Jeffrey Bedard, Crystal Dea Moore, and Wayne Shelton, "A Survey of Healthcare Industry Representatives' Participation in Surgery: Some New Ethical Concerns," *The Journal of Clinical Ethics* 25, no. 3 (Fall 2014): 238-44.

A Survey of Healthcare Industry Representatives' Participation in Surgery: Some New Ethical Concerns

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ABSTRACT

Objective

To provide preliminary evidence of the types and amount of involvement by healthcare industry representatives (HCIRs) in surgery, as well as the ethical concerns of those representatives.

Methods

A link to an anonymous, web-based survey was posted on several medical device boards of the website *http://www.cafepharma.com.* Additionally, members of two different medical device groups on LinkedIn were asked to participate. Respondents were self-identified HCIRs in the fields of orthopedics, cardiology, endoscopic devices, lasers, general surgery, ophthalmic surgery, oral surgery, anesthesia products, and urologic surgery.

Results

A total of 43 HCIRs replied to the survey over a period of one year: 35 men and eight women. Respondents reported attending an average of 184 surgeries in the prior year and had an average of 17 years as an HCIR and six years with their current employer. Of the respondents, 21 percent (nine of 43) had direct physical contact with a surgical team or patient during a surgery, and 88 percent (38 of 43) provided verbal instruction to a surgical team during a surgery. Additionally, 37 percent (16 of 43) had participated in a surgery in which they felt that their involvement was excessive, and 40 percent (17 of 43) had attended a surgery in which they questioned the competence of the surgeon.

Conclusions

HCIRs play a significant role in surgery. Involvement that exceeds their defined role, however, can raise serious ethical and legal questions for surgeons and surgical teams. Surgical teams may at times be substituting the knowledge of the HCIR for their own competence with a medical device or instrument. In some cases, contact with the surgical team or patient may violate the guidelines not only of hospitals and medical device companies, but the law as well. Further study is required to determine if the patients involved have any knowledge or understanding of the role that an HCIR played in their surgery.

INTRODUCTION

In 2010, nearly 51.4 million surgeries were performed in the United States.[1] At the end of 2011, the medical device market was worth more than $106 billion in the U.S.[2] and an estimated $300 billion worldwide.[3] In the U.S., orthopedic and cardiovas-

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cular surgeries accounted for approximately 13 million surgeries in 2010,[4] and device sales for orthopedic and prosthetic products alone in 2011 were estimated at $15.4 billion.[5] The U.S. Bureau of Labor Statistics estimates the number of healthcare industry representatives (HCIRs) who sell medical equipment and devices at 7,830.[6] No reliable data were found regarding the number of HCIRs who are in surgeries daily, monthly, or even annually.

HCIRs occupy a unique position in relation to the treatment and care of patients. Although they are not healthcare providers, the presence of HCIRs in the operating room is, for the most part, a routine event, and they frequently play an important role during surgery. Their expertise is often called upon to address technical issues that arise in the operating room with either the use of instrumentation or the implantation of a medical device. HCIRs are there to provide guidance to operating room (OR) staff on the technical aspects of the medical device they represent. There are times, however, when an HCIR's involvement in a surgery may become much more significant. In the past few years, discussion regarding the presence of HCIRs and their involvement in the OR has focused primarily on credentialing and consent issues, such as the HCIRs' training on and understanding of sterile technique, verification of the HCIRs' vaccination history, ensuring confidentiality and compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), proof of the HCIRs' competency with the product, obtaining the informed consent of the patient for the presence of an HCIR, and so on.[7]

Both the American Medical Association (AMA) and the American College of Surgeons (ACS) have position papers on the role of HCIRs in the operating room.[8] The ACS states, "The HCIR is present as an advisor to the perioperative team to ensure the safe and effective application of surgical devices and technologies. The presence of the HCIR in the operating room is not an appropriate substitute for preoperative training of the surgical team." The ACS statement goes on to state that an HCIR "should not engage in . . . the practice of medical decision-making."[9] The AMA states, "Participation by industry representatives should not be a substitute for training of the physician that is necessary for safe and effective use of medical equipment and devices."[10] It should be emphasized that these are guidelines only, and it is up to the respective hospitals and medical device/instrumentation manufacturers to establish regulations and enforcement mechanisms for HCIRs' involvement. As a result, there may be discrepancies between what is acceptable and what is not, based upon the individual hospital or medical device manufacturer.

