# NATIONAL POLICY & PROCEDURE FOR SAFE SURGERY


2022

Clinical Design & Innovation
Person-centred, co-ordinated care

Anaesthesia
National Clinical Programme for Anaesthesia

NCP T&O
National Clinical Programme for Trauma & Orthopaedic Surgery

NCPS
National Clinical Programme in Surgery

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| Title of Guidance Development Group: | HSE NATIONAL POLICY AND PROCEDURE FOR SAFE SURGERY: This policy and procedure was revised and updated by the National Clinical Programmes for Anaesthesia, Surgery, Trauma & Orthopaedics and HSE Quality &Patient Safety in consultation with HSE acute hospital, stakeholders and patient representatives |
| Approved by: | Dr Mike O'Connor, NCAGL Acute Operations |
| Unique Identifier Number: | CDI007/2022 |
| Version Number: | V2 |
| Publication Date: | June 2022 |
| Date for Revision: | June 2025 |
| Electronic Location: | *https://www.hse.ie/eng/about/who/cspd/ncps/anaesthesia/resources/* |

| Version | Date Approved | List Section Numbers Changed | Author |
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## 1.0 Table of Contents

## 2.0 Introduction

**Patient safety is a priority for the Health Service Executive (HSE) and all healthcare staff (*HSE Patient Safety Strategy 2019-2024*)**. It is the vision of the Patient Safety Strategy that all patients will consistently receive the safest care possible. One of the commitments of the strategy is to place increased emphasis on proactively identifying risks to patient safety to create and maintain safe and resilient systems of care, designed to reduce incidents and improve patient outcomes.

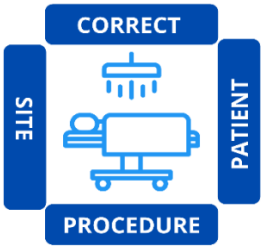
In 2013, the HSE published a '*National Policy and Procedure for Safer Surgery*' following on from the principles of the World Health Organisation (WHO) Surgical Safety Check list.

The WHO Surgical Safety checklist was initially adapted for use within the operating theatre. Healthcare has developed over recent years with procedures performed outside of the operating theatre becoming more complex, involving higher risk patients, multi-disciplinary teams and the requirement for sedation or general anaesthesia. Consequently, there is now a clear need for clinical interventions undertaken in clinical areas outside the operating department to fall within the ambit of the national Policy and Procedure for Safe Surgery

The HSE National Policy and Procedure for Safe Surgery, while primarily directed towards surgical procedures within the operating department, should be adapted by other specialties for use within their own area.

In 2019, The National Clinical Programme for Anaesthesia (NCPA), The National Clinical Programme for Trauma & Orthopaedic Surgery (NCPTOS, and The National Clinical Programme for Surgery (NCPS) undertook to review and update the HSE National Policy for Safer Surgery (2013). This project was sponsored by the National Clinical Advisory Group Lead (NCAGL) for Acute Hospitals.

The HSE is committed to supporting services to maintain safe practices of care within high risk environments such as surgery, to ensure that the correct procedure is performed on the correct patient and on the correct site on every occasion. Safe surgery practices require integrated governance structures with clear accountability and strong organisational leadership for planning and managing the development of systems and processes aimed at ensuring patient safety. Every member of the healthcare team involved in the patient pathway has a role to play in ensuring patient safety.



The State Claims Agency (SCA) completed a review (Appendix I) related to clinical claims relevant to safe surgery 2016-2020. This review indicates that an analysis of relevant National Incident Management System (NIMS) data relating to finalised perioperative claims identified 25 claims from 2016–2020 (inclusive) where the incident category (Problem/Cause on NIMS) included Wrong Body Part/Side/Site, Wrong Patient or Wrong Process/Treatment/Procedure. Costs for all 25 claims were analysed. Paid damages and costs for this cohort of claims were found to be in excess of €6 million.

The HSE mandates that all HSE/ S38 hospitals adopt and implement this National Policy and Procedure for Safe Surgery. Local sites may add additional checks to serve their requirements but all checklists must include the minimum safety steps as outlined.

**Appendix I: Review of Clinical Claims Relevant to Safe Surgery, 2016 – 2020**

## 3.0 Purpose

3.1 The purpose of this Policy is to endorse the principles of the World Health Organisation (WHO) Surgical Safety CheckLIST and the HSE Patient Safety Strategy to ensure that all patients undergoing surgical procedures do so safely, by providing guidance for safe practice throughout the surgical patient pathway, and introducing key safety steps that can be incorporated into the operating theatre. Patient safety can be maximised and incidents minimised. The critical safety steps proposed are intended to support the development of a safety culture for operating departments and teams.

3.2 The WHO initiative, Safe Surgery Saves Lives, which Ireland signed up to in 2008, aimed to identify a core set of safety standards that can be universally applied across countries and settings. A simple set of surgical safety standards were compiled into a one page checklist for use by healthcare professionals when delivering surgical care. The purpose of the checklist is to act as a reminder of the **minimum** safety steps and to facilitate focused communication between all members of the operating team.

3.3 Healthcare is an inherently complex industry dealing with invasive treatments and high levels of risk. A review of studies from the international literature by authors such as Haugen *et al.* (2019), Haugen & Sevalis (2019) and Cramer & Balakrisknas (2020), recognize that surgical safety checklists are effective interventions that have been shown to reduce patient safety events. Nevertheless, the UK Healthcare Safety Investigation Branch (HSIB 2021), highlight that checklists alone will not prevent incidents from occurring, and a collaborative focus should be placed on ensuring safe practices in addition to using the checklist.

