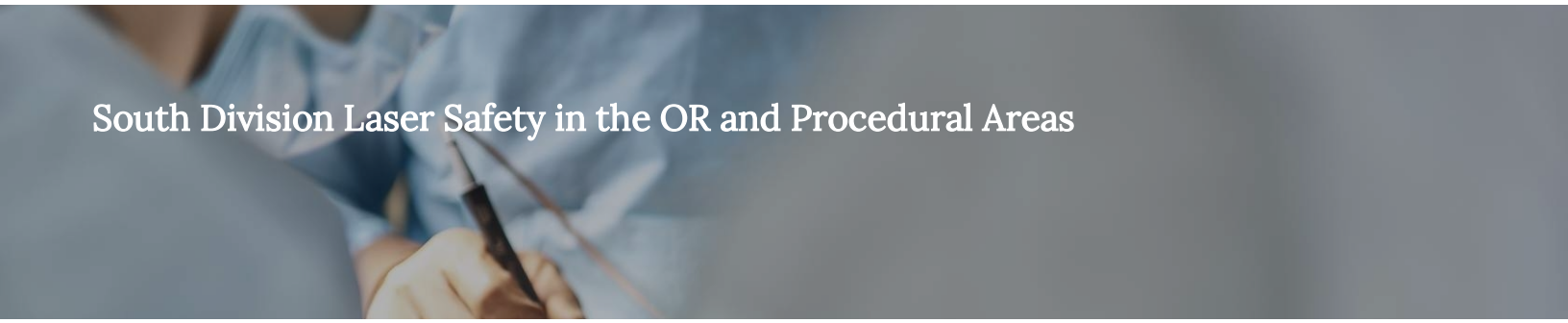


South Division Laser Safety in the OR and Procedural Areas

Providence

This module will review safety concerns, interventions, and policy/procedure relating to medical laser use in a hospital setting.

You will review the standardized procedure and then be presented with questions to test your understanding.

OVERVIEW

- Course and Concepts
- Laser Basics
- Laser Safety Education
- Non-Beam Hazards
- Xenon Chloride (XeCl) Excimer (Excited Dimer) Lasers

SAFETY PRECAUTIONS

- Laser Safety Controls
- Laser Safety Considerations for Patients

RESOURCES

- Laser Safety Resources
- References

KNOWLEDGE CHECK

- Post Test

COURSE COMPLETE

- Summary

Course and Concepts

Course Format

You will review the standardized procedure and then be presented with questions to test your understanding.

All activities must be completed before moving on to the next section.

Key concepts in this course are:

1. Identify the four laser classifications and their accompanying risks.
2. Examine beam and non-beam laser hazards.

CONTINUE

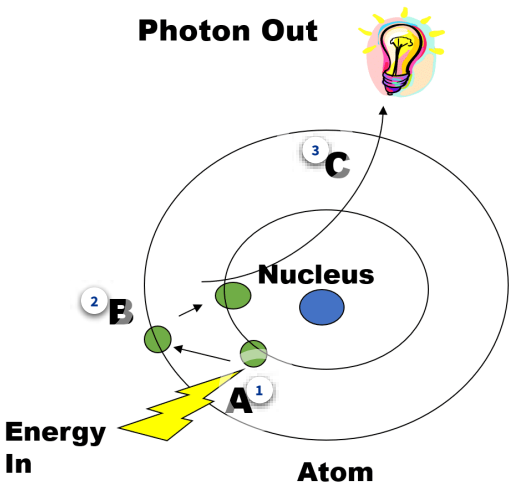
Laser Basics

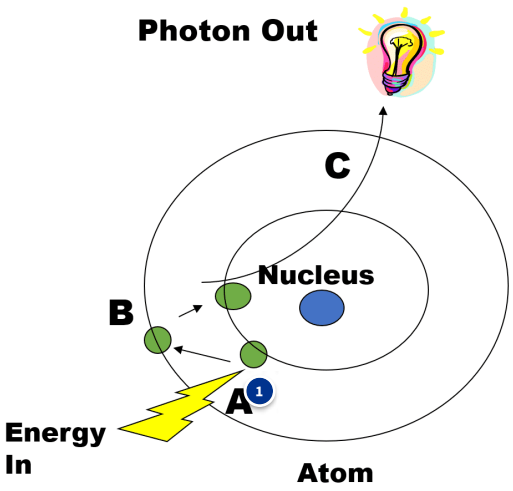
Laser Physics

- Laser is light
- Light is part of the Electromagnetic (EM) Spectrum
  - Non-ionizing radiation
  - Visible light only a small part of the EM spectrum
- Light is made up of particles called **photons**
  - Result of an electron returning to a steady state level
  - Energy difference between the excited and steady state electron level determines the frequency (color) of the light produced

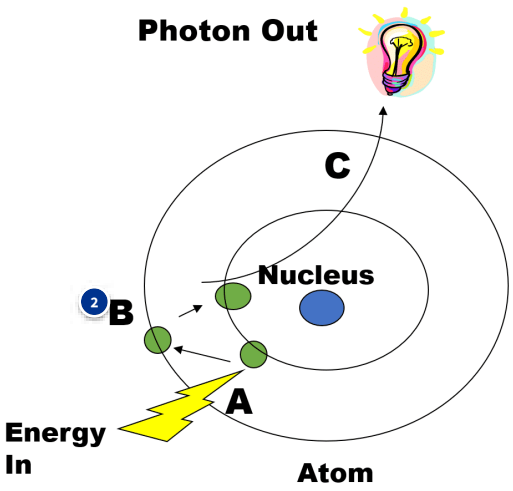
Photon Generation

Directions: Click or tap the numbered indicators below to review more about how photons are generated.

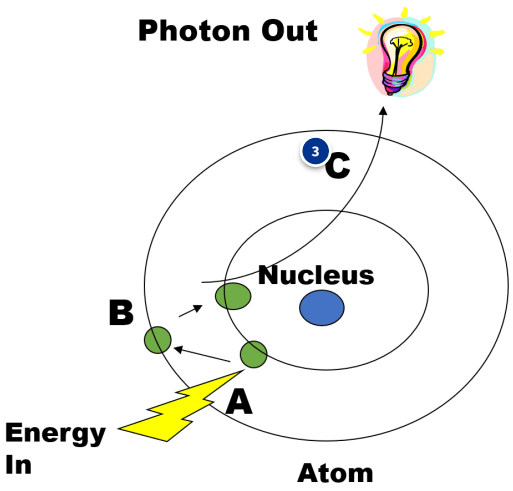




Energy is added to the atom, usually electrical.



Extra energy enables the electron to make a "quantum leap" to the next energy level, which is called the "excited state." The excited state is not stable.



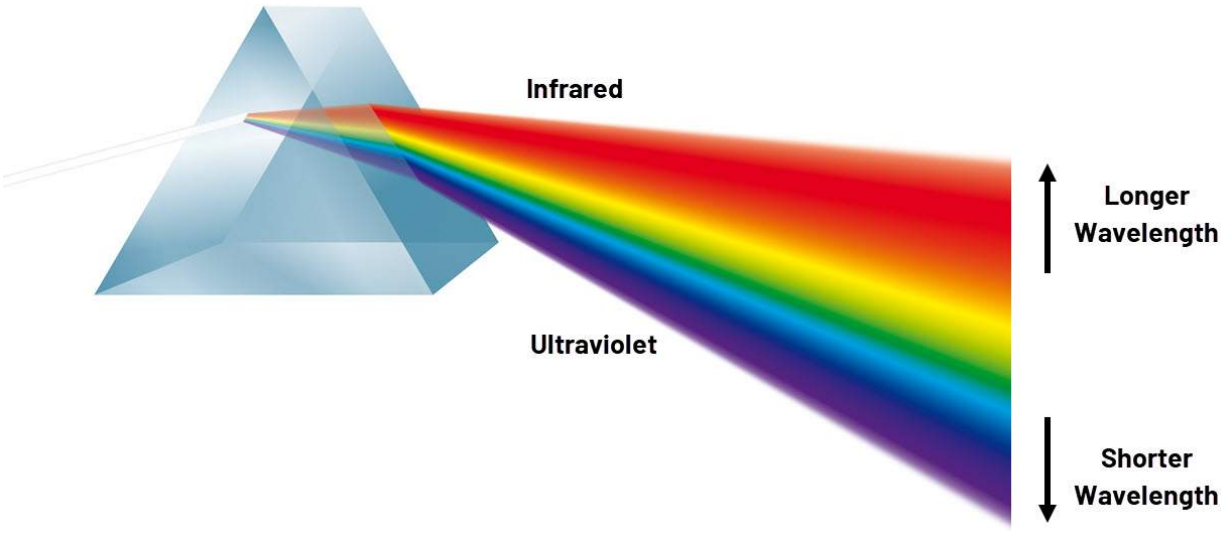
The electron returns to its normal energy level after it releases the extra energy in the form of a photon.

Light is a form of **electromagnetic radiation**

Not the dangerous type of radiation like X-Rays.

- [ ] Electromagnetic radiation is formed of particles of light called photons.
- [ ] Photons move in waves.
- [ ] The distance between the crests of each wave is called the wavelength.
- [ ] Wavelength determines color.
- [ ] May be invisible to humans.

Electromagnetic Spectrum



Laser Fundamentals

Laser light has three properties that differentiate it from ordinary light:

1. Monochromatic
   - Same frequency and wavelength
2. Directional
3. Coherent
   - Photons are in phase with each other

Laser light is **NOT** a natural phenomenon

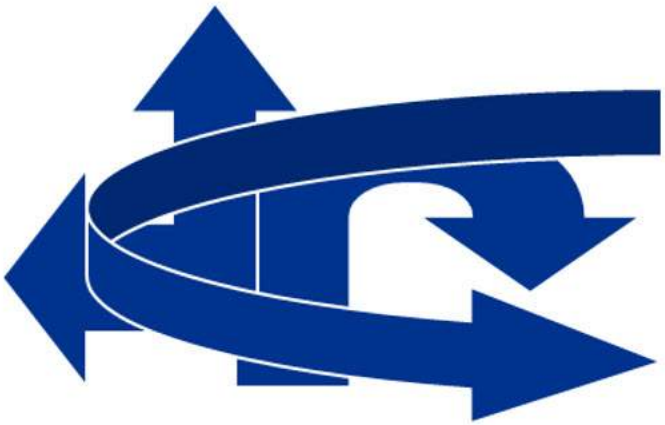
Normal Light vs. Laser Light

Directions: Click or tap each tab below to compare normal light and laser light.

NORMAL LIGHT

LASER LIGHT

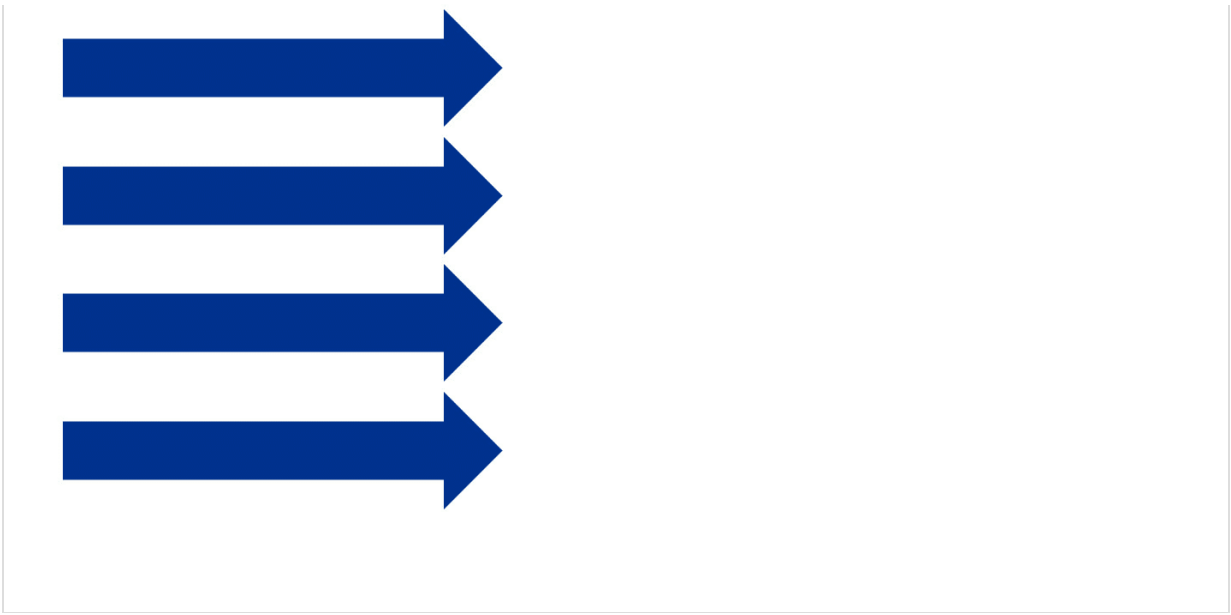
- Omnidirectional
- Non-coherent
  - "White noise"
  - Mob



NORMAL LIGHT

LASER LIGHT

- Unidirectional
- Coherent
  - In phase
  - Marching Band



Spontaneous vs. Stimulated Emission of Radiation

Directions: Click or tap the plus sign (+) next to each letter to review what it stands for.

