

From innovation to market adoption in the operating room: The “CFO as customer”



Ryan D. Egeland, MD, PhD, MBA,^a Zachary Rapp, MA,^b and Frank S. David, MD, PhD,^b Minneapolis, MN, and Milton, MA

Dr Egeland is senior director of business development and licensing in the Early Technologies business unit of the Minimally Invasive Therapies Group at Medtronic.

Mr Rapp is an associate consultant at Pharmagellan, a biotech consultancy.

Dr David is the founder and managing director of Pharmagellan. (Surgery 2017;162:477-82.)

From Medtronic,^a Minneapolis, MN; and Pharmagellan LLC,^b Milton, MA

“Anything that won’t sell, I don’t want to invent. Its sale is proof of utility, and utility is success.”

– Thomas Edison¹

“The single necessary and sufficient condition for a business is a paying customer.”

– Prof. Bill Aulet, Martin Trust Center for MIT Entrepreneurship²

FROM A BUSINESS PERSPECTIVE, these are mixed times for surgeon-innovators.^{3,4} On the positive side, venture capital funding of private medtech companies (devices, diagnostics, and other tools and supplies) achieved a record \$5.6 billion in 2016, a 10% increase over the prior year. At the same time, past medtech research and development investments are bearing fruit, as demonstrated by the 51 premarket approvals and humanitarian device exemptions granted to new medical devices in 2015 by the US Food and Drug Administration—the most in over a decade. Together, these data suggest that investments in the medtech sector are yielding new products and are poised to deliver more in the future.

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Reprint requests: Frank S. David, MD, PhD, Pharmagellan LLC, 499 Adams Street, Box 94, Milton, MA 02186. E-mail: frank@pharmagellan.com.

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Although medtech product development may be relatively healthy overall, new surgical devices face headwinds in the marketplace. Historically, surgical innovators have focused on improving and/or expanding the technical capabilities of the practitioner to improve both intraoperative techniques and patient outcomes.⁵ However, today, solely addressing the needs of patients and doctors is no longer enough because many new, clinically valuable surgical products are incompatible with the budgetary realities that buyers and payers face.

In fact, hospital financial stakeholders signal that clinical superiority and physician advocacy are still required to drive the adoption of a new product in the operating room, but they are no longer sufficient alone. These chief financial officers (CFOs), procurement specialists, business managers of departments of surgery, and members of value analysis committees—the actual check-writers who control or influence the adoption of new surgical products—report that it is increasingly challenging for innovative surgical devices to be adopted if these devices add costs to the already precarious budgets that they are struggling to manage.

The silver lining is that there is still hope for advanced medical devices in the operating room, provided surgeon-innovators can expand their focus to include not just clinical value but also economic value to financial stakeholders. By understanding the perspective of the “CFO as customer,” surgeons can focus their innovation efforts on new products that are not only functionally superior but also able to improve patient care by gaining widespread market adoption. This article summarizes insights from dozens of interactions with hospital finance professionals and

provides a roadmap for incorporating this perspective into new product innovation in the operating room for inpatient surgeries.

THE CONTINUING FINANCIAL SQUEEZE ON THE OPERATING ROOM

Despite recent gains, US hospitals (a major source of revenues for most global medtech companies) are on shaky financial ground. Due to a combination of demographic shifts and the effects of the Affordable Care Act, federal programs cover more (and a greater fraction of) patients, but reimbursement has not kept up with the costs of care.⁶ In response, hospitals have engaged in aggressive measures to cut costs and increase efficiency.⁷ Although hospital margins (revenue minus expenses) have stabilized over the past 5 years, the Congressional Budget Office has warned that the “recent trend does not necessarily provide a good indicator of hospitals’ financial health in the longer term.”⁸

The inpatient operating room, which accounts for about 40% of hospital surgical procedures, is particularly susceptible to fiscal pressures because of how hospitals are reimbursed.⁶ Medicare generally pays a fixed amount for each inpatient case under a capitated system, based on its complexity and cost, yet finance executives report that the costs of surgery and postoperative care, including labor, infrastructure, consumables, and capital equipment, are increasing far faster than reimbursement rates, squeezing margins and making it harder to adopt new products.^{9,10} A CFO at a Mid-Atlantic community hospital recently explained that, from his perspective, “[i]t’s becoming tighter and tougher. Medicare rates are about the same as they were in 2010, so we’re very judicious about what we approve. I have used the word ‘no’ more times in the last 3 years than in the previous 20 years.” Although private insurers often pay slightly greater rates, margin pressure is being felt here as well.¹¹

