In preparation for the upcoming IM Procedure day, we would like you to do the following. We have found this event is more beneficial to participants if you read these articles and watch the videos prior to attending.

1. Read the attached information on obtaining informed consent.

2. Read the attached information from CDC for new guidelines for the prevention of intravascular catheter-related infections.

3. Watch the videos describing the procedures that you will be practicing. These are from NEJM Online: [http://www.nejm.org/multimedia/medical-videos](http://www.nejm.org/multimedia/medical-videos)

You will need to log on to NEJM, which you should be able to do through your hospital library or from home if you have a subscription.


Total time for these is approximately 73 minutes.
What is informed consent?

Informed consent is the process by which a fully informed patient can participate in choices about her health care. It originates from the legal and ethical right the patient has to direct what happens to her body and from the ethical duty of the physician to involve the patient in her health care.

What are the elements of full informed consent?

The most important goal of informed consent is that the patient has an opportunity to be an informed participant in his/her health care decisions. It is generally accepted that complete informed consent includes a discussion of the following elements:

- the nature of the decision/procedure
- reasonable alternatives to the proposed intervention
- the relevant risks, benefits, and uncertainties related to each alternative
- assessment of patient understanding
- the acceptance of the intervention by the patient

In order for the patient's consent to be valid, he/she must be considered competent to make the decision at hand and his/her consent must be voluntary. It is easy for coercive situations to arise in medicine. Patients often feel powerless and vulnerable. To encourage voluntariness, the physician can make clear to the patient that he/she is participating in a decision, not merely signing a form. With this understanding, the informed consent process should be seen as an invitation to him/her to participate in his/her health care decisions. The physician is also generally obligated to provide a recommendation and share his/her reasoning process with the patient. Comprehension on the part of the patient is equally as important as the information provided. Consequently, the discussion should be carried on in layperson's terms and the patient's understanding should be assessed along the way.

Basic consent entails letting the patient know what you would like to do and asking him/her if that will be all right. Basic consent is appropriate, for example, when drawing blood. Decisions that merit this sort of basic informed consent process require a low-level of patient involvement because there is a high-level of community consensus.
How much information is considered "adequate"?

How do you know when you have said enough about a certain decision? Most of the literature and law in this area suggest one of three approaches:

- **reasonable physician standard**: what would a typical physician say about this intervention? This standard allows the physician to determine what information is appropriate to disclose. However, it is probably not enough, since most research in this area shows that the typical physician tells the patient very little. This standard is also generally considered inconsistent with the goals of informed consent as the focus is on the physician rather than on what the patient needs to know.

- **reasonable patient standard**: what would the average patient need to know in order to be an informed participant in the decision? This standard focuses on considering what a patient would need to know in order to understand the decision at hand.

- **subjective standard**: what would this patient need to know and understand in order to make an informed decision? This standard is the most challenging to incorporate into practice, since it requires tailoring information to each patient.

Most states have legislation or legal cases that determine the required standard for informed consent. In the state of Michigan, we use the "reasonable physician standard."

What sorts of interventions require informed consent?

Most health care institutions have policies that state which health interventions require a signed consent form. For example, surgery, anesthesia, and other invasive procedures are usually in this category. These signed forms are really the culmination of a dialogue required to foster the patient's informed participation in the clinical decision.

For a wide range of decisions, written consent is neither required nor needed, but some meaningful discussion is needed. For instance, a man contemplating having a prostate-specific antigen screen for prostate cancer should know the relevant arguments for and against this screening test, discussed in layman's terms. (See also Research Ethics.)

When is it appropriate to question a patient's ability to participate in decision making?

In most cases, it is clear whether or not patients are competent to make their own decisions. Occasionally, it is not so clear. Patients are under an unusual amount of stress during illness and can experience anxiety, fear, and depression. The stress associated with illness should not necessarily preclude one from participating in one's own care. However, precautions should be taken to ensure the
patient does have the capacity to make good decisions. There are several different standards of decision making capacity. Generally you should assess the patient’s ability to:

- understand his or her situation,
- understand the risks associated with the decision at hand, and
- communicate a decision based on that understanding.

When this is unclear, a psychiatric consultation can be helpful. Of course, just because a patient refuses a treatment does not in itself mean the patient is incompetent. Competent patients have the right to refuse treatment, even those treatments that may be life-saving. Treatment refusal may, however, be a flag to pursue further the patient's beliefs and understanding about the decision, as well as your own.

**What about the patient whose decision making capacity varies from day to day?**

Patients can move in and out of a coherent state as their medications or underlying disease processes ebb and flow. You should do what you can to catch a patient in a lucid state - even lightening up on the medications if necessary - in order to include him/her in the decision-making process.

