Investing in New Technology in Pulmonary Medicine–Navigating the Tortuous Path to Success.

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Investing in New Technology in Pulmonary Medicine

Navigating the Tortuous Path to Success

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The introduction of new technologies offers the promise to advance medicine. This occurs alongside improved efforts to control costs of health care by hospital administrators, the Centers for Medicare & Medicaid Services' (CMS) pivot to value programs, and commercial payers' efforts to reduce reimbursement. These trends present a challenge for the pulmonologist, among others, who must navigate increasingly complex and highly scrutinized evaluation processes used to secure new technology (NT). Health-care providers are turning toward value assessments while simultaneously tasked with the mission of offering state of the art technologies and services. Pulmonologists desiring NT are thus faced with increased scrutiny in their evaluation of costs and clinical data to support investments. Consideration of this scrutiny and further evidence to temper the evaluation will improve the likelihood of adoption and patient access to clinically impactful technology. The identification of this evidence may provide a comprehensive view of the clinical and economic benefits of such technologies to both administrators and pulmonary clinicians. It is imperative that all parties involved in the decision process work collaboratively to deploy value added and clinically impactful technologies. Although a physician group might invest in such NT, the capital required often leads such decisions to a larger organization such as a hospital, health-care system, or privately owned entity. This article aims to provide a framework for pulmonary clinicians to better understand the processes that purchasers use to evaluate NT, the pressures that influence their consideration, and what resources may be leveraged toward success.

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Over the past decade, new technology (NT) has revolutionized the practice and capabilities of pulmonary medicine. Less invasive innovative procedures and new diagnostic modalities have had a part in this ongoing technological evolution. With these changes comes an increasing need for physicians to interface with and persuade those purchasers who are often tasked with controlling and reducing costs and ensuring

ABBREVIATIONS: APC = ambulatory payment classifications; CMS = Centers for Medicare & Medicaid Services; CPT = Current Procedural Terminology; EBUS = endobronchial ultrasonography; LOS = location of service; NT = new technology; ROI = return on investment

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that these technologies provide value to patients and to the system. Evaluating investments more rigorously for inherent value, fee-generated pressures from accountable care organizations and "narrow" networks, and reimbursement reductions from payers all add to the pressures of advocating for NT. Investment in pulmonary services must compete with investment in other medical specialty service lines. In this age of innovation and tightened budgets, the pulmonologist not only must practice excellent clinical care but also must evaluate emerging technologies and communicate their impact to the broader organization in tandem.

In the past, solo or even small group practices implied a streamlined purchasing process—if the resources were available, clinician demand dictated the investment. Similar processes, dependent solely on physician demand, also occurred for some hospital-based purchases. Today, budgetary pressures have fostered greater emphasis on processes requiring evidence before purchase. The clinician needs to be the objective intermediary between those marketing the product and the committee tasked with controlling purchasing.

Although the physician group might invest in such new technologies, the capital required often leads such decisions to a larger organization such as a hospital, health-care system, or privately owned entity and its administration. As such, the purchaser will herein be referred to as the organization and its administrators rather than hospital or other specific system type. The purpose of this paper is to offer guidance to those who are tasked with navigating the broad challenges that must be met in the decision-making process.

Factors Influencing Adoption of New Technologies

When preparing a new technology (NT) request, the pulmonologist should carefully consider the administrator's perspective. Organizations are most interested in both the clinical and financial impact of the proposed NT and its effect on market share.

The clinical impact of NT is perhaps the easiest factor for the pulmonologist to discuss with the administration. The ideal technology will advance patient safety or improve the standard of care and has been shown to improve outcomes, patient satisfaction, or costs. Typically, the pulmonologist will become interested in the NT based on the projected positive clinical impact to their patient population gleaned from clinical trials and peer-reviewed literature. At times, administrators may approach the pulmonologist to review an NT. A clear and objective assessment best serves the organization and the pulmonologist in such circumstances. Credibility is important for best outcomes over time.