L _

Light

A _

Amplification by

S _

Stimulated

E _

Emission of

R

Radiation

Laser Components

Lasers consist of four main components:

1. Lasing medium
   - Crystal
   - Semiconductor
   - Gas
   - Liquid
2. Excitation Mechanism
   - Power Supply
3. Optical Resonator
   - Laser Pump
4. Waveguide
   - Light pipe
   - Fiber optic cable
   - Mirrors

- Etc.

CONTINUE

Laser Safety Education

Lasers in Healthcare

Lasers in healthcare pose a direct threat to the eyes, skin, and other tissues with exposure.

Annual Training

All applicable personnel are required to receive laser safety training annually. This is critical to ensure the safety of our patients, caregivers, and visitors.

Applicable Personnel

Applicable personnel includes laser operators, technical support staff, laser safety officer, nurses, and allied health professionals.

Laser Classification

Click on the + symbols to review the different classes of lasers.

Class 1 _

Enclosed system, considered safe.

Class 2 _

No risk to skin, momentary viewing is not considered dangerous.

Class 3A _

No risk to skin; minimal risk to eyes.

Class 3B

Direct beam is hazardous to the eye or skin, eye protection is required. May be hazardous under specular reflection viewing conditions, but normally not a diffuse reflection or fire hazard.

Class 4

Laser beam is a fire hazard. Direct or reflected beam is hazardous to the eye or skin, eye protection is required. May produce Laser Generated Airborne Contaminants (LGAC) and plasma radiation.

Virtually all lasers used in hospitals fall into Class 4.

Complete the interactivity above before moving on.

Laser Component Level Hazards

- Lasing medium is sometimes toxic
- Excitation Mechanism is or contains a high voltage power supply
- Optical Resonator is sensitive to the smallest amount of contamination
- Waveguide hand piece:
  - Keep hand piece tip clean
  - Utilized laser light is often not visible!
  - Always consider the laser as "**On**"
  - Guide beams are visible

CONTINUE

Different Effects of Different Lasers

Directions: Click or tap each card below to review information about some of the most common lasers.

CO2

- 10,600 nm
- Absorbed by water
- Causes surface tissue changes

Nd:YAG

- 1060 nm
- Usually absorbed by light-colored tissue
- Passes through clear membranes and fluids without effect

Argon	• 810 nm • Usually absorbed by reddish tissue • Passes through clear membranes and fluids without effect
KTP	• 532 nm • Absorbed by reddish tissue

Diode Lasers	These can be manufactured to create many different wavelengths, although usually each machine produces only 1 or 2 wavelengths
Holmium	• 2100 nm • Passes through clear membranes and fluid without effect • Has a unique photoacoustic effect which allows it to be a very effective tool for lithotripsy of particularly dense calculi

Ways to Affect Depth of Penetration

Directions: Click or tap the checkbox next to each statement to mark it as read. Review all to move on.

- [ ] Choice of Laser
- [ ] Contact Fiber vs. Free Beam
- [ ] Power Density
- [ ] Power Settings

- [ ] Focus of Beam
- [ ] Tissue Absorption

Complete the interactivity above before moving on.

CONTINUE

Non-Beam Hazards

Let's review the following non-beam hazards:

1. Fire
2. Laser Generated Airborne Contaminants (LGAC)
3. Electrical Hazards
4. Laser System component hazards including the following:

    - Lasing medium, which can be a gas, liquid, crystal, of semiconductor, depending on the laser used
    - Excitation mechanism (which can significantly increase the electrical hazard), optical resonator (i.e., "laser pump"),
    - Waveguide, which is the fiber, handpiece, or microscope used to deliver the energy

Fire Prevention During Laser Use

Fire requires a combination of three elements to ignite and continue burning:

- Fuel (e.g., alcohol-containing prep solutions, drapes, gowns, or bed linens)
- Oxidizer (usually oxygen in healthcare settings)
- Ignition source (e.g., electrosurgical devices, powered drills and saws, or static discharge)

- Saline or water must be on a surgical sterile field during laser cases.
- Eye lubricant must be water soluble and not petroleum based.
- FDA approved laser resistant tubes should be used during laser airway surgery.
    - Other techniques, such as Venturi jet ventilation or apnea without the presence of an ETT, may be used.
    - Oxygen and flammable anesthetic gas use in head and neck procedures where any ignition source is employed should be titrated to patient oxygen saturation needs.
- Lasers are to be in stand-by mode when not being activated by the physician.
- Health care personnel are to assess the laser fiber for integrity, visually inspecting for cracks prior to use and not securing fibers with metal clamps.

Laser Generated Airborne Contaminants (LGAC)

Laser Plume

Laser plume contains dead and live cellular material and viruses, as well as chemical by-products. Potentially harmful health effects can result from the inhalation of these materials.

Plume Evacuator

The first line of defense against LGACs is the use of a plume evacuator.

A plume evacuator is a filtered system designed to capture small, aerosolized particulates. The evacuator is also helpful in maintaining the Licensed Independent Practitioner's (LIP) field of view.

- Every aerosol generating laser case shall use plume evacuation (including laparoscopy procedures)
- Effective evacuation of surgical plume (including plume generated by laser energy) requires the evacuator tip be kept not more than 2 inches of the surgical site to effectively capture the plume
    - The smoke evacuator tip should be kept 1-2cm away from the site of LGAC generation as long as it does not interfere with the procedure.

NIOSH Recommendation

The NIOSH recommended PPE for laser plume is a properly fitted N95 mask.

Staff shall wear the N95 respirator during aerosol generating laser procedures.

ⓘ Cases where smoke evacuation are not necessary include those procedures performed under fluids (cystoscopy, hysteroscopy, arthroscopy) and intraocular surgery.

Electrical Hazards

Laser consoles utilize high voltage electrical currents.

Biomedical engineering staff must conduct an electrical safety assessment of laser consoles brought in by vendors prior to use.

Safety Check

During the safety check, Biomed staff also review vendor documentation of:

- Maintenance logs to ensure vendor compliance with manufacturer recommended service intervals.
- Recent repair logs to ensure any previous issues with the console have been remedied.

The same safety check should be performed before each use.

Visually inspect lasers before use to ensure there are no frayed or broken cords, and that the console is intact.

The laser should be test fired to ensure alignment of the laser beam to the guide beam, if possible.

Your ministry DOES NOT use Xenon Chloride (XeCl) Excimer (Excited Dimer) Lasers

Click or tap the button to the right to continue with the course.

CLICK OR TAP HERE

Your ministry DOES use Xenon Chloride (XeCl) Excimer (Excited Dimer) Lasers

Click or tap the button to the right to review additional information about exicmer laser safety.

CLICK OR TAP HERE

CONTINUE

Xenon Chloride (XeCl) Excimer (Excited Dimer) Lasers

If Xenon Chloride excimer lasers are used at your ministry, please review the safety information below:

Xenon chloride (XeCl) excimer lasers (short for excited dimer), are used to treat a variety of dermatological conditions by creating laser light in the ultraviolet range.

Excimer lasers mix a noble gas (xenon) and a reactive gas (chlorine). These gases are contained in high-pressure cylinders within the laser housing. Leaking gases create a risk of suffocation as oxygen is displaced.

- Turn off all laser gas cylinders when not in use.
- Listen carefully for gas hissing or leaking. If leaks are detected, notify the team immediately and stop the gas flow.
- Follow initial laser set-up instructions with regards to assessing for gas leaks.

CONTINUE

Laser Safety Controls

Wavelength Determines Safety Measures

- Type of safety eyeglasses used – wavelength specific
- Type of Laser resistant ET tubes in shared-airway procedures
- Window coverings
- Microscopes

Summary of Laser Safety Recommendations that Apply to All Lasers:

- Everyone's eyes must be protected
- Traffic in and out of the area must be minimized
- Exposure to outside areas must be minimized
- The laser must be in standby mode when surgeon is not firing it
- The laser safety officer should have no other responsibilities other than operating the laser
- The laser foot pedal must be available to the surgeon who delivers the laser energy to the tissue
- Dull or nonreflective anodized instruments should be used near the laser site when applicable
- Patients and healthcare workers should be protected from inhaling the smoke plume associated with laser use
- Patients and health care workers should be protected from fire hazards associated with laser use
- The laser key should never be left in the laser during storage
- Patients and health care workers should be protected from electrical hazards associated with laser use
- Perioperative personnel working in a laser treatment area should be required to obtain safety training and basic orientation to the technology
- Policies and procedures for laser safety should be developed with regard to the practice setting

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All caregivers:

- Report any laser related incidents/injuries to your manager or the Laser Safety Officer (LSO), if your ministry has one, for investigation.
    - Submit any reports per policy.
- Follow instructions from LSO or designee during procedures in observance of the chain of command.
- Attend mandatory annual laser safety training.

Click or tap the flashcards to review additional laser safety controls. Review all to move on.

Laser Keys

Access to laser keys/codes is decided by the LSO and

Laser Keys

is restricted only to authorized personnel.

Emergency Shut Off

Be aware of the Emergency Shut Off button location on any laser console being used in our environment.

Non-reflective Instruments

Use ***non-reflective instruments (matted or ebonized)*** during laser procedure to decrease reflectivity of laser beams.

Laser Foot Pedal

The laser foot pedal is to only be activated by the operator (LIP).

Complete the content above before moving on.

Please review the example of an Emergency Shut Off button to the right.

Eye Protection

Eye protection is required for all persons in the room when lasers are being used.

The approved laser protection glasses must match the wavelength of the laser being used. All laser protection glasses must be marked by the manufacturer with the wavelengths blocked. Laser glasses without manufacturer wavelength markings may not be used to protect caregivers and employees from eye injury.

Laser glasses or goggles should only be used on awake patients if they are sitting up - laying down creates gaps under the glasses which could allow laser energy to injure the eyes. The patient's eyes must be protected using laser-appropriate eye shields. Moistened gauze may not be positioned sufficiently to protect the

eyes.

Physicians can refuse to wear laser glasses. This refusal should be documented by the LSO in the room.

A pair of the appropriate laser glasses should be attached to the door of the room in which medical lasers are used in case someone must enter the room for care or emergencies.

Required Signage

FDA-approved signs are required by ANSI outside of a room in which medical lasers are used. These contain universal symbols and should not be handmade due to risk of omitting required information:

- The wavelength of the laser in use
- The type of eye protection required

Please review an example of an FDA-approved sign below:

Remember: Most lasers will pass through glass. To reduce the need for calculating the nominal hazard zone for each laser, cover all windows with towels (not paper) or non-flammable curtains to protect those outside the treatment area from injury.

CONTINUE

Laser Safety Considerations for Patients

1. **Non-target tissue** must be protected with wet cloth towels.

2. **Patient eye protection during laser procedures:**

   - General Anesthesia: Laser safe eye shields should be used if available. If not, the eyes may be taped shut with wet eye pads covering the entire orbital area.
   - MAC/Local Anesthesia: Appropriate wavelength goggles/glasses must be in place.
   - Procedures near the eye: metal (not plastic) corneal shields must be in place.
     - Corneal shields are not always appropriate, e.g., procedures in which the opposite eye is needed to direct the operative eye's position.

3. **Procedures in the airway** require an FDA approved laser ET tube.

CONTINUE

Laser Safety Resources

Refer to your ministry's Laser Safety Officer (LSO) with any questions and or to obtain resources.

CONTINUE

References

American National Standards Institute Z136.3 (2018): Laser Institute of America.

AORN Guidance Statement: Fire Prevention in the Operating Room. In: *Perioperative Standards and Recommended Practices.* Denver, CO: AORN, Inc. 2017.

California Code of Regulations, General Industry Safety Orders § 3382.

Centers for Disease Control and Prevention (CDC) & The National Institute for Occupational Safety and Health (NIOSH). Health and Safety Practices Survey of Healthcare Workers. Retrieved from: https://www.cdc.gov/niosh/topics/healthcarehsps/smoke.html.

Providence St. Joseph Health, Oregon Region (2017). Laser Safety Awareness Regional Training [Power Point slides].

Providence St. Jude Basic Laser Safety Class (2021). Laser Safety Training [Power Point slides].

CONTINUE

Post Test

Answer the following questions to confirm your understanding of the content in the standardized procedure. You must receive a score of 100% correct in order to successfully complete this course. You have unlimited attempts to achieve the required score.

Question

01/06

Multiple Choice:

What determines the color of light?

- ◯ Wavelength
- ◯ Electromagnetic Radiation
- ◯ Dye

Question

02/06

True or False:

Laser light is chaotic.

- ◯ True
- ◯ False

Question

03/06

Multiple Choice:

With a C02 laser, which glasses are OK for the OR team to use?

- ◯ Plastic glasses or goggles with side shields
- ◯ Sunglasses with UVA/UVB protection
- ◯ Wavelength-specific laser eyeglasses or goggles

Question

04/06

Multiple Choice:

With all lasers, it is important that the surgical drapes surrounding the operative site be wet to prevent:

- ◯ Drying of the tissue
- ◯ Fire hazard
- ◯ Reflection of the laser beam

Question

05/06

Multiple Choice:

Who may operate the foot pedal for the laser during a procedure?

