The development and the implementation of new endoscopic technology: what are the challenges?

"The significant problems we face cannot be solved at the same level of thinking we were at when we created them."
Albert Einstein

"I believe there is something out there watching us. Unfortunately it's the government."
Woody Allen

This may seem like an odd time to be writing about the challenges of incorporating new endoscopic technology into the practice of gastroenterology. Indeed, these are boom times for gastroenterologists in terms of both volume of work and new developments in the field. Our practices are busy and waiting times are extended; revenues realized from patient services and, consequently, physician incomes are up, and there is no shortage of clinical procedures. The endoscopic frontier continues to progress, and most of us can barely keep pace with the research and technology at hand, let alone contemplate continued advancements. From the sleepy field of Sippy diets and acid secretion studies of 30 years ago, a time when Billroth gastrectomy was the most common surgical procedure in the United States, we have moved to an era of routine EUS, videocapsule endoscopy and trans-gastric endoscopic surgery.

We now take for granted that new technology is our birthright, that endoscopic practice will continue to evolve without interference, and that gastroenterology will continue to be viewed as a specialty fully deserving of federal research dollars and adulation from device manufacturers. Most gastroenterologists do not perceive any significant hindrances within the field itself; from our current perspective, the only threat to gastroenterology seems to be from external competing technologies, e.g., CT colography, and even this is a relative concern because additional colon cancer screening modalities may actually be beneficial. Is our current complacency warranted, or are there unseen obstacles that may actually interfere with continued endoscopic progress and derail our heretofore rapidly evolving and productive field?

Unfortunately, there are other vantage points that are less sanguine concerning the technologic future of endoscopy. There are, in fact, several major current and pending problems that specifically confront new technology development in gastroenterology, problems that could significantly decrease corporate and government investment in us and our future needs, slow the "transit time" of breakthrough products, and impact our ability to care for patients. Some of these issues, including insufficient evidence-based endoscopic research and funding from government sources, have been noted in a recent, impassioned editorial.[1] The present editorial, in a similar vein, will extend those observations and highlight some additional pressing problems regarding gastroenterology and the continued advance of new endoscopic technology. These include the following: demographics, reimbursement issues, a consolidating manufacturing base, and looming federal deficits.

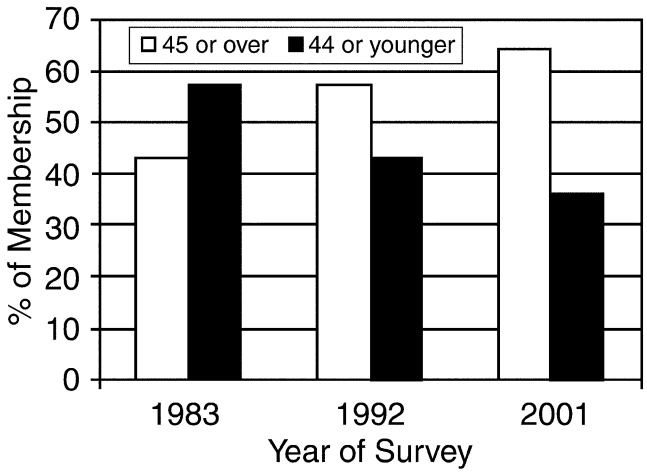

Figure 1. Results of ASGE membership surveys demonstrating aging of gastroenterologists (1983-2001).

DEMOGRAPHICS

If demography is destiny, then gastroenterology will be in trouble in coming years, because we are a rapidly aging specialty. In 1983, the American Society for Gastrointestinal Endoscopy (ASGE) conducted the first in-depth survey of its then nascent membership. Among the findings, approximately 55% of members were younger than the age of 44 years. In 2001, a follow-up survey of the 8000 members of the ASGE was conducted; 65% were older than 45 years (Fig. 1).[2] This rapid aging of our specialty is a significant problem, because older physicians tend to be less aggressive, less likely to learn new skills and adopt new technology, and, as Dr. Sivak[1] noted, less likely to perform endoscopic research and to publish. As every hospital executive knows, when the average age of a hospital staff

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becomes greater than 45 years, the bond rating of the hospital falls because of decreased productivity. If gastroenterology were a corporation listed on the New York Stock Exchange, it would have a crummy bond rating, and the perception of its future as a growth enterprise would be decidedly negative.

