

Health Affairs **Blog**

Medical Technology: What Changing Venture Capital Investments Signal

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The market for medical devices historically has been dominated by big-ticket “physician preference items” such as artificial joints, spinal implants, and cardiac pacemakers. Venture capital and private equity investors have been eager to fund new firms in this expanding and lucrative domain. Changes in physician payment and organization are reducing the demand for these cost-increasing innovations, however, and redirecting the flow of investment capital.

For the past decade we have been studying medical device innovation (startup firms) and adoption (hospital organizations), starting from different angles but arriving at similar conclusions. Josh is a venture capitalist affiliated with Sightline Partners and Split Rock Partners, with an investment focus on medical devices, instruments, and diagnostic tests. James is a university economist with a research focus on payment methods and how these influence the adoption of high-cost technologies. We decided to put our perspectives together and look at both ends of the innovation and adoption process.

Early-Stage Investment In Medical Devices

Venture capital investors raise funds from large endowments, pension funds, and foundations,

and invest them in promising technologies and start-up companies. Infrequently, a medical device investment proceeds all the way to a publicly traded corporation through an Initial Public Offering (IPO). More typically, startups are sold to large device and diagnostics companies such as Medtronic and Becton Dickinson.

Early stage investors review numerous unsolicited business plans but also take the lead in forming new firms themselves, building on their networks of entrepreneurs, engineers, and clinical advisors. For investors to be interested, the candidate technologies must serve a meaningful unmet need (scope of the market), deploy a potentially effective technology (solution for the market), and command a price that exceeds costs (profitability of the market).

In the new environment, traditional cost-increasing physician preference items are being adopted by hospitals, and hence generating a financial return for investors, only if they have exceptionally strong evidence of improved patient outcomes. Many devices and diagnostics lack compelling clinical evidence, at least in the early phase of their life cycles.

However, devices and diagnostics that reduce costs or improve safety are finding hospital buyers even if they don't have evidence of improved outcomes. Large life sciences firms are acquiring these cost-reducing and safety-enhancing technologies. In turn, early-stage investors have become interested in funding these start-ups, as they can discern an exit strategy and financial return. In short, medical device investors are shifting from cost-increasing physician preference items to cost-decreasing hospital preference items.

Hospitals As The Dominant Purchaser

Traditionally the principal decision-maker on the demand side of the medical device market was the individual physician, who compares alternative devices in terms of how they improve patient outcomes and physician productivity. In the past, physicians devoted little attention to how much their device selections affected their hospital's financial performance.

Medical device firms responded by developing extensive sales forces focused on relationships with individual physicians and paid little attention to the hospital's efforts at efficient supply chain management. Physician independence translated into autonomous device selection, which led to high prices for medical devices and attractive opportunities for investors.

This now is changing. Hospitals are employing physicians, shrinking the domain of independent practice and the role of idiosyncratic physician preferences. Hospitals are interested in technologies that reduce the cost of care, as they are reimbursed using case rates and episode-of-care payments. Many facilities are instituting "value assessment" committees that demand data on the cost as well as the quality of new technologies. Many hospitals now seek to narrow the range of medical device vendors with which they contract, as a means to obtaining volume-related price discounts and service improvements.

Central to this strategy have been efforts to weaken the relationship between physicians and medical device firms. Hospitals are requiring disclosure of, or imposing limits on, speaking honoraria, expense-paid educational junkets, and other financial inducements from medical device firms to physicians. Physician attitudes themselves are changing. Bundled payment and hospital employment facilitate gain-sharing with physicians who cooperate with the institution's supply chain initiatives.

Example: RF Surgical

RF Surgical (RFS) is a start-up company (recently acquired by Medtronic) that targets its selling efforts to hospital management rather than to individual physicians. Sightline Partners has invested in RFS, as well as in the other startups cited in this post.

RFS embeds tiny radio frequency tags into the cotton-based sponges used in surgical procedures, so as to minimize the risk of surgical objects being retained in the patient after a surgical procedure. By some accounts, retained objects occur in one of eight surgical procedures. Traditionally, hospitals manually count the sponges introduced into the surgical cavity and then do a reverse count before the surgical site is closed. The RFS technology provides a spell-check of sorts on manual counting, by using low-frequency radio waves to detect whether any sponges have been inadvertently left in the patient.

RFS products are not physician preference items. It would be almost impossible to sell the RFS product directly to physicians, since many surgeons believe that they are at minimal risk for a retained object error and that, in any case, the associated penalties are borne by the hospital. RFS technology is, however, a hospital preference item. Hospital management will mandate use by all physicians of the RFS product as a part of standard operating procedure, so as to minimize the clinical risks, financial exposure, and public reporting of retained surgical items.