- ◯ The surgeon and the assistant
- ◯ The surgeon only
- ◯ The surgeon and the scrub nurse
- ◯ The surgeon and the Laser Safety Officer

Question

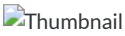
06/06

Multiple Choice:

When are the laser resistant Endotracheal tubes used?

- ◯ Whenever a laser surgery is performed where the pt is intubated
- ◯ When the anesthesiologist requests them
- ◯ During any laser shared airway procedure
- ◯ When the department is out of regular Endotracheal Tubes

Summary



Thank you for completing the Laser Safety in the OR and Procedural Areas course!

Exit

Click to exit the course.

EXIT

Status **Active** PolicyStat ID **2236552**

Origination	04/2017
Last Approved	04/2017
Effective	04/2017
Last Revised	04/2017
Next Review	04/2020
Owner	Mary Jane Neri: Executive Director Nursing
Policy Area	Perioperative
Applicability	CA - Divisional/ Regional
References	LA Region

Surgical Attire

In keeping with the mission and values of Providence Health & Services, it is the policy of Providence Health System-Southern California to adopt this regional clinical standard for use in the following*:

Providence Little Company of Mary Medical Center Torrance:	
x	Acute Care
	Transitional Care Center
	Providence Little Company of Mary Home Health
Providence Little Company of Mary Medical Center San Pedro:	
x	Acute Care
	Sub-Acute Care Center
	Psychiatric Unit
	Acute Rehabilitation
	Chemical Dependency Unit
Providence Holy Cross Medical Center:	
x	Acute Care
	Sub Acute Care Unit
	Rehabilitation Unit
Providence Saint Joseph Medical Center:	
x	Acute Care
	Providence Home Care
	Providence St. Elizabeth's
	Rehabilitation Unit

	Roy and Patricia Disney Family Cancer Center
Providence Tarzana Medical Center:	
x	Acute Care
Providence Saint John's Health Center:	
x	Acute Care

*An "x" identifies inclusion and the absence of an "x" indicates exclusion or exception.

Number: CA-PERIOP 13008

POLICY

When performing an invasive procedure these recommended practices provide guidelines for surgical attire. The human body and inanimate surfaces inherent to the surgical environment are major sources of microbial contamination and transmission of microbes; therefore surgical attire and appropriate personal protective equipment (PPE) are worn to promote worker safety and a high level of cleanliness and hygiene within the perioperative environment. These recommended practices are not intended to address sterile surgical attire worn at the surgical field or all PPE.

These practice settings include operating rooms, cardiac catheterization labs, radiology departments, ambulatory surgery centers and all other areas where surgery and other invasive procedures may be performed.

DEFINITIONS

***Semi-Restricted Areas* :** includes the peripheral support areas of the surgical suite and has storage areas for sterile and clean supplies, work areas for storage and processing instruments, and corridors leading to the restricted areas of the surgical suite, and clean core. (Hallways leading to the control rooms of the Cardiac Cath Labs and Interventional radiology are not restricted or semi restricted.)

Restricted Areas: includes the OR and procedure rooms.

Surgical Attire: non-sterile apparel designated for the OR practice setting that includes two-piece pant suits, cover jackets, head coverings, masks, protective eye wear and other protective barriers.

PROCEDURE/GENERAL INSTRUCTIONS

1. All staff and physicians working in the semi-restricted and restricted areas of the operating rooms are required to wear facility approved surgical attire laundered by healthcare accredited laundry facilities. Lab coats and other external jackets may not be worn in the semi-restricted and restricted areas.
2. A two-piece scrub suit should be worn with the top of the scrub suit secured at the waist, tucked into the pants or fit close to the body to prevent skin squames from being dispersed into the environment.
3. All personal clothing should be completely covered by the surgical attire. Cover apparel should be laundered daily. Undergarments, such as a t-shirt with a V-neck, which can be contained

underneath the scrub top, may be worn. Personal clothing that extends above the scrub top neckline or below the sleeve of the surgical attire should not be worn.

- When in the restricted areas, all non-scrubbed personnel should cover their arms with a long sleeved warm-up jacket snapped closed with the cuffs down to the wrists.

4. Surgical attire which is provided by the medical center is not to leave the campus. These surgical scrubs are only to be worn during working hours, must be removed at the end of shift and then returned to a soiled surgical scrub hamper.
    - Surgical attire that has been penetrated with blood or other potentially infectious materials should be removed immediately (or as soon as possible) and replaced with freshly laundered surgical attire.
5. Personnel who require access to semi-restricted or restricted areas may wear hospital provided disposable jump suits. (e.g., service employees, family members observing c-sections, interpreters). Direct patient care and scrubbed personnel are restricted from wearing a jump suit.
6. Persons entering the semi-restricted or restricted areas of the surgical suite for a brief time for a specific purpose (e.g., law enforcement officers, parents, biomedical engineers) should cover all head and facial hair and should don either freshly laundered surgical attire; single-use attire; or a hospital provided single-use jumpsuit (e.g., coveralls, bunny suit) designed to completely cover outside apparel.
7. Surgical attire should only be worn by personnel required to be in semi-restricted or restricted areas unless approved by management
8. Fanny packs, backpacks and briefcases or other personal items should not be taken into the semi-restricted areas or restricted areas. If circumstances dictate that the aforementioned items must be brought into the semi-restricted or restricted areas, they must be contained in a non-porous material that may be easily cleaned or disinfected should it become contaminated. Items that cannot be contained within a bag must be disinfected adequately. Cleaning must occur prior to entering the semi-restricted or restricted areas.
9. All personnel should cover head and facial hair, including side burns and the nape of the neck when in the restricted and semi-restricted areas. A clean low-lint surgical head cover or hood that confines all hair and covers scalp skin should be worn. Skull caps may fail to contain the side hairs above and in front of the ears and hair at the nape of the neck, and must either not be worn or covered by a bouffant style cap when in the semi-restricted or restricted areas. Used single-use head coverings should be discarded daily and when contaminated. Reusable head coverings must be covered with a single-use surgical head cover as they are not laundered by health care-accredited laundry facilities.
10. Shoes worn within the perioperative environment should be clean and should have closed toes and backs, low-heels, and non-skid soles. Shoes that are worn only in the perioperative area may help to reduce the contamination of the perioperative environment. Shoe covers may be worn when there is anticipation of contamination with blood and/or body fluids. They are removed before leaving the perioperative area.
11. All individuals entering the restricted area should wear a surgical mask when open sterile supplies and equipment are present. The mask should cover the mouth and nose and be

secured in a manner to prevent venting. A fresh, clean surgical mask should be worn for every procedure. The mask should be replaced and discarded whenever it becomes wet or soiled. Masks should not be worn hanging down from the neck. Surgical masks should be discarded after each procedure. Masks should be removed carefully by handling only the mask ties. Hand hygiene should be performed after removal of mask. Only one surgical mask should be worn at a time.

12. Jewelry including earrings, necklaces, watches and bracelets that cannot be contained or confined within the surgical attire should not be worn. Rings should be removed before hand washing or using hand rubs.
13. Identification badges should be worn by all personnel authorized to enter the perioperative setting. They should be secured on the surgical attire top, above the waist and be visible and be cleaned if they become soiled.

EDUCATION:

Health care personnel should receive education and guidance on appropriate articles of surgical attire worn in the perioperative environment at orientation and after changes are made.

REFERENCES:

AORN Guidelines for Perioperative Practices. Guideline for Surgical Attire p97-119, Denver 2015

Society of Interventional Radiology: Guideline: Sterile Technique for Vascular/Interventional Radiology : Volume 23 . Number 12 . December 2012

Joint Practice Guideline for Sterile Technique during Vascular and Interventional Radiology Procedures: From the Society of Interventional Radiology, Association of PeriOperative Registered

Nurses, and Association for Radiologic and Imaging Nursing, for the Society of Interventional Radiology (Wael Saad, MD, Chair), Standards of Practice Committee, and Endorsed by the Cardiovascular Interventional Radiological Society of Europe and the Canadian Interventional Radiology Association

COLLABORATION

This policy was developed in collaboration with the following involved Departments

Labor & Delivery

Cardiology

Surgery

Infection Control

Attachments

image1.jpeg

Approval Signatures

Step Description	Approver	Date
	Jan Keller-Unger: Reg Dir Nurs Workforce Dev-Tip	04/2017
	Michael Bernstein: Chief Medical Officer Fac	04/2017
Ministry MECs	Adrieanne Guerrero: Clin Nurse	03/2017
Ministry MECs	Denise Eastburn: Dir Med Staff/Patient Rel	01/2017
Ministry MECs	Susan Parrini: Director of Medical Staff	12/2016
Ministry MECs	Guenther Baerje: Director of Medical Staff	12/2016
Ministry MECs	Cecilia Hogenson Kida: Director of Medical Staff	12/2016
Ministry MECs	Sonia Ramos: Mgr Medical Staff	12/2016
Ministry Departments of Surgery	Sonia Ramos: Mgr Medical Staff	12/2016
Ministry Departments of Surgery	Susan Parrini: Director of Medical Staff	11/2016
Ministry Departments of Surgery	Cecilia Hogenson Kida: Director of Medical Staff	10/2016
Ministry Departments of Surgery	Guenther Baerje: Director of Medical Staff	07/2016
Ministry Departments of Surgery	Adrieanne Guerrero: Clin Nurse	07/2016
Ministry Departments of Surgery	Denise Eastburn: Dir Med Staff/Patient Rel	06/2016
CMOs	Robert Raggi: Chief Medical Officer Fac	06/2016
CMOs	Nicholas Testa: Chief Medical Officer Fac	06/2016
CMOs	Richard Glimp: Chief Medical Officer Fac	05/2016

CMOs	Howard Davis: Chief Medical Officer Fac	05/2016
CMOs	Donald Larsen Jr: Chief Medical Officer Fac	05/2016
CNOs	Elizabeth Hart: Chief Nursing Officer	05/2016
CNOs	David Neal: Chief Nursing Officer	05/2016
CNOs	Ann Dechairo Marino: Chief Nursing Officer	05/2016
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Regional Risk Management Excellence Council	Marianne Padden: Dir Risk Mgmt - So Bay Comm Svc	05/2016
Regional Infection Prevention Excellence Council	Angela Vassallo: Dir Infection Prevention	05/2016
Regional Performance Improvement Excellence Council	Steven Tanner: Director of QI and Accreditation	05/2016
Regional Perioperative Excellence Council	Yvonne Gaffney: Dir Periop Svcs Special Prjcts	04/2016

Standards

No standards are associated with this document

Status **Active** PolicyStat ID **15125825**

Origination	05/2011	Owner	Mary Jane Neri: Executive Director Nursing
Last Approved	03/2024	Policy Area	Perioperative
Effective	03/2024	Applicability	CA - Divisional/ Regional
Last Revised	03/2024	References	LA Region
Next Review	03/2027		

Surgical Safety Checklist

Number: CA-PERIOP-13002

POLICY

In keeping with the philosophy and mission of Providence Health & Services, it is the policy of Providence Health System – Southern California (PHS-SC) that the medical staff and all the personnel anywhere an invasive procedure is performed with anesthesia will be responsible for implementing and ensuring compliance with the WHO Surgical Safety Checklist. The WHO Surgical Safety Checklist is utilized in conjunction with the Universal Protocol.

PURPOSE

To reinforce accepted safety practices and foster better communication and teamwork between clinical disciplines of the operating team.

The operating team is comprised of the surgeons, anesthesiologist, nurses, technicians, and other personnel involved in surgery.

The goal of this checklist in conjunction with the Universal Protocol is to help ensure that teams consistently follow critical safety steps and thereby minimize the most common and avoidable risks endangering the lives and well being of surgical patients.

PROCEDURE/GENERAL INSTRUCTIONS

The Surgical Safety Checklist is not all inclusive of the steps taken prior to the beginning of a procedure. The Universal Protocol in addition to the Checklist defines the safety steps followed prior to the beginning of a surgical procedure.

1. The Surgical Safety Checklist is implemented by the circulating nurse/and the anesthesiologist.
2. Each step is checked verbally with the appropriate team member to ensure that the key actions have been performed.
3. The Surgical Safety Checklist is divided into three phases, each corresponding to a specific time period in the normal flow of a procedure.
    A. Before induction of anesthesia: Requires the presence of the anesthesiologist, nursing personnel and scrub.
    B. Before skin incision: Requires the presence of the circulating nurse, anesthesiologist, surgeon, assistant surgeon if appropriate, and other personnel necessary for case.
    C. End of case de-brief/Before patient leaves the operating room: Requires same team as before incision.
4. Before induction of anesthesia in any operating or procedure room the circulating nurse and the anesthesiologist will confirm the following:
    A. Confirm patient's identity using name and date of birth per policy, procedure, site and side. The consent is signed.
    B. Confirm that site has been marked per Universal Protocol.
    C. Verify with anesthesiologist the completion of anesthesia machine and medication check.
    D. Confirm that monitors are on the patient and are functioning.
    E. Confirm suction is available and turned on.
    F. Confirmation of patient allergies.
    G. Confirm that the anesthesiologist has assessed whether the patient has a difficult airway or risk of aspiration.
    H. Confirm Fire Risk Assessment score.
    I. Confirm that the appropriate antibiotic prophylaxis is available and administered prior to incision time.
    J. Confirm if patient is on a beta blocker and that the beta-blocker was administered as ordered.
    K. Confirm diagnostic tests and lab results are displayed and available as needed.
    L. Confirm presence of History and Physicial less than 30 days old, Interval Note within 24 hours, and pre-anesthesia assessment.
    M. Circulator and scrub technician confirm sterility verification.
    N. Confirm specialty equipment/implants and vendors are available in-house.
    O. Confirm warming plan.
    P. Confirm DVT prophylaxis (SCD).
    Q. Confirm blood availablity/refusal.
    R. Confirm additional safety precautions based on patient history and medications.

