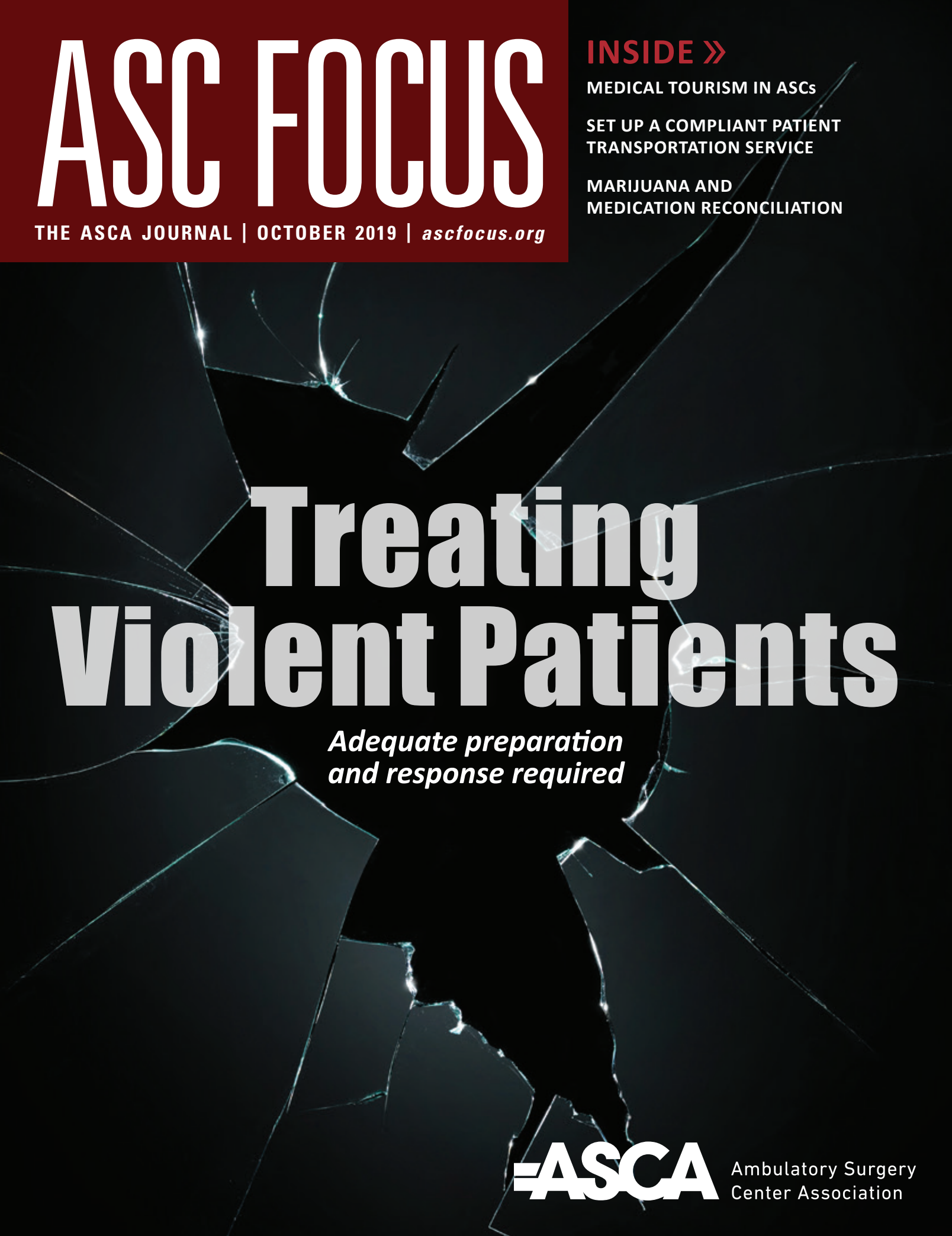
ASC FOCUS
THE ASCA JOURNAL | OCTOBER 2019 | ascfocus.org

INSIDE »



Treating Violent Patients

Adequate preparation and response required

ASCA Ambulatory Surgery Center Association

Informed Consent Process in Ambulatory Surgery

Review state laws and AHRQ materials before creating your policy

BY NESKO RADOVIC AND SANDRA JONES, CASC

Editor's note: This is part one of a two-part column. Look for the second part in the November–December 2019 issue of ASC Focus.


