Bioethics and Medicolegal Aspects in Breast Cancer Reconstruction

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73.1 Introduction

The integration of bioethics in reconstructive breast cancer surgery is essential, because few diseases represent such a complexity from the scientific, psychological, therapeutic, ethical, and social point of view as breast cancer. Surgeons who are dedicated to this delicate field of work face daily situations that demand great sensibility and deep bioethical and medicolegal analysis.

Bioethics is one of the most dynamic emerging fields of philosophy applied to professional praxis and research in biotechnology and in medical practice. Although bioethics was born in the USA in 1970, in Brazil and in Latin America, it appeared only in the mid-1980s and is considered now as late bioethics within the global scenario. Yet, it has been taking an increasing importance among the main specialized medical societies and medical associations. That is so because of its relationship with both individual and professional dilemmas that affect health professionals, legislators, and citizens. Therefore, this chapter will approach the most relevant bioethical issues and medicolegal aspects concerning breast cancer treatment, with a special focus on breast reconstruction.

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73.2 Current Concept

The concept that has come the closest to the ideal that bioethics proposes was elaborated by Reich in 1995 in his *Encyclopedia of Bioethics*: "A systematic study of the moral dimensions – including moral visions, decisions, conduct, and policies – of the life sciences and health care, employing a variety of ethical methodologies in an interdisciplinary setting" [1].

Bioethics must be considered a tool for medical decision-making, although being interdisciplinary is its most important characteristic. This is what makes it different from classical medical ethics, which is traditionally marked by an almost exclusive emphasis on the doctor-patient relationship. This deontological approach has proven to not be enough to encompass the emerging situations that have been aroused in the past decades [2]. Thus the domains of medical ethics and of today's deontology interact with bioethics for the resolution of conflicts in research, public health, and internal medicine.

73.3 Bioethics and Research in Breast Cancer

Breast cancer is one of the most currently researched diseases involving human subjects. The ethical regulations that govern such pieces of research were developed from events that raised great concern among the academic community due to history such as the research performed by the Nazi physicians and by the American postwar physicians, especially those in the study of Tuskegee, in the state of Alabama [1, 3].

One of the main bioethical elements found in the regulations for research involving human beings is the expectation that the knowledge and advances produced will ideally lead to the well-being of all humanity. Therefore, a moral principle in research with humans is respect for human dignity. Two components must be highlighted here. The first one is

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the choice of subjects for research, aiming to provide the subjects themselves and other groups with benefits, and also for the advance of science. The second one is the use of morally acceptable means to reach the same ends. The key point in moral objections of research is using another human being as a means to legitimate ends. It is unacceptable to treat people as a means or an object. Such an attitude harms the dignity that is innate to human beings, as it also downgrades the medical professionals, researchers, and humanity as a whole [3–5].

Risks in research must be interpreted from the bioethical principle of no harm, that is, the duty of forecasting or avoiding harm to the subjects involved in research. They must not be involved in unnecessary risks. Research with humans must be beneficial to society as a whole, but also to the subjects themselves. That means that all patients with breast cancer involved in research need to be benefited as well [3–5]. Professor Umberto Veronesi states that "*si cura meglio dove si fà ricerca*," which means we can treat patients better where we can perform research. It is necessary that this principle be respected and advocated by members of the institutional review board and also by the sponsors involved and by the researchers themselves.

The ethical approach to this research needs to center on the patient with cancer. Sometimes the expectations, interests, and hopes of the patient in research are not proportional to their real benefits. In order for their free and clear consent to be established in its full potential, the transmission of information must be technically adequate, individualized, and with clear language. Therefore, a positive and collaborative relationship between researcher and research subject is established. Considering the patients with breast cancer, it is important to highlight the vulnerability existing among patients diagnosed with a serious, chronic, and potentially mutilating disease. These patients demand special attention as to free and clear consent in order to respect their autonomy.

Research in breast surgery that involves patients either directly or indirectly (for instance, those researches that use health records or test results) must follow the principles specified in international recommendations like the Helsinki Declaration, the norms for good clinical practice, and the Human Rights Declaration. Research protocols must go through the approval of an Institutional Review Board, in agreement of each country's standards. Research involving areas such as genetics and human reproduction and research with new drugs with industry cooperation need special attention in order to protect patients and prevent them from being the subject of exploitation in research that involves significant conflict of interest, especially in developing countries and vulnerable populations [5]. Particularly, in breast reconstruction research, patients should be respected in regard to their privacy, with special care with photos.

73.4 Breast Cancer and Public Health Care

The remarkable American bioethicist Daniel Callahan has had severe criticism to the ways of western medicine. He argues that one of western medicine's main problems is setting unlimited horizons for its range of work. This lack of limits and the uncontrolled expansion (even disregarding the health-disease relationship) end up resulting in an increase of medical care costs that not always corresponds to an improvement in most people's health. Therefore, the use of sophisticated resources, with high costs and benefits that are not always proportional to such costs, has turned modern medicine into an impossible project to be accomplished [6].

