



**Integrated Healthcare Association (IHA)
and Berkeley Center for Health Technology (BCHT)**

**Pricing Confidentiality and Transparency for Medical Devices
Best Practices Roundtable**

April 3, 2009

Berkeley, California

Roundtable Summary

Background

The prices of implantable medical devices are negotiated between hospitals and device manufacturers but are of concern to physicians who select which device is to be used for which patient, to patients who are responsible for copayments, to insurers who reimburse hospitals for their input costs, and to purchasers who ultimately pay for the products as part of their insurance premiums. As is the case for many products used throughout the economy, contracts between hospitals and device manufacturers often contain confidentiality clauses that forbid the disclosure of negotiated prices to third parties. In recent years hospitals have sought to manage the rising costs of implantable devices in part by comparing the prices they are offered with those obtained by comparable facilities, either directly or through the initiatives of Group Purchasing Organizations and other intermediaries. Some device manufacturers have responded negatively to these initiatives, threatening and in one case initiating private action lawsuits against the hospitals and/or intermediaries. The litigation and ensuing publicity have contributed to the already strained relationships among the various parties, putting further obstacles to collaboration between physicians, hospitals, and device firms. In 2008 Federal legislation was proposed that would mandate public reporting by device firms of their average selling prices, engendering a robust debate over the virtues and vices of price confidentiality and disclosure. There is continued interest in transparency legislation as part of the new Congress and Administration, while hospital strategies continue to evolve within the context on contract negotiations.

The roundtable brought together 28 hospital executives and other key stakeholders to discuss the current context and emerging best practices for managing the confidentiality and disclosure of prices for implantable medical devices in orthopedics and cardiology.

Meeting Objectives

The principal goal of the roundtable was to identify the various approaches hospitals have been taking and to consider which, if any, deserves to be promoted and diffused to the broader hospital industry. The three principal sessions of the day provided an overview of the current market context, a discussion of the legislative proposals, and the identification of best practices for hospitals.

Session I: Price Confidentiality and Transparency: Multiple Perspectives

A. Discussion: Confidentiality and other price issues

- Guidant lawsuit had a chilling effect on hospital conduct. Now hospitals devote substantial time/cost of legal counsel to understand the reach/scope of the confidentiality agreements signed.
- There are various degrees of price confidentiality specified in a confidentiality agreement. Hospitals may be barred from sharing price data with: other medical device companies; other hospitals; physician staff.

- Certain large institutions have the capacity to generate highly competitive vendor prices; because of this they may view it to be to their competitive advantage to sign confidentiality agreements.
- Hospitals at times may wish to keep the prices they pay a secret for negotiation purposes. ‘Selective information sharing’ may be a more apt description of what hospitals desire.
- The price question is complicated by difficulty in comparing device brands/types (e.g. number of screws, implantables)
- Device vendors are quick to claim new variants on existing devices to constitute “new technology” – making it difficult to make price comparisons between old and new models.
- Variety of pricing mechanisms (e.g. rebates, administrative fees, etc.) obscure device costs.
- Hospitals are extremely dependent on device companies for tracking prices, rebates, etc. (Spot-checking shows discrepancies.)
- Device distributors could be distorting device prices below the radar.
- In practice, prices are not closely guarded; device companies are keenly aware of competitors’ prices, and hospitals’ market shares. Sales Reps (often independent distributors) share info with one another.

B. Discussion: Engaging the Front Lines

- The issue is how to engage the front lines in controlling costs; we lack a forum for doing so. Physicians get mixed signals about cost margins. They need some understanding of actual costs, a raised level of awareness.
- Hospitals are not able to share prices in a practical way with physicians (e.g. prices cannot be posted at scrub zones at the risk that competing device vendors will see them). No “safe harbor” within a hospital to sensitize staff to cost concerns
- One hospital employed colored stickers in operating room to indicate tiers of device prices so that physicians had some notion of comparative device cost.
- The quality question is extremely challenging; literature is lacking.
- While procedural improvements are easy for physicians to see upfront, questions of clinical outcomes are hard to answer because it takes many years to track patient outcomes.
- Hospitals, doctors and medical device companies need to engage in a deeper conversation about patient outcomes, how the products perform.

C. Discussion: Transparency as Interim Goal; End Goal: Rationality in Purchasing

- In the 1980s cost was almost a sacred cow. Today cost is a central issue - achieving affordability while maintaining high quality.
- Price transparency is an interim goal related to the end of cost containment. The end goal is rationality about how we price devices, pay for them, and assess their value in relation to what we pay for them.
- Suggested mindset for appropriate medical device usage: determining what’s best for ‘Uncle Charlie,’ when Uncle Charlie pays his own medical bills.

Session II: Legislatively Mandated Disclosure: Pros and Cons

A. Discussion: Price as ‘Trade Secret’

- Medical Device Companies claim each and every individual medical device price to be a trade secret.
- Trade Secret law is premised on notion of keeping trade secret information a secret from the competition (i.e. other device companies). However, in the device market, the consumers (i.e. the hospitals who purchase medical devices) are kept in the dark (doing so garners advantage to device vendors during negotiations).
- Trade Secret Law is a state law. For information to qualify as a trade secret, it must be a competitive advantage to its owners to keep the information secret; and owners of the information must make an effort to maintain its secrecy.

- Although prices have not historically been protected as a trade secret, signing a vendor's confidentiality agreement supports their effort to maintain its secrecy, thus has the effect of promoting the status of a medical device prices as vendor trade secrets.

