# The High 5s Project

# Implementation Guide

## Performance of Correct Procedure at Correct Body Site

# Implementation Guide
## for Implementing the Standard Operating Protocol for Performance of Correct Procedure at Correct Body Site

## The High 5s Project

## "Correct Site Surgery"

## Attribution Statement

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

This work is a part of the High 5s Project which has been supported by the Agency for Healthcare Research and Quality, USA, WHO, and the Commonwealth Fund, USA.

The Implementation Guide was developed, tested and refined within the context of the High5s Project, an internationally coordinated, participation activity for testing the feasibility of implementing standardized patient safety protocols and determining the impact of the implementation on certain specified patient safety outcomes.

# Table of Contents

## Introduction

This Implementation Guide 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 determining the success of the implementation and of the impact on reducing the risk of incorrect surgery. A considerable portion of this Implementation Guide will be devoted to the use of a 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 useful data in real time to enable efficient and effective implementation of the SOP.

### A Word about Standardization

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

The High 5s initiative has taken standardization a couple of steps further than the usual efforts to minimize variation—it not only sought to standardize certain processes among individuals within a health care organization but to standardize them in multiple organizations in multiple countries around the world. The High 5s Project posed the following questions: Is it possible to standardize on a multinational scale? If it is, will this effort measurably improve the safety of care? The first of these questions has now been answered as a qualified affirmative. That is, the High 5s Project has demonstrated that a standardized process for preparing patients for surgery, focused on the prevention of wrong site surgery, can be implemented on a multinational scale with minimal adaptation of the protocol. However, while most of the participating hospitals have achieved full implementation of the SOP, some have not and are still in

the process of spreading the implementation to include all eligible sites and patient groups. Also, performance measure data collected over the course of the Project demonstrates significant variation from hospital to hospital and country to country in the consistency of performance of the steps of the SOP. Finally, it should be noted that all but one of the participating countries are classified as developed economies. The question of impact is more difficult to answer, primarily because of the infrequency of the events the SOP is intended to prevent, lack of a reliable baseline of occurrence rate, and the inconsistency of reporting events that do occur. Nonetheless, while impact in terms of a change in outcomes cannot be demonstrated, there has clearly been an impact on the processes for preparing patients for surgery (e.g., evidence of the introduction of surgical site marking where it had not previously been practiced), and on the awareness of and attention to the problem of wrong site surgery and its prevention.

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

## 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.


CORRECT SITE

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 two decades. This may simply be a reflection of improved reporting, but the fact remains there is no evidence that the incidence or frequency of this problem has decreased in recent years despite the introduction of relevant international patient safety goals and standards, the Universal Protocol, the WHO World Alliance for Patient Safety's Solution #4: Performance of Correct Procedure at Correct Body Site, and the WHO 2nd Global Patient Safety Challenge: Safe Surgery Saves Lives.


CORRECT PROCEDURE

Considered preventable occurrences, these cases are largely the result of miscommunication and unavailable or incorrect information. Detailed analyses of these cases indicate that two major factors contributing to error are the lack of a standardized preoperative process and a degree of staff automaticity (checking without thinking) in the approaches to the preoperative check routines.


CORRECT PERSON

### What Has Been the 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 were 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. Preliminary results of the High 5s Project are available in an Interim Report at http://www.who.int/patientsafety/implementation/solutions/high5s/en/

## Where Do Activities to Promote Correct Site Surgery Take Place ?

The principles and detailed procedures of the Correct Site Surgery SOP are applicable wherever surgical and other invasive procedures are performed, including procedure units such as endoscopy and catheterization labs, as well as dedicated obstetrical operating rooms and facilities used exclusively for ambulatory surgery. It should include *all* cases performed in these settings such as day surgery cases, endoscopies, and other interventional procedures. A hospital may initially choose to implement the High 5s procedures and check list in a more limited scope, for example, all cases performed in the hospital inpatient operating room environment. However, the goal over time should be to achieve full implementation as described above.

## 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 staff 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. The High 5s correct site surgery SOP focuses on the preoperative—scheduling, admitting, assessing, testing, preparing—team and the intraoperative team.

Finally, the SOP includes the role of the most important individual on the team: the patient. The effectiveness of the High 5s correct site surgery initiative has been 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 process management strategy (This is the approach to knowing how well you are doing)

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

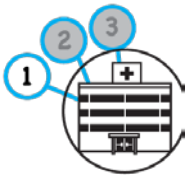
1. The Correct Site Surgery Process
    a. Preoperative verification process
    b. Surgical site marking
    c. Final "time out" before surgery
2. The implementation strategy
    a. Planning for implementation
    b. Pilot testing
    c. Full implementation
3. The process management strategy
    a.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

PREOPERATIVE VERIFICATION

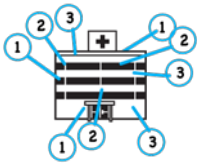
OPERATIVE SITE MARKING

FINAL "TIME OUT" VERIFICATION


PLAN THE IMPLEMENTATION



PILOT TEST



FULL IMPLEMENTATION


MANAGE THE PROCESS

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.

PREOPERATIVE VERIFICATION

2. Marking the operative site
    - *Purpose*: To identify unambiguously the intended site of incision or insertion.
    - *Process*: For procedures involving laterality, or multiple structures, surfaces or levels, the intended site must be marked such that the mark will be visible after the patient has been 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 13). Cases that are exempt from the site marking requirement are still subject to the preoperative verification and final time out processes.

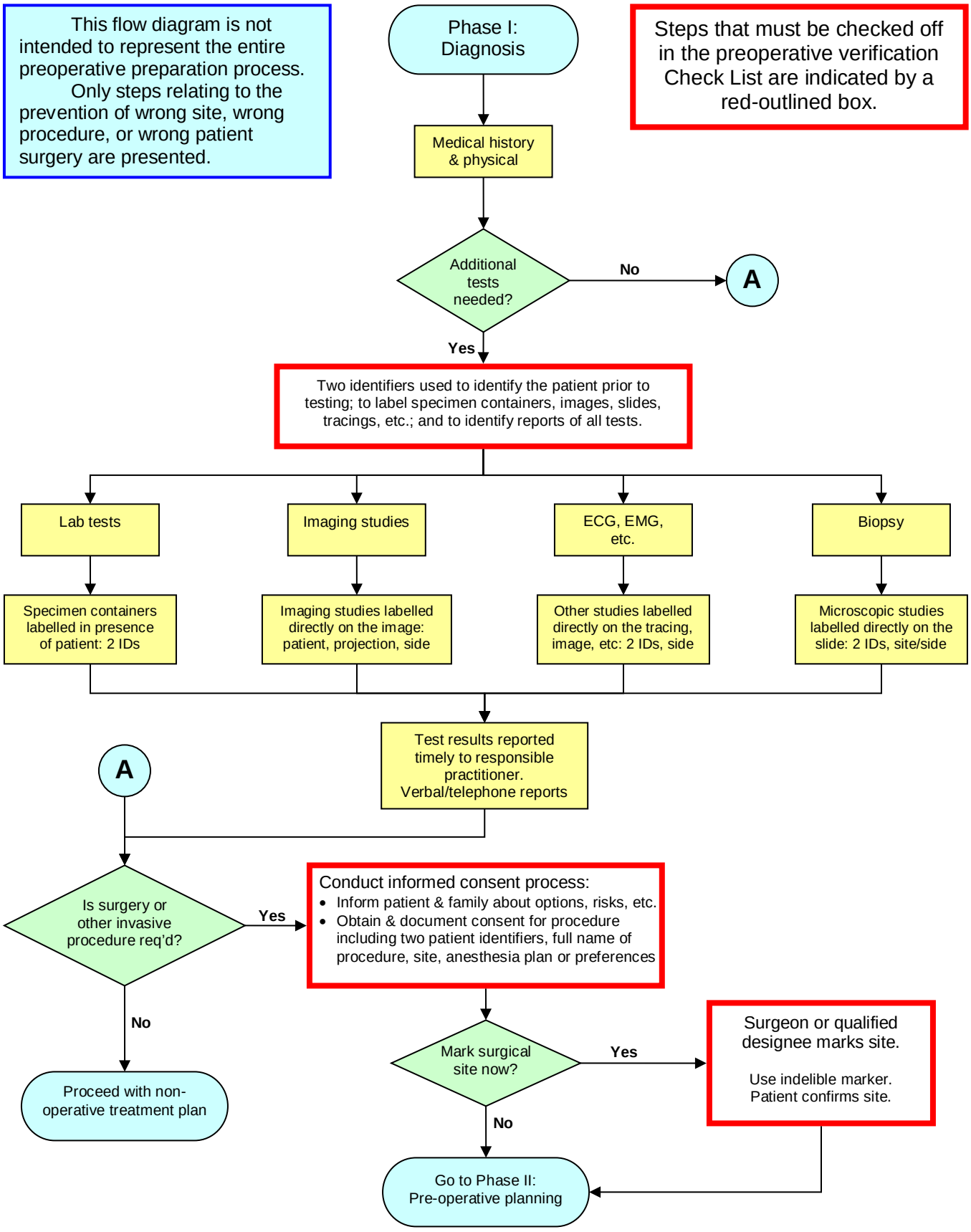
OPERATIVE SITE MARKING

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.

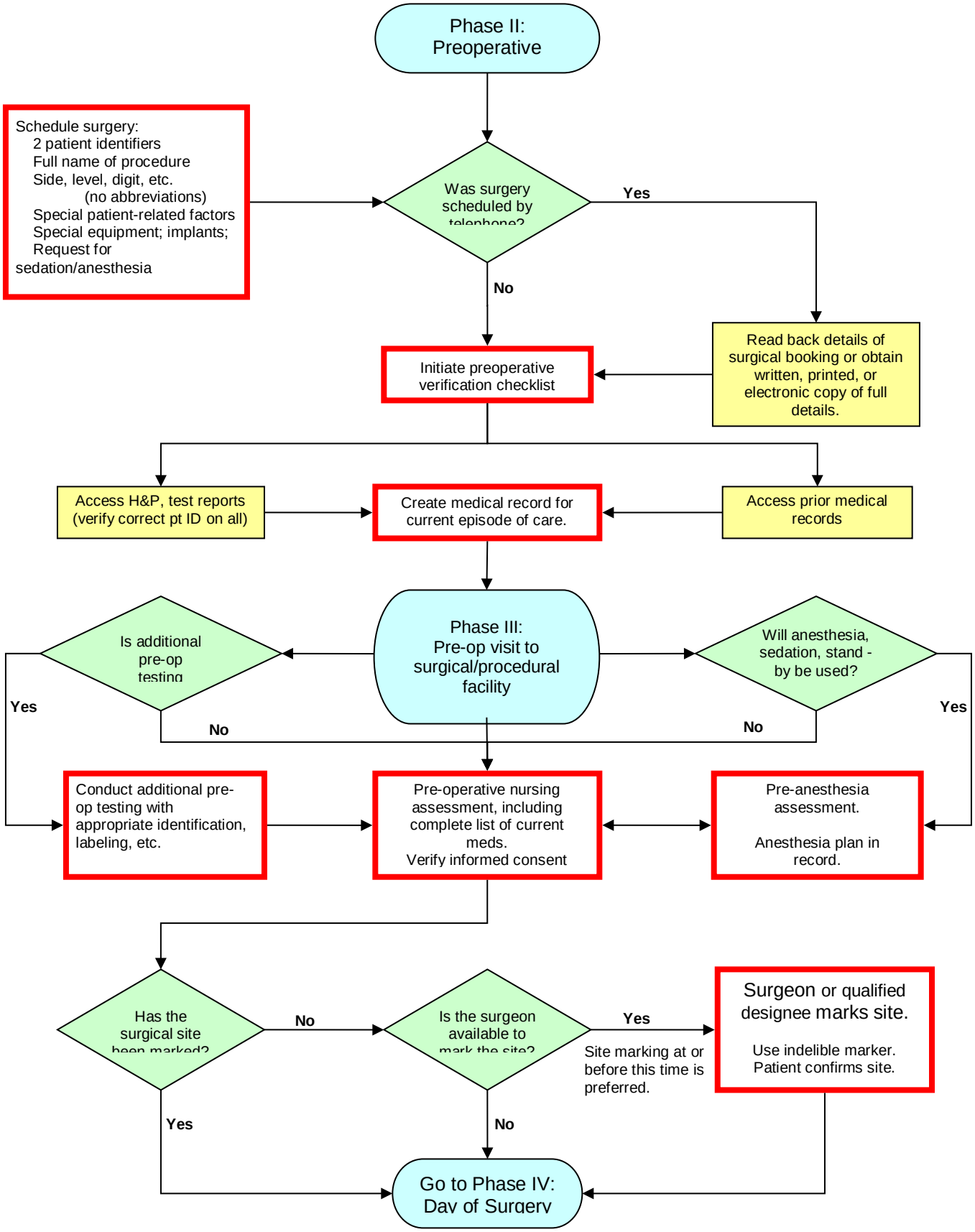
FINAL "TIME OUT" VERIFICATION

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.

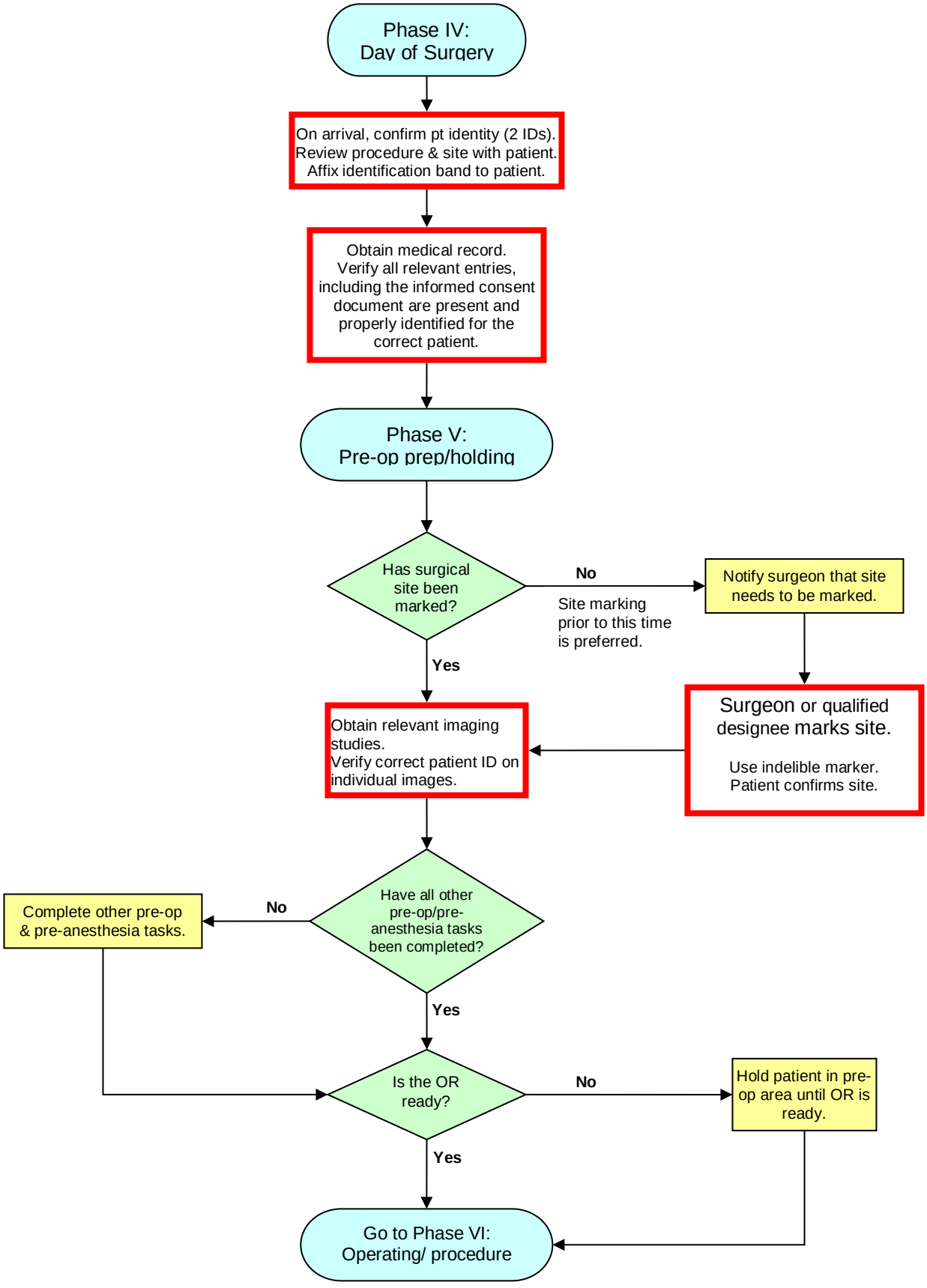
**Preoperative preparation as it relates to Correct Site Surgery, Phase I:**



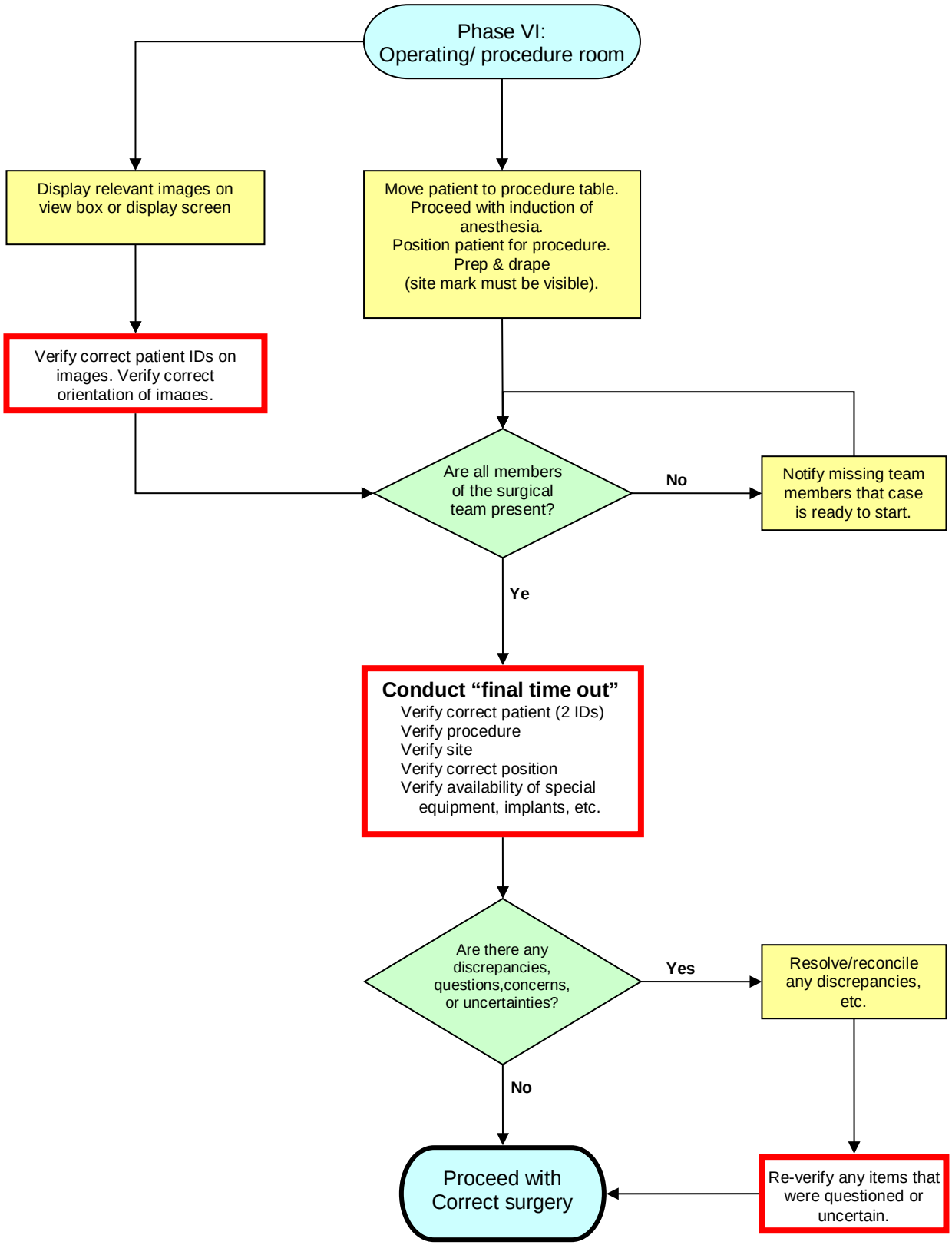
**Preoperative preparation as it relates to Correct Site Surgery, Phases II & III:**



**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

SCHEDULING

TESTING & ASSESSMENTS

ADMISSION

TRANSFER OF CARE

MOVE TO O.R.

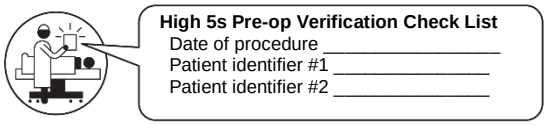
Verification of the correct person, procedure, and site occurs:

- 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 18) should be used as follows:

- To guide staff in implementing the SOP in a consistent manner, and to ensure the availability and review of the following items, 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 special equipment
- To document completion of the steps in the SOP
- To collect data *in real time* to support management of the SOP processes.




## *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.


OPERATIVE SITE MARKING

MARKING IS DONE BY THE SURGEON OR OTHER QUALIFIED PERSON

- 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 national/health-system oversight body or by the individual surgical facility if it is not part of a national or health system implementation program. For example, the surgeon's initials or a line representing the proposed incision may be used. In general, use of "X" to mark the intended site is not recommended, as it may be interpreted as "do not operate here." However, if "X" has been accepted as the standardized method of site marking in the hospital, health care system, or country (for example, as in Germany), then continued use of this method in the context of this SOP will be acceptable.
- The method of marking and type of mark is consistent for all applicable cases throughout the scope of implementation of this SOP, whether an individual hospital, health system or country.
- The mark is positioned to be visible after the patient is prepped and draped.
- The mark is made using a skin marker that is sufficiently permanent to remain visible after completion of the skin prep. Adhesive site markers are not used as the sole means of marking the site.
- 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.

WHENEVER POSSIBLE, THE PATIENT IS INVOLVED IN THE SITE MARKING

THE MARK IS VISIBLE AFTER PREP & DRAPE

THE MARK CANNOT BE WASHED OFF BY THE SKIN PREP

- 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 "final 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


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 Final 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 Final 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 Final 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 Final Time Out as well as any discrepancies between the responses and the informed consent document and other available documentation.
- The Final 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 Final Time Out is documented on the Preoperative Verification Check List.

THE FINAL "TIME OUT" VERIFIES THE FOLLOWING:


PATIENT IDENTITY

SIDE / SITE

PROCEDURE

PATIENT POSITION

IMPLANTS / EQUIPMENT

NO SURGERY UNTIL ALL CONCERNS ARE RESOLVED

## Tips for an effective and reliable Time Out:

The effectiveness of the Time Out in identifying discrepancies is entirely dependent on the degree to which the participants are able to focus on the information being exchanged and the documents that bear that information. This is not a time for multi-tasking. Ideally, during the Time Out, the only other awareness of the participants should be the well-being of the patient. In fact, the Time Out should not be commenced until the anesthesia provider confirms that the patient is sufficiently stable for the operation to proceed. One way to ensure this is to assign responsibility for initiating the Time Out to the anesthesia provider. One of the most obvious attributes of a well-functioning surgical team is the singular focus, during the procedure, of each member of the team on his or her specific responsibilities. To the extent that the Time Out can be considered the *first step of the procedure*, this same degree of mindfulness will ensure its effectiveness in protecting the patient from harm.

**The final time out may be facilitated and standardized by using a script that identifes what is to be verified, who the participants are and what their roles are in the time out. An example, which has been compiled from samples provided by High 5s participating hospitals, is provided below.**

## Sample Time Out Script

**Time Out initiator** (typically the surgeon or circulating nurse) calls for the Time Out when the team is ready to start the procedure.

All other activity pauses; team focuses on the Time Out.

**Circulating nurse:** Reads aloud the patient's name, procedure and procedure site from the informed consent document that has been verified during pre-op and asks the team to verify.

*Example:* "This is John Smith, MR#. We are doing a left hip replacement. Please verify."

**Anesthesia provider:** States patient's name, procedure and site from documentation.

*Example:* "John Smith, MR#. We are doing a left hip replacement."

**Scrub Person (and assistant surgeon, if applicable):** Verifies which procedure they have prepared for.

Example: "I'm set up for a left hip replacement."

**Circulating nurse:** Requests visualization of the site mark (if applicable)

**Scrub Person (and assistant surgeon, if applicable):** visualizes the mark and indicates aloud that he/she sees the mark and where it is located.

*Example:* "I see the mark, it is on the left hip."

**Surgeon:** States full procedure and site from memory.

**Circulating nurse:** Are images present and correct?

**Surgeon:** Confirms presence and correctness of images.

*Example*: "The images are on the screen. I've checked them. They're correct."

**Circulating nurse:** Are the implants and equipment present and correct for this procedure?

**Scrub Person:** visualizes the implants and instruments/equipment and indicates aloud that all is available in the OR.

*Example*: "Yes, I have the set of implants for a left hip replacement."

**This example includes the basic Time Out content. Hospital policy may also specify final checks on other aspects of the surgical procedure, such as anticipated blood loss and availability of blood for transfusion, prophylactic antibiotic administration, or other special considerations related to the patient or procedure.**

## 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 than 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 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 based on 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. If multi-hospital implementation of the SOP is being coordinated by an oversight body (for example, a Ministry of Health or a Health System central office), any hospital-specific adaptations of this SOP should be approved by the oversight body 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 Surgical Safety Checklist?

