

Standardise, educate, harmonise

**Commissioning the conditions for
safer surgery**

**Report of the NHS England Never
Events Taskforce**

February 2014

NHS England Surgical Never Events Task Force Report

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First published: 27 February 2014

Prepared by

NHS England Patient Safety Domain

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.

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

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.

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.

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Chapter by chapter summary

Chapter one – Definitions and prevalence of surgical never events in the NHS

This report presents the findings of the ‘surgical’ never events taskforce. Never events are serious, largely preventable, patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers. There are three ‘surgical’ never events: wrong site surgery; wrong implant; and retained foreign object post-operation.

In 2012/13 a total of 329 surgical never events were reported to the Strategic Executive Information System (STEIS). The most frequent was retained foreign object post-operation. The taskforce undertook its work through meetings, literature review, interviews with patients and professionals who have experienced never events, and consultation with leaders in the field of patient safety. We also ran an online consultation in association with the Royal College of Surgeons. Comments were invited from patients, professionals and organisations, and we received 638 responses.

Chapter two – The three ‘surgical’ never events: overview of causes

A consistent and compelling message emerges from our evidence review and consultation process.

This message is that a never event is almost invariably caused by multiple factors. There is no single, simple cause underlying the occurrence of ‘surgical’ never events. Importantly, this means that no single, simple solution will eliminate them.

Sources of error consistently recognised are:

- intrinsic complexity of surgical technologies and procedures, allied to the need to accommodate individual patient variation and preferences;
- significant variation in professional approaches to safety related processes (e.g. swab counting) leading to muddle, confusion and failure to respect unfamiliar protocols;
- failures in planning, organisation and co-ordination even where resources and personnel are not an issue (e.g. operating lists that are changed at the last minute, patient order being altered during operating lists);
- time pressures and the use of ‘work arounds’ to manage work pressure;
- unplanned events and distractions that disrupt work flow; and
- general communication failures, which may be viewed as symptomatic of the enormous challenge in communicating what needs to be communicated in all of the above circumstances.

Respondents to our consultation also highlighted risks created by:

- poor professional behaviour ; and
- chronic lack (or poor utilisation) of resources, creating an unsafe operating environment.

Chapter three - Action to prevent the three ‘surgical’ never events: evidence about the efficacy of interventions

We reviewed the evidence base for interventions to prevent each of the three ‘surgical’ never events. Strong evidence for efficacy is largely restricted to specific technological interventions. Aside from evidence supporting use of the WHO Surgical Safety Checklist, only weak evidence exists for approaches to achieving complex organisation-wide change.

Wrong site surgery

A range of pre-operative checks, supported by protocols such as the WHO Surgical Safety Checklist and pre- and post- list briefings are widely advocated.

Retained foreign objects

It is widely accepted that manual counting systems are vulnerable to human error. Technologies to prevent retained swabs rely on bar-coding and radio frequency-tagging. Sophisticated calculation would be required to identify the ‘cost per prevented retained object’ using technological aids. We found no evaluations of specific interventions designed to prevent other retained foreign objects such as surgical instruments or guidewires.

Chapter four – Action to improve surgical safety (1) The World Health Organization Surgical Safety Checklist

We were asked to examine the effectiveness of the roll-out of the World Health Organization Surgical Safety Checklist in the NHS.

The WHO Checklist has had undoubted benefits, and the introduction of team briefings before and after operating lists has met with support in many clinical teams. But if safety checklists and team briefings are to prevent adverse events as effectively in the NHS as they do in aviation, they require the same commitment to: systematic standardisation; appropriate education and training; rigorous enforcement; individual accountability; and adequate resources.

In our assessment we drew on the NIHR-funded national evaluation conducted by Imperial College London as well as the international literature.

The Checklist is perceived to work best when there is training and education around its use in practice; it is modified to suit different surgical specialities and the local context; when it is incorporated into existing processes; when

staff receive data highlighting a positive impact at a local level; and when senior surgeons actively drive and promote its use.

The Checklist is generally well received by patients.

Barriers to successful implementation include resistance from senior surgical and anaesthetic staff; a perceived lack of support from hospital management; a perception that the Checklist is time consuming and replicates systems already in place; and that the Checklist has design faults.

Where the Checklist is used well, and particularly where surgeons visibly lead the process, it can improve teamwork and concordance with optimal processes of care (such as checking patient identity, the procedure, administration of antibiotics). However, there is evidence that it has been poorly implemented in a number of locations.

Chapter five – Action to improve surgical safety (2) Patient Safety First ‘5 steps to safer surgery’

We also reviewed voluntary adoption of pre-list team briefings and post-list debriefings. These have been found to be useful by teams adopting them, although it is more difficult to ensure that all members of a team are able to be present at post-list briefings. In our consultation process, team briefings (pre-list in particular) received strong support from all grades of staff.

Chapter six – Action to improve surgical safety (3) Involving patients in safety activity

Our evidence scan, responses to our consultation, and the experience of task force members all suggest that there is some distance to go before we understand how best to involve patients and carers in safety related activity.

At individual level, familiar forms of patient involvement in safety such as self-identification, and collaboration in surgical site marking, may now be so much a part of routine that they are not commonly viewed as patient involvement.

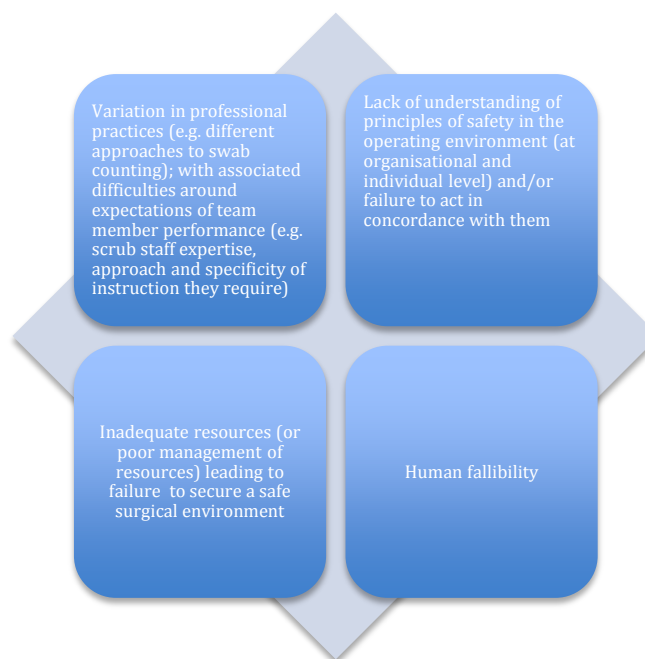
At service level, well-managed patient involvement can enhance service design, increase transparency, and prompt vigilance by reminding staff of the human consequences of error. Patients can also be valuable allies to clinical staff demanding improvement.

However, when patients are recruited to activities where their version of events challenges the organisation, their role is to propose or critique technical solutions, where they are not given adequate support, or if they do not see anything change, involvement works far less well.

There are also principled arguments against inappropriate reliance on patients as ‘safety partners’. These relate to effectiveness and burdening patients with responsibilities that they would be unable to fulfil.

Chapter seven – Adopting a systematic approach to improve surgical safety (1) Standardise, educate, harmonise

Against a background of intrinsic complexity in surgery and patient variation, we propose there are four central causes of error that any effective strategy should address. They are: (see figure below)



A series of 'fixes' is unlikely to provide an effective solution. We are therefore proposing a single strategy that consists of three interlocking elements.

At the centre of our strategy is the *standardisation* of operating environment procedures. Standardisation must be linked to *education and training* for all staff, including those managing the operating environment. *Harmonisation* of surrounding activity such as resource allocation, commissioning, regulation, and revalidation should ensure that professional and organisational incentives and disincentives are aligned.

This process starts with NHS England, as a commissioning body, working in collaboration with professionals and professional bodies to develop a coherent framework of national standards for operating department practice, and mandating provider concordance with the national standards. The mandate may be achieved through contractual means or secondary legislation. Providers will be required to develop, implement and enforce local standards consistent with those developed nationally.

In proposing *standardisation*, we cannot stress too strongly that our intention is *not* to introduce yet another set of boxes to tick. The aim of standardisation is to embed best professional practice in clear standards, minimising the risks of variation; thus maximising consistency of action across teams,

organisations, and the health system. The principle underlying standardisation is that *everyone*, from patients who ultimately undertake the risks of surgery, to professionals who may unintentionally harm them, is entitled to know exactly what standards of practice are expected.

In proposing *education and training* to support standardisation, we are convinced that the most important safety asset the NHS owns is its staff. If they possess a common understanding of principles of safer surgery, not only will they be able to support each other to implement them but they will use their intelligence and imagination in the service of future improvement.

In proposing *harmonisation* of all surrounding activity we aim to match human and financial resources to operational need, reduce bureaucratic burden, make regulation effective, and hold organisations or individuals accountable.

The overarching purpose of this system is to standardise *core operating environment processes*, whilst also encouraging planned local innovation, reinforcing provider and professional responsibility, and harmonising the activities of a range of national stakeholders (such as regulators) and local stakeholders (such as CCGs and Healthwatch).

We have set out in our proposals a process for developing national standards that utilises the expertise of clinical and safety experts. The national standards will be based on best evidence and best practice, drawing from World Health Organization and other guidelines already promoted by medical royal colleges and professional associations.

Chapter eight – Adopting a systematic approach to improve surgical safety (2) The new safety landscape

In the *Initial Government Response to the Report of the Mid-Staffordshire NHS Trust Public Inquiry*, national stakeholder signatories stated that it was their common purpose to: “*work together, collaborating on behalf of patients, combining and co-ordinating our strengths on their behalf, sharing what we know and taking collective responsibility for the quality of care that people experience. We will be ... unflinching in promoting what is excellent*”.

We describe in our proposals how national standards will enable care providers and other key stakeholders to standardise, educate, and harmonise their activities when all surgical care is commissioned in concordance with national standards. We believe that national standards will offer significant reassurance to patients and commissioners that NHS surgical services will meet the same standards for safety, whether treatment is provided by NHS trusts or by other qualified providers.

A strong message to come out of the taskforce work is that, despite good intentions, the NHS could do better at learning from serious incidents. National standards will provide a national mechanism for incorporating the learning from serious incidents into revised or new protocols and practice guidance. They will become an authoritative point of reference updated in light

of new thinking about optimal operating environment practice. Local standards will in turn both be the source of, and mirror, these developments.

National standards will supply a baseline indication of the knowledge, skills and attitudes required to make surgery safe. This will enable those with responsibilities in education and training to identify, assess and respond to the education and training needs of multi-professional teams. National standards should inform provision across basic education, continuing professional development and mandatory provider training.

National standards will supply professionals with an authoritative point of reference, enabling them to advise, audit, review and challenge the provider organisations within which they work. They will also provide a point of reference for determining the legal standard of care, and hence its breach, in respect of the professional practices with which it deals.

Finally, national standards provide a vehicle for focusing regulatory activity. This has potential to promote consistency in assessment, to support rationalisation in inspection, and to reduce bureaucratic burden.

Chapter nine – Implementing compassionate support after never events and other serious incidents

No matter how good we become at preventing never events, they and other serious incidents will happen. Just as we expect the airline industry to have a clear plan in place for how to deal with crashes when they occur, so we expect the NHS to provide appropriate support to patients, their supporters and the professionals caring for them, when things go wrong. An appropriate response after harm is a critical foundation stone of a just (and therefore safe) culture.

The taskforce therefore considered the needs of patients and professionals following never events and other adverse incidents. In this chapter we outline a framework of seven standards that if implemented could satisfy the requirements of making amends after harm. The taskforce recommends that these evidence-based standards 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.

Chapter ten – Views on how to improve the learning from never events

Finally, we present views from the consultation about how the NHS might better learn from never events. Robust mechanisms for disseminating learning throughout a mixed public/private health economy may become increasingly important if commissioners take the opportunity to award more contracts to qualified providers.

Many respondents chose to comment on the benefits of standardisation when invited to suggest what could be done nationally. Additionally, there is an appetite for learning from thematic reviews of recent patient safety incidents, delivered in a variety of ways to meet different learning styles.

It is apparent that there is huge variation in how effectively NHS trusts disseminate the lessons of serious incidents. Peer review has received favourable attention in the research literature and there are indications in our consultation that it may be a welcome but currently under-used approach.

Revalidation was also viewed as a potentially powerful lever to focus professional attention on learning from serious incidents.

Sophie's story

A surgeon removed the incorrect facial lesion from a female patient.

Sophie, a retired registered nurse and health visitor, was referred by GP for specialist opinion after discovering an abnormal growth near her eye. A basal cell carcinoma was suspected.

Sophie was seen in outpatient at her local hospital and referred for surgery. A series of administrative errors and miscommunications delayed Sophie's operation date, which was finally scheduled three months after her initial referral.

The procedure was to be completed over two appointments within the same week. Sophie was anxious. She had recently failed two bowel screenings and feared that the problem with her gut might be a secondary cancer. When she arrived for her surgery, it was the second day of five that Sophie would spend at the hospital for various appointments that week.

Sophie was told that the consultant surgeon, whom she had expected would perform the operation, was on holiday. Another staff grade surgeon would perform the first stage of the procedure. Sophie was surprised and complained. She was told she could cancel the appointment and rebook if she wished. Sophie desperately wanted to be treated, so went ahead. The hospital was keen to proceed to avoid a waiting time breach.

The surgeon who was to perform the operation had been expecting a day in clinic. On arrival at work she discovered she would be operating instead. She was running late. A new pre-list briefing session had been introduced during the previous week following a CQC inspection. This further delayed the list start time, as people were unfamiliar with the new process. The operation site was not marked before Sophie went into theatre. A local anaesthetic was given and the operation was performed. Sophie later discovered that the checklist recorded the site as "marked", the form having been completed ahead of the list to "save time".

Two days later, Sophie returned for completion of the procedure. Histopathology reported that the lesion was non-malignant. The second operation was therefore not considered necessary but some re-suturing was needed. The original consultant surgeon performed the procedure. When Sophie asked if he had had a good holiday he said that he had not been on holiday. He said that he only worked on alternate Tuesdays in this hospital. It later transpired that he had been on leave but had not given the required notice to cancel his list. Sophie was upset that she had been misinformed.

(continued/-)

Three days following the procedure the wound dressing came loose. Sophie examined the wound area, which was very red. She noticed that the suture line was in a position away from the lesion area. Sophie realised that the original lesion was still there. After an urgent referral to the hospital, a third doctor who had no access to her notes saw Sophie. After escalating her complaint to a senior manager, the surgeon who had performed the first procedure was called.

Although the surgeon acknowledged she had operated a lesion that Sophie had not expected, she would not admit that a mistake had been made.

An urgent appointment was made for Sophie to see the original consultant surgeon. Sophie sensed a defensive attitude when she arrived. She felt no one believed her that the wrong lesion had been operated on. Sophie left feeling that she was being blamed for the error.

“The one thing about all this which really won't go away is how awful the consultation was with the surgeon when I went back. He made out that he couldn't see the original lesion. I said to him that I didn't blame him to try and improve the atmosphere and make him be sympathetic and pleasant. I just felt he was trying to minimise it.”

A biopsy was arranged for the following week.

The original lesion proved positive for basal cell carcinoma.

(See Appendix 1 for information about this story)

Chapter one – Definitions and prevalence of ‘Surgical’ never events in the NHS

Never events are serious, largely preventable, patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers. There are three ‘surgical’ never events defined below. They are the subject of this report.

Following publication of the updated Never Events Policy Framework in October 2012, NHS England announced the creation of ‘a taskforce to look at surgical never events in order to make sure that these events are eradicated from NHS surgery’. The taskforce was formed in March 2013 and asked to present recommendations to NHS England by 31 July 2013. Our terms of reference and membership are set out in Appendix 1.

The taskforce undertook its work through meetings, an evidence scan, interviews with patients and professionals who have experienced never events, and consultation with leaders in the field of patient safety. We also ran an online consultation in association with the Royal College of Surgeons (June - July 2013). Comments were invited from patients, professionals and organisations, and we received 638 responses. We have used comments from the consultation throughout the report. They express the varied opinions of clinicians and managers in the service as well as views from a handful of patients and supporters, lawyers, researchers and others with an interest in reducing never events. They cannot of course be treated as representative of the totality of views on any given topic.

Comments submitted to our online consultation are included throughout the report in this format [including type of respondent]

‘Surgical’ never events in the policy context

The purpose of the never events framework is to protect patients from avoidable harm through promoting the adoption of known preventative measures, transparent disclosure, and accountability.

