AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

Ensuring Correct Patient, Correct Site, Correct Procedure Protocol for Surgery:

Review of implementation and proposals for action

October 2008

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1. Introduction

In Australia and internationally the failure to correctly identify patients and relate this information to an intended clinical intervention continues to result in wrong person or wrong site procedures, medication errors, transfusion errors and diagnostic testing errors. These errors are largely preventable. In recognition of this patient safety risk, the Australian Commission on Safety and Quality in Health Care (the Commission) established a Patient Identification program to take a national approach to reducing errors associated with the misidentification of patients and their care and improving the patient identification process.

One of the initiatives in this program was to review the implementation of the Ensuring Correct Patient, Correct Site, Correct Procedure Protocol (the Protocol). The Protocol was developed by the former Australian Council for Safety and Quality in Health Care with the Royal Australasian College of Surgeons, based on material developed by the Department of Veterans' Affairs in the United States. In April 2004 Health Ministers agreed that "all public hospitals will adopt the 5 step right patient, right site, right procedure protocol for verifying the site of surgery and other procedures to reduce the risk of wrong site procedures by the end of September 2004".

The main aim of this initiative was to gain an understanding of the way in which the Protocol has been implemented in Australia. The review was generally focussed on use of the Protocol in a surgical environment. Although the Protocol has been applied more broadly in some places, it is in surgery where most of the implementation work has been done.

The review of the implementation of the Protocol involved the following activities:

- examining the jurisdictional and private hospital policy framework in place regarding the Protocol
- obtaining information about the level of compliance with the Protocol
- interviewing individuals who have been involved in the implementation or use of the Protocol about their experiences.

The purpose of this discussion paper is to present the results of the review, as well as actions that have been proposed to reduce observed variation in the use of the Protocol. These actions have been informed by preliminary discussions with the Royal Australasian College of Surgeons.

This initiative has been conducted with input from Associate Professor Judith Healy from the Australian National University, as part of an Australian Research Council Linkage grant on which the Commission is an industry partner. This report draws on material obtained and prepared by Professor Healy, and the Commission acknowledges her work on this initiative, and thanks her for her contribution.

2. Wrong site surgery and the Protocol

Wrong site surgery was one of the first areas in which patient identification errors were identified. In 1998, the Joint Commission, the leading accreditation agency for health care facilities in the United States, issued a sentinel event alert based on 15 cases of wrong site surgery (1). A follow-up alert was issued in 2001 reporting on 150 cases (2). The Joint Commission released the Universal Protocol for Preventing Wrong Site, Wrong Person, Wrong Procedure Surgery™ in July 2003.

In 2004, the Department of Veteran's Affairs National Patient Safety Center in the United States released the Ensuring Correct Surgery Directive after determining that wrong surgeries were being reported at a rate of approximately one in 30,000 surgeries, or about one per month (3, 4).

In Australia wrong site surgery and other patient identification errors were also starting to be reported at this time. There was not yet any national reporting of adverse events, but Victoria reported in 2002-2003 on 16 procedures involving the wrong patient or body part (5). By 2003-2004 a number of other states had established their own sentinel event programs and published data (5-9). The Ensuring Correct Patient, Correct Site, Correct Procedure Protocol was one of first national responses to these reports.

The Protocol describes a five step process that is designed to prevent procedures being performed on the wrong patient or part of the body (Figure 1). The steps in the protocol are:

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

2. Mark the site with an indelible pen for the surgery or other invasive procedure

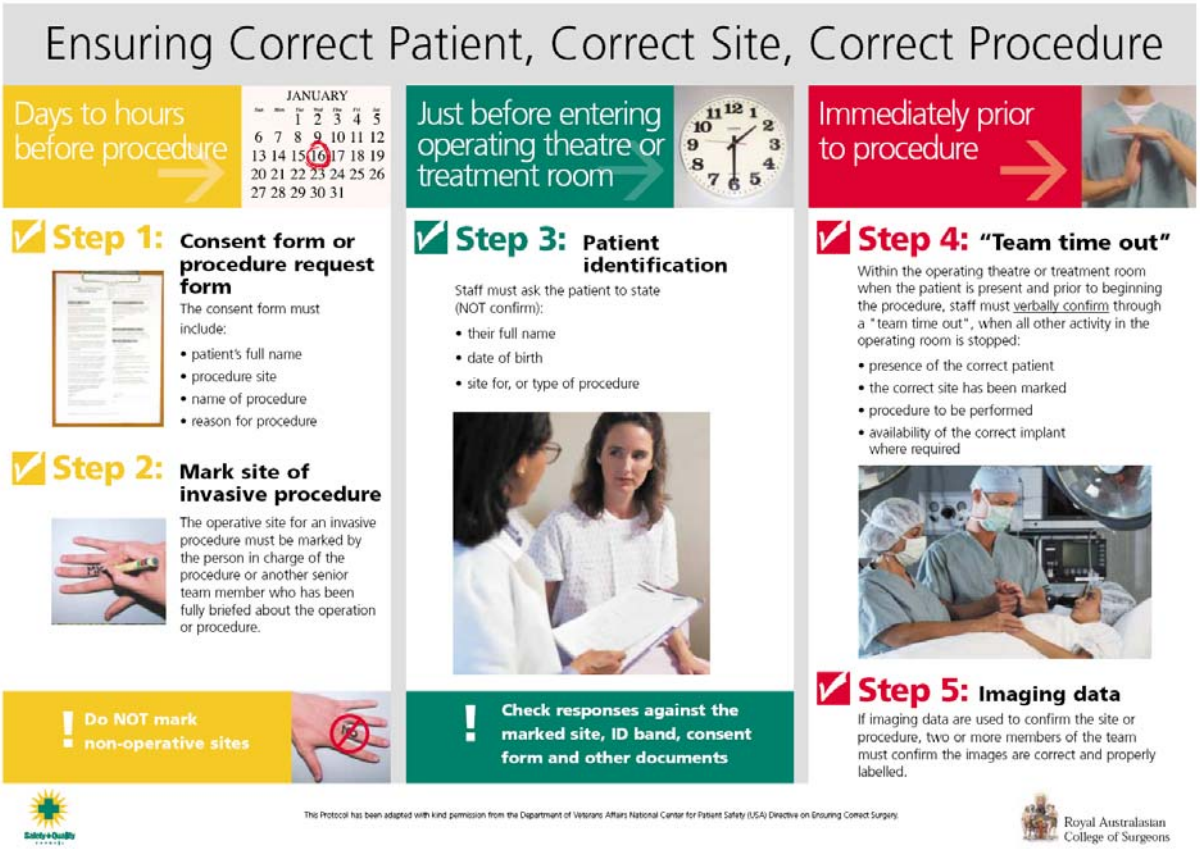
3. Confirm identification with the patient

4. Take a "team time out" in the operating theatre, treatment or examination area for staff to verbally confirm that all is correct

5. Ensure appropriate and available diagnostic images.

The Council produced and distributed a kit in 2004 that included a fact sheet, a patient brochure and workplace posters. (These are available from the Commission's website at http://www.safetyandquality.org/internet/safety/publishing.nsf/Content/former-pubs-archive-correct.)

