Consent, Procedural Verification and Site Marking

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. Full GMC guidance on obtaining consent is available[84]. Similar guidance is available from the Royal College of Surgeons[85], the Royal College of Anaesthetists[86] and the Association of Anaesthetists[87]. The patient gives consent - it is not taken.

Within NatSSIPs 2 the consent process and procedural verification are linked, and there a few particular areas where clarity and reinforcement are required.

Who

- The person obtaining consent should have clear knowledge of the procedure and the potential risks and complications.

When

- 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.

Documentation

- 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.
- In services where electronic notes are in use, measures must be in place to ensure that written information (consent form, printed operating list, body maps and/or photographs etc) is available to the operator or their deputy at the theatre trolley/bedside.
- To ensure accuracy, the consent form and waiting list entry card/request should be completed with the patient present in clinic. Dictated notes or electronic note entries should be completed while the patient is present, or before the next patient (and not saved until the end of clinic).

Recommendations for naming and marking the digits of the hand and feet

- The digits on the hand must be named thumb, index, middle, ring and little. **Diagram 1**
- 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.[88] **Diagram 2**
- 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.

Diagram 1: Right hand

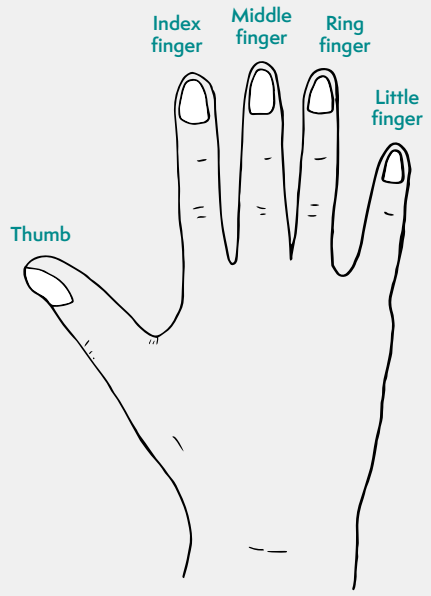

Diagram 2: Right foot

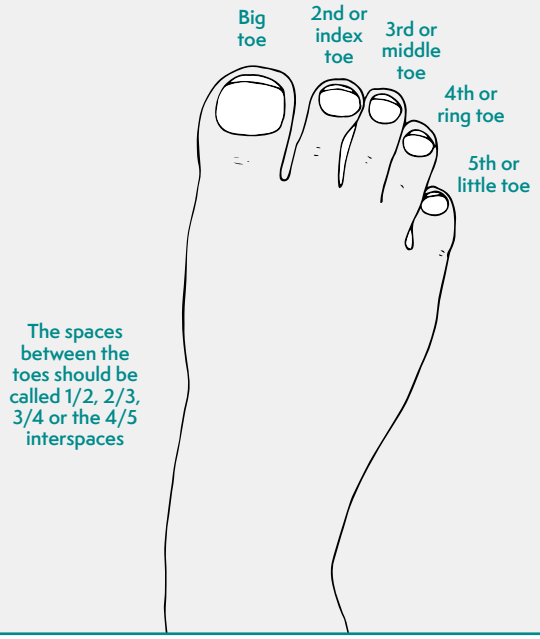

Diagram 3: Teeth should be numbered and named using Palmer notation

Permanent Teeth															
Upper right								Upper left							
8	7	6	5	4	3	2	1	1	2	3	4	5	6	7	8
8	7	6	5	4	3	2	1	1	2	3	4	5	6	7	8
Lower right								Lower left							
Deciduous Teeth															
Upper right								Upper left							
			E	D	C	B	A	A	B	C	D	E			
			E	D	C	B	A	A	B	C	D	E			
Lower right								Lower left							

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. Site marking cannot guarantee correct site procedures in and of itself.

A key aspect of site marking is consistency such that the same process is followed within an organisation. Inevitably, this will, on occasion, mean that site marking may appear superfluous but the need for consistency over-rides this.

If the operator has not met the patient prior to the procedure this creates an increased risk of a wrong site procedure.

Who?

- 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
  - Marking of stoma sites is usually carried out by specialist nurses[89]

When?

- 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 procedure site must be marked shortly before the procedure but not in the anaesthetic room or the procedure room. 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.