According to the US Agency for Healthcare Research and Quality the term "Never Event" was first introduced in 2001 by Ken Kizer, former CEO of the National Quality Forum. He used it to refer to particularly egregious errors (such as wrong-site surgery) that should never occur. The concept of never events was introduced to the NHS in England in April 2009, following Lord Darzi's report *High Quality Care for All* (DH, 2008). The National Patient Safety Agency selected eight types of preventable patient safety incident to test the never events initiative, and issued a policy framework containing guidance for commissioners and providers. This framework was updated in 2010, strengthening requirements for recording the occurrence of never

events; clarifying roles and responsibilities; and emphasising the learning that could be achieved following an incident. It also highlighted that a condition of Care Quality Commission registration included statutory notification of serious incidents, which include never events.

The never events policy framework permits commissioners to withhold payments for an episode of care where it has fallen below acceptable standards. However, the framework states that cost recovery after the occurrence of a never event should be secondary to reporting and learning from it. Commissioners therefore have discretion to waive the cost recovery process according to their judgment of the circumstances of the never event, and the quality of the provider's response.

The never events framework was last updated in 2012. Never events are also included in the NHS Serious Incidents Framework, reissued in March 2013, which sets out roles and responsibilities in relation to the occurrence of serious incidents.

The three 'surgical' never events

There are currently 25 specified never events, of which only three have been defined as 'surgical' never events for consideration by the taskforce. Whilst we have called them 'surgical' never events, it should be noted – as many of our consultees pointed out – that they may occur in a range of settings. Equally, some of the other 22 never events could occur in the operating theatre environment. The 'surgical' never events are described below using the NHS England definitions.

Wrong site surgery

A surgical intervention performed on the wrong site (for example wrong knee, wrong eye, wrong patient, wrong limb, or wrong organ). The incident is detected at any time after the start of the operation and the patient requires further surgery, on the correct site, and/or may have complications following the wrong surgery.

- Includes biopsy, radiological procedures and drain insertion, where the intervention is considered surgical.
- Excludes wrong site anaesthetic block.
- Excludes interventions where the wrong site is selected because of unknown/unexpected abnormalities in the patient's anatomy. This should be documented in the patient's notes.

Wrong implant

Surgical placement of the wrong implant or prosthesis where the implant/prosthesis placed in the patient is other than that specified in the operating plan either prior to or during the procedure. The incident is detected at any time after the implant/prosthesis is placed in the patient and the patient requires further surgery to replace the incorrect implant/prosthesis and/or suffers complications following the surgery.

- Excludes where the implant/prosthesis placed in the patient is intentionally different from the operating plan, where this is based on clinical judgement at the time of the operation.
- Excludes where the implant/prosthesis placed in the patient is intentionally planned and placed but later found to be suboptimal.

Retained foreign object post-procedure

Retention of a foreign object in a patient after a surgical/ invasive procedure.

‘Surgical/ invasive procedure’ includes interventional radiology, cardiology and interventions related to vaginal birth.

‘Foreign object’ includes any items that should be subject to a formal counting/ checking process at the commencement of the procedure and a counting/ checking process before the procedure is completed (such as swabs, needles, instruments and guidewires) except where:

- items are inserted during the procedure but are intentionally retained after completion of the procedure, with removal planned for a later time or date;
- items are known to be missing prior to the completion of the procedure and may be within the patient (e.g. screw fragments, drill bits) but where further action to locate and/or retrieve would be impossible or be more damaging than retention; and
- items were inserted at an earlier date or time and not removed as planned during a later surgical/ invasive procedure.

Reporting mechanisms and prevalence of ‘surgical’ never events

The NHS in England has two reporting systems, neither of which is able to supply an entirely reliable picture of the prevalence of never events.

One is the National Reporting and Learning System (NRLS), which retrieves data on a wide variety of incidents via local risk management reporting systems. In April 2010, it became mandatory for NHS organisations to report all patient safety incidents that result in severe harm or death to the NRLS. In addition, since April 2011 all NHS organisations have been required to flag never events in incident reports to NRLS. All patient incident reports submitted to the NRLS which are categorised as resulting in severe harm or death are individually reviewed by clinicians for NHS England, so that action may be taken at national level where appropriate.

The second database is that formerly maintained by the Strategic Health Authorities (SHAs), the Strategic Executive Information System (STEIS). The Serious Incident Framework, which covers never events, requires serious incidents to be reported on STEIS within two working days of occurrence. Never events should be flagged at the time of reporting, and must be reported

to the Care Quality Commission (CQC) via the NRLS. Foundation Trusts have in the past been required to report to the NRLS but not to STEIS.

Not surprisingly there is confusion across NHS organisations about reporting to both or either the NRLS and STEIS, and questions surrounding the reliability of data in either system. Analysis of the numbers and types of never events reported to both systems indicates that reporting is not consistent. Moreover, it is not possible to view figures in annual series, because reporting mechanisms have been inconsistent from year to year.

A reconciliation process conducted on data from the two systems for 2011-2012 indicated that STEIS probably contained the more comprehensive data on never events.

Surgical never events reported 2012 – 2013

| 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 |

Notes on the data:

- The total given above is for never events of all types for which reporting is mandatory. The taskforce was asked to look only at the three types of surgical never events.
- Some never events may only become apparent a considerable time after they occur. This was the case with the wrong implant case that we illustrate in the **A Surgeon's Story** case study on page 37. There it was only on review in an outpatient clinic 12 months after the procedure that it was reported the implant did not perform as well as might be expected. Similarly, cases of 'gossypiboma' (a term emanating from the US literature) have been reported (e.g. Zahiri 2011). Gossypiboma is an aseptic fibrinous response resulting in tissue adhesions or foreign body granuloma, where symptoms may not be present for months or years following surgery.
- The figures given above do not include never events which were unreported, for whatever reason.
- Current reporting systems enable us to identify the number of surgical never events by region, but it has not been possible to retrieve the total number of people admitted to hospital for surgical care or non-Caesarean birth by region. Moreover, we cannot provide a reliable series of annual

figures. As it is impossible to make any inference about prevalence by region, we have included only the national figure.

The Serious Incidents framework and current safety surveillance

Serious incidents were defined in the 2010 *National Framework for Reporting and Learning from Serious Incidents Requiring Investigation*. Never events may not result in severe harm or death to patients. However, all never events are automatically treated as serious incidents, primarily because they are viewed as preventable and may therefore be indicative of poor safety culture within an organisation.

The Serious Incident Framework outlines the roles and responsibilities of organisations in relation to serious incidents including never events.

| Organisation | Responsibilities |
|--------------------------------------|--|
| Provider of NHS funded care | Responding, reporting, investigating and implementing actions following a serious incident. |
| Clinical Commissioning Groups (CCGs) | Holding to account NHS funded acute, community, mental health and ambulance providers for their responses to SIs and where appropriate commissioning and coordinating serious incident investigations. |
| NHS England as direct commissioner | Holding to account providers of NHS funded primary care, specialised care and other directly commissioned services (e.g. screening and immunisation, healthy child) for their responses to serious incidents and, where appropriate, commissioning and coordinating serious incident investigations. |
| NHS England assurance | Oversight of serious incident investigations undertaken in NHS funded acute, community, mental health and ambulance care including reviewing trends, quality analysis and early warnings via Quality Surveillance Groups. |

| Organisation | Responsibilities |
|---------------------------------------|--|
| NHS Trust Development Authority (TDA) | Supporting NHS trusts in ensuring they have effective systems and processes in place in relation to serious incidents, coordinating responses where necessary alongside commissioners. Using relevant intelligence and information to inform their role in providing accountability of NHS trusts. |
| NHS England national policy team | Identifying intelligence and learning to be shared at national level and facilitating such learning and sharing. Keeping the SI management system under review, particularly to mitigate risks following transition. ² |

Since the abolition of the NPSA, NHS England has assumed the responsibility for ensuring that the NHS responds to and learns from patient safety incidents. It is planning to rationalise reporting systems and the NHS England Patient Safety Domain continues to provide oversight of the data.

It is expected that the Clinical Commissioning Groups (CCGs) will define requirements for responding to serious incidents in contracts with providers, including quality surveillance and assurance.

² The Serious Incident Framework does not include a role for Monitor

Chapter two - The three 'surgical' never events: overview of causes

"No place epitomizes the complexity of health care delivery better than the Operating Room (OR) where there is the routine interface of heterogeneous, variously trained personnel using high technology equipment while providing service to an unconscious, anesthetized patient. In fact it is most helpful to think of the modern OR as a complex adaptive system that consists of (1) heterogeneous interdependent decision making agents; (2) who interact frequently with each other; and (3) develop a characteristic called emergence which arises when the whole actually begins to perform better than the sum of its parts...Anyone who has worked in a highly functioning OR over time can understand how this entity can evolve but also how rare and difficult it is to achieve." (Gibbs, 2012)

In this chapter we outline the causal explanations for never events presented in the research literature, and augment these with views expressed through our public consultation.

We conducted an evidence scan of the published literature on the three types of surgical never events, and included in this some of the literature on human factors in surgery. The evidence scan underpins this chapter, and a bibliography is included in Appendix 2.

Most of the published data on prevalence and causes of surgical never events derive from retrospective review of reported cases, which have been drawn from a variety of databases. These include national and state-wide reporting systems in the UK and US, and databases of malpractice claims.

Retrospective review of such data gives an incomplete picture of prevalence and cause. Fear of retribution for making a report, avoidance of blame for error, or a wish to escape financial penalty deter reporting. Reporting systems therefore under represent the frequency of serious incidents, including never events. Claims databases are even less representative of the pattern of events, because many events will not lead to insurance claims or legal action. Finally, the analysis of the data can only be as good as the data in the database. The account of causation that is recorded in a database is several steps removed from reality. Moreover it is highly unlikely to include patients' views about what happened.

However, it is fair to say that a consistent and compelling message emerges from the literature analysing these different data sources.

This message is that there is no single or simple cause underlying the occurrence of the events under review. Importantly, this means that no single solution will eliminate never events.

Views on cause in our public consultation

The views on the causes of surgical never events expressed in our consultation were wholly consistent with the findings from formal research. We have therefore, where appropriate, included illustrative comments from the consultation in our overview of the literature.

Human factors in surgery

In their 2012 analytic review of human factors in surgery, Shouhed et al (2012) noted:

“Operating rooms are commonly intricate, high-stress environments occupied by a broad array of technological tools and inter-disciplinary staff. The operating room has a unique set of team dynamics, as professionals from multiple specialties whose goals and training differ widely are required to work in a closely coordinated fashion. This complex setting provides multiple opportunities for sub-optimal communication, clashing motivations, and errors arising not from technical incompetence but from cognitive biases, poor interpersonal skills, and substandard environmental factors.”

We do not share the learning as well as we might. The ‘system’ often ‘lays the ground’ for the never event to occur. [Surgeon]

Reviewing the factors that negatively affect surgical performance, and primarily citing data from studies in the US, Shouhed et al grouped the human factors that precipitate never events into three categories:

- problems in the operating room environment, largely resulting from interactions between humans and technology;
- problems with communication; and
- problems in team functioning.

The operating room environment becomes a source of error through factors such as clutter, congestion, excessive noise, poor lighting, uncomfortable temperature, equipment with ill-designed user interfaces, and equipment that is poorly maintained or not available when required.

Equipment and implants must be available for each list, so teams are not sharing or competing for them [ODP]

Miscommunication and partial communication are widely recognised to be one of the primary sources of error in the complex surgical environment. Examples of communication error include inattention and inaccuracy, misleading theatre lists, ambiguous abbreviations in notes, misunderstanding of instructions and requests, mishearing, misreading, and muddled information in handover.

Safety briefings don't stop never events. The two we had in this trust happened because we were not accurate at the briefing about what we were doing; and not enough attention was paid.
[Anaesthetist]

Studies frequently cite communication issues as the leading cause of serious incidents, but we should be careful to view communication failure in the context of the environmental demands of modern operating rooms. The more complex and pressurised the environment, the higher order are the communication systems and skills required by it. Communication failures are therefore at least as much a product of the system as they are of individual error.

Human error does not occur in isolation: there is always an organisational context [Surgeon]

Team functioning is not the same as communication; although the two are often treated as synonymous and do indeed overlap. Team functioning is about the coordination of work between people in different roles with specific and unique skills.

All great live performances rely on skilled personnel who know how to carry out the task at hand, adequate planning, sufficient rehearsal, good timing and coordination, etc. Surgery is no different. Errors may arise from not having appropriate skills on hand in the team, team members being unfamiliar with different approaches to procedures, inadequate planning and briefing, failure to carry out checks effectively either before or after a procedure, assuming something has been done and not double checking, not speaking up when things are thought to be amiss, disruptions to the flow of work, etc. Team functioning becomes more difficult when teams are composed of fluctuating members working under pressure. It can also be negatively affected by the opposite, when teams become confident, comfortable, but less vigilant.

In an observational study of cardiac surgery, Wiegmann et al (2007) demonstrated how the three factors of environment, communication and team functioning interact to produce error. Errors increase significantly when the flow of work is disrupted by equipment and technology problems, difficulty in accessing resources, communication failures, impaired teamwork, and extraneous interruptions.

These difficulties were frequently reflected in comments in our online consultation.

Never events result from latent system issues, lack of awareness and insight into risk by individuals, lack of standardised practice and usable protocols, and good practice / theatre discipline being diluted. [Peri-operative nurse, theatre manager, safety expert]

Allow all members to do the checks not just surgeons and scrub staff. Make sure there are no distractions on surgeons from management or wards. Make sure the team are left to concentrate on one case at a time. [ODP]

Weigmann's picture of how systemic and work design weaknesses contribute to error holds true in human factors analysis of NHS never events.

A review of nine English surgical never events carried out by the Clinical Human Factors Group (CHFG) identified seven factors *common to two or more cases*. Grouped according to Shouhed's classification, they included:

- Operating theatre environment
 - unfamiliar theatre layout, or equipment that disorientated or distracted surgical staff; and
 - time pressures that encouraged staff to take short cuts, omit safety checks or make errors when rushed.
- Communication
 - ineffective site marking practices;
 - confusing notation in patient records and notes, including misleading or ambiguous abbreviations; and
 - difficulties in communicating with patients because translation was not available.
- Team functioning (includes coordination, anticipation, leadership, decision-making, situational awareness)
 - not using the World Health Organization safe surgery checklist to anticipate safety issues;
 - staff changes, interruptions and distractions; and
 - ineffective leadership.

We would emphasise that even though both Shouhed and CHFG are conducting human factors analysis, they classify the human factors slightly differently. CHFG's analysis considered environmental factors more widely than Shouhed and colleagues. As well as looking at the operating theatre environment, CHFG identified causal factors elsewhere in the system:

- Information, data and records
 - Delays in patient records being filed
 - Information not being available at team meetings
- Job design and responsibilities
 - Management meetings conflicting with theatre schedules
 - Excessive workload allowing insufficient time to read notes before operating
- Work design
 - Staff breaks and interruptions were not planned for
 - WHO checklist was treated as a burden to be managed without reviewing work patterns
- Culture and organisation
 - Unrealistic expectations of staff to cope with time pressures and workload
 - Staff acceptance of time pressures causing shortcuts and failures to follow procedure
 - Hierarchies prevented staff speaking up or asking for help
 - Poor safety culture meant the World Health Organization safe surgery checklist was perceived as a burden rather than a tool for staff to protect against errors.

Never events are usually systematic problems that can be overcome by systematic review and implementation of changes based on evidence. [Surgeon]

Never events demonstrate a need for systematic and standardised processes, effective team building, cross speciality learning, improved assessment of risk, and system design to reduce the possibility of human error. [Deputy Medical Director]

Research literature on specific never events

The literature we review below gives us some insight into *risk* factors (which are associated with untoward incidents, but do not directly bring them about), *systems* factors (which increase the likelihood of risks materialising), *causal* factors (which directly contribute to the unwanted outcome), and specialty specific challenges.

Wrong site, wrong procedure and wrong patient

Seiden and Barach conducted an extensive study of wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse events in the US between 1990 & 2005 (Seiden 2006). Analysing several databases they listed the common causes, grouping them into human causes, patient-related factors and procedural factors.

- Human causes cited by Seiden and Barach include high workload, fatigue, multiple team members, diffusion of authority and lack of accountability, team communication, changes of personnel, haste, inexperience, and incompetence.

