Informed Consent for Chemotherapy: ASCO Member Resources

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Consent to treatment is an important part of the delivery of quality cancer care. Physician practices that participate in ASCO's Quality Oncology Practice Initiative (QOPI) and others expressed interest in having ASCO provide informed consent resources, and indicated that they would be more likely to use a consent form for chemotherapy if ASCO provided a template. Recent *Journal of Oncology Practice* articles outlining unique factors in consent for chemotherapy, documentation issues, and malpractice concerns also raised member interest. In response, members of ASCO's Ethics and Quality of Care Committees formed a joint working group to design a consent form template and other resources that provide a framework for consent conversations between oncologists and patients receiving chemotherapy.

Written Consent Forms for Chemotherapy: Ethics, Quality, and Risk Management Issues

The doctrine of informed consent is rooted in both legal doctrine and ethical theory. The common-law requirement that a patient consent to medical treatment has developed over time to include the disclosure of a patient's diagnosis, the nature of the proposed intervention, intended benefits, associated risks and adverse effects, and medically reasonable alternatives (and their corresponding risks and adverse effects).[1] Ethically, consent conversations allow physicians to fulfill their obligation to help patients make autonomous choices about their medical care. For this reason, informed consent is not limited to a single discussion or form; rather, it is an ongoing communication process that is central to the doctor-patient relationship.

Best practices dictate that consent conversations should be well documented. One way to document consent is through a written consent form that is reviewed with the patient, signed, and stored in the patient's medical record. Making a detailed note in a patient's medical record to document that all of the required elements of a consent conversation took place is equally appropriate because written consent forms are not required by law in most states. This is reflected in ASCO's QOPI quality measures, which look equally to either a note in the patient's medical record or use of a consent form as an indication that a consent conversation took place.

Though consent forms cannot replace direct communication, they can enhance the consent process. Consent forms can serve as a guide for physicians during consent conversations to help ensure that they address all required elements, and provide a take-home reference for patients about the risks, benefits, and alternatives of their treatment plan.

In addition, a signed consent form serves as instant, standardized documentation that can be helpful in litigation. A signed consent form can be considered strong evidence that the physician engaged the patient in an appropriate discussion. In some states, a signed document can create a presumption that the patient was adequately informed. (See, for example, Tex Stat Ann §74.104-74.105 [2007]; Utah Code Ann §78-14-5 [2008]; and Wash Rev Code Ann §7.70.060 [2008])

However, physician practices may be reluctant to use written consent forms due to risk management concerns. Physicians may be concerned that their forms would omit essential information or fail to comply with exacting legal requirements. In light of these concerns, physician practices participating in the QOPI and others indicated that they would be more likely to use a consent form for chemotherapy if ASCO provided a template.

Disclosure Standards

Generally, state statutes and case law are sufficiently uniform to allow for the creation of a single consent form template. (The legal elements of consent to medical treatment are regulated by state statutes and case law. Consent forms for medical treatment are different from research consents, and can be more general because they are not subject to the exacting requirements of federal law, including the Common Rule.) Most states require physicians to disclose information that is consistent with either what a reasonable patient would want to know under the circumstances (the patient-based standard) or what a reasonable physician in the community would disclose under the circumstances (the community-based standard). A small number of states have a hybrid patient-community standard. A few others are moving toward an individual-patient standard, which requires physicians to disclose what an individual patient wants to know based on his or her specific circumstances. Texas[2] and Hawaii[3] have appointed panels that meet periodically to develop specific disclosure requirements for certain treatments and procedures.

Elements of Consent

States generally require the same basic elements of consent, which should be addressed in all consent conversations and written forms. These elements—outlined below along with

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suggestions for what information physicians should consider sharing with patients during consent conversations—are also reflected in standards for informed consent set out by the Center for Medicare and Medicaid Services, the Joint Commission on the Accreditation of Healthcare Organizations, and the American Medical Association:

• *Disclosure.* A patient's ability to give informed consent to treatment is fundamentally based on an adequate understanding of his or her diagnosis. Patients should be aware of the location, type, and stage of their disease, and what these mean for their treatment options. Patients should also be informed of the results of diagnostic tests that could affect their treatment decisions.

• *Nature of proposed treatment.* Discussions that touch on a patient's prognosis can be difficult, depending on the nature of the patient's disease. Studies show a physician who is not direct can inadvertently mislead a patient about his or her prognosis and treatment goals.[4,5] Physicians should be straightforward when describing the intent of treatment to ensure that patients are well informed. Physicians may want to distinguish elements of a treatment plan that have curative potential from those that are intended to prolong survival or manage symptoms.

• *Potential benefits of proposed treatment.* Physicians should inform patients of the benefits they can reasonably expect from treatment if it is successful, such as reduction in tumor size, prolonged survival, or reduced discomfort, but should make clear that outcomes vary among patients.