One of the examples that can be mentioned regards the USA, a country that spends over 2 trillion dollars on health, which corresponds almost to the amount spent by all the other countries together [7, 8]; there are over 46 million Americans out of the health system. Suffice it to say that one of the key points of Barack Obama's presidential past campaign was health reform in the USA. This is something that will become even more difficult to be completed in a period of a global economic crisis.

Breast cancer, as a health problem all over the world, may bring important consequences if erroneous decisions in health policies are made. In Brazil, breast cancer is the main cause of death from cancer among females. The use of only 2–3% of the gross internal product (GIP) on health (in the USA more than 15% is used) results in an ethical dilemma of considerable proportions within the public health system, which is known by all Brazilian health professionals. The public health system in Brazil is a Universalist one, and it is similar to most of European models (guaranteed by article 196 of the Brazilian Federal Constitution of 1988—"… health is the right of all people and the duty of the State…"). However, as it happens in many European countries, the State cannot keep its costs unlimited, so it risks becoming bankrupt. That is why in the specific case of breast cancer, mammographic screening and timely access to updated treatments are inadequate given the distribution of existing resources. So the Universalist model does not manage to reach everybody equally. The unequal conditions in diagnosing and treating breast cancer in the Brazilian environment have not been properly studied yet. The damages in terms of life expectancy and years lost on work are noticeable and may increase in the forthcoming years.

The aim of health policies on cancer in developed countries is focused on prevention and early diagnosis. The mammographic screening test and the routine clinical exam may reduce mortality caused by breast cancer by 25–30% among women over 50 years of age. Such measures aim to find tumors of smaller size, which implies treatments will have more effective results and at lower costs. An example of how this can work is ductal carcinoma in situ (DCIS), which is the

sort of breast tumor with the highest incidence in developed countries. Over 90% of the cases are not palpable, and their diagnosis is only possible through mammography. There is no need for chemotherapy or sentinel node biopsy as well as axillary dissection. The rate of cure is approximately 100%, and for most of patients with breast preservation techniques.

Considering that the potential of years wasted with breast cancer is second only to cardiovascular diseases, its economic and social importance is evident. The reduction in the mortality of breast cancer, first noticed in the USA and then followed by Sweden and England and now reaching most of the countries in the European Union, is a result of investments in detection and access of most of the population to better diagnostic and therapeutic modalities. It is clear that the early diagnosis not only benefits women in terms of survival and less mutilating surgeries but also reduces treatment costs and keeps an important portion of society with breast cancer economically active.

On the other hand, in developing countries in reproductive age groups, breast cancer is considered a substantial problem with similar importance to major global priorities such as maternal mortality [8, 9]. Advanced tumors demand therapeutic resources at higher costs. Results in terms of disease-free survival, however, are less satisfactory than at the early breast cancer stages. Local recurrences and distant metastasis require the use of chemotherapy schemes, hormone therapy, radiotherapy, and monoclonal antibodies of growing complexity in relation with those applied to more precocious tumors. Besides that, they diminish the labor capacity of these patients and require longer rehabilitation periods. A patient with metastatic breast cancer currently under the recommended treatment will cost the state and health insurance companies more than the transplant of organs and a few mammography and ultrasonography devices.

In developing countries, an increase in both the incidence of cases and in the mortality caused by this disease is expected [8, 9]. Therefore, it is imperative that the population has access to early diagnosis and proper treatment at the right time. These are some of the challenges in breast cancer that public health systems all over the world have to face. In this situation, bioethics may work as an element of facilitation in the formation of governmental decisions, following the example of other countries such as the USA and Italy, which have national committees of bioethics involved in public health matters.

73.5 Genetics and Breast Cancer

Although a positive family history is reported between 15% and 20% among women with breast cancer, congenital breast cancer occurs only in 5–6% of all cases [10], and mutations in genes BRCA1 or BRCA2 are found in most of these cases [11]. Although mutations of the BRCA 1 and BRCA2 genes are most frequent, there are gene mutations associated with hereditary syndromes that may increase familial risk for breast cancer such as P53, PTEN, CDH1, STK11, MLH1, MSH2, MSH6, and PMS2 [12]. Today genetic tests to identify such mutations are commercially available. The frequency of these mutations is rare; however, they occur in approximately 0.1% of the population in general [12]. The prevalence of mutations BRCA is higher among Ashkenazi Jewish women, reaching 2% [13]. These genes are considered tumor suppression genes, and they work on repairing DNA. When there is a mutation, this function is not performed properly, which allows for the formation of a tumor. Transmission is dominant autosomal, but the penetration is incomplete; therefore, genetic mutation points to a higher susceptibility of developing a breast cancer, but that does not occur in all cases. It is estimated that a person holding mutation in gene BRCA1 or BRCA2 has a risk of developing breast cancer around 50–87% throughout life, and a risk of developing ovary cancer between 15% and 44% [14, 15].