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 practice, 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 potential 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 consider 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 programme of the WHO Patient Safety Programme. The goal of this Challenge was 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 has been a collaboration among a group of countries, the 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 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 optimize the effectiveness of implementing the High 5s SOP, participating hospitals should adhere to the SOP as written and track 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 available tools and methods 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 targeted several different types of particularly challenging adverse events, has been 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 agreed 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. These evaluation tools and techniques are now made available through this Implementation Guide to all hospitals choosing to implement the Correct Site Surgery SOP as a means for managing and sustaining implementation of the SOP and for evaluating its success.

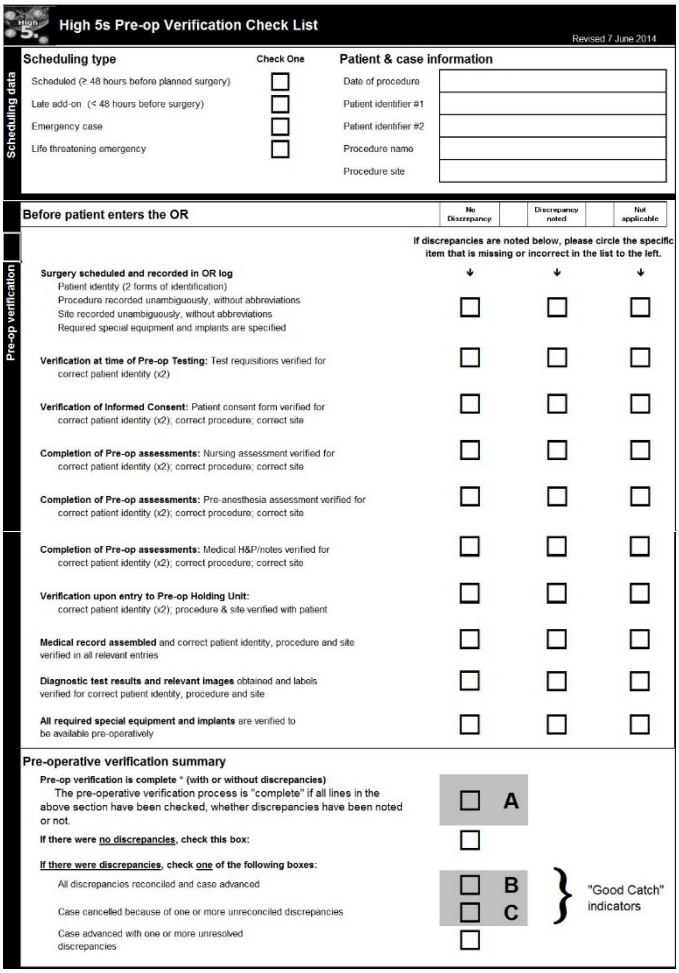
By contrast, the WHO Surgical Safety Checklist is directed at preventing a spectrum of surgical complications and has been widely distributed around the world. It includes no provision for measurement and evaluation activities. The principal dissemination and implementation strategy has been to encourage 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 implement the High 5s Correct Site Surgery SOP. An example of how this might be achieved is provided in Appendix 1 of this Implementation Guide.

# 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 data *in real time* to manage the process. 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 many useful 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 5s Pre-op Verification Check List

Revised 7 June 2014

Scheduling data

| Scheduling type | Check One |
|---|---|
| Scheduled (≥ 48 hours before planned 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

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 * (with or without discrepancies)** ☐ A

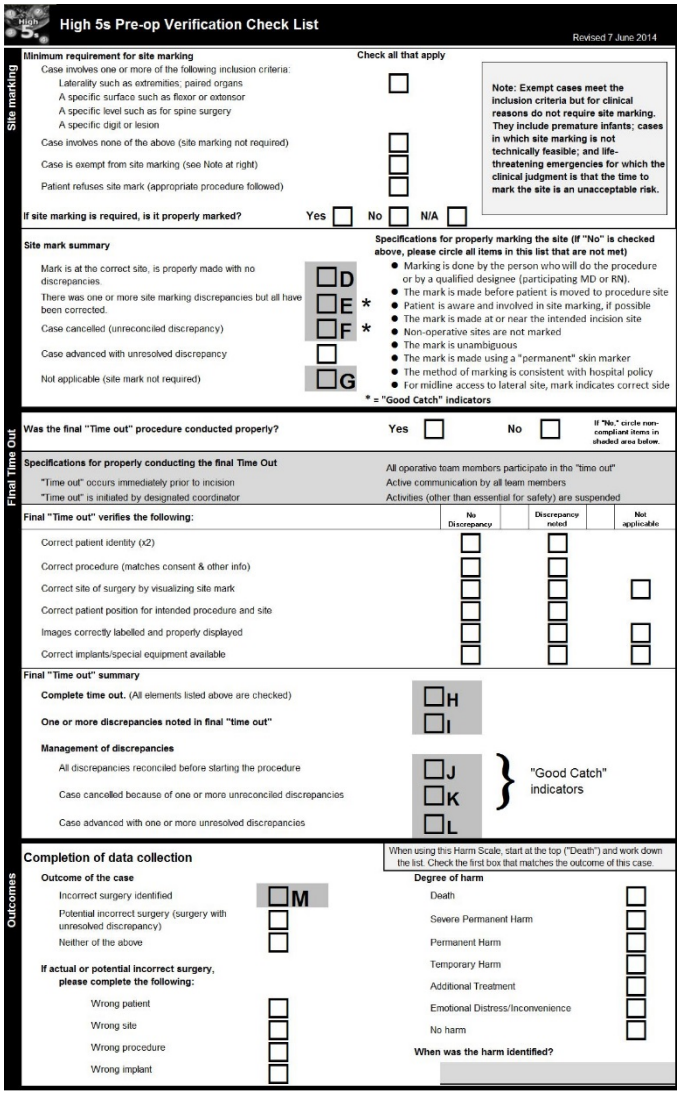
The pre-operative verification process is "complete" if all lines in the above section have been checked, whether discrepancies have been noted or not.

**If there were no discrepancies, check this box:** ☐

**If there were discrepancies, check one of the following boxes:**

- All discrepancies reconciled and case advanced ☐ B
- Case cancelled because of one or more unreconciled discrepancies ☐ C
- Case advanced with one or more unresolved discrepancies ☐

} "Good Catch" indicators



High 5s Pre-op Verification Check List

Revised 7 June 2014

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 ☐

**Site mark summary**

- Mark is at the correct site, is properly made with no discrepancies. ☐ D
- There was one or more site marking discrepancies but all have been corrected. ☐ E *
- Case cancelled (unreconciled discrepancy) ☐ F *
- Case advanced with unresolved discrepancy ☐
- Not applicable (site mark not required) ☐ G

**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 (participating MD or RN).
- 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
- 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

* = "Good Catch" indicators

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) ☐ H

**One or more discrepancies noted in final "time out"** ☐ I

**Management of discrepancies**
- All discrepancies reconciled before starting the procedure ☐ J
- Case cancelled because of one or more unreconciled discrepancies ☐ K
- Case advanced with one or more unresolved discrepancies ☐ L

} "Good Catch" indicators

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 ☐ M
- 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/Inconvenience ☐
- No harm ☐

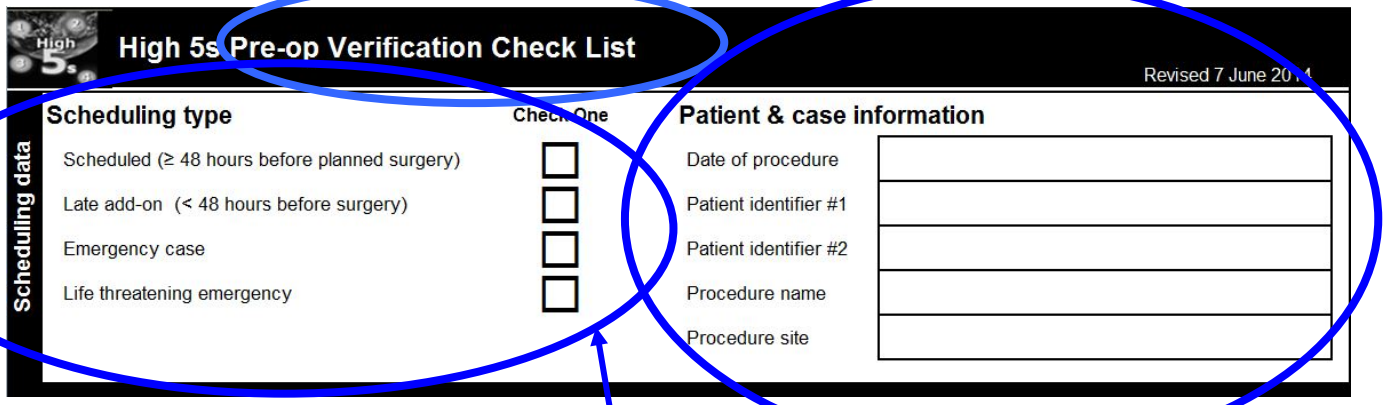
**When was the harm identified?**

## 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 implementing the High 5s Correct Site Surgery SOP, a Check List that includes all of the SOP process steps and useful data elements should be used.

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.




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

**Note:**
Once initiated, the check list should be available at each step of the pre-op process (see next page) to be filled out by staff as the patient is prepared for surgery.

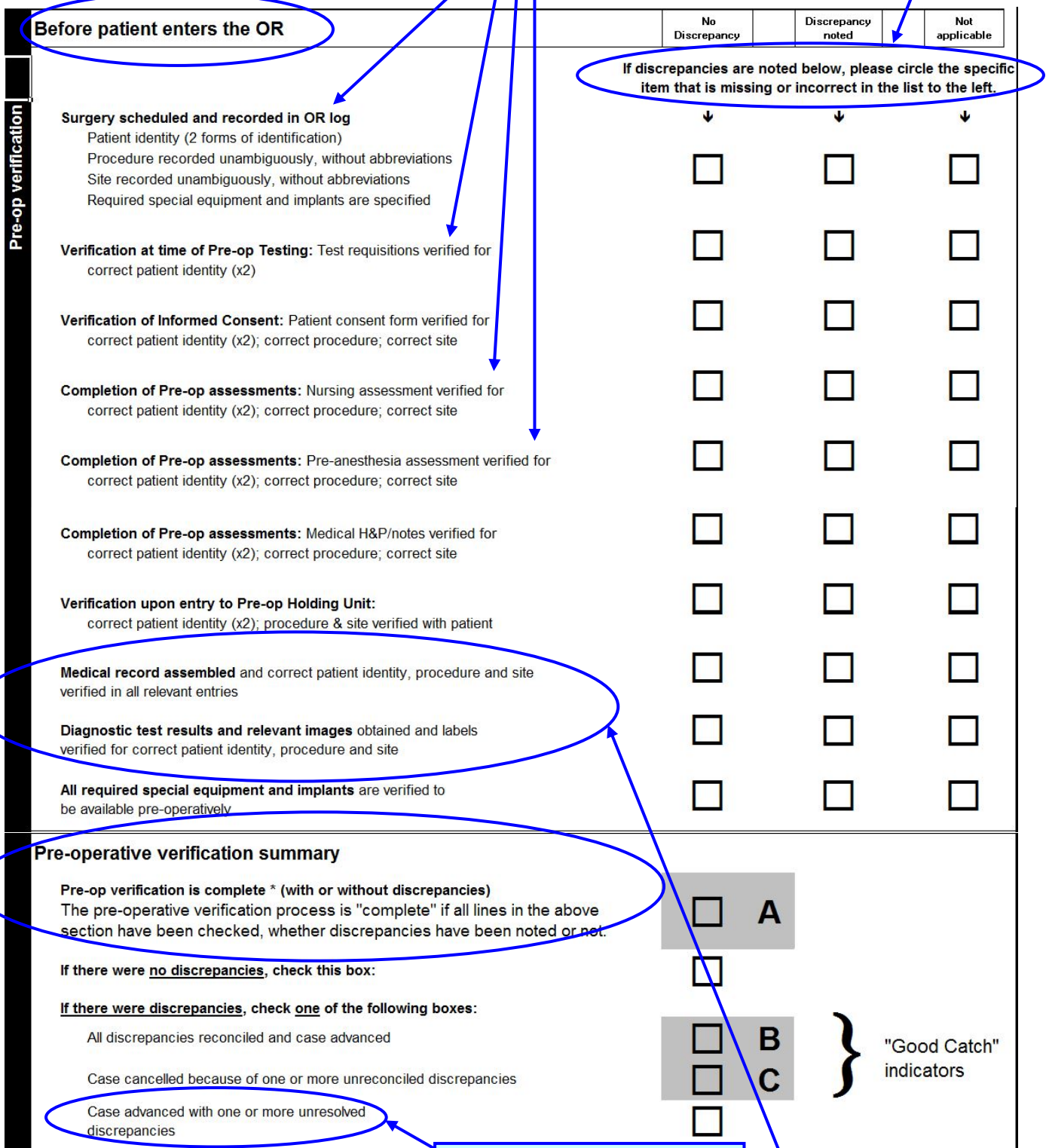
**This is the rest of Page 1 of the Preoperative Verification Check List. It should be completed before the patient is brought into the operating room where the procedure will be done.**

**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).




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

All unresolved discrepancies must be identified verbally to staff involved in subsequent pre-op steps so they can be addressed prior to start of surgery.

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

## Item-by-Item Tips for Completing The High 5s CSS Check List (continued)

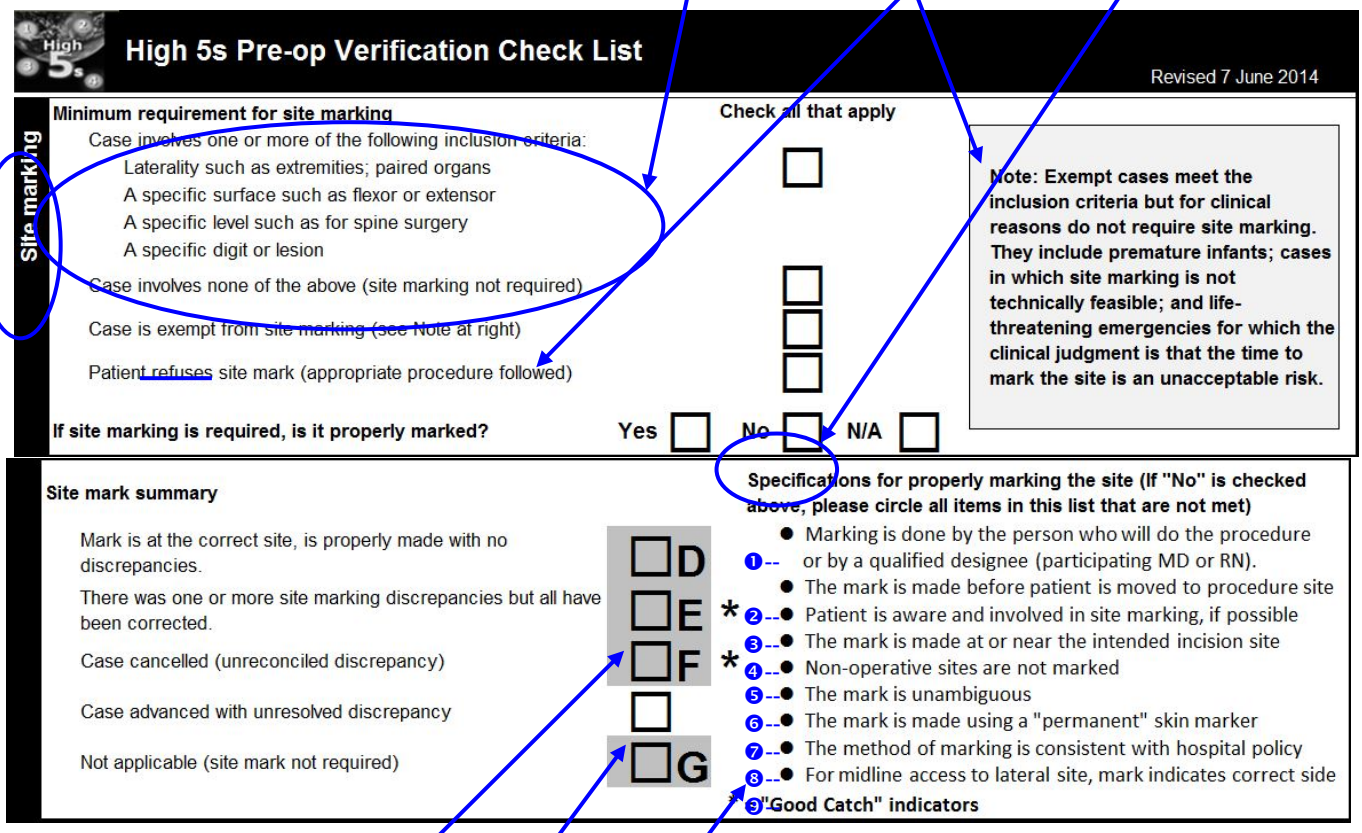
**This is the top portion of Page 2 of the Preoperative Verification Check List.**

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.

If any specifications for proper site marking are not followed, this is a discrepancy and the "No" box should be checked here.



**High 5s Pre-op Verification Check List** — Revised 7 June 2014

**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)

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

**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.**

**Site mark summary**

- Mark is at the correct site, is properly made with no discrepancies. ☐ D
- There was one or more site marking discrepancies but all have been corrected. ☐ E *
- Case cancelled (unreconciled discrepancy) ☐ F *
- Case advanced with unresolved discrepancy ☐
- Not applicable (site mark not required) ☐ G

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

❾ "Good Catch" indicators

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 any time 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.

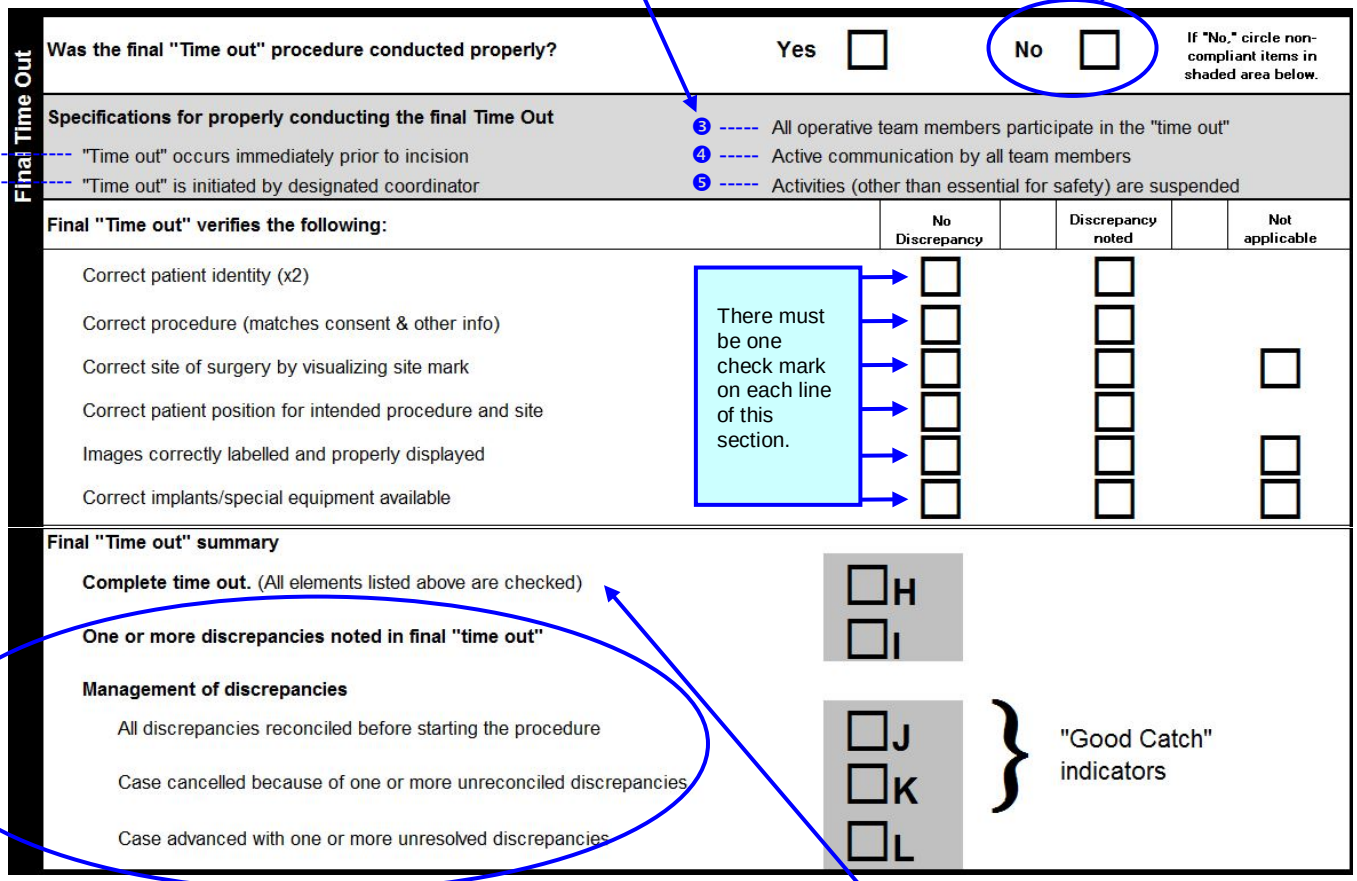
❷ To promote consistency, the same member of the surgical team should initiate the time out in all cases—for example, the surgeon or circulating nurse or other.

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.




**Event analysis** is recommended for cases in which the following have occurred:

- An actual incorrect surgery (data element M, next page)
- Case advanced with unresolved discrepancy (L)

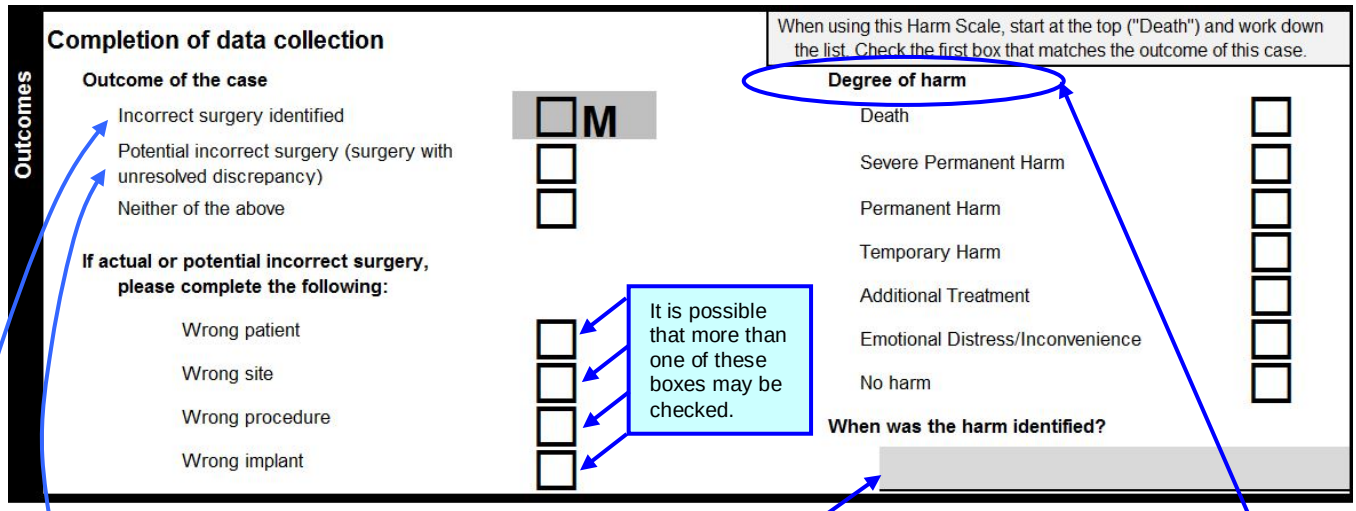
See section on event analysis for details on types and methods of analysis.

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.

## Item-by-Item Tips for Completing The High 5s CSS Check List (continued)

### 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.
**Event analysis is recommended.**

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.
**Event analysis is recommended.**

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 Project, 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 implementing the High 5s Correct Site Surgery SOP, hospitals are encouraged 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 data *in real time* to support management of the SOP processes.

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 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) 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 should be used consistently for all cases
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 in Appendix 1 of this Implementation Guide:

# 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 Correct Site Surgery SOP, 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?
- 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 an implementation 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

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 implement the Correct Site Surgery SOP. 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

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

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:

ENSURE ALL DISCIPLINES & FUNCTIONS ARE REPRESENTED

- 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 communication of data and information are important parts of process management, 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.

## Constructing a Detailed Implementation Work Plan


DEVELOP A TASK LIST

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 30) but other models may be used, especially if more familiar to the project coordinator. 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:


ASSIGN RESOURCES


IDENTIFY TIME LINE, DELIVERABLES & MILESTONES

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


IDENTIFY DEPENDENCIES & 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 30. 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?


DEVELOP A TASK LIST

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?


ASSIGN RESOURCES

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 that the hospital has projected for this implementation project. For example:

- July: Train staff on hospital units chosen for participation in the pilot test (if one is to be done)
- August-September: Pilot test conducted in selected units
- September: Training continues for staff not participating in the pilot test
- October: Update hospital training based on the results of the pilot test
- November-December: Spread implementation to all areas within scope of SOP
- January 1: Target date for full implementation of SOP

IDENTIFY TIME LINE, DELIVERABLES & MILESTONES

### 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 due dates. Milestones should include at least the following:

- Approval of the project work plan by hospital leadership or other oversight group
- Approval of the pilot test design
- "Go-live" date for the pilot test
- Presentation of pilot test results to hospital leadership or other oversight group
- "Go-live" date for full implementation (usually 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.

IDENTIFY DEPENDENCIES & CRITICAL PATH

## 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.

This Gannt chart is shown only for a 6-month period. Many activities may continue indefinitely.

