Integrated Healthcare Association (IHA)
and the Berkeley Center for Health Technology (BCHT)
Best Practices Roundtable
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Berkeley, California

Physician-Hospital Alignment in Device Selection: Roundtable Summary

Background

Working effectively with physicians to evaluate and purchase medical implants such as artificial joints and coronary stents is a key issue for hospitals in California and nationally. While many hospitals have established technology or value assessment committees, maintaining engagement and compliance with selection protocols has proven to be a significant challenge. Complex financial relationships among the manufacturers of these implants, the physicians who select the devices, and the hospitals who pay for them are widely viewed as exerting an inappropriate influence on selection decisions, but the impacts of voluntary disclosure protocols, the Department of Justice settlement with orthopedic device manufacturers, and state and federal sunshine legislation remain unclear. Clinical evidence to inform selection decisions, particularly with respect to device performance in large numbers of patients over time is often missing or inadequate, leading to increasingly urgent calls for device registries to fill these important evidence gaps.

Meeting Objectives

This roundtable brought together 29 hospital executives and thought leaders in the medical device, physician, employer, and public policy communities to discuss the current context and emerging best practices for improving data and aligning incentives in device selection. The three principal sessions of the day explored best practices for technology assessment and selection, considered the challenges of managing financial relationships that may influence device selection, and provided an overview of orthopedic and cardiac device registries, both existing and proposed.

Introductory Overview: Physician-Hospital Alignment in Device Selection: Challenges and Opportunities - James C. Robinson, Ph.D., IHA and University of California at Berkeley

- See Attachment A (page 6)

Session I: Best Practices for Technology and Value Assessment Committees

A. Logistics:

- Tech assessment committee should provide a structured mechanism for physician-led peer review of new medical technologies.
- Well established committees (3yrs old+), are typically appended to an existing organizational structure, and report to hospital CMO or CFO. A small hospital/system may have a single, umbrella committee. More commonly, hospitals/systems have several specific tech committees along areas of specialization.
- Tech committees are made up of expert clinicians, some hospital administrators and senior administrative staff. Administrators are informed by clinicians regarding: device safety, outcomes, satisfaction, best value, and reimbursement. Trend is for physicians to get out of making price decisions.
- Though not tied to financial incentives, tech assessment committees can be effective in analyzing cost vs. effectiveness given strong physician leadership and an organizational culture which promotes a joint sense of destiny, shared vision.

B. Processes:

- Approvals: Evaluation criteria must be met for each new technology approved. Device company claims (e.g. less infection, blood loss, OR time, etc.) should be substantiated, reviewed.
- Denials: The meaning of a denial varies per institution, from recommendation to prescriptive determination.
- The denial rate at one large, local hospital system ran at about 10% of cases reviewed. Example of a denial: device deemed to be an overpriced, or a repackaged, minor remake of a previous model.
- Appeals: An appeals process is available; applicants are provided with feedback.
- Exceptions: A robust exceptions process is needed for tech committees (similar to formulary exceptions).
- Report-Sharing: Part of an internal quality assurance program, tech committee reports are shared internally.
- COI policy: (See discussion Section II, especially on Disclosures.)

C. Types of New Technologies Reviewed:

- At one large, city hospital, tech committees review a variety of new medical technologies, from capital budget expenses (e.g. MRIs) to medical implants (e.g. CRMs) and disposables. For capital expenses, tech committees issue purchasing advisories. For other medical devices, tech committees evaluate appropriateness and make purchasing decisions.
- Most reviews are for innovative but unproven technology. E.g. a new material/shape/ number of bone screws for knee replacement. Very novel technologies and clinical trials are left for another venue.
- At one integrated delivery system, there are several other levels/venues for technology review besides tech committees:
    - Pharmacy DND committee - approves drugs/pricing; made up of pharmacists and clinicians
    - Device Technology Assessment /National Device Assessment Group - issues white papers on new technologies; clinical chiefs discuss new technologies for which limited evidence is available
    - Academy of Orthopedic Surgeons - determines treatment courses, evidence-based
    - Formulary for Medical Devices –a regional committee, usually at the Medical Group level

D. Technology Evaluation – Assessing Efficacy and Value

- Efficacy is difficult to assess in medical devices because of: frequent changes in new technologies, the complex nature of implants themselves, and lack of data on long-term outcomes. Other factors such as physician choice & appropriateness/fit can greatly also impact outcome, making device assessment all the more difficult.
- Advocates of statewide/national registries tout registries as a mechanism for bringing much-needed data to bear on questions of efficacy. Currently, physicians rely on industry or third-party studies of device efficacy.
- For value assessment, economic questions are weighed against questions of patient benefit. Some hospitals may also consider reimbursement-based pricing models when making determinations of value.
- Value analysis comes into play for many decisions, for e.g.- choosing between two similar types of stents. Conjecture is that only about 5% of tech committee cases have a clear right/wrong choice.

