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**ACROinsights – Informed Consent for Radiation Oncology Services**

The goal of this series of articles is to ensure that radiation oncologists are aware of and provided with the knowledge to ensure day-to-day processes are being addressed in a compliant manner. This installment will review the guidelines and information related to informed consent for radiation oncology services. The information contained within this ACROinsights article is meant as general guidance and is not meant to replace authoritative guidance for coding, billing, and compliance.

**Fundamentals of Informed Consent**

Informed consent is fundamental to all interventional processes for medical treatment, including those for radiation oncology services. This process allows for the physician to present or supervise the information regarding the patient's diagnosis, possible treatment options, and their various risk/benefit considerations, and for the patient to make a well-considered and informed decision about their care. The process for obtaining consent is not simply having the patient signing a document, rather it is an agreement between the physician and patient about a complex course of management for which their shared decision-making is taking place.

The American Medical Association (AMA) Code of Medical Ethics Opinion 2.1.1[1] states the physician should do the following regarding informed consent with their patient:

- *"Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision.*
- *Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The physician should include information about:*
    - *The diagnosis (when known)*
    - *The nature and purpose of recommended interventions*
    - *The burdens, risks, and expected benefits of all options, including forgoing treatment*
- *Document the informed consent conversation and the patient's (or surrogate's) decision in the medical record in some manner. When the patient/surrogate has provided specific written consent, the consent form should be included in the record."*

In the event of emergency, if the patient cannot give their informed consent and there is no legally authorized surrogate or family member to do so as well, the physician may initiate treatment without the prior informed consent, but they must ensure the patient or legally authorized surrogate is informed at the earliest opportunity and consent is obtained for ongoing treatment.

According to the American College of Radiology (ACR) Practice Parameter on Informed Consent – Radiation Oncology[2], informed consent must be obtained and appropriately documented prior to the initiation of any complex medical treatment. Complex procedures could include things like simulation when contrast is being utilized for imaging, additional reasons to the ACR may also include, but not limited to the following procedures:

1. *"Imaging for simulation, treatment set-up including field placement, and/or treatment planning; tattoo placement*
2. *Radiotherapy treatment such as external beam irradiation, radiopharmaceutical therapy, brachytherapy, etc.*
3. *Administration of conscious sedation"*

[1] https://www.ama-assn.org/delivering-care/ethics/informed-consent

[2] https://www.acr.org/-/media/ACR/Files/Practice-Parameters/informedconsent-ro.pdf

The parameters go on to also address emergent situations, similar to the AMA, or where the patient asks to not be given full disclosure, or in the rare circumstances where the disclosure of the information may cause an adverse effect and the physician withholds information under therapeutic privilege to ensure uncommon scenarios are addressed.

Informed consent should be obtained by or under the supervision of the licensed physician who is qualified to perform the procedure and they must be familiar with the procedure for which the consent is given. Other healthcare professionals, defined by the ACR as members of the treatment team, may assist in the informed consent process. This may include providing additional resources or ensuring the patient understands the content of the consent form, but the physician is the one responsible to ensure the accuracy of the information presented and the correct understanding of the patient and/or surrogate.

The use of a witness is not required, unless outlined per state law. Use of a witness when the patient signs the informed consent form is typically recommended, but lack of a witness does not mean the consent is not valid. As mentioned, it is the responsibility of the physician to ensure the information provided is accurate and the patient understands the information and content of the informed consent form.

There may be special circumstances with additional considerations when obtaining informed consent. If a patient is under the age of 18 or has been declared incompetent, the informed consent must be obtained from the parent, legal guardian, or person with medical power of attorney. If none of these are present or available, which would likely be a rare occurrence, then it may vary per state law or the guidelines set up by the institution where the services will be rendered as to how to proceed. In addition, the physician should do the best they can to follow any previous known wishes of the patient.

For patients who may require an interpreter, either because they do not understand the language of the physician or they may not be entirely comfortable with the language, one should be provided. In addition, an interpreter may be needed for a patient with vision, hearing, and/or a speech impediment and may need the assistance of an interpreter to convey the information from the physician or other healthcare professional. In any of these cases, it is recommended the interpreter not be a friend or family member and specifically not a minor. Only if the patient will not allow a third-party interpreter or there is none available should the consideration of a friend or family member be used. Regardless, documentation in the medical record should outline who the interpreter was, their title if applicable, and their relationship to the patient.

