—Review—

# Informed Consent for Breast Cancer: The Perspective of Physicians in Japan

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Informed consent (IC) is closely related to shared decision making (SDM), and SDM can lead to IC. IC is fundamental to medical ethics as described in the Geneva, Helsinki, and Lisbon declarations and is essential for clinical practice, as it provides legal protection for healthcare professionals. IC should be achieved through SDM based on both narrative-based medicine and evidence-based medicine. SDM should also involve healthcare professionals other than physicians (e.g., nurses, pharmacists, social workers). Communication skills for IC are important and are encapsulated in the SPIKES protocol. IC for breast cancer treatment requires explanation of the roles of local and systemic therapy. A documented "do not attempt resuscitation" order should be obtained for end-of-life IC.
(J Nippon Med Sch 2025; 92: 10–13)

**Key words:** informed consent, shared decision making, breast cancer

## Introduction

Breast cancer is the most common cancer among Japanese women, with an annual incidence of 97,812 in 2019 and a lifetime incidence of approximately one in nine[1]. Evidence-based medicine (EBM) guidelines recommend that optimal modalities for breast cancer treatment should be selected based on clinical and pathologic stages and molecular subtypes of breast cancer. When healthcare professionals assess the benefits and harms of a given treatment, they consider patient factors such as age, lifestyle, work, family, comorbidities, and preferences, in addition to EBM—a process called narrative-based medicine (NBM). Their assessment is then communicated to the patient and discussed, and both sides then reach a consensus and decide on a treatment plan. This shared decision-making (SDM) process culminates in informed consent (IC). This review article describes the perspective of Japanese physicians on IC for breast cancer treatment in daily practice.

## History of Informed Consent in Japan

The history of IC in Japan dates back to 1995, when a report[2] was submitted by the government-led Study Group on the Ideal Future of IC, in conjunction with the revision of the Medical Care Act. The report stated that "IC is the basis for building a better patient-provider relationship, where the patient is aware of his or her own situation and is aware of a positive way to fight illness and live, and the healthcare professional is motivated to be a better supporter of the patient's way of life." In other words, IC was positioned as a concept leading to SDM[3] and is based on a two-way dialog between patients and healthcare professionals. Later, the revised Medical Care Act of 2007[4] added the following text on IC: "In providing medical care, physicians and other healthcare providers shall provide appropriate explanations and endeavor to obtain the understanding of the patient receiving medical care."

## Content Explained in Informed Consent

Maruyama[5] presented three points to be explained in IC:

1. The name and condition of the disease, the proposed medical procedures (purpose, method, and associated risks), alternative methods, and predictions if no action is taken.
2. Matters that patients might reasonably disagree with and should be informed of before the medical procedures are performed.

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https://doi.org/10.1272/jnms.JNMS.2025_92-105
Journal Website (https://www.nms.ac.jp/sh/jnms/)

a. Matters generally considered important for a typical patient's decision making.
b. Matters deemed important, considering the specific circumstances of the patient, that are known or knowable by the physician.

3. Risks of death or complications that are deemed unavoidable according to medical standards.

Generally, these points can be summarized as follows[5]:

1. Name and condition of the disease;
2. Purpose and method of the medical procedure;
3. Expected benefits;
4. Anticipated risks;
5. Costs;
6. Alternative treatments and what might happen if no treatment is received.

### Legal Effects of Informed Consent

Maruyama[5] also presented the following points on the legal effects of IC:

1. Healthcare professionals are granted the authority/permission to perform medical procedures on the patient.
2. Patients assume responsibility for the outcomes of the medical procedures (acceptance of the risk of the outcomes) if the procedures are performed without negligence (i.e., according to medical standards).
3. Medical procedures performed without IC are illegal, even if the procedures themselves are performed without negligence.

Therefore, IC is essential for all medical procedures and provides legal protection for healthcare professionals. It is desirable to obtain IC in writing. To obtain IC efficiently in busy daily practice, documents detailing the content of the IC should be prepared in advance.

### Medical Ethics and Informed Consent

Three declarations are relevant to medical ethics: the Declaration of Geneva on the physician's pledge[6], the Declaration of Helsinki on ethical principles for medical research involving human subjects[7], and the Declaration of Lisbon on the rights of the patient[8]. These documents confirm that IC is essential to the provision of medical care. In particular, the content of the explanations given to patients in medical research must be based on the principles of the Declaration of Helsinki and approved by the ethical review committee of each institution[9].

### Evidence-Based Medicine and Narrative-Based Medicine

EBM refers to the provision of best medical care (standard of care) consistent with the results of medical research, as is recommended in guidelines and central to the content of IC. NBM, on the other hand, is defined as "clinical practice that helps patients tell their own life story and assists them in repairing their 'broken story'" [10]. NBM is characterized by the idea that illness is a chapter that unfolds in the larger story of a patient's life and living world, with the patient and the new narrative that emerges from the clinician's dialog expected to have a therapeutic impact[10]. Thus, NBM results from close collaboration between healthcare professionals and patients. These methods are referred to as SDM, and SDM encourages the patient's active participation in treatment and builds strong trust between healthcare professionals and patients.

