Issues in the Acquisition, Development, and Use of Technology in Health Care

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I would like to take this opportunity to thank the members of this Society for the privilege of serving as your president over this past year. Indeed the words of Joseph Heller ring true: "How did I get there? Somebody pushed me. Somebody must have set me off in this direction and clusters of other hands must have touched themselves to the controls at various times."

I am deeply honored and humbled to follow in the footsteps of true giants in minimally invasive surgery and to work with a group of extremely talented people. I would also like to take the opportunity to thank Janice and Paul Wetter for their tireless support, their innovativeness, and for being the true force behind SLS. These sentiments are not solely my own. They echo the sentiments of the entire board of directors who presented Janice and Paul with a Steuben glass apple as a small token of our appreciation at our recent strategic planning meeting in Boulder, Colorado. An organization is only as good as its leadership, and SLS is blessed to have an extremely capable and forward-thinking board of directors who have provided guidance and leadership as well as friendship over the many years of my association with this organization.

My topic today will investigate some of the issues concerning the interface of medicine with medical economics, business, science, and technology. There are many variables and changes on the horizon, and it is clear that we must embark on a path to understand the issues that affect our patients and ourselves.

We must first understand some of the bare facts about healthcare economics in this country. Healthcare spending is increasing at a rate of 9.3% per year, while the rate of economic growth is only 3.6%.[1–9] Putting this into real terms, healthcare spending represented 5.3% of the gross domestic product (GDP) in 1960 at $27 million.[1–9] By 1980, it represented 9.5% of the gross domestic product at $240 billion and was 12% of the GDP in 1990 at $755 billion.[1–9] By 2005, healthcare expenditures increased to 16% of the GDP at $1.6 trillion.[1–5] The overall cost of healthcare doubled from 1993 to 2004.[1–9] Current estimates are that healthcare spending will be $2.2 trillion dollars in 2008 and will reach 25% of the GDP by 2030.[1–9]

These figures mean that changes in healthcare and healthcare expenditures are critical issues for multiple constituencies, who in aggregate represent one seventh of our country's gross domestic product.[2,3,5,7] It also means that changes are more difficult to make given the multiple groups that are potentially impacted in the process.

Currently, there are 41 million Medicare beneficiaries and another 47 million on Medicaid. Medicare expenditures increased 30-fold from $7.7 billion to $224.4 billion as the number of beneficiaries expanded from 26 million to 38.6 million between 1970 and 2000.[2,3,7] Seventeen percent of the current United States population is beyond the age of 65.[2] That number will increase to 25% of the population by the year 2020.[2,7–9] Even more staggering is the fact that there are 77 million baby boomers, individuals born between 1946 and 1964, who will begin to be eligible for Medicare in 2010.[2,7–9] This has been labeled by some as a "medical tsunami" that will further strain our economic and medical resources. Health-care expenditures are also impacted by the general tendency of patients to ignore their physician's advice or to defer acting upon it for as long as is possible.[11,12]

At the same time, there are more than 12,000 insurance carriers in addition to Medicare and Medicaid in this country. In the period between 1970 and 1995, the number of physicians in the United States increased by about 25%.[2,3] The number of administrators increased by more than 2000% over that same period.[2,3] Currently, administrative costs represent 24% to 30% of annual U.S. health expenditures.[2,3,7]

On the administrative side, insurance company CEO salaries range from $1 million to more than $7 million with options as high as $95 million.[2,3,7] The incomes of the top for-profit hospital corporations range from $145 million to over $21 billion, and their profits range from $12 million to $1.3 billion.[2,3,7] The salaries for CEOs in the for-profit

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hospitals range from nearly $598,000 to more than $20 million with options as high as $27 million or more.[2,3,7]

Physicians are increasingly being asked to jump through more and higher hoops as the public, industry, and government demand more information, more data driven outcomes and increase in healthcare quality.[12–29] Several initiatives including Pay for Performance (P4P), Leapfrog, the Surgical Care Quality Improvement Project (SCQIP), and others are directed at some of these.[10,17,24,26]

Many in healthcare see these changing times as being as bleak and as fleeting as shifting sands in the desert. Others see new opportunities, particularly in the cosmetic and fee-for-service sectors.[28–32] For example, several devices including lasers, ultrasound, spa treatments, and other therapies are aggressively marketed across a broad range of medical and allied health disciplines to boost the bottom line. Practitioners are offering services that are paid for by an increasingly willing population of baby boomers, who have the means to afford them and the unwillingness to show their age.