The proximate cause of our aging problem is the loss of GI fellowship funding, which arose out of the administration of President Clinton. The Balanced Budget Act of 1997 (BBA '97) shifted federal dollars from specialty training to primary care and nursing education. In 1991, the United States trained approximately 500 GI fellows per year; in 1997 funded fellowship positions fell to 300, and by 1999 that number had dropped to 250, roughly the present level.[3] We now train so few fellows that the age of the average gastroenterologist increases every year.

Not only has the dearth of fellowship positions impacted the age of gastroenterologists, it also has, in the past several years, created a significant shortage of gastroenterologists in the United States. As noted by John Naisbitt in the book *Megatrends,*[4] "want ad" volume is a time-honored technique for determining personnel needs in a service industry, and want ads for gastroenterologists have risen dramatically in recent years; for example, the *New England Journal of Medicine* ad volume for gastroenterologists has increased approximately 4-fold since 1995.[3]

Further proof of a GI shortage comes from medical search firms; Merritt, Hawkins and Associates, the largest medical placement firm in the United States, has noted a 12-fold increase in requests for gastroenterologists between 1997 and 2001. (Certainly gastroenterology is not unique in this regard; other medical specialties are also shorthanded as a result of the BBA '97.)

The problems of aging and shortage have been greatly exacerbated by the dramatic upsurge in procedure volume, particularly the advent of primary screening colonoscopy. This change in practice with regard to colon cancer screening, at least partly because of the "Katie Couric effect," has doubled the number of colonoscopies performed in the United States in the past few years.[5,6] Certainly, this has been a positive development for our patients, practices, and incomes, but it has drained the time and the energy needed for the realization of new technologic advancements and research endeavors from an already shorthanded specialty.

We are, in fact, drowning in screening colonoscopies, a procedure that has come to dominate gastroenterology practice. Additional data from the ASGE membership surveys highlight the magnitude of this shift in our practices: in 1983, only 22% of gastroenterologists spent more than half of their time performing endoscopic procedures; by 2001, the number had risen to 55%, and the proportion is undoubtedly higher today (Fig. 2).[2] It is now common for a busy gastroenterologist in the United States to perform 50 or more endoscopic procedures per week, in half-hour time slots.

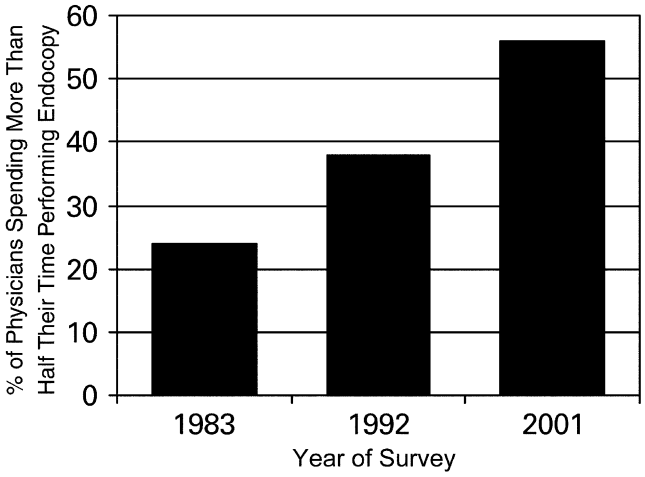

Figure 2. Increasing procedure time in gastroenterology practice: ASGE survey results.

