Local Safety Standards for Invasive Procedures based on NatSSIPs

THE HEADLINES

Implementing the National Safety Standards for Invasive Procedures
The National Safety Standards for Invasive Procedures (NatSSIPs)

The WHO safer surgery checklist was introduced in 2009. Now in 2016, there is a new goal that builds on this intervention and goes beyond the immediate team, to make surgery safer.

The National Safety Standards for Invasive Procedures (NatSSIPs) were published by NHS England in September 2015. This document was written by every ‘body’ involved in healthcare, including the CQC, GMC, AFPP, royal colleges and commissioners, with the aim to ‘Standardise, Harmonise and Educate’. It is multiple errors and system failures that allows patient harm to occur. NatSSIPs is based on national learning from harm, near misses and never events and provides a strong systemic protective barrier to preventing harm.

Invasive procedures include, not only surgery, but any procedure where a hole is made in the patient’s body and consent is required. It therefore includes procedures carried out in endoscopy, acute medicine, interventional radiology, emergency medicine and cardiology (but excludes cannula or catheter insertion and blood tests).

Multidisciplinary team members from across Barts Health have collaborated to develop our own local safety standards for invasive procedures (LocSSIPs) based on the NatSSIPs, and this document sets out a summary of the series of organisational standards and sequential steps. The organisational standards go beyond the immediate procedural team to improve the wider system and have a strong focus on human factors, multidisciplinary team training, quality improvement and local induction. The sequential steps incorporate the WHO safer surgery checklist but with three additional steps; site marking, prosthesis and implant checks and prevention of retained foreign objects, bringing us the ‘The NatSSIPs Eight’.

NatSSIPs is absolutely clear that everyone in an organisation involved in invasive procedures, has a responsibility to meet these standards. Never Events and preventable patient harm are still occurring. Our Barts Health LocSSIPs aim to shape the way we work, and improve patient safety.
1. Governance and Audit
   ‘a safety culture and system that is proactive as well as reactive’

1. **There should be a visible clinical governance system with clear leadership** that provides accountability and emphasises proactive improvement as well as reactive responses.

2. **Clinical improvement and governance groups/meetings** should be open and include the multidisciplinary team (MDT). These include mortality & morbidity meetings, ward or service meetings and local governance meetings. They should be minuted, with actions recorded and reviewed.

3. **Management of incidents**: A higher reporting rate equals a safer system. All incidents, including near misses, should be reported via Datix and reporters should expect a response and be involved in solutions. There should be a just culture and no fear of repercussion.

4. **Management of serious incidents**: Incidents graded as moderate harm or above should undergo assessment and review by an MDT. Actions should be SMART (Specific, Measurable, Achievable, Relevant, Time-specific).

5. **Management of patient concerns, compliments and complaints** should be seen as a driver for improving service quality. Service lines should work with the site governance team to ensure that they are responded to in a timely fashion, that investigation occurs and that lessons are learnt.

6. **Guidelines, standards, policies and protocols**: There should be a process for the development, review, authorisation and dissemination of locally and nationally produced guidelines, standards, policies, protocols and standard operating procedures.

7. **Risk management** identifies, assesses and grades risks in services. These risks can cover a wide spectrum including business continuity, staffing, equipment, issues with the estate and financial risks.

8. **Induction** (particularly local induction within a service) of new staff must cover our standards and expectations for clinical governance.

9. **Clinical effectiveness** should be monitored and driven through a process of audit and quality improvement projects which incorporates NICE, evidence-based practice, good practice and professional standards.
2. Documentation of Invasive Procedures

‘if its not documented it didn’t happen’

1. **Standardised documents must be used** to ensure recording of essential information throughout the invasive procedure patient pathway.

2. **The design of these documents** should ensure they contribute to safe working practice, allow key safety checks to be performed in sequence and make documentation easy.

3. **The documentation itself must be complete, legible, contemporaneous, without abbreviation or jargon,** and with standardised terminology.

4. **At a minimum, documentation should include:**
   - Pre-procedural assessment
   - Pre-procedural planning
   - Plan for anaesthesia or sedation

   Records from the invasive procedure itself;
   - Consent including risk
   - Pre-operative checklist
   - Conduct of anaesthesia
   - Team members present
   - Sequential steps LocSSIP compliance
   - Operation note
   - Post procedural care and handover

5. **The time and author of any alterations to the documentation must be recorded.**

6. **There should be a standardised process for recording adverse events/near misses/unexpected outcomes,** ie. Datix reporting and in notes.

