Performance of Correct Procedure at Correct Body Site: Correct Site Surgery

High 5s Project: Action on Patient Safety

Standard Operating Protocol

VOLUME 4

Getting Started Kit

Attribution Statement

The High 5s Project is patient safety collaboration among a group of countries and the WHO Collaborating Centre for Patient Safety in support of the World Health Organization (WHO), World Alliance for Patient Safety.

The Project, which is coordinated by the WHO Collaborating Centre for Patient Safety (designated as the Joint Commission and the Joint Commission International), has received generous funding from the U.S. Agency for Healthcare Research and Quality, WHO, and the Commonwealth Fund.

The Mission of the High 5s Project is to facilitate implementation and evaluation of standardized patient safety solutions within a global learning community to achieve measurable, significant, and sustained reductions in highly important patient safety problems. The countries currently participating in the High5s Project are Australia, Canada, France, Germany, the Netherlands, Singapore, the United Kingdom and the United States of America. In this collaboration, Canada has led development of the medication reconciliation standard operating protocol, the United Kingdom has led development of the concentrated injectables protocol, and the United States of America has led development of the correct site surgery protocol. All of the participating countries have provided technical expertise in the development of the implementation, performance measurement, event analysis, and evaluation frameworks that are integral to the standard operating protocols.

Table of Contents

Introduction

This *Getting Started Kit* is intended to assist front line hospital staff and leaders to achieve a smooth and successful implemention of the High 5s Correct Site Surgery Standard Operating Protocol (SOP). It will describe the continuing problem of wrong person, wrong procedure, wrong site sugery and what can be done to reduce the risk of these preventable events. It will then provide the tools and procedures for implementing the SOP in an efficient and effective manner and for measuring the success of the implementation and of the impact on reducing the risk of incorrect surgery. A considerable portion of this *Getting Started Kit* will be devoted to the use of the High 5s Preoperative Verification Check List as a tool for implementing the SOP in a consistent manner, for documenting completion of the steps in the SOP, and for collecting the needed data elements *in real time* to enable a robust evaluation of the implementation and effectiveness of the SOP.

A Word about Standardization

The basic assumption being 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 (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 being 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 favoured, but different, process than the others. Assuming each is a *good* practice, it matters less which process is selected as the basis for standardization; it is the standardization that matters most. Standardization trumps "best practice" when it comes to safety. And the High 5s initiative is taking standardization a couple of steps further than the usual efforts to minimize variation—it not only seeks to standardize certain processes among individuals within a health care organization but to standardize them in multiple organizations in multiple countries around the world. Is it possible to standardize on this scale? If it is, will it measurably improve the safety of care? These are the questions we hope to answer. You can help.

Overview of Correct Site Surgery (CSS)

What Do We Mean by Correct Site Surgery?

"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 234 million or so major surgical operations that are conducted each year, these are infrequent, though not "rare" events. In fact, there has been a steady increase in the number of reported cases over the past decade. 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 Global Patient Safety Challenge #2: *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.

What Is the Potential Impact of the High 5s Initiative for Correct Site Surgery?

The High 5s Correct Site Surgery Standard Operating Protocol (SOP) is one of several standardized protocols developed specifically

1. to test the feasibility of implementing standardized patient safety protocols within a group of countries that are representative of major regions of the world, and
2. To demonstrate the effectiveness of such standardization in reducing the risk of certain types of adverse events in participating hospitals in these countries.

The Correct Site Surgery SOP focuses on reducing the risk of incorrect surgery. To achieve these goals, participating hospitals are required to adhere to the SOP as written and to measure their performance both in implementing the Protocol and in achieving success in reducing or eliminating wrong site surgery.

Where Do Activities to Promote Correct Site Surgery Take Place ?

While the principles and detailed procedures of the Correct Site Surgery SOP are applicable wherever surgical and other invasive procedures are performed, the implementation of this Protocol as part of the High 5s initiative will include only cases performed in the hospital operating room environment that serves the hospital's inpatients (excludes procedure units such as endoscopy and catheterization labs, as well as dedicated obstetrical operating rooms and facilities used exclusively for ambulatory surgery). It will include *all* cases performed in this environment such as day surgery cases, endoscopies, and other interventional procedures. A participating hospital may choose to implement the High 5s procedures and check list in other areas but the High 5s measurement and evaluation activities will be limited to the cases performed in the hospital inpatient operating room environment.

Who Should Be Involved in Efforts to Promote Correct Site Surgery?

Surgery is a team activity. Success depends on the reliable performance of all members of the team *as a team.* To the extent that each member of the surgical team is seen as an equal partner, each with his or her specific roles, responsibilities and accountabilities; that each can share relevant information freely; is listened to; is respected and supported by the others—to the extent that this is the prevailing culture, the chances of success are increased. In a typical surgical environment, the team will include the surgeon, one or more assistants, a circulating nurse, one or more "scrub" nurses or technicians, an anesthesia provider and may include other technical support and trainees.

In addition to this surgical team that functions in the operating room at the time of the operation, there is a larger team that supports and provides the preoperative and postoperative care of the patient. All are involved in efforts to promote correct site surgery and other desirable outcomes. For purposes of the High 5s correct site surgery initiative, the focus will be on the preoperative—scheduling, admitting, assessing, testing, preparing—team and the intraoperative team.

Finally, the most important individual on the team: the patient. The effectiveness of High 5s correct site surgery initiative 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.

The High 5s Standard Operating Protocol (SOP) for Correct Site Surgery

The SOP At-a-Glance

This Protocol, as for each of the High 5s SOPs, is most easily viewed in "3s." It has 3 major components:

1. The Correct Site Surgery process (This is the standardized process to be implemented)
2. The implementation strategy (This is how to implement it)
3. The evaluation strategy (This is the approach to knowing how well you are doing)

And each of these 3 components has 3 sections, as follows:

1. The Correct Site Surgery Process
    a. Preoperative verification process
    b. Surgical site marking
    c. Final "time out" before surgery
2. The implementation strategy
    a. Planning for implementation
    b. Pilot testing
    c. Full implementation
3. The evaluation strategy
    a. Performance measures
    b. Event analysis
    c. Implementation evaluation

Each of these components and their sections will be explored in greater detail in the following pages.

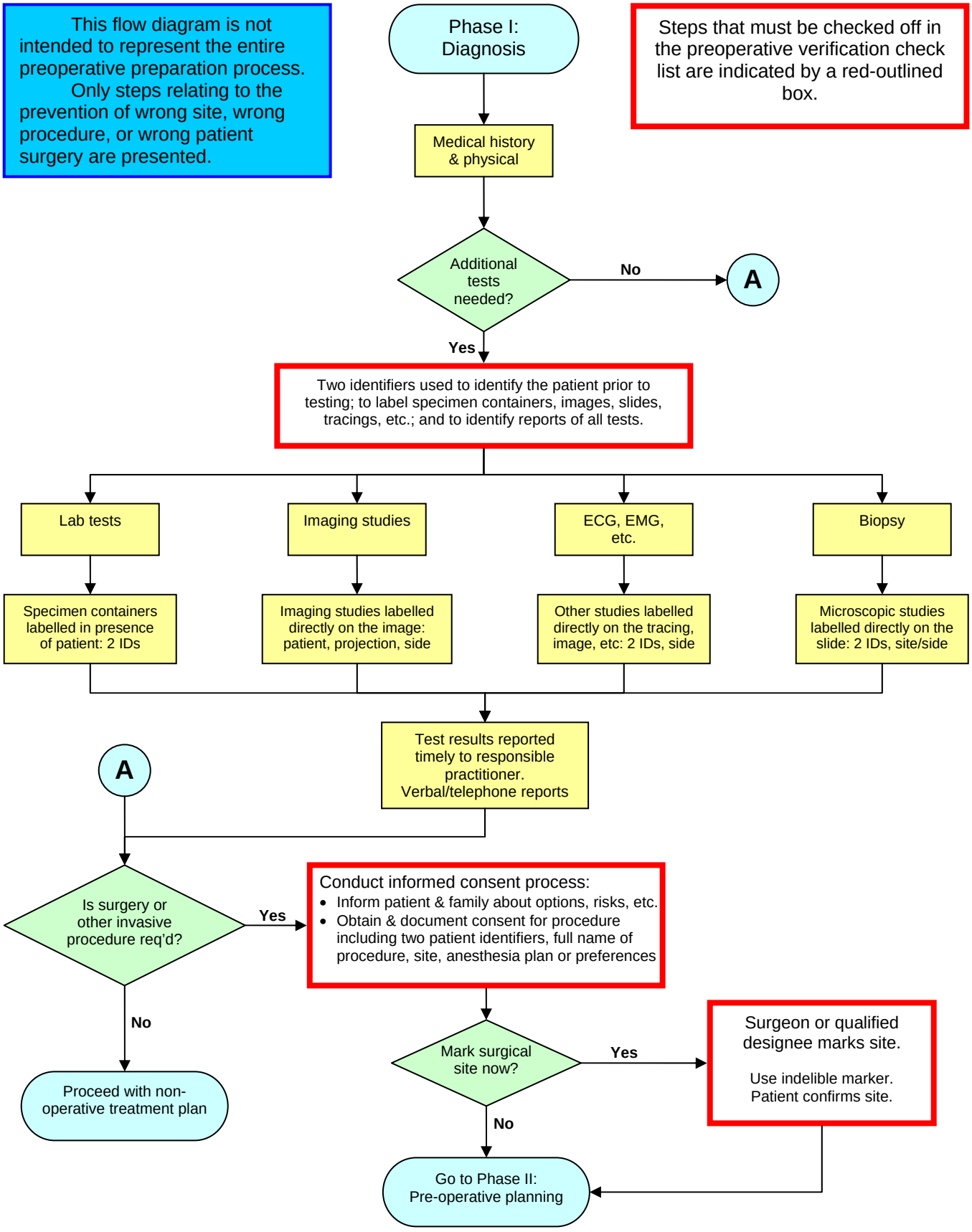
The Correct Site Surgery processes

The consistent achievement of Correct Site Surgery requires a robust approach using multiple, complementary strategies; the active involvement and effective communication among all members of the perioperative team; the active involvement, of the patient (or legally designated representative); and the consistent, effective implementation of the following three components of the SOP:

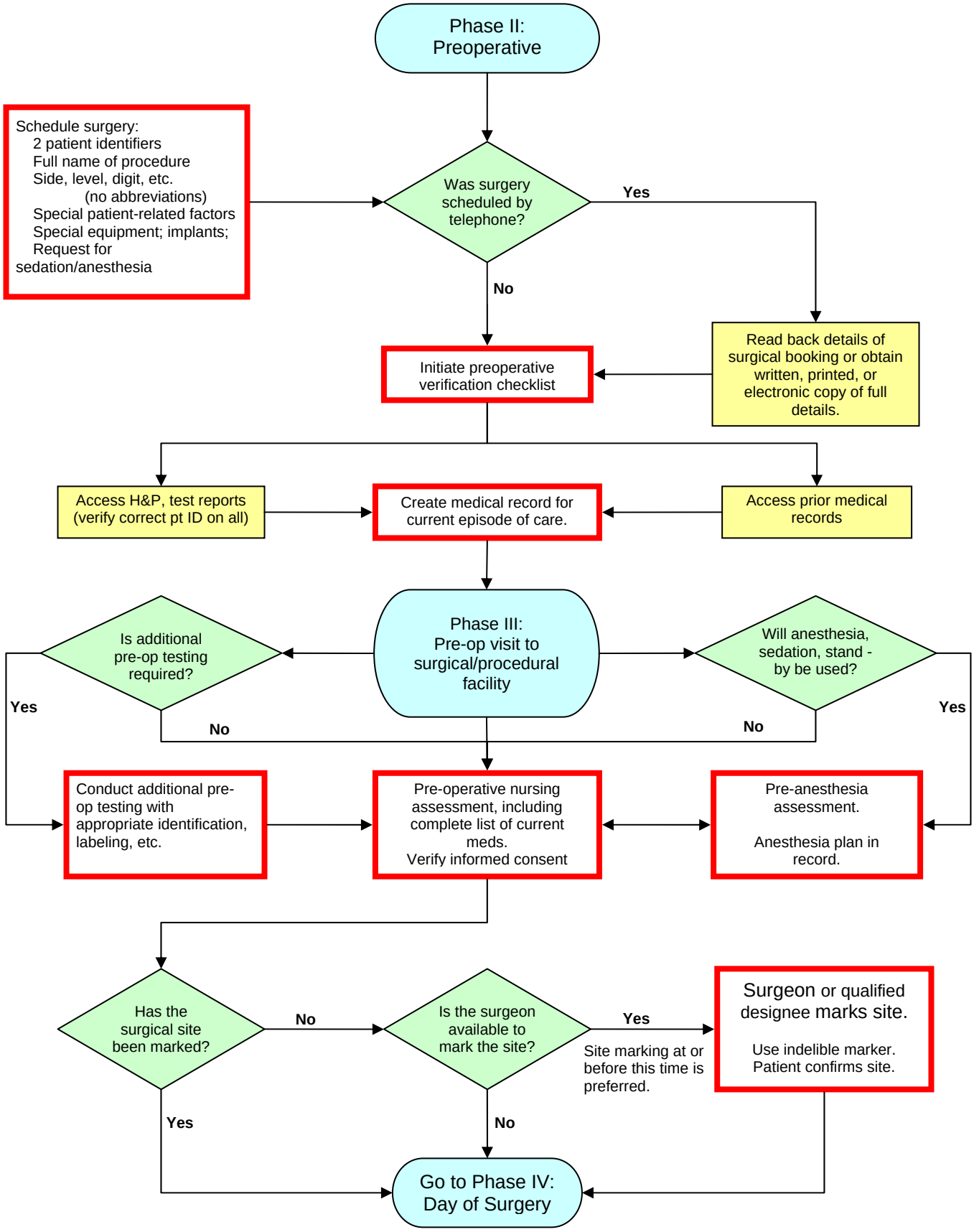
1. Pre-operative verification process
    - *Purpose*: To reduce the risk of patient and procedure misidentification by ensuring that all of the relevant documents and diagnostic studies are available prior to the start of the procedure; that they are correctly identified, labelled, and matched to the 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 "time out" just before the start of the procedure.
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 prepped and draped. Some surgical cases that meet these criteria for site marking may be exempt from this requirement because of special circumstances (see page 11). Cases that are exempt from the site marking requirement are still subject to the preoperative verification and final time out processes.
3. "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.

The flow diagrams on the following 4 pages provide a graphical representation of the processes relevant to the Correct Site Surgery SOP. They are not intended to represent the entire preoperative preparation process. Only steps relating to the prevention of wrong site, wrong procedure, or wrong patient surgery are presented.

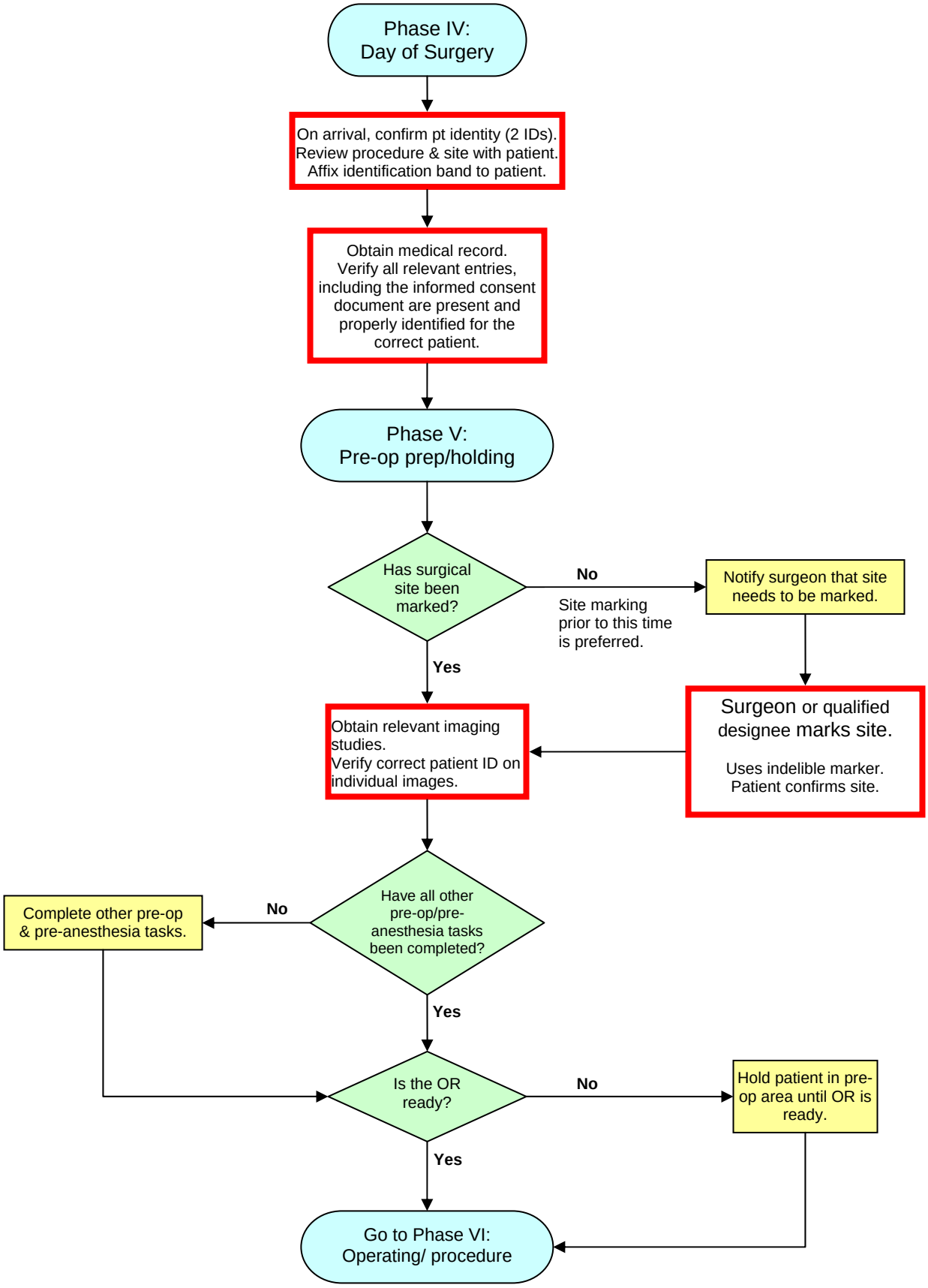
Preoperative preparation as it relates to Correct Site Surgery, Phase I:



