

QUALITY & PATIENT SAFETY AUDIT FINAL AUDIT REPORT – EXECUTIVE SUMMARY

Audit Title:	Audit of Compliance to Develop and Implement a Correct Site Surgery Policy		
Audit Number:	QPSA0242011		
Audit Requester:	Dr. Philip Crowley, Director of Quality & Patient Safety		
Audit Team Members:	1. Anne Keane, Quality and Patient Safety Auditor (Lead)		
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Audit Sponsor:	Ms. Edwina Dunne – Director of Quality & Patient Safety Audit		
Source of Evidence	Type	Location	Date
	CSS Policy Assessment Tool	All acute hospitals (n = 49)	August 2011
	Site visit to 10 acute hospitals (interviews with key personnel)	Letterkenny General Hospital – 28/08/2011 Mid Western Regional Hospital Limerick - 21/09/2011 Cavan General – 06/09/2011 Connolly Hospital Blanchardstown – 25/08/2011 St Vincent's University Hospital – 31/08/2011	
	Review of a sample patient healthcare records at 10 acute hospitals.	Naas General Hospital – 01/09/2011 Midland Regional Hospital Tullamore – 16/08/2011 Children's University Hospital Temple St. – 13/08/2011 St. Luke's Hospital, Kilkenny – 11/08/2011 Kerry General Hospital – 22/08/2011	
Date of Issue of Final Report:	13/12/2011		

1. AUDIT BACKGROUND/RATIONALE

Following a case of wrong site surgery in 2008 the National Hospitals Office (NHO) of the HSE issued a directive to all HSE acute hospitals to implement a correct site surgery policy (CSS). Guidance provided with this directive referred to both the World Health Organisation (WHO) and the Joint Commission on Accreditation of Healthcare Organisations (JCAHO) standards. Subsequent cases of wrong site surgery raised the concern that all hospitals may not have or were not adhering to a correct site surgery policy. For this reason an assurance audit was requested by the National Director of Quality and Patient Safety to ensure that effective and implemented policies for correct site surgery were in place in all HSE hospitals.

Wrong site surgery is defined as a surgical intervention performed on the wrong site (this includes wrong patient, wrong limb, or wrong organ or side)ⁱ. Unusually in the field of medical errors wrong site surgery errors are thought to be entirely preventableⁱⁱ.

In England and Wales, 129,419 incidents relating to surgical specialties were reported to The National Reporting and Learning Service (NRLS) in 2007 with a range of degrees of harm including 271 deathsⁱⁱⁱ. In Ireland information from the Clinical Indemnity Scheme (CIS) indicates that in 2009 there were a total of 16

cases categorised as 'Wrong Operation/Procedure' and 37 cases of 'Wrong Site Surgery'. In 2010 there were 37 cases categorised as 'Wrong Operation/Procedure' and 34 cases of 'Wrong Site Surgery'.

Wrong site surgery is generally caused by a lack of a formal system to verify the site of surgery or a breakdown of the system that verifies the correct site of surgery^{iv}. In using root-cause analysis, a process that determines the underlying organisational causes or factors that contributed to an event, The Joint Commission (JCAHO) found the top root causes of wrong site surgery to be communication failure (70 percent), procedural non-compliance (64 percent), and leadership (46 percent)^v.

The WHO has undertaken a number of global and regional initiatives to address surgical safety. In June 2008 under its 'Safe Surgery Saves Lives' initiative the WHO developed a safe surgery checklist to reduce the number of surgical deaths worldwide. This checklist identifies three key phases of an operation, each corresponding to a specific period in the normal flow of work: Before the induction of anaesthesia ("sign in"), before the incision of the skin ("time out") and before the patient leaves the operating room ("sign out"). Each phase which has a list of tasks must be confirmed by the surgical team and completed before they should proceed with the operation. This included improving anaesthetic safety practices, ensuring correct site surgery, avoiding surgical site infections as well as improving communication and teamwork within the surgical team. The effective implementation of the WHO surgical safety checklist would prevent at least half a million deaths per year worldwide^{vi}. In some countries hospitals are now legally required to publish their surgical safety compliance percentages on hospital websites^{vii}.

The checklist was developed as a verbal tool to support patient care through good preparation, communication and teamwork. The checklist has been expanded to formally incorporate team briefing and debriefing^{viii}.

The literature indicates that many hospitals are already undertaking most of the processes on the checklist but may not be reviewing them as a team. If there is no designated point when these items are reviewed, it is common to find that they are verified *most* of the time, but not *every* time, i.e., not reliably^{ix}.