Figure 1: Ensuring Correct Patient, Correct Site, Correct Procedure Protocol



3. Correct patient, correct site, correct procedure policies

As part of the review of the implementation of the Protocol a range of policies, guidelines and protocols to prevent wrong site surgery in Australia was reviewed. Policies from State and Territory health departments, some private hospitals and the Royal Australasian College of Surgeons (RACS) are summarised in this section.

Relevant policies were mostly obtained from organisational websites, or if not available there, directly from the organisation.

3.1 State and Territory health departments

Following the decision by Health Ministers that the Protocol would be used in all public hospitals, all jurisdictional health departments disseminated information about the protocol to their hospitals and health facilities. Most jurisdictions also took steps to develop their own policies, protocols or guidelines, although in some instances this activity was conducted by individual hospitals or health services.

Since the initial release of the Protocol, many jurisdictions have reviewed their policies at least once, sometimes making significant changes. The initial policies were generally based on the national Protocol released by the Council, however as they have been progressively implemented and reviewed, changes in scope and content have been introduced. These changes have varied between jurisdictions.

The requirements placed on health services and hospitals to implement the protocol have also changed over time (for example some were initially guidelines, and then became mandatory).

Table 1 provides a summary of the details of the policies in place in each jurisdiction as at June 2008.

Table 1: Jurisdictional wrong site surgery prevention policies

Jurisdiction	Protocol title	Date	Type of authority	Clinical coverage	Comments
Australian Capital Territory	5 Step Correct Patient, Correct Site, Correct Procedure Policy	May 2006	Mandatory policy	All operative and other interventional procedures	Policy aligns with the steps in the Protocol
New South Wales	Correct Patient Correct Procedure and Correct Site	October 2007	Mandatory policy	Invasive or diagnostic procedures, including surgery, endoscopy, dentistry, radiology, nuclear medicine, chemotherapy and radiation therapy	Policy aligns with the steps in the Protocol Policy provides considerable additional detail regarding the steps to be taken, including specific information for particular therapeutic areas
Northern Territory	Correct Patient, Correct Procedure, Correct Site Policy	January 2007	Policy	Interventional procedures	Policy aligns with the steps in the Protocol
Queensland	Ensuring Intended Surgery	March 2005	Mandatory policy	Surgery	Policy includes a four step process: 1. Check informed consent 2. Mark the site 3. Identify patient 4. Final check
South Australia	Ensuring Correct Patient, Correct Site, Correct Procedure	September 2004	Policy	All operative and other invasive procedures, including procedures performed outside operating theatres	Policy aligns with the steps in the Protocol
Tasmania	N/A	N/A	N/A	N/A	Tasmania does not currently have a finalised jurisdictional correct patient policy
Victoria	RACS Implementation Guidelines for Ensuring Correct Patient, Correct Side and Correct Site Surgery	N/A	Guidelines	Not stated	Adopted by the Victorian Surgical Consultative Council, which was established by the Minister for Health in Victoria to improve the quality and safety of surgery in Victoria In 2004 the Department of Human Services wrote to all hospital chief executives requesting that the Protocol be implemented
Western Australia	Correct Patient, Correct Site and Correct Procedure Policy and Guidelines for WA Health Services	November 2006	Operational Directive	All surgical, anaesthetic and medical procedures that potentially expose patients to harm, including diagnostic procedures and those performed outside the operating theatre	Policy aligns with the steps in the Protocol Policy provides considerable detail about the way the policy should be implemented Operational directive states that policy represents the minimum standard of care and that all health services are expected to implement the five-step process

3.2 Implementation requirements set by States and Territories

In addition to the differences between jurisdictional level policies, procedures and guidelines, additional variation in the use of the Protocol is introduced by the requirements and guidance provided to hospitals and health facilities in each jurisdiction.

Table 2 provides a summary of the statements included in jurisdictional policies regarding how the Protocol (or jurisdictional variations of the Protocol) should be used in individual health areas and hospitals. Again, this information comes from published jurisdictional policies and guidelines.

This table shows the variation between jurisdictional policies regarding responsibility for implementation, as well as details of two specific steps of the Protocol, site marking and conducting the time out. These are generally the most controversial areas and where there is the most variation in processes.

In general health services and hospitals are required to have a local correct patient correct site policy in place. The variation that exists between jurisdictions is likely to be magnified in these local policies. This was highlighted in the interviews conducted with individuals responsible for implementing and using the protocol, and is discussed further in Section 4.

Table 2: Implementation requirements set by jurisdictional policies

Jurisdiction	Responsible service manager	Responsible clinician	Site marking	Time out
Australian Capital Territory	Not stated	All team members, but ultimately the person performing the intervention	Conducted by person performing intervention Site is marked with initials At minimum mark all cases with laterality, multiple structures or levels	Person performing procedure initiates and is responsible All team members participate Conducted where procedure performed Conducted immediately before procedure (patient usually anaesthetised)
New South Wales	Area Chief Executive, Area Director of Clinical Governance, hospital managers Line managers are responsible for ensuring that policy is followed	Person in charge of procedure	Marked by surgeon / proceduralist or nominated team member Essential where potential for error involving laterality, multiple structures or levels Method of marking should be consistent throughout organisation Initials should not be used	Person initiates time out designated by organisation – should be most senior proceduralist All team members participate Other team members can remind the team leader that the time out should occur Conducted where procedure performed Conducted immediately before procedure (patient usually anaesthetised)
Northern Territory	Medical Superintendent / Manager, General Managers	All team members	Marked by person in change of interventional procedure Mark is on or near incision site At a minimum mark all cases with laterality and multiple structures Method of marking should be consistent in all hospitals	Initiated by designated member of the team (operating theatre team leader) All team members participate Performed immediately before procedure commences
Queensland	District manager, Director Nursing Services, Director Medical Services	Treating medical officer	Treating medical officer or another medical officer is responsible Marked with doctor's initials	Treating medical officer ultimately responsible All team members stop activity Treating medical officer checks with anaesthetist, circulating or instrument nurse to verify Ideally best to carry out step when patient is awake – if not possible perform after anaesthesia but before prepping and draping
South Australia	Health service chief executive officer	All team members, but ultimate responsibility rests with doctor or other credentialed clinician	Member of the operating team responsible (consultant or registrar) Method of marking should be consistent throughout organisation At minimum mark all sites involving laterality or multiple structures, preferable to mark all surgical sites where appropriate	Doctor or other credentialed clinician responsible At least three team members participate
Tasmania	Jurisdictional policy not final			
Victoria	Dependent on policy of each health service			
Western Australia	Hospitals / health services	All team members, but person in charge of clinical team carriers overall responsibility	Ideally marked by person performing surgical or interventional procedure, but may be delegated to another health practitioner All cases involving laterality, multiple structures or levels should be marked Method of marking should be consistent throughout hospital	Initiated by designated member of clinical team All team members participate Up to individual clinicians to determine whether or not the patient should be anaesthetised before time out is completed Conducted in room where procedure will be done

