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SAFE SURGERY IN AUSTRALIAN HOSPITALS: IMPLEMENTATION OF THE CORRECT PATIENT, CORRECT SITE, CORRECT PROCEDURE PROTOCOL

Judith Healy

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Safe Surgery in Australian Hospitals:

Implementation of the Correct Patient, Correct Site, Correct Procedure Protocol

Judith Healy

Australian National University

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Summary

Background: Health policy makers in many countries have proposed protocols to reduce so-called 'never events', meaning adverse incidents in hospitals that are preventable, such as incidents involving the wrong patient, wrong site, or wrong procedure. Reporting systems now indicate that these types of adverse incidents are more frequent than initially assumed; for example, 53 such incidents were reported across Australia for 2004-05. The Australian Health Ministers in April 2004 called for all public hospitals in Australia to implement the 'Ensuring Correct Patient, Correct Site, Correct Procedure' protocol, as part of a broad strategy to introduce and standardize patient safety check procedures in hospitals.

Aims: This study sought lessons for health sector governance from experiences with the protocol. Did policy implementation differ between States and between hospitals? Did different groups of professionals support or object to the protocol? What strategies were used to promote compliance with the protocol by hospitals and health professionals?

Methods: Information was obtained from the eight States and Territories on implementation strategies and audits. A literature review and website search was undertaken. Over 72 interviews were conducted with national and State policy makers, hospital managers, and health professionals.

Results: Promulgation of the protocol differed between the States, reflecting different public sector cultures and administrative structures, with the States variously issuing guidelines, policies and directives. Most States left it to hospitals to work out the details of the protocol and many hospitals left it to units and/or clinicians. Most hospitals began by introducing the protocol in operating theatres. The take-up of a protocol within a hospital depends upon its acceptability to health professionals, and introducing a standard procedure into operating theatres proved more difficult than expected, especially since patient identification practices vary between surgical specialties. The protocol also revealed different safety cultures, since nurses generally tend to prefer rules-based practice while surgeons prefer discretionary practice. In some hospitals, rather than an opportunity for team-building, the protocol aggravated tensions between professional groups. Hospital managers tried multiple regulatory mechanisms, both supports and sanctions, to promote compliance. Most began with softer mechanisms, such as information and training, and later escalated to stronger mechanisms, but stopped short of severe sanctions. Some hospital audits suggest that protocol compliance in operating theatres in general rose over four years from below 30 percent to over 70 percent and in some units rose to over 90 percent.

Conclusions: Policy makers saw the protocol as a self-evidently sensible solution. Compliance by health professionals, however, proved to be low and slow, especially since the authority attached to the protocol was often ambiguous. Hospital managers proved to be responsive regulators in that they tried multiple regulatory mechanisms. Achieving compliance required supplementing the soft mechanisms traditionally used by the health sector by stronger mechanisms, however, such as directives issued by clinical leaders, and by regular compliance monitoring. Once embedded in operating theatres as 'the way we do things', the protocol appears to be low-cost and not intrusive in terms of staff time and effort. Although the principle of a patient safety check generally is accepted, there was little agreement on the principle of a standard protocol, either within many hospitals or within a State, let alone across Australia.

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1. Introduction

1.1 Why study compliance with a national protocol?

Patient safety alerts issued in the United States identified surgery involving the wrong patient, site or procedure as rare but potentially catastrophic events. These were dubbed 'never events', that is, adverse events that should never occur as they were preventable through a standard checking procedure. Patient safety experts in Australia, in line with international initiatives, therefore highlighted safe surgery as a problem for which a simple and low-cost solution was available. The Australian Health Ministers' Conference in April 2004 subsequently included a five-step identification protocol as one of eight national initiatives, accompanied by target dates, in order to improve patient safety in public hospitals throughout Australia:

> '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' (Department of Health and Ageing 2004).

The aim of the correct patient, correct site and correct procedure protocol (the word 'right' was replaced by 'correct') was to prevent avoidable adverse incidents arising from misidentification by implementing a standard checking procedure. The protocol (hereafter termed the 3Cs protocol) set out five steps to be undertaken before any invasive procedure was performed on a patient. The Health Ministers also included wrong patient or body part incidents among the eight 'sentinel events', regarded as serious and avoidable, which were to be reported by public hospitals.

This study on the implementation of the 3Cs protocol arose for two reasons. First, it was part of an ARC Linkage Project on the governance of patient safety, the partners being the Australian National University, the Australian Commission for Safety and Quality in Healthcare, and ACT Health. The study aimed to analyse the 3Cs implementation from a regulatory perspective; regulation broadly meaning steering the flow of events. Although the 3Cs protocol was endorsed by the Health Ministers as a simple and self-evidently sensible risk management procedure, compliance within hospitals appeared to be slow and variable. Public hospitals in Australia are administered, directly or indirectly, by the States and Territories (hereafter for convenience termed States). Each State accordingly promulgated its own protocol policy and undertook its implementation strategy. This study aimed to trace the bumpy road from policy to practice, to identify the barriers to implementing the protocol, and to identify promising regulatory mechanisms for promoting compliance. The 3Cs story illuminates the different regulatory styles of State governments, hospitals, and professional groups.

The second impetus for this study was that Australian Commission for Safety and Quality in Healthcare included an implementation review of the 'Ensuring correct patient, correct site, correct procedure' protocol in its work program (endorsed by the Australian Health Ministers' Conference in July 2007) under Priority Program 4 'Patient Identification'.

This study of the 3Cs protocol explored several questions as follows:

- What can be learned from the 3Cs story about governance strategies?
- Did policy implementation differ between the States?
- Did policy implementation differ between hospitals?
- What were the perspectives of different professional groups?
- What strategies were used to promote compliance with the protocol and what was the impact upon compliance: What was done? What worked? What did not work? Why or why not?

- Do we know whether risks to patient safety have been reduced?

The literature was reviewed on international and Australian published research, and documentation was obtained on the correct patient/site/procedure protocol from website searches. Interviews with key informants were undertaken at several levels: overseas patient safety experts, Australian national bodies (the Commission, professional colleges, and accreditation bodies), State health authorities, hospital managers, and clinicians. Semi-structured interviews were undertaken in all State jurisdictions (New South Wales, Victoria, Queensland, Western Australia, South Australia, Tasmania, the Australian Capital Territory and the Northern Territory) in order to explore the implementation of the protocol from three perspectives: policy makers, hospital managers, and clinicians. In total 72 interviews were conducted between June 2007 and July 2008, mostly face-to-face and some by telephone, with 34 national and State-level policy makers, and 38 hospital managers and clinicians. These interviews involved staff from 20 hospitals in seven States.

1.2 Australian Health Ministers April 2004 resolutions

The Health Ministers' Conference in April 2004 resolved that all public hospitals would adopt the protocol, although authority for ensuring its adoption rests with State health departments. The Australian Council (later the Commission) for Safety and Quality in Health Care, as the advisory body to the Health Ministers, was tasked with promoting the protocol. The Council distributed a kit containing the five-step protocol, a fact sheet, a patient brochure, and workplace posters, all available for download from the Council (and later the Commission) website. A one-page poster (see Appendix A) set out five steps:

> Step 1: Check the consent form or procedure request form is correct;
> Step 2: Mark the site with an indelible pen 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 for staff to verbally confirm that all is correct;
> Step 5: Ensure appropriate and available diagnostic images

The rationale was that 'better ways of doing things can reduce the likelihood of something going wrong' (Australian Council for Safety and Quality in Health Care 2004). Some statistics was presented on wrong surgery incidents and several case examples were given. 'Robert' had a knee arthroscopy done on the right knee instead of the left knee because the site was not marked and medical record not checked. 'Joe Smart' replied to a call for 'Joe Short', was not required to state his name and date of birth, and received the wrong dose of radiation. 'Kylie' was admitted for an adenoidectomy but instead had both adenoids and tonsils removed because the wrong consent form was signed and her medical record was not checked.

The Australian Health Ministers, also at the April 2004 meeting, decided that public hospitals should report eight types of 'sentinel events', including 'procedures involving the wrong patient or body part'. A system for reporting sentinel events by public hospitals in each State, followed by the publication of a national report, thus was an opportunity to measure the extent of wrong patient/site/procedures and to track the impact of a standard checking procedure. The Health Ministers called for a national report to be compiled by the end of 2005:

> 'To require all public hospitals to report all sentinel events, either to the state department or to an agreed third party, no later than the end of 2005;
> That all states and territories will contribute to a national report on sentinel events to be produced by the end of 2005' (Department of Health and Ageing 2004).

1.3 International initiatives

Hospitals have long had policies for double-checking treatment procedures, for example, before administering medication. Hospitals now increasingly urge or require staff to undertake standard checks before undertaking any procedure on a patient. North American surgical groups from the 1990s onwards identified wrong surgery as an infrequent but potentially catastrophic error, prompted by extensive publicity over cases, such as amputation of the wrong leg in a Florida hospital (Carney 2006), and concerns by medical indemnity groups about the high costs involved in such events. Canadian and American associations of orthopaedic surgeons from 1994 onwards urged their members to mark the operative site. Other professional associations also began to issue alerts and guidelines, including surgeons (American College of Surgeons 2001) and operating theatre nurses (Canale 2005; Carney 2006). Much more attention now is being paid to this type of adverse incident. Searches of electronic databases, such as PubMed, identify increasing numbers of publications on the topic, such as 63 published papers for the search term 'correct site surgery' as at April 2008. Patient identification errors thus reached health policy agendas in several countries in the early 2000s with a confluence of concern by several groups: professional associations, hospital accreditation agencies, safety and quality NGOs, government health departments, medical indemnity organisations, and patient advocacy groups (see Appendix B).

The Joint Commission, the major US hospital accreditation body, has been a leader in promoting a correct surgery protocol. The Joint Commission issued a sentinel event alert on wrong site surgery in 1998 as a wake-up call that this type of avoidable adverse incident, although assumed to be infrequent, could be catastrophic for the patient. In 2001, it recommended that surgical teams undertake five steps or checks before operating, and included this procedure in accreditation criteria from 2003. In 2004, the Joint Commission issued and trademarked its 'Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery', which set out three main steps: a pre-operative verification process, marking the operative site, and time out immediately before starting the procedure (The Joint Commission 2004). Compliance was made mandatory from July 2004 for hospitals seeking accreditation. At a 'summit' with professional organisations in 2007, the Joint Commission agreed that the protocol should be extended to cover all invasive procedures, and that there should be 'zero tolerance' for failure to follow the protocol

The US Veterans Health Administration in 2002 issued a Directive, 'Ensuring Correct Surgery', to its over 150 hospitals and many clinics, and in June 2004 issued a revised Directive 'Ensuring Correct Surgery and Invasive Procedures', which required mandatory compliance with the five-step procedure (Veterans Health Administration 2004). (The Australian national 3Cs protocol issued in 2004 was based on the 2002 VHA directive). Many US States from the 2000s onwards, including New York, Florida, Pennsylvania and Tennessee, now recommend or require that that their hospitals implement correct surgery checking protocols (Carney 2006).

Other countries also have produced policies on correct surgery. For example, the UK National Patient Safety Agency issued a 'Correct Site Surgery Alert' to NHS staff in England in March 2005, but as a 'recommendation' rather than a directive, which referred to 'operating on the correct side of the patient and/or the correct anatomical location or level' (National Patient Safety Agency 2004). The focus was on surgery and the guidelines set out a 'pre-operative marking verification checklist' of four checks. The New Zealand Orthopaedic Association issued guidelines on surgical site marking in 2000 after a highly-publicised case of wrong-site surgery (Peterson 2003).

A standard checking procedure is now being promoted internationally. The World Alliance for Patient Safety, launched by the World Health Organization in 2004, endorsed the Joint Commission's Universal Protocol. The US Joint Commission was designated as a WHO Collaborating Centre on Patient Safety Solutions in 2005, and announced five Solutions for

Patient Safety (the High 5s), one of which is the Performance of Correct Procedure at Correct Body Site (WHO Collaborating Centre for Patient Safety Solutions 2007). The Alliance embarked on a 'Safe Surgery Saves Lives' campaign in 2007 and issued a safe surgery checklist and manual (World Health Organization 2008).

1.4 How frequent are wrong patient/site/procedure events?

In objecting to regulatory intervention on patient safety, many doctors maintain that medical errors are uncommon and atypical, despite accumulating reports on adverse events, and similarly the main objection to regulatory action on wrong surgery and wrong procedures is that such mistakes are too rare to warrant a checking protocol. Protocol advocates initially argued that misidentification errors were a problem, not necessarily in numeric terms, but rather because such avoidable errors could have disastrous consequences for patients, let alone for the doctor or nurse: 'Wrong site, wrong patient, and wrong implant procedures are relatively uncommon events in health care but are often devastating when they occur' (Veterans Health Administration 2004).

While the frequency of patient misidentifications errors is not yet clear, it appears that these incidents are not as rare as first thought. Better reporting in recent years has revealed that adverse incidents, including wrong procedures, are not uncommon. For example, US hospitals have reported increasing numbers of wrong-site surgery events each year to the Sentinel Events Database of the US Joint Commission, with the 625 reported wrong-site surgery events from 1995 to 2008 comprising 13 percent of all sentinel events (The Joint Commission 2007). Since this is a voluntary reporting system, these events are likely to be under-reported.

Several US States have established mandatory adverse event reporting systems. For example, State legislation in Pennsylvania requires all health services to report all 'serious events' to the Pennsylvania Patient Safety Reporting System. Large hospitals (300-bed plus) report one wrong-site surgery event on average each year, with 67 State reports in 2005, 76 in 2006 and 49 in 2007. Analysts believe these incidents also are under-reported, however, and that the drop in 2007 does not necessarily represent improved compliance with the wrong-site surgery protocol (Pennsylvania Patient Safety Authority 2008).

A spate of studies from particular specialties has begun to quantify the professional risk to clinicians. For example, the American Association of Orthopaedic Surgeons reviewed litigation data from 1985-1995 that suggested that an orthopaedic surgeon had a 25 percent chance of wrong-site surgery during his or her career (Canale 2005). This is likely to be an under-estimate, since not all patients sue. A survey of hand surgeons in the US found that at least 21 percent had undertaken wrong site surgery at least once in their career and a further 16 percent had had a near miss (Meinberg and Stern 2003). A survey of US spine surgeons found that half said that they had done one or more wrong level surgeries in their career (Mody et al. 2008).

The National Patient Safety Agency in the UK publishes quarterly summaries from the National Reporting and Learning System of reported patient safety incidents in the NHS. A Patient Safety Bulletin reported that 855 wrong surgery reports were made between 2003 and 2006 (National Patient Safety Agency 2007).

In Australia, a national report on sentinel events in public hospitals for 2004-05, found that wrong patient or body part procedures were the largest category, 53 out of 130, that is, 41 percent of total sentinel events (Australian Institute of Health and Welfare and the Australian Commission on Safety and Quality in Health Care 2007: 14). The report released in July 2007 attracted considerable media attention. The *Sydney Morning Herald* pointed out that 'the classic hospital horror story – surgery on the wrong patient or body part – also turns out to be the most common significant medical mistake in Australia'. *The Australian* heading read 'hospital bungles are killing scores'. The Australian Healthcare Association said that Australian hospitals are among

the safest in the world although ‘even one mistake is one too many’, while the AMA President described the number of errors as ‘very small’ and ‘almost reassuring’.

All States collect statistics on sentinel events through their adverse incident reporting systems although only four States regularly publish data. Table 1.1 shows the number of reported incidents since 2003-04 involving the wrong patient or body part by State as well as for the total for Australia in 2004-05. Comparisons across States are problematic, however, as measurements differ somewhat, and trend data are difficult to interpret. For example, does an increasing number of reports indicate better reporting or more sentinel events?

Table 1.1 Number of reports* of procedures involving the wrong patient or body part by State, 2003-04 to 2006-07

State/Territory	2003-04	2004-05	2005-06	2006-07
NSW	13	14	36	-
Vic	14	25	25	20
Qld	-	-	6	31
WA	1	10	5	6
SA	0	10	-	-
Tas				
ACT	-	-	-	-
NT				
Australia		53		

Source: Sources: NSW (NSW Health 2006), Victoria (Victorian Department of Human Services 2007); Queensland (Wakefield 2007: 25); WA (WA Office of Safety and Quality in Healthcare 2007: 6); SA (South Australian Department of Health 2007); Australia 2005-05 (Australian Institute of Health and Welfare and the Australian Commission on Safety and Quality in Health Care 2007);
*Note: Definitional differences limit comparability across States.

The first conclusion from Table 1.1 is that wrong patient/body part incidents are not uncommon; for example, there were 36 such incidents in NSW in 2005-06 and 25 in Victoria. These numbers are likely to be an under-estimate, however, since State adverse event reporting systems are still in the early stages. Taking the Pennsylvania reports as a guide, at least one wrong surgery incident could be expected each year from a 300-bed hospital. Given 52,236 beds in Australian public acute hospitals (Australian Institute of Health and Welfare 2008: 347-348), one might expect 174 incidents, rather than the 53 wrong patient or body part events reported across Australia.

The second point is that these incidents involve the wrong patient not just the wrong site or procedure. The national report on 2004-05 data found that of the 53 incidents, 20 involved the wrong patient (Australian Institute of Health and Welfare and the Australian Commission on Safety and Quality in Health Care 2007: 14). An analysis of the 31 wrong patient/body part incidents in Queensland in 2006-07, found that 14 involved the wrong patient, seven the incorrect site, five a left/right mix-up, and five the incorrect procedure (Patient Safety Centre 2007).

The third point is that incidents are not confined to surgery but also occur in non-surgical areas. For example, NSW data for wrong patient/site/procedure events for the first six months of 2007 found 32 errors with diagnostic tests, three errors in surgery, two in radiology, one in dentistry, and seven in other hospital areas (NSW Health 2007b). Victorian data for 2006-07 reported nine errors in surgery, nine in radiology, and two in other areas (Victorian Department of Human Services 2007). For example, radiation incidents in hospitals indicate the importance of extending the protocol. A report from the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) summarises incidents nationally (for 2004 data), and while it is unclear how well the States report incidents, the number of wrong patient/site/procedure radiation incidents in hospitals indicate that incidents are not uncommon: there were 31 reported incidents involving Nuclear Medicine patients, 16 incidents in Diagnostic Radiology, and 6 incidents in Radiotherapy

(ARPANSA 2007). The conditions of licence, under Regulation 46 of the *Australian Radiation Protection and Nuclear Safety Regulations* (Cth 1999), require a licence holder to notify the (ARPANSA) about any accident, while State legislation and/or regulations also require reporting of radiation incidents as a condition of licence, although details differ including the allowable thresholds for unplanned exposures.