7. **Paper and electronic documentation should be aligned** to avoid duplication and inconsistency, with a paperless system as the ultimate goal.

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3. Workforce

‘safe staffing at all times’

1. **No staff, no start:** A procedure can only begin when the agreed minimum number and skill-mix of staff for that procedure are present.

2. **Day and night:** The same minimum standards apply both inside and outside of normal working hours.

3. **Sufficient time:** Job plans and staffing establishments for all groups must ensure that individual staff have sufficient time for participation in the key safety steps before, during and after procedures. This includes the Team Brief at the beginning and Debrief at the end of sessions.

4. **Sufficient staff:** Establishments and day-to-day staffing for all professional groups must be adequate to meet the predicted procedural workload.

5. **Allocations** should reflect a risk managed mix of substantive and on substantive staff.

6. **Surge management:** All professional groups must have clear plans for escalation when clinical demand overwhelms resources and a risk management plan for monitoring the frequency of these events.

7. **Regular training:** All staff must receive continuous professional development to keep up to date with changing practice.

8. **Trainees and students** should be supervised.

9. **Escalation process for concerns** raised and these should be documented as a safety issue.
4. Scheduling and List Management
‘planned list with clear information enables safer care’

1. Good scheduling **communicates key patient and procedural information** to teams.
2. Scheduling should take into account workload and the need to follow the ‘NatSSIPs 8’.
3. The scheduling team should **improve the clinical teams’ scheduling through information, feedback, improvement and training**.
4. There is a scheduling SOP and, in some specialties, specific scheduling manuals that must be followed.

5. **List information**
   a. The operator must select the most precise procedure code available on CRS.
   b. The information that accompanies the scheduling of a procedure should include: name, number, date of birth, gender, planned procedure, site and side of procedure, source of patient e.g. ward or admissions lounge.
   c. Laterality must always be written in full, i.e. ‘left’ or ‘right’.
   d. Further information should be included when relevant: NCEPOD urgency, significant comorbidities, allergies, infection risk, any non-standard equipment requirements or non-stock prostheses, BMI, planned post-procedural care.
   e. The use of abbreviations should generally be avoided but, when common abbreviations are used, a list of locally approved abbreviations should be readily available to all staff.
   f. If the list information is incorrect, an incident form should be completed.

6. **List order**
   a. Priority should be given for clinical criteria.
   b. After clinical priority, day-case procedures should be scheduled first.
   c. The order should only change for clinical/safety reasons and be seen as a risk.
   d. If reordered, the list should be reprinted.
   e. Any list changes made after the deadline for the publication of a final version of the list must be agreed with the procedure team and should be discussed by all members at the team brief.
   f. A clear, effective mechanism must exist for removing old lists, when a new version has been published.
   g. The procedure list should be clearly displayed in the room in which the procedures are performed, and any other areas that are deemed important for the safe care of the patient.

7. **List lockdown**
   a. List review should occur at 6, 4 and 2 week intervals prior to lockdown and 3pm the day before to identify list errors (abbreviations, spelling mistakes, unnecessary information) prior to the list date.

5. Handovers and Information Transfer
‘optimise patient handover, optimise patient care’

1. **All Handovers**
   o Verbal and written.
   o Non handover activities should cease and only one person should speak at a time.
   o Each team member should be given the opportunity to ask questions and clarify information.

2. **Ward to Procedure Team**
   o WHO Patient, admitting nurse or ward nurse familiar with patient, anaesthetist or holding bay nurse (where applicable) and surgeon (when a patient’s care pathway has deviated from that planned).
   o WHERE Anaesthetic or procedure room (or holding bay where applicable).
   o DOCUMENT Peri-operative patient care plan dated and signed, printed wrist bands, drug chart, consent and WHO checklist.

3. **During Procedural Care**
   o WHO Outgoing and incoming team.
   o WHERE In theatre.
   o DOCUMENT Intra-operative team change policy.

4. **Procedure Team to Post-procedure Area**
   o WHO Patient, anaesthetist, surgeon, scrub nurse and recovery nurse.
   o WHERE Post anaesthetic care unit.
   o DOCUMENT Recovery handover checklist.

