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ORIGINAL ARTICLE – BREAST ONCOLOGY

The Ethics of Breast Surgery

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ABSTRACT Breast surgery has evolved as a subspecialty of general surgery and requires a working knowledge of benign and malignant diseases, surgical techniques, shared decision-making with patients, collaboration with a multidisciplinary team, and a basic foundation in surgical ethics. Ethics is defined as the practice of analyzing, evaluating, and promoting best conduct based upon available standards. As new information is obtained or as cultural values change, best conduct may be re-defined. In 2014, the Ethics Committee of the ASBrS acknowledged numerous ethical issues, specific to the practice of breast surgery. This independent review of ethical concerns was created by the Ethics Committee to provide a resource for ASBrS members as well as other surgeons who perform breast surgery. In this review, the professional, clinical, research and technology considerations that breast surgeons face are reviewed with guidelines for ethical physician behavior.

Breast surgery has evolved as a subspecialty of general surgery complete with a specialty society (The American Society of Breast Surgeons—ASBrS) and dedicated fellowship-training programs. The practice of breast surgery requires a working knowledge of benign and malignant diseases, surgical techniques, shared decision-making with patients, collaboration with a multidisciplinary team, and a basic foundation in surgical ethics.

Ethics is defined as the practice of analyzing, evaluating, and promoting best conduct based on available standards. As new information is obtained or as cultural values change, best conduct may be redefined. In the 1900s, William Halsted, arguing for beneficence and citing measured results, convinced the surgical world that his operation would extend the lives of those affected by breast cancer. An understanding that different surgical approaches provide equal outcomes, as well as an emphasis on patient autonomy and informed consent, has influenced the second half of the twentieth century. These principles continue to be cornerstones of breast cancer care today; however, a number of ethical issues are unique to breast surgery. In this review, the professional, clinical, research, and technology considerations that breast surgeons face are reviewed with guidelines for ethical physician behavior.

METHODS

In 2014, the Ethics Committee of the ASBrS acknowledged numerous ethical issues specific to the practice of breast surgery. Prior ethics-related issues had been limited to conflicts of interest (COI) regarding industry relationships with ASBrS board members. This independent exercise by the Ethics Committee provides a resource for ASBrS members, as well as other surgeons who perform breast surgery. The final draft of this manuscript was submitted to the ASBrS Publications Committee and endorsed by the Board of Directors.

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Professional Ethical Duties

Patients with breast cancer in the modern era often are well informed. The diagnosis often is made in the outpatient setting, providing the opportunity to seek information before the initial consultation. The previous "paternalistic" era, when treatment plans were given to the patient by the physician, has been replaced by a more contemporary model of "shared decision making," integrating the physician's professional expertise with patient values and expectations.[1]

Ethical principles (below) provide guidance to the physician throughout this process. Respect for persons/autonomy obliges the physician to respect the patient's wishes and guides care in accordance to the patient's values and preferences.[2,3] Beneficence promotes the best interest of the patient by maximizing clinical benefit and minimizing harm.[2] Upholding the principle of beneficence includes full disclosure of therapeutic options, including the absence of intervention if therapeutic benefit is low.[4] Nonmaleficence, most well known as "do no harm," indicates that physicians should not cause or intentionally harm the patient by acts of either commission or omission.[2,5] Surgery is somewhat unique in that there is always inherent risk, including postoperative pain, change in appearance, risk related to comorbid conditions, and potential complications.[6] Surgeons must inform patients of these risks and minimize potential for harm. Justice mostly focuses on access and barriers to health care. Under the principle of justice, patients with similar clinical situations should be afforded similar access to resources and equal therapeutic options, regardless of age, gender, race, sexual orientation, socioeconomic status, educational level, or religious practice.[4] These principles are nonhierarchical, or *prima facie*; no one principle is superior to the other. When applying these principles, it is the responsibility of the treating physician to determine which principle is the most morally compelling.[5,6] At any time that a significant conflict arises, consultation of an ethics committee should be considered. If an institutional committee is not available, one can obtain clinical consultation by contacting the American Society of Bioethics and Humanities (www.asbh.org).[2]