3.4 The WHO outlines five steps along the patient pathway where effective teamwork and communication are essential to reducing risk to the patient. These steps are:

a) Team Briefing, which allows for the plan of care to be discussed and agreed;
b) Sign in, which **must** be completed prior to administration of anaesthesia;
c) Time out, which **must** be completed prior to commencement of procedure;
d) Sign out, which **must** be completed before the patient and team members leave the room;
e) Team debrief, which affords the team the opportunity to discuss what went well and if future improvements are required.

## 4.0 Scope

4.1 This Policy and Procedure applies to all patients admitted for and undergoing surgery in the hospital setting.

4.2 This Policy and Procedure applies to all healthcare staff involved in the patient pathway.

4.3. This Policy and Procedure supersedes *the HSE National Policy and Procedure for Safe Surgery 2013*

## 5.0 Supporting Evidence

Findings from an initial literature review concluded that the safe surgery checklist had a favourable impact on patient outcomes when implemented. A further review was conducted to search for information on whether improvements had been made to checklists internationally The findings were limited: Solsky *et al.,*(2020), suggested that adding to the WHO checklist perpetuated staff resistance as they found the checklist too cumbersome. Jelacic *et al.,* (2021), found that the use of computerized surgical safety checklist systems resulted in improved compliance, while Cushley *et al.* (2020), advocated for moving to a large wall-mounted checklist enabling visualisation by the entire team.

## 6.0 Related PPGs

The following PPGs are pertinent to the development of this policy:
Guideline for the use of blood and blood components in the management of massive haemorrhage (2002)

- A Guideline for the administration of blood and blood components (2004)
- WHO Guidelines for Safe Surgery: safe surgery saves lives (2009)
- Guidelines for Antimicrobial Stewardship in Hospitals in Ireland (2009)
- HSE Standards and Recommended Practice for Healthcare Records Management (2011)
- Elective Surgery Model of Care (2011)
- Acute Surgery Model of Care (2012)
- HSE Clinical Governance Information Leaflet (2012)
- Model of Care for Pre Admission Units (2014)
- Prevention of Intravascular Catheter-related Infection in Ireland HPSC (2014)
- National Model of Care for Trauma & Orthopaedic Surgery (2015)
- Nursing Midwifery Board of Ireland
  (i) Scope of Nursing and Midwifery Practice framework (2015)
  (ii) Recording Clinical Practice Guidance to Nurses and Midwives (2015)
- HSE Integrated Risk Management Policy (2020)
- HSE Code of Practice for Decontamination of Reusable Invasive Medical Devices (2018)
- Model of Care for Anaesthesiology (2019)
- HSE Patient Safety Strategy (2019-2024)
- HSE Open Disclosure Policy (2019)
- HSE Incident Management Framework (2020)
- Interim HSE Guidance on Infection Prevention and Control (2020)
- Guideline for the Management of Unexpected Intraoperative Life Threatening Haemorrhage (2021)
- Surgical Antibiotic Prophylaxis Duration Position Paper (2021)
- HSE National Consent Policy (2022)

## 7.0 Glossary of Terms/Terminology

**Procedure:** For the purpose of this policy the term 'Procedure' refers to a surgical intervention.

**Advocate:** A person nominated by an individual adult to speak on their behalf and represent their views

**ASA grading:** The ASA physical status classification system is a system for assessing the fitness of patients prior to surgery.

**Nominated Competent Delegate**: A surgeon, either trainee or deputy who has been clearly designated by the Consultant Surgeon in charge of the case**.** The nominated delegate person must be competent to perform the required procedure.

**Operating team/team**: In this Policy, the operating team/team is understood to comprise of the Surgeons, Anaesthesiologists, Nurses, Midwives, Healthcare Assistants or other operating room personnel involved in the surgery

**Briefing:** Period prior to commencement of theatre list where discussion takes place with all team members and information and plans are shared

**Safe Surgery Checklist**: A tool designed to bring together best practice about safety checks within the theatre environment.

**Sign In:** The period before induction of anaesthesia.

**Time Out:** The period before skin incision

**Sign Out**: The period immediately after wound closure, before dressings are applied

**Debriefing:** Period at end of theatre list to allow for reflection, review and discussion

## 8.0 Objectives

8.1 By implementing this Policy, the operating team will be supporting the HSE Patient Safety vision that all patients will consistently receive the safest possible care, while recognizing the complexity and risks associated with the delivery of that care

8.2 To define core minimum safety steps that are applicable to all hospitals in the Republic of Ireland

8.3 To reduce avoidable harm within high risk environments such as surgery

8.4 To recognise and prepare for expected and unexpected scenarios

8.5 To support services to implement a monitoring schedule including review, analysis of incidents, audit and implementation of quality improvements

8.6 To minimise the risk of surgical site infection

## 9.0 Outcome

This Policy sets out a standardised approach to improve patient safety by providing a structured process and framework for teams to discuss plans, communicate, and address any concerns or critical points along the patient pathway. It promotes teamwork and communication, and provides a trigger to complete steps aimed at optimising patient safety.

## 10.0 Implementation

- Effective leadership and governance are required to provide the necessary structures, processes, standards and oversight to shape an effective robust implementation plan (Mason *et al*. 2018). Oversight should incorporate risk management, be proactive in risk assessment and reactive by reviewing incidents in a timely manner.
- Each hospital should have a named individual to implement and provide the necessary governance supports and monitoring arrangements to ensure compliance.
- Education and Training **must** be provided and documented for all staff involved in implementation.
- The implementation of the checklist requires dedicated engagement from Surgeons, Anaesthesiologists and Nursing/Midwifery personnel who will champion patient safety as a priority and make the checklist a reality. All staff in the department should be involved in the collaborative development of a locally agreed checklist and empowered to challenge any points of concern before, during and after the procedure. (WHO 2009)

## 11.0 Roles and Responsibilities

11.1 The Chief Executive Officer/General Manager, in collaboration with the Lead Clinical Director and the Clinical Director/Lead for Peri-Operative Care and Director of Nursing/Midwifery are accountable and responsible for ensuring that this Policy, and its framework, are adopted and implemented throughout their organisations.

