The High 5s Project
Standard Operating Protocol

Performance of Correct Procedure at Correct Body Site

Standard Operating Protocol for Performance of Correct Procedure at Correct Body Site

The High 5s Project "Correct Site Surgery"

Attribution Statement

This work was carried out as part of the High 5s Project set up by the World Health Organization in 2007 and coordinated globally by the WHO Collaborating Centre for Patient Safety, The Joint Commission in the United States of America, with the participation of the following Lead Technical Agencies including: Australian Commission on Safety and Quality in Health Care, Australia; Canadian Patient Safety Institute, Canada and the Institute for Safe Medication Practices Canada, Canada; National Authority for Health- HAS, France, with CEPPRAL (Coordination pour L' Evaluation des pratiques professionnelles en santé en Rhône-Alpes), France, OMEDIT Aquitaine (Observatoire du Medicament, Dispositifs medicaux et Innovation Therapeutique), France (from 2012- 2015) and EVALOR (EVAluation LORraine), France (from 2009-2011); German Agency for Quality in Medicine, Germany and the German Coalition for Patient Safety, Germany; CBO Dutch Institute for Healthcare Improvement, the Netherlands; Singapore Ministry of Health, Singapore; Trinidad and Tobago Ministry of Health, Trinidad & Tobago; Former National Patient Safety Agency, United Kingdom of Great Britain and Northern Ireland; and the Agency for Healthcare Research and Quality, USA.

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The following Standard Operating Protocol (SOP) was developed, tested and refined within the context of the Action on Patient Safety ("High 5s") initiative, an internationally coordinated, limited participation activity for testing the feasibility of implementing standardized patient safety protocols and determining the impact of the implementation on certain specified patient safety outcomes. Because the efficacy of this and other High 5s SOPs have now been demonstrated,[1] their implementation outside of the High 5s testing environment is recommended at this time.

[1] http://www.who.int/patientsafety/implementation/solutions/high5s/en/

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The patient safety problem to be addressed by this protocol

CORRECT SITE

CORRECT PROCEDURE

CORRECT PERSON

"Correct site surgery" means that the correct procedure has been performed on the correct patient at the correct anatomical site and, when applicable, using the correct implant. Conversely, "wrong site surgery," also called "incorrect surgery," means surgery that has been initiated involving the wrong procedure, wrong patient, wrong site (including wrong side or wrong organ), or wrong implant. Such a procedure is considered "incorrect" whether or not a process error has occurred and whether or not any harm resulted. Use of the term "correct" in this context is in relation to what was intended to be done; it is not in any way a clinical judgment about the appropriateness or necessity of the planned procedure.

In relation to the total number of surgical procedures that are conducted each year, these are infrequent, though not "rare" events[2,3] In fact, there has been a steady increase in the number of reported cases over the past two decades.[4] This may simply be a reflection of improved reporting, but the fact remains there is no evidence that the incidence or frequency of this problem has decreased in recent years despite the introduction of relevant international patient safety goals and standards, the Universal Protocol, the WHO World Alliance for Patient Safety's Solution #4: Performance of Correct Procedure at Correct Body Site, and the WHO 2nd Global Patient Safety Challenge: Safe Surgery Saves Lives.

Considered preventable occurrences, these cases are largely the result of miscommunication and unavailable or incorrect information. Detailed analyses of these cases indicate that a major contributing factor to error is the lack of a standardized preoperative process and likely a degree of staff automaticity (checking without thinking) in the approaches to the preoperative check routines.[5] Wrong site, wrong procedure, wrong person surgery is preventable through consistent, mindful implementation of this SOP.[6,7]

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2 Croteau RJ, Wrong Site Surgery in *Surgical Patient Safety: Essential Information for Surgeons in Today's Environment*, American College of Surgeons, Chicago, 2005.

3 Gawande AA, *et al*, Incidence, Patterns, and Prevention of Wrong-Site Surgery, *Archives of Surgery*; 141:353-358; 2006.