Genetic consultaion and a genetic test should be proposed when (a) the patient has a personal or family history that points to a genetic condition susceptible to cancer (the criteria established by the *National Comprehensive Cancer Network* are as follows: family history of a patient in the family with ovarian cancer, a history of breast cancer before age 50, a history of triple-negative breast cancer diagnosed before 60 years of age, two primary breast cancers in the same individual, breast cancer at any age with a first-degree relative with a history of breast cancer before age 50 or ovarian cancer at any age or two high-grade relatives with breast cancer and or pancreatic cancer at any age, individual with no personal history of cancer but with a family history of two primary cancers in the same individual, male breast cancer, and family history of three or more family tumors such as pancreas, prostate, sarcoma, adrenal, lung, leukemia, colon, stomach, endometrial, and thyroid) [16]; (b) the genetic test may be adequately interpreted; (c) test results contribute to the diagnosis or influence the clinical or surgical treatment of the patients or of their families with risk of congenital cancer. It is recommended that the genetic test be only performed together with genetic advice pre- and posttest, which must include a discussion over possible risks and benefits of early detection of cancer and the modalities of prevention [17].

It is critical to interpret results adequately. There are three types of results: (a) positive result (the mutation with deleterious effects in BRCA1 or BRCA2 was found, and it put the person at risk by increasing the development of a breast cancer and ovarian cancer), (b) negative result (there is a mutation known by the family, but the person tested is not a holder of such mutation), and (c) inconclusive or

undetermined (no mutation is identified in the person tested, and there is no case of mutation known in the family, or a mutation was found in the test but its meaning is unknown).

The choice for undergoing the diagnostic test must be exclusively made by the patients. They must be aware of their choice to either accept or refuse the genetic test. In the pretest advice session, all of the important and necessary information must be given to the patient. This must cover the advantages and limitations of the test, the possible types of results, and the measures to minimize risk that can be taken. Informed consent is, therefore, a mandatory prerequisite for any type of genetic test. The principle of autonomy is the base of informed consent, and it is essential for preserving the individual's freedom and his right to make choices [18].

When an inherited breast cancer syndrome is suspected in a family, the first person that has to be tested is the relative affected with the disease. Once the test identifies the mutation, a genetic test to this specific mutation can be done in the other family members. Each relative has 50% chance of being a mutation carrier [19].

If the genetic test is positive for a mutation, one of the most effective methods that can be considered to reduce the breast cancer risk is prophylactic surgery. The prophylactic surgery includes prophylactic bilateral mastectomy and/or prophylactic bilateral salpingoophorectomy. If the patient doesn't want to undergo a prophylactic surgery, chemoprevention (tamoxifen) and surveillance (clinical breast examination, self breast examination, mammography, and magnetic resonance imaging) could also be discussed [19].

Although there are no randomized prospective trials that evaluated the efficacy of prophylactic bilateral mastectomy, and not many studies approached this issue, the literature shows that bilateral prophylactic mastectomy reduces the risk of breast cancer by approximately 90% in BRCA 1/2 mutation carriers and high-risk breast cancer patients [20–24]. Even though the accomplishment of a prospective randomized trial would be the best way to evaluate the efficacy of the prophylactic surgery, it probably would be not possible because not many patients would accept to be randomized to do a prophylactic surgery or nothing.

In terms of surgery, there are four kinds of prophylactic mastectomy: total mastectomy, skin-sparing total mastectomy, nipple-sparing mastectomy, and areola-sparing mastectomy. The lack of prospective randomized studies comparing these different techniques makes more difficult to establish which one is the ideal approach. The total mastectomy initially appears to be the safest procedure, because it removes the breast tissue, skin, and nipple-areola complex; on the other hand, the aesthetic outcome is poor. The skin-sparing mastectomy emerged as an alternative to total mastectomy, with better aesthetic outcome because it preserves the skin and, when it is associated with a reconstruction procedure, can reach a better outcome. Recently, the subcutaneous mastectomy (nipple-sparing mastectomy) has appeared as a surgical variation that consists in preservation of the skin and the nipple-areola complex ensuring an even better aesthetic result, with a more natural appearance of the breast. This technique however brings a serious concern, because a greater amount of tissue is preserved along with the nipple-areola complex and this could be associated with a higher incidence of cancer. Although this fear came from pathologic studies that shown the presence of cancer cells in the nipple ducts, there are insufficient data to support this argument, and some studies has already demonstrated good results with this technique [19, 25]. At last, the areola-sparing mastectomy consists in the preservation of the skin and the areola and the removal of the breast and the nipple. There are insufficient data with this kind of surgery in terms of aesthetic-functional outcomes and/or long-term oncologic results.

Privacy and confidentiality: respect to the privacy of patient's genetic information demands that the result of the test be not revealed to anyone without the consent of the individual tested. When family mutations are identified, individuals should be strongly encouraged to share results with other family members who are also at risk, especially when risk reduction measures can be taken [17]. However, some people may not feel like revealing genetic information to other members of the family. The doctor may face an ethical dilemma if the patient refuses to reveal genetic information to relatives that are at risk. In such situations, the subject of reliability is in conflict with the ethical principle of avoiding damage to others [18]. Most authors do not support the revealing of family genetic information without the patient's consent, unless the possibility of serious damage exists and is very high [26, 27].

