology. There is one major exception. In engineering, one builds and tests prototypes and then from the tests improves the device or system. Turnaround time is measured in minutes, hours, or days. When the lab and operating staff are satisfied—then and only then is it turned over to manufacturing for limited manufactured runs and wider testing. Development of computer systems will call for a continuous learning organization receptive to new capabilities as they are in medical sciences.

REENGINEERING THE SYSTEM

It is important to recognize that there is no technology/engineering "silver bullet." Rather, progress requires understanding and leadership at all levels of the delivery system, appreciation for and commitment to the organizational change/innovation that will ultimately secure the transformation to patient-centered care, and continuous improvement.

As we translate this new knowledge into practice, each element of the organization must have becoming a "learning organization" as part of its basic values. It cannot become a dynamic and responsive system without this characteristic. Learning can only be accomplished through experimentation—exploring alternative approaches or reaching out to learn from other successful organizations. But with experimentation comes the possibility, even the likelihood, that some experiments will fail. The foremost principle of a "learning organization" is that failure in the presence of a good faith effort must not be punished. The tendency to "shoot the messenger" when the message is bad must be eliminated. Individuals and organizations must be encouraged to seek new ways of accomplishing their objectives. The habit of creating an institutional memory of both successes and failures is important in formalizing these processes—not to reward success or punish failure but to record lessons learned.

[20] D. Cortese, Remarks at Mayo Clinic Trustee Meeting, February 20, 2004.

Accepting that some experiments will fail is as important in creating an "innovative environment" as it is in creating a "learning environment." Innovation begins with developing new ways of attacking problems, the introduction of new tools, or the identification of new ways to accomplish tasks and processes. Innovation may start with an invention or with the application of an existing procedure/process in a new way. The organization will become innovative only when it has matured to the point that it encourages its employees to think in new ways and to propose alternatives.

A key first step in this process is for the management team and key stakeholders to create a clear view of the future for the organization. Goals and objectives must be defined in ways that can be made clear and acceptable to all members of the organization. This must be communicated to everyone in the organization. A unified approach in seeking to achieve the goals of the organization is necessary for success. Achieving this will be no easy task for the health care delivery system. The current system, with its many silos of local interest, must be replaced by a system view. That is, each silo must consider how the overall system can benefit rather than seek to optimize the performance of individual entities.

Care must be given to identifying how individual roles will be affected in the reengineered system. Interactions among elements of the system will change. New teams will be created, different individuals will be expected to work together, and responsibilities may be shared among individuals who are geographically dispersed. Under such circumstances, it will be easy for individuals and elements of the system to be confused about their roles and responsibilities. Addressing this successfully will require a carefully orchestrated, ongoing education process and continuing discussions with individuals and team members.

A good model of the future system will help rationalize the objectives as well as ensure that the new interactions among the elements are consistent with the new goals. This is particularly important for the health care delivery system as it seeks to encourage patients to assume more responsibility for their own care. The education of individuals to their responsibilities and the creation of new means of communication between the patient and caregivers are particularly critical in the reengineering of the system.