B. Discussion: Pending Legislation - Mandated Disclosure

- Grassley /Specter 'Transparency in Medical Device Pricing Act of 2007' (S.2221) provides for disclosure of national average and national median prices by price category, no local information provided.
- Grassley/Specter Price Transparency bill has an odd exemption clause, "certain sales may be exempted."
- Shortcomings of bill as written:
 - Total Procedure Costs - The price of the total procedure, not just the price of the medical device is what is relevant. (Device cost is but a portion of total procedure cost; other components can add up to a substantial portion of the total procedure cost.)
 - Regional Data Missing - The bill lacks geographical, regional data.
 - Margin as target - The real info desired is margin, not price per se.
 - Ineffective, too little - Not worth the political capital to get it passed.

C. Discussion: State vs. Federal Legislation

- State law just prohibiting confidentiality agreements would be challenged as violation of 1st amendment and "Right of Contract" legislation.
- Recent state law in Maine in which pharmacy benefit managers were required to disclose prices to a limited number of constituencies has been challenged and survived.
- Advantages of State Legislation - State bill might be easier to pass.
- Advantages of Federal Legislation - Device mark-ups generally range from 20% to 300% or even 400% in most parts of the country. (In California mark-ups are typically not this extreme.)

D. Discussion: Mandated Transparency vs. Market Solution

- Advantages of Mandated Price Transparency:
 - Transparency would create safe harbor for sharing with hospital staff.
 - Even if minimal, "More is better" when it comes to transparency
 - Transparency Act would serve as a camel's nose under the tent
- Potential Advantages of Market Solution/Disadvantages of Mandated Price Transparency:
 - Getting/maintaining price info adds expense; higher costs get passed along.
 - Potential vendor backlash to mandated pricing transparency.
 - May drive out the vendor market, reduce competitive marketplace.
 - Unclear whether price transparency will result in much price negotiation leverage
 - Transparency is open for gaming in various ways which would be hard to regulate
- Results of poll on desirability of market solution vs. federal legislation:
 - Group was evenly split on support of Grassley/Specter Bill. Some felt it didn't go far enough to be worth the effort; others would support it as a step in the right direction.
 - There was strong consensus that regional data was needed to make transparency relevant.
 - Roughly a third supported the notion of a state-level transparency initiative.

Session III: Best Practices for Hospitals

A. Discussion: Alignment of Physician & Hospital Incentives

- Hospital/physician/device vendor alignment of incentives is the central issue. Demand-matching not key; Gain-sharing overrated.
- Physicians and hospital administration typically tend toward an adversarial relationship (although staff culture varies by type of institution). Collaboration between the two is critical to control costs.

- Elimination of Physician Conflict of Interest: Device vendors grant large payments to physicians for volume, use of brand, speaking engagements. (How does this impact device costs?)
- Financial incentives are not the only way to motivate physicians. Other physician incentives: control over operating room; greater efficiency; own room or anesthesiologist; more involved in decision-making process; device registry

Discussion: Physician Buy-In

- Physician preferences drive device choice, not end-user/consumer
- Physician buy-in is crucial for any best practice strategy or new procedure. Very useful to have a physician to champion, as well as to vet, your cause. Ownership in advance is also helpful.
- Strong physician leadership is necessary; bonds are made at the scrub sink.
- Peer Review/Peer Pressure is highly effective in managing device selection, appropriate use, etc.
- Physician leaders need to discuss this and create camaraderie, a nucleus to spread it out.

Discussion: Alignment of Sales Rep & Hospital Incentives

- Sales Reps play an integral role, but are external, independent agents, paid by commission
- Sales Rep Incentives Alignment: For some procedures substantial device follow-up is critical. Need to align sales rep incentives (independent reps, on commission, often for multiple vendors) with hospital incentives. Perhaps call them “service reps” instead.
- Ways to align Sales Rep and Hospital Incentives: episode of payment would fix cost regardless of brand; sales reps could be paid on a fee-for-service basis, not bundled to device cost.

Discussion: Alignment of Interests, Consumer/Patient Involvement

- As means for patient alignment, patients could be asked to pay extra if the medical device they desire is a pricier than a certain pre-specified level of cost.
- Consumer input: Today’s patients have opinions about choice of medical device. Patient-driven is not necessarily a better outcome for the patient, but makes great marketing.
- Role of Consumer: The consumer has no direct way to participate in efforts to control cost. Who are we speaking on behalf of? The hospitals? The consumer? The community?

Discussion: Hospital & Vendor Incentive Alignment, Areas of Collaboration, Best Negotiation Practices

Ability of hospitals to negotiate with vendors is highly dependent on the particulars of individual markets (e.g. size of hospital, number of vendors who service the area). Some best practices:

- *Reduce Mark-Up*: Work with manufacturers to bring product to market more easily, predictably. Consistency, commitment can help reduce vendor’s need for mark-up.
- *Use Automatic Reordering*: to avoid unused product on shelves, but it gets push-back from both sides: vendors don’t like it because they want to protect their business; MDs don’t trust it.
- *Standardize Products*: Greater standardization of increments used in devices could simplify selection, eliminate need for switching between different systems. (e.g. Instrument trays range from \$30-\$40K)
- *Cap prices*: Set specified limits within device categories.
- *Redefine “new”*: Ask vendor for proof that the new devices perform demonstrably better for the patient. Ask also whether the ‘new’ technology necessitated the filing of a 510K or PMA.
- *‘Reverse Auction’*: Conduct a ‘reverse auction’ on medical devices/suppliers to reduce supply pool.
- *Move Market Share*: For credibility, critical to demonstrate the ability to move market share.
- *Credible Data*: Having credible and accurate data is important, whether it be during vendor negotiations, or within surgeon committees, to build credibility re: product choice.
- *Forward-Looking Negotiations*: Keep an eye toward the future of the market 6-12 months out; specify during time of agreement stipulations about the pricing structure of future products.