Another important aspect to be considered is genetic discrimination. This refers to less favorable or adverse treatment that an individual without traces or symptoms of the disease gets, based on their genetic or genotypic characteristics [26]. The affected individual may experience discrimination from insurance companies and job agencies. The fear of discrimination is one of the most commonly identified reasons among women who are not willing to take a BRCA genetic test [28–30]. Considering that, preserving the individual's confidentiality of genetic information is very important.

Finally, the psychosocial influences that the result of the genetic test will bring to the life of the patient must be considered. Knowing that a genetic mutation is present and the consequences of the personal risk of breast cancer may affect a person in various ways. Women with positive test results might experience a wide variety of emotions such as anxiety, depression, fear, and anger. Women who have already had breast cancer may feel disturbed when learning that they have the risk of developing other types of cancer. Also, individuals

might have a feeling of guilt, despite the existence of a possible mutation. Bearers of mutation BRCA may experience "transmission sense of guilt" for they can transfer an increased genetic risk of cancer to their children, while non-bearers may experience the "survivor's sense of guilt" for being among the members of the family who did not inherit the mutation. Therefore, a proper psychological preparation of the patient before performing the genetic test is important.

73.6 Clinical Bioethics

> *Clinical case study*: A 37-year-old, white, homemaker, Catholic, diagnosed with breast cancer, T2N0, ER/PR positive, and HER-2 negative. She is in her 7th week of pregnancy and wants to have an immediate breast reconstruction. The breast surgeon was asked to give an opinion of the case.

Regardful medical virtues such as integrity, compassion, and altruism are determinant for the exercise of medicine [24]. Albert Jonsen, professor emeritus of medical ethics at the University of Washington, created a practical method to aid in the resolution of complex clinical cases, like the one presented above. It is based on four fundamental points: medical indications, patients' preferences, quality of life, and contextual aspects [2]. A favorable point of this method is that it allows for a shared bioethical sense that is easy to understand.

73.6.1 Medical Indications

It is the relationship between pathophysiology and therapeutic/diagnostic interventions that are indicated to solve the case properly. It refers to the application of medical and scientific knowledge. Whenever possible (and when such conditions are available), they must be based on clear scientific evidence. In breast oncology, around 60–80% of all decisions can use data from evidence-based medicine (MBE), in contrast with general medicine, in which a little more than 15% of the clinical decisions are based on consistent scientific evidence, and around 40% are based solely on professional expertise, since they do not provide published clinical studies that could respond to all existing questions. Important points to be considered and those with bioethical implications:

- What is the patient's health problem?
- Is it a severe or a chronic problem? A critical one? An emergency? Is it reversible?
- What are the targets of the treatment?
- What are the probabilities of success?
- What are the perspectives of failure of the treatment?
- To sum up, how can the patient benefit from the treatment in question?

73.6.2 Patients' Preferences

In all medical treatments, patients' preferences, based on their own values and perceptions as to the benefits and risks, are ethically relevant. The following points must be clarified before decision-making:

- Did the patient express their preferences concerning the treatment?
- Was the patient correctly informed about the risks, benefits, and their consent?
- Is the patient mentally capable and legally competent?
- If incapable, who is the legally responsible individual?
- To sum up, is the patient's autonomy being respected?

73.6.3 Quality of Life

Besides preserving the life of the patient, another major target of medical intervention is to reestablish, keep, and improve the quality of life. What is the expectation with and without the treatment for the patient to go back to a normal life? The questions that must be clarified:

- What problems may impede the evaluation of the patient's quality of life?
- What physical, mental, and social limitations will the patient present with after treatment?
- Is present or future condition of the patient be considered undesirable?
- What are the plans to offer the patient some comfort or palliation?

73.6.4 Contextual Aspects

The care of patients is influenced either positively or negatively by the family and by a variety of contexts such as personal, emotional, psychological, religious, financial, educational, legal, institutional, scientific, and social. The questions that must be clarified:

- Are there family problems that may influence therapeutic decisions?
- Are there any financial problems?
- Are there any medical or nursing problems?
- Are there any religious or cultural problems involved?
- What about the allocation of resources?
- Is there any reason for breaking confidentiality?
- And how about legal matters?
- Is there any research/teaching involved?
- Is there any conflict of interest?

Some important points emerge from this type of methodology. One of the most important of them is that no bioethical analysis of clinical problems should be performed without a deep scientific knowledge and clinical experience of the matter. A lack of knowledge invalidates any conclusion a posteriori. The second one is that a bioethical background is fundamental to the specialist decision.

By applying Albert Jonsen's method to help the breast surgeon find an answer to the clinical dilemma, one can find (a) *medical indications*—it refers to a 37-year-old patient with a breast neoplasia in the 7th week of pregnancy who is asking to maintain the pregnancy (in some countries it is not allowed to perform unless the patient is at risk to die) and wants a breast reconstruction. The patient is not a good candidate for neoadjuvant chemotherapy due to the risk of malformation. Since the patient is not in an urgent situation, there is no need to make an immediate decision—the decision can be discussed with the bioethical committee, patient, and family. Breast reconstruction in this case can be done with less aggressive techniques like expander/implants, without compromising the pregnancy or oncologic treatment. (b) Patient's preferences—the patient requested a breast reconstruction and to maintain the pregnancy. She is legally competent. (c) *Quality of life*—the quality of life without reconstruction is expected to be worse. The patient has a chance to return to a normal life, and the absence of the breast will cause damage to her quality of life in the near future. (d) *Contextual aspects*—there are legal-medical implications for abortion in Brazil, and the patient would not terminate the pregnancy influenced by her Catholic origins [31]. Breast reconstruction in this case, once it is well documented in the medical records and properly authorized by the patient, is ethically acceptable in such case.