11.2 Hospital Management are responsible for ensuring that all healthcare staff who are involved in any aspect of a patient's care pathway receive education and training in respect of the implementation of this Policy.

11.3 All healthcare staff who are involved in any aspect of a patient's care pathway (outpatient visit, booking for procedure, compilation of the theatre lists, admission, peri and post-operative care) have a responsibility to adhere to this Policy within the scope of their work practice.

11.4 Local hospital management may adapt this National Policy for Safe Surgery for local implementation, but are responsible for ensuring that it contains the core minimum steps in this document and associated checklist. Hospital managers should apply this Policy and checklist across all specialties.

11.5 It is the responsibility of hospital management to ensure that The National Policy for Safe Surgery is easily accessible in all care settings where surgical procedures are planned to take place.

## 12.0 Guidance for Achieving Safe Practice when Planning a Procedure for a Patient

The decision to plan and book a surgical procedure often occurs in the outpatient department/emergency department. To ensure safe surgery is planned at this point, the guidance is as follows:

12.1 All of the patient's **relevant** healthcare records, imaging, diagnostics and original reports **must** be available for review by the Consultant in charge or nominated competent delegate to plan and book any procedure, and to complete the informed consent process as per the National Consent Policy.

12.2 Verification of the patient's identity to include first and last name, date of birth, health care record number (HCRN) against relevant documentation **must** be completed.

12.3 The planned procedure **must** be clearly documented in the healthcare record (including IT systems).

The record of the scheduled procedure should state:

(a) The exact procedure, exact side/site/level/digit

(b) Left/Right should be written in full, abbreviations **must not** be used

(c) IT systems used for logging planned procedures **must** have the capacity for the inclusion of procedures that are not part of the standard menu. Where such a procedure is intended, it should be possible to choose "other" from the dropdown menu and insert free text

*Note: See Corbally v Medical Council and Ors [2013] IEHC 500*

12.4 Information regarding the procedure **must** be provided to the patient/child/parents/legal guardian. This discussion should be documented in the patient's healthcare record.

12.5 Where a patient is scheduled for a procedure by, or through, an institution or clinic that is not the one in which the procedure will be performed, (e.g. different hospitals within the same hospital group), unless the original health care record is accompanying the patient, a detailed letter or pro forma containing all of the above information **must** be forwarded to the hospital in which the procedure is being carried out for inclusion in the patient's healthcare record. (Unless it is an emergency admission)

12.6 Records relating to the planned procedure (healthcare record and relevant hospital documentation for scheduling the patient for theatre) should be completed before the next patient consultation commences.

12.7 In the absence of a clear record of the planned procedure in the healthcare record at a Pre-Admission Unit or on admission to a ward area, the patient **must** be reviewed by the Consultant in charge of the patient's care, or their nominated competent delegate, before they are prepared for surgery.

12.8 It is essential, and an expectation of patients, that they are involved in all discussions and are central to the decision-making processes relevant to their care (HSE/NCPS MOC for Elective Surgery).

## 13.0 Pre-operative Verification Process Work-Up

To ensure safe surgery the following steps are required:

13.1 Informed Consent **must** be obtained in accordance with the National Consent Policy prior to commencement of any procedure in all locations. https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/consent/national-consent-policy-hse-v1-3-june-2019.pdf

13.2 The patient's name to include first name and last name, address, date of birth, healthcare record number and planned procedure should be verified with the patient/child/parent/guardian during each stage of the admission process (nursing/midwifery admission, medical admission and informed consent/confirmation).

13.3 All of the patient's **relevant** healthcare records, imaging, diagnostics and original reports **must** be available for review by the Consultant or nominated competent delegate during pre-operative preparations.

13.4 The planned procedure **must** be clearly documented in the healthcare record. Absence of this information must be referred to the Consultant Surgeon in charge of the patient's care.

13.5 Any queries in relation to the planned procedure including side/site/level/digit **must** be escalated to the Consultant Surgeon in charge of the patient's care before the patient leaves the ward area for surgery.

13.6 All relevant preoperative preparation related to the planned procedure should be undertaken to ensure safe surgery, e.g. fasting, blood group or cross match, pre-operative microbiological screening etc. in line with local policy.

## 14.0 Pre-operative site marking

The patient's identity to include first and last name, planned procedure, side/site/level/digit should be verified with the patient/parent/ guardian prior to site marking. Site marking **must** be performed by the Consultant Surgeon in charge of the patient's care or nominated competent deputy, who will be performing/assisting with the procedure and be present for the "Time Out" process. Relevant imaging, diagnostics and original reports **must** be available and reviewed by the consultant or nominated competent deputy prior to site marking.

The mark should be clearly visible and made with indelible ink *in the presence of a parent or guardian if applicable* prior to the patient being transferred to the area where the procedure will take place. In the event that site marking may not be considered possible, local agreed processes should be developed and implemented to ensure the appropriate site/side/level/digit is communicated and agreed prior to the procedure. For procedures where imaging is used to confirm the correct side/site/level/digit, this should be confirmed by at least two members of the team.

For Procedures that are not site specific, not applicable should be marked on the checklist.