How? (with information and the patient)

- The mark should be applied after confirming the procedure to be undertaken by verifying the procedure with the records, including images and previous investigations and in conjunction with confirming the consent form and, where possible and most importantly, with discussion with the patient.
- The scheduled printed / electronic operating list must not be relied upon as it may not be accurate for the site of the procedure being performed.

How to make the mark

- The mark must be made with an indelible marker, the ink of which is not easily removed with alcoholic solutions.
- An arrow should mark the operative site.
- In addition, if digits are involved, they may be marked with an extra arrow placed on the nail of the digit or at the base of the digit. (See diagram digits above.)
- Do not mark with an 'X'.
- 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.
- Text or other markings are discouraged except for when deemed necessary for procedural planning and safety such as a procedure where there are:

  i) Multiple teams and multiple procedures/scenarios (e.g. 'OSTEOTOMY' on one limb, 'REDUCT' on one breast) or if the operator wishes to add clarity.

ii) Markings for the procedure e.g. plastics and breast lines.

iii) To indicate medial, lateral, posterior, anterior if positioning requires it.

In scenarios where text is required for the procedure:

iv) The marks should either be made after Sign In and be considered part of the procedure or text should be written in block capital, legible and read aloud at Time Out.

v) The operator is the only clinician who should write text.

vi) Text should be agreed per specialty and should always still include a clear arrow to denote the side. It should be recognised that text is error prone.

vii) Initials, messages or other symbols should not be used.

- A circle may be added (in addition to the arrow) if the operator requires this to target an abscess, ganglion, lesion, deformity or similar.
- Other markings may be needed to identify particular procedural sites such as pacemakers, generators or stomas.[89]
- The mark must not include a date or operator's initials.
- 'Single use' marker pens should be used in patients with a known infection or in the immunocompromised.
- The colour of the marking pen is irrelevant provided it is clearly visible on the skin. Pens which have had the cap kept on are safe to use between patients who do not pose an infection risk.
- A ballpoint pen should not be used; ballpoint pens on skin are painful.
- Organisations should have risk-assessed, agreed systems for specific contexts. e.g. the use of markers in certain oncology procedures. These systems should conform to the principles outlined in these standards.

Where?

- 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.

Cautions and Amendments

Reliable marking of procedural sites such as teeth, which may be small, broken down, filled or buried, may not be possible.

- Tooth notation: must be standardised such that only the Palmer notation is used. This must be clearly documented on the consent form, checklist, and whiteboard for verification by the team. To minimise the risk of a procedural site error, the correct procedure should be verified by full review to ensure consistency of the initial request, clinical record, diagnosis, treatment plan, investigation results, written consent, intraoral procedural site check and confirmation with the patient. Reference to radiological imaging should be used when appropriate.
- Stoma sites: should be marked[89] (and consent taken) by a professional experienced in siting stomas, and an indication of the planned stoma position must be maintained during the procedure.
- Regional anaesthesia: the mark should be used to check side during Prep Stop Block Checks[77] for regional anaesthesia after Sign In and immediately prior to block insertion.
- Remote access: for procedures where access is remote from the lesion. e.g. interventional radiology, ureteric access etc. an arrow should be drawn relevant to the correct side. This arrow is to aid team awareness at Sign In / Time Out / during the procedure.
- For some procedures it may be useful to use clear drapes to allow visibility of the arrow or to mark the drapes with a sterile marker. If these practices are adopted, they should be consistently applied (e.g. the same approach for all patients within an interventional radiology unit).
- Wrist bands to indicate laterality are not recommended. They have invisibility issues and are liable to being removed and replaced on another limb.
- In cases where the procedure is required following referral from another specialty, there should be easy access to a specialist. For example, if a patient is undergoing excision of a dermatological lesion the operator should have received education in skin conditions and the referring dermatology team should be available, in case of any ambiguity.[39]

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.

Check Points of Consent and Site Marking: Pathway schematic is in design

Checking of consent and site marking is a team process to aid team understanding and to support the team's ability to challenge discrepancy. At some points these checks are more concerned with ensuring that correct documentation has been transferred with the patient (e.g. notes, displayed imaging) than (re)identifying the patient per se. Particular caution is needed with patients presenting for repeat procedures, where more than one body part is affected, or where ability to communicate is impaired.

On the ward or admission area

- The consent is checked to be valid.
- 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.

At Sign In (Sequential step 3)

- 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 Sign In standards).

At Time Out (Sequential step 4)

- The consent form should be checked by the team against the printed / electronic operation / procedure list as well as against the patient's identity band.

At Sign Out (Sequential step 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.

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'