The final point is that root cause analyses of wrong surgery incidents, as for all adverse incidents, indicate multiple causes, both human factors and system factors, with poor communication between staff generally emerging as a key factor (Vincent et al. 2000; Lingard et al. 2004). Checklists to ensure that communications between hospital staff are clear thus are one way to reduce patient safety risks.

Despite efforts to improve reporting, adverse events in Australian public hospitals generally are believed to be under-reported, although the extent is not known. Informants thought that less serious wrong patient/site/procedure incidents were under-reported, especially in non-surgical areas, although reports are likely to rise once the protocol is extended to these areas. State adverse incident reporting systems, given doubts about reporting reliability in hospitals, thus are not necessarily a good indicator to the effectiveness of the correct patient/site/procedure protocol.

It should also be noted that private hospitals (which provide about one-third of all beds) do not report adverse incidents to State databases. At least one private hospital chain, however, maintains its own database on adverse events and near misses, and monitors clinical risk trends based on the number and severity of adverse events by hospital and speciality group. Managers were confident that virtually all adverse events are reported given sensitivity to litigation by patients.

> (Manager private hospital chain) *Our reporting system on adverse events is pretty good. The doctors know when they may have medical indemnity exposure and they also notify us. Even if they did not notify us others around them would, since it is pretty rare that something happens and no-one else is around.*

1.5 Research on patient safety strategies

This study draws upon three areas of research literature: safety systems research, theories of implementation and the take-up of research knowledge, and theories of regulation. Key ideas relevant to implementing and monitoring a patient safety protocol are summarised below.

Research on safety systems

The 3Cs protocol is part of a larger effort to install safe system procedures and to inculcate a patient safety culture in hospitals. An important part of this effort is the push to greater standardisation. This arises from a view of a hospital as a form of 'high reliability organisation', a term coined to describe organisations where, since error can involve dire consequences, much effort goes into implementing safety systems that produce excellent safety track records. High reliability organisations seek to standardise procedures, but also to train staff able to make decisions in risky and unforeseen situations. There are two school of thought on strategies that best prevent accidents: high reliability theory and normal accident theory (Pizzi et al. 2001). High reliability theory holds that accidents can be prevented through better design and management, such as specification of work practices, while normal accident theory holds that since near misses and accidents are to be expected, people must be able to make decisions in a crisis rather than rely on a situation being covered by 'a rule'. A hospital must combine both these approaches.

Human factors research on errors in organisations has greatly influenced thinking on patient safety. James Reason argues that errors generally have inter-twined and multiple causes (Reason 1990; Reason 2000). Reason's central idea is that a high reliability organisation, such as a hospital, should engineer a series of safeguards to prevent a confluence of factors that allows an error to occur. Reason's 'Swiss cheese' model of how accidents can occur shows that an adverse

incident can result from a confluence of mistakes that singly might not matter, but together can be serious (Reason 2000). A high reliability organisation has several defensive layers that in an ideal world are intact, but in reality are more like slices of Swiss cheese with many holes, so that these holes can momentarily line up to permit a trajectory of accident opportunity that can result in harm.

> (Hospital CEO 1) *We had one actual event that shook people up. It got through all the safety layers. There was potentially a whole heap of stop signs that could have alerted people, but didn't, which is why that lesson was quite instructive. It showed that even with all those potential fail-safes, mistakes can happen.*

Modern hospitals are much busier and more complex places than in earlier decades. The risk of patient misidentification errors increases with more patients undergoing surgery and quicker patient throughput. For example, separations of patients from public and private hospitals in Australia increased steadily from 5.9 million in 1990-00 to 7.3 million in 2005-06, while the proportion of same-day separations increased from 49.2 percent to 55.3 percent (Australian Institute of Health and Welfare 2005; Australian Institute of Health and Welfare 2007).

Informants believed that the faster pace of work in public hospitals increases the risk of error. 'Everything has sped up, and that is why we need better checks'. For example, a surgeon may operate on over a dozen patients in the course of the day. In earlier years, a surgeon would see a patient in outpatients, then in the ward the night before, and again in the holding bay before the operation, but now in large public hospitals, the majority of surgery cases come in a few hours before surgery: 'the first time a surgeon sees a patient is when the patient is wheeled into the operating theatre'. The patient may be seen by a registrar in the outpatient clinic, an intern in the pre-operative clinic admission, the anaesthetist in the holding bay, and the surgeon in the operating theatre. Managing the operating list also is a complex task. A large teaching hospital has eight or more operating theatres and surgeons move between theatres and may only arrive for the first incision. An operating suite manager commented that 'there is quite a bit of coming and going. We usually have to chop and change the theatre list depending on availability schedules, clinical priorities and what is happening in theatre'.

> (State S&Q coordinator 1) *Some surgeons don't understand the number of risk points leading up to the person being rolled onto the operating table, given the way work is organised in a hospital. . . At the last moment the surgeons arrive. They scrub up and go in and expect that everything has been done correctly. They don't fully appreciate that they are taking responsibility for all the vulnerabilities in the system if they don't do that last check. That time out check is the last line of defence against mistakes being made.*

While the standardisation of equipment, devices, procedures and forms is common practice in other high-risk industries, the hospital sector has been slow to standardise, and mostly has left hospitals and clinicians to manage their own domains. This lack of standardisation causes confusion for staff, who work across several areas and more than one hospital in the course of their working life, and increases the risk of adverse events for patients (Runciman and Moller 2001). Different procedures are used even within one hospital, let alone across hospitals in one State and across several States. Efforts thus are underway to promote standardisation within the hospital sector, including a clinical handover procedure, a national medication chart, and electronic clinical documents. The 3Cs protocol is a prime example of this push to standardise. But as this study shows, it is difficult to standardise the details, as opposed to the principles, of patient safety checks that apply to all invasive procedures in one hospital, let alone in all public hospitals.

Implementation theory

An accumulating literature attests that governments, professional associations and employers are promulgating a correct patient/site/procedure, but less is known about its successful implementation, or about its impact upon patient safety outcomes (Michaels et al. 2007). As pointed out in an implementation literature classic, people should not be surprised when events do not turn out as expected, since 'implementation, under the best of circumstances, is exceedingly difficult' (Pressman and Wildavsky 1973: xii-xiii). The 3Cs policy was formulated as a self-evidently good idea that was expected to be easy to put in place in hospitals. Health policy makers and hospital managers thought that the simple and quick five-step standard checking procedure would be readily accepted and so were surprised to encounter a barrage of objections from clinicians.

> (Director of Surgery 3) *When it first came out I thought that's a no-brainer. Everyone assumed it was sort of being done already. And there are numerous occasions in everyone's experience where they had either heard of, or had been part of, a near miss, or had actually done the wrong thing. So we thought it wasn't going to be an issue.*

Implementation research typically finds that policy makers pay insufficient attention to implementation since practice is expected to seamlessly follow policy. There is, however, a large terrain to traverse between agreeing on a solution and putting it into practice at the local level. Considering that the protocol had to be implemented at several levels (national, State, hospital, hospital unit, and health professional), Chase's admonition to 'walk through' the political and bureaucratic terrain is particularly apt:

> 'One must have a keen sense of the political and bureaucratic terrain where the program is taking place and be able to 'walk through', step by step, all the functions involved in the program's continuing operation, all the actions necessary to assemble the required resources, and all the likely intersections with relevant political and bureaucratic actors … In walking through the program one must try to anticipate what is going to happen – and especially what will go wrong' (Chase 1979: 387).

National policy implementation in the Australian health sector involves blurred lines of accountability and several administrative layers: the Australian Government, State health departments, hospital managers, and health professionals. There are few levers of direct governance in relation to clinical performance at the national level. Public hospitals are the responsibility of the eight States and Territories although approximately half-funded by the Australian Government via the Australian Health Care Agreements. The protocol had to be rolled out across many hospitals and many health professionals. Australia has over 1,290 hospitals, including private sector hospitals that provide a sizeable proportion (about 34 percent) of hospital beds (Australian Institute of Health and Welfare 2007: 16). Most State governments have governance power over public hospitals, but very little power over private sector hospitals.

Hospitals also are a pre-eminently complex form of organisation. Their governance structure varies according to the State (hospitals in some States have boards and in others are directly run by health departments), type of ownership (public or private), and the size of the hospital (large teaching hospital or small community hospital) (Duckett 2007: 176-179). Nearly 570,000 health workers, in increasingly specialised occupational groups, were employed in 2005 in the Australian economy, with nurses by far the largest group (305,400), and medical practitioners (59,900) the most powerful group (Australian Institute of Health and Welfare 2006: 316). The internal governance arrangement between doctors and hospital manager is notoriously delicate, as are relationships between professional groups. Doctors, both salaried and visiting, are in a strong bargaining position in hospitals, as are nurses by virtue of their numbers and union power (Willis et al. 2005). The take-up of a protocol within a hospital thus depends upon its acceptability to clinical leaders and to several professional groups.

(Hospital clinical governance director 1) *The correct patient protocol has to take account of the dynamics that go on within hospital teams. The time out procedure has to be implemented in a human factor-rich environment with a very narrow view of the world. There hasn't been much support or guidance across the nation on how to do this.*

Evidence-based systematic reviews show that standardised protocols and clinical guidelines improve the safety and quality of patient care (Shojania et al. 2001; Leape and Berwick 2005). The correct patient/site/procedure protocol was based on lessons from other high risk industries, on 'best practice' consensus, and on analyses of the causes of adverse incidents. 'Considered preventable occurrences, these cases are largely the result of miscommunication and unavailable or incorrect information. Detailed analyses of these cases indicate that a major contributing factor to error is the lack of a standardised pre-operative process and likely a degree of staff automaticity (checking without thinking) in the approaches to pre-operative check routines' (WHO Collaborating Centre for Patient Safety Solutions 2007). Studies in specialty journals indicate the frequency of wrong patient/site/procedure incidents and the introduction of the protocol in some specialty units, but so far there are few studies on implementation strategies (Michaels et al. 2007).

The take-up of research knowledge and policy innovations in the health sector tends to be slow. Research studies show that the take-up by health professionals of voluntary clinical practice guidelines is low and slow, that multifaceted interventions to improve compliance are much more successful than single interventions, and that well-designed and sustained implementation programs are required (Freemantle 2002) (Grimshaw et al. 2001) (Grol and Buchan 2006). This suggests that embedding the 3Cs protocol in a hospital would require multiple and repeated regulatory interventions. Informants in this study also commented that it is not easy to change entrenched professional cultures and practices.

(Hospital medical director 2) *It takes awhile to change entrenched cultures and ways of doing things. . . I guess it's like all people with change. They don't embrace it willingly. The response is, you have to show me why this is necessary, as opposed to saying, well, this looks interesting. Mm, I can reflect and think about that and maybe I should do something about that.*

Regulatory theory: encouraging and/or enforcing compliance

Regulation in the Australian health sector traditionally has relied upon health professionals to voluntarily adopt clinical practice innovations. Health policy makers and managers, however, are looking for ways to ensure that facilities and professionals comply with evidence-based practices that are intended to reduce the risk of harm to patients. Regulation within the era of regulatory capitalism generally is defined in its broad sense, meaning much the same as governance in its broad sense: both meaning steering the flow of events through governance as well as through the provision of equitable resources (Braithwaite 2008). How can health sector managers steer professionals towards performing patient safety checks? Julia Black points out that regulation is mainly about changing the behaviour of individuals, a view that resonates within hospitals:

'Regulation is the sustained and focused attempt to alter the behaviour of others according to defined standards or purposes with the intention of producing a broadly identified outcome or outcomes, which may involve mechanisms of standard-setting, information-gathering and behaviour-modification' (Black 2002: 96).

Regulatory action in most sectors of the economy mostly takes place at the bottom of a regulatory pyramid (Braithwaite and Drahos 2000). The responsive regulation model argues that regulation is not just about enforcing compliance with a 'rule', but involves multiple regulatory actors and multiple strategies ranging from persuasion to enforcement (Ayres and Braithwaite 1992;

Gunningham and Grabosky 1998: 424-426). Regulators should begin with soft mechanisms at the base of the regulatory pyramid, such as providing information, which gives the cheaper and more respectful options a chance to work first, rather than opting immediately for harder mechanisms at the apex, such as reprimands and dismissal (Ayres and Braithwaite 1992; Braithwaite 2002). These multiple regulatory mechanisms can be located on a pyramid of supports as well as a pyramid of sanctions (Braithwaite et al. 2007).

The responsive regulation model is particularly relevant to the health sector, since it argues that regulators are more likely to succeed by being responsive to the context, conduct, and culture of those being regulated. The health sector is characterised by many regulatory actors who apply a diverse range of regulatory mechanisms. Much governance, especially in relation to clinical performance, however, relies on voluntary compliance by clinicians and on self-regulation by professional groups (Braithwaite et al. 2005; Healy and Braithwaite 2006). Multiple regulatory mechanisms are necessary since a single mechanism is seldom sufficient, and the weaknesses of one mechanism should be complemented by the strengths of another. Further, the regulators must have the capacity to escalate up the pyramid if necessary, since those being regulated must believe that regulators will inexorably insist upon compliance. The learning model approach usually taken in the health sector may need to be backed up by an inspectorial approach, if it transpires that compliance with an agreed standard is low.

2. Australia and the States: promulgating the protocol

Authority for implementing the 'Ensuring Correct Patient, Correct Site, Correct Procedure'2004 protocol derived from several sources. Political authority came from the Australian Health Ministers who tasked the Australian Council for Safety and Quality in Health Care with promoting the protocol. Professional authority came from endorsements from the US Veterans Health Administration (VHA), the Royal Australasian College of Surgeons (RACS), as well as from the patient safety professionals on the Australian Council for Safety and Quality in Health Care. Financial authority was not sought in the form of incentives or sanctions attached to the protocol, and legislative authority was not sought through State legislation. Administrative authority depended upon the State health departments.

The States promulgated the protocol with varying degrees of authority. State health departments differ in their governance of public hospitals: some issued the protocol as a mandatory directive and others as a recommended guideline. State health departments traditionally have left the monitoring of clinical performance to hospitals and doctors. The Health Ministers have not called for an audit on implementation within hospitals of the patient safety protocol. While State health departments all maintain that a protocol has been implemented in all their public hospitals, there is little national-level data to verify that it is in place. Information on protocol compliance by health professionals also is patchy, since State health departments mostly assigned monitoring responsibility to hospitals or area administrations.

This chapter reviews the national and State regulatory authorities that are involved in promoting the protocol, and summarises their main regulatory strategies: engaging the leaders, issuing a guideline/directive, reporting on wrong patient/site/procedure incidents, analysing information on wrong patient/site/procedure incidents, and monitoring compliance with the protocol.

2.1 National regulatory bodies

No single authority is responsible for the Australian health sector. Several national bodies take a regulatory interest in patient safety issues: the Health Ministers, the Australian Council for Safety and Quality in Health Care as the advisory body to the Health Ministers, the medical colleges through advice to their members, and the Australian Council on Healthcare Standards (the hospital accreditation NGO).

Australian Health Ministers' Conference

The Australian Health Ministers' Conference is the main intergovernmental health sector forum, comprising Health Ministers from each of the States as well as the Australian Government. While decisions are not binding in the contractual or legal sense, the expectation is that State Health Ministers take an endorsed policy back to their States to be implemented. Authority for implementing patient safety initiatives thus mostly depends upon the State jurisdiction. The associated Australian Health Ministers' Advisory Council (AHMAC) consists of senior national and State health officials who consider health matters referred by the Conference, or by any of the Health Ministers, and who report back on these matters to the Conference.

> (State S&Q coordinator 1) *It was important that the protocol came out as a directive from the Health Ministers. But we initially had lots of resistance because people said why would the health ministers come up with this one? We don't have a problem. Why would we start with this?*

Australian Council (later the Commission) on Safety and Quality in Healthcare

The Australian Council for Safety and Quality in Health Care (2000-05) was set up as an advisory body by the Australian Health Ministers' Conference. Its mandate was to lead and coordinate safety and quality improvements, identify policy directions, and recommend priorities for action.

The Council was replaced in January 2006 by the Australian Commission on Safety and Quality in Health Care with a twelve-member council, an inter-jurisdictional sub-committee of health department officials, and managed by a chief executive officer. As an advisory body, the Commission has no direct authority, and recommendations for action go to AHMAC and then to the Australian Health Ministers' Conference.

> (Orthopaedic surgeon 2) *Bruce Barraclough's [Council chair] protocol came out with pretty pictures. It was adopted by the State health department and we were told by the hospital that we had to implement it.*

The Colleges

The Colleges provide specialist training, ensure that applicants have the appropriate qualifications for membership, offer professional development programs, and represent the interests of their members. They are not statutory bodies and have no legislative power over their members. The 12 medical colleges issue position statements, communiqués, reports and guidelines. Some colleges have issued correct patient/site/procedure guidelines, namely the Royal Australasian College of Surgeons (RACS), the Royal Australian and New Zealand College of Opthalmologists (RANZCO), and the Australian College of Operating Room Nurses (ACORN). Since State health departments are rolling out the protocol to clinical areas in addition to surgery, other Colleges may wish to develop their position on a protocol. The Colleges generally advise their members, rather than tell them what to do, and are reluctant to badge a policy or a position statement as 'a standard'.

The Royal Australasian College of Surgeons, which covers 13 surgical specialties across Australia and New Zealand, has been the most active on this issue. The RACS Council issued its 'Correct Side and Correct Site Surgery Guidelines' in 2003 followed by 'Implementation Guidelines for Ensuring Correct Patient, Correct Side and Correct Site Surgery' in 2004 and again in 2006 (Royal Australasian College of Surgeons 2006). The 2006 version strengthened the time out recommendation from a 'may' to a 'should'. RACS wishes to maintain the highest professional standards but also wants to defend its Fellows from 'unwarranted intrusion' and warns that 'draconian bureaucratic interference would be counterproductive' (Atkinson 2008). The RACS website also directs members to the protocol put out by the Australian Council for Safety and Quality in Health Care. (The Chair of the Council, Professor Bruce Barraclough, was a previous RACS President).

> (RACS council member) *The College of Surgeons said that Bruce Barraclough's protocol was almost identical to the RACS guideline … There was a bit of argy-bargy at the College about how much people were prepared to accept this time out business. But the protocols were about the same and so the College endorsed it.*

> (Hospital clinical governance director 1) *The College of Surgeons material was very, very important. Peer processes are needed to get some traction.*

The next RACS review, scheduled for late 2008, will be undertaken by a working party, chaired by an orthopaedic surgeon, and will involve consultation with 13 RACS specialty societies across Australia and New Zealand, RACS regional committees, other Medical Colleges, and medical defence organisations. Issues likely to be discussed include marking the site, whether the final check should occur before the patient is anaesthetised, and delegation within the operating team. It would be a major challenge to harmonise the protocol with the practices of different surgical specialties and views of other colleges.