A force multiplier with respect to the above developments is the rapid aging of the population of the United States; we are now the oldest society in the history of America. There were approximately 30 million Americans over the age of 65 years in the 2000 census, and it is estimated that there will be 70 million citizens over the age of 65 by 2020. Because demand for medical services, including gastroenterology, rises 2- to 3-fold per capita over the age of 65 years, we face the possibility of being overwhelmed with work in the next 10 to 15 years.[3]

What is the upshot of these demographic trends? Gastroenterology is faced with the reality of being an increasingly aging and shorthanded specialty, inundated with lower-level established endoscopic procedures, dependent on mid-level workers to provide cognitive service, with less and less time or financial inclination to pursue research or to incorporate new technologies. This new reality has significant, unattractive implications for GI device manufacturers; the acceptance and adoption of new technology will be slower than in the past; there simply are not as many willing users, and the rest are extremely busy. To achieve maximal penetration, any new endoscopic technology will have to fit into the existing lucrative practice pattern, i.e., take 30 minutes or less to perform, be simple, very safe, and easy to learn. It is no mystery that many complex endoscopic techniques are first adopted outside of the United States[1]; any procedure that takes more than

Table 1. Practice expense revenue per hour for gastroenterology, cardiology, rheumatology, and dermatology

Gastroenterology	$60
Cardiology	$70
Rheumatology	$95
Dermatology	$120

30 minutes is a financial drain and a practice stressor.

REIMBURSEMENT

To paraphrase a recent Oldsmobile advertisement, this is not your father's reimbursement system. One of the main problems with the existing system is that, similar to other medical specialties, gastroenterologists now face monopsony pricing for the work that we do. A monopoly is single entity control over the production of a product or service; a monopsony, a term less commonly known, occurs when a single entity has control over the purchase of a product or service. Most gastroenterology practices are approximately 40% Medicare and 10% Medicaid[7]; the government directly pays for 50% of our services, but it essentially sets the price for 100% of what we do because the private payers almost always follow the government's lead in pricing. In reality, we function in a single-payer environment. This would be tolerable if the pricing across specialties was fair and unbiased, but it is not—gastroenterology is underpaid by the de facto single payer system that we work under.

As background, note that the government (and the private insurance industry) sets a rigid formula for determining annual payment for all physician services in the United States, the so-called "relative value system" (RVS), which was created by federal law in 1992. The RVS functions as a national payment schedule and determines relative payment for all physicians as work relative values (WRVU), practice expense values (PE), and malpractice values (MP), where physician work is 55% of payment, practice expense is 42% of payment, and physician liability expense is 3%. The payment formula is $\{(WRVU + PE + MP) \times GAF\} \times CF$, where GAF is one of 80 geographic adjustment factors based on regional expenses, such as labor and rent, and CF (now about $36) is the national conversion factor, which floats up or down every year (usually down), based on the volume of medical work annually performed in the United States.[8]

It is commonly accepted that work RVUs for gastroenterology are low relative to other specialties, such as cardiology and dermatology; it is less well known that practice expense RVU payment for gastroenterology suffers as well. Table 1 compares practice expense revenue per hour between gastroenterology and 3 other specialties. Note that compared with dermatology, for example, a gastroenterologist earns *$60 less per hour* in the practice expense RVU formula.[9] Because practice expense accounts for 40% of every service (cognitive or procedural) that gastroenterologists provide, payment declines accordingly. Moreover, because reimbursement for new endoscopic technology and procedures is based, at least in part, on historical RVU rates, payment for progressively more difficult procedures is proportionately reduced so as not to create what the Centers for Medicare and Medicaid Services (CMS, the former the Health Care Financing Administration) calls a "rank order anomaly."

Thus, because payment for basic endoscopy is too low, payment for more complex procedures, such as EUS or videocapsule endoscopy, although higher, remains relatively low as well. The monopsony pricing system has us chasing our tails; the more time intensive and complex the procedure, the less we make; thus, the system favors the performance of high volume, relatively simple procedures. Worse yet, the specialty in general may suffer because lower professional payment translates into lower payment for gastroenterology devices; this means less profit for GI device manufacturers, which has led to a reduction in interested corporate parties (vide infra), with the potential for less overall investment in the field in the future.

The current noncompetitive pricing environment is responsible for another significant problem specific to technology-dependent specialties, e.g., gastroenterology, that being the delay in introduction of new devices and techniques. Budget-wise, it is in the short-term interest of the government to delay paying for new technology as long as possible. For this same reason, private payers will almost never reimburse a new technique or procedure until the government moves first. Consequently, the mechanism for approving and pricing new technology is unnecessarily cumbersome, inefficient, and slow.

