Safety Standards for Invasive Procedures

(Operating Theatres)

Procedure information

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Summary of document:
The document details the 8 procedures for following the safety standards contained in the National Safety Standards for Invasive procedures version 2.

Scope:
This procedure applies to Anaesthetic, Scrub & Recovery Practitioners, Health Care Support Workers and all Medical Staff working within the Theatre Department.

It also applies to all patients having an invasive procedure within the Theatre Department.

To be read in conjunction with:
008 – Consent to Examination or Treatment policy (opens in a new tab)
982 - Incident, Near Miss and Hazard Reporting Procedure (opens in a new tab),
312 -Chaperone procedure – opens in a new tab

Patient information:
Include links to Patient Information Library

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Keywords
Invasive procedure

Glossary of terms
ODP - Operating Department Practitioners
ID - patient's identity
DOB – Date of birth
CVC - central venous catheters
IOL - Intra Ocular Lens

MDT

Key points:
To detail the 8 procedures for following the safety standards in the NSS for invasive procedures version 2

Contents

Scope

This procedure applies to Anaesthetic, Scrub & Recovery Practitioners, Health Care Support Workers and all Medical Staff working within the Theatre Department.

It also applies to all patients having an invasive procedure within the Theatre Department.

Aim

This document and the appendices aims to define the pathway for patients undergoing invasive procedures within the operating theatres in Hywel Dda University Health Board and provide the safest care possible.

Objectives

The aims will be achieved by;

- Ensuring patients who have an invasive procedure in theatre have been appropriately consented
- Ensuring that all patients who have an invasive procedure carried out in theatre have the correct site/side/digit/limb operated upon and therefore do not come to avoidable harm.
- Ensuring the correct participation in the Team Brief and provides guidance for staff on dealing with non-engagement and variance.
- Ensuring the correct participation in the “Sign In” and provides guidance for staff on dealing with non-engagement and variance.
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- Ensuring the correct participation in the “Time Out” and provides guidance for staff on dealing with non-engagement and variance.
- Ensuring that all patients who have invasive procedures that require an implant, are identified and staff follow a standard, incremental safety checking procedure.
- Ensuring the safe, consistent and efficient practice in accounting for all items used during invasive procedures.
- Ensuring the correct participation in the “Sign Out” and provides guidance for staff on dealing with non-engagement and variance.
- Ensuring the correct participation in the “Debrief” and provides guidance for staff on dealing with non-engagement and variance

Introduction

The Operating Theatres within Hywel Dda University Health Board have adopted the principles and standards of the National Safety Standards for Invasive Procedures 2 (NATSSIP's 2).

The original NatSSIP's were published in 2016 in Wales and were developed to set out the key steps necessary to deliver safe care for patients undergoing invasive procedures and to allow organisations delivering NHS-funded care to standardise the processes that underpin patient safety.

The revised NatSSIP's 2 were published in 2023 and are intended to enable safe, reliable and efficient care to every patient having an invasive procedure. NatSSIP's 2 maintains a focus on staff and patients.

The revised standards (NatSSIP's 2) are intended to share the learning and best practice to support multi-disciplinary teams to deliver safer care

The NATSSIP' Principles

The delivery of safe invasive procedures is a multidisciplinary event within the patient's surgical pathway and aims to;

Promote behaviours that;

- Focus on the patient
- Involve teamwork that promotes kindness and compassion
- Encourage patient safety throughout their surgical journey

Improve communication by;

- Appropriate planning
- Using checklists where appropriate
- Improving the handover process

Involving teams;

- In audit and improvement

The 8 Safety Standards

Following the 8 safety standards will help to ensure that our operating theatres,

- Have sufficiently skilled and knowledgeable teams to deliver invasive care safely
- Have staff that are trained in safety behaviours and practices.
- Perform checks for procedural safety that are proportionate to what is needed.
- Have staff that have had appropriate induction that covers the 8 safety standards.

For the procedures required for each standard please see the appendices.

Standard 1, Consent, Procedural verification and Site Marking (See Appendix One)

The process of obtaining consent and shared decision making with the patient is 'an ongoing process' focussed on meaningful dialogue: the exchange of relevant information specific to the individual patient. The patient gives consent - it is not taken.

Within this standard the consent process and procedural verification are linked, and there a few particular areas where clarity and reinforcement are required.

Standard 2, Team Brief (See Appendix 2)

The procedural multidisciplinary Team Brief is a key element of practice in the delivery of safe patient care in invasive procedure pathways, and forms part of the WHO Surgical Safety Checklist and the 8 Safety Standards.

Engagement with the Team Brief is a required behaviour in the delivery of safe care and is a demonstration of mutual respect to the multidisciplinary team and an aspect of professionalism. It shows a commitment to the importance of communication for patients, staff and patient safety.

Good leadership will ensure all members of the team feel comfortable, valued and empowered so that any issues of safety can be volunteered and this will encourage an environment of openness and flattened hierarchy.

Continuing with tasks and trying to listen is a distraction for the individual, it is a distraction for the rest of the team, and it is a poor example to the rest of the team.

Standard 3, Sign In (See appendix 3)

Sign In is the point at which the team checks that it is safe and appropriate to commence anaesthesia.

Sign In is not a replacement for safe and efficient processes in admissions and ward areas

Standard 4, Time Out (See Appendix 4)
Time Out is the most critical check in the WHO Surgical Safety Checklist and is the final check before the procedure. Time Out is a checking opportunity to support the whole team in providing safe, effective and efficient patient care. Time Out is a team process that relies on engagement of the whole team throughout.

Some aspects of the Time Out process may appear more relevant to some team members than others, but all are important.

Good leadership will ensure all members of the team feel comfortable, valued and empowered so that any issues of safety will be volunteered. The Time Out is important for training and education.

The key decisions and knowledge of potential safety issues need to be conveyed by and shared with the senior clinicians involved in the case / list.

This helps to bring the team together, raise situation awareness and ensure the essential equipment/prostheses/ kit is readily available.

Standard 5, Implant Verification (See Appendix 5)
Insertion of an implant is a key procedural event. It is important that the correct patient receives the correct implant(s) and that this is achieved safely and efficiently.

These simple safety standards aim to minimise errors and take away some of the cognitive burden, helping teams to insert implants safely by providing standardised pre- and peri-procedural processes for checking that the correct implant is selected for use.

The implant checks should be brief/minimal in duration, to reduce the risk of a wrong implant and keep in perspective the actual level of risk. Lengthy checks may introduce new risks by over burden of checks, checking fatigue and unnecessary delay.

Planning in advance of the procedure, standardisation of processes and education of all staff are important elements in ensuring that the correct implant is chosen.
These processes aim to increase understanding of risk and to strike a balance between a rigid checklist and the avoidance of automaticity which may lead to error.

Standard 6, Reconciliation of Items (See Appendix 6)
This standard supports safe, consistent and efficient practice in accounting for all items used during invasive procedures and in minimising the risk of them being retained unintentionally.

The processes outlined in this standard should ensure that all items are accounted for and that no item is unintentionally retained at the invasive site, in a body cavity, on the surface of the body, or in the patient's clothing or bedding. This standard represents the gold standard in count procedure and practice.

The need to prevent the rare occurrence of unintentional retention of items must be balanced against the need to support timely and efficient surgery and other procedures. Enforcing counting procedures where the possibility of retained objects is unlikely, will be counter-productive to engagement with safety procedures and may makes processes less efficient.

The prevention of retained foreign objects is a shared responsibility and the risk of occurrence is reduced through education, effective teamwork and processes.

These standards apply wherever and whenever invasive procedures are carried out within the operating theatres. This includes all aspects of maternity care, as well as those used as part of anaesthesia and sedation, e.g. throat packs placed by the anaesthetist during oral or nasal surgery.

Standard 7, Sign Out (See Appendix 7)
Sign out is a specific set of checks which: supports safe completion of the invasive procedure, including relevant documentation; starts the process of safe and efficient handover of care; and identifies patient, equipment, staff or process concerns that need addressing.

Standard 8, Handover/Debrief (See Appendix 8)

There are formal handover points in the patient pathway at which professional responsibility and accountability is transferred between individuals or teams. There will also be planned or unplanned changes in the members of a procedural team that occur during procedures or lists of procedures.

Staff Awareness of the Safety Standards for Invasive Procedures

All staff are required to have an in depth knowledge of the Standards for Invasive Procedures. This will be achieved by;

- Being part of the member of staff's induction into theatre
- Attending in-house training sessions on the standards and how and why they were developed.

Audit and Monitoring

Compliance with the Standards for Invasive Procedures will be monitored as detailed within the individual standards.

References

National Safety Standards for Invasive Procedures (2023), Centre for Perioperative Care

Appendix 1:- Procedure for Consent, Procedural Verification and Site Marking

Procedure

The process of obtaining consent and shared decision making with the patient is 'an ongoing process' focussed on meaningful dialogue: the exchange of relevant information specific to the individual patient. Within NatSSIP's 2 the consent process and procedural verification are linked, and there a few particular areas where clarity and reinforcement are required. This procedure also details the requirements for marking the surgical site.

Please note:- You must refer to the Health Board's 008 – Consent to Examination or Treatment policy (opens in a new tab), for the full consent process.

Consent

- The person obtaining consent should have clear knowledge of the procedure and the potential risks and complications.
- Consent may be obtained in advance and verified/confirmed on the day of the procedure. The verification and confirmation must include checking the records, including relevant images, biopsy results and investigations, and consent form rather than relying solely on the printed operating list for the procedure being performed.
- Consent verification and surgical/procedural site marking should occur at the same time, by a suitably trained clinician.
- Wherever possible verification of consent and marking should involve the patient.
- Except for life / limb threatening emergencies, a patient's primary consent should never be taken in the anaesthetic room.
- Patient confirmation of understanding consent is part of the Sign In process.
- Procedures involving anatomical sites that have laterality, the word(s) Right, Left or Bilateral should be documented on the operating list, consent form and all other relevant documentation in full. The use of the abbreviations R / L to indicate laterality is not acceptable.

Site Marking

The purpose of site marking is to provide a visual cue to the whole team of the intended procedural site that has been agreed with the patient. Team awareness and engagement with correct site is an important aspect of safety.

When to mark

Pre-operative marking must take place whenever there is potential for confusion of site or side of surgery/invasive procedure. This also includes invasive procedures requiring;

- A midline or laparoscopic approach,
- Radiological intervention,
- Ophthalmology interventions,
- Anaesthetic blocks including for pain treatments.