Financial impact of the NT is also important to the organization. It is best if there is reimbursement and the procedure has a favorable margin. The margin refers to the amount of money the organization retains from the procedure after subtracting the associated fixed and variable costs. A higher margin indicates a more profitable procedure, thereby making the technology more attractive. Other departments' reimbursements and costs associated with separate "downstream" procedures may also be considered. For example, the technology might reduce expenses for a particular department while growing the volume of existing more profitable procedures (eg, an evidence-based screening program can increase procedure and treatment volumes).[1]

Depending on the local competitive environment and the organization's growth ambitions, the market impact might be carefully considered by the administration. Furthermore, there are a number of nonfinancial reasons for acquisition of NT, which include enhancing competitive advantage, attracting new patients or providers, defining a reputation among the existing patients and providers, and differentiating the organization from its competition. Administrators often see NT as a means to positively impact market share. Figure 1 illustrates various components of NT evaluation.

Evaluation Process

Before advocating for the adoption of NT, the pulmonologist should evaluate a technology for positive clinical impact. If a clinical impact is apparent, several other factors should be considered. Although these specific factors are US oriented, all countries have systems of valuation and payment to be considered, and the same thought process would apply. First, the procedure needs a unique designation. Unique procedures can be valued distinctly and have distinct codes for computer-based reimbursement and tracking systems. In the United States, Current Procedural Terminology (CPT), which is a registered trademark of

Figure 1 – *Components of new technology evaluation.*

the American Medical Association)[2] delineates reference codes for billing and payment. CPT codes describe the procedure performed to insurance companies and the CMS. Reimbursement for the procedure is then separated into a professional fee for the practitioner and a technical fee for the facility. The fees are further differentiated by the location of service (LOS). The distribution of these fees is determined by who owns the LOS and equipment and who employs the provider (Table 1).

TABLE 1] Basics of Reimbursement

Reimbursement	Focus	Captured By
Facility fee	Payment to hospitals, clinics, ambulatory surgical centers for services ancillary to the professional fees provided by clinicians	The facility owners (note: these facility owners may be medical professionals)
Professional fee	Payment to the clinician for the services performed	The professional or employer of the professional, if the professional's employment contract so stipulates

A procedure performed in a physician's office, ambulatory surgery center, or inpatient hospital location has a different distribution of costs to the provider and entity and so is reimbursed differently. Discussions of these differences are beyond the scope of this paper; however, they might have bearing on the location in which an NT is best deployed. Obviously, patient safety and resources needed to perform the procedure must factor into the location chosen. For our purpose, we discuss procedures performed in an outpatient ambulatory setting, which is the most typical setting for pulmonary procedures. Separate analysis would be required when evaluating technologies for less typical settings. CPT codes are associated with specific Ambulatory Payment Classifications (APC) codes, which are groups of services that are similar in clinical intensity, resource use, and cost. Typically, a procedure is not reimbursed for actual costs nor is a specific procedure reimbursed for its average costs across the board. Rather, similar procedures are grouped together, and a reimbursement for the facility cost is determined. All services that are grouped under a specific APC result in an annually updated Medicare payment for that particular APC. Since this payment is a fixed payment to the organization, it is at risk for potential "profit or loss" with each APC payment it receives, depending on the actual cost of providing the procedure.[3]

If a CPT code does not exist, the technology vendor will need to work with the relevant societies and the AMA to establish one.[2,4] In the case of nonexistent CPT codes, CMS and commercial carriers are unlikely to pay for the service. The vendor, physician, and organization should determine if the procedure will be paid for by other means, eg, directly by the patient, by the organization, or with grant funds. NT has to be valued highly enough that providing it to the community outweighs the lack of reimbursement, at least initially.

Once the level of reimbursement is determined, it must be analyzed for whether it will cover the cost of the technology either directly or indirectly. For example, diagnostic technologies may provide opportunities to detect disease, allowing separate treatment and additional reimbursements to be considered. Conversely, if the total cost per procedure is greater than the payment, or if no CPT code or reimbursement is established, the organization will need to evaluate other factors such as a decrease in other costs, unmet patient needs, or prestige brought by being an "early adopter," among other factors not tied to reimbursement for the specific procedure. Such situations are generally a more difficult path toward successful adoption. Vendors of new technologies can be a key resource for these reimbursement questions. Accurate coding for procedures may also be found in medical societies' materials such as the American College of Chest Physicians' coding for chest medicine references and others.[5,6]

Beyond cost and reimbursement, community need and potential market expansion should be considered. One must determine if the diseases targeted by the NT exist in sufficient volume in the organization's current catchment area or if outside referrals are required to support the investment. Although both these factors can be estimated quickly by looking at current volume, adoption of an NT may change these volumes. For example, patients and referring physicians may wish to direct their needed care to institutions deemed more "state of the art" in pulmonary medicine.[7-9] Epidemiologic data and projections from governmental agencies such as the Centers for Disease Control or other organizations such as the American Cancer Society, American Lung Association, or other national or international societies can provide a sense of those disease areas potentially requiring greater future attention. Partnering with patient advocacy organizations, industry, and specialty societies may provide turnkey solutions to describe the epidemiologic burden of the disease addressed by the NT and how this technology may reduce that burden or enhance hospital census.