S. There is active VERBAL communication from all team members.

5. Before surgical incision the checklist coordinator will confirm the following:
    A. Confirm all new/visitor team members have introduced themselves by name and role. Familiar/ staff team members names are listed on the white board. Effective management of high risk situations requires that all team members understand who each member is and their roles and capabilities.
    B. Confirm the patient's name, date of birth, procedure and site, using consent form.
    C. Confirm site is visible after draping, if applicable.
    D. Confirm that the appropriate antibiotic prophylaxis is available and administered prior to incision time.
    E. Confirmation of sterility including indicator results.
    F. Confirmation that essential imaging is displayed and medications and fluids are labeled.
    G. Verbalize any problems/concerns with equipment.
    H. Determine length of case, anticipated blood loss, type and cross available.
    I. Confirm Fire Risk Assessment score.
    J. Confirm DVT prophylaxis (SCD).
    K. There is active VERBAL communication from all team members. The blade is not passed until the timeout has been completed.
6. End of the case de-brief before the patient leaves the operating room the checklist coordinator will confirm the following:
    A. Confirm with surgeon the name of the surgical procedure.
    B. Completion of instrument, sponge, and needle counts, including notification of surgeon of count results. Verbal confirmation of the surgeon is required.
    C. Confirm correct labeling of specimen including patient name, and special markings.
    D. Confirm wound classification.
    E. Ensure that equipment problems arising during a case are identified by the team.
    F. Surgeon, anesthesiologist, and nurse review the post-operative recovery and management plan, focusing on intra-operative or anesthetic issues that might affect the patient.
    G. In the event an employee observes non-compliance with the surgical safety checklist policy, the employee is encouraged to speak up; in the event the employee is not successful s/he should notify his/her immediate supervisor.

Documentation

Document completion of Surgical Safety Checklist on the Electronic Medical Record (EHR).

REFERENCE(S)/RELATED POLICIES

- Implementation Manual
  Atul Guwande, The Checklist Manifesto 2009
- WHO (2009). WHO | WHO Surgical Safety Checklist

COLLABORATION

This policy was developed in collaboration with the following:
Perioperative Departments
Department of Nursing
Quality Improvement
Department of Anesthesia
Department of Surgery

Approval Signatures

Step Description	Approver	Date
b/o Divisional Nursing Cabinet	Wen Yun Chang: Senior Business Analyst	03/2024
Division CNO - South	Daniel Kelly: Division Chief Nursing Officer - South	01/2024
Regional Policy Owner	Mary Jane Neri: Executive Director Nursing	01/2024

Applicability

CA - Regional/Divisional

Standards

No standards are associated with this document

Status **Active** PolicyStat ID **1703310**

Origination	02/2012
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Next Review	03/2020

Owner	Mary Jane Neri: Executive Director Nursing
Policy Area	Perioperative
Applicability	CA - Divisional/ Regional
References	LA Region

To find another policy, use the browser BACK button to return to your Ministry.

Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Invasive Procedures

In keeping with the mission and values of Providence Health & Services, it is the policy of Providence Health System-Southern California to adopt this regional clinical standard for use in the following*:

Providence Little Company of Mary Medical Center Torrance:	
X	Acute Care
	Transitional Care Center
	Providence Little Company of Mary Home Health
Providence Little Company of Mary Medical Center San Pedro:	
X	Acute Care
	Sub-Acute Care Center
	Psychiatric Unit
	Acute Rehabilitation
	Chemical Dependency Unit
Providence Holy Cross Medical Center:	
X	Acute Care
	Sub Acute Care Unit
	Rehabilitation Unit
Providence Saint Joseph Medical Center:	
X	Acute Care
	Providence Home Care

	Providence St. Elizabeth's
	Rehabilitation Unit
	Roy and Patricia Disney Family Cancer Center
Providence Tarzana Medical Center:	
X	Acute Care
Providence Saint John's Health Center:	
X	Acute Care

*An "x" identifies inclusion and the absence of an "x" indicates exclusion or exception.

Number: CA-PERIOP-13005

POLICY

In keeping with the mission and values of Providence Health & Services, it is the policy of Providence Health System – Southern California (PHS-SC) to ensure patient safety and eliminate risk of wrong site, wrong procedure, wrong person invasive procedures.

PROCEDURE/GENERAL INSTRUCTIONS

1. The Universal Protocol requirements are applicable to all operative and other invasive procedures including procedures done in settings other than the operating room such as a special procedures unit, interventional radiology department and at the bedside.
    A. Certain routine 'minor' procedures such as venipuncture, peripheral IV line placement, insertion of a NG tube, foley catheter or closed reductions are NOT within the scope of this protocol.
    B. Site marking is NOT required (nor is it prohibited) for all procedures. These may include mid-line sternotomy and bilateral procedures, Cesarean sections, laparotomy or laparoscopy, cardiac catheterization and other interventional procedures for which the site of insertion is **NOT predetermined** . However, most other procedures that involve puncture or incision of the skin or insertion of an instrument or foreign material into the body, including, but not limited to, implantable devices, percutaneous aspirations, biopsies, vascular catheterizations, epidurals, and endoscopies are within the scope of the Universal protocol.
    C. Pre-procedural Universal Protocol verification "time out" will be completed for all surgical and nonsurgical invasive procedures.
2. Procedural / operative site marking is performed to eliminate confusion.
    A. Mark site for:
        1. Laterality (right / left).
        2. Fingers, identified as thumb, index, long, ring, little.
        3. Toes, identified as big, 2 nd , 3 rd , 4 th , 5 th .
        4. Multiple structures, locations, palpable masses and hernias.

5. Surface (flexor, extensor).
6. Spinal surgery to differentiate levels:
    a. Mark general level (cervical / thoracic / lumbar), side and approach prior to surgery.
    b. Mark precise level intra-operatively using radiographic technique.

B. Diagnostic radiological procedures where site / level / laterality is predetermined.
C. Minimal access procedures that intend to treat a lateralized organ.
D. Cranial procedures (mark pre-auricular area on appropriate side).
E. Eye procedures (mark per hospital policy).

3. Exemptions:
    A. Single organ case (i.e., appendectomy).
    B. Teeth (mark dental radiograph or diagram).
    C. Site NOT predetermined ("possible").
    D. Premature infants.
    E. Bilateral procedures.
    F. Emergencies where delay may risk life or limb.Pre-Procedure Verification:
4. Verification of the correct person, procedure and site occurs.
    A. At the time the surgery / procedure is scheduled. The surgery or procedure schedule list designates laterality (right / left) as appropriate.
    B. At the time of preadmission testing and assessment.
    C. At the time of admission or entry into the facility on elective or emergent procedures.
    D. Anytime responsibility for care of the patient is transferred to another caregiver.
    E. With the patient involved, awake and aware, if possible.
5. Verify the patient identification as described in clinical procedures: (See ministry specific Patient Identification policies and procedures.)
6. The patient's procedure is verified by checking the physician orders against the surgical consent, history and physical (H&P), interval note, and / or progress notes. Any discrepancies are resolved through verification by the physician operator.

Marking the Procedural Site:

1. After verification of the site, the physician marks the patient at PROVIDENCE SAINT JOSEPH MEDICAL CENTER, PROVIDENCE HOLY CROSS MEDICAL CENTER, and PROVIDENCE TARZANA MEDICAL CENTER the surgeon marks with his/her initials near the incision / insertion site.
   At PROVIDENCE LITTLE COMPANY OF MARY MEDICAL CENTER SAN PEDRO, PROVIDENCE LITTLE COMPANY OF MARY MEDICAL CENTER TORRANCE and PROVIDENCE SAINT JOHN'S HEALTH CENTER the surgeon marks using the word "YES" near the incision / insertion site.

A. If the patient is a minor, the patient's guardian verifies the site with the patient and clinical staff.

B. Marking takes place with the patient involved, awake, and aware, if possible.

C. A physician, nurse practitioner who works privately for the operating physician or physician assistant, with privileges to perform the procedure and who will be involved directly with, and present at the time of performing the procedure, marks the procedure site.

D. The mark is made at or near the intended incision site. Do not mark any non-operative sites.

E. The mark is made using a marker that is sufficiently permanent to remain visible after completion of the positioning, skin prep and sterile draping.

F. Multiple sites must be marked.

G. Minimal access procedures: the intended site of a lateralized internal organ must be indicated by a mark at or near the insertion site (e.g., to the right of the insertion site for a right sided organ).

H. Anytime either another practitioner or the same practitioner performs second procedure on the same patient, a second site marking is required.

2. Alternative site identification processes: (to be used for cases in which it is technically or anatomically impossible or impractical to mark the site) See **Appendix A** for list of procedures.

A. At **PSJMC , PHCMC, and PTMC** : A temporary wristband is placed on the upper extremity on the operative side by the surgeon or proceduralist. Remove the armband during the pre-induction briefing, prior to prepping and draping with two licensed people to verify the patient identification and correct procedure side and site. Tape the armband to the white board at PSJ and PHC, or secured to the front of the chart at PTMC and utilized during the final time-out.

B. At **PLCMMC-Torrance** : 1) Verbalize the “side” in the Time Out and indicate the absence of a skin mark. 2) Write on the WHO board the “side” indicated in the consent so all can see it at any time during the procedure

C. At **PLCMMC-San Pedro** : Verbal confirmation of the unmarked site as part of each Time-Out in the procedure room.

D. At **PSJHC** : All sites are marked. Concerning "orifices", site marking is not required for procedures done through or immediately adjacent to "natural body orifices." This includes mid-line orifices such as mouth, anus and urethra. However, many procedures done through a mid-line orifice are intended to treat an organ that is "right" or "left" and therefore subject to a lateralization error. For "open" or endoscopic procedures that are done through a mid-line incision or insertion site but are intended to treat an organ that is "right" or "left," mark the skin at or near the proposed incision/insertion site to indicate the correct side of the proposed procedure, even when the proposed incision/insertion site is in the mid-line or through a natural body orifice. This mark, as for other site marks, must be positioned to be visible after the patient is prepped and draped unless it is technically or anatomically impossible or impractical to do so.

E. Patient refusal of site marking: If patient or patient's legal representative refuses skin marking of the site, the surgical care team should provide education to the patient (and/or legal representative) explaining why site marking is an important safety process and that additional risk is incurred if site marking is refused or not done. The patient and/or legal representative can make an informed decision after this discussion. An alternative process may follow.

   a. If the patient maintains refusal for skin site marking or acceptable alternative process this refusal should be documented in the medical record.

   b. Confirmation of the correct site should be made verbally at the patient's bedside, reconfirmed with the medical record, and communicated with the full team at each step of the surgical event.

   c. The physician may opt not to perform the procedure if there is no immediate risk to life or limb.

Time-Out

1. Time-Out: Pre-Anesthesia. In surgical or non-surgical invasive procedures requiring anesthesia providers, a Pre-Anesthesia Time-out must be performed in the procedure room prior to the anesthesia caregiver begining care. At minimum, this time-out must include the RN Circulator and the anesthesia care-giver. Other care-givers present in the room at the Time-Out must participate. During a Time-Out, activities are suspended to the extent possible so that team members can focus on active confirmation of the patient, site, and procedure.
2. Time-Out: Intra-Procedure Verification:

   A. 'Time-Out' is defined as a pre-procedural / pre-operative pause to verify patient identity per hospital policy, procedure, side / site, patient marking, position, need for and availability of special equipment, and / or implants, relevant images and results properly labeled and displayed, the need to administer antibiotics, fluids or blood products and safety precautions based on patient history or medication use.

   B. The 'Time-Out' provides fail-safe process; the team must be in agreement on all of the verification components or the procedure is a 'NO GO' until discrepancies are resolved.

   C. 'Time-Out' conducted in the location where the procedure is to be performed, which includes bedside procedures.

   D. The 'Time-Out' is performed before the start of the procedure.

   E. During a 'Time-Out', activities are suspended to the extent possible so that team members can focus on active confirmation.

   F. Clinical staff are responsible for initiating 'Time-Out', i.e., Circulator in Surgery and the clinical assist staff (or physician if alone) in the non-surgery setting. In the surgical suite, at a minimum, the team involved in the 'Time-Out' is composed of the RN Circulator, Scrub RN / Technician, surgeon, assistant surgeon/PA/RNFA if there is one, and anesthesia care provider.

   G. In surgery, the Scrub Tech / RN does not hand the blade to the physician until the final 'Time-Out' is completed.

H. Performing two or more procedures on the same patient and the person performing procedure changes, a 'Time-Out' is performed before each procedure is initiated.