Personnel responsible for marking

- The marking should be performed by the operator, a nominated deputy who will be present during the procedure or, in the case of emergency procedures, by a member of the clinical team (staff) who is familiar with the patient and capable of performing the procedure. This fits with the requirement that the operator should meet the patient prior to the procedure.
- There may be particular contexts where this process needs adapting. These include:
    - Emergency work e.g. marking of affected limbs by on-call staff in orthopaedic trauma. In these cases, units must have a risk-assessed, locally agreed process proportionate to the service and work. In emergency and urgent work for example, the risk may be mitigated by having the operator present at Sign In and a second confirmatory arrow over the first

Timing of surgical site marking

- Site marking must be performed for all procedures for which variation is possible. i.e. where there is laterality, level or more than one operating site.
- The mark must be made on the ward / day care area prior to transfer of the patient to the operating theatre/procedure room.
- The procedure site must be marked shortly before the procedure. This should be done with the patient's agreement while the patient is awake and prior to premedication.
- Marking should be performed in parallel with signing the re-confirmation of consent by the operator if a primary consent is made in clinic or on another date.

Surgical site marking in the anaesthetic/procedure room is not acceptable. Where a patient is marked in the anaesthetic room, a DATIX incident report must be completed in line with Hywel Dda UHB Policy 982 - Incident, Near Miss and Hazard Reporting Procedure (opens in a new tab), detailing the circumstances which led to marking not being performed on the ward. Subsequently follow section the section entitled Procedures for Unmarked Patients below.

How to mark

The patient's identity (ID) must be checked and matched against their ID band. The patient, whenever possible, must also verbally confirm their name and Date of Birth (DOB) against their ID band.

The patients' medical records must be checked, including the consent form and diagnostic imaging and/or biopsies when relevant, to verify the operation to be undertaken. The patient, whenever

possible, must also be asked to confirm the operation they are having including the side to be operated on.

The consent form and operating list must include the side to be operated on. The terms ‘left’, ‘right’ and ‘bilateral’ must be written in full on all clinical documentation, and not abbreviated. An indelible marker pen must be used, which is sufficiently permanent to remain visible after skin preparation. There must be 30 second drying time to reduce the risk of the mark being transferred to another body part.

Single use pens must be used in patients with a known/suspected infection, colonised with a multi-drug resistant organism, or who are immunocompromised

Permanent pen markers have ethanol based ink which has bactericidal activity and studies have shown that after marking a routine / non infected patient there should be a period of 10mins before the pen is used on another patient – as in the 10min time frame any bacteria picked up will be eliminated by the Ethanol (dry board markers must not be used as markers as they remain highly contaminated with bacteria after use, regardless of time span. Marker pens for routine use on non-infected patients should be hygienically wiped over with a clinell wipe after use.

The mark will be an arrow made at or near the incision site, preferably within 6 inches of the incision. Do not mark with an ‘X’

A circle may be added (in addition to the arrow) if the operator requires this to target an abscess, ganglion, lesion, deformity or similar.

The mark must be placed such that it will remain visible in the procedure field after preparation of the patient and application of drapes. For procedures during which the patient’s position may be changed, marking must be applied such that it is visible at all times. When the patient’s position is changed during a procedure, the site should be re-verified and the mark checked. An exception is when marking is limited by a dressing or cast; the mark should be made as close to the operative site as possible.

There is some evidence that marking patients close to the surgical site does not increase risk of infection. Cullen et al marked within the surgical site and did not find an increased infection rate within marked areas. Cronen et al evaluated growths from 20 volunteers after marking one arm with a site marker and leaving one arm unmarked. Neither side developed growth 3 days after sampling.

If marking at the surgical site will cause pain, i.e. in cases of unstable fractures, it may be appropriate to mark a more distal site. Careful attention must be paid to ensuring correct laterality at the Sign in and Time Out safety checks. If marking at the surgical site is not possible because of bandages, burns, Plaster of Paris then the site should be marked as close as possible. The non-operative side must never be marked. Careful attention must be paid to ensuring correct laterality at Team Brief, Sign in and Time Out safety checks.

The non-operative side must never be marked - not even with statements such as “not this side”.

If the procedure involves multiple sides/sites during the same procedure, each site and side should be marked as indicated on the consent.

The mark must not include a date or operator’s initials.

A ballpoint pen should not be used; ballpoint pens on skin are painful.

Surgical site marking must be made in a confidential manner which respects patient privacy. It is advisable to use a chaperone when marking (in line with Hywel Dda UHB Policy 312 -Chaperone – opens in a new tab). There should be appropriate space and chaperones available in all pre-operative preparation areas.

A patient with decision making capacity must:

- consent to pre-operative skin marking,
- fully understand the nature of the proposed procedure and
- be fully informed of the relevant benefits and risks.

Where a patient lacks capacity, pre-operative skin marking can be undertaken in the patient's best interests.

Working with interpreters is essential for patients with limited or no English and British Sign Language. Advocates may be needed to support people who are blind or deaf. An Independent Mental Capacity Advocate may be involved with a patient who lacks capacity to make decisions for themselves but have no-one close to them (family or friends) who can be consulted.

Marking Confused or Un-cooperative Patients

In the event that a patient is confused, un-cooperative or unconscious surgical site marking is of particular importance as they will not be able to participate in Sign In/Time Out laterality checks. In these situations it is good practice to ask a registered nurse or doctor as the second witness to the marking with reference to the section above

Marking is performed using the notes, imaging, consent form and clinical examination.

Marking digits

The digits on the hand must be named thumb, index, middle, ring and little.

Toes should be named with either of these names: hallux or big toe, 2nd or index toe, 3rd or middle toe, 4th or ring toe or 5th or little toe.

The spaces between the toes should be named as 1/2, 2/3, 3/4 or the 4/5 interspaces.

Any digit for amputation must have a preoperative arrow on the digit itself. There will be rare occasions where this is physically impossible due to pathology and clinical teams should be mindful of the risks of marks further away from the site of surgery.

The digit names must be indicated on the consent form and similarly marked with a marking pen with the patient's agreement while they are awake.

Marking Stomas

Stoma sites must be marked by a professional experienced in siting stomas, and an indication of the planned stoma position must be maintained throughout the invasive procedure.

Patient Refusal

If the patient refuses to have a mark, explain to them the importance of pre-operative marking and the role of marking in preventing wrong site surgery.

If the patient continues to refuse to have a mark the Surgeon/Operator, Anaesthetist, Scrub nurse should seek verbal confirmation in conjunction with the patient's medical notes, images, results, consent and operation list. Verbal verification of site to be operated on agreed with the patient and team and documented in the patients' medical notes and care plan. Verbal confirmation of site needs to be documented in theatre/procedure room in designated area easily visible to all theatre/procedural team.

If the patient continues to refuse to have a mark then follow the section entitled "Procedure for Unmarked Patients" and document the reasons for non-marking in the patients' medical notes.

Verification must be confirmed at Time Out.

Marking Check at Transfer

Before transfer to the procedural area, the following personnel must check that the appropriate site marking has occurred and verified against Consent form and operating/procedure list

- **On the ward or admission area**
    - A registered Healthcare Professional (HCP) checks the presence of the site mark prior to the patient leaving the ward / admission area and that the side matches the consent and the patient expectation.
    - The procedure site mark should be recorded as meeting these standards in the patient's peri-operative patient care plan.
- **pre -operative preparation area**
    - Registered nursing staff
- **To the theatre**
- Theatre staff responsible for transferring the patient to theatre.

The presence of appropriate surgical site marking must be documented in the patients' preoperative documentation.

If at this point, the surgical site has not been appropriately marked, the patient must not be transferred to the procedural area until they have been marked (unless they have refused to be marked then the section Procedure for Unmarked Patients must be followed).

Marking Check at Sign In (Safety Standard :- 3)

On arrival at the procedural area the Operator/Anaesthetist and an assistant must perform the Sign In safety check.

The planned procedure is confirmed with the patient and their valid consent, against their identity band and by checking the site marking (2 practitioners. See Sequential step 3:- Sign In).

During regional anaesthesia the mark should be used to check the side during Prep Stop Block Checks after Sign In and immediately prior to block insertion.

Marking Check at Time Out (Safety Standard:- 4)

Prior to commencement of surgery the team must perform the Time Out safety check.

As part of Time Out the one of the safety checks requires the operator and assistant confirming the operative side, confirmation of correct site marking and verification of the procedure to be performed.

The site mark and laterality must be checked against the patient's consent form.

Laterality Check at Sign Out (Safety Standard:- 7)

Confirmation that the procedure has been performed on the correct site and side occurs.

If there are multiple procedures, confirmation they have been completed.

Marks may be erased or crossed off at the end of the procedure if another procedure is planned or likely to occur on the same patient within the same admission.

Removing previous arrows prior to a new mark is advised.

Procedure for Unmarked Patients

When it is identified during Sign In that a patient has been brought to the procedural area (i.e. anaesthetic room) without being marked, the operator and anaesthetist, where relevant, must be informed. The patient must not be anaesthetised, or given any medication that may affect their capacity to consent, until they have been correctly marked. The patient must confirm their identity, the procedure being performed and the side. Relevant patient's medical notes, diagnostic imaging, biopsy results and the consent form must also be reviewed and used to verify the side of the surgical site. Marking can proceed within the procedural area as per steps outlined in this section.

In the unusual event that a patient is anaesthetised without being marked correctly then at the Time Out check the following should be verified by the operator:

- Patient ID using the wrist band
- Intended procedure using Consent Form
- Relevant documentation including patient's medical notes, operating list, diagnostic imaging, biopsy results and the consent form.

An incident report on DATIX in line with Hywel Dda UHB Policy 514 – Management and Investigation of Incidents must be completed (by the member of staff who identified the incident) for patients that are anaesthetised without correct marking, detailing any system failures which could be improved.

Exclusions

- Patient refusal (try to explain the reason for the site marking).
- Religious or cultural beliefs that exclude site marking.
- Intravenous access.
- Insertion of Hickman lines, central venous catheters (CVC) as the site may change. However, where a specific site is needed or should be avoided this should be explicitly stated on the consent form and procedure list.
- Cardiac catheters and interventional neuroradiology as imaging is used to guide the procedure on table and the entry point will be in artery.
- Critical emergencies where delay due to marking could have an adverse effect on the patient's condition. This is at the discretion of the lead consultant(s).
- Cases of bilateral internal procedures (e.g. bilateral tonsillectomy, oophorectomy) if bilateral is indicated in the consent.