Session II: Managing Potential Financial Relationships Surrounding Device Selection

A. COI – General Background

- COI touches a public nerve due to high level of trust in physicians. Recent reports on COI (e.g. Pew Charitable Trust) and patient advocacy groups (e.g. Med Now) demonstrate/foster greater public interest. Expectations are for a higher level of scrutiny and systemic changes for medical device COI.
- Vendors view some COIs as needing to be eliminated, others as needing to be 'managed,' such as (R&D and CME). Vendors caution that in scrutinizing physician payment data, one should avoid equating money from industry with degree of COI taint; this oversimplification would impugn all industry-physician collaboration, when much is wholly appropriate.

- To function properly, it is critical that tech committees are perceived to be free from COI. It is a challenge to get people with experience but without conflict to serve on tech committees.
- Independent research groups are paid by hospitals, health plans, government agencies and (to a lesser extent) vendors to provide 'objective' information.
- Surgeons rely heavily on sales rep expertise and service, and particularly on their reliability in providing inventory. Surgeons develop bonds with sales reps and these close relationships can upstage financial and other factors in device choice. Since sales reps are paid by commission, they are incentivized to promote their brand(s)/more expensive models. Hence, sales rep-hospital relations are inherently financially misaligned. Separating service from sales aspects may fail; lower paid OR techs may be less reliable. Hospitals are willing to pay a premium to have highly-compensated vendor sales reps babysit the process.
- Role of hospital has changed. Hospitals are now corporate entities, receiving benefits from vendors. Is there an institutional COI? Some perks do not go directly to individuals, but to the institution itself: resident funding, "free" consulting services on OR efficiency, research grants for their physicians, contributions to new buildings/equipment. Hospitals may soon be asked about their payment structures, just as docs have been queried about taking kick-backs. Hospital executives could be asked to sign disclosure forms revealing their financial relationships with vendors and others outside the hospital.

B. Existing Disclosure Policies - Voluntary Protocols and Legislative Mandates

- The Dept of Justice settlement requiring disclosure of physician payments requires time-consuming navigation of each device company's site in order to research a single physician.
- If enacted, the Sunshine Act (a.k.a. Physicians Payments Disclosure Act s.301) would usher in voluminous disclosures. How to access and interpret this information as well as to what end it should be used remains unclear.
- At a minimum, public disclosure can be valuable as a reminder that 'someone is watching.' Concerns over the appearance of impropriety can have a beneficial effect on behavior.
- Some cases (e.g. a physician offered royalties merely for "trying out" a new technology) are clear causes for concern, but most cases will require some schema of appropriateness in order to ferret out which payments are appropriate/inappropriate.

C. Physician Disclosure Mandates – Survey of Hospitals Present:

- Half of hospitals present at the roundtable require physicians to sign disclosures. Some hospitals require full disclosure from all surgeons and persons with R&D contracts. Some hospitals mandate disclosures by all those who make purchasing decisions. The degree of limitation on financial conflicts may depend on a physician's level of tech committee/hospital involvement (e.g. a hospital CMO or committee chair might have stronger limits on conflicts). Even where hospitals have disclosure policies, there is no real recourse for failure to comply. Also, full disclosure isn't always forthcoming, even with employed physicians.
- Of the hospitals lacking disclosure mandates, some are in the process of developing a COI policy, but are finding it difficult to reach consensus. Other hospitals have a COI policy which asks a physician with COIs to recuse herself from related technology decisions.

D. Mitigating COI:

- Self-Fund R&D and CME - One very large group set aside $3M/year to self-fund their own R&D and CME; their physicians were happy to be in a conflict-free environment. This is not feasible for small groups. At a minimum, hospitals should rely on multiple sources/device companies to fund CME.
- Arm's-length funding - through a third party, independent grant or foundation
- Peer review/"Group Think" process can help dilute impact of individual COIs.
- Hospitals can request that vendors provide individualized COI disclosure info when soliciting for their business.
- Compliance officer/committee and definitions of COI for each organization would bring greater clarity on COI.

