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Standardise, educate, harmonise

Commissioning the conditions for safer surgery

Summary of the report of the NHS England Never Events Taskforce

February 2014

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Publications Gateway Reference:	**01220(s)**
Document Purpose	---
Document Name	Summary of the report of the NHS England Never Events Taskforce
Author	Patient Safety Domain
Publication Date	27 February 2014
Target Audience	CCG Clinical Leaders, CCG Chief Officers, Foundation Trust CEs , Medical Directors, Directors of Nursing, NHS England Regional Directors, NHS England Area Directors, NHS Trust CEs
Additional Circulation List	
Description	Summary of report and recommendations of the NHS England commisioned Surgical Never Events Taskforce.
Cross Reference	N/A
Superseded Docs (if applicable)	N/A
Action Required	N/A
Timing / Deadlines (if applicable)	**N/A**
Contact Details for further information	Patient Safety Domain 4-8 Maple Street London W1T 5HD

Document Status

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First published: 27 February 2014

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NHS England Patient Safety Domain

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Executive summary of NHS England Surgical Never Events Taskforce report

Surgical never events are the most commonly reported types of never event in the English NHS. This table summarises the most recent published information in relation to surgical never events;

Never event	**Number of never events reported to SHAs 2012/13**
Wrong site surgery	83
Wrong implant/prosthesis	42
Retained foreign object post-operation	130
Total of all never events reported (including non-surgical never events)	**329**

Never events can lead to very serious adverse outcomes, and they damage patients' confidence and trust. They can almost always be avoided when existing best practice is implemented. They can also be an indicator of problems with an organisation's safety culture and its processes for learning and improvement.

Following the publication of the never events policy framework in October 2012, the NHS Commissioning Board set up "*a taskforce to look at surgical never events in order to make sure that these events are eradicated from NHS surgery*"[1] It should be noted that whilst entitled surgical never events these incidents may occur in a range of settings.

The taskforce concluded that to achieve a continual reduction in harm, we must reduce variation in practice, promote learning from our mistakes and from improvement activities, and continue to promote organisational and professional responsibility. It has proposed a strategy of three interlocking elements:

- *Standardisation* of generic operating department procedures*
- Systematic *education and training* for operating theatre environments
- *Harmonising* activity to support a safer environment for patients

* *This should also be interpreted in the broader context for surgical procedures undertaken outside the operating theatre/department.*

Surgical Never Events are not over when patients leave theatre. They have long term effects on patients, supporters, staff, and the wider organisation. The taskforce also therefore considered how patients and staff are supported following these events.

Approach

The taskforce consulted key stakeholders, carried out an evidence review, invited staff and public views through an online consultation, and commissioned narrative accounts of patient and staff experience of surgical never events.

[1] Protecting patients from harm, Department of Health, October 2012

The underlying causes of surgical never events

Surgery is an inherently risky process, and surgical systems are highly complex. A high volume of care, tailored to individual patient needs, is delivered by differently trained staff working with specialised technology in a sometimes challenging environment. Despite a genuine commitment to safe practice and a high degree of technical competence, there is ample scope for error. Evidence from across the world demonstrates that the recognised sources of error in surgery include human fallibility, miscommunication, poor co-ordination of team activity, human-technology interaction and sub-optimal management of the environment. Safer surgery depends upon reducing the scope for error from each of these sources. The WHO Safer Surgery Checklist (below) aimed to assist in this.

National and international data yield evidence that a single surgical never event is almost invariably caused by several factors, often combining unsafe systems and unsafe behaviours. Unsafe systems (such as poorly managed operating lists) produce unsafe behaviours (such as disruption during swab counts). Equally, unsafe behaviours (such as disrespect towards junior staff) undermine safety processes (such as use of the WHO Safer Surgery checklist). Examples of poor systems and practices in the NHS included: widespread toleration of variation in standard procedures such as surgical counts; operating lists with multiple changes in list order; failure to adhere to surgical site marking procedures; inadequate staffing; and absent or inadequate training, particularly in team working and clinical human factors.

