NOTES®: Is it time for introduction to clinical practice?

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It has been three years since the publication of the initial White Paper describing a potential pathway for the responsible introduction of natural orifice surgery was first proposed.[1] The Natural Orifice Surgery Consortium for Assessment and Research® (NOSCAR®) remains steadfast in its position that this approach to minimally invasive procedures is experimental and that research and clinical studies be conducted under the oversight of IRB-approved protocols. At this point in time, the clinical feasibility of performing human NOTES® (Natural Orifice Translumenal Endoscopic Surgery®) cases has been demonstrated.

What are the next steps to clinical acceptance? NOTES® may be viewed as the next phase in the natural evolution of thoracic and abdominal therapeutic procedures. Along each step of the way, controversy has swirled around those who are on the forefront. The early days of thyroid surgery or heart surgery were not without their vocal detractors, but the results of these advances have been dramatic. The advent of flexible endoscopy, so integral today to the practice of most gastroenterologists, was once lambasted by the president of the American Gastroenterological Association.[2] The impact of diagnostic and therapeutic endoscopy in improving patient care is undeniable – ready examples are in the management of choledocholithiasis and in screening for colorectal neoplasia. The introduction of the video laparoscope produced revolutionary changes in the ability to access the chest and abdomen with dramatic reductions in the size of the incisions we made on our patients – decreasing pain and wound complications. Many surgeons adopted this new technology reluctantly or only after facing the economic reality of losing their patients and referrals to the state-of-the-art competitors.

Many dramatic advances in the treatment of gastrointestinal disorders have occurred because of individual practitioners' vision, courage, and persistence. Rarely have new procedures been introduced in a thoughtful, unified and prospective fashion by collecting data, assessing benefit and evaluating risk before introduction into clinical practice. The moral stain of a weekend course held up as adequate training to perform laparoscopic surgery remains fresh in many of our memories. The medical, cultural, political, and scientific environments in 2009 are far different than 20 years ago. Today we must now also assess the economic impact of our innovations as part of the adoption process if we are to be responsible stewards of our profession. In addition, determination of the pathway to clinical competency has to be part of our responsibility. There are too many recent examples of the introduction of ineffective procedures and devices resulting in no benefit and, in some cases, harm to patients and commercial enterprises.

The introduction of new surgical and therapeutic endoscopic procedures into clinical practice poses unique challenges when compared to drug therapies. Surgeons and therapeutic endoscopists face a variety of significant hurdles that include (re)training, understanding the technical learning curve, and establishment of reimbursement. Third-party payers are looking for medical and economic value upon which they can base their reimbursement decisions. It is incumbent upon us to provide that value.

The overarching goal of medical innovation is to improve the health and welfare of our patients. In a world of finite resources this means that those improvements need to make financial sense, i.e., if we are to expend limited resources on new technology there has to be something tangible to show for it, otherwise we simply find ourselves engaged in a medical technology arms race, one in which the physician or hospital is an accomplice out of self preservation.

NOTES® is a platform technology that has provided us with a unique opportunity to assess value in an organized fashion. NOSCAR® has seized that opportunity and outlined a set of principles that include the concept that NOTES® procedures are still experimental and should be done under IRB protocol. The NOSCAR® Research Subcommittee is currently organizing the design and obtaining funding for a prospective multicenter trial of NOTES® cholecystectomy versus conventional laparoscopic cholecystectomy. In a perfect world this clinical trial should be funded by all of the various stakeholders who will be impacted by the introduction of a new disruptive technology that could affect millions of procedures annually. Like the very concept of NOSCAR® itself (a collaborative consortium of medical and surgical societies), we are reaching out to industry, insurers, and the federal government to assist us in funding this trial. This concept makes sense if we are going to come to meaningful and timely answers to guide the introduction (or not) of NOTES® procedures.

As clinicians we must not abdicate our leadership role in assessing what new advances are to be brought to our patients, but we must provide a constructive framework within which all parties can effectively evaluate these advances. By forming NOSCAR®, SAGES and ASGE are taking the leadership positions that are expected by their members, the medical industry, insurers, the government, and especially patients. By creating broad partnerships and early dialogue with all stakeholders to consider the responsible evidence-based introduction of NOTES®, we will be more successful at bringing real value to our patients than ever before. Historically surgeons and therapeutic endoscopists have not demonstrated the patience and discipline this approach requires, often preferring rugged individualism. The world is changing and the old approaches clinicians, industry, and payers have utilized in the past are due for change. It is not quite time for NOTES® to be introduced into daily practice, but it <u>is</u> time for meaningful prospective clinical trials.

1. Rattner D, Kalloo A. ASGE/SAGES Working Group on Natural Orifice Translumenal Endoscopic Surgery. October 2005. Surg Endosc 2006;20:329-33.
2. Kern F, Jr. Clinical training in gastroenterology: a proposal for restoring balance. Gastroenterology 1979;76:1489-92.