- Regulatory system on vendor pricing - vendors don't reveal profit margins, totals, methods of price determination.
- A well-defined methodology for rep behavior could make some impact on mitigating overzealous sales approaches.

Session III: Device Registries

A. ACC (currently operational)

- ACC has 5 registries (4 procedure-based, 1 ambulatory): Cardiac, Defib, AHA Condition-Based, Pediatric implant pilot, and Ambulatory. (ACC is also planning 2 future registries: Arial Fib, Imaging)
- ACC's Cardiac Registry: 4 million, voluntary, with 2/3rds compliance
- Purpose of ACC Registry: doesn't implement, just gives data to hospitals for their own evaluations.
- Funding for ACC Registry: subscription at hospital level, or funding through Rx companies at arms- length
- ACC Registry is evidence-based; guidelines, performance, appropriate use are linked via registries.

B. Kaiser Permanente (currently operational)

- KP's Joint Registry began in 2001, now has records on 80,000 total joints
- KP's Joint Registry is a Level 1 Registry, like Swedish double-joint registry (see below)
- Purposes of KP Registry:
    - Patient Safety – within 24hours recall notices and directions are sent to patients
    - Spot Investigations – to confirm surgeon hunches/anecdotal stories of trouble
    - Quality Studies – to determine correlates of success, (e.g. for certain procedures failure rate was highly correlated with number of procedures performed/year by surgeon
- Reduced choice of vendor implants down to two vendors.
- Funding for KP Registry: negotiated contribution from vendors to fund registry

Levels of Registries:

- **Level 1 Registry** - Includes: patient id, physician id, implant id, when the implant goes in/comes out, revision rate.
- **Level 2 Registry** – all Level 1 registry plus more info about co-morbidity
- **Level 3 Registry** – all Level 2 registry plus patient derived info before and after procedure

C. CA Statewide Ortho Device Registry (proposed)

- Purpose: to report device level, hospital level and physician level data, to foster better outcomes & lower cost in CA
- Types of registry: Use ACC model for peri-operative data. Supplement w/ additional data on: satisfaction, physical and functional states, long-term outcomes (Comparative effectiveness data is built into this).
- Status: grant obtained, orthopedic leadership identified, steering committee formed, survey of surgeons planned

D. Benefits/Strengths of Registries:

- For hospitals: data helps with tech committee evaluations, benchmarking, and gives opportunity for recognition
- At an individual physician's level: an awareness that performance is publically available, opportunity to educate (e.g. volume is needed for good results w/certain procedures). However, most data on physician performance are not statistically significant/ relevant (volume too small, many confounding variables); and this concerns physicians.
- Registries can identify device failures, but are not so good at identifying best practices or comparing devices.

- In combination with EMRS, Virtual Follow-Up: Registries can enable automatic emails, updates, e-visits. Email correspondence determines if patient has pain.
- KP has used virtual follow-up to successfully to reduce in-office appointments for patients who are doing well. Surgeons now spend more time in OR, less on routine follow-ups.

E. Shortcomings/Difficulties for Registries:

- Moving targets - changes in implants can make original data less relevant
- Cross-implant comparisons are difficult, need to consider multiple parameters
- Analyzing is time & resource intensive. Who funds?

F. Work Involved/Cost of Registry:

- Set-up: Create forms, system for the connection. Each hospital will have local costs, usually low.
- KP Cost: 100,000 to 1.2 M for registry depending on how you allocate the overhead
- Estimated Cost of National Ortho Registry: For Level 1 = ~$10.00/joint, For Level 4 = ~$100.00/joint

G. Cost Return for Registries:

- For KP, cost return is far in favor of running registry: KP Joint is a Level 1 registry at a cost of 10cents/joint. (A level 4 KP joint registry would run $4.00/joint) Patient safety initiatives alone make KP Joint Registry worthwhile. Over $2.5 M was saved in the case of a tibia device recall. Registry also helps to negotiate cost, and enables virtual "e visits."
- KP supplements Level 1 data with electronic medical record (an outside registry couldn't do that). KP uses revision as surrogate for patient satisfaction, but has found mismatch between revision and satisfaction rates.

The roundtable was sponsored by the Integrated Healthcare Association as part of its Value Assessment and Purchasing of Medical Devices initiative and is open to representatives of hospitals participating in that project and to other invited guests. The event is co-sponsored by the Berkeley Center for Health Technology (BCHT), which has as part of its mission the dissemination of proposals that potentially improve efficiency and innovation in the medical technology sector.

