Crossing the chasm: tools to define the value of innovative endoscopic technologies to encourage adoption in clinical practice

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Ether anesthesia was first introduced in October of 1846 by Drs William Morton and Henry Jacob Bigelow at Massachusetts General Hospital, Boston at a time when surgeons worked rapidly while assistants held their patients down for as short a time as possible. Within 4 months, ether anesthesia had spread throughout Europe and within 8 months, the world. Surgical sepsis was the leading cause of death after surgery at the time. Surgical antisepsis with carbolic acid was described in 1867, but unlike ether anesthesia took an entire generation to be adopted.[1] Why was there such a disparity in adoption? We posit that this may be related to the stakeholder value proposition.

Promising endoscopic technologies are ever abundant in gastroenterology, yet the path to widespread adoption crosses a dark abyss from which a random few ever seem to emerge. Commercial payers, and taxpayers who fund Medicare and Medicaid programs, have a limited appetite for new technology at a time when they must already cover healthcare costs now accounting for over 17.9% of the total U.S. gross domestic product. No longer can innovative technologies simply bring incremental or statistical benefit to patients—successful technologies must either clearly transform how health care is delivered (such as peroral endoscopic myotomy for the treatment of achalasia[2] or EMR to manage large colon polyps,[3] which can transition care downstream from expensive operative settings to nonsurgical endoscopic centers) or open completely new avenues of care (such as natural orifice transluminal endoscopic surgery[4]). Other new technologies or techniques must show clear evidence of cost-savings.[5] Thus, new technologies must ultimately prove "valuable." However, understanding value requires a specific set of tools and techniques that are commonly taught in business schools and entrepreneurship programs but not in healthcare settings.

We first provide a framework for academic innovators and their industry partners to understand the components of value and provide useful and valid tools to value new technologies. We then discuss the innovation curve as a conceptual model to help academic innovators and their industry partners understand how the value proposition they define is actually perceived by clinicians in practice.

WHAT VALUE IS BEING DELIVERED, AND TO WHOM?

Value is an in-vogue term in health care but is often misunderstood.[6] The basic concept of value is based on the payoff to a customer at the exact moment that the answers to 2 important questions, "Is this technology worth the price?" and "Do I care enough?" are both a resounding yes.[7] What makes definitions of value so malleable is their incredible dependence on the perspective from which a value assessment is made.[8] Importantly, value is not determined by hospitals or payers but by actual people, for example, leaders in payer groups, senior partners in physician groups, or capital purchasing staff in hospitals. A patient might value greater health at a lower out-of-pocket expense and would prefer a high likelihood of success, fewer risks in care, more healthy time spent at work and with family, and fewer unexpected healthcare bills. Value to a clinician might be increased patient referrals, stroking their

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personal ego, or a public relations enhancement for their practice.

COMPONENTS OF VALUE

The 2 basic components to value are functional value and emotional value. Both types of value are distinct and often competing. For example, hospital administrators might place high emotional value on new innovations that enhance public relations such as a peroral endoscopic myotomy program, but the functional value might be incredibly low when every competing practice offers this service. Functional and emotional value are discussed further in the following 2 sections, supported by appropriate tools and techniques to conceptualize and quantify these types of value in practice.

What makes up functional value?

In health care, functional value can incorporate both costs (which can be derived from local or national sources as appropriate) and health gains (gleaned from clinical trials or case series), but functional value can also be determined on costs or health gains alone. Overall, functional value can and should be quantified using budget impact and cost-effectiveness analysis from the perspective of every stakeholder involved (usually patients, physician group practices/hospitals, payers, and society at large). Value in cost-effectiveness analysis is typically reported using incremental cost-effectiveness ratios, calculated as the additional cost divided by the additional health gains associated with adopting new technology. However, there is no discrete cutoff to guide whether a technology is valuable. In fact, the standard incremental cost-effectiveness ratios cutoff in cost-effectiveness literature of $50,000 per healthy-year gained was originally derived from renal dialysis equipment in the early 1990s yet remains unchanged after almost 30 years.[9] Instead, it is important to understand functional value of a new innovation within the context of the status quo. In our ether anesthesia and surgical antisepsis examples, the respective health benefits by introducing surgical sedation and reducing death from septicemia represent functional value to patients. As examples of functional value in GI endoscopy, peroral endoscopy myotomy and EMR provide opportunities for definitive treatment in significantly less-expensive endoscopy centers rather than operating settings (from a payer perspective) while reducing morbidity by avoiding a surgical approach (from a patient perspective).

Functional value is gleaned from cost-effectiveness studies and budget-impact analyses. However, several factors are important to consider when interpreting these studies: (1) generalized sources of data must be adapted to local costs and expected outcomes, and (2) estimates are highly dependent on the set of assumptions needed to model potential cost and health outcomes, so sensitivity analyses should be reported routinely to enable readers to assess robustness of value estimates.