3.3 Private hospital sector policies and implementation requirements

Although private hospitals were not included in the Health Ministers' requirement that the Protocol be implemented in 2004, they also proceeded to implement the Protocol, largely driven by material released by the Council and RACS, as well as concerns about safety.

Members of the Commission's Private Hospital Sector Committee were requested to provide copies of any available policies developed to prevent wrong site surgery. Fifteen policies were provided from private hospitals that varied in terms of their size and location. Some polices were applicable to a large number of hospitals nationally. The policies are summarised in Appendix 1. While these policies are only a small sample of the number and range of policies that exist in private hospitals, they provide another view of the way in which the Protocol has been applied.

The variation shown in the implementation requirements set by the jurisdictions is mirrored in the private hospital policies. These policies vary in terms of their level of detail, and directions they give for performing site marking and time outs. The policies also vary in terms of who is responsible for ensuring that the Protocol is implemented, both organisationally and clinically. Two of the policies provided do not include a time out step, and therefore do not align with the steps in the Protocol.

3.4 Royal Australasian College of Surgeons

The Royal Australasian College of Surgeons was one of the first organisations in Australia to develop guidelines to prevent wrong site surgery. RACS released their first correct patient guidelines in 2003. Currently RACS has "Implementation Guidelines for Ensuring Correct Patient, Correct Side and Correct Site Surgery" that were released in 2006, and are due for review in September 2008 (10).

The main components of the RACS guidelines are as follows:

- Consent and documentation.
- Marking the site: should be done in consultation with the patient by the surgeon. The nature of the mark is not specified, but the guidelines state that the mark should be initialled.
- Final verification: surgeon, anaesthetist and nursing team must conduct the time out. This should preferably occur before anaesthesia.
- Checking implants and imaging.

Some other professional colleges also have guidelines that include information relevant to this issue. For example, the Royal Australian And New Zealand College of Ophthalmologists has a Correct Eye Surgery Guideline which sets out ten steps that are similar to those in the Protocol and the RACS guidelines, but do not include a team time out.

Other colleges include information about correct patients identification within their standards. For example, the Australian College of Operating Room Nurses includes Ensuring Correct Patient, Correct Site, Correct Procedure as one of their standards for perioperative nursing.

4. How the Protocol is being implemented in practice

The policies summarised in the previous section describe how the Protocol is *intended* be implemented in hospitals and health facilities. The interviews conducted as part of this review provided information about what happens in practice in hospitals regarding the use of the Protocol.

Seventy two interviews or meetings were conducted to inform this review. Some interviews were conducted in June and September 2007, and others between April and July 2008. The interviews covered all States and Territories, and included clinicians, safety and quality practitioners, administrators and policy makers. (See Appendix 2 for details of the interviews.)

The Protocol has provoked considerable discussion at all levels of clinical and managerial practice, which is positive in terms of increased awareness of patient safety issues. However it has proven difficult to implement in a consistent way, given different implementation processes, different hospital procedures and different views and practices by the various specialties and professions. As a result there is variation in policy and implementation at all levels: national, jurisdictional, regional and hospital.

The main areas where there is variation in implementation are marking the site of the procedure and conducting the time out. This section describes some of the variations and issues that occur in these steps within hospitals and health facilities. In addition, some of the general issues that affect how the Protocol as a whole has been implemented in practice are considered.

Although the variations described in this section are drawn from the 42 interviews conducted as part of this review, the issues raised in the interviews were fairly consistent across jurisdictions and public and private hospitals. Accordingly, there is no reason to expect that similar variations are not present throughout all Australian hospitals.

4.1 Marking the site

Marking the site has been common practice with some surgical specialties, although not all, and the manner of marking varies. As seen in Table 2 and Appendix 1, the various policies and guidelines address this issue in different ways. The main issues that arise concerning site marking are discussed below.

Who marks the site

The various individuals identified by participants as being responsible for site marking include the surgeon, the registrar, another member of the operating team or a ward nurse, depending on local practice.

One of the issues that has emerged is whether or not the patient should be involved in marking the site. While this is recommended in some policies, concerns were raised about this practice.

> *"…what we would strongly not recommend is to have patients mark their own leg. … so that's a bit of an issue because then the patient puts a cross on the leg that he doesn't want to have done and there's always issues with that and the doctor thinks that's of course the side he wants to have done…"* (Orthopaedic Surgeon)

What mark should be made

There is considerable variation in the mark used. This includes crosses, ticks, arrows, circles, initials, dates and the letters "R" and "L". Participants were concerned that this variation can cause confusion with staff moving between units and hospitals.

> *"I think because people moving between different hospitals and using different marks, I mean it's a recipe for disaster and so we need national standardisation."* (Anaesthetist)

What should and should not be marked

This is the most contentious of the issues associated with site marking. There is general agreement that any site with laterality or multiple structures such as fingers should be marked, but considerable variation of opinion exists for procedures without these features, such as for Caesarean sections or cardiothoracic surgery. Other concerns expressed are for marking the face in ophthalmic surgery, laproscopic surgery and for procedures that would involve marking mucous membranes rather than skin.

> *"…the initial thrust was that we need to take strong stand on this and that all sites should be marked … But the feedback from staff was the thing they really struggled with was the site marking … [so changes were made to] … make it compulsory to mark in instances of laterality, but then it is up to specific groups on how they decide if they want the site marked or other areas. … Most of them dropped site marking unless there was laterality involved."* (Safety and Quality Manager)

Concerns have been raised about the variation in marking practices between different surgical specialties and the confusion this could cause.

