

**Objective 1: The team will operate on the correct patient at the correct site.**

While wrong-site or wrong-patient surgery is rare, even a single incident can result in considerable harm to the patient. There are recurrent and persistent reports of wrong-site operations on limbs and the brain and of patients who have had the wrong kidney, adrenal gland, breast or other organ removed. The attention that such events invariably attract in the media undermines public confidence in health-care systems and in the physicians who provide care.

It has been estimated that wrong-site and wrong-patient surgery occurs in about 1 in 50 000–100 000 procedures in the United States, equivalent to 1500–2500 incidents each year (1,2). In an analysis of sentinel events reported between 1995 and 2006, the Joint Commission for Accreditation of Health Organizations found that just over 13% of reported adverse events were due to wrong-site surgery (3). An analysis of 126 cases of wrong-site or wrong-patient surgery in 2005 revealed that 76% were performed on the wrong site, 13% on the wrong patient and 11% involved the wrong procedure. The literature supports the supposition that wrong-site surgery is more common in certain fields, particularly orthopaedic surgery. In a survey of 1050 hand surgeons, 21% reported having performed wrong-site surgery at least once in their careers (4). An analysis of malpractice insurance claims following orthopaedic surgery showed that 68% were for wrong-site surgery (5).

Wrong-site surgery is more likely to occur in procedures associated with bilaterality. Failures in communication between team members and problems with leadership were the major contributory factors in the report of the Joint Commission for Accreditation of Health Organizations (3). In a separate analysis of 13 non-spine wrong-site procedures, Kwaan et al. (1) showed that four cases were due to errors in the operating schedule, and in 66% of cases in which the consent form was reviewed the site or side was not specified. Factors such as the absence of radiographic images and wrong site labelling on the images play a causative role in faulty orthopaedic and spinal procedures (1,2). Organizational culture, interpersonal dynamics and steep hierarchical structures in the operating room contribute to error by creating an environment in which persons who could prevent an error are reluctant to speak up (6). Thus, systems failures account for a large number of wrong-site events. Accurate patient identification and labelling, patient involvement in preoperative planning, informed consent, better communication among team members and improved teamwork and protocols could all reduce these types of error. Elimination of wrong site, wrong patient and wrong procedure errors has been a goal of the Joint Commission since 2000 (7).

Wrong-site surgery received prominent attention in the early 1990s, and surgeons (in particular orthopaedists) and professional organizations made attempts to address the issue. The Canadian Orthopaedic Association recommended ‘marking the incision site with a permanent marker’ in 1994 (8). Professional orthopaedic organizations took this up as a matter of policy, and in 1998 the American Academy of Orthopaedic Surgeons started a campaign called ‘Sign Your Site’. That same year the Joint Commission gathered information on sentinel events of wrong-site surgery and sought strategies to address the issue. In 2003, the Joint Commission formulated and mandated use of a universal protocol for the prevention of wrong-site, wrong-patient and wrong-procedure errors (9) which has been adopted by many professional organizations, including the American College of Surgeons (10).

## The Universal Protocol

The Universal Protocol is a three-step process in which each step is complementary and adds redundancy to the practice of confirming the correct patient, site and procedure.

*Step 1. Verification:* This consists of verifying the correct patient, site and procedure at every stage from the time a decision is made to operate to the time the patient undergoes the operation. This should be done:

- when the procedure is scheduled;
- at the time of admission or entry to the operating theatre;
- any time the responsibility for care of the patient is transferred to another person; and
- before the patient leaves the preoperative area or enters the procedure or surgical room.

The step is undertaken insofar as possible with the patient involved, awake and aware. Verification is done by labelling and identifying the patient and during the consent process; the site, laterality and procedure are confirmed by checking the patient's records and radiographs. This is an active process that must include all members of the team involved in the patient's care. When many team members are involved in verification, each check should be performed independently. Team members must also be aware, however, that the involvement of multiple caregivers in verification can make the task appear onerous and could lead to violations of the protocol. Adherence to the verification procedure can be facilitated by the use of reminders in the form of checklists or systematic protocols (11).

*Step 2. Marking:* The Universal Protocol states that the site or sites to be operated on must be marked. This is particularly important in case of laterality, multiple structures (e.g. fingers, toes, ribs) and multiple levels (e.g. vertebral column). The protocol stipulates that marking must be:

- at or next to the operative site; non-operative sites should not be marked;
- unambiguous, clearly visible and made with a permanent marker so that the mark is not removed during site preparation (Health-care organizations may choose different methods of marking, but the protocol should be consistent in order to prevent any ambiguity. The guidelines of the National Patient Safety Agency in the United Kingdom recommend use of an arrow drawn on the skin and pointing to the site, as a cross could denote a site that should not be operated and introduces an element of ambiguity (12). The American Academy of Orthopaedic Surgeons endorses a 'sign your site' protocol in which surgeons write their initials or name on the operative site (13).);
- made by the surgeon performing the procedure (To make the recommendations practicable, however, this task may be delegated, as long as the person doing the marking is also present during surgery, particularly at the time of incision (14).); and

- completed, to the extent possible, while the patient is alert and awake, as the patient's involvement is important.