Informed consent, a fundamental patient right, is the process wherein the physician provides the patient with the necessary information to make a fully informed decision about the course of recommended care. Informed consent is a process, not a piece of paper. Treating the consent process as just a piece of paper or as another item to check off the to-do list can lead to mistakes and patient and physician dissatisfaction. It could also expose healthcare providers to potential malpractice liability. Lack of informed consent remains the most common secondary claim in physician medical malpractice actions.

The long-standing legal standard for informed consent was first articulated in a famous New York case, Schloendorff versus Society of N.Y. Hospital, in which a surgeon failed to obtain consent for a hysterectomy. The case was decided on the theory of battery, reserved for situations where the doctor performs an operation to which the patient has not consented. In contrast, when the patient consents to certain treatment and an undisclosed inherent complication occurs, the lack of informed consent will constitute negligence (see Cobbs versus Grant, 1972). In short, the physician has a legal duty to disclose to the patient all material information (Arato versus Avedon, 1993). When the planned procedure involves a known risk of death or serious bodily injury, a doctor, at a minimum, has a duty to disclose the potential risks of harm and to explain in lay terms the complications that might occur. If a physician does not make the minimal disclosure, he or she could be liable for all injuries sustained by the patient during the treatment whether it satisfied the standard of care or not.

Consents in a surgery center include 1) the physician's procedure consent, 2) the facility's consent to proceed with ordered treatment, and, if anesthesia will be administered, 3) the anesthesia consent.

Anytime a physician examines or treats a patient, informed consent must be obtained. It is the communication between the patient and the surgeon when the patient learns and understands the reasons for the procedure, its risks and benefits and alternative treatment options. It is also when the patient has questions answered and agrees to the procedure. The patient's signature on a consent form is not informed consent. The patient should not be asked to sign a consent form at the admissions desk nor should a consent form be presented prior to the patient having a conversation with the provider. The signature on the consent form simply evidences that the informed consent process occurred. Best practice would be to include both a signed consent form and a surgeon's note in the patient's medical record describing the process of informed consent. The ASC staff should also consider state law and whether physician assistants can facilitate the process by providing information to the patient. State law on this issue varies greatly.

The advice and opinions expressed in this column are those of the authors and do not represent official Ambulatory Surgery Center Association policy or opinion.

A recent Pennsylvania case, Shinal versus Toms, 2017, ruled that members of a physician's staff, e.g. physician assistants, may not obtain informed consent from patients. Florida's Medical Consent Law assigns the responsibility to the surgeon, attending, or a resident physician to explain the procedure. In Alabama, however, no case law specifically requires a face-to-face meeting with the patient to give informed consent and there are no restrictions on a physician assistant or other qualified healthcare professional explaining the risks associated with a procedure. To further complicate the issue, Nebraska Supreme Court, on April 25, 2019, held that a written form of informed consent is not required.

After the patient receives a pre-anesthesia assessment, the anesthesia services provider should discuss with the patient the proposed type of anesthesia and the risks. All this should occur prior to the patient receiving medication that can impact their ability to concentrate, comprehend and make decisions. The form used to document the process, whether provided by the anesthesia service or the ASC, should contain information about the type of anesthesia planned, the risks associated with the proposed type of anesthesia and the alternatives. The form should also include a statement that the anesthesia provider, when applicable to the arrangement for anesthesia services, is an independent contractor, not an employee of the ASC.

Even when a signed anesthesia consent form is obtained, verifying that the anesthesia provider explained the material facts to the patient concerning the proposed use of anesthesia is crucial. In a Washington state case, Brown v. Dahl, 1985, a patient signed several admission forms that indicated the risks associated with anesthesia and consent to receive anesthesia. The doctor, however, did not discuss any of the risks associated with the procedure or alternatives to the anesthetic. As the anesthetic began to take effect, the patient's airway became partially blocked and he went into cardiac arrest. The court held that a signed consent form was not sufficient evidence of informed consent. The court found that the patient only signed the form because a nurse told him to do so. Because the doctor did not disclose any risks and alternatives, it was not an "informed" consent.