> *"One of the ones was … neuro, they didn't want a marked site, especially with heads and stuff … I said it's okay for you, you're a small department, but I've got lots of nurses and I can't say 'No there's also ortho and plastics and neuro [that] doesn't mark'. I said everyone needs to be the same otherwise they get confused and that's when we won't mark and the way to make mistakes."* (Clinical Nurse Consultant, Operating Theatres)

Whether or not to mark the site

A participant from one hospital reported that they had decided not to include site marking in their policy. This decision was made on the basis of this hospital being a large metropolitan centre that dealt with a very high proportion of trauma patients. It was considered that it was not possible to include the site marking step in the process; instead there was an increased focus on the time out as the final checking mechanism.

> *"Well when this first came out … we found at this hospital being largely trauma, 80 per cent trauma, we couldn't actually do what was being asked of us … we felt it was impractical here. So we don't mark the limb, necessarily, of patients who come in here, because often they are lucky to be seen by someone before they hit the theatre."* (Nursing Director, Operating Theatres)

4.2 Time out

The time out step of the Protocol had not been routine prior to the introduction of correct patient, correct site, correct procedure guidelines, policies and protocols. The main issues associated with the time out are discussed below.

Who should initiate the time out

Generally the policies state that the person performing the procedure should conduct the time out, although there is some variation and allowances for other members of the team to initiate the time out. In practice, here appear to be two main approaches to initiating the time out. Firstly, it is common that a nurse initiates the time out.

> *"We have put out a policy saying that the anaesthetic nurse needs to initiate it, In the absence of the anaesthetic nurse, it's the scrub nurse. … So whilst it's the surgeon's responsibility to do it, because I wasn't getting what we needed, we put out a policy saying that."* (Nursing Manager, Operating Suite)

In some cases a deliberate approach of allowing anyone in a team to call the time out has been taken, to emphasise the team based nature of the process.

> *We have also said that the person calling it will be up to the team because we are very strong on operating theatre work is team work and there are leaders at different stages but everyone is part of that team and everyone has equal responsibility and you can't abrogate that. So the anaesthetist may call it, the nursing staff may call it or the surgeon may call it and I think its spread in the various units across those."* (Anaesthetist)

Although there were a few reports of individual surgeons initiating the time out, this does not appear to be widespread.

When should the time out occur

The practice around the timing of the time out is also variable. Some hospitals and units prefer to do it before the patient is anaesthetised so the patient can participate, and some prefer to have the time out as the final check just before the incision as this is when it is easier to have the whole team together. Some started doing the

time out before anaesthetic and have changed to do it after, and some currently do it after anaesthetic and are considering changing to do it before.

> *"And there wasn't any consistency about when the actual time out happens. so some of them were doing it in the anaesthetic bay, some of them were waiting till the patient's on the table and anaesthetised for that final check. So one team preferred to do it here, one team preferred to do it at another time."* (Quality Co-ordinator)

Quality of participation in the time out

In some situations it was reported that although the time out was being completed, not all members of the team were actively participating. Surgeons, and sometimes anaesthetists, were mentioned as members of the operating team who were less likely to actively participate in the time out. In some cases an active refusal to participate in the time out was reported.

> *"The problem is making sure that the time outs are done with the surgeon involved or the anaesthetist. … some people's interpretation of the level of participation is a bit of an issue as well because some people will say well they're in the room they're listening, but they're chatting. … Whereas we really need to have them not talking, paying attention."* (Manager, Surgical Services)

Whether or not to conduct the time out

In one hospital a local policy has been developed that does not require the time out step. This policy is based on a checklist that should be completed by the surgeon before the operation. The rationale for the approach taken was to ensure the surgeons took responsibility for the process, reduce unnecessary delay and comply with the RACS guidelines.

> *"Therefore the way I've done our policy is it encourages surgeons to make sure that they check the patient identity to make sure the X-rays are available and have been checked, to make sure the consent form has been done, to make sure the patient has been marked and any special instruments or special bits are available before the patient even gets to the operating theatre. That's why we have a checklist which now has a surgeons column in that checklist. What that means is if a patient turns up in the operating theatre and the surgeon has completed the surgeon column that there is no need to have a team time out. You can just get on with the procedure, get on with the operation."* (Director of Surgery)

4.3 Overall implementation

As well as the variation observed in the site marking and time out steps, some issues were identified that are relevant to the way the Protocol as a whole is used.

How policies and guidelines were introduced

The jurisdictions took different approaches to introducing their policies and guidelines following the requirement to implement the Protocol.

In some cases these were issued as mandatory and detailed policies. While this has not necessarily led to a consistent approach in all hospitals within these jurisdictions, it does reduce the potential for locally developed policies that do not align with the steps in the Protocol. However being too prescriptive about the way in which policies are introduced can mean that they are seen as not relevant to the needs of specific environments. This can increase the likelihood of non-compliance.

In some cases hospitals and health services considered that policies were introduced without any guidelines or support by jurisdictions for implementation. However in one small jurisdiction coordinated support led to all the hospitals conducting audits using the same tools.

> *"…they really just landed the policy and there was no implementation plan or even suggestion of you know this is how you could go about it."* (Clinical Risk Coordinator)

> *"…we try and have the same program of activities across all … sites and the quality coordinators actually work together to set up the audits so correct site is part of their scheduled audit program."* (Quality Manager)

Who is responsible for implementation

Many policies stated that the clinician conducting the procedure was responsible for the ensuring that policies were followed. However, in practice who has been responsible for implementation has not always been clear.

> *"We made [the policy] available and just assumed that people would take responsibility for it, but nothing happened. Then the next response was interesting … from the surgeons it was bureaucracy gone mad … From the nursing staff it was well if the doctors aren't taking it seriously why should we, it's not a nursing problem it's a doctor issue and the doctors need to own it. … The anaesthetists: yes it should happen. It's not our problem, the surgeons need to take responsibility for it."* (Anaesthetist)

While in some cases the Protocol has provided an opportunity to reinforce the team based nature of surgery, in other cases it has reinforced existing inter-disciplinary disagreements, and has been seen as divisive.

> *"…the surgeons felt very strongly that it was not a nursing task, it was a surgical task to be doing. The nurses felt it was not a surgical task, it was a nursing task to be doing. So we had to resolve that."* (Director of Surgery)

Failure to follow the Protocol

A number of circumstances were mentioned when some steps in the Protocol are not followed. These circumstances are not necessarily documented in policies, and appear to be specific to individual hospitals or units. These circumstances include:

- when the surgeon is already familiar with the patient. This may be particularly an issue in private hospitals where surgeons are more likely than those in public hospitals to have seen the patient before.
- when patients are “fast-tracked” or brought in quickly to fill a gap in an operating list.
- in emergency situations. While it is reasonable that there are times when the Protocol is not used because of the urgency of the surgery required, there were reports that in some situations cases can be classified as emergencies inappropriately.
- when there are time pressures to move through the operating list quickly.