4 Sentinel Event Statistics, The Joint Commission: http://www.jointcommission.org/sentinel_event.aspx

5 "A follow-up review of wrong site surgery," Sentinel Event Alert, Issue 24, December 5, 2001, Joint Commission on Accreditation of Healthcare Organizations. http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_24.htm

6 Michaels RK, et al. Achieving the National Quality Forum's "Never Events": prevention of wrong site, wrong procedure, and wrong patient operations. *Ann Surg* 2007; 245(4):526-532.

7 Rogers ML, Cook RI, Bower R, et al. Barriers to implementing wrong site surgery guidelines: a cognitive work analysis. *IEEE Transactions on Systems, Man, and Cybernetics — Part A: Systems and Humans* 2004 Nov;34(6):757-63.

A word about standardization

The basic assumption that was tested in the High 5s initiative is that process standardization will improve patient safety. We know that in a general sense, the tendency for a process to fail is diminished in relation to the consistency with which it is carried out; that is, the degree to which it is standardized. Despite this, efforts in recent years to standardize health care processes through the introduction of practice parameters, protocols, clinical pathways, and so forth have been met with limited enthusiasm among practitioners and are only slowly affecting the actual delivery of care. Achieving process consistency while retaining the ability to recognize and accommodate variation in the input to the process (for example, the patient's severity of illness, co-morbidities, other treatments, and preferences) is one of the major challenges to standardization in health care. Process variation to meet individual patient needs is an essential principle of modern medicine; variation to meet individual health care organization or practitioner preferences need not be. The thesis that has been tested in the High 5s initiative is that standardization will be advantageous—will get better overall results more safely—even if we concede that each practitioner working independently could get better results than the others by using a personally favored, but different, process than the others. The reason, of course, is that in modern medicine, practitioners do not work independently. Clinical results are determined by the complex interrelationships among practitioners, supporting staff and services, and the clinical environment. Assuming each preferred practice is a good practice, it matters less which process is selected as the basis for standardization; it is the standardization that matters most. Standardization produces better results than a variety of "best practices" when it comes to safety.

The High 5s initiative has taken standardization a couple of steps further than the usual efforts to minimize variation—it not only sought to standardize certain processes among individuals within a health care organization but to standardize them in multiple organizations in multiple countries around the world. The High 5s Project posed the following questions: Is it possible to standardize on a multinational scale? If it is, will this effort measurably improve the safety of care? The first of these questions has now been answered as a qualified affirmative. That is, the High 5s Project has demonstrated that a standardized process for preparing patients for surgery, focused on the prevention of wrong site surgery, can be implemented on a multinational scale with minimal adaptation of the protocol. However, while most of the participating hospitals have achieved full implementation of the SOP, some have not and are still in the process of spreading the implementation to include all eligible sites and patient groups. Also, performance measure data collected over the course of the Project demonstrates significant variation from hospital to hospital and country to country in the consistency of performance of the steps of the SOP. Finally, it should be noted that all but one of the participating countries are classified as developed economies. The question of impact is more difficult to answer, primarily because of the infrequency of the events the SOP is intended to prevent, lack of a reliable baseline of occurrence rate, and the inconsistency of reporting events that do occur. Nonetheless, while impact in terms of a change in outcomes cannot be demonstrated, there has clearly been an impact on the processes for preparing patients for surgery (e.g., evidence of the introduction of surgical site marking where it had not previously been practiced), and on the awareness of and attention to the problem of wrong site surgery and its prevention.

The High 5s SOPs are now available for general implementation. In the interest of improving patient safety, WHO encourages Member States to promote implementation of these SOPs in their health care facilities and recommends their implementation as written. To do otherwise defeats the purpose and the value of the standard operating protocols.

The preoperative preparation process

Basic principles and rationale

Correct surgery requires correct patient identification, correct diagnosis, selection of the appropriate procedure, determination of the correct site of the surgery, proper positioning of the patient, and availability of all necessary equipment. The principles supporting this Standard Operating Protocol (SOP) are as follows:

- Wrong site, wrong procedure, and wrong person surgery can and must be prevented.
- A robust approach—using multiple, complementary strategies—is necessary to achieve the goal of eliminating wrong site, wrong procedure, wrong person surgery.
- Active involvement and effective communication among all members of the perioperative team is important for success.
- To the extent possible, the patient (or legally designated representative) should be involved in the process.
- Consistent implementation of a standard operating protocol will be most effective.

