Concentrated electrolytes should not be available as unit stock on any patient care units (including in operating room/anesthesia regular stock) as much as is possible given the pharmacy capabilities. Wherever concentrated electrolytes are stored, it is critical that the hospital perform a risk assessment such as a failure mode and effects analysis (FMEA) or other recognized risk assessment methodology to identify and mitigate potential risks associated with it. In addition, concentrated electrolytes must always be segregated from other medications, and access to these restricted to only qualified and trained staff. For example, if the hospital determines it is necessary to stock concentrated electrolytes in emergency carts, they must still be segregated from the other medications in the cart with appropriate warning labels, staff must be trained on the risks and safety considerations, a risk assessment must have been conducted that includes mitigation of those risks, and this must be outlined in hospital policy.

Electrolytes should not be dispensed in their concentrated form to patient care units for individual patients. The exceptions to this recommendation are for vials contained in a cardiac surgery kit or a cardiac surgery locked storage area and available only to the operating team, magnesium sulfate contained in emergency carts or in areas where patients with preeclampsia may be treated (labor and delivery, emergency department, or intensive care unit), concentrated sodium in areas treating patients who may suffer from increased intracranial pressure (intensive care unit, emergency department, and operating room), and other special areas and circumstances defined by hospital policy and procedures.

The hospital can use labeling practices to decrease the risk of inadvertent administration of concentrated electrolytes, when it is possible for a single vial to be removed or transported from an open bin, box, or container. The individual vial must be labeled in addition to the storage container. Only qualified and trained individuals should have access to these vials.

Administration of electrolyte replacement therapy for hypokalemia, hyponatremia, and hypophosphatemia is safest when standardized guidelines and/or protocols with prediluted electrolytes (such as 20 mEq of potassium chloride in 100 cc of normal saline) are used, and the dispensing or handling of concentrated electrolyte vials on the patient care units is prohibited.

Measurable Elements of IPSG.03.02

1. Only qualified and trained individuals have access to concentrated electrolytes, and they are labeled with appropriate warnings and segregated from other medications throughout the storage and dispensing process. (*See also* MMU.04.00, ME 1; MMU.04.01, MEs 4 and 5; MMU.05.00, ME 1; MMU.05.03, ME 4)
2. The hospital only stores vials of concentrated electrolytes outside of the pharmacy for emergency situations or specific purposes, and these are clearly identified in hospital policy. (*See also* MMU.03.00, MEs 1 and 2)
3. Ⓓ The hospital performs initial and ongoing proactive risk assessments at least annually for all areas where concentrated electrolytes are stored.

Goal 4: Ensure Safe Surgery

Standard IPSG.04.00

The hospital implements a process for the preoperative verification and surgical/invasive procedure site marking.

Intent of IPSG.04.00

Wrong-patient, wrong-site, and wrong-procedure surgery present a risk for significant patient safety events that result in patient injury. Wrong-patient, wrong-site, and wrong-procedure surgery events can result from

ineffective or inadequate communication between members of the team performing the surgical or invasive procedure. The following are common risk factors for these surgery events:

- Lack of a standardized process for marking the procedure site
- Use of ambiguous site marks, such as "X" (which could be interpreted as "do not operate here" instead of marking the operative site)
- Use of materials or media that can easily be removed, such as tape, or ink that washes off during the skin preparation process
- Lack of patient involvement in the site marking
- Inadequate patient assessment
- Inadequate medical record review
- A culture that does not support open communication among team members
- Problems related to illegible handwriting
- Use of abbreviations

Surgical and invasive procedures include all procedures involving an incision or puncture, including but not limited to the following:

- Open surgical procedures
- Percutaneous aspiration
- Selected injections
- Biopsy
- Percutaneous cardiac and vascular diagnostic or interventional procedures
- Laparoscopies
- Endoscopies
- Central line insertions outside the operating theatre

Organizations need to identify all areas within the hospital where surgical and invasive procedures take place. Examples include the following:

- Cardiac catheterization lab
- Interventional radiology department
- Gastrointestinal lab
- Intensive care or critical care units

The approach the hospital takes to ensuring safe surgery applies to all areas of the hospital in which surgical and invasive procedures occur.

The (US) Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery™ is based in part on the principle of using multiple strategies to achieve the goal of always identifying the correct patient, correct procedure, and correct site. The essential elements of the Universal Protocol are the preoperative verification process, marking the surgical site, and the time-out that is held immediately before the start of the procedure.

Preoperative Verification Process

Preoperative verification is an ongoing process of information gathering and confirmation. The purpose of the preoperative verification process is to do the following:

- Verify the correct patient, procedure, and site.
- Ensure that all relevant documents, images, and studies are available, properly labeled, and displayed.
- Verify that any required blood products, special medical equipment, and/or implants are present.