How an NT or program fits into overall strategy needs to be considered.[10] Every organization has a strategic plan, and NT may be perceived to hamper or facilitate this plan. The pulmonologist wishing to advocate for investment in an NT would be wise to consider how that technology may impact and actually support the organization's strategic goals. Active involvement in this goal setting may be beneficial. If the administration sees an NT as integral to advancing care and dovetailing with its strategic aims, it will be more readily supported. This is particularly true for those technologies requiring significant capital investment (eg, advanced diagnostic equipment). Beyond this top-level organizational strategy, cross-departmental interaction should be sought. Some NTs can be used

by, or drive value across, other departments. It is likely that these departments will be "coendorsers" of this investment. Appropriate and effective networking across departments can significantly improve the likelihood of adoption. For teaching intuitions, one can explore whether there is potential for training clinicians and possible revenue or cost sharing from the medical school. One must also consider if a technology has new requirements to train staff or personnel. It is worth noting that the single greatest cost to an organization's operations is staff labor.[11] Thus, although there is cost associated with new training, new technologies have the potential to free up staff to focus on other more efficient tasks or allow for reduced staffing levels, which are both welcomed by most organizations.

Competition between and within organizations (ie, across departments) and across vendors adds to the factors considered when evaluating an NT. In many situations, organizations may consider investment in NT as a mechanism to enhance their competitiveness with other systems. Counterintuitively, organizations that are in a position of relative competitive advantage may be less apt to adopt novel pulmonary technology, as they already have a favorable market position. In such situations, arguments centering on the gains pulmonary medicine has made over the past years,[12] along with opportunities for the administration to strengthen the linkage between pulmonary medicine and other specialties (Table 2), should be leveraged.

Evaluating the Return on Investment

Presenting the most relevant argument to purchasing managers and the administration often requires an analysis of the expected returns from an investment. Very often, these will come in the form of a return on investment (ROI) analysis. ROI analyses examine the current and future value of all benefits of using a particular technology, including reimbursements, potential future revenues, staff efficiencies, and other revenues, and considering these benefits in relation to all costs of the technology, including capital outlays, training, and other costs. The final analysis will divide all benefits by all costs. Values greater than 1.0 imply a favorable investment. Essentially, an ROI of 1.0 means the money invested was generated to compensate for the expense (ie, break even). Most entities will want to get beyond a breakeven point and have some excess or profit from the investment. The ROI target, typically

TABLE 2] Factors to Consider When Evaluating New Pulmonary Medicine Technologies

Factor	Consideration	Potential Resources to Address
Reimbursement	Current reimbursement (or lack thereof) for the procedure or service	Medical specialty society organizations Industry CPT codes[4] CMS/Commercial Carriers
Community need	"Market" size given the catchment area, epidemiology of the disease and guidelines	Industry Medical specialty societies Epidemiologic data CDC NIH HCUPnet
Organizational strategy	Marketwide: hospital strategic initiatives and positioning within the regional market; pulmonary position against other departments regionally Hospitalwide: strategic planning and positioning of pulmonary medicine against other specialties or practices	Attendance of hospital strategy discussions Networking meetings and informal discussion with colleagues in regional meetings and committees Close scrutiny of hospital marketing campaigns and community outreach Industry partnership in technology adoption
Competition	Competition among potential vendors, across hospitals, across specialties, and departments Collaboration opportunities	Understanding strategic initiatives of various vendors, hospitals, and departments Negotiating with key stakeholders up front

CDC = Centers for Disease Control; CPT = Current Procedural Terminology; HCUP = Healthcare Cost and Utilization Project; NIH = National Institutes of Health.

> 1.0, of the organization should be considered in planning. The mathematical depiction of the ROI analysis is shown[13]:

$$\frac{\sum_{i=0}^{n} \frac{B}{(1+d)^i}}{\sum_{i=o}^{n} \frac{C}{(1+d)^i}}$$

Notation: '*B*' defines the measure of a benefit of a new technology (NT)

'*C*' defines the measure of a cost of a new technology (NT)

'*d*' defines the discount rate for a period of time

'*i*' (typically annually, so that a cost/benefit avoided by one year would avoid $d/(1+d)$ fraction. Some analyses may consider d equaling the prevailing interest rate.)

