Value-Based Purchasing For Medical Devices

A misalignment of information and incentives between hospitals and surgeons blocks the path to value-based purchasing.

by James C. Robinson

ABSTRACT: The performance of the medical device sector falls short of its remarkable potential because of weaknesses on the demand side of the market, in the way products are assessed, purchased, and used. This paper applies the core principles of value-based purchasing (integrated data on price and performance; alignment of financial incentives; and organizational capability to evaluate alternatives) to the medical device market. Emphasis is placed on the challenges posed by information inadequacies, incentive misalignments, and organizational fragmentation between hospitals and surgeons. [*Health Affairs* 27, no. 6 (2008): 1523–1531; 10.1377/hlthaff.27.6.1523]

THE U.S. HEALTH CARE SYSTEM is characterized by continual innovation in products and procedures that improve the ability to diagnose and treat previously intractable conditions. It suffers, however, from weak mechanisms to encourage the development of lower-cost methods of care and thereby promote efficiency as well as quality. The medical device industry, which produces knee and hip joints, spine disks and surgical components, vascular stents, cardiac pacemakers and defibrillators, and related components of care, has been particularly dynamic. Along with important contributions to patients' well-being, however, the device industry and its device-intensive orthopedic and cardiology sectors have been plagued with disputes over appropriate use, safety, prices, and spending. Many of the limiting features of these sectors can be traced to inadequate data systems, misaligned incentives, and fragmented organization on the demand side of the market, and to a paucity of sophisticated purchasers able to demand improved value from sophisticated producers.

Value-Based Purchasing

Decisions made by purchasers, in terms of which services are chosen and which prices are paid, send important signals to producers as to where to extend capabilities, where to invest, and where to innovate. These signals are most effective when purchasers have good information on the price and performance of particular ser-

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vices, when they are paying for those services directly and without subsidies, and when they possess the capability to compare among alternatives, including services that resemble one another and those that accomplish the same ends through different means. The conceptual ideal of value-based purchasing is the informed, cost-conscious, and sophisticated consumer spending his or her own money and choosing among simple services in a technologically stable environment.

The conceptual ideal of value-based purchasing can be approximated in some aspects of health care and has been celebrated as a standard for "consumer-driven health care." Many health services, however, are complex and technologically dynamic, are consumed by patients with limited information and ability to evaluate performance, and are reimbursed via insurance rather than from the consumer's own pocket. In these contexts, the principles of value-based purchasing (information on performance, aligned incentives, and ability to evaluate alternatives) must be adapted to the roles played by the parties that purchase services on behalf of the patient. The injection of intermediaries complicates the process because these agents tend to pursue their own interests as well as those of the patient and because information, incentives, and organizational capabilities need to be coordinated among the agents as well as between the agents and the patient.

For medical devices, choice among technologically advanced and evolving products is made by the surgeon, in consultation with the patient, but purchasing is performed by the hospital or ambulatory surgery center. Device costs are then bundled by the facilities into prices charged to insurers, either implicitly in per case or per diem rates or explicitly when carved out and billed on a fee-for-service (invoice or itemized charges) basis. The main obstacle to value-based purchasing therefore is the fragmentation and misalignment of information, incentives, and organizational capabilities between the hospital and the surgeon.

Strained Relationships

High-cost and high-quality devices, frequently referred to as physician preference items (PPIs) to distinguish them from more humble supplies purchased through bulk discounts, account for one-third of overall hospital supply costs and are rising as a percentage of the total.[1] They are concentrated in the orthopedic, neurosurgery, cardiovascular surgery, and interventional cardiology services that account for a large share of hospital revenues and earnings and hence are of special concern to management.[2] The price the hospital must pay for medical devices accounts for 30–80 percent of the reimbursement it receives from public and private insurers, and hence management of device choice is central to the hospital's supply-chain efficiency and financial well-being.[3]

■ **Physicians' weak business affinities with their hospitals.** The physician decides whether the patient is to receive a device and, if so, which class of device and from which manufacturer, yet typically is neither aware of nor concerned about the economic effects of those choices. Because most insurer payments to hospitals are

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determined by a contracted rate, instead of being based on incurred costs, the hospital's profits from each case depends on whether the surgeon selects a basic or improved device, whether this was obtained from vendors with which the hospital was able to negotiate low prices, and whether the device is covered by the contract or is considered a novel technology that must be reimbursed at the high list price.

