Addressing the imperative to evolve the hospital new product value analysis process

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Central Message

The value analysis process needs to be revamped. We must think more episodically, such that the clinical, economic, and patient-reported outcomes after discharge are included in any value calculation.

See Editorial Commentary page 686.

See Editorial page 681.

The new product acquisition process that exists in most hospitals has at some time frustrated nearly every engaged physician. Typically, physicians identify a promising innovative new technology that they believe may improve patient outcomes. This might be a novel drug, a new medical device, a promising diagnostic biomarker, or health care services that physicians believe will decrease health care costs and improve patient outcomes. The practitioners gather the relevant information about the technology, review the published literature, and then network with their clinical colleagues to garner support for initial implementation.

The next step is to engage in a hospital administrative vetting process by submitting a proposal to the hospital value analysis committee (VAC) for approval. Unfortunately, what often follows is an onerous, circuitous, and unpredictable process of VAC requests for further literature support, unavailable additional studies, and application resubmissions. The results are often delayed or rescheduled meetings, pushback by the committee, and, all too frequently, rejection of the proposal. This is very frustrating for the clinician champion, who continues to push the committee, leading to cycles of appeals and political maneuvering and generating organizational tension, ill will, and discouragement.

This drawn-out process not only is an inefficient use of physician and hospital personnel time, it also contributes to rising medtech industry and pharmaceutical costs as companies must raise prices to cover the growing expense of supporting their sales personnel through this increasingly arduous and inefficient value analysis process. The result is that the bedside clinician's input and ability to influence patient care directly by selecting and ushering in innovative new technologies has severely eroded. To address this current process, we have to ask, is a VAC truly judging health care value, or simply comparing short-term costs? Further, we have to ask, what else can we do as clinicians to make the process better?

The typical modern multidisciplinary VAC is charged with "improving patient care and controlling product costs

with an emphasis on the purchase and utilization of cost-effective, high quality products through an approved process of determining clinical efficacy, product evaluation, and financial impact to the health system."¹ The role of the VAC emerged as reimbursement rates dropped, uncompensated care rose, and thin hospital margins narrowed, necessitating a means of controlling rising health care costs. Originally, the idea was to reduce unnecessary spending by putting in place a cost comparison process for new supplies and technologies.

Most hospitals traditionally divide budgets into silos (operating room, intensive care unit, service lines, laboratory, radiology), each tasked with controlling what is spent in the respective departments. Many have also been charged with ensuring that products were safe and effective before being purchased. (Given that all newly proposed products have been cleared by the Food and Drug Administration, this is potentially redundant.) In modern times their mission has now expanded to consider the cost differential within a particular silo between a proposed new product and what it may supplant. This math is easy with commodity products, where 2 or more suppliers are available and both have the same indications, features, and benefits, with the only difference being price. In that scenario, it makes sense to switch suppliers. When a new product or technology is indeed more expensive within a single department budget silo, however, it is often stalled

or rejected by the VAC. This is especially the case with promising new technologies that are significantly disruptive and differentiated by providing the ability to improve patient outcomes through the course of months but may not immediately save money within a short-term, siloed budget. This creates a disconnect between what the physician believes is best for patients in the long term and what the VAC believes is best for the hospital system, as viewed with a short-term timeline.

What is often missed in the calculations is that preventing avoidable adverse outcomes during recovery can be a huge contributor to overall cost savings over the continuum of patient recovery.² Economist Michael Porter³ pioneered the concept of health care value, which is defined as the best possible clinical outcomes for the lowest possible price. He rightly defined this from the patient's perspective, not the hospital's budget within a particular silo. He also included in the value calculation a patient's full recovery after discharge, not just during the index hospitalization. This revolutionary concept of health care value has significantly influenced recent political initiatives to transition reimbursement models in the United States to migrate from fee-for-service to value-based modules. This is represented by the introduction of the Medicare Access and CHIP Reauthorization Act (MACRA), Merit Based Incentive Payments System (MIPS), accountable care organizations (ACOs), and mandated payment bundles that are coming online in the next several years.^{4,5} Physicians and hospitals are now increasingly responsible for costs and outcomes through the postacute period, where costs can be high and their control limited. Most hospital systems, however, are ill equipped to handle this situation.