It has been identified that excessive prescribing about the way in which policies are introduced can mean that they are seen as not relevant to the needs of specific environments. The use of surgical check lists has evolved and requirements for individual specialties such as ophthalmology, spinal surgery and radiology have recently been developed^x.

The other international standard used to support correct site surgery is that of the Universal Protocol originally developed by JCAHO^{xi} in 2003. This protocol calls for standardisation of pre-surgery procedures for verifying the correct patient, the correct procedure and the correct surgical site.

In June 2008 the Health Information and Quality Authority (HIQA) and the Royal College of Surgeons in Ireland (RCSI) formally endorsed the WHO standards for use in all Irish hospitals. The Operating Department Nurses Section of the Irish Nurses and Midwives Organisation (INMO) published the findings of a questionnaire on efficiency and experience with the WHO surgical safety checklist issued at their 2010 annual conference. Key findings (from the 120 responses) indicated that a quarter of operating theatres in Ireland had no policy and fifty percent (50%) of those who have policies do not implement them fully. They found the checklist is primarily a nursing process and commented that anecdotal evidence from within 26 operating departments suggested that no two hospitals were performing the checks in the same manner^{xii}.

International evidence indicates that for a CSS policy to be truly successful it requires many other ingredients including **teamwork**, the opening of **communication** channels, resources, feedback and **audit**. The recent Royal College of Surgeons in Ireland (RCSI) survey of operating departments in Ireland found where it had been introduced, the use of a Surgical Safety Checklist (SSC) has led to a perceived positive change in safety culture. However, overall greater education, endorsement, teamwork and communication are required to optimise the benefits associated with this safety instrument^{xiii}.

The independent review of the 2008 case of wrong site surgery produced a number of recommendations including the need to introduce a correct site surgery policy to establish best practice at all the relevant points in the patient's journey, from outpatient review to the point of making the incision in theatre. A subsequent incident involving a case of wrong site surgery elsewhere in the HSE was the impetus for an assurance audit on the development and implementation of correct site surgery policies in all acute hospitals. In a follow up survey to the NHO directive on the development of a CSS policy in early 2011, all except three acute hospitals confirmed that they had developed a correct site surgery policy.

It is the effectiveness of the implementation of these CSS policies that is the subject of this assurance

audit.

2. AUDIT OBJECTIVES

The objectives of this assurance audit were to:

- Confirm the existence of a correct site surgery policy in all HSE acute hospitals.
- Determine the extent of implementation of an effective hospital policy for correct site surgery by reviewing health care records for a given period in order to confirm the use of the policy.
- Identify gaps in compliance with the hospitals own policy.
- Make recommendations on good practices.

The scope of the audit was limited to the HSE acute hospitals and the practices within theatre relating to a correct site surgery policy.

3. SIGNIFICANT FINDINGS

Following a case of wrong site surgery in 2008 the National Hospitals Office (NHO) of the HSE issued a directive to all HSE acute hospitals to implement a correct site surgery policy (CSS). Subsequent cases of wrong site surgery raised the concern that all hospitals may not have or were not adhering to a correct site surgery policy. This audit reviewed CSS policies and associated documentation from all acute hospitals nationally and included site visits to a representative sample of ten hospitals to assess the implementation of the policy.

The audit team can confirm that all hospitals (or hospital groups) have developed a CSS policy most of which are in line with either WHO or JCAHO guidelines and most of which include the key elements of pre-procedure verification, site marking and a formal surgical 'time out' prior to actual commencement of the surgery.

There is however widespread variation in the implementation of the policy, both in terms of compliance with specific elements and in its application to day surgery and local procedures. The main areas of non compliance were identified as marking of surgical sites prior to the patient's presentation in theatre reception and completion of related documentation.

The team also found extensive variation in the documentation used to record completion of the various stages in the process. Some hospitals use formal CSS checklists while others capture the stages of the policy in perioperative nursing documentation. The responsibility for initiating and documenting the processes around CSS are seen as a nursing responsibility and over 95% of all documentation relating to compliance with the policy was found to be recorded by nursing.

Many hospitals reported challenges in the development and implementation of the CSS policy with some hospitals commenting that there was an initial reticence by a small number of staff to support the policy however most hospitals are now considered compliant. Some surgeons met on audit site visits consider that the CSS process has become too time consuming and too broad, with the inclusion of additional elements to the checklist which detract from the core elements of right patient, side & site.

