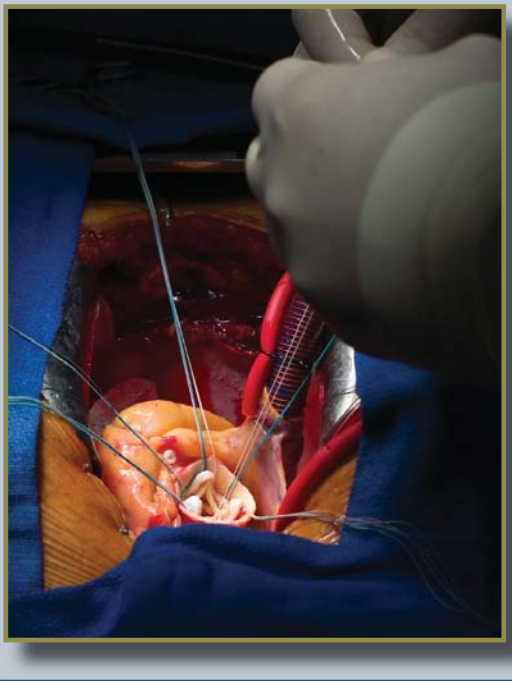
BERKELEY CENTER
FOR HEALTH TECHNOLOGY

Issue Brief

Physician-Hospital Alignment in the Evaluation, Purchasing, and Use of Implantable Medical Devices



On October 2, 2009, the Integrated Healthcare Association (IHA) and the Berkeley Center for Health Technology (BCHT) hosted a Roundtable to discuss mechanisms for strengthening physician–hospital alignment in the selection of medical devices. Participants included executives, managers, and physicians with responsibility for device purchasing in or for academic, community and safety-net hospitals from across California, as well as representatives of medical device firms, technology assessment organizations, the employer community, and academia. This was the second in a series of IHA/BCHT Roundtables sponsored by the Blue Shield of California Foundation devoted to value-based purchasing and the use of medical devices.

The Unacceptable Status Quo

Misalignment begins with a status quo in which most hospitals do not employ their physicians, and most physicians do not own the hospitals where they practice. While both share a concern for quality, often they fail to share a joint economic destiny. With the trend towards more procedures being performed in outpatient and short-stay facilities, physicians are now directly competing with hospitals, especially in device-intensive specialties such as orthopedics and cardiology. Physician ownership of, or investment in, ambulatory surgery and diagnostic centers and short-stay specialty hospitals is increasingly prevalent. Consulting arrangements between physicians and device manufacturers exacerbate the misalignment between hospitals and doctors; payments from device companies to physicians influence their choice of device and impede hospital efforts to negotiate volume-discount contracts.

Currently, a surgeon selects which devices to implant on a procedure-by-procedure basis, often without respect to price, and with limited

information on relative clinical performance. This decision is based on what the physician views is best for the patient, as well as a physician's relationship with the device manufacturer. The hospital then pays for the device, and charges a third party—a public or private payer—for the procedure. Hospitals are often successful in "carving out" the cost of the implant from the inpatient stay and billing it separately. While this strategy offers the hospital protection against device costs, it weakens its incentive to work with its surgeons to lower treatment costs. Health plans then pass the higher device costs on to consumers in the form of higher premiums or coinsurance rates, adding to overall cost growth in the health care system.

Achieving Service Line Efficiency and Quality

Ideally, device-intensive service lines should be organized, reimbursed, and managed in a manner that encourages continual self-analysis and improvement. This requires informed consumer choice among competing facilities and surgeons, as well as coordination between care providers. Coordination is built on data systems that track information from pre-admission to post-discharge; quality monitoring that encompasses the entire course of care; mechanisms for bolstering performance and reducing variance on the part of the clinical team; and collaboration on all aspects of care, including ensuring the appropriateness of a procedure and educating the patient on his or her treatment options.

Over the long term, ensuring physician-hospital alignment will require a culture of cooperation and strong leadership in both parties. In the short term, it is imperative that structures and rules are put into place that align incentives and improve information flow. These can include value assessment committees at the hospital level, rules for managing physician and hospital conflicts of interest, and registries for implantable devices. These three topics formed the basis of the Roundtable discussion.