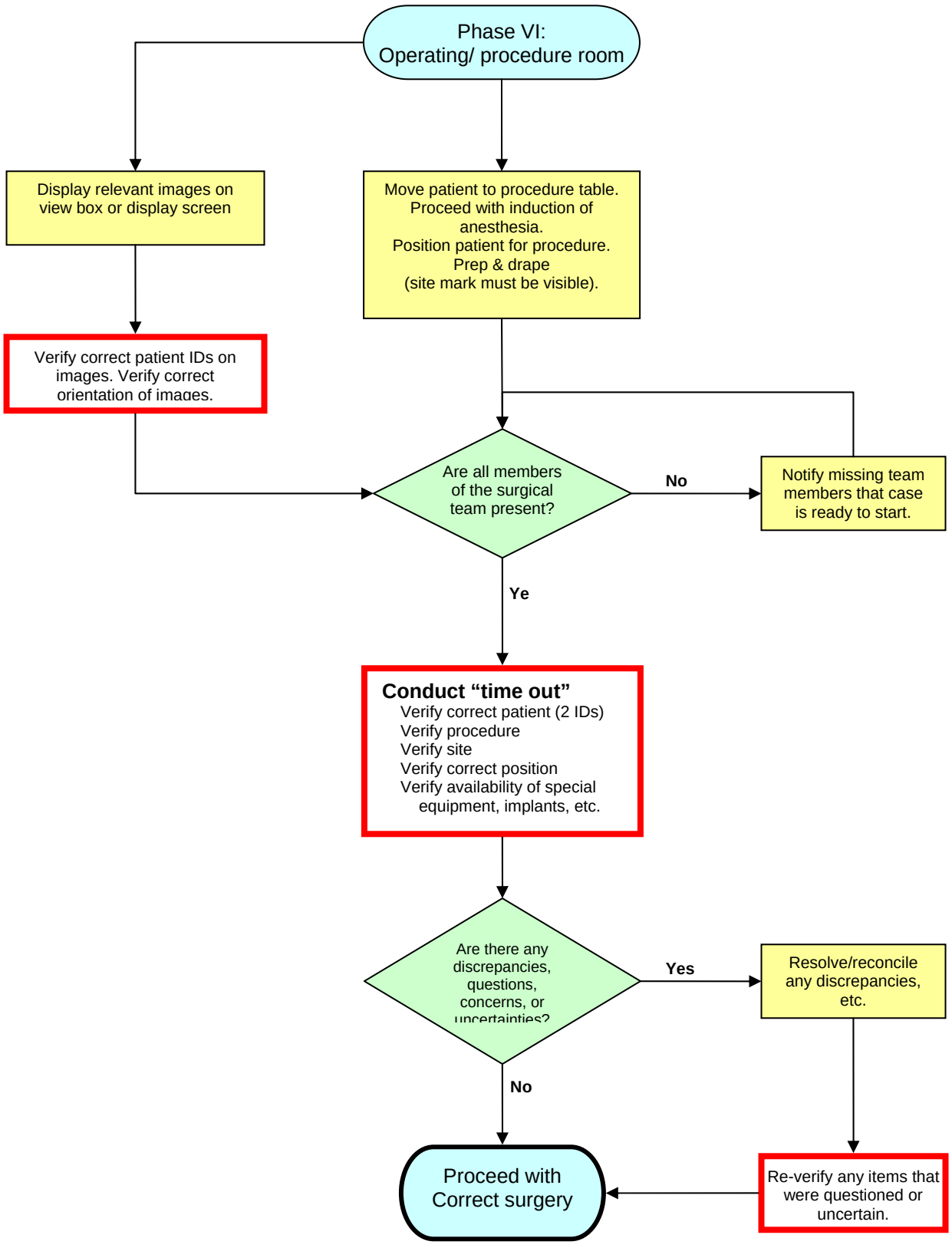
Preoperative preparation as it relates to Correct Site Surgery, Phases II & III:



Preoperative preparation as it relates to Correct Site Surgery, Phases IV & V:



Preoperative preparation as it relates to Correct Site Surgery, Phase VI:



The Preoperative 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
- Just before the patient leaves the preoperative area and upon entry into the operating room
- Anytime the responsibility for care of the patient is transferred to another caregiver, as a formal part of the handover process

To the extent possible, all verification activities should involve the patient. If the patient is not able to participate, a family member or other surrogate should be engaged.

Throughout the preoperative preparation of the patient and the surgical environment, a preoperative verification check list (see Page 16) will be used

- To guide staff in implementing the SOP in a consistent manner, include an assurance of the 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 labelled and displayed
  - Specific size and type of any required implants and detailed requirements of special equipment
- To document completion of the steps in the SOP
- To collect the needed data elements *in real time* to support evaluation of the SOP

Surgical Site Marking

- 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.
- Cases that do not meet these minimum criteria for required site marking may also be marked at the discretion of the hospital 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.
- The hospital 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 check list).
- 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 LTA or, at the LTA's discretion, by each participating hospital. For example, the surgeon's initials or a line representing the proposed incision may be used. Do not use "X" to mark the intended site, as it may be interpreted as "do not operate here."
- 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.
- The method of marking and type of mark is consistent for all applicable cases
- 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 lateralised 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.
- 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.

The 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 hospital 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 Verification Check List.

Guidelines for Integrating the High 5s CSS SOP into Exisiting Pre-op Procedures

Effective and efficient implementation of the High 5s SOP 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 then simply adding it as a set of new tasks. It is therefore important to identify, in your hospital, the other aspects of patient care with which this SOP will interface. These may include the following:

- Pre-admission assessment (physician's office or clinic setting)
- Diagnostic testing (laboratory, imaging, biopsy, etc.)
- Informed consent process
- 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

Recognising 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 your hospital'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, check lists, data collection tools, etc.) and aligning work flow to optimise efficiency of the integrated process.

For example, implementation of the Correct Site Surgery SOP anticipates the use of a check list as a guide to standardizing the many steps in pre-op preparation, to document the completion and results of those steps, and to efficiently collect the needed data in real time. Since preoperative preparation involves many steps performed by many people in many locations, you will need to find an efficient way to make this check list available to the people performing each of the tasks at the places and times that they do these tasks. It may be a single paper form carried from place to place, person to person; or it may be an electronic form accessible by staff at the various locations where they do their work. An example of an *unacceptable solution* is a paper form that is split into separate pages, each page available at the different locations involved in preoperative preparation. The reason this is not acceptable is that an important aspect of the processes for ensuring correct surgery is the ability to compare the information obtained at one point in the process to the information obtained in prior steps of the process. To do this, all the relevant information about that case will need to be available in one place, recognizing that the "one place" will change as the preoperative preparation proceeds from step to step. See page 24 for a more in-depth discussion about adapting the High 5s Preoperative Verification Check List and consolidating it with other forms currently in use.

The cultural and physical environment—the context—in which this High 5s SOP will be implemented, as well as the unique features and resources of your hospital and the details of its existing processes that interface with and support preoperative preparation, will influence its implementation. In this SOP, 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 and measurement requirements, while allowing flexibility in the format of the documentation and measurement tools. It is the intent of this SOP that preoperative preparation be conducted as a multidisciplinary activity with responsibilities shared among surgeons, anaesthesia providers, nurses, technicians, and others involved in the surgical patient's 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 for any adaptations, must be accompanied by a rationale for the change and demonstration that the adaptation is equivalent, with respect to patient safety, to the process as presented in the Protocol. Any hospital-specific adaptations of this SOP must be approved by the Lead Technical Agency based on the hospital's rationale for the change and demonstration that the adaptation is equivalent to the process as presented in the SOP.

How Does the High 5s CSS SOP Relate to the WHO Safe Surgery Saves Lives Initiative?

The WHO Surgical Safety Checklist and the High 5s Standard Operating Protocol (SOP) for Correct Site Surgery, each being a surgery-related international patient safety initiative, have attracted considerable attention and interest around the world. While this bodes well for those who have argued for greater emphasis on patient safety in the surgical theatre, the co-existence of the two initiatives has raised questions as to how they interrelate and, indeed, whether it is feasible for a given hospital to participate in both initiatives simultaneously. Questions have also arisen as to how the impacts of each initiative might best be measured. The following Brief and attached materials describe and compare the purpose, scope, focus, and measurement expectations of each initiative.

The WHO Surgical Safety Checklist is the operational component of the second Global Patient Safety Challenge: *Safe Surgery Saves Lives*, a core element of the WHO World Alliance for Patient Safety. The goal of this Challenge is to improve the safety of surgical care around the world by defining a core set of safety standards that can be applied in all WHO Member States. The WHO Surgical Safety Checklist seeks not to prescribe a single approach, but rather to ensure that key safety elements are incorporated into the operating room routine. The WHO Surgical Safety Checklist and its Implementation Manual are available at http://www.who.int/patientsafety/safesurgery/en/

The High 5s Correct Site Surgery SOP is one of several standardized protocols developed specifically to test the feasibility of implementing standardized patient safety protocols and to demonstrate the effectiveness of such standardization in reducing the risk of certain types of adverse events. *The High 5s* Project is a collaboration among a group of countries, World Health Organization (WHO), the WHO Collaborating Centre for Patient Safety (designated as the Joint Commission and Joint Commission International) in support of WHO's World Alliance for Patient Safety efforts to improve patient safety worldwide.

Both initiatives seek to improve the safety of surgical procedures. As a result, they have certain features in common, and they are in fact compatible with each other. However, each initiative takes a different approach to achieve its ends. The WHO Surgical Safety Checklist addresses an array of perioperative risks, and seeks to reduce the frequency of related complications, including mortality. It is available to any organization wishing to use it and is a tool that is being adapted at the user's discretion to fit local practice. By contrast, the High 5s Correct Site Surgery SOP focuses on reducing the risk of a specific group of surgical complications—wrong patient, wrong procedure, or wrong site surgery. To achieve the goals of the High 5s Project, participating hospitals are required to adhere to the SOP as written and to measure their performance both in implementing the protocol and in achieving success in reducing or eliminating wrong patient, wrong procedure, and wrong site surgery.

Where the provisions of the two initiatives overlap—certain preoperative checks, surgical site marking, and a required "time out" before surgery—the performance expectations are internally consistent. Where they differ is in the range of perioperative activities included in each. The High 5s Correct Site Surgery SOP has a more fully developed preoperative verification process that begins when the surgical procedure is first scheduled and continues throughout the preoperative process, while the WHO Surgical Safety Checklist is initiated preoperatively on the day of, or the day before, surgery. On the other hand, the Checklist includes a postoperative "Sign Out" process that is not part of the High 5s Protocol. All of these components have value and, indeed, should be implemented by all organizations that provide surgical services.

The expectations for measuring and evaluating the implementation and impact of these initiatives differ significantly. These differences relate primarily to their stated purposes and scopes. The High 5s Project, which is targeting several different types of particularly challenging adverse events, is in effect a multi-country test to assess the feasibility of implementing detailed standardized protocols and their potential utility in reducing preventable adverse outcomes. The operative term here is "standardized". Testing takes place in a modest number of volunteer hospitals in 9 countries. All of the High 5s SOPs (specifically including the Correct Site Surgery SOP) include a robust measurement and evaluation component that provides for the use of standardized performance measures, data collection procedures, event analysis protocols, and other evaluation tools and techniques. In volunteering to participate in the High 5s Project, a Lead Technical Agency in a country and its participating hospitals agree to implement one or more SOPs, to collect the specified data elements and other evaluative information in a standardized fashion, and to conduct the other evaluation activities associated with each protocol.

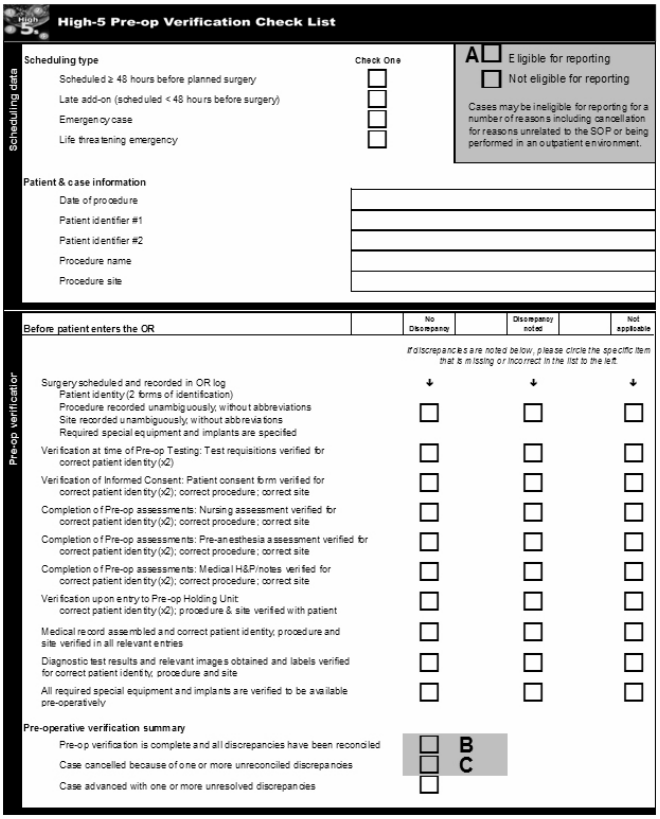
By contrast, the WHO Surgical Safety Checklist is directed at preventing a spectrum of surgical complications and has been widely distributed around the world. It includes no provision for measurement and evaluation activities. The principal dissemination and implementation strategy has been to encourage all hospitals worldwide to adapt the Checklist for their own use so long as its key principles are retained. This adaptation flexibility is a clear strength of the *Safe Surgery Saves Lives* initiative, but the inherent variation thus introduced by different Checklist adaptations limits the ability to assess its impact.

While the two initiatives differ in significant ways and for valid reasons, they are in no way incompatible with each other. Use of the WHO Surgical Safety Checklist is encouraged for all hospitals that provide surgical services, including those that choose to participate in the High 5s Project. An example of how this might be achieved is provided in this Getting Started Kit.

The High 5s Preoperative Verification Check List for Correct Site Surgery

The Basic High 5s Preoperative Verification Check list

The High 5s Correct Site Surgery SOP requires the use of a Preoperative Verification Check List as a tool for (1) implementing the SOP, (2) documenting completion of the steps of the SOP and (3) collecting the data elements *in real time* that are required by the Evaluation Strategy. A "Basic" High 5s Preoperative Verification Check List has been developed. This 2-page check list, which contains all of the steps of the SOP and all of the required data elements, is shown below. On the following pages, we will describe the details of the Basic Check List and provide Tips on how to complete the form as part of your regular preoperative activities. After that, we will discuss how you can adapt or combine the High 5s Check List items into your existing preoperative check list to improve efficiency.



High-5 Pre-op Verification Check List

Scheduling data

Scheduling type — Check One

- Scheduled ≥ 48 hours before planned surgery
- Late add-on (scheduled < 48 hours before surgery)
- Emergency case
- Life threatening emergency

A — Eligible for reporting

Not eligible for reporting

Cases may be ineligible for reporting for a number of reasons including cancellation for reasons unrelated to the SOP or being performed in an outpatient environment.

Patient & case information

- Date of procedure
- Patient identifier #1
- Patient identifier #2
- Procedure name
- Procedure site

Pre-op verification

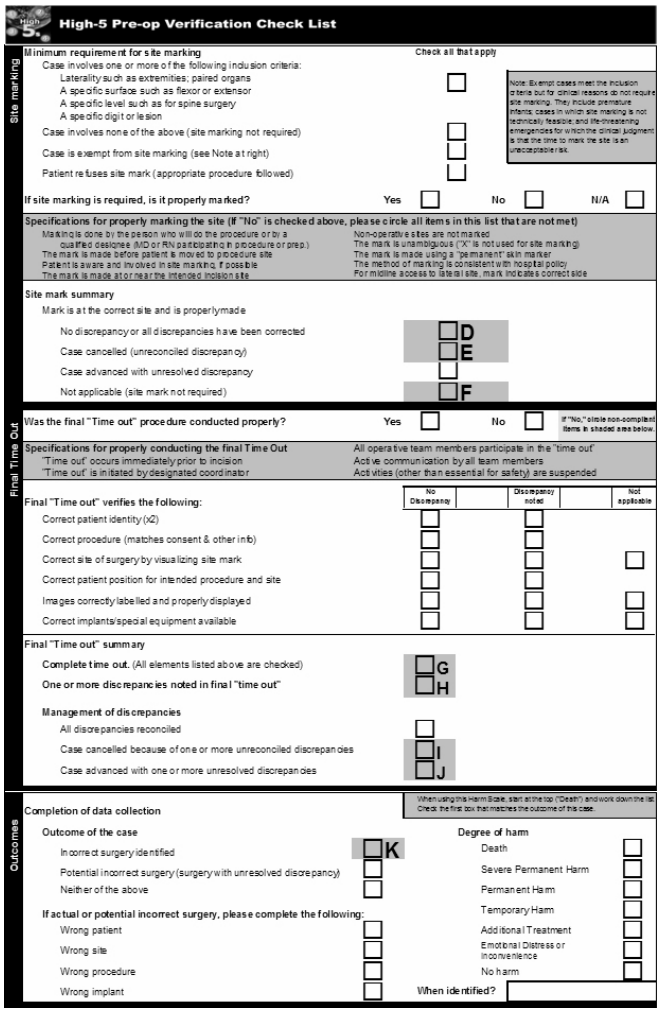
Before patient enters the OR — No Discrepancy | Discrepancy noted | Not applicable

If discrepancies are noted below, please circle the specific item that is missing or incorrect in the list to the left.