What makes up emotional value?

Emotional value requires energy on the customer's part to challenge his or her own status quo, which is the largest competitor for any technologic innovation (ie, answering the "So what?"). Emotional value must address potential health risks, cost uncertainty, medicolegal issues, compatibility with current clinical workflow, ease of use, and impact on other areas of practice.[10] In our ether anesthesia example, the obvious and palpable benefits of sedation lent urgency and momentum (ie, emotional value) toward adopting ether anesthesia rapidly. With surgical antisepsis, emotional value was low because the slow onset of infection blunted urgency and recognition of this important issue until decades later. In current endoscopic practice, peroral endoscopic myotomy and EMR are possible within existing skillsets of advanced endoscopists and do not compete with their other endoscopic services—translating into high emotional value. Comparatively, the high level of training and specific endoscopic equipment required to pursue natural orifice transluminal endoscopic surgery currently limits the momentum of most gastroenterology practices toward routinely adopting these techniques—translating into lower emotional value despite the clinical promise.[11]

A series of tools can be used to understand emotional value. The value proposition canvas links functional value of an innovative technology with the problems the customer faces, obstacles the customer has toward solving these problems, and the benefits the customer desires to gain through solving the problems.[12] Workflows and ecosystem maps identify chokepoints in current clinical practice and provide insight on how an innovative technology might improve or diminish ease of practice to front-line clinicians and endoscopists.[13] Each tool is designed to help establish whether there is product–market fit with a minimum viable product to validate the value proposition—in other words, whether people actually buy and adopt the technology and replace the status quo.

TIMING OF ECONOMIC AND HEALTH GAINS IMPACTS VALUE

Value is critically dependent on the time frame in which benefits are realized. Immediate health benefits and cost-savings are more likely to be obvious, palpable, and highly prized. In contrast, delayed benefits may not even be realized at all. With surgical antisepsis, the benefits were found long after the patient left the surgeon's surgical suite. But with ether anesthesia, both the surgeon and patient had less pain and agony—the benefit was immediately palpable for both stakeholders.[1]

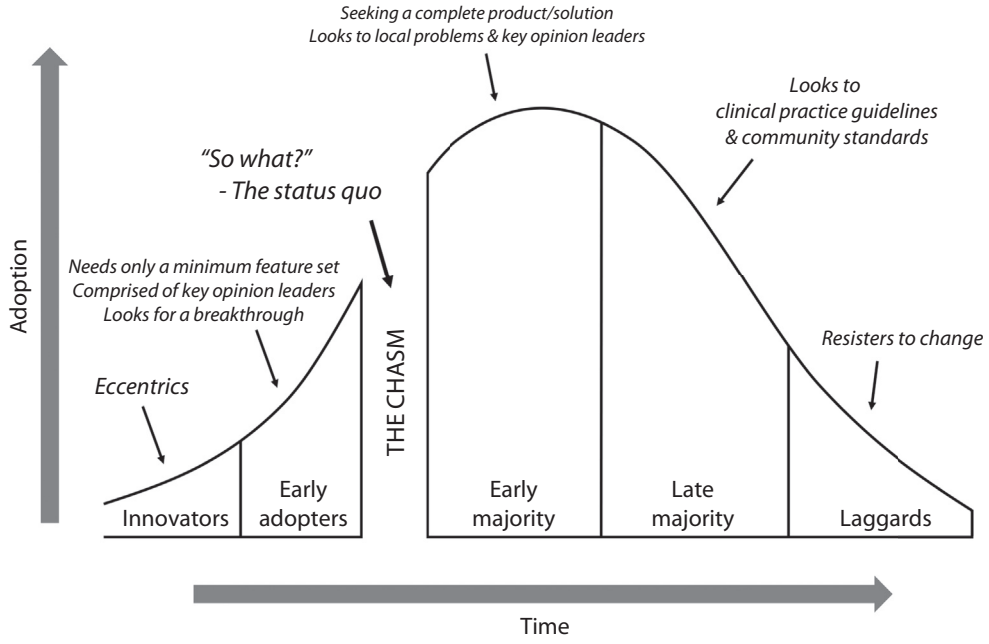

Figure 1. The innovation life cycle. (From Rogers[15]).

TRANSLATING VALUE PROPOSITION INTO MARKET ADOPTION: THE INNOVATION CURVE

Despite a clear functional and emotional value proposition, efficacious technology in clinical trials often fails to "cross the chasm," or, in other words, fails to adopt in practice. The chasm is that space between entrepreneurs and key opinion leaders who see the promise of a new innovation and the willingness of general practice to take ownership of what a new innovation can bring. Recent innovations, such as recent endoscopic antireflux devices and obesity devices, have been difficult to adopt not because of lack of value but rather because clinical practice (ie, the market) may not have been ready for the technology. This problem can be conceptualized using the innovation curve.[14] Within this framework, adopters can be classified into 1 of 5 groups based of their readiness to adopt new technology and their perception of value[10,15] (Fig. 1).