Hospital Technology and Value Assessment Committees

Value assessment committees act as gatekeepers for the introduction of new devices into a hospital and are analogous to the well-established model of pharmacy and therapeutic committees. Ideally, a value assessment committee should authorize a device before the hospital will reimburse the device company, and the committee should serve a role in promoting a new physician culture of cost-consciousness and comparative effectiveness.

Three separate hospital value assessment initiatives were outlined by the Roundtable participants: one in an integrated care setting, one in a hospital with non-employed surgical staff, and one that is being launched in a hospital-orthopedic surgeon joint venture. Despite differences among the three initiatives, a number of common themes emerged. Committees can vary in scope, and once they are set up, hospitals must decide whether there will be one organization-wide umbrella committee or separate committees based on service lines. Furthermore, a hospital must decide whether the final decision-making power will rest with the committee or with the hospital's CFO. Committees predominantly or exclusively composed of practicing physicians foster "buy-in" among the medical staff and avoid the potential for the surgeons to feel that technology and value assessment are simply means to cut costs, regardless of any impact on quality.

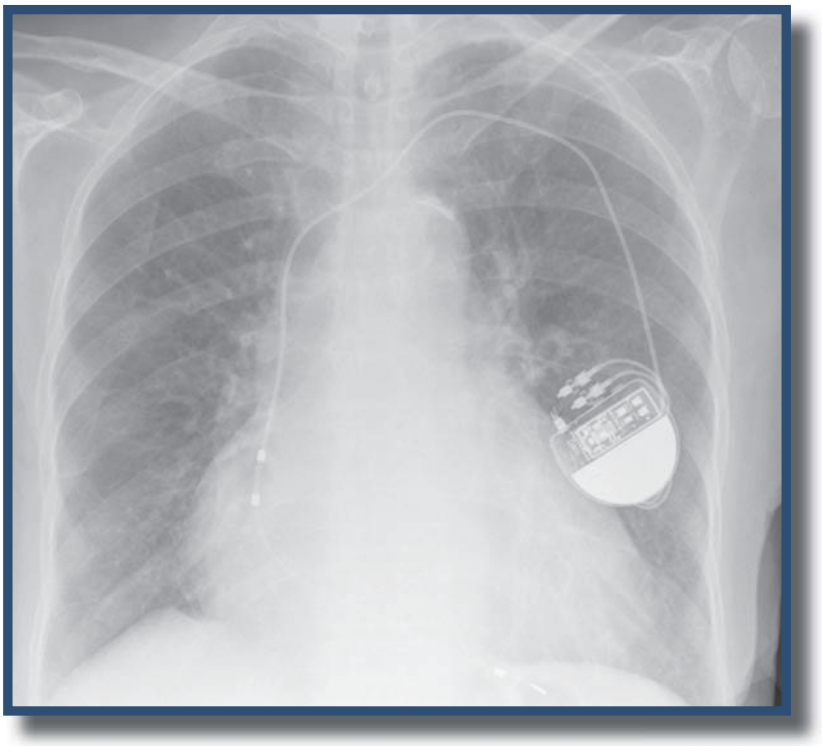
The typical value assessment committee is structured to review medical staff requests for the use and financial reimbursement of a drug, device, or other clinical technology that has not previously been used at the facility. The physician requesting the review is required to disclose any financial relationship with the technology manufacturer—such as equity ownership or consulting relationships—and then presents the available data on quality, risks, and price.

