Surgery and Endoscopy

Ensuring Patient Safety and Compliance with CMS and Joint Commission Requirements

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Joint Commission Resources
Objectives

- Discuss regulatory requirements for surgery and endoscopy
- Identify one process to improve patient safety
Safety and Compliance

- Life Safety
- Environment of Care
- Patient Rights (consents and AD)
- Provision of Care (Assessment, Communication, Orders, Care Plans, Sedation, Anesthesia)
- Medication Management
- Record of Care
- Transplant Safety
- Human Resources
- Infection Control
- Patient Safety (NPSG, Universal Protocol)
Life Safety

- Suite (non-sleeping maximum 10,000 sq ft)
  - Suite designations MUST be on LS drawings
- Egress obstruction
  - May **not** obstruct egress out of the suite
  - If designated as suite, must meet minimum 36 inch clearance - NFPA LSC 7.3.4.1
- Block fire pull stations & fire extinguishers
Environment of Care

Ventilation

- Who is monitoring?
- Which rooms or areas are monitored?
- Documentation?
Environment of Care

Ventilation system must provide appropriate pressure relationships, air-exchange rates and filtration efficiencies

- Negative or positive pressures in relationship to adjacent areas - i.e. Endoscopy Processing Room should be negative to egress corridor
- Correct number of air changes per hour
Ventilation

- Based on how much air is exhausted and how much air is supplied, area is either negative, neutral or positive
  - More air out, negative pressure
  - Same air in and out, neutral
  - More air in, positive pressure

- Normally cleanest location should be more positive, and least clean the most negative
Ventilation

Tissue test: only used as pre-screening tool to evaluate if further investigation needs to occur

- “Flutter” test: place tissue just off the floor near bottom edge of door
- If tissue indicates incorrect air flow, stabilize area by closing doors and windows, wait few minutes and re-test
- Periodic testing & balancing report
  - when was balancing done (seasonal issues)
  - are any specific requirements (such as keeping a door closed) needed to achieve satisfactory results
Ventilation – Recent Changes

- ASHRAE moved endoscopy procedure rooms from positive to N/A, in Addendum W - 2014 FGI Guidelines.
- If organization documented decision based on risk assessment to no longer monitor endoscopy procedure rooms per ASHRAE action, JC would accept this.
- If organization has not made documented decision, room should be evaluated as per table (next slide) and construction date.
- No change to bronchoscopy procedure rooms (neg)
# Guidelines Ventilation Table: Endoscopy & Bronchoscopy

<table>
<thead>
<tr>
<th>Edition</th>
<th>Procedure</th>
<th>Processing (Cleaning)</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pressures</td>
<td>Direct Exhaust</td>
<td>Pressures</td>
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<tr>
<td></td>
<td>Direct</td>
<td></td>
<td>Direct</td>
</tr>
<tr>
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<td>N/A</td>
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<td>Negative (-)</td>
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<tr>
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<td>1979-1993</td>
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</tr>
</tbody>
</table>
## Ventilation, Humidity, Temp

<table>
<thead>
<tr>
<th>Room</th>
<th>Ventilation</th>
<th>Humidity</th>
<th>Temperature °F</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR</td>
<td>+</td>
<td>20-60</td>
<td>68-75</td>
</tr>
<tr>
<td>C-Section Room</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central Sterile Clean Workroom &amp; Sterile Storage</td>
<td>+</td>
<td>Max 60</td>
<td>72-78</td>
</tr>
<tr>
<td>Central Sterile Decontamination</td>
<td>—</td>
<td>No Requirement</td>
<td>72-78</td>
</tr>
<tr>
<td>Endoscopy</td>
<td>No Requirement</td>
<td>20-60</td>
<td>68-73</td>
</tr>
<tr>
<td>Bronchoscopy</td>
<td>—</td>
<td>No Requirement</td>
<td>68-73</td>
</tr>
<tr>
<td>Endoscope Reprocessing Room</td>
<td>—</td>
<td>No Requirement</td>
<td>No Requirement</td>
</tr>
</tbody>
</table>
Environment of Care

- Block medical gas shut-off valves
- Blanket warmers
- Fire safety (ECRI, AORN, ASA)
  - Prevention plan
  - Response
  - Risk assessment
  - Education, training, drills
Multiple Outlet Connections