> (Director of Surgery 3) *It would help if the major professional bodies said the same thing. If they can't agree then a government body should say how it's going to be done and lay down the law and then there is no argy bargy about it. . . It is no good*

saying 'Here's a policy, if you fancy taking it on that would be a good thing, but if you don't we don't really care'.

Australian Council on Healthcare Standards

Accreditation standards potentially offer a regulatory strategy for embedding the patient safety protocol. The Australian Council on Healthcare Standards is the main hospital accreditation body. The great majority of hospitals in Australia seek accreditation: 83 percent of all public hospitals in Australia in 2004-05 were accredited (Department of Health and Ageing 2006: 11). The third edition of the accreditation manual, EQuIP 3rd edition, set out a non-mandatory standard 2.4.2 on a correct patient/procedure safety check. The accreditation manual, EQuIP 4th edition, sets out 13 standards plus sub-standards (58 criteria including 14 mandatory criteria), including non-mandatory sub-standard 1.5.6 'The organisation ensures that the correct patient receives the correct procedure on the correct site' (Australian Council on Healthcare Standards 2006: 49-50). The five point score (levels of achievement) awarded for compliance with 1.5.6 ranges upwards from adopting the protocol, achieving total compliance with the protocol, having no wrong patient/site/procedure incidents, to being a leader in the field. From January to June 2007, applicants could choose to be reviewed against old or new standards (60 percent chose new standards), and from July 2007 all were reviewed against EQuIP 4 standards. Data could be gathered from 2007, therefore, on the extent of achievement by accreditation applicants against criterion 1.5.6.

2.2 Issuing guidelines/directives

The Australian Health Ministers Conference in April 2004 set a target date for the end of September 2004 for the adoption of the national 3Cs protocol by all public hospitals. The Health Ministers stated that hospitals 'will adopt' the protocol but did not state unambiguously that compliance was mandatory since this was a matter for the States. State health departments must promulgate a protocol if it is to carry administrative force with public hospitals. What's in a name? The term 'protocol' means 'the accepted or established code of behaviour in any group, organisation, or situation' (Oxford English Dictionary), or 'a detailed plan of a … treatment or procedure' (Medline Plus Dictionary). The procedure was variously termed a protocol, a guideline, an alert, an operational circular, a policy, a position statement, a standard, and a directive.

Table 2.1 sets out the protocols and revisions issued nationally and in each State. The States vary in the degree of authority attached to the protocol and the extent of compliance expected form health professionals. Three States (NSW, WA, SA) issued a directive, four States a policy (Queensland, SA, Tasmania, NT), and Victoria issued a guideline. Is a policy, as opposed to a directive, intended to be mandatory? Mandatory directives also tend to contain let out words and clauses to allow for special or unforeseen circumstance. Even if a State issues a mandatory directive, a hospital must then disseminate the policy, and may find it difficult to enforce compliance by health professionals (as discussed in Chapter 3).

Table 2.1 Protocols on correct patient/site/procedure

Authority	Protocol title	Issued by	Date	Authority	Clinical area
Australian Commission on Safety & Quality in Healthcare	Ensuring correct patient, correct site, correct procedure	Council/Commission Health Ministers	April 2004	Policy	All invasive procedures
Royal Australasian	Correct Side and Correct Site Surgery Guidelines;	RACS Council	Oct 2003	Guideline	Surgery

College of Surgeons	Implementation Guidelines for Ensuring Correct Patient, Correct Side and Correct Site Surgery; Implementation Guidelines etc		Oct 2004 Oct 2006		
Australian Council for Healthcare Standards	Standard 1.5.6	ACHS	2006	Voluntary standard	All invasive procedures
NSW	Patient Identification, Correct Patient Correct Procedure and Correct Site Model Policy 2005_380	D-G NSW Health	Nov 2004	Model Policy	Surgery
	Policy Directive: Correct Patient Correct Procedure and Correct Site PD2007_079	D-G NSW Health	Oct 2007	Directive	Surgery, Radiation Oncology, Nuclear Medicine, Radiology, Oral Health.
Vic	Ensuring Correct Patient, Correct Site, Correct Procedure	DHS	2004	Guideline	Surgery
	DHS letter to CEOs	DHS	2006	Guideline	All invasive procedures
	RACS 2006 Guidelines	Victorian Surgical Consultative Council	April 2007	Guideline	All invasive procedures
Qld	Ensuring Intended Surgery (EIS) Policy No. 26961	Health Safety and Quality Board; Qld Health	March 2005	Policy	Surgery
WA	Correct Patient, Correct Site and Correct Procedure Policy and Guidelines 2005	Council Safety & Quality in Health Care; Office Safety & Quality in Health Care	March 2005	Circular	Surgery
	Correct Patient, Correct Site and Correct Procedure Policy and Guidelines for WA Health Services OD0004/06	Council Safety & Quality in Health Care; Office Safety & Quality in Health Care	Nov 2006	Directive	All invasive procedures
SA	Patient Safety Framework Policy (PSFP-04-1) Ensuring Correct Patient, Correct Site, Correct Procedure.	CEO Health Dept	Oct 2004	Policy	Surgery and other invasive procedures
Tas	In draft form			Draft policy	
ACT	5 Step Correct Patient, Correct Site, Correct Procedure Policy	Chief Executive, ACT Health	Sept 2005	Directive	All operative and interventional procedures
NT	Correct Patient, Correct Procedure, Correct Site Policy	Executive Acute Care Division	March 2007	Policy	surgery

A clinical practice guideline is regarded by clinicians as discretionary. Clinical guidelines are becoming an important part of clinical risk management, however, since the standard of care exercised by a practitioner may be regarded as unsatisfactory by a court or an employer, should a clinical practice guideline not be followed, unless a departure can be justified on clinical grounds. The intention of a guideline, however, is to guide rather than prescribe.

> ‘Clinical practice guidelines are not intended to replace clinical judgement, nor can they. They are not prescriptive, but serve to guide practitioners in making relevant clinical interventions. Used correctly, they can assist more informed and meaningful patient participation in treatment decisions. They can enhance and maintain professional standards and quality assurance programs. By reducing unnecessary

> variations in practice they may encourage cost-effective healthcare' (Dwyer 1998:292).

By mid 2008, there was no standard protocol across Australian public hospitals, but rather a variety of protocols and revisions (see Table 2.1). Some States had issued the national 3Cs protocol largely unchanged (SA, ACT), some States retain a focus on surgery (Queensland, Tasmania, NT), some States have revised and expanded the scope (NSW, WA), while others (Victoria) promote the RACS protocol.

The issuing authority differed somewhat in each State depending upon the administrative structure and culture of its health sector. A protocol (as at mid 2008) was issued in four States by the CEO or a director of the State health department, in two jointly by the State health department and State safety and quality body, and in one State by the Surgical Consultative Council. All the States have advisory safety and quality councils and in Queensland and WA these were involved in issuing the protocol. In other States, health departments drew on other consultative groups; for example, specialty working parties in NSW, a Clinical Risk Management Group in Victoria, and Acute Care Quality Committee in the NT, and a working party of hospital quality coordinators in SA.

> (Hospital S&Q coordinator) *I have been on the State 3Cs working party for a couple of years … It has been beneficial in that we have a central forum where people from different hospitals can discuss their issues and hear what the health department thinks and what they are doing in other States. Networking in safety and quality is incredibly valuable and certainly in our State it is done well.*

The protocol in most States initially was applied to surgery with the intention of phasing in its introduction to other clinical areas. Four States (as at mid 2008) had issued protocols to cover all invasive procedures. NSW has done considerable work in adapting the protocol to cover areas of hospital practice additional to surgery. The extension of the surgery protocol to cover all invasive procedures is in line with some overseas practice, such as the 2004 US Veterans Health Administration Directive:

> 'Surgical or other invasive procedures are those involving a skin incision or puncture including, but not limited to: open surgical procedures, percutaneous aspiration, selected injections, biopsy, percutaneous cardiac and vascular diagnostic or other interventional procedures, laparoscopies, endoscopies, and excluding venipuncture or intravenous therapy' (Veterans Health Administration 2004).

2.3 The States and the protocol

The history of the protocol in each State is summarised below, focussing on the type of protocol, the issuing authority, the strength of authority (whether mandatory or voluntary), revisions to the protocol, its roll out to all invasive procedures, and strategies for monitoring implementation.

New South Wales

NSW Health in November 2004 required Area Health Services to implement and to monitor compliance with a protocol 'model policy'. Public hospitals are administered by Area Health Services (reduced from 17 to eight in 2005). The policy was adapted from the national 3Cs protocol, signed by the Director-General of NSW Health, endorsed by several professional colleges, and was accompanied by a poster for staff, and a brochure for patients translated into 18 languages. In October 2007, NSW Health issued a revised protocol, the 'Policy Directive: Correct Patient, Correct Procedure and Correct Site' (NSW Health 2007c). The 15-page policy stated that compliance was mandatory, set out responsibilities at each management level, and a checklist for each step of the protocol for staff. The Directive covered Surgical Services, Radiology, Nuclear Medicine, Radiation Oncology, and Oral Health, and a 'Correct Patient/Procedure/Site Safety

Toolkit for Clinicians' was developed for each specialty by specialty working parties (NSW Health 2007a). The NSW Quality and Safety Branch has proposed a standard methodology since the Area Health Services each had developed their own method for audit compliance by clinicians. The 2007 policy toolkit contains a standard audit tool including a form for auditing patient records, an Excel workbook to calculate the extent of non-compliance, and a State-wide audit was being planned.

Victoria

The Victorian Department of Human Services does not directly administer hospitals and promotes patient safety and quality through its Quality Branch. Hospitals and other public health services in Victoria are grouped into administrative networks, each with an autonomous board (15 metropolitan and five rural health services in 2007). The Department circulated the protocol to area boards in 2004, and wrote to CEOs in 2006 requesting them to extend the protocol to all invasive procedures. In April 2007, the Victorian Surgical Consultative Council, via the Department, issued the revised RACS 'Correct Side and Correct Site Surgery Guidelines' (Victorian Surgical Consultative Council 2007). The Department periodically requests health services boards to report back on implementation and compliance with the protocol.

Queensland

The Queensland Health Safety and Quality Board approved the 'Ensuring Intended Surgery (EIS) Policy' in March 2005 (Queensland Health 2005). Hospitals are administered by Queensland Health via district administrative offices (20 districts in 2008 and the Mater Hospitals). Queensland Health embarked upon extensive reforms in 2006 after several public inquiries; for example, the Patient Safety and Quality Board was reorganised and a new Health Quality and Complaints Commission was given greater investigative powers. Queensland Health engaged in stakeholder consultations on the EIS policy, which applies to surgery and calls for a four-step checking procedure, and assigned responsibility for monitoring the policy to its Patient Safety Centre.

Western Australia

The WA policy was released in 2005 by the WA Council for Safety and Quality in Health Care and the departmental Office of Safety and Quality in Health Care. Hospitals in WA are administered by the health department through four Area Health Services. In 2006, the 'Correct Patient, Correct Site and Correct Procedure Policy and Guidelines' was re-issued as a policy directive and extended to all invasive interventions (WA Office of Safety and Quality in Healthcare 2006). An accompanying 24-page report, including a verification checklist, recommended that 'all WA clinicians and hospitals /health services' adopt the policy, which could be 'tailored to suit clinical and administrative conditions at the local level'. Area Health Services were to implement regular audits to verify compliance with the five-step process.

South Australia

The Department of Health issued the 'Ensuring Correct Patient, Correct Site, Correct Procedure' as a departmental policy in October 2004 (South Australian Department of Health 2004). The protocol was endorsed by the Royal Australasian College of Surgeons, Australia and New Zealand College of Anaesthetists and the SA Perioperative Nurses Association. Hospitals are administered by the Department after hospital boards were abolished in 2004. The protocol was adapted from the national 3Cs protocol and the NSW directive. The health department CEO informed all health facility CEOs that they were required to implement and monitor compliance with the protocol. The protocol applied to surgery and other invasive procedures that expose patients to risk of harm. The Departmental safety and quality advisor convened a State-wide working party to advise on implementation.

Tasmania

The Department of Health and Human Services has a quality assurance committee in each of the three large public hospitals (Royal Hobart, Launceston General, and the North-West Regional

Hospital at Burnie), and in the community health division, and the ambulance service. The department has developed a draft policy on the protocol.

Australian Capital Territory

ACT Health directly administers three public hospitals, has a safety and quality unit and an advisory Quality and Safety Forum. The CEO in September 2005 issued a '5 Step Correct Patient, Correct Site, Correct Procedure Policy' that stated that compliance was mandatory (ACT Health 2005). The protocol, based on the national 3Cs protocol, applies to all operative and interventional procedures with potential to cause unintended harm to patients.

Northern Territory

The Department of Health and Community Services directly administers the five public hospitals. The 'Correct Patient, Correct Procedure, Correct Site Policy' issued in 2007 applied to surgery and was adapted from the NSW Directive. Hospital CEOS were made responsible for implementing the policy. The Acute Care Quality Committee of hospital quality coordinators advises the department on implementation and monitoring.

2.4 Monitoring protocol compliance

Analysing information on wrong patient/site/procedure events

Most States require their public hospitals to undertake investigations, including root cause analyses, of serious adverse events, since these present an opportunity to learn from mistakes. Learning is widened if cases are aggregated at State or national level so that patterns can be discerned. An informative analysis was done in Queensland on the 31 cases involving the wrong patient or body part reported in 2006-07 to the Queensland Sentinel Event Register (Patient Safety Centre 2007). The first point is that the 17 incident categories demonstrate the many things that can go wrong. The second point is that the analysis showed that the four safety steps in the Queensland protocol generally had not been followed in these cases. Informed consent was checked in only 13 percent of cases; the site was marked in only 6 percent; the patient ID was checked in 39 percent; and a final check was performed in only 3 percent of cases. These findings suggest that errors might have been prevented if the protocol had been followed (Patient Safety Centre 2007: 7).

Monitoring compliance with the protocol

The Health Ministers did not request a national regulator to monitor implementation of the protocol in public hospitals, although State health departments reported via the Health Ministers in mid 2005 that the protocol and accompanying material had been issued to all public hospitals (Australian Council for Safety and Quality in Health Care 2005). What hospitals mean by implementation varies, however, and the extent of compliance by clinicians with the protocol also varies. Overseas studies have found that clinicians vary considerably in how they interpret, and whether they comply with, the correct patient/site/procedure protocol. For example, surgeons in the English NHS continued to vary on whether and how they marked the operative site after the issue of the 2005 'Correct Site Surgery Alert' (Giles et al. 2006). The Pennsylvania Patient Safety Authority, in an observational audit in six hospitals in 2007, also found considerable variation in the use of the Joint Commission Universal Protocol (Pennsylvania Patient Safety Authority 2008).

All State health departments, except Queensland, assigned responsibility for monitoring compliance with the protocol to their area administrations or to the hospitals. Some State health departments invoked a meta-regulation strategy by requiring hospitals to report back on their implementation and on the results of compliance audits. The regulatory argument is that a State health department need not act as a direct regulator so long as it can be assured that a hospital is internally monitoring itself. Some States set up a working group to negotiate an audit with hospitals, and some are considering whether a report-back mechanism should be included in any future protocols.

(State S&Q coordinator 1) *I think a failure in the planning of this policy was not to have a report back mechanism on implementation and compliance auditing. We need to respond on how well or not people are doing. . . We should have attached an audit tool to the protocol.*

The Australian Commission for Safety and Quality in Health Care asked each jurisdiction for an update on progress with the eight national actions agreed in 2004, and later in 2007 asked for information about any compliance audits conducted on the 3Cs protocol. Most States responded with a general indication that a protocol was in place. Only a few States had conducted some type of audit, which varied on whether this was State-wide, a sample of hospitals, or an audit of particular clinical areas. The audit methodology differed, being based on reports from hospitals, or a retrospective audit of records across hospitals, or an observational audit, while the audits varied on whether they covered some or all steps. Three States provided some audit results confidentially to the Commission.

One jurisdiction said that the majority of health services stated that they have achieved 90-97 percent compliance with the protocol, although it is unclear whether this meant all steps or only the final check (team time out). Other jurisdictions that conducted observational surveys found lower rates of compliance of around 70-80 percent, with variation across sites and specialties, and with compliance lowest for marking the site and for full team participation in time out.

For example, one jurisdiction conducted observational audits on 40 hospitals/facilities across 20 districts with 682 surgical cases audited in 2006 and 649 in 2007. The survey found that compliance in operating theatres increased over those two years, although there was considerable variation across the sites. In 2007, patients were checked against the consent form in 76 percent of cases; the procedure was checked against the consent form in 72 percent of cases; the site was marked (mostly with initials) in 54 percent of cases prior to the patient entering the operating theatre; and a final check was carried out in 82 percent of cases, with full team participation in 57 percent of cases. An observational audit in another jurisdiction in 2006-07 on 1704 surgical procedures in hospital operating theatres across 11 districts also found considerable variation across districts and specialties. The patient and procedure was checked against the consent form in 95 percent of cases; the site was marked in 69 percent of cases (with compliance highest for laterality issues); and team time out was performed in 80 percent of cases.

In summary, the few robust studies of compliance with the protocol among clinicians have found that compliance is not universal, that it varies across the steps in the protocol, and across specialities and geographic sites, but that compliance has improved over time with repeated regulatory interventions.

3 The professionals: views on the protocol

The protocol stimulated discussion in Australian hospitals about hospital procedures, professional cultures, and clinical practices. On the positive side, these regulatory conversations raised awareness about patient safety risks and preventive practices. On the negative side, it provoked another round of disagreements between professional groups: 'it gave them something else to argue about'. Objections to the protocol revolved around three main issues: the applicability of the protocol to a specialty area, who was responsible for each check, and how each check should be undertaken. While the correct patient/site/procedure protocol issued in 2004 by the Australian Council for Safety and Quality in Health Care covered all invasive procedures, most public hospitals began by introducing the protocol in surgery. Informants thus mostly reflected on their experiences in implementing the protocol in operating suites.