What is lacking from the previously referenced position papers are guidelines related to situations in which an HCIR is being asked to provide a level of guidance and direction to the surgical team that exceeds the HCIR's level of responsibility. Statements from the ACS, the AMA, and the Association of Perioperative Registered Nurses (AORN) acknowledge that there is a possibility that this situation can occur and have provided language in their statements highlighting this issue.[11] The highly publicized case from 1997 of Lisa Smart, a 30-year-old patient who died during the surgical removal of a fibroid tumor, brought to light the issue of an HCIR's involvement in the surgery.[12] While the HCIR's presence and involvement were ultimately found not to be contributing factors in the death of the patient, they brought the issue of HCIRs' involvement in surgery out into the mainstream media.[13]

Since that time, the issue of HCIRs in the operating room has continued to receive some, albeit limited, attention within the mainstream media. According to a report in the *Washington Post,* in 2005, Charles Bates, III, and Craig Patrick filed a whistleblower lawsuit against Kyphon, a manufacturer of medical devices, alleging that Kyphon encouraged its representatives to have physicians admit patients for procedures so that hospitals and physicians would maximize federal reimbursement for the procedure.[14] The case was settled in May 2008 when Kyphon agreed to pay the federal government $75 million, although Kyphon denied any wrongdoing.[15]

At present, there is no guidance or consideration given in the ACS, AMA, or AORN statements on how an HCIR should respond when asked to provide a level of guidance that could be construed as practicing medicine. On the one hand, should an HCIR refuse to respond, a patient could be placed at risk. On the other hand, should an HCIR choose to respond, a patient could be at risk as well, due to the HCIR's overreaching the scope of his or her role in the surgery. There is also a dearth of information on the experiences of HCIRs in the OR environment. While there are certainly examples of when HCIRs have been asked to exceed the scope of their role, there is a need to better understand the issues and challenges HCIRs face in the OR. Either from within the medical device industry or without, there has been no attempt made, to our knowledge, to glean from HCIRs themselves what kinds of ethical issues they face and must deal with in the OR.

This exploratory study attempts to fill an important gap in our knowledge by describing a num-

ber of self-reported ethical issues that HCIRs have encountered as a part of their involvement in surgery. Given the limitations in the study's design and sample size, the results are not intended to provide definitive data or make any conclusions about this issue, but to begin the difficult process of uncovering an understudied area of healthcare activity that deserves more attention.

METHODS

To recruit HCIRs to participate in this study, an advertisement with a link to an anonymous questionnaire was placed on several medical device discussion boards on the website *http://www.cafepharma.com/boards/forumdisplay.php?f=9,* as well as on the discussion boards of two different medical device groups on LinkedIn, a business-oriented social networking service. Self-identified HCIRs were asked to participate in a 20-question survey regarding their experiences in surgery. The design of the survey was based on the first author's prior professional experience as an HCIR, to gather some basic descriptive information about the experiences of working HCIRs that raise ethical issues or concerns. The survey contained items that addressed HCIRs' assessment of their level of involvement in surgical procedures and their perceptions of surgeons' competence to use the medical device that the HCIRs represented. The survey was developed specifically for this study, and its contents were based on the first author's considerable experience working as an HCIR; therefore, no data on its reliability or validity are available, and the survey was not pilot tested. The commercial website *http://www.surveymonkey.com* was used to collect the results. The site used secure SSL technology to ensure the confidentiality of the data, and the survey did not capture any IP addresses. The questionnaire and responses are included in table 1. This study was reviewed and approved by the Albany Medical College Institutional Review Board.