5. **Procedure team or post procedure area to ACCU**
   o WHO Consultant anaesthetist, consultant surgeon, ACCU doctor and nurse responsible for ongoing care of patient.
   o WHERE ACCU
   o DOCUMENT Major surgery handover headlines document
6. Induction
‘dedicated staff, dedicated time, structured and formal’

1. Mandatory: A local invasive areas induction is mandatory for all new staff working in areas where invasive procedures are carried out.

2. Induction pack: A comprehensive induction pack should be sent to all new staff members before their start date.

3. Prioritised: Induction requires dedicated time, staffing and space to enable delivery without any adverse effect on patient care.

4. Structured and comprehensive: The induction programme should be planned in advance with named speakers. The programme should be included in the induction pack.

5. Substantive and non-substantive staff should be included in local induction.

7. MDT Team Development
‘a team of experts is not an expert team - its not just what we did but how well we did it’

1. Multidisciplinary team training is a minimum standard.

2. It must include multi-professional groups.

3. It must be planned and delivered on a rolling basis.

4. It must include teaching and understanding of the local standards LocSSIPs.

5. It must embed safety practice.

6. It must include non-technical skills and human factors.

7. All MDT team members must receive regular updates and continuous professional development.
1. **Procedural Verification of Site Marking**
   ‘correct procedure on the correct site and sides’

1. **Verify the mark**: The operator or a nominated deputy should verify the site marked with the patient or parent, with the consent, with the notes and with the operating list.

2. **Mark on the ward**: The procedure site must be marked shortly before the procedure but not in the anaesthetic room or the procedure room. If the mark is done in the anaesthetic room, an incident form should be filed.

3. **Mark by the operator**: Where possible the marking must be performed by the operator or a nominated deputy who will be present during the procedure. If this is impossible, the surgeon must also re-confirm the mark and be present at sign in.

4. **Use a permanent marker**: The mark must be made with an indelible marker, the ink of which is not easily removed with alcoholic solutions.

5. **Only use a single use marker, in certain situations** such as for a patient who has an infection, is immunocompromised or where marking occurs as part of the surgical procedure.

6. **Mark in the surgical field**: Wherever possible the mark must be placed such that it will remain visible in the operative field after preparation of the patient and application of drapes.

7. **For teeth use the Palmer Notation**: Tooth notation must be standardised such that only the Palmer notation is used, and this must be clearly documented on the consent form, checklist and whiteboard for verification by the team.

8. **Check the mark**: A registered nurse will check the mark on the ward and record that the standard has been met on the patient’s peri-operative patient care plan. The anaesthetist and ODP will check the mark at Sign in.
2. Team Brief
‘briefing opens communications channels to plan and assure safe care’

1. **Introduce the team and everyone in the room:** Name, role and responsibilities should be declared and this should be written on the whiteboard in addition to the Team Brief record.

2. **All MDT team members:** The whole team should be at the team brief. The briefing cannot start without the nominated lead surgeon or a senior operator who is capable of performing the operation independently and lead anaesthetist present.

3. **Briefing timing:** Should occur at an agreed set time.

4. **Silent focus during the briefing:** All team members must pay attention and display a silent focus during the briefing. No music, interruptions, distractions. No non-essential conversation.

5. **Discuss each patient:** Each patient should be discussed in list order.

6. **Sharing vital information:** A Briefing record should be completed and a specialty specific checklist can be used to ensure essential planning.

7. **Keep a record:** A Briefing record should be on display and reviewed as part of the debrief.

8. **Report issues identified:** Any issues raised in the briefing that may have relevance for the care given to other patients, should be reported via Datix and governance systems by an identified team member.

3. Sign In
‘the final gatekeepers of invasive safety checks’

1. **All patients having invasive procedures must undergo Sign in:** All patients under general, regional or local anaesthesia, or under sedation, must undergo the Sign in.

2. **Sign in should occur prior to sedation or anaesthesia:** Premedication should only be given once the Sign in is done.

3. **A two person check:** For procedures performed under general or regional anaesthesia, these should include the anaesthetist and anaesthetic assistant. For procedures not involving an anaesthetist, the operator and an assistant should perform the Sign in.