Authority should be across the team and all members' contribution should be acknowledged and acted upon. Often the non-doctor staff are 'bullied' into actions that they know are wrong. [ODP]

- So-called patient factors (this is not in our view an entirely appropriate label, as it seems to suggest that patients are the cause of error). These included patients not consulted before block or anaesthesia, patient confusion about side, site, or procedure, patients having the same name as another patient, and patients being under stress prior to a procedure so mistakenly verifying facts that are incorrect.

Suggestion for improvement: Robust medical records system over entire NHS, one number, one barcode for individual patients from GP/dental referral to hospital. [Peri-operative nurse]

- Procedural factors included the wrong side draped and prepped, conducting similar or same procedures back-to-back in the same room, not observing marked site or marking the wrong site, and not cross-checking for consistency in consent form, patient chart, and theatre list.

A US review of wrong site surgery cases revealed that multiple errors occurred along the patient pathway to the operating theatre, and multiple defences failed which might have caught the mistakes (Clarke 2008). The review supports Gibbs' conclusion that: "inadequate standardization of practices and poor training and enforcement of practices provide the latent factors which exist that sets OR personnel up for failure." (Gibbs 2012)

In addition, the specialty literature from the UK and the US has noted a range of specialty-specific challenges in relation to wrong site surgery.

These include difficulties in site marking for tooth extraction (Knepil 2013), ambiguity in site marking in head and neck surgery (Liou 2013), and errors in identifying correct level in spinal surgery (Devine 2010, Longo 2012). Overall, specialty-specific risks appear to arise in the main from difficulties in standardising practice in highly specialised fields, implementing appropriate site-marking protocols in special circumstances, and inherent anatomical complexity.

Wrong implant

There is scant published literature on wrong implant never events. Intraocular lens implantation (following cataract removal) is one of the most common elective surgical procedures, so it also features prominently in the wrong implant literature.

In a 2011 review of incidents involving implantation of an incorrect intraocular lens reported to the National Reporting and Learning System (Kelly 2011) the findings were consistent with those relating to other surgical never events. The authors noted that: "many errors in IOL implantation were not complex technological issues, but the result of poor organisation such as misfiling or misreading of biometry printouts, transcription mix-ups, and communication breakdowns between the operating surgeon and nursing staff."

Although there may be specific technical reasons for a wrong implant being used, the reasons for the error may be the same as in cases of wrong site surgery.

The never event demonstrated greater awareness of the need to 'pause' in order to check that the patient is the correct one, that the team is all agreed on the site/side that is being operated, therefore reducing wrong implants being placed in patient. [ODP]

Retained foreign objects

The US and UK experience of retained surgical instruments is similar, with the most common retained instrument the cotton gauze surgical swab (the term in the US literature is surgical sponge). Other foreign bodies include: patties, pledgets, blades, suture and hypodermic needles, clips, clamps, surgical instruments and medical devices not designed for implantation during the procedure.

Reports consistently identify the abdomen/pelvis, chest and the vagina as the commonest location for retained swabs. While copious blood loss and number of sponges used are risk factors, Gibbs noted that: “sponges have been retained when only 10 sponges were used and small biopsy or skin incision made.” (Gibbs 2012)

Gibbs also draws attention to increased incidence of retained guidewires, sheaths and catheters found after interventional vascular, cardiac and radiological procedures. As these are performed at varied sites outside of the core operating theatre environment, the implications are significant. The risk of retained objects affects an ever-larger range of providers of invasive procedures, and any strategy to prevent these never events in NHS care will have to take account of the range of locations for invasive procedures.

Surgical never events don't just happen in theatre. We do procedures in outpatients without the same controls. Do we count everything that we put in and out of body cavities? [Other professional, role not identified]

WHO Checklist needs to apply in non-theatre settings where invasive procedures take place, such as outpatients. Identity checks are important. So is listing of patients, inexperience and unfamiliarity with implantable devices. [Manager]

In a comprehensive recent review of research on retained surgical swabs, needles and instruments, Hariharan & Lobo (2013) report a variety of risk factors (further confirmed in research published after their review). They identify a number of risk factors associated with the occurrence of this form of never event:

- Patient-related risk factors include the extent of blood loss, and patient body mass index. Several studies converge on finding that risk of a retained foreign object rises in line with the duration of surgery, and also when complications arise during a procedure.
- Consistent with the emphasis in human factors analyses, work design is a significant source of risk. The risks of retained instruments rise with changes in perioperative staff during a procedure, where multiple surgical teams are present. (These factors may be associated with duration of surgery and complexity of procedure, as above). An additional risk factor is equipment failure (Moffat-Bruce 2012).

Generally it is human error that is the main culprit, however, additional factors are late running lists, distraction of the team at swab count and loss of the lead surgeon towards the end of the case before the final count. Safety relies on the ability of the scrub nurse to assert themselves over the team when there is doubt ("swab missing" "no it will be in the bag, don't worry"). We must instil a little of the fearsome dragon into the scrub staff so that they are heard. [ODP]

It is clear that the sheer unreliability of counting may constitute a source of error, even when staff strive hard to comply with count protocols. As Gibbs notes:

"Traditional means of accounting for sponges has relied on the longstanding practice of counting. Observational audits and focused reviews of cases of retained sponges has shown that the practice of counting sponges is highly variable between ORs and even within rooms in the same OR suite. This variation leads to sources of error ... Examination of cases of retained sponges have often revealed that the sponges were counted during the procedure but no one knows where the error occurred or how the sponge was retained. In fact, overall about 80% of retained sponge cases occur in the setting of a correct count." (Gibbs, 2012)

Count errors increase when there are multiple nursing teams present in theatre, personnel changes during the procedure, when surgery is of long duration, and when procedures are performed late in the day. (Hariharan 2013)

Appropriateness of scrub nurse skill and experience and staff availability needs to be taken into account. [Medical Director]

The never event showed the importance of communication and for junior members of staff to be supported and feel confident in challenging surgeons when there is any type of discrepancy or query over the surgical procedure. Also, for all the theatre team to understand the importance of the counts and various checking procedures that necessitate safe surgery. At no stage should any bullying behaviour be allowed or tolerated, i.e. interruptions during counts or lack of acknowledgement by the surgical team of the final count. [Nurse]

Investigating and describing cause

Reviewing the literature it is striking that there is as yet no commonly accepted international framework for investigating and describing the causes of surgical preventable events.

- Some of the research we have reviewed is underpinned by analysis of human factors. Human factors analysis accounts for error by looking at human-human and human-technology interaction across organisational systems. However, even within human factors analysis the focus of

inquiry might be the operating environment, or analysis might trace error through whole organisational systems.

- Some of the reviewed research aims to identify specific risk factors associated with poor outcomes. The ranking of risk factors seen in retrospective quantitative risk analysis is very different from an accident analysis through the lens of human factors. Quantitative risk analysis does not look for cause as such. Rather, it identifies an association – such as BMI - that directs attention to possible sources of error.
- Some of the research has adopted a legalistic account of cause. This is shaped by the requirements for pursuing or defending a legal action, so tends to focus on individual responsibility for one or more actions or omissions. If a surgeon makes a culpable error, it is of no legal relevance that he or she was working under stress because of a bed shortage. Legalistic analysis is therefore less interested in the totality of surrounding circumstances.
- Finally, there is a slender research base testing the frames of reference (Wallace 2010, Mahajan 2010). These include the effectiveness of root cause analysis (Khorsandi 2012) and a framework for discussing events in Mortality and Morbidity meetings (Mitchell 2013).

Several consultees, as well as members of the taskforce, drew attention to the relationship between the quality of investigations and the quality of remedial action.

In the absence of an authoritative approach to investigating and understanding sources of error, it is more challenging to design, prioritise and gain consensus around potential solutions.

The lessons from never events are that human error is inevitably compounded by system error. The other concern is that people tasked to 'investigate' these events have no training and often no experience relative to the case or system within the theatre. Look at aviation: investigations aren't done by air hostesses and pilots they are carried out by trained investigators who have an open mind and are not part of the airline company involved. [Anaesthetist]

Overview of evidence as to cause

Sources of error that are consistently recognised in the literature are:

- intrinsic complexity of surgical technologies and procedures, allied to the need to accommodate individual patient variation and preferences;
- significant variation in professional approaches to safety related processes (e.g. swab counting) leading to muddle, confusion and failure to respect unfamiliar protocols;

- failures in planning, organisation and coordination even where resources and personnel are not an issue (e.g. operating lists that are changed at the last minute, patient order being altered during operating lists);
- time pressures and the use of 'work arounds' to manage work pressure;
- unplanned events and distractions that disrupt work flow; and
- general communication failures, which may be viewed as symptomatic of the enormous challenge in communicating what needs to be communicated in all of the above circumstances.

Pressure and stress add to the likelihood of never events. Poor communication adds to the likelihood of never events. Surgeons on the list not being the surgeon who saw the patient in clinic, or the surgeon who saw the patient on the day of surgery, adds to the likelihood of a never event. [Anaesthetist]

Professional behaviour

With the exception of research into implementation of the World Health Organization Surgical Safety Checklist (see chapter four) and a recent article by Mehtsun et al (2013), the literature is peculiarly muted on individual professional responsibility for implementing safety procedures.

Mehtsun's review of US malpractice claims data found that 12.4% of physicians named in a surgical never event claim were later named in at least one future surgical never event claim.

Our public and expert consultation also presents a clear picture of individual professional failure alongside systemic issues: e.g. not using the World Health Organization Checklist properly, harassment of junior staff, incompetence, failure to raise concerns and so on. Comments in the consultation supply a flavour of the culture that may prevail in some theatres, departments or organisations.

The WHO Checklist is being used just as that - a checklist - without really understanding the philosophy behind it. Some surgeons just don't buy into it. [Perioperative professional]

Staff complete the Checklist even when behaviour of team members is not inclusive and appropriate...Unwitting bullies in the system which creates pressure to engage in work arounds and to cut corners. Lack of a speaking up culture and fear of retribution. [Perioperative professional]

There is poor compliance with the swab count. Senior medical staff are not aware of the correct protocols. Midwives and medical team do not always work together as a team...[Manager]

While I was not involved in a never event I was a witness to a practitioner taking an unnecessary risk that could have resulted in a Retained Foreign Object. A mentor who was supposed to be teaching me safe practice failed to do instrument counts on an open abdominal surgery case. When I reported this I was targeted for removal, but the ODP continued to teach students. [Non-surgical medical practitioner]

Resources

The safety research literature is equally silent on the question of resourcing. It is evident that never events occur in well-resourced organisations with well-resourced and committed teams. However, it is equally clear from our consultation process that some never events or near misses are symptomatic of organisations seriously under pressure.

Provide us with the resources we need: theatre nurses, trained, and experienced in the specialities they are to be assigned to. There is no such thing as a 'generic', 'can-do-anything', theatre nurse. Keep an eye on theatre Recovery. This is the one key indicator of a hospital's performance: if Recovery is blocked with patients who should not be there, then hospital management has failed. Usually it is blocked with HDU /ITU patients, or patients who should be on the ward (or at home) but there is no process to move them on (no ward beds, no nurses, no porters). Provide enough staff, so that the consultant neurosurgeon does not have to mop the theatre floor. [Anaesthetist]

High level overview of causes with potential systemic solutions

| Problem | Potential solution | Background responsibility* | Operational responsibility** |
|--|--|---|---|
| Variation in professional practices (e.g. different approaches to swab counting) and inconsistent expectations in team (e.g. level of scrub staff expertise and specificity of instructions required). | Standardisation, with multi-professional training for implementing operational standards. | NHS England Providers Commissioners Regulators Professional associations | Professional concordance Management concordance |
| Lack of understanding of principles of safety in the operating environment (at organisational and individual level) and/or failure to act in concordance with them. | Standardisation, with multi-professional training to operational standards; with education in principles of safety and training to support behavioural skills. | NHS England Health Education England Commissioners Regulators Professional associations | Professional concordance Management concordance Provider (induction and training) |
| Inadequate resources to ensure safe surgical environment. | Standardisation, with resources allocated to meet standards (one without the other is insufficient). | Department of Health NHS England Commissioners Professional associations (advisory role) | Providers Managers Professionals (responsibility to raise concerns) |
| Human fallibility. | Risk assessment, work design and ergonomics (human factors), and safety training. | NHS England Professional associations | Providers Professional associations |

*By background responsibility, we mean responsibility to provide the conditions for concordance: e.g. consult, develop, update, maintain, commission, implement at organisational level, enforce, regulate etc.

**By operational responsibility, we mean responsibility on the ground for activity concordant with safety requirements.

A surgeon's story

An experienced surgeon put the wrong sized implant into a male patient during a hip replacement.

The surgical team work together regularly. The team was an early adopter of the WHO Surgical Safety Checklist. They are strong supporters of both pre and post-op briefings, which have been part of their routine practice for several years. They work in a very busy environment where rapid surgical technique and turnaround is the norm. Expectations regarding continuous efficiency gains are an uncomfortable part of daily life.

During the pre-operative briefing, the implant sizes were discussed. The hip implant comprises four elements. The socket and a separate liner are packed together in one box, the head in a second, and the stem in a third. Each element can be of a different size to suit the patient, and each has specific measurement. The head though has two measurements – the head diameter, which must fit snugly with the socket that is fitted, and the length, which is an independent variable. One combination of these implant sizes was considered most likely to suit the patient, but another was brought into theatre as a contingency.

The surgeon made the final size decisions regarding size during a visual examination after the commencement of surgery. He was passed the correct sized socket, which was then positioned. When ready for the head of the implant, the surgeon asked for a “+5” a reference to the length not the diameter of the head. The diameter is not normally specified at that point as this it is automatically defined by the size of the cup, which had already been implanted. It was seen as a given by all involved.

The runner passed the head to the scrub practitioner who confirmed the length as “+5” but not the diameter. The surgeon assumed that he was being passed a head that matched the socket.

The socket and the head of the implants are packaged separately. The head length is identifiable on the box under a cellophane wrapper. The head diameter however is amongst other text and less prominent. Some manufacturers colour code the boxes, this manufacturer does not.

The operation was duly completed; the sticker from the implants attached to the operation notes and entered into the computerised national register.

The error came to light approximately 12 months later when the patient was reviewed in outpatients. The patient reported some on-going discomfort and occasional looseness of the joint when coming down stairs. Whilst investigating the possible causes the surgeon reviewed the operation notes. He noticed that the implant stickers showed that the diameter of the socket and the head were incompatible.

The surgeon disclosed the error to the patient and apologised. The patient consented for a further operation to correct the error.

The patient was upset and unhappy. The team felt devastated that their error had caused harm especially given the high priority they place on safety in their practice. No specific support was offered to them or the patient.

The incident was reported and duly investigated. The patient made a claim for compensation and the Trust admitted liability. The surgeon is not aware of the final outcome of the legal claim.

When asked what he thought went wrong, the surgeon replied:

“The runner thought the scrub nurse would check the size, the scrub nurse thought the runner has already checked it, and I thought the scrub nurse had checked it. In practice therefore no one had checked it. We all believed that what we were being passed was the right thing.”

Chapter three - Action to prevent the three 'surgical' never events: evidence about the efficacy of interventions targeted at never events

When I read about never events and how they have happened, I always think "there but for the grace of God go I". Almost all of the scenarios have occurred in my professional life, but for the outcome. Something has always stopped it. Some things happen because of carelessness or incompetence, but often it is a chain reaction of everyone involved just not doing their job 100%. Today's NHS is much more difficult to work in than when I started 30 years ago. [Surgeon]

The evidence base in respect of interventions to prevent surgical never events is limited, and strong evidence for efficacy is largely restricted to specific technological interventions. For complex organisation-wide interventions to drive systemic change, only very weak evidence is available.

The extant evidence relating to causes of harm and efficacy of specific interventions informed development of the World Health Organization Surgical Checklist. This evidence was summarised in the 2009 *World Health Organization Guidelines*³ and we include it where appropriate below.

Evaluation of the World Health Organization Checklist is discussed in chapter four. There is also a growing literature on the efficacy of specialty-specific and procedure-specific variants of the WHO Checklist, which is included in our bibliography.

We canvassed suggestions for practical interventions in our consultation and these are included in Appendix 3.

Specific interventions targeted at particular never events

Wrong site surgery

Whilst a number of studies have described the prevalence and cause of wrong site surgery there is a paucity of evidence about the effectiveness of interventions.