### 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 |
|---|---|---|---|---|---|---|---|
| | | Time line → | | | | | 2014 (Jun, Jul, Aug, Sep, Oct, Nov, Dec) |
| A | **Define project management team** | | 06/01/14 | 30 | 7/1/14 | | 100% |
| A1 | Identify oversight group | CEO | 06/01/14 | 7 | 6/8/14 | | 100% |
| A2 | Assign project coordinator | CEO | 06/01/14 | 7 | 6/8/14 | | 100% |
| A3 | Identify senior administrator "contact" for resource decisions | CEO | 06/01/14 | 7 | 6/8/14 | | 100% |
| A4 | Select team with representation from each professional discipline | PC | 06/01/14 | 30 | 7/1/14 | | 100% |
| A5 | Identify direct caregiver "champions" from each discipline/function | PC | 06/01/14 | 30 | 7/1/14 | | 100% |
| B | **Communicate with staff** | | 06/01/14 | 578 | 12/31/15 | | 14% |
| B1 | Announce decision to implement the High 5s SOP | CEO | 06/01/14 | 7 | 6/8/14 | | 100% |
| B2 | Present and publish the hospital's rationale for implementing the High 5s SOP | PC | 06/01/14 | 30 | 7/1/14 | | 100% |
| B3 | Provide periodic feedback to staff participating in and effected by the SOP implementation | PC | 07/01/14 | 548 | 12/31/15 | | 0% |
| B4 | Publicly recognize the effort, contributions, and successes of all participants | CEO | 07/01/14 | 548 | 12/31/15 | | 0% |
| C | **Develop work plan** | | 06/01/14 | 214 | 1/1/15 | | 14% |
| C1 | Flow chart existing pre-op process | PT | 06/08/14 | 7 | 6/15/14 | | 100% |
| C2 | Identify differences from High 5s SOP pre-op process | PT | 06/15/14 | 7 | 6/22/14 | | 100% |
| C3 | Reconcile differences by developing a redesigned process that includes features of both processes | PT | 06/15/14 | 21 | 7/8/14 | | 67% |
| C4 | Champions identify details of change, barriers, and needed resources for their areas of responsibility | CH | 06/22/14 | 14 | 7/8/14 | | 50% |
| C5 | Identify milestones/deadlines outside the control of the project team (see below for placement) | CEO | 06/08/14 | 7 | 6/15/14 | ◆ | 100% |
| C5a | Approval of project work plan | | 09/01/14 | 0 | 9/1/14 | | |
| C5b | Approval of pilot test design | | 10/01/14 | 0 | 10/1/14 | | |
| C5c | "Go live" date for pilot test | | 11/01/14 | 0 | 11/1/14 | | |
| C5d | Present pilot test results to oversight group | | 12/01/14 | 0 | 12/1/14 | | |
| C5e | Approval of full implementation plan | | 12/15/14 | 0 | 12/15/14 | | |
| C5f | "Go live" date for full implementation | | 01/01/15 | 0 | 1/1/15 | | |
| C6 | Define necessary steps to implement the redesigned process in all areas | PT | 07/15/14 | 16 | 7/31/14 | | 0% |
| C6a | Scheduling | PT | 07/15/14 | 16 | 7/31/14 | | |
| C6b | Pre-op testing (lab, imaging, ECG) | PT | 07/15/14 | 16 | 7/31/14 | | |
| C6c | Informed consent | PT | 07/15/14 | 16 | 7/31/14 | | |
| C6d | Pre-op nursing assessment | PT | 07/15/14 | 16 | 7/31/14 | | |
| C6e | Pre-anesthesia assessment | PT | 07/15/14 | 16 | 7/31/14 | | |
| C6f | Medical history & physical exam | PT | 07/15/14 | 16 | 7/31/14 | | |
| C6g | Pre-op holding unit | PT | 07/15/14 | 16 | 7/31/14 | | |
| C6h | Assembled medical record | PT | 07/15/14 | 16 | 7/31/14 | | |
| C6i | Pre-op test results | PT | 07/15/14 | 16 | 7/31/14 | | |
| C6j | Special equipment/implants | PT | 07/15/14 | 16 | 7/31/14 | | |
| C7 | For each area, identify needed inputs and sources | CH | 07/22/14 | 16 | 8/7/14 | | 0% |
| C8 | For each area, identify deliverables and to whom delivered | PT | 07/22/14 | 16 | 8/7/14 | | 0% |
| C9 | For each step, assign responsibility for completion (champion or team member) | PT | 07/22/14 | 16 | 8/7/14 | | 0% |
| C10 | For each step, estimate start date, time needed for completion, and due date | PT | 07/22/14 | 16 | 8/7/14 | | 0% |
| C11 | For each step, identify dependencies | PT | 07/22/14 | 16 | 8/7/14 | | 0% |
| C12 | For each step, identify resource needs | PT | 07/22/14 | 16 | 8/7/14 | | 0% |
| C13 | Determine critical path and adjust timing of steps to meet uncontrollable milestones | PT | 08/03/14 | 7 | 8/10/14 | | 0% |
| C14 | Define site-specific adaptations that are necessary and allowable with project team approval | Ch | 08/03/14 | 7 | 8/10/14 | | 0% |
| C15 | Review and revise as needed | PT | 08/11/14 | 10 | 8/21/14 | | 0% |
| C16 | Confirm team's acceptance of draft work plan | PT | 08/21/14 | 2 | 8/23/14 | | 0% |
| C17 | Present to oversight group | PC | 08/21/14 | 2 | 8/23/14 | | 0% |
| C18 | Revise as directed by oversight group | PT | 08/23/14 | 8 | 8/31/14 | | 0% |
| C19 | Approve work plan | OG | 09/01/14 | 0 | 9/1/14 | | 0% |
| C20 | Monitor progress of work plan | PC | 09/01/14 | 122 | 1/1/15 | | 0% |

Solid bars indicate the full duration of the task. The inner white bar indicates the portion that has been 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

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 |
|---|---|---|---|---|---|---|---|
| | | | Time line → | | | | 2014 |
| D | **Risk assess the redesigned process** | | 09/01/14 | 14 | 9/15/14 | | 0% |
| D1 | Update flow chart to include all aspects of redesigned process | PC | 09/01/14 | 7 | 9/8/14 | | 0% |
| D2 | Identify failure modes at each step and link between steps (hand-offs) | PT | 09/07/14 | 7 | 9/14/14 | | 0% |
| D3 | Identify potential effects of failure modes on stability and outcomes of pre-op process | PT | 09/07/14 | 7 | 9/14/14 | | 0% |
| D4 | Prioritize failure modes based on probable frequency, effects, and detectability | PT | 09/07/14 | 7 | 9/14/14 | | 0% |
| D5 | For the high priority failure modes, determine what might cause them | PT | 09/07/14 | 7 | 9/14/14 | | 0% |
| D6 | Based on results of risk assessment, propose redesign of the process | PT | 09/14/14 | 7 | 9/21/14 | | 0% |
| D7 | Approve the redesigned process | OG | 09/21/14 | 0 | 9/21/14 | | 0% |
| E | **Pilot test the process** | | 08/01/14 | 153 | 1/1/15 | | 0% |
| E1 | Define scope of pilot test | PT | 08/01/14 | 3 | 8/4/14 | | 0% |
| E2 | Identify test site(s) / unit(s) / population(s) | PT | 08/01/14 | 3 | 8/4/14 | | 0% |
| E3 | Meet with all direct care givers at the pilot test sites to explain purpose of pilot test and hear concerns | PC/CH | 09/14/14 | 16 | 9/30/14 | | 0% |
| E4 | Apply adaptations of proposed new process necessitated by unique features of test sites | PT | 10/01/14 | 14 | 10/15/14 | | 0% |
| E5 | Approval of adaptations by project team | PT | 10/12/14 | 3 | 10/15/14 | | 0% |
| E6 | Train staff at pilot test sites (see below) | PC/CH | 10/15/14 | 16 | 10/31/14 | | 0% |
| E7 | Implement new process at pilot test sites | US | 11/01/14 | 0 | 11/1/14 | | 0% |
| E8 | Measure & analyze results of pilot test (see below) | DA | 11/01/14 | 29 | 11/30/14 | | 0% |
| E9 | Report results of pilot test to oversight group | PC | 12/01/14 | 0 | 12/1/14 | | 0% |
| F | **Full Implementation** | | 08/01/14 | 517 | 12/31/15 | | 0% |
| F1 | Determine sequence and timing of implementation in all units involved in pre-op preparation of cases | PT | 08/01/14 | 3 | 8/4/14 | | 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 | 11/01/14 | 30 | 12/1/14 | | 0% |
| F3 | Apply adaptations of new process necessitated by unique features of implementation sites | PT | 12/01/14 | 7 | 12/8/14 | | 0% |
| F4 | Approval of adaptations by project team | PT | 12/07/14 | 3 | 12/10/14 | | 0% |
| F5 | Approval of full implementation plan | OG | 12/15/14 | 0 | 12/15/14 | | 0% |
| F6 | Train staff at implementation sites (see below) | PC/CH | 12/01/14 | 30 | 12/31/14 | | 0% |
| F7 | Implement new process at implementation sites | US | 01/01/15 | 0 | 1/1/15 | | 0% |
| F8 | Monitor and report results of implementation (see below) | DA | 01/01/15 | 364 | 12/31/15 | | 0% |
| G | **Evaluate implementation and impact** | | 08/01/14 | 578 | 12/31/15 | | 5% |
| G1 | Performance measurement | | 08/01/14 | 578 | 12/31/15 | | 5% |
| G1a | Assign responsibility for collecting and analyzing performance data | PC | 08/01/14 | 7 | 8/8/14 | | 100% |
| G1b | Review the available performance measures and decide which measures to use at various stages of SOP implementation. (Note that the measures may change as the process | DA | 08/01/14 | 75 | 10/15/14 | | 0% |
| G1c | Begin data collection (using Pre-op Verification Check Lists) | US | 11/01/14 | 0 | 11/1/14 | | 0% |
| G1d | aggregate data for selected performance measures. | DA | 11/01/14 | 425 | 12/31/15 | | 0% |
| G1e | Conduct quality checks on the data | DA | 11/01/14 | 425 | 12/31/15 | | 0% |
| G1f | Identify cases for event analysis | DA/US | 11/01/14 | 425 | 12/31/15 | | 0% |
| G1g | Report results to project team & oversight group | DA | 11/27/14 | 3 | 11/30/14 | | 0% |
| G2 | Event analysis | | 08/01/14 | 153 | 1/1/15 | | 0% |
| G2a | Develop and implement method for identifying cases for possible event analysis (certain data elements on Check List; independent reports) | PT | 08/01/14 | 7 | 8/8/14 | | 0% |
| G2b | Conduct event analysis on each case identified by performance data analyst or independent report | PC/US | 11/01/14 | 425 | 12/31/15 | | 0% |
| G2c | Report results of event analyses to project team & oversight group | PC | 11/27/14 | 3 | 11/30/14 | | 0% |
| G3 | Implementation evaluation | | 01/01/15 | 364 | 12/31/15 | | 0% |
| G3a | Complete and submit narrative questionnaire | US | 01/01/15 | 31 | 2/1/15 | | 0% |
| G3b | Participate in unit visits / interviews | ALL | 05/01/15 | 0 | 5/1/15 | | |
| H | **Maintain and improve the new process** | | 11/01/14 | 425 | 12/31/15 | | 0% |
| H1 | Continue ongoing performance measurement and event analyses | PC/DA/US | 11/01/14 | 425 | 12/31/15 | | 0% |
| H2 | Identify opportunities to improve the consistency, timeliness, and accuracy of SOP implementation | PC/US | 11/01/14 | 60 | 12/31/14 | | 0% |
| H3 | Report opportunities to improve SOP implementation to the project team | PC | 12/01/14 | 0 | 12/1/14 | | 0% |
| H4 | Take steps to maintain and improve the SOP implementation | PT | 12/01/14 | 395 | 12/31/15 | | 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 implementing this SOP, 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.

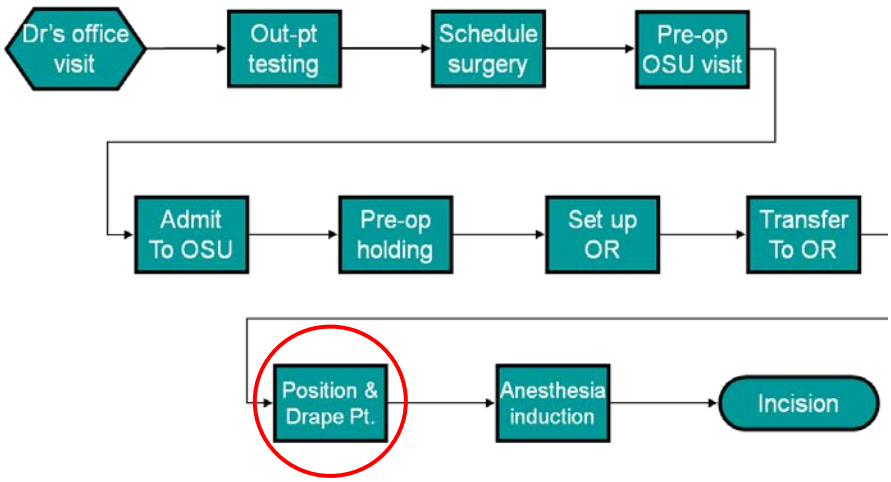
### STEP 1 – Define the Process

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 implementing this SOP (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 steps in the High 5s SOP. 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 – Flow chart the Process – for example, Patient Preparation for Surgery*




*Further refine the Process flow chart to include relevant sub-processes – for example, the Sub-Process for Position & Drape Patient*

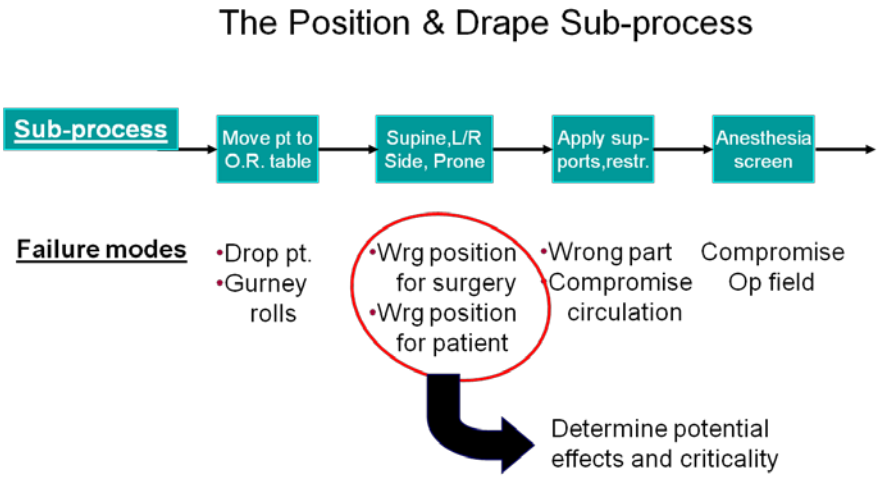

**STEP 2 – Identify the Failure Modes/Risk Points**

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?

*Identify the Failure Modes/Risk Points – for Patient Preparation for Surgery Sub-Process for Position & Drape Patient*



**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<br>Wrong documentation<br>No Final Time Out |
| Root Cause(s) | Insufficient staffing<br>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.

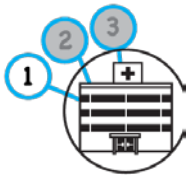
*Fail-safe design:* It is usually safer to *not* act (at least for a while) than to act incorrectly. So a process that is designed to detect failure and to interrupt the flow of the process is preferred over a process that will proceed in spite of the failure. In a more general sense, we should favor 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



IDENTIFY PILOT TEST SITE(S)


DESIGN THE PILOT TEST


TRAIN PARTICIPATING STAFF


IMPLEMENT AND MEASURE


REPORT RESULTS TO OVERSIGHT GROUP

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 pages 39-56 for specifics on how to do this). It is also important to monitor the impact on other related or interfacing activities as well as any 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

## Adaptation of the SOP

At times, due to requirements or policies outside the individual hospital's control, it may be necessary to modify the SOP in order for it to be successfully implemented. A modification that has a local impact for a specific hospital or group of hospitals is considered an *adaptation*. An adaptation to an SOP does not change the SOP itself. It may alter the way the SOP is implemented in a specific hospital because of local considerations that may make it impossible to implement the SOP in the way that it is explicitly written. The process for requesting an adaptation to a Standard Operating Protocol (SOP) should require review and approval by hospital leadership or other oversight body.

## 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. Sharing evaluation data and information is a good method for gauging how well the SOP is being implemented and for disseminating the progressive work being undertaken to improve patient safety and patient outcomes.

## Process Management, Evaluation and Feedback

The following methods of gathering and using information about the Patient Preparation Process have been thoroughly tested and refined in the High 5s Project and are recommended for use by hospitals choosing to implement this Correct Site Surgery SOP. Not all of the tools described in the following pages may be considered necessary or practical at all phases of implementation. However, familiarity with them by the hospital's project manager and selective use will facilitate effective management of the SOP implementation process. After reaching full implementation, continued use of selected evaluation tools will help to ensure consistent performance of the processes for preparing patients for surgery.

The full set of evaluation methods and tools used in the High 5s Project are provided in this Implementation Guide. However, in order to minimize the burden of monitoring and evaluation, simplified versions of certain tools (implementation experience questionnaire and interview forms) and a phase-in approach to performance measurement are also provided.

### SOP Implementation Evaluation

- Periodic inquiry by means of questionnaire, direct observation and/or interview of participants in the process

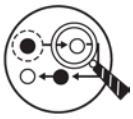
EVALUATE THE PROCESS OF IMPLEMENTING THE SOP

### Performance Measures

- Collecting data to determine how consistently the process steps are being carried out and how the SOP is impacting patient safety

### Event Analysis

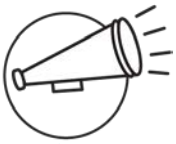
- Identifying SOP-related adverse events
- Conducting complete and accurate event analyses appropriate to the type of events
- Using the results of the event analyses to improve performance of the surgical patient preparation process



ANALYZE ADVERSE EVENTS

### Feedback/Communication

- Communicating regularly with hospital leadership and clinical and administrative staff about the SOP implementation process and status, achievements, and barriers, etc.
- Within the hospital, promoting the hospital's decision to implement the High 5s Correct Site Surgery SOP
- Publicly recognizing participating clinical and administrative staff for their participation in implementing the SOP and improving patient safety.



PROVIDE REGULAR UPDATES, FEEDBACK & RECOGNITION

## SOP Implementation Evaluation

It may be useful, especially during the early stages of SOP implementation, to use an implementation experience questionnaire to gather information directly from the individuals engaging in SOP implementation.

The goals of this activity are to:

1. Determine if the Correct Site Surgery SOP can be implemented as designed and intended;
2. Gain a better understanding of what it takes to implement and sustain implementation of the Correct Site Surgery SOP;
3. Identify barriers to implementation and sustainability of the Correct Site Surgery SOP and strategies for overcoming those barriers; and
4. Determine the perceived impact of the Correct Site Surgery SOP upon relevant processes of care, patient outcomes and patient safety.

The Implementation Experience Questionnaire used in the High 5s Project consisted of eight (8) sections, each corresponding directly with an implementation component described in the SOP

- Section 1 focuses on the oversight of the SOP implementation – was there an implementation oversight group? Was it multidisciplinary? Were there individuals that served as role models or champions for the implementation of this SOP?
- Section 2, the Project Work Plan, focuses on experiences with developing a specific task list to successfully implement the SOP.
- Section 3 relates to risk assessment - identifying potential areas for breakdown or failure and controls or warning systems developed to minimize process failures related to the identified risk points.
- Section 4 applies to those hospitals that conducted a pilot test prior to proceeding with full implementation. If a pilot test was conducted, what was learned? If a pilot test was not done, in hindsight, would it have been helpful?
- Section 5 looks at how the SOP was implemented throughout the hospital sites (ie. Spread Methodology).
- Section 6 focuses on how the information about the SOP and its implementation was disseminated throughout the hospital and whether staff involved in implementing the SOP were recognized for their contributions. This is the hospital's "communication plan".
- Section 7 relates to the experience of implementing the High 5s evaluation activities
- Section 8, Maintenance and Improvement Strategy, focuses on sustainability of the SOP implementation.

The complete ***Implementation Experience Questionnaire*** used in the High 5s Project was 19 pages long and, as such, impractical for general implementation of the SOP. However, a "short version" Implementation Experience Questionnaire was developed by the French High 5s Lead Technical Agency and its participating hospitals. It has been translated to English and is provided on the following page as a means for tracking the implementation experience efficiently and with minimal resource requirements. The abbreviated format can be used for eliciting either written (questionnaire) or oral (interview) responses. For those interested in the comprehensive High 5s questionnaire, it can be accessed at XXXXX.

**Implementation experience questionnaire (Short version)**

*"Track the improvement and be ready to act"*

We suggest this short questionnaire to help the project team adjust its actions and project plan, and track the project's improvement.

1. Which units are currently included in the High 5s SOP implementation?
    a. Do we need to plan any actions to improve or maintain this situation?

2. What communication has been done on the project? Inside the hospital (patients /professionals/management) and outside the hospital (local/national/international)?
    a. Do we need to plan any actions to improve or maintain this situation?

3. What successes did we obtain in the last 3 (or 6) months in the High 5s implementation?

    What barriers are we (still) encountering in the High 5s implementation?
    a. Do we need to plan any actions to improve/maintain High 5s implementation?

4. Did the results (indicators, observational audits, success stories…) of our hospitals correspond to our objectives?
    a. What do we decide to do to improve our results?
    b. What objectives do we set for the next 3 (or 6) months?

5. Have we noticed any positive/negative impact of the project in the last 3 (or 6) months?

    For example: patient safety, patients' experience, organization, culture, institution….
    a. How are we going to share and use the lessons learned?

## Observation and Interviews

First-hand observation has two great benefits. First, observation provides insight into how processes "actually" work; and second, observation by individuals not directly involved in the process on a regular basis allows for the discovery of issues or behavior that have become routine or hidden to those engaged in any part of the process. In order to take advantage of this, hospital leaders and other oversight bodies should consider conducting structured interviews with hospital clinical and administrative staff that play strategic roles in carrying out the SOP.

Interview questions are broken into three sections.

- Section 1 – Prior to Implementation – These questions relate to the hospital's expectations before implementing the SOP.
- Section 2 – During Implementation – These questions relate to the hospital's current experience with implementation (e.g., what additional resources are required; were adaptations to processes required; were there barriers to implementation; were there pleasant surprises once the SOP was implemented; has the SOP had an impact [hopefully positive] on processes of care, patient outcomes and levels of patient safety).
- Section 3 – After reaching full implementation – These questions relate to impact on patient safety, sustainability and long-term lessons learned.

The following template was used by the High 5s Lead Technical Agencies to conduct interviews at their participating hospitals:

| **High 5s Lead Technical Agency Interview Summary** | | |
|---|---|---|
| Motivations | 1. Why did you decide to participate in the High 5s project?<br>2. What did you expect the benefits of implementing and sustaining the SOP would be to your organization? | |
| Resources | 3. What resources did you foresee being need to implement and sustain the SOP?<br>4. What resources were actually required to implement and sustain the SOP?<br>5. Were the resources readily available?<br>6. What additional resources were needed in order to implement and sustain the SOP? | |
| Organization | 7. What adaptations to your environment, organizational culture or current processes were required to implement and sustain the SOP? If adaptations were made to implement the SOP, why were such adaptations necessary? | |
| Barriers | 8. What barriers to implementation did you encounter? How did you address them? | |

| | | |
|---|---|---|
| Impact | 9. Were there unintended consequences as a result of the implementation of the SOP? How did you address them?<br>10. What impact did the SOP have on patient safety at your organization? {insert something about performance measures}<br>11. Were there any events potentially or actually related to the SOP for which an event analysis was required? If yes, did the hospital complete an analysis for each one? Were the event analyses performed concise or comprehensive or a combination of these approaches? Did specific recommendations arise from these analyses? If so,<br>a. Were the recommendations fully implemented?<br>b. Was there actual evidence of resulting improvement in patient care?<br>12. If an event analysis was not done, why? | |
| Considerations for future sustainability | 13. What key lessons were learned that will facilitate the dissemination and implementation of the SOP in other settings?<br>14. What is your impression of the SOP implementation process? Include positive and negative perceptions.<br>15. Do you believe implementation of the SOP is sustainable in your organization?<br>16. Would you recommend implementation of this SOP to other hospitals? Why or why not? If yes, what advice would you provide to the other hospitals?<br>17. Is your organization going to continue carrying out this SOP? | |

## Performance Measures

### The High 5s Correct Site Surgery Measures

These are the performance measures that were used by the High 5s participating hospitals to evaluate the process and impact of implementing the Correct Site Surgery SOP. They include 6 process and 2 outcome measures. In addition, a third outcome measure has been developed (CS-8) to monitor successful identification and resolution of discrepancies. Individual hospitals choosing to implement the CSS SOP outside of the High 5s Project are encouraged to consider using some or all of these measures to support effective management of the implementation process. As a means of easing the burden of data collection and analysis, hospitals may choose to use a subset of these measures. The choice of measures to use may vary over time and should be based on the stage of implementation of the SOP as outlined on page 49.

| Type | Description of Standardized Measures |
|---|---|
| Process | CS-0. Eligible Cases with a Preoperative Verification Checklist |
| Process | CS-1. Number of eligible surgical cases with a complete preoperative verification process (exclusive of site marking and time-out) |
| Process | CS-2. Properly Marked Surgical Site |
| Process | CS-3. Complete Final Time Out |
| Process | CS-4. Cases with Discrepancy Noted at Final Time-Out |
| Process | CS-5. Cases Undergoing Surgery with Unresolved Time Out Discrepancies |
| Outcome | CS-6. Case Cancellation Resulting From SOP Implementation |
| Outcome | CS-7. Incorrect Surgery (wrong site, procedure or person cases) |
| Outcome | CS-8. "Good Catch" (one or more discrepancies identified and resolved pre-operatively) |

All but one of the data elements necessary to calculate the correct site surgery performance measures are integrated into the High 5s/hospital surgical check list so while it might first appear that there will be additional work to do to implement the Correct Site Surgery SOP, it is not as daunting as originally thought. At the conclusion of the surgical experience, the check list itself can be used to determine the numerator and denominator counts for performance measures CS-1 through CS-8. The only additional datum is the total number of eligible cases performed during the month (denominator for CS-0, 1, 6, 7 and 8).