'*i*' defines the time index (typically annually, so that $i -> i + 1$ defines the time period of one year)

Most entities have a specific understanding of their cost and operational structures and have developed internal ROI formulas that are best used for local understanding and buy-in.

Factors that should be included in every ROI analysis include an examination of (1) "fixed costs," ie, capital purchases that must be made before a single patient is seen; (2) "variable costs," ie, continuous purchases made for each and every patient seen; (3) reimbursement, ie, the economic benefits to the organization; (4) patient volumes, which determines the impact of reimbursement and variable costs; (5) "indirect costs," ie, costs that support multiple nonprocedure-related activities, such as hospital insurance, rent, utilities, and administrative salaries. Different approaches to cost of the purchase, such as per-case lease and lease vs purchase, can impact the fixed or variable cost of the ROI and should be discussed between the vendor and administration. Finally, the total cost of the procedure, considering both fixed and variable costs and indirect costs should be compared with overall reimbursement. For simplicity, we will look at a breakeven analysis in an example further on. Although less complex than a full ROI analysis, it gets at the essence of offsetting the cost of the equipment, supplies, and setting by the excess from the reimbursement for each case and how many cases over time are required to break even. This is well described for other pulmonary equipment-dependent procedures.[14]

Opportunities to collaborate with finance and value analysis or similar committees to understand guidelines for ROI analyses should be identified prior to the assessment and followed by those advocating for NT. Organizations know their own cost structure and typically have their own specific ROI calculation process. Using an established approach will be more acceptable to the decision makers.

Formal Request for Investment: "The Ask"

Once the decision has been made to acquire a technology, the question of whose budget this technology falls into arises. The two primary budgets that an organization uses for technology purchase are the capital and operational budgets. The capital budget is for equipment and infrastructure, whereas the operational budget covers the day to day expenses. Large capital outlays, by necessity, demand appropriate timing and fiscal justification. Typically, capital budgets are approved annually but are developed over longer periods. Most organizations have a threshold for what is considered major and minor capital. Amounts less than the threshold often have a more limited number of steps for evaluation and may even be acceptable purchases outside a specific timeline. Amounts greater than the threshold have more rigorous reviews and often take longer to approve. The existence and magnitude of this threshold varies by institution. Inclusion of key decision makers from the outset will improve the likelihood of success and better alignment with institutional strategy, as well as which technology can or cannot be pursued. Funding sources vary by institution (Table 3) and should be analyzed locally.

Concrete Example

For simplicity, we will use a breakeven analysis for this concrete example, ie, will the reimbursement cover the cost of the purchase and when? The ROI calculation that one will perform with their administration covers additional things, such as depreciation of the value of the equipment over time and its related accounting. This is all best done within the organization's model to best reflect their internal accounting and knowledge of their

TABLE 3] Sources of Funding

Entity	Subcategory	Considerations
Hospital	Capital budget	Annual cycle for capital items
	Operational budget	Limited cycle for lower cost items
Grants/Research	Industry sponsored	May require nuanced buy in from compliance by industry or hospital, or both
	Government	Difficult funding cycle and burden of grant writing
	Nonprofit	Limited longevity Potential political consideration
	Investigator initiated	Increasingly difficult to secure NIH or other government funding; funding generally for only a limited time, continuation of the program may be difficult
Endowments	. . .	Infrequent availability; funds may come with restrictions on use
Practice physicians Venture capital Joint venture with hospital or other investors	. . .	Buy in of physicians Buy in of investors Aggressive financial targets

See Table 2 legend for expansion of abbreviations.

costs. A simple breakeven analysis should be further supported by the subsequent ROI analysis.