In the 2009 *World Health Organization Guidelines* it was noted: "Preoperative verification protocols have only recently been introduced in many parts of the world. Evidence of their efficacy in reducing the incidence of wrong-site surgery is lacking, although preliminary data suggest that such actions are effective." A 2012 recent Cochrane review of interventions to reduce wrong site surgery found only one study that satisfied the Cochrane inclusion criteria. (Mahar 2012) As this was an educational intervention to reduce the incidence

³ http://whqlibdoc.who.int/publications/2009/9789241598552_eng.pdf

of wrong-site tooth extractions in dental outpatient settings it is of limited generalisability.

Wrong implant

We did not locate any research evidence for specific interventions to prevent wrong implant events.

Retained foreign objects

The focus for research and technological development has been prevention of retained swabs (the term sponges is also widely used).

Three technological aids to swab management have been assessed: devices to count sponges tagged with '2D matrix labels' (black and white cell pattern barcodes) (Cima 2011, Greenberg 2008); devices to detect radiofrequency tagged sponges (this system does not count sponges so must be used in conjunction with a manual counting practice) (Rupp 2012); and devices to count and detect RadioFrequency IDentification (RFID) chip embedded sponges (Macario 2006). RFID sponge systems are in clinical trials around the world, but there is as yet only one published research study and no economic assessment.

Hariharan and Lobo (2013) concluded that each preventive strategy for retained swabs has advantages and disadvantages, and that none are immune to failure as a result of human error. However, they advocate economic assessment of the technologies and testing in NHS multi-centre trials. In 2009 the World Health Organization estimated the cost of technological management aids as US\$13 per case for bar-coded swabs and US\$75 per case for radiofrequency-tagged swabs. Further calculation is required to estimate of the 'cost per prevented retained object' from using technological aids as an adjunct to counting.

We are aware of one research study undertaken for Addenbrooke's Hospital in Cambridge that demonstrated significant design flaws in guidewire design (publication forthcoming; data shared with MHRA).

Other interventions to prevent retained foreign objects attempt to improve the effectiveness of intra-operative X-rays, where it is estimated that over 30% of cases, generate a false negative finding (Asiyanbola 2012). There is as yet no well-proven technology.

System wide interventions to reduce never events

If something can go wrong it will. Systems involving the whole team can to a large extent prevent them. The WHO Checklist has had a huge effect, but only where it has been properly embedded into care. [Anaesthetist]

The World Health Organization Surgical Safety Checklist is one attempted system wide solution (although not specifically targeted at never events) and we review its implementation in the next chapter.

Analyses of the cause of never events indicate that error is multi-factoral and produced in complex systems. Interventions that target multiple factors and systems rarely yield the evidence that satisfies requirements for inclusion in a Cochrane review. The evidence base for effective system-wide interventions is thus almost non-existent, and with rare exceptions much of the literature is hypothetical.

From a human factors perspective, Shouhed et al conclude that: “checklists, briefings, and teamwork training can all be effective in reducing systemic failures,” (Shouhed 2012) but hypothesise that: “improving the design of equipment, the order, allocation, and definition of surgical tasks, the design of the surgical environment, and the organization of services and support around the maintenance and improvement of surgical flow could all yield improvements in surgical performance”.

The importance of viewing the prevention of never events as a task to be embedded across the care pathway is amply demonstrated by a well-resourced demonstration project to eliminate wrong site surgery in eight large US hospitals. Gibbs (2012) noted: “preliminary results...have shown that in 39% of cases, errors were introduced in the verification step that increased the risk of a wrong site surgery event. *Usually these errors involved inadequate information about the patient and scheduling confusion.* Identifying this failure mode lead to the development of standardized ways of collecting and having the information accessible. Site marking and time out practices have been contributory but were not as frequent a source of errors as the initial verification process”. [Emphasis added]

The Cochrane database yields some slender evidence to support the design of programmatic interventions. Audit and feedback generally leads to small but potentially important improvements in professional practice (Ivers 2012). It was also found that a bulletin which summarises systematic review evidence might improve evidence-based practice when there is a single clear message, if the change is relatively simple to accomplish, and there is a growing awareness by users of the evidence that a change in practice is required (Murthy 2012).

A further Cochrane review of interventions to change organisational culture located 4239 records. After assessment, no studies met the quality criteria for inclusion. The authors' view was that it was impossible to draw any

conclusions about the effectiveness of strategies to change organisational culture. (Parmelli 2011)

Weaker evidence of approaches to improvement that may be effective can be derived from evaluation of demonstration projects.

There is some encouraging evidence for the role that peer review might play in driving improvement. (Aveling 2012)

Assessing The Health Foundation's UK based improvement projects, Dixon Woods and colleagues identified ten key challenges: convincing people there is a problem that is relevant to them; convincing them that the solution chosen is the right one; getting data collection and monitoring systems right; limiting excessive ambitions; navigating organisational cultures and capacities; countering professional tribalism and lack of staff engagement; finding appropriate leadership; incentivising participation; securing sustainability; and avoiding the risk of unintended consequences. (Dixon Woods 2012)

All of these challenges were, and continued to be, faced in implementing the WHO Safer Surgery Checklist, which we now consider.

Chapter four - Action to improve surgical safety (1): The World Health Organization Surgical Safety Checklist

Never events still happen despite all WHO checks being fully and enthusiastically implemented. [Anaesthetist]

Never events are largely preventable by implementation of WHO recommendations. Anaesthetists and surgeons should see patients themselves on the day of surgery, having checked X-rays etc. the day before so they have a plan in mind before starting the list. [Anaesthetist]

The World Health Organization's (WHO) Surgical Safety Checklist was a key output of the 2007 'Safe Surgery Saves Lives' campaign.⁴ It was mandated for use by the NHS through issue of a patient safety alert in 2010. In this chapter we provide a brief background to the Checklist and then review what is known about its implementation in the UK.

Background

The key aims of the Checklist are to ensure standardisation in surgical care, to reinforce basic safety procedures in the operating theatre (e.g. patient identity, nature of procedure, administration of antibiotics, DVT prophylaxis, etc.); to overcome negative effects of hierarchy; and to foster open communication amongst operating team members. (Gawande 2011)⁵

The Checklist is based on the principles set out in the WHO *Safe Surgery Saves Lives* campaign evidence review and recommendations. It comprises a set of core safety checks that are split according to three safety critical phases of an operation:

- when the patient arrives in the operating theatre complex ("sign in");
- before commencement of the procedure ("time out"); and
- before the patient leaves the operating theatre ("sign out").

The Checklist was pilot-tested in a pre-post global study across eight hospitals in the developed and developing world. The results were published in January 2009 and showed a significant reduction in mortality and morbidity following Checklist implementation. (Haynes 2009)

⁴ World Health Organization. Safe Surgery Saves Lives: Second Global Patient Safety Challenge & WHO Surgical Safety Checklist. Available at: http://www.who.int/patientsafety/safesurgery/knowledge_base/SSSL_Brochure_finalJun08.pdf
http://www.who.int/patientsafety/safesurgery/tools_resources/SSSL_Checklist_finalJun08.pdf

⁵ World Health Organization. Implementation Manual WHO Surgical Safety Checklist 2009. Available at: http://whqlibdoc.who.int/publications/2009/9789241598590_eng.pdf.

While the initial report on the pilot testing has received some criticism for methodological short-comings, several further studies, including a robust randomised controlled trial, have shown that the Checklist is performing a valuable role.

A number of studies of Checklist use around the world indicated that it could improve patient outcomes, measured in terms of reduced mortality and morbidity. Observational and self-report studies suggest that it also leads to improved communication and team working. (Lingard 2008, de Vries 2010a, de Vries 2010b, Askarian 2011, Takala 2011, Sewell 2011, Truran 2011, Boormeester 2011, Bliss 2012, Fargen 2012, Fudickar 2012). Other studies have demonstrated mixed outcomes, which may be attributable to the quality of the safety culture prior to its introduction. (Haugen 2013)

The perceived value to professionals of the Checklist is reflected in the ever growing literature reporting specialty-specific versions with positive outcomes. (Abdel-Rahim 2011, Helmiö 2011, Sewell 2011, Da Silva-Freitas 2012, Joshi 2012, Lee 2012, Romain 2012, Ahmed 2013, Astrom 2013, Cavallini 2013, Kelly 2013, Knevil 2013, Ladak 2013, Low 2013, Singh 2013, Song 2013)

However, there is also a substantial literature demonstrating that the Checklist is frequently poorly implemented. For example, key elements may be excluded, core members of the team may not be present, and team members may fail to raise concerns when prompted by the Checklist. (Calland 2011, Conley 2011, Vogts 2011, Dackiewicz 2012, Levey 2012, Wæhle 2012, Cullati 2013, Poon 2013, Rydenfalt 2013)

The strong message that emerges from all of the cited studies on implementation is an unsurprising one. The Checklist aims to challenge prevalent operating theatre behaviours. This makes it an uncomfortable tool to adopt. Effective Checklist use therefore requires training and ongoing support, particularly if the quality of Checklist use is to be maintained after its novelty wanes.

Introduction into the UK

Following the WHO pilot study, the National Patient Safety Agency (NPSA), in collaboration with a group of experts, modified the WHO Checklist for use in England and Wales⁶ and issued a patient safety alert to all NHS trusts. This stated that:

- The Checklist must be used for all surgical procedures (including local anaesthetic procedures) by February 2010 (giving trusts a year to fully implement the initiative).
- An executive and clinical lead must be identified for its implementation.

⁶ NPSA modified version of the WHO Checklist. Available at:
<http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59860>

- Use of the Checklist must be entered into the patient clinical notes or electronic record by a registered member of the team.

Guidance regarding implementation, correct use and modification of the Checklist was made available online.⁷

As well as being mandated via the alert, the Checklist was highlighted as part of the '1000 lives' campaign in Wales and the 'Patient Safety First' campaign in England. 'Patient Safety First' went beyond just promoting the Checklist. The campaign advocated '5 Steps to Safer Surgery'.⁸ The '5 Steps' referred to the three elements of the WHO Checklist preceded by a pre-operating list team briefing and followed by a post-list team debriefing.

Evaluation of the implementation of the Checklist in the NHS

The SCIP project

Imperial College London, with funding from the National Institute for Health Research (NIHR), conducted a national evaluation of the implementation of the WHO Checklist across 20 NHS trusts between September 2009 and September 2011: The Surgical Checklist Implementation Project (SCIP)⁹. This project included over 4000 surveys and over 150 in-depth interviews with NHS personnel, observations of over 550 full surgical procedures, the collection of outcome data from more than 6500 patients, and survey data from over 100 patients.

Introduction of the Checklist

Although online guidance was made available and widely promoted by the NPSA, the way in which the Checklist was initially introduced differed greatly, both between and within trusts. The more effective trusts trialled the tool in 'early implementer' theatres to troubleshoot problems, adapted it to fit local systems and procedures early on, and prepared teams through education and training in use of the Checklist. Other trusts simply expected staff to start using an unamended version of the Checklist with no training.

Staff attitudes towards the Checklist

Theatre personnel's attitudes towards the Checklist itself varied. Nurses, healthcare assistants and operating department practitioners (theatre staff)

⁷ NPSA guidance on implementation and correct use of the Checklist. Available at: <http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59860>

⁸ 5 steps to safer surgery video. Available at:

<http://www.patientsafetyfirst.nhs.uk/Content.aspx?path=/interventions/Perioperativecare/5stepsvideo/>

⁹ Findings from SCIP have been disseminated at NHS events, across the Royal colleges and at patient safety conferences. They are currently in preparation for publication in peer-reviewed journals. For details contact Dr Stephanie Russ (s.russ@imperial.ac.uk)

were generally more positive than surgeons and anaesthetists (see table below).

Collectively however, a majority reported that they wanted to use the Checklist and that the Checklist would make surgical care safer. Around two thirds of the sample thought that the Checklist would reduce the risk of adverse events such as never events in theatre. At the time the research was carried out, staff were less certain about the *specific* beneficial impact the Checklist could have on post-operative patient outcomes (infection rates etc.). A significant proportion of staff still agreed that the Checklist was a tick box exercise.

Despite this, when staff were asked if they would like the Checklist to be used if they were having an operation, a strong majority agreed.

Theatre personnel perceptions of the Checklist:

| | % Agree | | |
|--|----------|---------------|---------------|
| | Surgeons | Anaesthetists | Theatre staff |
| I want to use the Checklist | 76% | 72% | 83% |
| The Checklist makes surgical care safer | 73% | 65% | 86% |
| The Checklist reduces the risk of post-operative infection | 23% | 32% | 50% |
| The Checklist reduces the risk of adverse events in theatre | 68% | 61% | 79% |
| The Checklist improves teamwork and communication in theatre | 58% | 58% | 70% |
| The Checklist improves efficiency of OT lists | 23% | 18% | 49% |
| The Checklist is a tick-box exercise | 41% | 45% | 29% |
| If I had an operation I would want the Checklist to be used | 81% | 77% | 91% |

Facilitators and Barriers to Checklist implementation

Data from in-depth interviews with theatre personnel revealed the facilitators (conditions that enhanced uptake) and barriers (conditions that hindered uptake) affecting Checklist implementation.

Facilitators of successful implementation encompassed factors at the behavioural, systems and tool-specific levels. The Checklist was perceived to work best when there was training and education around its use in practice; it was modified to suit different surgical specialities and the local context; when it was incorporated into existing processes; when staff received clinical and anecdotal data highlighting a positive impact at a local level; and when senior surgeons actively drove and promoted its use.

Barriers to successful implementation again encompassed behavioural, systems, and tool-specific factors. These included active resistance from senior surgical and anaesthetic staff (most commonly at consultant level); a perceived lack of support from hospital management during implementation; a

perception that the Checklist was replicating systems already in place and taking too much time; and the perception that the Checklist had design faults (e.g. unusual wording, or lack of appropriateness for certain surgical specialties or for use in front of awake patients).

There was also a concern that the Checklist might have unexpected negative consequences if not used in the intended manner, for example, if it created friction amongst the team or if it were used as a tick-box exercise.

Other evaluative data from implementation in the UK

We found two other published studies of Checklist use in the UK.

One retrospective study showed that using the WHO Checklist could have prevented 14.9% of all wrong-side errors (such as marking the wrong side) that *did not* in fact lead to wrong-side surgery being performed; and 85.3% of all wrong-side errors that actually *did* lead to surgery being performed on the wrong side. (Panesar 2011)

A retrospective audit undertaken in a teaching hospital indicated that use of the Checklist improved communication between obstetricians and anaesthetists regarding the grading (urgency of need) of Caesarean section. (Mohammed 2013)

Patient views of the Checklist

As part of the Imperial SCIP research, 141 surgical patients were sampled from two large teaching hospitals following surgery, and asked for their views of the Checklist. Patients were shown two professionally produced videos; the first depicting the typical procedures that previously occurred at equivalent stages to which the “sign in”, “time-out” and “sign-out” parts of the Checklist are completed, and the second showing the Checklist itself being completed. Patients’ views of the Checklist and its use in practice were then captured via questionnaire.

Patients were positive towards use of the Checklist and its potential to reduce error:

- 78% agreed that they would like the Checklist to be used;
- 68% disagreed that the Checklist was a tick-box exercise; and
- 67% agreed that errors in surgery would be reduced if the Checklist was used.

Those who were worried about coming to harm in hospital or had experienced a previous error in their care were particularly supportive of its use. Views were divided with regards to hearing discussions around blood-loss/airway before their procedure (part of the “sign in” checks), some (26%) feeling that it would reassure them that the team were prepared, others (30%) feeling that it would make them feel anxious (particularly if they were having major surgery).

How effective is the Checklist in preventing never events?

In our consultation, we asked “Do you have any practical suggestions for activities or technologies that could help prevent surgical never events?” Just over one third of those who answered the question proposed that enhancing and enforcing the WHO Checklist would be of value.

Support from consultees for the Checklist suggests there is growing conviction, perhaps based on practice experience, that it does prevent never events. We cited the UK (Panesar 2011) study above, which suggested using the Checklist could avert orthopaedic wrong site errors. Similar findings emerged from an audit of over 12,000 neurological procedures carried out in a German hospital

However, researchers face two fundamental difficulties assessing the effectiveness of the Checklist for preventing never events. The first question is whether its effectiveness in preventing errors should be assessed when it is being implemented effectively, as it is in some parts of the NHS; or whether we are interested in its effectiveness when implemented poorly, as there is always a risk it will be. The second problem is the formidable difficulty in gathering evidence of the ‘near misses’ that show how it prevents never events. We deal with each of these in turn.

Variation in how effectively the Checklist has been used in the UK

The findings from the UK evaluation are consistent with the international literature.