Clinical Ethical Duties

Surgical Treatment With these above-mentioned principles as the foundation for ethical practice, there are special clinical considerations in breast surgery. The practice of breast cancer surgery is unique, because surgical options—breast conservation and mastectomy—have equivalent oncologic outcomes; therefore, patients should be presented with an unbiased discussion of surgical options for local treatment of breast cancer. Providers should avoid projection bias in which the provider influences surgical decision making with his/her preferences.[7] Patient preference should be honored when medically equivalent treatment options are available. Preoperative therapies, such as neoadjuvant chemotherapy or endocrine therapy, that maximize the chance a patient could choose less invasive surgery should be considered and discussed with the patient, whenever possible. Discussion of prophylactic procedures must include the same elements of informed consent as any other surgical procedure, including an honest discussion of the risks and benefits of the procedure. Studies have demonstrated that reconstruction does not compromise the oncologic outcome; therefore, patients who are candidates for reconstructive surgery should have the opportunity to consult with a plastic surgeon when medically appropriate.[8–10] Support for these clinical principles are provided by the National Accreditation Program for Breast Centers (NAPBC), which has standards requiring surgeons to offer breast-conserving surgery to appropriate candidates and reconstructive surgery consultations to those having mastectomies.[11]

Genetic Testing The ethical issues surrounding genetic counseling/testing are one of the important aspects of breast surgery. With the completion of the human genome project and the increasing understanding of the role of oncogenes and tumor-suppressor genes, more patients are undergoing genetic testing to identify mutations that increase the risk of cancer. Genetic counseling and potential testing should be offered to patients with personal or family history suggestive of a hereditary breast cancer syndrome, according to National Comprehensive Cancer Network (NCCN) guidelines. This consultation should be done in conjunction with a certified genetic counselor or by a practitioner well educated about genetic testing. Patients must be informed of the potential for positive, inconclusive, or negative results and counseled as to the clinical applicability of test results.[12] With newer multigene panel testing available, mutations can be found in moderate-risk genes for which evidence-based management recommendations are not available, and surgeons should not offer prophylactic mastectomies based on these results alone.

Patients should be aware of the possible emotional impact of a positive test result, as well as potential for genetic discrimination. The federal Genetic Information Nondiscrimination Act of 2008 protects against discrimination, and patients should be made aware of this.[13] Assistance with disclosure of results to potentially affected family members should be offered to patients with positive results.[14] For patients who do not wish to disclose their

positive results, the physician is obligated to protect the patient's right to confidentiality as dictated by the Health Insurance Portability and Accountability Act (HIPAA). In situations where the provider believes serious harm may result with nondisclosure of test results, an ethics consultation should be obtained[15]

Following Clinical Guidelines Much of breast cancer treatment, including surgery, is dictated by clinical guidelines, consensus statements, and evidence-based medicine. Clinical practice guidelines, as a surrogate to define "standards of care," aim to encourage quality of care through evidence-based treatments and attempt to reduce healthcare disparities. Economically they play an increasing role in guiding reimbursements and containing health care costs.[16] For breast surgery, there are numerous clinical practice guidelines from groups, including but not limited to: NCCN, American Cancer Society, American Society of Clinical Oncology, St Gallen International Breast Cancer Guidelines, as well as NAPBC.

Lack of compliance with published guidelines may result from inherent limitations in the guidelines themselves or be physician or patient driven. When various organizations within a single specialty create separate guidelines, such as for patient selection for accelerated partial breast acceleration from ASBrS, ASTRO, and the American Brachytherapy Society, measuring adherence can be difficult.[17–19] The clinical adoption of changes in evidence-based medicine can lead to nonadherence, either from resistance of a physician to change practice, slow dissemination of changes in practice recommendations, or changes in physician practice that may outpace updates in guidelines. Several studies looking at guideline nonadherence exist in the breast oncology literature, although most examine adjuvant therapy guidelines rather than surgical management. Most cited reasons for guideline nonadherence in these studies include patient autonomy, practice of evidence-based medicine prior to change in guidelines, system differences, and access disparities.[20–27]

When the provided care deviates from guidelines or perceived standards, the reasons for deviation should be well-documented and communicated to the patient, other care providers, and potentially their payers. If conflicts arise, consideration should be given to involving the institution's ethics committee.

Informed Consent and Refusal of Treatment

The basis of informed consent is patient autonomy and the right of the patient to protect his or her interests and privacy. It requires that before providing treatment the surgeon provides adequate information about the nature and purpose of the treatment. There should be a balanced discussion of the treatment, including risks and benefits. Alternative treatments and their risks and benefits as well as the consequences of no treatment also should be discussed. Informed consent includes the right to refuse care. Competent patients have the right to make decisions regarding the refusal or termination of treatment for themselves as established by the 1986 case, *Bouvia v Superior Court*. Consent can be withdrawn at any time. Whether the reason is rational or irrational, the decision is legally binding and the surgeon must respect the patient's choice, as long as the patient has decisional capacity. For example, a patient may refuse any treatment for a locally advanced breast cancer or after achieving a complete clinical response after neoadjuvant therapy; a patient may refuse surgery, although microscopic disease may remain. Decisional capacity includes the ability to communicate choice, understand relevant information, appreciate possible consequences, and manipulate information rationally.[28–30] If the physician believes the patient to be incompetent and is refusing an apparently beneficial treatment, the physician should request an evaluation by a psychiatrist to determine competency. Some states require that hospitals obtain consent for no treatment, a document that contains a release of medical responsibility and any associated liability.[31] In summary, competent patients, in any state of health, can refuse any medical care.[32]