The verification and marking processes are complementary. They are intended to introduce redundancy into the system, which is an important aspect of safety. Either one used alone is unlikely to reduce the incidence of wrong-site surgery.

Patients or their caregivers should participate actively in verification. The Joint Commission views failure to engage the patient (or his or her caregiver) as one of the causes of wrong-site surgery. The Joint Commission has published information leaflets for patients to inform them of their important role in preventing wrong-site surgery (15); patient awareness initiatives have also been adopted by the National Patient Safety Agency in the United Kingdom (16) and the Australian Commission of Safety and Quality in Healthcare (17).

*Step 3. 'Time out':* The 'time out' or 'surgical pause' is a brief pause before the incision to confirm the patient, the procedure and the site of operation. It is also an opportunity to ensure that the patient is correctly positioned and that any necessary implants or special equipment are available. The Joint Commission stipulates that all team members be actively involved in this process. Any concerns or inconsistencies must be clarified at this stage. The checks during the 'time out' must be documented, potentially in the form of a checklist, but the Universal Protocol leaves the design and delivery to individual organizations. The 'time out' also serves to foster communication among team members.

The Australian Commission on Safety and Quality in Healthcare uses a five-step process similar to the Universal Protocol to prevent wrong-site surgery (17):

Step 1: Check that the consent form or procedure request form is correct.

Step 2: Mark the site for the surgery or other invasive procedure.

Step 3: Confirm identification with the patient.

Step 4: Take a 'team time out' in the operating theatre, treatment or examination area.

Step 5: Ensure appropriate and available diagnostic images.

Consent is part of both protocols. It is the first step in the Australian protocol and is included as critical documentation in the Universal Protocol in the United States. While consent is being obtained, the patient must be awake and alert and have the capacity to understand the details and implications of the procedure. Consent must be obtained in a language that the patient understands or through an interpreter. It should include a clear statement of the procedure to be performed and the site of operation, including laterality or level (18). The consent protocol can, however, be waived in emergency cases with threat to life or limb.

Preoperative verification protocols have only recently been introduced in many parts of the world. Evidence of their efficacy in reducing the incidence of wrong-site surgery is lacking, although preliminary data suggest that such actions are effective. The Orange County Kaiser Permanente organization in the United States found a reduction in the incidence of wrong-site surgery after the introduction of a checklist (19). Similarly, there has been a reduction in wrong-site surgery in Western Australia, from 10 reported cases in 2004–2005 to four in 2005–2006 (20). A study by Makary et al. at Johns Hopkins hospital in the United States showed that team awareness of the correct site of operation increased with use of a checklist and briefing (21). While evidence is still being

gathered, protocols for ensuring correct patient and procedure are well established, inexpensive, recommended by many professional societies and, if followed with care and consideration, promote safe surgical practice.

### ***Recommendations***

#### *Highly recommended:*

- Before induction of anaesthesia, a member of the team should confirm that the patient is correctly identified, usually verbally with the patient or family member and with an identity bracelet or other appropriate means of physical identification. Identity should be confirmed from not just the name but also a second identifier (e.g. date of birth, address, hospital number).
- A team member should confirm that the patient has given informed consent for the procedure and should confirm the correct site and procedure with the patient.
- The surgeon performing the operation should mark the site of surgery in cases involving laterality or multiple structures or levels (e.g. a finger, toe, skin lesion, vertebra). Both the anaesthesia professional and the nurse should check the site to confirm that it has been marked by the surgeon performing the operation and reconcile the mark with the information in the patient's records. The mark should be unambiguous, clearly visible and usually made with a permanent marker so that it does not come off during site preparation. The type of mark can be determined locally (signing, initialling or placing an arrow at the site). A cross or 'X' should be avoided, however, as this has been misinterpreted to mean that the site is the one *not* to be operated on.
- As a final safety check, the operating team should collectively verify the correct patient, site and procedure during a 'time out' or pause immediately before skin incision. The surgeon should state out loud the patient's name, the operation to be performed, and the side and site of surgery. The nurse and anaesthesia professional should confirm that the information is correct.

### **References**

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