The dilemma for the hospital is that its physicians may be indifferent or antagonistic to the institution's business imperatives. With the salient exception of those employed by large medical groups and delivery systems, most physicians are independent business people who can view the hospital as a financial competitor as well as a clinical partner. Entrepreneurial surgeons own freestanding diagnostic and surgery centers and may invest in orthopedic or cardiac inpatient facilities.[4] Even absent direct competition, surgeons often place low value on the hospital's initiatives to manage the cost of its supply chain.[5] This indifference is particularly acute where hospitals seek to negotiate lower device prices from vendors in exchange for higher volume, which could require some physicians to switch brands.

■ **Physicians' strong affinities with device firms.** Not only do surgeons often have weak business affinities with their hospitals, but many have strong affinities with the manufacturers and distributors of medical devices. Relationships between physicians and device firms often are closer than those between physicians and pharmaceutical firms, given the close ties that develop in product development and, especially, in the operating room. Some devices are engineered through incremental and collaborative interactions between manufacturers and practicing physicians, who then may be granted stock options or other financial interests in the pricing and utilization of their products.[6] More importantly, surgeons often are trained in the use of specific lines of instruments and are reluctant to switch to new vendors.[7] Sales representatives are present in the operating rooms and catheterization laboratories to help with last-minute clinical decisions, a presence that provides ample opportunities for influencing physicians' choice of devices.[8]

Device firms foster personal relationships between their sales representatives and high-volume physicians. The payments received by high-volume surgeons for consulting, promotional speaking engagements, stock options, and continuing medical education can reach into the seven figures and may exceed the professional fees received for performing the clinical procedures.[9] In an out-of-court settlement in 2007, the leading manufacturers of orthopedic devices agreed to $310 million in fines plus federal supervision of future payments to surgeons.[10] Attention is spreading from surgeons to professional societies and hospitals that sponsor activities promoting particular technologies.[11]

■ **Shifts of surgical facilities to competing sites.** The difficulties faced by hospitals in coordinating physicians' preferences extend beyond the culture of autonomy and financial conflicts of interest to the deeper shift in control of surgical facilities. Clinical developments continue to permit the transfer of surgery and interventional cardiology from community hospitals to short-stay inpatient facili-

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ties and freestanding ambulatory surgery centers. Investor-owned chains are partnering with physicians in many markets to create these entities, often in direct competition with incumbent hospitals. Hospitals are responding by building ambulatory surgery centers and specialty inpatient facilities that mimic the focus and physician-friendly culture of the competition, sometimes financed as a joint venture with the physicians or national chains.[12] Any hospital supply-chain initiative that alienates the physicians risks accelerating the shift of loyalties and admissions from the hospital to competing sites of care.

Information On Performance And Price

Some new devices represent major technological innovations and are supported by significant clinical evidence on safety and efficacy. However, most are introduced as incremental modifications of existing products without studies of performance relative to alternatives and for specific patient populations. Registries of postoperative outcomes are maintained for some cardiac devices, such as implantable defibrillators, but not for orthopedic and spine surgery components outside of special organizational contexts such as Kaiser Permanente.[13] New devices may be brought into the facility by distributors on behalf of the surgeon and come to the attention of management only when it receives an invoice. Some hospitals have created technology assessment committees analogous to the pharmacy and therapeutics committees maintained by health plans for making coverage decisions. In these contexts, surgeons who desire to use a new device must present it, with supporting clinical and pricing information, to a committee of their clinical peers. The dominant culture of professional autonomy renders difficult any attempt to encourage physicians to question the clinical decisions of their peers, and these committees may serve as much as a locus to promote general physician cost-consciousness as one for formal evaluations of cost and quality.[14]