Today, Medicare measures the medical spend per beneficiary (MSPB), a summary of the costs of care from admission to 30 days after hospital discharge. Hospitals and physicians are being measured on this outcome, and the performance is used to influence reimbursement. In addition, in the near future, physicians and hospitals with the highest costs and worst outcomes, measured at least 90 days after discharge, will see significant reimbursement penalties, not to mention that these results will be increasingly transparent to the public. It is speculated that the time horizon will stretch beyond 90 days as this reimbursement model evolves. In contrast to the hospitals' traditional focus on immediate departmental budgets and the index admission, hospitals must now assess the ability of a new technology to deliver better long-term value and reduce complications. This includes prevention of readmissions and wound infections and promotion of the best possible wound healing with the least amount of avoidable pain. Taking the long-term view of the patient's perspective of health care value should result not only in improved outcomes but enhanced patient satisfaction. Although physicians and hospitals cannot always control

what happens after the patient leaves the hospital, they can endeavor to choose new technologies, drugs, and services that may cost more up-front but contribute positively to the bottom line value assessment long after the patient leaves the hospital.

VACs must evolve to meet this challenge. First, hospitals should commit to evolving their mission to create value through the continuum of care and recovery by better acknowledging that this may require up-front investments in new technology, pharmaceuticals, and services. The first question in a VAC should not be the cost; rather, it should be the value to our patients in a global bundle of services. In doing so, the VAC mission must evolve to facilitate analyses that go beyond simple departmental silo costs and focus on patient health care through recovery. This process should be streamlined by making costs entirely transparent and then adding in the long-term element of outcomes assessment, so that all parties can truly evaluate the health care value equation. Where value-based outcomes are uncertain, the process needs to provide practitioners with greater hospital resources (in the form of time and budget) to investigate quality improvement opportunities, implement system-wide care pathways, redefine order sets, and then measure and report the results. New hypotheses of value creation must be tested, through rigorous quality improvement initiatives, and then reevaluated according to the outcomes. Becoming facile with available big data tools that allow specific outcomes and cost assessment should become part of the armamentarium of every medical center. This will require personnel, funding, and, most importantly, administrative support to chaperone the process. The modern VAC must look to unlock the health care value of a new intervention, technology, pharmaceutical, or service across hospital service lines and through patient recovery after discharge.

Second, the modern VAC may need to be reorganized to bring hospital controllers and administrators into the process, rather than silo department budget managers, so that the broader value picture can be assessed by those with administrative influence to make decisions. Additionally, a true value analysis process will require physician and nurse engagement that is respectful to the time demands on busy clinicians. Administrators must recognize this, and mechanisms to engage and empower physicians must return to this process.⁶ All this will require a streamlining of the process and having the administrative support needed to make VAC decisions quickly. It is also important that the VAC engage the correct team for each task. Rather than recruiting a separate group of physicians for a VAC, hospitals must leverage their existing structures and teams that are close to the service line being optimized. Optimally, the service line structure should allow hospitals and physicians to prioritize several aspects of their practice to encourage a focus on initiatives or care

TABLE 1. Conceptual framework for modern value analysis committee evolution

1. Recognition of a potential new technology for value analysis by a team member
2. Identification of a key team of decision makers (surgeons, anesthesiologists, nursing, administrators, controllers)
3. Assignments to various team members to define the following: <ul style="list-style-type: none"> • The problem that the technology is meant to assess (eg, acute kidney injury, wound infection, delirium) • The incidence of the problem through recovery (at 90 days postoperatively) • The costs of the problem • The technology an implementation requires • Supporting data and rationale for implementation (from all available sources, including society guidelines, individual clinical studies, real-world case studies, and patient-reported outcomes assessments) • The total hospital costs to acquire and implement the technology
4. Discussion and definitions of criteria for approval
5. Compilation of report with an assessment as to whether the technology will improve outcomes and reduce costs
6. Voting within a defined timeline (include online survey tools to be more inclusive of clinical personnel who may have a stake in the discussion but cannot attend meetings)
7. Publishing the decision with transparency and defining next steps
8. Scheduled reassessment of the new technology in a defined period after implementation

bundles that will standardize best practice, improve outcomes, and lower costs well beyond discharge. Some of the larger cardiovascular institutes have already made efforts to include members of their alternative payment model accountable care organizations and bundled care representatives on these committees. This should evolve to include a majority of programs.