The process

Prevention of Wrong Site, Wrong Procedure, and Wrong Person Surgery requires consistent, effective implementation of the following three complementary components

1. Pre-operative verification
    - **Purpose:** To reduce the risk of patient and procedure misidentification by ensuring that all of the relevant documents and diagnostic studies are available prior to the start of the procedure; that they are correctly identified, labeled, and matched to the patient's identifiers; and that they have been reviewed and are consistent with the patient's expectations and with the team's understanding of the intended patient, procedure, site and, as applicable, any implants. Missing information or discrepancies must be addressed before starting the procedure.
    - **Process:** An ongoing process of information gathering and verification, beginning with the determination to do the procedure, continuing through all settings and interventions involved in the preoperative preparation of the patient, up to and including the "final time out" just before the start of the procedure.

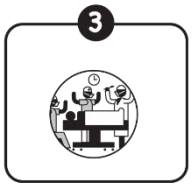
PREOPERATIVE VERIFICATION

2. Marking the operative site
    - **Purpose:** To identify unambiguously the intended site of incision or insertion.
    - **Process:** For procedures involving laterality, or multiple structures, surfaces or levels, the intended site must be marked such that the mark will be visible after the patient has been

OPERATIVE SITE MARKING

prepped and draped (does not apply to routine venipuncture or peripheral intravenous line placement).

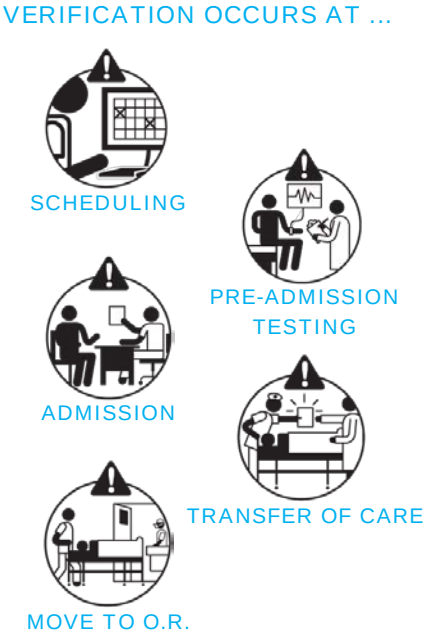
3. "Final time out" immediately before starting the procedure
    - **Purpose:** To conduct a final verification of the correct patient, procedure, site and, as applicable, patient position, implants, and necessary special equipment.
    - **Process:** Active communication among all members of the surgical team, consistently initiated by a designated member of the team, conducted in a "fail-safe" mode; that is, the procedure is not started until any questions or concerns are resolved.



FINAL "TIME OUT" VERIFICATION

Detailed specifications for the components of the preoperative preparation process

Consistent performance of the three basic components of this Protocol (preoperative verification; site marking; "time out") requires adherence to the following specifications:



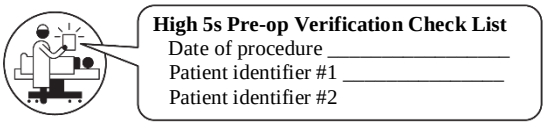
Pre-operative verification process

Verification of the correct person, procedure, and site occurs:

- At the time the surgery is scheduled
- At the time of preadmission testing and assessment
- At the time of admission or entry into the facility
- Anytime the responsibility for care of the patient is transferred to another caregiver, as a formal part of the handover process
- With the patient involved, awake and aware, if possible
- Before the patient leaves the preoperative area or enters the operating room

A preoperative verification Checklist is used to ensure availability and review of the following, prior to the start of the procedure:

- Relevant documentation (e.g., medical history, physical examination, consent, nursing and pre-anesthesia assessments)
- Diagnostic test results, including biopsy reports
- Relevant images, properly labeled and displayed
- Specific size and type of any required implants and detailed requirements of special equipment



A Sample Correct Site Surgery Checklist is provided as Appendix A.