- Relocatable Power Taps – RPT’s
- Special Purpose Relocatable Power Taps - SPRPT’s (integral part of equipment assembly, permanently attached)

NFPA 99, 1999 Edition: Section 7-5.1.2.5 permitted only if integral part of the medical equipment (SPRPT)
Categorical Waiver for Power Strips Use in Patient Care Areas

To adopt waiver: reach consensus, document (e.g. EC meeting minutes), notify surveyor upon arrival for any survey, enter comment under JC BBI in e-SOC

If adopt waiver, may use power strips if:

- Comply with 2012 LSC power strip requirements
- Comply with 1999 NFPA 99 & 2000 LSC electrical system and equipment provisions
Environment of Care

2012 NFPA 99 section 10.2.3.6 – MUST meet ALL

- Receptacles permanently attached to equipment assembly
- Sum of ampacity of all appliances connected to outlets does not exceed 75% of ampacity of flexible cord supplying outlets
- Ampacity of flexible cord is in accordance with current edition *NFPA 70, National Electrical Code*
- Electrical and mechanical integrity of assembly is regularly verified and documented via ongoing maintenance program
- Ensure additional devices or nonmedical equipment cannot be connected to multiple outlet extension cord after leakage currents verified as safe
May not be used in patient care vicinity to power non-patient care-related electrical equipment (e.g., personal electronics).

May be used outside of patient care vicinity for both patient care-related electrical equipment & non-patient-care-related electrical equipment.

Power strips providing power to rack-, table-, pedestal-, or cart-mounted patient care-related electrical equipment assemblies are not required to be integral component of manufacturer tested equipment. Power strips may be permanently attached to mounted equipment assemblies by personnel who are qualified to ensure compliance with section 10.2.3.6.
Multiple Outlet Connections
What to Do???

- Evaluate and inventory current locations and use
- Eliminate nonessential
- Evaluate safety: Trip hazard? Daisy chained? Mounted off floor?
- Ensure ground fault circuit interruption (GFCIs) in locations near water sources to prevent electrocution
- Evaluate process for purchase approval & use of power strips (biomed/engineering involved?)
- Define process for verifying & documenting electrical & mechanical integrity & ongoing maintenance
  - Patient care-related electrical equipment must be Special-purpose Relocatable Power Taps (SPRPT) listed as UL 1363A or UL 60601-1
  - Non-patient-care-related electrical equipment must be Relocatable Power Taps (RPT) listed as UL 1363
Patient Rights

- Inform patient or support person of rights in advance of furnishing care (includes outpatients)
  - How to inform? Handouts? Signs?
  - Visitation policy
- Cultural, personal values, beliefs, preferences, religious, spiritual
- Language interpretation & translation
Informed Consent

- Written Policy
  - Specific care, treatment, and services that require
  - Exceptions
  - Process to obtain
  - How to document
  - Who may obtain
  - When surrogate may give consent
Informed Consent Required Elements

- Proposed care, treatment, and services.
- Potential benefits, risks, and side effects
- Likelihood of achieving goals
- Potential problems that might occur during recuperation
- Reasonable alternatives
- Risks, benefits, and side effects related to alternatives
- Risks related to not receiving proposed care
Minimal Requirements

- Name of organization where procedure will take place
- Name of specific procedure
- Name of responsible practitioner who is performing
- Statement that procedure, including anticipated benefits, material risks, and alternative therapies, was explained to patient or patient’s legal representative
Well-designed form may also include:

- Name of practitioner conducting informed consent discussion
- Date, time, & signature of witnessing signature (CAH requires witness)
- Indication or listing of material risks discussed
- Statement that physicians (residents) & qualified medical practitioners (e.g. PA, RNFA) other than operating practitioner will be performing important tasks related to surgery
Informed Consent

- Written consent for anesthesia?
- Blood/transfusion consent
  - American Association Blood Bank
    - Medical Director participates in policy development
    - Minimum elements: risks, benefits, treatment alternatives (non-treatment), opportunity to ask questions, right to accept or refuse
  - Who is qualified to obtain?
  - What time period does a blood consent cover – including peri-operative consent?
Informed Consent

