Undisclosed Surgical Incentives Compromise Informed Consent

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INTRODUCTION

Rigorous oversight has achieved great success in ensuring fully informed consent from patients when choosing to take prescription drugs. As concerns about the influence of pharmaceutical gifts on physicians have increased, state legislatures have adopted statutes intended to reduce the influence of such gifts; "sunshine laws" require pharmaceutical companies to disclose gifts to doctors. The Department of Health and Human Services Office of the Inspector General has issued industry guidance that delineates marketing that is not permissible.[1] The Patient Protection and Affordable Care Act requires drug companies to disclose payments made to physicians for consulting, speaking and travel.[2]

Full disclosure and transparent reporting enable patients to discern financial motive or any other incentive a physician may have in prescribing drugs, but when patients seek a new procedure or innovative surgery, achieving informed consent is challenging without a regulating body's control.

BACKGROUND

Informed consent constitutes a process in which a fully informed patient can take part in decisions about his or her health care.[3] Informed consent is based on the principle that people are the best guardians of their own interests. Elements of informed consent include disclosure, cognition and a process of consent, refusal or choice. This

paper shall focus on the current gap in disclosure requirements in doctor-patient dialogue regarding surgeries or other procedures and the impacts of that gap.

While state and federal oversight have enhanced informed consent among patients in regards to pharmaceuticals, safeguarding informed consent is more challenging when providing care dependent on the skill of a surgeon or when seeking a new procedure without the control of a regulating body. This difficulty can be remedied through increased oversight, with the burden upon both the physician and health care facility to pursue objective evidence of benefit and risks and then disclose such data to the patient.

CYTOREDUCTIVE SURGERY WITH HYPERTHERMIC CHEMOTHERAPY (HIPEC)

HIPEC is a complex surgical procedure now offered to patients with advanced cancers of the gastrointestinal tract without definitive evidence of benefit. HIPEC involves surgical removal of all visible metastatic cancer within the abdominal cavity and the instillation of heated chemotherapy in the cavity to penetrate the surfaces; the goal is to eradicate all metastatic disease.[4]

HIPEC was popularized by Paul Sugarbaker, MD, to treat the rare condition of pseudomyxoma peritonei, a complication of appendix cancer. Appendix cancer affects 1,500 Americans annually, while pseudomyxoma peritonei occurs in one to two per million per year.[5] The success of HIPEC to eradicate disease in this rare condition led to the extrapolation of the approach to other cancers of the gastrointestinal tract that have spread within the abdominal cavity, mainly colon cancer.

Due to the complexities of randomized studies of surgical procedures, scant evidence exists showing HIPEC works for metastatic colon cancer. One randomized study showed that patients undergoing HIPEC lived an average of 22.4 months post-surgery, while those who pursued traditional chemotherapy lived only 12.6 months.[6] However, the study's flaws were rampant. Those who pursued chemotherapy alone received a now outdated regimen; average current survival for chemotherapy alone is more than 22 months.[7] Second, the extent of disease was known only in those patients who underwent surgery; a wide variation in survival existed dependent on those with small volume as compared to large volume disease (29 months and 5 months, respectively). The extent of disease for the control group, those receiving chemotherapy alone, is not known. Third, 8 percent of surgical patients died in the post-operative period.

A recent retrospective review of the experience at the Roswell Park Cancer Institute, in Buffalo, New York, over an eight-year period supports a benefit of HIPEC for colon cancer with intra-abdominal spread.[8] Of 38 patients treated in this manner, the five-year overall survival rate was 38 percent. Using standard chemotherapy regimens for advanced colon cancer during this time period, the expected five-year survival rate would be less than 10 percent. The limitations of this study are its retrospective and nonrandomized design. It is important to note that in this series, the five-year overall survival rate for appendix cancer treated with HIPEC, its original intent, was greater than 66 percent.

Despite scant evidence of efficacy, patients—anecdotally younger, healthier and wealthier—seek out this treatment, and the number of physicians offering it has increased. David Ryan, MD, a gastrointestinal oncologist at Massachusetts General Hospital, has noted that HIPEC's use has been growing due to the inability of surgeons to make a living performing it only on appendix cancer patients, its original intent.[9]

Because such an innovative surgery involves a departure from standard practice, greater caution and regulation is needed for a number of reasons. When that innovation is in the surgeon's self interest, the surgeon's judgment about the patient's best interest may be clouded. Surgeons may hold an economic interest in promoting the procedure, they may fear being left behind the curve of medical advancement, or they may be influenced by a desire for rewards.[10]

LESSONS LEARNED

By the late 1980s, nearly every American academic medical center had established bone marrow transplantation programs for the treatment of breast cancer after several small, uncontrolled phase 1 and 2 studies suggested that high-dose chemotherapy with autologous bone marrow transplantation resulted in better outcomes than would have been expected with standard chemotherapy alone. A single randomized study, in 1995, supported this hypothesis.[11] As a result of this single study, an estimated 30,000 breast cancer patients in the U.S. received bone marrow transplants between 1985 and 1998. Despite scant data, the presumption of benefit was widespread.[12]

In an attempt to ensure objective evidence of efficacy, multiple academic institutions pursued rigorous randomized clinical trials comparing high-dose chemotherapy with autologous bone marrow transplant to standard chemotherapy for all stages of breast cancer. In 1999, results of five randomized trials were presented at the American Society of Clinical Oncology meeting, only one of which supported the therapy's use. That study was conducted by the same investigators who presented the first data in 1995. An on-site investigation and review of records of the institution revealed scientific misconduct, including no signed informed consent and no institutional review board approval. The results of both studies were retracted.[13] Medical centers moved to shutter their programs.[14]

The same conflicts at play in the decision to perform HIPEC are evidenced in this historical lesson. Academic medical centers opened programs as others did, maintaining competitiveness in the fast-moving field of cancer care. Doctors performed transplants on little data; if they did not, these women—often desperate—would go elsewhere in search of a doctor willing to perform the procedure. There was little regulation over tens of thousands of treatments that were later deemed to have no proven benefit.

CONCLUSION

Conflicting values and interests among physicians and patients are inescapable. When disclosure is required in cases in which an outside commercial entity may profit, such as pharmaceutical companies, patients are made better aware of any reason outside of his or her best medical interest for which he or she may be prescribed a drug.

In the absence of a regulatory body, patients are at risk of incomplete disclosure. Such incomplete disclosure impedes informed consent in these medical instances of pursuing surgeries or other procedures. Outside interests, such as prestige sought by a physician, financial gain, or support of a burgeoning academic program may induce medical providers to encourage or perform a surgery or procedure absent data regarding efficacy. Patients may be unaware of the need of the physician or hospital to justify the expense of these programs, such as those currently opening for HIPEC treatment, or those that performed bone marrow transplants on breast cancer patients.

In such cases in which statutory framework is nonexistent and in which no federal agency governs medical care with clear rules, it is the responsibility of physicians to both ensure that true informed consent is secured and expose their motivation, in the absence of objective data, to this vulnerable population.

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