Albert Jonsen's method improves the knowledge about conflicts, protects patients' autonomy, and integrates medical decisions. On the other hand, although it examines these situations and organizes them systematically, it does not solve them in all cases. The conflicts may occur within each of these points mentioned. Decision-making is sometimes so complex that it is necessary to resort to technical support from a consultancy professional with bioethical competence in the resolution of problems or, preferentially, of a bioethical committee.

73.7 Medicolegal Aspects in Breast Cancer Reconstruction

According to the American Society of Plastic Surgeons in 2010, 93,083 breast reconstruction procedures were performed. Seventy-four percent of these used either saline (20%) or silicon (54%) implants. Another 19.5% were accomplished using various flaps including TRAM, latisimus dorsi, DIEP, and others. Twenty-two percent of the implants were ultimately removed. According to Mark Gorney from The Doctors' Company [32, 33], 31% of claims against plastic surgeons involve elective breast operations. Of these, 55% are related to scarring or tissue loss/necrosis, and 45% are related to augmentation or reconstruction of the breast done with expanders and subsequent implants [33]. As oncoplastic surgery done by breast surgeons is a relatively new concept in the USA, further evaluation in this area is not available but will be carefully examined in the near future. This section will outline several areas that both plastic and oncoplastic breast surgeons need to address to limit their liability. These include patient selection and expectation, communication, informed consent, documentation, and event management.

73.7.1 Patient Selection and Expectations

It is important to realize that patients that present for purely aesthetic breast procedures are very different in their expectations from those that need reconstruction as part of their breast cancer treatment. The former will want a result that is better than their baseline in terms of aesthetics and symmetry. These patients will not present ordinarily with a breast cancer diagnosis and may be unrealistic in their expectations. The ability of the surgeon to perform to these expectations is fundamental. The cancer patient will undergo a destructive procedure to cure their cancer, and the final result is not usually expected to be as good as the original breast. Reconstructive surgeons should be well suited to this task with appropriate training. Though expectations are somewhat lower, a near normal breast with symmetry should be accomplished. This, of course, is made harder by the removal of breast tissue, chemotherapy, and radiation therapy. These patients may also return some time after their initial care for further aesthetic-functional adjustments and surgery. The surgeon should be able to handle this as well. Surgeons should learn to identify these patients when they present to serve them in the most appropriate manner.

When dealing with a patient's expectations, a careful history is very important to ascertain the patient's motives and desires. This requires good patient contact, empathy, attention, and questioning. It may also be useful to talk with significant others such as spouse or family members to further determine the results desired.

Not only are patient factors important in planning surgery, but the surgeon's comfort level with the patient, experience, and training are also variables to consider before operating. The patient must have reasonable expectations regarding what is possible, and the surgeon must be comfortable that he can deliver the desired result. If not, then not operating or referring the patient to someone more qualified is certainly a good outcome.

73.7.2 Communication

Honest and timely communication is of utmost importance in any doctor-patient encounter. Being on time in the office or giving the patient a cell phone number or email address is powerful communication. Eye contact, body language, and vocabulary choice also come together to send a message to the patient and her family, either good or bad. The ability to communicate and establish a relationship will significantly add to the credibility of the surgeon. The acronym HEAL [34] has been very useful in establishing and continuing relationships with patients and families especially in times of poor outcomes. H is for hear. Hear what your patients and families are trying to say. E is emotions. Address the patient's and family's emotions. A is for ask and answer. Ask patients and their families to tell you what they already know and answer what they want to know. Finally, L is loyalty. Foster already existing loyalty and rebuild that portion that may have been lost. Most medical malpractice cases are caused by no or misunderstood information and the patient's or family's need to learn the facts of the care given [34, 35]. The surgeon must learn to be a good communicator and, thus, educator of his patients. This education informs the patient of the disease process, prognosis, treatments, and alternatives and explains possible negative outcomes. This begins with the first handshake and never ends.

73.7.3 Informed Consent

The process of informed consent is the foundation of the doctor/patient relationship. Through this interaction, the patient comes to understand her diagnosis, options for management, potential outcomes and risks of each option, and what can be expected as an ultimate result. From this information, the patient can choose a course of action by including her own preferences and desires. Informed consent is not a simple form the patient signs but a process that begins with the first consultation and continues with each encounter. It involves the previously mentioned areas of patient selection, communication, and management of expectations. It is the surgeon's best friend in malpractice litigation. It is one of the first areas of examination by plaintiff's attorneys and, if absent or weak, is almost always included in complaints.