Consent Issues

- Ask family to sign when patient is competent – staff convenience, not appropriate
- General consent to treat not signed
- Include all required elements in consent process and documentation
- Name of practitioner performing procedure completed?
- Does procedure include location & laterality?
- Use of abbreviations?
- Physician attestation/signature required?
Advance Directives

§ 482.13(a)(1)

- Provide AD notice to inpatients and outpatients (or representatives) undergoing same-day surgery
- Presented at registration
Advance Directives

- Policy addresses if AD will be honored in OP setting (RI.01.05.01)
- Document presence of AD
- Communication to patient if AD will not be honored

Consider:
- Plan ahead for OP surgeries and request bring AD prior to - or day of - surgery
- If DPOA identified and document not available, document name and contact information
Assessment

- History and Physical
  - If not completed before entry, must be completed within 24 hours after admission or registration, but prior to surgery/invasive procedure

30 days  Entry  Proc  24 hrs
Admission or Entry for OP Surgery
H & P MAY be done up to 30 days prior to entry into the hospital, but MUST be updated after entry/registration and prior to procedure
Assessment

482.22(c)(5)(ii) H&P Update Documentation:

- H&P was reviewed
- Patient was examined
- “No change“ (or change) has occurred in patient condition since H&P completed

Inpatient H&Ps do NOT require update (admission note, consultations, progress notes)
Assessment

History & Physical – Medical Staff Bylaws & Policies
- What is a complete H & P?
- May a “consult” or office visit note be used?
- May it vary by setting or procedure?
- Are any procedures excluded from H&P?
- What parts may be delegated to others?
- Who is privileged to perform?
- May others gather information to use for H&P?
- May someone other than surgeon perform update?
Assessment

H&P Issues

- H&P in medical record and updated prior to procedure (not just transcribed, not written after procedure)?
- Does pre-procedure staff know requirements for H&P and update before checklist marked as completed?
- Who can perform the update (podiatrist, ophthalmologist)?
Provision of Care

Challenges with Interpreter and Translation

- H&P, nursing & anesthesia assessments
- Patient teaching
- Consent (? obtained in physician office)
- Discharge instructions
- Use of interpreter documented?
Orders

- Date, time, signed
- Pre-op orders or approved protocols for IV’s, medications, tests
- Can post-op orders be written pre-operatively?
Anesthesia

Pre-anesthesia Evaluation

- General, regional, monitored, deep
- § 482.52(b)(1) may not delegate to practitioners who are not qualified to administer anesthesia
- Completed and documented within 48 hours immediately prior to any inpatient or outpatient procedure requiring anesthesia services (1st induction medication = start of anesthesia)
- Required elements per policy
Anesthesia

Post-anesthesia Evaluation

- By anesthesia provider
- Within 48 hrs after anesthesia is completed
- Required elements
  - Respiratory function, including rate, airway patency, & oxygen saturation
  - Cardiovascular function (pulse rate and BP)
  - Mental status
  - Temperature
  - Pain
  - Nausea and vomiting
  - Postoperative hydration
Moderate (Conscious) Sedation

- Presedation Assessment Policy
  - Required elements, who?, documentation before sedation
- Medical staff privileges
- Sufficient number qualified staff
- Reevaluate immediately before administering sedation
- Assessment pre-, intra-, post sedation

Deep sedation is **anesthesia**, NOT moderate sedation!
Unintended Retained Foreign Objects

- Reviewed by JC
  - 2011 = 188
  - 2012 = 115
  - 2013 = 102

- Root Causes
  - No policies
  - Failure to comply with policies
  - Intimidation
  - Failure in communication with physicians
  - Failure of staff to communicate relevant information
  - Inadequate or incomplete staff education
Sentinel Event Alert - October 2013
Unintended Retained Foreign Objects

- Common risk factors
  - High BMI
  - Emergent or urgent procedure (9x)
  - Unanticipated/unexpected change during procedure (4x)
  - Intra-abdominal procedure
  - More than one procedure
  - Multiple teams
  - Multiple staff turnovers during procedures
- 80% procedures with URFO indicated a correct count
Have you developed a highly reliable and standardized counting system?

Is your process effective, collaborative, and evidence-based?

Have you implemented your process organization-wide?

Do you follow your process as designed?