- Surgery scheduled and recorded in OR log
  - Patient identity (2 forms of identification)
  - Procedure recorded unambiguously, without abbreviations
  - Site recorded unambiguously, without abbreviations
  - Required special equipment and implants are specified
- Verification at time of Pre-op Testing: Test requisitions verified for correct patient identity (x2)
- Verification of Informed Consent: Patient consent form verified for correct patient identity (x2); correct procedure; correct site
- Completion of Pre-op assessments: Nursing assessment verified for correct patient identity (x2); correct procedure; correct site
- Completion of Pre-op assessments: Pre-anesthesia assessment verified for correct patient identity (x2); correct procedure; correct site
- Completion of Pre-op assessments: Medical H&P/notes verified for correct patient identity (x2); correct procedure; correct site
- Verification upon entry to Pre-op Holding Unit: correct patient identity (x2); procedure & site verified with patient
- Medical record assembled and correct patient identity, procedure and site verified in all relevant entries
- Diagnostic test results and relevant images obtained and labels verified for correct patient identity, procedure and site
- All required special equipment and implants are verified to be available pre-operatively

Pre-operative verification summary

- Pre-op verification is complete and all discrepancies have been reconciled
- Case cancelled because of one or more unreconciled discrepancies — B C
- Case advanced with one or more unresolved discrepancies



High-5 Pre-op Verification Check List

Site marking

Minimum requirement for site marking — Check all that apply

Case involves one or more of the following inclusion criteria:
- Laterality such as extremities; paired organs
- A specific surface such as flexor or extensor
- A specific level such as for spine surgery
- A specific digit or lesion

Note: Exempt cases meet the inclusion criteria but for clinical reasons do not require site marking. They include premature infants; cases in which site marking is not technically feasible; and life-threatening emergencies for which the clinical judgment is that the time to mark the site is an unacceptable risk.

- Case involves none of the above (site marking not required)
- Case is exempt from site marking (see Note at right)
- Patient refuses site mark (appropriate procedure followed)

If site marking is required, is it properly marked? Yes ☐ No ☐ N/A ☐

Specifications for properly marking the site (If "No" is checked above, please circle all items in this list that are not met)

- Marking is done by the person who will do the procedure or by a qualified designee (MD or RN participating in procedure or prep.)
- The mark is made before patient is moved to procedure site
- Patient is aware and involved in site marking, if possible
- The mark is made at or near the intended incision site
- Non-operative sites are not marked
- The mark is unambiguous ("X" is not used for site marking)
- The mark is made using a "permanent" skin marker
- The method of marking is consistent with hospital policy
- For midline access to lateral site, mark indicates correct side

Site mark summary

Mark is at the correct site and is properly made

- No discrepancy or all discrepancies have been corrected — D E
- Case cancelled (unreconciled discrepancy)
- Case advanced with unresolved discrepancy
- Not applicable (site mark not required) — F

Final "Time out"

Was the final "Time out" procedure conducted properly? Yes ☐ No ☐ — If "No," circle non-compliant items in shaded area below.

Specifications for properly conducting the final Time Out

- "Time out" occurs immediately prior to incision
- "Time out" is initiated by designated coordinator
- All operative team members participate in the "time out"
- Active communication by all team members
- Activities (other than essential for safety) are suspended

Final "Time out" verifies the following: — No Discrepancy | Discrepancy noted | Not applicable

- Correct patient identity (x2)
- Correct procedure (matches consent & other info)
- Correct site of surgery by visualizing site mark
- Correct patient position for intended procedure and site
- Images correctly labelled and properly displayed
- Correct implants/special equipment available

Final "Time out" summary

- Complete time out. (All elements listed above are checked) — G
- One or more discrepancies noted in final "time out" — H

Management of discrepancies

- All discrepancies reconciled
- Case cancelled because of one or more unreconciled discrepancies — I
- Case advanced with one or more unresolved discrepancies — J

Outcomes

Completion of data collection

When using this Harm Scale, start at the top ("Death") and work down the list. Check the first box that matches the outcome of this case.

Outcome of the case

- Incorrect surgery identified — K
- Potential incorrect surgery (surgery with unresolved discrepancy)
- Neither of the above

If actual or potential incorrect surgery, please complete the following:

- Wrong patient
- Wrong site
- Wrong procedure
- Wrong implant

Degree of harm

- Death
- Severe Permanent Harm
- Permanent Harm
- Temporary Harm
- Additional Treatment
- Emotional Distress or Inconvenience
- No harm

When identified?

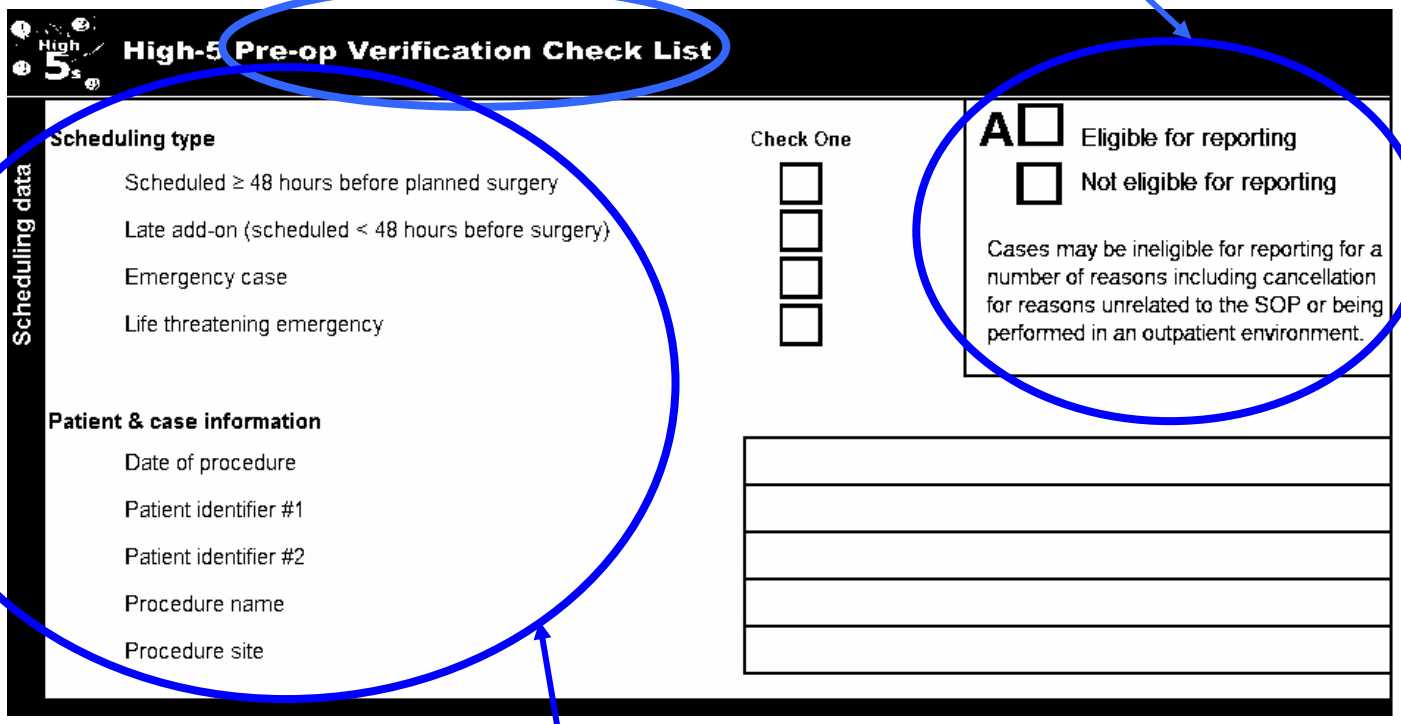
Item-by-Item Tips for Completing The High 5s CSS Check List

This is the top portion of Page 1 of the Preoperative Verification Check List.

For hospitals participating in the High 5s project, a Check List that includes all of the SOP process steps and required data elements must be used for all "eligible" cases. It may be used in other settings but the High 5s measurement data will be collected only for those cases that are eligible for inclusion in the High 5s.

This check list is to be initiated by the OR scheduling staff at the time the patient is scheduled for surgery or, in the case of a late add-on or an emergency case, when the operating room is first notified of the case.

Eligibility is determined by whether the case is scheduled for or done in the inpatient O.R. setting. All cases done in that setting, including day surgery and special procedures, are "eligible."



These items are to be filled in by the O.R. scheduling staff.

This is the rest of Page 1 of the Preoperative Verification Check List. It should be completed before the patient is brought into the operating room where the procedure will be done.

IMPORTANT !!

Any missing item of information must be considered a discrepancy.

Each section of this form should be checked off by the staff person who performs the function when it is done.

Compare the information that you obtain with other available information, including previous check list entries. If there is a discrepancy, check the box for that item that best describes how the discrepancy was managed. Check "Not applicable" only when the particular function does not apply to this case (e.g., no special equipment is needed).

Pre-op verification

Before patient enters the OR	No Discrepancy	Discrepancy noted	Not applicable
	If discrepancies are noted below, please circle the specific item that is missing or incorrect in the list to the left.		
Surgery scheduled and recorded in OR log Patient identity (2 forms of identification) Procedure recorded unambiguously, without abbreviations Site recorded unambiguously, without abbreviations Required special equipment and implants are specified	☐	☐	☐
Verification at time of Pre-op Testing: Test requisitions verified for correct patient identity (x2)	☐	☐	☐
Verification of Informed Consent: Patient consent form verified for correct patient identity (x2); correct procedure; correct site	☐	☐	☐
Completion of Pre-op assessments: Nursing assessment verified for correct patient identity (x2); correct procedure; correct site	☐	☐	☐
Completion of Pre-op assessments: Pre-anesthesia assessment verified for correct patient identity (x2); correct procedure; correct site	☐	☐	☐
Completion of Pre-op assessments: Medical H&P/notes verified for correct patient identity (x2); correct procedure; correct site	☐	☐	☐
Verification upon entry to Pre-op Holding Unit: correct patient identity (x2); procedure & site verified with patient	☐	☐	☐
Medical record assembled and correct patient identity, procedure and site verified in all relevant entries	☐	☐	☐
Diagnostic test results and relevant images obtained and labels verified for correct patient identity, procedure and site	☐	☐	☐
All required special equipment and implants are verified to be available pre-operatively	☐	☐	☐

Pre-operative verification summary

Pre-op verification is complete and all discrepancies have been reconciled	☐ B
Case cancelled because of one or more unreconciled discrepancies	☐ C
Case advanced with one or more unresolved discrepancies	☐

The pre-op verification process is considered "complete" if all elements listed above have been checked, whether or not any discrepancies have been identified.

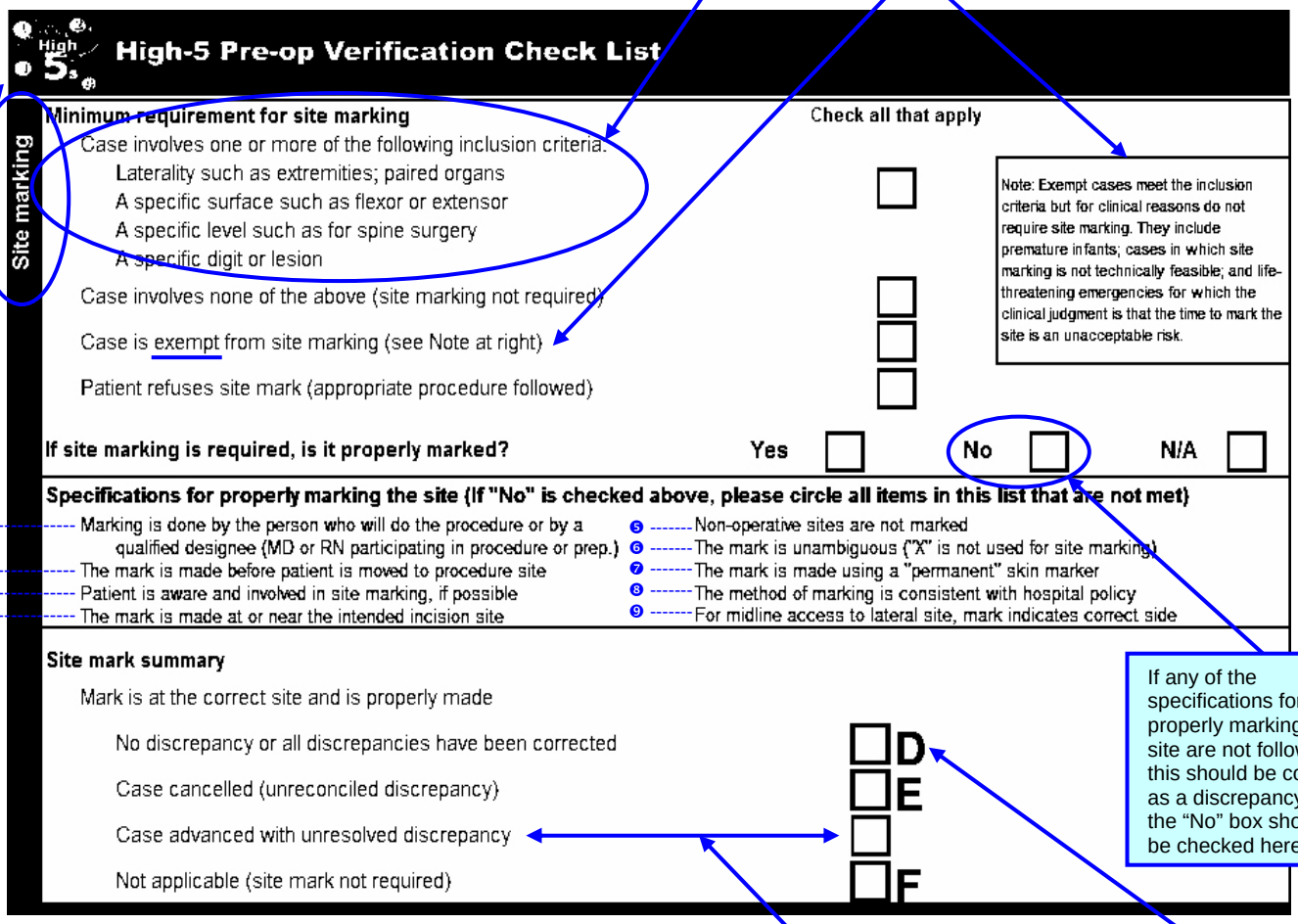
For these items, don't just check that they are present; check that the information in them is correct.

This is the top portion of Page 2 of the Preoperative Verification Check List.

This section documents whether site marking is required or not, and if it is, whether it was done in the proper manner.

For the High 5s SOP, not all cases require marking of the surgical site—only the cases that meet these criteria.

Note that "Exempt" cases are not the same as cases that don't require site marking. Exempt cases do meet the criteria for site marking but for special reasons, as noted, site marking is not done.



High-5 Pre-op Verification Check List

Site marking

Minimum requirement for site marking — **Check all that apply**

Case involves one or more of the following inclusion criteria:
- Laterality such as extremities; paired organs
- A specific surface such as flexor or extensor
- A specific level such as for spine surgery
- A specific digit or lesion

☐

Case involves none of the above (site marking not required) ☐

Case is exempt from site marking (see Note at right) ☐

Patient refuses site mark (appropriate procedure followed) ☐

Note: Exempt cases meet the inclusion criteria but for clinical reasons do not require site marking. They include premature infants; cases in which site marking is not technically feasible; and life-threatening emergencies for which the clinical judgment is that the time to mark the site is an unacceptable risk.

If site marking is required, is it properly marked? Yes ☐ No ☐ N/A ☐

Specifications for properly marking the site (If "No" is checked above, please circle all items in this list that are not met)

❶ Marking is done by the person who will do the procedure or by a qualified designee (MD or RN participating in procedure or prep.)
❷ The mark is made before patient is moved to procedure site
❸ Patient is aware and involved in site marking, if possible
❹ The mark is made at or near the intended incision site
❺ Non-operative sites are not marked
❻ The mark is unambiguous ("X" is not used for site marking)
❼ The mark is made using a "permanent" skin marker
❽ The method of marking is consistent with hospital policy
❾ For midline access to lateral site, mark indicates correct side

Site mark summary

Mark is at the correct site and is properly made

No discrepancy or all discrepancies have been corrected ☐ D

Case cancelled (unreconciled discrepancy) ☐ E

Case advanced with unresolved discrepancy ☐

Not applicable (site mark not required) ☐ F

If any of the specifications for properly marking the site are not followed, this should be counted as a discrepancy and the "No" box should be checked here.

If a discrepancy is resolved before the start of surgery, check this box.

If there is a discrepancy with respect to the site marking process, including absence of a required site mark, and the discrepancy is not resolved before moving the patient into the O.R., this box should be checked and the O.R. team verbally informed of the unresolved discrepancy so that it can be addressed no later than at the final "time out" verification.

Notes on the specifications for site marking:

❶ This should be the responsible surgeon or a resident-in-training if that person will be acting as the primary surgeon in the case. Alternatively, site marking may be delegated by the surgeon to another MD or RN who will participate in the surgery or be directly involved in preparing the patient for surgery.

❷ Marking may be done anytime before the patient is brought into the O.R.—in the surgeon's office; when consent is obtained; in the pre-op holding area; etc.

❸ It is not recommended for the patient to make the mark, but the patient should understand why the mark is being made and verify that it is in the right place.

❹ This is so the mark will be visible in the O.R. after the patient has been positioned, prepped and draped, when the final "time out" verification is done.

❺ Mark only the intended surgical site. Marking "NO" on a non-surgical site (such as the opposite limb) is prohibited under the High 5s SOP.

❻ Marking with an "X" is not advisable because different people interpret it differently. Does it mean "Operate here" or does it mean "Don't operate here"?

❼ For purposes of surgical site marking, "permanent" just means it will remain visible after the skin prep is completed. It doesn't have to last forever.

❽ Each hospital may develop its own policy consistent with these specifications. All surgeons must then comply with the hospital's policy on site marking.

❾ For this type of case, consider using a short arrow as the mark. Place it at or near the midline incision site, pointing to the appropriate side.