Several opportunities for the future require us to think outside of the box as we manage the balance between rising practice costs, declining reimbursement, and the need to keep pace with technology. Some view medical technology as both a solution and a problem in the mix of health-care delivery, particularly at the hospital level. Eric Cassell[33] stated:

> . . .[I]f there's one thing that can be singled out as the engine of medical economic inflation now occurring everywhere in the world, it is the seemingly irresistible spread of technology into every level of medicine irresistible to doctors, patients, and nations alike.

In fact, we are enamored with technology, but there are those who would say that we should not be tempted. Cassell[33] further admonishes:

> Doctors who have mastered a technology tend to use it as often as possible not necessarily for reasons of profit, but because they love their skills and technologies. . . . Problems tend to be redefined so that a technology becomes appropriate when it might otherwise not be . . . . It is also used where it is inappropriate, defined by the capabilities of the technology and the consequent expertise of physicians rather than—or even contrary to—the good of the sick person.

Still others are concerned about the substitution of technology for the surgeon or the presumption that technology will solve all of our ills. Such sentiments are echoed in the words of the late Claude Organ[6]:

> In today's environment, we are surrounded by machines that have become substitutes for common sense and reason. With increasing frequency, attempts are being made to substitute technology for the surgeon. . . . This is the fault of the surgeon not of technology. This has diminished our profession as a cognitive discipline. In short, we have become technology addicts.

The hospital feels caught between the costs of new technology and returns on the investment for these new technologies from their perspective. Elizabeth Gardner analyzed this situation recently from the vantage of the institution.[34] The basic thesis of her article is that high price tags for state-of-the-art surgical equipment have hospitals attempting to decide when or even whether they should invest in technology. Examples provided range from the $100,000 to $500,000 cost to outfit a basic minimally invasive surgical suite or acquire instrumentation for image-guided surgery for otolaryngology, versus the $1.3 million cost of a Da Vinci surgical robot or the $5.3 million cost of an intraoperative MRI for neurosurgery. The article points out that "extras" for these investments include the variable costs for disposables, which can be significant, depending on the specific procedures performed, and the substantial maintenance and upgrade requirements, which, in the case of Da Vinci, is $100,000 annually. So the questions for the institution are shall we invest in this new technology, do we want to be ahead of the curve, or do we want to follow the pack after the technology has been refined and is more stable and, we hope, less expensive?

Technology is indeed changing rapidly as it moves from large mainframe computers to PDAs, other digital devices, from large robots like Da Vinci to smaller devices such as the Peine[35] and even mini-robots as have been reported recently, and that have been used investigationally in "standard" and N.O.T.E.S. type procedures.[36] However, it is a great technologic leap from concept to commercial product, and that transition often involves basic and clinical research in addition to a good business plan. Money must be gathered, intellectual property must be protected, and the technology must be approved for clinical use.

Let us examine some of the details of healthcare research spending that drives technological development. Biomedical research funding increased from $37.1 billion in 1994 to $94.3 billion in 2003.[37] Research spending doubled during this period when it is adjusted for inflation. Over $95 billion was spent on medical research in 2005.[37] This

means that the United States spent 5.6% of its total health expenditures on biomedical research.[37] The breakdown of spending demonstrates that 99 cents of every research dollar was spent on new drugs and medical devices, while only 1 cent of each research dollar was spent on health services research.[1] NIH funding was $26.4 billion in 2003, which was 28% of the total expenditure, and industry support was $54.1 billion or 57% in 2003.[37] Not only did funding double between 1994 and 2003, but the largest increases in funding occurred in the devices, biotechnology, and pharmaceutical firm support sectors, as well as funding through the NIH.[37] Private funding, state and local government financing, and other federal support remained relatively constant over the same period.[37] The cumulative stock market return of publicly traded life science companies generally performed at or above the Standard and Poor's 500 Index between 1994 and 2003.[37]