The first is a small group of physician innovators who are highly risk-tolerant, highly focused in specific clinical areas, inherently ready to try new technology, and are either well funded or otherwise able to mitigate the possible risks associated with innovative technologies. The second group of early adopters is composed of key opinion leaders who are less risk-tolerant but still connected to physician innovators. They are well connected in their local referral networks and generally knowledgeable on several potentially competing technologies. What distinguishes the first from the second group is that other physicians look to early adopters for guidance on when to adopt and not to physician innovators. The third group, the early majority, adopts technology based on feedback from early adopters (ie, key opinion leaders) and are not connected to physician innovators. Individuals in this group are also more likely to adopt when an innovative technology clearly solves a problem applicable to their own practice and may not wait for new technology to become embedded in guidelines or clinical practice updates. Common questions might include the following: will the technology be reimbursed, or how will patients pay? Is it time intensive? Is it straightforward to learn, or will I need specific training and credentialing? How will that be accomplished? Will my practice or facility support it? What happens to patients after the procedure? The fourth group, the late majority, is risk-averse and is more likely to wait to adopt new technology until it is incorporated into clinical practice guidelines or community standards of practice. These adopters also look to the success or failure of innovative technologies within other local group practice settings who are more willing to take "the risk." Finally, laggards generally rely on their own experience and knowledge in determining how they practice, do not readily look to others for guidance, and are ultimately less likely to adopt.

CONCLUSION

Value is an elusive yet highly relevant concept in today's gastroenterology practice and tomorrow's promise of innovation. We first defined the basic components of value and tools to assess them and then defined a standard diffusion framework to apply the value proposition toward technology adoption. Even in the current healthcare climate of uncertain future reimbursement and

cost-containment,[16] continued innovation is possible and inevitable. It is our hope that academic innovators and their industry partners can take ownership of the concept of value to embolden their continued future development of promising and innovative endoscopic technologies in the years to come.

REFERENCES

1. Gawande A. Slow ideas. The New Yorker, July 29 2013. Available at: https://www.newyorker.com/magazine/2013/07/29/slow-ideas.
2. Shah ED, Chang AC, Law R. Valuing innovative endoscopic techniques: per-oral endoscopic myotomy for the management of achalasia. Gastrointest Endosc 2019;89:264-73.
3. Shah ED, Pohl H, Rex DK, et al. Routine prophylactic clip closure is cost saving after endoscopic resection of large colon polyps in a medicare population. Gastroenterology. Epub 2019 Nov 15.
4. Garud SS, Willingham FF. Natural orifice transluminal endoscopic surgery. Gastrointest Endosc 2012;76:491-5.
5. Shah ED, Hosmer AE, Patel A, et al. Valuing innovative endoscopic techniques: endoscopic suturing to prevent stent migration for benign esophageal disease. Gastrointest Endosc 2020;91:278-85.
6. Fredriksson JJ, Ebbevi D, Savage C. Pseudo-understanding: an analysis of the dilution of value in healthcare. BMJ Qual Saf 2015;24:451-7.
7. Butz HE, Goodstein LD. Measuring customer value: gaining the strategic advantage. Organ Dyn 1996;24:63-77.
8. Porter ME. What is value in health care? N Engl J Med 2010;363:2477-81.
9. Grosse SD. Assessing cost-effectiveness in healthcare: history of the $50,000 per QALY threshold. Expert Rev Pharmacoecon Outcomes Res 2008;8:165-78.
10. Berwick DM. Disseminating innovations in health care. JAMA 2003;289:1969-75.
11. Aslanian HR, Sethi A, Bhutani MS, et al. ASGE guideline for endoscopic full-thickness resection and submucosal tunnel endoscopic resection. VideoGIE 2019;4:343-50.
12. Osterwalder A, Pigneur Y, Bernarda G, et al. Value proposition design: how to create products and services customers want. Hoboken, NJ: John Wiley & Sons; 2014.
13. Agency for Healthcare Research and Quality. Practice facilitation handbook. Module 5. Mapping and redesigning workflow. Available at: https://www.ahrq.gov/ncepcr/tools/pf-handbook/mod5.html. Accessed November 11, 2019.
14. Baffy G, Fisichella PM. Gastrointestinal surgery and endoscopy: recent trends in competition and collaboration. Clin Gastroenterol Hepatol 2017;15:799-803.
15. Rogers EM. Diffusion of Innovations. 5th ed. New York, NY: Free Press; 2003.
16. Muthusamy VR, Komanduri S. Innovating in your practice: overcoming barriers to create new opportunities. Clin Gastroenterol Hepatol 2019;17:580-3.