Marking the operative site

- Mark the intended surgical/procedural site in all cases of incision or percutaneous instrumentation that involve laterality, surface (flexor, extensor), level (spine), or specific digit or lesion to be treated.

OPERATIVE SITE MARKING

- Cases that do not meet these minimum criteria for required site marking may also be marked at the discretion of the surgical facility or individual operating surgeon.
- The surgical/procedural site is marked by the person who will perform the procedure (preferred) or by another physician or registered nurse who will participate in the procedure or is directly involved in preparing the patient for the procedure.
- Organization policy states the minimum qualifications (for example: MD; RN) and the role (participating; preparing) of the individual to whom the responsibility for site marking may be delegated.
- For each case requiring site marking, the individual who marks the site is identified in the medical record (preferably, on the preoperative verification Checklist).
- The site is marked before the patient is moved to the location where the procedure will be done.
- Marking takes place with the patient involved, awake and aware, if possible.
- The mark is made at or near the intended incision site. Do not mark any non-operative site(s) unless necessary for some other aspect of care.
- The mark is unambiguous. The specific type of mark is determined by the national/health-system oversight body or by the individual surgical facility if it is not part of a national or health system implementation program. For example, the surgeon's initials or a line representing the proposed incision may be used. In general, use of "X" to mark the intended site is not recommended, as it may be interpreted as "do not operate here." However, if "X" has been accepted as the standardized method of site marking in the hospital, health care system, or country (for example, as in Germany), then continued use of this method in the context of this SOP will be acceptable.
- The method of marking and type of mark is consistent for all applicable cases throughout the scope of implementation of this SOP, whether an individual hospital, health system or country.
- The mark is positioned to be visible after the patient is prepped and draped.
- The mark is made using a skin marker that is sufficiently permanent to remain visible after completion of the skin prep.
- Adhesive site markers are not used as the sole means of marking the site.
- For spinal procedures, in addition to pre-operative skin marking of the general spinal region, special intraoperative radiographic techniques are used for marking the exact vertebral level.
- For minimal access procedures that intend to treat a lateralized internal organ, whether percutaneous or through a natural orifice, the intended side must be indicated by a mark at or near the insertion site (see below for alternative approaches, where appropriate).
- Final verification of the site mark takes place during the "time out."
- A defined procedure is in place for patients who refuse site marking.

MARKING IS DONE BY THE SURGEON OR OTHER QUALIFIED PERSON

WHENEVER POSSIBLE, THE PATIENT IS INVOLVED IN THE SITE MARKING

THE MARK IS VISIBLE AFTER PREP & DRAPE

THE MARK CANNOT BE WASHED OFF BY THE SKIN PREP

- Exemptions and permissible alternative approaches for site marking:
  - Premature infants, for whom the mark may cause a permanent tattoo.
  - For cases in which it is technically or anatomically impossible or impractical to mark the site (perineum, premature infants), an alternative method for visually identifying the correct side is used: for example, a temporary unique wrist band on the side of the procedure, which contains the patient's name, a second identifier, the intended procedure and site.
  - Life-threatening emergencies in which even the minimal time required to mark the site introduces more risk to the patient than the possibility of a wrong site or wrong person procedure.

Final "Time out" verification immediately before starting the procedure

FINAL "TIME OUT" VERIFICATION

- This final verification is conducted in the location where the procedure will be done, with the patient properly positioned for the procedure, just before starting the procedure.
- It must involve the entire operative team, using active communication.
- The "time out" is initiated by a designated coordinator with the informed consent document "in hand." The designated coordinator will often be a circulating nurse, but may be any clinician or health care professional participating in the operation who has been determined by the facility to be qualified for this role.
- During the "time out," other activities are suspended—to the extent possible without compromising the safety of the patient—so that all members of the team are focused on the active verification of the correct patient, procedure, site, and other critical elements.
- The "time out" must, at the least, include:
  - Correct patient identity
  - Correct side and site
  - Agreement on the procedure to be done
  - Correct patient position
  - Availability of correct implants and any special equipment or special requirements
- There is a defined process for reconciling differences in responses during the "time out" as well as any discrepancies between the responses and the informed consent document and other available documentation.
- The "time out" is conducted in a "fail-safe" mode; that is, the procedure is not started until any discrepancies, questions or concerns are resolved.
- The "time out" is documented on the preoperative Checklist.