■ **Lack of price transparency.** Information gaps in the medical device sector are not limited to performance but include difficulties in ascertaining the price of a particular device before it is used and billed. Manufacturers tend to post list prices and then negotiate off them with hospitals that can promise sizable volume, penetration within the range of devices purchased, or handling practices that reduce selling and servicing costs. Hospitals use group-purchasing organizations (GPOs) and consulting firms to gain insight into the prices paid by similar hospitals, but they face severe problems in obtaining benchmark information on average and best-available prices across vendors and geographic areas. Some medical device firms have inserted price confidentiality clauses into their invoices and enforce these against efforts by GPOs and hospital consultants to gather and compare price information.[15] These confidentiality clauses can prevent hospital management from disclosing comparative price information to any third party, including the physicians who order the devices for their patients. The Guidant corporation, now part of Boston Scientific, successfully sued the Aspen Health Metrics consulting firm to prevent it from sharing price com-

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parison data among its hospital clients.[16] Legislation was introduced in 2007 to mandate disclosure of medical device prices, generating much policy debate over the virtues and vices of price transparency.[17] The available surveys reveal sizable price disparities across vendors and hospitals for equivalent devices.[18]

■ **Need for performance data.** The most important need in the device-intensive clinical sectors is not for information on particular devices but for performance data on the entire course of treatment and its components, including the physicians, diagnostic tests, surgical implants, hospital and ambulatory facilities, and postoperative rehabilitation.[19] Only integrated data systems will permit physicians and managers to improve the entire clinical process and consumers meaningfully to choose among the alternatives. However, hospital data currently are embedded in multiple systems that communicate with one another only imperfectly, including patient medical records, operating room logs, purchasing department records, and health insurer billing systems. It can be difficult to match which brand or functional level of device was used with a particular patient, and how much actually paid for that device after accounting for list prices, negotiated discounts, off-contract price supplements, rebates, and other modifications. Hospital systems typically do not record physician charges and reimbursements and almost never have information on preadmission and postdischarge activities related to the hospital stay. Measures of quality are limited to in-hospital complications and typically will not extend to postdischarge events or even to readmission for complications.

Alignment Of Incentives

Hospitals' efforts to manage device costs center on which mix of vendors to use, which mix of functionalities to maintain for each type of device, and how much to pay for each item. An efficient purchasing strategy is built on relationships with a limited number of vendors (but not with just one, to avoid difficulties with ensuring service and with contract renewals) that cover the full range of devices and functional levels.[20] Limiting the number of vendors helps hospitals' administrative and clinical staffs remain familiar with devices' features and performance and permits the hospital to offer volume guarantees in exchange for lower unit prices. However, limits on the number of vendors potentially interfere with physicians' clinical choices. Within the group-practice setting, physicians themselves can assume responsibility for deciding which vendors to use for most procedures. Group practices such as the Lahey Clinic and Aurora Physician Services have enjoyed much success with this approach.[21] In the more frequent context of small physician practices, however, coordination of device purchasing requires that the hospital convince autonomous and often competitive physicians to relinquish part of their authority for the hospital's benefit—always an uncertain proposition.

■ **Strategies for dealing with PPIs.** Three principal avenues present themselves for hospitals' purchasing departments when dealing with PPIs.[22] The most obvious is to limit the number of vendors for each class of device and then to negoti-

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ate on the basis of volume discounts. As noted, this works poorly in the absence of integrated physician organization. Limiting the number of vendors also may reduce competition, and hence the willingness to discount prices, if incumbent vendors believe they cannot easily be replaced in future contracting cycles. The second approach permits all device firms to sell to the hospital (that is, permits all device sales representatives access to the operating rooms) but imposes a price cap on each class of device, regardless of vendor. This strategy avoids interference with physicians' preferences but risks having the sales representatives substitute low-function for high-function devices. Price-cap strategies also may motivate device sales representatives to convince the physician to use a novel permutation of the device that falls outside the price caps and hence must be reimbursed by the hospital at the manufacturer's noncontract list price. The third strategy is to negotiate a percentage discount off unit prices for all of the devices and associated hardware from each vendor. This avoids off-contract device charges but encourages inflation in list prices and the substitution of high-function for low-function devices.

