The Dual Role of the Medical Device Representative: Supporting the Surgeon and Selling the Product, Which Role Takes Priority?

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ABSTRACT

Surgeons have an increasing strong relationship with the medical device industry prompting several questions about the duty owed to patients and the financial motives of the industry's sales representatives.

Keywords: medical device, surgeons, products, medical industry, ethics committees

INTRODUCTION

Surgeons have an increasingly strong relationship with the medical device industry prompting several questions about the duty owed to patients and the financial motives of the industry's sales representatives. Sales representatives are crucial to the profit-driven medical device industry with $180 billion in US sales revenue for 2017.[1] Device manufacturers market aggressively. Manufacturers' sales representatives are on the front lines of these marketing efforts, acting as liaisons between surgeon and manufacturer.

ANALYSIS

Device representatives perform a dual role both as a clinical advisor to the surgeon and as an agent of the manufacturer. Representatives have the expertise to support surgeons and facilitate procedures, but they also have financial motives to influence surgeons to select expensive or brand-specific devices. This relationship creates conflict between the surgeon's ability to do what is best for the patient and the representative's ability to make a profit. Given the competing interests of surgeons and device representatives, is it not ethically justifiable for representatives to be present in the operating room unless they can be untethered from the commission-based sales structure.[2]

The pharmaceutical industry's questionable practices receive substantial media attention. Mylan's astronomical increase in the price of the EpiPen and Purdue's targeted marketing of oxycontin are two prime examples. By comparison, the practices of the medical device industry receive little attention. Both industries have a myopic focus on profit and threaten the integrity of medical practice in similar ways. A November 2018 byline of an NPR commentary suggests that medical device representatives "may be wearing out their welcome in the operating room," though this is primarily because of attention to rising costs and not ethical conflicts.[3]

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Rather than banning representatives from operating rooms, I suggest dividing their roles and restricting sales in the clinical setting. Recognized by the American College of Surgeons (ACS) "by their training, knowledge, and expertise," representatives provide technical assistance to expedite procedures and facilitate the safe and effective application of products and technologies.[4] Manufacturers provide representatives with extensive training and education, making them experts in the use of medical devices. Because it is not feasible for surgeons to be experts on every device, the support that representatives provide is essential. Also, surgeons depend on representatives to provide 24/7 on-call support. Over time, representatives learn the surgeons' specific preferences and style, ensuring the availability of necessary device components and anticipating the need for alternative sizes, instruments, and components. Confident that representatives will provide technical support and guidance, surgeons may forego industry-offered training. In short, representatives make surgeons' jobs easier. Nevertheless, the experts providing this support should have no financial motive.

Representatives depend on surgeons for commission, making their relationship symbiotic. According to HealthTrust, the average representative earns a 10 to 25 percent commission on top of their salary.[5] Simply put, representatives are "upselling" because they have a financial incentive to encourage surgeons to select the most expensive device. Manufacturers coach representatives to promote the newest, most expensive models, even if they are not yet proven superior.[6] The FDA approval process allows manufacturers to bypass stringent premarket testing if the new device has "substantial equivalence" to already marketed products.[7] An unofficial *quid pro quo* exists: representatives provide a concierge level of service, and in return surgeons feel obligated to accept suggestions to use the newer device.[8]

Upselling also has a broad effect on resource allocation. Representatives and hospital administrators negotiate contracts and prices with the representative offering what is often a confidential price.[9] If the representative is the only one who knows the cost, the surgeon selects the device without being fully informed. The manufacturer bills the hospital, and the hospital bills the insurer or patient. Increasingly, payors reimburse on a flat fee per case, meaning the hospital may not recover the actual cost. As with the skyrocketing costs of pharmaceuticals, the overutilization of expensive devices depletes funds, ultimately harming the patient and society.

Additionally, representatives who observe poor surgical skills may be reluctant to become whistle blowers due to their dependence on commission. In 2014, a survey of representatives found that 40 percent had observed surgeries in which they questioned the surgeon's competence. In one account, a former orthopedic device representative personally observed a surgery which he described as a "train wreck." The surgeon, who had refused training, struggled to perform a procedure. The emphasis on profit resonates in the words of the representative's supervisor: "You just earned $1,000 for three hours' worth of work, what are you complaining about?"[10] The surgeon purchases and the representative protects.

Due to the nature of surgical procedures, patients are unaware of what happens in the operating room. Surgeons owe a fiduciary duty to patients[11] and must focus exclusively on patients' well-being.[12] This fiduciary duty is eroded if the surgeon selects a device for reasons other than clinically-proven efficacy. By contrast, representatives have a fiduciary duty to their employer and any perceived moral duty to patients is secondary. Patients are not privy to the conversations or the data and may not be aware of the device selection process.