3.1 Professional groups

The protocol opened up another arena for hospital power battles: between managers and clinicians over medical governance, between doctors and nurses over medical dominance, and between specialty groups over professional cultures since each of the surgical specialities had different checking procedures. While the protocol offered an opportunity to reinforce teamwork in some hospitals, in others it aggravated territorial demarcation disputes. In considering these disagreements, it is salutary to remember that an operating theatre is a high-pressure work environment, a range of system and human factors are involved, and implementing any new procedure is seldom easy.

> (Hospital clinical governance director 1) *People are too quick to blame surgeons for not complying with the protocol. . . In my experience, failures have nothing to do with personality, but rather big things going on that directly impact on performance. It is an insult and disrespectful to the surgeons and others to say it is a personality issue. It's not about that. It's about human factors and about working in high-pressure, often stressful situations, and getting a safe outcome for the patient.*

Surgeons

Many surgeons initially were not enthusiastic despite the protocol having been championed by their College. Surgeons had been expected to 'own' the protocol in line with the guideline from the Royal Australasian College of Surgeons. Informants thought that most surgeons finally came 'on board' but several objections had to be overcome. The personal responsibility objection by surgeons was that safety in an operating theatre is up to them rather than a system responsibility of the hospital: 'ultimate responsibility for things going right or wrong rests with the surgeon'. The related professional autonomy objection was that surgeons do not like being told what to do by 'managers', and did not like 'rules' since 'surgeons are trained to make split second decisions not follow set procedures'. The infallibility objection was that some surgeons did not believe there was significant risk of error, or that they could get it wrong with their patients. Despite the anecdotes recounted by all surgeons, some did not acknowledge that 'mistakes can happen to the best of surgeons'. Others did not appreciate the many points within a hospital where identification errors could occur before a patient is lifted onto the operating table. The efficiency objection was that the protocol would take up too much operating theatre time. The relevance objection was that each specialty had its own way of doing things, particularly on marking the site on the patient. Finally, the authority objection was that some surgeons were annoyed that the hospital assigned responsibility for safety checks to other team members and urged them to speak up if there were concerns.

> (Director of Surgery 1) *We ran it past the surgeons at our meeting and nobody was particularly negative. But nothing much happened for awhile except for some*

stalling. Then the objections started. The surgeons said it was another example of bureaucracy gone mad. The nursing staff said if the surgeons aren't taking it seriously why should we, it's not a nursing problem. The anaesthetists said, yes it should happen, but it's not our problem, the surgeons need to take responsibility.

(State S&Q coordinator 1) *The surgeons believe that mistakes only happen to bad surgeons. But lawyers point out that the surgeons that they represent usually are not bad surgeons. They are good surgeons and of high repute. The surgeon in New South Wales who removed the wrong breast was a well respected surgeon.*

Anaesthetists

Anaesthetists do their own identification checks prior to administering an anaesthetic block or general anaesthetic, often in an anaesthetics room adjacent to the operating suite, and often assisted by an anaesthetics nurse. Some anaesthetists did not view the final check as their responsibility: 'We just put the patient to sleep and wake them up'. Nurses complained that they had to watch that the anaesthetist participated in team time out along with the surgeon and the nurse. There are exceptions, of course, and anaesthetists in some hospitals are strong patient safety advocates. As discussed later, some anaesthetists argue that the final check should be done before, not after, the anaesthetic is administered.

(Director of Surgery 1) *Anaesthetists have a long history of initiating safety practices. But some anaesthetists said, I'm just there to give the anaesthetic, it's nothing to do with me. Others embraced it saying it is imperative that time out occurs when the patient is awake. It's a waste of time when the patient is anaesthetised. We've got to do it when the patient is awake and you must issue a directive to that effect. I groaned but I was really pleased they were owning it. You know, if we're going to do it, we're going to do it bloody well properly.*

Orthopaedic surgeons

Orthopaedic surgeons generally were regarded by informants as a pro-protocol group who had pushed the protocol within the Royal Australasian College of Surgeons. As noted earlier, associations of orthopaedic surgeons internationally have been active on this issue. But while the 'sign your site' campaign by the American Association of Surgeons reached 70 percent of its members, only about half routinely follow the recommendations (Canale 2005). Orthopaedic surgeons are used to dealing with laterality issues, however, and are trained to be careful about wrong side surgery. They have a long-standing practice of marking the site, although the method of marking may differ, since in nearly every procedure there is a query about which side or site.

(Orthopaedic surgeon 1) The message is that the likelihood of wrong patient or wrong site surgery is low, but if it happens it has a devastating effect on the patient so we should pay attention. I don't think any orthopaedic surgeon argues with that. It is also devastating for the doctor. So every orthopaedic consultant that I know is not too fussed about taking on board the formal checking procedure.

(Hospital CEO 1) *To be fair to the orthopods, they're quite modern thinkers and very procedurally orientated. In my organisation, they are the ones who embraced adverse incident reporting and open audits and have done checks for a long time.*

Opthalmology, Ear, Nose and Throat (ENT)

The Royal Australian and New Zealand College of Opthalmologists in 2006 issued 'Correct Eye Surgery Guidelines' on marking the site but it does not explicitly include a time out step (Royal Australian and New Zealand College of Opthalmologists 2006). A survey of UK opthalmologists in 2006 found variability in marking and checking procedures despite the 2005 alert issued by the National Patient Safety Agency (Baylis and Fraser 2007). Although eyes and ears involve laterality, unlike the orthopaedic surgeons, it appears that these surgeons do not necessarily mark

the site. Opthalmologists point out that the drops put in to dilate an eye represent a mark. But mistakes do occur and several informants gave examples of near misses and incidents involving ears and eyes.

> (Orthopaedic surgeon 2) *I don't understand why ENT surgeons and eye surgeons don't mark the site. They say it isn't an issue, and it's not part of our culture. They say I've never operated on the wrong side so I am not going to start doing it now. But if I was going to operate on somebody's eye, I would want a big texta mark over the eye. And if I was going to do middle ear surgery, where once again there's no external sign of pathology, I'd want to mark the ear.*

Obstetrics & Gynaecology

O&G doctors were dubious about the protocol although they are very nervous about the risk of adverse incidents and the potential for patient litigation, and obstetricians certainly pay high medical indemnity premiums. One might expect, therefore, that this group would be keen to reduce the risk of errors. Several informants gave examples of errors occurring involving the wrong patient but argued that marking the site generally was unnecessary.

> (Hospital S&Q coordinator 8) *In the O&G department, the concept of site marking was an issue. If I do a caesarean section do I have to put a big cross on a belly? Why would I do that? The patient would think I was mad. One surgeon was quite passionate about it. I said for various reasons the operating lists can change. Where you've got Mrs Smith number one and Mrs Jones number two they might be changed around. So many things happen in theatre that you need to ensure that you have got the right patient and that it is the right procedure.*

Nurses

Nurses put several views on why they, compared to the surgeons, strongly supported the protocol. The professional ethics view was that nurses care more about patient safety since 'we are the caring profession'. The compliance view was that the protocol was hospital policy and nurses 'want to abide by the rules'; although in this they are over-scrupulous according to some surgeons. The responsibility argument was that nurses were left to push the protocol because 'they couldn't rely on the surgeons to do it', although many nurses felt that they did not have the power or status within the hospital to drive the protocol. Much disagreement revolved around who was responsible for ensuring that team time out occurred. Views on this were influenced by the culture in particular hospitals and units: 'it was all about the culture of the place'. In some hospitals, nurses were viewed as attempting to usurp the surgeons' control over the operating theatre, in other hospitals the nurses argued that the surgeons must take responsibility for the final check, while in others the surgeons were happy for the nurses to take responsibility. But if an operating theatre nurse was made responsible for calling team time out, then should it be the anaesthetics nurse, the circulating or scout nurse, the scrub or instrument nurse, or the most senior nurse?

> (Director of Surgery 1) *Before the hospital issued a directive, we got buy in from the nursing staff. They were at the stage of saying, this is ridiculous, if the surgeons won't do time out, then we'll take it on.*

> (State S&Q coordinator 1) *In our experience the person left holding the bag was the senior nurse in theatre. We didn't get surgical ownership right from the start. The protocol only happened where nurses had a no-nonsense approach, were respected, and had power in the operating environment. When they introduced the protocol as this is the way it is, it happened. It depended on what authority certain operating theatre nurses had. You know, you don't mess with her. It's just going to happen. So it was all about the culture of the place.*

(Nurse manager operating theatres 2) *The Director of Surgery says that it is the surgeon's responsibility. If he makes an error it is his responsibility and he is the one who ends up in court. But you can't say to a nurse don't worry about the patient safety protocol because you are not the one going to court.*

(Director of Surgery 3) I don't think the final check is a nursing task. But if it was going to be the nurses who lead it, which nurse was it going to be? The nurses said it could be any nurse. It can't be any nurse. The only nurse who could do it is the anaesthetic nurse. The patient gets transferred from the ward to the operating theatre, the handover is from the ward nurse to the anaesthetic nurse.

3.2 Who should do it? How should it be done?

The protocols variously set out three, four, five, or ten steps. Some protocols were specific as to which staff member was responsible for each step, while others left a decision up to the hospital or to the clinical team. The usual injunction was that all the team were responsible but ultimately the lead clinician. The initial expectation was that the surgeon would perform most of the steps in the protocol, but there are logistical issues in a complex and busy operating suite as to when and how each check could be undertaken. The most contentious steps in the protocol are informed consent, marking the site, and team time out. While much debate initially concentrated upon finding exceptions to the rule, in many operating theatres, after sorting out roles and logistics, the team finally decided that the procedure worked reasonably well.

(Orthopaedic surgeon 1) *The people in the holding bay go through the forms and make sure that we have the right patient. They check the date and the type of surgery and what the patient is here for. They check that the notes and the consent form match the patient. Then the surgeons come in and do the site-marking. The patient is not taken into theatre until he or she is marked. After that the patient comes into the theatre and usually it is the surgeon who calls for a team time out.*

Surgeons generally interpreted the hospital protocol as a general principle, while nurses interpreted it as a 'rule' that required compliance. Several surgeon informants said that they thought a lot of the difficulties came from an inflexible interpretation of the rules rather than an appreciation of the underlying principles.

(Director of Surgery 2) *When we began timeout they over-dramatised it. Nurses were diving under the drapes looking for the wrist band again, or flicking through case notes to check operating consent is signed. Team time out is not a time to redo all the checks, it is a matter of eyeballing each other. Are we confident that the checks have been done?*

(Orthopaedic surgeon 1) *The nurses are extremely strict about marking the site, sometimes to a point where it seems ridiculous. Somebody comes in with a mangled limb and everything all over the place and they don't want to take the patient into theatre because the site is not marked. So, sometimes the surgeons get annoyed. The first month there were always issues of some kind with a form or a signature missing somewhere. It took a few months to crystallise who should be involved in the checking procedure.*

Informed consent

The basic legal requirement is that a consent form be signed by the patient, which could be at different points in an admission process. Not all hospitals had a formal pre-operative checking procedure to ensure that a consent form had been signed, the procedure and site was correct, and there was a match between the patient, the consent form, and the operating list. The protocol prompted some hospitals to improve their consent procedure. In some cases, getting the patient to

sign a consent form was overlooked, or forms were not signed by the operating surgeon. Checking informed consent as a step in the protocol was not contentious, however, since this built upon current practice, mostly was done by nursing staff in the holding bay.

> (Director of Surgery 1) *No patient leaves our pre-operative holding area unless all consents are in place. Awhile ago we had a number of patients where we had completed their surgery but had no written evidence of their consent. It was just ridiculous. Oh, by the way, now that you've had your surgery we need written evidence of your consent.*

> (CEO private hospital) *The biggest risk for our hospital is doing the wrong consent or getting the operating list wrong. It is very easy when you're writing orthopaedic consents all day to put right instead of left, and likewise for the surgeon's secretary to type left when she means right. You would be surprised at how many errors like that we find. . . So you have to be careful that you don't rely entirely on what is written on the consent form and operating list.*

Marking the site

Marking the site of a procedure has long been common practice with some, although not all, surgical specialities. It is a contentious step in the protocol with disagreements on whether marking is necessary in all cases, and over how, when and where a mark should be made. The State audits found most variability and lowest compliance with site marking. Some protocols address site marking in detail, such as the VHA Directive (Veterans Health Administration 2004), and the NSW and WA protocol revisions.

Given the lack of agreement on a standard marking practice, hospitals have tended to leave it to the specialist surgical units or to individual surgeons. The uniformity argument is that a standard practice is desirable on patient safety grounds both within a hospital and nationally. The diversity argument is that there are legitimate reasons for different specialty marking practices. The pragmatic argument is that differences have to be accepted in order to get the protocol in place.

> (Director of Surgery 1) *The College of Surgeons should set up a working party to standardise marking. People move between different hospitals and use different marks. It's a recipe for disaster and we need a national standard. People are interpreting the guidelines quite creatively.*

> (State S&Q coordinator 1) *Different surgical groups interpret site marking in certain ways and they have quite valid reasons why they might not want to do site marking. We would like surgeons to look at getting consensus within each surgical specialty about site marking.*

Who marks? The 2004 national 3Cs protocol states that it should be a member of the operating team: 'the operative site for an invasive procedure must be marked by the person in charge of the procedure or another team member who has been fully briefed about the operation or procedure'. Some hospitals allow marking by the chief operating surgeon, the assisting surgical registrar, another operating team member, or an operating theatre nurse. Others state that marking must be done by the person who will perform the procedure.

> (Nurse manager operating theatres 1) *I said to the surgeons, the people who mark the site have to be the surgeon doing the operation or the assistant. You can't just get the intern to come and do it or whoever. Some surgeons mark the site in the ward before the patient comes to theatre. But there often isn't time because things have speeded up so much and patients come straight up from admissions. . . Most of the marking is done in the holding bay often by the surgical registrar. The senior*

surgeon may come out and have a look at the patient in the holding bay, but the patient may be unconscious by then.

Which mark? Should the symbol be a cross, tick, arrow, circle, initials, R or L, Right of Left, or should the site just be painted with betadine? Does an X mean 'operate here' or 'do not operate here' (WHO Collaborating Centre for Patient Safety Solutions 2007). One informant recalled the scene in the TV series, ER, where Dr Romano before going into surgery to have one arm amputated, instructed a fellow surgeon to write 'not this one, idiot' in pen on his good arm. Some orthopaedic surgeons write their initials and a date; for example, the Queensland protocol says that initials should be used.

(Orthopaedic surgeon 1) *The registrar marks with the date and his initials. The reason we want the date is that we have trauma patients that have surgery today, tomorrow, three days from now. They may have eight or nine surgeries in a row and the whole body is marked so we look at the dates.*

What type of pen should be used? While most protocols call for marking with an indelible pen, a variety of markers are used in practice including white board markers, biros, black texta pens, and yellow texta pens on dark skin. Some concerns have been raised about cross-infection if the same non-antiseptic pen is used on a series of patients.

(Orthopaedic surgeon 2) The nurses wanted the marking to be sterile. I've been marking things with ballpoint pens and textas for 30 years and it doesn't affect the sterility, you just clean the skin. But the nurses ran around at one stage sourcing sterile pens. So every time you marked you had to take out a sterile pen. But the surgeons just ignored that and kept on doing it with the ballpoint pen out of our pocket.

Where should the mark be made on the patient? Is the mark intended as a general guide or to prescribe precisely where the incision is to be made? Most surgeons mark the general site. One surgeon said that it was ludicrous to argue that the protocol meant that the surgeon had to make the incision exactly on the cross, and that such objections were raised by people intent on argument.

(Director of Surgery 2) *The trouble was the guideline was very prescriptive. It said the operative site of the base incision must be marked. And when you deal with a group like surgeons, they tend to argue by taking the illogical extreme. The paediatric surgeons got up in arms about foreskins. And the gynaecologists got up in arms about vaginas. And others got up in arms about laparoscopic surgery - how do you mark where we're going inside when there's no incision? So we modified it at our hospital just to try and get the protocol in. We said there must be skin marking where laterality is an issue. Although I recognise there is some advantage to marking where there is no laterality. At least it tells people that we are going to operate on the foreskin and not on the child's toe or their ear.*

When should the mark be made? Most protocols call for pre-operative marking, that is, before the patient is anaesthetised, so that he/she is involved in consenting that the mark is correct. The logistical issue is that the surgeon often does not see hospital patients until they are already anaesthetised and wheeled into the operating theatre.

(Orthopaedic surgeon 1) *The surgeon is supposed to site-mark when the patient is more or less able to consent. But that is not always possible because the surgeon usually is doing another operation when the patient is in the holding bay.*

What should be marked? Some surgeons argue that marking is not necessary when the type of surgery is self-evident. The VHA Directive waives marking the site for some procedures, such as those performed through the mouth or anus, or where marking the site would require marking mucous membrane rather than skin, but if the site cannot be marked, then a special-purpose wristband should be marked (Veterans Health Administration 2004). As a Director of Surgery said 'the paediatric surgeons think it is unacceptable to run around marking little kids penises', and with surgery on infants there is also concern that marking may leave permanent marks on immature skin.

> (Director of Surgery 2) *Surgeons tend to be very intolerant of what they think is nonsense and there is an over-emphasis on marking everyone. They said, what about tonsils, you want me to mark tonsils? What about burns? The patient has come in for a skin graft and has 40 percent burns so which bit do you want me to mark? So the policy of the marking has to be interpreted with common sense.*

Team time out

Team time out is the final check before an operation begins: 'this is the last chance if something has been stuffed up that it will be picked up at that point'. Hospital managers tend to concentrate on getting this crucial last check in the protocol in place. The team time out check originally was devised in US hospitals and is now promoted internationally. 'Time out' is a specifically allocated period where no clinical activity is taking place and when a final check takes place (WHO Collaborating Centre for Patient Safety Solutions 2007). Australian protocols adopted time out from the detailed procedure set out in the VHA Directive:

> 'A standard method is a 'time out', during which a designated member of the OR team states the name of the patient , the procedure to be performed, the location of the site (including laterality if applicable), the required position of the patient (e.g.supine), and the specification of the implant to be used (if applicable). After the statement, other members of the team verbally state that they concur with this information before the procedure begins. At a minimum, this process must include the surgeon, the circulating nurse, and the anaesthesia provider. For procedures involving special equipment or technology, the surgical technologist must also participate in the time out. Successful completion of this process must be documented' (Veterans Health Administration 2004: Attachment C).

