Salespeople in the Surgical Suite

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The authors have no conflicts to disclose.

Our Exploratory Study (2013-2014)

- 2 Focus Groups of Surgeons:
  - Orthopedists (n=5)
  - ENTs (n=9)
- 5 Individual Interviewees:
  - 1 Surgery Residency Director
  - 3 Device Reps (2 former; 1 current)
  - 1 MA in Ortho Surgery practice
- Convenience sample; total n=19
- $: GU Engaged Ethics Initiative (collaborative work on "complex moral issues"
- GU IRB approval
- Published in PLoS ONE August 2016

Background Data . . .

- ~ 61% of hospital supply cost = for "physician preference" items, such as implantable devices specifically chosen by physicians

  (Montgomery & Schellner, Millbank Qtrly, 2007)

- Surgeons tend to ally more closely with device industry reps than with hospital representatives

  (Korenstein et al., Arch Surg, 2010)

- Surgeons = more likely to approve of industry funding for residencies, education & training, meals, travel, & payments for lectures

  (Korenstein et al., 2010)

- Orthos receive largest # of and $ from industry

  (Hockenberry et al., Arch Intern Med, 2011)

Background Data

- Orthopedists use the greatest number & variety if implantable devices (and their attendant specialized tools)
- Orthopedic surgeons tend to use a single vendor for most of their implantables, and to maintain brand loyalty over an extended time period

  (Burns et al., Health Care Manage Rev, 2009)
- Surgeons' relationships with Reps often shade into friendships, adding personal to professional sense of loyalty

Parallel Perspectives

- Surgeons: Reps = experts in informational and technical assistance; must be reliable and "know their place;" increase efficiency

"The Rep is another set of eyes. They know the system and the trays – and when you're not worried , that helps you focus on the patient more because you know what's coming into your hand is the right next step." (Ortho)

"If something doesn't work, fix it."(ENT)

Parallel Perspectives

- Device Reps: Surgeons = "Clients" to be cultivated, helped when help is needed

"If you develop a good relationship and he likes you and he feels there's no difference b/w my knee and their knee, he'll just go with the guy he likes more, the guy he trusts more. (…) then he never has to use the other guy and you convert all his business. That's the goal." (Rep)

Role of Device Rep in the OR

- Stock OR with all necessary sterilized, wrapped device & tool trays for the indicated surgery (additional sizes, variations, upgrades)

  e.g., for TKR = "Typically 8 trays of instruments, each with b/w 30-60 pieces of metal" (DR1)
- Indicate (laser pointer) needed tools to OR tech in order of succession
- Provide technical information, advice, troubleshooting when requested by surgeon
- Not touch patient, personnel, equipment (wears scrubs, but is not scrubbed in)**

ETHICAL CONCERNS

Financial Incentive for Reps

- Reps earn a commission (%age) on every sale they make (as soon as the tray is opened): More expensive items bring larger commissions, which can substantially exceed Reps' base pay, and more than double their annual compensation

(Medreps.com, 2015)

Financial Incentives for Industry

"We used to sell an implant that has 99% survivorship at 15 years. We were told to not ever market it to anybody. If a doctor asked for it by name, we would give it to him. We want to market the 'newer, better' technology." (Rep)

"Once surgeons get used to 'driving a Ferrari,' they always want to 'drive the Ferrari'. The surgeon isn't paying for it; the hospital is. What I see as a big issue is surgeons being able to say 'No. For 90% of my fractures the $300 device will be fine'." (Rep)

Financial Incentives, Industry

"Some companies are sneaky. If a device works fine, they'll do a little tweak and they'll charge more for the newer device, but then they'll discontinue the one that worked just fine and then you're forced to buy the new one." (ENT)

Manipulating Relationships

" [Docs] understand that the Rep is just trying to earn a living. They feel somewhat obligated to use the most expensive device, b/c they obviously called you in for it." (Rep)

"The device Rep would tell me, 'Hey, remember to keep getting people to use the new knee.' [He's] nice; I like him, and I said OK. He would hand me all the material to put in the surgery packet. He'd be my go-to resource for what to tell they patient if they had questions." (MA)

FDA 510(k) Device Approval Process

- Allows new devices considered to have "substantial equivalence" to already marketed products to be implanted into humans without clinical testing to provide proofs of safety and efficacy before marketing approval
- Newer (more expensive) are marketed aggressively to promote early adoption
- Problems: e.g., metal-on-metal hips –> high failure rate. Removed from market after 500,000 had already been implanted. (FDA Device Evaluation, 2012)

New Products – Scant Peer-Review Data

"I'm not certain I ever thought the newer technology was better. There certainly wasn't data on it. I was uncomfortable with those sorts of things." (Rep)

"[So I tell the surgeon] we also ordered ceramic heads. The coefficient of friction is lower & should make the part last longer. I don't know if that's true or not. It's what we were taught to say. [but] the ceramic costs 3x as much as the other." (Rep)

Industry Trains Surgeons

- Each manufacturer offers (and pays for) courses on its own devices
  (also pays for travel, lodging, meals during courses)

- Our participating surgeons generally approved of and appreciated industry-sponsored education & training, and believed they were sufficiently aware of the possibility of bias to be able to counteract it

Informed Consent?