  “The failures are often related to other circumstances that people find themselves in. So particularly busyness and emergency-type situations where people are quite stressed and you might have a lot of things going on at the same time.” (Director of Clinical Governance)

5. Compliance with the Protocol

Information about compliance with the Protocol and associated policies in Australia is limited. The former Council, and subsequently the Commission, collected some information about how the Protocol had been implemented in both the public and private sectors, however there is no national process or requirement to monitor or report on levels of compliance.

Monitoring of compliance within jurisdictions is not consistent. Some jurisdictions have conducted audits, or collated information from audits done within hospitals and health services. Where these have been done different methods have been used, and sometimes different steps of the Protocol have been audited.

The process of monitoring compliance has largely rested with, and results stayed at the level of, individual hospitals and health services.

There appear to be two main ways in which compliance is monitored. The first method is with observational audits that can require considerable resources to conduct. In some cases jurisdictions have developed audit tools to assist their hospitals to monitor compliance and ensure consistency across hospitals. The second method is through the use of routine data collected through processes such as the theatre management system in operating theatres. The inclusion of fields that need to be checked off to indicate whether or not a time out has been conducted facilitates this process, although the interpretation of this information is not always straightforward.[*]

As part of this review the Commission requested information from jurisdictions about levels of compliance with the protocol. At the time of this request only three jurisdictions that had conducted jurisdiction-wide audits were able to provide data about compliance. Although some information about compliance from individual public and private hospitals was provided to the Commission during the review, this is not included here because of the small numbers of sites and different data collection methods used.

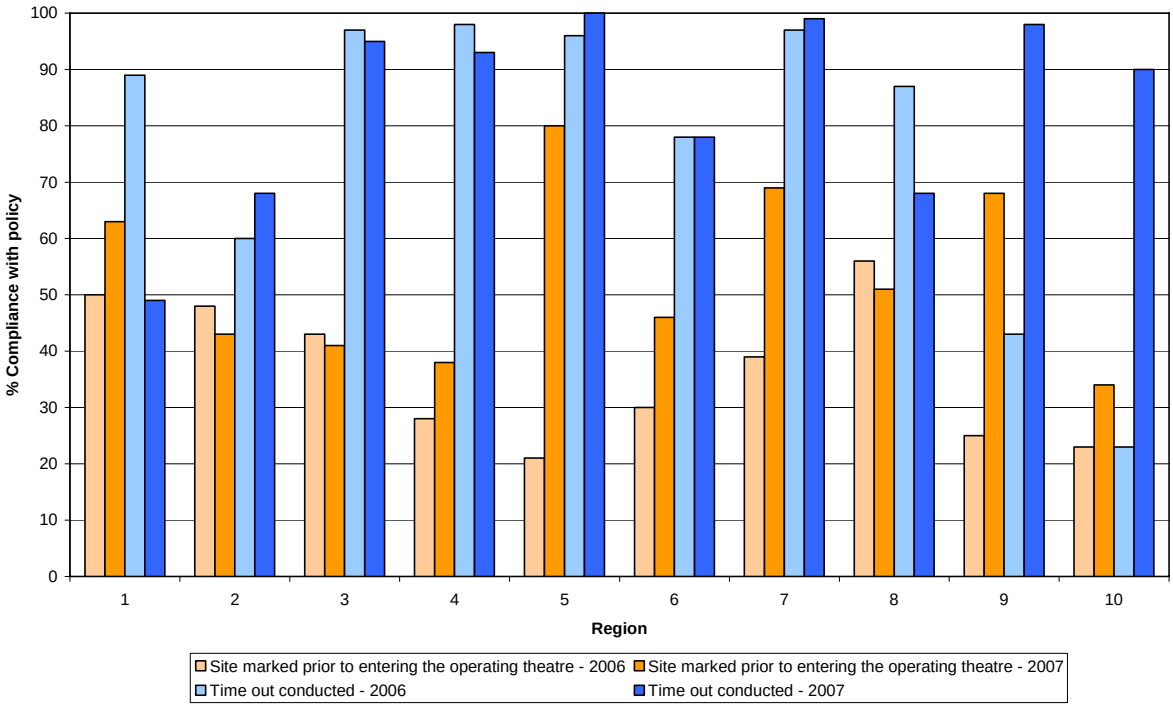
One jurisdiction has conducted two jurisdiction-wide audits of compliance in operating theatres with two of the key steps in this protocol: marking the site and conducting a time out. These observational audits were conducted in most health service regions within the state in 2006 and 2007. In 2006, 682 surgical cases were audited and 649 were audited in 2007. These audits found that across the jurisdiction:

- in 2006 the site was correctly marked in 37% of cases, this increased to 54% in 2007
- in 2006 the time out was performed in 71% of cases, this increased to 82% in 2007.

[*] For example, a field that has been checked that a time out has been conducted does not actually confirm that the time out was done, or whether the time out was done as required by policy.

To indicate the range of results across the jurisdiction, Figure 2 summarises the results of the audits for regions within the jurisdiction that had at least 30 audited surgical cases. There is considerable variation in compliance with these steps of the protocol across the jurisdiction over the two years. However it is clear that the jurisdiction has used the information from the first audit to focus on improving compliance.

Figure 2: Proportion of surgical cases complying with required steps to mark the site prior to entering the operating theatre and conduct a time out[†]



Another jurisdiction has conducted a jurisdiction-wide observational audit between November 2006 and March 2007. During the audit period 6736 procedures were performed, of which 1704 (25%) were audited. For four of the key steps in the protocol the audit found:

- the consent form identified the correct patient and correct procedure in 95% of cases
- the site was marked as per the consent form in 69% of cases
- the time out was performed appropriately in 80% of cases
- the time out was documented and appropriately signed in 77% of cases.