In the SCIP study:

- Only around two-thirds of the items on the Checklist were read out loud (in 10% of cases identity and procedure were not checked);
- Team members were absent from the checks in over 40% of cases;
- Team members failed to pause or focus on the checks in over 70% of cases; and
- Over a third of cases had no “sign-out”.

More recent work has shown that these figures have changed little over time.

There was often little clarity around whose responsibility it was to lead the checks. While nurses most commonly took on this role (54% of the time), in some teams this task was undertaken by a member of the surgical (20% of the time) or the anaesthetic sub-team (17% of the time). These figures are significant in light of other findings on the importance of senior leadership, because senior leadership seems to be closely associated with effectiveness.

When there is effective senior leadership of the Checklist process, the quality of surgical care shows marked improvement. The SCIP project found that:

- The patient was more likely to receive antibiotic prophylaxis in accordance with guidelines (in the hour immediately before the procedure) and appropriate DVT prophylaxis when the surgeon led the checks;
- Teamwork (communication, coordination, leadership and situational awareness) was better when the surgeon led the checks, when all team members were present and paused and when more information was shared;
- There were fewer equipment problems when all team members were present for the checks; and
- Post-operative complications reduced significantly when all three parts of the Checklist were used (i.e. including the sign-out).

These data suggest that surgeon leadership of the process has significant positive effects.

Difficulties in assessing whether the Checklist prevents never events

The global data on effectiveness of the Checklist tend to indicate an overall improvement in patient outcomes (mortality and complications) following its introduction, together with a general improvement in teamwork. These outcomes may indicate that preventable error has been reduced, that other practices have improved, or that a little of both has occurred.

There are formidable problems evidencing that the checklist is of value *specifically* in preventing never events and other serious incidents in the NHS.

It is of course possible to draw some inferences from existing data. For example, in 10% of the cases observed in the SCIP study, patient identity and procedure were not checked at “time-out”, or key members of the operating team were absent. This presents a clear risk for wrong site surgery. On the other hand, in 90% of cases identity and procedure were checked and key members of the operating team were present. This may represent a significant improvement in risk reducing behaviour. Due to the limitations of the study we cannot know for certain.

As it stands we do not know how many incidents have been averted by the Checklist’s effective use (near misses), whether the never events that have occurred when the checklist was done badly would have been averted had it been done well, or whether the never events that have occurred when the checklist was not used at all would have been averted had it been used. Whether using the checklist would have avoided any given incident is logically impossible to prove.

Near miss information is costly to gather. Researching the effects of the Checklist on near misses and never events is prohibitively resource intensive. Real-time observations of Checklist use would be necessary, and within any

single institution never events remain relatively infrequent. This makes the chance of capturing them via observation very unlikely; and is the reason it was not possible to link Checklist usability data to never events in the SCIP study.

If nothing else, this reinforces the importance of sharing clinical stories about occasions when the Checklist has prevented an error, for example, of the sort published by CORESS.¹⁰

Comparison with aviation industry use of checklists

There is a view among some of the experts we consulted during our work, and some respondents to our consultation, that the Checklist will not function to prevent error in the NHS in the way it does in aviation from where the idea derives. In the following table we compare the WHO aims for the Checklist with practice in aviation:

| WHO checklist aims | Aviation industry practice |
|--|---|
| To ensure standardisation in surgical care. | The industry has a coherent framework of safety regulations and requires providers to implement standard procedures that comply with these regulations. It rigorously enforces provider compliance. |
| To reinforce basic safety procedures in the operating theatre. | The aviation checklist rests on a coherent framework of industry-wide standardised procedures, and reinforces safety by requiring a final sign-off by individual professionals. |
| To help overcome negative effects of hierarchy. | The aviation industry invests heavily in 'Crew Resource Management' training (i.e. non-technical skills) and safety training, and recognises that employees are still inhibited from acting across status boundaries. |
| To foster open communication amongst operating team members. | As above. |

The WHO Checklist and the aviation checklist are functioning in different contexts and serving different purposes.

One of the key aims of the WHO Checklist is to promote the incorporation of evidence-based standards into operating room practice. It does not mandate those standards. Rather, the Checklist indirectly incorporates them through being based on principles elaborated in the 'Safe Surgery Saves Lives' guidance and its recommendations. This is the reverse of the process

¹⁰ <http://www.coress.org.uk/>

adopted in aviation. That industry mandates safety standards. It then uses checklists to enforce concordance with the standards.

Another key aim of the WHO Checklist is to help overcome the negative impact of status hierarchies in the operating room. Again, it does so somewhat obliquely by eliciting prompts, and seeking cooperative responses. By way of contrast, the aviation industry invests heavily in behavioural education (the non-technical skills taught as Crew Resource Management) (Kanki 2010, Flin 2008) including proper use of checklists. It does not rely on the checklists alone to change strongly ingrained patterns of human behaviour.

Conclusions

There is clear evidence linking the *quality* of Checklist use to markers of surgical performance. Where the Checklist is used well, and particularly where surgeons visibly lead the process, it can improve teamwork and compliance with processes of care (such as checking ID, procedure, antibiotics). As well as being general markers of surgical performance, some of these demonstrated improvements are likely also to prevent never events.

However, the WHO Checklist cannot compensate for an unsafe level of human or technological resource.

There are important lessons to learn from the manner in which the Checklist is implemented. Both the international evidence and the SCIP evaluation demonstrate clearly that Checklist use has to be supported by multi-professional education and training. The Checklist can prompt awareness of the need for behavioural change, but cannot accomplish this aim on its own.

The systemic and behavioural factors that impede implementation of the Checklist are just those factors that contribute to unsafe care. NHS organisations that implemented the WHO Checklist in the spirit that was intended will have reviewed their safety systems and invested in training. But we have noted that other organisations merely complied with the requirement to introduce the Checklist, did so on top of existing systems, and took no steps to change ingrained ways of working.

For safety checklists to function across the NHS in the way they do across the aviation industry would require the same commitment to systematic standardisation; appropriate education and training; rigorous enforcement; individual accountability; and adequate organisational facilities.

In the meantime, we would recognise that the WHO Checklist has had undoubted benefits. As well as the evidence we have discussed, it has raised awareness of safety issues. As one respondent told Imperial College researchers, *'When people witnessed an error that was avoided by the Checklist they were transformed overnight'*. (Anaesthetist)

Our concern is that where the Checklist alone is relied upon to drive systematic improvement or change behaviours, it will achieve limited success.

Chapter five - Action to improve surgical safety (2): Patient Safety First '5 Steps to Safer Surgery'

The 'Patient Safety First' campaign for England ran between June 2008 and March 2010 and aimed to foster cultural change in how safety and preventable error is perceived and addressed in surgery.

The WHO Checklist was a key feature in the campaign's '5 Steps to Safer Surgery'. The five steps included, in addition to the three stages mandated by the checklist, team briefings prior to the commencement of the operating list and team de-briefings at the end of the list.

- Step 1: Briefing
- Step 2: Sign in
- Step 3: Time out
- Step 4: Sign out
- Step 5: De-briefing

Briefings are a routine part of safety procedures in other industries, including the military and aviation. The evidence review underpinning the WHO *Safe Surgery Saves Lives* campaign pointed up the significant benefits of briefings and de-briefings, which are associated with improved team/safety culture and improved patient outcomes (DeFontes 2004, Neily 2010). Within the context of surgery these processes have the following aims:

- **Briefing:** A short (around five minutes) meeting at the start of the operating list where core team members representing each of the sub-teams in theatre (ODPs, nurses, surgeons and anaesthetists) attend to discuss the running and order of the list, each individual patient's history and risks, any particular safety concerns, equipment requirements and staffing. The aim is that all staff members share the same expectations, any issues can be addressed before the patients arrive, and individual staff can contribute to discussion as equal professionals without undue anxiety.
- **De-briefing:** A short (around five minutes) meeting at end of the list for core team members to discuss any concerns, any specific issues/incidents that occurred, how they will be avoided in future, and what went well. This is intended to act as a vehicle for learning and improvement.

These processes should be seen as distinct from safety checklists, which serve a different purpose:

- **Safety Checklist:** A *final*, patient-specific reminder of the key concerns and the safety steps that must be completed before moving on to the next part of the operation. This involves the whole team and is designed to act as a final trap for picking up omissions and mitigating errors.

While the three parts of the WHO Checklist are now mandatory for use in surgery, the briefing and de-briefing were never mandated and as such it has been left to individual teams and hospitals to decide if they would like to introduce these two steps.

Current learning suggests that briefings happen more often than de-briefings (much like the “time-out” is completed more often than the “sign out”), but that a structured pre-list briefing is not commonplace (only 13% of the lists observed for the Imperial SCIP study had a structured a briefing).

Interviews in the Imperial SCIP research suggested that clinical staff perceive clear benefit in the safety briefings:

‘The briefing is great because it gives us time to act on any potential issues, particularly regarding the order of the list and the equipment, and to plan accordingly with the whole team – reducing the chance of error later on. It also seems to make the checklist itself run more smoothly because they are already aware of some of the likely hazards from having completed the brief’ (Anaesthetist).

The challenges faced in conducting briefings and de-briefings have appeared to be more of a case of practicality than a lack of willingness. In particular, finding a time when all team members can get together at the start or end of a list takes structured planning and strong leadership, due to the very different competing tasks and priorities faced by each individual. This is made more difficult by poor scheduling and pressure placed on teams to start the list ‘on time’.

Views on team briefings in the public consultation

Pre-list team briefing is a waste of time, which leads to inefficiency and delays. [Surgeon]

Pre-list team briefings lead to greater productivity. [Surgeon]

On the whole, those who engaged in our consultation expressed high levels of support for team briefings. Just over 85% of respondents believed it helped with recognition of individual patient needs, while nearly 80% thought it would raise greater awareness of patient safety matters. (See Figure below)

Notably, only nine consultees (just under 1.5%) thought that it had no benefits.

Comments on the benefits included:

They give greater awareness of potential hazards and planning to prepare for these hazards...and are especially important when any element of procedure is experimental. [Patient who had experienced a never event]

Allows inexperienced staff to get to know other team members and have a better idea of what is happening. Also ensures all team members have the same information. [ODP]

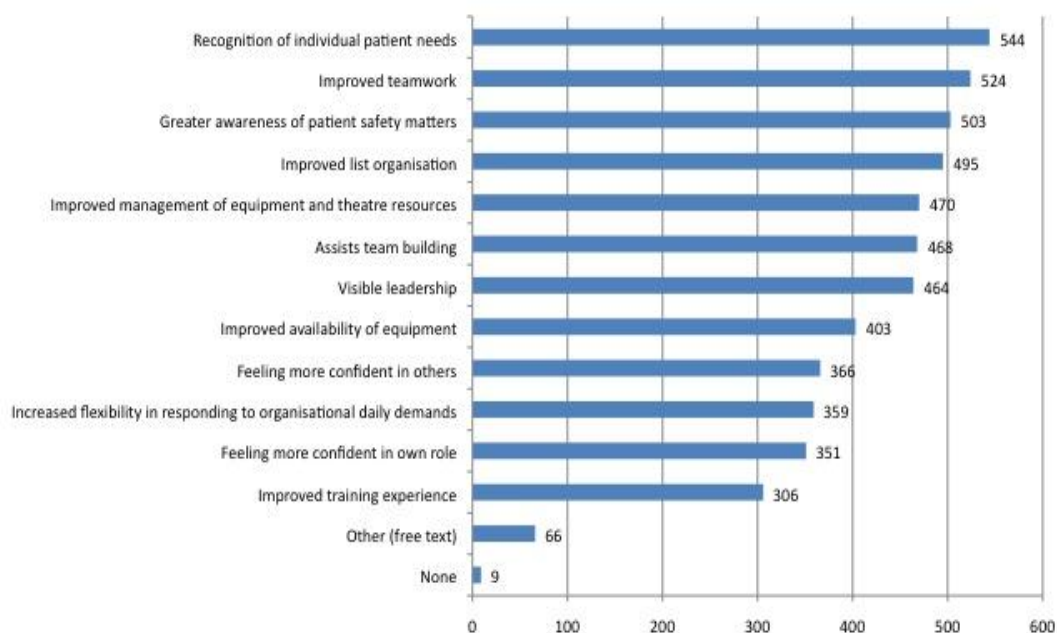
Pre-list team briefing could be counted as evidence of Good Medical Practice. [Surgeon]

But, as with the WHO Checklist, pre-list briefings require skilled implementation.

Briefing is often used to list a series of demands rather than communicate issues surrounding safety. Often the surgical team send a representative of the team rather than all being present. [Anaesthetist]

FIGURE

In your view, what benefits could a 3–5 minute team briefing at the start of an operating list have?



There were important reservations about viewing team briefings as a panacea. Comments indicated that underlying organisational dysfunction could not be glossed over by an intervention designed for a largely functional clinical environment.

We already know the problems (no nurse, no instruments, no porter, no radiographer, no space in recovery, because ITU is full, and the beds on the wards are already occupied by patients who "should have been discharged by now", but will not be until next week). A "3-5 minute team briefing" is not going to address any of these faults. [Anaesthetist]

Comments on the usefulness of pre-list briefings also reflected a wider problem of last minute changes to operating lists, to which many consultees drew attention.

Not useful in NHS as the team and/or surgeon and/or anaesthetist and/or patients on the list may change any time. Many times equipment which is required is OK at the briefing, but during the operation is not so. [Anaesthetist]

Post-list debriefings

There was also fairly widespread support for post-list debriefings, although rather less than there was for pre-list briefing. Some 68% of our consultees viewed it as useful for improving team work, although more favoured a pre-list briefing for these purposes. On the other hand, rather more respondents thought a post-list briefing would enhance the training experience.

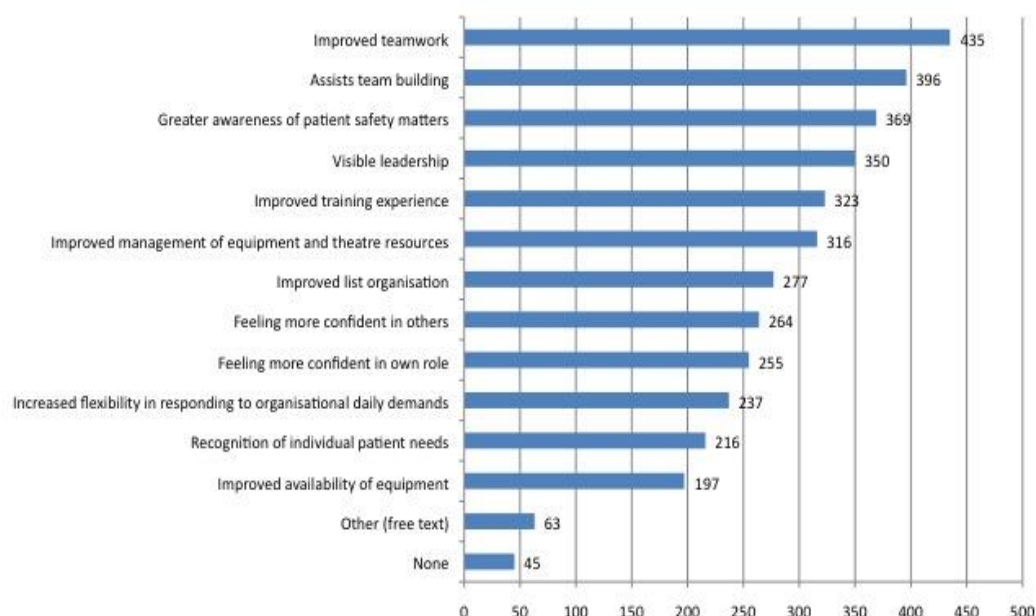
Notably, only a fraction over 7% of consultees thought post-list briefings would serve no useful purpose.

I have seldom seen or heard an operating surgeon show good leadership at the end of a surgical list. It is my opinion that the operating surgeon should lead on the end of list de-brief giving clear instructions and feedback to others... There is a clear need for a change in ethos of healthcare professionals with heavy penalties for those who negate this duty. [Surgeon]

A post-list briefing could help identify and address latent conditions that are contributing to compromised safety, efficiency and patient experience/staff satisfaction. [Anaesthetist]

FIGURE

In your view, what benefits could a 3–5 minute team briefing at the end of an operating list have?