The population for all of the performance measures (CS-0 through CS-8) is the same as the population of cases within the scope of applicability of the SOP. Initially, this scope may be limited, for example, if a pilot test is done. Ultimately, the scope should include all procedures performed in all of the settings in which surgical and other invasive procedures are performed, including emergency procedures and other late add-on procedures.

The phrase "all surgical cases" **includes** outpatient surgery cases, special procedures, and any other cases that are performed or scheduled to be performed in the hospital.

Individual measure specifications are identified on the Measure Information Forms (MIFs) available on the WHO web site at www.who.int/XXXXX

## *Sampling*

Sampling may be used **only for the process measures**. Sampling is not recommended for the outcome measures (CS-6 and CS-7) due to the rarity of these outcomes. Sampling applies to data collection, not to implementation of the SOP procedures. All eligible cases are expected to follow the SOP, including use of a check list that contains each of the 13 key data elements). Whenever possible, 100% of eligible cases should be included in the collection of data for the performance measures.

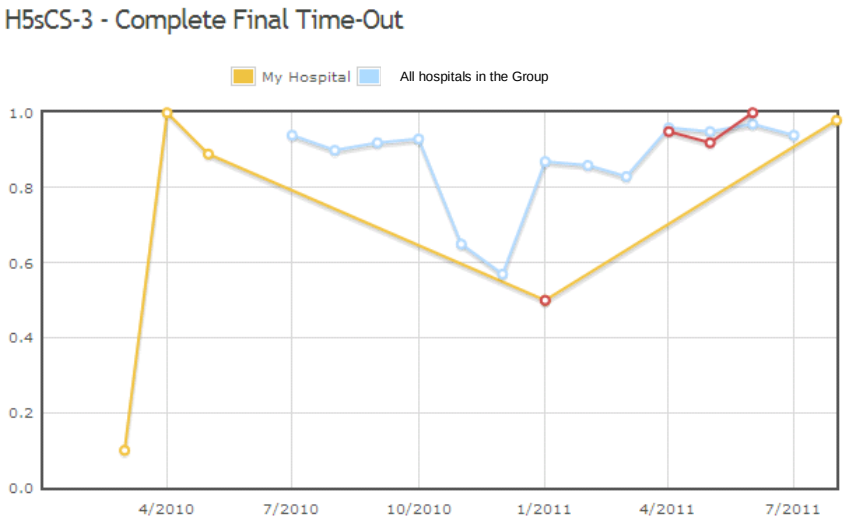
## *Collecting performance measure data*

The hospital's implementation team will develop a process for collecting performance measure data in real time as the patient progresses through the preoperative activities. By integrating data collection with the patient care activities in real time through the use of a check list, significant efficiencies can be achieved because the data collectors are the same people who provide and document the patient care. A person designated in the implementation project work plan, though, should aggregate the case-level data from the check lists in order to calculate the value of the measures on a periodic (for example, monthly) basis.

## *How is the performance measure data used?*

The individual hospital's performance measure data are used to calculate its performance on a specific measure and to track that performance over time. If the hospital is part of a multi-hospital group, sharing of the performance data will enable inter-hospital comparisons. Sharing of performance data with hospital staff participating in the implementation can also be a powerful motivation tool for achieving improved performance.

One way of presenting the data is to display it graphically in a line chart. This way, if the hospital is one of a group of hospitals that are implementing the SOP, comparative data charts showing the hospital's performance compared to the group's performance can be generated. For example:




The data points for a multi-hospital group (for example, a national comparison group) are calculated using a similar approach to the one employed to calculate an individual hospital's performance on a specific measure. All the hospital numerator cases are summed and all of the hospital denominator cases are summed before calculating the measure rate or ratio. The measure is calculated in the aggregate for all hospitals in the group during the specific time period. This calculation creates a weighted mean (weighted by the number of cases contributed by each hospital) rather than a grand mean (simply taking the average of the calculated hospital rates).

## Process Measures

### CS-0 Eligible Cases with a Preoperative Verification Checklist

Proportion of verification checklists for all eligible surgical cases =

$$\frac{\text{\# eligible surgical cases with a preoperative verification check list}}{\text{\# of eligible cases within the scope of the Correct Site Surgery SOP}}$$

"# of eligible surgical cases with a preoperative verification check list" = all eligible cases with a check list whether the check list is completed or not.

The total number of eligible cases (CS-0 denominator) = all cases within the current scope of SOP implementation. When the SOP is fully implemented, the total eligible cases will be ALL cases done in the hospital's surgical facilities.

Note: This is the only data element that will not be available on the check list.

Most of the measures for the Correct Site Surgery SOP are based on the total eligible population. If the total number of check lists is used to represent this total eligible population, it may underestimate the total eligible population and introduce inaccuracies to the measures. Measuring the degree of implementation of the check list is a useful process measure in itself and will also ensure that the true total eligible population is known and used for other measures.

### CS-1 Number of eligible surgical cases with a complete preoperative verification process (exclusive of site marking and time-out)

% of completed preoperative verification process (exclusive of site marking and time out) =

$$\frac{\text{\# of eligible surgical cases with a complete pre-op verification process (exclusive of site marking and time out)}}{\text{\# of eligible cases within the scope of the Correct Site Surgery SOP}}$$

"Eligible cases" means the common population described above. It includes cases cancelled for potential incorrect surgery (for example, because of an unreconciled discrepancy) that would otherwise have been eligible.

This process measure focuses on one of the three necessary components of the correct surgery strategy: the preoperative verification process, which involves the collection, assembly, and cross-verification of information generated throughout the preoperative period. Improvement is associated with an increase in the measure rate. The goal of the measure is to move as close to 100% as possible.

### CS-2 Properly Marked Surgical Site

% of cases with properly marked surgical sites =

$$\frac{\text{\# of eligible cases with correct surgical sites(s) marked properly}}{\text{\# of eligible cases for this measure}}$$

"Eligible cases" for this measure is a subset of the common population described above. Specifically, it includes only cases for which site marking is required: cases with incision or percutaneous instrumentation that involves laterality, surface (flexor, extensor), level (spine), or specific digit or lesion to be treated. Cases that meet these criteria but are exempt from the site marking requirement and cases cancelled because of an unreconciled discrepancy prior to site marking are excluded.

This process measure focuses on the second of the three necessary components of the correct surgery strategy: marking the surgical site. It measures the degree to which the process is carried out consistently and successfully. Improvement is associated with an increase in the measure rate. The goal of the measure is to approach 100%.

**CS-3 Complete Final Time Out**

% complete final time outs =

$$\frac{\text{\# of eligible cases for which all required elements of the final time out are done}}{\text{\# of eligible cases for this measure}}$$

"Eligible cases" for this measure includes the common population described above but excludes cases cancelled due to unreconciled discrepancies in preoperative verification or site marking.

This process measure focuses on the third of the three necessary components of the correct surgery strategy; the final "time out" verification. This final step of verifying agreement among all members of the surgical team on the key aspects of the procedure they are about to undertake is the most important and the last opportunity to intercept a potential incorrect surgery. Improvement is associated with an increase in the measure rate. The goal of the measure is to move as close to 100% as possible.

**CS-4 Cases with Discrepancy Noted at Final Time-Out**

% cases with discrepancy noted at final time out =

$$\frac{\text{\# eligible cases with one or more discrepancies noted at the final time out}}{\text{\# of eligible cases for this measure}}$$

"Eligible cases" for this measure includes the common population described above but excludes cases cancelled due to unreconciled discrepancies in preoperative verification or site marking.

This process measure tracks the number of cases in which one or more discrepancies were identified in the final time out and how they were handled: discrepancies reconciled; case cancelled due to unreconciled discrepancies (CS-6); or case moved forward with unresolved discrepancy (CS-5). The reconciliation of discrepancies and cancellation of cases due to discrepancies represent successes in avoiding potentially incorrect surgery through effective application of the SOP. Improvement is associated with a decrease in the measure rate. The goal of the measure is to move as close to 0% as possible.

**The following measure has been modified from the version used in the High 5s Project, based on "lessons learned". Specifically, the denominator has been modified to include "all eligible cases". It is expected that this change will make the results of this measure easier to interpret. It was not used in the High 5s Project in this form so no data are available for comparison if this measure is used when implementing the CSS SOP outside of the High 5s Project.**

**CS-5 Cases Undergoing Surgery with Unresolved Time Out Discrepancies**

% cases undergoing surgery with unresolved time out discrepancies =

$$\frac{\text{\# of eligible cases with at least one discrepancy unresolved before incision}}{\text{\# of eligible cases within the scope of the Correct Site Surgery SOP}}$$

"Eligible cases" for this measure is a subset of the common population described above. Specifically, it includes only cases with discrepancies noted at the final time out. Cases cancelled due to incomplete preoperative verification or site marking are excluded.

This process measure isolates cases in which there were once or more discrepancies that were not or could not be resolved but proceeded to surgery nonetheless. This measure identifies failures of the SOP since any case that proceeds to surgery with an unresolved discrepancy is regarded as a potential incorrect surgery. Improvement is associated with a decrease in the measure rate. The goal of the measure is to move to as close to 0% as possible.

## Outcome Measures

### CS-6 Case Cancellation Resulting From SOP Implementation

% case cancellation resulting from SOP Implementation =

$$\frac{\text{\# of eligible cases cancelled due to discrepancies at any step of the SOP}}{\text{\# of eligible cases within the scope of the Correct Site Surgery SOP}}$$

"Eligible cases" includes the common population described above, including all cases cancelled for unreconciled discrepancies.

This outcome measure is an overall accounting of case cancellations and postponements due to discrepancies identified at any point in the conduct of the SOP. The measure provides information about the impact of the SOP on patient safety and on the efficiency of surgical processes and facilities. Improvement is noted as either an increase or decrease in the rate depending on the context of the measure.

### CS-7 Incorrect Surgery (wrong site, procedure, or person cases)

% Incorrect surgeries =

$$\frac{\text{\# of eligible cases where an incision was made and the case was subsequently determined to have been performed on the wrong patient, or at the wrong site, or to have employed the wrong procedure or implant}}{\text{\# of eligible cases within the scope of the Correct Site Surgery SOP}}$$

"Eligible cases" includes the common population described above, including all cases cancelled for unreconciled discrepancies.

This outcome measure identifies cases of actual incorrect surgeries – the specific type of adverse surgical events that the SOP is designed to prevent. Because all cases identified by this measure will undergo comprehensive event analysis, it will help to identify barriers to consistent implementation of the SOP as well as potential inadequacies of the SOP itself. Improvement is associated with a decrease in the measure rate. The goal of the measure is to move to 0%.

***The following measure was developed based on "lessons learned" from the High 5s Project. It was not used in the High 5s Project so no data are available for this measure. However, it is offered here for consideration by hospitals that choose to implement the High 5s Correct Site Surgery SOP.***

### CS-8 "Good Catch" (one or more discrepancies identified and resolved pre-operatively)

% "Good Catches" =

$$\frac{\text{\# of eligible cases in which one or more discrepancies were identified and resolved prior to the start of the procedure}}{\text{\# of eligible cases within the scope of the Correct Site Surgery SOP}}$$

"Eligible cases" includes the common population described above, including all cases cancelled for unreconciled discrepancies.

This outcome measure identifies cases in which the process of preparing patients for surgery, according to the High 5s SOP, has achieved its purpose, that is, to prevent incorrect surgeries by identifying discrepancies and resolving them. Resolution of a discrepancy may occur by reconciling apparent differences in information about the patient, procedure or other related factors or, if that is not possible, by cancelling or postponing the case.

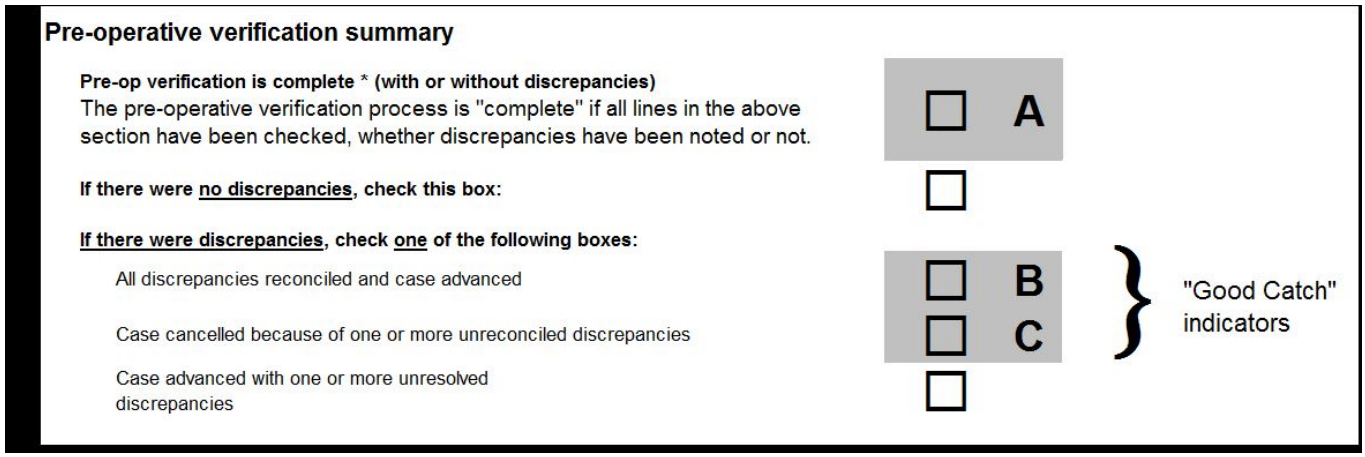
## Correct Site Surgery Performance Measure Calculation Sheets

The calculation sheets will help aggregate the data for use in managing the implementation process.

### WHERE DO I GET THE DATA?

Except for the "Total Number of Eligible Cases", all data necessary to use this calculation sheet are derived from the highlighted "boxes" on the High 5s model check list. The "Total Number of Eligible Cases" equals all cases within the current scope of SOP implementation. When the SOP is fully implemented, the total eligible cases will be ALL cases done in the hospital's surgical facilities.

Example:




NOTE: A hospital's check list may differ in form and content from the High 5s model check list but must include all data elements indicated by shaded boxes on the High 5s model check list.

*Be sure to include ALL eligible cases, despite the presence or absence of a check list.*

### WHICH MEASURES SHOULD I USE?

As a means of easing the burden of data collection and analysis, hospitals may choose to use a subset of these measures. The choice of which measures to use may vary over time and should be based on the stage of implementation of the SOP, as follows:

| Stage of implementation | Suggested performance measures |
|---|---|
| Early stages of implementation/pilot test | CS-0 and CS-7 |
| Intermediate stages | Add CS-1, CS-2, CS-3 and CS-6 |
| Full implementation | Add CS-4, CS-5 and CS-8 |

**Set Measure ID:** H5sCS-0
**Performance Measure Name:** Eligible Cases with a Preoperative Verification Check List
**Collected From:** High-5 Pre-op Verification Check List & Calculation of Eligible Cases

| Element | Total |
|---|---|
| Number of eligible surgical cases with a preoperative verification check list<br>****Count all eligible cases with a check list whether the check list is complete or not**** | Total # of check lists |
| Number of Eligible Surgical Cases | Total # of eligible cases |

**Set Measure ID:** H5sCS-1
**Performance Measure Name:** Completed Preoperative Verification Check List
**Collected From:** High-5 Pre-op Verification Check List

| Element | Total |
|---|---|
| Number of eligible surgical cases with a complete preoperative verification process (exclusive of site marking and time-out) | Box A |
| Number of Eligible Surgical Cases | Total # of eligible cases |

**Set Measure ID:** H5sCS-2
**Performance Measure Name:** Properly Marked Surgical Site
**Collected From:** High-5 Pre-op Verification Check List

| Element | Total |
|---|---|
| Number of Cases with Correct Surgical Site Marked Properly | Box D + E |
| Number of Eligible Surgical Cases for which site marking is required | Total # of eligible cases minus the sum of (Box C plus Box G) |

**Set Measure ID:** H5sCS-3
**Performance Measure Name:** Complete Final Time Out
**Collected From:** High-5 Pre-op Verification Check List

| Element | Total |
|---|---|
| Number of Surgical Cases with Complete Final Time Out | Box H |
| Number of Eligible Surgical Cases minus cases that have been cancelled before arrival in the OR | Total # of eligible cases minus the sum of (Box C plus Box F) |

**Set Measure ID:** H5sCS-4
**Performance Measure Name:** Cases with Discrepancy Noted at Final Time-Out
**Collected From:** High-5 Pre-op Verification Check List

| Element | Total |
|---|---|
| Number of Surgical Cases with Discrepancy at Final Time Out | Box I |
| Number of Eligible Surgical Cases minus cases that have been cancelled before arrival in the OR | Total # of eligible cases minus the sum of (Box C plus Box F) |

**Set Measure ID:** H5sCS-5
**Performance Measure Name:** Cases Undergoing Surgery with Unresolved Time Out Discrepancies.
**Collected From:** High-5 Pre-op Verification Check List

| Element | Total |
|---|---|
| Number of Surgical Cases with Unresolved Discrepancy at Final Time-Out | Box L |
| Number of Eligible Surgical Cases | Total # of eligible cases |

**Set Measure ID:** H5sCS-6
**Performance Measure Name:** Case Cancellation Resulting From SOP Implementation
**Collected From:** High-5 Pre-op Verification Check List

| Element | Total |
|---|---|
| Number of Surgical Cases Cancelled for Discrepancies noted in SOP Implementation | Box C + Box F+ Box K |
| Number of Eligible Surgical Cases | Total # of eligible cases |

**Set Measure ID:** H5sCS-7
**Performance Measure Name:** Incorrect Surgery (Wrong site, procedure or person cases)
**Collected From:** High-5 Pre-op Verification Check List

| Element | Total |
|---|---|
| Number of Incorrect Surgery Cases | Box M |
| Number of Eligible Surgical Cases | Total # of eligible cases |

**Set Measure ID:** H5sCS-8
**Performance Measure Name:** "Good Catch" (One or more discrepancies identified and resolved preoperatively)
**Collected From:** High-5 Pre-op Verification Check List

| Element | Total |
|---|---|
| Number of cases with one or more discrepancies identified and resolved pre-op | Box B + Box C + Box E + Box E + Box J+ Box K |
| Number of Eligible Surgical Cases | Total # of eligible cases |

# Event Analysis

## Background

The goal of implementing the Correct Site Surgery (CSS) SOP is to ensure that patients do not experience events related to incomplete or incorrect information relating to the surgical patient's identity, the procedure to be performed or the anatomical site of the procedure. These events could, and often do, result in unnecessary and significant psychological harm to a patient and may result in severe physical harm.

Event analysis, in this context, is designed to identify and learn from any events shown to be related to the CSS SOP or its implementation. Specifically, event analysis seeks to answer the following key questions:

- Was the event possibly related to activities addressed by the SOP?
- If yes, was a contributing factor the incomplete or incorrect implementation of the SOP?
- If yes, was the incomplete or incorrect implementation of the SOP an isolated occurrence or an example of a systemic problem?

The answers to these questions will help to identify the underlying causes of the event and ways to improve the SOP implementation.

There are four types of events[1] that should be considered for analysis:

1. Hazard: a circumstance, agent or action with the potential to cause harm
2. Near miss/Close Call/Good Catch: an event which did not reach the patient
3. No-harm Event: an event which reached a patient but no discernable harm resulted
4. Adverse Event: an event which resulted in harm to a patient

Event analysis is a systematic process whereby the facts, contributing factors and recommendations arising, are identified and reported as a result of investigating an event or a group of related events. This learning is then integrated with other sources of information to inform hospital risk management and quality improvement processes.

Types of Event Analysis:

a. Comprehensive (traditional approach such as Root Cause Analysis[2,3,4])
b. Concise (abbreviated approach that focuses primarily on four aspects: the agreed upon facts, key contributing factors, actions for improvement and evaluation of action effectiveness)
    - The High 5s initiative informed the development of a formal Concise Incident Analysis Tool[5] that was tested by staff experienced in analysis in eleven hospitals, across five countries.
c. Cluster (an alternative process of analyzing multiple events of the same type *as a group*)
    - This approach helps to identify patterns in causation and enhance the effectiveness of actions for improvement, while increasing efficiency of the analysis process. It is recommended that cluster analysis be used only for no-harm events. Events that cause patient harm should be reviewed using individual concise or comprehensive event analyses. This is an efficient means of assessing and responding to frequently occurring, low impact (no-harm) events.

For hospitals that perform event analysis frequently, an additional analytical tool call Aggregate Analysis is available. Aggregate Event Analysis is the process of analyzing data combined from the findings of several completed event analyses (concise or comprehensive) of similar event characteristics, in order to identify patterns in causation and enhance the effectiveness of actions for improvement.

Hospitals implementing the High 5s SOPs and submitting Event Analysis reports, most often used Concise analyses and Cluster analyses as part of their evaluation activities.

---

[1] Definitions used with permission from the WHO Programme for Patient Safety International Classification for Patient Safety

[2] http://www.patientsafety.va.gov/professionals/onthejob/rca.asp

[3] http://www.patientsafetyinstitute.ca/English/toolsResources/IncidentAnalysis/Pages/Tools.aspx

[4] http://www.jointcommission.org/sentinel_event.aspx

[5] Pham J, Hoffman C, Popescu I, & Ijagbemi M; Concise Incident Analysis. Canadian Patient Safety Institute: website to be inserted shortly

**Event Analysis Before SOP Implementation**

Hospital leaders may decide to implement the CSS SOP as a targeted improvement strategy following the identification and analysis of a surgical event(s). Sharing this baseline information will help the leaders to build the knowledge and desire for change across the organization.

**Event Analysis During SOP Implementation**

A quality improvement approach to implementing the SOP within the hospital should include a strategy for analyzing some surgical event(s). In particular, Event Analysis can provide important insight into events related to the following three aspects of CSS SOP implementation.

a. Quality of the preoperative patient preparation process

Examples

- ❖ Incomplete or inaccurate information during the preoperative process
- ❖ Absent or improper surgical site marking
- ❖ Absent or improperly conducted final time out.

b. Extent of SOP Implementation

Example

- ❖ The goal of 100% of the target patient population having a completed preoperative verification check list is not achieved

c. Outcomes associated with the SOP or its implementation

Examples

- ❖ Good catches; actual incorrect surgeries

**Event Analysis After SOP Implementation**

After the SOP is fully implemented, Event Analysis should be used to review events to determine if there are any key issues with sustaining consistent SOP implementation. Mechanisms for identifying the events are the same as those used during implementation. Each hospital or multi-hospital oversight group should identify a specific event analysis methodology to be used by their hospital(s). Where there is no preferred methodology, one of the established methodologies listed below may be used.

United States Department of Veterans Affairs, National Center for Patient Safety
http://www.va.gov/ncps/cogaids/rca/index.html

Canadian Patient Safety Institute
http://www.patientsafetyinstitute.ca/English/toolsResources/rca/Pages/default.aspx

The Joint Commission
http://www.jointcommission.org/sentinelevents/forms/

Refer to the WHO High 5s Interim Report for a complete description of the High 5s Event Analysis methodology and findings[6].

[6] WHO Action on Patient Safety: High 5s Interim Report, http://www.who.int/patientsafety/implementation/solutions/high5s/en/

## Event Analysis Tools Developed and Tested in the High 5s Project

Health care providers implementing the High 5s CSS SOP are encouraged to use the methods and tools provided on the next few pages to identify applicable events for analysis, organize the analysis, and document the findings.

## Identification of Cases for which Event Analysis may be useful

### 1. Checklist Review

As required by the SOP, a preoperative checklist will be used to document the steps in preparing each patient for surgery and for recording the outcomes relevant to the SOP. The four outcomes listed below will be identified by:

a. the health care provider team concurrently; and/or,

b. a reviewer of the check lists on a retrospective basis.

| OUTCOME | RELEVANT MEASURE | TYPE OF ANALYSIS |
|---|---|---|
| Incorrect surgery (wrong patient, procedure, site, or implant) | H5sCS-7 | • Comprehensive event analysis.<br>• Also consider Aggregate Analysis of a group of individual event analyses of these cases.<br>• This type of event is not eligible for Cluster Analysis. |
| Cases that proceed to incision with unresolved discrepancy | H5sCS-5 | • Minimum of Concise event analysis.<br>• Also consider aggregate analysis of a group of individual event analyses of these cases.<br>• If 3 or more no-harm cases of this type occur within a one-month period, Cluster Analysis may be used |
| Case cancelled due to SOP-related discrepancy | H5sCS-6 | • Minimum of Concise event analysis<br>• Also consider aggregate analysis of a group of individual event analyses of these cases.<br>• If 3 or more no-harm cases of this type occur within a one-month period, Cluster Analysis may be used |
| Cases with discrepancy resolved at final Time Out | H5sCS-4 | • Minimum of Concise event analysis<br>• Also consider aggregate analysis of a group of individual event analyses of these cases.<br>• If 3 or more no-harm cases of this type occur within a one-month period, Cluster Analysis may be used |

### 2. Independently Reported Surgical Events

Any suspected incorrect surgery reported by any member of the surgical team, any other hospital staff member, the patient or family will be investigated to determine whether an incorrect surgery actually occurred (and was not already identified). If so, proceed with comprehensive event analysis. An *incorrect surgery* is defined as a surgery (an incision or instrument insertion must have occurred) in which the patient, procedure, site, or implant is not what was intended unless the change was based on a clinical judgment made in the patient's best interest. If the error is noted before the incision and is corrected, then the case would be a Good Catch Surgery Event and not an incorrect surgery.