Caution moments during consent and site marking

- Emergency and urgent work
- Confused patients
- Casts covering the operative site
- Multiple operative sites
- A rare or less commonly performed procedure
- A newly formed team
- Unfamiliar environment
- Please see the 'Performance Indicators NatSSIPs'

Audit of Standard 1

Audit and monitoring of this standard will be by the Health Boards Annual consent audit and by the observation of 5 random operations (on each site) on a quarterly basis using the audit form (see Appendix 11). These patients WHO checklist will also be audited, and also by ensuring that the following has taken place;

- Patient marking was discussed during the “Sign In”
- Patient consent was discussed during the “Sign In”

References

Cullan D, Wongworawat M. Sterility of the surgical site marking between the ink and the epidermis. J Am Coll Surg 2007 Aug; 205(2):319-21.

Cronen G, Ringus V, Sigle G, et al. Sterility of surgical site marking. J Bone Joint Surg Am 2005 Oct;87-A(10):2193-5.

National Safety Standards for Invasive Procedures 2 (2023), Centre for Perioperative care

Appendix 2:- Procedure for Standard 2, Team Brief

Procedure

The procedural multidisciplinary Team Brief is a key element of practice in the delivery of safe patient care in invasive procedure pathways, and forms part of the WHO Surgical Safety Checklist the Five Steps to Safer Surgery and now 'The NatSSIPs Eight' (Safety Standards).

A Team Brief must be performed at the start of all procedural sessions whether elective, scheduled, urgent/unscheduled or emergency procedures.

The Team Brief should occur at 0830 for an AM/All Day list and 13:00 for a PM list.

Any MDT staff member who will undertake an active role in the invasive procedure should be present. The team should confirm their names and roles. These should always include (in major procedures) but are not limited to:

- The senior operator and trainee(s)/assistant(s),
- The senior anaesthetist, and trainee(s),
- The anaesthetic practitioner,
- Scrub, circulating & recovery practitioners or other procedural assistants, including those in training
- Other healthcare professionals involved in the procedure should be involved at this communication point as appropriate.
- Radiographers can attend Team Brief, but their absence should not delay it. It is unlikely in most settings that the same in-theatre radiographer will be present during a list.

The Team Brief may need to be conducted on a case-by-case basis if there are changes in key team members during a procedure session, list changes due to other factors or staggered patient admissions. Any changes to team members during the day should be recorded and trigger a re-brief where appropriate.

In emergency or life-threatening procedures covered by on-call teams, a Team Brief may not always be possible. In exceptional circumstances, where responsibility may need to be delegated, the colleague must be able to perform the procedure independently and must be able to convey the lead's requirements and plan to the procedural team.

The Team Brief should take place in a discreet location in which patient confidentiality can be maintained, while enabling inclusivity and contribution from all team members. The Team Brief should usually be conducted before the first patient arrives in the procedural area. For operating theatres, Team Brief generally should occur within the anaesthetic room or theatre itself so that detail can be added to a team board and patient confidentiality can be maintained.

It is accepted that, on some occasions, it will not be possible for the surgeon and or anaesthetist to have seen all patients on the list prior to briefing (e.g. all day list with admissions later in the day, large list with time constraints, no space available to see day of surgery admission patients)

Where this is the case, an additional mini-briefing session must be held when practicable to update staff on patients not seen prior to the commencement of the list.

Any team member may lead the safety briefing, but usually a senior member of the nursing or medical staff should do this. They will:

1. Invite the team members to introduce themselves to ensure that their roles and names are known and to encourage communication.

2. Consider each patient on the procedural list in order.

   If a patient is admitted after the start of the list, the content of the safety briefing must be modified locally, in a manner which is relevant to the patient and the invasive procedure to be performed.

3. Have a discussion about each patient, which includes when relevant, but not limited to:

   - Diagnosis, consent, planned procedure and laterality (Sequential Step 1)
   - Relevant comorbidities or complications
   - Airway management plans if applicable
   - Additional monitoring or equipment needed
   - Patient communication issues or disability
   - Allergy status
   - Blood management plans should be confirmed as appropriate to the patient and procedure (e.g. tourniquets, tranexamic acid, cell salvage, availability of blood products)
   - Patient positioning
   - Infection Prevention and Control issues
   - Implant, prosthesis, stent availability (Sequential Step 5)
   - Equipment requirements/Special equipment and extras (Sequential Standard 6 Equipment Reconciliation)
   - Antibiotics and / or other drugs required
   - Other risks e.g. lasers, fire risk and management plan
   - Postoperative destination e.g. ward or critical care unit

4. Confirm in conjunction with the MDT members the expected duration of each invasive procedure, including the anaesthetic procedure. This will promote a discussion about agreed plans if it appears that the duration of the planned invasive procedures will exceed the time allocated.

5. Confirm the order of the list.

6. Lead the discussion on any additional concerns from a surgical, anaesthetic or practitioner's perspective and make contingency plans if necessary.

7. Encourage every team member to ask questions, seek clarification or raise concerns about any aspect of the patient's care or the planned invasive procedure.

8. A record of the safety team briefing is made on the Hywel Dda University Health Boards WHO Surgical Safety Checklist (see appendix 9), and display this in the procedural area for reference during the invasive procedure(s)/session.

9. Any issues raised at the Team Brief should be recorded and used to address issues and support quality improvements. This can help identify failures and opportunities for learning especially if used in conjunction with the Debrief (Safety Standard 8).

Caution moments during Team Brief

- Emergency and urgent work
- Confused patients
- Altered list order
- Lack of senior engagement with Team Brief

Audit of standard 2

Audit and monitoring of this standard will be, by the observation of 5 random operations (on each site) on a quarterly basis using the audit form (see Appendix 11). These patients WHO checklist will also be audited, and also by ensuring that the following has taken place;

- The team brief has started on time
- The senior clinicians are present
- All team members are present
- All team members are engaged in the process ("Silent Focus)
- A team brief record is kept

References

National Safety Standards for Invasive Procedures 2 (2023), Centre for Perioperative Care

Appendix 3:- Procedure for Standard 3, Sign In

Procedure

Sign In is the point at which the team checks that it is safe and appropriate to commence anaesthesia. In minor procedures Sign In can be combined with Time Out. Sign In is not a replacement for safe and efficient processes in admissions and ward areas. Staff should treat the Sign In process as a safety critical moment.

The anaesthetist in charge should lead the sign in. They must encourage participation of the patient (and/or parent, guardian, carer or birth partner) in when possible.

The following team members should be present at sign in:

- Anaesthetist
- ODP/Anaesthetic Nurse
- Qualified scrub staff
- Surgeon

In general, sign in must be performed for all patients of all ages. Occasionally (e.g. for very anxious or distressed patients) it is acceptable for just the anaesthetist and ODP/anaesthetic nurse to complete this section.

Note: The Sign In should not be completed until any omissions, discrepancies or uncertainties identified in the handover from the ward or admission area to the receiving practitioner in the procedure area or anaesthetic room have been fully resolved. On rare occasions, the immediate urgency of a procedure may mean that it may have to be performed without full resolution of omissions, discrepancies, or uncertainties. Such occurrences should be reported as safety incidents. DATIX incident report must be completed in line with Hywel Dda UHB Policy 982 - Incident, Near Miss and Hazard Reporting Procedure (opens in a new tab),.

At least two people should complete the Sign In process, alongside the patient. For procedures performed under sedation or general /regional anaesthesia, this should be the anaesthetist and anaesthetic practitioner. For procedures not involving an anaesthetist, the operator and a registered member of staff should perform Sign In.

Questions to the patient should be open, such as:

- Can you confirm your name and date of birth?' Not 'Your name is XXX, is that correct?'
- Tell us in your own words what procedure you are expecting and which side?' (where relevant) Not 'The form says we are fixing your right ankle, is that right?'
- Do you have any allergies?' Not 'no allergies?'

Where required interpreters should come into the anaesthetic room or procedure area, or an adult family member if this is not possible. Otherwise, the person confirming consent should be present to confirm prior comprehension via the interpreter

Safety checks should include the following for any invasive procedures:

- Patient name, date of birth and medical record number check with the patient and the consent form. In major procedure areas, it must also be checked against the printed identity band, nursing documentation /perioperative care plan and operating list
- The consent form should be checked to confirm the absence of abbreviations, understanding of patient and date of consent
- Site marking, if applicable, to be cross-checked with the patient, consent and operating list
- Allergy status
- Safety checks should also include the following where appropriate:
    - Pregnancy status
    - Infection risk to staff
    - Fasting time
    - Anaesthetic and emergency equipment/drugs checks
    - Airway strategies and preparedness
    - A re-cap on the plan for management of blood loss. This goes beyond the previously used question about expected volume of blood loss and includes (where appropriate) questions around tourniquet, anticoagulant use, tranexamic acid, cell salvage etc. This should be planned at the Team Brief
    - **Regional anaesthesia 'Stop Before You Block/Prep Stop Block' checks (See separate "Stop Before You Block" procedure)**
    - Availability of essential instrumentation
    - Availability of implants, stents, prostheses
    - Implants (surgical metalwork, pacemakers etc.)
    - Availability of additional staff e.g. radiographers
    - Others to be decided locally as appropriate for specialty

Priority checks are appropriate in life threatening situations and by nature are always major procedures and include command and control from team lead and role allocation, and blood management plan.

Ensure a record of the team safety briefing is made on the WHO Surgical Safety Checklist, and display this in the procedural area for reference during the invasive procedure(s)/session.

Caution moments during Sign In

- Emergency and urgent work
- Regional anaesthesia
- Confused patients or those less fluent
- Patients presenting for second procedures
- Disengagement of staff

Audit of Standard 3

Audit and monitoring this standard will be through the audit of the WHO checklist on a quarterly basis and by observing 5 random operations (on each site) ensuring that the following has taken place;

- Provision has been made for patients who do not speak English or Welsh
- Open questions have been used
- The patient is involved in the process
- Appropriate safety checks occur

References

National Safety Standards for Invasive Procedures 2 (2023), Centre for Perioperative Care

Appendix 4:- Procedure for Standard 4, Time Out

Procedure

Time Out is the most critical check in the WHO Surgical Safety Checklist and is the final check before the procedure. Time Out is a checking opportunity to support the whole team in providing safe, effective and efficient patient care. Time Out is a team process that relies on engagement of the whole team throughout.

It is not absolutely prescriptive who should lead this, any team member may do so, however, the named person should be identified at the beginning of the case. Time out should be administered after safety critical tasks are completed following transfer into theatre. All staff must agree they are ready to participate and stop other tasks and pay full attention to the checklist.

In order to facilitate this the Time Out should be performed as close as possible to skin incision. This will usually be before skin prep and draping;

Meaning:

- After all staff are scrubbed and instruments are checked,
- The patient is positioned
- Safe transfer of the patient onto in-theatre anaesthetic machine and monitoring has been completed and maintenance of anaesthesia is established with a stable patient.