Disclosure and patient consent are essential elements of autonomy. Despite the recommendations of ACS and the not-for-profit watchdog, ECRI,[13] surgeons do not always inform the patient about representatives' involvement in their procedure. The surgeon should select clinically proven devices as doing so benefits the patient. If surgeons lack training and skill in using the devices, they can harm the patient. Patients may experience poorer outcomes if they are not informed about the role of sales representatives in their procedure.

Hospital ethics committees can mitigate any ethical concerns. Hospitals should complete an ethics review to identify, analyze, and resolve the ethical concerns presented by the representatives' presence in the clinical setting.[14] There is a need for preventive ethics to identify, prioritize, and address this ethical issue.[15] This process will lead to interventions, such as policies and procedures prohibiting direct sales during a procedure and restricting the representative's role to providing resources and support.[16] Most hospitals do not call an ethics committee meeting unless a doctor reports an ethical breach or conflict. Patients tend to not know they can also access the ethics committee.

Transparency is critical: hospitals, surgeons, and the medical device industry should inform and educate the public. Patients should be encouraged to ask questions about costs and options if the price of devices were public and easily accessible. Surgeons need to know the actual cost of devices to discern whether upselling is occurring. Patients and insurance companies should ask questions about the surgeon's device selection criteria and degree of training and experience. They should also ask about the involvement of a device representative during the procedure.

CONCLUSION

In conclusion, the medical device representative's dual role should be changed. Since the representatives are trained in the products, rather than barring them from the operating room, they could act as trained clinical specialists and drop their role as sales representatives while in the operating room. Alternatively, increased device training for surgeons may alleviate the need for representatives in the operating room but this may not be feasible. A compromise would be to allow another employee of the manufacturer who does not operate based on commission to have an advisory role in the clinical setting. Hospital ethics committees, surgeons, patients, and the medical device industry can each contribute to a solution that eliminates the conflict and better serves patients, the insurers who pay for devices, and doctors who owe their patients the best care.

[1] Zacks.com. (2018, June 14). Medical Device Industry Outlook - June 2018. Retrieved from https://www.nasdaq.com/article/medical-device-industry-outlook-june-2018-cm978557

[2] The ethical issues include, issues of patient autonomy, and informed consent, the outsourcing of clinical expertise, the surgeon's over reliance on the representative the representative overstepping boundaries, the delegation of responsibility, the surgeon's financial gains from the industry, and an array of legal issues.

[3] Farmer, B. (n.d.). Sales Reps May Be Wearing Out Their Welcome In The Operating Room. Retrieved from http://www.krwg.org/post/sales-reps-may-be-wearing-out-their-welcome- operating-room.

[4] 1, 2. R. (n.d.). Revised Statement on Health Care Industry Representatives in the Operating Room. Retrieved from https://www.facs.org/about-acs/statements/91-industry-reps-in-or

[5] Farmer

[6] O'Connor, B., Pollner, F., & Fugh-Berman, A. (2016). Salespeople in the Surgical Suite: Relationships between Surgeons and Medical Device Representatives. *Plos One, 11*(8). doi:10.1371/journal.pone.0158510

[7] O'Connor, B., et al.., p.15

[8] O'Connor, B., et al., .p.8

[9] How Much do Medical Devices Costs? Doctors have no idea. (n.d.). Retrieved from https://www.bloomberg.com/news/articles/2014-01-23/how-much-do-medical-devices-cost- doctors-have-no-idea

[10] Bedard, J., Moore, C. D., & Shelton, W. (2014). A survey of healthcare industry representatives' participation in surgery: some new ethical concerns. *The Journal of clinical ethics*, *25*(3), 238–244.

[11] Grundy, Q., Hutchison, K., Johnson, J., Blakely, B., Clay-Williams, R., Richards, B., & Rogers, W. A. (2018). Device representatives in hospitals: Are commercial imperatives driving clinical decision-making? *Journal of Medical Ethics, 44*(9), 589-592. doi:10.1136/medethics- 2018-104804

[12] O'Conner, *Supra.;* Furrow, B. R., Greaney, T. L., Johnson, S. H., Jost, T. S., & Schwartz, R. L. (2018). *Health law: Cases, materials, and problems*. St. Paul, MN: West Academic Publishing.

[13] ECRI.org. A not for profit watchdog that monitors, inter alia, medical devices

[14] Ethics Consultation: Responding to Ethics Questions in ... (n.d.). Retrieved from http://www.ethics.va.gov/docs/integratedethics/ec_primer_2nd_ed_080515.pdf

[15] INTEGRATEDETHICS: AN INNOVATIVE PROGRAM TO IMPROVE ETHICS ... (n.d.).

Retrieved from http://www.ethics.va.gov/IEoverview.pdf

[16] Farmer