There are no prior studies of this type, and options for surveying this professional group are limited. Therefore, this is an exploratory study and is intended present preliminary data that may begin a new conversation about ethical and professional issues that face HCIRs in the OR.

RESULTS

Over a period of one year, a total of 43 HCIRs responded to the survey link. Of the 43 respondents, 35 were male and eight were female. The respondents had attended an average of 184 surgeries in the last year and came from a wide variety of backgrounds: 15 represented general surgery/operating room products, nine represented orthopedic products, six represented cardiology products, five represented endosurgical products, two represented laser surgical products, two represented anesthesia products, two represented urologic surgical products, and one represented oral surgical products. The respondents had an average of 17 years as HCIRs.

In the last year, 88 percent of the HCIRs (38 of 43) provided verbal instruction to surgical teams during surgery, and 21 percent (nine of 34) had some type of physical contact with either the patient or the surgical team. Additionally, 7 percent of the HCIRs (three of 43) felt that their involvement in a surgery exceeded their professional comfort level in the past year, and 30 percent (13 of 43) felt that their involvement in a surgery exceeded their professional comfort level over the course of their career. More than one-third of the respondents, 37 percent (16 of 43), reported that, over their careers, they had participated in a surgery in which they felt that their involvement was excessive.

Of the 43 respondents, 40 percent (17 of 43) indicated that within the last year they had attended a surgery in which they questioned the competence of the surgeon, and 72 percent (31 of 43) discussed ethical issues related to their professional role with another professional. Of those 31 respondents, 30 percent (13 of 30—one respondent did not answer this question) were satisfied with how these issues had been handled. Table 1 lists the survey items and the percentage of respondents who endorsed each item.

Participants were given the opportunity to provide qualitative responses regarding their perceptions of the competence of the surgeons with whom they had worked. The following are a few examples of the responses:

- "When the surgeon asks [the HCIR] what the best approach is for the case, there is a problem."
- "Surgeon was given opportunity preoperatively to review surgical DVD, OR manual, IFU [information for use], scientific articles prior to his first case. Obvious at the time of surgery, he had done nothing prior to OR case. Literally, had to talk him thru each step of the procedure."
- "[Surgeon] asking where to place an implant and if that looked good."
- "Our current medical environment does not allow for a 'sales rep' to question the ability of a surgeon regardless of the patient outcome. There is no 'whistle blower law' in healthcare. The rep

would lose their ability to call on the hospital and likely lose their job."

DISCUSSION

This study has several limitations, including sample size and its self-selected nature, that limits its generalizability and also creates the possibility that the responses were skewed in the direction of those who have had previous concerns about HCIRs in the OR. The survey was not standardized and was developed specifically for the purposes of this research. Therefore, the generalizability of the results is highly limited, but the data do indicate that some HCIRs have serious ethical concerns. The data were analyzed using descriptive statistics only, as more sophisticated analyses were precluded by the small sample and unstandardized nature of the questionnaire. Nevertheless, the purpose of the study is to elucidate some segment of the experiences and perceptions of self-selected HCIRs for the purposes of initiating a conversation and exploring an understudied area.

The results of the survey are consistent with the generally held view that HCIRs are often called upon to provide verbal instruction or a demonstration on some aspect of their medical device or instrument to ensure its proper use or placement. Most of the respondents, almost 90 percent, reported providing verbal information to surgical teams during the surgeries the respondents attended in the past year. This result is consistent with the well-recognized and accepted role of HCIRs in the operating room during surgery. Moreover, the data suggest that, as expected, most HCIRs' actions and interactions during the course of surgery fall within the accepted professional boundaries of their role and therefore do not raise ethical or professional concerns. The results also suggest, however, that for some HCIRs there are very serious ethical, professional, and even legal issues that appear to violate current professional guidelines.