• *Risks and adverse effects of proposed treatment.* The toxic nature of chemotherapy introduces numerous risks and potential adverse effects that physicians must disclose. Generally, physicians should disclose risks and adverse effects that are common as well as those that are not common but could be severe. Physicians should consider whether a patient's specific circumstances would make some risks more material than others. Disclosure should include how short-term adverse effects can be managed to make the patient more comfortable. In some cases, long-term planning initiatives are appropriate. For example, physicians should advise patients about the fertility preservation strategies available to them.[6]

• *Alternatives to proposed treatment and associated risks.* Physicians should inform patients about reasonable alternatives to proposed treatment. What is reasonable will depend on the circumstances of a patient's case; the patient's medical, social, and personal concerns; and the judgment of the physician. When considering alternatives, patients may value information about cost, length of recuperation, likely success, and risks, compared with the proposed treatment. Receiving comfort or palliative care should be presented as an alternative where appropriate.

Though it is not legally required, patients should be encouraged to ask questions during the initial consent conversation and at any time thereafter. Physicians can also ask questions to assess a patient's level of understanding before the consent form is signed, and revisit topics where necessary. It is helpful to give patients a copy of their consent form and any additional information about their diagnosis and treatment plan.

It is also important for physicians to continually look for and resolve obstacles that could impede their patients' ability to give informed consent, such as language barriers and competency issues. Consent forms should be written at an eighth-grade level and in a large font. Physicians should also access translators for patients who are not comfortable speaking English during the consent process. If a patient may not be competent to give consent, the physician should initiate the process of identifying a suitable surrogate. Physicians should encourage patients to have a family member or close friend present during the consent process where appropriate.

Risk Management

Although signed consent forms can be helpful in the event of litigation, they do not offer absolute protection from lawsuits. In some cases, the presence of a signed consent form still leaves room for factual disputes that can lead to litigation. (For example, in *Rogers v Brown*,[7] the plaintiff alleged that the consent form was incomplete when he signed it.) Forms that are overly detailed can give rise to a presumption that any omitted information was not disclosed. On the other hand, blanket consent forms (which state generally that all material risks have been explained to the patient) are usually found to have little evidentiary value. Furthermore, overly detailed consent forms and blanket consent forms may not comply with legally required disclosure standards and may fail to provide appropriate information in the manner most useful for patients.

Best Practices

When determining what information to disclose to a patient, it is best for physicians to abide by applicable disclosure standards. In addition, physicians should consider whether the unique needs of an individual patient require the disclosure of additional information beyond the general standard. When in doubt about whether information is material under the circumstances, physicians should disclose. If any information is disclosed that is not included in the form, a note should be made in the patient's medical record.

Most importantly, physicians must adhere rigorously to any consent documentation system their practices adopt. Deviation from standard operating procedures—such as failure to include the form or note in a patient's medical record—could serve as evidence of lack of consent.[8] (For example, in *Rogers v Brown*,[7] based in part on the nurse's description of standard consent procedures, the appellate

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The Consent Process in Practice

Over time, physicians' requirement to obtain consent has evolved. Until relatively recently, the physician's concern was getting the patient to assent to care. The totality of consent was contained in the consent implied when the patient simply showed up and allowed treatment.

Explicit consent for procedures became commonplace during the mid-17th century, during a time of more dramatic treatments and the concurrent rise of malpractice claims. More recently, after the painful lessons of Nuremberg and Tuskegee, the current standard of informed consent with its attendant necessity for documenting (and participating in) a thorough discussion of the risks, benefits, alternatives, and likelihood of various outcomes has become the norm for virtually any procedure that a physician performs or causes to be performed on a patient.

A subject of continuous interest and voluminous literature, the process of informed consent has been extensively reviewed. A list of some relevant books and articles is found under Selected References, which serves as a guide to additional reading that those interested in the subject may wish to pursue. Included in this list is a reference to the British Society for Haematology's practice guideline for obtaining consent for chemotherapy, which provides an interesting perspective within the context of our legal tradition, if not specifically within the constraints of US legal standards.

It is critical to recognize that the consent process is just that—a process over time and not a discrete paper-signing ritual. Patients may ask for additional information as their understanding changes over time, and their clinical status may result in a changing ability to understand the information they are given. One must always be aware of the fact that patients may not have the decision-making capacity to give consent, and the patient's surrogate may need to be identified and involved. This applies to children as well as variably competent adults, although, of course, just because a person is less than totally competent does not mean that he or she can be ignored in the process. Finally, it should be obvious that no consent discussion or document serves as immunity to legal action if treatment is inappropriately or improperly administered.

The iconoclast O'Neill points out that the process is not universal: emergency circumstances clearly allow physicians to proceed without consent, and societal pressures, such as guarding the rights of others exposed to infectious disease or of the unborn, may also negate the requirement that informed consent be obtained before some treatments. Additionally, she points out (undoubtedly while smiling) that when one takes a family history, one obtains medical information on people who clearly have not given their consent to the sharing of this information.