There are many new technologies on the horizon that will take us to new heights, but we should also understand that there are aspects of healthcare economics that do not fit the standard free market microeconomic analysis of supply and demand. Microeconomic theory states that there is an optimum price and quantity where there are equal numbers of satisfied buyers and sellers in the system.[38] It is important to understand that cost does not equal charge in healthcare.[39] Charge does not equal reimbursement. Reimbursement does not equal global cost, and the concept of global cost for the insurance carrier is different from the concept of global cost for an employer. The global cost for an employer or industry is different from the global cost to society.[30–32,38,39]

The perspective of the individual patient relative to the cost of care differs from that of the other stakeholders. The patient places the greatest value on the procedure or treatment that will solve the problem with the least discomfort, the least scarring, and the least disability. Patients often equate high technology with being the "best" option, and demand the "latest" advance for their care.[13–16,29–32,39] Most patients have very little connection with the true economic costs of their treatment. Much of the cost of care is borne by third parties, even in cases of rising deductibles and copayments.

These differing perspectives on cost versus benefit are illustrated by the following examples. The case of the Ford Pinto demonstrates the concept of cost to the individual versus the cost to industry.[40,41] Ford developed the Pinto to sell at a price of less than $2,000 and was to produce the vehicle at a street weight of less than 2,000 pounds. The assembly line had already been tooled when it became apparent that the fuel tank was defective. A cost benefit analysis was performed. It was estimated that the defects could be corrected at a cost of $11 per vehicle. It was estimated that there would be 2,100 burned vehicles, 180 burn deaths, and 180 serious burn injuries if the defects were not corrected. This would cost approximately $200,000 per death, $67,000 per injury, and $700 reimbursement for each destroyed vehicle. The total payments for these damages would result in an expenditure of $49.5 million. The costs to fix the defects were estimated at $137 million based on sales of 11 million cars and 1.5 million light trucks at a cost of $11 per vehicle sold. The executives ultimately placed a dollar value on human life and successfully argued that it was not cost effective or profitable to repair the defects. They argued that it was considerably less expensive to pay the costs incurred by exploding gas tanks.[40,41] Similarly, GM was fined $4.9 billion for defective gas tanks in the 1979 Chevy Malibu, which could have been corrected at a cost of $8.59 per vehicle.[42] The take home lesson is that even in an industry where costs can be passed on directly to the consumer, the business decision is out of sync with the best interest of the individual or the public.

A recent medical example is drug-eluting stents.[43–48] The development of stent technology has improved and expanded the utility and the efficacy of percutaneous coronary angioplasty. Bare stents cost about $1000 per unit. Drug-eluting stents cost between $2,500 and $3,500 each, and an average of 1.43 stents are implanted per case.[47] The DRG payments increase by about $1,800 when drug-eluting stent codes are billed.[47] The rate of restenosis drops from 30% to less than 9%.[44,47] There is a 10% reduction in surgical volume due to fewer coronary bypass procedures being performed.[47] At the same time, there is a 50% reduction in interventions necessitated by coronary restenosis.[47] It was estimated that Beaumont Hospital would lose $3.8 million if drug-eluting stents (DES) were used in 50% of angioplasty cases and that a greater proportionate loss would occur with higher rates of use.[47] Hospitals see less revenue generation and enormous increases in their supply costs with DES use. Patients and insurance companies benefit by having fewer repeat interventions and fewer CABG procedures. However, hospitals, insurance companies, and thoracic surgeons call into question whether the technology is truly cost effective.[44,46–48] Indeed the role of DES technology is being hotly debated in the literature, including attempts to define the specific circumstances where the stents are clearly beneficial.[46–48] There is increasing pressure from patients to have the latest drug-eluting technology im-

planted, and cardiologists fearing litigation should complications occur if bare stents are used, are willingly complying.[43–48] It is clear that health care issues are often complex and require careful consideration.