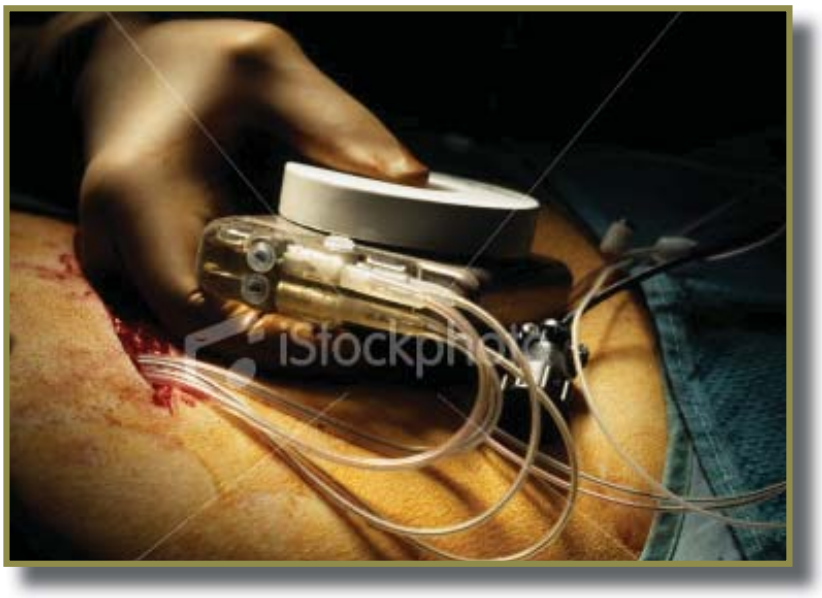
The committee evaluates the data on specific technologies, which over time helps to create a culture of cost-consciousness among the committee members and, ideally, across the entire medical staff. The fundamental principle underlying physician-driven value assessment is that the escalating costs of medical care are driving some form of cost controls, and that if physicians do not adopt a leadership position, other entities will do so.

Managing Physician and Hospital Conflicts of Interest

Ideally, physicians are paid for the care that they deliver to patients, rather than their choice of implant device. Although many physicians provide legitimate consulting and other services to device companies, including assisting with the development of new devices, often these companies also make payments to physicians implicitly based on their use of a device, or their promotion of a device to colleagues. These payments distort physician incentives and lead to strong brand loyalties that make it harder for hospitals to bring down device costs by buying in bulk from a restricted number of vendors.

The first step in dealing with physician conflicts of interest is to require disclosure. However, disclosure policies require careful consideration of what is being disclosed, and by whom, to whom. Should these be enacted at the hospital level, or is





legislation required? If so, should this be enacted at the state or federal level? Should the responsibility to disclose fall on the physician or the device company? Who has the responsibility to monitor these relationships?

A key topic of Roundtable discussion was the Physician Payment Sunshine Act, introduced in January 2009 by Senators Chuck Grassley and Herb Kohl. If passed, this bill would mandate companies to annually report cumulative payments to physicians in excess of $100. This information would be posted online and would be searchable by members of the general public. The Act recognizes that physician conflicts of interest touch a public nerve, and that patients should have access to information about their doctors' financial relationships with device companies.

One Roundtable participant questioned whether a regulatory response was overdoing it, pointing out that just because an individual is being paid by a device company does not mean that he or she automatically is "in that company's pocket."

An alternative to legislation would be disclosure policies at the hospital level, although the effectiveness of this method will vary depending on how much influence a hospital has with its physicians. While many hospitals do not require disclosure, or are in the process of building a framework, others have robust regulations in place. One hospital participant said that, rather than relying on staff to disclose any financial relationships with manufacturers, his institution requires vendors to disclose whether they have any financial relationships with hospital staff. Companies were initially unhappy with this arrangement, but have complied. Once a conflict has been identified, what steps should a hospital take? Conflicts of interest can be managed in several ways, but any initiative must balance limits on inappropriate relationships with support for those relationships that yield important innovations.

Implant Registries

Registries collect data on implant utilization that can be used to identify affected patients in the event of a device recall, for tracking device performance, and for clinical research. There are three levels of registries: level one registries identify the physician, patient, implant used, what side it has been implanted on (for joint replacements), and whether a revision was needed; level two registries capture co-morbidities at the time of the procedure; and level three registries include more patient-level variables before and after the procedure.

In the United States, there are several registries that track the use and outcomes of cardiac implants. Kaiser Permanente is the only U.S. system that operates an orthopedic registry, although these are prevalent in other nations, such as Sweden and Australia. The parameters of cardiac registries were outlined for participants, as was Kaiser's orthopedic registry. A presentation was also made about a new initiative for a California-wide voluntary private-sector device registry.