EBM is the mainstay of local and pharmacological IC, as discussed below, but SDM must incorporate the NBM perspective. To achieve the best possible medical treatment, SDM based on NBM is particularly important for conditions and pathologies for which an evidence-based standard of care has not been established. In addition, even in the presence of an evidence-based standard of care, SDM should be based on NBM. Thus, healthcare professionals other than physicians (e.g., nurses, pharmacists, social workers) should be involved. On the patient's side, key persons, such as family members, should also be present.

### Communication Skills and Informed Consent

Six important communication skill steps in notification have been proposed and are referred to by the acronym SPIKES (see below)[11,12]. IC must be achieved by good communication between the patient and healthcare provider, and we believe that it is important to follow these steps.

Step 1. SETTING up the interview;

Step 2. Assessing the patient's PERCEPTION;

Step 3. Obtaining the patient's INVITATION;

Step 4. Giving KNOWLEDGE and information to the patient;

Step 5. Addressing the patient's EMOTIONS with empathic responses;

Step 6. STRATEGY and SUMMARY.

### Informed Consent for Local Therapies

The substance of IC for local therapy (surgery and radio-

therapy) is discussed below. Surgery aims to achieve a complete cure for breast cancer by completely resecting the tumor. Complete resection is defined as negative pathologic tumor margins in patients without distant metastases. Breast surgery includes total mastectomy (the standard procedure in which the skin directly over the tumor and the nipple-areola complex is removed), skin-sparing mastectomy (removal of the nipple-areola complex), nipple-sparing mastectomy, and partial mastectomy. Skin-sparing mastectomy and nipple-sparing mastectomy are usually followed by breast reconstruction, which may be a single-stage primary reconstruction (autologous tissue or direct-to-implant reconstruction) or a two-stage primary reconstruction (expander-to-implant or autologous tissue reconstruction). The standard approach to the axillary lymph nodes is sentinel lymph node biopsy if clinically negative for lymph node metastases and axillary lymph node dissection if lymph node metastases are positive at the initial presentation or if sentinel lymph nodes are positive for macrometastases (>2 mm in diameter). Surgical complications include seroma (especially after axillary lymph node dissection or total mastectomy), postoperative bleeding, and wound infection.

Radiotherapy is used to complement surgery and increase the curative effect. It is standard in cases of positive lymph nodes, regardless of surgical technique, and in cases of partial mastectomy with or without lymph node involvement. The subclavian, internal mammary, and supraclavicular lymph nodes are mainly treated with radiotherapy in their respective areas. In patients with clinically negative lymph nodes but positive sentinel nodes, there is no difference in disease-free survival between axillary lymph node dissection and axillary radiotherapy, and radiotherapy is associated with a lower incidence of upper extremity edema, as compared with axillary lymph node dissection. Radiotherapy complications are mainly dermatitis, skin pigmentation and, rarely, radiation pneumonitis.

## Informed Consent for Systemic Therapy

Drug therapy is a systemic treatment, and in patients with clinical stage I-III disease the combination of drug therapy and local therapy can improve the curative effect on breast cancer. However, in patients with distant metastases, local therapy is less important, and drug therapy is the mainstay treatment to prolong survival, improve quality of life, and achieve stability rather than curing the disease. Drug therapy consists of chemotherapy, endocrine therapy, and molecular targeted therapy; IC based on EBM is required for each of these, including the method of administration, efficacy, and side effects. In addition, IC from pharmacists is also essential.

## Informed Consent for End-of-Life Care

Optimal end-of-life care for breast cancer patients varies from patient to patient. NBM requires us to respect advance directives and engage in SDM while the patient still has decision-making capacity. In addition, obtaining IC is desirable before sedation. Furthermore, IC is essential for "do not attempt resuscitation" (DNAR) orders[13]. Consideration of DNAR orders should always involve a medical care team comprising healthcare professionals from multiple disciplines. If the patient has decision-making capacity, IC must be obtained after providing necessary and sufficient information. If the patient lacks capacity, the consent of the family (proxy) or the presumed will of the patient should be respected. Consent must be obtained in writing, recorded in the medical record, shared within the healthcare team, and reviewed periodically to reflect changes over time in the patient's condition and the wishes of the patient or family.

## Conclusion

IC is essential in modern breast cancer treatment and is well positioned to be created with SDM. The historical background of IC in Japan introduced the concept of SDM. We believe that this review of the essence of IC will be helpful for clinicians treating breast cancer.

**Funding:** None.

**Conflict of Interest:** None declared.

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(Received, July 2, 2024)

(Accepted, July 12, 2024)