How should a hospital respond to pressures to acquire new technology?[49–52] Most healthcare costs are fixed and sunk over any reasonable time horizon.[51] Fixed costs do not vary with the level of patient activity, and once sunk they cannot be easily reversed.[51] Once dollars have been invested to acquire a technology, the more frequently it is used, the less expensive its per case cost will be. This is demonstrated in the example of the acquisition of a $100,000 machine. If that $100,000 machine is used only once in 10 years, it costs $100,000 per case to use it. Using that same machine a thousand times a year for each of 10 years, the cost per case is reduced to $10. Of course, the variable costs for any disposable items used with the machine would be the same per case. This is a strong argument for encouraging the use of a technology once it has been acquired.[51–54]

Many of the least expensive, quickest, and highest return reforms in health care are process rather than technology related.[51,53] We must understand that managed care organizations focus on the variable cost of health care delivery and largely neglect capacity decisions. However, for the hospital at the extreme of excess capacity, there is little disincentive to do additional cases, and at reduced capacity there are incentives to increase throughput to increase volume. This is so because resource consumption in healthcare is front-loaded with most of the expenses being incurred on the first day of a patient's stay. Reducing length of stay is important in cases of high-capacity utilization, because it frees up capacity and creates opportunities for more admissions. There is very little incentive to reduce length of stay under conditions at the extreme of low utilization of capacity. It is estimated that the last day of a hospital stay contributes approximately 3% to the cost of care.[14,51–56]

What is the impact of the clinician on costs? Individual surgeons have statistically and clinically significant differences in their costs and volatility of costs when holding patient factors and procedural complexity constant.[55–63] Even surgeons who see similar case mixes can have very different ranges of cost as they treat their patients.[55,57]

There is also a dichotomy between what payers pay in professional fees to doctors and what they pay to the hospital.[55–57] The interaction between the amount of OR time used, the RVUs per case, and the number of cases performed per year determine the contribution to the hospital margin by any particular surgeon or surgical service.[55–57] The choice of technologies used and the use of disposables rather than reusable instruments can adversely affect the hospital's margin.[4,55–57] Such choices can very quickly transform a modestly profitable or break even procedure into an economic loser for the hospital.[4,55–57] However, the surgeon is still reimbursed at the usual and customary fee for the procedure.

There are many other threats that need to be considered in the changing healthcare environment. There is a trend on the part of the federal government to mandate more transparency relative to CMS payments to hospitals, ambulatory care centers, and providers.[11,16,20–25,53,59] This is viewed as a way of providing consumers with cost information in an effort to encourage them to choose the least expensive alternative.[24,26,53] However, it is unclear how the public will respond to this information.

One survey found that 76% of the public believes that the convenience of a hospital is more important than hospital quality.[53] At the same time, 70% of the public do not trust their employers' choice of health insurance.[53] Patients are ill equipped to make decisions on quality of care. They use word of mouth or service and customer satisfaction attributes as the primary basis when making their healthcare choices, because they cannot evaluate expertise or quality effectively.[59–67] The convenience factor is helping to fuel point-of-service health-care opportunities at retail locations including pharmacies, department stores, and shopping malls.[67] Patients are willing to trade convenience and speed of access for more comprehensive or ongoing care. It is likely that this trend will continue in the future. It is truly unknown, however, to what degree an individual patient will make decisions based on the cheapest price, particularly because economic responsibility for healthcare is limited at best for most patients.

Quality Surgical Solutions, a quality initiative in the State of Kentucky, found that there was no single clinical situation in which safer practices were intrinsically more expensive than those that were less safe in 6 years of study.[53] Similarly, they found no instances where practices that are more expensive were associated with better outcomes.[53] The negative effects of reports of medical error and postoperative deaths for individual hospitals more than offset the recognized value of volume or accreditation, regardless of whether they were a teaching hospital or were rated as the best in their local area.[53]

What scientific breakthroughs and technologic innovations will be developed, and how will they affect healthcare in the future? Technology and innovation are vital

components of our daily life that are undergoing constant and accelerating change. They are juxtaposed with increasing social pressures relative to healthcare and science funding.[6,13,15,16,18,27–34,37,49,50,55,56,63] The pace of innovation truly staggers the imagination. Many innovative products never make it to the market or fail when they are introduced. Discontinuous product innovations may not have a perceived use or benefit when they are first introduced.[29–34,37,38,49,50,63]

Consider the development of the Argon Beam Coagulator.[68–70] Patents in 1969 and in the 1970s described the development of a plasma arc scalpel that could be used to both cut and coagulate tissue.[69–70] Sales and marketing experts in the companies developing the device for clinical use transformed the concept from a device that could both cut and coagulate tissues to a device used solely for coagulation. The technology used in both open and laparoscopic procedures today bears little resemblance to the original concept.