■ **Financial disclosure policies for physicians.** Every permutation of device purchasing tactics requires the hospital to confront the conflicts of interest represented by financial ties between physicians and vendors. Some of these are royalties off past development collaborations, but most are tied in some way to the physician's continued use of the manufacturer's line of devices. The largest payments go to the clinically most active surgeons with the largest volumes of procedures. Some hospitals request that physicians disclose the nature and extent of financial relationships, and some make analogous disclosure requests of vendors and distributors. Not surprisingly, both physicians and vendors have resisted such policies. The terrain is now changing, as both the federal and state governments in different ways are mandating disclosure of financial payments. Pursuant to a consent decree with the U.S. Department of Justice, the major orthopedic device manufacturers now disclose all consulting fees on their Web sites, listing annual payments for each surgeon.[23] Several states require pharmaceutical manufacturers to disclose payments to physicians, and federal legislators have discussed an analogous federal disclosure mandate that would cover device as well as drug manufacturers.[24]

■ **The battle over gainsharing incentives.** Since physician cooperation is needed to manage medical devices, a natural hospital strategy would be to share with physicians any resulting financial savings. However, gainsharing initiatives of this form are banned for Medicare patients, out of concern that an interest in reducing costs could create financial incentives for physicians to reduce the quality of care.[25] Proposals by the Medicare Payment Advisory Commission (MedPAC) to modify or eliminate the ban on gainsharing have been opposed vigorously by the medical device industry.[26] The Health and Human Services (HHS) Office of Inspector General (OIG) has permitted several demonstration projects on gainsharing but has imposed onerous participation criteria, and few hospitals have sought to participate.[27] More popular are supply-chain initiatives where financial savings are not

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shared directly with the responsible physicians but are invested in improved equipment and staffing of the relevant clinical service line.[28]

Organizational Coordination

The price and mix of medical devices constitute only one component of the hospital's surgical cost and quality considerations. Some devices entering clinical practice merely modify existing products and require no changes in staffing, physical layout, or process flows; others embody major innovations and necessitate major changes in the larger context of care. The third component of value-based purchasing, after information and incentives, thus involves the organizational capability to evaluate and respond to changes in technological opportunities, to evaluate the potential cost and quality of innovative products, and to predict the longer-term consequences of adoption. The uncommitted and at times conflicted relationship between hospitals and their physicians impede this process. Hospitals traditionally catered to physicians' cost-indifferent preferences by acquiring major new clinical technologies and passively reimbursing new types of implantable devices, a process sometimes referred to as the medical arms race.[29] In the contemporary context of tighter reimbursements, especially from Medicare, hospitals must develop internal structures, and the physician relationships that sustain them, capable of evaluating new technologies in a more informed and cost-conscious manner. Ability to adapt to the changing technological environment is one component of a larger organizational ability to evaluate and improve the many processes of hospital care.[30]

Hospitals are multiproduct firms where it is often difficult to measure, much less modify, the performance of particular units. Although hospitals are organized along departmental lines, these administrative entities often are too broad to focus attention and accountability on particular physicians and the staff who support them. Leading hospitals recognize the need to organize themselves internally by service lines, bringing data systems, performance measurement, efficiency ratios, staffing authority, and financial accountability to the level where clinical decisions actually are made.[31] Service lines can take the form of freestanding ambulatory surgery centers or short-stay hospitals, sometimes referred to as focused factories.[32] Alternatively, they can provide the specialty-specific foundations of multispecialty medical groups and hospital systems.[33] The most important service lines often are those that involve the most expensive medical devices, and so the hospital's strategic imperative in restructuring internal organization overlaps with its tactical approach to managing its supply chain.

The performance of the medical device sector falls short of its remarkable potential because of weaknesses on the demand side of the market, in the data systems, payment methods, and organizational structures through which products are assessed, purchased, and used. Bringing performance up to potential would require overcoming data gaps, conflicts of interest, perverse payment incentives,

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opaque quality outcomes, and fragmented service lines. Continued improvements in quality and efficiency, and hence in value, require sophisticated purchasing on the demand side of the market as well as engineering expertise and an entrepreneurial ethos on the supply side.

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