I. The 'Time-Out' includes at a minimum:

1. Correct patient identity (per hospital policy).
2. Confirmation that correct side and site are marked and visible after draping.
3. Agreement on the procedure to be done / accurate consent form (the clinical staff must be reading the consent form to verify 'time-out').

A. 'Time-Out' involves ACTIVE communication and a moment of pause, i.e., team members indicating their agreement by oral acknowledgment. Silence is NOT an acknowledgment.

B. The procedure cannot proceed until verification of discrepancies are resolved; verified records, radiographic images, consultation, and history and physical, consent, order, and / or physician office records confirmed and verified.

C. Documentation of the completed components of the Universal Protocol and time-out are either in the electronic medical record (EMR) or on the Pre-procedure Verification Checklist if EMR is in downtime.

Roles and Responsibilities

A Clear definition of roles and responsibilities for all practitioners / care providers involved in the invasive procedure patient's care is essential to reduce the risk of harm to patients. All care givers present must suspend activities to the extent possible so that team members can focus on active confirmation or resolution of discrepancies.

1. Patient / Designated Representative:
    A. The patient or designated representative actively participates in the confirmation of the patient's identification and the appropriate procedure and site.
    B. If the patient is unable to respond and family / designated representative is NOT present, procedure and side / site, where applicable, is validated utilizing all pertinent available documents to include history and physical, progress notes, medical records, imaging and / or diagnostic studies.
2. Physician/Provider/Surgeon:
    A. Schedule the procedure according to the scheduling guidelines.
    B. Complete a history and physical or emergent note or interval note prior to the patient entering the procedure suite.
    C. Provide orders that include an order for the procedural consent to be completed. The order identifies the procedure, including right / left distinction, multiple structures (fingers, toes, and lesions) or levels (spine).
    D. The proceduralist marks the site per hospital policy and with patient's involvement.
    E. As a member of the procedural team, the proceduralist actively participates in a final, audible (time out) with a minimum requirement of verification of the correct patient and appropriate procedure, side / site, correct position, implants, radiograph studies, need to administer antibiotics or fluids for irrigation purposes, and safety

precautions based on the patient's history or medication use may be discussed as a second verification at this time as well.

3. Anesthesiologist / anesthesia provider
    A. During the anesthesia consultation with the patient / designated representative, verify the correct patient, procedure to be performed and the correct surgical / procedure side / site. This is documented on the verification on the pre-anesthesia record.
4. Pre-Op / Pre-Procedural Personnel:
    A. As a member of procedural team the pre-procedure personnel verifies the correct patient, procedure, and site.
5. RN Circulator / Procedural Personnel:
    A. In the operating room suite or procedure suite prior to incision, conduct a final audible confirmation (time out) of the correct patient, procedure, side / site, patient position. May also reconfirm as applicable, implants, radiograph studies, need to administer antibiotics or fluids, and any safety precautions based on the patient's history or medication use.
6. Scrub / Procedural Personnel:
    A. As a member of the procedure team, the scrub / procedural personnel actively participates in a final, audible (time out) verification of the correct patient, procedure, side / site, patient position.
    B. The scrub / procedural personnel may NOT pass the scalpel to the proceduralist until the completion of the time out. The procedure is not initiated until any discrepancies or concerns are resolved.

Documentation

Universal Protocol completion is documented in the EMR. Clinical staff directly involved with the procedure in care areas not using electronic documentation must complete the Procedure Verification Checklist. This documents the elements of the 'time out' also known as the Universal Protocol. This is required for all invasive procedures.

For Providence Tarzana Medical Center ONLY

1. When a procedure begins as a laparoscopy, the correct side / site is always reconfirmed prior to the procedure becoming an 'open' procedure.
2. When a scrub / RN Circulator is relieved, they give report to the person relieving them, which include the surgical procedure and the correct side / site.
3. The following criteria for all laparoscopic surgery of colon for tumor / lesion removal applies:
    A. The gastroenterologist performing the pre-procedural colonoscopy must tattoo the lesion in all four quadrants less than 14 days prior to surgery.
    B. The colonoscopy report and the gastroenterology and / or Internal Medicine Consult must be present on the medical record and refer to the above-described tattoo prior to the procedure. This applies even if the colonoscopy previously performed at

another facility.

C. The colonoscopy report must describe the site and type of lesion.

D. The surgeon must visualize the anti-mesenteric border of the tumor / lesion and / or tattoo if the procedure is done laparoscopically. If the lesion / tumor / tattoo is not visualized, the surgeon is required to:

    1. Open the patient to visualize the tattoo **OR**
    2. The gastroenterologist must be present, intraoperatively, to transilluminate the lesion for the surgeon.

E. Exceptions to Tattooing:

    1. Within view of the ileocecal valve
    2. Within reach of a rigid sigmoid scope (20cm) and recorded in the History and Physical
    3. Diverticulosis
    4. Total Colectomy

Appendix A.

Invasive procedures for which it may be necessary to use an alternative site identification process.

Arch Bar Application Removal

Biopsy Mouth

Biopsy Testis

Cystoscopy Stent Insertion Retro Pyelogram

Epididymectomy

Hydrocelectomy

Hypospadias Repair

Hysterectomy Vaginal with Unilateral Salpingooophorectomy

Lacrimal Duct probing Nasal (If Pediatric)

Laparoscopic Orchiectomy

Lithotripsy ESWL Lasertripsy +

Orchiectomy

Orchiopexy

Spermatocelectomy

Teeth

Testicular Prosthesis Implant

Testicular Tortion

Transuretheral Needle Ablation

Ureteroscopy

Varicocelectomy

Vasovasostomy

REFERENCE(S)/RELATED POLICIES

1. Association of periOperative Registered Nurses (AORN) Position Statement, "Preventing Wrong-Patient, Wrong-Site, Wrong-Procedure Events." http ://www.aorn.org/Clinical_Practice/Position_Statements/Position_Statements. aspx . Retrieved online 12/1/2015.
2. American Academy of orthopedic Surgeons advisory document #1042, "Consistency for Safety in Orthopedic Surgery" (**http://www.aaos.org**).
3. The Joint Commission Comprehensive Accreditation Manual for Hospitals (2015).
4. The Joint Commission 2015 Hospital National Patient Safety Goals: "Prevent Mistakes in Surgery." UP.01.01.01. UP.01.02.01. UP.01.03.01. www.jointcommission.org/assets/1/6/2015_NPSG_HAP. pdf . Retrieved 12/1/2015.

Approval Signatures

Step Description	Approver	Date
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Ministry MECs	Denise Eastburn: Dir Med Staff/Patient Rel	11/2016

Ministry MECs	Adrieanne Guerrero: Clin Nurse [DD]	11/2016
Ministry MECs	Cecilia Hogenson Kida: Director of Medical Staff	11/2016
Ministry MECs	Guenther Baerje: Director of Medical Staff	11/2016
Ministry Departments of Surgery	Guenther Baerje: Director of Medical Staff	11/2016
Ministry Departments of Surgery	Sonia Ramos: Mgr Medical Staff	07/2016
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CNOs	Dawna Hendel: Chief Nursing Officer [MC]	04/2016
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CNOs	Ann Dechairo Marino: Chief Nursing Officer	03/2016
CNOs	Elizabeth Hart: Chief Nursing Officer	02/2016
CNOs	David Neal: Chief Nursing Officer	02/2016
CNOs	Michael Jongsma: Chief Nursing Officer	02/2016

	Michael Hanson: Reg Dir Prof Dev And Practice	02/2016
Regional Risk Management Excellence Council	Marianne Padden: Dir Risk Mgmt - So Bay Comm Svc	02/2016
Regional Performance Improvement Excellence Council	Steven Tanner: Director of QI and Accreditation	01/2016
Regional Perioperative Excellence Council	Yvonne Gaffney: Dir Periop Svcs Special Prjcts	01/2016

Applicability

CA - Regional/Divisional

Standards

No standards are associated with this document

Status **Active** PolicyStat ID **5042914**

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Next Review	07/2021

Owner	Jeremy Baker: Executive Director Quality
Policy Area	Quality & Risk Management
Applicability	CA - Divisional/ Regional
References	LA Region

Consents

In keeping with the mission and values of Providence Health & Services, it is the policy of Providence Health System-Southern California to adopt this regional clinical standard for use in the following*:

Providence Little Company of Mary Medical Center Torrance:	
X	Acute Care
X	Transitional Care Center
	Providence Little Company of Mary Home Health
Providence Little Company of Mary Medical Center San Pedro:	
X	Acute Care
X	Sub-Acute Care Center
X	Psychiatric Unit
X	Acute Rehabilitation
X	Chemical Dependency Unit
Providence Holy Cross Medical Center:	
X	Acute Care
X	Sub Acute Care Unit
X	Rehabilitation Unit
Providence Saint Joseph Medical Center:	
X	Acute Care
	Providence Home Care
	Providence St. Elizabeth's

X	Rehabilitation Unit
X	Roy and Patricia Disney Family Cancer Center
Providence Tarzana Medical Center:	
X	Acute Care
Providence Saint John's Health Center:	
X	Acute Care

*An "x" identifies inclusion and the absence of an "x" indicates exclusion or exception.

SUPERSEDES: CA-RM-9006 (Effective date: 06/01/12)

POLICY

In keeping with the mission and values of Providence Health & Services, it is the policy of PHS-CA LA Region to require patients give their consent to the treating physician as an informed consent and their verification of the consent obtained by the physician to the medical center in written form prior to undergoing any treatment, test or procedure for which specific consent is required by law as described in the current CONSENT MANUAL published by the California Healthcare Association or by the medical staff bylaws and/or rules and regulations.

DEFINITIONS

1. Self-Determination. Every competent person has the fundamental right of self-determination over his/her person and property. Individuals who are not competent have the right to be represented by another person who will act in their best interest and carry out their known desires.
    a. A competent patient may wish to delegate his or her right to make informed decisions to another person. To the degree permitted by state law, the hospital will respect the patient's wishes. This may be executed by appointment in an Advance Health Care Directive or Power of Attorney for Health Care.
2. Consent for General Medical Care. Consent is required for the general medical care provided to patients admitted to the hospital for inpatient or outpatient services, including services provided in the Emergency Department. "Informed Consent" is not required for general medical care. The most commonly used general consent is the "Conditions of Admission" which provides permission to give basic/simple/common hospital services and medical treatment.
3. Consent for Release of Information. Consent may be required for the release of individually identifiable protected health information.
4. Informed Consent. "Informed Consent" is required for those procedures, which are complex or involve material risks that are not commonly understood. The patient's physician is responsible for providing the information the patient or an incompetent patient's surrogate decision-maker needs in order to make an informed decision and for obtaining the patient's informed consent or refusal for the recommended procedure. The hospital's role in the informed consent process is to verify that the physician obtained the patient's informed consent before the physician is permitted to perform the procedure or that an exception (such

as the emergency exception) applies that allows treatment to proceed.

   a. If there is a doubt as to whether a procedure requires an informed consent, it is appropriate for the physician to obtain one.
   b. For procedures requiring informed consent that are within the scope of practice of the R.N. and are being performed by the registered nurse (i.e., PIC line insertion), the provider performing the procedure is responsible for providing the information the patient needs and for obtaining the consent.

5. Consent Freely Given. Consent must be freely given and must not be obtained through the exercise of either duress or coercion.
6. Minors. In general minors (persons aged 17 and under) may not give consent for medical care unless they fall into one of the categories of minors who are allowed to give consent.

PROCEDURE/GENERAL INSTRUCTIONS

1. THE COMMON CONSENT ISSUES addressed by medical center staff on a day-to-day basis involve patients consenting to:
   a. Outpatient diagnostic and treatment procedures including surgical procedures
   b. Emergency Department treatment
   c. Admission to the medical center for general inpatient care
   d. Inpatient diagnostic and treatment procedures including surgical procedures
   This policy will address the issues most commonly encountered by staff as they deal with obtaining consents in these above described circumstances. All consent topics not covered in this policy or about which staff desire further information or definition can be found in the CHA CONSENT MANUAL available in several areas throughout the health system including, but not limited to, the Admitting Departments, the Nursing Offices, the Emergency Departments, the Operating Rooms, the Health Information Management Departments, and the offices of the Directors of Risk Management. Staff should refer to that manual whenever necessary for additional information or clarification.

2. EMERGENCY TREATMENT EXCEPTION
   Treatment may proceed without the patient's or their legal representative's consent when a medical emergency exists. The law implies consent in emergency circumstances on the theory that if the patient were able, or if a qualified legal representative were present, the consent would be given.
   California law states that a medical emergency exists when:
   a. Immediate services are required for the alleviation of severe pain; or
   b. The condition could/would lead to serious disability or death if diagnosis and treatment are not done immediately.

Since the emergency treatment exception is based on the theory of implied consent, it is important to note that the procedure may not proceed if there is any evidence to suggest, including a relative's statement regarding the patient's wishes, that the patient would refuse the procedure, or there is an advance directive stating the patient's wishes. While the treatment

proceeds, efforts must continue to be made to contact a surrogate decision- maker. Once the determination has been made that the emergency treatment exception applies, the physician must do the following:

a. Limit the scope of treatment to what is needed to address the emergency condition to the least invasive approach.
b. Document all pertinent clinical details and plan in the progress notes explaining how the patient's condition qualifies for the emergency treatment exception and what the outcome to the patient would be if the procedure was not performed. The efforts made to identify and talk with a qualified surrogate decision-maker should also be documented in the patient's record.