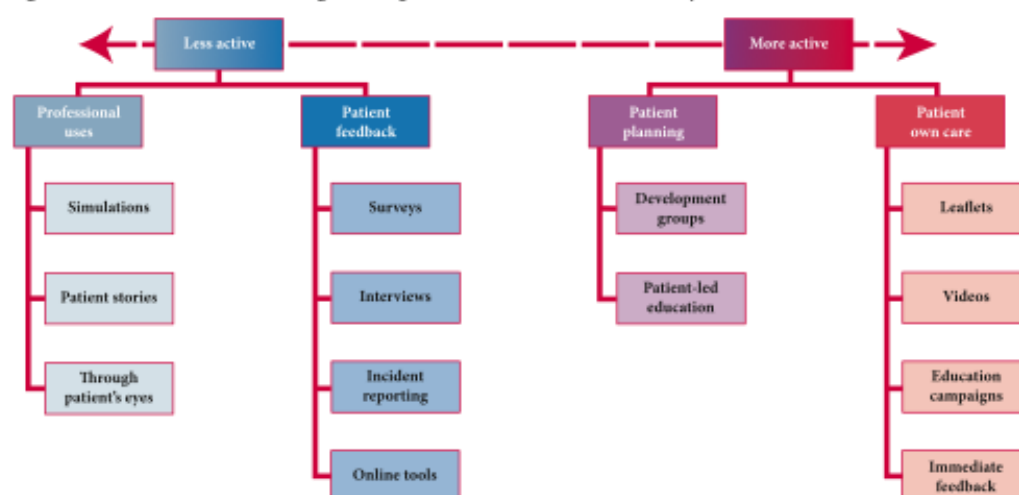
Chapter six - Action to improve surgical safety (3): Involving patients in safety activity

This is the future for safer care and development of a patient focused service. Example: Experience-based design - if used skilfully can meaningfully involve patients in design of services. Example: fish bowl patient feedback. I have experienced this - very powerful experience for whole team. [Peri-operative nurse, theatre manager, safety expert]

Davis et al noted that the NPSA had: “placed promoting patient and public involvement in safety firmly on their agenda.” (Davis 2011) However, in a recent evidence scan commissioned by The Health Foundation, the authors conclude that: “progress has been slow in involving people in their own safety and in the development of safer services”. The evidence scan, responses to our consultation, and the experience of task force members all suggest that patients and carers have tended to be involved in the ‘less active’ end of the continuum below.¹¹

¹¹ Evidence Scan: Involving Patients in Improving Safety The Evidence Centre for The Health Foundation January 2013

Figure 1: Continuum of strategies for patient involvement in safety



Individual patient stories have tremendous impact...a strong reminder of the job we aspire to do, as well as a reminder that our performance sometimes does not meet a reasonable standard or expected standard. [Surgeon]

NHS managers and clinicians hear the impact that policies and procedures have on service users, and the personal cost. Sometimes personal stories have more impact. Patient input and feedback are essential. [Patient who had suffered harm, but not a never event]

In our consultation, we asked what works when NHS organisations invite patients to be partners in patient safety. It may be that some of the 'more active' forms of patient involvement in safety, such as self-identification and collaboration in surgical site marking, may now be so much a part of routine that they are not commonly viewed as patient involvement in safety. Involving patients in investigations and discussing the findings with them was viewed as a form of partnership.

There is an overall anxiety about asking patients to take charge of their own safety which I do not share: each patient has only one patient to worry about, whereas clinicians have many, and so the patient is their own best guardian angel. Provided patients are given specific tasks (follow up your investigation results, check your own drug chart) they can be partners. [Anaesthetist]

Patients have a unique view of occurrences, which can facilitate learning; their experience can contribute positively to the investigation. By the same token, by being open with the patient/relatives it can provide a clearer view of services to them and how events can occur, that it is rarely one person, more a system wide process that leads to failures. [Patient safety team lead]

However, the evidence base for the added value gained through patient involvement in safety activities is currently thin. Moreover, the ethical or other policy reasons for patient involvement (or non-involvement) in safety activity would seem not to be widely articulated in either the literature or practice.

Davis (2011) posed important questions about expectations around patient safety-related behaviour in surgical pathways. They suggested that safety-related behaviours should be conceptualised in terms of three main properties:

- the type of error the behaviour is trying to prevent (e.g., medication error);
- the action required by the patient (e.g., asking questions); and
- the characteristics of the action (e.g., whether the behaviour involves interacting with a health care professional).

They suggest that paying attention to the characteristics of the safety-related behavior might enable more effective interventions to be designed for appropriate stages in the care pathway.

When patients are treated as partners safety improves! Patients ask the most direct and simple questions. [Surgeon]

Davis also identified interpersonal, intrapersonal, and cultural barriers to patients' safety-related behaviour. Any proposed intervention has to take these barriers to patient action into consideration. For example, actions such as collaborating with patients to mark operative sites may be hindered by patients not knowing why it is being done.

They get impatient when they are checked in for theatre, assuming that we are incompetent because we are asking questions such as 'what side are we operating on'? [Anaesthetist]

Other well intended initiatives that rely on patients to challenge staff when they perceive error are thwarted by obvious power inequities. (Ocloo 2012)

It may not work expecting them to speak up against health professionals, especially when they are feeling vulnerable. [Anaesthetist]

Whilst supporters of patient involvement generally promote it as an unalloyed good, there are principled arguments to be made against inappropriate reliance on patients as 'safety partners'. Lyons has used principles of safety engineering to argue that a general strategy of relying on patients to check on delivery of health care would prove ineffective to promote patient safety. She also argued that such reliance would burden patients with responsibilities that many would be unable to fulfil. (Lyons 2007, Entwistle 2007)

Our consultation data suggest that professionals are divided over the value of viewing patients as partners in safety.

Around half of comments suggested that a patient perspective was valuable because it challenged professional orthodoxies and opinions. A substantial minority of comments was about how it could lead to better design of services, improved communication, greater transparency, and serve to remind clinicians of the human consequences of their actions.

Brings home to the team performing the technical work that it is a human being experiencing the results - good or bad, intended or adverse. [Surgeon]

A different perspective and two-way learning! Working with patients as a partner is placing trust in their judgement, this in turn places trust in healthcare professionals. [Patient]

However, there was also a significant minority view that either patient involvement was not appropriate, because professionals have responsibility for safety; or that it was a waste of time, because patients were not sufficiently well informed.

It is daft. By all means have a group of patients who can visit and talk to consultants. That is good practice. But my patient isn't my partner in treatment or risk management. [Anaesthetist]

I do not understand this proposal. It is self-evident that doctor and nurses have responsibility to be a patient's advocate. [Anaesthetist]

I often find patients coming in explores the patients' journey, but fails to help with clinical practicalities and cultures. [ODP]

Divided views on the benefits of patient involvement indicate differing conceptions of professional responsibility, different experiences of involving patients in safety activity, and important questions about the value that is achieved through various types of initiative.

When patients are recruited to activities that use their knowledge - well designed, experience-based co-design projects for example - they are able to offer a very useful perspective. Patient contributions of this sort are typically highly valued.

Seeing things through the eyes of patients and their relatives. Knowledge of what really happens. Empathy with service users. ... Improvements to facilities fitting patients and the staff, not just staff. [Manager]

Comments also indicate that patients' involvement is useful to ensure that management decisions really were in patients' interests. Several clinicians commented that patients could become valuable allies to clinical staff undertaking improvement activity.

The Trust listens! They don't always listen to us. Patients are very powerful. [Anaesthetist]

Real life stories, and patient stories, are very powerful drivers to overcome obstacles for change. [Anaesthetist]

For obvious reasons, when patients are recruited to activities where their version of events challenges the organisation, their role is to propose or critique technical solutions, where they are not given adequate support, or if they do not see anything change, involvement works far less well.

There were a number of comments from professionals expressing anxiety that patients who had experienced harm viewed involvement as a way of pursuing a 'vendetta', or would base their views wholly on their own experience. Professionals who were generally positive about involvement activity also recognised, along with patients and their representatives, that when it was done badly all parties became disenchanted.

Patients need support and training to be effective representatives: debriefing their own experience is essential in order to represent others, and training and support is essential to enable patients to understand and participate in discussions of policies etc. [ODP]

Comments made in response to our question about what *doesn't* work when the NHS tries to include patients as partners in safety included:

There is refusal to accept the families' version of events. Refusal to include families in SI and RCA investigations. Holding back the truth for fear of litigation. [Healthwatch member]

There is no evidence of listening and acting on their advice and experience. [Patient]

Being condescending, formal meeting formats only, picking the patients they want to work with or see as suitable. [Patient]

Tokenism. Discounting patients' ideas. [Anaesthetist]

When it discourages staff from being as full and frank in their discussions about events as they might otherwise be. [Manager]

Some comments identified difficulties in professional – patient interactions when patients had continuing very strong feelings about their experiences of poor care. Others pointed out that patients were often recruited from a narrow section of society, so that systems could end up designed around a narrow range of experience.

Usually only English speaking patients are recruited, creating a system of safety build around their experience. [Other medical practitioner]

Avoid engaging with the same people again and again - diversity of ideas, values, culture is needed. [Manager]

Whether respondents favoured or questioned patient involvement in safety activity, there was widespread condemnation of tokenistic or ill thought out patient involvement activity.

We therefore concur with Davis (2011, also 2007, 2012) that the pressing challenge for future work in this field is to identify appropriate avenues for patient involvement. We are also of the view that the ethical arguments for involving patients in safety need to be more clearly spelled out.

Carl's story

A surgical team mistakenly performed a frenuloplasty: an operation where an incision is made to the penis to loosen the foreskin. The patient had been listed for the removal of a cyst on his testicle.

Carl was pleased to have been offered an early appointment for his operation. The cyst had become very uncomfortable and was preoccupying him.

Arriving at the hospital on the morning of surgery, the anaesthetist and the operating surgeon met with him in turn. The operation was discussed and he gave his consent. The exact time of his surgery could not be confirmed by any of the staff. The anaesthetist commented that they were expecting it to be "a very busy day".

Carl was prepared for surgery. He felt a little nervous. The frequent checking and double-checking of his identity, the intended operation site and the nature of the procedure was reassuring. An arrow on his leg pointed toward the correct surgical site.

Just before 4.00pm Carl was taken into theatre. His last memory was a discussion with the anaesthetist about the drugs he was about to be given. Carl is allergic to penicillin. An hour and a half later he woke up feeling extremely nauseous.

The surgeon came to see Carl in the recovery area. He needed to talk to him once he was settled back on the ward. Carl was still feeling very sick.

An hour later the surgeon informed Carl that he had performed two operations – the frenuloplasty and the cyst removal. The former had been performed in error. The surgeon explained the procedure, apologised and then left.

Carl still felt sick. He was unsure of what he had just been told. Over the next hour, he asked to see the surgeon on three or four occasions. The nursing staff couldn't locate him. Carl kept asking what exactly had happened to him. The nursing staff provided him with two leaflets explaining each operation and requisite the aftercare. He was discharged just after 8.00pm. Carl did not see the surgeon again until weeks later.

Carl awoke the next morning at his grandparents' home. He still felt unsure what had happened to him. He was in some pain. His grandfather contacted Carl's uncle and aunt, both of whom work for the NHS. They were shocked and upset.

Two weeks passed. On the advice of family members, Carl contacted the PALS service. They were shocked to hear his story and advised that he write to the chief executive. On receipt of his letter, the complaints department contacted Carl by phone. A few days later he received a letter of apology. A senior manager was appointed to run the investigation.

For Carl, weekly visits to his GP, anti-biotics and months off work ensued. The stitches from the frenuloplasty opened up and the wound became infected. In contrast, the cyst incision healed well.

A full investigation took place and the report was shared with Carl. He was shocked by what he read – positively angry, in fact. “I was truly shocked. I couldn’t believe so much of what had gone on. How can it be that a surgeon can operate all day with no properly scheduled break? Why wasn’t a “time out” performed immediately before the operation? I just couldn’t believe that it could happen.”

A single pre-list briefing for the whole day’s surgery had been performed at the beginning of the day. The surgeon had been expecting to perform a frenuloplasty at 4.00pm. The list had been delayed in the morning by a procedure that was new to the team. Carl entered the theatre just before 4.00pm.

The scrub practitioner was concentrating on another task as the surgeon commenced. The list was over-running and a consultant anaesthetist in another theatre had applied pressure for the team to expedite the list.

Carl commented: “I am a police firearms officer. Believe me, I understand the effects that stress and pressure of the job can have. But that is why we follow procedure. We work with the same people everyday, we get a bit complacent; we think we know what each other can do, but that is why we have such strict procedures. Everyone has to follow them, no matter what rank, we all have to follow procedure.

“I’ve now got what I consider to be a nasty scar on a place that you don’t want a scar. Even though I know it could have been worse, it’s had a huge psychological impact.”

Carl missed his six monthly re-licensing to carry firearms. He is back at work but is currently on light duties.

(See Appendix 1 for information about this story)

Chapter seven – Adopting a systematic approach to improving surgical safety (1): standardise, educate, harmonise

The initial approach of the task force was to compile a list of specific recommendations that were directed towards the varied causes of the surgical never events. However, when we reviewed the opinions expressed through our consultation process and discussions alongside these detailed recommendations, it became apparent that a list of 'fixes' was unlikely to provide an effective solution.

In our high level overview of causes of surgical never events at the end of chapter two we identified four core themes:

- variation in professional practices (e.g. different approaches to swab counting) and associated difficulties around expectations of team member performance (e.g. scrub staff expertise and specificity of instructions they require);
- lack of understanding of principles of safety in the operating environment (at organisational and individual level) and/or failure to act in concordance with them;
- inadequate resources to ensure a safe surgical environment; and
- human fallibility.

We are of the view that it will not be possible to reduce never events further without implementing an integrated approach that addresses all four of those sources of error.

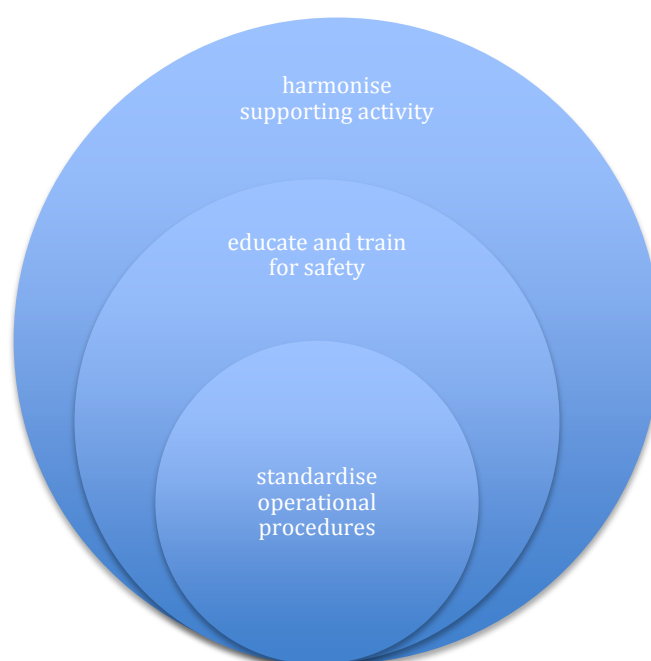
We are therefore proposing a single strategy that consists of three interlocking elements set out in the Figure below.

At the centre of our strategy is the *standardisation* of operating environment procedures. Professionals will lead the development of optimal national standards informed by best practice.

Standardisation must be linked to *education and training* for all staff, including those managing the operating environment. All perioperative professionals should be supported to understand and implement the national standards.

Finally *harmonisation* should ensure consistent support for professional and organisational concordance with the standards across NHS England commissioning, regulation, and other surrounding activity (including resource allocation).

FIGURE



NHS England should sponsor the development of a coherent framework of national standards for operating department practice, mandating provider concordance with the national standards. It will be for professional experts to take the lead role in developing and continuously reviewing these national standards. The standards will set out broad principles of best practice, and indicate 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. These local protocols must accord with the national standards, but are likely to be more specific and detailed.

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.

We believe that providing national direction but requiring local ownership will foster provider and professional responsibility. So long as local standards are consistent with the acceptable means of compliance stipulated in the national standards there is scope for innovation and appropriate variation.

The scope of the national standards will be *core generic processes for conducting surgical procedures in operating environments wherever they are located*. The intention is that the national standards will focus on generic processes underpinning safer surgery (such as swab and instrument counting); and will cover the growing range of interventional procedures taking

place outside of theatres that also result in the 'surgical' never events (such as retained guidewires).

Once published, national and local standards will require concordance of all parties, except in circumstances where practitioners or providers are able to justify non-concordance on grounds of patient safety or well being.