Participation of the patient (and/or parent, guardian, partner or birth partner) in the time out should be encouraged when possible. (I.e. not undergoing general anaesthesia)

Note: The time out should not be performed until any omissions, discrepancies or uncertainties identified in the handover from the ward or admission area to the receiving practitioner in the procedure area or anaesthetic room have been fully resolved. On rare occasions, the immediate urgency of a procedure may mean that it may have to be performed without full resolution of any omissions, discrepancies or uncertainties, such occurrences must be reported as safety incidents in line with Policy 982 - Incident, Near Miss and Hazard Reporting Procedure (opens in a new tab),.

The time out must include when relevant, but is not limited to checks of:

- Patient’s name
- The results of any relevant tests that must be present and available in theatre e.g. imaging, hearing tests and eye tests
- The procedure to be performed
- Verification of correct position and site/side prepped

Surgeon:

- The anticipated blood loss.
- Any specific equipment requirements or special investigations.
- Any critical or potential complications.

Anaesthetist:

- Any patient specific concerns.
- Patient's ASA.
- Monitoring equipment and other specific support e.g. blood availability.

Scrub Practitioner:

- Confirmation of sterility of instruments and equipment
- Any equipment issues or concerns.

Surgical site infection:

- Antibiotic prophylaxis – confirm that antibiotics agreed upon in the Sign in have been given
- Patient Warming
- Glycaemic control
- VTE prophylaxis

When different surgical teams are performing separately, sequential procedures on the same patient, a time out must be performed before each new procedure is started. This may be a modified version of the initial time out.

Any omissions, discrepancies or uncertainties identified during the time out must be resolved before the procedure starts.

A record of the team safety briefing is made on the WHO Surgical Safety Checklist, and this should be displayed in the procedural area for reference during the invasive procedure (s) / session.

Who

- All patients undergoing invasive procedures under general, regional or local anaesthesia, with or without sedation, must undergo team Time Out immediately before the start of the procedure.
- The lead/senior named responsible operator holds responsibility to ensure Time Out meets the standards.
- Leadership of the Time Out checks can be delegated to any team member, but the operator carries responsibility: they should ensure the whole team is listening and participating.

- If a clinician wishes to perform a procedure there is an expectation that they are present and engaged a Time Out. There are few exceptions to this rule e.g. emergency out of hours work, on-table specialist input.

- The primary operator should summarise the key events/steps/safety issues of the procedure planned, particularly in complex procedures or if some members of the team may be unfamiliar with the steps of the case.

- The primary operator, if not the responsible consultant, should know who and how to call for assistance.

When

- The Time Out should be performed as close as possible to skin incision. This will usually be just before skin prep and draping.

Time Out should take place only when:

- Every team member is giving the process their full attention.

- When the lead operator (and lead anaesthetist) is present.

- All other activities have stopped (e.g. side/other conversations, scrubbing, patient positioning).

How

- The approved Hywel Dda University WHO safety checklist must be used to ensure all the steps are followed. Specialty-specific, emergency and minor procedure checklists can be used where appropriate.

- Every member of the team must participate in the Time Out process.

- When all checks are confirmed and addressed the lead should declare Time Out is complete and that the procedure can commence.

- A record of Time Out should be kept in the Hywel Dda University Health Boards WHO check list contained within the theatre care plan; the senior lead operator should take responsibility and they are accountable for the completion of Time Out. There are various ways to validate checklist completion; using a paper, electronic, laminated checklist or poster followed by an electronic or actual signature.

- If any problems or concerns are raised at Time Out the procedure should not begin until they are resolved.

- The senior operator and / or anaesthetist should always acknowledge these concerns. If these are not resolved and are creating a risk in themselves (e.g. due to excessive delay), the lead operator should assess the situation and discuss the options with the team. If a decision is taken to proceed at risk with a workaround, it should be reported as a safety incident and the rationale documented in the notes.

Basic checks for any invasive procedure

- Confirmation that the team members know each other's names. This should occur for the first patient on the list. If any staff changes occur after Team Brief, and if team members subsequently change, the team introductions should be repeated.
- Confirmation of concordance of patient identity, verbal or written consent, relevant imaging and / or test, site(s) of procedure. It is important that the team understands that this is as much a check of documentation, imaging etc. as of the patient per se. It is also an opportunity to ensure that the whole team understands exactly what procedure is planned.
- Confirmation of any allergies or intolerances indicated via a red wrist band.
- Confirmation that whole team is aware of any key/critical or unusual/potentially unexpected aspects of the procedure and any specific equipment or investigation requirement.
- Confirmation that all equipment, including implants and drugs, needed are present, working and sterile.

Advanced/additional checks relevant to more involved or specialty specific procedures

- Confirmation of the agreed blood loss management plan.
- Confirmation of a diabetes management plan.
- Confirmation of an individualised patient risk assessment using tools such as ASA, generic scores such as SORT,or surgery / procedure specific tools.
- Confirmation of anaesthetic concerns and readiness.
- Confirmation of management plan in event of a surgical fire.
- Confirmation of appropriate infection prevention measures and infection risk from patient.
- Confirmation of warming and temperature monitoring.
- Confirmation of antibiotic administration if appropriate.
- Confirmation of appropriate VTE prophylaxis in place.
- Confirmation of relevant medications e.g. anticoagulants, insulin, steroids, DDAVP.
- Confirmation of any existing intentional foreign objects in situ, e.g. packs.
- Others to be decided locally as appropriate, e.g. perfusion checks.

Additional points of clarification

- There may be legitimate reasons to perform Time Out earlier (e.g. complex positioning) or later (after draping) but the same standards of performance apply.

- If the patient is moved significantly after Time Out, an abbreviated check for correct site and procedure must take place.

- More than one Time Out is required if multiple procedures or multiple teams are involved. e.g. sequential procedures on the same patient with different operating teams.

- In minor procedure areas, e.g. OPD procedures where there is minimal sedation and no general anaesthesia, Sign In and Time Out can be merged for efficiency and to avoid unnecessary duplication.

The awake patient

- The team should encourage the patient/parent to be involved if appropriate. Only relevant introductions need to be made to the patient and this can be judged on an individual basis, i.e. there is no need for every team member for every procedure to identify themselves to the patient as this can be intimidating and overwhelming.

- Reassurance for the patient is most important. Teams should allocate one team member for that role and where appropriate and respectful they should provide reassuring hand hold / gestures / conversation.

- The patient's dignity should be maintained at all times, e.g. avoiding unnecessary skin exposure.

Consent discrepancy

- If there is discrepancy between the consent form and the procedure expected / proposed by the operator or the medical record in an anaesthetised patient the procedure should STOP.

- Where possible seek advice from senior clinical staff not directly involved

- Review all the relevant medical records, relevant results and imaging

- In cases of children or adults unable to consent for themselves, it may be possible to confirm the correct procedure with the person who provided consent

- In cases of adults who gave their own consent, it is not appropriate to seek consent from a relative

- If there is any doubt as to the correct procedure, the patient should be woken up, followed by explanation by senior clinicians and completion of Duty of Candour

<u>Caution moments during Time Out</u>

- Emergency and urgent work

- Multiple procedures and / or teams

- Lack of appropriate conduct for Time Out
- Lack of senior clinical engagement with Time Out

Audit of Standard 4

Audit and monitoring this standard will be through the audit of the WHO checklist on a quarterly basis and by observing 5 random operations (on each site) ensuring that the following has taken place;

- Appropriate safety checks occur

References

National safety Standards for Invasive Procedures 2 (2023), Centre for Perioperative Care

Appendix 5:- Procedure for Verification and Opening of Implant(s) for Invasive Procedures

Introduction

Some invasive procedures will require the placement of devices or tissues (implant) inside or on the surface of the body. Many of these devices or tissues are prosthetics, intended to replace missing body parts.

Definition of an Implant

NatSSIP's 2 defines an implant as an item intended to remain within the patient's body long term. The term prosthesis is sometimes used, but this usually implies a replacement part. The term implant is used here as it is broader and includes stents, pacemakers and similar devices.

Types of Implant Terminology

Implant Type	Example
Type specific implant	Chosen for laterality, power, size e.g. knee, breast, lens, coils, stents
Custom implant	Made for the patient e.g. cranioplasty
Biological implant	From a human or animal e.g. rib in rhinoplasty or valve in cardiac
Electrical implant	E.g. generator or pacemaker
Multi-part implant	Compatible parts fit together
Onyx/Glue Implant	Is an injectable substance that hardens into an implant

Standards dependent on timing of implant decision

In general, the choice of implant is made at one of three times, and this will affect the process for checking the implant(s) before implantation:

A. Known implant. When the exact implant(s) is known before the procedure. This includes custom-made or biological implants. It also includes batteries / generators for an in-situ device that need changing, a lens in eye surgery or a custom cranioplasty implant.

B. Restricted/evolving decision/choice. When the exact size or type of implant is decided upon during the procedure. e.g. joint prostheses.

C. Unplanned or unexpected implant insertion. Local practice will determine whether on table measurement or templating is required to guide which intended implant is requested, for example, endovascular stents or knee replacement.

The requested implant details should be written down in any situations where there is an appreciable time gap between request and implantation, or where implants are in a different physical location.

All implants consigned or owned by Hywel Dda University Health Board are required to be pre-sterilised, individually wrapped items with product traceability enclosed.

- Type of implant/prosthesis/device
- Laterality (when applicable)
- Size (all relevant dimensions)
- Expiry date
- Sterility

Any loaned items need to be individually wrapped, have traceability and be pre-sterilised

General Procedure

Pre-Procedural Steps

Procedural area staff will check the operating list by accessing Welsh PAS to ascertain implant requirements for all operating Theatres at least one week ahead of any scheduled procedural session. This is to ascertain if any implant not owned or consigned to the Health Board are required.

The operating clinician must have previous knowledge of the implant manufacturer's instructions, literature and implantation instructions. It is the operating clinician's responsibility to follow and understand the manufacturer's guidelines and to arrange manufacturer representative support where required.

Loaned instruments

For any non-standard loaned equipment requirements a Surgical Equipment Loan Procedure form must be completed and sent with the instruments that require sterilisation and packing in CSSD. (Sections A & B).

Section C and D will be completed by CSSD prior to the return of the instruments to theatre of the instruments along with a decontamination certificate.

A decontamination certificate/ Declaration of Decontamination status form must be included with the instruments when returning the instruments to the manufacturer.

Verification and Opening of Implant for Invasive Procedures

It is the responsibility of each procedural area to liaise with the operating clinician and waiting list team to ensure that any non-standard implant have been ordered and delivery arranged in advance of any processing requirements.

The waiting list team must enter any non-standard implant requirements requested by the operating clinician to the additional requirements area on the operating lists on Welsh PAS.