Team work and interpersonal communication are recognised as key elements in the successful implementation of the policy. While these subjective measures are not easily captured in an audit, the team found that where strong clinical leadership and a culture of patient safety were embedded, the policy was fully implemented.

Unlike other international jurisdictions, the HSE corporately does not monitor compliance with CSS policy. The team found an inconsistent approach to audit in theatre nationally: Fewer than forty percent of hospitals have undertaken an audit of some element of their CSS policy. The notification of this assurance audit was the impetus for many of these hospitals to undertake a local audit of implementation.

The NHS Productive Operating Theatre (TPOT) initiative which is currently being rolled out by the national surgical programme has been identified as a useful framework which could be used to support the roll out of a national CSS Policy and checklist.

4. RECOMMENDATIONS

The audit team recommends:

- A standardised approach to Correct Site Surgery based on the WHO guidelines should be adopted

and implemented within a twelve month period within all HSE acute hospitals. This should be overseen by the Quality and Patient Safety Directorate.

- The HSE should collaborate with the RCSI and other relevant agencies to support consistent use of the CSS policy. This should incorporate direction on which elements of the policy should not be varied and where flexibility should be allowed.
- In developing local CSS policies and related documentation each hospital should ensure input from surgical, anaesthesia, nursing and administrative personnel (with input from OPD and ward staff). CSS checklist can be adapted locally or for specific specialities (e.g. ophthalmology, obstetrics) through local clinical governance arrangements. Policies should be tailored to suit clinical and administrative processes at local level. Notwithstanding the need for local input, all hospitals should use the WHO checklist, either incorporated fully into existing documentation or as a stand alone sheet.
- In conjunction with the development of the national policy, a standard audit tool should be developed. Each hospital should establish a regular programme of audit of implementation of their local CSS policy. Results of these audits should be included and published as key quality indicators for patient safety.
- Each hospital should identify a clinical lead to implement and monitor compliance with the CSS policy within their organisation. The national surgical programme would be an appropriate framework to support this work.

The introduction of a national checklist should not add to existing workloads; where necessary review of documentation locally should ensure that recording of the elements of the checklist are not duplicated.

5. CONCLUSION

The audit team can conclude that while all hospitals have developed a correct site surgery policy, there is widespread variation in the development and implementation of these policies. The team found that strong clinical leadership and a culture of patient safety are the factors most conducive to supporting the policy and theatre safety in general.

Of the ten sites visited, five were given reasonable assurance that the controls in place can reduce the likelihood of a wrong site surgery occurring. Limited assurance was given to the other five sites. Based on these results, the audit team recommends that a more significant focus be placed on improving policies and compliance related to CSS.

A national approach is required in the development of a CSS policy and this should incorporate the introduction of the WHO surgical checklist as well as regular audit. Findings from local audits should be included as part of national key quality indicators for patient safety.

The audit team suggests the WHO CSS standard be adopted and implemented nationally within the next twelve months with the support of all professional bodies.

6. ACKNOWLEDGEMENT

The audit team wish to acknowledge the cooperation and goodwill afforded them by all persons who participated in the audit.

ⁱ <http://www.nrls.npsa.nhs.uk/resources/collections/never-events/core-list/wrong-site-surgery/> - accessed 23/9/11

ⁱⁱ <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1857133/> - (accessed 29/9/11)

ⁱⁱⁱ <http://www.nrls.npsa.nhs.uk/resources/?entryid45=59860>

^{iv} Safl NM. Universal protocol for preventing wrong site, wrong procedure, wrong person surgery. *J Perianesth Nurs*. 2004;19:348–51.

^v Joint Commission. Root causes of wrong site surgery. http://www.jointcommission.org/NR/rdonlyres/90B92D9B-9D55-4469-94B1-DA64A8147F74/0/se_rc_wss.jpg.

^{vi} <http://www.who.int/patientsafety/safesurgery/en/>

^{vii} <http://www.hoteldieu.com/surgicalchecklistFAQ.pdf>

^{viii} <http://www.nrls.npsa.nhs.uk/resources/collections/10-for-2010/five-steps-to-safer-surgery/>

^{ix} <http://www.chpso.org/whosurg/>

^x <http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/surgery/> - accessed 23/9/11

^{xi} http://www.jointcommission.org/standards_information/up.aspx

^{xii} http://www.inmo.ie/INO/Documents/INMO_ODN_Checklist.pdf - accessed 23/9/11

^{xiii} The Surgical Safety Checklist: A National Perspective on Patient Safety; E. Nugent, K. Ryan, O Traynor, P Nearly, FV Keane; Unpublished article Royal College of Surgeons, 2011.