This is the middle portion of Page 2 of the Preoperative Verification Check List.

Notes on the final Time Out procedure:

❶ Other "time out" verifications may be done, such as prior to induction of anesthesia, but this section pertains only to the final time out just before incision.

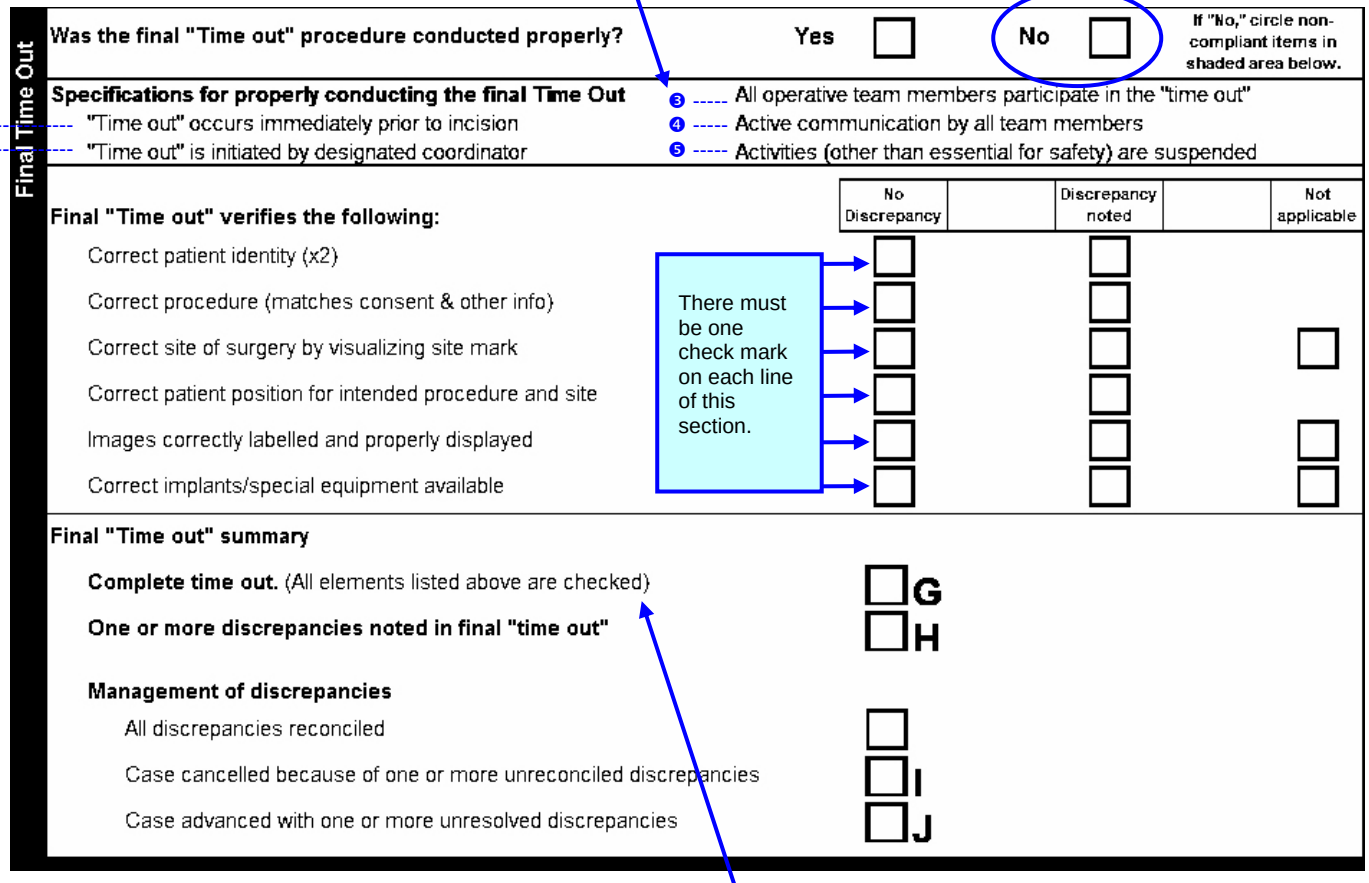
❷ To promote consistency, the same member of the surgical team should initiate the time out in all cases—for example, the surgeon or circulating nurse or other.

❸ This means the surgeon, any surgical assistants, circulating nurse, scrub nurse or technicians, anesthesia provider, and any other active participants.

❹ Active communication means indicating agreement or disagreement by word or gesture. Lack of response is not agreement. A response must be sought.

❺ To the extent possible without compromising the safety of the patient, each team member must focus attention on verifying the key information.

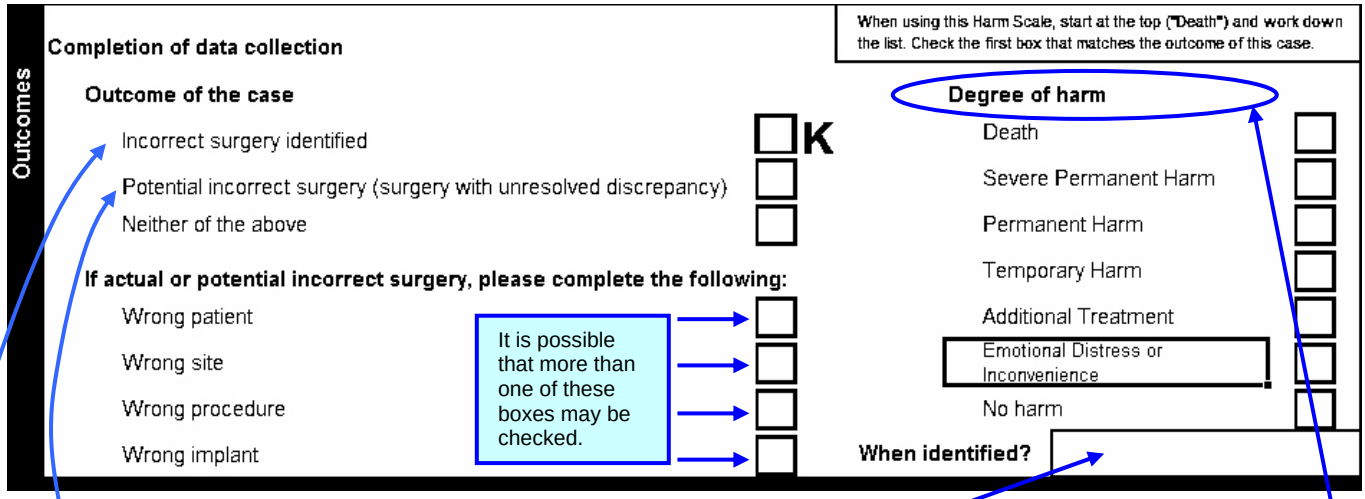
If any of the specifications for properly conducting the Time Out are not followed, this item should be checked "No." These are discrepancies and must be managed accordingly.



A "Complete time out" means each of the items in the time out procedure and the information to be verified has been checked, whether or not any discrepancies were noted.

This is the bottom portion of Page 2 of the Preoperative Verification Check List.

This final section will usually be completed at the end of the case, but some items may depend on information obtained later (such as pathology results).



It is possible that more than one of these boxes may be checked.

A "potential incorrect surgery" is any surgery that is started (the initial incision is made) with a discrepancy that is unresolved at that time.

An "incorrect surgery" is any surgery in which a wrong person, procedure or site error is discovered when the initial incision is made or at any time thereafter, even if the error is recognized and corrected immediately.

Record when the error was first recognized in terms of the patient care activity at the time:

- Intra-operatively
- Post-op but still in the OR
- PACU
- Post-PACU but still in hospital
- Post discharge.

The degree of harm of an incorrect surgery is determined by application of the Harm Scale adopted for use in the High 5s initiative, as follows:

Select first applicable category, in descending order:

1. **Death.**
2. **Severe permanent harm.** Severe life-long bodily or psychological injury or disfigurement that interferes significantly with functional ability or quality of life.
3. **Permanent harm.** Life-long bodily or psychological injury or increased susceptibility to disease.
4. **Temporary harm.** Bodily or psychological injury, but likely not permanent.
5. **Additional treatment.** Injury limited to additional intervention during admission or encounter and/or increased length of stay, but no other injury.
6. **Emotional distress or inconvenience.** Mild and transient anxiety or pain or physical discomfort, but without the need for additional treatment other than monitoring (such as by observation, physical examination, laboratory testing, including phlebotomy, and/or imaging studies).
7. **No harm.** Event reached patient, but no harm evident.

Guide to Combining the Basic High 5s Pre-op Verification Check List with Other Pre-operative Documentation and Data Collection Tools

Most surgical programs use some form of check list to guide and document their processes for preparing the patient and the operating environment for a surgical procedure. Some health care systems and professional associations have developed forms that have gained widespread acceptance. Recently, the World Health Organization introduced and is encouraging adoption of a *Surgical Safety Checklist* in support of its second Global Patient Safety Challenge: *Safe Surgery Saves Lives*.

In order to minimize the additional burden on hospital staff of participating in the High 5s Initiative to promote Correct Surgery, hospitals are invited to consolidate the Basic High 5s Preoperative Verification Check List with their existing forms and check lists.

The purpose of the High 5s Preoperative Verification Check List is to serve as a tool for

1. Implementing the SOP in a consistent manner
2. Documenting completion of the steps in the SOP
3. Collecting the required data elements *in real time* to enable a robust evaluation of the implementation and effectiveness of the SOP.

With that in mind, changes in the format of the check list and the addition of items beyond those on the basic High 5s check list are acceptable adaptations. The following guidelines are provided to participating hospitals that wish to modify the Basic High 5s Preoperative Verification Check List to reduce duplication and improve the efficiency of documentation and data collection:

1. The content (items to be checked off and other data elements) of the Basic High 5s Preoperative Verification Check List must be retained
2. Additional data fields and process steps may be added to align the form with existing preoperative preparation processes and documentation needs
3. The format of the check list may be changed to more closely match the look and feel of existing forms that hospital staff have been using
4. If the check list is modified, that new form must be used consistently for all cases eligible for inclusion in the High 5s initiative
5. It is strongly encouraged that user input be obtained as part of the process for adapting the check list
6. It is recommended that any adaptation of the check list be pilot tested before full implementation
7. Any adaptation or modification of the Basic High 5s Preoperative Verification Check List must be approved by the country's High 5s Lead Technical Agency.

Examples of consolidated check lists are provided on the following pages:

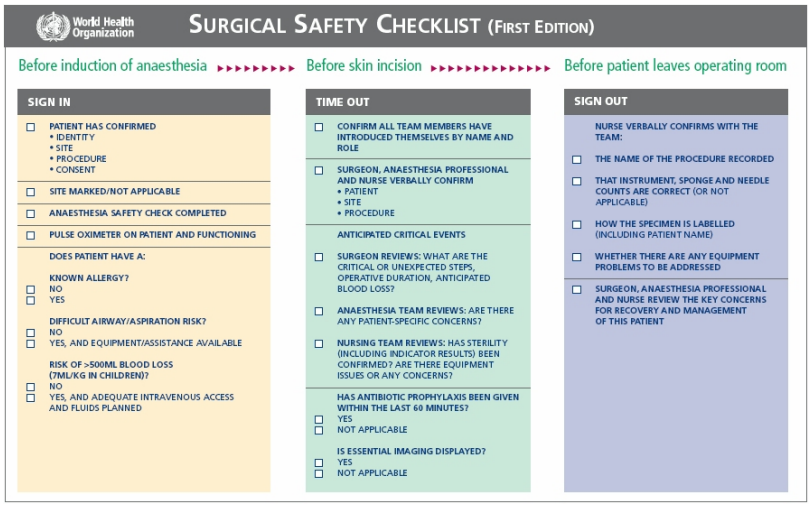
1. High 5s Check List and WHO Surgical Safety Checklist (landscape orientation)
2. High 5s Check List and WHO Surgical Safety Checklist (portrait orientation)
3. High 5s Check List and Association of Operating Room Nurses (AORN) Sample Surgical Checklist

Examples of consolidated check lists

WHO Surgical Safety Checklist (First Edition, 2008, without modification)

Key features of the WHO Checklist that distinguish it from the High 5s check list:

- The "Sign In" checks are done only on the day of surgery
- Other issues of surgical safety beyond correct person, correct procedure and correct site are addressed
- There is an end-of-procedure "Sign Out" process.



World Health Organization

SURGICAL SAFETY CHECKLIST (FIRST EDITION)

Before induction of anaesthesia ▸▸▸▸▸▸▸▸▸ Before skin incision ▸▸▸▸▸▸▸▸▸▸▸▸▸ Before patient leaves operating room

SIGN IN

- ☐ PATIENT HAS CONFIRMED
  - IDENTITY
  - SITE
  - PROCEDURE
  - CONSENT
- ☐ SITE MARKED/NOT APPLICABLE
- ☐ ANAESTHESIA SAFETY CHECK COMPLETED
- ☐ PULSE OXIMETER ON PATIENT AND FUNCTIONING

DOES PATIENT HAVE A:

KNOWN ALLERGY?
- ☐ NO
- ☐ YES

DIFFICULT AIRWAY/ASPIRATION RISK?
- ☐ NO
- ☐ YES, AND EQUIPMENT/ASSISTANCE AVAILABLE

RISK OF >500ML BLOOD LOSS (7ML/KG IN CHILDREN)?
- ☐ NO
- ☐ YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED

TIME OUT

- ☐ CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE
- ☐ SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM
  - PATIENT
  - SITE
  - PROCEDURE

ANTICIPATED CRITICAL EVENTS

- ☐ SURGEON REVIEWS: WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS?
- ☐ ANAESTHESIA TEAM REVIEWS: ARE THERE ANY PATIENT-SPECIFIC CONCERNS?
- ☐ NURSING TEAM REVIEWS: HAS STERILITY (INCLUDING INDICATOR RESULTS) BEEN CONFIRMED? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS?

HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES?
- ☐ YES
- ☐ NOT APPLICABLE

IS ESSENTIAL IMAGING DISPLAYED?
- ☐ YES
- ☐ NOT APPLICABLE

SIGN OUT

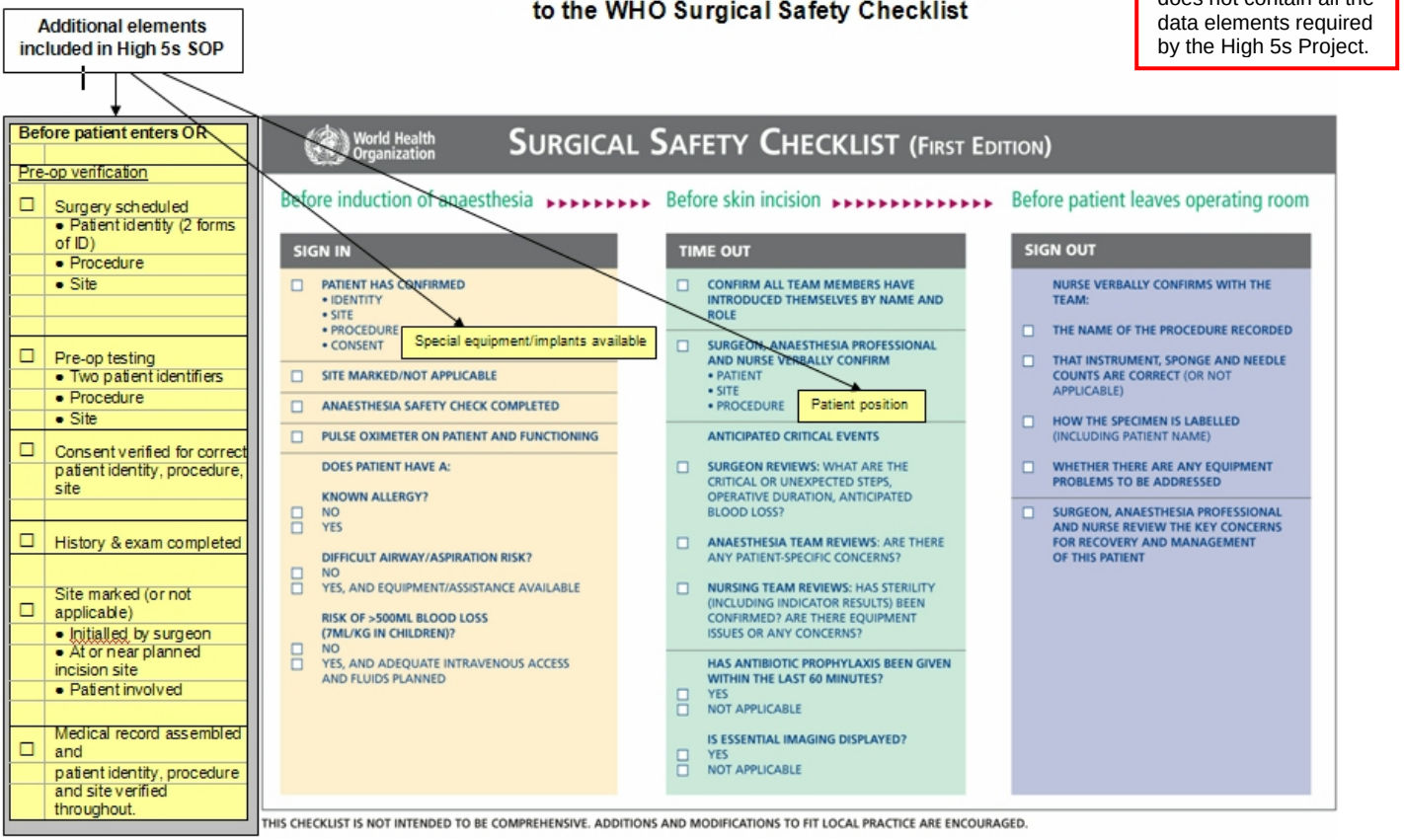
NURSE VERBALLY CONFIRMS WITH THE TEAM:
- ☐ THE NAME OF THE PROCEDURE RECORDED
- ☐ THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT (OR NOT APPLICABLE)
- ☐ HOW THE SPECIMEN IS LABELLED (INCLUDING PATIENT NAME)
- ☐ WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED
- ☐ SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS PATIENT

CAUTIONARY NOTE

The examples that follow are intended to demonstrate the principles and approaches to consolidating check lists and other preoperative tools. These specific examples should not be taken as acceptable for use in the High 5s Project if they do not meet the guidelines on page 24. In particular, the content (items to be checked off and other data elements) of the Basic High 5s Preoperative Verification Check List must be retained.

