





Road Map to a Comprehensive Safe Site Procedure Program

SAFE SITE based on the ICSI Safe Site Protocol and Adverse Health Event Learnings



INFRASTRUCTURE





SAFE SITE Component	Specific Action(s)	SAFE SITE Audit Questions
 <p>SAFE SITE Teams</p>	<ol style="list-style-type: none"> 1) Provide support and expectations for SAFE SITE champions. 2) Adopt an interdisciplinary team approach to SAFE SITE with a designated coordinator for the operating room to oversee implementation. 3) Adopt an interdisciplinary team approach to SAFE SITE with a designated coordinator for invasive procedures outside the operating room to oversee implementation. 	<ol style="list-style-type: none"> 1a) Senior Leadership has identified a physician champion(s) for SAFE SITE. 1b) Senior Leadership has identified an operational champion(s) for SAFE SITE in the OR (e.g. OR director, nurse manager). 1c) Senior Leadership has identified an operational champion(s) for SAFE SITE in other invasive procedure areas (e.g. OR director, nurse manager). 1d) The facility has a process in place to partner the physician and operational champions. 1e) Senior Leadership has defined roles, set expectations and provides support for the champion(s). 2a) The facility adopts a team approach to safe site surgery with an interdisciplinary team in the operating room to oversee and support the SAFE SITE work. 2b) The facility has a designated coordinator to oversee SAFE SITE implementation (e.g. schedule team meetings, plan staff education). 2c) Individual roles in the SITE Bundle (patient care steps) are clearly defined and documented for the OR. 3a) The facility promotes a team approach to safe site invasive procedures with an interdisciplinary team for invasive procedures outside the operating room (e.g. radiology, bedside procedures) to oversee and support the SAFE SITE work. 3b) The facility has a designated coordinator to oversee SAFE SITE for invasive procedures outside the operating room. 3c) Individual role(s) in the SITE Bundle (patient care steps) are clearly defined and documented for other invasive procedures.
 <p>Access to information</p>	<ol style="list-style-type: none"> 1) Verify the completion of each step of the SITE Bundle in "real-time". 2) Audit the effective completion of the SITE Bundle. 3) Measure the outcomes of the SAFE SITE efforts 4) Measure the culture in the OR and other invasive procedure areas. 5) Evaluate the SAFE SITE efforts for learning opportunities. 	<p>Data Collection</p> <ol style="list-style-type: none"> 1a) The facility has a process in place for real-time documentation of the completion of the SITE bundle steps for all interdisciplinary team members involved in the procedure (e.g. a pre-procedure checklist). 2a) The facility has a process in place to audit the completion of the SITE Bundle through chart audits. 2b) The facility has a process in place to audit the effective completion of the SITE Bundle through observational audits. 2c) The facility has developed standard criteria for auditors. 3a) The facility has a process in place for reporting near-miss wrong site, wrong patient, and wrong procedure events. 4a) The facility has a process in place to gather staff perceptions of the safety culture in the OR. 4b) The facility has a process in place to gather staff perceptions of the safety culture in other invasive procedure areas. <p>Data Analysis</p> <ol style="list-style-type: none"> 5a) The facility has a process in place to review and analyze data on a regular basis for learnings and improvement opportunities. 5b) Data is shared within and across teams on a regular basis. 5c) Data is shared with senior leadership on a regular basis. 5d) Data is shared with the facility's medical staff on a regular basis.
 <p>Facility Expectations</p>	<ol style="list-style-type: none"> 1) Set expectations for implementation of the SITE Bundle for any invasive procedure. 2) Participate in a statewide effort to institute a "hard stop" when the SITE Bundle is not completed or until inconsistencies are reconciled. 3) Hold team members accountable when the SITE Bundle is not completed regardless of whether or not an adverse event occurs. 4) Expect staff to "speak up" when they become aware of a patient safety issue. 	<ol style="list-style-type: none"> 1a) Senior Leadership has set clear expectations for effective completion of the SITE Bundle prior to any surgical procedure. 1b) Senior Leadership has set clear expectations for effective completion of the SITE Bundle prior to any invasive procedure. 2a) The facility has a process in place to institute a Level I Hard Stop for OR procedures (the patient is not moved into the OR) if the site has not been signed or the informed consent and verification process (SITE steps S and I) has not been completed and reconciled. 2b) The facility has a process in place to institute a Level II Hard Stop for OR procedures (staff do not complete any additional steps to begin the surgery) if an active, verbal time-out by the full team has not been conducted. 2c) The facility has a process in place to institute a Level I Hard Stop (the patient is not moved into the procedure area, if applicable) for other invasive procedures if the site has not been signed or the informed consent and verification process has not been completed and reconciled. 2d) The facility has a process in place to institute a Level II Hard Stop for other invasive procedures (staff do not complete any additional steps to begin the procedure) if an active, verbal time-out by the full team has not been conducted. 3a) The facility has a process in place to determine at-risk or reckless behavior, and the consequences, when the SITE Bundle steps are not completed regardless of whether or not an adverse event occurs. 3b) The facility's medical staff policies address safe site surgery and other invasive procedures and include expectations for following the SITE Bundle. 4a) Senior Leadership has clearly communicated that all staff are expected to speak up, and will be supported in speaking up, when safety issues are noted.
 <p>Educate Staff and Patients</p>	<ol style="list-style-type: none"> 1) Provide SAFE SITE education for all clinical staff involved in invasive procedures. 2) Educate patients and families on their role in SAFE SITE. 	<ol style="list-style-type: none"> 1a) Expectations and supporting education have been incorporated into new employee orientation for all staff involved in invasive procedures. 1b) Expectations and supporting education have been incorporated into orientation for new surgeons and other providers involved in performing invasive procedures. 1c) Ongoing SAFE SITE clinical staff education is provided at least annually. 2a) Patient/family safe site procedure education tools are disseminated as appropriate.

