**Panel Summary**

**Informed Consent: When Patients Change Their Minds**
Presented March 19, 2019

The March EFL explored the ethical challenges associated with patients who change their minds during the informed consent process. The ethical basis of informed consent focuses on the ethical principle of respect for autonomy--patients with decision-making capacity have the right to accept or reject any medical therapy at any time. To give their consent patients must understand the treatment and consequences and be able to choose freely. Within the informed consent process, patients must weigh the benefits and burdens of the proposed treatment to determine if the balance is consistent with their goals, values and risk appraisal.

The panel discussed the case of a woman initially agrees to surgery in the presence of her daughter but then expresses doubts later on when talking to her nurse the night before her scheduled operation. The case was analyzed through the lens of various perspectives including nursing, surgery and patient/family.

Highlights included:

1. The elements of informed consent include:
	1. Preconditions or threshold elements of decision-making capacity and voluntariness
	2. Informational elements
		1. Disclosure of medical information including consequences of treatment options and non-treatment; likelihood of benefit and risks; and other information that is meaningful for decision-making, including the recovery process.
		2. Professional recommendation and rationale
		3. Checking patient understanding of disclosure and recommendations
	3. Consent elements
		1. Decision
		2. Authorization (the signature on the form)
2. It is important to distinguish between the fear of undergoing a procedure and the decision whether or not to have the procedure. Clinicians should listen to the patient’s fears surrounding the procedure and try to elicit what the person’s actual goal is. This would entail embracing, rather than discounting, the patient’s concern. Even if the patient has signed the form in the past, a new refusal or concern should prompt another conversation with the patient to discern whether the prior consent is still valid.
3. The panel explored the complexity of distinguishing between ambivalence, normal worry and anxiety before surgery, and authentic refusal. Responding to concerns could take the paths of “paternalistic” reassurance or of scolding the person for disrupting the institutional flow, but the preferred approach would be taking the time to understand the nature of the refusal and postponing the procedure, if necessary. Time pressures may undermine clinicians’ availability to listen to and understand patient’s concerns empathetically, but finding the time to do so would be the optimal means of showing respect for a patient expressing uncertainty.
4. A competent patient has the right to accept or reject any medical therapy. When competent patient’s refuse, “No means no.” At the same time it may mean putting the brakes on the process leading to surgery in order to discern whether there may be other issues at play. It also has to be determined whether the patient’s refusal is temporary (“No—not now”) or a permanent refusal.
5. In some cases, it is helpful to discern how the patient wants to make decisions and who they want to be involved in the process, including other family members. In some cases, patients may choose to exercise their autonomy by transferring their decision-making authority to someone else. Absent this transfer of authority, the presence of a health care agent does not negate the fact that a patient with decision-making capacity should be approached to make independent decisions.
6. Clinicians should be mindful of the distinction between persuasion and coercion. A clinician threatening to discontinue caring for the patient if the patient does not accept their recommendation could be viewed as coercive. It is also important to recognize the power imbalance that may create undue pressure on patients to accept the team’s recommendation.
7. The panel proposed that we re-frame refusal—rather than being seen as a rejection of clinical expertise, a patient’s refusal should be viewed as an exercise of autonomy. Even if the team perceives the informed refusal to be unwise and contrary to their recommendation, the patient’s decision should be accepted without real or perceived abandonment of the patient.
8. Clinicians should be aware of how biases may influence how they appraise a patient’s refusal Demographic factors, such as race and gender, may affect the way that clinicians assess the nature of the refusal, and they should guard against implicit biases influencing their response to the refusal.
9. The panel proposed that all refusals should be taken seriously and fully explored, even it means disrupting the schedule, to assure that the informed consent process is fully upheld. This includes creating a climate where any person on the clinical team who has knowledge of the patient’s concerns can raise their concerns without pushback or recrimination. All members of the healthcare team have an important role in assuring the integrity of the consent process.