**Appendix II Guidance for Pre-operative Site Marking**
**Appendix III Site Marking Verification Template**

## 15.0 Briefing

The WHO (2009) states that pre-procedural briefing assists with fostering a culture of open communication and facilitates the transfer of critical information. The WHO goes on to say that briefing also enables an atmosphere of shared learning and responsibility. "The importance of communication for effective performance, reducing errors and improving safety cannot be over-emphasised" (HSE 2021). The team briefing should be conducted at a locally agreed time within the clinical area where the procedure is to take place. The list order can be confirmed and communicated to relevant clinical areas. The briefing facilitates an opportunity for discussion around any patient specific concerns (e.g. infection status, instrumentation, equipment, staffing issues, post-operative bed availability) and can be individualised at local level. It also facilitates the opportunity for team members to discuss the steps to be taken in the event of any emergency situation e.g. unexpected massive haemorrhage. This briefing should be attended by all members of the theatre team. A standardised template should be used to ensure all cases are discussed in a structured manner. Briefings **must** be documented and records maintained.

**Appendix IV Briefing Template**

## 16.0 Safe Surgery Checklist

The Safe Surgery Checklist (Appendix V) divides the operation into three phases; **Sign In, Time Out and Sign Out** each corresponding to a specific time period in the normal flow of a procedure.
The checklist has been designed to be as simple as possible and each EHR (Electronic Health Record) Provider is responsible for ensuring that it can be adapted for electronic use and incorporated into the EHR.

If any team member identifies any inconsistencies in any of the phases, the procedure **must not** be allowed to progress until the Consultant or competent nominated person assesses the situation, rectifies the inconsistency and a decision is agreed whether to proceed or not with the procedure. Any team member can initiate each stage. In the case of emergency lifesaving surgery (e.g. Category 1 Caesarean Section), where completing these steps may delay intervention, the reasons for omission of any stages **must** be justified and documented in the patient's healthcare record at the earliest opportunity. A copy of the completed checklist **must** be filed in the patient healthcare record or electronic healthcare record
All incidents **must** be documented, reported and reviewed (HSE Incident Management Framework 2020).

**Appendix V Safe Surgery Checklist Template**

## 16.1 Sign In

The Sign In phase **must** be completed when the patient is in the anaesthetic room, block room or theatre, prior to administration of anaesthesia or sedation when there is silence. Members of the team present include Anaesthesiologist, Nurse/Midwife, and ideally the Consultant Surgeon or, if not, a nominated competent delegate capable of carrying out the procedure. If the Consultant Surgeon cannot be present for the Sign In phase, then they are responsible for ensuring that the nominated competent delegate possesses the following information:

- Surgery to be performed
- Site/side/digit/level of surgery
- Specialist equipment required
- Requirement for prophylactic antibiotics
- ASA grade

The patient/parent/legal guardian should be involved where possible and asked verbally to state their/child's name to include first and last names, date of birth and their understanding of the procedure for which they have consented and to verify their signature on the consent form. This information is verified against their wristband and consent form. The surgical site markings are verified also with the patient/parent where applicable.

The team **must** verify the following core minimum steps:

- Patient identification to include first and last name using identity wristband and consent form
- Correct procedure
- Site/side/level/digit of procedure and marking if applicable
- Allergy status
- Requirement for prophylactic antibiotics
- Availability of all equipment/specialist equipment required for the procedure
- Microbiological screening and results available
- Difficult airway/aspiration risk
- Anticipated and unanticipated blood loss and availability of blood products [1]
- Requirement for VTE prophylaxis
- ASA grade

In the event that any required equipment is not available, the reason for proceeding should be clearly documented in the patient's healthcare record.

A simplified version combining both the "Sign in" phase and the "Time Out" phase can be utilized for patients requiring local anaesthesia only.

**Appendix VI Local Anaesthesia Safe Surgery Checklist Template**

[1] *The Unexpected Intraoperative Life Threatening Haemorrhage National Clinical Guideline includes a recommendation that 'Consideration should be given to the possibility of unexpected life threatening haemorrhage and if it is a possibility, the team should identify specific parts of the operation when life threatening haemorrhage could occur, particularly when any operative intervention in the chest, abdomen or pelvis occurs'. The brief of this Guideline covers 'unexpected' life threatening haemorrhage, i.e. a life threatening haemorrhage event that may not have been considered in advance of the procedure. Reducing risk for this scenario is challenging but the GDG see an opportunity of capturing this as a question in the HSE Safe Surgery Checklist to ensure this risk is considered in advance of all surgical procedures. This guideline is currently awaiting approval by The Department of Health.*

## 16.2 Nerve Blocks

In 2011, The Royal College of Anaesthetists (RCoA) championed the introduction of the "Stop before you block" (SBYB) campaign following recommendations of the Healthcare Safety Investigation Branch (HSIB) report (2017) on wrong site anaesthetic nerve blocks. https://www.rcoa.ac.uk/sites/default/files/documents/2020-08/SBYB-Supporting-Info.pdf.

HSIB noted the effectiveness of SBYB depends on training, implementation and theatre culture. Nottingham University Hospital NHS Trust identified three contributing factors to wrong site blocks:

- distraction in the anaesthetic room,
- time delay between conducting Sign In phase and the block being carried out and
- covering up of surgical site marking in order to maintain patient's temperature.

Prior to administration of any nerve blocks the Anaesthesiologist **must** perform a "Stop before you block" check. A Working Group led by The Safe Anaesthesia Liaison Group UK (SLAG) have developed a template for the Standard Operating Procedure and a poster for peripheral nerve blocks, which are available at https://www.ra-uk.org/index.php/prep-stop-block

The operating team **must not** proceed to the next stage of the operation until the relevant phase of the checklist has been completed satisfactorily e.g. if the "Sign In" check has not been completed, induction of anaesthesia cannot be commenced.

## 16.3 Time Out

All team members are responsible for ensuring Time Out occurs. Any team member can initiate Time Out and it requires interactive communication where all other activities are suspended without compromising patient safety.