A healthcare facility's consent form, at a minimum, should include the confirmation of the name of the physician who will perform the procedure, the name of the procedure and the laterality, when applicable. Further, the Centers for Medicare & Medicaid Services' (CMS) Interpretive Guidelines specify that the information in the informed consent form must be specific to the patient and that the patient or patient's representative must receive the information needed in order to make "informed" decisions regarding his or her care. The CMS guidelines further list minimum elements an ASC may consider adding to forms. The facility's consent form should include a statement that affirms the patient has gone through an informed consent process and that the provider(s) addressed all of the patient's questions and concerns. Finally, the patient should sign the form to attest their agreement to proceed. This process of ongoing dialogue between the patient and healthcare providers will ensure the best blending of practitioner's expertise and patient's choice.

Capacity vs. Competency

The term capacity is often confused with competency. Capacity is the mental ability to make a decision. To paraphrase an August 2011 article, "How Do I Determine If My Patient Has Decision-Making Capacity?" from *The Hospitalist*, capacity is a functional assessment that includes four key components:

1. communication—expressing a treatment option, not necessarily the terminology, but the general intent;
2. understanding—the reason for considering any treatment and options;
3. appreciation—know that there is a real or potential illness and possible outcomes; and
4. rationalization—consider the risks and benefits.

Competency refers to the mental ability and cognitive capabilities required to rationally execute a legal act. A person is presumed competent and is allowed to make decisions, even decisions others might find foolish. The process for determining incompetency is not accomplished in the pre-operative area. Finding of incompetency is a complicated legal process, which denies an individual's autonomy to make decisions. Based on medical assessments of the patient, courts may declare a person incompetent. Patients in a persistent vegetative state, those who are severely demented or severely mentally handicapped or actively psychotic patients would likely be found incompetent. On the other hand, courts have ruled that forgetfulness and periods of confusion could not be used as a basis for appointment of a guard-

ian because the patient exhibited lucid periods of being fully aware of treatment choices. Lack of decision-making capacity is not always permanent and can be impacted by the time of day, medications given or withheld, familiarity with surroundings, depression and anxiety, among other things.

Capacity is determined by physicians, not the judiciary. The physicians determine the patient's capacity based on the individual's psychological abilities to understand, appreciate and process information to make rational decisions. A patient evaluated by physicians to lack capacity to make rational health care decisions cannot consent to or refuse treatment and requires another individual to make his or her healthcare decisions.

Serving a patient population that could become incapacitated due to circumstances and medication presents a need for the ASC staff to understand who has the legal authority to consent to treatment and sign documents confirming that the informed consent process has occurred. Remember that informed consent is a process that starts with a discussion between a provider and the patient. Since this discussion must include the reasons for and risks of having or not having the procedure, the physician who will perform the procedure might be aware of any potential condition that would impair the patient's ability to consent to the procedure. Learning in advance from the physician or physician's office if the patient has executed a durable healthcare power of attorney or appointed a healthcare surrogate or relies on a spouse or daughter will assist staff at the surgery center in planning for the patient's admission. It also will assist the staff in determining who can receive discharge instructions and provide assistance to the patient after discharge, as well as how to document patient care instructions in the medical record.

Allowing someone else to make a decision for a patient is addressed in state regulations and rules. Many statutes include a list of individuals who are authorized to make decisions when the patient lacks capacity. There may be circumstances attached to that authority, however, such as the requirement for two physicians to determine that the patient is lacking capacity to make the decision. A patient in the pre-operative area might seem confused. Would there be two physicians present to determine and document that the patient is lacking capacity to make a decision and, therefore, a surrogate should be contacted? If no surrogate has previously been appointed by the patient, who has the right to make decisions for a patient lacking capacity? Since the ASC procedures are not usually emergency procedures, for which exceptions to proceed would apply, should the procedure be cancelled or can someone else be contacted to consent for the patient?

Is cataract surgery a medical emergency? Is a colonoscopy a medical emergency? Of course not. Although having to cancel a colonoscopy after the patient has gone through the exhausting preparation for the procedure is not convenient to the patient, facility or physician, proceeding without a proper consent process would be difficult to support and could expose all parties involved to medical malpractice liability. Gathering information prior to admission and knowing what to do should the patient not have ability to consent on the day of the procedure is important. «

Nesko Radovic is an associate with McGuireWoods LLP in Chicago, Illinois, and Sandra Jones, CASC, is the president and chief executive officer of Ambulatory Strategies Inc. in Dade City, Florida. Write Radovic at *nradovic@mcguirewoods.com* and Jones at *sjones@aboutascs.com*.