In documenting informed consent, a preprinted form (Fig. 73.1) is usually required, but in addition hospital or office notes should reflect the thought process the surgeon and patient have taken in support of the final written consent. These notes should include the patient's thoughts, expectations, and specific refusal of offered options. A specific summary statement should be included in the notes (e.g., I have talked with the patient at length regarding her diagnosis, proposed procedure, potential risks, possible benefits, and alternative modes of therapy. Risks discussed included but were not limited to _____. She understands the procedure, accepts the risks, and wishes us to proceed. We will do so in the near future.) Risks should be listed but this is not meant to be all inclusive. Table 73.1 lists the most common potential risks of oncoplastic surgery. A good informed consent process will not only protect the surgeon but enhance the relationship with the patient.

73.7.4 Documentation

Documentation is the cornerstone of any malpractice defense. Good documentation may convince a plaintiff's attorney not to pursue a case. In addition, it certainly is valuable when reviewing a patient's care and outcomes as well as making treatment plans. Documentation includes many aspects of the medical record. The hospital chart should be complete in a timely manner including the history, physical, consents, operative notes, and discharge summary. The office records should include all interactions and contacts with the patient such as telephone calls, literature given to the patient, notes of office visits, consents, correspondence, and photographs (preop and postop). The office notes should include history, physical, diagnostic results, diagnosis, treatment plans, referrals, alternatives, risks, and the patient's desires and expectations. Of course, no record should be altered after being signed off as this greatly weakens the credibility of the medical record. Late entries are allowable if identified as such. The records should also be legible.

73.7.5 Event Management

Despite the surgeon's best efforts, poor outcomes do occur (Table 73.1). Patients and their families are often very disappointed in these results. They have trusted the surgeon to meet their expectations, and when that does not occur, trust is shaken, and the surgeon is likely to be second guessed. It is at this point that the relationship with the patient may be lost. The surgeon must continue to communicate. A full and honest explanation to the patient and family is required. Sincere and empathic apologies may also help to ease the disappointment. In this regard, many lawsuits are filed simply because of lack of explanation [36]. These patients and families may not have been personally approached by their surgeon or feel that there may be something "covered up." Many plaintiffs file complaints to find the truth.

In addition, some progressive malpractice insurers wish to be notified of adverse events when they happen to help guide the surgeon in recovering the patient's trust.

CONSENT FOR SURGERY

1. I,.....
   according to my own will, hereby authorize doctor CICERO URBAN and all the other members of his team of professionals related to my medical assistance to perform the surgery herein described.....
   .....
   .....
   ....., as well as the medical treatments and follow-up care derived from it.
2. I certify that this surgery I now consent has been fully explained to me by doctor CICERO URBAN and his team both in person and through printed information material, therefore I understand that:

   A permanent **SCAR** will form as a result of the surgery, but all the necessary measures will be taken in order to minimize its effects and visibility.

   There might be a **SWELL** in the operated site, which may remain for weeks and even, though rarely, for a few months.

   SPOTS or **DEPIGMENTATION OR DISCOLOURATION AREAS** may also appear in the operated site for some time. In very rare cases they can remain permanently.

   Occasionally, **LIQUIDS** (blood or secretion or fluids) may accumulate in the operated site, so there is the need for draining, aspiration or surgical repair. This is more frequent after axillary dissection.

   There may be **LOSS OF SENSITIVITY AND/OR MOBILITY** in the operated site for an indefinite period of time, which varies from patient to patient. It occurs more frequently after axillary dissection.

   There may be **LOSS OF BIOLOGICAL VITALITY** in the operated site, caused by blood vascularisation reduction, which may result in alterations of the skin and, in more rare cases, necrosis, which demands repair through another operation or even operations.

   There may be **POSTOPERATIVE PAIN**, in either higher or lower levels of intensity, for an indefinite period of time, which varies from patient to patient.

   Every surgery may demand better **FINISHING** or small complementary surgeries performed to achieve better results.

   Considering that I have been informed of all the above:

3. **I assume** that throughout the surgical procedure there may be unexpected situations that had not previously been identified and, as a result, **ADDITIONAL PROCEDURES OR**

Fig. 73.1 Informed consent model for oncoplastic and reconstructive surgery from Our Lady of Grace Hospital Breast Unit, Curitiba, Brazil

DIFFERENT ONES from those that had been arranged may be needed. Bearing that in mind, I allow the team to perform procedures that match such new situations.

4. **I assume** that Doctor XXXXXXXXX and his team will solely use all the necessary technical and scientific means at their disposal to achieve the results that are so desired, nevertheless such results are not guaranteed. Medicine is not an exact science, and consequently **GUARANTEES OF GOOD RESULTS CANNOT BE OFFERED.**

5. **I assume** that **TOBACCO SMOKING**, the use of **DRUGS** and **ALCOHOL**, though they are not able to prevent the surgery from being performed, are risk factors that can produce surgical-medical complications.

6. **I allow** the recording (photos, sound and/or filming) of the surgical procedures to be made because I understand that such registering is a legal-medical demand and a source of study and scientific information.