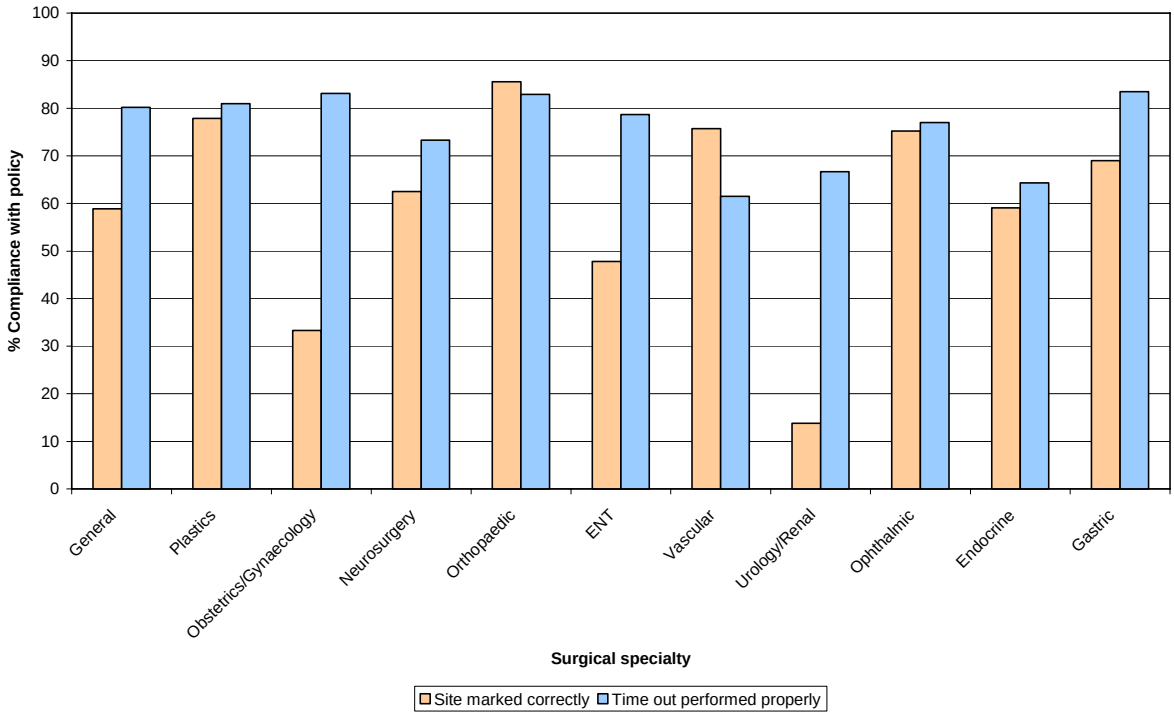
This jurisdiction found a similar variability to that shown above in terms of performance of these steps by region. For example, the range proportion of cases for which the team time out was performed appropriately varied between 22% of cases and 100% of cases depending on the region concerned.

Of particular interest with this audit is that the jurisdiction also collected information about the speciality of each surgical case, and was able to provide information about

[†] For data relating to site marking, the calculation of the percentage of cases was adjusted to take into account the cases reported as not applicable for marking the site of the procedure.

compliance with the protocol by specialty. Figure 3 shows the percentage of cases where the site marking and time out steps were performed properly for the surgical specialties where at least 20 cases were audited. While there is some variability in compliance with the time out between the specialties (64% to 83%), the variation in site marking by specialty is considerable, ranging from between 14% and 86%. These results mirror the comments made in the interviews regarding the varying processes for site marking.

Figure 3: Proportion of cases complying with site marking and time out steps, by surgical specialty



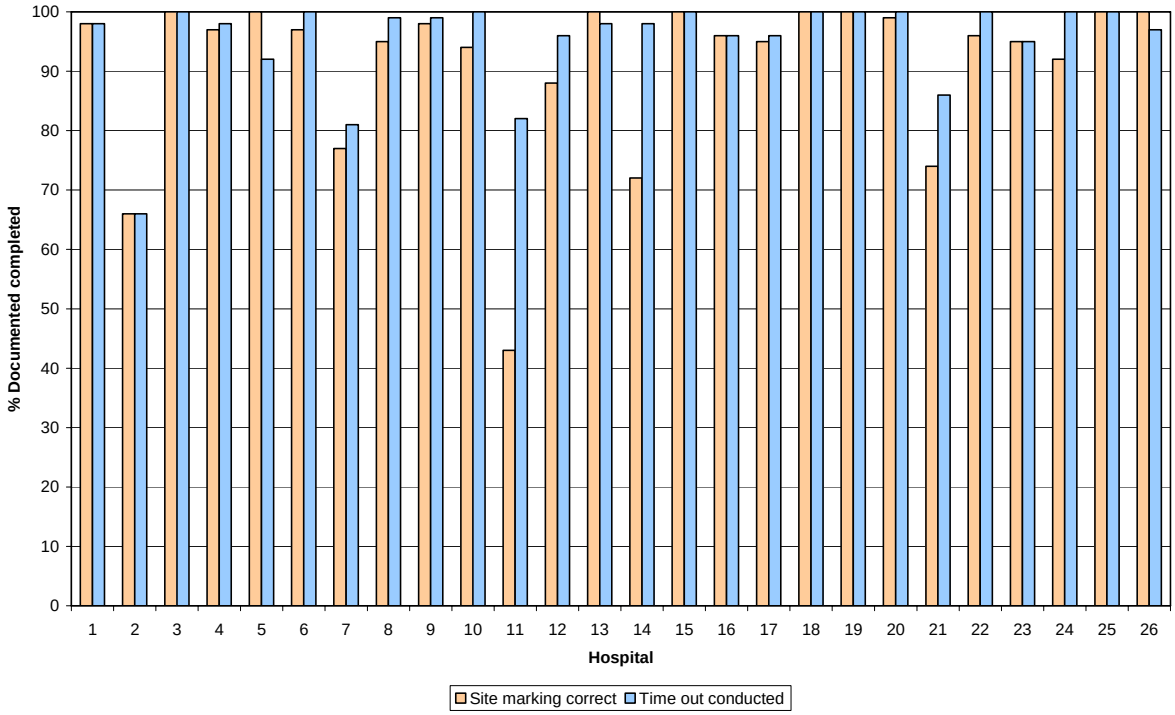
Finally, another jurisdiction conducted a documentation audit 4678 patient records across 87 hospitals in April 2008. The steps in protocol were considered to be correct if they were correctly documented in the patient records, or noted as not applicable. The audit found that on average across the jurisdiction:

- the consent form was complete and correct in 94% of cases
- the site marking was correct in 91% of cases
- the patient identification was correct in 96% of cases
- the time out was conducted correctly in 95% of cases
- medical imaging was correct in 92% of cases.

These results show a much higher level of compliance than the other jurisdictions because this was a documentation, rather than observational, audit.

Figure 4 shows the proportion of records where the site marking and time out steps were documented as completed for hospitals with at least 50 cases audited. It is of interest that even though the overall level of documented compliance was high, there were still some individual hospitals that had much lower levels of documented compliance.