As a result, hospitals are more attentive to the price of both inpatient and outpatient surgical technologies, and many hospitals are less likely to approve even the most clinically valuable products if they add substantial cost. The director of supply chain management at a Northeast community hospital cited a recent example of a new thoracic surgery device for asthma that his institution recently evaluated. “Reimbursement wasn’t going to come close to covering the consumables,” he explained. “It was clearly something that would be good for patients, but we’d take a loss on every

case.” In the end, the hospital decided it simply could not afford to adopt the new product.

Another community hospital CFO had blunt words for companies producing surgical products: The heyday for one historic innovation strategy is long over. “The device industry traditionally made money on a simple business model: Come out with a replacement product that costs 3 to 5 times more than the old one,” he said. “But the ability to do that has gone away. My advice is, don’t spend money developing more expensive devices. We’re not going to buy them.”

“VALUE” IN THE OPERATING ROOM—MYTH AND REALITY

As the costs for health care have increased and placed more pressure on the organizations and institutions that pay for goods and services, many manufacturers of drugs and devices have embraced the idea that the value of their products should be measured as the difference between their cost and the health economic value they create.¹²⁻¹⁴ This calculus underpins the framework of the cost-effectiveness analyses used in the United Kingdom to evaluate new drugs, whereby a new therapy is adopted if the dollar value of its long-term health benefits (measured as quality-adjusted life years) exceeds its price.¹⁵

Although value-based payments are starting to gain traction in some areas of health care in the US,¹⁶ including orthopedic and cardiac surgery,¹⁷ most surgical procedures and devices are reimbursed currently under diagnosis-related group payment schedules, and this creates a conflict between value and affordability in the operating room. Renowned investor Warren Buffett has noted that “[p]rice is what you pay; value is what you get,”¹⁸ and under capitated payments, hospitals pay for operating room-based technologies, but much of the health economic value in terms of better clinical outcomes and lesser lifetime costs of health care accrues to patients, payers, and society as a whole, far in the future. As long as this situation persists, hospitals will continue to be asked to pay for new inpatient surgical devices without recouping their full value.

It is little wonder that financial stakeholders say that, when it comes to new surgical products, their primary concern is cost; long-term health economic calculations typically play little or no role in their decision-making. A supply chain management executive at a Mid-Atlantic academic hospital explained, “We’re open to looking at [health

economic] analyses, but those are soft dollars. They don't have much value."

Importantly, this is not to suggest that surgical device innovators should ignore the opportunity to deliver innovative, long-term improvements in health. As a society, there is a growing realization that we need to move in this direction to sustain our health care system. Vendor contracting that incorporates health economics is being implemented currently in some clinical settings, but it is impossible to know when, if ever, this approach will broadly transform the decisions of many or most hospitals to adopt new operating room technologies. In the meantime, hospital finance executives are struggling (and will continue to struggle) to afford many innovative surgical products, even if they offer high clinical and long-term health economic value.

"CFO AS CUSTOMER"—WHAT SURGICAL INNOVATIONS DO HOSPITALS WANT TO PURCHASE?

Surgical innovators need to better understand the key economic customers for new surgical devices: the CFO and others in the financial arm of the various institutions that they plan to target.

Who is the "customer" of a new surgical device? Traditionally, manufacturers focused almost single-mindedly on satisfying clinicians and patients. Essentially, companies decided whether or not to develop and commercialize a new technology based on whether the product would help surgeons reliably achieve a higher-quality outcome and lead to better clinical care for the patient.

Strictly speaking, however, surgeons and patients do not meet the definition of device "customers" because they usually bear little or none of the cost of the product. They are important users and/or beneficiaries of medical products, but they have only a share of the purchasing influence in the hospital operating room.¹⁹ Financial managers ultimately hold the purse strings.

As hospital budgets have tightened, the "CFO as customer" has become more important in the decision-making process. It is increasingly rare for value analysis committees to automatically green light "surgeon preference items." Instead, financial managers force clinical colleagues to justify the added expense. The CFO of a large suburban hospital in the Midwest said, "If there's a major price difference, we can show the surgeons the numbers, and then they sometimes say, 'The increase in quality is not worth that much.'"