7. **I accept** that considering breast implants, the possibility of hardening may occur, as well as shape alterations, local pain and loss of sensitivity, and implant rupture, which derive from the use of silicon (or other kind of implants), and reactions of my body to it. This effect might imply that new surgeries be performed.

8. **I am aware** that I may experience limitations to perform everyday activities for an indefinite period of time.

I have had the opportunity to **CLARIFY ALL OF MY DOUBTS** concerning the surgery that I am voluntarily about to undergo, reason why **I ALLOW Doctor _____ and his team** to perform all the necessary procedures.

Location:

Date: _____

Doctor's signature: _____

ID:_____

Witnesses:

1._____

ID:_____

2._____

ID:_____

Fig. 73.1 (continued)

Table 73.1 Potential complications in oncoplastic surgery

Death
Myocardial infarction
Stroke
Deep venous thrombosis
Pneumonia
Infection
Bleeding
Prolonged drainage
Partial or total necrosis of skin or flaps
Seroma
Hematoma
Multiple surgeries/reoperation
Loss of implant or expander
Non-symmetry of breasts
Expectations not met
Recurrence of cancer
Prolonged care/wound care
Necrosis of nipple/areolar complex
Loss of sensation of nipple/areolar complex
Chronic pain
Keloids/scars
Discoloration
Need for drainage/aspiration
Lymphedema
Pain, swelling, numbness, disability, dysfunction of arms
Nerve or blood vessel damage
Hernia
Pneumothorax
Fat necrosis
Implant contracture, immediate or delayed
Rejection of implant at any time
Rupture of expander or implant

This interaction is important as the surgeon and his ego are most vulnerable at this time. The initial impulse is to avoid the situation and that is precisely the wrong approach [37–39]. Advice from an event manager can prove to be quite helpful in avoiding litigation. Many feel that this transparency is full of potential problems, but, in fact, this approach can actually decrease the frequency of lawsuits, increase credibility, and maintain the physician-patient relationship.

73.8 Conclusions and Perspectives

Bioethics has been walking together with the development of biotechnology and with its dilemmas, which go far beyond the technical-scientific debate. Within reconstructive breast cancer surgery specifically, there is the need for introducing bioethics and medicolegal aspects in the educational programs for specialists. It is true that technological development has improved the possibilities of the diagnosis and therapy of breast cancer, but the individual experience of those who deal with this malady daily is not the only object of scientific calculation. In addition to scientific competence, the physicians must have the humility to recognize their role and their limits: taking care above curing. This is the most important virtue to be cultivated by the breast surgeon with the aid of bioethics, reducing claims and improving breast cancer patient's survival and quality of life.

References

1. Callahan D (2004) Bioethics. In: Post SG (ed) Encyclopedia of bioethics. Thomson & Gale, New York, pp 278–287
2. Jonsen AR, Siegler M, Winslade WJ (2010) Clinical ethics, 7th edn. McGraw Hill, New York
3. Beecher HK (1966) Ethics and clinical research. N Engl J Med 274(24):1354–1360
4. Emanuel EJ, Wendler D, Grady C (2000) What makes clinical research ethical? JAMA 283(20):2701–2711
5. Emanuel EJ, Currie XE, Herman A (2005) Undue inducement in clinical research in developing countries: is it a worry? Lancet 366(9482):336–340
6. Callahan D (1999) False hopes: overcoming the obstacles to a sustainable, affordable medicine. Rutgers University Press, New Brunswick
7. Dalen JE (2000) Health care in America: the good, the bad, and the ugly. Arch Intern Med 160(17):2573–2576
8. Herzlinger R (2007) Who killed health care? America's $2 trillion medical problems and the consumer-driven cure. McGraw Hill, New York
9. Forouzanfar MH, Foreman KJ, Delossantos AM, Lozano R, Lopez AD, Murray CJ et al (2011) Breast and cervical cancer in 187 countries between 1980 and 2010: a systematic analysis. Lancet 378(9801):1461–1484
10. Malone KE, Daling JR, Thompson JD, O'Brien CA, Francisco LV, Ostrander EA (1998) BRCA1 mutations and breast cancer in the general population: analyses in women before age 35 years and in women before age 45 years with first-degree family history. JAMA 279(12):922–929
11. Couch FJ, DeShano ML, Blackwood MA, Calzone K, Stopfer J, Campeau L et al (1997) BRCA1 mutations in women attending clinics that evaluate the risk of breast cancer. N Engl J Med 336(20):1409–1415
12. Paluch S, Cardoso F, Sessa C, Balmana J, Cardoso MJ, Gilbert F (2016) Prevention and screening in BRCA mutation carriers and other breast/ovarian hereditary cancer syndromes: ESMO Clinical Practice Guidelines for cancer prevention and screening. Ann Oncol 27(suppl_S):v103–v110
13. Newman B, Austin MA, Lee M, King MC (1988) Inheritance of human breast cancer: evidence for autosomal dominant transmission in high-risk families. Proc Natl Acad Sci U S A 85(9):3044–3048
14. Struewing JP, Hartge P, Wacholder S, Baker SM, Berlin M, McAdams M et al (1997) The risk of cancer associated with specific mutations of BRCA1 and BRCA2 among Ashkenazi Jews. N Engl J Med 336(20):1401–1408
15. Thull DL, Vogel VG (2004) Recognition and management of hereditary breast cancer syndromes. Oncologist 9(1):13–24
16. National Comprehnsive Cancer Network version 2. 6 Apr 2017. https://www.nccn.org
17. American Society of Clinical Oncology (2003) American Society of Clinical Oncology policy statement update: genetic testing for cancer susceptibility. J Clin Oncol 21(12):2397–2406
18. Lowrey KM (2004) Legal and ethical issues in cancer genetics nursing. Semin Oncol Nurs 20(3):203–208
19. Guillem JG, Wood WC, Moley JF, Berchuck A, Karlan BY, Mutch DG et al (2006) ASCO/SSO review of current role of risk-reducing