Have you achieved zero defects?
Medication Management

- Procedural verbal orders
- Pharmacy review of orders
- PACU Orders
  - Therapeutic duplication
  - Unclear orders (surgeon & anesthesia both order pain meds)
  - High-risk medications, maximum doses
  - Range orders
- Security and access
- Expired (special procedure carts, bags, tackle boxes)
- Spike IV solutions in advance of use
Medication Management

Storage

- Refrigeration
- Fluid and solution warmers
- Contrast warmers
- Multi-dose vials labeled with 28-day expiration date
- Use of multi-dose vials in immediate patient care areas
- Single-use vials are SINGLE-USE (one hour)
- New expiration date when unopened refrigerated drugs removed from refrigerator (anesthesia carts)
Record of Care

- Date and time entries
- Post-procedure note
  - Name(s) of surgeon, assistant(s)
  - Procedure performed
  - Findings
  - Any estimated blood loss
  - Any specimens removed
  - Postoperative diagnosis
Transplant Safety

- Follow manufacturers’ written directions for transporting, handling, storing, and using tissue
- Verify (document) upon receipt package integrity and transport temperature range controlled and acceptable for tissues requiring controlled environment
- Maintain daily records for tissues requiring controlled environment (room temperature, refrigerated, frozen, liquid nitrogen storage)
- Daily records NOT required for “ambient temperature”
- Refrigerators, freezers, nitrogen tanks have functional alarms & emergency back-up plan
Transplant Safety

- Bi-directional traceability
- Identify in writing, materials and related instructions used to prepare or process tissues
- Document dates, times, and staff involved (accepted, prepared, issued)
- Document in recipient’s medical record the tissue type and unique identifier
Human Resources

- Unit-specific orientation & training
- Competence assessment (skills and knowledge assessed by someone with similar skills and knowledge)
- Non-employed and contracted staff (scrub tech, RNFA, perfusionist) – job descriptions, orientation, competence assessment
- Vendors (health screen, HIPAA, policies)
Human Resources

Practicing outside scope of licensure, registration, certification

- Adverse accreditation decision (accreditation with follow up survey, preliminary denial of accreditation)

- Examples:
  - Performing parts of procedure not within license or privileges
  - Staff entering orders as verbal or telephone orders because they know what physician wants
Infection Control - Immediate-use Steam Sterilization (IUSS)

- Should be exception not norm
- Ensure proper cleaning & decontamination, inspection, and arrangement of instruments into recommended sterilizing trays or containment devices before sterilization
- Documentation consistent with requirements for wrapped loads
- Transported in manner to prevent contamination
- Do NOT use for implants
- Frequency? Reasons?
- Reports: analyzed, aggregated, trended, reviewed, reported to IC/OR Committee

S&C: 14-44-Hospital/CAH/ASC August 29, 2014
Infection Control – High-level Disinfection

- Staff PPE
- Cleaning starts immediately after use by flushing with enzymatic if scope has channels
- Disinfection or Sterilization
  - Contact with intact mucous membranes = high-level disinfection
  - Enters sterile tissue or vascular = sterilization
- Follow manufacturers’ instructions for use
- Test concentration of disinfectant and record results
- Check temperature of disinfectant
- Positive and negative controls for test strips
Automated reprocessing system – ensure correct connectors for scope

- Store – clean, dry, hanging, not coiled, vented cabinet at least 3 feet from reprocessor

- Reprocessing interval when not used?
Endoscopes

- Transport used scopes in closed containers
- Fail-safe system to identify clean and dirty scopes
- Staff training, competency must be documented
- Oversight is critical
Infection Control

Supply Storage

- Laryngoscope blades
- Sterile items protected from excess humidity (< 60%)
- Cardboard boxes, outside shipping containers
- Height from floor, impervious bottom shelf
- Manage expiration dates (special carts, tackle boxes, bags)
Infection Control

- Safe injection practices
- Prep solutions - evidence-based guidelines or personal preference, dry time
- Room cleaning, inspections?
- Low-level disinfection equipment, supplies, surfaces
- OR attire
- Surgical hand scrubs (initial vs. subsequent; soap, chlorhexidine, iodine, alcohol; CDC/AORN)
NPSG - 2 Identifiers