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PATIENT CARE BUNDLE

SAFE SITE Component	Specific Action(s)	SAFE SITE Audit Questions
 <p>Sign site with initials</p>	<ol style="list-style-type: none"> 1) Mark the procedure site 2) Multiple sites are labeled in medical record and are numbered accordingly. 	<ol style="list-style-type: none"> 1a) The facility requires, AND has a designated place to document, that the provider performing the procedure marks the procedure site with their initials. 1b) The facility requires that an indelible (permanent) non-toxic marker is used to mark the procedure site. 1c) The facility has a process in place to address patient refusal of site marking. 2a) The facility requires, AND has a designated place to document, that multiple procedure sites are labeled in the medical record and are numbered accordingly on the procedure sites.
 <p>Informed Consent and verification</p>	<ol style="list-style-type: none"> 1) Verify: <ol style="list-style-type: none"> a) Informed consent with patient's medical record. b) Patient identification with 2 indicators. c) Procedure to be performed d) Procedure site and laterality and/or level. 	<ol style="list-style-type: none"> 1a) The facility requires, AND has a designated place to document, that the informed consent is verified with the patient's medical record, patient identity was checked using 2 unique identifiers, and the procedure, site, laterality and/or level is verified with the patient's medical record.
 <p>Time-Out</p>	<ol style="list-style-type: none"> 1) Active, verbal participation in "Time-out" by the Full Team. 2) Institute a Hard Stop if a 'time-out' is not performed. 3) Final visual check for site marking. 	<p>The facility has the following processes in place for an effective "time-out":</p> <ol style="list-style-type: none"> 1a) In the OR, the surgeon is responsible for "calling for" the "time-out" prior to starting the procedure. 1b) In other invasive procedure areas, the person performing the procedure is responsible for "calling for" the "time-out" prior to starting the procedure. 1c) All team members are required to stop other activities and pause for the duration of the "time-out". 1d) Each member of the surgical/procedure team is required to give an independent, verbal confirmation. 1e) A reconciliation process is in place for any discrepancies noted during the "time out". 1f) An additional time-out is performed if there is a disruption during the "time-out". 1g) A briefing (hand-off) is in place for replacement staff if staff changes occur during the procedure. 2a) The facility has a process in place to stop work to begin the procedure if a "time-out" is not conducted. 2b) The facility has a process in place to support any member of the team in calling for a hard stop. 3a) The facility has a process in place for the person performing the procedure to conduct a final visual check for the site mark immediately preceding the procedure after patient has been draped and positioned.
 <p>Effective Communication</p>	<ol style="list-style-type: none"> 1) The team reviews: <ol style="list-style-type: none"> a) Relevant images b) Implants or special equipment c) Patient positioning d) Special patient issues 	<ol style="list-style-type: none"> 1a) The facility requires, AND has a designated place to document, a pre-operative team briefing or huddle to review relevant images, implants or special equipment, special patient issues, patient positioning and other pertinent information. 1b) The facility has a process in place to communicate intra-operatively (e.g. intra-operative time-out) to verify internal laterality and implants. 1c) The facility has a process in place to clearly identify the person responsible for ensuring the pre-operative safe site processes are completed for each patient. 1d) The facility has a process in place to clearly identify the person(s) responsible for ensuring the pre-procedure safe site processes are completed for each patient undergoing an invasive procedure.