As I have become more aware of these issues, it has taken me longer to discuss chemotherapy with my patients. It is hoped that this time is not wasted, and they are benefitting from the interaction. Clearly, I am.

Michael Neuss, MD

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court could not find that the jury was wrong in finding that the plaintiff's informed consent had been secured before surgery.)

Physicians who opt to use written consent forms should keep some additional rules of thumb in mind:

1. Written consent forms should only be used in consultation with legal counsel.

2. The type of information disclosed on the consent form and during consent conversations should be consistent with the applicable disclosure standards.

3. Written consent forms should be regularly updated to keep pace with advances in oncology, including newly issued or updated clinical practice guidelines, and changing state laws.

4. State and federal privacy laws apply to uses and disclosures of the form. A written consent form should be treated with the same concern for confidentiality as all other information in a patient's medical record.

Conclusion

Informed consent is an ongoing communication process that is subject to both legal requirements and ethical standards. Patients' consent should be obtained before medical treatment in accordance with legally required elements and in a manner that helps them make autonomous treatment choices. Best practices stress the importance of documenting consent conversations. Written consent forms can be an effective form of documentation, but can also raise risk management concerns. Consent forms, including the form template provided by ASCO, can help address these concerns when used in consultation with legal counsel and in accordance with the rules of thumb described in the Best Practices section.

Consent Template

The ASCO informed consent for chemotherapy template is reproduced on pages 293-295. A modifiable Microsoft Word version of the template can be found at www.asco.org/consent; this version facilitates customization by practices. An annotated user guide is also posted on the Web site, with details on each field of the template. Comments and feedback regarding the consent template can be sent to cancerquality@asco.org.

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Consent to Chemotherapy

I, _____, understand that I have been diagnosed with _____.

I understand that the treatment suggested by my doctor, Dr. _____, will involve

_____
_____
_____
_____.

The goal of my treatment is

_____
_____
_____.

I understand that health professionals at _____ will help my doctor provide this treatment. I also understand that other health care providers may be needed for my care.

I understand that there are benefits of this treatment if it is successful. I also understand that my doctors cannot be sure that the treatment will help me.

I understand that the chemotherapy medications recommended by my doctor can have short-term and long-term side effects. My doctor talked to me about the following side effects that I might experience because of my chemotherapy: *(check all that apply; additional space provided for physician comments)*

☐ Nausea/Vomiting _____

☐ Hair Loss_____

☐ Low red blood cell count/Anemia_____

☐ Fatigue_____

☐ Risk of Infection_____

☐ Risk of Bleeding_____

_____ Patient D.O.B.

_____ Patient I.D.

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☐ Constipation_____

☐ Diarrhea_____

☐ Sores of Mouth and Throat_____

☐ Skin Effects_____

☐ Muscle/Bone Effects_____

☐ Nerve Effects_____

☐ Kidney/Bladder Effects_____

☐ Sexual Effects_____

☐ Heart Effects _____

☐ Lung Effects_____

☐ Reproductive/Fertility Effects_____

☐ Other_____

I understand that complications from chemotherapy could cause my death.

I understand that I could have side effects from my chemotherapy that are not listed on this form. Each patient can respond differently to chemotherapy, and could have side effects that have not been reported by others.

The reasonable alternatives to this chemotherapy treatment have been explained to me, including:

_____

_____

_____.

I also understand that I may stop this treatment at any time.

_____ _____

Patient D.O.B. Patient I.D.

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I have had the chance to ask questions about this treatment, and my questions have been answered to my satisfaction. I understand that I can contact my health care provider at any time if I have questions, by calling _____.

I will receive a copy of this consent form.

I understand that by signing this document I am consenting to receive the chemotherapy medicines proposed by my health care provider.

Patient Signature _____ Date_____

For patients requiring translation or verbal reading of this document, the person reading/translating should document and sign below:

Reader/Translator Signature_____ Date_____

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Informed consent is an ongoing communication process. Consent forms, including this template, are in no way intended to replace or limit, in whole or in part, the thorough exchange of information between physicians and patients, and should not be used in this manner. Though the consent template reflects basic informed consent requirements, no single consent form could be appropriate for all patients. It is the responsibility of the treating physician or other health care provider to tailor the consent process to meet individual patient's needs. Because the consent form can include confidential information about a patient's medical record and treatment regimen, it should be used or disclosed only in accordance with federal and state privacy laws. Laws governing informed consent vary from state to state and may change over time. Before using the template, health care providers are advised to consult legal counsel to determine whether all required elements of informed consent are addressed. Use of this consent template is entirely voluntary and does not imply ASCO's endorsement of any physician practice, treatment regimen, or product. ASCO assumes no responsibility for any injury or damage to persons or property arising out of or related any use of this Template, any changes made to this Template by the user, or any errors or omissions.

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