- Providing treatments and procedures
  - When?
    - Transport to procedure room?
    - During time out?
  - What to compare to? Consent, schedule, order?
- Label specimens in presence of patient
  - Process to ensure labels match patient?
Transfusion safety
- Match blood or component to order
- Match patient to blood
- Use two-person verification process or one-person verification process accompanied by automated identification technology, such as bar coding
- One individual conducting identification verification is qualified transfusionist who will administer
- Second individual qualified to participate in verification process
Label meds, med containers, & solutions on and off sterile field in peri-operative & other procedural settings

- If not immediately administered
- Even if only one used
- Label at time of transfer
- 2-person visual and verbal verification if preparer is not user

Label includes
- name, strength
- amount, diluent, volume (if not apparent from container)
- expiration date when not used within 24 hours
- expiration time when expiration < 24 hours

(Date & time not necessary for short procedures, as defined by policy)

- Reviewed by entering and exiting staff responsible for management of medications
NPSG - Medication Reconciliation

- Obtain current medication list (good faith effort)
- Decide what the med list looks like in OP settings
- Compare the med list to med orders for interactions, meds that should be continued during visit (e.g. beta blocker, antihypertensive)
- Discharge written list - OPs, if no long-term meds change, may provide list of new prescriptions (name, dose, frequency). If long-term meds are changed, give complete and accurate list
Universal Protocol

Applies to all surgical and nonsurgical invasive procedures

- Pre-procedure verification
- Site marking
- Time-out
Pre-procedure Verification

- Scope of may depend on type & complexity procedure
- Identify what must be available & use standardized list to verify availability
  - Relevant documentation (H&P, consent, pre-anesthesia/pre-sedation assessment)
  - Labeled diagnostic & radiology test results (images, pathology reports) properly displayed
  - Blood products, implants, devices, and/or special equipment
- Match items to patient
Pre-procedure Verification

- Which diagnostics need to be available at time of procedure?
- Which blood products, implants, supplies need to be present?
- How they are to matched to patient?
- Who is responsible for the match?
Pre-procedure Verification

- Checklist used to verify documents and supplies
- Standardized list, does NOT need to be part of medical record
  - It may be a laminated card or clipboard
  - It may be a poster or white board
- May vary by procedure and setting
Site Marking

- Identify procedures that require marking of incision or insertion site. At minimum, mark when there is more than one possible location for procedure and when performing procedure in different location would negatively affect quality or safety.
- Note: For spinal procedures, in addition to preoperative skin marking of general spinal region, special intra-operative imaging techniques may be used for locating and marking exact vertebral level.
Site Marking

- Mark before procedure is performed and, if possible, with patient involved
- Marked by licensed independent practitioner accountable for procedure and will be present when procedure performed
- Method of marking and type of mark is unambiguous and used consistently throughout the hospital
Site Marking

- Mark at or near procedure/incision site
- Sufficiently permanent to be visible after prepping and draping
- Adhesive markers are not sole means of marking
- Is visible and final verification occurs during time-out
- Written, alternative process when patients refuse site marking or when technically or anatomically impossible or impractical to mark (mucosa, perineum, teeth, premature infant, minimal access procedures treating lateralized internal organ, whether percutaneous or through natural orifice)
Time Out

- Immediately before starting the invasive procedure or making the incision
  - What is your definition of immediately??
- Required characteristics
  - Standardized, as defined by hospital
  - Initiated by designated member of team
  - Involves immediate members of procedure team, including individual performing procedure, anesthesia providers, circulating nurse, OR tech, and other active participants who will participating in procedure from the beginning
Time Out

- When two or more procedures are being performed on the same patient, and the person performing the procedure changes, perform time-out before each procedure is initiated.
- Members agree, at a minimum, on the following:
  - Correct patient identity
  - Correct site
  - Correct procedure
- Document completion of time-out
Time Out

- Who is designated as the leader?
- Do team members have defined roles?
- What do you use as your source of truth?
- How do you confirm patient identity?
- What process is followed when all team members are not totally engaged?
Presentation “Sign Out”

- Did we accomplish our objectives??
- Are you leaving with at least one idea of how you can improve patient safety at your organization??
- Did we answer your questions??
- Did we do no harm??
Questions