THE FINAL "TIME OUT" VERIFIES THE FOLLOWING:

PATIENT IDENTITY

SIDE / SITE

PROCEDURE

PATIENT POSITION

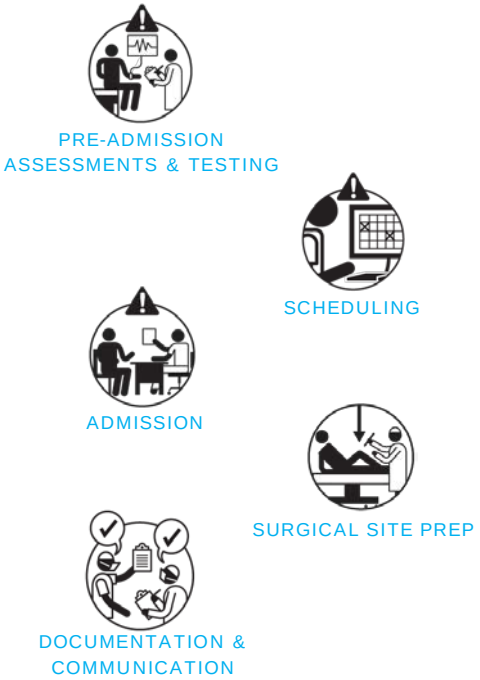
IMPLANTS / EQUIPMENT

NO SURGERY UNTIL ALL CONCERNS ARE RESOLVED

The context for standardized preoperative preparation to assure correct site surgery

Preoperative preparation is a complex process that involves many professional disciplines in several settings of care—beginning with the initial diagnostic encounter through to the beginning of the surgical procedure. Given that context, effective and efficient implementation of the preoperative process for assuring correct site, correct procedure, correct person surgery will require **integration** of its steps into existing processes for patient assessment and diagnosis, preoperative preparation, and patient flow, rather than simply adding new tasks. It is therefore important to identify the other aspects of patient care with which this aspect of preoperative preparation must interface, including the following:

- Pre-admission assessment (physician's office or clinic setting)
- Informed consent process
- Diagnostic testing (laboratory, imaging, biopsy, etc.)
- Surgical scheduling procedures
- Pre-anesthesia and preoperative nursing assessments
- Patient admission/intake to the surgical facility
- Surgical site preparation
- Pre-anesthesia medication and instrumentation
- Operating room set-up
- Documentation of care
- Communication of information among providers



Recognizing that the prevention of wrong site surgery is largely a matter of information gathering and communication among members of the perioperative team, the specifics of implementation will depend to a considerable degree on the health care organization's existing systems and processes for collecting, using, and communicating information, for example, hand-written paper medical records versus electronic medical records. The information management activities in support of this protocol should be integrated as much as possible into these existing systems and processes by adapting the tools currently used (forms, Checklists, data collection tools, etc.) and aligning work flow to optimize efficiency of the integrated process.

Finally, the culture of the organization with respect to interdisciplinary collaboration and teamwork will significantly influence the efficiency and effectiveness of the preoperative preparation process. This process is best conducted in an environment of shared accountability and it is in this context that this Standard Operating Protocol is based.

Scope of applicability of the Correct Site Surgery Standard Operating Protocol

This SOP may be applied to all cases performed in hospital inpatient or outpatient operating rooms, freestanding ambulatory surgical facilities or other specialized facilities providing surgical or other invasive procedures. The site marking specifications (see next page) will, at a minimum, apply to cases involving laterality (for example, an extremity or a paired internal organ) or multiple surfaces, structures or levels (for example, flexor or extensor surface, a particular finger, toe, skin lesion, or vertebra). These are the minimum site marking expectations for this SOP. However, a surgical facility, group of facilities, or an entire country may choose to implement site marking more broadly, such as a requirement for site marking on all cases.