It is important to get the regulatory language right. Some informants said that people don't like the term 'time out' because 'it is an American thing'. This American baseball term, meaning that all play stops for a short period, causes confusion since in Australia it has punitive connotations of banishing a player from the field for a period, or a child from the room, in order to reflect upon his/her misdeeds. Some protocols do not use the term. For example, the UK 2005 Correct Site Surgery Alert recommends a 'pause for verbal briefing', and Queensland refers to the 'final check'. The RACS working party was unhappy with the American term, and hedged its bets, so that the 2006 guideline reads: 'A 'time out' or 'final check' should be part of this procedure'. Many informants referred to 'team time out' in order to emphasise that at least three members of the operating team (surgeon, anaesthetist, nurse) should take part.

> (State health authority CEO) *When I ask surgeons what time out means, they say it's time out of the game to discuss something or other. I say, so you think this is something outside of your surgery? It is time out and you want to get back to the operating room? They see it as interference in what they want to do, not as part of it. So I say, supposing we call it the final check, the pre-flight check if you like. Ah, now they get it. We have confused the simplicity of the idea by our failure to understand language.*

The idea behind time out is best captured by a widely cited aviation analogy. Several surgeons referred to the aviation principle that the pilot always performs a pre-flight check before taxiing down the runway. The pilot analogy impresses upon health professionals that a final check is a common safety practice in other high risk sectors. Cynics point out, of course, that the pilot has a personal interest in a checking procedure since he/she goes down with the plane. Making a change from the usual pilot analogy, one surgeon described himself as the conductor who comes on after the orchestra leader has tuned up the players and they are ready to perform. Standing still, taking a deep breath, and concentrating, is a natural thing to do before one embarks on a complex procedure.

> (State health authority CEO) *The pilot does a pre-flight check in every plane that takes off from the airport. They don't take off until it's complete. This is the same principle.*

> (Orthopaedic surgeon 2) *I try and discipline myself to say, hold it there everybody, just stand still, is this correct, are we doing the right thing here? Even if sometimes we've got a scoliosis and the patient has a crooked back, or we have someone with a broken arm on a 45 degree angle. Sometimes it just slips through if it's so bleeding obvious.*

> (Director of Surgery 2) *To me it is good practice to stop talking about the footy scores, stop talking about what you did on the weekend, or even stop worrying about how I am going to do the operation. Just stand, take a deep breath, it takes about five seconds 'Are we all agreed this is the correct patient having the correct operation on the correct site?'*

Who calls time out?

Performing team time out can be a logistic challenge. 'How do you do time out in a very high-pressure setting, especially in emergency-type situations where people are quite stressed and a lot of things are going on at the same time'? Who calls time out? Who verifies that the check occurred? Should roles be assigned or is the whole team responsible? For example, the RACS position is that the final check is a surgeon's responsibility, although there may be delegation, and every team member has a duty to speak out if they have a concern. The aviation analogy used by several informants is that everyone in the cockpit is trained to speak up if they are concerned, rather than automatically defer to the chief pilot. The policy in one hospital required the operating surgeon to do all the checks before the patient came into the operating theatre: patient identity, consent form, x-rays and instruments, and mark the site. The NSW directive says that a hospital should assign individual responsibility and not leave it to the group as a whole. Interviews with hospital informants, however, showed that team time out is handled in different ways by hospitals and surgical units: time out may be called by the surgeon, by the nurse, or by the team jointly. The decision as to responsibility may be made by the hospital or left to individual surgeons.

> (Director of Surgery 3) *The person who is ultimately responsible is the surgeon. I'm not aware of a nurse having ever been sued because a surgeon did the operation on the wrong side or the wrong site or without the appropriate prosthesis. . . We have a checklist with a surgeon's column. That means if the surgeon has completed the checks in the surgeon column, then there is no need to have a team time out. You can just get on with the operation.*

> (Hospital clinical governance director 1) *The clear message here is that time out is the surgeon's responsibility. Many surgeons here very clearly call it. They say are we doing time out now? Other surgeons wait for the nurse, usually the anaesthetic nurse in our hospital.*

(Hospital medical director 1) *If you're trying to promote that the people in the theatre are a team rather than a hierarchy, then anyone in the theatre should feel that they can call time out. And our view as an executive is that anyone in the theatre, if they're worried about something, should be able to raise a concern..*

(Director of Surgery 1) *Different surgical units have different processes. Who calls time out is up to the team.*

Surgeons thus vary on whether they call time out or delegate the task to a nurse. In many hospitals, the nurse initiates time out on behalf of the surgeon, but in some hospitals it became a matter of contention. Some surgeons control the step of team time out in order to make very clear that they are in charge in the operating theatre.

(Nurse manager operating suite 1) *It tends to be the nursing staff who initiate time out. I've talked to surgeons and said 'You should be the ones to initiate it'. I also had a discussion with a senior registrar and he said 'Don't want it'. One of the consultants said 'I don't want it to be them and us' and I said 'No, I agree. It can be a team'. But when a nurse asks them to participate in time out they look the other way.*

(Director of Surgery 3) *Without consultation with the surgeons, the nurses simply went ahead and started doing the time out procedure in the operating theatre. The nurses wanted to jump on the bandwagon and show that they were doing the right thing. This riled a number of the surgeons because they felt that it was not a nursing responsibility, and if anybody should be doing it, it should be the operating surgeon.*

One of the steps in the protocol, sometimes left to the time out step, involves checking that the operating team has the correct images and devices for that patient. A neurosurgeon said that a check was necessary to ensure that the scans were not reversed as sometimes happens, and that many such cases have been reported in the literature. Several informants gave examples of near misses and adverse incidents where the wrong images were used or the images were reversed.

(Orthopaedic surgeon 1) *Sometimes there is an administrative error. Somebody puts an R on the x-ray when it should be an L. Or somebody files the x-ray under the wrong patient. Part of our procedure is to check the x-rays. We have two big screens in the theatre. One is the computer system for tracking the medical notes and the equipment that we use. The other is for the x-rays projected large enough to see from the operating table. We find the images by typing in the name of the patient, and then it pulls up the photos. The photos and the site on the photos should match the consent and the site-marking. If there is any issue then we sort it out.*

Who verifies that team time out was performed? How should it be documented? The documentation done in the operating theatre varies both within and across hospitals. The surgeon may sign or tick a box, or the nurse, or all three team members. Time out verification might be included on the operation report, the scout nurse sheet, the count sheet, or on a separate checklist, and might be on paper or computer form. A signature acts as a forcing function if staff must verify that time out has been done before the operation can proceed. The requirement of a signature also lends authority to a nurse insisting that team time out occur. One informant argued that there was a precedent since signing a time out sheet was similar to signing a count sheet. A surgeon must sign a count sheet that tallies all the swabs and instruments used during an operation, in order to prevent the risk of swabs and even scissors left inside a patient after an operation. Documentation also makes it possible to audit compliance with the protocol.

(Director of Surgery 1) *The nurses sign off on time out for the members of the team. I can see no point in all members of the team signing off on it. It's either been*

completed or it hasn't been completed. The procedure doesn't commence until everyone is participating.

(State health authority CEO) *We are putting responsibility in the wrong place for verifying time out. We have tried to get senior clinicians, who are not paper pushers, to do what they see as a bureaucratic exercise. Instead, the process should be like the count sheet. There isn't a surgeon who would gallop home without signing the count sheet that signs off on all the swabs and instruments used in surgery. . . The principle is that although it's the surgeon who has to sign it, it's the nurse who has the delegated authority to demand that it be signed.*

When should the final check occur?

Should the final check occur before the patient is anaesthetised? Some hospitals are considering changing their policy to make time out a pre-anaesthetic instead of post-anaesthetic check. The patient could then participate and so provide another check; and if the operation has to be postponed for whatever reason, then the patient avoids an unnecessary dose of anaesthesia. But it is hard to get the final check timing right in a busy operating suite, so that time out sometimes occurs in the anaesthetics room and sometimes in the operating theatre.

(Director of Surgery 3) *What was happening was that the patient was being put to sleep, the theatre team was all scrubbed and ready to go, and then they were doing the time out. This is the wrong time to do it. In a couple of instances in this hospital patients have been on the operating table, anaesthetised, ready to go and the surgeon turned up and decided that this wasn't his patient or the correct prosthesis was not available.*

(Hospital clinical governance director 1) *I know of several cases where the patient has been anaesthetised, and then the operating team discover the operation has already been done. That happens more often than you would think for a number of reasons. One is that patients don't know, for example, that a laparoscopic cholecystectomy is the same as a lapcholy, and so they sign the consent form. Also, patients often are on multiple elective waiting lists, so can have things done in another hospital. They sign the consent thinking that the doctor knows or they are not sure what they had done last time. . . That's why I'm saying that time out should be done before the anaesthetic.*

3.3 Other invasive clinical areas

Surgery was the initial focus for the correct patient/site/procedure protocol after the surgical colleges drew attention to wrong site surgery. Also, studies of hospital adverse events had estimated that one-half to two-thirds of adverse events involve surgical patients (Leape et al. 1991; Gawande et al. 1992; Thomas et al. 2000). The risks for patients in procedural settings other than the operating theatre, however, are now being recognised (WHO Collaborating Centre for Patient Safety Solutions 2007). The national 3Cs protocol referred to all invasive procedures, but the initial protocols in most Australian States and most public hospitals began with surgery, because the risks were better recognised, and the view was that it was only a matter of reinforcing existing practice since many surgeons already undertook checking procedures. Many hospitals began by concentrating upon surgery, whether or not the State protocol covered all invasive procedures. By mid 2008, however, protocols in five out of eight Australian States covered all invasive procedures.

(State S&Q coordinator 1) *The State policy directive from the beginning said all interventional areas. But we've had a staged approach where it was introduced in theatre first and then to other interventional areas . . . We did not know the extent of the problem when we implemented the protocol. Now that we have a reporting*

structure for sentinel events we realise that it's not such a small problem. And it is not restricted to surgery.

Radiology, imaging, laboratory tests

Reports of wrong patient/site/procedure events now are coming in from areas besides surgery. Patients can suffer harm from the wrong tests or the wrong doses. For example, although the repercussions for patients mostly are not serious from a mistaken low dose of radiation, no patient should be exposed to unnecessary radiation. Other procedural areas have become more aware of the risk of patient misidentification incidents and more incidents near misses are being reported. For example, one hospital radiology department was notifying three to five near misses a week. Many errors were said to occur with laboratory tests but these errors are harder to pick up. For example, if staff can't find a test result, they don't necessarily check whether it might had been put in another patient file but order it again.

One reason for increasing errors is the increasing number and complexity of scans and tests being ordered. Another reason is that inpatients usually are taken away from the ward for tests. Nurses say that they have has less time to check who is going for what type of test, because of heavier patient workloads and large numbers and different types of tests. An orderly will pick up a patient and wheel them away and ward staff may not be aware that the patient has gone. A breakdown in communications is evident, therefore, on patient handover and care plans.

(State S&Q coordinator 1) *Radiology has many different types of scans. Junior doctors do most of the ordering and might select the wrong type of scan or the wrong type for that person. The patient doesn't know what to call the test they are having as no-one gives it to them in writing. The patient just says I'm here for a scan.*

Other procedural departments, in addition to surgery, are beginning to tighten their checking procedures. NSW has put out a directive with procedures appropriate to each of five specialty areas. In other State hospitals, some radiology and imaging departments have introduced a stamp and sign off system for each of the patient safety checks. Others want the ward staff to check before-hand that they are sending the correct patient for the correct procedure, and for the ordering doctor to send a clear and signed request form with the patient presenting for a procedure. Some departments are instituting a cross check procedure, as the hospital pharmacy department has long done, to query cases where they are not sure that the right test has been ordered for a patient. A checking procedure has to take account of departments that rely on one duty staff member with no colleague to provide a counter check. But even the most rigorous checking procedure would find it hard to detect deliberate cases of patient false identity!

(Hospital medical director 1) *Every now and again we CT the wrong patient, which isn't a disaster, and these incidents usually are reportable under the radiation safety legislation. A multi-slice CT delivers can deliver quite a lot of radiation. But it is not like an operating theatre, where you've got a team to pick up possible errors. It is difficult to know what to do to prevent mistakes in future when there is only one person, just the radiographer, and people make slips. The director periodically says maybe we should just fire the next person who slips up. But I said this is meant to be a no-blame thing. We need a systems approach. We have to try to set up visual prompts and make the system better.*

(State S&Q coordinator 1) *One hospital has instituted the concept of a 'ticket to ride'. A patient can't leave the ward unless the orderly receives a ticket that says the patient is going for a particular test and the nurse signs off on it.*

(Hospital S&Q coordinator 5) *I was working in the TB clinic and a man had an abnormal chest x-ray. We referred him for a CT scan and it came back normal so we though it must have been an abnormality. I reviewed him six months later and the x-*

ray did not look normal. We referred him for another CT scan and it came back normal. So we had a series of abnormal x-ray, normal CT, abnormal x-ray, normal CT. When he came back to the TB clinic I said to him what's going on? He was an illegal immigrant and he didn't have a Medicare card so he sent his brother each time to have the CT scan.

Outpatients and emergency departments

Some States and hospitals have set up working groups to consider how to implement a correct patient/site/procedure protocol in other hospital areas, drawing on their experience in implementing the protocol in surgery. They want to design a procedure that they know will work. 'We lose too much credibility by setting up a process that is designed to fail'. Outpatient clinics have identification problems with patients and discontinuities between referring a patient and carrying out the procedure. A patient often carries no identification in contrast to visits to GP practices where they show their Medicare card since that is needed for billing. A patient may be checked into the clinic, and then asked to wait until the treatment room is free, and then be treated without another check. Emergency departments are problematic areas of a hospital for patient misidentification problems given the pressure of work with large numbers of patients and frequent medical crises.

(State S&Q coordinator 1) *A patient is sitting in the waiting room and then someone comes out and calls Mrs Jones. Patients expect to hear their name called and will go with whoever has called a name they thought was theirs. Outpatient areas don't yet have an armband system for identification. Patients don't have anything on them that says this is who I am. Staff don't actively ask a patient to state their name, date of birth, and then do all the checks on the correct procedure.*

(State S&Q coordinator 1) *Patients are moved around from cubicle to cubicle in the emergency department. Staff don't know the patients who are there a short time and the department usually is very busy and under time pressure. It is too easy in the nature of the business to do a procedure on the wrong person. Near misses and errors become accepted within that culture. It is like the normalisation of deviance. If there are 75 patients in the emergency department, you expect that a number of things are not going to go smoothly, and you might sometimes have the wrong test on the wrong person.*

3.4 Private hospitals

The Australian Health Ministers Conferences in 2004 required public hospitals, but not private hospitals, to implement the correct patient/site/procedure protocol. The private sector, however, did take note, although it is not known to what the extent private hospitals have implemented a protocol. Some surgeons thought that the risks were less in private hospitals but that the legal repercussions of error were greater. Some argued that surgeons were more likely to have talked to the patient before surgery, and work in a smaller team with more continuity, and also that private hospitals generally are less complex than large public teaching hospitals. Surgeons had different views on whether private hospitals were more or less likely than public hospitals to implement the protocol. Some said that the higher risk of litigation by patients meant that private hospitals implemented the guideline as a risk management exercise since a hospital risked being sued if something went wrong and a protocol was not in place. Informants also pointed out that surgeons often worked in both the public and private sector and thus it was important to have a standard procedure.

(Manager private hospital chain) *After the Council's protocol came out in 2004, the Group's risk manager issued a recommendation to all its hospitals to implement correct site surgery protocols.*

(State health authority CEO) *I don't know whether a surgeon knows his or her private patients better. But a good hospital ought to implement the patient safety protocol, if for no other reason than it is the right thing to do. Anyway, the surgeon might be running late and phones the private hospital operating room to get started on the anaesthetic. He walks in and the patient is draped and anaesthetised and on the operating table and he whips out the wrong organ. I wouldn't have thought a mistake was any less likely if you're in private.*

3.5 A low-cost, low-intrusion protocol?

The Australian Council for Safety and Quality in Health Care in issuing the national 3Cs protocol in 2004 argued that the 12 minutes required to follow the five steps was a sound investment compared to the time and distress involved for patients and staff in fixing an error (Australian Council for Safety and Quality in Health Care 2004). The argument is that hospitals would devote more resources to patient safety if they took into account the costs of wrong patient/site/procedure as well as the costs of litigation. The World Health Organization has called for more studies on the costs and benefits of implementing patient safety solutions (WHO Collaborating Centre for Patient Safety Solutions 2007). While there are no Australian studies specifically on the costs of wrong patient/site/procedure surgery, clearly the costs of addressing a major error, such as a hysterectomy on the wrong patient, are considerable in medical and legal terms. The costs of lesser adverse incidents also accumulate. For example, several studies have estimated that the costs of adverse events overall account for over 15% of hospital budgets, mainly because patients who experience an adverse event then stay longer in hospital. Potentially avoidable adverse events thus cost Australian hospitals about $2 billion per year (Runciman and Moller 2001; Ehsani et al. 2006).

The main objection by many surgeons initially was that the five-step check would hold up proceedings, reduce their operating time significantly, and so reduce hospital efficiency – and in the case of private surgeons reduce their private operating list. This was 'bureaucracy run amok', a major intrusion on how they ran their operating theatres, and a drain on their operating time. The surgeons mainly objected to the time they expected it would take to carry out the final check, team time out, before embarking on an operation.

Director of Surgery 3) When the protocol came out I was very opposed to time out. This was yet another bureaucratic step that would slow down the efficiency and change over between patients in the operating theatre. It was more paperwork, more signatures, and basically a delay. The last thing we wanted was yet another process in the operating theatre that slowed down the whole business.

The efficiency objection was laid to rest, however, once hospital staff incorporated the steps in their usual checks and became used to quickly performing the final pre-operative check. While it is not clear whether the original 12-minute estimate for all five steps is realistic, most agreed that the final check, team time out, took only a minute or so and intruded very little upon operating theatre preparations. Informants said that when the operating team agreed on their roles and all took part, team time out ran smoothly, and was very quick.

(Nurse manager operating theatres 3) There was hesitation from several surgeons to come on board. They thought time out was going to be a time waster. But in actual fact that final check really doesn't take more than about 10 or 15 seconds if it's done at the right time by the right people.