NHS England will be responsible for developing the national standards through collaboration with professional associations and provider organisations, ensuring that they are based in best evidence and best practice. Having published the national standards it will retain responsibility for updating and maintaining them, still in collaboration with the professions and providers. In particular, it will incorporate into the national standards and any associated guidance the learning gained from investigation of incidents, research, and developmental activity.

We envisage that the introduction of national standards will create a single unified framework for all commissioning, service provision, quality assurance, education and training, regulation, legal standards of care, investigatory practice, and national learning in relation to surgical serious incidents including never events.

We discuss this in further detail in the next chapter, but comment here on the three elements of our strategy.

Standardise

In proposing *standardisation*, we cannot stress too much that our intention is *not* to introduce yet another set of boxes to tick. The aim of standardisation is to set standards that will serve to minimise the risks of variation; and that also serve to maximise consistency of action across teams, organisations, and the health system. The principle underlying standardisation is that *everyone*, from patients who ultimately undertake the risks of surgery, to staff who may unintentionally harm them, is entitled to know exactly what standards of practice are expected.

Educate

In proposing *education and training* to support standardisation, we are conscious that effective use of the WHO Safer Surgery Checklist has been shown to rest upon understanding how and why it works. But more importantly, we are convinced that the most important safety asset the NHS owns is its staff. If they possess a common understanding of principles of safer surgery, not only will they be able to support each other to implement them but they will use their intelligence and imagination in the service of future improvement.

Harmonise

The NHS is a complex system of incentives and disincentives; and it is one where the bureaucratic burden of poorly aligned initiatives is widely recognised. In proposing *harmonisation* of all surrounding activity we want to ensure that all of the incentives and disincentives to safer practice are in alignment. For example, our recommendation for multi-professional education and training will have little effect if training budgets can only be used for single professions (to mention only one of several issues relating to training raised in our consultation). Additionally, we want to maximise both effectiveness and efficiency. Harmonisation should help to match human and financial resources to operational need, reduce bureaucratic burden, make regulation effective, and hold organisations or individuals accountable.

Supporting standardisation and education with harmonisation of all of the activity surrounding provision of care will enable organisations to focus effort where it is needed.

The national standards will set out clearly the responsibilities and accountabilities of providers and external agencies. We consider these in the next chapter where we situate the national standards in the context of the safety landscape created by new NHS structures.

Developing and implementing national standards

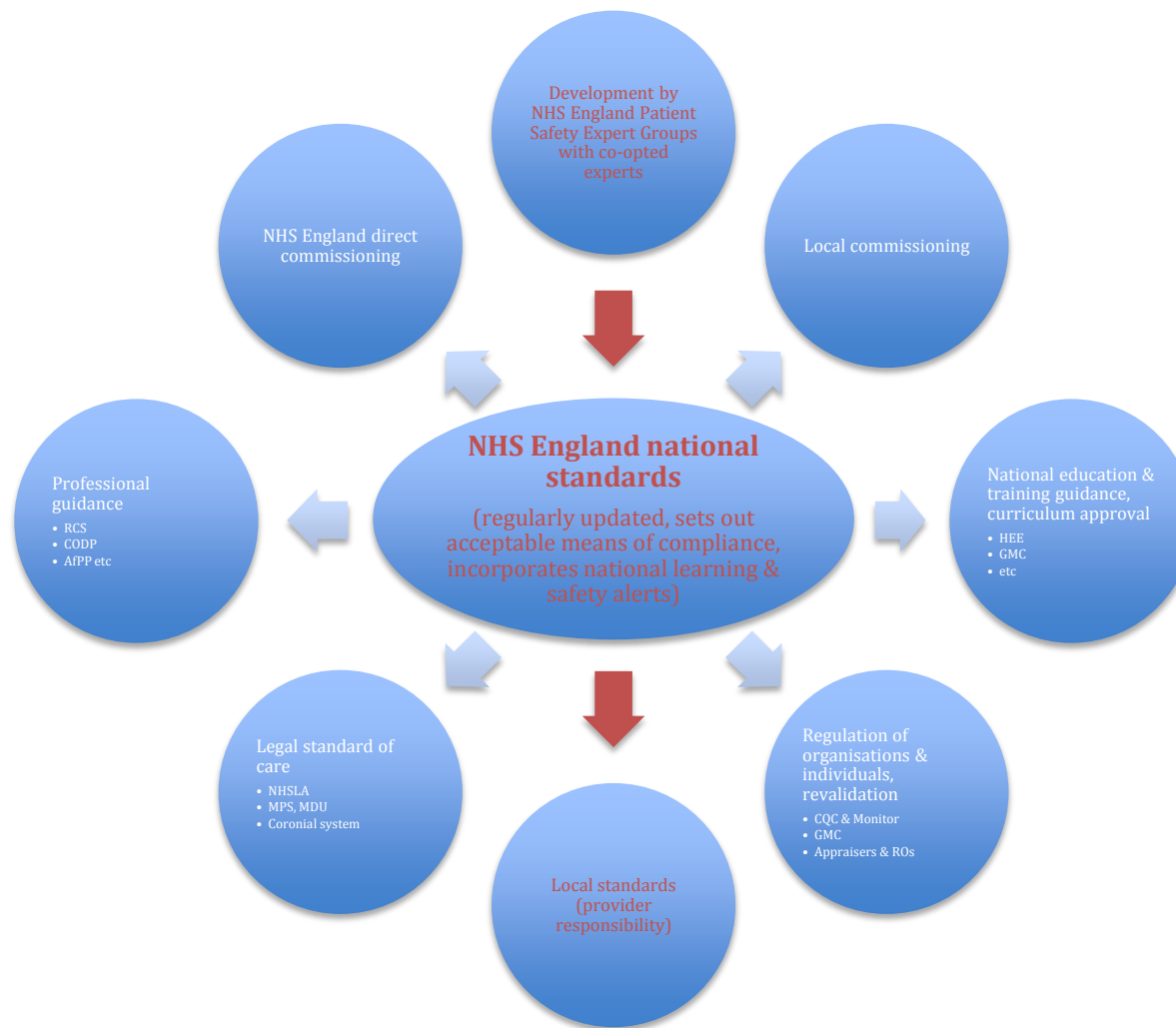
The Figure on the next page illustrates how the national standards could be developed, and how they would constitute the focus of surrounding activities.

We envisage that the national standards would be developed in association with NHS England's existing Patient Safety Expert Groups, with co-opted expertise as required. The expert groups would have responsibility for ensuring that the content of the standards was consistent with best evidence and best practice guidelines. These would include for example the *WHO Guidelines* as well as protocols such as those promoted by the Association for Perioperative Practice and College of Operating Department Practitioners.

The Patient Safety Expert Groups would co-opt members to ensure that they draw upon experience of other industries. For instance, we suggest they would benefit by inclusion of practitioners who have expertise and experience both in the aviation industry and in medicine.

Our detailed recommendations make clear how the national standards can be used to engineer safety into the system from top to bottom: from European level training requirements to agency provision of locum staff.

I am amazed that with all the publicity about never events and patient safety there is no nationally approved format for intra operative counts and checking procedures. [Perioperative nurse]



FIGURE

A trainee surgeon's story

A surgeon in training left a swab inside a woman following a double mastectomy.

Having performed the procedure jointly, the surgeon in training agreed to finalise the surgery as his senior supervising colleague wrote the operation note. In the final stage of the operation, the surgeon in training used an additional swab to manage some bleeding.

The scrub nurse - who was relatively newly qualified and had recently joined the team - completed the swab count before the end of the operation. She was not aware that an extra swab had been used. The trainee did not remove the swab before the final skin stitch was placed.

The patient went home the day after the operation. Two weeks later the patient returned to the surgical admissions unit complaining of pain. The surgeon in training was 'on call' and as he removed the dressing to examine the wound discovered the swab, which was concealed amongst the packing. He was shocked, realised what had happened and consulted a senior colleague immediately.

They both quickly decided to disclose the error and apologise. The patient was very upset. She later chose to delay her chemotherapy treatment, albeit only temporarily.

The team were distressed that they had caused harm to the patient. They recognised that the patient's confidence in them had evaporated as a result of the error.

The multi-disciplinary team reviewed the event and had an open discussion about the conditions that had led to the error. Both the surgeon in training and the newly qualified scrub nurse quickly recognised and freely admitted their mistakes. The surgeon in training had been focussing on finishing the procedure. The scrub nurse was relatively new to the team and had not realised that she should not complete the swab count until the operation was completed.

(See Appendix 1 for information about this story)

Chapter eight - Adopting a systematic approach to improve surgical safety (2): the new safety landscape

As set out in the preceding chapter our strategy is one of *standardisation* of operational procedures, *education and training* in safety standards, and *harmonisation* of all surrounding organisational activity.

Our principal recommendation, and the foundation on which all others rest, is that NHS England develops a coherent framework of national standards, and mandates provider compliance with the national standards. This will be done by requiring provider organisations to develop, implement and enforce local standards consistent with the national ones.

The overarching purpose of the national standards is to promote the standardisation of core operating environment processes, whilst also encouraging planned local innovation, reinforcing provider and professional responsibility, and harmonising the activities of a range of national stakeholders (such as regulators) and local stakeholders (such as CCGs and Healthwatch).

In this chapter we summarise the rationale for proposing national standards in terms of its fit with responsibilities and accountabilities in NHS structures, as they exist following the Health and Social Care Act 2012.

Responsibility for commissioning safer services

AS NHS England notes on its website, “the role of commissioning, as a key driver of quality, efficiency and outcomes for patients, has become increasingly important to the health system in England”. We therefore start by considering how NHS England’s lead role in commissioning can drive improvements in surgical safety.

NHS England has two core functions in relation to commissioning safer surgery:

- Direct commissioning of specialised services
- Commissioning development

Direct commissioning

Direct commissioning of specialised services account for approximately 10% of the total NHS budget. Although a smaller percentage of this is specialist surgical services, where NHS England directly commissions surgical services, the standard contract should require provider concordance with the national standards.

All providers of directly commissioned specialist surgical services (whether NHS trusts or other qualified providers) will therefore be required to develop, implement and enforce local standards consistent with national standards.

We anticipate that requiring concordance with national standards in direct commissioning would, even on its own, have an indirect impact on provision of non-specialised surgical services. National and local standards will clarify the minimum standards for safe operating environments and safe practice. It would be both irrational (and, for private sector qualified providers commercially self-defeating) to claim standards that fell below these thresholds for specialised services were 'good enough' for non-specialised surgical services.

Commissioning development

NHS England's commissioning development responsibilities (as set out on its website) include:

- To have an overarching strategy for development of appropriate commissioning strategies, processes and best practices

The development and promotion of national standards sits squarely within this function. The "appropriate commissioning strategies and processes" will be for all local commissioning to require providers to supply surgical services in concordance with the national standards.

- To ensure that the commissioning architecture and systems deliver improvements in quality and outcomes.

NHS England will be responsible for leading the development of national standards, and local commissioners will be responsible for incorporating them into the standard contract for local commissioning. Together with local enforcement by commissioners, this will ensure that local standards align with the best practice signaled in the national standards.

From the provider perspective, national standards will set common core standards for all commissioned surgical services, reducing complexity where providers are commissioned by more than one CCG.

- To develop specific tools and resources to improve commissioning for service transformation

National standards will be based on understanding of best practice as this stands at the date of issue, but are a dynamic entity. National standards will be regularly updated to encapsulate and disseminate learning from serious incidents. National standards will thus be the repository of contemporary understanding of how to provide the conditions for safer surgery. By tracking national standards, local standards should provide a tool for improvement at local level.

- To support the community of leaders for NHS commissioning

Reducing never events to a minimum will require shared leadership and national direction such as that envisaged by the NHS Assembly. National standards will provide a common language of surgical standards for commissioners and organisational leaders, both within the NHS commissioning system and beyond.

- To manage the external partnerships with the range of national stakeholders.

The core aim of national standards is standardisation of procedure, and harmonisation of all surrounding activity. NHS England's role in managing external partnerships with national stakeholders is therefore vital. The national standards are intended to provide a focal point for the plethora of organisations whose activities contribute to the provision of safer surgery. This means not just commissioners and providers but also:

- national professional bodies for surgical, anaesthetic and perioperative staff;
- national voluntary and statutory patient organisations;
- national regulators;
- national education and training bodies, including Health Education England, and regulators with responsibility for approving curricula; and
- legal authorities such as the coronial system and the NHS Litigation Authority.

In the *Initial Government Response to the Report of the Mid-Staffordshire NHS Trust Public Inquiry*, the national stakeholder signatories stated that it was their common purpose to:

“work together, collaborating on behalf of patients, combining and co-ordinating our strengths on their behalf, sharing what we know and taking collective responsibility for the quality of care that people experience. We will be ... unflinching in promoting what is excellent”.

The purpose of the national standards is to support that aspiration.

Responsibility for learning from serious incidents

The single most consistent message that came out of taskforce discussions and our public consultation is that despite its good intentions, the NHS could do better at first analysing and then learning from never events and serious incidents. Both analysis and dissemination of learning are equally important. If the initial analysis is ineffective, neither the action planning nor any organisational learning that follow are likely to improve matters.

In the course of our discussions and consultation, many observers raised doubts about the quality of local investigations (for instance, they may be conducted by someone with little experience of preventable event investigations, or may not systematically review human factors). Moreover, there was widespread agreement among those we consulted that while some trusts effectively disseminate local learning many do not; and that the NHS nationally does not aggregate the learning from events, nor effectively disseminate the learning that it does achieve.

National standards will provide a national mechanism for incorporating the learning from serious incidents into new protocols and practice guidance. Local standards will in turn mirror these developments. National standards will become a single, authoritative point of reference updated in light of new thinking about optimal operating environment practice.

Responsibility for providing safer services

Provider organisations have an overriding responsibility to patients to provide safe surgery. When an error results in a never event or causes other harm to patients, it can also be devastating for the professional teams concerned. For this reason, we believe provider organisations owe an additional responsibility to their professional staff to provide a safe environment for surgical procedures.

The intention of national standards is to set a framework of national operational procedures that signal best practice and reduce unnecessary and potentially dangerous variation. Responsibility for deciding how the standards may best be implemented locally rests with the providers of services to NHS patients, who will be required to develop and maintain their local standards. We expect that providers will draw on the professional expertise of their own clinical staff to do so. This approach thus promotes provider and professional responsibility and permits innovation, whilst maintaining concordance with a national framework of best practice.

It is unclear how far the procurement regulations promulgated under s.75 of the Health and Social Care Act 2012 will affect the market for provision of surgical services.¹² However, the NHS already commissions surgical procedures from non-NHS organisations and will no doubt continue to do so. Under the national standards all organisations providing surgical services commissioned by the NHS will be required to do so consistent with the same national framework.

We believe that national standards will offer significant reassurance to patients and commissioners that NHS surgical services will meet the same standards for safety, whatever the nature of the organisation providing them.

¹² Under s.75, regulations aim to ensure NHS bodies (i) adhere to good practice in relation to procurement (ii) protect and promote the right of patients to make choices with respect to treatment or other health care services and (iii) do not engage in anti-competitive behaviour.

The national and local standards will also provide an authoritative point of reference for determining the standard of the legal primary duty of care (as distinct from vicarious liability for staff) that provider organisations owe to their patients in respect of the services they provide.¹³

Responsibility for conducting procedures safely

The taskforce recognises that there are many contextual causes of human error, including under-resourced services, unsafe systems and faulty or missing equipment. However, it is also an unavoidable fact that some human error arises out of carelessness, incompetence or ignorance.

We believe that all clinical professionals have responsibility to ensure that their own behaviour accords with commonly recognised standards of good practice; and also to ensure that the systems they are working in are safe.

Professionals are entitled, in return, to have providers ensure that they are adequately supported and have the facilities and training that enable them to do their risky job safely.

The national standards will supply professionals with a single authoritative point of reference, enabling them to advise, audit, review and challenge the provider organisations within which they work. We also hope that they will become a source of information for peer review, so that professionals are able to support one another to set high standards across regional or national networks.

The national and local standards will also provide a point of reference for determining the legal standard of care, and hence its breach, in respect of the individual professional practices with which it deals. This will make legal standards of practice more apparent both to professionals and to those advising them.

Education and training for safer surgery

We would recall here Shouter's description of the operating room as having "a unique set of team dynamics, as professionals from multiple specialties whose goals and training differ widely are required to work in a closely coordinated fashion".