Third, medical device, pharmaceutical, and health care service companies developing promising new technologies have to do their part as well. They must increasingly focus not just on evaluating safety and efficacy for product regulatory approval but also on carrying out robust comparative effectiveness trials and supplying a rationale for economic justification across the continuum of care. This is a big shift, because this will mean going beyond selling product features and benefits to demonstrating their role in the health care value process. Health care reimbursement leaders, like the Centers for Medicare and Medicaid Services, could do more to offer broadly available and streamlined reimbursement incentives for promising new technologies to demonstrate long-term value, as is done in other countries.

Fourth, patient-reported outcomes (PROs) may need to be included in the value analysis process. A patient-reported outcome is an outcome that is directly reported by the patient, without interpretation of the patient's response by a clinician, and pertains to the patient's health,

quality of life, and functional status associated with a treatment. Traditional survival, disease, and physiologic outcomes may demonstrate the physiologic benefits of a new treatment; however, the patient perspective provides a more comprehensive assessment of all potential benefits.⁷

Finally, the professional societies and organizations must commit to assessing available clinical evidence of value in published consensus statements and evidence-based guidelines for new technology, services, and pharmaceuticals. We cannot rely on product manufactures to provide comparative analyses assessing long-term value. We should develop a collaborative of academic institutions that will contribute registry data to a central repository of intermediate- and long-term standardized cost and outcomes data for new products. Such data would be quite valuable to participating institutions to improve their value analysis assessment of new technology. This data contribution could be an addendum to the Society of Thoracic Surgeons database.

An attempt is already being made in cardiac surgery at defining "value" through consensus work and analytic review of the literature.⁸ As part of this, the conversation must evolve from "How much does it cost?" to "What is the value to the patient across the continuum of recovery?" As an example, we propose to establish a new technology comparisons guideline to be considered to include a simple value negative, value neutral, or value positive determination (based on data demonstrating whether the costs exceed the benefits at 90 days) to help guide individual VACs with peer-reviewed, unbiased consensus statements.

The involvement of all key stakeholders will be needed to improve this process of new product assessment. Novel processes should be evolved so that new technologies that might financially affect a single budget silo are not reflexively rejected if they can demonstrate a reduction in complications in the first 3 to 6 months after surgery or significantly affect patient comfort or outcomes. Physicians need to recognize that the days of hospitals rapidly honoring physician product preferences for new technology are over. Physicians are often the best judges of which technologies can best bring value to their patients, however, and they thus must remain key players in the process. A conceptual framework for a modern VAC evolution is described in [Table 1](#).

Going forward, we must commit the time to engage in the analytic process of assessing true long-term value, defined as the health outcomes achieved per dollar spent through a full episode of care. It should be recognized that physician time is often committed to patient care. Modern tools should be used that rely less on having surgeons show up at meetings (eg, survey tools, online conferencing). To facilitate this, hospital administrators must commit to making the process less onerous, time-consuming, and arbitrary by evolving the VAC to focus more effectively on long-term value for patients rather than the immediate

cost differential within a hospital budget silo. The expansion of medical spend per beneficiary, mandated 90-day bundled payment structures, Hospital Consumer Assessment of Healthcare Providers and Systems surveys, readmission penalties, and Merit Based Incentive Payments System reporting, will create even greater impetus on hospitals to reassess the VAC. Physicians, however, as the primary advocates for patients, must continue to promote themselves as the ultimate champions for these changes.

Conflict of Interest Statement

Dr Engelman is a speaker for Mallinkrodt Pharmaceutical and serves on the medical advisory board for Pavillion Medical. Dr Boyle is a consultant and equity holder in ClearFlow, Inc. Dr Benjamin has nothing to disclose with regard to commercial support.

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