Patient and family involvement

The effectiveness of this process will be enhanced by participation of the patient and family. This involvement should be expected and encouraged by engaging them in the informed consent process, involving them in identity verification and surgical site marking, keeping them informed about the preoperative process the patient will experience, educating them about the risks and what to look for, and providing the means and encouragement to report any concerns they might have. Patients who refuse site marking should be advised of the associated risks.

Permissible adaptations in the preoperative preparation process

As noted above, the cultural and physical environment—the context—in which this process will be implemented, as well as the unique features and resources of the individual health care organization and the details of its existing processes that interface with preoperative preparation, will influence its implementation. In this Standard Operating Protocol, we seek uniformity of the basic steps in the process and their interdependencies, the assignment of certain critical tasks to specific professional disciplines, and the minimum documentation requirements, while allowing flexibility in the format of the documentation and data collection tools.

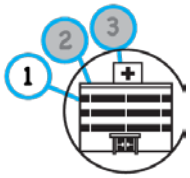
It is the intent of this Protocol that preoperative preparation be conducted as a multidisciplinary activity with responsibilities shared among surgeons, anesthesia providers, nurses, technicians, and others involved in the patient's preoperative care. Where an activity is assigned to a specific member of the surgical team, any delegation of that activity is considered an adaptation of the Protocol and, as such, may decrease the efficacy of the standardized process. In evaluating requests for adaptations of this SOP, the organization's leadership and any local or national oversight body should consider the rationale for the change and determine whether the adaptation is equivalent, with respect to patient safety, to the process as presented in the Protocol. If an organization determines that an adaptation of the Protocol is appropriate, that adaptation should be implemented consistently in all relevant locations and by all participating practitioners and staff.

Implementation Strategy for Performance of Correct Procedure at Correct Body Site

Preoperative preparation is a complex process that involves many professional disciplines in several settings of care—beginning with the initial diagnostic encounter through to the beginning of the surgical procedure. While the basic principles of information-based decision making and communication among team members are generally accepted, the process itself is often highly variable, provider-centered (rather than patient-centered), hierarchical (rather than team-based), and likely will be resisted if not implemented in a systematic manner with appropriate oversight, resources, and early engagement of the participants in the process.

The elements of a systematic implementation process are outlined below. Recognizing that each organization has its own preferred approach to project management and quality improvement, this section of the SOP should be considered a guide for designing an organization-specific implementation process. Additional details including guidelines for work plan development, integration techniques, sample Checklists, and training materials are provided in the Implementation Guide.

1. <u>Oversight of the implementation</u>:
    a. Determine the overall scope of the implementation. This may be an individual surgical unit within a larger organization; an entire organization with multiple surgical units/facilities; a group of organizations (such as a hospital chain), a geographic region containing multiple facilities; or an entire country.
    b. If the scope of implementation is greater than an individual organization, designation of a central oversight group is recommended (for example, the Ministry of Health for a country-wide implementation).
    c. At the level of the individual organization, identify an Oversight Group for the implementation project (for example, the organization's governing body or a senior leadership group).
    d. Assign a senior administrative or clinical leader to provide direct oversight of the implementation activities, assignment of staff, allocation of time for staff to do the work, and allocation of other resources (clinician leadership of the implementation effort may facilitate buy-in by other clinicians).
    e. Assign one or more representatives of the professional disciplines and clinical functions involved in the preoperative process—at a minimum, surgeons, anesthesia providers, nurses, surgical technicians, laboratory and imaging technologists, and schedulers—to guide the design, testing, and roll-out of the redesigned preoperative process and to serve as role models and "champions" of the new process for their respective disciplines.
    f. Assign a facilitator—a person with knowledge of the preoperative and surgical process and project management skills—to develop and manage the project work plan.