## Event Analysis Findings

Event Analysis Minimum Data Set (MDS) forms were developed for use in the High 5s Project to capture the key findings. Hospitals may wish to use these forms or may prefer their own designs. The High 5s MDS forms are provided in Appendix 2 of this Implementation Guide. However it is done, it is essential that the event analysis documentation is accurate and complete. Criteria for **accuracy and completeness** include the following:

**Overall**

- ❑ All questions are answered
- ❑ Where "other" has been selected, the narrative description is clear and understandable
- ❑ Information provided is consistent across all answers (inconsistencies are flagged and resolved)

**Narrative/Characteristics of the Event**

- ❑ Describes fully what happened, who was involved, and if any measures were taken to prevent and/or mitigate harm to the patient as a result of the event (using the steps of the process to describe the sequence)
- ❑ Device / Product information has been provided if directly involved in the event

**Characteristics of the Event Analysis Process**

- ❑ The appropriate level of event analysis (concise or comprehensive) is completed based on type of SOP event
- ❑ The analysis process was initiated by the hospital within a few days of the event or where applicable, date of discovery
- ❑ Team members are selected if a comprehensive event analysis was completed
- ❑ The report of the analysis was submitted within 90 days of the event or where applicable, the date of discovery

**Primary and Secondary Contributing Factors**

- ❑ The primary (most important) and other contributing factors selected reflect a thoughtful review of human factors as well as the related processes, systems and environment
- ❑ The contributing factors can be correlated to the applicable step of the SOP process (clarify with the hospital if needed)

**Recommendations**

- ❑ Recommendations are clear and understandable
- ❑ The recommendations incorporate a human factors engineering approach (i.e., try to move away from actions that continue to rely on human memory/vigilance; avoid training and policy/procedure fixes; and focus instead on those that will design-in "knowledge in the world", like: checklists, diagrams, forcing functions, standardization, simplification, elimination of look/sound-alikes, read-back, cognitive aids, story telling, etc.)[4]
- ❑ Any additional information included is clear and understandable regarding the relevance to the event and/or analysis

**Relationship to the SOP**

- ❑ **Recommendations** and other related documentation clearly describe any relationship to the SOP as written; inaccurate or incomplete implementation of the SOP; and/or factors beyond the scope of the SOP.

**Regulatory Requirements**

❑ Each hospital or oversight body should ensure that the Event Analysis process complies with all applicable regulatory requirements.

## High 5s Patient Outcome Harm Scale For Reporting

The harm scale used in the High 5s Project is a very simple approach to documenting the expected health quality of a patient's life after a patient safety event.

**High 5s Patient Outcome Harm Scale**

**Select the first applicable category below that best describes the extent of harm to the patient as assessed 24 hours post event.**

**a. Death**

**b. Severe permanent harm.** Severe life-long bodily or psychological injury or disfigurement that interferes significantly with functional ability or quality of life

**c. Permanent harm.** Life-long bodily or psychological injury or increased susceptibility to disease

**d. Temporary harm.** Bodily or psychological injury, but likely not permanent

**e. Additional treatment.** Injury limited to additional intervention during admission or encounter and/or increased length of stay, but no other injury

**f. 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).

**g. No harm.** Event reached patient, but no harm evident

**Used with the permission of the Agency for Healthcare Research and Quality**

## Data Quality Management

Recognizing that the quality and usefulness of the results of process evaluation can only be as good as the quality of the data that go into it, hospitals are encouraged to implement a means of ensuring the quality of its data. In service of simplicity, economy and practicality, the recommended approach to data quality assessment is as follows::

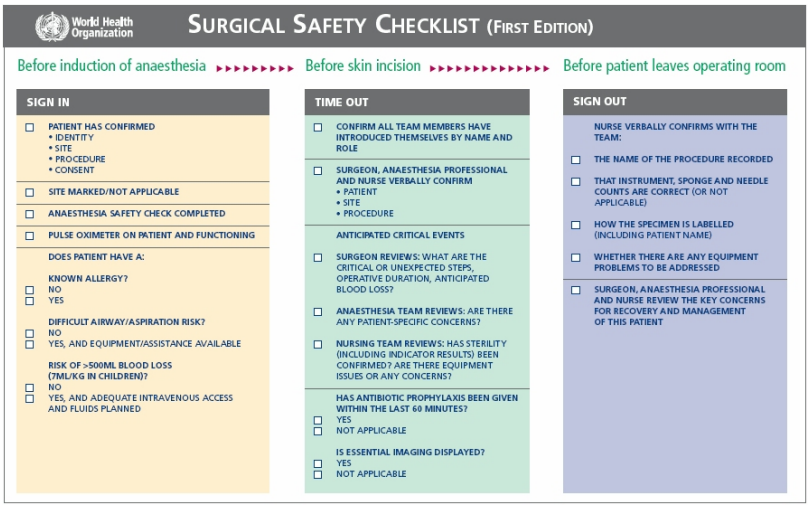
1. Use existing structures within the hospital's quality improvement systems
2. Minimize additional work and resource consumption by the hospitals
3. Customize the process to the specific measures and data collection methods used by the hospital
4. Aim is for a level of data quality consistent with the limits of precision that are achievable with respect to the analytic tools and sample sizes used in implementing the SOP.
5. Seek to identify significant patterns of deviation from the desired level of data quality rather than attempt to assure a comprehensive and statistically verifiable level of quality
6. Focus on the completeness and reliability of the data.

# Appendix 1: 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**

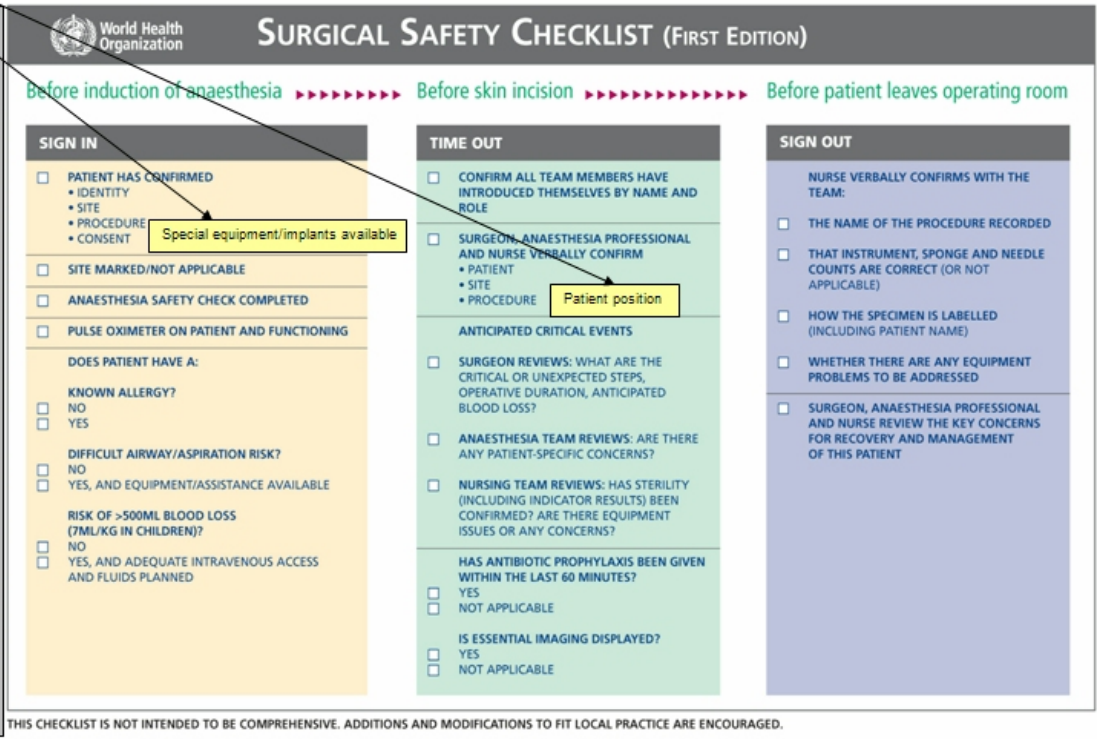
The examples that follow are intended to demonstrate the principles and approaches to consolidating check lists and other preoperative tools. These specific examples, as shown here, should not be taken as recommendations for use in any particular hospital. However, in implementing the High 5s SOP, the content (items to be checked off) of the Basic High 5s Preoperative Verification Check List should 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<br>• Patient identity (2 forms of ID)<br>• Procedure<br>• Site |
| ☐ | Pre-op testing<br>• Two patient identifiers<br>• Procedure<br>• Site |
| ☐ | Consent verified for correct patient identity, procedure, site |
| ☐ | History & exam completed |
| ☐ | Site marked (or not applicable)<br>• Initialled by surgeon<br>• At or near planned incision site<br>• 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

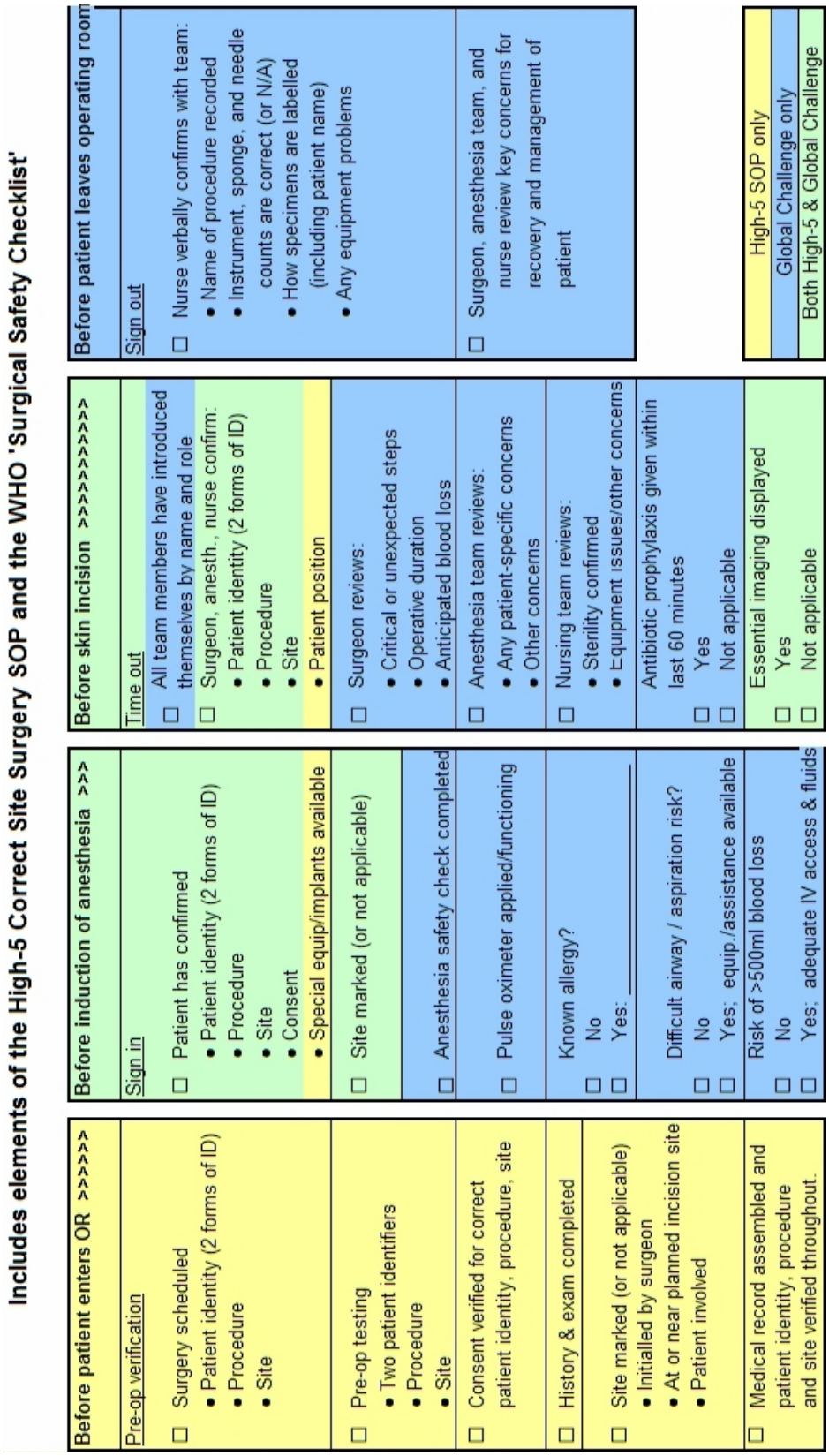
IS ESSENTIAL IMAGING DISPLAYED?
- ☐ YES
- ☐ NOT APPLICABLE

**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

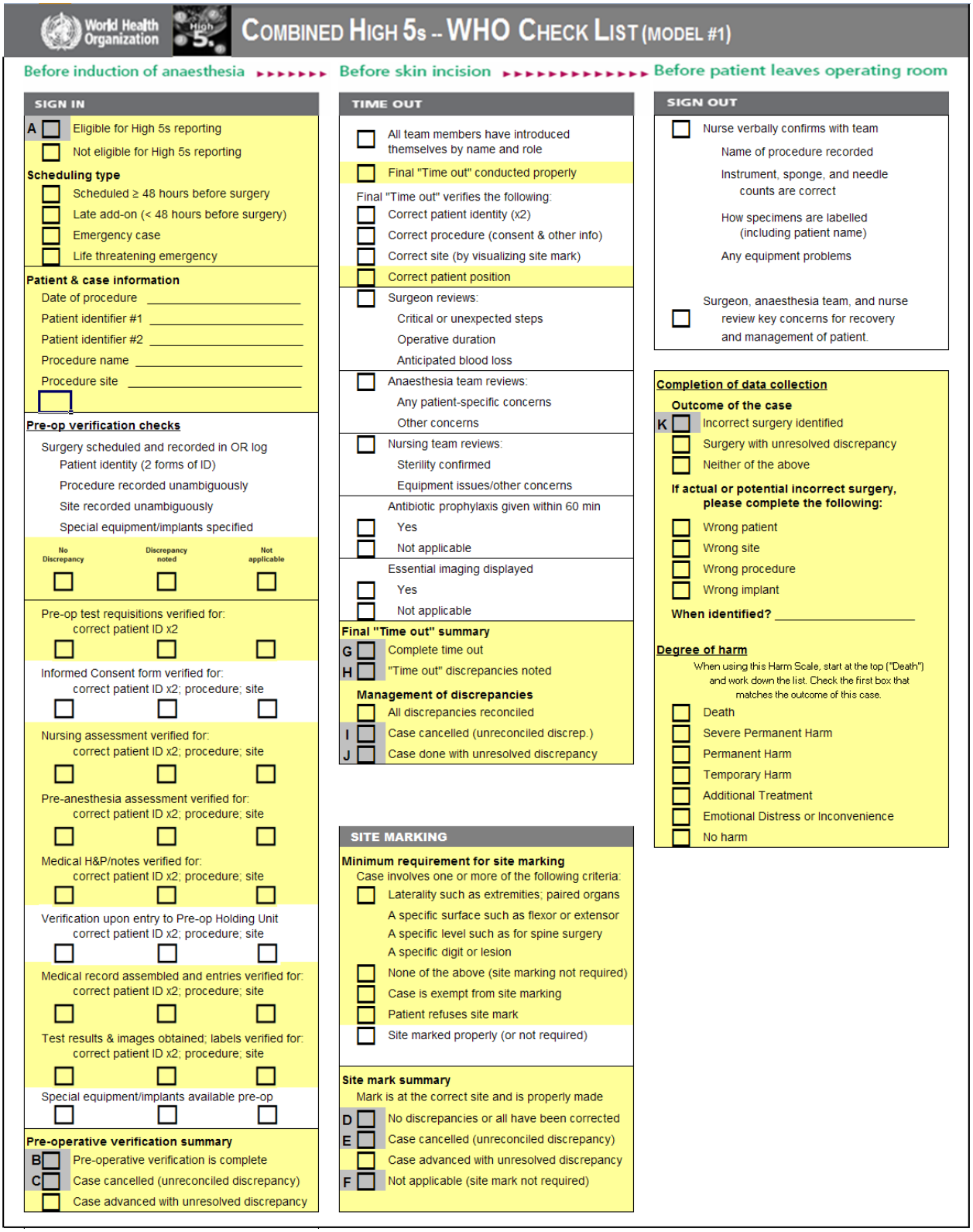
THIS CHECKLIST IS NOT INTENDED TO BE COMPREHENSIVE. ADDITIONS AND MODIFICATIONS TO FIT LOCAL PRACTICE ARE ENCOURAGED.

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 _____

☐

**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 noted | Not applicable |
|---|---|---|---|
| | ☐ | ☐ | ☐ |
| Pre-op test requisitions verified for: correct patient ID x2 | ☐ | ☐ | ☐ |
| 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

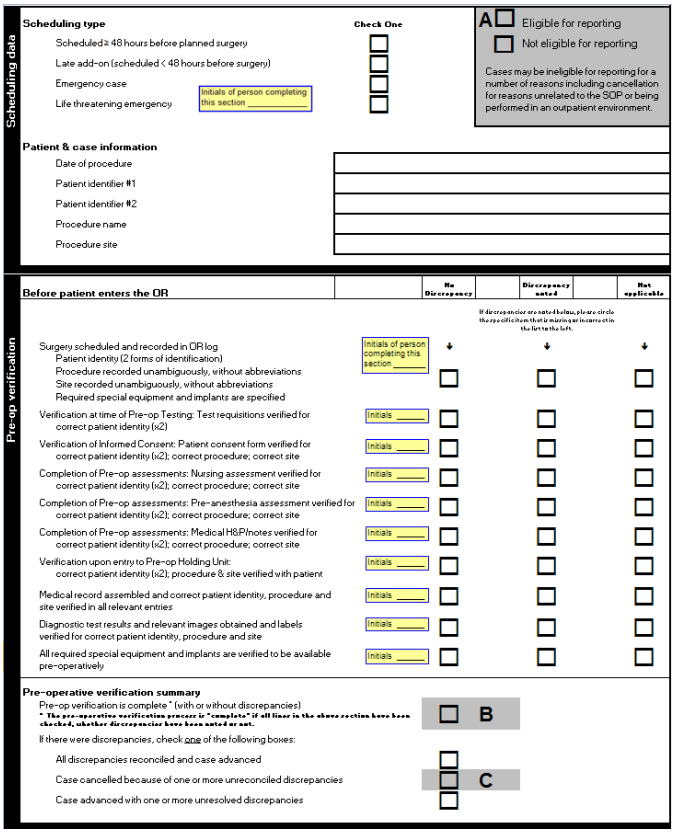
☐ No harm

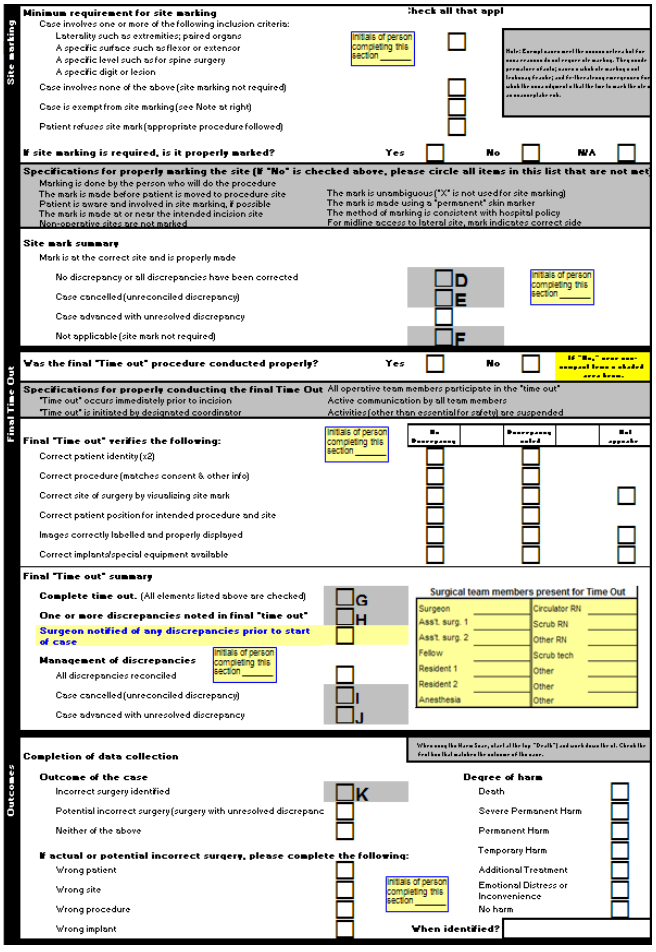
## AORN Sample Surgical Checklist

| √ when completed before entering procedure room | Criteria | Signature (s) |
|---|---|---|
| | **Patient Verification** | |
| | Person Completing Verification of Patient<br><br>Patient<br><br>Other:_____<br>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."<br>_____ MD<br>_____ MD Fellow<br>_____ MD Resident<br>_____ Anesthesia<br>_____ CRNA<br>_____ RN Circulator<br>_____ CRNFA/RNFA<br>_____ Scrub Technician<br>_____ Other (s) | |
| **Discrepancy Noted** | Surgeon Notified:<br><br>Date: Time:<br><br>Surgeon final site and side verified and communicated with team.<br><br>Documented note completed. | |

## Consolidated High 5s – AORN Check List

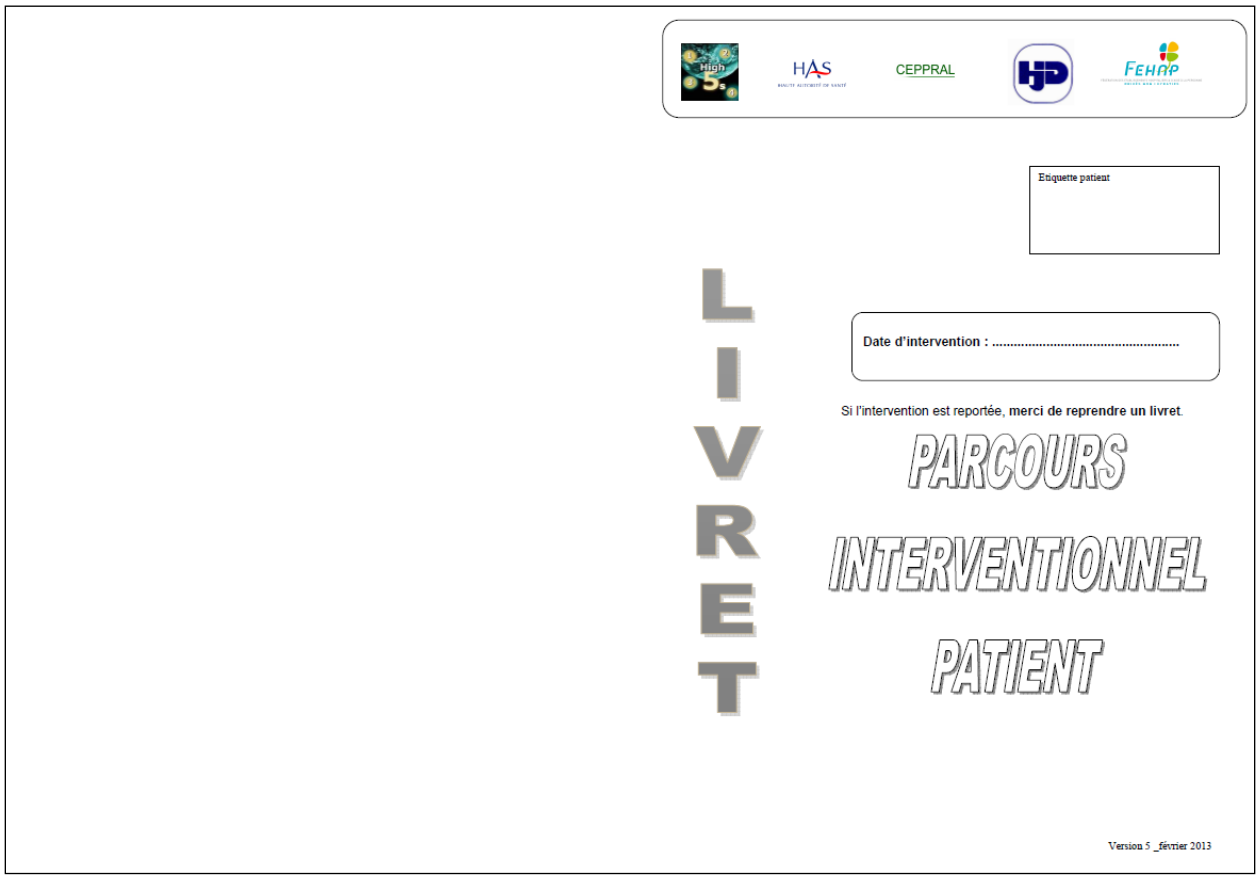


## Appendix 1: Examples of consolidated check lists (continued)

### From France: *Hopital Joseph Ducuing* – A comprehensive check list in booklet form

(Note page numbering)



**CHIRURGIEN**

Etiquette patient

***EN CONSULTATION***

**Type de programmation**

| | |
|---|---|
| Programmée plus de 48h avant la date d'intervention | ☐ |
| Programmée tardivement (moins de 48h avant la date d'intervention) | ☐ |
| Urgence fonctionnelle | ☐ |
| Urgence vitale | ☐ |

| *Informations concernant le patient* | |
|---|---|
| 1ère modalité d'identification du patient : NOM - PRENOM | |
| 2ème modalité d'identification du patient : date de naissance | |

***Vérification du consentement éclairé.*** *Le B/A/R expliqué (Bénéfice/Alternative/Risque) + autorisation parentale de consentement tracé :* ☐ Oui ☐ Non