When the unlocked or locked operating lists are changed on the PAS Theatre System, the waiting list team must inform the procedural area lead via email to confirm availability of any specialist implant requirements.

Within 24hrs of Interventional Procedure

A designated member of the procedural area staff and a member of the operating clinician team will check the required implant range for the interventional procedures listed on the operating list whilst ensuring that:

1. The packaging is undamaged and sterility is not compromised.

2. The implant manufacturer, type, size, side (if applicable) are within date.

3. All required instrumentation sets are available and that the sterility and integrity of wrapping is confirmed.

4. The number of implant available for use is adequate to ensure availability for each and every patient planned on that day's operating list.

It is the operating clinician's responsibility to check implant availability for any invasive procedure they undertake.

Failure to Verify Implant Availability

There will be occasions, due to a high volume of invasive procedures, or damage identified in the packaging of a particular implant or instrument tray, where verification cannot be confirmed prior to the session's team brief.

If there are discrepancies or concerns with implant availability then the designated staff member checking implant must inform immediately the operating clinician, procedural area manager and anaesthetic team.

At this stage the following actions must be undertaken:

1. If there is unavailability of implant or compromised instrument integrity. It is ultimately the operating clinician's decision to continue with the surgery, change systems, or to cancel the patient if that is the most appropriate action.

2. Only the operating clinician after careful consideration of these facts can take the decision to continue without a full set of implant or instrumentation available. Availability of instrumentation across sites or Health Boards would be assessed and Risk Assessment completed regarding time for transfer and impact on patient operating time. Sterile instrument trays can only be accepted from another NHS accredited site.

3. If any discrepancy is linked to implant availability, Instrumentation and this can be sourced from another location, then an agreement to change list order can be made to Verification and Opening of Implant for Invasive Procedures allow transfer of the missing implant. Any resultant list order change must be confirmed via team brief.

4. The patients' invasive procedure or anaesthetic intervention must never be commenced if any implant or instrument tray identified as essential is not present within the procedural area and checked by the operating clinician and procedural area lead.

Ophthalmic Intra Ocular Lens Implants Procedure

Preoerative assessment: IOL selection

- IOL selection should take place during the assessment clinic or in the preoperative ward-round
- IOL selection performed during the assessment clinic should be checked at the preop ward round on the day of surgery
- IOL selection should be performed by the operating surgeon if possible, or by a suitably trained clinical professional to be confirmed by the operating surgeon. For IOL selection: o Ensure active confirmation by patient of patient identity details and eye to be operated and that this matches operating list, medical records, consent form and biometry data
    - Ensure the biometry is within date
    - Ensure any data has been transcribed correctly (e.g. ultrasound axial length, keratometry)
    - Ensure high quality scans
    - Ensure correct A-constant used for desired lens and biometry method (optical or ultrasound)
    - Ensure correct IOL formula used for axial length of eye
    - Check astigmatism and any requirements to manage it
    - Confirm refractive aims for patient. Undertake, or confirm, selection of IOL model and power, and record this in the notes/biometry

- Be especially vigilant when patients change their mind regarding their refractive aim or which eye. Clearly cross out any non-current paperwork (or amend/delete any old electronic selections) and ensure the patient record only contains one correct and up-to-date IOL selection when the patient reaches theatre.

Toric IOLs

- Manual typing in of Ks, meridia and axial lengths into online toric IOL calculators can very easily be complicated by transcription errors. Always ensure all the figures match the biometry and corneal topography printouts, and that the flat and steep meridia are not inadvertently reversed.
- The checks for toric IOLs are mostly as for monofocal IOLs but also require:
  - marking of the meridian on the eye, done with patient sitting up, ideally at the slit lamp
  - the correct power IOL (both spherical *and cylindrical*)
  - the correct biometry *and correct toric IOL calculation* printouts for the patient
  - care to avoid inadvertent insertion of a non toric lens.

Safety

- Adhere to operative protocols and surgical safety checklists, adapted to be cataract surgery specific, which should include:
  - Team brief (including all team members introduced by name and role) and debrief
  - 2+ person checks at key steps of the procedure (e.g. sign in = entry into theatre, time -out = before anaesthesia or immediately pre-procedure, immediately before implantation)
  - 2+ person confirm choice of lens model and power
  - Verbal active patient identity and surgical side verification at all checks
  - Procedure site is marked with permanent marker and visible after prep and if possible after drape
  - Verbal and documented lens verification with cross checks to side/eye marked, source biometry sheet, record of IOL selected (in history sheets/biometry/IOL selection sheet/EPR/whiteboard), consent form and theatre list
  - The final “surgical plan” for the implant is clearly and loudly confirmed during ‘Time Out’ by the scrub practitioner in the presence of the operating surgeon, who verifies that the IOL power and model is accurate to the rest of the team.
  - Any error up to this point resulting in wrong implant is a serious incident
  - Any error after that point results in a wrong implant is a never event

- Check lens and backup are available and only one lens is in theatre prior to anaesthetic. There should only be one lens out in theatre at any one time

- Be particularly careful where staff other than the surgeon obtain the IOL from the lens bank and ensure the IOL is shown to and positively confirmed by the surgeon as correct. It is of utmost importance that staff make a conscious effort to concentrate while checking patient identity, IOL selection and side for which IOL has been chosen, instead of just going through the motions of the checking process.

- The WHO surgical time-out is an appropriate time to perform these checks, during which no other activities or distractions should be tolerated. Staff of all disciplines and ranks should feel empowered to speak up if they have any doubts at any time.

- Avoid disruption or interruption during surgery and last-minute changes to the list.

- Patient ID and biometry and IOL check is completed again prior to implantation.

- If a new IOL is selected during the procedure, remove the original IOL from theatre and repeat full IOL checks as an intra-operative complication and change in IOL selection during the procedure is a vulnerable stage of the procedure, particularly if using a different IOL model, A-constant and IOL power.

- If staff change during a list, repeat the team brief.

- Surgeons in training should be closely supervised, including for IOL selection and insertion.

- Train staff in non-technical skills (teamwork, leadership, situation awareness, decision making, communication, challenging uncertainties regarding procedure and IOL selection). Multidisciplinary simulation team training is recommended, particularly to develop non-technical skills and to have training on vulnerable stages of procedure/process for wrong IOL including intra-operative complications, change in staff or change in list order.

- Educate non-medical theatre staff in understanding biometry data, IOL types and selection principles.

- Adapt local processes according to staff feedback, experience and learning from previous incidents (local and national).

Other Implants Procedure

Procedural Steps Undertaken During Invasive Procedure (Non IOL)

1. During the invasive procedure the operating clinician will state what implant is required by size, type, manufacturer, dioptre and side (if applicable).

2. The procedural circulator must record the requested item clearly on to the count board in a manner that is visible to both operating clinician and procedural staff.

3. The operating clinician and scrub practitioner must confirm that all recorded details are correct before the circulator leaves the procedural area to collect the items.

4. Where possible the items must be located as close as possible to the procedural area.

5. **CHECK ONE.**

   The procedural circulator will collect the implant components requested by the operating clinician and confirm that the details are consistent with those recorded on the count board and that the implant is within date. –

6. At an appropriate point during the invasive procedure, the operating clinician and scrub practitioner will pause and focus on checking the implant confirming that it matches the requested item(s) documented on the count board.

7. **CHECK TWO**

   The operating clinician must read out loud the details of the implant which must include: manufacturer, type, size, side (if applicable) and expiry date. The scrub practitioner will also audibly confirm the manufacturer, type, size, side (if applicable) and Expiry date. These details must also be consistent with those recorded on the white board –**.**

8. Once confirmed that all implant requirements are correct, the operating clinician will state verbally that the implant can be opened.

9. **CHECK THREE.**

   The circulator will open the outer packaging of the implant and before proceeding will hold the item so that the operating clinician can visualise the INNER packaging to confirm manufacturer, size, type, side (if applicable) and expiry date. –

   The operating clinician may delegate the verbalising of the implant details to the scrub practitioner during **CHECK THREE** if this is deemed more appropriate by the operating team at that time.

10. Once confirmed the scrub practitioner or operating clinician will receive the implant onto the sterile trolley.

11. It is the scrub practitioner's responsibility to ensure the implant is kept in a secure manner. Placing it in an unused sterile receiver or identifying a clear area on the sterile trolley will assist with minimal handling of the implant until required for placement.

12. When the implant is implanted the operating clinician and scrub practitioner must ensure that any non-retainable packaging is disposed of and not at risk being retained.

13. The procedural circulator will retain all labels associated with the implant and ensure that the implant is accurately recorded on all relevant documentation, this may include but is not limited to:

    a) Theatre Register/Implant Register

b) Nursing Care Plan

c) Where applicable the Cataract care pathway documents

d) Operation Note

e) Health Edge Track and Trace System/Scan 4 Safety

f) Procedural area order form

g) National Joint Registry and where applicable post op cataract report form

h) Where applicable Patient IOL card

i) Any additional audit forms required at that time.

Whilst the operating clinician retains the overall responsibility for ensuring that the correct IOL implant is implanted there is a shared responsibility for the compliance of this patient safety check procedure.

For cataract surgery the operating clinician retains the overall responsibility for ensuring that the correct implant is implanted there is a shared responsibility for the compliance of this patient safety check procedure.

Company representatives

Company representatives who are attending a procedural area to provide support during procedures are NOT to open any implant onto the sterile field.

Audit and Monitoring of Standard

The compliance with these guidelines will be reviewed on a quarterly basis by observational audit and the audit form (see appendix 11).

Elements to be monitored:

References

- AfPP Standards and Recommendations for Safe Perioperative Practice, 5th ed, 2022
- Operations included in the National Joint Registry (NJR 2016);
- National Safety Standards for Invasive Procedures 2, Centre for Perioperative Care, 2023
- Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices
- http://www.wales.nhs.uk/governance-emanual/medical-device

Appendix 6:- Procedure for Standard 6, Equipment Reconciliation

Introduction

There is potential for a countable item to be retained inadvertently during any surgical procedure regardless of the type or complexity of the procedure and irrespective of the clinical setting.

The retaining of foreign objects post procedure is wholly preventable and therefore considered a Never Event; as it has the potential to cause serious patient harm or death. Many factors, including communication, situational awareness and consistent compliance with standardised procedures have been shown to reduce the risk of a countable item being retained post-surgery.

