Legal Corner

Documenting Informed Consent for Chemotherapy

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As a result of its participation in the American Society of Clinical Oncology's (ASCO) Quality Oncology Practice Initiative project, the University of Michigan Health System (UMHS) discovered it was performing below its peers in documenting patient consent for cancer chemotherapy. This led to an examination of the process for obtaining a patient's consent for chemotherapy, and the requirements for obtaining a patient's consent. We were asked to comment on our role as attorneys in advising the health system on its risk management strategies and on ways to address this problem, and to identify options for documenting informed consent.

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Background

Informed consent is intended to assure that the patient understands the purpose, benefits, risks, and alternatives to all treatment options before deciding to accept or refuse treatment. There are two components to proper informed consent: content and documentation. The content of informed consent is the discussion with the patient; it is the education and understanding of the patient. The documentation is evidence that the legal obligation of obtaining informed consent has been fulfilled; it is evidence the discussion occurred, the patient was educated, and the patient understood. In its recent evaluation, the UMHS learned it was beneath its peers in the documentation component. Whether documentation is achieved by way of a standardized form or a good clinic note does not matter. It is, however, important to ensure informed consent is documented in some manner.

Options for Documenting Informed Consent

Standardized Forms

Standardized consent forms can be useful simply because they ensure that documentation of informed consent gets into the

patient's chart in some fashion. These forms are not informed consent; they are confirmation the informed consent conversation with the patient occurred. They are signed by the patient and can be convincing evidence of informed consent. Standardized consent forms are easy and efficient for the clinicians to use.

There are downsides to using standardized consent forms. Consent forms are often presented to the patient along with many other forms for signing. With a new diagnosis of cancer, the patient is likely struggling with lifestyle changes and the enormity of coping with cancer. The patient may not take the time to read and fully understand what is written. Standardized forms discourage tailoring the consent for an individual patient. With constant changes and advancement in oncology, the form can become out of date. Informed consent is an ongoing process and should be revisited when there is a substantive change in the treatment regimen or the purpose of the chemotherapy treatment. A standardized form present in the chart may cause physicians to be less attuned to revisiting informed consent when revision is warranted.

There are ways around some of the problems associated with standardized forms. If the written consent form is available electronically, it can easily be modified to be more tailored to an individual patient. Consent forms may be reviewed and discussed at annual departmental meetings to ensure they remain current.

If a standardized form is used, it should be concise and written in terms patients will understand. Many times, patients are provided with preprinted materials or videos to aid in their understanding of chemotherapy. When using a standardized form, it is good to reference these materials to demonstrate the effort made to educate the patient.

Physician Note

A detailed, contemporaneous clinic note outlining the informed consent discussion probably trumps a standardized consent form in the courtroom. The benefit to the patient is the conversation, not the form. A good clinic note that accurately reflects the tailored conversation between the clinician and patient is strong evidence the patient was informed and the physician fulfilled his or her legal obligation. The physician note should reflect that the proposed treatment (including the risks, benefits, and alternatives) was discussed with the patient and that the patient understood the risks and benefits.

A clinic note is more in line with informed consent as an ongoing process. When treatment or the purpose thereof changes, this is documented in the chart; documenting the renewed consent naturally follows.

A downside to the clinic note is that it takes more concerted effort to document the informed consent conversation. This may cause some clinicians to neglect documenting consent in any manner.

Checklist

Adding consent to a checklist that is reviewed before chemotherapy is administered is one way to force compliance of informed consent documentation. Nursing or ancillary staff can review a checklist. No chemotherapy is given without documented consent. This checklist can be used in conjunction with either the standardized form or clinic note.

Conclusion

Informed consent needs to be documented. Legally, it makes no difference whether the documentation is a standardized form or a clinic note. There are pros and cons of each method.

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DOI: 10.1200/JOP.0742501

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The 2008 ACRA in Hematologic Malignancies is generously supported by Genentech BioOncology.