4. **Make provision for those who cannot speak English:** Provision must be made for patients who cannot speak English or who have special requirements (e.g. disability, impaired hearing or sight etc.). Trust registered interpreters can come into the anaesthetic room or a family member if this is not possible. Otherwise, the consenter should be present at Sign in to confirm comprehension.

5. **Safety checks with signature INCLUDE:**
   a. Anaesthetic checks: machine, monitoring, medications.
   b. Emergency equipment checks.
   c. Paperwork required: Care Plan, notes, consent, drug chart, VTE risk assessment and allergy status.
   d. Patient name check with the patient and against the printed identity band, consent form and operating list.
   e. Consent form checks to include no abbreviations, understanding of patient, date of consent.
   f. Surgical site marking if applicable to be checked with patient, consent and operating list.
   g. Pregnancy status.
   h. Allergies.
   i. Starvation time / aspiration risk.
   j. Potential airway problems.
   k. Infection risk.
   l. Arrangements in case of blood loss.
   m. Availability of essential instrumentation / implants, if applicable.
   n. Availability of additional staff, if applicable, eg radiographers; midwives.
4. Time Out
‘time out for the final safety check before the cut’

1. **The checks immediately before the procedure:** This is the final check. Specialty specific versions are available for Maternity, Ophthalmology, Cardiac, Interventional Radiology and Code Red emergency time out.

   Content of Time Outs includes:
   a. Patient’s name and name band checked against the consent form, procedure to be performed, verification of surgical site marking when relevant.
   b. Operator: The anticipated blood loss. Any specific equipment requirements or special investigations. Any critical or unexpected steps. Relevant imaging/tests available/implants/equipment.
   c. Anaesthetist: Any patient specific concerns. Patient’s ASA Physical Status. Monitoring equipment and other specific support, e.g. blood availability.
   d. Scrub practitioner or operator’s assistant: Confirmation of sterility of instruments and equipment. Any equipment issues or concerns.
   e. Surgical site infection: Antibiotic prophylaxis/patient warming/ glycaemic control/ hair removal if required.
   f. VTE prophylaxis, allergies, infection, pregnancy status.

2. **Silent focus:** Noise should be kept to a minimum.

3. **Any team member who has professional accountability** can lead time out.

4. **Introduce** yourselves during the first time out and verify names on board.

5. **All team members must be present** and the lead should verify all team members are participating. This will usually require that they stop all other tasks and face the Time out lead.

6. **Encourage the patient to be involved** if they are awake.

7. **Declare time out complete** and that the procedure can start. Keep a signed record.

5. Stent, Prosthesis and Implant Checks
‘artificial replacement matters, right size, right process, every time’

1. **A stent, prosthesis or implant (SPI)** is defined as a permanent internal or external medical device for artificial replacement of an absent or impaired structure.

2. Pre-operative communication by the operating team is essential to plan for specific SPI requirements.

3. Efficient management and ordering of stocks of SPI is the role of the specialist nurse in that area.

4. The team brief is used to ‘SPI Sign in’ device before anaesthesia and at this point the chosen size and type is written on the whiteboard.

5. Checks are essential for correct surgical placement of the appropriate SPI.

6. The SPI is verified with a silent focus by the team with an ‘SPI Time out’ before opening which includes the scrub nurse, the surgeon, with view of the white board and covers the detail below:
   a. The product: Type, design, style or material.
   b. Size.
   c. The correct side. Laterality.
   d. Manufacturer. The make.
   e. Expiry date.
   f. Sterility.
   g. Compatibility of multi-component device.
   h. Any other required characteristics.

7. Deleterious effects arising from incorrect SPI selection may include:
   a. Patient factors, e.g. mortality, morbidity and further procedures.
   b. Surgical factors, e.g. substandard clinical outcome.
   c. Financial costs, e.g. discarded prostheses, medico-legal repercussions, cancelled cases due to lack of prosthesis availability.

8. Correct recording of SPI insertion should occur via the ‘SPI Sign out’ where the label is checked and detail is added to the patient notes including the operation record, care plan, computer sheet and via specialty specific registers if applicable.
6. Retained Foreign Objects
‘Nothing left behind, that was not intended’

1. Organisational Responsibilities
   ○ Methods and documentation for counting and reconciliation should be standardised in all areas.
   ○ A list of items that are included in the count should be understood by the team and edited locally with analysis of risks and safety incidents via governance processes.
   ○ Local induction and handover practice should reinforce safe count procedure.