Of special note:

a. The physician does NOT sign a consent form on behalf of the patient. Such consent is implied by law from the existence of the emergency.
b. A second medical opinion is not legally required, although many physicians choose to request one. If such a consultation is obtained, the consulting physician must document his or her findings in the patient's medical record.

The appropriately completed consent form is placed in the medical record with *"see progress notes"* entered where the patient's consenting signature would appear.

3. INFORMED CONSENT

a. **Informed consent must be obtained for all procedures performed in the operating room, cardiac catheterization laboratory, gastrointestinal lab, lithotripsy or invasive diagnostic or therapeutic procedures; for the administration of medications marked in the formulary; for chemotherapy; for radiation therapy; for the insertion of central lines and the insertion of PIC lines, including those inserted bedside. It is the Physician's/LIPs responsibility to determine the patient's capacity and to obtain informed consent.**
    1. While an informed consent is not required for the performance of "simple and common" procedures when the related risks are commonly understood, it is required whenever the treatment or procedure is associated with risks not generally understood and usually of a significant nature. The patient must be instructed on:
        a. The patient's health status, diagnosis, and prognosis
        b. The nature of the proposed care, treatment, services, medications, interventions, or procedures. If surgical, a description of the proposed surgery, including the anesthesia to be used, and the indications.
        c. Potential benefits, short- and long-term material risks, or side effects, including potential problems that might occur during recuperation
        d. The likelihood of achieving goals
        e. Reasonable treatment alternatives and their material risks and benefits
        f. The relevant potential short- and long-term risks, benefits, and side effects related to alternatives, including the possible results of not receiving care, treatment, and services

g. When indicated, any limitations on the confidentiality of information learned from or about the patient

h. The physician performing the procedure, anesthesia, and other non-physicians who will be performing important tasks during the procedure for which they have been granted privileges by the hospital, permitted by state law, and within the practitioner's scope of practice

i. Any potentially conflicting interest of the doctor such as research or financial interests related to the performance of the proposed operation or procedure.

2. The physician is responsible for documenting in the patient's medical center medical record that s/he has obtained an Informed Consent, and the medical center and organized medical staff are responsible for monitoring compliance and assuring that this documentation is occurring.

b. If a non-physician/LIP will perform the procedure, then the ordering physician is responsible for obtaining informed consent. If more than one doctor is involved, they can determine together which one will obtain consent and document in the medical record.

c. Special Requirements. In addition, "informed consent" will be obtained as required by law, and consistent with the special legal requirements set forth in the CHA CONSENT MANUAL for the following:

1. Blood transfusions - and obligations as set forth in the Paul Gann Blood Safety Act
2. HIV Testing
3. Bilateral tubal ligations, hysterectomies and other procedures that result in sterilization
4. Investigational drugs or devices
5. Human experimentation
6. Reuse of hemodialysis filters
7. Treatment for breast or prostate cancer
8. Psychosurgery and Antipsychotic Medications, if applicable
9. Convulsive Therapy and Insulin Coma Treatment
10. Involuntary commitment for psychiatric disorders
11. Use of Organs, Tissues, and Fluids
12. Telemedicine/Telehealth

d. Discontinuing Life-Sustaining Treatment. Consent to discontinue life-sustaining treatment shall be obtained and documented as addressed in the policies on withholding or withdrawing life-sustaining treatment.

4. SIGNING/COMPLETING THE CONSENT FORM

A signed consent form is the step in the process to receive verification of informed consent by the patient/surrogate. This attestation is usually obtained by medical center staff and allows the medical

center to proceed with plans to conduct and/or assist in the treatment or procedure as ordered by the physician. The form specifies what treatment or procedure they are consenting to and, by signing the form, the patient is acknowledging that, if required by law, they have given their "Informed Consent" to their treating physician.

a. The most commonly used general consent, authorization for treatment, is the one patients sign upon admission called the "Conditions of Admission" which provides permission to give basic/simple/common hospital services and medical treatment not requiring "informed" consent.

b. The next most commonly used consent form is one authorizing for and consenting to surgery or special diagnostic procedures. This consent is required for any of the following:

    1. Major or minor surgery which involves an entry into the body, either through an incision or through one of the natural body openings
    2. All procedures in which anesthesia is used, regardless of whether an entry into the body is involved.
        a. A separate consent form may be required by the patient for each epidural procedure performed by an anesthesiologist
    3. Non-surgical procedures involving higher risk of harm to the patient or involving the risk of a change in the patient's body structure. Such procedures would include, but are not limited to, myelograms, arteriograms, pyelograms, discograms, PTCA.
    4. Procedures involving the use of cobalt or radiation therapy
    5. Experimental procedures

c. All other procedures which the medical staff has determined require a specific explanation to the patient, e.g.:

    - lumbar puncture
    - epidural
    - central venous catheter insertion
    - chest tube insertion
    - aspiration procedures (e.g., bone marrow, thoracentesis/paracentesis)
    - endoscopic procedures
    - elective cardioversion
    - biopsy procedures
    - certain neonatal procedures (e.g., UA line placement, circumcision)

Any doubts as to the necessity of obtaining a signed consent form should be resolved in favor of procuring the signed consent.

5. MEDICAL CENTER STAFF RESPONSIBILITY

a. The procedure(s) shall be entered without using abbreviations.

b. Careful attention must be given to "right" and "left."

c. All physicians and LIPs (Licensed Independent Practitioners) performing significant procedures, as defined in the Professional Staff Rules and Regulations and/or Bylaws, will have their name listed with the significant procedure(s) they are performing.

d. If two or more procedures are planned to be performed at the same time by the same physician, they may all be described on the same form; however, if two or more specific procedures are to be performed by different physicians, a separate consent must be obtained for each physician.

e. There must be a separate consent form signed EACH time a procedure is done.
Note: **Hysterectomy Consent Form**
The Hysterectomy Consent Form must be signed by all patients undergoing a hysterectomy sterilization procedure. By signing this form the patient acknowledges that she has received, both orally and in writing, the following information from her physician:

    1. The surgery will render the patient permanently sterile
    2. The patient has the right to seek a consultation from another physician

6. WHO MAY GIVE CONSENT

The following may by law sign medical consents and, if a competent adult, must sign the consent to provide legal authorization to proceed with planned treatment.

a. **Capacity to Consent**. A person may give a valid consent only if he or she has "capacity" which means he or she is able to understand the nature and consequence of a decision and to make and communicate the decision.
As such, mental incompetency is not limited to those who have been declared incompetent. It includes those who, in the opinion of the primary physician are either permanently or temporarily incapable of giving an informed consent. Where borderline cases exist, the consent should be obtained from both the patient and the legal representative.

b. **A competent adult**, defined as: 18 years * of age or older or a person of minor age who has contracted a valid marriage, regardless of subsequent divorce or annulment. Where uncertainty reasonably exists, a copy of the marriage certificate should be obtained to verify the marriage and, if the certificate is not furnished, the consent of a parent or guardian may be required.

c. **A self-sufficient minor**, that is, 15 years of age or older, living separately from parents and managing his/her own financial affairs, regardless of income source.

d. **A minor 14 years of age or older who is emancipated** by declaration of the Supreme Court and provides written evidence of that emancipation.

e. **A minor receiving pregnancy or contraceptive care.**

f. **A minor 12 years of age or older may consent to treatment under the following circumstances**:

    1. An alleged rape or sexual assault. May consent for any care related to the diagnosis/ treatment of such condition. If possible, the minor's parents or legal guardian must be contacted and notified (document date and time of notification or attempt to notify in medical record) unless there is reasonable suspicion that they committed the alleged crime.

2. Has a communicable disease or a sexually transmitted disease which must be reported to the local health officer. May consent for treatment relating to the diagnosis and treatment of the disease.
3. Is seeking medical care and counseling related to a drug or alcohol related problem. NOTE: parents or legal guardians incur no financial obligation unless they participate in the counseling.
4. Is seeking mental health treatment as an outpatient and, in the opinion of the attending professional, is mature enough to participate in treatment and has either been a victim of incest or child abuse, or would present a danger of serious physical or mental harm to self or others without the counseling.

g. **A minor 17 years or older wishing to donate blood**.
h. **A minor on active duty with United States Armed Forces**.
i. **An adult agent** designated by the patient in a Durable Power of Attorney for Health Care (DPAHC).
j. **Parent or legal guardian** when the patient is a minor and does not therefore have the legal capacity to consent and does not fall into one of the exclusions listed above.
k. **Either parent is sufficient in the case of a minor with divorced parents** unless there is a conflict between the parents in which case the one having legal custody has the final authority.
l. **Adoptive parent** may sign for a legally adopted child.

Refer to the CHA CONSENT MANUAL for specific direction on less common occurrences with minors such as:

1. Minor parent with a child
2. Minor born out of wedlock
3. Minor pupil
4. Non-abandoned minor whose parents are unavailable
5. Caregiver's authorization to treat minors
6. Obtaining a court order to treat a child

7. Selection of Health Care Surrogates/consent by the CLOSEST AVAILABLE RELATIVE

Guiding Principles:

In many situations, medical decision-making is a collaborative effort among the patient's family, friends, and loved ones. Surrogate decision-makers "step into the shoes" of the patient. When deciding who is the most appropriate person to "step into those shoes," make the decisions and sign the consent forms, the relationship that person has with the patient must be considered. Looking first to a patient's closest relatives is based on the presumption that those are the people who are likely to know the patient the best, care most about the well-being of the patient, and want to assume the role of surrogate decision-makers. California law allows but does not mandate that a surrogate decision-maker be the closest available relative. The laws set forth these guidelines to assist in choosing the most appropriate decision-maker. The quality of the relationship the person has with the patient and their legal relationship

to the patient are equally important factors to consider.

a. In the absence of a surrogate or a court appointed conservator, an incompetent patient's immediate family (closest available relative) may make health care decisions for the patient.
    1. The person must be guided by the patient's own desires and feelings to the extent they were expressed before the patient became incompetent.
    2. If the patient did not express specific desires and they cannot be ascertained, the person must be guided by what is in the patient's best interests.

b. "Closest available" is used in this context to mean the relative with the closest relationship that can be contacted. It does not mean any relative that happens to be at the bedside and therefore the closest to the hospital.

c. Where concern arises, possibly reported by other relatives or friends of the patient, that the person representing him or herself as the "closest available relative" is not actually the closest available relative, steps should be taken to verify the relationship.

d. Where adult children or siblings are the closest available relatives and disagreement exists between them regarding what to do for the patient, the physician and medical center should choose the option that presents the least risk to the patient until the disagreement can be resolved.

e. The physician and medical center should NOT rely on the closest available relative's consent if the relative's motives are questionable, there is substantial question as to whether the patient, if competent, would consent to the planned procedure or if the relative's refusal to give consent appears unreasonable.

f. Registered domestic partners have the same authority to make a health care decision for his or her incapacitated domestic partner as a spouse.

8. WHEN NO DECISION-MAKER CAN BE FOUND

In patients who lack capacity, have no family, no surrogate, no court appointed conservator, and no Durable Power of Attorney for Healthcare, the following guidelines will apply:

a. The hospital and medical staff will render basic medical care and services to serve the best interest of the patient.

b. When multiple care options exist, the least invasive care options should be provided.

c. Specialty procedures, complex medical interventions or surgery may not be performed unless an emergent condition exists (see General Instruction #2).

d. Ministries may refer to relevant surrogate decision maker policies, "Consent – Patient Without a Surrogate Decision-Maker Policy", "Surrogate Decision-Makers - Selection of", and a Surrogate Decision-Making Committee (Ethics) may be utilized to support healthcare decision if ordered by the patient's physician.

9. CONSENT BY TELEPHONE, FAX, AND E-MAIL

a. When the person legally authorized to give consent for the patient is not and will not be soon enough present, consent may be obtained by telephone, fax, or e-mail.

b. Refer to the CHA CONSENT MANUAL for directions when an e-mail or fax alone is the only

method available to communicate with the patient's representative.

c. Another responsible medical center employee should listen to the discussion between the patient's legal representative and the medical center employee obtaining the consent.

d. The exact date and time the call was made along with the name of the witnessing caregiver must be clearly documented in the medical record and in the progress notes with reference to the progress notes made on the consent form where a patient's signature would appear.

e. The employee/caregivers obtaining verification of consent must tell the patient's representative that another employee is listening to the conversation to serve as a witness and then request verification of consent and permission to perform the planned treatment or procedure.

f. If the planned procedure requires an informed consent and the patient's representative has not yet spoken with the physician or needs to speak again with the physician, the medical center employee/caregiver will assist in facilitating that communication if necessary.

g. An e-mail, fax, or letter should be requested to follow the telephone consent, and that e-mail/ fax/letter must be placed in the medical record when it arrives.

h. Electronic scanned documents are acceptable if the patient or patient surrogate is not within the hospital.

i. Electronic documents may be used if the patient/surrogate has on file within the hospital an original signature or legal signed identification. Verification of the signature must be made against the signed electronic message.