Time Out **must** be read aloud immediately prior to the beginning of the procedure and in the room where the procedure will take place. Where possible this should take place once the patient is draped with all members of the team scrubbed and standing at the procedure table. In certain procedures, where there may be a requirement to conduct Time Out prior to draping, an additional check for the correct procedure and site/side/digit/level should be conducted when the entire team are scrubbed and prior to skin incision. If more than one surgical procedure is to be carried out, or different operating teams are performing procedures on the same patient, a separate Time Out **must** be conducted before each procedure commences.

There should be confirmation that all team members know one another and if there are new team members present, all team members should state their names and roles.

If the patient is awake and not sedated, they should be asked to state their name, to include forename and surname, date of birth, their understanding of the procedure, site/side/digit/level and signature on consent form.

All team members **must** be present and pause to confirm the following core minimum steps:

- Patient's identification to include first and last name using identity wristband and consent form
- Procedure to be performed
- Site/side/level/digit of procedure and marking if applicable
- Patient position
- Allergy status
- Administration of antibiotics if required
- Plan for procedure, critical areas/challenges

✓ To ensure patient safety, effective communication of critical patient issues or challenges is essential by all team members.

✓ The Surgeon, Anaesthesiologist and scrub Nurse are asked aloud if there are any critical areas of concerns/ challenges and the plan for the procedure. This allows a discussion to inform all team members of any steps in the procedure where the patient may be at particular risk and gives an opportunity to review steps that may require specialist equipment/instrumentation.

## 16.4 Sign Out

Sign Out is the third phase and is the period after wound closure before the patient is transferred from the procedure room and again requires participation from all members of the operating team. The aim is to facilitate the transfer of important information to the care teams responsible for the patient post operatively.

The following core minimum steps **must** be confirmed:

- Procedure performed
- Completion of instrument, sponge and needle counts
- Identification and labeling of specimens
- The post-operative recovery and management plan which involves the operating Surgeon, the Anaesthesiologist and the Scrub Nurse/Midwife being asked individually if they have any specific concerns. Events that present a specific risk to the patient during recovery and that may not be evident to all involved are especially pertinent.

In organisations where electronic healthcare records are used, an electronic checklist can be used, but it is important that all principles of the checklist are adhered to and all the steps of the checklist are systematically followed with provision to have all the questions ticked off and signed and to include any comments as appropriate.

## 16.5 Debriefing

The WHO state that debriefing gives the team an opportunity to discuss and review the procedure and should include any critical incidents that took place, any equipment issues that need to be addressed and develop post-operative management plans. Debriefing increases collaboration of all team members and decreases the risk of post-operative complications.

Actions arising from debriefing should be documented and assigned to a responsible member of staff.

**Appendix VII Debriefing template**

## 17.0 Education and Training

All relevant staff should receive education and training on the HSE National Policy and Procedure for Safe Surgery, be familiar with and practice in accordance with the policy. It is the proposed aim of the Policy Development Group that a national interactive training tool should be developed to provide education and training in line with this updated Policy.

## 18.0 Audit and Monitoring Compliance

Clinical Audit is an essential tool for improving patient care (HSE 2019). Self-audit is part of a continuous quality improvement process and identifies opportunities for improvement.

1. Audit should be scheduled bi-annually
2. This should include retrospective and concurrent observational audits. It is recommended that 70% of cases will be audited retrospectively and 30% will have a concurrent observational audit conducted
3. The audit schedule should include time for analysis and reporting and implementation of QI where appropriate
4. The recommended sample size should be 20-50 cases, taking into consideration volume of theatre activity*
5. The recommended aim is 100% compliance

For the purpose of auditing, a mixture of structure and process has been utilised to develop an audit tool to support the audit activity. A process based audit examines if processes are being followed as per the clinical standards and the structure based audit looks at how the completion of the form is carried out in practice e.g. *Were all team members present for briefing as outlined in the Policy?* The audit tool can be found in Appendix VIII.

**The University Hospital Bristol Clinical Audit Group recommend that for a process-based clinical audit project, a 'snapshot' sample is usually sufficient, roughly 20-50 cases. Choosing a larger sample size than is necessary can take time and resources without adding value. This approach provides a sample which is both pragmatic and persuasive so that senior clinicians and managers are willing to implement changes based on the findings. The recommended template allows for auditing of processes and structures.*

**Appendix VIII Safe Surgery Audit tool Template.**

## 19.0 Objectives of the audit:

1. To determine compliance with the checklist
2. To identify areas for improvement

## 20.0 Governance for audit

It is essential that the implementation of this Policy is monitored to ensure patient safety. Accountability lies with the accountable officer of the organisation who will delegate responsibility and identify monitoring arrangements.

The Policy Development Group recommend the national appointment of 1 WTE Project Manager to support sites in implementing the audit tool and undertaking the bi annual self-assessment audit along with a 0.5 WTE data analyst to assist in collating and analysing the data and to provide reports nationally. For further information on the National Office for Clinical Audit see link below

https://www.hse.ie/eng/about/who/nqpsd/ncca/

**Appendix IX Safe Surgery Audit Tool Template (Excel tool)**

## 21.0 Review

The content of this National Policy and Procedure for Safe Surgery will be reviewed every three years or earlier if indicated.

## 22.0 PPPG Development Group

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## 23.0 Acknowledgements

Ciara Hughes, Programme Manager, National Clinical Programme for Surgery
Marina Cronin, National Office of Clinical Audit
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## 25.0 Appendices

## Appendix I: Review of Clinical Claims Relevant to Safe Surgery, 2016 - 2020

**Review of Clinical Claims Relevant to Safe Surgery, 2016–2020**

**1. Background**

This review was conducted in response to a request from a HSE working group who are reviewing and updating the HSE National Policy and Procedure for Safe Surgery[1]. An analysis of relevant National Incident Management System (NIMS) data relating to *finalised claims from 2016 – 2020 (inclusive) was undertaken.