Limiting Treatment There are times when it may be medically and ethically appropriate not to initiate a treatment (withhold) or to stop a current treatment (withdrawal). Most bioethicists and courts consider withdrawing and withholding care equally justifiable.[33] It is advisable for providers faced with the decision of withholding or withdrawing care to be familiar with institutional policies and their state law. Most institutions support initiating care that will prolong life if there is any uncertainty. Uncertainty can be avoided by ensuring that a patient or his or her surrogate understands the illness, prognosis, and expected quality of life and the provider understands the patient's values. In the absence of a healthcare power of attorney, who serves as the surrogate varies by state law. Treatments not congruent with the patient's values may then be withheld or discontinued. The American Medical Association's Education for Physicians on End-of-life Care curriculum includes the "Eight-Step Protocol to Discuss Withholding or Withdrawing Therapy."[34]

RESEARCH ETHICAL DUTIES

Advances in breast cancer care would not have been achieved without the participation of women and men in clinical trials. Physicians are encouraged to participate in

research by enrolling patients in clinical trials when available. However, there are specific ethical concerns with regards to research participation. Many of these issues are outlined in the Belmont Report.[35]

Treatment trials must involve clinical equipoise or lack of consensus regarding the most effective treatment. It would be unethical to enroll patients in a trial where one intervention is known to be more effective than the other. Additional requirements for clinical research include having the potential to enhance health or knowledge, methodologic rigor, risk and benefits of the research must be distributed fairly between groups, benefit must outweigh risks, well-being of research subjects is monitored, consent is voluntary, privacy is protected, and research is approved by an independent body.[36]

Informed consent for trial participation must appropriately describe the research activity involved, the anticipated outcome if known, and potential adverse events. There is no standardization for this process and physicians must refer to their institutional guidelines. Finally, there has been an increasing focus on COI in research. To maintain integrity, the impact of COI must be considered in the interpretation of research results. There are increasing requirements for self-disclosure, including those for authorship in biomedical journals, scientific meeting faculty, and for clinical researchers.[36]

ETHICS OF TECHNOLOGY

Physicians and surgeons have partnered with industry to develop and translate their ideas into important innovations in patient care. Examples include percutaneous core biopsy devices allowing patients to undergo minimally invasive biopsies instead of operative surgical biopsy, improved electrocautery instruments for facilitating dissection, hemostatic agents, and devices to "accelerate" or decrease the length of time required to administer radiation therapy. However, care must be taken to introduce new medical devices and techniques to ensure patient safety and adherence to the highest quality of care. As physicians, whether it is a new device or procedure, there is an ethical responsibility to have the appropriate institutional support, a defined need to support the use of this new technology, and appropriate background laboratory evidence. Whenever implementing new treatment changes, a full disclosure to the patient, including any COI, concerning this new technology is required. The "surgical scientist" must always avoid exploiting the willingness of patients to try something new in a desperate situation, such as patients with severe or life-threatening illnesses. It is the surgeon, not the patient, who should judge the appropriateness of a new procedure or device in these cases.

Physician-industry relationships and concerns regarding COI have spurred a national effort by the federal government to make such financial ties more transparent. The Open Payments program, otherwise known as the Physicians Payment Sunshine Act, requires that pharmaceutical and device companies report payments made to physicians and teaching hospitals.[37]

When introducing new technology or new surgical techniques, the surgeon should disclose not only the potential benefits of the innovation but also the known and potential risks associated with it. This discussion may require disclosing uncertainty to the patient. In this scenario, the fundamental ethical principles must be respected.[38]

Finally, another critical ethical consideration in the era of modern medicine is the use of social media and the internet in the care of and communication with our patients. Physicians can protect themselves and their patients by observing the same code of ethics and professionalism online as they do in practice. To define an appropriate boundary between physician and patient, surgeons should maintain separate personal and professional social media sites. Patient confidentiality must be maintained at all times in compliance with HIPAA.[39] Stringent privacy settings should be used to avoid dissemination of unintended content. The most common breaches of HIPAA occur from direct communication with patients on social media and inadvertent posts of employees to personal social media accounts. Inappropriate posts have the potential to harm the physician, practice associates, hospitals, and patients.[40]

With the use of internet-based platforms, appropriate technical safeguards must be in place to protect the patient against breach of private medical records. For example, many practices now have an internet-based patient portal, which may lead to the unintended sharing of protected health information. Also, practices that collect credit card information for billing and provide Wi-Fi in the office must ensure appropriate electronic security measures. Patients who participate with online support groups or blogs must be counseled that these sites may not protect their confidentiality.[41] Use of social media for clinical trial recruitment should be done only with approval of the Institutional Review Board. In summary, awareness and education are key factors in protecting confidentiality of health information online.