There are various elements of the preoperative verification process that can be completed before the patient arrives at the preoperative area—such as ensuring that documents, imaging, test results, and paperwork are properly labeled and match the patient's identifiers. Waiting until the time-out to complete the preoperative verification process may unnecessarily delay surgery if paperwork or imaging are not labeled or available when surgery is about to begin. It is more likely that portions of the preoperative verification may occur more than once and in more than one place. For example, the surgical informed consent may be obtained in the surgeon's office, and then verification that it has been completed may take place in the preoperative holding area.

Marking the Site

Marking the surgical/invasive site involves the patient and is done with an instantly recognizable and unambiguous mark. Ideally, an "X" is not used as the mark, as it may be interpreted as "not here" or "wrong side" and could potentially lead to errors in patient care, nor should other ambiguous marks such as a line or a dot be used. The mark must be consistent throughout the hospital. The site is marked in all cases involving laterality, multiple structures (fingers, toes, lesions), or multiple levels (spine). When an anesthesia provider performs a procedure, such as a regional block, that involves any of the above, that provider must also mark the site in addition to the surgeon marking the surgical site. The practitioner performing the invasive procedure must be the one who marks the site.

Marking of the surgical site can be performed in the preoperative holding area, the day surgery unit (DSU), and in patient units, prior to entering the operating/procedure room by a physician who will be participating during the entire procedure. In cases of surgical procedures, the surgeon who performs the surgery should mark the site. There are different titles used for the responsible surgeon, such as attending or consulting surgeon. For nonsurgical invasive procedures, it may be a general physician who will do the procedure. The hospital should identify who is authorized to perform surgical site marking in policy and procedure, or medical staff governing documents.

There are circumstances when a trainee or other authorized designee may perform the site marking—this is when the trainee performs the entire procedure, requiring minimal or no supervision from the responsible surgeon or physician. In these circumstances, the trainee marks the surgical site. When a trainee assists the surgeon or physician responsible, only the surgeon or physician may perform the site marking.

The site marking may take place any time before the surgical/invasive procedure begins, as long as the patient is actively involved in the site marking whenever possible and the mark is visible after the patient is prepped and draped. Examples of when patient participation may not be possible include the following:

- Patients who are not competent to make health care decisions
- Children
- Patients requiring emergent surgery

The hospital has an alternative procedure for identifying the correct site in cases in which site marking may cause harm, such as premature infants, or when a patient refuses site marking, and this should be outlined in policies and procedures. The site mark must be located where it will be visible after draping of the surgical site, so that it can be verified during the final time-out.

Measurable Elements of IPSG.04.00

1. The hospital implements a preoperative verification process using a checklist or other mechanism to document verification of the following:
   - Informed consent that is appropriate to the procedure
   - Correct patient, correct procedure, and correct site
   - All required documents, blood products, medical equipment, and implantable medical devices are on hand, correct, and functional
   - Whether there is a risk of blood loss > 500 mL (7 mL/kg in children)
   - Whether the patient has a difficult airway or aspiration risk
   - Any known allergies

   (*See also* PCC.03.00, ME 2)
2. Ⓓ The hospital uses an instantly recognizable and unambiguous mark for identifying the surgical/invasive site that is consistent throughout the hospital.
3. Ⓓ The surgical/invasive site marking process includes the following:
   - Marking completed by the person performing the procedure
   - Patient involved in the marking process
   - Alternative site-marking process for cases in which marking may result in harm
   - Alternative site-identification process for patients who refuse site marking
   - Alternative site-marking techniques for situations in which routine site marking is not possible (for example, laser, stereotactic radiosurgery, dental)

Standard IPSG.04.01

The hospital implements a process for the time-out that is performed immediately prior to the start of the surgical/invasive procedure and the sign-out that is conducted after the procedure.

Intent of IPSG.04.01

The time-out allows any unanswered questions or confusion to be resolved and provides a final opportunity to identify potential errors such as wrong-site surgery, surgery on the wrong patient, or the wrong surgical procedure on the right patient. The sign-out process after surgery allows for identification of areas needing improvement and for discussion of what went well during the surgery to assist the hospital in making decisions about overall surgery processes.

The time-out process applies to all surgical and nonsurgical invasive procedures. Evidence indicates that procedures that place the patient at the most risk include those that involve general anesthesia or deep sedation, although other procedures may also affect patient safety. Hospitals can enhance safety by correctly identifying the patient, the appropriate procedure, and the correct site of the procedure.

The time-out requirement is based on the following principles:

- Wrong-person, wrong-site, and wrong-procedure surgery can and must be prevented.
- A robust approach using multiple, complementary strategies is necessary to achieve the goal of always conducting the correct procedure on the correct person, at the correct site.
- Active involvement and use of effective methods to improve communication among all members of the procedure team are important for success.
- To the extent possible, the patient and, as needed, the family are involved in the process.
- Consistent implementation of a standardized protocol is most effective in achieving safety.

The time-out is implemented most successfully in hospitals with a culture that promotes teamwork and where all individuals feel empowered to protect patient safety. A hospital should consider its culture when designing