Lastly, there are special considerations regarding informed consent for clinical research. If a patient is participating in a clinical study, they must sign the standard informed consent form ***and*** they must sign a study-specific informed consent form. The informed consent form for the clinical study must be approved for use by the Institutional Review Board (IRB) prior to the initiation of the study. If a physician is uncertain whether a research study requires the approval of the IRB, they can contact the Office for Human Research Protections by Health and Human Services (HHS) or can review the Common Rule (45 CFR 46), updated for use in 2018[3]. Even if a study is not overseen by the IRB, informed consent of the patient is necessary. Physicians should verify with the journal through which they plan to publish any studies or findings about the specific informed consent form which may be necessary.

**Documentation of Informed Consent**

Ensuring the content and context of the information within the informed consent form is extremely important. A 2019 study, *Assessment of Use, Specificity, and Readability of Written Clinical Informed Consent Forms for Patients With Cancer Undergoing Radiotherapy*, by The Journal of American Medical Association (JAMA)[4], found of the 113-cancer radiotherapy clinical consent forms reviewed only 9 (8%) of them met national

[3] https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html
[4] https://jamanetwork.com/journals/jamaoncology/fullarticle/2732507

recommendations for patient materials. National recommendations include language written at a maximum of an eight-grade level; the forms reviewed for the study contained content well above this comprehension level. In addition, the forms reviewed contained on average 7.2 common difficult words (3 syllables or more). Use of high-grade reading and comprehension level language and common difficult words result in informed consent forms many patients do not fully understand and could lead to confusion, lack of compliance with treatment plan, additional resources provided by staff, and additional time spent to assist the patient in comprehending the course of treatment.

To help ensure understanding by the patient of the information contained within the form, it is recommended to include the following:

- Specificity about the treatment site. This includes using words or descriptions of the work and processes during the course of treatment.
    - For example, when using the word simulation add context or use a different word, such as "practice setup used to plan your treatment". These suggestions as well as several others were provided in the supplement to the JAMA article.
- Remove long lists of adverse effects and replace with list of the common side effects vs. the rare side effects, short-term sides effects vs. the long-term ones etc.

Overall, the documentation of the consent form should include and be made available to the patient or legally authorized surrogate when requested:

- Patient's name, medical record number, date of birth, or some other identifier
- Name of the physician or practice performing the procedure
- Statement in first person with patent's name or indication they are authorizing the services for themselves
- Statement in first person the side effects, alternatives, risks, and nature of treatment have been explained to them
- Statement in first person authorizing tattoos and photographs for documentation
- Statements about the following as appropriate per the patient and/or course of treatment:
    - When using templates ensure details are provided for patients who will be treated with brachytherapy, specifically permanently implanted radionuclides.
        - This includes risk to family members and general public following the implant of the sources.
    - Considerations for patients who are of childbearing age and the potential implications of radiation treatments which could impact future childbearing.
    - Information and additional considerations for patients with pacemakers or other electronic medical devices which may be impacted or require additional monitoring during the course of treatment.
- Forms should also include space for the following:
    - Signatures for both patient and surrogate
    - Relationship of signatures to the patient
    - Date of signature(s)
    - Signature for witness, if required or policy
    - Signature for translator, if applicable
    - If the patient refused consent, if applicable

**The Take Home Message**

It is important for physicians and staff in hospitals and freestanding centers to understand the critical role that informed consent plays in the ability to treat patients. It is much more than just the work of the patient signing

a form. The verbiage of the informed consent form is extremely important. Since the physician is ultimately responsible for the content of the informed consent and ensuring comprehension and understanding of the discussions and paperwork related to the patient giving consent for treatment, physicians and their staff should regularly review their consent forms to ensure they meet the national guidelines for comprehension level of the content. Lack of understanding by patients and legally authorized surrogates can have greater implications to the course of treatment and potentially the practice.