2. Equipment Management
   ○ Instrument sets and equipment should be risk assessed in order to rationalise and maintain an up-to-date list including the number of parts.
   ○ The integrity of all items must be checked before and after use.
   ○ All swabs used for invasive procedures should contain radio-opaque markers.

3. During the Procedure
   ○ WHO The count is completed audibly by two trained and competency assessed staff. Staff changes should be minimised and seen as a risk. The final count is confirmed by the surgeon/operator. Any time a discrepancy is suspected, any member of the team can request a count at any time during the procedure.
   ○ WHEN
     a. Baseline. (NB. Throat packs inserted by anaesthetist should be added to the count)
     b. Before closure of a cavity, major organs, abdomen
     c. Before closure of the pericardium/pleura in cardiothoracic procedures.
     d. Before closure of the first layer of muscle e.g. spinal and joint replacement surgery.
     e. Before wound closure begins.
     f. When skin closure begins or at the end of the procedure.
     g. Prior to handing over to another scrub practitioner.
   ○ HOW A team ‘focus’ without distraction is critical to an accurate count. The start of this is announced to the team, when the scrub practitioner says ‘Pause for Gauze’. The end is when the ‘Final count’ is announced as check complete by the surgeon.
   ○ WHAT Any item that enters the surgical field should be accounted for. This includes swabs, instruments, sharps, disposable items and packs.

4. Failed Reconciliation
   ○ Inform operating surgeon, repeat count, theatre and operating site search, x-ray, document, report to theatre co-ordinator, complete incident form, provide information to patient.

5. Intentional Retention of Objects
   ○ Retained packs (Pink4packs) procedure should be followed which includes a pink band, a sticker and patient leaflet and includes documentation, handover, patient information, plans for future care and removal.

7. Sign Out
‘pause for gauze, discuss the procedure and issues with the team’

1. Sign out is an essential safety check at the end of the procedure which occurs before the patient leaves the procedure room.

2. Announced out loud before the surgeon leaves the table and after completion of skin closure and prior to removal of drapes.

3. All team members should be present.

4. A silent focus should be observed

5. Any team member may lead Sign out, but the surgeon carries responsibility.

6. The surgeon verbally confirms the name of the procedure, the site and side, as the procedure may have been altered or expanded.

7. The scrub nurse confirms:
   a. The count including the instruments, swabs and sharps are correct.
   b. Deliberately retained packs should follow pink for packs.
   c. Specimens are labelled correctly and in the correct container.

8. The team including the surgeon, anaesthetist and registered scrub practitioner review the key concerns for recovery and management of the patient including:
   b. Drains and clamps.
   c. Variation in the discharge plan.

9. Any equipment problems should be communicated and documented via the theatre coordinator, via Datix and via the debrief.

10. The operation notes (CRS), WHO documents and care plan should be completed by the surgeon and scrub nurse as soon as it is feasible. TTA’s should be prescribed for day case patients.

11. Location of relatives in cases where they are waiting locally for news or expecting a telephone call can be discussed to remind the team to keep them informed.
8. Debrief
‘what went well, what not so well, how can we improve?’

1. **Debriefing** is essential for team communication and to continuously improve for safer invasive care.

2. **It should involve the whole team:** Every member of the procedural team should take part in debriefing.

3. **Capture of points for debrief:**
   a. **Can occur during the list:** debriefing issues can be identified during the list and captured for summary at the end.
   b. **Can occur on a case-by-case basis in emergency theatre:**
      Debriefing can be conducted on a case by case basis, if there is a change in team members eg. in emergency theatre.

4. **Job plans, scheduling and working patterns** should allow and oblige staff to participate in debrief.

5. **Key ELEMENTS of the Debrief** are:
   a. Things that went well
   b. Any problems
   c. Any areas for improvement?
   Actions to include:
   a. What we the team can change
   b. Who will lead on this to feedback at the next specialty team brief?

8. **A debrief action log should be maintained:** Debrief actions should be entered into an action log which should include:
   a. Problem or issue identified
   b. Action taking place to resolve the issue
   c. The person leading on the action
   d. The timeframe for action

9. The themes from the debrief should be openly available and shared with the team.

10. **Local governance processes** must ensure that issues identified in debriefing action logs are discussed and communicated.