Example of a High 5s Participating Hospital Adaptation to the WHO Surgical Safety Checklist

Note: This example does not contain all the data elements required by the High 5s Project.



Additional elements included in High 5s SOP

Before patient enters OR

Pre-op verification

- ☐ Surgery scheduled
  - Patient identity (2 forms of ID)
  - Procedure
  - Site
- ☐ Pre-op testing
  - Two patient identifiers
  - Procedure
  - Site
- ☐ Consent verified for correct patient identity, procedure, site
- ☐ History & exam completed
- ☐ Site marked (or not applicable)
  - Initialled by surgeon
  - At or near planned incision site
  - Patient involved
- ☐ Medical record assembled and patient identity, procedure and site verified throughout.

World Health Organization

SURGICAL SAFETY CHECKLIST (FIRST EDITION)

Before induction of anaesthesia ▸▸▸▸▸▸▸▸▸ Before skin incision ▸▸▸▸▸▸▸▸▸▸▸▸▸ Before patient leaves operating room

SIGN IN

- ☐ PATIENT HAS CONFIRMED
  - IDENTITY
  - SITE
  - PROCEDURE
  - CONSENT

Special equipment/implants available

- ☐ SITE MARKED/NOT APPLICABLE
- ☐ ANAESTHESIA SAFETY CHECK COMPLETED
- ☐ PULSE OXIMETER ON PATIENT AND FUNCTIONING

DOES PATIENT HAVE A:

KNOWN ALLERGY?
- ☐ NO
- ☐ YES

DIFFICULT AIRWAY/ASPIRATION RISK?
- ☐ NO
- ☐ YES, AND EQUIPMENT/ASSISTANCE AVAILABLE

RISK OF >500ML BLOOD LOSS (7ML/KG IN CHILDREN)?
- ☐ NO
- ☐ YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED

TIME OUT

- ☐ CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE
- ☐ SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM
  - PATIENT
  - SITE
  - PROCEDURE

Patient position

ANTICIPATED CRITICAL EVENTS

- ☐ SURGEON REVIEWS: WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS?
- ☐ ANAESTHESIA TEAM REVIEWS: ARE THERE ANY PATIENT-SPECIFIC CONCERNS?
- ☐ NURSING TEAM REVIEWS: HAS STERILITY (INCLUDING INDICATOR RESULTS) BEEN CONFIRMED? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS?

HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES?
- ☐ YES
- ☐ NOT APPLICABLE

IS ESSENTIAL IMAGING DISPLAYED?
- ☐ YES
- ☐ NOT APPLICABLE

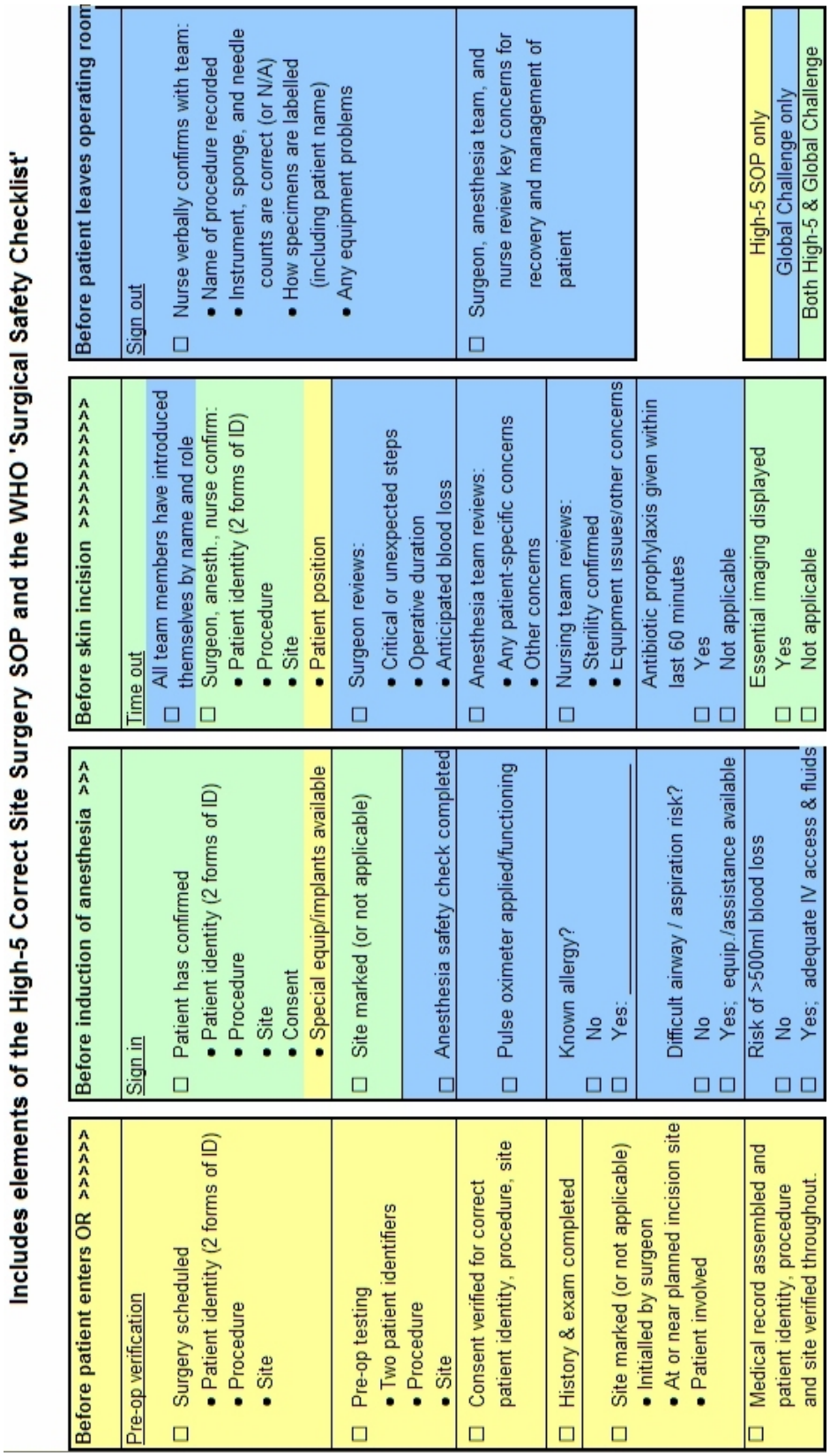
SIGN OUT

NURSE VERBALLY CONFIRMS WITH THE TEAM:
- ☐ THE NAME OF THE PROCEDURE RECORDED
- ☐ THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT (OR NOT APPLICABLE)
- ☐ HOW THE SPECIMEN IS LABELLED (INCLUDING PATIENT NAME)
- ☐ WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED
- ☐ SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS PATIENT

THIS CHECKLIST IS NOT INTENDED TO BE COMPREHENSIVE. ADDITIONS AND MODIFICATIONS TO FIT LOCAL PRACTICE ARE ENCOURAGED.

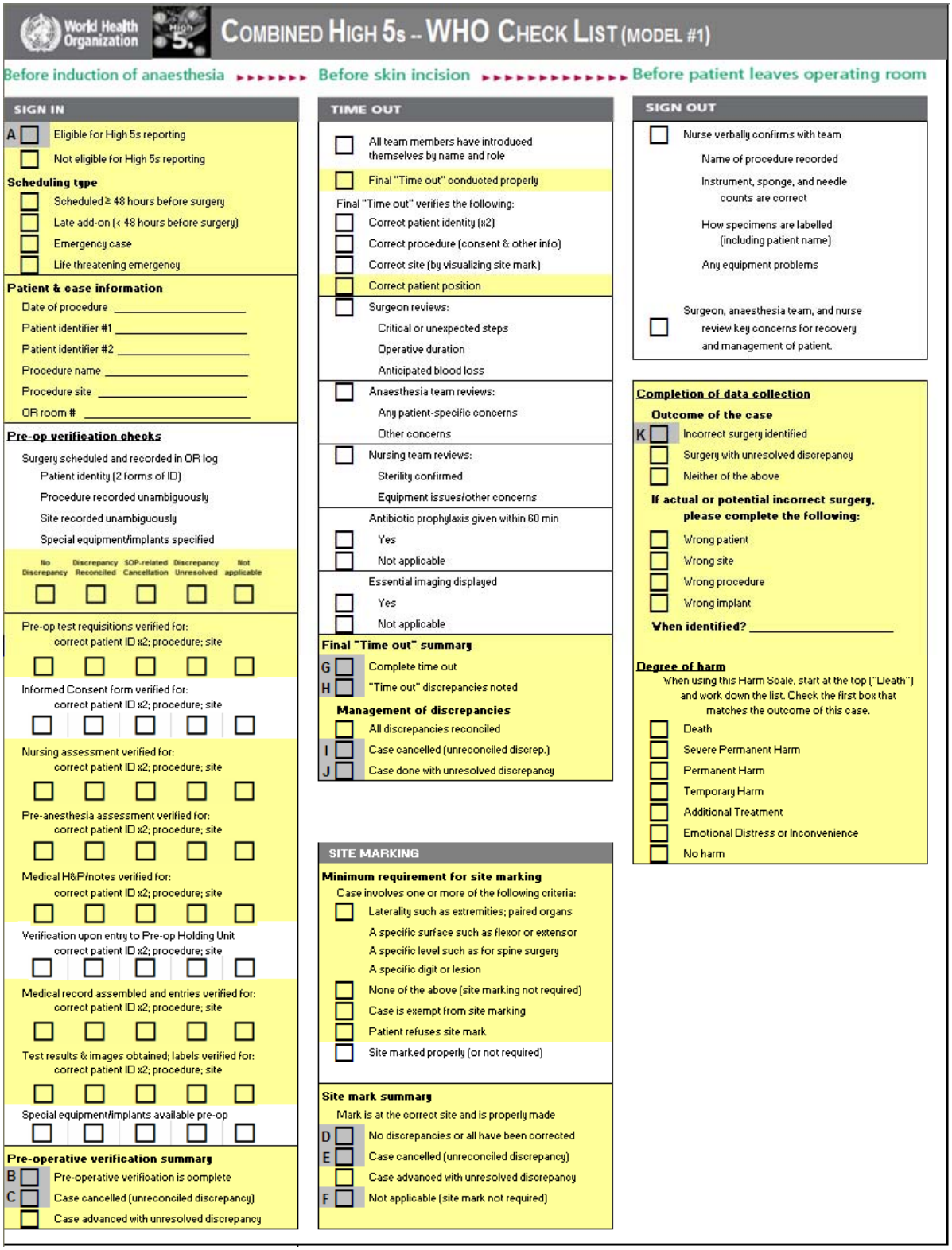
Examples of consolidated check lists (continued)

Consolidated High 5s Check List and WHO Surgical Safety Checklist (landscape orientation):



Note that the color coding shown in this example is only for purposes of highlighting the relationships of specific items to their respective original forms. In an actual implementation, such color coding would not be necessary.

Consolidated High 5s Check List and WHO Surgical Safety Checklist (portrait orientation):



World Health Organization

COMBINED HIGH 5s -- WHO CHECK LIST (MODEL #1)

Before induction of anaesthesia ▸▸▸▸▸▸▸ Before skin incision ▸▸▸▸▸▸▸▸▸▸▸▸ Before patient leaves operating room

SIGN IN

A ☐ Eligible for High 5s reporting

☐ Not eligible for High 5s reporting

Scheduling type

☐ Scheduled ≥ 48 hours before surgery

☐ Late add-on (< 48 hours before surgery)

☐ Emergency case

☐ Life threatening emergency

Patient & case information

Date of procedure _____

Patient identifier #1 _____

Patient identifier #2 _____

Procedure name _____

Procedure site _____

OR room # _____

Pre-op verification checks

Surgery scheduled and recorded in OR log

Patient identity (2 forms of ID)

Procedure recorded unambiguously

Site recorded unambiguously

Special equipment/implants specified

No Discrepancy	Discrepancy Reconciled	SOP-related Cancellation	Discrepancy Unresolved	Not applicable
☐	☐	☐	☐	☐

Pre-op test requisitions verified for: correct patient ID x2; procedure; site ☐ ☐ ☐ ☐ ☐

Informed Consent form verified for: correct patient ID x2; procedure; site ☐ ☐ ☐ ☐ ☐

Nursing assessment verified for: correct patient ID x2; procedure; site ☐ ☐ ☐ ☐ ☐

Pre-anesthesia assessment verified for: correct patient ID x2; procedure; site ☐ ☐ ☐ ☐ ☐

Medical H&P/notes verified for: correct patient ID x2; procedure; site ☐ ☐ ☐ ☐ ☐

Verification upon entry to Pre-op Holding Unit correct patient ID x2; procedure; site ☐ ☐ ☐ ☐ ☐

Medical record assembled and entries verified for: correct patient ID x2; procedure; site ☐ ☐ ☐ ☐ ☐

Test results & images obtained; labels verified for: correct patient ID x2; procedure; site ☐ ☐ ☐ ☐ ☐

Special equipment/implants available pre-op ☐ ☐ ☐ ☐ ☐

Pre-operative verification summary

B ☐ Pre-operative verification is complete

C ☐ Case cancelled (unreconciled discrepancy)

☐ Case advanced with unresolved discrepancy

TIME OUT

☐ All team members have introduced themselves by name and role

☐ Final "Time out" conducted properly

Final "Time out" verifies the following:

☐ Correct patient identity (x2)

☐ Correct procedure (consent & other info)

☐ Correct site (by visualizing site mark)

☐ Correct patient position

☐ Surgeon reviews:

Critical or unexpected steps

Operative duration

Anticipated blood loss

☐ Anaesthesia team reviews:

Any patient-specific concerns

Other concerns

☐ Nursing team reviews:

Sterility confirmed

Equipment issues/other concerns

Antibiotic prophylaxis given within 60 min

☐ Yes

☐ Not applicable

Essential imaging displayed

☐ Yes

☐ Not applicable

Final "Time out" summary

G ☐ Complete time out

H ☐ "Time out" discrepancies noted

Management of discrepancies

☐ All discrepancies reconciled

I ☐ Case cancelled (unreconciled discrep.)

J ☐ Case done with unresolved discrepancy

SITE MARKING

Minimum requirement for site marking

Case involves one or more of the following criteria:

☐ Laterality such as extremities; paired organs

A specific surface such as flexor or extensor

A specific level such as for spine surgery

A specific digit or lesion

☐ None of the above (site marking not required)

☐ Case is exempt from site marking

☐ Patient refuses site mark

☐ Site marked properly (or not required)

Site mark summary

Mark is at the correct site and is properly made

D ☐ No discrepancies or all have been corrected

E ☐ Case cancelled (unreconciled discrepancy)

☐ Case advanced with unresolved discrepancy

F ☐ Not applicable (site mark not required)

SIGN OUT

☐ Nurse verbally confirms with team

Name of procedure recorded

Instrument, sponge, and needle counts are correct

How specimens are labelled (including patient name)

Any equipment problems

☐ Surgeon, anaesthesia team, and nurse review key concerns for recovery and management of patient.

Completion of data collection

Outcome of the case

K ☐ Incorrect surgery identified

☐ Surgery with unresolved discrepancy

☐ Neither of the above

If actual or potential incorrect surgery, please complete the following:

☐ Wrong patient

☐ Wrong site

☐ Wrong procedure

☐ Wrong implant

When identified? _____

Degree of harm

When using this Harm Scale, start at the top ("Death") and work down the list. Check the first box that matches the outcome of this case.