**What should occur if the patient cannot give informed consent?**

If the patient is determined to be incapacitated/incompetent to make health care decisions, a surrogate decision maker must speak for him/her. There is a specific hierarchy of appropriate decision makers defined by state law (also see the DNR topic page). If no appropriate surrogate decision maker is available, the physicians are expected to act in the best interest of the patient until a surrogate is found or appointed.

**Is there such a thing as presumed/implied consent?**

The patient's consent should only be "presumed", rather than obtained, in emergency situations when the patient is unconscious or incompetent and no surrogate decision maker is available. In general, the patient's presence in the hospital ward, ICU or clinic does not represent implied consent to all treatment and procedures. The patient's wishes and values may be quite different than the values of the physician. While the principle of respect for person obligates you to do your best to include the patient in the health care decisions that affect his/her life and body, the principle of beneficence may require you to act on the patient's behalf when his/her life is at stake.

2011 Guidelines for the Prevention of Intravascular Catheter-Related Infections

Summary of New Recommendations

Education, Training and Staffing

1. Educate healthcare personnel regarding the indications for intravascular catheter use, proper procedures for the insertion and maintenance of intravascular catheters, and appropriate infection control measures to prevent intravascular catheter-related infections [7–15]. Category IA
2. Periodically assess knowledge of and adherence to guidelines for all personnel involved in the insertion and maintenance of intravascular catheters [7–15]. Category IA
3. Designate only trained personnel who demonstrate competence for the insertion and maintenance of peripheral and central intravascular catheters. [14–28]. Category IA
4. Ensure appropriate nursing staff levels in ICUs. Observational studies suggest that a higher proportion of "pool nurses" or an elevated patient–to-nurse ratio is associated with CRBSI in ICUs where nurses are managing patients with CVCs [29–31]. Category IB

Selection of Catheters and Sites

Peripheral Catheters and Midline Catheters

1. In adults, use an upper-extremity site for catheter insertion. Replace a catheter inserted in a lower extremity site to an upper extremity site as soon as possible. Category II
2. In pediatric patients, the upper or lower extremities or the scalp (in neonates or young infants) can be used as the catheter insertion site [32, 33]. Category II
3. Select catheters on the basis of the intended purpose and duration of use, known infectious and non-infectious complications (e.g., phlebitis and infiltration), and experience of individual catheter operators [33–35]. Category IB
4. Avoid the use of steel needles for the administration of fluids and medication that might cause tissue necrosis if extravasation occurs [33, 34]. Category IA
5. Use a midline catheter or peripherally inserted central catheter (PICC), instead of a short peripheral catheter, when the duration of IV therapy will likely exceed six days. Category II
6. Evaluate the catheter insertion site daily by palpation through the dressing to discern tenderness and by inspection if a transparent dressing is in use. Gauze and opaque dressings should not be removed if the patient has no clinical signs of infection. If the patient has local tenderness or other signs of possible CRBSI, an opaque dressing should be removed and the site inspected visually. Category II
7. Remove peripheral venous catheters if the patients develops signs of phlebitis (warmth, tenderness, erythema or palpable venous cord), infection, or a malfunctioning catheter [36]. Category IB
Central Venous Catheters

1. Weigh the risks and benefits of placing a central venous device at a recommended site to reduce infectious complications against the risk for mechanical complications (e.g., pneumothorax, subclavian artery puncture, subclavian vein laceration, subclavian vein stenosis, hemothorax, thrombosis, air embolism, and catheter misplacement) [37–53]. Category IA

2. Avoid using the femoral vein for central venous access in adult patients [38, 50, 51, 54]. Category 1A

3. Use a subclavian site, rather than a jugular or a femoral site, in adult patients to minimize infection risk for nontunneled CVC placement [50–52]. Category IB

4. No recommendation can be made for a preferred site of insertion to minimize infection risk for a tunneled CVC. Unresolved issue

5. Avoid the subclavian site in hemodialysis patients and patients with advanced kidney disease, to avoid subclavian vein stenosis [53, 55–58]. Category IA

6. Use a fistula or graft in patients with chronic renal failure instead of a CVC for permanent access for dialysis [59]. Category 1A

7. Use ultrasound guidance to place central venous catheters (if this technology is available) to reduce the number of cannulation attempts and mechanical complications. Ultrasound guidance should only be used by those fully trained in its technique. [60–64]. Category 1B

8. Use a CVC with the minimum number of ports or lumens essential for the management of the patient [65–68]. Category IB

9. No recommendation can be made regarding the use of a designated lumen for parenteral nutrition. Unresolved issue

10. Promptly remove any intravascular catheter that is no longer essential [69–72]. Category IA

11. When adherence to aseptic technique cannot be ensured (i.e. catheters inserted during a medical emergency), replace the catheter as soon as possible, i.e., within 48 hours [37, 73–76]. Category IB