10. PATIENTS UNDER PRE-OPERATIVE SEDATION and/or NARCOTICS

a. As a general practice, patients should sign consents prior to receiving any sedation or narcotics.

b. Often patients have received sedation or narcotics to treat the condition that is requiring them to undergo a procedure and, as long as they have remained alert and competent, they may sign the consent. The nurse should document this in the medical record.

11. PATIENTS WHO CANNOT SIGN THE CONSENT

a. If a patient cannot hold a pen to sign his/her name or make an "X," two medical center employees should be involved in obtaining the consent form. They should both witness the verbal consent given by the patient and sign the form as witnesses, describing the circumstances that rendered the patient unable to sign (fracture, position, injury, isolation).

12. PATIENTS WHO HAVE A COMMUNICATION BARRIER

a. The consent form must either be in a language the patient can read and understand or be translated into the patient's preferred language for the patient **by an approved translator**. Refer to the policy on interpreter and translation services.

b. When an interpreter is used, the section of the English language consent form dedicated to documenting the translation must be completed.The operator/translator number is entered to the interpreter section of the consent form. The caregiver reads the consent form to be interpreted verbatim.

c. Family members and friends are **not** to be used to interpret consent. If the patient requests

family/friends be used, they may also be present to translate along with the certified translator.

13. CONSENT TERM

a. The consent is in effect for the duration of the hospital stay.

b. Discharge from the acute facility, i.e., acute hospital to Acute Rehab, will require a new consent.

c. A consent can be revoked at anytime by the patient or surrogate or if the physician feels that, based on the clinical condition of the patient, the procedure will no longer benefit the patient or will increase risk of a negative outcome.

d. Chemotherapy, blood consents, consents for ongoing outpatient procedures are good for 12 months.

14. WITNESSING

a. Role of the Witness. The person who is asked to serve as a witness/hospital representative has a very limited role in the process. The person is expected only to confirm that the person signing the form appeared reasonably competent and appeared to understand what he or she was signing. The person who is asked to serve as the witness should not answer questions the patient may have about the proposed surgery or procedure and should refer such questions back to the doctor.

b. Documentation. The witness/hospital representative should legibly print his or her name, sign the document, and note the date and time.

15. REFUSAL OF TREATMENT

a. The right to self determination necessarily includes the right to refuse recommended treatment. If a patient, or the patient's surrogate decision-maker, refuses treatment, the attending physician shall be contacted so that he or she can explain the reason for the treatment and the possible implications of not accepting the care.

   If a competent patient persists in refusing care, such wishes shall be respected. If a surrogate decision-maker is refusing care recommended for the patient, such as when an agent refuses care for an adult or parents refuse care for the minor child, the attending physician shall consider whether the surrogate decision-maker is acting in the patient's best interests and carrying out the patient's desires and, if not, whether a court order for care should be considered. A court order should be considered if there appears to be medical neglect of a child or dependent adult. Any refusal of care is documented by having the patient or surrogate decision-maker sign the "Against Medical Advice" or the "Refusal to Permit Medical Treatment" form or other designated refusal form.

16. PATIENTS UNDER CUSTODY (LAW ENFORCEMENT/CORRECTIONAL FACILITY)

a. A person in custody of law enforcement officers must still consent to a nonemergency medical examination, treatment, or operation before such a procedure may be performed.

b. Law enforcement officers may ONLY consent in a narrowly defined scope and may request limited medical examinations and tests pursuant to their authority to make constitutionally

permissible searches, i.e., drug and alcohol testing (Vehicle Code Section 23612).

1. The person driving under the influence of alcohol has the choice of whether the test shall be of their blood or breath.
2. If the person arrested is incapable (or states they are incapable) of completing the chosen test of blood or breath testing, the person must submit to a urine test.
3. If the person is also suspected of being under the influence of drugs, they will also be required to submit to either a blood or urine test.
4. A patient who is unconscious or dead (or otherwise in a condition that renders the patient incapable of refusal) is deemed NOT to have withdrawn consent for the test. This implied consent provision for the test also applies to minors; NO parental consent is necessary for the test.

c. HIV Testing: The law provides for involuntary testing of criminal defendants and inmates of correctional institutions in the following instances:

1. Persons, including juveniles, who are convicted of certain sexual offenses shall be ordered by the court to submit a blood or oral mucosal sample. Results pursuant to a court order under Penal Code 1202 must be disclosed to the clerk of the court ordering the test.
2. Defendants, including minors charged with certain crimes involving sexual offenses, are subjected to testing for HIV/AIDS and other communicable diseases pursuant to court order if a peace officer, custodial officer, firefighter or emergency personnel have been exposed to the defendant or arrestee's blood or bodily fluids.
3. Inmates of correctional institutions and other persons in custody or on probation or parole are subject to testing for Hep B, C and HIV when there is a significant risk of transmission. These tests may be made by the order of the chief medical officer of a correctional institute.

REFERENCE(S)/RELATED POLICIES

California Hospital Consent Manual
American College of Radiology – Practice Guideline on Informed Consent

Approval Signatures

Step Description	Approver	Date
Prepare for go-live	Wen Yun Chang: Ni Progrm Coord And Analyst	07/2018
Regional Chief Clinical Executive	Sylvain Trepanier: Reg Chief Clinical Executive CA	07/2018

PSO/MSO Directors on behalf of Chiefs of Staff's	Guenther Baerje: Director of Medical Staff [EM]	07/2018
PSO/MSO Directors on behalf of Chiefs of Staff's	Sonia Ramos: Mgr Medical Staff	07/2018
PSO/MSO Directors on behalf of Chiefs of Staff's	Debra Miller: Director of Med Staff Services	07/2018
PSO/MSO Directors on behalf of Chiefs of Staff's	Susan Parrini: Director of Medical Staff	06/2018
PSO/MSO Directors on behalf of Chiefs of Staff's	Cecilia Hogenson Kida: Director of Medical Staff	06/2018
PSO/MSO Directors on behalf of Chiefs of Staff's	Denise Eastburn: Dir Med Staff/Patient Rel	06/2018
Ministry CNOs & CMOs	Donald Larsen Jr: Chief Medical Officer Fac [CO]	06/2018
Ministry CNOs & CMOs	Colleen Wilcoxen: Chief Nursing Officer [JB]	06/2018
Ministry CNOs & CMOs	Steven Brass: Chief Medical Officer, LCM San Pedro [JB]	06/2018
Ministry CNOs & CMOs	Robert Raggi: Chief Medical Officer Fac	06/2018
Ministry CNOs & CMOs	Garry Olney: COO South Bay Community [PH]	06/2018
Ministry CNOs & CMOs	Patty Mayberry: Interim CNO [PM]	06/2018
Ministry CNOs & CMOs	Susan Melvin: Chief Medical Officer	06/2018
Ministry CNOs & CMOs	Deborah Lynne Voskamp: CNO	06/2018
Ministry CNOs & CMOs	Richard Glimp: Chief Medical Officer [JB]	06/2018
Ministry CNOs & CMOs	Elizabeth Hart: Chief Nursing Officer	06/2018
Ministry CNOs & CMOs	Deborah Carver: CNO	06/2018
Ministry CNOs & CMOs	Howard Davis: Chief Medical Officer Fac	06/2018
Regional Chief Clinical Executive - communicate to CMOs/CNOs	Sylvain Trepanier: Reg Chief Clinical Executive CA	06/2018
Regional Practice Leader	Jan Keller-Unger: Reg Dir Nurs Workforce Dev-Tip	06/2018

Regional PI/Risk Council	Steven Tanner: Director of QI and Accreditation	06/2018
Regional PolicyStat Site Administrator	Wen Yun Chang: Ni Progrm Coord And Analyst	06/2018
Policy Owner with Clinical Team	Jennie Ritchie: Risk Management	06/2018

Standards

No standards are associated with this document

Status **Active** PolicyStat ID **7232373**

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Last Approved	08/2022	Policy Area	Perioperative
Effective	08/2022	Applicability	CA - Providence Cedars-Sinai Tarzana MC
Last Revised	06/2007		
Next Review	08/2025		

Specimen Care/Handling

Number: PTMC-OR-F21a

STATEMENT OF POLICY

Tissues and/or foreign objects removed from patients at Providence Tarzana Medical Center are to be sent to the Pathology Laboratory for identification and/or gross and/or microscopic examination, as is appropriate for the particular specimen. All specimens sent will be recorded in a specimen log to be retained for future reference. The Pathologist shall make a written report and sign it.

The following is a list of Exempt Specimens which are not required to be sent to pathology but may be sent at the discretion of the practitioner:

1. Foreskin for Children
2. Cataract Extraction Tissue
3. Sternal Wires and metallic hardware
4. Fat/lipo suction
5. Bone (part of corrective or reconstructive ortho. Procedure)
6. Dental Appliance
7. Middle ear Ossicles
8. Saphenous vein segments harvested for coronary artery bypass
9. Teeth when there is no attached soft tissue
10. Skin or other normal tissue removed during a cosmetic or reconstructive procedure provided it is not contiguous with a lesion and the patient does not have a history of malignancy
11. Normal toenails and fingernails that are incidentally removed

12. Any previously implanted items which are now being removed, including but not limited to:
    a. Pacemakers (document disposal)
    b. Ear Tubes (document disposal)
    c. Hickmans, Port-a-caths, Peritoneal Dialysis and any similar type catheters. (document disposal)
    d. Total Joints (document disposal)
    e. Lens Implants (document disposal)
    f. Ureteral Stents and Catheters (document disposal)
    g. Penile Implants (document disposal)
    h. Intra-uterine Devices (IUDs) (document disposal)
13. Cord Lipomas
14. Eyelid Tissue

Specimens that must be sent include the following:

1. Placental Tissue
2. Prosthetic breast implants
3. Prosthetic cardiac valves without attached tissue
4. Hernia sacs. Umbilical and Inguinal. Gross only is accepted for pediatrics.

Approval Signatures

Step Description	Approver	Date
Board	Deborah Denney: Manager Nursing	08/2022
MEC (Medical Executive Committee)	Deborah Denney: Manager Nursing	08/2022
Surgery Committee	Deborah Denney: Manager Nursing	08/2022
Director of Surgical Services	Marleen Hafer: Dir Nursing	11/2019

Standards

No standards are associated with this document

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Owner	Mary Jane Neri: Executive Director Nursing
Policy Area	Perioperative
Applicability	CA - Divisional/ Regional
References	LA Region

To find another policy, use the browser BACK button to return to your Ministry.

Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Invasive Procedures

In keeping with the mission and values of Providence Health & Services, it is the policy of Providence Health System-Southern California to adopt this regional clinical standard for use in the following*:

Providence Little Company of Mary Medical Center Torrance:	
X	Acute Care
	Transitional Care Center
	Providence Little Company of Mary Home Health
Providence Little Company of Mary Medical Center San Pedro:	
X	Acute Care
	Sub-Acute Care Center
	Psychiatric Unit
	Acute Rehabilitation
	Chemical Dependency Unit
Providence Holy Cross Medical Center:	
X	Acute Care
	Sub Acute Care Unit
	Rehabilitation Unit
Providence Saint Joseph Medical Center:	
X	Acute Care
	Providence Home Care

	Providence St. Elizabeth's
	Rehabilitation Unit
	Roy and Patricia Disney Family Cancer Center
Providence Tarzana Medical Center:	
X	Acute Care
Providence Saint John's Health Center:	
X	Acute Care

*An "x" identifies inclusion and the absence of an "x" indicates exclusion or exception.

Number: CA-PERIOP-13005

POLICY

In keeping with the mission and values of Providence Health & Services, it is the policy of Providence Health System – Southern California (PHS-SC) to ensure patient safety and eliminate risk of wrong site, wrong procedure, wrong person invasive procedures.

PROCEDURE/GENERAL INSTRUCTIONS

1. The Universal Protocol requirements are applicable to all operative and other invasive procedures including procedures done in settings other than the operating room such as a special procedures unit, interventional radiology department and at the bedside.
    A. Certain routine 'minor' procedures such as venipuncture, peripheral IV line placement, insertion of a NG tube, foley catheter or closed reductions are NOT within the scope of this protocol.
    B. Site marking is NOT required (nor is it prohibited) for all procedures. These may include mid-line sternotomy and bilateral procedures, Cesarean sections, laparotomy or laparoscopy, cardiac catheterization and other interventional procedures for which the site of insertion is **NOT predetermined** . However, most other procedures that involve puncture or incision of the skin or insertion of an instrument or foreign material into the body, including, but not limited to, implantable devices, percutaneous aspirations, biopsies, vascular catheterizations, epidurals, and endoscopies are within the scope of the Universal protocol.
    C. Pre-procedural Universal Protocol verification "time out" will be completed for all surgical and nonsurgical invasive procedures.
2. Procedural / operative site marking is performed to eliminate confusion.
    A. Mark site for:
        1. Laterality (right / left).
        2. Fingers, identified as thumb, index, long, ring, little.
        3. Toes, identified as big, 2 nd , 3 rd , 4 th , 5 th .
        4. Multiple structures, locations, palpable masses and hernias.

5. Surface (flexor, extensor).
6. Spinal surgery to differentiate levels:
    a. Mark general level (cervical / thoracic / lumbar), side and approach prior to surgery.
    b. Mark precise level intra-operatively using radiographic technique.