Countable Items

Countable Items may include, but are not limited to;

- Blades
- Bulldogs
- Cotton wool balls
- Diathermy tip cleaners
- Instruments including screws or detachable parts
- Lahey swabs (peanuts, pledgets)
- Liga-reels
- Local infiltration needles
- Laparoscopic retrieval bag
- Other isolation bags
- Needles (both suture and hypodermic)
- Ophthalmic micro sponges
- Patties
- Red ties from swab packs (also acts as an additional check with the count board for swab number accuracy)
- Slings/sloops
- Shods

- Sponges
- Tapes
- X-ray detectable gauze
- swabs, mops or packs – names vary according to local requirements

What

- The count should include any item that enters the procedural field, including swabs, sharps, disposable items and instruments and their constituent parts.

Who

- Two trained staff should perform the count. One should be GMC (General Medical Council), GDC (General Dental Council), NMC (Nursing and Midwifery Council) or HCPC (Health and Care Professions Council) registered; any unregistered staff should be assessed as competent.
- Count competencies should be maintained. See Online Sequential Step Implementation portal
- All scrub practitioners / operators' assistants and operators in the full count areas must be familiar with the count as it applies to their area. Other members of staff need an understanding of the basic count method outlined below to support those performing the count.

When

- A pre-procedure count should be performed prior to commencing a procedure to establish a baseline. This should include any existing intentional foreign objects in situ and anaesthetic packs.
- An intra-procedure count should be performed when appropriate: before intentionally packing a cavity and when there is a change in scrub personnel.
- A first count should be performed (as appropriate to the procedure):
    - Before closure of a cavity or major organs
    - Before closure of the first layer of muscle, e.g. during spinal and joint replacement surgery
    - Before wound closure begins
- The final count should occur at the beginning of closure of the skin or before the end of the procedure. This point should be identified to the team (e.g. 'pause for gauze') as a point when the scrub team need time and concentration to count carefully. The end is when 'final count complete' is announced. This is confirmed at Sign Out (Safety Standard 7).
- A count should be performed any time a discrepancy is suspected that cannot be readily checked.

- A count should be performed if there is a changeover of either the scrub or circulating practitioner.

How

- Staff should be allowed to count without distraction unless there is urgent, unforeseen clinical need.

- If the count is interrupted, it should restart from a point before the interruption.

Procedure

Every person completing checks should be signed off as competent by a qualified registered practitioner.

All staff or students who are not yet deemed competent must be supervised by a suitably competent third party who must also sign the care plan.

All surgical counts must be performed by two members of staff, one of whom must be a registered practitioner. The other participant must be either:

- A registered practitioner who is familiar with the instruments.

- Assistant practitioner scrub, or trainee assistant practitioner

- A HCSW who is familiar with the instruments.

- Trainee ODP/Student nurse/HCSW who is under supervision.

- Operating Surgeon

A count must not be completed between two circulators or two scrubbed practitioners.

Counts for each surgical procedure must be recorded in an area designated for the reconciliation of surgical counts.

The count board must be suitably located so as to be visible to all members of the multi-disciplinary team during the surgery.

For each individual surgical procedure the same two members of staff must perform all the counts required.

Where, due to exceptional circumstances, the initial staff members cannot complete all counts for a surgical procedure the name of replacement or relieving members of staff must be recorded on the intra-operative record.

A change of scrub personnel must only occur when absolutely necessary. Should it become necessary to replace the scrub practitioner during the procedure, then it must be at an appropriate time and with the agreement of the surgeon. A complete count of the instruments must be performed at the

changeover and this must be recorded and signed dated and timed by both the incoming and outgoing practitioners.

A count may be requested by any member of the surgical team. All staff are encouraged to immediately raise any concerns they may have regarding any aspect of the count.

Breaks must be planned to facilitate continuity between the count practitioners and to allow a full hand over to take place between scrub nurses if a change is deemed essential.

When a scrub practitioner is not required for a minor procedure, the circulating practitioner must be a registered practitioner with whom the operating surgeon must perform each count. Both members are required to document the checks.

The surgical team must allow time for the count to be undertaken without interruption.

If a surgical procedure is expected to run over six hours, the operating surgeon is responsible for determining a suitable time for a comfort break. The operating surgeon must cease all activity until the scrub practitioner has returned to the table and is ready to proceed.

Procedural Steps

An initial count must be performed immediately prior to the commencement of surgery. Further counts must occur:

- Before closure of a cavity within a cavity
- Before wound closure begins
- At skin closure or at the end of the surgery

The two practitioners must count aloud and in unison with actual visualisation of countable items. Both practitioners must confirm independently that the count is accurate and that the record on the count board is complete.

The sequence of surgical counts will be:

- initial count – instruments, swabs, sharps
- subsequent counts - swabs, sharps, instruments

All countable items must be separately recorded. The circulating staff who open the countable item must be the person who records on the board.

After the initial count is complete, additional instruments may be added after both Practitioners have counted and checked as correct against the number marked on the outer package. There is no requirement to open all packages during the initial count.

The GATE method must be used for the addition of countable items (Appendix 1). This excludes swabs which are covered below.

The count must not be interrupted and all possible attempts must be made to ensure that a count, once commenced, is progressed to completion. If an interruption does occur then the count should start from the beginning. During the count, count time out should be established. All non- essential conversation and music should stop.

Countable items must not be cut or altered unless specifically intended for the purpose as detailed above. However, if any alterations of a countable item are needed, this must be documented in the patient's theatre record and highlighted on the count board.

Countable items with disposable protective covers must be recorded as one item. When the item is requested for use by the operating surgeon then any sheath or cover must be removed from the surgical field and placed in clinical waste.

At all times during a surgical procedure, the scrub practitioner must be aware of the location of all instruments and medical devices. Awareness in approach must be encouraged to ensure that only necessary instruments are in use at any given time.

If a patient's surgery requires separate surgical fields, or teams operating concurrently, a separate count must be completed for each instance. During the closure of a wound all counts require to be aligned.

If a counted item is dropped off the sterile field, the circulating practitioner must retrieve it safely, show it to the scrub practitioner, and place it in an appropriate safe location or container so that it may be reconciled at the time of the count.

On completion of a count, a verbal statement must be made by the scrub practitioner to the operating surgeon to confirm that all countable items have reconciled. Verbal acknowledgement must be received from the operating surgeon in order to prevent any misunderstanding. The circulating practitioner must verify with the scrub practitioner that the operating surgeon has acknowledged this statement.

At the end of the surgical procedure the practitioners must record in the patient's theatre record that satisfactory checks have been completed.

The completion of the count and confirmation that all items have been reconciled must be documented on and verbally confirmed at the patient sign out phase of the procedural area checklist.

All items must remain within the theatre until the surgical procedure has been completed and all counts have been concluded satisfactorily – this includes laundry and clinical waste containers.

Clinical waste bags must be traceable as per Local site procedure and labelled prior to each procedure as for example, Th1, case 1 and the date.

Used swabs should be disposed into an approved swab collection receptacle as used ensuring the radio opaque marker is visible. Once 5 have been collected, these are checked with the circulator, crossed off the board and left in view of the theatre team. The red string should be handed out as removed from each bundle, verbally confirmed and handed out to the circulator to attach with tape to the swab receptacle.

Management of swabs and packs

All swabs that are used during surgical procedures, including wound site preparation, must have an x-ray detectable marker fixed securely across the width of the swab.

When checking swabs, the scrub Practioner should ensure the item is fully opened to check integrity and the presence of x-ray detectable marker.

All swabs must be packed in bundles of five and contain a red band tie.

In the event of an incorrect number of swabs (i.e. not five), or lack of x-ray detectable indicator, the entire packet must be removed from the procedural area.

The batch and lot numbers must be identified and the relevant lot numbers must be removed from stock. A Datix incident report must be filed in accordance with UHB Policy 514 - Management and Investigation of Incidents and the senior nurse manager and service delivery responsible for the procedural area, head of procurement and medical devices co-ordinator must be notified.

Swabs without radio- opaque marking must not be added to the operative field at any time nor used for skin preparation. This includes dressings, which should only be opened at skin closure.

All sites should refer to swabs by size dimension

- Small as 10 x 7.5
- Taped as 22.5 x 22.5
- Saline as 45 x 45
- Tonsil as 7.5 x 2.5

If a swab is placed in a cavity intra-operatively for homeostasis or retraction purposes, the scrub and circulating practitioner are responsible for ensuring that it is removed. This process should be verbalised and documented on the white board.

Instrumentation

All trays must be inspected for damage, perforations, expiry date, sterility indicators and traceability before being opened. HSDU labels must be removed and added to either the operating care plan, supplementary traceability sheet or surgeon operation record where appropriate and also scanned to Health Edge.

Once opened the external wrap must be inspected for integrity before the tray is moved to the sterile trolley. If the tray is on the trolley to be prepared as a sterile field then the tray must be lifted and liner inspected for integrity before opening any further packs or sterile supplies.

Instruments must be counted audibly and viewed by both practitioners.

Instrument check lists must be available to provide an accurate record of the instruments on the set. The list must be used to check the instruments prior to the start of the procedure and at the completion of the procedure.

Any discrepancies found in the instrument list at the preparation stage must be noted on the tray list and a non-conformance report submitted. The instrument set must only be used if considered safe to do so by both scrub practitioner and operating surgeon.

All supplemental instrumentation that is opened must also be recorded in the count and reconciled as any other countable item.

If at any stage an instrument is identified to be malfunctioning, it is identified accordingly on the checklist, and a cable tie ‘repair’ tag is to be attached to the instrument.

In the event of an instrument breaking during the procedure, the scrub practitioner must ensure that all pieces have been accounted for at the time of the count and a DATIX incident report filed in accordance with UHB Policy 514 -Management and Investigation of Incidents.

The retention of a foreign object post-surgery requires a full investigation under the Serious Incident Framework, in accordance with UHB Policy 514 –Management and Investigation of Incidents.

Sterile fields should be opened and prepared as close as possible to the time of use. Prepared sterile fields should be double covered and only kept for 2 hours. Coverings for sterile field should not be used as sterile drapes in the procedure.

Count Discrepancy

If a discrepancy in the count is identified at any point during the surgery, the operating surgeon must be informed immediately by the scrub practitioner.

A search is implemented immediately to include the entire sterile field, floor, swab containers, waste and linen, footwear and surrounding equipment by members of the procedural team.

If the item is not reconciled after the initial wound and room search then the consultant with overall responsibility for the patient must be informed by a member of the procedural team. The departmental manager must also be informed at this point to assist with further coordination or staffing if deemed appropriate.

In the case of a missing needle, if any staff have left the unit, a search is made of their footwear, changing room and linen bag.

Where possible assistance from another consultant surgeon not previously involved in the operation should be sought. This surgeon should assist by scrubbing and performing an exploration of the operative site.

Non-consultant surgeons must seek assistance from their supervising consultant if a count is not reconciled.