HOPITAL Joseph DUCUING
15 rue de Varsovie BP 53160 31027 TOULOUSE Cedex 3

**UF : Bloc opératoire**

Etiquette Patient

**TRACABILITE DES DISPOSITIFS MEDICAUX OUVERTS MAIS NON POSES**

Date : .....
Conforme à la LPP : ☐ Non conforme à la LPP : ☐

| PRESCRIPTEUR | DENOMINATION / N°DE LOT / LABORATOIRE |
|---|---|
| Dr ALCAIDE-ROBERTO Aline | |
| ☐ Dr APREDOAEI Costel | |
| ☐ Dr CHARASSON Thierry | |
| ☐ Dr DUCLUSAUD Anne | |
| ☐ Dr FRITSCH Sylvie | |
| ☐ Dr GNANIH Joël | |
| ☐ Dr GIORDANO Gérard | |
| ☐ Dr HENRY Anne | |
| ☐ Dr LABEYRIE Evelyne | |
| ☐ Dr LAPUELLE Jean | |
| ☐ Dr MERVANT-PINAR Cécile | |
| ☐ Dr REMI Julien | |
| ☐ Dr VINCEGINI Jean-François | |
| ☐ Dr _____ | |
| ☐ Dr _____ | |
| ☐ Dr _____ | |
| ☐ Dr _____ | |
| Signature du prescripteur : | |



**CHIRURGIEN** ***EN CONSULTATION***

Etiquette Patient

**QUESTIONNAIRE DE DEPISTAGE DES SITUATIONS A RISQUE DE TRANSMISSION D'AGENTS TRANSMISSIBLES NON CONVENTIONNELS (ATNC, PRIONS)- INSTRUCTION N° DGS/RI3/2011/449 du 1er décembre 2011 relative à l'actualisation des recommandations visant à réduire les risques de transmission d'agents transmissibles non conventionnels lors des actes invasifs. HJD-2008-553**

*A REMPLIR PAR LE MEDECIN LORS DE LA CONSULTATION DU PATIENT AVANT TOUTE INTERVENTION CHIRURGICALE*

(cocher les cases correspondantes)

| Niveau de risque de l'acte / Niveau de risque de patient | | Actes invasifs à risque vis-à-vis des ATNC/ choix procédure | Autres actes invasifs/ choix procédure |
|---|---|---|---|
| **PATIENT NI SUSPECT NI ATTEINT D'EST** ☐ C'est-à-dire : -Patient sans caractéristique particulière -Patient présentant des facteurs de risque individuel d'EST -Traitement par hormone de croissance d'origine humaine -Patient ayant bénéficié d'une greffe de dure mère d'origine humaine -Patient ayant dans la famille génétique 1 cas d'EST lié à 1 mutation codant la PrP | | ☐ neurochirurgie (sauf chirurgie rachis extradurale) ☐ chirurgie touchant la rétine ou le nerf optique ☐ chirurgie ou endoscopie ORL touchant la muqueuse olfactive | ☐ actes n'entrant pas en contact avec les tissus à haute infectiosité |
| | Niveau de traitement : matériel stérilisable ou thermosensible | Suivre: FICHE 1 **Procédure HJD-2008-553** | Suivre: FICHE 2 **Procédure HJD-2008-553** |
| **PATIENT SUSPECT OU ATTEINT D'EST** ☐ Présence d'apparition récente et d'évolution progressive **sans rémission**, d'au moins 1 signe neurologique associé à des troubles intellectuels ou psychiatriques et après élimination de toute autre cause Avis neurologue demandé ☐ | | ☐ neurochirurgie (sauf chirurgie rachis extradurale ) ☐ chirurgie touchant la rétine ou le nerf optique ☐ chirurgie ou endoscopie ORL touchant la muqueuse olfactive ☐ actes invasifs chirurgicaux avec contact, biopsie ou curage d'un ganglion, ☐ contact, biopsie ou exérèse d'une formation lymphoïde organisée ☐ intubation ou utilisation de masque laryngé ☐ échographie passant par carrefour aérodigestif ☐ endoscopie passant par carrefour aérodigestif ☐ endoscopie par voie rectale | ☐ actes n'entrant pas en contact avec les tissus à haute infectiosité |
| | Niveau de traitement matériel stérilisable ou thermosensible | Suivre: FICHE 3 **Procédure HJD-2008-553** | Suivre: FICHE 4 **Procédure HJD-2008-553** |

DATE : SIGNATURE et cachet du praticien

Etiquette Patient

## CHIRURGIEN / ANESTHESISTE

Date d'entrée : ...../...../.....  A jeun : Oui ☐ à partir de ..... H .....
Heure d'entrée : ..... H .....  Non ☐

Opérateur :  Date d'intervention : .....

Motif de l'hospitalisation : .....

Intitulé de l'intervention (abréviation selon lexique) : .....

Site et côté de l'intervention : .....

MATERIEL A PREVOIR :

| DUREE PREVISIBLE DE L'INTERVENTION | POSITION PATIENT(E) | TYPE D'ANESTHESIE PROPOSE |
|---|---|---|
| EXAMENS A FAIRE A L'ENTREE | EXAMENS A VOIR | PROTOCOLE PRE-OPERATOIRE |

**DUREE PREVISIBLE D'HOSPITALISATION** ☐ Retour à domicile ☐ Maison de repos ☐ Centre de rééducation
A prévoir : en cours d'hospitalisation ☐
avant l'hospitalisation ☐
RDV assistante sociale le : .....

Rendez-vous pré-opératoires

Radiologie le ...../...../20.... à ....H .....  Laboratoire le ...../...../20.... à ....H .....
Cardiologie le ...../...../20.... à ....H .....  Anesthésie le ...../...../20.... à ....H .....

Autres : .....

**MODE D'HOSPITALISATION PROPOSE :** ☐ USC ☐ ambulatoire ☐ conventionnelle ☐ externe

*Médecin prescripteur* Date : Signature :

**MODE D'ANESTHESIE RETENU :** ☐ AG ☐ ALR ☐ AL ☐ AL + sédation / ☐ Allergie au latex

**MODE D'HOSPITALISATION RETENU :** ☐ USC ☐ ambulatoire ☐ conventionnelle

| *Réalisation de l'évaluation pré-opératoire. L'évaluation pré-anesthésique comprend la vérification de :* | Aucune discordance | Une discordance est notée | Non applicable |
|---|---|---|---|
| | Si une discordance est notée, merci d'entourer l'item spécifique qui est manquant ou incorrect dans la liste de gauche | | |
| Identité du patient (x2) ; Intervention ; Site | ☐ | ☐ | ☐ |

***Validation anesthésiste*** **Date :** **Signature :**

**Observations :**

3

HOPITAL Joseph DUCUING
15 rue de Varsovie BP 53160 31027 TOULOUSE Cedex 3

## UF : Bloc opératoire

Etiquette Patient

### PRESCRIPTION ET TRACABILITE DES DISPOSITIFS MEDICAUX

Date : .....

Conforme à la LPP : ☐  Non conforme à la LPP : ☐

| PRESCRIPTEUR | DENOMINATION / N°DE LOT / LABORATOIRE |
|---|---|
| ☐ Dr ALCAIDE-ROBERTO Aline | |
| ☐ Dr APREDOAEI Costel | |
| ☐ Dr CHARASSON Thierry | |
| ☐ Dr DUCLUSAUD Anne | |
| ☐ Dr FRITSCH Sylvie | |
| ☐ Dr GNANIH Joël | |
| ☐ Dr GIORDANO Gérard | |
| ☐ Dr HENRY Anne | |
| ☐ Dr LABEYRIE Evelyne | |
| ☐ Dr LAPUELLE Jean | |
| ☐ Dr MERVANT-PINAR Cécile | |
| ☐ Dr REMI Julien | |
| ☐ Dr VINCENSINI Jean-François | |
| ☐ Dr _____ | |
| ☐ Dr _____ | |
| ☐ Dr _____ | |
| ☐ Dr _____ | |
| Signature du prescripteur : | |

Signature du patient ou du professionnel ayant remis le document

16

HOPITAL Joseph DUCUING
15 rue de Varsovie BP 53160 31027 TOULOUSE Cedex 3

## UF : Bloc opératoire

Etiquette Patient

### PRESCRIPTION ET TRACABILITE DES DISPOSITIFS MEDICAUX

Date : .....

Conforme à la LPP : ☐  Non conforme à la LPP : ☐

| PRESCRIPTEUR | DENOMINATION / N°DE LOT / LABORATOIRE |
|---|---|
| ☐ Dr ALCAIDE-ROBERTO Aline | |
| ☐ Dr APREDOAEI Costel | |
| ☐ Dr CHARASSON Thierry | |
| ☐ Dr DUCLUSAUD Anne | |
| ☐ Dr FRITSCH Sylvie | |
| ☐ Dr GNANIH Joël | |
| ☐ Dr GIORDANO Gérard | |
| ☐ Dr HENRY Anne | |
| ☐ Dr LABEYRIE Evelyne | |
| ☐ Dr LAPUELLE Jean | |
| ☐ Dr MERVANT-PINAR Cécile | |
| ☐ Dr REMI Julien | |
| ☐ Dr VINCENSINI Jean-François | |
| ☐ Dr _____ | |
| ☐ Dr _____ | |
| ☐ Dr _____ | |
| ☐ Dr _____ | |
| Signature du prescripteur : | |

Signature du patient ou du professionnel ayant remis le document :

15

## VERIFICATIONS PRE-OPERATOIRES

**IDE Service**

| | Aucune discordance | Une discordance est notée | Non applicable |
|---|---|---|---|
| | Si une discordance est notée, merci d'entourer l'item spécifique qui est manquant ou incorrect dans la liste de gauche | | |
| ***La vérification pré-opératoire du dossier porte sur la présence et la conformité des éléments suivants :*** | | | |
| **Le formulaire de consentement éclairé (lorsqu'il est nécessaire ; ex : don de tête fémorale, enfant mineur ou majeur protégé ....) trace :** | | | |
| - Identité du patient (x2) ; Intervention ; Site | ☐ | ☐ | ☐ |
| **Observation médicale / dossier (fiche observation ou courriers de consultation) comprend :** | | | |
| - Identité du patient (x2) ; Intervention ; Site | ☐ | ☐ | ☐ |
| **Dossier anesthésie** | | | |
| - Identité du patient (x2) ; Intervention ; Site | ☐ | ☐ | ☐ |
| **Vérification des examens pré opératoires : contrôle de la présence et de l'identité (X2) des pièces ci-dessous** | | | |
| - Imagerie oui ☐ NA ☐ | ☐ | ☐ | ☐ |
| - Biologie oui ☐ NA ☐ | | | |
| - Carte de groupe sanguin 1ère détermination oui ☐ NA ☐ | | | |
| - Carte de groupe sanguin 2ème détermination oui ☐ NA ☐ | | | |
| - RAI oui ☐ NA ☐ | | | |
| - ECG oui ☐ NA ☐ | | | |
| - Examens complémentaires oui ☐ NA ☐ | | | |
| - Etiquettes : 2 planches au moins oui ☐ | | | |
| - Feuille de RSS oui ☐ | | | |
| **Dossier médical complet et vérifié quant à l'exactitude des données relatives à l'identité, l'intervention, le site dans toutes les rubriques pertinentes. Toutes les pièces du dossier sont vérifiées et conformes, collecte des examens de laboratoire, imagerie pertinente, étiquettes vérifiées quant à l'identité, l'intervention et le site.** | ☐ | ☐ | ☐ |

4

## VERIFICATIONS PRE-OPERATOIRES

*AVANT DEPART POUR LE BLOC*

Etiquette patient

**IDE Service**

| | Aucune discordance | Une discordance est notée | Non applicable |
|---|---|---|---|
| | Si une discordance est notée, merci d'entourer l'item spécifique qui est manquant ou incorrect dans la liste de gauche | | |

*Avant le départ au bloc l'ide prépare le patient et procède aux vérifications suivantes :*

*Réalisation de l'évaluation pré-opératoire. L'évaluation par les IDE comprend :*

- Identité du patient (x2) ; Intervention ; Site ☐ ☐ ☐

**Côté à opérer** : Droit ☐ Gauche ☐ NA ☐

**Allergies** : Oui ☐ Non ☐

***Préparation générale et locale***

Ablation **Prothèses Dentaires** : Oui ☐ NA ☐
Inférieure ☐ Supérieure ☐

Ablation **lentilles** : Oui ☐ NA ☐

Ablation **Prothèses Auditives** : Oui ☐ NA ☐
Laissé en place / ordre médical ☐

Ablation **bijoux/piercing** : Oui ☐ NA ☐

Ablation **lunettes** : Oui ☐ NA ☐

Ablation **sous vêtements** Oui ☐ NA ☐

Ablation **vernis à ongles/maquillage** Oui ☐ NA ☐

Autre (préciser) :

**Dépilation** : Oui ☐ Non ☐

**Douche pré-opératoire** : Oui ☐ Non ☐
Iode ☐ Chlorexidine ☐
Domicile ☐ Dans le service ☐

**Toilette au lit** : Oui ☐ Non ☐
Iode ☐ Chlorexidine ☐

**Miction** : Oui ☐ Non ☐

**Bas de contention** : Oui ☐ Non ☐

**Patient à jeun** : Oui ☐ Non ☐

**Prémédication** : Oui ☐ Heure ..... Non ☐

***Etat psychologique du patient*** :
Calme : Oui ☐ Non ☐ / Anxieux : Oui ☐ Non ☐
Endormi : Oui ☐ Non ☐ / Algique : Oui ☐ Non ☐

Autre :

BRACELET D'IDENTIFICATION : Oui ☐

| | |
|---|---|
| SERVICE :<br>Chambre : | SIGNATURE AS : |
| Date : | SIGNATURE IDE/SAGE FEMME : |

5

## APRES INTERVENTION

*Pause avant sortie de salle d'opération*

**10. Confirmation orale par le personnel auprès de l'équipe :**

| | | | |
|---|---|---|---|
| De l'intervention enregistrée | Oui ☐ | Non *☐ | |
| Du compte final correct des compresses, aiguilles, instruments, etc. | Oui ☐ | Non *☐ | N/A ☐ |
| De l'étiquetage des prélèvements, pièces opératoires, etc. | Oui ☐ | Non *☐ | N/A ☐ |
| Si des évènements indésirables ou porteurs de risques médicaux sont survenus : ont-ils fait l'objet d'un signalement / déclaration ? (*si aucun évènement indésirable n'est survenu pendant l'intervention, cochez N/A*) | Oui ☐ | Non *☐ | N/A ☐ |
| **11. Les prescriptions pour les suites opératoires immédiates sont faites de manière conjointe entre les équipes chirurgicale et anesthésique** | Oui ☐ | Non *☐ | |
| Décision concertée en cas de non-conformité ou de réponse marquée d'un * | | | |

**Conséquences** :
Intervention incorrecte (erreur de procédure, de site ou de patient) ☐ K
Intervention correcte ☐

**Si l'intervention a été incorrecte, merci de compléter ce qui suit :**

| | | | |
|---|---|---|---|
| Mauvais patient | ☐ | Mauvais site | ☐ |
| Mauvaise intervention | ☐ | Mauvais implant | ☐ |

**Niveau de dommage** :

| | | | |
|---|---|---|---|
| Décès | ☐ | Dommage sévère et permanent | ☐ |
| Dommage permanent | ☐ | Dommage temporaire | ☐ |
| Nécessité d'un traitement additionnel | ☐ | Atteinte émotionnelle ou gêne | ☐ |
| Pas de dommage | ☐ | | |

A quel moment a-t-il été identifié ?

☐ Eligible A
☐ Non éligible*
Exemple : annulation de l'intervention pour des raisons indépendantes du protocole ou intervention ayant lieu dans une salle non incluse dans l'étude.

**SELON PROCEDURE EN VIGUEUR DANS L'ETABLISSEMENT**
**Attestation que la check-list a été renseignée suite à un partage des informations entre les membres de l'équipe.**

**Chirurgien** **Anesthésiste/IADE** **Coordonnateur Check list**

Heure de sortie de salle : .....

**IDE Salle de réveil**

| | |
|---|---|
| Transmissions SSPI/SERVICE : | |
| Nom et signature IDE SSPI : | |

14

I B O

**TRACABILITE DES DMS**

## MARQUAGE du site et du côté à opérer

**CHIRURGIEN / INTERNE/IDE**

**Le marquage est requis si :**
→ **Latéralité, Surface (fléchisseur, extenseur), Niveau (colonne vertébrale), Doigt ou Lésion**

Le marquage du site est-il requis / possible ? → OUI ☐ NON ☐ F

***Marquage impossible si*** :
-Urgences vitales
- Prématurés
- Marquage techniquement impossible à réaliser

**Si oui, précisez :**

Le marquage du site satisfait-il aux caractéristiques d'un marquage correct ?

OUI ☐ D NON ☐ Le patient refuse le marquage ☐

**Si non, précisez :**
(Si la case « Non » est cochée ci-dessus, merci de cocher tous les items dans cette liste qui ne sont pas satisfaits) :

| | | | |
|---|---|---|---|
| ☐ | ➢ Le marquage n'est pas effectué par le chirurgien qui opère ou par une personne qualifiée désignée (Médecin ou infirmière participant à la préparation ou à l'intervention) | ☐ | ➢ Le marquage est ambiguë (« X » n'est pas un symbole utilisable pour marquer un site) |
| ☐ | ➢ Le marquage n'est pas fait avant que le patient ne soit amené dans la salle d'opération | ☐ | ➢ Le marquage n'est pas réalisé avec une encre indélébile |
| ☐ | ➢ Le patient n'est pas conscient et n'est pas impliqué lors du marquage lorsque c'est possible | ☐ | ➢ Les modalités de marquage ne sont pas cohérentes avec les règles de l'établissement |
| ☐ | ➢ Le marquage n'est pas réalisé au plus près du site d'incision | ☐ | ➢ Lors d'un accès médian à un organe latéral, le marquage n'indique pas le côté à opérer |
| ☐ | ➢ Seul le site devant être opéré n'est pas marqué | | |

**Nom de la personne qui a effectué le marquage :**

*Si le marquage ne satisfait pas aux caractéristiques d'un marquage correct, décision prise :*

Intervention annulée ☐ E
Intervention maintenue ☐

Décision concertée en cas de non-conformité

6

## VERIFICATIONS PRE-OPERATOIRES

Etiquette patient

**I B O / EQUIPE**

| Avant le jour de l'opération l'ibode aura vérifié que | | | |
|---|---|---|---|
| **Chirurgie programmée et inscrite au programme du bloc opératoire** | Si une discordance est notée, merci d'entourer l'item spécifique qui est manquant ou incorrect dans la liste de gauche | | |
| | Aucune discordance | Une discordance est notée | Non applicable |
| Identité du patient (x2) | ☐ | ☐ | ☐ |
| Intervention notée sans ambiguité ni abréviation | | | |
| Site noté sans ambiguité ni abréviation | | | |
| Les dispositifs médicaux stériles sont spécifiquement mentionnés | | | |
| Vérification de la disponibilité de tout dispositif médical stérile nécessaire | ☐ | ☐ | ☐ |

| Accueil du patient au bloc | |
|---|---|
| Salle d'intervention (à indiquer lorsque la salle est attribuée) | |

| Vérification à l'entrée de la salle de préparation avec le patient | Si une discordance est notée, merci d'entourer l'item spécifique qui est manquant ou incorrect dans la liste de gauche | | |
|---|---|---|---|
| | Aucune discordance | Une discordance est notée | Non applicable |
| Identité du patient (x2) | ☐ | ☐ | ☐ |
| Intervention | | | |
| Site | | | |

| Vérification pré-opératoire : résumé | | |
|---|---|---|
| La vérification pré-opératoire est complète (avec ou sans discordance) | ☐ | B |
| Intervention annulée car une ou plusieurs discordances non résolues | ☐ | C |
| Intervention maintenue malgré une ou plusieurs discordances non résolues | ☐ | |

| Coordonnateur check list | |
|---|---|

7

| COMPRESSES | | | | CHAMPS ABDO | | | | NOIX/NOIXETTES | | | | AUTRES | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DONNEES | RECUES | DONNEES | RECUES | DONNES | RECUS | DONNES | RECUS | DONNEES | RECUES | DONNEES | RECUES | DONNES | RECUS | DONNES | RECUS |
| | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |

Si compte non-conforme : Chirurgien informé ☐ Signature :
Contrôle radiologique ☐

| Type de soluté | Poche N° | Contenance de la poche (3 litres, 1litres ....) | Quantité de liquide récupéré | Estimation des pertes de liquide (champs, sol..) |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

**PROTOCOLE D'ENTRETIEN DE LA SALLE APPLIQUE EN FIN D'INTERVENTION : BIONETTOYAGE**

**ENTRE DEUX INTERVENTIONS ☐ FIN DE PROGRAMME ☐ HEBDOMADAIRE ☐**

**NOM ET SIGNATURE IBODE/DE :**

Commentaires :

12

I B O

***EN SALLE DE BLOC***

Etiquette patient

Heure d'arrivée : .....

Salle 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ Césa ☐ Date d'intervention : .....Heure (début) : ..... Fin : .....
Chirurgien « intervenant » : ..... Anesthésie « intervenant » :.....

**Vérification du questionnaire CREUTZFELD JAKOB** ☐

**INTERVENTION**

TYPE : .....

COTE A OPERER : DROITE ☐ GAUCHE ☐
INSTRUMENTISTE : ..... AIDE-OPERATOIRE :.....
PANSEUSE : ..... AUTRE : .....

**TYPE D'ANESTHESIE**

☐ AG INTUBATION : ☐ OUI ☐NON
☐ MASQUE LARYNGE
☐ ALR : ☐ RACHI ☐ PERI ☐ BLOC
ALLERGIE : ☐ OUI ☐ NON

**INSTALLATION**

DECUBITUS : ☐ DORSAL ☐ VENTRAL ☐ LATERAL
☐ GYNECO ☐ ASSIS ☐ AUTRE .....
☐ INCIDENT (points d'appuis) ☐ OUI ☐ NON

**BISTOURI ELECTRIQUE** : ☐ OUI ☐ NON
EMPLACEMENT : .....
☐ INCIDENT ☐ OUI ☐ NON

**GARROT PNEUMATIQUE**

EMPLACEMENT :.....
DEBUT : ..... FIN : .....
PRESSION : .....
INCIDENT ☐ OUI ☐ NON

**CONTROLE RADIO** :

☐ ECHO
☐ PRODUIT DE CONTRASTE
☐ CLICHE PER. OP
☐ AMPLI
- MA : .....
- KV : .....
- Temps de scopie : .....

**PRELEVEMENTS (noter directement le nombre)**

ANAPATH :..... FIXE : .....
ETAT FRAIS : ..... EXTEMPO : .....
BACTERIO : ..... CYTOLOGIE : .....
AUTRES .....

☐ CATHETER D'ANALGESIE LOCO-REGIONALE

**SONDAGE**

URINAIRE : ☐ EVACUATEUR ☐ A DEMEURE
TYPE ET TAILLE DE SONDE : .....
☐ GASTRIQUE ☐ AUTRE
TYPE ET TAILLE DE SONDE : .....

**DRAINAGE (noter directement le nombre)**

REDON : ..... LAME : .....
MANOVAC : ..... FIXEE A LA PEAU : .....
CRINS : ..... MECHE : .....
DRAIN DE KHER : ..... STOMIES : .....
AUTRES : .....