Reimbursement to a manufacturer for new technology involves multiple sequential processes. For a company to achieve final Medicare payment for a new device, the government first has to issue a current procedural terminology (CPT) identifying code for the device and accompanying procedure, then it has to issue a RVU payment to cover the physician professional fee for same, then comes a payment code to the manufacturer for the device

itself, then hospital payment to support the procedure, and finally payment for ambulatory surgery centers. At some point well into this process, third party payers may consider approval and reimbursement for the new procedure, typically paying a minor multiple higher or lower than the government price.

As a further example of the sluggishness of the process, consider that to obtain a 5-digit identifying CPT code, any novel device has to first be approved by the Food and Drug Administration (FDA), and there must be at least one peer-reviewed publication pertaining to the device; a requirement that of itself can take years.

Obtaining a CPT code for a FDA-approved device should take only a few weeks at most. However, the current system requires a manufacturer to apply before a dilatory CPT committee, made up of practicing physicians, and administered by the American Medical Association (AMA) under contract to CMS. In reality, code issuance can take up to 12 months, because the CPT committee publishes codes only once per year. Only after obtaining a CPT code can a manufacturer then apply for physician payment by going to a different AMA body, the Relative Value Update Committee (RUC), which also is staffed by practicing physicians representing various medical subspecialties. The RUC then wrestles with the professional fee, in a peer review manner, based on historical RVU rates as noted above; time and complexity involved in using the new device and in performing the procedure; and miscellaneous politics. It should be noted that gastroenterology procedures are at payment disadvantage with respect to the RUC, because the AMA does not currently allow a permanent gastroenterology RUC representative to argue the merits of the procedure and to maximize RVU work units. The RUC payment process is purposely slow and methodical, and 2 to 3 years may elapse before a novel device or technique is assigned professional payment. The entire process of obtaining reimbursement in all spheres can take 4 to 5 years after a device or technique is approved by the FDA.

Without being overly cynical, the technology reimbursement process closely resembles the procurement system at the Department of Defense, i.e., a "cost-plus" system. That is to say that CMS and the RUC do not evaluate novel technology as beneficial cost-effective advancements; rather, they pay on a strict formula of historical rates, time required to do the procedure, and the complexity involved. Simply put, and counter intuitively, the longer and more complex a procedure is, the better it pays; as any procedure becomes easier and simpler, it pays less. The current system thus rewards "incrementalism" and penalizes breakthrough cost-effective technology. It also favors large well-capitalized companies, because of the costs and lengthy processes involved in establishing reimbursement. Few small start-up ventures can afford to wait 4 to 5 years before getting paid for a new device. The system also forces GI (and other) device manufacturers to confront an interesting dilemma: patients and, as noted earlier, the demographics of the gastroenterologist user, demand easy and quick procedures, but reimbursement is higher if the initial version of the device is made as difficult to use and as complex as possible.

CONSOLIDATING MANUFACTURING BASE

From the above discussion of gastroenterology demographics, as well as the cost, inefficiencies, and inherent unfairness of the current reimbursement system, it should be no surprise to learn that the once crowded endoscopic accessories market has consolidated significantly over the past several years. Companies such Wiltek, Mill Rose Laboratories, Ballard, Cox Medical, Schneider, American Endoscopy, and US Endoscopy have either disappeared, changed manufacturing focus, or have been acquired by larger companies.

In the endoscopic accessories market, gastroenterology now faces a potential oligopoly of just 4 manufacturers (Boston Scientific Endoscopy, Boston Scientific Corp.; Bard Interventional Products; Wilson-Cook Medical Inc., and Olympus America, Inc.), with the field being dominated by one major player, Boston Scientific Endoscopy, which has a larger market share than its next 3 competitors combined. Moreover, two of the presently remaining accessory companies, Bard and Wilson-Cook, both tried to sell themselves in recent years: Bard to Tyco International and Wilson-Cook to Guidant. Alleged corporate malfeasance prevented the Bard sale from being consummated, and patent issues ended the Wilson-Cook deal; otherwise, gastroenterology would have been left with a single committed American GI accessory manufacturer, i.e., Boston Scientific Endoscopy. (Medtronic has recently entered the GI field but currently is a niche player in esophageal reflux diagnostics).