From High-Acuity To Low-Acuity Clinical Sites

There is a strong movement of care from high-acuity institutional settings to lower-cost alternatives. Insurer payments tend to be lower in freestanding than in hospital-based settings, but procedural costs also are lower. Freestanding surgical centers can pay a reasonable price for a device, instrument, or diagnostic test and still turn a profit. Medical technologies that facilitate shifts from hospitals to ambulatory surgical centers (ASC) are of great interest to investors for this reason. Technologies that shift care even further, from hospitals and ASCs to the physician's office or the patient's home, are equally or even more attractive.

Insurers reimburse procedures involving medical devices that are performed in hospitals and ASCs with a professional code for physician services and a technical code for facility services. Procedures performed in low-acuity, non-institutional settings are reimbursed with a professional code but without a technical code. Many insurers have sought to accelerate the shift to lower-acuity settings by raising the professional fees paid for procedures performed in the physician office, still benefitting financially by avoiding the facility payment. Physicians are attracted to higher professional fees and also appreciate the time saved from no longer traveling to the institutional facility. If both physicians and insurers like a new class of medical technologies, so do investors.

Example: Entellus Medical

Entellus Medical supports treatment of patients with chronic sinusitis in the physician's office, as well as in an ASC or hospital outpatient department. Traditional sinus surgery is performed under general anesthesia in an operating room and frequently involves the removal of bone, cartilage, and other tissue to widen the drainage pathways of the sinuses. As an alternative for some patients, Entellus offers a line of minimally invasive products that can be used under local anesthesia in the physician's office. These products involve guiding a small balloon sinus dilation device through the nostril and up into the sinuses where it is inflated. The inflated balloon gently

expands the sinus openings, creating better drainage for the patient.

On average, balloon sinus dilation patients return to normal activity faster than traditional sinus surgery patients. In-office treatment of sinusitis balloon technology like Entellus' can result in over 50 percent cost savings.

Payers Are Refusing To Pay For 'Never Events'

Payers increasingly are refusing to pay for "never events," such as surgical procedures involving, and hospital readmissions resulting from, avoidable complications. CMS has published a list of non-reimbursed events, and private insurers are strengthening their utilization management to retroactively deny payment. The impact of these payment changes is magnified by mandates for the public reporting of antibiotic use and associated complications that can result from false positive diagnoses. Mandatory reporting as well as payment denials and global reimbursement reductions levied by CMS attract investor interest in technologies that reduce the likelihood that never events will occur.

One example of a CMS never event is "patient death or serious disability associated with a medication error...". These errors include using the wrong drug or dose, on the wrong patient, at the wrong time, with the wrong preparation, or wrong route of administration. They also include providing a drug to a patient who has been incorrectly diagnosed.

False positive diagnoses of bacterial infection, such as sepsis, can occur frequently in emergency department settings. In an emergency department the attending physician typically goes through a series of screening tests for the patient, often including one for sepsis, by drawing blood from the vein below the elbow. Traditional phlebotomy techniques of this sort can lead to high rates of false positives due to capturing bacteria from the patient's skin or surrounding environment.

Reducing false positives reduces unnecessary use of antibiotics, adverse side effects of treatment, hospital-acquired infection risk driven by increased length of patient stay, and population antibiotic resistance. Antibiotic prescriptions and false positives are under increased surveillance by the Joint Commission and the White House. Hospitals will pay for medical devices that ensure these never happen. In turn, large device firms are purchasing, and venture capitalists are creating, startups that develop these technologies.

Example: Magnolia Medical

Magnolia Medical is a start-up that has developed a novel device for extracting blood samples in the emergency department, with the goal of reducing the rate of false positive diagnoses of sepsis. Magnolia's SteriPath vacuum-assisted system diverts and sequesters contaminants from the initial blood sample specimen before facilitating sterile flow of the main sample into the test vial.

The SteriPath device has been shown to reduce the rate of false positives for sepsis by almost 90 percent. It is priced at a premium to traditional syringes, yet hospitals are willing to pay for it given the clinical benefits. The sale is made to the hospital infection control and supply chain management team, without a need for large sales teams targeting the preferences of individual physicians. Must-have medical devices that sell themselves are very attractive to early-stage investors.

Venture Capital Investment As An Early Indicator Of A New Health Care System

Medical technology, broadly defined to include new drugs, diagnostics, devices, and procedures, is a principal driver of the long-term growth of health care spending. Whereas innovation in other sectors often reduces costs, innovations in medicine historically have been marketed to physicians who are indifferent to price or, in some cases, receive financial inducements to select the most expensive treatment. It is no wonder that newer devices often have been more expensive than those they replace, adding features and functions that appeal to physician preferences with only limited concern for those who will be paying the tab.

It is still too early to declare a meaningful and lasting change in the trajectory of medical device innovation. The evidence suggests a strong preliminary case, however, that the contemporary shift in methods of payment and regulation, from those that reward cost-increasing innovations to those that reward cost-decreasing alternatives, is in fact altering that trajectory. Venture capitalists are paid to predict, and in some cases to create, the future. The pattern of their investments may be an early indicator for a new health care system that rewards efficiency as well as quality in assessment, pricing, and use of new medical technology.

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