**FERMETURE**

☐ AGRAFES ☐ FILS ☐ POINTS SEPARES
☐ RESORBABABLES ☐ NON RESORBABLES
☐ SURJET INTRADERMIQUE ☐ POINTS TOTAUX
☐ AUTRES

**PANSEMENT**

☐ SIMPLE ☐ COMPRESSIF
☐ TULLE GRAS ☐ TULLE BETADINE
☐ AUTRE (préciser) .....
OBSERVATIONS OU SURVEILLANCE PARTICULIER

11

## AVANT INDUCTION ANESTHESIQUE
### Temps de pause avant anesthésie

| | | |
|---|---|---|
| **1 Identité du patient** | | |
| Le patient a décliné son nom, par défaut, autre moyen de vérification de son identité | ☐ Oui | ☐ Non* |
| **2. L'intervention et le site opératoire sont confirmés** : | | |
| Idéalement par le patient et dans tous les cas, par le dossier ou procédure spécifique | ☐ Oui | ☐ Non* |
| La documentation clinique et para clinique nécessaire est disponible en salle | ☐ Oui | ☐ Non* |
| **3. Le mode d'installation est connu de l'équipe en salle, cohérent avec le site/intervention et non dangereux pour le patient.** | ☐ Oui | ☐ Non* |
| **4. La préparation cutanée de l'opéré est documentée dans la fiche de liaison service/bloc opératoire (ou autre procédure en œuvre dans l'établissement** | ☐ Oui<br>☐ Non* | ☐ NA |
| **5. L'équipement /matériel nécessaire pour l'intervention est vérifié et ne présente pas de dysfonctionnements** | | |
| Pour la partie chirurgicale | ☐ Oui | ☐ Non* |
| Pour la partie anesthésique | ☐ Oui | ☐ Non* |
| *Acte sans prise en charge anesthésique* | ☐ NA | |
| **6. Vérification croisée par l'équipe de points critiques et des mesures adéquates à prendre**<br>Le patient présente-t-il une : | | |
| Risque allergique | ☐ Oui* | ☐ Non |
| Allergie au latex | ☐ Oui | ☐ Non |
| Risque d'inhalation, de difficulté d'intubation ou de ventilation au masque | ☐ Oui* ☐ Non ☐ NA | |
| Risque de saignement important | ☐ Oui* | ☐ Non |
| Protection spécifique à porter par l'équipe | ☐ Oui | ☐ Non |

Décision concertée en cas de non-conformité ou de réponse marquée d'un *

8

**I B O / EQUIPE**

| **AVANT INTERVENTION CHIRURGICALE**<br>**Temps de pause avant incision ou « Time out »** | | | |
|---|---|---|---|
| **« time out » correct :** | Oui ☐ | Non ☐ | |
| Si « **NON** » cochez dans la liste ci-dessous tous les items non conformes | | | |
| ☐ | ➢ Le « time out » a lieu immédiatement avant l'incision | ☐ | ➢ Il y a une communication active entre tous les membres de l'équipe opératoire |
| ☐ | ➢ Le « time out » est initié par un coordonnateur désigné | ☐ | ➢ Durant ce temps, les activités non essentielles sont suspendues |
| ☐ | ➢ Tous les membres de l'équipe opératoire participent au « time out | | |

| **7. Le « time out » permet une vérification croisée au sein de l'équipe en présence des chirurgien(s) – anesthésiste(s) / IADE – IBODE/IDE :** | Aucune discordance | Si une discordance a été notée, veuillez préciser | |
|---|---|---|---|
| | | Une discordance est notée | Non applicable |
| L'identité correcte du patient (x2) | ☐ | ☐ | |
| La procédure d'intervention (consentement et autres informations sont croisées) | ☐ | ☐ | |
| Site opératoire confirmé | ☐ | ☐ | |
| Le site opératoire correct avec visualisation du marquage | ☐ | ☐ | ☐ |
| Le positionnement correct du patient au regard de la procédure opératoire et du site | ☐ | ☐ | |
| La disponibilité et l'étiquetage correct de l'imagerie | ☐ | ☐ | ☐ |
| La disponibilité des dispositifs médicaux stériles | ☐ | ☐ | ☐ |



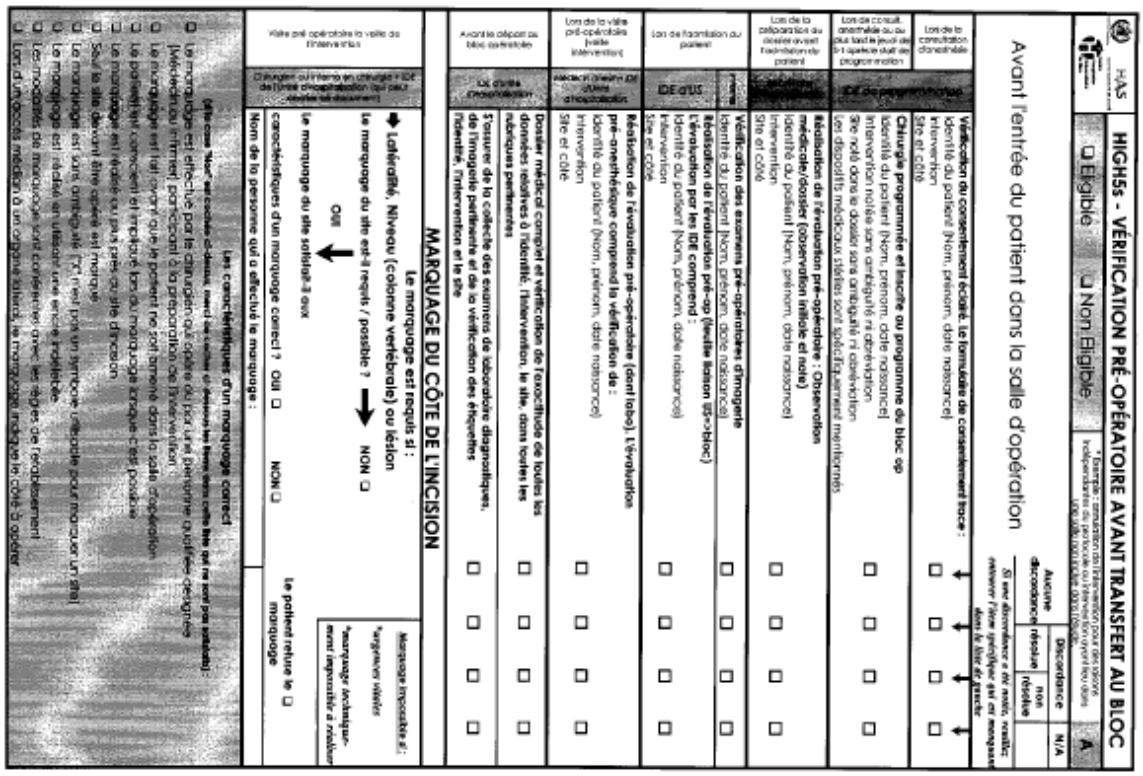
| **8. Partage des informations essentielles dans l'équipe sur des éléments à risque / étapes critiques de l'intervention :** | | | |
|---|---|---|---|
| Sur le plan chirurgical (temps opératoire difficile, points spécifiques de l'intervention, identification des matériels nécessaires, confirmation de leur opérationnalité, etc..) | ☐ Oui | ☐ Non* | |
| Sur le plan anesthésique (risques potentiels liés au terrain ou à des traitements éventuellement maintenus) | ☐ Oui | ☐ Non* | |
| *Acte sans prise en charge anesthésique* | | | ☐ N/A |
| **9. L'antibioprophylaxie a été effectuée selon les recommandations et protocoles en vigueur dans l'établissement** | ☐ Oui | ☐ Non* | ☐ N/R |
| La préparation du champ opératoire est réalisée selon le protocole en vigueur dans l'établissement | ☐ Oui | ☐ Non* | ☐ N/A |
| Si oui :<br>☐ IODE ☐ Autre Lequel : | | | |

| **Temps de « time out » résumé :** | | |
|---|---|---|
| « Time out » complet (tous les éléments listés ci-dessus sont cochés) | ☐ | G |
| Une ou plusieurs discordances ont été notées dans le « time out » | ☐ | H |
| **Gestion des discordances :** | | |
| Toutes les discordances ont été résolues | ☐ | |
| Intervention annulée car discordance non résolue | ☐ | I |
| Intervention maintenue malgré une discordance non résolue | ☐ | J |

| Décision concertée en cas de non-conformité ou de réponse marquée d'un * |
|---|
| |

# Appendix 1: Examples of consolidated check lists (continued)

## From France: *Nice Hospital* – Pre-op paper form & Electronic OR form



HIGH5s - VÉRIFICATION PRÉ-OPÉRATOIRE AVANT TRANSFERT AU BLOC

Eligible / Non Eligible

Avant l'entrée du patient dans la salle d'opération

MARQUAGE DU CÔTE DE L'INCISION

Le marquage est requis si :

Latéralité, Niveau (colonne vertébrale) ou lésion

Le marquage du site est-il requis / possible ? NON

Oui

Le marquage du site solidaire à ceux

caractéristiques d'un marquage correct ? Oui NON

Le patient refuse le marquage

Les caractéristiques d'un marquage correct

Le marquage est effectué par le chirurgien qui opère ou par une personne qualifiée désignée [Médecin ou interne] participant à la préparation de l'intervention.

Le marquage est fait avant que le patient ne soit amené dans la salle d'opération

Le patient est conscient et implique lors du marquage lorsque c'est possible

Le marquage est réalisé au stylo près du site d'incision

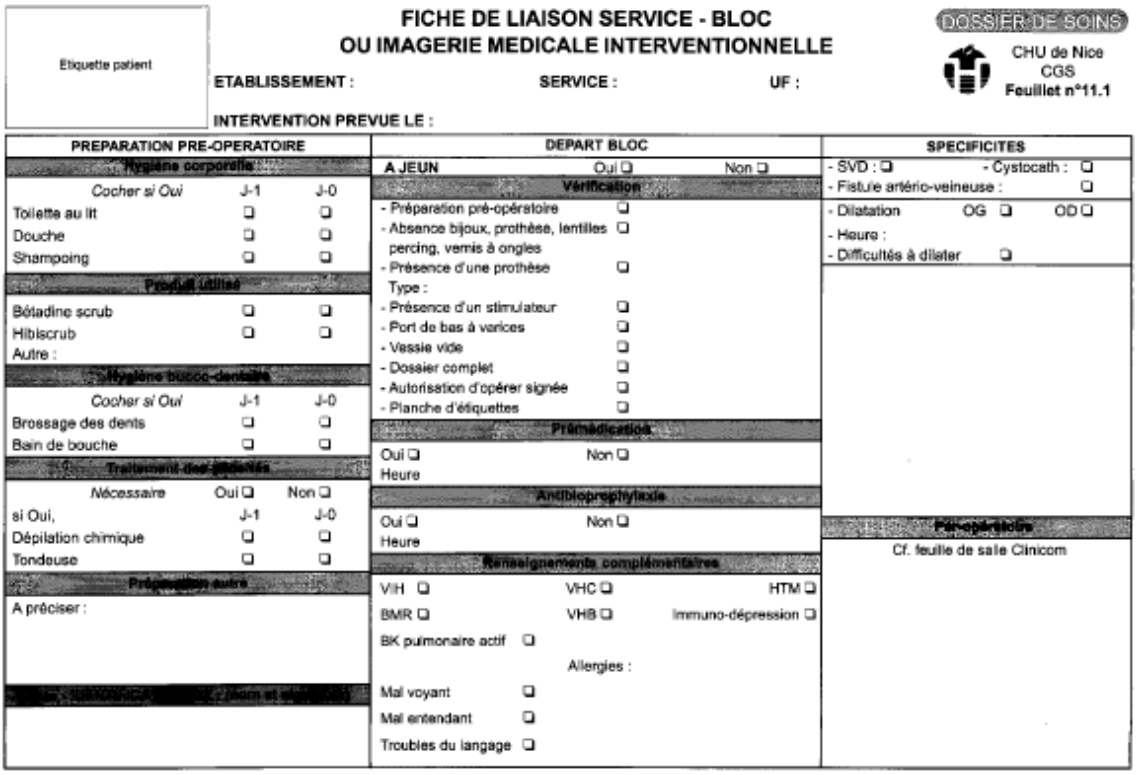
Sur le site devant être opéré est marqué

Le marquage est sans ambiguïté (IC n'est pas un symbole : interdit pour marquer un site)

Le marquage est réalisé en utilisant une encre indélébile

Les modalités de marquage sont conformes avec les règles de l'établissement

Lors d'un accès médian à un organe pair, le marquage indique le côté à opérer



FICHE DE LIAISON SERVICE - BLOC
OU IMAGERIE MEDICALE INTERVENTIONNELLE

Etiquette patient

ETABLISSEMENT : SERVICE : UF :

INTERVENTION PREVUE LE :

DOSSIER DE SOINS

CHU de Nice
CGS
Feuillet n°11.1

PREPARATION PRE-OPERATOIRE

Hygiène corporelle

| Cocher si Oui | J-1 | J-0 |
|---|---|---|
| Toilette au lit | ❑ | ❑ |
| Douche | ❑ | ❑ |
| Shampoing | ❑ | ❑ |

Produit utilisé

| | | |
|---|---|---|
| Bétadine scrub | ❑ | ❑ |
| Hibiscrub | ❑ | ❑ |

Autre :

Hygiène bucco-dentaire

| Cocher si Oui | J-1 | J-0 |
|---|---|---|
| Brossage des dents | ❑ | ❑ |
| Bain de bouche | ❑ | ❑ |

Traitement des phanères

| Nécessaire | Oui ❑ | Non ❑ |
|---|---|---|
| si Oui, | J-1 | J-0 |
| Dépilation chimique | ❑ | ❑ |
| Tondeuse | ❑ | ❑ |

Préparation autre

A préciser :

Nom et signature

DEPART BLOC

A JEUN Oui ❑ Non ❑

Vérification

- Préparation pré-opératoire ❑
- Absence bijoux, prothèse, lentilles perçing, vernis à ongles ❑
- Présence d'une prothèse ❑
  Type :
- Présence d'un stimulateur ❑
- Port de bas à varices ❑
- Vessie vide ❑
- Dossier complet ❑
- Autorisation d'opérer signée ❑
- Planche d'étiquettes ❑

Prémédication

Oui ❑ Non ❑
Heure

Antibioprophylaxie

Oui ❑ Non ❑
Heure

Renseignements complémentaires

VIH ❑ VHC ❑ HTM ❑
BMR ❑ VHB ❑ Immuno-dépression ❑
BK pulmonaire actif ❑

Allergies :

Mal voyant ❑
Mal entendant ❑
Troubles du langage ❑

SPECIFICITES

- SVD : ❑ - Cystocath : ❑
- Fistule artério-veineuse : ❑
- Dilatation OG ❑ OD ❑
- Heure :
- Difficultés à dilater ❑

Pré-opératoire

Cf. feuille de salle Clinicom

## FICHE DE LIAISON BLOC OU IMAGERIE MEDICALE INTERVENTIONNELLE - SERVICE

**INTERVENTION REALISEE LE :**

| | | N° | TYPE | EMPLACEMENT | ASPIRATION SYPHONNAGE BALLONNET |
|---|---|---|---|---|---|
| DRAINAGE | 1 | | | | |
| | 2 | | | | |
| | 3 | | | | |
| | 4 | | | | |
| | 5 | | | | |
| SONDES | 1 | | | | |
| | 2 | | | | |
| | 3 | | | | |

Lavage : Oui ❑ Non ❑

**FERMETURE DES PLAIES :** Agrafes ❑ Points séparés ❑ Surjet ❑ Résorbables oui ❑ non ❑ Sutures adhésives ❑

**PANSEMENT :** Simple ❑ Compressif ❑ Oculaire ❑ Coque ❑ Autre :

⇨ à desserrer le :
⇨ à enlever dans :
⇨ à refaire le :

**SPECIFICITES**

Déficit droit ❑ gauche ❑
Mydriase droite ❑ gauche ❑
Epilepsie ❑
Aphasie ❑
Gaz : SF6 ❑ C3 F8 ❑
Eponge + ATB ❑
Cerclage + ATB ❑
Silicone ❑
Visqueux ❑
Autres (préciser) :

**INSTALLATION POST-OPERATOIRE :**

Membre surélevé ❑
Plâtre ❑
Coussin d'abduction ❑
Attelle ❑
Attelle plâtrée ❑
Minerve ou collier ❑

Traction-type :
Poids :
Décubitus latéral droit ❑
Décubitus latéral gauche ❑
Position demi assise ❑
Position bulle ❑
Autre ❑

**OBSERVATIONS PARTICULIERES :**

**KINESITHERAPIE** ❑

Type :

**MOBILISATION POST-OPERATOIRE**

Lever autorisé ❑ le : .....
Lever avec corset ❑ le : .....
Position assise ❑ le : .....
Appui autorisé ❑ le : .....
contact ❑ partiel ❑ total ❑

**DATE :** **Nom du prescripteur :** **Nom et signature de l'IBO / IDE :**

---

HAS

**HIGH5s - SERVICE DE NEUROCHIRURGIE**
**FICHE DE PROGRAMMATION**

**PATIENT**

*ETIQUETTE PATIENT*

*Nom :*
*Prénom :*
*Date de naissance :*
*Sexe : ❑ F ❑ M*

Tél : .....

Ville de résidence : .....

**Nom de l'opérateur :**

**Intitulé de l'intervention :**

**Site et côté :**

**Voie d'abord :**

**Date prévue de l'intervention :** ...../...../20.....

**Position :** ❑ Décubitus Ventral ❑ Genu-pectoral ❑ Décubitus Dorsal
❑ Décubitus Latéral : ○ gauche ○ droit ❑ Position Assise ❑ Tête en pointe

**Matériel spécifique nécessaire :** ❑ Amplificateur de brillance ❑ Echographe
❑ Neuronavigation ❑ Microscope ❑ Autres : .....

**Matériel à commander :** .....

❑ Banque de tissus (lumioroth-bique) ❑ Examen per opératoire
❑ IRM ○ pré ○ per ○ post
❑ Scanner ○ pré ○ per ○ post

Date : ...../...../20..... Commentaires :

.....

**CONSULTATION D'ANESTHESIE**

.....

**PRECAUTIONS PARTICULIERES**

❑ **Risque MCJ** ❑ **Sérologie positive** ❑ **FontogeBMR** ❑ **Sepsis** ❑ **Autre**

❑ **Allergies :** ○ Latex ○ Bétadine ❑ **Pacemaker** ❑ **Prothèse de hanche**

**HOSPITALISATION**

**Sortie du bloc :** ❑ **Réanimation** ❑ **Surveillance continue**
Durée prévue du séjour : .....nuits ❑ Chambre particulière
❑ Régime privé ❑ Chambre accompagnant

**SORTIE**

❑ **Domicile** ❑ **Rééducation** ❑ **Convalescence**
❑ Autre unité CHU : .....
❑ Assistante sociale à solliciter : .....

**Commentaires :**

.....

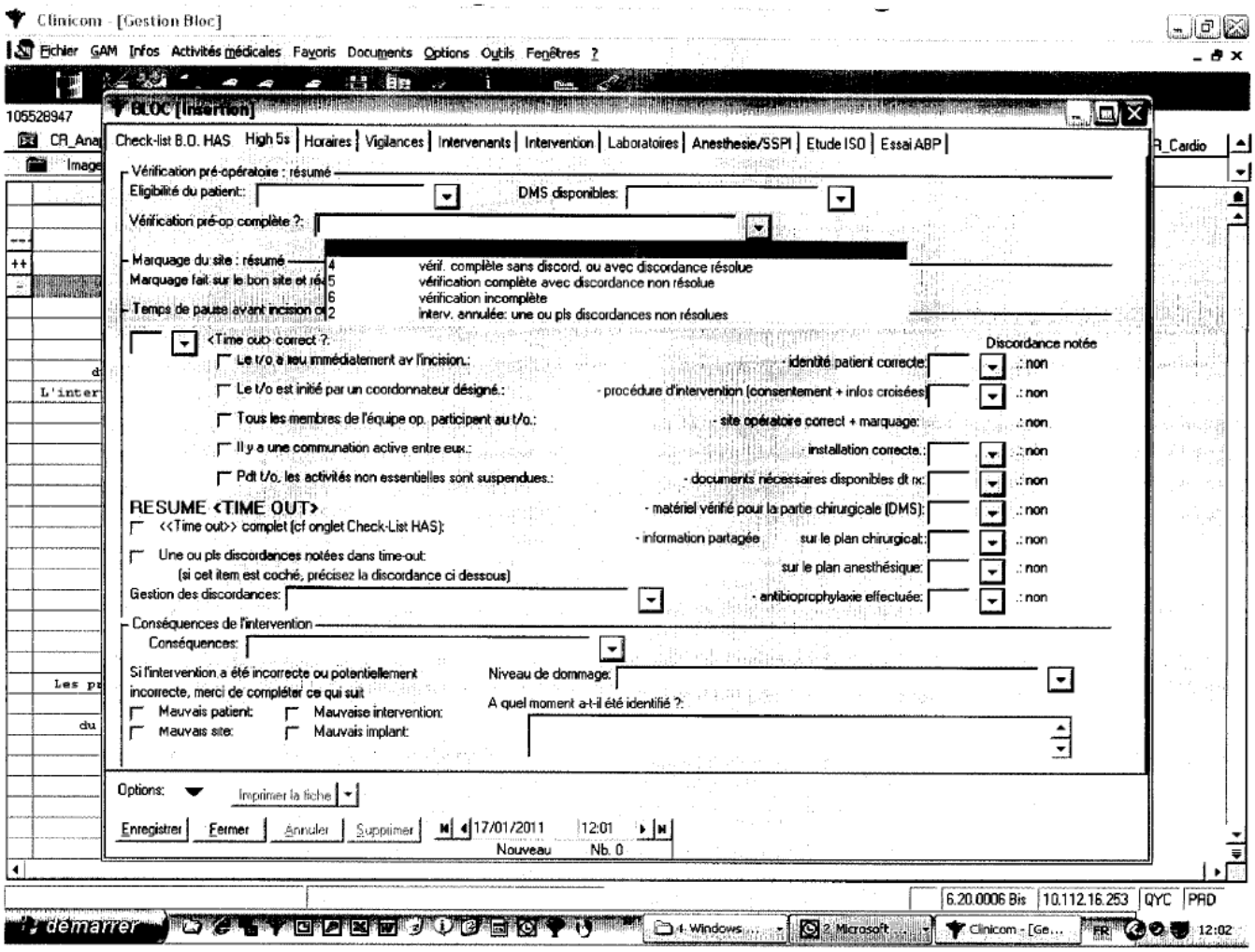
**Appels téléphoniques (pb patient, changement d'avis, refus d'opération ...) :**

**Date :** ...../...../ **/20** ..... **: Motifs:**

**Date :** ...../...../ **/20** ..... **: Motifs:**

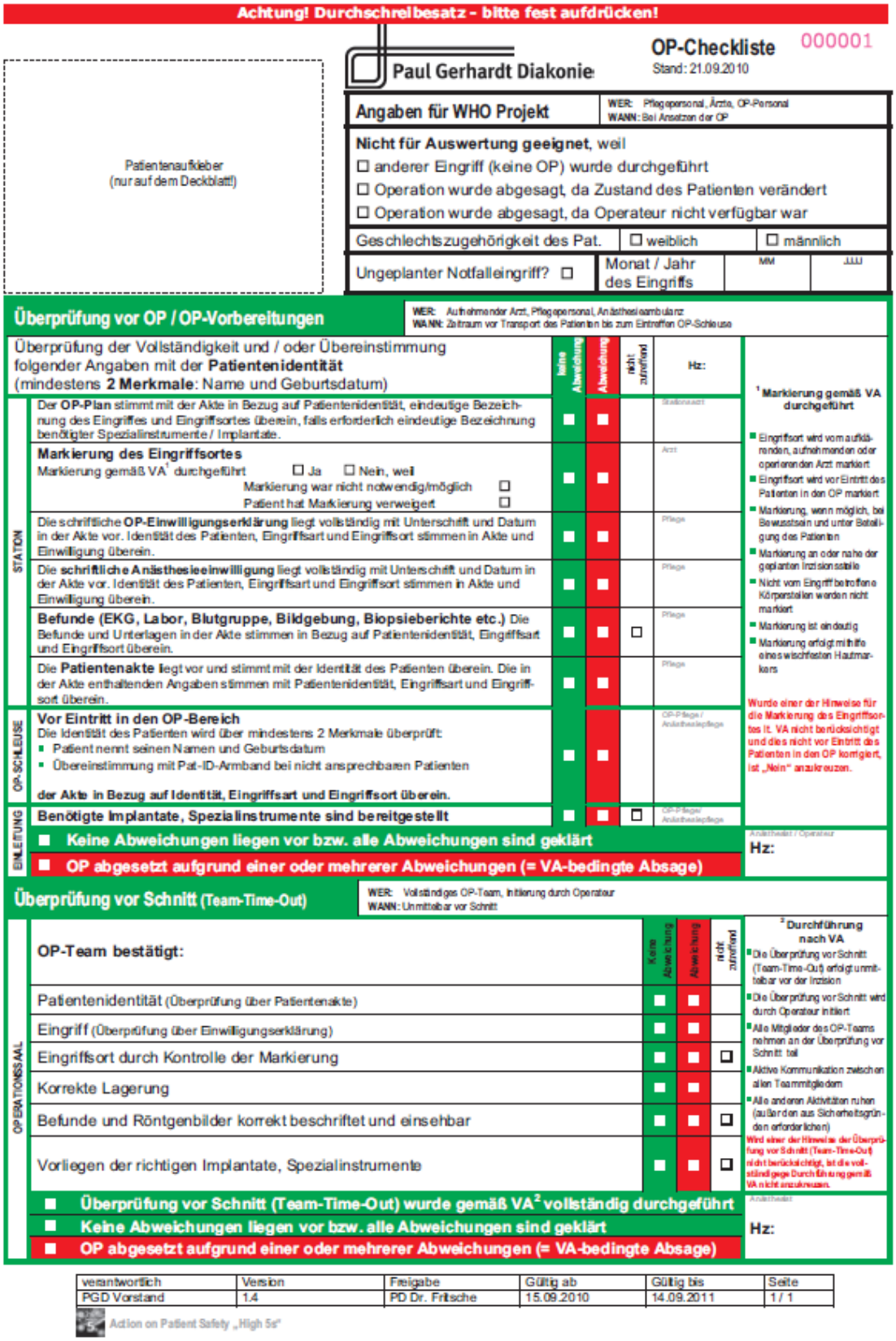
**Signature du chirurgien :** **Signature du médecin anesthésiste :**

PAOPA5618


Clinicom - [Gestion Bloc]
Fichier GAM Infos Activités médicales Favoris Documents Options Outils Fenêtres ?
BLOC [Insertion]
Check-list B.O. HAS High 5s Horaires Vigilances Intervenants Intervention Laboratoires Anesthesie/SSPI Etude ISO Essai ABP
Vérification pré-opératoire : résumé
Eligibilité du patient:
DMS disponibles:
Vérification pré-op complète ?:
4 vérif. complète sans discord. ou avec discordance résolue
5 vérification complète avec discordance non résolue
6 vérification incomplète
2 interv. annulée: une ou pls discordances non résolues
Marquage du site : résumé
Marquage fait sur le bon site et ré
Temps de pause avant incision c
<Time out> correct ?:
Le t/o a lieu immédiatement av l'incision.:
Le t/o est initié par un coordonnateur désigné.:
Tous les membres de l'équipe op. participent au t/o.:
Il y a une communication active entre eux.:
Pdt t/o, les activités non essentielles sont suspendues.:
Discordance notée
- identité patient correcte: .: non
- procédure d'intervention (consentement + infos croisées): .: non
- site opératoire correct + marquage: .: non
installation correcte.: .: non
- documents nécessaires disponibles dt rx: .: non
- matériel vérifié pour la partie chirurgicale (DMS): .: non
- information partagée sur le plan chirurgical: .: non
sur le plan anesthésique: .: non
- antibioprophylaxie effectuée: .: non
RESUME <TIME OUT>
<<Time out>> complet (cf onglet Check-List HAS):
Une ou pls discordances notées dans time-out:
(si cet item est coché, précisez la discordance ci dessous)
Gestion des discordances:
Conséquences de l'intervention
Conséquences:
Si l'intervention a été incorrecte ou potentiellement incorrecte, merci de compléter ce qui suit
Mauvais patient:
Mauvaise intervention:
Mauvais site:
Mauvais implant:
Niveau de dommage:
A quel moment a-t-il été identifié ?:
Options:
Imprimer la fiche
Enregistrer Fermer Annuler Supprimer
17/01/2011 12:01
Nouveau Nb. 0
6.20.0006 Bis 10.112.16.253 QYC PRD
démarrer
1 Windows... 2 Microsoft... Clinicom - [Ge... FR 12:02

# Appendix 1: Examples of consolidated check lists (continued)

## From Germany: *Paul Gerhardt Diakonie*



**Achtung! Durchschreibesatz - bitte fest aufdrücken!**

Paul Gerhardt Diakonie

**OP-Checkliste** 000001
Stand: 21.09.2010

Patientenaufkleber
(nur auf dem Deckblatt!)