**2. Results**

The search identified 25 surgical claims finalised from 2016–2020 (inclusive) where the incident category (Problem/Cause on NIMS) included Wrong Body Part/Side/Site, Wrong Patient or Wrong Process/Treatment/Procedure. Figure 1 (below) presents the claims by year in which the claim was finalised. An average of five claims were finalised each year over the study period and all claims were settled by negotiation.

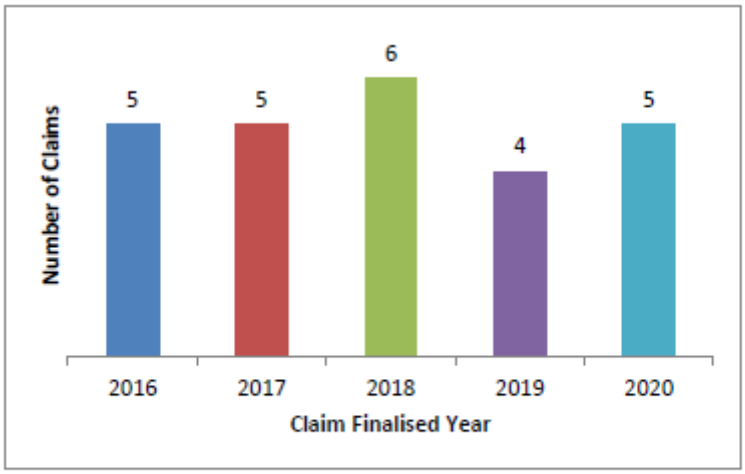


*Figure 1. Claims by year in which claim finalised (n=25)*

* Finalised claim - A claim has been finalised when all damages, legal and other costs have been agreed (but not necessarily paid). There may be some outstanding payments waiting to be processed.

**2.1 Cost of Claims**

Costs for all 25 claims were analysed. Paid damages for this cohort of claims totalled over €3.5 million and the paid total, including agency legal costs, expert costs, plaintiff legal costs and damages, was in excess of €6 million.

- • 10 claims resulted in paid damages of €50,000 or less.
- • 7 claims resulted in paid damages of greater than €50,000 but less than €100,000.
- • 4 claims resulted in paid damages of greater than €100,000 but less than €350,000.
- • 2 claims resulted in paid damages of greater than €350,000 but less than €500,000.
- • 2 claims resulted in paid damages of greater than €500,000 but less than €1 million.

**3. References**

1 Health Service Executive. National Policy and Procedure for Safe Surgery [Internet]. HSE; 2013 [cited 2021 June 24]. Available from: https://www.hse.ie/eng/about/who/qid/resourcespublications/safesurg14june.pdf

## Appendix II: Guidance for Pre-operative Site Marking

**The role of marking to promote correct site surgery**

Pre-operative marking has a significant role in promoting correct site surgery, including operating on the correct side of the patient and/or the correct anatomical location or level (such as the correct finger on the correct hand). This procedure is essential for all patients attending for surgical procedures (with the exception of those procedures mentioned in Exceptional Cases, outlined below).

**How to mark?**

A single use indelible marker pen should be used. The site mark should be legible and unambiguous. The mark should be an arrow that extends to or near to the incision site with the exception of cases where a smaller mark is required, e.g. in Ophthalmic/Facial surgery where a small dot may be used. It is desirable that the mark should remain visible after the application of theatre drapes.

**Where to mark?**

Surgical operations involving side (laterality e.g. brain), upper/lower and/or paired organs (e.g. kidney), multiple structures (fingers, toes, lesions) or multiple levels (e.g. spine) should be marked at or near the intended incision. For digits on the hand or foot, the mark should extend to the correct specific digit on the anterior, posterior or both. For surgery of the spine, pre-operative skin marking is required to indicate laterality, when appropriate.

**Who marks?**

Marking **must** be undertaken by the Consultant Surgeon in charge of the patient or Nominated Competent Deputy who will be performing/assisting at the surgery and present for the “Sign In” and ”Time Out” process.

**Involving the patient/parent/guardian**

The process of pre-operative marking of the intended site should involve the patient/child/parents/legal guardian as appropriate. Any concerns regarding the correct procedure and/or correct site/side/digit must be conveyed to the Consultant Surgeon or nominated Competent Deputy in charge and recorded in the healthcare record.

**Marking time and place**

The surgical site mark should be marked on the ward or day care unit prior to the patients transfer to the operating theatre.

**Verification of marking**

The surgical site mark should subsequently be checked against the healthcare record documentation, imaging and diagnostic reports to confirm it is correctly located, and visible.

These checks should be verbally confirmed on transfer to theatre, and end with a final verification, as part of the Safe Surgery (Procedure) Checklist, prior to commencement of surgery. The operating team members (Surgeon, Anaesthetist and Scrub/Circulating Nurse/Midwife) **must** be involved in checking pre-operative marking during the Time Out phase.

**Circumstances where marking may not be appropriate**

It is recognised that in some situations, it may not be appropriate or possible for surgical site marking. Examples include:

- Premature infants cannot be marked in any circumstances due to risk of permanent marking
- Single organ cases, which do not involve laterality, such as Cardiac cases, Appendectomy
- Life threatening emergency when any delay in initiating the surgery would compromise the safety or outcome of the patient.
- When movement of a patient to create a marking would compromise the safety or outcome of the procedure, e.g. movement of a patient with an unstable spine fracture.
- Situations in which the primary pathology itself is plainly visible (single laceration)
- Dental cases, where the operative tooth number or name(s) can be indicated on documentation or the operative tooth (teeth) including laterality can be marked on the dental radiographs or dental diagram.
- Situations where the surgical site needs to be identified under radiology screening in the theatre e.g. neurosurgery, spinal surgery

**Refusal of patient to allow site marking**

Should the patient refuse to allow site marking to take place the following procedure will apply

- The Surgeon must inform the patient /child/parents/legal guardian of the risks of their decision.
- The Surgeon must document the patient's refusal and subsequent discussion in the patient's healthcare record.
- The verification "Sign In" and "Time Out" will proceed as normal.

