What Is Informed Refusal?
Tracy L. Melina, BS, MS, CPHRM

Almost all healthcare providers will eventually have a patient who will refuse recommended testing or treatment that the provider feels is needed for the patient’s well-being. Such a refusal can be frustrating when the provider is trying to help the patient achieve optimal health or to improve his/her quality of life.

The history of informed consent/refusal dates back to the late 1800s and early to mid-1900s, with the cases of Union Pacific Railroad Company v. Botsford (1891) and Schloendorff v. Society of New York Hospitals (1941). These two cases addressed a person’s right to control what may be done to his/her body. In Cruzan v. Director, Missouri Department of Health (1990), the U.S. Supreme Court stated the "logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, to refuse treatment." In Truman v. Thomas, the California Supreme Court held that a duty exists to inform the patient of the risks of not undergoing the recommended treatment or procedure. In that case, the patient had declined a Pap smear and ultimately died of cervical cancer at age 30.

Existing case law also supports the notion that a provider has a fiduciary duty to the patient and that a patient has the right to chart his/her own destiny. This duty to the patient includes providing the patient with the material facts he/she needs to "intelligently chart that destiny with dignity."

Informed refusal is closely related to the informed consent process. Informed refusal is a "patient's decision to decline recommended treatment after all options, risks, and benefits have been thoroughly explained." Any adult with decision-making capacity has the right to refuse medical treatment, even if the healthcare provider thinks the refusal is not in the patient’s best interest.

A patient who refuses to have a procedure, test, or treatment should not automatically be considered as being non-compliant or incompetent. Refusal to comply with a provider’s recommended treatment plans can be an important cautionary flag. Many issues may cause a patient to refuse consent. The refusal may be due to a patient’s inability to understand, financial burdens, or cultural issues (e.g., a patient’s religion forbids a blood transfusions or a transplant). Patients may also fear the unknown. A patient’s fears should be addressed before the patient makes a decision. Providers should carefully consider the reasoning behind a patient's refusal. Providers who explain all the options associated with a given treatment or procedure, as well as all the associated risks and benefits, give the patient an opportunity to decide which option best fits with the patient's goals, values, and preferences.

It is imperative that providers complete all of the components of the informed consent process. Generally, the following should be explained:

- The proposed treatment
- The risks and benefits associated with the proposed treatment
- Alternatives to the proposed treatment, as well as the associated risks and benefits
- The anticipated outcome of the proposed treatment and the alternatives, as well as the risks,
benefits, and anticipated outcome of doing nothing at all

The Informed Refusal Process

- The treating healthcare provider should perform an assessment of a patient and determine which specific tests, interventions, or treatment are medically necessary.
- The patient must be provided the relevant medical facts with regard to the proposed treatment.
- If the patient refuses to consent to the proposed medical treatment, the healthcare provider should consider the following:
  - The patient must have the ability or capacity to be able to make an informed decision.

Assessing Competence to Consent to Treatment: A Guide for Physicians and Other Health Professionals provides four instances requiring caution with regard to assessing a patient's decision-making capacity:

1. When the patient exhibits an abrupt change in his/her mental status
2. When the medical treatment is refused and the patient does not want to discuss why
3. The patient consents to a risky treatment without carefully considering the risks and benefits
4. The patient has known risk factors for impaired decision making (e.g., a neurological condition, language or cultural barriers, advanced age)

- The patient's judgment must not be impaired at the time of refusal. Some examples of potentially having impaired judgment include being ill, being under the influence of drugs and/or alcohol, and having had insufficient sleep.
- In cases in which an individual is considered unable to give informed refusal, another person (e.g., parent, guardian) may be authorized to give consent or refuse on the individual's behalf.

- If the treating healthcare provider feels that the patient has capacity to make an informed refusal, the provider needs to make certain that he/she has thoroughly explained the risks of not following through with the proposed treatment.
- In all instances, and especially when the refusal of treatment may result in significant damage or death, the discussions need to be thoroughly documented. The healthcare provider may complete an informed refusal document. (See the Coverys online toolkit for a sample refusal of treatment form.) A signed refusal of care form by itself, without accompanying documentation regarding the potential consequences of the refusal, may ultimately be decided to be insufficient. If the patient refuses to sign an informed refusal document, a witness should sign the documentation to validate that the informed refusal process did in fact take place.

Documentation in a Patient's Medical Record

The medical record documentation of a patient's refusal should address the information that was provided to the patient during the informed consent process. For example, the documentation should address the information provided regarding the patient's condition and the reasons for the proposed treatment or test. The documentation should also address the following:

- The possible risks and/or consequences of the treatment
- Any referrals to a specialist, including the reasons for the referral and possible risks of not seeing the specialist
- The patient's refusal of the treatment or recommended plan of care and his/her reason for the refusal
- The refusal of treatment form, if completed

Informed consent and informed refusal critically reflect that patients have and exercise autonomy in making healthcare decisions. Ultimately, competent patients have the right to make informed decisions about their care, even if their decisions go against the advice of their healthcare provider. Healthcare providers should ensure that the informed consent/refusal discussion includes all options and reasons for recommended treatment, as well as the potential consequences of refusing treatment. The healthcare provider has a responsibility to ensure that the patient has the capacity to understand the discussion and to also honor the patient's right to make a decision based on his/her own preferences, values, and beliefs.

To access the refusal sample document noted above, please click here. Coverys policyholders may also
visit the Policyholder Online Services website to read the full chapter on the informed consent process. To do so, log in, select Resources, and then select Manual- Physicians and Practice Groups, Informed Consent: Process.

We hope you found this RisKey helpful. If you have questions or would like further resources on this topic, please contact your Coverys Risk Management Consultant.

References

5. Ibid.
7. Ibid.

These links are being provided as a convenience and for informational purposes only; they are not intended and should not be construed as legal or medical advice. Coverys Risk Management bears no responsibility for the accuracy, legality or content of the external site or for that of subsequent links. Contact the external site for answers to questions regarding its content.

COPYRIGHTED
RisKey Emails are a publication of Coverys’ Risk Management Department. This information is intended to provide general guidelines for risk management. It is not intended and should not be construed as legal or medical advice.