☐ Death

☐ Severe Permanent Harm

☐ Permanent Harm

☐ Temporary Harm

☐ Additional Treatment

☐ Emotional Distress or Inconvenience

☐ No harm

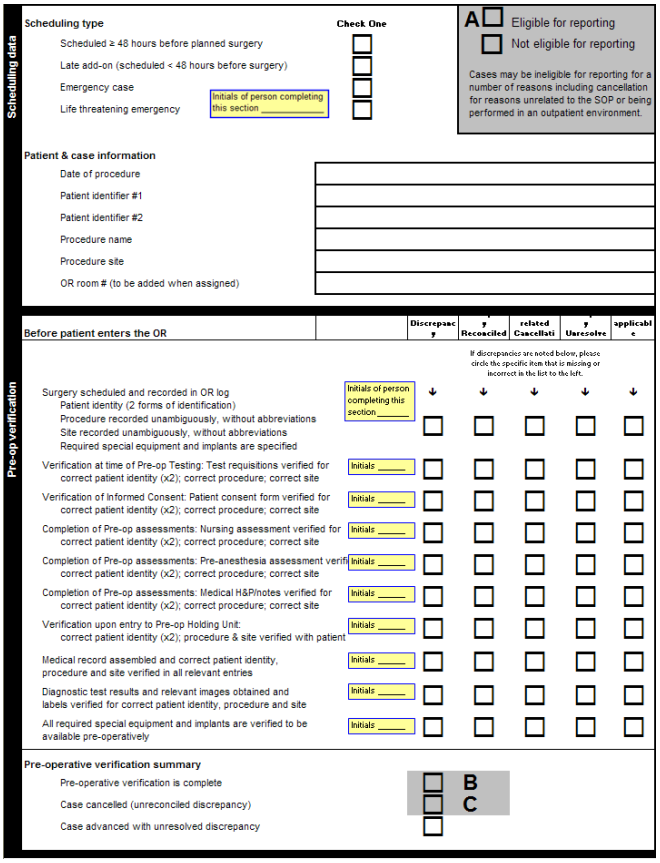
Examples of consolidated check lists (continued)

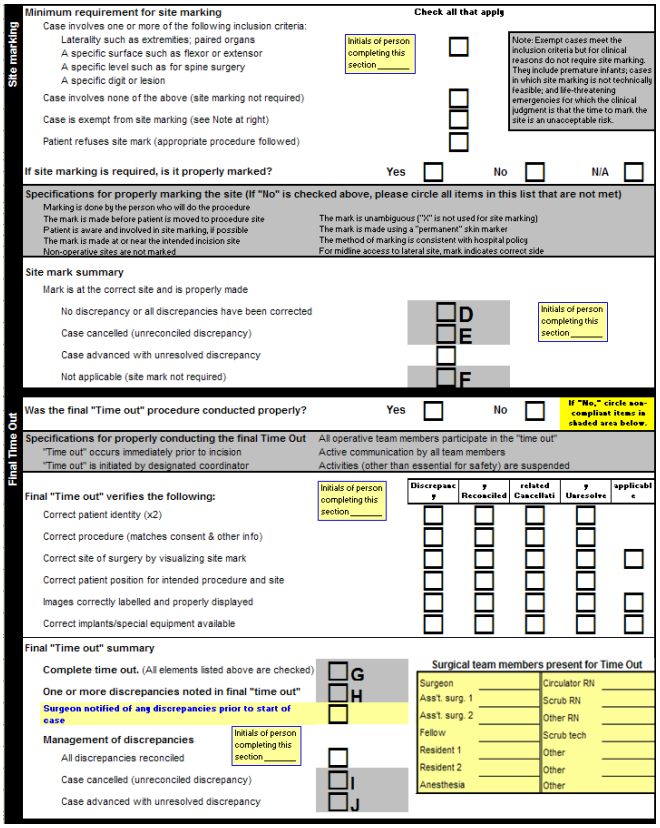
AORN Sample Surgical Checklist

√ when completed before entering procedure room	Criteria	Signature (s)
	Patient Verification	
	Person Completing Verification of Patient Patient Other:_____ NAME	
☐	The patient was asked to state first identifier (e.g., full name).	
☐	Patient asked to stated second identifier per facility policy (e.g., DOB, or SS #).	
☐	Patient's responses match ID band, consents, X-rays (if applicable) and all other relevant data.	
N/A per policy	**SITE MARK**	
☐	Patient states procedure, side, and site to be performed and points to the site.	
☐	Patient's informed consent describes the operative/procedural site and laterality as described by patient.	
☐	All relevant data in the medical record is consistent with patient response.	
☐	Invasive procedure schedule /operative schedule is consistent with patient response.	
☐ ☐ N/A	Radiographs (e.g., X-ray) available.	
☐ ☐ N/A	Implants available.	
☐ ☐ N/A	Special equipment available.	
☐ ☐ N/A	Invasive or surgical site is marked over or adjacent to the surgical/procedural site incision.	

√ when completed in OR/Procedure Room	Criteria	Signature (s)
☐	Confirms: patient identity, consent(s), patient position, operative procedure, laterality, and site mark.	
☐ ☐ N/A	Review medical record for consistency in identifying the correct surgical site or procedural site.	
☐	(*Operating Physician*) hangs imaging studies and confirms surgical site, if applicable.	
☐ ☐ N/A	Implant system available.	
☐ ☐ N/A	Special equipment available.	
☐	"TIME OUT" immediately before start of the procedure for final verification of correct patient, correct site, correct procedure, x-rays are displayed appropriately on the correct patient.	
☐	Document members present for "time out." _____ MD _____ MD Fellow _____ MD Resident _____ Anesthesia _____ CRNA _____ RN Circulator _____ CRNFA/RNFA _____ Scrub Technician _____ Other (s)	
Discrepancy Noted	Surgeon Notified: Date: Time: Surgeon final site and side verified and communicated with team. Documented note completed.	

Consolidated High 5s – AORN Check List





Implementing the High 5s SOP for Correct Site Surgery

Quick-Start Check List — Are You Ready?

The sections that follow lay out the basic strategy for implementing the High 5s SOP for Correct Site Surgery including …

What needs to be done?

- Who should be involved and what are their roles and responsibilities?
- What is the time line for implementing the SOP as part of the High 5s initiative?
- What are the major milestones and deliverables along the road to full implementation?
- Should a pilot test be done?
- How is a full, successful, and sustainable implementation achieved?

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.

Here is a short check list of pre-implementation activities and necessities that will put you in good position to move forward with a smooth and successful implementation within the context of the High 5s initiative. Each of the following items should be completed as soon as possible and definitely before starting the actual process of implementation:

- ☐ Secure senior leadership commitment
- ☐ Appoint a project coordinator
- ☐ Form a team
- ☐ Confirm availability of team members
- ☐ Convene the team
- ☐ Define the problem and the goals

In the pages that follow, we will go into a fair amount of detail about each of the items on this check list, and more, so that you can proceed with confidence as you implement the High 5s Correct Site Surgery SOP.

The Implementation Team

Secure senior leadership commitment

In most cases, if you are at the point of thinking about forming an implementation team, the hospital leadership will have made a commitment to participate in the High 5s initiative, including implementation of the Correct Site Surgery SOP and its associated measurement and evaluation activities. For success, that commitment must be communicated from the highest levels of administration to the hospital at large and the implementation team in particular. Visible senior leadership support can help to remove obstacles and allocate resources, including time for staff to participate on this team, enhancing the likelihood of success.

Other roles of senior leadership are to provide oversight of the project, to allocate resources for the project, and to assign an individual to represent senior leadership on the implementation team. While the representative of senior leadership may not be able to participate in every team meeting, regular progress reports should be provided to the hospital leaders, including achievements, barriers encountered, resources needed, and data showing the progress and impact of implementation.

Appoint a project coordinator

The project coordinator can be anyone with proven ability to organize and motivate a team and manage a goal-oriented project. Familiarity with the surgical process is desirable but less important than team-building skills and project management skills. This person will convene the team and facilitate meetings, develop a detailed project work plan (a template is provided later in this Guide), oversee implementation and data collection, and communicate with hospital leaders and direct care staff.

Form a team

As emphasized in the preceding section, successful implementation requires teamwork. The team should be representative of all the care units, preoperative functions, professional disciplines and other stakeholders involved in the process of preparing and caring for surgical patients. The team should include representation from the following:

- Senior administrative leadership
- Surgeons (Chief of surgery or his/her designee)
- Anesthesia providers (Chief of anesthesia or his/her designee)
- OR nurses (OR supervisor or his/her designee)
- OR technicians
- Medical records administrator
- Admission unit
- Laboratory & imaging departments
- Preoperative holding unit
- Surgical inpatient care unit
- Post anesthesia care unit
- Patient or family member

In many cases, one person may be able to fill two or more of these positions. In addition to these participants and the project coordinator, if the hospital has a patient safety officer who is not already represented on the team, that person should be included. Finally, because collection, aggregation, and transmission of data is an important part of this initiative, someone familiar with health information management and technology should also be included.

Confirm availability of team members

Each person invited and agreeing to participate on the implementation team must commit to providing a reasonable amount of time for that participation. In the case of employed staff, this means the hospital leadership, as part of its resource allocation responsibilities, must provide for the necessary time away from these individuals' regular duties.

Convene the team

The initial meeting of the implementation team should be face-to-face with as many members of the team present, in person, as possible. If it is not possible for a person to attend in person, provisions for call-in should be considered. At that first meeting, all members should introduce themselves and the clinical discipline/unit/function they are representing; the ground rules for the meetings (including scheduling, attendance, provision for alternates, timeliness, cell phone/pager/blackberry management) should be agreed to; and the problem being addressed and the goals of the project should be defined and agreed on.

Define the problem and the goals

A clear and consistent understanding of the problem to be addressed through implementation of the High 5s Correct Site Surgery SOP is essential to a successful implementation. The problem, of course is "incorrect surgery," which means any surgical procedure that has been initiated on the wrong patient, at the wrong site (including wrong side or wrong organ), with the wrong procedure, or using the wrong implant. Such a procedure is considered "incorrect" whether or not a process error has occurred and whether or not any harm resulted. The surgical procedure "has been initiated" when the initial incision (or instrument insertion) is made. Use of the term "wrong procedure" 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.

The goals for the hospital's participation in this SOP implementation must at least include the goals of the High 5s initiative: to test the feasibility of implementing a standardized patient safety protocol and to demonstrate the effectiveness of such standardization in reducing the risk of wrong site surgery. This may also be an opportunity to pursue certain hospital-specific goals, such as demonstrating effective use of the hospital's performance improvement methodology.

Constructing a Detailed Implementation Work Plan

The first important deliverable for the implementation team is a work plan that delineates all of the tasks to be done, the time line for doing them, the person(s) responsible for doing each task, the dependencies between tasks, specific milestones, and all deliverables with due dates. A useful format for doing this is a Gannt Chart, which provides a graphical representation of the time line and dependencies for each task listed and includes all of the other components of a complete work plan. Project management software is readily available to assist with this but a Gannt Chart can also be developed on a spread sheet or with pen and paper. This model for displaying the work plan is used in the examples provided below (see page 34) but it is not a requirement of the High 5s initiative—other models may be used and, if more familiar to the project coordinator—should be used. That said, the basic components of a work plan are universally accepted and are expected to be developed in some form as the initial step in planning the implementation. These components are as follows:

1. List all of the tasks necessary for a successful implementation
2. For each task, assign responsibility for completing the task
3. For each task, determine how much time it will take and when it must be completed
4. For each task, identify whether there are any associated deliverables
5. Identify and list along with the tasks any milestones to be achieved
6. Identify all dependencies between tasks
7. Determine the critical path

A Template Work Plan using the Gannt Chart format and including the tasks that are expected to be necessary for full implementation of the Correct Site Surgery SOP is provided on page 34. It may be helpful to refer to this as an example when reading through the next several sections on the details of developing your work plan. It will also be a useful starting point for constructing your hospital-specific work plan.

What are the required tasks for a successful implementation?

Start with the Template Work Plan and engage the team in brainstorming additions or modifications appropriate to your hospital's surgical environment and preoperative preparation processes. This likely will include a redesign of the hospital's preoperative preparation process to accommodate the provisions of the High 5s SOP. It will also address conducting a risk assessment of the redesigned process, pilot testing it, training staff who will be affected by the changes, implementing the redesigned process, and measuring the progress of implementation and its impact. Note that tasks are listed in outline format where high-level activities may have subordinate tasks and sub-tasks. Include as much detail as you find useful but not so much that just the process of doing the work plan becomes overly tedious. For example, related tasks assigned to the same person often can be grouped and treated as a single task.

Who does what?

Now that you have listed all the activities and tasks, assign responsibility for each. Assigning responsibility for a task does not means that person has to do the task him- or herself, but that person is responsible for getting it done. Confirm that each person assigns accepts the responsibility and has the time and other resources necessary to do it.

What is the time line?

Each task should be assigned a duration—the amount of time, start to finish, it will take to do the task—and a start date. For the first pass at the work plan, these will just be the best estimates that the team can provide; later, they can be adjusted to fit into the overall time line of the High 5s initiative, as follows:

- June: Train hospitals chosen for participation in the pre-test
- July-August: Pre-test conducted in selected hospitals
- August: Training continues for hospitals not participating in the pre-test
- September: Update hospital training based on the pretest
- October: Hospital implementation begins
- November: Data collection begins

What are the deliverables & milestones?

Many tasks will have an associated deliverable—for example, a report, draft procedure, data set, etc. The deliverable is due at the end date of the associated task (its start date + duration). The expectations for each deliverable should be clearly specified, including to whom and in what form and manner it should be delivered.

Certain "tasks" will more properly be identified as milestones: important events along the time line of the work plan. Milestones are often associated with completion of a group of related tasks or presentation of a progress report to hospital leadership. Their timing may be dictated by events that are outside the control of the implementation team, such as a hospital board meeting. Milestones do not have durations but do have a due dates. Milestones should include at least the following:

- Approval of the project work plan by the oversight group
- Approval of the pilot test design
- "Go-live" date for the pilot test
- Presentation of pilot test results to the oversight group
- "Go-live" date for full implementation (12-18 months following start date)

What are the dependencies and the critical path?

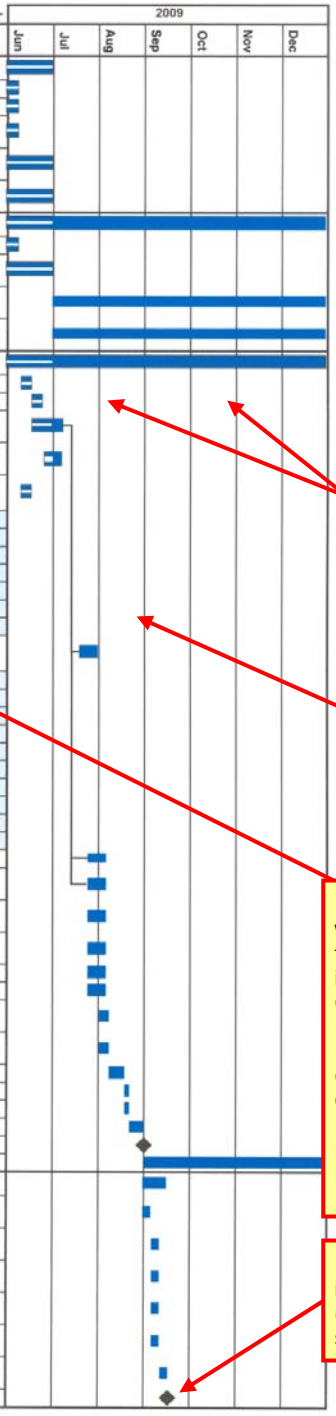
Dependencies describe how tasks interrelate. Identifying dependencies is best done as a team activity. For any task "X" on the list, does another task "Y" have to be started (or completed) before "X" can be started (or completed)? Knowing the dependencies will help determine the order in which tasks must be accomplished, which tasks can be worked on simultaneously and, ultimately, whether the work plan can be completed within the constraints of time and resources. If project management software is available, it will only take a keystroke or mouse click to determine the critical path. This is the minimum time it will take to complete implementation of the work plan based on the task durations and dependencies previously entered.

Template Work Plan

Sample work plans for planning, testing and implementing the SOP, and measuring the consistency of implementation and impact on the safety of patient care.

Template Work Plan for Implementing the High 5s Correct Site Surgery SOP

Task #	Task name	Person/group responsible	Start date	Duration (days)	End date	Resource requirements	Percent complete
A	**Define project management team**		06/01/09	30	7/1/09		100%
A1	Identify oversight group	CEO	06/01/09	7	6/8/09		100%
A2	Assign project coordinator	CEO	06/01/09	7	6/8/09		100%
A3	Identify senior administrator "contact" for resource decisions	CEO	06/01/09	7	6/8/09		100%
A4	Select team with representation from each professional discipline	PC	06/01/09	30	7/1/09		100%
A5	Identify direct caregiver "champions" from each discipline/function	PC	06/01/09	30	7/1/09		100%
B	**Communicate with staff**		06/01/09	578	12/31/10		14%
B1	Announce participation in the High 5s Project	CEO	06/01/09	7	6/8/09		100%
B2	Present and publish the hospital's rationale for participating in the High 5s Project	PC	06/01/09	30	7/1/09		100%
B3	Provide periodic feedback to staff participating in and affected by the High 5s Project	PC	07/01/09	548	12/31/10		0%
B4	Publicly recognize the effort, contributions, and successes of all participants	CEO	07/01/09	548	12/31/10		0%
C	**Develop work plan**		06/01/09	214	1/1/10		14%
C1	Flow chart existing pre-op process	PT	06/08/09	7	6/15/09		100%
C2	Identify differences from High 5s process	PT	06/15/09	7	6/22/09		100%
C3	Reconcile differences by developing a redesigned process that includes features of both processes	PT	06/15/09	21	7/6/09		67%
C4	Champions identify details of change, barriers, and needed resources for their areas of responsibility	CH	06/22/09	14	7/6/09		50%
C5	Identify milestones/deadlines outside the control of the project team (see below for placement)	CEO/LTA	06/01/09	7	6/15/09	◆	100%
C5a	Approval of project work plan		09/01/09	0	09/01/09		
C5b	Approval of pilot test design		10/01/09	0	10/01/09		
C5c	"Go live" date for pilot test		11/01/09	0	11/01/09		
C5d	Present pilot test results to oversight group		12/01/09	0	12/01/09		
C5e	Approval of full implementation plan		12/15/09	0	12/15/09		
C5f	"Go live" date for full implementation		01/01/10	0	01/01/10		
C5g	Data collection begins		11/01/09	0	11/01/09		
C6	Define necessary steps to implement the redesigned process in all areas	PT	07/15/09	16	7/31/09		0%
C6a	Scheduling	PT	07/15/09	16	7/31/09		
C6b	Pre-op testing (lab, imaging, ECG)	PT	07/15/09	16	7/31/09		
C6c	Informed consent	PT	07/15/09	16	7/31/09		
C6d	Pre-op nursing assessment	PT	07/15/09	16	7/31/09		
C6e	Pre-anesthesia assessment	PT	07/15/09	16	7/31/09		
C6f	Medical history & physical exam	PT	07/15/09	16	7/31/09		
C6g	Pre-op holding unit	PT	07/15/09	16	7/31/09		
C6h	Assembled medical record	PT	07/15/09	16	7/31/09		
C6i	Pre-op test results	PT	07/15/09	16	7/31/09		
C6j	Special equipment/implants	PT	07/15/09	16	7/31/09		
C7	For each area, identify needed inputs and sources	CH	07/22/09	16	8/7/09		0%
C8	For each area, identify deliverables and to whom delivered	PT	07/22/09	16	8/7/09		0%
C9	For each step, assign responsibility for completion (champion or team member)	PT	07/22/09	16	8/7/09		0%
C10	For each step, estimate start date, time needed for completion, and due date	PT	07/22/09	16	8/7/09		0%
C11	For each step, identify dependencies	PT	07/22/09	16	8/7/09		0%
C12	For each step, identify resource needs	PT	07/22/09	16	8/7/09		0%
C13	Determine critical path and adjust timing of steps to meet uncontrollable milestones	PT	08/03/09	7	8/10/09		0%
C14	Define site-specific adaptations that are necessary and allowable with project team approval	Ch	08/03/09	7	8/10/09		0%
C15	Review and revise as needed	PT	08/11/09	10	8/21/09		0%
C16	Confirm team's acceptance of draft work plan	PT	08/21/09	2	8/23/09		0%
C17	Present to oversight group	PC	08/21/09	2	8/23/09		0%
C18	Revise as directed by oversight group	PT	08/23/09	8	8/31/09		0%
C19	Approve work plan	OG	09/01/09	0	9/1/09		0%
C20	Monitor progress of work plan	PC	09/01/09	122	1/1/10		0%
D	**Risk assess the redesigned process**		09/01/09	14	9/15/09		0%
D1	Update flow chart to include all aspects of redesigned process	PC	09/01/09	7	9/8/09		0%
D2	Identify failure modes at each step and link between steps (hand-offs)	PT	09/07/09	7	9/14/09		0%
D3	Identify potential effects of failure modes on stability and outcomes of pre-op process	PT	09/07/09	7	9/14/09		0%
D4	Prioritize failure modes based on probable frequency, effects, and detectability	PT	09/07/09	7	9/14/09		0%
D5	For the high priority failure modes, determine what might cause them	PT	09/07/09	7	9/14/09		0%
D6	Based on results of risk assessment, propose redesign of the process	PT	09/14/09	7	9/21/09		0%
D7	Approve the redesigned process	OG	09/21/09	0	9/21/09		0%



This Gannt chart is shown only for 2009. Many activities will continue for up to 5 years.