## Appendix III Site Marking Verification Template

# Pre-Operative Site Marking Verification

Patient Details (Addressograph Label)

**Name:**

**HCRN:**

**DOB:**

**Date of Procedure:**

The operating surgeon or nominated deputy who will be present in the theatre at the time of the patient's procedure, signs to confirm that the site is marked and patient identity is checked

- **Patients identity, name, Date of Birth, Address and Health Care Record Number checked** ☐
- **Consent form checked that indicates correct procedure and side** ☐
- **Site/side/digit/level confirmed in medical record (*or with imaging if appropriate*) and marked with indelible ink** ☐

**Doctor's Name (PRINT):**

**Doctor's Signature:**

**IMC:** **Bleep No.:**

**Date:** **Time:**

**Mobile No. (If used) :**

August 2022 v2

# HSE Safe Surgery Team Brief

| | |
|---|---|
| Theatre: | |
| Consultant Surgeon: | |
| Date: | |
| Time Started: | |

## STAFF PRESENT

| | | | |
|---|---|---|---|
| Consultant Surgeon | | Scrub Nurse/Midwife | |
| Consultant Anaesthesiologist | | Circulating Nurse/Midwife | |
| NCHD Surgeon | | Anaesthesia Nurse/Midwife | |
| NCHD Anaesthesiologist | | Nurse/Midwife in Charge | |
| Other (Please Specify) | | | |

| | | | |
|---|---|---|---|
| Have all team members introduced themselves by name and role? | | Are there any changes to list order? | |
| Any equipment issues? | | Is an ICU/HDU bed required and available? | |
| Any similarities between patients on theatre list? | | Are there any outstanding investigations? | |
| Infection Control Status? | | Other | |

| Patient Name, HCRN & Procedure | Concerns raised by Nurse/Midwife | Concerns raised by Anaesthesiologist | Concerns raised by Surgeons |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

November 2021 v1

# HSE Safe Surgery Checklist

## SIGN IN

**To be completed in anaesthesia room/operating theatre/blockroom prior to induction of anaesthesia when there is silence**

- Has the patient stated their name, date of birth, procedure, site/side/digit/level and confirmed signature on consent form *(This should be checked against wrist band and consent form).* Yes ☐ or
- Have these been confirmed with Parent/ Guardian? Yes ☐
- Does the HCR number on consent match wrist band? Yes ☐
- Is the site marked? *(Check with surgeon if any issues)* Yes ☐
- Does the patient have a known allergy? Yes ☐ No ☐

  Details:_____
- Are prophylactic antibiotics required? Yes ☐ No ☐
- Has the risk of expected/unexpected blood loss been discussed? No ☐ Yes ☐
- If blood products are required, are they available? Yes ☐
- If unexpected blood loss should occur, are protocols in place to recognise, treat and manage it? Yes ☐
- Is all necessary equipment/implants etc. available? Yes ☐
- Does the patient require:
  - Contact precautions Yes ☐ No ☐
  - Droplet precautions Yes ☐ No ☐
  - Airborne precautions Yes ☐ No ☐
- Is specific PPE required and available? Yes ☐ No ☐
- Is VTE prophylaxis required? No ☐

  If yes, is it Mechanical ☐ Medicinal ☐
- Is there a difficult airway risk/risk of aspiration Yes ☐ No ☐
- ASA Grade:_____

Signature: Time:

## TIME OUT

**To be completed in operating/procedure room prior to skin incision. To be read aloud in the presence of all team members when there is silence**

- Confirm that new team members have been introduced to all of the team ☐
- All team members stop and confirm the patients name, DOB, HCRN, procedure, site/side/digit/level and visually check where the incision will be made. *(This should be checked against wrist band on patient and consent form)* ☐
- Confirm the patient is positioned correctly and safely ☐
- Is essential imaging displayed and consistent with all patient dea? Yes ☐ N/A ☐
- Has antibiotic prophylaxis been given within the last 60 minutes? Yes ☐ N/A ☐
- Does the patient have a known allergy? Yes ☐ No ☐

  Details:
- Confirm the plan for procedure and ask the team members if there are any critical areas of concern
  - Surgeon ☐
  - Anaesthesiologist ☐
  - Scrub Nurse/Midwife ☐

  Details:

Signature: Time:

## SIGN OUT

**To be completed prior to patient leaving the operating/procedure room**

- Confirm the name of the procedure ☐
- Confirm Instrument, sponge and needle count are correct ☐
- Confirm that specimens are identified and labelled (read specimen labels aloud, including patient name & HCRN) Yes ☐ N/A ☐
- Ask Surgeon, Anaesthesiologist and Scrub Nurse/Midwife if there is any specific post-operative information that must be relayed to staff
  - Surgeon ☐
  - Anaesthesiologist ☐
  - Scrub Nurse/Midwife ☐

Details:

Signature:

Time:

**Patient Details (Addressograph Label)**

**Name:**

**HCRN:**

**DOB:**

**Date of Procedure:**

March 2022 v1

# HSE Safe Surgery Checklist

## SIGN IN / TIME OUT

**To be completed prior to administration of local anaesthesia and skin incision. To be read aloud in the presence of all team members when there is silence**