Solutions

In all high-risk activities, *variation* – in processes, protocols, technical language, training, and team member status – leads to uncertainty and increases opportunity for error. Reliable and resilient systems are built by reducing variation, promoting the development of safe behaviours, and supporting the exercise of responsibility.

The Berwick Report argued that *"the best routes to badly needed improvements will build on the strengths of the NHS, not ignore them or take them for granted".* NHS professionals have been implementing the WHO Safer Surgery Checklist since the NPSA mandated its use in 2009. There are valuable lessons to be learned from this initiative. The Checklist aims to promote safety by standardising aspects of surgical care, reinforcing safety processes (e.g. identifying patient & procedure), and fostering open communication across professional hierarchies. Professionals, researchers, patient representatives, and organisational leaders agree that:

- The Checklist *is* changing culture. There is now an increasingly widespread view that 'this is the way things should be done'. By 2011, 91% of theatre staff surveyed would have wanted the Checklist used for their own surgery.

- Where the Checklist is treated as a tick-box exercise it is of limited use. The Checklist is not an end in itself, but a tool to promote systemic change and prompt safer behaviour. Like all tools, its effectiveness depends on the skill with which it is applied.

- The Checklist has promoted systemic change when professionals and organisations have embedded it into wider practices, protocols, and pathways. Similarly it has prompted safer behaviour when other means of changing behaviour – such as education and peer pressure – have been mobilised to support it. Beneficial outcomes are thus the result of professional leadership, organisational commitment, and time spent on local implementation.

- The Checklist alone is not sufficient. We must lower the prevalence of harm still further.

To achieve a continual reduction in harm, we must persist in reducing unwarranted variation, better share learning from mistakes and from improvement activity, and continue to promote provider and professional responsibility. The taskforce propose we achieve this by emulating the practice of other high risk industries.

The taskforce are therefore proposing a strategic approach that consists of three *interlocking and equally vital* elements.

The first element is *standardising* generic operating environment procedures (for example, swab and instrument counts, prosthesis verification and list management). The taskforce propose professionals take the lead role in *developing* and *continuously reviewing* national standards. These will set out broad principles of best practice, and suggest a range of acceptable means of implementing best practice. Providers will be required to embed these standards into their local processes by developing, in collaboration with their staff, their own local standards. The taskforce recommend that NHS England mandate concordance with the new national standards through the NHS Standard Contract. Future consideration should be given to whether secondary legislation is necessary to enable the CQC to take enforcement action where standards have not been met.

Professional leaders, with support from NHS England, should aim to establish a plan – practice – learn loop. This would operate both at local level, with providers developing and reviewing local standards and sharing learning through regional peer review; and at national level with a responsive mechanism for providers to feed back learning and propose modifications to national standards. This system of profession-led national and local standards will reduce variation and promote best practice, whilst providing scope for local innovation and reinforcing responsibility at provider level.

- The second element is systematic *education and training*, including for those managing operating environments. The taskforce recommendations make clear that learning needs relating to surgical safety must be addressed in undergraduate qualifications for doctors, nurses, and operating department practitioners; in postgraduate training, including the NHS Management training programme; and in trust provision for continuing professional development. Learning needs include clinical human factors, and the nature and purpose of standards. Further recommendations address the responsibilities of HEE, GMC, Deaneries and medical royal colleges for ensuring that curricula and training programmes incorporate appropriate safety training; and of CQC for ensuring the adequacy of provider training.

- The final element is *harmonising* activity to support patient safety in hospitals. The Berwick report and this report are equally clear that professional and organisational incentives must align to support safety and the development of a just culture. Examples of the taskforce's recommendations under the theme of harmonisation include: NHS England and CCGs to impose financial penalties only where a provider's *response* to a never event, including patient support, is assessed as ineffective (thus avoiding creating a deterrent to reporting); responsible officers to ensure that appraisal for revalidation includes evidence of activity concordant with local standards; NHSLA to make explicit that national standards and local standards determine the legal standard of care; GMC, NMC, and HPC to consider concordance with standards when assessing Fitness to Practice and issuing professional guidance.