New products that are qualitatively "better" but whose advantages are hard to quantify are particularly vulnerable. "Quality of the product is almost

a nonexistent factor," one regional hospital executive stated. "It's purely dollars and cents—you're competing for dollars in the operating room budget with minimal involvement of what the product brings to the table." Another CFO concurred, explaining, "The efficacy argument is hard to make. It's easier if there's an offset in terms of time reduction or something else."

That leads to the key need of the "CFO as customer": improving care without busting the budget. Although a few categories of innovative surgical devices purport to offer hospitals incremental revenues and a marketing hook to attract patients in competitive regions,²⁰ for the majority of surgical devices, financial stakeholders want to see that the increased cost of a new product is balanced by tangible, near-term offsets in areas that they already understand, measure, and manage (Figure). (A surgical device could provide other sources of value to a hospital, like revenue from new procedures or increased patient attraction or retention, but finance stakeholders told us that for most new operating room products, these sorts of potential benefits are less compelling than near-term cost offsets.) Specifically, CFOs and other hospital finance professionals point to 3 ways that a new surgical product can be most financially attractive:

1. Boost efficiency. Devices that decrease the duration of operations or procedures or the turnover and down time between them could lead to direct cost savings or even greater revenue (if they allowed the hospital to schedule more procedures during the day).²¹ As one director of materials management for a regional hospital described, "If we can get the next patient in [the operating room] 30 minutes earlier, that's a big deal for us." Realistic opportunities for saving time also exist beyond the operating room in the postoperative period because the added cost per day (or even per hour) typically falls under the capitated payment. One supply chain executive of a management group of a large ambulatory surgery center claimed forcefully that "[a device that] reduces length of stay is a no-brainer." Finally, surgical devices that directly decrease staff needs could be particularly attractive to CFOs, given that the cost of personnel is a large expense category in most hospitals.²²

2. Prevent high-cost events. The economic value of a surgical device that prevents undesirable outcomes like postoperative complications can be calculated by multiplying the cost of the adverse event by the number of events the device would prevent,²³ provided that the cost of the expensive

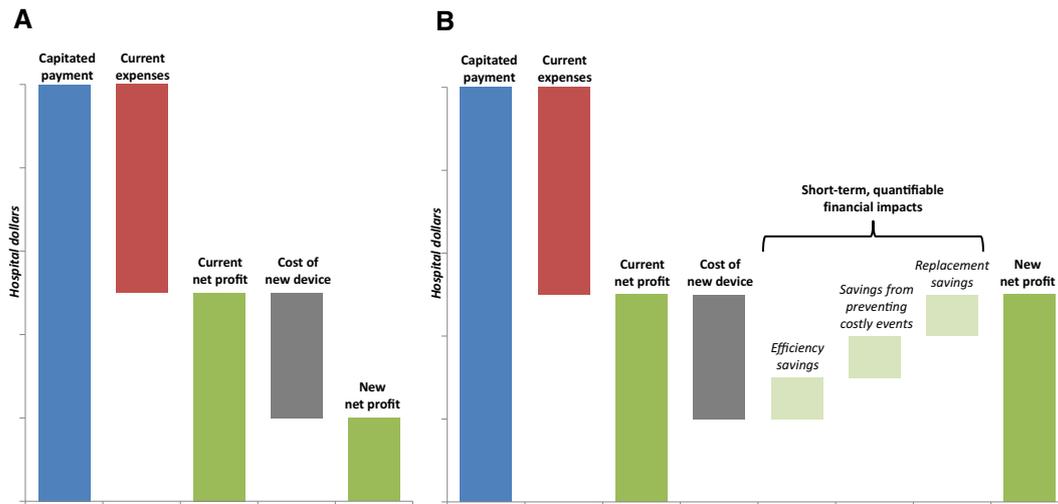


Fig. Illustrative sources of near-term, quantifiable financial value for a surgical device. (A) Under capitated reimbursement, the hospital receives a fixed payment for a case, from which its expenses are subtracted to yield current net profit. The cost of a proposed new device is an additional expense, which reduces the net profit. (B) Cost savings due to increasing efficiency, preventing costly events, and/or saving money through substitution can restore net profit—even, in theory, to a level at which the savings reach or even exceed the new device's cost.