Hand Hygiene and Aseptic Technique

1. Perform hand hygiene procedures, either by washing hands with conventional soap and water or with alcohol-based hand rubs (ABHR). Hand hygiene should be performed before and after palpating catheter insertion sites as well as before and after inserting, replacing, accessing, repairing, or dressing an intravascular catheter. Palpation of the insertion site should not be performed after the application of antiseptic, unless aseptic technique is maintained [12, 77–79]. Category IB

2. Maintain aseptic technique for the insertion and care of intravascular catheters [37, 73, 74, 76]. Category IB

3. Wear clean gloves, rather than sterile gloves, for the insertion of peripheral intravascular catheters, if the access site is not touched after the application of skin antiseptics. Category IC

4. Sterile gloves should be worn for the insertion of arterial, central, and midline catheters [37, 73, 74, 76]. Category IA

5. Use new sterile gloves before handling the new catheter when guidewire exchanges are performed. Category II

6. Wear either clean or sterile gloves when changing the dressing on intravascular catheters. Category IC
Maximal Sterile Barrier Precautions

1. Use maximal sterile barrier precautions, including the use of a cap, mask, sterile gown, sterile gloves, and a sterile full body drape, for the insertion of CVCs, PICCs, or guidewire exchange [14, 75, 76, 80]. Category IB

2. Use a sterile sleeve to protect pulmonary artery catheters during insertion [81]. Category IB

Skin Preparation

1. Prepare clean skin with an antiseptic (70% alcohol, tincture of iodine, or alcoholic chlorhexidine gluconate solution) before peripheral venous catheter insertion [82]. Category IB

2. Prepare clean skin with a >0.5% chlorhexidine preparation with alcohol before central venous catheter and peripheral arterial catheter insertion and during dressing changes. If there is a contraindication to chlorhexidine, tincture of iodine, an iodophor, or 70% alcohol can be used as alternatives [82, 83]. Category IA

3. No comparison has been made between using chlorhexidine preparations with alcohol and povidone-iodine in alcohol to prepare clean skin. Unresolved issue.

4. No recommendation can be made for the safety or efficacy of chlorhexidine in infants aged <2 months. Unresolved issue

5. Antiseptics should be allowed to dry according to the manufacturer’s recommendation prior to placing the catheter [82, 83]. Category IB

Catheter Site Dressing Regimens

1. Use either sterile gauze or sterile, transparent, semipermeable dressing to cover the catheter site [84–87]. Category IA

2. If the patient is diaphoretic or if the site is bleeding or oozing, use a gauze dressing until this is resolved [84–87]. Category II

3. Replace catheter site dressing if the dressing becomes damp, loosened, or visibly soiled [84, 85]. Category IB

4. Do not use topical antibiotic ointment or creams on insertion sites, except for dialysis catheters, because of their potential to promote fungal infections and antimicrobial resistance [88, 89]. Category IB

5. Do not submerge the catheter or catheter site in water. Showering should be permitted if precautions can be taken to reduce the likelihood of introducing organisms into the catheter (e.g., if the catheter and connecting device are protected with an impermeable cover during the shower) [90–92]. Category IB

6. Replace dressings used on short-term CVC sites every 2 days for gauze dressings. Category II

7. Replace dressings used on short-term CVC sites at least every 7 days for transparent dressings, except in those pediatric patients in which the risk for dislodging the catheter may outweigh the benefit of changing the dressing [87, 93]. Category IB

8. Replace transparent dressings used on tunneled or implanted CVC sites no more than once per week (unless the dressing is soiled or loose), until the insertion site has healed. Category II

9. No recommendation can be made regarding the necessity for any dressing on well-healed exit sites of long-term cuffed and tunneled CVCs. Unresolved issue

10. Ensure that catheter site care is compatible with the catheter material [94, 95]. Category IB

11. Use a sterile sleeve for all pulmonary artery catheters [81]. Category IB
12. Use a chlorhexidine-impregnated sponge dressing for temporary short-term catheters in patients older than 2 months of age if the CLABSI rate is not decreasing despite adherence to basic prevention measures, including education and training, appropriate use of chlorhexidine for skin antisepsis, and MSB [93, 96–98]. Category 1B

13. No recommendation is made for other types of chlorhexidine dressings. Unresolved issue

14. Monitor the catheter sites visually when changing the dressing or by palpation through an intact dressing on a regular basis, depending on the clinical situation of the individual patient. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or bloodstream infection, the dressing should be removed to allow thorough examination of the site [99–101]. Category IB

15. Encourage patients to report any changes in their catheter site or any new discomfort to their provider. Category II