- American College of Surgeons (2000/2005): "The patient should be informed of the presence and purpose of the [health care industry representative] in the OR and give written, informed consent. This should be documented within the medical records." (Bull Am Coll Surg 2000)
- Our surgeon participants were uncertain if standard Informed Consent forms/processes mentioned Reps' presence in OR. One exception (Ortho) mentioned a separate Consent re: Reps in one hospital where he operated.

Informed Consent?

- One surgeon (ENT) felt that adding mention of or calling attention to Reps' presence in the OR was unnecessary and would be "confusing" to patients, who would have no basis for judging whether they wanted a Rep there or not.

- Others felt uncomfortable about calling attention to it because patients might refuse. Withholding information because patients might say "no" if they knew it is by definition an ethical problem.

HIPAA Concerns?

- Device Reps have access to patients' identities, medical records, imaging, and other PHI which they use to plan their inventories for specific surgeries.
- "A medical device company meets the Privacy Rule's definition of 'health care provider' if it furnishes, bills for, or is paid for 'health care' in the normal course of business." (www.hhs.gov/ocr/privacy/hipaa/fac/public_health_uses)
- "… without the individual's authorization."

Does being a salesperson AND being an advisor and troubleshooter in the OR constitute a *prima facie* Conflict of Interest?

References

American College of Surgeons. Statement on Health Care Industry Representatives in the Operating Room. Bull Am Coll Surg. 2000 May;85(5):31-2. https://www.facs.org/about-acs/statements/33-industry-reps-in-or (Accessed March 5, 2016.)

Bedard J, Moore CD, Shelton W. A survey of healthcare industry representatives' participation in surgery: some new ethical concerns. J Clin Ethics. 2014 Fall;25(3):238-44.6.

Burns LR, Housman MG, Booth RE Jr., Koenig A. Implant vendors and hospitals: competing influences over product choice by orthopedic surgeons. Health Care Manage Rev. 2009 Jan-Mar;34(1):2-18. doi:10.1097/01.HMR.0000342984.22426.ac.

FDA Office of Device Evaluation. Transcript of the proceedings of the FDA Orthopaedic and Rehabilitation Devices Panel meeting June 27-28, 2012. Free State Reporting, Inc., 1378 Cape Saint Claire Road Annapolis, MD 21409, (410) 974-0947, for the Orthopedic Joint Devices Branch, FDA Office of Device Evaluation. Available at: http://www.fda.gov/AdvisoryCommittees/Calendar/ucm306172.htm. (Accessed March 5, 2016.)

Fifth annual surgical sales salary report, 2015. Medreps.com. Available at:https://www.medreps.com/medical-sales-careers/surgical-sales-salary-report/ (Accessed March 9, 2016).

Hockenberry JM, Weigel P, Auerbach A, Cram P. Financial payments by orthopedic device makers to orthopedic surgeons. Arch Intern Med. 2011 Oct 24;171(19):1759-65. doi: 10.1001/archinternmed.2011.454. Montgomery K, Schneller ES. Hospitals' strategies for orchestrating selection of physician preference items. Milbank Q. 2007 Jun;85(2):307-35.

References, cont'd.

Korenstein D, Keyhani S, Ross JS, Hockenberry JM, Weigel P, Auerbah A, et al. Physician attitudes toward industry: a view across specialities. Arch Surg. 2010 Jun;145(6):570-7. doi: 10.1001/archsurg.2010.75.

Montgomery K, Schneller ES. Hospitals' strategies for orchestrating selection of physician preference items. Milbank Q. 2007 Jun;85(2):307-35.

U.S. Department of Health and Human Services. Health Information Privacy: When may a covered health provider disclose protected health information, without an authorization or business associate agreement, to a medical device company representative http://www.hhs.gov/hipaa/for-professionals/faq/490/when-may-a-covered-health-care-provider-disclose-protected-health-information-without-authorization/ (Accessed March 31, 2016.)