Figure 4: Proportion of surgical cases with site marking and time out documented as complete in the patient's records



6. Discussion

The Ensuring Correct Patient, Correct Site, Correct Procedure Protocol was developed by the former Australian Council on Safety and Quality in Health Care to provide a standard national approach to prevention of wrong site surgery and other patient identification errors. As the successor body to the Council the Commission has a responsibility to monitor the Protocol and its use. Accordingly, the Commission conducted a review to examine the way in which the Protocol has been implemented nationally.

The focus of this review was specifically on surgery, as this is the area that has been using the Protocol for the longest period of time. This discussion, and the proposals put forward are also specifically related to the use of the Protocol in surgery.

This review did not indicate any widespread dissatisfaction or disagreement with the Protocol. There was recognition among individuals from all professions interviewed that prevention of wrong site surgery was important and that the policies, guidelines and procedures that were developed from the Protocol were useful contributors to this process.

The review was not exhaustive. However it did consistently show significant variability in the way the Protocol is used in both the public and private sectors. This variation occurs at national, jurisdictional, regional and hospital level. The Protocol was developed as a standardised national tool to reduce patient identification errors. Standardisation of clinical processes is known to contribute to increased safety and reduce error; however the safety benefits of standard processes are reduced if they are not implemented consistently, or not complied with.

There are legitimate issues that have contributed to the variations observed in the use of the Protocol, and some flexibility is necessary to encourage compliance with the Protocol and ensure that it is best adapted to the needs of specific users. There are also costs to implementation, and the level of consistency sought needs to be balanced against the efforts required to achieve a uniform approach.

Jurisdictions and the private hospital sector have put considerable work into implementing and maintaining use of the Protocol through their own policies and guidelines. Nonetheless, from a national perspective concerns remain about:

- the failure to consistently specify who is responsible for ensuring that the steps in the Protocol are followed
- the potential for confusion resulting from varying practices with activities such as site marking
- the nature of participation of all members of the surgical team in steps such as the time out
- the use of Protocol in different surgical specialties, raising issues about whether the Protocol as it stands is clinically appropriate in all cases
- the broad level of variability in compliance with the Protocol within individual jurisdictions.

These concerns, and the results of the review, do not indicate that the Protocol needs to be replaced, or changed in any major way. However they do suggest that there would be merit in considering how the Protocol is used in surgery to reduce variation in implementation and compliance. To facilitate this process the Commission has undertaken some preliminary consultation with the Royal Australasian College of Surgeons regarding the steps that could be taken to achieve this. RACS are one of the key stakeholders in this area, and the Commission is looking to work closely with it to support consistent use of the Protocol in surgery. The following action have been informed by these discussions.

6.1 Proposals for action

There are a number of actions that would be needed to reduce the observed variation in policy and compliance regarding the Protocol. Some of these would be within the remit of the Commission, while others would rest with jurisdictions, public and private hospitals and organisations such as RACS and other Colleges. The following approach is proposed for actions to support the quality and safety role of the Protocol in surgery.

1. *Undertake coordinated action regarding the Protocol:* The Commission will work with RACS and other relevant organisations to support consistent use of the Protocol in surgery. RACS has a Correct Patient, Correct Site, Correct Side Working Party which will be reviewing the RACS Guidelines in late 2008. The Commission will be part of this process.
2. *Specify the core elements of the Protocol that cannot be varied:* Many participants in the review commented on the importance of flexibility in the use of the Protocol; the importance of clinical autonomy to surgeons was also noted. While this is reasonable, there has been little discussion about what degree of flexibility is appropriate, or what core elements are needed to maintain the integrity of the Protocol. Based on this review, and concerns already identified by RACS, it is possible to identify some of the issues that will need to be addressed in these core elements. These are summarised in Table 3.
3. *Consult with surgical specialty societies:* One of the issues that emerged in the review was the variable way in which the Protocol was used in the different surgical specialties. It will be important to gain input from these specialties regarding the ways in which the core elements of the Protocol can be implemented in their specific contexts.
4. *Consult with other organisations:* It will also be important to consult with other organisations such as jurisdictions and public and private providers regarding the proposed core elements to the Protocol.
5. *Release revised guidance:* At the end of this process RACS will release revised guidelines for College fellows. The Commission may also release a revised version of the Protocol, or may subsume the current Protocol into the Commissions work on a patient identification standard (see below).
6. *Include a requirement to correctly match patients to their care in the Australian Health Standard on patient identification:* The Commission is currently developing a patient identification standard. This is one of the Australian Health Standards being developed by the Commission as part of the national

accreditation reform program. The patient identification standard will include a requirement to match the correct patient to their intended clinical care. The standard will need to be applicable in a range of contexts, including institutional health services, community health services and practice-based health services. Accordingly, the requirement in the standard to correctly match patients to their care will need to be broadly applicable, and will not include details specifically relevant for surgery. Nonetheless, the existence of an overarching requirement to correctly match patients to their care that has the status of a standard, provides a strong driver to support any specific guidelines on this issue from RACS, the Commission or other organisations. In addition, any guidelines or protocols developed specifically for surgery will be linked to this standard.

Table 3: Some of the issues to be addressed in the identification of possible core elements to support the correct patient, correct site, correct side and correct procedure in surgery

Issue	Suggested approach
Overall	• Health service executives and line managers are responsible for ensuring that the Protocol is implemented in accordance with local policy. A formal system of accountability and performance management is needed to ensure this occurs. • The person responsible for undertaking the procedure is also responsible for ensuring that the steps in the Protocol are followed. For surgery this will be the surgeon. Organisations are responsible for ensuring appropriate procedures are in place to support the undertaking of the Protocol including checkpoints in the lead up to the procedure. • All members of the team are part of the process of ensuring that the correct patient is matched to the correct care. • Any decision not to use the Protocol must be considered a protocol violation and the clinical circumstances appropriately documented. All violations must then be reviewed in accordance with local quality and safety processes for risk management.
Site marking	• Site marking is a core part of the Protocol and should be mandatory. Where an organisational decision is taken to remove part of the Protocol this must be clearly documented to all staff and an *additional* process of risk assessment and risk management to reduce the patient risk of procedural mismatching must be undertaken and documented. • For surgery, the person responsible for undertaking the procedure should mark the site. This task can be delegated to another clinician who will be participating in the procedure. • A consistent method of marking should be used. Agreement should be sought about the nature of this mark. The mark should be visible in the procedural field when preparation and draping is complete. • As a minimum, procedures that involve laterality (i.e. are not midline procedures), multiple structures (e.g. fingers) and spinal levels must be marked. Additional marking, including any incision marking, remains at the discretion of person responsible for the procedure.
Team time out	• A team time out or final check is a core part of the Protocol and should be mandatory. Where an organisational decision is taken to remove part of the Protocol this must be clearly documented to all staff and an additional process of risk assessment and risk management to reduce the patient risk of procedural mismatching must be undertaken and documented. • The person responsible for undertaking the procedure is also responsible for ensuring that the time out has occurred. Local procedures should specify who may initiate the time out process, but the responsibility remains with the lead clinician. For surgery, the surgeon, anaesthetist and anaesthetic and/or scrub nurse must confer and agree on the correct patient, side and procedure as part of the time out. If this check does not occur, none of these clinicians is authorised to proceed with the procedure. • Patient involvement in the time out reduces the risk of wrong site surgery. However this is not always possible or appropriate. If an organisational decision is made to conduct the time out after anaesthesia, an additional process of risk assessment and risk management to reduce patient risk of procedural mismatching must be undertaken and documented.