DETERMINE THE SCOPE OF THE PROJECT


SELECT OVERSIGHT GROUP(S)

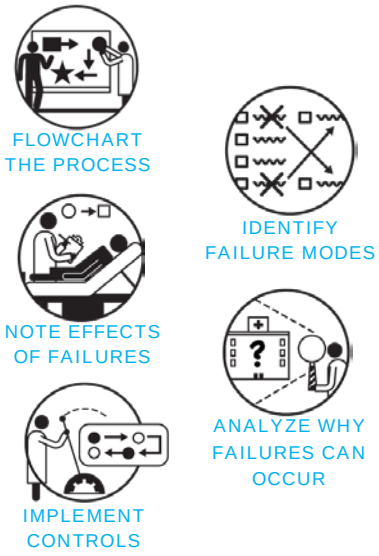

SELECT LEADER OF THE OVERIGHT GROUP


ENSURE ALL DISCIPLINES & FUNCTIONS ARE REPRESENTED

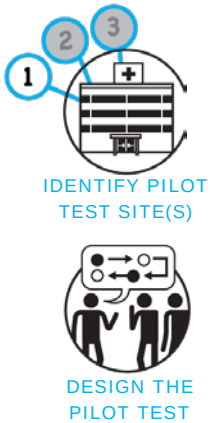

ASSIGN A FACILITATOR

2. Project work plan (all relevant professional disciplines should be involved in each step of the plan).
    a. Develop a detailed task list for design, testing, training, implementation, and management of the preoperative preparation process.
    b. Identify milestones and their target dates to include at least the following:
        i. Approval of the project work plan by the oversight group
        ii. Approval of the pilot test design
        iii. "Go-live" date for the pilot test
        iv. Presentation of pilot test results to the oversight group
        v. "Go-live" date for full implementation.
    c. Identify dependencies and realistic time frames for each of the project tasks.
    d. Identify deliverables and due dates for each of the project tasks.
    e. Assign resources to each of the tasks.

3. Risk assessment of the proposed preoperative preparation process
    a. Describe the process (for example, through the use of a flowchart).
    b. Identify for each of the steps in the process and for each linkage between steps, the ways that the process could break down or fail to perform its desired function.
    c. Identify the possible effects that a breakdown or failure of the process could have on patients and the seriousness of the possible effects.
    d. Prioritize the potential process breakdowns or failures.
    e. Determine why the high priority breakdowns or failures could occur.
    f. Implement controls, warnings, or protections to minimize the risk of harm to patients.



4. Pilot test of the preoperative preparation process (Recommended but may not be necessary in all cases)
    a. Identify one or more pilot test sites—typically, this will be a general-purpose surgical facility, either inpatient or ambulatory, that is representative of the organization's preoperative and intraoperative functions.
    b. Identify variations within current processes on the pilot test site(s).
    c. Engage representatives from the pilot test site(s) to participate in the test design and implementation.
    d. Adapt the proposed preoperative preparation process to the unique features of the pilot test site.



e. Train the staff who will be participating in the pilot test of the new process—consider that these individuals will become the trainers for the rest of the facility staff when the new process is ready for full implementation.

TRAIN PARTICIPATING STAFF

f. Implement the new process on the pilot test unit(s).

g. Gather information about the consistency, timeliness, and accuracy of implementation of each of the steps in the process (see below for recommendations for specific approaches to evaluating and managing the process).

IMPLEMENT AND MEASURE

h. Determine impact on other related or interfacing activities.

i. Determine impact on patients.

j. Summarize and review information from the pilot test and present to oversight group for decision on next steps, including possible redesign of the process.

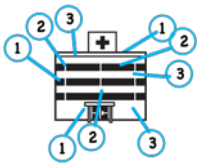
REPORT RESULTS TO OVERSIGHT GROUP

5. <u>Spread methodology</u> (If the organization conducts a pilot test)

a. Determine the sequence and timing of implementation in other surgical facilities in the organization.