(Orthopaedic surgeon 1) *Some said we would need more staff to do it. But it partially replaces other less official ways to check on patients. So if you take that time off and add this, I think the whole gain is not more than a minute. So time-wise I don't think it is an issue.*

(Director of Surgery 1) *I have together the surgeon, the anaesthetist and nursing staff. We identify that we have the correct patient pulled up on the computer screen for the electronic x-rays. We have the case notes, we have the wrist band, and we have the patient. The patient is interrogated if possible. Can you tell me your full name, what's your date of birth, and what are we providing for you today? Then we read off the UR number on the armband, the UR number on the case record, the name on sticky labels, and the name on the operating list. That takes about 60 seconds.*

(Nurse manager operating suite 1) *Timeout is very quick. We have three people checking at the same time. I say to the surgeon 'Okay, David, we're doing a timeout. This is Mr Smith and his UR number is blah, blah, and I look at the patient's armband, I hold up the consent, and the operating form, and read out the notes that we are doing this procedure, and we look for the marked site.*

4. The hospitals: implementing and promoting the protocol

The responsive regulation model argues that regulatory actors need the capacity to apply both supports and sanctions, to use multiple mechanisms, and to escalate upwards to harder mechanisms if softer mechanisms fail (Braithwaite et al. 2005; Healy and Braithwaite 2006). Since there are few studies on patient safety implementation experiences, health policy makers need more information on how to go about embedding patient safety practices in hospitals (WHO Collaborating Centre for Patient Safety Solutions 2007). This study aimed to explore with informants the ways in which they sought to embed the protocol in Australian hospitals as 'the way we do things around here'. These regulatory mechanisms can be located on the twin responsive regulation pyramids of supports and sanctions devised by John Braithwaite (Braithwaite et al. 2007). Based on interviews with informants in this study, it emerged that the usual pattern of protocol implementation in hospitals was to begin softly, try several mechanisms, and when compliance proved to be patchy to escalate to more forceful action over time.

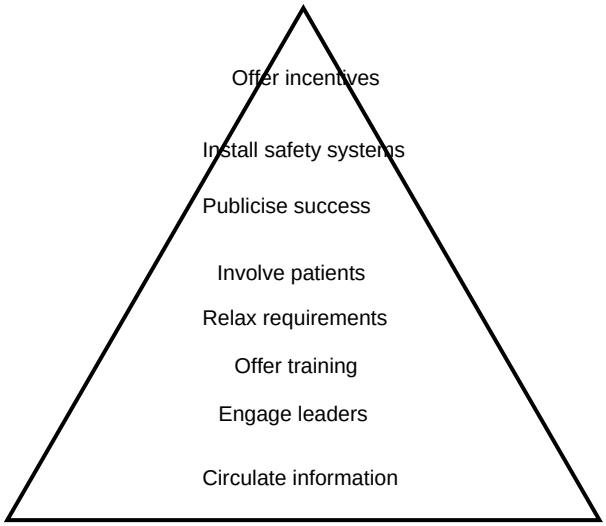
What regulatory influence can a hospital exert over its health professionals? The constant refrain in interviews with hospital managers was that embedding the protocol in practice turned out to be much more difficult than expected and required more than information dissemination. A hospital had to 'get serious' about promoting, or insisting upon, compliance with the protocol.

> (Director of Surgery 1) *We printed off the protocol poster from the health department. We posted them around the place and just assumed that people would take responsibility for doing it but nothing much happened, except for a bit more stalling.*
>
> (Director of Surgery 2) *I thought it would be pretty easy. I just sent the notice out in my hospital that we are going to do it. And then looked at it six months later and nothing had really happened. I found I was the only one doing it.*
>
> (Hospital medical director 1) *The initial reaction when the hospital policy came out in late 2005 was that it was unnecessary stuff but then momentum began to swing the other way. The College of Surgeons came out with their endorsement and revised statement, and the State surgical consultative council was active in promoting safe surgery. The other factor is that over time every hospital has an incident or a near miss and that gets to be widely known and we had a couple. People then think, there but for the grace of God. So in late 2006 our hospital started to get serious*

4.1 Support mechanisms for improving compliance

The medical profession upholds an ethos of professional autonomy and generally resists the state or employers telling doctors how to do their job. Governance of clinical performance has relied upon health professionals changing their behaviour voluntarily when presented with evidence on how to do better, and upon professional associations influencing their members through persuasion and peer pressure. Hospital managers initially sought to promote the protocol through such supportive mechanisms rather than sanctions. Figure 4.1 sets out a pyramid of support mechanisms, which are discussed below, beginning with the softer approaches at the base of the pyramid.

Figure 4.1 Regulatory pyramid of supports



Circulate information

The protocol was widely publicised within hospitals. The hospital staff interviewed knew about the protocol although they were not always clear on the details of who issued it or exactly what it said. Health professionals are showered by missives on many matters from hospital management, so that it is difficult to be sure that a protocol reaches people and is sufficiently memorable. Hospital managers used a cascade method of communication down the line of management as well as other avenues of information. A hospital CEO sent the State health department policy to the relevant hospital committee, clinical directors, and safety and quality staff (clinical governance directors, risk managers, safety and quality coordinators). Many hospitals also adapted the State-issued protocol and formulated their own protocol policy after committee discussions. Clinical directors were expected to inform their staff about the agreed protocol. Different information formats were used. Posters are a common way of disseminating information within hospitals and the poster from the Australian Council for Safety and Quality in Health Care and the RACS statement were 'slapped up everywhere'. The Council's five-step protocol, designed as a colourful one-page poster, was regarded as an effective form of information. Notices were put up in operating theatres and in some hospitals were pasted on staff lockers. The protocol was included in information manuals and intranet sites on hospital policies and procedures, and in teaching hospitals was included in the orientation material given to each new group of interns and registrars.

> (Hospital risk manager 1) *We used the Council poster. Then we pasted on pictures of hospital surgeons who people would recognise. We tried to make it more personalised so people could see who was supposed to be doing what.*

Patient safety advocates were invited to talk about the protocol to regular hospital forums. Speakers included State safety and quality coordinators, RACS members, hospital quality committee members, and hospital medical legal advisors. For example, a State safety and quality coordinator pointed out in talks to hospitals that 'more checking occurs to make sure that you're the right person on that airplane than the right person for that operation'. Several informants said that health professionals were persuaded more by stories of medical errors, particularly in hospitals in their State, than by statistics.

> (Hospital S&Q coordinator 8) *You have to talk the right talk to your audience. If you are talking to doctors and surgeons you need to give them statistics to support your argument. If you are talking to an administrator you have to get across a financial message. . . Another way is to talk about the adverse events that have happened in your own organisation. That brings the message home. Our message is that this is*

about improving the system and not about pursuing individual surgeons. When a patient goes into surgery, not only the surgeon is accountable, but also the hospital system. The surgeon is just the one at the end of a long line.

Many surgeons believed that the risk that they personally would make a mistake was very small so that the protocol was 'unnecessary vigilance'. The paradox is that while clinicians all knew of cases of errors, many think that it won't happen to them. Surgeons initially argued that too much emphasis was being put on a rare event, since they only encounter serious wrong patient/site surgery a few times in their career, and it generally happens with some other doctor not them. They knew of stories from other hospitals, but argued that procedures in that hospital were flawed, and did not accept the possibility it could happen at their hospital.

(State S&Q coordinator 1) *I tell the surgeons the Jim Bagian [Director US VHA Patient Safety Centre] story about marking the site. He had difficulty getting a cardiothoracic surgeon on board with the policy. The surgeon said why would I mark the site of the heart? My patient would think I was an idiot. Bagian said, just try it for several months, mark the site, and tell your patients you're doing it because I said so. The surgeon called up later to say thank you. A patient had come into his operating theatre for open heart surgery and did not have a mark on the chest. He then realised that the patient was intended for another procedure in another operating room and couldn't be his patient.*

Some surgeons asked for evidence that patient misidentification was a significant rather than rare problem. In other words, was the protocol a proportionate response to a small number of adverse events? One State safety and quality coordinator presented a case for change by obtaining data on wrong patient/site surgical events from government and private insurers, which turned out to be many more cases than surgeons had expected. The objection that wrong patient/site surgery is too infrequent to warrant a checking procedure has now been countered by data from adverse events reporting systems (as noted earlier), both the national sentinel events report and State databases, which show that such errors are more frequent than initially thought.

(Director of Surgery 5) *It is arrogance speaking when surgeons say that nothing goes wrong for them, or else they haven't done enough operations, or they are lying.*

(Director of Surgery 2) *I try and get them to do it but it's only variously successful. It's because wrong surgery errors are relatively low numbers. The chance of you doing it yourself is actually quite small, and near misses aren't necessarily reported. The mistakes at our hospital have been relatively minor. At least somebody's wrong kidney wasn't taken out or the wrong breast removed.*

Engage leaders

The take-up of procedures in a hospital, arguably more than in other complex organisations, depends upon their acceptability to the professional staff. The support of the right people, such as clinical leaders, is crucial. Many hospital leaders used the organisational culture mantra about seeking to embed patient safety practices: 'this is the way we do things around here'. But changing long-established cultures and practices is not easy. Governance is divided between hospital management leaders and leaders of the multiple professional groups. Governance in hospitals is not a straight-forward line management exercise. Top-down edicts do not necessarily work. Policy formulation processes within a hospital can be tortuous, since policies and management in large hospitals, whether public or private, proceed through an array of committees, as well as through informal regulatory conversations. Governance structures involve groups of specialties or larger cross-specialty clinical directorates, such as surgical services or cancer services. Public hospitals depend upon salaried medical staff, but also upon visiting medical staff over whom they have fewer controls.

(Manager private hospital chain) *Our doctors are all visiting medical practitioners, not employees, so we have no direct authority over them. This means that communication strategies have to be very sophisticated. You can't rely on autocratic control or any sort of management structure. It just doesn't work. So we use our committee structure, such as our medical advisory committees, clinical review committees, theatre committee, and specialty committees. When we develop a protocol, it has to be signed off as a policy or recommendation usually by several of these committees.*

Professional governance structures also are complex. A hospital workforce is divided into many, increasingly specialised occupational groups who may have different ideas on how things should be done. The division of work within a hospital largely is shaped by the power relationships between professional groups and demarcation disputes are endemic (Abbott 1988; Productivity Commission 2005). The take-up of a protocol in a hospital thus depends upon its acceptability to multiple professional groups.

(Director of Surgery 2) *I keep saying 'surgery is a team sport' and the team in the operating theatre consists of an anaesthetist, a surgeon and a nurse. That is the team and the team do have to agree. The other big problem in trying to run a surgical department is getting all the specialities to agree.*

(Director of Surgery 3) *It's been a very traumatic process to get this process established in our hospital. The nursing staff did not like it. The surgeons did not like it. The anaesthetists did not like it. The surgeons felt very strongly that it was a surgical task not a nursing task. The nurses felt it was nursing task not a surgical task.*

Entrenched professional cultures are slow to change. Several informants commented that the protocol was well accepted by junior staff but less so by senior staff. New trainees quickly got used to the safety checks protocol and did it without reluctance as part of 'the way we do things around here'. Younger doctors were said to be readier than older doctors to adapt to the changing hospital environment, consider the evidence, and adopt protocols. They were not veterans of many battles with 'management' and were less cynical than doctors with a long career in the health system. One surgical director commented that 'younger surgeons come in and they do patient safety checks routinely, they don't even blink an eye, they just do it, whereas the older ones are harder to train'.

(Hospital medical director 1) *We are building patient safety checks into the operating theatre culture. Hopefully, when this group of trainees become surgeons, it will just be the way we do things. Surgeons by and large don't like rules and regulations but they are coming to realise that life has changed. It has changed dramatically in the 25 years since I graduated. Nursing staff in theatre now can say, excuse me, the consent form says left and we're now preparing for a right, can we do time out and make sure this is correct? They could never do that when I trained.*

(Hospital CEO 1) *Some people are more willing to embrace change than others and to reflect on their practice and the evidence for change. I do think it is a bit age related. If you engage with the younger people, they seem to get this a lot quicker and embrace it a lot quicker. They have been trained differently. They are coming up fresh-faced and well-trained and good communicators and easy to educate. But within two or three years, some become inculcated with the old culture, because that's the way they progress, particularly in surgery.*

Hospital managers sought endorsement for the protocol from clinical leaders within the hospital as well as publicising endorsements for the protocol from national and State professional groups.

Clinical leadership within the hospitals was crucial, however, because even if the protocol was issued as a directive by the State health department and by hospital management, this did not mean that it would be followed by clinicians: 'If clinicians don't buy a protocol they are not going to do it. So it's really important to have strong clinical leadership'. Hospital quality and safety staff set out on a round of consultations on the protocol with clinical directors and key committees. "You can't underestimate the role of the clinical leader in putting the message into practice. In the end, it's about what they see done by their leaders'. First, they stressed that the protocol was not just about protecting patients, but was also about protecting surgeons: 'If something goes wrong it is the surgeon who gets their photo in the paper and the headlines'. Second, they stressed that the protocol was in line with the RACS guideline. Third, they pointed out that the protocol was not a new practice but incorporated several existing checks (patient identification, informed consent, marking the site) into a standard protocol. The protocol stalled in many hospitals, however, until a clinical leader emerged who actively promoted it. While the nursing leadership generally supported the protocol, the surgeons were less willing to comply until it was promoted by a surgeon champion. Nursing leaders in some hospitals urged clinical directors of surgery and other clinical leaders to get involved in promoting the protocol.

> (Director of Surgery 1) *When we had had no success with the government document, we decided for political reasons to promote the College of Surgeons statement. So we enlarged and laminated it and put it up in each theatre. The surgeons then could not come back with whose stupid idea is this? I've seen this patient before, I know this patient, I don't need to do it. You're just eroding operating time and I thought we were striving for efficiency not inefficiency. So right, if that's the line, I needed a tool that said this is a surgical concern and it is important to surgeons.*

> (Nurse manager operating theatres 3) *The nursing staff took it up first. Then about 10 months after the pamphlets came out, the surgeon on the quality committee decided to get involved. That's when it really took off. We needed a champion with clout amongst his colleagues, the surgeons. The quality committee then took it to the CEO and it became hospital policy.*

Offer training

Hospitals sent staff to patient safety training courses, ran in-service training sessions, and discussed the protocol in quality assurance meetings, such as monthly hospital-wide morbidity and mortality (M&M) seminars. Teaching hospitals included the protocol in induction sessions for each new group of interns and nurses, and operating theatre managers went through the protocol each time the registrars rotated. Case studies also were used as an opportunity to learn from mistakes with cases from within the hospital having the most impact. Other material was drawn from State websites, such as summaries of wrong patient/site/procedure cases from the NSW Quality and Safety Branch intranet, and cases published in its 'Risk Watch' newsletter by the Victorian Department of Human Services. The New Zealand Quality Improvement Committee also publishes summaries of sentinel and serious adverse events, including wrong surgery, reported by the 21 district health boards, which set out a description, review findings, recommendations, and follow-up (New Zealand Quality Improvement Committee 2007). Scenarios for discussion and simulation exercises were developed. The main message was that training needs to be geared to particular groups, regularly repeated, and backed up with other regulatory mechanisms.

> (Hospital S&Q coordinator 8) *We showed a training video from the US. It portrayed wrong site procedures perfectly. It was the one where Mr Bean goes to the dentist and he accidentally injects the dentist with the anaesthetic and the dentist gets knocked out. So Mr Bean says, 'I'll do it myself'. He puts his x-rays up and looking at the x-ray drills into his teeth and puts in the filling. Then he turns the x-ray around and does the same thing on the other side, and then he turns the x-ray upside down ….*

(Hospital risk manager 1) *We are working on some simulation exercises on worst-case scenario planning and how you deal with those kinds of situations. . You do a scenario that simulates an emergency situation where people are anxious and rushing from one patient to the other. You play it out to a script so that 'time out' gets missed and something bad happens. You use that as an opportunity to debrief and then re-run the script and ask how could we do that better?*

(Hospital clinical governance director 1) *People need to learn how to handle stressful situations in the operating theatre. They need scripts for the words that they can practise in simulation exercises. I'm talking about how you escalate up in grades of assertiveness if necessary. There is not that sort of training in the health sector but there is in the airline industry who train their pilots in zero tolerance on stand down and stop.*

Relax requirements

Some State protocols allow for local variation recognising that different hospitals have different practices: 'one size does not fit all'. Many hospitals also allow clinicians to vary the standard hospital protocol. Different specialties, operating theatres, and surgeons thus have developed their own version of the protocol, especially around site marking and team time out. Some informants suggested that the sensible approach would be to allow a trial period in a hospital in order to iron out problems before agreeing on a final procedure. In particular, they did not think that a procedure standardised in US hospitals would necessarily work in Australian hospitals.

(Hospital S&Q coordinator 8) *After several months the feedback from staff was that they were struggling with the site marking part of the directive. We suggested to the executive group that site marking was holding up implementation, and we should free up groups to decide if and how they wanted the site marked, but the bottom line was that all laterality must be marked. That was agreed and our hospital procedure was rewritten.*

This issue becomes a trade-off between the costs and benefits of uniformity versus diversity. The trade-off in getting a protocol in place in many hospitals meant abandoning a standard protocol and allowing variation on grounds of local ownership and responsiveness. The problem with diversity is that it can result in uncertainty and confusion, and thus cause errors, if different checking procedures apply across hospital units and across hospitals, since staff move between units and hospitals. The original intention of the Health Ministers in 2004 was to promulgate a standard national protocol across public hospitals in Australia in order to reduce risks to patients. The WHO Collaborating Centre for Patient Safety Solutions, for example, argues that a standard checking procedure would prevent many cases of wrong surgery. Many versions of the protocol had emerged in Australia by mid 2008, however, within hospitals and across the States. First, a national protocol has been revised by several States in order to respond to hospital experiences and in order to roll out a protocol to non-surgical areas. Second, many hospitals then adapted a protocol. Third, units within the hospital and individual surgeons also made their own modifications. While it should be possible to agree on uniform principles, authority rests with the States who typically fail to agree on a uniform approach across Australia in the absence of strong external pressure. Can one size fit all? The alternative is to accept multiple versions on the grounds that any version of the patient safety check is an improvement on no checks. The current solution, at least in NSW, is to adapt safety checks for different hospital procedures and areas.

(Nurse manager operating theatres 1) *State-wide we should all be doing the same thing. But even in this hospital we do slightly different things. I say to the surgeons, it's okay for you, you're a small department, but I've got lots of nurses. I can't say, no, ortho and general surgery do mark, but plastics and ENT and neuro don't. I said everyone needs to be the same otherwise people get confused and that's when we*

might make a mistake. We have to have one rule in a big place like this otherwise it is too hard.

(Hospital S&Q coordinator 8) *Each hospital in our State was creating their own written procedure on how this directive would be interpreted within their organisation. I think there are strengths and weaknesses in that. If you put out a directive and say this is how it will be done, then it is a forcing function to make everyone do it like that. From a practical perspective, however, if you want to get people to support a procedure then you have to let them adapt it in some way to make it work for them.*

(State health authority CEO) We should have a fairly standard procedure nationally. I don't have a problem with one State leading the charge and saying, this is the best model, so long as we agree on a standard way of doing things. For example, I don't think it is particularly relevant how the site is marked, provided one unit doesn't do it one way and another do it another way.