Recent events have highlighted that the NHS must do better by patients, their families and its own staff in the wake of error, poor care and harm. The taskforce has therefore recommended adoption of evidence-based standards for rebuilding trust and confidence in all those affected by untoward outcomes, which should be consistent with the findings of the review undertaken by Professor Norman Williams and Sir David Dalton into statutory duty of candour www.rcseng.ac.uk/policy/duty-of-candour-review.

The taskforce's proposed strategy of profession-led standardisation, aligned to education and harmonisation, will harness the knowledge and commitment of professional and patient leaders to the goal of minimising harm. The ultimate aim – to use the words of one of the taskforce's online consultees – is to create the conditions in which front line staff can provide the quality of care they crave to give.

This taskforce report and its recommendations have now been endorsed by the NHS England Surgical Services Patient Safety Expert Group. Formal submission of the report to NHS England should signal the start of a wider conversation about implementation with patient organisations, professionals, service leaders, regulators and other stakeholders identified in the taskforce's recommendations. Funding should now be identified for a programme of work, to be led by professionals and representatives of the public interest jointly with NHS England, to embed the strategy into practice.

Table of recommendations (Note that recommendations are set out by theme and by responsible body, and numbered from left to right)

THEME 1 - STANDARDISE			
For action by NHS England	**1** Produce national standards through NHS England Patient Safety Expert Groups and co-opted experts, based on existing best practice protocols and evidence review. Scope of national standards is *core generic processes for conducting surgical procedures in operating environments wherever they are located.*	**2** NHS England mandate concordance with the new national standards through the NHS Standard Contract.	**3** National standards require all providers of NHS funded care to develop and maintain local standards consistent with the national standards. NHS England should support providers to develop local standards (e.g. by providing templates and guidance, expert advice and promoting a peer guidance network).
	4 National standards to be maintained and revised dynamically to reflect learning from all never events and serious incidents, and to incorporate new patient safety alerts.	**5** Consider standards of good practice concerning support for patients and staff following never events and other incidents of harm, taking the Williams/ Dalton review into account (*see rec 10).*	**6** Set up an independent **Surgical Incident Investigation Panel** to conduct external investigation of selected serious incidents, peer review investigations, propose amendments to national standards, and develop and disseminate best practice investigation protocols.
	7 Encourage National Institute for Health Research (NIHR) themed call for research on preventing and managing serious incidents and commissioning for safety.	**8** Further consideration to be given to the nomenclature for 'never events' in the future to ensure that 'never' or 'serious incidents' remain a focus for action, including fostering and creating a culture to improve rather than apply penalty.	
For action by NHS Local Commissioners	**9** Surgical services commissioned for NHS patients shall be provided in concordance with national standards (once defined), through development and implementation of local standards, and consistent with the NHS Standard Contract.	**10** When assessing quality of service in qualified provider, commissioners to take into account concordance with standards for good practice in supporting patients and staff following never events and other harm *(see rec 5).*	

For action by provider organisations	**11** Engage professional staff in developing and implementing local standards concordant with national standards. Establish mechanisms for quality assurance and review, and for sharing learning within peer networks and the national standards team.	**12** Where surgical services are provided to NHS patients, the chair and chief executive in NHS organisations (and their equivalents in private providers) to be held accountable for ensuring local standards are implemented in concordance with national standards.	*Also see recommendations 5, 10; and 45-49.*
For action by professional associations	**13** All professional associations concerned with surgical care to support the development of national and local standards, incorporate reference to concordance with standards in professional guidance; and state that local standards determine standard of care required of competent practitioner.		
For action by regulators	**14** Future consideration to be given to whether secondary legislation is necessary to enable the CQC to take enforcement action where standards have not been met.		