If a missing item or swab still cannot be found after searching, on table imaging must be performed. It is acceptable in a first instance to use image intensification, but this result is not definitive and a plain film using at least two different views must be performed if the count remains un-reconciled and consideration given to CT the Patient.

The patient must not leave the operating room until the missing item is accounted for.

Plain film results must be reviewed face to face by both the surgeon and the radiographer. In situations where this not possible (and this may be in the patient's best interest) the reason must be written in the operation notes and the medical records and a forward plan must be recorded by the consultant with responsibility for the patient in the medical records. Further appropriate imaging must be requested and performed within 12 hours.

The operating and/or consultant surgeon must be informed when the missing item has been reconciled.

In the rare event an item cannot be reconciled the consultant will make the decision regarding the patient's discharge from theatre. When the patient leaves the theatre with an un-reconciled count, a thorough search is commenced again and all actions clearly documented in the Patient record. A Datix incident report must be filed in accordance with UHB Policy 514- - Management and Investigation of Incidents. The operating surgeon documents the incident in the medical records and follows up arrangements.

It is the scrub practitioner's responsibility to complete any nursing documentation i.e. care plans, theatre register and file a Datix incident report in accordance with UHB Policy 514 - Management and Investigation of Incidents. The operating surgeon documents the incident in the medical records. All parties involved must record a statement of events to be included in the Datix incident report.

The department manager must inform the Head of Nursing for Scheduled Care if the surgeon completes the operation and the count has not been reconciled. An immediate investigation into the incident is commenced by the relevant Departmental lead, in accordance with the Senior Incident Framework.

Under the duty of candour, patients must be made aware of any unintentional retention of a foreign object and detail of impact this may have on their health.

In the event of an NCEPOD immediate life-threatening emergency (NCEPOD 2004) it is recognised that in the emergency setting it is not always feasible to perform a complete initial swab and instrument count. All packaging must be retained to facilitate a count being undertaken at the earliest appropriate opportunity. This must be documented in the patient's theatre record.

Consideration should be given to performing a two view plain film x-ray of the surgical wound whilst in theatre to confirm that no items have been retained, once the patient is stable. These images must be reviewed by both the surgeon and the radiographer.

Note: Imaging is unreliable in identifying small suture sizes. Studies demonstrate that needles smaller than 10mm are not consistently visible and this must be taken into account in the decision making process as to when to allow the patient to leave the operating theatre.

Insertion and Removal of Intentionally Retained Items

Definition of Intentionally Retained Item

All countable items that remain in the patient intentionally such as swabs or packs must have a radio opaque marker.

On Occasion an Open Abdomen will require packing with specialist dressings e.g. Vac Therapy, these are not Radio – opaque and should be documented in the theatre care plan and Patient Operation notes.

The number and type of items retained must be recorded by the scrub practitioner using the theatre care plan, in the theatre register and this should be recorded on the retained items log (Appendix 10).

Separate retained items log sheets should be used for each wound site. This should be handed over to recovery staff who subsequently hand over to discharge ward/location.

The surgeon must record all items that remain in the patient intentionally in the patient's medical record with a plan for the removal of the retained items.

If the patient is returned to theatre for removal of any planned retained items both the surgeon and the scrub team must collaboratively review the previous surgical documentation prior to any subsequent surgery to confirm the quantity, type and location of the retained items to be removed.

The retained items log must be updated. Retained packs, once checked, should be disposed of in to an orange bag, sealed and marked as removed packs.

In the event of a pack discrepancy, consideration must be given to performing a two-view plain film x-ray of the surgical wound whilst in theatre to confirm that no countable items unintentionally remain. These images must be reviewed by both the surgeon and the radiographer. Such occurrences must be reported as safety incidents in line with Policy 982 - Incident, Near Miss and Hazard Reporting Procedure (opens in a new tab).

Maternity Services

Maternity remains the highest risk area for retained foreign objects. This is in part due to a number of caregivers in the pathway, a series of handovers, the urgent nature of some interventions and the desire to avoid unnecessary medicalisation of the process.

- The count procedure in obstetric theatre or delivery room should be as in any theatre with a full count procedure and use of a count board.

- The standards of counting, equipment reconciliation, training in the count and count handover detailed above apply in full to birthing / labour suite rooms.

Emergency procedures

On occasion procedures may be of such urgency that following every standard above would pose a greater risk to the patient than providing immediate care. This is fully justifiable and supported by NatSSIPs. However, we should strive to have processes to reduce the risks even when certain checks cannot be performed. These include pre-prepared emergency kits, allocation of staff to specifically address equipment issues etc.

Training, competency assessment in counting and item reconciliation

- Organisations must have a robust and proportionate (risk-based) approach to training, assessment and ongoing competence for the processes described above. Details of standards expected are given in Online Sequential Step Implementation portal.
- AfPP Standards expect the whole MDT to receive training and assessment in count procedure.
- AfPP Stanadards do not yet include the proportionate count concept although this change in practice is intended for non-perioperative areas such as interventional radiology or minor procedures in OPD.

Caution moments during reconciliation of items in prevention of retained foreign objects

- Emergency and urgent work
- Multiple operative sites or cavities
- Multiple trays, teams, and handovers
- Maternity services
- White swabs without a radio-opaque line in dressing packs
- Green swabs near mouth or cavity areas
- Please see the Performance Indicators 'NatSSIPs'

Materials used for packing. There are a number of materials which are used for packing wounds. Those which are absorbable do not need to be counted.

Audit of Standard 6

The retention of a foreign object post-surgery requires a full investigation under the Serious Incident Framework, in accordance with Hywel Dda UHB Policy 514 – Management and Investigation of Incidents.

References

- WHC/2018/12 – Never Events List 2018 and Assurance Review Process
- National Safety Standards for Invasive Procedures 2 (2023), Centre for Perioperative Care
- Standards and Recommendations for Safe Peri-operative Practice. AfPP 2022
- Recommended practises for sponge, sharp and instrument counts, AORN 2014
- WHO Surgical Checklist, National Patient Safety Agency 2009a
- WHO Guidelines for safe surgery: Safe surgery saves lives, World Health Organisation 2009

- The Meaning of Intra-operative Errors: Peri-operative Nurse Perspectives
- Toft Report - external review of 'Never Events' that occurred at Oxford University Hospitals NHS Trust during the period 13 September 2013 to 26 March 2015

Appendix 7:- Procedure for Sign Out

Procedure

Sign out is a specific set of checks which: supports safe completion of the invasive procedure, including relevant documentation; starts the process of safe and efficient handover of care; and identifies patient, equipment, staff or process concerns that need addressing.

The circulating scrub practitioner should lead this section.

Sign out checks must be conducted at the end of the invasive procedure and before the patient is awoken from general anaesthesia or, when general anaesthesia is not used, before the patient leaves the procedural area.

Usually this will be following the final instrument and swab count.

All MDT members involved in the invasive procedure must be present at the sign out and pay full attention to it.

The person leading the sign out must:

1. Verify that all MDT members are participating. This requires that team members stop all other tasks and face the sign out lead.

2. Perform the following checks when relevant, but not limited to:

    - Confirmation of the procedure performed, to include site and side.

    - Confirmation that instruments, sharps and swab counts are complete (or not applicable)Invasive Procedure Counts Procedure[Local Safety Standard (LocSSIP)]

    - Confirmation that any specimens have been labelled correctly, to include the patient's name and site or side when relevant.

    - Discussion of post-procedural care, to include any patient-specific concerns.

    - Equipment problems for inclusion in the debriefing..

Standards

- All patients who have had procedures under general, regional, or local anaesthesia, or under sedation, must undergo Sign Out using the Hywel Dda University Health boards WHO check list. Specialty-specific checklists are available and should be used where appropriate.

- All team members should still be present: as a minimum, this must include the operator, the operator's assistant, the anaesthetist (if applicable) and the member of staff who will be handing over to the post-procedure team (if different).

- Any team member can lead, but the operator carries responsibility: they should ensure the whole team is listening and participating. This will usually require that the team stop all other tasks and face the Sign Out lead.

- Sign Out should occur once the count is complete, but before the patient leaves the theatre or procedure room and prior to handover to post procedure care team

- Safety checks should include the following:

    - Confirmation of the exact name of the procedure, site and side; this may have been altered or expanded

    - Estimated blood loss if relevant

    - Explicitly checking that specimens are labelled correctly and in the correct container

    - Confirmation of a correct count including instruments, swabs, throat packs and sharps. All items must be confirmed to be intact

    - Confirmation of any intentionally retained items (if appropriate)

    - Implant check if applicable

    - Key procedural / surgical and anaesthetic plans for recovery and post procedural management including level of care and any patient-specific concerns

    - Equipment or process problems for inclusion in the Debrief

    - Confirmation that VTE risk assessment is completed and actioned

    - IV lines are flushed, and unnecessary extensions removed in preparation to handover to recovery. Timing may depend on procedure and the situation

    - The patient is still wearing identity bands when appropriate

- Sign Out should also include the following where appropriate:

    - Drain and clamp instructions

    - Responsibility assigned for talking to the patient and / or family

    - Others to be decided locally as appropriate

- Sign Out should not end until all steps to prevent retained foreign objects are complete. Sign Out should stop and wait for reconciliation tasks to be done.

- Notes should be completed as soon as feasible.

Audit of Standard 7

Audit and monitoring this standard will be through the audit of the WHO checklist on a six monthly basis and by observing 5 random operations (on each site) ensuring that the following has taken place;

- Completed before the patient leaves the procedure room

References

National Safety Standards for Invasive Procedures 2 (2023), Centre for Perioperative care

Appendix 8:- Procedure for Debrief/Handover

Procedure

Debrief

The Debrief is an opportunity to confirm the recording of good practice, incidents and near misses to ensure that information is input in a timely manner to improve data quality and accuracy of reporting.

A de-briefing must be performed at the end of all elective invasive procedure sessions. A debriefing must also be performed after all unscheduled or emergency invasive procedure sessions. The de-briefing may need to be conducted on a case-by-case basis, if there is any change in key team members during an invasive procedure session.

The de-briefing should occur in a manner and location that ensures patient confidentiality while enabling inclusivity and contribution from all team members. This should be agreed at the team safety briefing at the start of the list/case.

Every member of the procedural team must take part in the de-briefing. Any team member may lead the de-briefing, but the surgeon and anaesthetist (if an anaesthetist has been involved) must be present. If any team member, and especially the senior surgeon, scrub practitioner or anaesthetist, has to leave before the de-briefing is conducted, they should have the opportunity to comment on and document any positive feedback or issues for improvement they wish to see addressed during the de-briefing. In this circumstance, their absence from the de-briefing should be recorded and included in routine audit of compliance with this procedure.