surgery in common hereditary cancer syndromes. J Clin Oncol 24(28):4642–4660
20. Hartmann LC, Schaid DJ, Woods JE, Crotty TP, Myers JL, Arnold PG et al (1999) Efficacy of bilateral prophylactic mastectomy in women with a family history of breast cancer. N Engl J Med 340(2):77–84
21. Rebbeck TR, Friebel T, Lynch HT, Neuhausen SL, van't Veer L, Garber JE et al (2004) Bilateral prophylactic mastectomy reduces breast cancer risk in BRCA1 and BRCA2 mutation carriers: the PROSE Study Group. J Clin Oncol 22(6):1055–1062
22. Hartmann LC, Sellers TA, Schaid DJ, Frank TS, Soderberg CL, Sitta DL et al (2001) Efficacy of bilateral prophylactic mastectomy in BRCA1 and BRCA2 gene mutation carriers. J Natl Cancer Inst 93(21):1633–1637
23. Heemskerk-Gerritsen BA, Brekelmans CT, Menke-Pluymers MB, van Geel AN, Tilanus-Linthorst MM, Bartels CC et al (2007) Prophylactic mastectomy in BRCA1/2 mutation carriers and women at risk of hereditary breast cancer: long-term experiences at the Rotterdam Family Cancer Clinic. Ann Surg Oncol 14(12):3335–3344
24. Meijers-Heijboer H, van Geel B, van Putten WL, Henzen-Logmans SC, Seynaeve C, Menke-Pluymers MB et al (2001) Breast cancer after prophylactic bilateral mastectomy in women with a BRCA1 or BRCA2 mutation. N Engl J Med 345(3):159–164
25. Sacchini V, Pinotti JA, Barros AC, Luini A, Pluchinotta A, Pinotti M et al (2006) Nipple-sparing mastectomy for breast cancer and risk reduction: oncologic or technical problem? J Am Coll Surg 203(5):704–714
26. Harris M, Winship I, Spriggs M (2005) Controversies and ethical issues in cancer-genetics clinics. Lancet Oncol 6(5):301–310
27. Clayton EW (2003) Ethical, legal, and social implications of genomic medicine. N Engl J Med 349(6):562–569
28. Armstrong K, Calzone K, Stopfer J, Fitzgerald G, Coyne J, Weber B (2000) Factors associated with decisions about clinical BRCA1/2 testing. Cancer Epidemiol Biomarkers Prev 9(11):1251–1254
29. Armstrong K, Weber B, FitzGerald G, Hershey JC, Pauly MV, Lemaire J et al (2003) Life insurance and breast cancer risk assessment: adverse selection, genetic testing decisions, and discrimination. Am J Med Genet A 120A(3):359–364
30. Peterson EA, Milliron KJ, Lewis KE, Goold SD, Merajver SD (2002) Health insurance and discrimination concerns and BRCA1/2 testing in a clinic population. Cancer Epidemiol Biomarkers Prev 11(1):79–87
31. Post SG, Puchalski CM, Larson DB (2000) Physicians and patient spirituality: professional boundaries, competency, and ethics. Ann Intern Med 132(7):578–583
32. Gorney M (1999) The wheel of misfortune. Genesis of malpractice claims. Clin Plast Surg 26(1):15–19, v
33. Gorney M (2001) Preventing litigation in breast augmentation. Clin Plast Surg 28(3):607–615
34. Saxton JWKP, Baker L, Reifsteck S (2006) Communication strategies to help patients H.E.A.L. HCPro Inc, Marblehead
35. Saxton J (2007) The satisfied patient: a guide to preventing claims by providing excellent customer service, 2nd edn. HCPro Inc, Marblehead
36. Wojcieszak DSJ, Finkelstein MF (2010) Sorry works! Disclosure, apology, and relationships prevent medical malpractice claims, 2nd edn. Authorhouse, Bloomington
37. Banja J (2005) Medical errors and medical narcissism. Jones and Bartlett, Sudbury
38. Gorney M, Martello J (1999) The genesis of plastic surgeon claims. A review of recurring problems. Clin Plast Surg 26(1):123–131, ix
39. Shestak K (2006) Reoperative plastic surgery of the breast. Lippincott Williams & Wilkins, Philadelphia