Although the minority of HCIRs in the study (about 20 percent) reported being asked in the past year to have physical contact with the surgical team or patient, it appears that, for some HCIRs, situations have arisen over the course of their careers in which they perceived their involvement as excessive. We do not know the time frame of these reported events. Moreover, about 40 percent of the HCIRs reported that within the past year they had had concerns about the competence of the surgeon in the OR regarding his or her area of expertise. Although these data do not allow for generalization,

TABLE 1. Survey items and descriptive statistics (*N* = 43)

	Yes		No	
Survey item	%	*n*	%	*n*
For those cases that you have personally attended in the last year, were you asked to have physical contact with the surgical team or patient? (e.g. were you asked by the surgeon, first assistance, scrub nurse, or any other member of the surgical team to hand off a blade or suture, to help position the patient on the table, etc.)	20.9	9	79.1	34
For those cases that you have personally attended in the last year, did you provide verbal instruction to the surgical team in order to facilitate the use or placement of your device/product?	88.4	38	11.6	5
As you think about the surgical cases you have attended over the last year, did your degree of involvement (either hands-on involvement, verbal instruction, or demonstration) exceed your professional comfort level?	7.0	3	93.0	40
In your entire career as a Healthcare Industry Representative, have you attended a surgical case where you felt that your involvement was excessive?	37.2	16	62.8	27
In your entire career as a Healthcare Industry Representative, have you attended a surgical case where you felt that your involvement exceeded your professional comfort level?	30.2	13	69.8	30
In the last year, have you attended a surgical case where you questioned the competence of the surgeon relative to your area of expertise?	39.5	17	60.5	26
Did you discuss these ethical issues with your supervisor, surgeon, or others?	72.1	31	27.9	12
Have you been satisfied with how these ethical issues have been handled? [Of those who did discuss ethical issues.]	43.3	13	56.7	17

we can say these perceptions do exist, if only to a limited extent, and that they warrant further investigation and scrutiny. As the qualitative data illustrate, there are indeed situations in which surgical teams have relied excessively on an HCIR in order to complete a surgery, which raises two key medical ethical issues.

The first issue is the inappropriate touching of patients by HCIRs. Most hospitals and medical device manufacturers have strict rules regarding the interaction of HCIRs with patients and surgical teams. Unauthorized touching of patients can constitute battery or medical battery, depending upon how broadly or narrowly a consent form is written. Many medical device companies and hospitals have guidelines that prohibit HCIRs from touching patients. Unauthorized touching could conceivably result in a battery charge against an HCIR, and additional legal action against the employers, if a patient was made aware of it. Additionally, when HCIRs hand off sterile items to a surgical team, it poses significant issues. Clearly there could be serious risks and complications for patients if HCIRs fail to observe sterile technique while handing off an instrument blade. Based on HCIRs' reports in the survey results, it appears the potential for such situations occur on a limited but regular basis.

Currently, the AMA and the ACS have differing opinions on whether a patient's prior approval needs to be formally documented when an HCIR is going to be present in the OR. The AMA's position is, "If industry representatives are present during patient-physician encounters, physicians or their designees must obtain the patient's approval" (see E-5.0591, "Patient Privacy and Outside Observers to the Clinical Encounter"). "Although this does not require a formal informed consent process, patients should be informed regarding the role that the representative will have in facilitating the care of the patient."[16]

The ACS's position forcefully advocates the necessity to have a written, signed consent document that is entered as a part of the medical record: "The patient should be informed of the presence and purpose of the HCIR in the OR and give written, informed consent. This should be documented within the medical records."[17] A written record provides verifiable evidence that the patient was aware of the HCIR's presence and assented to it, which in turn provides a necessary protection to the HCIR, physician, and institution. The ACS does not address the issue of a patient's refusal to allow an HCIR into the OR, however. The AMA has drafted guidelines to address this issue:

> The patient may accept or refuse the representative's participation. If the absence of the representative jeopardizes the patient's welfare, the physician must find someone else who is able to provide the necessary assistance. If no alternative is available and the patient persists in refusing the presence of the expert representative, the physician should offer an alternative treatment or cancel the procedure in the interest of patient safety.[18]

The second ethical issue pertains to breaching the appropriate boundaries of HCIRs in the OR. As the data indicate, at times HCIRs are reported to be called upon to provide guidance and make decisions that affect clinical outcomes. Any attending surgeon who calls upon an HCIR to participate in this manner is potentially forsaking his or her professional, fiduciary responsibility to act in the best interest of the patient. It is clearly wrong to put HCIRs in situations in which they must make decisions and provide guidance that will directly impact the clinical outcome of a surgery. It raises the possibility that the surgical team has neglected its obligation to be technically competent, which could have serious legal implications. While HCIRs and medical device manufacturers do not have a legal duty to warn patients or supervise surgeons' use of a manufacturer's product, HCIRs are putting themselves and their employers at risk of liability when they are called upon to make medical decisions that fall outside the scope of their role and training.[19] HCIRs' participation, regardless of the level of their skills, cannot be a substitute for a physician's proficiency to perform the procedure in question.

It appears that, in some cases, the expertise of HCIRs is being substituted for technical proficiency. HCIRs typically feel that they have no recourse when put into this situation. Thus, there is a concern on the part of HCIRs that while they may desire to bring issues of medical competence or even malpractice to the attention of a hospital or their employer, there is a real fear that they may be terminated or suffer some sort of retaliation for doing so. To our knowledge, there are no formal mechanisms for raising and addressing ethical concerns about which only HCIRs and surgeons have direct knowledge and involvement.

Moreover, given the power dynamics of the OR, where the surgeon is completely in charge, other team members may not feel comfortable raising questions about decisions that are being made in the moment. The role and effect of silence and fear in the physician-nurse relationship is well docu-

mented.[20] Depending upon the culture of the institution where the surgery is being performed and the attitude of the surgeon, team members may feel they need to remain silent for fear of retribution for raising legitimate concerns. Nevertheless, we believe increased anonymous feedback from surgical team members, particularly nurses, regarding their perceptions of the interaction between HCIRs and surgeons would further elucidate the prevalence of ethical concerns in this area.

HCIRs have other types of disincentives to speak up. Given that the surgeon is responsible for the financial remuneration that an HCIR receives, there is a distinct disincentive for an HCIR to raise any concerns or issues with the institution where the surgery was performed. Perhaps this is part of the reason why some HCIRs do not speak with their supervisor or the surgeon, and why many feel dissatisfied with how ethical issues have been handled. Finally, we do not know the correlation between the length of time an individual has worked as an HCIR and that individual's concerns about professional violations. In the present study, the average number of years that respondents had been employed as an HCIR was 17. Although there is value in hearing from seasoned HCIRs, newer HCIRs may not share the same concerns or may have other concerns.

CONCLUSION

An HCIR plays an important role in ensuring the success of a surgery. In most cases, an HCIR's involvement is limited to providing verbal guidance and a demonstration to ensure the proper use and placement of a medical device or instrument. Excessive involvement in surgery by HCIRs that has a direct impact on clinical decision making, however, raises significant ethical issues regarding the blurring of professional boundaries and obligations. This is an area about which little is known except for anecdotal reports by HCIRs. Further investigation and scrutiny of this area are needed.

At the very least, medical device companies, perhaps in conjunction with hospitals and hospital ethics committees (HECs), need to provide HCIRs adequate education about ethical and professional boundaries and obligations, as well as provide them with a formal mechanism through which they can be heard if they raise ethical concerns. This mechanism needs to be readily accessible, as concerns may arise quickly during the course of a surgery. An open but interesting question is the extent to which an HEC could be part of the solution in creating such a mechanism.

NOTES

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15. Ibid.

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