This example is of a breakeven analysis of endobronchial ultrasonography (EBUS). For this example, assume the capital investment to buy the EBUS equipment is $200,000, the payment to the facility (the average APC [for level four airway endoscopy; code 5154] is approximately $1,992 per procedure,[15] the bronchoscopy suite time is estimated at $22/min or $1,320/h,[16] disposable supplies are $150 (local EBUS needle, rounded estimate), and the physician fee is $267 (2016 estimate). The APC value is available online from many sources that have distilled the complex CMS data. The cost/min is difficult to assess. Data are rarely reported and are often charges rather than costs. The reference used from 2010 suggests costs of $15 to $20/min and lists a reference range of operating room charges of $22 to $62/min from least to most complex cases. In choosing the lower charge number for our calculations to represent cost, we assume that endoscopy suite time fits the into the lower complexity case type, that costs are lower than charges, and that there has been an increase in cost over time. This way, we may overestimate cost but assume this is better than underestimating it. The calculation looks at the cost of the equipment, suite time, and disposables and offsets it with the dollars generated for the procedure to determine time to breakeven status. The professional fee for the physician is not included in the calculation. Typically, this fee does not go to the facility. However, it may be factored in if it does at select institutions. Further, this will vary by whether moderate sedation (which has a new separated value in 2017in the United States) is performed by the endoscopist or by a separate anesthesia practitioner. The reimbursement of $1,992 minus the cost of $1,470 ($1,320 + $150) in the example gives a margin of $522 for each case. It would then require dividing the cost of the equipment by the margin ($200,000/$522) to determine that approximately 383 cases would need to be performed to break even. Assuming 50 cases per year, it would take 7.7 years (383/50) to break even, which may not be reasonable, whereas 150 cases per year would take a more reasonable 2.6 years (383/150). More cases per year shorten the payoff period. One then will determine if this is adequate for the institution in amount and time it takes. Although the physician fee is noted, it does not typically factor into the calculation but may be considered by the entity employing the physician or by the physician to see if the amount is worth the time needed to perform such procedures. Added costs such as endoscope repair costs or contracts are not considered but can be factored in using locally available data.

In all cases, additional factors can be considered that may allow for a lower acceptable margin. The factors most impactful to both the pulmonary department and the administration include reduced risk of complications, potentially improved patient satisfaction

due to less invasive collection of samples, and alignment with guidelines for staging with the fewest number of procedures relative to the more invasive mediastinoscopy procedure.[17-21] As many entities are migrating to less invasive procedures and more explicitly considering patient satisfaction, these qualitative factors may be as important as a purely economic analysis. Moreover, potential increased revenue from subsequent procedures to treat the diagnoses obtained from the EBUS procedure may also be considered. Even when base reimbursement does not produce a favorable breakeven time, it is this balance of these many factors and deliberate construction of the most impactful argument, whether exclusively economic or also aligned with hospital strategic initiatives, that produces the greatest likelihood of successful adoption and investment.

Who Pays

The classic purchaser of NT has been hospitals. Historically, most pulmonary procedures have been performed in a hospital ambulatory setting. As the larger share of revenue was garnered by the hospital (ie, the deeper pocket) and the hospital wanted to accommodate its practitioners, the hospital paid for the technology. This remains the case in most settings. However, those practitioners desiring NT must be aware of changing patterns of control and ownership and be answerable to value-based reimbursement. The solo or small group practice is becoming difficult to maintain, and it would be rare for such a practice to have the resources to purchase advanced technologies. Larger practices, specialty specific or multispecialty, may have the resources to own the LOS and thus compete with traditional hospital-owned settings and purchase these NTs on their own. Conversely, many practitioners are now employees of hospital systems, and their approach is of necessity that of the hospital system's. As we look at value for dollars spent, we must realize that hospitals are very expensive places to provide services. Hospitals realize this as well. This may drive more creative outside settings for care. Organizations may be created that look for joint ventures between practitioners and hospitals, between practitioners and venture capitalists, between commercial insurance carriers and practitioners or hospitals, or other permutations. The practitioner in the middle of this desiring NT must be aware of these permutations, understand where he or she fits in this matrix, and analyze cost and need for NTs, accounting for these factors.

Conclusions

Pulmonologists must increasingly be advocates of advances in the field and be aware of the challenge to secure investment in emergent technologies that strengthen specialties and improve patient outcomes. This challenge echoes a far-reaching movement in health care to an emphasis on providing greater value to patients. Although the US health-care system has a different structure than elsewhere, NT has costs and benefits in every system, and the general approach we describe applies globally. Pulmonologists advocating for investment in NT must focus their arguments on providing value to patients and the health-care system. Pulmonologists who successfully navigate these challenges will improve their likelihood of success, increase hospitals' willingness to invest in clinically advantageous NTs, and improve their patients' health.

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