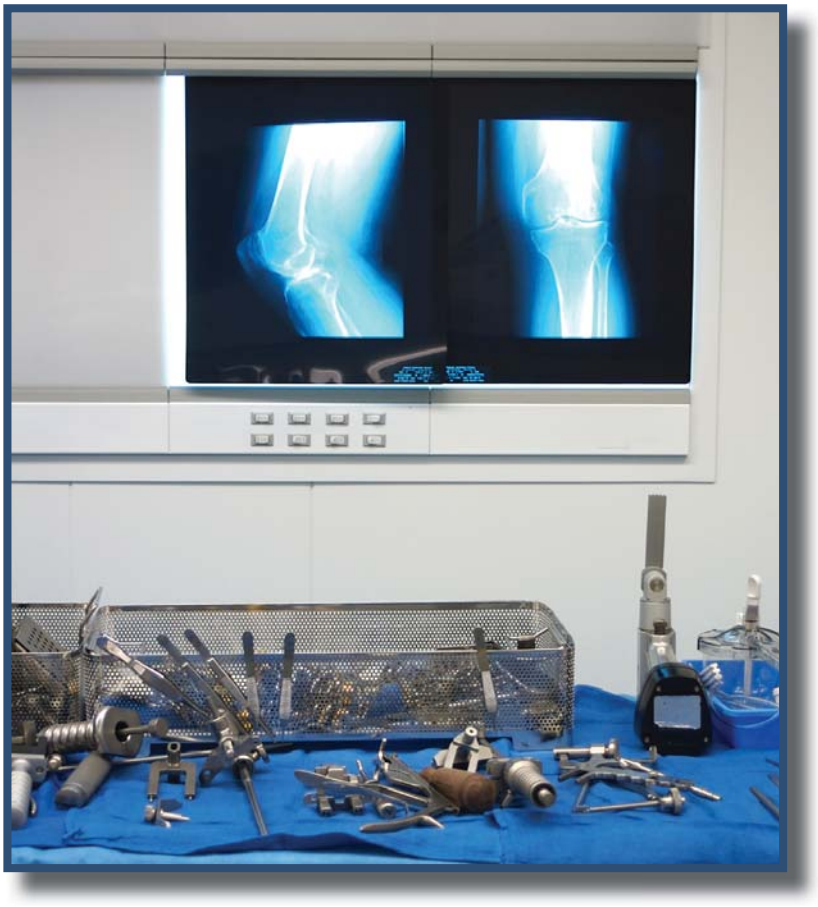
Device registries can be mandatory or optional; when they are optional, there must be appropriate incentives in place to ensure that reporting takes place. When the data collected are useful and institutions have appropriate capacity and funding for analysis, registries can be indispensable for informing physician and hospital decision-making. Existing registries have changed physician behavior, as they have identified patterns of care that can be changed for better outcomes. They have also allowed physicians to compare themselves to others, which has led to a process of quality improvement among individual physicians. When registries are linked with electronic medical records, surgical efficiency is enhanced because a doctor can spend more time in surgery instead of office visits.

Finally, registries have helped to identify device failures, and have been used for investigatory purposes when a practitioner suspects that a device may be faulty. A robust implant registry with links to an EMR infrastructure would yield a compelling return on investment if this could be achieved on a large scale.

Owing in part to the large amount of attention focused on joint registries, the Pacific Business Group on Health (PBGH) has been talking to leading surgeons across California about a voluntary private sector registry based on principles of rewarding physicians for "right care," improving outcomes and reducing costs. PBGH is concerned with the current lack of systematic knowledge about long-term health outcomes, thus the registry will be designed to collect intermediate and long-term outcomes data. PBGH believes that the best way to handle the runaway cost trend is through the participation of physician leaders with patient outcomes in mind, and that effective registries require robust governance structures. In order to reign in spending, some comparative effectiveness metrics must be built in to the registry.

Looking Toward the Future

Although physician-hospital alignment is still more ideal than reality, many hospitals have developed robust technology evaluation initiatives and are moving towards managing physician relations in a spirit of cooperation and service line improvement. While much remains to be achieved, improved efficiency in device-intensive surgical service lines is on the horizon. Roundtable participants offered concrete examples of how to approach this goal and lessons about what has and has not worked. Needed now are commitments by hospital executives and physicians to continue sharing best practices in pursuit of a culture of cost consciousness and comparative effectiveness.



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