Involve patients

Patients can be regulatory actors in monitoring the safety of their own health care. The WHO Patient Safety Alliance calls for patients to be involved in ensuring that their own procedure is correctly undertaken, and the US Joint Commission 'Speak Up' booklets for patients include tips to help prevent surgery mistakes (The Joint Commission 2002). While informants in this study agreed that checking with the patient was ethically and pragmatically desirable, they warned that one should not rely on a patient's understanding of what was happening. Problems arise because patients do not have the confidence or the medical knowledge to query hospital staff, or are too ill, frightened or confused to pay attention. Examples were given of near misses and adverse events where patients were involved in the checks: consent forms signed for operations on the wrong limb; the wrong operative site marked or marked ambiguously; and anaesthetic blocks were administered to wrong sites without the patient objecting. The main message, therefore, is that checking with the patient is just one check in a series of checks rather than the definitive check.

(State S&Q coordinator 1) *Patients trust us so implicitly and completely that it's scary. They don't understand how vulnerable they are. But the government does not want to say health care is risky business and you could be harmed, so make sure you take care that we don't hurt you. It's not in the politicians' interests to inform the public of this. In America, they've gotten over that.*

(Orthopaedic surgeon 2) *There was an arthroscopy on the wrong knee. The knee was clearly marked in the presence of the child and the parents and yet it was the wrong knee.*

(Hospital medical director 1) *I don't think relying on empowering patients, the ten tips thing, is realistic for much of our caseload. We are a major trauma hospital and patients aren't competent in much of our emergency work, and in some we don't even get consent because they are straight to theatre. So first, most of our patients are really sick. Second, if a patient has something that is not really simple, it's difficult for them to tell you that back reliably. Third, I don't think many patients are confident enough to challenge professionals. Unless you're part of the health culture, it's difficult to question professional advice; people just tend not to do it, and their view is that the doctors know what they're doing. . . We had a case where the person was called the wrong name, answered to that name, went in and saw the doctor, had tests ordered in the wrong name, and went home. The patient rang up the following day and said, Why did doctor call me Smith when my name is Jones? Does that mean something?*

Publicise progress

Several States require hospitals to regularly monitor compliance, but whether or not this is a requirement, many hospitals do undertake occasional or regular audits of compliance with the protocol. The results are taken to theatre management committees and/or up the management hierarchy to executive committees. Several hospitals publicise the audit results by pinning up graphs for staff to compare the units, and some announce competitions with prizes for the most improved – whether a gold star or a small present. Depending on the hospital, such benchmarking and comparisons can be viewed as support-based learning, or as sanctions-based naming and shaming. The idea in publicising the results is to promote peer pressure and competition, since performance comparison is an effective mechanism for promoting change, that is, the leaders pull up the laggards.

> *(Hospital CEO 1) One thing I find really potent with clinicians is to give them data about their own performance in relation to everyone else. . . They see their outcomes next to a benchmark for another unit or hospital or State. That gets them to engage. They say, oh that can't be right, blah-blah-blah. But they start thinking about it.*

Hospital managers and clinical leaders said that they were dismayed by the results from their first audit of compliance with the protocol. The results in many hospitals showed that compliance across the surgical specialties was far lower than expected - in the order of 10-30 percent compliance. 'We drew up an audit form and went through the five step process last year and came up with about 10 percent compliance'. Compliance improved markedly over time, however, in hospitals that conducted regular audits. Some hospitals said they have conducted regular audits over about two years. While informants acknowledged that some 'gaming' may be involved they thought that the improved compliance mostly was real – especially when the audits were based on observation or 'real time' documentation in the operating theatre that team time out was performed. Monitoring and feedback on results thus appears to be a powerful regulatory mechanism.

> (Hospital S&Q coordinator 4) *We did several audits. Our first audit was about 32 percent compliance, and the next was about 62 percent and the last one was about 94 percent. The response from the surgeons has been good. They all want to know the statistics. They get regular feedback and they ask at the theatre management meetings.*

> (Hospital medical director 1) *We started a blitz on safe surgery in late 2006. We began monitoring compliance with the protocol across all nine surgical units. The results went to the theatre management group attended by the heads of units and hospital executives. These data tell unit heads what's really happening, because they often think, yes, all my staff are doing this, and they're not. So if a unit was aberrant then it was obvious to their peers. The results steadily improved over the two years and are up to 98 percent compliance in some units. We will continue regular audits because if you don't keep on people take things for granted.*

There are two issues with the audit strategy. First, does improvement over time mean that staff are performing better, that is, compliance with the protocol has improved, or does it mean that staff get better at massaging the data? Second, a robust and standard audit methodology needs to be developed to enable a hospital to check progress against a benchmark and also compare their results with other hospitals. Hospitals generally were left to devise their own audits and thus there is considerable variation. Some hospitals monitor only whether team time out occurred rather than each of the five steps; the audit methodology varies and may be observation, 'real-time' entry into a database, or some form of retrospective document review. Hospitals in the States that conducted a State-wide audit used the results as a lever for improving compliance.

(Director of Surgery 1) *We use the State department of health audit tool. We were involved in one State-wide audit in 2006. Our compliance rate was only between 20 and 25 percent and we used that as a trigger for issuing a hospital directive. But we are not sure that hospitals are comparing the same things across the State.*

(Hospital clinical governance director 1) *The State toolkit needs to include an auditing tool. There is not a lot of clarity around auditing and people have very variable auditing practices.*

(Nurse manager operating suite 1) *I don't think it is useful just checking the paperwork. It's about watching the way people do it. If I am looking at team time out, I go in and watch people doing it. I can go to the paperwork and go 'Oh yeah, there are three people's names and it's all ticked'. But how do I know that they all participated actively?'*

Install safety systems

While much effort in hospitals goes on promoting safety cultures, less attention has been paid to installing and monitoring safety systems. For example, wristbands on patients are a common form of inpatient identification, although an audit in one London hospital found that one-third of patients were not wearing wristbands (Ranger and Bothwell 2004). More attention is being paid to safety in medication packaging and storage and safer design of medical devices. Modern technologies that improve patient identification include scanning technologies such as bar coding, smart bracelets, electronic prescribing, electronic cross-checks of patient data, and computer systems in operating theatres. Such technologies can be expensive so that informants said it was hard to persuade hospitals to invest in patient identification technology. Safety systems increasingly are installing forcing functions to make people stop and think before taking the next step; for example, one hospital has built a forcing function into its operating theatre software in that the operation information cannot be called up until the time out check has been done.

(Hospital CEO 1) *A lot of identification problems could be solved with scanning technology. But it is hard to sell systems solutions up the budget chain because it requires an upfront and large investment.*

(Hospital medical director 1) *We set up a visual prompt. A cardboard cut out of a red key is laid over the instrument tray to indicate that you can't unlock the tray and hand over the scalpel unless time out has been done. The idea is to give a bit more authority to the scrub nurse or whoever calls team time out.*

(Hospital S&Q coordinator 4) We have full compliance now that we have a failsafe method. We have a new computer system with a new operating theatre module and time out is a compulsory field on the IT program. You cannot go ahead with your data entry and get up the patient information until that is ticked. It prompts everybody, it's an automatic thing, and it has saved us several times from making an error.

Offer incentives/resources

Implementing the protocol in a hospital involves an extra workload in terms of training staff and monitoring compliance. Large public hospitals in Australia now have staff designated variously as safety and quality coordinators, risk managers and clinical governance directors, and these mostly were given the job of promoting the protocol. Hospitals generally do not provide extra staff and funds for facilitating patient safety solutions (WHO Collaborating Centre for Patient Safety Solutions 2007). Some informants commented that hospitals devote a significant part of their budget to financial audits but very little to patient safety audits. State health departments thus have an important role in providing material on patient safety practices, literature on patient safety risks and solutions, and assistance with implementation, such as training resources, audit material,

and surveys of compliance. Informants thought it would be useful for patient safety authorities to work with hospitals in developing training videos and simulation exercises for general distribution rather than each hospital being left to devise their own training programs.

Australian public hospitals do not apply a pay-for-performance strategy in terms of rewarding staff for a good job or for not making mistakes. Some hospitals rewarded the leaders by awarding gold stars, or tried to shame the laggards into compliance by exerting peer pressure. A $2.50 Time Out chocolate bar awarded by one hospital to the teams with the highest compliance with the protocol obviously was meant as morale-raising recognition rather than a material incentive.

> (Director of Surgery 1) *After we put up the posters, and nothing much happened, we tried bribery. We purchased $200 of Cadbury Time Out bars and said that we would reward each team when the correct patient/site/procedure was completed correctly. We had a wonderful response while the bars lasted. But as soon as the bars ran out, well people said we no longer have to do it. I said I'm not spending any more money on that. It's not good for the staff, it's not a long term solution, and it's not appropriate so we stopped that.*

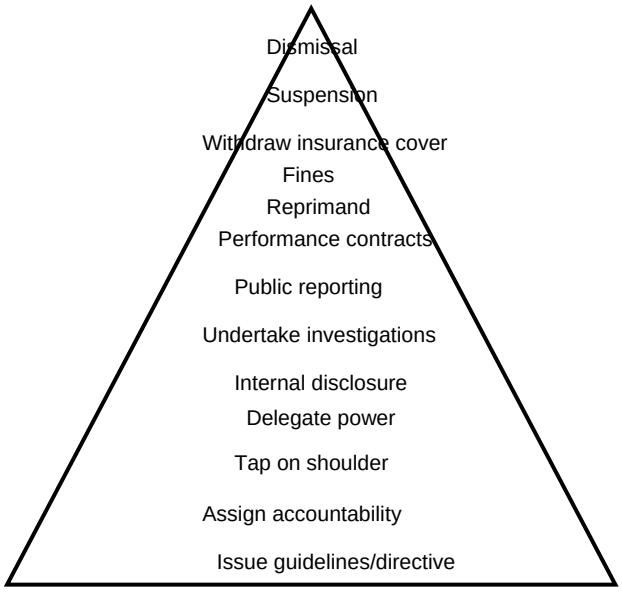
4.2 Sanctions for improving compliance

Hospital managers strengthened their regulatory action by adding sanctions to supports once it became apparent that compliance with the protocol was low and patchy. The sanctions available began with issuing a directive and range upwards, potentially to suspension or dismissal in egregious cases of non-compliance (see Figure 4.2). Hospitals mainly used soft sanctions, however, and did not escalate beyond reprimands. Informants knew of no cases of strong sanctions being applied in relation to non-compliance by clinicians with the protocol, and non-compliance by clinicians generally was not framed as a deliberate violation of a standard. While some States and hospitals issued the protocol as a mandatory directive, it is not clear what disciplinary sanctions potentially apply when staff do not comply with the directive.

Issue guidelines/directive

The status of a protocol, in terms of authority within a hospital, is often ambiguous. In most States and hospitals, health professionals initially saw compliance with a correct patient/site/procedure protocol as voluntary rather than mandatory. State health departments variously issued guidelines, policies or directives. Hospitals then issued and adapted a protocol as a guideline, policy or directive, and followed up with varying degrees of encouragement or enforcement. Governance in the health sector often is disguised or ambiguous, and regulatory strategies aimed at clinicians generally rely on persuasion and peer pressure. While a guideline appears a soft mechanism that clinicians regard as discretionary, in practice they increasingly follow evidence-based guidelines. One reason is that a guideline potentially has 'soft law' disciplinary or legal implications if a clinician diverges from a guideline and an adverse patient outcome occurs. Some senior clinicians oppose clinical guidelines as 'cook book medicine' and also strongly oppose the setting of standards. Policy makers in the Australian health sector thus are reluctant regulators in relation to issuing standards. The correct patient/site/procedure protocol is due for revision and national and State health authorities should discuss whether or not the protocol should be a directive that requires mandatory compliance. Several States have moved in this direction after concerns about patient safety in their hospitals. Authority within hospitals, however, is a complex matter that proceeds through a range of regulatory mechanisms.

Figure 4.2 Regulatory pyramid of sanctions



Some hospital managers sent a policy or directive on the protocol to clinicians accompanied by a letter stating in effect that 'this is the way we will work in this hospital'. Other hospitals began with a guideline but later issued a policy or directive when it became clear that persuasion was not working. Such missives were sent variously by a CEO, hospital committee, or director of surgery. Several directors of surgery maintained that stronger mechanisms than persuasion are necessary before surgeons take notice. One battle-weary director claimed that one-third of surgeons respond to persuasion but a hard-core one-third respond only to threats! Some surgeons said universal compliance with a protocol would only be achieved when it was elevated from guideline to a policy to a standard. Another director of surgery said he had three simple rules for the protocol: 'Keep it simple. Empower every eye and hand. Make clear that disciplinary action will follow non-compliance'.

(Director of Surgery 4) *As the clinical leader, I wrote letters to the proceduralists about the protocol. We have reasonably good processes in our hospital. Because we want stuff to happen, we inform people individually. We often send them a repeat of a policy or procedure.*

(Director of Surgery 1) *The surgical representative said everyone is waiting while we muck around. You've just got to say you're going to do it. We had spent 18 months fluffing around. We got buy-in from the nursing staff and then the clinical director issued a directive. . . We did it the week before the new lot of interns and residents came on board, so if there was a load of shit in response we would have dealt with it. We said this is the way we do business when the new staff began and it went like a dream.*

(Director of Surgery 2) *The directive from the Department of Health to the public hospitals was 'you will do it'. The CEO put it through the medical committee and they said 'you will do it'. But the hospital also should say that this is a standard and we will not take responsibility if you don't do it. . . That's the only thing that will work.*

(Nurse manager operating theatres 3) *The bottom up approach stalled because the surgeons were not on board with it. The nurses didn't have the clout or the respect to drive it further. But once it became hospital policy then it was easier because we had the support of the CEO.*

(CEO private hospital) *We have a policy and procedure that's been developed and approved by the board and put into place. We went through the guidelines from the Commission and the College of Surgeons. My board has 10 surgeons and they all had different ways of doing the checks, but in the end they knew that they had to come to an agreement, and that we couldn't have half the staff doing this and others doing something else.*

Assign accountability

Some protocols, such as the NSW Health 2007 Directive, assign responsibility for each step to particular members of the hospital team. The rationale was that an assigned person, rather than a group, had to be held accountable. 'You can't hold a group accountable'. The NSW protocol checklist asks a series of questions for each step of the procedure: who will do it, what will be done, and when will it be done? In most other States and hospitals, however, it was left to each surgical team to decide who would undertake each task. Some units assigned responsibility for each step to roles within the team, others decided at each operation according to the surgeon's preference. One director of surgery said that while surgical units in his hospital did things differently, in his unit the registrar marks the site, the senior nurse calls team time out, and the registrar makes the first incision after the surgeon arrives for the operation. While the protocol is performed marginally differently between the surgical groups, it is accepted as part of the process of surgery.

(State health authority CEO 1) *It's not a matter of hierarchy any more in a hospital. It is a matter of delegating authority to the right person, and empowering that person with back up from the head of the unit. . . Your job description says that you are responsible for this task and therefore you will do it. You can't assign accountability to a committee. It has to be assigned to a specific person so you know who to ask, 'Why wasn't the count sheet signed? Why wasn't the team time out form signed'?*

(Hospital S&Q coordinator 8) *In interpreting the State directive we didn't specify who should instigate time out. There has been a lot of angst about that. Our belief is that it doesn't matter which member of the team instigates team time out, so long as all the key players are actively involved. But the surgeon is always the responsible clinician.*

Tap on the shoulder

The responsive regulation model argues that for many of us all that is required is a tap on the shoulder to remind us to comply with an agreed procedure (Braithwaite 2002). Stronger sanctions usually are not required since most people want to do the right thing, or at least not be out of step with their colleagues. According to one hospital CEO, peer pressure usually works: 'If nine out of ten surgeons follow the protocol and the tenth one does not, there is peer pressure on that person to do it'. Since hospital managers do not want to annoy powerful surgeons who do not take kindly to being told what to do by managers, other surgeons are enrolled to apply peer pressure in 'a chat' with their colleague. One hospital CEO said that the chair of the medical committee or the director of clinical services sometimes was enrolled to have 'a little fireside chat' with a recalcitrant surgeon.

(Nurse manager operating theatres 1) Every few months I go around and check that people are doing it. The less experienced nurses find it really difficult to say to a surgeon or anaesthetist 'Excuse me, could you concentrate and participate in team time out'. I say 'Look, just give me a name and I'll follow it up'. I do a little run-around and talk to the surgeons and the senior registrars. It is often just a matter of reminding people.

(Nurse manager operating theatres 3) *The surgeons complied when it became hospital policy. Although one surgeon still refused until we got the surgeon on the*

quality committee to have a chat and explain it was a safeguard for him and that it was hospital policy and therefore he must comply.

Delegate power

Some hospitals empowered the senior theatre nurse to refuse to proceed with the operation until all the checks and documents were confirmed correct and everyone participated in team time out. If there was any uncertainty they were to call for the team to 'stop and stand down'. A management hierarchy was nominated to back up the nurse if a team member refused to comply with the protocol: the operating suite manager, the Director of Nursing or Director of Surgery, then the CEO. A Director of Surgery commented that 'if it's not safe, end of story, we don't do it, we stop'. Informants in a few hospitals said that there was full compliance now that authority had been delegated to operating theatre nurses to not hand the instruments to surgeons until the final check, the team time out, had been performed. Other hospitals were contemplating such veto power but the nurses were reluctant to take on that responsibility and perhaps incur the wrath of the surgeons.

(Director of Surgery 2) *I think the nurses should not hand someone a scalpel, until time out is completed. But the nurses say, we are not responsible for the surgery, and the surgeons will abuse us. We'll say 'team time out' and the surgeon will say, get lost, a lot of nonsense. If the nurse says, no, I can't give you knife, the surgeon will say, yes, give me the bloody knife. So nurses are reluctant to do it because they are the bottom of the pile and they would end up shouldering the difficulties.*

(Director of Surgery 1) I wanted the theatre nursing staff to have the appropriate skills not to be confrontational but to be quite comfortable, so we set up training sessions and went through various scenarios where the nurses would not allow surgery to continue. We said to the nurses, if a surgeon does not cooperate then you contact the operating suite manager, and then either the Director of Nursing or the Director of Surgery. Two episodes were managed internally by the nursing staff because they had a hierarchy of authority to back them up.