**Angaben für WHO Projekt**
WER: Pflegepersonal, Ärzte, OP-Personal
WANN: Bei Ansetzen der OP

**Nicht für Auswertung geeignet**, weil
☐ anderer Eingriff (keine OP) wurde durchgeführt
☐ Operation wurde abgesagt, da Zustand des Patienten verändert
☐ Operation wurde abgesagt, da Operateur nicht verfügbar war

Geschlechtszugehörigkeit des Pat. ☐ weiblich ☐ männlich

Ungeplanter Notfalleingriff? ☐ Monat / Jahr des Eingriffs MM JJJJ

**Überprüfung vor OP / OP-Vorbereitungen**
WER: Aufnehmender Arzt, Pflegepersonal, Anästhesieambulanz
WANN: Zeitraum vor Transport des Patienten bis zum Eintreffen OP-Schleuse

| | keine Abweichung | Abweichung | nicht zutreffend | Hz: |
|---|---|---|---|---|
| **STATION** | | | | |
| Überprüfung der Vollständigkeit und / oder Übereinstimmung folgender Angaben mit der **Patientenidentität** (mindestens **2 Merkmale**: Name und Geburtsdatum) | | | | |
| Der **OP-Plan** stimmt mit der Akte in Bezug auf Patientenidentität, eindeutige Bezeichnung des Eingriffes und Eingriffsortes überein, falls erforderlich eindeutige Bezeichnung benötigter Spezialinstrumente / Implantate. | ■ | ■ | | Stationsarzt |
| **Markierung des Eingriffsortes** Markierung gemäß VA[1] durchgeführt ☐ Ja ☐ Nein, weil Markierung war nicht notwendig/möglich ☐ Patient hat Markierung verweigert ☐ | ■ | ■ | | Arzt |
| Die schriftliche **OP-Einwilligungserklärung** liegt vollständig mit Unterschrift und Datum in der Akte vor. Identität des Patienten, Eingriffsart und Eingriffsort stimmen in Akte und Einwilligung überein. | ■ | ■ | | Pflege |
| Die **schriftliche Anästhesieeinwilligung** liegt vollständig mit Unterschrift und Datum in der Akte vor. Identität des Patienten, Eingriffsart und Eingriffsort stimmen in Akte und Einwilligung überein. | ■ | ■ | | Pflege |
| **Befunde (EKG, Labor, Blutgruppe, Bildgebung, Biopsieberichte etc.)** Die Befunde und Unterlagen in der Akte stimmen in Bezug auf Patientenidentität, Eingriffsart und Eingriffsort überein. | ■ | ■ | ☐ | Pflege |
| Die **Patientenakte** liegt vor und stimmt mit der Identität des Patienten überein. Die in der Akte enthaltenden Angaben stimmen mit Patientenidentität, Eingriffsart und Eingriffsort überein. | ■ | ■ | | Pflege |
| **OP-SCHLEUSE** | | | | |
| **Vor Eintritt in den OP-Bereich** Die Identität des Patienten wird über mindestens 2 Merkmale überprüft: ▪ Patient nennt seinen Namen und Geburtsdatum ▪ Übereinstimmung mit Pat-ID-Armband bei nicht ansprechbaren Patienten **der Akte in Bezug auf Identität, Eingriffsart und Eingriffsort überein.** | ■ | ■ | | OP-Pflege / Anästhesiepflege |
| **EINLEITUNG** | | | | |
| **Benötigte Implantate, Spezialinstrumente sind bereitgestellt** | ■ | ■ | ☐ | OP-Pflege/ Anästhesiepflege |

[1] **Markierung gemäß VA durchgeführt**
- Eingriffsort wird vom aufklärenden, aufnehmenden oder operierenden Arzt markiert
- Eingriffsort wird vor Eintritt des Patienten in den OP markiert
- Markierung, wenn möglich, bei Bewusstsein und unter Beteiligung des Patienten
- Markierung an oder nahe der geplanten Inzisionsstelle
- Nicht vom Eingriff betroffene Körperstellen werden nicht markiert
- Markierung ist eindeutig
- Markierung erfolgt mithilfe eines wischfesten Hautmarkers

Wurde einer der Hinweise für die Markierung des Eingriffsortes lt. VA nicht berücksichtigt und dies nicht vor Eintritt des Patienten in den OP korrigiert, ist „Nein" anzukreuzen.

■ **Keine Abweichungen liegen vor bzw. alle Abweichungen sind geklärt**
■ **OP abgesetzt aufgrund einer oder mehrerer Abweichungen (= VA-bedingte Absage)**

Anästhesist / Operateur **Hz:**

**Überprüfung vor Schnitt (Team-Time-Out)**
WER: Vollständiges OP-Team, Initiierung durch Operateur
WANN: Unmittelbar vor Schnitt

| **OPERATIONSSAAL** OP-Team bestätigt: | Keine Abweichung | Abweichung | nicht zutreffend |
|---|---|---|---|
| Patientenidentität (Überprüfung über Patientenakte) | ■ | ■ | |
| Eingriff (Überprüfung über Einwilligungserklärung) | ■ | ■ | |
| Eingriffsort durch Kontrolle der Markierung | ■ | ■ | ☐ |
| Korrekte Lagerung | ■ | ■ | |
| Befunde und Röntgenbilder korrekt beschriftet und einsehbar | ■ | ■ | ☐ |
| Vorliegen der richtigen Implantate, Spezialinstrumente | ■ | ■ | ☐ |

[2] **Durchführung nach VA**
- Die Überprüfung vor Schnitt (Team-Time-Out) erfolgt unmittelbar vor der Inzision
- Die Überprüfung vor Schnitt wird durch Operateur initiiert
- Alle Mitglieder des OP-Teams nehmen an der Überprüfung vor Schnitt teil
- Aktive Kommunikation zwischen allen Teammitgliedern
- Alle anderen Aktivitäten ruhen (außer den aus Sicherheitsgründen erforderlichen)

Wird einer der Hinweise der Überprüfung vor Schnitt (Team-Time-Out) nicht berücksichtigt, ist die vollständige Durchführung gemäß VA nicht anzukreuzen.

■ **Überprüfung vor Schnitt (Team-Time-Out) wurde gemäß VA[2] vollständig durchgeführt**
■ **Keine Abweichungen liegen vor bzw. alle Abweichungen sind geklärt**
■ **OP abgesetzt aufgrund einer oder mehrerer Abweichungen (= VA-bedingte Absage)**

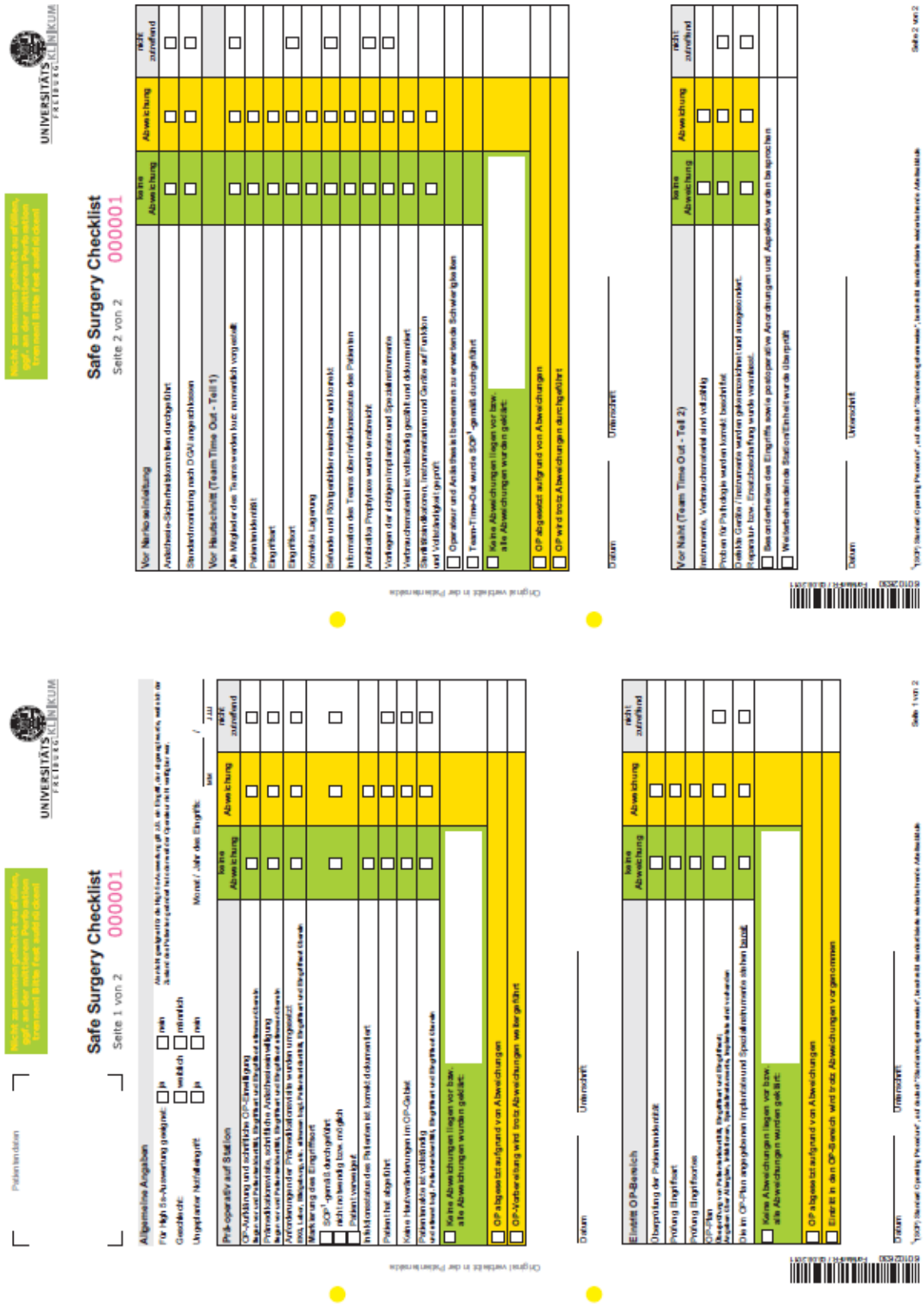
Anästhesist **Hz:**

| verantwortlich | Version | Freigabe | Gültig ab | Gültig bis | Seite |
|---|---|---|---|---|---|
| PGD Vorstand | 1.4 | PD Dr. Fritsche | 15.09.2010 | 14.09.2011 | 1 / 1 |

Action on Patient Safety „High 5s"

# Appendix 1: Examples of consolidated check lists (continued)

## From Germany: *Universitäts Klinikum Freiburg*



## Appendix 2: High 5s Event Analysis Reporting Form (7 pages)


Event Analysis
Minimum Data Set - CSS

DRAFT 4.1 13 January 2011

# REPORTING FORM EA - CORRECT SITE SURGERY

_____ - _____ - _____

*(report #)* *(unique hospital identifier)* *(country)*

*(report # - each hospital starts with #01 and numbers consecutively for each report submitted)*

*When did the event take place ( e.g. when was the patient harmed, or, in case of a near miss, when did the mix up take place, etc.)?*

**1. Date of Event** (___ ___/___ ___/___ ___) **2. Time of Event (24 HOUR CLOCK)** (_____ : _____)
MM DD YYYY

**3. Date Event was discovered** (___ ___/___ ___/___ ___)
MM DD YYYY

**4. Date that the Hospital Event Analysis process was initiated** (___ ___/___ ___/___ ___)
MM DD YYY

**5. Event identified by (circle all that are applicable):**

a. Outcome identified concurrently or retrospectively from Checklist review

Please indicate which checklist if possible: _____

Please select outcome from list below:

- ☐ Incorrect Surgery
- ☐ Case proceeded with unresolved discrepancy
- ☐ Case cancelled due to SOP-related discrepancy
- ☐ Case with discrepancy resolved at final Time Out
- ☐ Incorrect Surgery

b. Patient / Family Concern

c. Disclosed by staff

d. Reported to hospital incident or other reporting system

e. Other (PLEASE SPECIFY) _____

**6. Was more than one patient involved or affected (e.g., mix up of patients)**

___ Yes* *If Yes, please conduct a separate event analysis and complete a separate MDS for each patient*
___ No

**7. Circle type of analysis completed**

a. Concise

b. Comprehensive

For Comprehensive, please list the disciplines that participated.

_____ _____
_____ _____
_____ _____
_____ _____

8. Patient's age _____

9. What was the patient's principal diagnosis? (Please use ICD code and note country specific ICD modification)

_____

10. Did the event involve the principal procedure planned or the one falsely conducted?

_____ Principal procedure planned
Principal procedure planned was _____
Please use ICD code and note country specific ICD modification)

_____ Procedure actually performed
Procedure actually performed was _____
Please use ICD code and note country specific ICD modification)

11. Select the first applicable category below (in descending order) that best describes the extent of harm to the patient as assessed 24 hours post event.

- ☐ Death
- ☐ Severe permanent harm. Severe life-long bodily or psychological injury or disfigurement that interferes significantly with functional ability or quality of life
- ☐ Permanent harm. Life-long bodily or psychological injury or increased susceptibility to disease
- ☐ Temporary harm. Bodily or psychological injury, but likely not permanent
- ☐ Additional treatment. Injury limited to additional intervention during admission or encounter and/or increased length of stay, but no other injury
- ☐ 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).
- ☐ No harm. Event reached patient, but no harm evident

(PATIENT OUTCOME HARM SCALE - Used with the permission of the Agency for Healthcare Research and Quality)

12. After analysis, where was it determined that the care process first deviated and the event began to unfold?

Check applicable answer

- ☐ Emergency Department
- ☐ Patient's Room - Inpatient Unit
- ☐ Admitting Office
- ☐ Outpatient Unit
- ☐ Pre-Operative Holding Area
- ☐ Operating Room
- ☐ Post Anesthesia Care Unit
- ☐ Intensive Care Unit/Coronary Care Unit/Other High Intensity Care Unit
- ☐ Pharmacy
- ☐ Other (please specify) _____

**13. Was the surgery / procedure performed as an emergency? Check one:**

____ Yes
____ No
____ Unable to determine

**14. What was the body site(s) of the intended surgery/procedure?** _____

**15. What was incorrect about the surgery/procedure that almost occurred (if stopped) or was completed in error?**

_____
_____

**16. Was a device or product directly involved in the event?**

____ Yes *If Yes, describe the device or product and how it was involved*
_____
_____
_____

____ No

**17. When was the event discovered? Check applicable answer**

☐ Inpatient/Outpatient Unit (pre-operatively)
☐ Before anesthesia started in the operating room
☐ After anesthesia started but before incision, or, if non-surgical procedure, before procedure started
☐ After procedure started (incision) but before it ended (completion of closure)
☐ After procedure ended (if surgical operation, after closure), but before patient left the operating room
☐ Post-anesthesia care unit
☐ Other hospital unit
☐ After patient was discharged
☐ Unknown
☐ Other (please specify) _____

**18. Narrative of Event...What happened?** *Do not include provider or patient identifiable information.*

Describe these relevant facts according to each step of the applicable SOP Process (I. Pre-operative verification process; II. Marking the operative site; and, III. "Time out" immediately before starting procedure). Include any measures taken to prevent and/or mitigate the harm to this patient as a result of this event.

**(add page as needed)**

**19. Which were the contributing factors for the occurrence of the event?**

**Please indicate all that apply and provide a short description of the selected factors and how they contributed to the event**

a. Communication (e.g. verbal, unclear handwriting, non-verbal...)

_____

b. Education and Training (e.g. knowledge, lack of practice, lack of relevant training...)

_____

c. Staffing (e.g. workload, staff to patient ratio, skill mix...)

_____

d. Rules / Policies / Procedures (e.g. outdated, lack of relevant policy...)

_____

e. Equipment (e.g. unavailable, difficult to operate...)

_____

f. Environment (e.g. lighting, noise, temperature, storage...)

_____

g. Individual (e.g. health issues, fatigue, stress, distraction, personality...)

_____

h. Teamwork (e.g. cooperation, stability of team, allocation of tasks, clinical / managerial support...)

_____ _____

i. Patient (e.g. physical and mental factors, ability to communicate, personality...)

_____ _____

j. Other, specify_____

_____ _____

**20. Which of the identified contributing factors do you consider to be the most important/primary contributing factor? Please check applicable answer**

- ☐ Communication
- ☐ Education and Training
- ☐ Staffing
- ☐ Rules/Policies/Procedures
- ☐ Equipment
- ☐ Environment
- ☐ Individual
- ☐ Teamwork
- ☐ Patient
- ☐ Other (please specify) _____

Conclusions of event analysis *as applicable to High 5s*

**21. Was the SOP fully implemented at the time of the event (for the specific patient)? Check one:**

____ Yes
____ No
____ Unable to determine

**If the SOP was *not* fully implemented, describe what aspects were in place at the time of the event.**

_____
_____
_____

**22. Following the Event Analysis, are there recommendations for improving the SOP or other related High 5s processes?**

____ Yes
____ No

**If yes, recommendations apply to (check all that apply):**

- ☐ Correct Procedure/Correct Body Site SOP
- ☐ SOP implementation tools/training
- ☐ Data collection process
- ☐ Event Analysis methodology and/or Event analysis MDS

**Please describe the recommendations:**

_____
_____
_____

**23. What other actions are going to be taken as a result of the event analysis?**

_____

_____

_____

_____

_____

**24. Was literature used to inform the recommendations?**

____ Yes
____ No

**Conclusions of event analysis as applicable to concrete actions/changes /recommendations for your hospital.**

**In the following table please provide a short description of the actions you have planned or executed as a result of the event analysis.**

| What will be changed/ Which action/measure will be taken? | Who is responsible? | Until when? | How will the action/measure be evaluated? |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

# Appendix 3: 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.

### Q. What is the definition of "eligible" cases?

A. All surgical cases scheduled to be performed in the hospital's in-patient operating room environment, including emergency procedures and other late add-on procedures performed in that environment.

The phrase "all surgical cases" **includes** outpatient surgery cases, special procedures, and any other cases that are performed or scheduled to be performed in that inpatient surgical environment. It **excludes** (a) cases done elsewhere in the hospital such as a dedicated outpatient surgery facility, a special procedures unit, or a separate obstetrical surgery unit; and (b) surgical cases that are cancelled for reasons unrelated to the SOP (OR not ready, surgeon not available, patient expired prior to arriving to the surgical suite, etc.).

An inpatient operating room environment is defined as the hospital's operating room/theatre environment (suite of ORs) 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).

### Q. Is sampling permitted for performance measures?

A. Sampling is permissible **only for the process measures**. Sampling is not permitted for the outcome measures (CS-6 and CS-7) due to the rarity of these outcomes. Sampling applies to data collection, not to implementation of the SOP procedures. All eligible cases must follow the SOP, including use of a check list that contains each of the 11 required data elements).

Whenever possible, 100% of eligible cases should be included in the collection of data for the performance measures.

A participating hospital may use sampling if the following conditions are met:

1. The sample size is at least 261 cases per month [this is the minimum sample size to detect a 10% difference (up or down) in monthly process measure rates at the 95% confidence level and 90% power]
2. The sample is drawn from the full population of eligible cases and is determined independently from the set of check lists
3. To a reasonable approximation, the sample is proportionally representative with respect to time (shifts, days, including weekends/holidays), specialty (all major surgical specialties which together account for at least 75% of total case volume), and urgency (elective, add-on, emergency)
4. The following information is provided to the hospital leadership or other oversight body:
    a. A written explanation for why 100% data collection cannot be achieved; and
    b. A description of the data collection process that meets the above specifications.

**Q. What does "full implementation" mean?**

A. Each SOP defines the expected full scope of implementation as (1) all of the required steps in the process to be standardized, (2) all of the locations where those steps are to be put into effect, and (3) the population of patients to which those steps will apply (the eligible population).A distinction is drawn between performance of the process that the SOP seeks to standardize and implementation of that process. In this context, to implement the process means to put into effect the procedures and resources necessary to perform the process and evaluation. Once the process is implemented, performance of the process means the degree to which it is consistently executed. The extent of *implementation* is determined primarily through the SOP implementation experience evaluation. *Performance* is determined primarily through the High 5s performance measures.

Only when the implementation has reached the full scope as defined in the SOP will the hospital be considered at "full implementation." For purposes of analyzing and reporting evaluation data, hospitals will report their level of implementation as "Full implementation" only if throughout the entire time period for which the data are being reported, all of the process and evaluation steps in the SOP have been in place in all of the locations required by the SOP and available to the entire defined eligible population. Anything less than this is reported as "Not full implementation."

## *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.

## Appendix 4: References, including evidence base, and other resources


1. "Lessons learned: Wrong site surgery," Sentinel Event Alert, Issue 6, August 28, 1998, Joint Commission on Accreditation of Healthcare Organizations. http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_6.htm
2. "A follow-up review of wrong site surgery," Sentinel Event Alert, Issue 24, December 5, 2001, Joint Commission on Accreditation of Healthcare Organizations. http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_24.htm
3. "Statement on ensuring correct patient, correct site, and correct procedure surgery," *Bulletin of the American College of Surgeons*, Vol. 87, No. 12, December 2002. http://www.facs.org/fellows_info/statements/st-41.html
4. 2003 National Patient Safety Goals, Joint Commission on Accreditation of Healthcare Organizations. http://www.acha.org/info_resources/jcaho2_02.pdf
5. "AAOS launches 2003 public service ad campaign," *AAOS Bulletin*, February 2003, American Academy of Orthopaedic Surgeons' "Sign Your Site" initiative.
6. Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery ™, Joint Commission Resources, July 2004.
7. Correct site surgery. National Patient Safety Agency Alert, 2 March 2005. http://www.npsa.nhs.uk/site/media/documents/883_CSS%20PSA06%20FINAL.pdf
8. Croteau RJ, Wrong Site Surgery in *Surgical Patient Safety: Essential Information for Surgeons in Today's Environment*, American College of Surgeons, Chicago, 2005.
9. Gawande AA, *et al*, Incidence, Patterns, and Prevention of Wrong-Site Surgery, *Archives of Surgery*; 141:353-358; 2006.
10. Pronovost PJ, *et al*, Operating Room Briefing and Wrong-Site Surgery, *Journal of the American College of Surgeons*; Volume 204, No.2, February 2007
11. Seiden SC, Barach P, Wrong-Side/Wrong-Site, Wrong-Procedure, and Wrong-Patient adverse events. Are they preventable? *Arch Surg* 2006; 141:931-9.
12. Meinberg RG, Stern PJ. Incidence of wrong-site surgery among hand surgeons. *J Bone Joint Surg Am.* 2003;85:193–197
13. Michaels RK, et al. Achieving the National Quality Forum's "Never Events": prevention of wrong site, wrong procedure, and wrong patient operations. *Ann Surg* 2007; 245(4):526-532.
14. Department of Veterans Affairs. Veterans Health Administration. Ensuring correct surgery and invasive procedures. *VHA Directive* 2004-028 [online]. 2005 Jun 25. http://www.va.gov/NCPS/SafetyTopics/CorrectSurg/CorrectSurgDir.DOC.
15. Kwaan MR, Studdert DM, Zinner MJ, et al. Incidence, patterns, and prevention of wrong-site surgery. *Arch Surg* 2006 Apr;141(4):353-7.
16. Edwards P. Promoting correct site surgery: a national approach. *J Perioper Pract* 2006 Feb;16(2):80-6.

17. Dunn D. Surgical site verification: A through Z. *J Perianesth Nurs* 2006 Oct;21(5):317-331.

18. National Patient Safety Agency. Correct site surgery. Patient Safety Alert 06. 2005 Mar 2. http://www.npsa.nhs.uk/site/media/documents/883CSS%20PSA%20FINAL.pdf. [cited 2007 Mar 23]

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

20. Association of periOperative Registered Nurses. AORN position statement on correct site surgery, Feb 2003. Available from Internet: http://www.aorn.org/PracticeResources/AORNPositionStatements/. [cited 2007 Mar 23].

21. TeamSTEPPS™: Team Strategies and Tools to Enhance Performance and Patient Safety, (Developed by the U.S. Department of Defense), *AHRQ Publication No. 06-0020-3*, Rockville, MD, Sept 2006.

22. Aktionsbündnis Patientensicherheit (German Coalition for Patient Safety) Handlungsempfehlungen zur Vermeidung von Eingriffsverwechslungen in der Chirurgie (Instruction to prevent wrong site procedures in surgery) http://www.aktionsbuendnis-patientensicherheit.de/apsside/07-07-25-EV_Handlungsempfehlungen.pdf

23. Aktionsbündnis Patientensicherheit (German Coalition for Patient Safety) Empfehlungen zur Prävention von Eingriffsverwechslungen – Flyer (Recommendations to prevent wrong site surgery - Flyer) http://www.aktionsbuendnis-patientensicherheit.de/apsside/07-07-25-_EV_Flyer.pdf

24. WHO Collaborating Centre: Performance of Correct Procedure at Correct Body Site, *Patient Safety Solutions,* volume 1, solution 4, May 2007. http://www.jcipatientsafety.org/fpdf/presskit/PS-Solution4.pdf

25. Bate P, Robert G, Fulop N, Øvretveit J, Dixon-Woods M; Perspectives on Context, *The Health Foundation*, London, March 2014; http://www.health.org.uk/publications/perspectives-on-context/

26. A Framework for Measuring and Monitoring Safety, *The Health Foundation*, London, April 2014.

27. Vincent C, Burnett S, Carthey J; Safety Measurement and Monitoring in Healthcare: A Framework to Guide Clinical Teams and Healthcare Organisations in Maintaining Safety; BMJ Publishing Group Ltd, April 2014.

28. High 5sProject Interim Report, http://www.who.int/patientsafety/implementation/solutions/high5s/en/