THEME 2 - EDUCATE			
For action by NHS England	**15** Work with patient and professional organisations to co-produce a range of multi-media tools about implementing and using standards, disseminating through social media and other networks.	**16** Utilise the evidenced potential of peer education, peer review, audit and associated improvement methods by promoting standards implementation and improvement through networks (e.g. NHSLA buddy scheme, Patient Safety Collaboratives).	**17** Examine the effectiveness of a range of methods of after action review and incident investigation, identify the learning needs associated with these, and work with relevant stakeholders to ensure these learning needs are met. *(See also rec 6).*
	18 Engage a cohort of keen clinical champions, e.g. through the clinical fellowship scheme, to support the rollout of national standards.	**19** Make appropriate representations to encourage training in surgical safety and human factors for healthcare professionals from the European community.	

For action by NHS Local Commissioners	**20** Commissioners to take account of education and training in relation to local standards when commissioning surgical services.		
For action by provider organisations	**21** Providers to base safety training needs analysis on local incidents, appraisal and other data indicating concordance with local standards; and incorporate local standards training into induction and mandatory training provision.	**22** Contracts with agency providers of locum clinical staff shall require locums to be familiar with national standards and aware of their responsibility for working in concordance with local standards.	(*Note: Local training requirements will be specified under 'acceptable means of concordance' in national standards, and local training policies should be specified in local standards.)*
	23 All providers of NHS services to have an appropriately qualified and rewarded clinical champion to lead work reviewing, training and responding to breaches of local standards.	**24** Professionals involved in never events should participate in a comprehensive debriefing relating to the findings following the conclusion of an investigation.	
For action by professional associations	**25** Membership examinations for surgical specialties, and curricula for peri-operative practice to include knowledge and skills relating to national standards and clinical human factors.	**26** Faculty of Medical Leadership and Management to consider how to support and train for multi-professional leadership of patient safety in surgical settings.	**27** Colleges and specialty associations to investigate the possibility of retrospective audit (under amnesty) of never events, to identify cases and their causes.
For action by educational bodies	**28 HEE** and **Local Education and Training Boards (LETBs)** to ensure that knowledge and skills relating to national standards and clinical human factors are included in training of all perioperative staff.	**29 Higher Education Institutions (HEIs)** to ensure that undergraduate and postgraduate qualifications for perioperative staff include knowledge and skills relating to national standards and clinical human factors.	**30 Deaneries** to ensure that postgraduate training adequately addresses knowledge and skills relating to national standards and clinical human factors.
For action by regulators	**31 GMC** to make approval of surgical specialty curricula conditional on adequately addressing national standards and clinical human factors.	**32 GMC** to consider adequacy of education in patient safety when reviewing basic medical education and deanery provision.	**33 CQC** to consider adequacy of local education and training in national standards and clinical human factors when assessing providers.

THEME 3 - HARMONISE			
For action by NHS England	**34** Data on serious incidents and never events to be reported via a single point of access reporting system, thematically analysed, with learning incorporated into national standards.	**35** Financial penalties to be imposed only where there is failure to report in timely fashion, inadequate disclosure, or failure to support patients and staff adequately following event (assessed through patient and staff feedback).	**36** Working with stakeholders, develop intelligent indicators of local standards concordance, including qualitative audit (e.g. walk arounds, assessing provider response); commissioning work from suitably qualified organisation to carry out research to support indicator development.
	37 Lead relevant stakeholder organisations to develop a communications concordat on learning from serious incidents, disseminating information and notifying national standards review team.		
For action by NHS Local commissioners	*See recommendations 35, 36, 37.*		
For action by provider organisations	**38** When investigating serious incidents take into account concordance with local standards; report learning about standards-related issues to national standards review body.	**39** Incorporate reference to local standards in disciplinary procedures. Unjustified refusal to comply with local standards should trigger performance review.	**40** Responsible officers should ensure that appraisal data includes evidence of concordance with local standards and make revalidation conditional upon concordance.
For action by Regulators	**41 CQC**, **Monitor** and **NHS TDA** to assess organisations using intelligent indicators of local standards concordance (*see recommendation 35*).	**42 CQC** to encourage adherence to local standards by focusing on how organisations support learning and implement improvements.	**43 GMC, NMC** and **HPC** to incorporate concordance with local standards into relevant action (e.g. Fitness to Practice) and guidance.
For action by NHSLA	**44** NHSLA to make explicit that local standards are relevant to determining legal liability, including for breach of standards of care and breach of any duty of candour.	**45** NHSLA to incorporate evidence of concordance with national standards and local standards in revised criteria for Clinical Negligence Scheme for Trusts (CNST) discounts.	*See also recommendations 36, 37.*