B. Diagnostic radiological procedures where site / level / laterality is predetermined.
C. Minimal access procedures that intend to treat a lateralized organ.
D. Cranial procedures (mark pre-auricular area on appropriate side).
E. Eye procedures (mark per hospital policy).

3. Exemptions:
    A. Single organ case (i.e., appendectomy).
    B. Teeth (mark dental radiograph or diagram).
    C. Site NOT predetermined ("possible").
    D. Premature infants.
    E. Bilateral procedures.
    F. Emergencies where delay may risk life or limb.Pre-Procedure Verification:
4. Verification of the correct person, procedure and site occurs.
    A. At the time the surgery / procedure is scheduled. The surgery or procedure schedule list designates laterality (right / left) as appropriate.
    B. At the time of preadmission testing and assessment.
    C. At the time of admission or entry into the facility on elective or emergent procedures.
    D. Anytime responsibility for care of the patient is transferred to another caregiver.
    E. With the patient involved, awake and aware, if possible.
5. Verify the patient identification as described in clinical procedures: (See ministry specific Patient Identification policies and procedures.)
6. The patient's procedure is verified by checking the physician orders against the surgical consent, history and physical (H&P), interval note, and / or progress notes. Any discrepancies are resolved through verification by the physician operator.

Marking the Procedural Site:

1. After verification of the site, the physician marks the patient at PROVIDENCE SAINT JOSEPH MEDICAL CENTER, PROVIDENCE HOLY CROSS MEDICAL CENTER, and PROVIDENCE TARZANA MEDICAL CENTER the surgeon marks with his/her initials near the incision / insertion site.
   At PROVIDENCE LITTLE COMPANY OF MARY MEDICAL CENTER SAN PEDRO, PROVIDENCE LITTLE COMPANY OF MARY MEDICAL CENTER TORRANCE and PROVIDENCE SAINT JOHN'S HEALTH CENTER the surgeon marks using the word "YES" near the incision / insertion site.

A. If the patient is a minor, the patient's guardian verifies the site with the patient and clinical staff.

B. Marking takes place with the patient involved, awake, and aware, if possible.

C. A physician, nurse practitioner who works privately for the operating physician or physician assistant, with privileges to perform the procedure and who will be involved directly with, and present at the time of performing the procedure, marks the procedure site.

D. The mark is made at or near the intended incision site. Do not mark any non-operative sites.

E. The mark is made using a marker that is sufficiently permanent to remain visible after completion of the positioning, skin prep and sterile draping.

F. Multiple sites must be marked.

G. Minimal access procedures: the intended site of a lateralized internal organ must be indicated by a mark at or near the insertion site (e.g., to the right of the insertion site for a right sided organ).

H. Anytime either another practitioner or the same practitioner performs second procedure on the same patient, a second site marking is required.

2. Alternative site identification processes: (to be used for cases in which it is technically or anatomically impossible or impractical to mark the site) See **Appendix A** for list of procedures.

A. At **PSJMC , PHCMC, and PTMC** : A temporary wristband is placed on the upper extremity on the operative side by the surgeon or proceduralist. Remove the armband during the pre-induction briefing, prior to prepping and draping with two licensed people to verify the patient identification and correct procedure side and site. Tape the armband to the white board at PSJ and PHC, or secured to the front of the chart at PTMC and utilized during the final time-out.

B. At **PLCMMC-Torrance** : 1) Verbalize the “side” in the Time Out and indicate the absence of a skin mark. 2) Write on the WHO board the “side” indicated in the consent so all can see it at any time during the procedure

C. At **PLCMMC-San Pedro** : Verbal confirmation of the unmarked site as part of each Time-Out in the procedure room.

D. At **PSJHC** : All sites are marked. Concerning "orifices", site marking is not required for procedures done through or immediately adjacent to "natural body orifices." This includes mid-line orifices such as mouth, anus and urethra. However, many procedures done through a mid-line orifice are intended to treat an organ that is "right" or "left" and therefore subject to a lateralization error. For "open" or endoscopic procedures that are done through a mid-line incision or insertion site but are intended to treat an organ that is "right" or "left," mark the skin at or near the proposed incision/insertion site to indicate the correct side of the proposed procedure, even when the proposed incision/insertion site is in the mid-line or through a natural body orifice. This mark, as for other site marks, must be positioned to be visible after the patient is prepped and draped unless it is technically or anatomically impossible or impractical to do so.

E. Patient refusal of site marking: If patient or patient's legal representative refuses skin marking of the site, the surgical care team should provide education to the patient (and/or legal representative) explaining why site marking is an important safety process and that additional risk is incurred if site marking is refused or not done. The patient and/or legal representative can make an informed decision after this discussion. An alternative process may follow.

   a. If the patient maintains refusal for skin site marking or acceptable alternative process this refusal should be documented in the medical record.

   b. Confirmation of the correct site should be made verbally at the patient's bedside, reconfirmed with the medical record, and communicated with the full team at each step of the surgical event.

   c. The physician may opt not to perform the procedure if there is no immediate risk to life or limb.

Time-Out

1. Time-Out: Pre-Anesthesia. In surgical or non-surgical invasive procedures requiring anesthesia providers, a Pre-Anesthesia Time-out must be performed in the procedure room prior to the anesthesia caregiver begining care. At minimum, this time-out must include the RN Circulator and the anesthesia care-giver. Other care-givers present in the room at the Time-Out must participate. During a Time-Out, activities are suspended to the extent possible so that team members can focus on active confirmation of the patient, site, and procedure.
2. Time-Out: Intra-Procedure Verification:

   A. 'Time-Out' is defined as a pre-procedural / pre-operative pause to verify patient identity per hospital policy, procedure, side / site, patient marking, position, need for and availability of special equipment, and / or implants, relevant images and results properly labeled and displayed, the need to administer antibiotics, fluids or blood products and safety precautions based on patient history or medication use.

   B. The 'Time-Out' provides fail-safe process; the team must be in agreement on all of the verification components or the procedure is a 'NO GO' until discrepancies are resolved.

   C. 'Time-Out' conducted in the location where the procedure is to be performed, which includes bedside procedures.

   D. The 'Time-Out' is performed before the start of the procedure.

   E. During a 'Time-Out', activities are suspended to the extent possible so that team members can focus on active confirmation.

   F. Clinical staff are responsible for initiating 'Time-Out', i.e., Circulator in Surgery and the clinical assist staff (or physician if alone) in the non-surgery setting. In the surgical suite, at a minimum, the team involved in the 'Time-Out' is composed of the RN Circulator, Scrub RN / Technician, surgeon, assistant surgeon/PA/RNFA if there is one, and anesthesia care provider.

   G. In surgery, the Scrub Tech / RN does not hand the blade to the physician until the final 'Time-Out' is completed.

H. Performing two or more procedures on the same patient and the person performing procedure changes, a 'Time-Out' is performed before each procedure is initiated.

I. The 'Time-Out' includes at a minimum:

1. Correct patient identity (per hospital policy).
2. Confirmation that correct side and site are marked and visible after draping.
3. Agreement on the procedure to be done / accurate consent form (the clinical staff must be reading the consent form to verify 'time-out').

A. 'Time-Out' involves ACTIVE communication and a moment of pause, i.e., team members indicating their agreement by oral acknowledgment. Silence is NOT an acknowledgment.

B. The procedure cannot proceed until verification of discrepancies are resolved; verified records, radiographic images, consultation, and history and physical, consent, order, and / or physician office records confirmed and verified.

C. Documentation of the completed components of the Universal Protocol and time-out are either in the electronic medical record (EMR) or on the Pre-procedure Verification Checklist if EMR is in downtime.

Roles and Responsibilities

A Clear definition of roles and responsibilities for all practitioners / care providers involved in the invasive procedure patient's care is essential to reduce the risk of harm to patients. All care givers present must suspend activities to the extent possible so that team members can focus on active confirmation or resolution of discrepancies.

1. Patient / Designated Representative:
    A. The patient or designated representative actively participates in the confirmation of the patient's identification and the appropriate procedure and site.
    B. If the patient is unable to respond and family / designated representative is NOT present, procedure and side / site, where applicable, is validated utilizing all pertinent available documents to include history and physical, progress notes, medical records, imaging and / or diagnostic studies.
2. Physician/Provider/Surgeon:
    A. Schedule the procedure according to the scheduling guidelines.
    B. Complete a history and physical or emergent note or interval note prior to the patient entering the procedure suite.
    C. Provide orders that include an order for the procedural consent to be completed. The order identifies the procedure, including right / left distinction, multiple structures (fingers, toes, and lesions) or levels (spine).
    D. The proceduralist marks the site per hospital policy and with patient's involvement.
    E. As a member of the procedural team, the proceduralist actively participates in a final, audible (time out) with a minimum requirement of verification of the correct patient and appropriate procedure, side / site, correct position, implants, radiograph studies, need to administer antibiotics or fluids for irrigation purposes, and safety

precautions based on the patient's history or medication use may be discussed as a second verification at this time as well.

3. Anesthesiologist / anesthesia provider
    A. During the anesthesia consultation with the patient / designated representative, verify the correct patient, procedure to be performed and the correct surgical / procedure side / site. This is documented on the verification on the pre-anesthesia record.
4. Pre-Op / Pre-Procedural Personnel:
    A. As a member of procedural team the pre-procedure personnel verifies the correct patient, procedure, and site.
5. RN Circulator / Procedural Personnel:
    A. In the operating room suite or procedure suite prior to incision, conduct a final audible confirmation (time out) of the correct patient, procedure, side / site, patient position. May also reconfirm as applicable, implants, radiograph studies, need to administer antibiotics or fluids, and any safety precautions based on the patient's history or medication use.
6. Scrub / Procedural Personnel:
    A. As a member of the procedure team, the scrub / procedural personnel actively participates in a final, audible (time out) verification of the correct patient, procedure, side / site, patient position.
    B. The scrub / procedural personnel may NOT pass the scalpel to the proceduralist until the completion of the time out. The procedure is not initiated until any discrepancies or concerns are resolved.

Documentation

Universal Protocol completion is documented in the EMR. Clinical staff directly involved with the procedure in care areas not using electronic documentation must complete the Procedure Verification Checklist. This documents the elements of the 'time out' also known as the Universal Protocol. This is required for all invasive procedures.

For Providence Tarzana Medical Center ONLY

1. When a procedure begins as a laparoscopy, the correct side / site is always reconfirmed prior to the procedure becoming an 'open' procedure.
2. When a scrub / RN Circulator is relieved, they give report to the person relieving them, which include the surgical procedure and the correct side / site.
3. The following criteria for all laparoscopic surgery of colon for tumor / lesion removal applies:
    A. The gastroenterologist performing the pre-procedural colonoscopy must tattoo the lesion in all four quadrants less than 14 days prior to surgery.
    B. The colonoscopy report and the gastroenterology and / or Internal Medicine Consult must be present on the medical record and refer to the above-described tattoo prior to the procedure. This applies even if the colonoscopy previously performed at

another facility.

C. The colonoscopy report must describe the site and type of lesion.

D. The surgeon must visualize the anti-mesenteric border of the tumor / lesion and / or tattoo if the procedure is done laparoscopically. If the lesion / tumor / tattoo is not visualized, the surgeon is required to:

    1. Open the patient to visualize the tattoo **OR**
    2. The gastroenterologist must be present, intraoperatively, to transilluminate the lesion for the surgeon.

E. Exceptions to Tattooing:

    1. Within view of the ileocecal valve
    2. Within reach of a rigid sigmoid scope (20cm) and recorded in the History and Physical
    3. Diverticulosis
    4. Total Colectomy

Appendix A.

Invasive procedures for which it may be necessary to use an alternative site identification process.

Arch Bar Application Removal

Biopsy Mouth

Biopsy Testis

Cystoscopy Stent Insertion Retro Pyelogram

Epididymectomy

Hydrocelectomy

Hypospadias Repair

Hysterectomy Vaginal with Unilateral Salpingooophorectomy

Lacrimal Duct probing Nasal (If Pediatric)

Laparoscopic Orchiectomy

Lithotripsy ESWL Lasertripsy +

Orchiectomy

Orchiopexy

Spermatocelectomy

Teeth

Testicular Prosthesis Implant

Testicular Tortion

Transuretheral Needle Ablation

Ureteroscopy

Varicocelectomy

Vasovasostomy

REFERENCE(S)/RELATED POLICIES

1. Association of periOperative Registered Nurses (AORN) Position Statement, "Preventing Wrong-Patient, Wrong-Site, Wrong-Procedure Events." http ://www.aorn.org/Clinical_Practice/Position_Statements/Position_Statements. aspx . Retrieved online 12/1/2015.
2. American Academy of orthopedic Surgeons advisory document #1042, "Consistency for Safety in Orthopedic Surgery" (**http://www.aaos.org**).
3. The Joint Commission Comprehensive Accreditation Manual for Hospitals (2015).
4. The Joint Commission 2015 Hospital National Patient Safety Goals: "Prevent Mistakes in Surgery." UP.01.01.01. UP.01.02.01. UP.01.03.01. www.jointcommission.org/assets/1/6/2015_NPSG_HAP. pdf . Retrieved 12/1/2015.

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Standards

No standards are associated with this document