Solid bars indicate the full duration of the task. The inner bar indicates the portion completed.

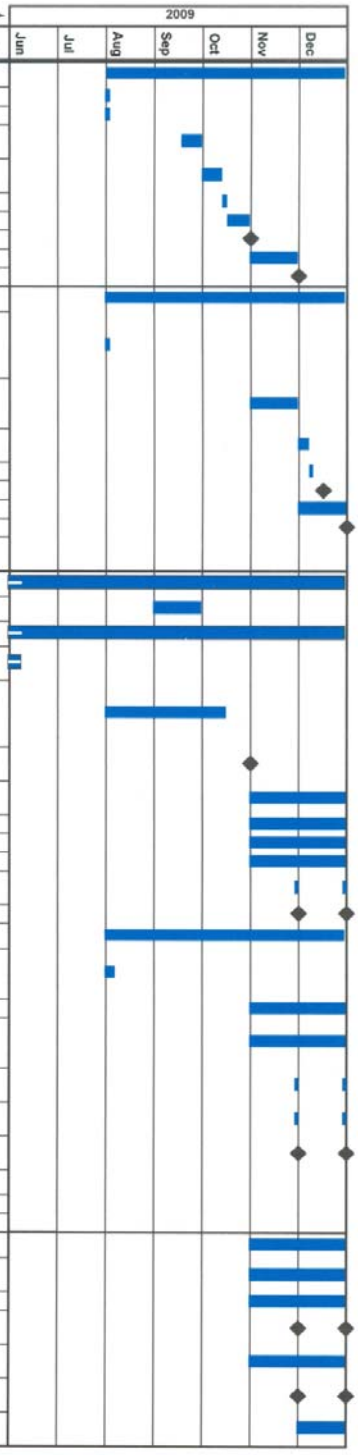
One way to show dependencies.

It is helpful to show who is responsible for each task using initials:
CEO = Chief exec
PC = Project coord.
PT = Project team
CH = "Champion"
OG = Oversight Grp
DA = Data analyst
US = Unit staff
LTA = Lead Technical Agency

Black diamonds indicate milestones (or especially difficult ski trails)

Template Work Plan for Implementing the High 5s Correct Site Surgery SOP

Task #	Task name	Person/group responsible	Start date	Duration (days)	End date	Resource requirements	Percent complete
E	**Pilot test the process**		08/01/09	153	1/1/10		0%
E1	Define scope of pilot test	PT	08/01/09	3	8/4/09		0%
E2	Identify test site(s) / unit(s) / population(s)	PT	08/01/09	3	8/4/09		0%
E3	Meet with all direct care givers at the pilot test sites to explain purpose of pilot test and hear concerns	PC/CH	09/14/09	16	9/30/09		0%
E4	Apply adaptations of proposed new process necessitated by unique features of test sites	PT	10/01/09	14	10/15/09		0%
E5	Approval of adaptations by project team	PT	10/12/09	3	10/15/09		0%
E6	Train staff at pilot test sites (see below)	PC/CH	10/15/09	16	10/31/09		0%
E7	Implement new process at pilot test sites	US	11/01/09	0	11/1/09		0%
E8	Measure & analyze results of pilot test (see below)	DA	11/01/09	29	11/30/09		0%
E9	Report results of pilot test to oversight group	PC	12/01/09	0	12/1/09		0%
F	**Full implementation**		08/01/09	517	12/31/10		0%
F1	Determine sequence and timing of implementation in all units involved in the pre-op preparation of cases to be done in the hospital's inpatient surgical environment	PT	08/01/09	3	8/4/09		0%
F2	Meet with all direct care givers at the affected sites to explain what is expected, to hear concerns, and to answer questions	PC/CH	11/01/09	30	12/1/09		0%
F3	Apply adaptations of new process necessitated by unique features of implementation sites	PT	12/01/09	7	12/8/09		0%
F4	Approval of adaptations by project team	PT	12/07/09	3	12/10/09		0%
F5	Approval of full implementation plan	OG	12/15/09	0	12/15/09		0%
F6	Train staff at implementation sites (see below)	PC/CH	12/01/09	30	12/31/09		0%
F7	Implement new process at implementation sites	US	01/01/10	0	1/1/10		0%
F8	Measure, analyze, and report results of implementation (see below)	DA	01/01/10	364	12/31/10		0%
G	**Evaluate implementation and impact**		06/01/09	578	12/31/10		5%
G1	Collect & submit baseline demographic data to LTA	DA	09/01/09	30	10/1/09		0%
G2	Performance measurement		06/01/09	578	12/31/10		5%
G2a	Assign responsibility for aggregating, de-identifying, and submitting performance data	PC	06/01/09	7	6/8/09		100%
G2b	Access and understand the performance measures, data collection protocols, aggregation and de-identification procedures, and data quality requirements	DA	08/01/09	75	10/15/09		0%
G2c	Begin data collection (using pre-op verifica-tion forms in pilot test & full implementation)	US	11/01/09	0	11/1/09		0%
G2d	Collect pre-op verification (data collection) forms	DA	11/01/09	425	12/31/10		0%
G2e	Conduct quality checks on the data	DA	11/01/09	425	12/31/10		0%
G2f	Identify cases for event analysis	DA/US	11/01/09	425	12/31/10		0%
G2g	De-identify and aggregate the data	DA	11/01/09	425	12/31/10		0%
G2h	Report results to project team & oversight group	DA	11/27/09	3	11/30/09		0%
G2i	Submit performance data to LTA	DA	12/01/09	0	12/1/09		0%
G3	Event analysis		08/01/09	153	1/1/10		0%
G3a	Develop and implement method for identifying occurrences of "prompts" for possible event analysis cases	PT	08/01/09	7	8/8/09		0%
G3b	Investigate occurrences of "prompts"	PC/DA	11/01/09	425	12/31/10		0%
G3c	Conduct event analysis on each case identified by performance data analyst, "prompt" review, or independent report	PC/US	11/01/09	425	12/31/10		0%
G3d	Report results of event analyses to project team & oversight group	PC	11/27/09	3	11/30/09		0%
G3e	Confirm de-identification of event analysis reports	DA	11/02/09	3	11/5/09		0%
G3f	Submit de-identified event analysis data to LTA	DA	12/01/09	0	12/1/09		0%
G4	Implementation evaluation		01/01/10	364	12/31/10		0%
G4a	Complete and submit narrative questionnaire	DA	01/01/10	31	2/1/10		0%
G4b	Participate in LTA site visit	ALL	05/01/10	0	5/1/10		
H	**Maintain and improve the new process**		11/01/09	425	12/31/10		0%
H1	Continue ongoing performance measurement and event analyses	PC/DA/US	11/01/09	425	12/31/10		0%
H2	Identify opportunities to improve the SOP	PT/US	11/01/09	425	12/31/10		0%
H3	Report opportunities to improve the SOP to the oversight group and the LTA	PC	12/01/09	0	12/1/09		0%
H4	Identify opportunities to improve the consistency, timeliness, and accuracy of SOP implementation	PC/US	11/01/09	60	12/31/09		0%
H5	Report opportunities to improve SOP implementation to the project team	PC	12/01/09	0	12/1/09		0%
H6	Take steps to maintain and improve the SOP implementation	PT	12/01/09	395	12/31/10		0%



Risk assessment of the redesigned preoperative process

Remember, the High 5s SOP and check list are designed to be integrated into existing hospital preoperative preparation processes. Since this will probably require some redesign of the existing processes and/or check list, it is necessary for the sake of safety and efficiency to conduct a risk assessment of the new process before it is fully implemented throughout the hospital (i.e., spread). *The purpose of risk assessment is to identify any potential unintended consequences of the redesign and to make appropriate changes or develop/insert controls to ensure that the new process will be safe and efficient.*

The particular model of proactive risk assessment we recommend here is a simplified version of failure mode and effects analysis (FMEA), a risk assessment strategy that has been employed for decades in most high-risk fields and is being increasingly employed in health care as a key tool in the safe design of clinical processes. Simply put, this is a non-statistical, "What can go wrong?" type of analysis that we all do to some degree as a matter of course in our daily lives. Its more formal application, in a structured activity like the High 5s Project, is as follows, using patient preparation for surgery as an example.

Proactive risk assessment, step-by-step:

1. Define the process using flow charts
2. Identify the failure modes/risk points - For each of the steps in the new (High 5s) process, identify the failures that might occur (taking into consideration the differences between the new and the established process, as it was originally designed and as currently practiced)
3. Identify the effects of the failures - For each identified "failure mode" identify the possible effects if that failure were to occur
4. Prioritize the failure modes/risk points - Prioritize the failure modes for further analysis based on the frequency with which the failure may occur and the seriousness of its effects
5. Identify causes for high priority failure modes/risk points - For the highest priority failure modes, conduct an analysis to determine why those failures might occur
6. Redesign the process - Using that information, redesign the process and/or support systems to minimize the risk of the failure modes or to protect patients from the effects of the failure modes.

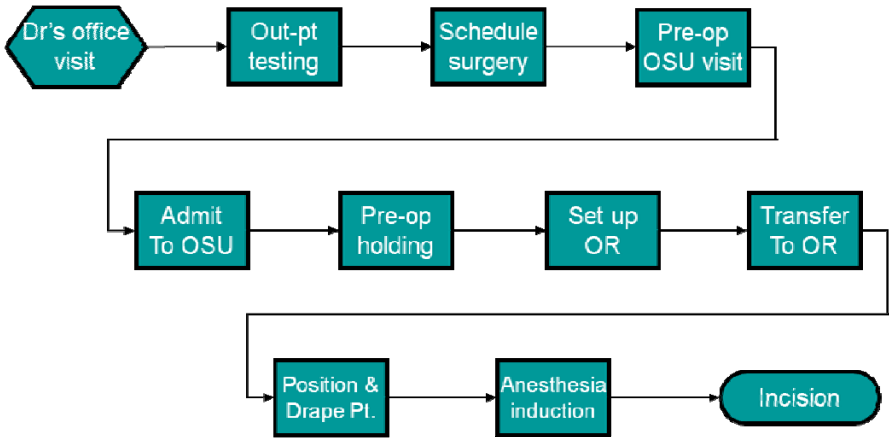
STEP 1 – Define the Process

Describe the preoperative preparation process using flow charts. Be sure to note where the process begins and ends (the "boundaries of the process") For purposes of this analysis, there will need to be three different descriptions of the process:

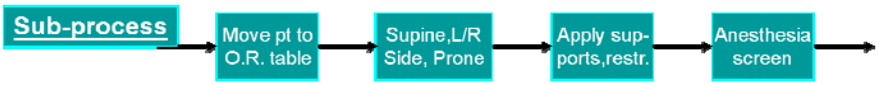
1. The process as it was intended to be done prior to any changes relating to the High 5s Project (i.e., how it is ideally supposed to be done; this can usually be found in the hospital's policy and procedure manuals)
2. The process as it was routinely done prior to any changes relating to the High 5s Project (i.e., what really happens). This includes any undocumented redesigns and shortcuts that have found their way into the process. This second flow chart is most easily created by starting with a copy of the originally designed process and modifying it based on input from the people who actually do the process on a day-to-day basis.
3. The newly redesigned process that incorporates changes needed to accommodate the High 5s requirements and data collection. Again, this third flow chart may be developed by starting with the previously created flow charts describing the actual day-to-day activities and modifying it to display any new or altered steps.

For example:

Step 1 – Define the Process – Patient Preparation for Surgery



Define the Process – Patient Preparation for Surgery – The Redesign for the Process which includes a Sub-Process for Position & Drape Patient

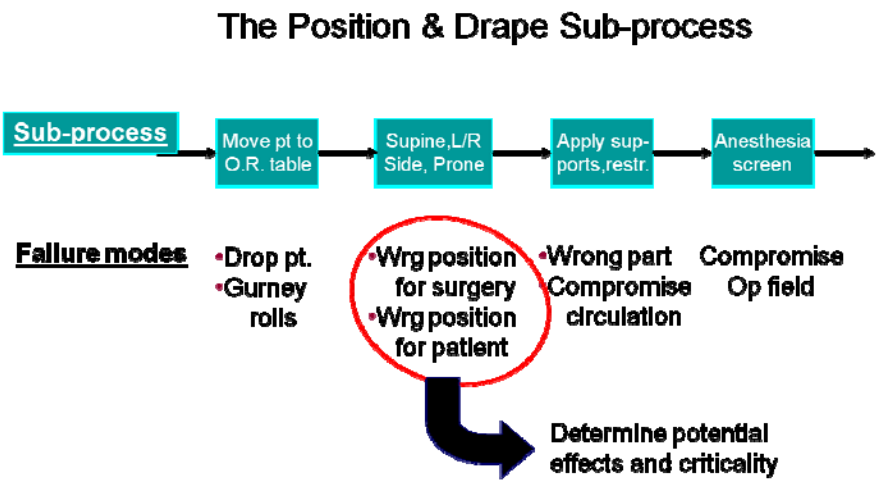


STEP 2 – Identify the Failure Modes/Risk Points

Now comes the fun part: the "What can go wrong?" analysis. This is best done as a brainstorming session by a group of individuals who take part in the process in one way or another (direct care providers or organizational leadership). Someone should be acting as a scribe during this brainstorming session, writing it all down, perhaps in a table format with the following columns: (1) the step, (2) what can go wrong with the step (these are the "failure modes" or "risk points"), (3) what will be the effect of such a failure if it occurs?

Using primarily the third flow chart (the new process which incorporates the High 5s SOP), but not forgetting about referring to other flow charts to compare what is new with and what was originally intended to happen, go through the new process, step-by-step asking "What can go wrong?" and "What if…? Keep in mind the context – how does each step relate to or affect other activities outside of the pre-op preparation process and how do other activities relate to or affect each step of the pre-op preparation process?

1. The inputs to this step—what if an input is missing, faulty, or not on time?
2. The step itself—what can go wrong in the performance of the step?
3. The output of the step—what can go wrong with the hand-over from this step to the next step or next care giver or next location?



STEP 3 – Identify the Effects of the Failures

For each risk point identified, ask

a. What are the likely consequences (the "effects") if a failure in that step occurs?

b. What is the probability (how likely is it) that the failure will occur (i.e., the risk will manifest/happen)?

c. Is it possible to detect, or how likely is it to detect, the risk point before something goes wrong?

Identify the Effects of the Failure – for Patient Preparation for Surgery Sub-Process for Position & Drape Patient

The Step	Failure Mode/Risk Point	Effect if Failure Occurs
Wrong position for **surgery**	Delay in start time	Delay in OR availability
	Poor exposure	Difficult to see operative field
	Wrong site surgery	Wrong site surgery
Wrong position for **patient**	Orthopaedic injury	Additional surgery; longer recovery period
	Ventilatory compromise	Difficulty breathing without assistance

STEP 4 – Prioritize the Failure Modes/Risk Points

It is likely that by the time you have reached this point, you will have come up with a lot of failure modes (things that potentially could go wrong) with the new process. Do not despair! You don't need to deal with all of them. Some failure modes are more important than others, either because they are more likely to happen or because the consequences if they do happen are that much more severe. So we need to identify the most important failure modes by going through the list and prioritizing them—nothing fancy here, just high, medium, or low priority—taking into consideration how likely the failure is and how severe the consequences might be.

Prioritize the Effects of the Failure – for Patient Preparation for Surgery Sub-Process for Position & Drape Patient

Failure Mode/Risk Point	**Effect if Failure Occurs**	**Criticality**
Wrong position for **surgery**	Delay in start time	Low
	Poor exposure	Medium
	Wrong site surgery	High
Wrong position for **patient**	Orthopaedic injury	High
	Ventilatory compromise	Medium

STEP 5 – Identify Causes for High Priority Failure Modes/Risk Points

Now that you have a more manageable list of high-priority failure modes, it's time to figure out what to do about them. For this, we use an abbreviated form of an old favorite: root cause analysis. For each of the high-priority failure modes, the question is, "Why would this failure occur?" In other words, what are the underlying causes of this potential failure?

Identify Causes for High Priority Failure Modes/Risk Points – for Patient Preparation for Surgery Sub-Process for Position & Drape Patient

Failure Mode/Risk Point	**Wrong Position for Surgery**
Direct Cause(s)	Distraction Wrong documentation No time out
Root Cause(s)	Insufficient staffing Inadequate communication

STEP 6 – Redesign the process

Having identified the possible causes of high-priority failures in the new process, we can decide on how to manage these risks. The options are as follows:

a. Redesign the process to eliminate internal causes of potential failures

b. Redesign related processes (the context, as described above) to eliminate external causes of potential failures

c. Introduce "alarm" functions to alert staff as early as possible when something begins to go wrong

d. Introduce controls that limit the degree of failure before it gets "out of control"

e. Introduce protections so the patient is not harmed or the schedule disrupted if the failure does occur

Which of the options is used is up to the team but do whatever will optimize safety and efficiency with the least additional burden.