Internal disclosure

Informants commented that 'a big fright' within their hospital, that is, a potentially serious near miss, or an actual adverse event, had a big impact upon getting support for the protocol and in improving compliance. Near misses in hospital operating theatres had caused 'a high level of anxiety' among various surgical groups. Near misses and minor events in the past have been hushed up in order to not damage reputations and for fear of litigation. But hospitals slowly are becoming more transparent, at least internally, in their governance decisions and in sharing information on clinical performance indicators. Adverse events become common knowledge through the hospital rumour mill, especially since few occur in isolation known only to one member of staff. Staff are expected to notify adverse events to the hospital reporting system. Many hospitals have a policy of open disclosure of any adverse event: 'you have to go and explain it to the family, and it can be devastating for the patient and family and also personally for the surgeon'. Given that hospitals are becoming more transparent, information could be made available about de-identified incidents in order to impress upon staff how easily mistakes can occur in order to promote compliance with the protocol.

(Hospital CEO 1) *The reason the protocol gained traction in our hospital was because there were three near-miss clinical incidents. They weren't serious, but enough to make three different groups of surgeons take notice because of the angst caused to them and to their patients. The surgeons also realised that while those were near misses on minor surgery, it showed the potential for error with major surgery. It opened their minds to the issue.*

(Hospital medical director 1) *The thing that really galvanises surgeons in a hospital is when they, or one of their colleagues, have a near miss. Or particularly an actual adverse event, because then the surgeon has got to do the open disclosure and tell the patient, and do the root cause analysis and the whole thing. Surgeons don't like doing that, of course, who would?*

Undertake investigations

Depending on how an investigation is conducted within a hospital, it could be viewed as a learning opportunity or as a disciplinary measure. As Jim Bagian has said, adverse events and near misses present a learning opportunity (Bagian et al. 2001). Several informants gave examples where the team time out check forestalled an adverse event thus transforming it into a near miss, which could be construed as a success for the protocol rather than as a hospital failure, but near misses tend not to be investigated as thoroughly as actual adverse events. In most large hospitals, a serious adverse event triggers a root cause analysis (RCA). The philosophy underlying the root cause analysis of an adverse event is to concentrate upon systemic causes rather than personal failures (NSW Department of Health 2004). One way to monitor compliance with the correct patient/site/procedure protocol would be to investigate whether the checking procedure had occurred in actual adverse events and in near misses. An investigation could move into the disciplinary realm, however, if a hospital had issued a clear directive, a staff member was found to have flouted the protocol, and an adverse event occurred. In cases where an adverse event occurred and the protocol appeared not to have been followed, one informant said it is not necessarily clear from RCA reports whether this was construed as a breach of protocol, and whether the breach is regarded as an accidental slip or a deliberate violation. These are issues that a hospital would have to consider if the protocol is to be treated as a mandatory directive. No examples were given of cases where hospitals followed through with disciplinary sanctions against a clinician who did not follow the protocol.

(Hospital S&Q coordinator 8) *We talk about the Swiss cheese diagram and have identified some holes in the safety checks. Now we need to go back over our adverse events and find if there are any more holes in the checking process. We do about between 13 and 17 RCAs [root cause analyses] a year on adverse events in our hospital. We don't do RCAs on near misses but we do undertake a form of investigation. In many ways we should celebrate the near misses because they often indicate that the safety checks are working.*

(State health authority CEO) *In my view, there is no excuse for operating on the wrong side, or on the wrong site, or on the wrong patient. If the protocols are there, it should not happen. We should be investigating whether there was a breach in protocol.*

Public reporting

Pressure is mounting for more public reporting of clinical performance indicators in relation to identified hospitals. Some State health departments feed back comparative data to hospitals on categories of clinical performance and adverse events without identifying other hospitals. For example, Queensland Health publishes de-identified hospital performance indicators. In the next round of Australian Health Care Agreements between the Australian Government and the States there will be a requirement for the States to collect agreed measures on quality of care in hospitals and supply this data to the Australian Government. Indicators that bear upon patient safety are particularly contentious. Informants said that the national sentinel events report published in 2007 raised staff consciousness about errors and triggered greater efforts by hospitals to promote compliance with the protocol. While a much contested area of research, other studies have found that public reporting on the clinical performance of surgeons and hospitals has had an impact in improving the quality of care (Marshall et al. 2004). In relation to public reporting of wrong patient/site/procedure incidents, first, identification would be statistically problematic, and

second, the strategy so far has been to promote a safety culture of adverse event reporting rather than embark on blaming and shaming.

Some State health departments disseminate results internally on protocol compliance without naming hospitals. Again, the audit methodology is doubtful, and poor results for a particular hospital could have political and legal ramifications. Protocol compliance potentially could used by national and/or State regulators to indicate whether patient safety solutions are in place. Public reporting of such indicators, including adverse events, now is being more actively discussed as a regulatory mechanism for improving hospital performance. Many clinicians and hospital managers, however, are not enthusiastic.

> (Director of Surgery 1) *I don't have a problem with transparency and making things public. Sometimes making things public is a great motivator. But Australian hospitals have a big problem with public reporting of adverse incidents. Misinformation is highly political. The number of reports by a hospital to the State reporting system may be high because you're bloody awful and have many incidents. Or it may be high because you've got a culture of safety and everyone is reporting. You can have two hospitals that are poles apart on the safety issue but from the data are identical and both get hammered. The hospital that is doing badly thinks it wasn't as bad as it could have been. The hospital that is trying thinks, well, why do we bother? You may destroy efforts to build up a patient safety culture.*

> (Hospital S&Q coordinator 8) *The last time the health department published a sentinel event report there was headline on page two of the newspaper saying 'Public Hospital Hangs Head in Shame'. Unfortunately these incidents get sensationalised. All we can do is to work with the media to understand we are trying to improve.*

Performance contracts

Hospitals set out performance expectations in their letters of employment to staff and in their letters of agreement with visiting medical officers (VMOs). The terms contain general clauses, such as abiding by the reasonable directives of the hospital, and may contain specific matters, such as complying with certain standards. One private hospital chain in contracts with its hospital CEOs sets out their expected performance against a benchmark, adds peer pressure through circulating performance comparisons, and offers financial incentives for excellent performance. The chain negotiates best practice agreements with surgeons that set out expectations on both sides. NSW Health, which directly administers the State's public hospitals, also uses agreements. Performance agreements with Chief Executives of health services for 2007-08 included a 50percent reduction in incorrect patient/site/procedure incidents for surgical, radiology, nuclear medicine and radiation oncology, in line with a goal in the NSW Health State Plan to reduce such incidents by June 2010 (NSW Health 2007a: 25-26). The employment contract thus puts pressure on hospital CEOs to enforce the protocol.

> (Manager private hospital chain) *The CEO and the Director of Clinical Services in hospitals have direct accountability but also a lot of power. They are not puppets to corporate but are in control of their destiny. Expectations of a hospital's future performance against a benchmark will be written into a contract, and there are also financial incentives. We don't issue central directives to CEOs. We work in other ways. We give them the performance evidence and add a bit of peer pressure. So on adverse incidents, they get comparative benchmark reports on incidents plus their risk ratings. We might then phone a CEO and say, Joanne, do you need any help from us? It is always help and support.*

Reprimand

Hospital managers prefer to have 'a chat' with their surgeons rather than issue a formal reprimand. Hospital managers do not want their surgeons to take umbrage and resign, which is a

real risk since many surgeons operate in private as well as public hospitals. One public hospital manager commented that he was prepared to issue reprimands to surgeons, if necessary, because 'we either have a safety ethos or we have not. If we haven't got a safety ethos then we should not be doing surgery anyway'. One director of surgery had backed operating theatre nurses who had been delegated authority to refuse to proceed with an operation if the safety protocol was not followed.

> (Director of Surgery 1) *There was a stand up fight in theatre and they refused to proceed until the surgeon participated in time out and was able to identify the patient. I had to go in and arbitrate. But we have not had any further problems and team time out now occurs. We were expecting a confrontation might occur and that we would have to take the high moral ground. You either want to work here and abide by a reasonable directive of the hospital or you don't. But it settled down.*

Fines

Financial mechanisms are a strong sanction in forcing hospitals to improve their performance. Financial sanctions have not been applied in Australia in relation to adverse events, however, although this mechanism potentially is available via methods of funding hospitals. Hospitals after all are penalised through Diagnosis Related Group (DRG) payment mechanisms if patient care is not cost-effective. Financial sanctions also are available through private health insurance funds. Refusal by a private health insurance fund to pay a hospital for care incurred due to an adverse event in the hospital may cause financial problems for the patient. An insurance fund could consider whether to continue to recognise a problematic hospital as a preferred provider. Several US States have introduced penalties for doctors and organisations that perform wrong site surgery. For example, the Florida Board of Medicine in 2001 set penalties for doctors including fines up to US$10,000, five hours of risk management education, 50 hours of community service, and a one hour lecture to the medical community on wrong site surgery (The Joint Commission 2001). *The Providence Journal* reported in December 2007 that the Rhode Island Hospital was fined US$50,000 by its State health department for its third case that year of a wrong-site surgery incident following the failure to perform the time out checking protocol.

Withdraw insurance cover

Several informants thought that refusal to provide medical indemnity cover in cases of patient litigation, for legal costs and malpractice awards, potentially was the strongest driver for protocol compliance. In the US, government insurers and medical indemnity organisations have discussed refusing to provide cover where a health professional knowingly violates a protocol directive, resulting in an adverse event that causes harm to a patient, and the patient or family then sues. Some insurance funds in the US also have refused to pay hospitals for treatment costs arising from preventable adverse events. For example, in January 2008, the *Wall Street Journal* reported that many of the large US health insurance companies were adopting policies banning payment for medical care required as a result of a serious error, such as surgical site errors or procedures done on the wrong patient. Additionally, the policies are written to prevent the hospitals from billing the patient directly. Medical indemnity insurance also is a strong lever for protocol compliance on the part of both hospitals and surgeons. Informants knew of no cases so far in Australia where medical indemnity cover had been refused for wrong patient/site/procedure incidents.

> (State S&Q coordinator 1) *We have talked with legal people and medical insurers. The medical indemnity insurers are probably the strongest driver of change. They could say that if you don't follow the protocol and something goes wrong, then we won't cover you. But that would be a really strong measure. And all the MDOs would have to agree on that, not just one company.*

(Manager private hospital chain) *Our VMOs are fully private practitioners with their own medical indemnity cover. So the liability exposure to the hospital if a surgeon perforates a bowel is quite limited, assuming the hospital is not in any way at fault. However, with wrong surgery the hospital system is implicated from the word go, as well as the surgeon, on whether a protocol was in place and whether it was followed.*

Suspension or dismissal

Hospitals can suspend or dismiss staff for malpractice or for refusal to follow a reasonable directive. Such sanctions usually are reserved for egregious cases of ongoing poor performance. Private and public hospitals have the option of not renewing an extension to a private surgeon's operating rights. Two serious and well-known cases of wrong site surgery are summarised below. The NSW Medical Tribunal issued a reprimand and awarded costs in a case where a surgeon removed the wrong breast, while in the UK the General Medical Council suspended a surgeon and a registrar who removed the wrong kidney. Both cases were prior to the promulgation of the correct patient/site/procedure protocol.

Event description: In November 2002, Patient S was seen by Dr A and diagnosed with cancer of the left breast. In December 2002, Dr A assisted the surgical registrar perform a right total mastectomy. Prior to the surgery Dr A had failed to correctly complete the patient's consent form and the hospital admission request form, and did not have the patient's medical records in the operating theatre.
Contributing factors: Patient S was an elderly woman who suffered from dementia and spoke little English. The patient's daughter attended the first consultation but the patient was admitted to hospital from the nursing home by her son-in-law. Dr A was very busy the day of the surgery, completed the admission forms without consulting the patient's medical record, and entered R as short-hand for right mastectomy instead of entering left mastectomy. The patient was not brought to the hospital pre-admission clinic and did not go through the usual checking procedure.
What action followed? After the error was discovered, Dr A spoke to the family and performed the left mastectomy that evening. The patient recovered with no evidence of further cancer as at December 2003. Dr A instituted safety changes to his surgical checking procedure, and the hospital adopted the 3Cs protocol in 2004. The NSW Medical Tribunal at its hearing in 2006 reprimanded Dr A and ordered him to pay 70 percent of the costs of the complainant, the Health Care Complaints Commission (Medical Tribunal of New South Wales 2006).

Event description (UK): The healthy left kidney, instead of the diseased right kidney, was removed from a 70-year-old patient at the Prince Philip Hospital in Llanelli, Wales, in January 2000. The registrar made an incorrect entry in the urology department diary using the information on a wrongly completed admission form. The error was compounded in the operating theatre when the consultant placed the x ray back to front, positioned the patient for a left nephrectomy, and did not check with the registrar before operating. The patient suffered a myocardial infarction after the operation and died five weeks later.
Contributing factors: Wrongly completed forms, wrong placement of x ray image, failure of staff communication.
What action followed? The consultant urologist was suspended on full pay by the NHS Trust. The registrar's contract with the Trust was not renewed when it expired in 2001. The consultant urologist and the registrar both were acquitted of manslaughter in 2002, and in 2004 both were suspended for 12 months by the General Medical Council (Dyer 2004). The surgeon then retired from practice. The registrar in 2005 was suspended for 12 months by the General Medical Council for falsely answering a question about previous suspensions on a license application to the West Virginia Board of Medicine (Dyer 2005).

5. Conclusions

Hospital managers generally find that a command and control strategy does not work well in hospitals given powerful professional groups and a collegial style of management. Hospital managers in this study found that multiple regulatory mechanisms were necessary to improve clinical compliance. These mechanisms involved a mix of both supports and sanctions, but compliance was low until regulatory action escalated towards a clear directive with more forceful sanctions. The responsive regulation injunction, which calls for taking into account the context, culture and behaviour of those being regulated, is particularly relevant to the health sector. Hospital managers proved to be responsive regulators – although they generally escalated upwards only to the mid-point of a regulatory pyramid.

Large hospitals employ a range of effective learning mechanisms involving information and training. They are developing training scenarios, case examples and simulations. This learning could be extended to other hospitals around a State and nationally. Engaging the clinical leaders was a key strategy. Since surgeons are ultimately held responsible for events in the operating theatre, many surgeons found it difficult to reconcile personal responsibility with the concept of responsibility for patient safety by all team members. Many State and hospital protocols have moved to assigning responsibility and accountability to team roles. No examples were given of State health departments or hospital managers applying strong disciplinary sanctions from the top of the regulatory pyramid, such as fines, suspension and dismissal, although such punishments have been handed out in other countries.

Many informants regarded monitoring as an effective regulatory mechanism for improving compliance. This combined a ‘tap on the shoulder’ with peer pressure, since audit results usually were reported to hospital teams, clinical leaders and hospital executives. While State health departments generally have acted as meta-regulators in requiring area administrations or hospitals to undertake regular monitoring, a standardised State-wide audit would exert pressure upon laggard hospitals to aspire to be leader hospitals. In the absence of a standard audit methodology, it is difficult to benchmark and track progress over time. The story of the 3Cs protocol thus illustrates the multifaceted nature of regulation in the health sector. The last word should go to hospital staff:

> (Hospital clinical governance director 1) *We have learned a lot from this experience on how to go about putting a procedure in place in the hospital. First, you need clinical leaders. For example, if it mainly involves the surgeons you need the strategy to be surgeon-led, or if it is about the operating theatre then you need the whole theatre group. Second, we need to be clear on the level of authority. Is it a mandatory directive or a clinical alert? Third, the procedure needs to be well-designed in its forms and processes. You need pictures of activities and a well-designed suite of tools, such as forms and checklists. Fourth, the education strategy needs to be multi-tiered, including posters, fact sheets, case studies, personal experiences, and training sessions. Fifth, the rationale has to be based on better patient care rather than just saying thou shalt do this. Finally, you need to decide on what is to be audited and to develop a good audit tool. These are the things we will definitely do better next time.*

Appendix A. Ensuring Correct Patient, Correct Site, Correct Procedure: Australian Council for Safety and Quality in Healthcare, 2004 protocol

Step 1: Consent form or procedure request form.

The consent form must include:

- patient's full name
- procedure site
- name of procedure
- reason for procedure.

Step 2: Mark site of invasive procedure

(Do NOT mark non-operative sites)
The operative site for an invasive procedure must be marked by the person in charge of the procedure or another senior team member who has been fully briefed about the operation of procedure.

Step 3: Patient identification

(Check responses against the marked site, ID band, consent form and other documents.)
Staff must ask the patient to state (NOT confirm):

- their full name
- date of birth
- site for, or type of procedure.

Step 4: "Team time out"

Within the operating theatre or treatment room when the patient is present and prior to beginning the procedure, staff must verbally confirm through a "team time out", when all other activity in the operating room is stopped:

- presence of the correct patient
- the correct site has been marked
- procedure to be performed
- availability of the correct implant where required.

Step 5: Imaging data

If imaging data are used to confirm the site or procedure, two or more members of the team must confirm the images are correct and properly labelled.

Source: (Australian Council for Safety and Quality in Health Care 2004).

Appendix B. Chronology of international initiatives

Date	Organisation	Initiative
June 1994	Canadian Orthopaedic Association	Position paper 'Operate through your initials'
1998	American Academy of Orthopaedic Surgeons	Advisory statement 'Wrong site surgery'
August 1998	Joint Commission	Sentinel Event Alert 6: Lessons learned: wrong site surger y
December 2001	Joint Commission	Sentinel Event Alert 24: A follow-up review of wrong site surgery
July 2002	Joint Commission	Board approved 6 National Patient Safety Goals, #4 Eliminate wrong-site, wrong-patient, wrong-procedure surgery
December 2002	American College of Surgeons	Statement on ensuring correct patient, correct site, and correct procedure surgery
2002	US Association of Perioperative Registered Nurses	Statement on ensuring correct patient, correct site, and correct procedure surgery
2003	Joint Commission	Universal protocol
June 2004	US Veterans Affairs	Directive 2004-028 'Ensuring correct surgery invasive procedures'
October 2004	Royal Australian College of Surgeons	'Implementation guidelines for ensuring correct patient, correct side and correct site surgery'
April 2004	Australian Health Ministers	Endorsed 8 patient safety initiatives including correct patient surgery protocol, with September 2004 target date
April 2004	Australian Council for Safety and Quality in Healthcare	'Ensuring correct patient, correct site, correct patient procedure protocol'
March 2005	UK National Patient Safety Agency	Patient Safety Alert 06: Correct Site Surgery
July 2007	Australian Institute of Health & Welfare & Australian Commission on Safety and Quality in Health Care	'Sentinel events in Australian public hospitals 2004-05'

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