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Physician-Hospital Alignment in Device Selection: Challenges and Opportunities

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The Unacceptable Status Quo

It is essential that physicians and hospitals cooperate in the organization, delivery, and improvement of care. This is especially important in the context of rapid introduction of new and complex clinical technologies, such as implantable devices.

Yet the structure and culture of physician-hospital relationships often reflect conflict as much as cooperation.

- The two entities often lack a sense of joint destiny. The hospital does not employ the physician and the physician does not own the hospital. They are paid separately. The physician may practice at multiple competing facilities.

- With the trend towards more outpatient and short-stay facilities, physicians increasingly are entering into direct competition with hospitals, especially in the device-intensive specialties such as orthopedics and cardiology:
    - Physician-owned or invested ambulatory surgery centers (ASC) and ambulatory diagnostic centers
    - Short-stay specialty hospitals with physician ownership or investment
    - Consulting arrangements between physicians and device manufacturers that impede hospital efforts to negotiate volume-discount contracts with those manufacturers

These inefficiencies currently are passed through the system, adding to overall costs:

- The surgeon selects the device without respect to price, and often with poor information on clinical performance relative to other devices and vendors.
- The hospital must pay for the device, and may have to pay high prices due to inability to influence physician choices.
- The hospital typically is paid by the commercial insurance firms on a negotiated per-day or per-admission rate, but 'carves out' the device and bills it separately to the insurer on a cost-plus basis. This protects the hospital but weakens the hospital's incentive to manage device costs and, in some cases, creates a new 'mark-up' profit opportunity for the hospital.
- The insurers pass a portion of the rising device costs through to the enrollee through coinsurance and are contemplating new benefit designs and contractual relationships (DBM, 'device benefit managers', modeled on PBM and RBM) that will add another level of complexity to the health system.

The goal: service line efficiency and quality

The desired structure and functioning of the device-intensive specialty services is for them to be organized, reimbursed, and managed in a manner that encourages continual self-analysis and self-improvement, with informed consumer choice among competing facilities and surgeons. This requires various forms of integration and coordination:

- Data systems that combine information on pre-admission services, hospital services, physician services, device implants, and post-discharge services, e.g., for the entire course of care.
- Quality monitoring that encompasses the entire course of care (which is what the patient means by quality, in contrast to the quality of just one or two components).
- Care pathways and other mechanisms for reducing the variance and raising the average performance of the clinical team.
- Collaboration between the physicians and hospital management in discussions over the range of services to be provided, staffing, equipment, etc.
- Collaboration on marketing of the service line to patients, based on quality and price.
- Collaboration on ensuring patient understanding, education, and readiness before and after surgery (may involve the health plan).
- Collaboration on establishing criteria for appropriateness of the procedure (may involve the health plan).

Mechanisms for getting from here to there

Over the long term, the 'soft' factors of culture, governance, and leadership are the most important for improving service line and system performance. In the short term, the imperative is to improve information and align incentives.

- Value assessment committees at the hospital level.
  - Analogy to P&T committee at the health plan level.
  - Gateway for introduction of new devices into the hospital; ideally no device will be contracted or reimbursed by the hospital without going through value committee.
  - Physician interested in a new device or procedure must present it to committee of physician peers, with some management representation (perhaps non-voting), with data on quality and price compared to other procedures or devices.
  - Committee may serve the intangible role of promoting a culture among the physicians of considering comparative effectiveness and cost in clinical decision-making and device selection.

- Managing physician conflicts of interest
  - Physicians should be paid for their clinical services by insurers, not implicitly by device firms based on brand loyalty, promotion to other physicians of off-label uses, etc.
  - There are legitimate consulting services and arrangements between physicians and device vendors (innovation and patents) but current payments are broadly paid to physicians who have little such activity
  - Disclosure policies
    - At the hospital level?
    - Sunshine legislation at the state and federal level?
    - Example of the orthopedics disclosure settlement
    - How useful have these been?
  - Beyond disclosure: limits on conflicts of interest
    - The TPMG model
    - How to limit inappropriate relationships while supporting appropriate relationships between physicians and device firms?

- Registries
  - Registries collect data on use (coded by patient, physician, device, date, etc.) with information subsequently added on performance, where applicable
  - Can be used in case of recalls, for clinical research (while not as good as RCT, can provide observational data useful for identifying unusual performance)
  - Many registries exist for cardiac devices
  - Ortho registries exist in most non-US industrial nations, in US for Kaiser-Permanente
  - Considerable interest in establishing a national or state orthopedics registry
  - Should also discuss ways to maximize the value of existing cardiac registries