Principles for Safe and Reliable Preoperative Preparation Processes

Certain general principles for designing safe and reliable processes and systems are specifically applicable to the preoperative preparation process and should be considered in its redesign. These include fail-safe design, redundancy, simplification, and the appropriate use of technology to support and enhance the work of the caregivers.

Fail-safe design: It is usually safer to *not* act (at least for a while) than to act incorrectly. So a process that is designed to detect failure and to interrupt the flow of the process is preferred over a process that will proceed in spite of the failure. In a more general sense, we should favor a process that can, by design, respond automatically to a failure by reverting to a predetermined (usually "safe" or default) mode. This is to "pause" the process to allow for human intervention to assess and deal with the contingency--the adaptation function. Modern software design with its warnings and required confirmations for high-risk actions such as "Confirm delete all files" is an example.

Redundancy: What other ways are there for designing safety into this health care process? In systems design, "redundancy" refers to a back-up, a secondary means of accomplishing what the primary system is designed to do if the primary system fails. Even when well-designed, redundancy always increases the complexity of a process and, therefore, the risk of a failure. The failure of a redundant system will usually not be evident until the redundancy is activated. This establishes an additional requirement for regularly testing and maintaining back-up systems, for example, the emergency power supply for a hospital.

Simplification: Simplicity is desirable. But simplification is not equal to a shortcut. Be very careful not to confuse the two. Taking shortcuts, including breaking safety rules, unfortunately is often without immediate consequences and temporarily relieves the perpetrator of the burden imposed by the rules. This kind of "simplification" is obviously undesirable. Eventually the shortcut will be revealed in the form of an adverse event. Simplification, on the other hand, means designing a process that fully addresses the need without any extraneous parts or motion, thereby eliminating the need for shortcuts.

Technological support: Finally, in designing for safety, the role of technology must be carefully considered. Technology is a tool—actually an extensive, very powerful set of tools, but tools nonetheless. These tools should be seen as complementary to human intervention, not competitive or replacements. Computers and other technology lack the ability to make allowances for incomplete or incorrect information, an important requirement for dealing with complex situations. In other words, computers can't think and aren't flexible. Human judgment is still superior to a machine when dealing with an unanticipated contingency and adjusting the process to avoid harm. Technology is more effective than humans in enhancing process consistency and receiving, storing, and processing information. Technology does not take shortcuts. It is not influenced by emotion. Technology does, though, have certain benefits that should not be ignored, but used together with other risk-reduction strategies.

Pilot testing the SOP (Does not apply to hospitals participating in the "Pre-test")

It is strongly recommended that process changes that involve large numbers of patients or high risk procedures, both of which apply to the preoperative preparation process, be initially implemented on a limited basis—a pilot test—with close monitoring to identify barriers and new risk points. The information gained from such a limited implementation can then be used to refine the new process for further pilot testing or gradual expansion of the implementation, eventually to all relevant areas. The general approach is first to identify one or more pilot test sites. For this SOP, the selection might be based on a particular physical unit such as one of the operating rooms with application of the SOP to all the patients scheduled for surgery in that room; or it could be a specific patient population such as elective orthopedic patients; or a defined time frame such as all patients operated on in the inpatient surgical facility during a designated one week period. Whatever approach is used for defining the scope of the pilot test, it should be representative of the hospital's typical preoperative work flow. Time permitting, it will be very useful to collect baseline data identifying variation in the existing preoperative process before starting the pilot.

Engage front line workers from the pilot test site(s) to participate in the test design, implementation, monitoring and analysis of results. 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 hospital staff when the new process is ready for full implementation. While pilot testing the new process, monitor the consistency, timeliness, and accuracy of implementation of each of the steps in the process (see page 38 for specific measures to use). It is also important to monitor the impact on other related or interfacing activities as well as any measurable impact on the patients. Gather feedback from all the participating staff, including surgeons and anesthesia providers. Analyze the pilot test data and present a report of the test results to the oversight group for a decision on next steps, which might be a redesign of the process or an OK to move forward with full implementation.

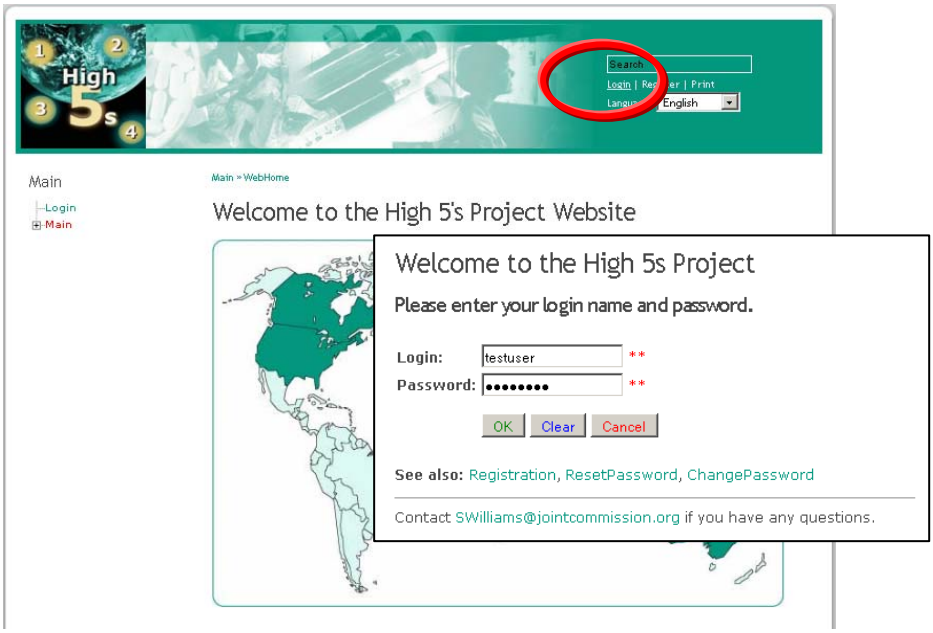
Requesting a Revision or Adaptation of the SOP

The process for requesting an adaptation and/or revision to a Standard Operating Protocol (SOP) requires all requests be submitted by the country's Lead Technical Agency (LTA). Requests originating from a participating hospital should be communicated to that participating hospital's LTA. All requests, regardless of origination (participating hospital or LTA), should be entered into the High 5s Information Management System through the link on the LTA home page.

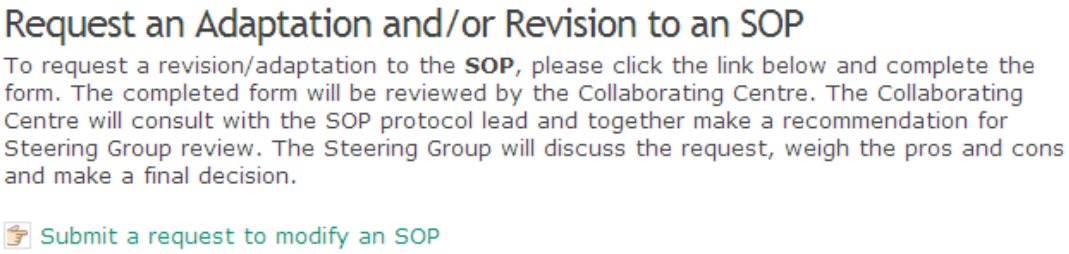
All requests for adaptations or revisions will be reviewed by the Collaborating Centre. The Collaborating Centre will consult with the appropriate SOP protocol lead. Together, the SOP protocol lead and Collaborating Centre will make a recommendation to the Steering Group for discussion and decision.

How to submit a request for an adaptation and/or revision to an SOP:

Step 1: Login to the site

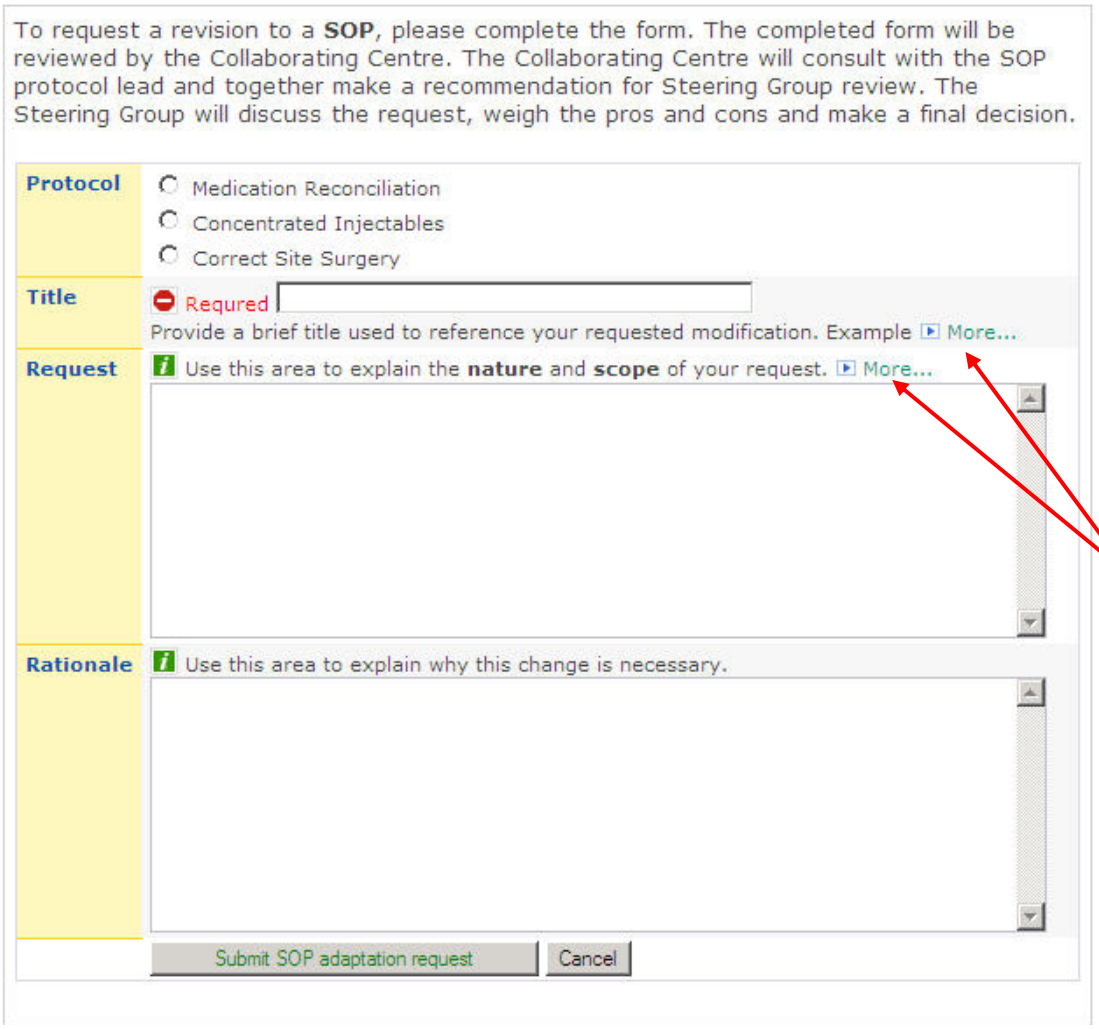


Step 2: Go to your LTA home page. Under the section *Request an Adaptation and/or Revision to an SOP* click "Submit a request to modify an SOP".

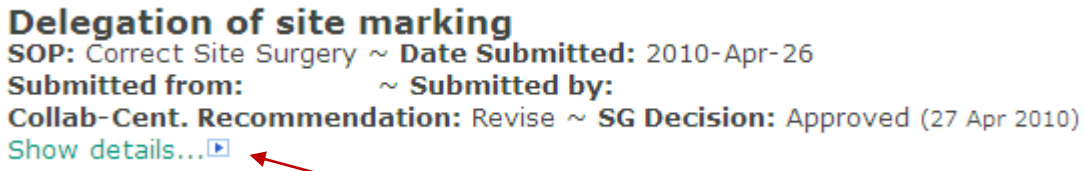


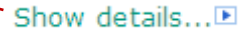
Step 3: Complete the form.

A. Indicate whether this is a request for an adaptation or revision in the *Request Type* section
B. Identify the applicable SOP(s) in the *Protocol* section
C. Provide a brief, descriptive title for the request (e.g., Request to change site marking rules) in the *Title* section
D. Describe the adaptation/revision you would like made to the SOP in the *Request* section
E. Provide a rationale for why the requested adaptation/revision to the SOP is necessary in the *Rationale* section
F. Click *Submit Adaptation Request* at the bottom of the form



Step 4: To confirm that your request was registered in the High 5s Information Management System, return to the LTA home page. A list of all requests originating from your country is shown, along with the Collaborating Centre recommendation and Steering Group decision.



To see the details (request, rationale) and disposition (the Collaborating Centre and Steering Group decisions, including an explanation, the impact), of the request, click 

Progressing to full implementation

Part of the planning process and work plan development will be to determine the sequence and timing of implementation to include all cases done in the hospital's inpatient surgical environment. In large surgical facilities, sequential, rather than concurrent, implementation is recommended to provide for adequate pre-implementation training, oversight and coaching during the early phases of implementation, and close monitoring of the new process.

Maintaining and improving the new process

Once the redesigned preoperative preparation process is fully implemented, ongoing monitoring using the performance measures and evaluation techniques outlined in the next section will continue for the duration of the High 5s initiative and, thereafter, at the discretion of the hospital. Opportunities to improve efficiency and effectiveness of the process may be identified along the way and should be reported as part of the implementation evaluation along with recommendations for improvement of the SOP. 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; or technical support.

Throughout the testing, implementation and maintenance phases of the project, provide feedback to all the participants and other stakeholders on a regular basis with special attention to the "good catches." Incorrect surgery is an infrequent occurrence but good catches are much more common—use them for motivation and recognition of the efforts by staff to improve the safety of your surgical patients.

Frequently Asked Questions (FAQs)

General

Q. What procedures fall within the scope of the SOP?

A. The Correct Site Surgery SOP is applicable to all operative and other invasive procedures scheduled for or done in the group of operating rooms designated for inpatient cases. If outpatient cases are also done in this "inpatient operating environment," they are also included. Participating hospitals may choose to apply the SOP more broadly, but data submitted to the High 5s Project will be limited to procedures done in the inpatient operating room environment.

Pre-operative verification

Q. Is a pre-operative verification check list required?

A. Yes; a pre-operative verification check list is required. The purpose of this check list is to serve as a guide for completing all the steps of the SOP; to document completion of those steps along with any discrepancies and how they were managed; and to collect the required data elements for the High 5s Project.

Site Marking

Q. What about dental procedures? I understand there have been several cases of extraction of the wrong teeth.

A. Since there is no practical or reliable method to directly mark the teeth that are intended for extraction, dental procedures are considered exempt from the site marking requirement. However, because this type of surgery involves "multiple structures," an alternative approach to site identification is required, as follows:

- Review the dental record including the medical history, laboratory findings, appropriate charts and dental radiographs. Indicate the tooth number(s) or mark the tooth site or surgical site on the diagram or radiograph to be included as part of the patient record.
- Ensure that radiographs are properly oriented and visually confirm that the correct teeth or tissues have been charted.

Q. Does the site have to be marked if there is an obvious wound or lesion?

A. In general, site marking is not required if there is an obvious wound or lesion that is the site of the intended procedure. However, if there are multiple wounds or lesions and only some of them are to be treated, and the decision and direction for which ones are to be treated is determined at some time prior to the procedure itself, then the sites to be treated should be marked as soon as possible after the decision is made.

Q. What if the patient refuses site marking?

A. The patient always has the right to refuse. This situation should be handled the same way as for any other refusal by a patient offered care, treatment or services. The organization's responsibility is to provide the patient with information to understand why site marking is appropriate and desirable, and the implications of refusing the site marking. Then the patient can make an informed decision. The SOP does not require that the procedure be cancelled because the patient refuses site marking. The preoperative verification check list has a place to document this situation. Organization policy should describe the related procedural and other documentation requirements.

Q. What is the recommended procedure for marking spinal surgery cases?

A. For spinal surgery, we advise a two-stage marking process. First, the general level of the procedure (cervical, thoracic or lumbar) must be marked preoperatively. If the approach involves anterior versus posterior, or right versus left, then the mark must indicate this. Then, intraoperatively, the exact interspace(s) to be operated on should be precisely marked using the standard intraoperative radiographic marking technique.

Q. Who should mark the site?

A. Effective 27 April 2010, the SOP was revised to allow site marking to be done by the person who will do 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.

Q. Is site marking required for bilateral procedures?

A. While the SOP site marking requirement focuses primarily on lateral procedures or those that involve multiple levels or structures, site marking for bilateral procedures (identical procedure, surgical team and equipment) is recommended but not required unless there is a predetermined plan to operate on a specific side first. In that case, the two sides should be marked in a way that indicates which side is to be done first, such as 1 and 2.

Final Time Out

Q. Sometimes our surgeons are running multiple rooms. We are preparing, positioning and anesthetizing one patient while the surgeon finishes the previous case. In this situation, is it okay for the rest of the team to conduct the time-out without the surgeon?

A. In recognition of the critical role of the surgeon as part of the operative team, it is not allowable under the High 5s SOP to conduct the time-out without the surgeon being present.

Q. Are there situations, such as when there are two separate procedures, when we should conduct more than a single time-out?

A. Whenever there is more than one procedure being performed by separate procedure teams, there needs to be a time-out prior to each team commencing its procedure. This does not apply to those situations where the same team is performing multiple components during a single procedure. In all other circumstances, each organization may define when more than one time-out must be performed. If more than one time out is conducted, data will be submitted to the High 5s Project only for the final (pre-incision) time out.