outcome is actually borne by the purchaser. For example, the costs of postoperative readmissions within 30 days of discharge are typically subsumed under the capped reimbursement for the initial admission; thus, decreasing their incidence has tangible, quantifiable value to the hospital. In contrast, reducing readmissions (or reoperations) at later dates is certainly a worthy clinical goal with enormous benefits, but this does not translate directly into immediate financial benefits for the institution. Importantly, the “value of prevention” is typically most compelling for common and/or expensive events for which hospitals already have robust data on cost and incidence. In these cases, the CFO already understands the expense of doing nothing and is likely to support such cost-saving technologies.

3. Replace expensive goods with cheaper ones.

Innovation can create new clinical capabilities, but it can also deliver similar clinical capabilities at decreased cost or enhanced quality and reliability. For example, some new devices in the operating room may fit the “LED light bulb” model, in which replacing a cheap (but less durable) product with a new one that is more expensive but longer-lasting can yield substantial net savings. Other new product opportunities in this category may “replace” device usage in a completely different class of products. For example, some types of physiologic monitors could enable surgeons and anesthesiologists to titrate more precisely their use of fluids, drugs, or other products, which could avoid paying

for needless overadministration in addition to yielding potential clinical benefits.

The 3 categories above are united by the key fact that the CFO defines value as a positive, short-term, quantifiable financial impact on the hospital, and all 3 of those components—short term, quantifiable, and financial—are critical. CFOs generally value short-term savings (within a budget quarter or, at the longest, a fiscal year) much more highly than promised longer-term benefits, which are harder to predict or measure accurately. These savings must be quantified using rigorous, accepted data and metrics that reflect real-world hospital economics. Finally, although benefits to patients, physicians, and others in the health care system are important “table stakes” to gain adoption of a new surgical device, the CFOs are responsible for controlling the financial impact on the hospital budget.

IMPLICATIONS FOR SURGEON-INNOVATORS

Surgery remains a fertile area for medical innovation—there is no shortage of passionate and creative practitioners, clinically important problems, and viable solutions. Surgical innovators are uniquely qualified to continue to win over colleagues with new devices and technologies that improve outcomes and patient care.

To have the broadest clinical impact, however, surgical device innovators need to understand, consider, and focus on ideas that will succeed not just clinically but also in the marketplace—which

means paying increased attention to the economic needs of customers (hospital financial committees/CFOs) who actually buy new technologies. Technologies that deliver better clinical and economic outcomes appeal to the widest set of customers and are more likely to be successful in the market.

Surgeon-innovators are advised to evolve their approaches in two important ways. First, they need to invest at least as much time and effort into understanding the perspective of the CFO as customer as they currently do characterizing the needs of peers and patients. This means they may need to “get out of the building”²⁴ to listen to and learn from their colleagues in finance, procurement, and materials management and the administration in their department of surgery, particularly when it comes to understanding how the operating room functions financially. This important approach will allow surgical innovators to understand the level of economic evidence the CFO will require to judge the merits of a new device and will ensure that these innovators apply the same rigor in financial data-gathering and analysis as they do when evaluating relevant clinical outcomes.

Second, the most successful surgical innovators will be those who adopt very stringent criteria for what to work on and, at least as importantly, what not to work on. Like all busy professionals, surgeons have limited and potentially fungible time, and it is a poor use of their effort, talent, and insight to work on ideas that have little or no chance of being adopted widely in the market. Because the opportunities to innovate in the operating room are almost limitless, surgeons need to focus on those potential innovations that both improve patient care and create meaningful economic value for customers; surgeons may benefit from adopting some of the methods that successful tech entrepreneurs use to explore, refine, and prioritize new product concepts.²⁵

In the operating room, innovations directed toward cost-reduction and fiscal efficiency will likely reap greater rewards in the marketplace than those directed toward purely clinical or technical advances. Through this lens, surgical innovators will give their technologies the greatest chance of attracting funding and partnerships from investors and established medical device companies and ultimately being adopted broadly. As Thomas Edison observed almost a century ago, broad adoption of an innovative new product by paying customers is the surest sign of success.

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