7. Conclusion

This review of the implementation of the Ensuring Correct Patient, Correct Site, Correct Procedure Protocol conducted as part of the Commission's Patient Identification program found that all jurisdictions and the private hospital sector have made considerable efforts to implement the Protocol. Nonetheless there is considerable variation in how the Protocol is used.

The Commission is concerned that inconsistent use of the Protocol could dilute the benefits that standardisation of clinical process brings, and increase the chances of wrong site surgery occurring.

The actions proposed in this paper are designed to support standard use of the Protocol (or equivalent guidelines or policies) in surgery, taking into account the specific requirements and practices of different surgical specialties. In the longer term, the requirement to correctly match patients to their care will be included as a accreditation requirement across the health system within the Australian Health Standards. The will contribute to the reduction of all patient identification errors, including wrong site surgery.

Appendix 1: Private hospital policies

The following table provides details of implementation requirements regarding correct patient correct site processes in the private hospital policies provided to the Commission as part of this review. In some cases one policy applies across a chain of private hospitals. In other cases one chain hospitals will use different policies.

	Responsible service manager	Responsible clinician	Site marking	Time out
Hospital 1	Not stated	Person performing the procedure	Site marked by person performing procedure Method of marking should be consistent throughout the organisation At a minimum mark all cases involving laterality, multiple structures or levels	Verification prompted by senior member All staff must stop and conduct final verification Conducted where procedure performed Performed immediately before starting procedure If possible should be performed before anaesthetic, but can occur after
Hospital 2	Not stated	Not stated	Surgeon marks site in consultation with patient and medical record Marks should be initialled “Private body parts” should not be marked	Minimum team to participate: scrub nurse, anaesthetic nurse and scout nurse anaesthetist Performed prior to anaesthesia
Hospital 3	General manager	Director of nursing	Site marked by person performing procedure Method of marking should be consistent throughout the organisation At a minimum mark all cases involving laterality, multiple structures or levels	All staff must stop and conduct final verification Conducted where procedure performed Performed immediately before starting procedure If possible should be performed before anaesthetic
Hospital 4	Not stated	Not stated	Site marked by person in charge of procedure or another senior tem member who has been fully briefed Conducted in consultation with the patient and medical record Site/side of procedure is marked Mark must not be ambiguous; an arrow is preferable	Initiated by theatre team nurse who has undertaken pre-operative check Conducted by three members of theatre team, one of who is the medical officer Can be performed before or after anaesthesia
Hospital 5	Line manager	Person in charge of procedure	Site marked by surgeon / proceduralist who is performing or assisting Conducted with the patient where possible Preferred in cases where potential for error involving laterality, multiple structures and levels Mark is such that intended site is unambiguous	Initiated by designated team leader Conducted where procedure performed Conducted immediately before procedure Patient usually anaesthetised Must include whole team, each member should independently verify details
Hospital 6	Not stated	Not stated	Conducted by surgeon / proceduralist Confirmed with patient	Anaesthetic nurse should ask patient to confirm details Answer must be heard and verified by team

	Responsible service manager	Responsible clinician	Site marking	Time out
				If patient unable to participate anaesthetic nurse will provide details that will be verified by team
Hospital 7	Not stated	Not stated	Treating medical officer or another medical officer who will be present during procedure marks the site Consult with patient where possible Mark site and sign with initials	Treating medical officer is responsible Preferably carry out when patient awake, but can be performed after anaesthetic Must include treating medical officer, anaesthetist and circulating or instrument nurse
Hospital 8	Not stated	Each team member	Surgeon marks the site	Time out preferably occurs before anaesthesia All activity ceases while theatre team verify details
Hospital 9	Not stated	Each team member	Surgeon marks the site Should be in consultation with the patient	All members of team call the time out
Hospital 10	Not stated	Not stated	Medical officer who is performing surgery marks the site Consult with patient Area for surgery should be signed	Medical officer is responsible for ensuring the time out occurs
Hospital 11	Not stated	Person responsible for procedure	Person responsible for procedure marks the site Occurs in consultation with patient All cases of laterality, multiple structures and levels should be marked	Time must occur before anaesthesia for any procedure that requires an implant or prosthesis Circulating nurse conducts the time out
Hospital 12	Not stated	Surgeon	Marked by surgeon or surgical assistant	No time out included
Hospital 13	Not stated	Not stated	Marked by surgeon or surgical assistant	Anaesthetic nurse or theatre nurse conducts time out and informs theatre team
Hospital 14	Not stated	Surgeon	Marked by surgeon or designated medical assistant	Surgeon calls time out Anaesthetist, circulating nurse and anaesthetic nurse participate
Hospital 15	Not stated	Surgeon	Marked by surgeon or surgical assistant Performed with patient where possible	No time out included

Appendix 2: Details of interviews

A total of 72 interviews were conducted as part of this review. Some interviews were conducted between June and September 2007, and others between April and July 2008.

Interviews were conducted with:

- clinicians who use the Protocol in their day to day work, including both medical and nursing staff
- line managers and safety and quality practitioners who are responsible for implementing the Protocol
- hospital or other executives who have overall responsibility for use of the Protocol and prevention of errors
- jurisidictional officers with responsibility for the development and implementation of jurisdictional policies
- representatives from other organisations such as professional colleges with an interest in the Protocol.

Interviews were conducted in all States and Territories. Most of the interviews were with individuals from the public sector, although a small number were representatives from the private sector.

The focus of the interviews was on issues including:

- what actions had been taken to implement the Protocol initially, and ongoing activities to support its use
- success of strategies to implement the Protocol
- reporting, review and audit activities
- organisational, individual, professional or cultural issues that affected the use of the Protocol
- drivers to support compliance with the Protocol.

All interview participants were guaranteed confidentiality and anonymity as part of their participation.

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