Members of the procedural team must note any key points for consideration at the de-briefing as the invasive procedure list progresses.

For each patient, the discussion should include, but is not limited to:

- Things that went well
- Any problems with equipment or other issues that occurred.
- Any areas for improvement
- Maintain a debrief action log: problems identified; action taking place to resolve the issue; named member of staff leading on the action, timeframe for action
- Share and learn from themes in the Debrief: these should be openly available and shared with the wider procedural team. Local governance processes must ensure that any issues identified lead to learning and improvement
- If there are further debrief is needed the After Action Review (AAR) model can be considered to help team learning.

The record of the de-briefing must include an action log that can be used to communicate. Examples of good practice and any problems or errors that occurred. Each procedural team must have an identified member who is responsible for feeding this information into local governance processes.

Handover

There are formal handover points in the patient pathway at which professional responsibility and accountability is transferred between individuals or teams. There will also be planned or unplanned changes in the members of a procedural team that occur during procedures or lists of procedures. Handovers may occur pre-operatively, during the procedure and post procedure.

- Basic
    - General information
    - Name of patient, checked against identity band
    - Relevant comorbidities
    - Allergies
    - Planned and actual procedure(s) performed, with site and side if relevant, and procedural course
    - Post-procedure management plan, to include provision of analgesia
    - Relevant intraoperative medications, including opioids, anti-emetics and antibiotics
- Advanced/Additional
    - Target range for physiological variables
    - Course of anticipated recovery and problems anticipated
    - Plan for oral or intravenous intake
    - Medications
    - VTE prophylaxis
    - Early warning scores when in use in the organisation
    - Information given to the patient about the procedure, or any plans for information to be given after the procedure
    - Any patient safety incidents
    - Procedural complications and interventions to correct these
    - Procedural site dressings, tubes, drains or packs

- Any further information or instructions in relation to drains, e.g. whether suction should be applied or not
- Any intentionally retained objects and plans for their removal, if relevant
- Anaesthesia information; ASA physical status / Risk assessment
- Anaesthetic complications and interventions to correct these
- Any problems related to the airway
- Confirmation that intravenous lines and cannulae have been flushed
- Confirmation that the lumens of multi-lumen catheters have been both clamped shut and occluded with caps or needleless connectors
- Confirmation that any throat pack has been removed
- Intravenous fluids and blood products given, with estimated losses
- Participation of the patient (and/or parent, guardian, carer or birth partner) in handovers should be encouraged when feasible.
- The participants should be focussed on the handover and ensure the team are actively listening.
- Handover should take place before or after monitoring is applied. Handover should not be attempted whilst staff are performing other tasks.
- Read back can be used to confirm understanding.
- Each team member should be given the opportunity to ask questions and clarify information.

Audit of Standard 8

Audit and monitoring this standard will by observing 5 random operations (on each site) quarterly ensuring that the following has taken place;

- A structured handover format has been used
- Debrief log and action log is completed

References

National Safety Standards for Invasive Procedures 2 (2023), Centre for Perioperative Care

Appendix 9:- Approved versions of the WHO checklist used within Theatres

1. Theatre Checklist
2. Cataract Checklist
3. Maternity Checklist

BEFORE STARTING FIRST CASE

Patient has been discussed in team brief and all safety checks have been completed ☐

Surgical Safety Checklist

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol
Hywel Dda
University Health Board

SIGN IN	TIME OUT	SIGN OUT
Prior To Any Intervention	Before First Incision	After Final Count

Led by Anaesthetist

- ❒ Patient identity
- ❒ Consent
- ❒ Surgical site marked appropriately ❒N/A
- ❒ Fasting status
- ❒ Airway assessment/plan
- ❒ Antibiotic required?
- ❒ Allergies
- ❒ Pregnancy status
- ❒ Blood product availability
- ❒ Monitoring appropriate
- ❒ Surgeon and all required staff are present

Led by Operating Clinician/Anaesthetist

- ❒Introduction - if any new team members present
- ❒ Patient ID and procedure
- ❒Confirm allergies
- ❒ Patient position and operation site correct?
- ❒ Imaging displayed and reviewed
- ❒Significant blood loss possible?
- ❒ Sterility of instruments and prosthesis availability
- ❒ Thromboprophylaxis plan
- ❒ Infection prevention
  - ❒Antibiotics within last 60 minutes?
  - ❒Patient warming in situ?
  - ❒ Glycaemic control?
- ❒ ASA grade
- ❒ Concerns and critical steps
  - ❒Anaesthetist
  - ❒Surgeon
  - ❒ Theatre staff
  - ❒Other disciplines

Led by Circulating Practitioner

- ❒ Instruments and counts
- ❒ Confirm Procedure performed
- ❒ Specimens collected
- ❒ Ongoing Antibiotic and thromboprophylaxis requirements
- ❒ Plan for post operative care

☐ **In Recovery**
Confirm all IV lines and cannulas have been flushed and any unecessary extensions and venflons removed

Affix Patient Label Here

Date:

Location:

Hospital:

Planned Procedure:

STOP BEFORE YOU BLOCK

Is everybody happy that the injection is about to be made to the correct side? (Tick if N/A ❒)

_____
Anaesthetic Practitioner

_____
Anaesthetist

Safety Standards for Invasive Procedures

GIG CYMRU NHS WALES | Bwrdd Iechyd Prifysgol Hywel Dda University Health Board

Surgical Safety Checklist: for Cataract Surgery ONLY

(adapted from the WHO Surgical Safety Checklist)

NHS
National Patient Safety Agency

SIGN IN (To be read out loud)

Before giving anaesthetic

Has the patient confirmed his/her identity, site, procedure and consent?
- ☐ Yes

Is the surgical site marked?
- ☐ Yes

Is the anaesthesia machine and medication check complete?
- ☐ Yes ☐ Not applicable

Does the patient have a:

Known allergy?
- ☐ No ☐ Yes

Difficult airway/aspiration risk? (General Anaesthetic)
- ☐ No ☐ Yes, and equipment/assistance available

Any special requirements for positioning or draping?
- ☐ No ☐ Yes, surgeon notified

Is the patient taking warfarin?
- ☐ No ☐ Yes, last INR result available

Is the patient taking tamsulosin or other alpha blocker?
- ☐ No ☐ Yes, surgeon notified

Has pre-operative VTE risk assessment been undertaken?
- ☐ Yes ☐ Not applicable

TIME OUT (To be read out loud)

Before start of cataract surgery

Have all team members introduced themselves by name and role?
- ☐ Yes

Surgeon, Scrub Nurse and Registered Practitioner verbally confirm:
- ☐ What is the patient's name?
- ☐ What procedure, and which eye?
- ☐ What refractive outcome is planned?
- ☐ What lens model and power is to be used?
- ☐ Is the correct lens implant present?

Anticipated variations and critical events

Surgeon:
- ☐ Are there any special equipment requirements or special investigations?
- ☐ Are any variations to the standard procedure planned or likely?
- ☐ Is an alternative lens implant available, if needed?

Anaesthetist (GA or sedation)
- ☐ Are there any patient-specific concerns?
- ☐ What is the patient's ASA grade?
- ☐ Any special monitoring requirements?

Scrub Nurse/ ODP:
- ☐ Has the sterility of the instrumentation been confirmed (including indicator results)?
- ☐ Are there any equipment issues or concerns?

SIGN OUT (To be read out loud)

Before any member of the team leaves the operating room

Registered Practitioner verbally confirms with the team:
- ☐ Has the name and side of the procedure been recorded?
- ☐ Has it been confirmed that instruments, swabs and sharps counts are complete (or not applicable)?
- ☐ Have any equipment problems been identified that need to be addressed?
- ☐ Are any variations to standard recovery and discharge protocol planned for this patient?

PATIENT DETAILS

Last name:

First name:

Date of birth:

NHS Number:*

Date of Procedure:

*If the NHS Number is not immediately available, a temporary number should be used until it is

The checklist is for Cataract Surgery ONLY

This modified checklist must not be used for other surgical procedures.

www.nrls.npsa.nhs.uk

Ref: 1096 March 2010

Modified Obstetric WHO Checklist

Date:

Procedure:

Sign in

- ❑Pt identity and consent
- ❑Category of Caesarean
- ❑Allergies
- ❑Antibiotics necessary?
- ❑Resuscitaire checked?
- ❑Anaesthetic machine & drugs checked?
- ❑Risk of difficult airway?
- ❑Neonatal team needed?
- ❑Increased risk of bleeding?
  - ➢ Ensure wide bore access
  - ➢ Consider cell salvage
- ❑Blood availability?
- ❑White boards cleared?

Time Out

- ❑Team introduction
- ❑Surgeons
  - ➢Any additional procedures or steps?
- ❑Anaesthetists
  - ➢ Any concerns with anaesthesia?
  - ➢Antibiotics given if needed?
  - ➢Temperature checked and warming considered?
- ❑Scrub
  - ➢Any concerns with prep and confirm equipment sterility?
  - ➢Calf compression on?
- ❑Midwife
  - ➢Cord bloods necessary?
  - ➢Catheter draining?
  - ➢FSE removed if applicable?

Sign Out

- ❑Measured blood loss recorded?
- ❑Swabs, sharps and instrument counts confirmed
- ❑Post operative plan?
  - ➢ Ensure appropriate location and monitoring
  - ➢ Is a postoperative surgical and anaesthetic review required?
  - ➢ Is handover to on call team required
  - ➢ When should post op bloods be taken?
- ❑Any specimens?
- ❑Baby name tags?
- ❑Equipment problems?
- ❑VTE prophylaxis and analgesia prescribed?

Category 1 Caesarean Section checks

(During pre-oxygenation or skin prep)

- ❑Patient identity
- ❑Allergies
- ❑Anaesthetic concerns
- ❑Surgical concerns
- ❑Blood availability
- ❑Neonatal team called?
- ❑Catheterised & FSE removed?
- ❑Do we need senior help?

Patient ID Label

Appendix 10:- Intentionally Retained Items Log

GIG CYMRU NHS WALES | Bwrdd Iechyd Prifysgol Hywel Dda University Health Board

Directorate of Scheduled Care

Intentionally Retained Items Log.

Hospital: .....

Wound site: ..... Complete 1 form for each site when there is more than 1 site

This document is to be completed for the whole duration of dressing changes until the patient is discharged

Date & Time:	Location i.e., Theatre / Ward / ITU/ Surgery / Home	Procedure	Number & type of packs inserted:	Number & type of packs removed:	Number & type of packs re-packed:	Registered Practitioner/ Doctor undertaking dressing change – Please sign:

1

Appendix 11:- NatSSIP's 2 Audit Form

NEW WHO Checklist Audit Tool 2022.pdf