SUNDRY MATTERS TO BE INCLUDED IN NATIONAL STANDARDS
NOTE: The scope of national standards is defined as 'core generic processes for conducting surgical procedures in operating environments wherever they are located'.
THEME 1 STANDARDISE
46 All operating lists shall commence with a pre-list briefing at which all staff are present.
47 A national standard on list preparation shall be developed, addressing the following specific recommendations: (a) that lists shall not be altered without compelling reason; (b) that where lists are altered a further team briefing / time out shall take place; (c) that lists shall include a scheduled time for a pre-list briefing.
THEME 2 EDUCATE
48 Where appropriate national standards will make reference to provision of appropriate training an 'acceptable means of compliance'.
49 Providers shall be responsible for ensuring that staff, particularly those trained outside the NHS national standards system, receive training in local standards.
THEME 3 HARMONISE
50 Local standards shall include a description of providers' own safety and quality management system and professional responsibilities within it; this should include provider approaches to training, appraisal, ensuring concordance with standards, action in response to breaches of standards, and reporting learning from incidents to national standards.

Appendix

Sample national standard and matching local standard

(A) National Standard for Prevention of Retained Material

1.1 A system shall be in place to ensure that all devices and materials used during surgical or other invasive procedures are properly accounted for at the beginning; during; and at the end of the intervention. The system shall ensure that no unintended material is retained at the end of the procedure(s), either at the surgical site, in body cavities, on the surface of the body, or in patient's clothing or bedding.

1.2 Examples of such devices include but are not limited to; swabs; sponges; patties; pledgets; blades; suture and hypodermic needles; clips; clamps; surgical instruments and; medical devices not designed for implantation during the procedure.

1.3 The system should be designed to avoid the need to expose the patient to ionising radiation without good cause, or to expose staff to biological material, or to subject the patient to additional surgical intervention.

1.4 The system may include manual or automated reconciliation, electronic detection or other techniques.

1.5 The system will specify the responsibilities of personnel, who is accountable for the final reconciliation, and what records will be kept.

1.6 The system will specify the process to be followed in the event that an item is unaccounted for during or at the end of the procedure.

1.7 The system shall be designed to be applied consistently across all locations in the provider organisation where invasive procedures are carried out. Any exceptions should be explicitly noted.

1.8 If variations or modifications are necessary for identified sites or procedures, these should be detailed.

2.0 Reference documents: [e.g. AfPP & WHO best practice protocols]

(B) Local Standard for Prevention of Retained Materials

24 PREVENTING UNWANTED RETAINED MATERIALS FOLLOWING INVASIVE PROCEDURES

24.1 POLICY

The Trust's policy is to use manual counting methods to ensure that all devices and materials used during a surgical or other invasive procedures are properly accounted for at the beginning, during; and at the end of the intervention, and that no unwanted material is retained at the end of the procedure(s), either at the surgical site, in body cavities, on the surface of the body, or in patient's clothing or bedding.