CONCLUSIONS

For breast surgeons, advances in medical, surgical, and radiation treatment have added to the complexity of the treatment plan available to each individual patient. The environment in which physicians practice is changing with

shifts in practice structures, expanding use of social media, and pressure to separate industry from surgical practice. To continue to be successful at our primary goal, the compassionate and excellent care of patients with diseases of the breast, we must keep a solid foundation of ethical principles in addition to medical knowledge and technical proficiency.

REFERENCES

1. Andersson GB, Chapman JR, Dekutoski MB, et al. Do no harm: the balance of "beneficence" and "non-maleficence." *Spine*. 2010;35(suppl 9):S2–8.
2. Rosenthal, Angelos P, Cooper DS, et al. Clinical and professional ethics guidelines for the practice of thyroidology. *Thyroid*. 2013;23:1203–10.
3. Rosenthal MS. Ethical issues in the management of thyroid disease. *Endocrinol Metab Clin North Am*. 2014;43:545–64.
4. University of Ottawa medical curriculum: Basic Ethical Principles. Basic Concepts in Medical Ethics page. Society, the Individual, and Medicine website. http://www.med.uottawa.ca/sim/data/Ethics_e.htm. Accessed 1 Dec 2014.
5. McCormick TR. Principles of bioethics. [University of Washington School of Medicine Department of Bioethics & Humanities Ethics in Medicine website, Bioethics Tools] 2013 (last modified October 1, 2013). https://depts.washington.edu/bioethx/tools/princpl.html. Accessed 1 Dec 2014.
6. Adedeji S, Sokol DK, Palser T, McKneally M. Ethics of surgical complications. *World J Surg*. 2009;33:732–7.
7. Loewenstein G. Projection bias in medical decision making. *Med Decision Making*. 2005;25:96–105.
8. Langstein HN, Cheng MH, Singletary SE, et al. Breast cancer recurrence after immediate reconstruction: patterns and significance. *Plast Reconstr Surg*. 2003;111;712–20.
9. Kroll SS, Schusterman MA, Tadjalli HE, Singletary SE, Ames FC. Risk of recurrence after treatment of early breast cancer with skin-sparing mastectomy. *Ann Surg Oncol*. 1997;4:193–7.
10. Foster RD, Esserman LJ, Anthony JP, Hwang ES, Do H. Skin sparing mastectomy and immediate breast reconstruction: a prospective cohort study for the treatment of advanced stages of breast carcinoma. *Ann Surg Oncol*. 2002;9:462–6.
11. National Accreditation Program for Breast Centers. *NAPBC Standards Manual*. 2014 ed. Chicago: American College of Surgeons; 2014. https://www.facs.org/~/media/files/quality%20programs/napbc/2014%20napbc%20standards%20manual.ashx. Accessed 15 May 2015.
12. Moyer VA, U.S. Preventive Services Task Force. Risk assessment, genetic counseling, and genetic testing for BRCA-related cancer in women: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2014;160:271–81.
13. The Genetic Information Nondiscrimination Act of 2008. http://www.eeoc.gov/laws/statutes/gina.cfm. Accessed 20 May 2015.
14. Patenaude AF, Dorval M, DiGianni LS, Schneider KA, Chittenden A, Garber JE. Sharing BRCA1/2 test results with first-degree relatives: factors predicting who women tell. *J Clin Oncol*. 2006;24:700–6.
15. Surbone A. Social and ethical implications of BRCA testing. *Ann Oncol*. 2011;22:160–6.
16. Irwin B, Peppercorn J. Promise and perils of guidelines in quality cancer care. *J Oncol Pract*. 2012;8:354–7.
17. American Society of Breast Surgeons Consensus Statement on Accelerated Partial Breast Irradiation. 2011. https://www.breastsurgeons.org/new_layout/about/statements/index.php. Accessed 15 May 2015.
18. Smith B, Arthur DW, Buchholz TA. Accelerated Partial Breast Irradiation Consensus Statement from American Society for Radiation Oncology (ASTRO). *Int J Rad Oncol Biol Phys*. 2009;74:987–1001.
19. Shah C, Vicini F, Wazer DE, Arthur D, Patel RR. The American Brachytherapy Society consensus statement for accelerated partial breast irradiation. *Brachytherapy*. 2013;12:267–77.