Technology has made some important advances, but the leaps from product development to channel distribution and return on investment are important considerations from the business perspective.[49,50,63] These factors determine whether a promising idea will ultimately find its way to clinical practice. Declining revenues in health-care segments and the fact that the technology is negatively impacted by regulation and that FDA approval is necessary for the use of drugs and devices are additional drivers in the medical environment. The FDA approval process can significantly impact the decision to develop a technology.[13–16,29–32] Those who are the first to market products can incur substantial expenses in gaining approval via the PMA process (premarket approval), while subsequent competitors can more rapidly market their products using the 510k process (substantial equivalence to an already approved device). Steven Wright's quip "[t]he early bird gets the worm, but the second mouse gets the cheese" is fitting in this environment.

It is also important for us to understand the fickle nature and changeability of medical opinion. Consider laparoscopic cholecystectomy.[29–32] "Lap chole" has an anatomically identical result to that of open cholecystectomy. It was not recognized as a standard of care and was considered "experimental" by insurers and academics alike in 1989. However, by 1994, it accounted for approximately 90% of elective cholecystectomies and was recognized as the "standard of care."[16,39] It is estimated that approximately 75% of all cholecystectomies performed in the United States today are completed laparoscopically. Change in opinion is not unique to lap chole.

Consider arthroscopy, flexible endoscopy, and laparoscopic surgery in general. Each technique was initially spurned by the mainstream medical and surgical communities. In each instance, pressure from patients and competition between surgeons and facilities drove market penetration acceptance of these techniques. Payers were concerned that unnecessary procedures would be performed. However, these fears have not been realized as we have migrated from open to less invasive procedures. The transformation has been so complete in the case of lap chole that we are currently concerned that present day trainees are ill prepared to perform open cholecystectomy.

Laparoscopic appendectomy is also increasing in frequency. I am sure for most in this audience "lap appy" is viewed favorably despite equivocal reviews by the Cochrane Collaboration and the surgical mainstream.[16] The improved ability to visualize the appendix and to perform a diagnostic laparoscopy no doubt helps to drive this phenomenon. Another area of controversy is the debate over laparoscopic versus open herniorrhaphy, which is being eclipsed by recent literature that questions the need for herniorrhaphy in general.[71]

There are also compelling arguments for surgical rather than medical management in some cases. This includes a growing literature demonstrating that laparoscopic Nissen fundoplication is more cost-effective than nonsurgical therapies in the management of GERDs and hiatus hernia.[16,32,44] Yet H_2 blockers and PPIs continue to be prescribed for the long-term management of these conditions.

It becomes incumbent upon us to continue to critically review and question the literature. We should recognize that inappropriate questions will result in erroneous conclusions. For example, if the anatomic outcome in the intraoperative conduct of a laparoscopic procedure is identical to its open counterpart, it is reasonable to presume that the so-called long-term outcome for both will be identical. To state it another way, the long-term outcome of removal of the appendix should be identical irrespective of whether the procedure is performed as an open or a laparoscopic procedure. Comparisons of outcomes in such cases should be limited to short-term issues, such as morbidity, mortality, length of stay, and disability defined as return to unrestricted activity. However, it is not appropriate to conclude that laparoscopic

appendectomy has no value because its long-term outcome is the same as that of the open procedure.

We should refrain from overinterpreting learning curve results and should not assume that they are reflective of a procedure's duration, utility, or cost ad infinitum. Our literature is unfortunately replete with examples that pit the early experience using a new technique or technology against the career-long experience of the surgical expert. Rhetoric from the untrained or poorly trained should not be confused with an actual scientific investigation. We must continue to discuss, share, and dialogue with our colleagues about the risks, the benefits, the alternatives, and the limits of our techniques and technologies.

In conclusion, medicine and healthcare are changing rapidly. There are many threats and opportunities in our changing healthcare environment. Aging baby boomers and the use of new technology are impacting our ability to provide appropriate care at a reasonable cost. Consumers and other stakeholders are demanding more information and more accountability from providers. Consumers continue to base their decisions on service and satisfaction because they cannot evaluate technical skills. Multiple forces will continue to drive the minimally invasive surgical revolution into the foreseeable future. We must use technology responsibly and honestly evaluate our outcomes. It is our responsibility to educate our patients, ourselves, and our colleagues about the benefits and limits of minimally invasive surgery.

I would like to thank you for your attention and for the honor and privilege of serving as your president.

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