To be sure, gastroenterology has recently seen significant innovation from smaller, independent start-up companies (e.g., Given Imaging, Curon, NDO). However, these companies tend to be single-device ventures that have struggled for adequate payment codes or reimbursement in the current harsh federal environment, have heretofore not been profitable, and typically look to be acquired by a

larger company as soon as possible. It has proven to be extremely difficult for small start-up companies to stay well capitalized while awaiting the codes or payment necessary to sell their products.

The present narrow base of manufacturing is limiting with respect to future technologic innovation in gastroenterology, because there are fewer companies to invest in the field, less impetus to innovate, owing to the lack of competition, and fewer options for smaller companies to either access capital or to be acquired. Although gastroenterology seemingly has a surfeit of recent new technology, as a result of the consolidating device market and the less-favorable reimbursement climate for GI products relative to other specialties, we may, in fact, be losing opportunities for the acquisition of new technology.

Most new GI devices fall into the FDA 510k category, i.e., an extension of previous technology, as opposed to the premarket approval (PMA) category, which signifies innovative breakthrough technology for which a higher initial capital investment is required.[10] In fact, since the beginning of 2003, gastroenterology has had only a single FDA-approved PMA product, the Enteryx device (Enteric Medical, acquired by Boston Scientific Endoscopy), while, during the same period of time, cardiology has had 15 PMA products approved![11] It would be regrettable for us, and for our patients, if this trend continues.

ERA OF LOOMING DEFICITS

Most physicians consider federal budget policy to be arcane and irrelevant, consequently few in the medical community understand the magnitude of the national deficit or the impact this will have on future health care spending in the United States, including National Institutes of Health (NIH) funding, payment for medical services, and technology investment. Unfortunately, this information cannot be ignored, particularly by specialties that are dependent on the government and corporate largess for continued technologic growth. The baseline national debt at the end of 2003 was well over 7 trillion dollars; that amount alone translates to a cost to each taxpayer in excess of $100,000. In addition to that figure, the 2004 federal deficit is currently estimated at $521 billion, without factoring in the cost of the war in Iraq, which is unknown but will probably exceed $200 billion. National health care costs have increased at a furious pace, up 25% in the past 2 years, and now stand at $1.7 trillion annually, with anticipated increases of 10% to 15% in fiscal years 2004 and 2005. No one knows exactly how much the new Medicare prescription drug benefit will cost in the first 10 years; it is now estimated at roughly $550 billion dollars, a number that has risen by more than a third since the legislation was passed in January of this year.[12]

All of these numbers get progressively worse as baby boomers age and begin to retire, and the costs of entitlement programs skyrocket. By 2014, the Congressional Budget Office (CBO) estimates that Medicare alone will cost more than $1 trillion per year, and the second 10 years of the drug benefit will likely exceed an additional $1 trillion, even with incomplete coverage. These costs do not factor in any additional longevity gains for the American population, which, if significant, could beggar current Medicare projections. Also, none of the debt projections account for fixing the alternative minimum tax, which will cost hundreds of billions of dollars, or making the tax cuts of the Bush administration permanent, which will cost $2 trillion more.[12]

The bottom line according to CBO projections is that with current spending policies, and assuming permanent tax cuts, achieving a balanced budget by 2030 would require either a 50% reduction in federal spending or a doubling of taxes.[12] It is clear that the federal government has overreached its budget and that a day of reckoning is fast approaching. Physicians, in general, other health care providers, and device manufacturers should anticipate marked reductions in federal spending on health care over the next several years. More germane to this discussion, there will be ongoing resistance from CMS and private insurers with regard to paying for new technology, which will be a direct hit to specialties like gastroenterology.

We also can anticipate further cuts in professional fees, other services, and research funding. Some of the cutbacks have already begun: the president's fiscal 2005 budget calls for the lowest increase in the allocation to the NIH in years, a paltry 2.6%, which is not enough to keep pace with inflation.[13] Worse yet, the 5-year projection of the White House Office of Management and Budget calls for outright cuts in the NIH budget. Gastroenterology, a particularly expensive and visible specialty, because of rapidly rising volumes of procedures and new technology costs, could be in for a particularly rough time. This year has already seen CMS cut office endoscopy and colonoscopy rates by 15% to 19%; ambulatory endoscopy facility fees also were cut 2% and are now frozen until 2009, and future gastroenterology professional fee cuts are anticipated. As the implications of the current debt crisis become manifest, the overall environment for investment in medicine, in general, and technology-dependent fields like gastroenterology, in particular, may deteriorate.