20. Thuerlimann B, Koeberle D, Senn H. Guidelines for the adjuvant treatment of postmenopausal women with endocrine-responsive breast cancer: past, present and future recommendations. *Eur J Cancer*. 2007;43:46–52.
21. Verma S, Trudeau M. Canadian oncologists attitudes towards guideline development and outcomes of clinical trials based on results of the ATAC trial [abstract]. *Proceedings of the 26th Annual San Antonio Breast Cancer Symposium*. December 3–6; 2003. Abstract 657.
22. Palazzi M, De Tomasi D, D'Affronto C, et al. Are international guidelines for the prescription of adjuvant treatment for early breast cancer followed in clinical practice? Results of a population based study on 1547 patients. *Tumori*. 2002;88:503–6.
23. Roila F, Ballatori E, Patoia L, et al. Drug utilization review team in oncology. Adjuvant systemic therapies in women with breast cancer: an audit of clinical practice in Italy. *Ann Oncol*. 2003;14:843–8.
24. Hebert-Croteau N, Brisson J, Latreille J, et al. Compliance with consensus recommendations for systemic therapy is associated with improved survival of women with node-negative breast cancer. *J Clin Oncol*. 2004;22:3685–93.
25. Bloom BS, de Pouvourville N, Chhatre S, Jayadevappa R, Weinberg D. Breast cancer treatment in clinical practices compared to best evidence and practice guidelines. *Br J Cancer*. 2004;90:26–30.
26. Landercasper J, Dietrich LL, Johnson JM. A breast center review of compliance with National Comprehensive Cancer Network Breast Cancer guidelines. *Am J Surg*. 2006;192:526–7.
27. Wu X-C, Lund MJ, Kimmick GG, et al. Influence of race, insurance, socioeconomic status, and hospital type on receipt of guideline-concordant adjuvant systemic therapy for locoregional breast cancers. *J Clin Oncol*. 2012;30:142–8.
28. Lim T, Marin D. The assessment of decisional capacity. *Neuro Clin*. 2011;29:115–26.
29. Sessums LL, Zembrzuska H, Jackson JL. Does this patient have medical decision-making capacity? *JAMA*. 2011;306:420–7.
30. Brendel RW, Wei MH, Schouten R, Edersheim JG. An approach to selected legal issues: confidentiality, mandatory reporting, abuse and neglect, informed consent, capacity decisions, boundary issues, and malpractice claims. *Med Clinic NA*. 2010;94:1229–40.
31. Paterick T, Carson G, Allen M, et al. Medical informed consent: general considerations for physicians. *Mayo Clin Proc*. 2008;83:313–9.
32. Emanuel E. A review of the ethical and legal aspects of terminating medical care. *Am J Med*. 1988;84:291–301.
33. Braddock CH III. Do different standards apply to withholding and withdrawing care? Termination of Life-Sustaining Treatment. [University of Washington School of Medicine Department of Bioethics & Humanities Ethics in Medicine website, Bioethics Topics]. 1998 (last modified April 6, 2009). https://depts.washington.edu/bioethx/topics/termlife.html#vs. Accessed 8 May 2015.
34. Ackerman RJ. Withholding and withdrawing life-sustaining treatment. *Am Fam Phys*. 2000;62:1555–60.
35. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report:

Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Bethesda, MD: US Government Printing Office; 1978. http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html. Accessed 15 May 2015.
36. McDonald PJ, Kulkarni AV, Farrokhyar F, Bhandari M. Ethical issues in surgical research. *Can J Surg*. 2010;53:133–6.
37. Transparency reports and reporting of physician ownership or investment interests. Social Security Act. Section 1128G. http://www.ssa.gov/OP_Home/ssact/title11/1128G.htm. Accessed 20 May 2015.
38. Angelos P. Surgical ethics and the challenge of surgical innovation. *Am J Surg*. 2014;208(6):881–5.
39. Shore R, Halsey J, Shah K, et al. Report of the AMA council on ethical and judicial affairs: report on professionalism and use of social media. *J Clin Ethics*. 2011;22:165–72.
40. Professionalism in the use of social media. Code of Medical Ethics of the American Medical Association [e-book]. 2014–15 edn. American Medical Association, Chicago. Sec 9.124:641–848.
41. Shay D. Physician use of social media: navigating the risk. *Med Econ*. 2014;25:44–6.