- Confirm that new team members have been introduced to all of the team — Yes ☐
- Has the patient stated their name, date of birth, procedure, site/side/digit/level, and confirmed signature on consent form? *(This should be checked against wrist band and consent form).* — Yes ☐
- Have these been confirmed with Parent/Guardian — Not Applicable ☐ Yes ☐
- Does the HCR number on consent match wristband? — Yes ☐
- Is the site marked? *(Check with surgeon if any issues)* — N/A ☐ Yes ☐
- Is monitoring required and attached? — Yes ☐ No ☐
- Does the patient have a known allergy? Details_____ — Yes ☐ No ☐
- Is antibiotic prophylaxis required? — Yes ☐ No ☐
- Is all necessary equipment/implants etc. available? — Yes ☐
- Is all required imaging available and displayed? — Yes ☐
- Does the patient require:
  - Contact precautions — Yes ☐ No ☐
  - Droplet precautions — Yes ☐ No ☐
  - Airborn precautions — Yes ☐ No ☐
- Is specific PPE required and available? — Yes ☐ No ☐
- Is the patient positioned correctly and safely? — Yes ☐
- ASA Grade:_____

Signature: _____ Time: _____

**For Local Anaesthesia**

## SIGN OUT

**To be completed prior to patient leaving the operating/procedure room**

- Confirm the name of the procedure ☐
- Confirm instrument, sponge and needle count are correct ☐
- Confirm that specimens are identified and labelled (read specimen labels aloud, including patient name & HCRN) — Yes ☐ N/A ☐
- Ask Surgeon and Scrub Nurse/Midwife if there is any specific post-operative information that must be relayed to staff:
  - Surgeon ☐
  - Scrub Nurse/Midwife ☐

Details:

Signature: _____ Time: _____

**Patient Details (Addressograph Label)**

**Name:**

**HCRN:**

**DOB:**

**Date of Procedure:**

March 2022 v1

# HSE Safe Surgery Team Debrief

Theatre:

Consultant Surgeon:

Date:

Time Finished:

## STAFF PRESENT

| | | | |
|---|---|---|---|
| Consultant Surgeon | | Scrub Nurse/Midwife | |
| Consultant Anaesthesiologist | | Circulating Nurse/Midwife | |
| NCHD Surgeon | | Anaesthesia Nurse/Midwife | |
| NCHD Anaesthesiologist | | Nurse/Midwife in Charge | |
| Other (Please Specify) | | | |

**Achievements and What Worked Well**

| ISSUE | ACTION | ACTION ASSIGNED TO | COMPLETED | DATE |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

November 2021 v1

## Appendix VIII Safe Surgery Checklist Audit Tool

**Respondent Number: _____**

| | Question | Yes | No |
|---|---|---|---|
| | **Documentation** | | |
| 1 | Is the consent form available in the Healthcare Record (HCR)? | | |
| 2 | Is the consent form clear, readable and comprehensible? | | |
| 3 | Is the consent form signed by a Doctor who was present during the surgery? | | |
| 4 | Is the consent form completed without abbreviations? | | |
| 5 | Is there an addressograph on the checklist? | | |
| 6 | Is the date of the operation recorded on the checklist? | | |
| 7 | Was the checklist filed with the theatre documentation in the HCR? | | |
| | **Sign In** | | |
| 8 | Patient confirmed identity, consent, procedure | | |
| 9 | Surgical site/side/digit/level marked/ not applicable | | |
| 10 | Was microbiological screening and specific PPE requirement checked | | |
| 11 | Known allergies checked | | |
| 12 | Was risk of anticipated and unanticipated blood loss discussed | | |
| 13 | VTE Prophylaxis check | | |
| 14 | ASA grade checked | | |
| 15 | Sign In section signed | | |
| 16 | Sign In section dated and timed | | |
| | Time Out | | |
| 17 | All new team members introduced themselves | | |
| 18 | Verbal confirmation of patients name, procedure and site/side/digit/level | | |
| 19 | Verification that patient positioned correctly and safely | | |
| 20 | Essential imaging displayed/ not applicable | | |
| 21 | Antibiotic prophylaxis / not applicable | | |
| 22 | Plan for surgery confirmed and critical areas of concern communicated | | |
| 23 | Verify any equipment issues | | |
| 24 | Time Out section signed | | |
| 25 | Time Out section dated and timed | | |
| | Sign Out | | |
| 26 | Name of procedure confirmed | | |
| 27 | Completion of instrument, sponge and needle count | | |
| 28 | Specimen labelling with correct details | | |
| 29 | Patient specific post-op concerns: Surgeon | | |
| 30 | Patient specific post-op concerns: Anaesthesiologist | | |
| 31 | Patient specific post-op concerns: Nurse /Midwife | | |
| 32 | Sign Out section signed | | |
| 33 | Sign Out section dated and timed | | |
| | **To be included when conducting Observational audit** | | |
| | Communication | | |
| 34 | Did Briefing take place? | | |
| 35 | Was Briefing documented? | | |
| 36 | Were all team members present for Briefing as outlined in Policy? | | |
| 37 | Did all team members participate in Sign In phase? | | |
| 38 | Was the checklist read aloud without any interruptions? | | |
| 39 | Did all team members participate in Time Out phase? | | |
| 40 | Was the plan for surgery outlined and confirmed? | | |
| 41 | Did all team members participate in Sign Out phase? | | |

## Appendix IX Safe Surgery Checklist Audit Tool (Excel File)

**ONLINE VERSION**
(Note: Please have Microsoft Excel open on your computer before clicking on this icon to ensure that it will open successfully)

Safe Site Surgery Audit tool.xlsx

*In the event, that you are unable to open this audit tool, please see the links below to download*

**PRINTED VERSION**

*The Audit tool can be downloaded from either:*

*https://www.hse.ie/eng/about/who/cspd/ncps/anaesthesia/resources/*
*or*
*https://www.rcsi.com/surgery/practice/national-clinical-programmes/surgery*

*Alternatively, you can email ncpa@coa.ie or the surgeryprogramme@rcsi.ie*