FUTURE STRATEGIES

"As we know, there are known knowns, there are things we know we know. We also know there are known unknowns, that is to say we know there are some things we do not know. But there are also unknown unknowns, the ones we don't know we don't know."

Donald Rumsfeld (February 12, 2002, Department of Defense news briefing regarding Iraq)

What then should be our strategies for dealing with the problems facing gastroenterology?

First, we should address our manpower needs in a forthright manner. Organized GI societies have understandably taken a laissez-faire attitude toward this issue, mainly because, until recently, it was generally perceived that there was a glut of physicians in the United States, including gastroenterologists.[14] Recognizing that it is almost impossible to accurately predict future manpower needs in any specialty, given the rapid changes in technology, aging, and other patient care issues, we nonetheless need to consider the relative risks of having too many gastroenterologists compared with having too few, particularly regarding the development and the implementation of new endoscopic technology. Having too many gastroenterologists certainly has its attendant consequences, but it actually is beneficial for the incorporation of new technology; too few practitioners in the field is, as previously noted, potentially damaging to the prospects for research and technologic development in the long run.[1]

Second, we need to acknowledge that the federal government is unlikely to fix gastroenterology's practice expense RVU problem. Despite years of organized political activity and intense federal lobbying efforts from the ASGE and other gastroenterology professional societies, we have been unable to get CMS or other government agencies, e.g., the General Accounting Office, to budge from the current formulation regarding practice overhead.[15] We must then recognize that gains in payment for GI procedures and devices are only going to come through reduced overhead, increased productivity, and changes in the GI practice paradigm that will allow us to do more work with less office support. This aspect of gastroenterology practice should be emphasized, with societal support, in a cohesive nationwide manner to identify "best practices" and to allow for standardization of office activities.

Third, we must continue to lobby for permanent RUC representation. Gastroenterology is a technology-rich specialty, with more activity related to the use of devices than almost any other field and should be recognized as such. We deserve and require a seat at the professional fee valuation table, to allow for an accurate description of our work activities and to avoid having other specialties disparage our work RVUs.

Fourth, another valuable activity would be the creation of an "Endoscopic Innovation Task Force," either through the ASGE alone or in conjunction with other professional societies, to annually identify priorities for endoscopy, set an agenda for future endoscopic research activities, function as a clearing house to encourage and to coordinate the development of new ideas in the field, and to foster better communication between us and industry. We must also consider new paradigms for technology development and innovation by establishing society-sponsored invention "special interest groups," invention symposia and awards, and combined endoscopy-innovation summit meetings involving research leaders from gastroenterology, and representatives from the device industry, regulatory agencies, including the FDA, the NIH, CMS, the insurance industry, and bio-engineering.

Fifth, gastroenterology must continue to lobby the NIH for greater endoscopic research funding. However, given the dismal outlook regarding the national debt, we are probably not going to get it. Consequently, we will need to be creative in developing outside sources of funding, i.e., additional grants from industry, the creation of more endowed endoscopic research chairs, and continued support from non-profit foundations for endoscopic research, such as the ASGE foundation.

Sixth, we also need to recognize that additional funding is worthless unless we have enough researchers and innovators to use the money; therefore, novel ways must be found to encourage and train more young physician investigators.[1]

Seventh, we need to maintain a balance between skepticism and enthusiasm. Gastroenterologists in the United States are currently perceived by many in the device industry as being overly busy, satisfied with the status quo, and somewhat resistant to the introduction of complex endoscopic techniques. We cannot run the risk of appearing indifferent to new developments in the field. We must remain true to our mantra of evidenced-based medicine and our commitment to quality, safety, and cost-effectiveness, yet, at the same time, we have to remain open to all possibilities, lest we discourage transformative innovation and financial commitment from corporate partners. Only with vigilance and attention to the problems at hand

will we be able to preserve our maximum technologic potential.

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