24.2 ACCOUNTABILITY

The surgeon or operator (or lead surgeon / operator) is the member of staff accountable for ensuring that the policy is observed.

24.3 PROCEDURES

24.3.0 PRINCIPLES AND HUMAN FACTORS

No method for preventing unwanted retained materials is infallible, and this includes reconciliation by counting.

However, we can greatly improve our effectiveness by carefully following the procedures set out below and working together as a team. Not only the staff directly involved, but everyone in the room or theatre has a responsibility for the safety of the patient and to support each other.

Counts should be carried out aloud by at least two members of staff. Interruptions or distractions should be avoided. Music should be turned down or off and other members of the team should 'protect' the counting procedure. Any doubts on the part of anyone in the team should be raised immediately and be treated seriously.

24.3.1 PREPARATION

Before any patient is brought into the operating theatre, a thorough check must be made to ensure that all swabs, instruments and sharps from the previous surgical procedure have been removed from the area, and disposed of in accordance with the Trust procedures.

24.3.2 INITIAL CHECK

All swabs, instruments and sharps must be diligently checked before the surgical procedure begins. Items should be completely separated during the checking

procedure. At least one member of staff must be a registered practitioner and the circulator must have completed a surgical count competency assessment.

The number of swabs, sharps and specialist instruments must be recorded on the white board.

The counting sequence should be in a logical progression, for example, from small to large. The recommended sequence of surgical counts is: swabs, sharps, instruments, and should be performed uninterrupted. If an interruption occurs, the count should be resumed at the end of the last recorded item. The integrity of the X-ray detectable markers in swabs, packs, peanuts etc., as well as the integrity of tapes on abdominal swabs/ packs with a gentle tug , must be checked during the count by fully opening each individual swab. All swabs that are used during invasive procedures excluding neurosurgery lintine must have an X-ray detectable marker fixed securely across the width of the swab.

At the initial count, and when added during the procedure, swabs and packs should always be counted into groups of five. These should not be added to those already counted until the number in the packet has been verified. The additions should be in multiples of five. In the event of an incorrect number of swabs or packs (ie not five) the entire packet must be removed from the procedure area and appropriately reported. Hypodermic and suture needles should be recorded as a total amount at the commencement of the procedure and additional items should be added individually on the white board according to the number marked on the outer package. Suture packs may be retained and used for a check-back procedure if required. Opening all packages during the initial needle count is not recommended. Used needles on the sterile field should be retained in a disposable, puncture-resistant needle container.

24.3.3 SUBSEQUENT CHECKS

Further counts shall be carried out:

1. At the closure of an every cavity eg stomach/ uterus/ joint cavity/ abdominal.
2. At any other time deemed necessary.
3. At final closure of skin layer.

The scrub practitioner informs the surgeon of the result of the counts prior to each cavity and wound closure. Verbal acknowledgement must be received from the surgeon. The surgical team must allow time for these checks to be undertaken without pressure and in silence ie music turned off and noise levels to be minimal. Both practitioners must count aloud and in unison. At all times during a surgical procedure the scrub practitioner must be aware of the location of all the instrumentation and swabs etc. When additional items are added to the field, they should be counted at the time and recorded on the white board or supplementary instrumentation documentation.

On completion of the count, a verbal statement is made by the scrub practitioner to the effect that all "swabs, needles and instruments are correct."

Verbal acknowledgement is required from the surgeon in order to prevent any misunderstanding.

Swabs, instruments, sharps or bags of rubbish should not be removed from theatre until the end of the surgical procedure. At the end of the case and before the patient leaves the theatre all remaining swabs must be counted out with the circulator in batches of five into a clear plastic bag for disposal and marked off the whiteboard.

24.3.4 FINAL RECONCILIATION

It is the responsibility of the scrub practitioner to confirm to the surgeon that all swabs are accounted for and safely disposed.

24.3.5 RECORDING

The scrub practitioner and circulator will record and sign all documentation to confirm the count is correct at the end of the procedure.