DETERMINE TIMING & SEQUENCE OF SPREAD

b. In larger organizations, sequential implementation, rather than concurrent implementation, is recommended to provide for adequate pre-implementation training, oversight and coaching during the early phases of implementation, and monitoring of the new processes as they are spread to achieve full implementation.

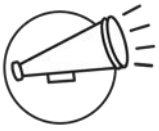


CONTINUE SPREAD TO REACH FULL IMPLEMENTATION

c. "Full implementation" of the Correct Site Surgery SOP is defined as having in place the procedures and resources necessary to perform the processes in this SOP for all surgical cases performed in the organization. Once the SOP is implemented, the degree to which it is consistently executed should be monitored to permit ongoing management of the process.

6. <u>Communication plan</u>

a. Announcement of organization's decision and commitment to implement a process to prevent wrong site surgery: the WHO's Standard Operating Protocol for Correct Site Surgery.



ANNOUNCE THE PROJECT AND EXPLAIN WHY IT MATTERS

b. Rationale for participation in the initiative:
   i. Description of the problem (wrong site, wrong procedure, wrong person surgery)
   ii. The proposed solution (redesigned preoperative preparation process)
   iii. The costs and benefits of implementing the SOP
   iv. Incentives to clinical staff to participate (improved safety for patients; efficiencies and lower risk exposure for staff).

c. Regular updates to all staff on the progress of the project work plan.

d. Feedback to all staff of information gathered throughout the pilot test and implementation phases of the project.

PROVIDE REGULAR UPDATES, FEEDBACK & RECOGNITION

e. Recognition of the contributions and successes of all staff participating in the project.

7. Process management strategy

Successful implementation and sustained performance of this process will require information. In developing and testing the High 5s SOPs, three complementary approaches to information gathering were used and are provided here and in accompanying materials as a resource for organizations that choose, not only to implement the SOP, but to manage its ongoing performance. Of the various methods and tools provided, some may be useful in the early stages of implementation, others in the later maintenance of the process, and still others not applicable for the individual organization. Decisions about how best to monitor and manage the process should be made by the designated oversight body with input from individuals who are involved in the process itself. The information obtained through the management strategy will also be valuable for providing feedback to participating staff. The following components of a process management strategy were thoroughly tested in the High 5s Project:

MANAGE THE PROCESS USING QUALITATIVE & QUANTITATIVE MEASUREMENT

IDENTIFY AND ANALYZE ADVERSE EVENTS

a. SOP Implementation Evaluation – self-reported information regarding the implementation experience in a sample of surgical units.

b. Performance Measures – quantitative measurement of processes and outcomes associated with the SOP.

c. Event Analysis – identification and analysis of any adverse events directly associated with/related to the SOP or its implementation.

Additional information on these process management tools is available in the Implementation Guide.

8. Maintenance and improvement strategy

a. Once the redesigned preoperative preparation process is fully implemented, regular monitoring of key parameters should continue to support sustained consistent performance and provide feedback to organization leadership and participating staff.

b. Opportunities to improve efficiency and effectiveness of the process should be identified, prioritized and, as appropriate, acted upon.

c. Evidence of "drifting" from the intended procedures should be analyzed to identify the reasons and to determine an appropriate response—for example: additional training; process redesign; technical support.

APPENDIX A

Sample Correct Site Surgery Checklist

The checklist presented below and on the next page was developed and used in the High 5s Project as a tool for (1) implementing the SOP, (2) documenting completion of the steps of the SOP and (3) collecting relevant process management data in real time as the patient progresses through the surgical encounter. It is recommended that the checklist be initiated by the surgical scheduling staff at the time the patient is scheduled for surgery, or in the case of a late add-on or emergency case, when the operating room is first notified of the case. Multiple individuals will be responsible for completing the form as the patient moves through the scheduling, informed consent, pre-operative assessments and testing, site marking and other preoperative preparation processes, and the final time out. By integrating data collection with the patient care activities in real time, the data collectors are the same people who provide the patient care. The Implementation Guide contains a detailed description of the checklist, an explanation of how to implement it, as well as tips for integrating it into existing checklists and operational systems to improve efficiency.