It is axiomatic that professionals in different specialties will follow different education and training pathways, and bring different knowledge, skill and experiences to the operating room. Role specialisation is what makes surgery possible, but it also makes the task of orchestrating activity across the group a

¹³ *Wilsher v Essex AHA* [1987] QB 730, *Bull v Devon AHA* [1993] 4 Med LR 117 (CA)

demanding one. It is even more demanding when, as many respondents to our consultation pointed out, team members do not understand or respect the protocols that govern each other's work.

We therefore emphasise here that education and training for safer surgery must take into account the training needs of multi-professional teams: teams that work together must, at appropriate stages, learn together. This may mean more multi-professional education, more multi-professional training, or both.

Health Education England has been charged with providing leadership for the reformed education and training system that is part of the new commissioning landscape. The driving principle behind reform is to improve care and outcomes for patients. Key national functions of HEE include:

- promoting high quality education and training responsive to the changing needs of patients and delivered to standards set by regulators;
- allocating NHS education and training resources, ensuring transparency, fairness and efficiency; and
- assisting the spread of innovation across the NHS in order to improve quality of care.

Through setting out in clear terms the content of and accountabilities for core generic operational procedures, national standards will facilitate the planning and provision of education, training and assessment in aspects of surgery across the clinical professions. This will make it possible to develop interlocking professional curricula, and plan consistent approaches to inter-professional and multi-professional education.

The national standards should be a key point of reference for those engaged in workforce planning, curriculum development, curriculum approval, educational quality assurance, teaching training and assessment.

For individual professionals in training, national standards will facilitate a foundational understanding of how the operating environment works, and what is expected of all the actors within it.

Regulating for safer services

We have referred above to the aim of harmonising inspection and regulation through the introduction of national standards and noted in the previous chapter that provider concordance with national standards could be mandated through contract or legislation. If a legislative route were chosen, it would be possible for CQC to take enforcement action for breaches.

It is now widely accepted that failure to align regulatory activity undermines regulatory aims and imposes a burden of inspection and bureaucracy on providers. The national standards provide a vehicle for focusing judgment and

harmonising activity around nationally agreed standards. This has potential to promote consistency in assessment, to support rationalisation in inspection, and to reduce bureaucratic burden.

CQC is supportive of our proposals. It is currently working with the Department of Health to draft revised registration regulations and associated guidance. The CQC view on supporting national standards is that, whilst it is unlikely that the revised registration regulations will be written at a level of detail that would make direct reference to national standards, it is highly likely that the regulations will include a fundamental standard relating to incidents leading to harm. CQC could write their guidance in such a way that it could take compliance with national standards into account when making judgments about compliance with this fundamental standard. Alternatively, or in addition, the guidance could make reference to national standards in respect of compliance with a more general standard relating to safe care.

CQC will also be writing a narrative in relation to judgments about their five quality domains (these ask how safe, how effective, how caring, how responsive and how well led organisations are). These judgments will inform the provider's rating. Concordance with the national standards could influence this narrative, and hence provider rating.

National and local standards will also provide clear standards for individual professional behaviour. This is of course of relevance to the professional regulators (GMC, NMC, HCPC) in so far as they approve education and training provision and carry out Fitness to Practice assessments.

Sophie's Story: dealing with the aftermath.

"All I needed that day was for a doctor to say *"Yes, I can see the lesion, don't worry, I will sort it out for you"*. There is no admission of guilt in that, but it would have stopped me feeling that no one believed me."

In the weeks following her wrong site surgery, Sophie was surprised by the response. No one seemed to want to openly admit the mistake. She discovered that the incident had not been reported as a "never event".

As importantly Sophie needed ongoing care. Her lesion was confirmed as malignant and she still needed the original operation to be performed. The first operation had made surgery to the original lesion more complex and a specialist referral to another hospital was now required. Sophie joined the waiting list for an appointment.

"I'd expected that given it was so obviously their mistake, that they would have taken responsibility for sorting things out for me, made it a real priority. I just felt they were trying to get rid of me."

Rather than being prioritised, Sophie felt she was being ignored. To Sophie's great surprise when she finally got an appointment to see the specialist, he seemed entirely unaware that she has experienced wrong site surgery. Rather it had been implied that the first lesion had been operated on and found to be non-malignant, and that the basal cell carcinoma had been discovered in the process. Sophie's sense that the incident was being "brushed under the carpet" was strengthened and yet again she felt her experience was being denied. She was deeply distressed.

Further administrative errors and a lost referral resulted in further delays.

"I was so very distressed by what was happening through no fault of my own. There seemed to be no end in sight."

Eight months after her original referral and five months after the wrong site surgery, her basal cell carcinoma was finally removed.

After seven months of complaints, investigations, discussions with PALS services at the hospital, PCT and the SHA, and three meetings with the hospital chief executive, Sophie was invited to a meeting with the consultant surgeon. A formal - but in Sophie's view - begrudged apology was offered. But it all felt too little, too late.

The hospital asked Sophie to help them learn from her experience. She agreed willingly. Although some of her initial suggestions for change were acted upon, months have passed with no progress in other areas. Sophie now wonders if this was empty rhetoric designed for "damage limitation" rather than genuine learning.

"I still feel angry and upset. The way I was treated after the incident was just terrible. I've had to push them every step of the way. They've tried to minimise things and deny things. I thought at one point they were all concluding against me, that's how bad it got.

"They wouldn't listen to me any other way. So, this is the only way I can get back at them."

Sophie has issued proceedings against the Trust.

Chapter nine - Implementing compassionate support after never events and other serious incidents

Be completely open and honest. Work out a solution to the problem, and make its implementation a true priority. Offer emotional and physical support and aid the patient throughout the remedial process in every possible way. Be pro-active with compensation and make it a short and expedient process. Involve the patient in the investigation and in implementation of measures to prevent recurrence. [Surgeon]

Counselling for patients, meetings with explanations and apologies help. Staff are very vulnerable around this time, and this needs to be recognised immediately, and support offered. Every contact from Quality & Standards needs to be carefully thought out. Trainees may need support from seniors, as an email requesting a statement can seem very threatening if unexpected. [Anaesthetist]

During a speech at University College Hospital on 12 July 2013, Jeremy Hunt commented, “whilst we aspire to zero harm, we will never deliver zero harm - just as the airline industry can never deliver zero crashes”.

No matter how good we become at preventing never events, they and other serious incidents will happen. Just as we expect the airline industry to have a clear plan in place for how to deal with crashes when they occur, so we expect the NHS to provide appropriate support to patients, their supporters and the professionals caring for them, when things go wrong.

The link between the way in which we respond after harm and our ability to prevent harm is well known and widely discussed. If professionals are to be able to report and learn from never events, there *has* to be a culture supportive of openness and frank discussion. Justice and prevention of poor practice also demand accountability when appropriate. However, a just and open culture in the NHS remains an elusive goal.

The taskforce therefore considered the needs of patients and professionals when never events happen.

Current practice in the NHS

Current practice in disclosure and support after harm is guided by the National Patient Safety Agency's *Being Open* guidance. This was first published in 2005 and subsequently reissued, endorsed by key stakeholders, in 2009. Our consultation indicated that the quality of support being provided to patients differs widely across organisations, with some surpassing the standards of *Being Open* and others falling well below them.

In a recent survey of NHS managers responsible for implementing *Being Open*, 98% of participants reported that they are familiar with the guidance and 82% that they implement it more than half the time when incidents occur.

However, information was not being given to patients in a timely fashion, with two-thirds of discussions with patients taking place three to six weeks after an incident investigation had been completed. Fewer than half of patients who suffered injury were followed up in the long term, and fewer than half received *ex gratia* payments. The most frequently cited barriers to open disclosure were fear of negative reactions from patients or their families on the part of clinical staff, and anxiety about litigation. Debriefing and training in open disclosure were thought to be very important, but were not always available. (Pinto 2012)

Views expressed in the consultation

Responses to the consultation were remarkably consistent.

Apologise and be honest. It worked for me. [Surgeon]

Honest discussion of what happened, why and what is being done. In our trust (and probably many others) the report of the investigation is given to the patient, with a face-to-face meeting if they wish. Sometimes it does feel as though the patient is an afterthought in this process rather than integral to the learning. [Anaesthetist]

Writing about the support that should be offered to patients, one respondent (an experienced perioperative nurse and theatre manager) encapsulated views widespread amongst others:

- Sensitive, well planned disclosure with supporter available if possible
- Explain all aspects and options and involve them in plan
- Sincere apology
- Named impartial contact/case worker
- Supportive at every contact
- Early settlement if appropriate.

The same respondent then went on to summarise equally well the approach that respondents thought should be adopted towards staff:

- Supportive management of investigation
- Don't isolate the individual/s
- Recognise the distress/shame that they will feel
- Don't blame and be punitive
- Constructive accountability
- Training if required - will probably be required for wider workforce
- Celebrate near misses as a good catch, and learn from them - this will encourage reporting.

There may be a tendency to view individual patient and professional needs as unrelated. However, the impact that failing to appropriately support staff can have on their patients was summed up by one of our respondents who had

suffered a serious incident. This respondent has never had a frank conversation with the clinician who treated them, and continues to try and piece together what happened from other sources.

For staff, get support and help to acknowledge what has happened, help to discuss it with patient and family and perhaps other colleagues. This certainly didn't happen in my case...I would like my consultant to have been supported in telling me (what I now believe is the case)...

Many respondents commented on the need to build a just culture, which balanced openness with appropriate accountability. However, there may be some disagreement about quite where the balance between support and accountability is to be found.

Counselling and support, rather than bullying and disciplinary action, as currently happens. [Anaesthetist]

Critical incident recorded and placed in appraisal folder. Shared with clinical director, medical director, CEO. Written statement of involvement/explanation. Medico-legal representation. Peer support. [Surgeon]

Full debrief psychological support and ongoing support after the event. If there is any adverse event in the future the staff may need further support as the never event is brought back to mind. Education and training for individuals and discussion within the wider team of any learning. [ODP]

Take steps to find out why this happened and honestly deal with problems. [Surgeon]

A further aspect of just culture that received a number of comments concerned inequity in the treatment of different staff groups.

Treating all members of the team the same - when we had a recent never event, the two health professions were immediately suspended but the surgeon wasn't, even though he admitted he was at fault!! [ODP]

Some respondents called attention to wrongdoing or incompetence attributable to individuals, and expressed the view that record keeping and appraisal could help to identify 'repeat offenders'. These concerns are consistent with recent evidence from the US that some doctors are involved in repeated never events (Mehtsun 2013) and from Australia, where a retrospective review found 3% of doctors generated 49% of complaints to the healthcare ombudsman, and that a mere 1% of doctors accounted for 25% of all complaints (Shojania 2013).

Honesty is needed with individuals regarding shortcomings, training requirements etc. Where there are frequent repeats of similar incidents involving same individuals, a robust system to manage this which ensures accountability and responsibility is required. [ODP]

An integrated framework for responding to harm

Patients seeking treatment are obliged to place their well being in the hands of others. Giving up control calls for confidence, trust and hope. Confidence means believing that 'the system' will protect you from harm. Trust means that you rely on professionals to take responsibility for what you cannot do yourself. And hope is the conviction that things will turn out well. Harm from surgery undermines all three. Patients become fearful that systems are not organised to protect them. They wonder if they can rely upon people to take responsibility. They may be anxious about the future. Fear, mistrust, and worry ignite understandable anger.

Healthcare harm also has immense impact on professionals involved. Many are expected to carry on as if nothing has happened. The supposed 'benefit' professionals derive from being absolved of responsibility by organisational 'cover-ups' denies them opportunity to ask for support or come to terms with what has happened. Other professionals get caught in a whirlwind of unjust blame and punishment. Neither unjust absolution, nor unjust retribution, helps professionals to live with their mistakes or makes surgery safer.

Seven domains for action¹⁴

The taskforce reviewed a framework for an integrated organisational response to healthcare harm developed by Shale and Anderson Wallace; and a framework for supporting professionals developed by the College of Emergency Medicine. Both are consistent with patient and professional views expressed in the consultation process. There thus appears to be widespread consensus about what needs to be done, alongside a view that support for patients and professionals is rarely done consistently well in NHS organisations.

Domain 1 - Active seeking of critical comment and supportive action in response to complaints

Organisations must create effective avenues for patients to offer critical accounts of care, and not view all negative feedback as synonymous with complaints. Even when things go badly wrong, patients may not want to turn their story into a complaint. Rather, they need their experience to be heard, to have answers to questions, and to know what will happen in future. On the other hand, some patients will indeed wish to make a formal complaint. If they do, they should meet with a supportive, measured response.

Support needs to be tailored to the patient and their supporters...In addition to Being Open we always meet with them in their home (rather than making them come to the hospital) and have offered counselling when this has felt appropriate. [Manager]

¹⁴ These seven domains are derived from research into medical leadership in the NHS (Shale 2012), patient testimony (www.patientstories.org.uk) and developmental activity by Murray Anderson Wallace and Suzanne Shale.

Domain 2 - Supportive disclosure to patients and their interested supporters

This domain concerns supportive disclosure of harm. The more usual term is 'open disclosure', but openness alone is not enough. Openness could be satisfied by a surgeon in blood stained scrubs blurting out an unvarnished account of how your family member died. Supportive disclosure requires careful communication about events, a continuing relationship with time to ask questions whenever they arise, considerate and thoughtful support, and practical help when it is needed.

Duty of candour - Being Open - staff aren't good at this because they are frightened of the consequences. More training is required. [Manager]

Avoid being competitive or explicitly triumphalist...In my case, surgeons on the ITU next day were virtually whooping with joy at having 'saved' a cardiology patient and I was told several times that surgery was superior to cardiology (while cardiologists slunk in and out of the ward). This was quite out of sync with shock and horror being experienced by myself and family. A further result was that I was neither a surgery patient nor a cardiology patient - and neither team organised my discharge medication or properly informed my GP of what had happened. At the GP's first visit, he said: 'This discharge information is dangerous'. [Patient who experienced a serious incident]

Domain 3 - Support after harm for clinicians, teams and their interested supporters

Support for clinical teams is vital, but often overlooked. When care goes wrong, clinicians can be disorientated, deeply shocked, and fearful of repercussions. They may feel they have let people down. They may lose confidence in their ability to provide care. In most cases clinical teams will be continuing to provide care to other patients, and may also be providing care to the person they have harmed. Support for professionals should acknowledge their needs, reinforce clinical competence, and foster a culture of fair accountability.

Domain 4 - Transparent, impartial and authoritative inquiry

Domain 4 attends to the need for answers about what happened, and for genuine reassurance that the same thing will not happen again. Domain 4, which deals with the need to conduct an appropriate inquiry, is thus closely associated with Domain 5, which deals with the need to hear what preventive action will be put in place. In the first instance, people need to understand what went wrong in order to make sense of this bewildering turn of events. Answers about what went wrong need to come from an authoritative source, possibly one independent of the organisation. Critically, they need to include patients' and supporters' perspectives. Failure to incorporate the perspective

of complainants or those who have suffered harm, or to accord credence to their version of events, is one of the most glaring failings in current investigatory practice.

A full independent review should occur from a healthcare professional (and lay person) outside the organisation. [Anaesthetist]

Active involvement and updates during the investigation. Clinical appointments and corrective treatment not affected by situation. Sharing of investigation report within set and agreed timescales. Meeting with patients and relatives to discuss investigation findings. One point of contact and open door policy for questions. Coordination between trusts where necessary allowing patient a seamless approach. Reassurance of anonymity in sharing information including when used for teaching purposes. [Manager]

Domain 5 - Implementation of action plan approved by patients and supporters

Hearing what will be done to prevent future injury helps rebuild trust by demonstrating that professionals are truly taking responsibility for things that patients cannot control. This is especially so in complex or especially severe cases. The action plan needs to address underlying issues, and result in meaningful activity.

Communication is paramount – open, honest. Rather than move into litigation mode we need to rectify the situation to the patient's satisfaction and make them safe first. More communication is required than most people imagine, and a consistent contact is preferable. [ODP]

Domain 6 - Restorative approach to restitution

After something has gone wrong in a trusted relationship, it needs to be repaired. This is the role of restitution. Familiar forms of restitution to patients include formal apology, agreement on preventative action, and monetary compensation. However, there is scope to be more imaginative. Restitution should be considered in the short term (e.g. assisting with immediate hardship) as well as in the long term (e.g. commissioning practical or therapeutic support). Professionals who have done harm often similarly wish to 'make good', and they should be supported to do so.

Truth and reconciliation are the only honest ways forward. To err is human but to cover up is unforgivable. Explain, support, engage! Offer a genuine apology and don't make patient and/or supporter feel like it's their fault. "I'm sorry YOU feel like that" is deeply offensive! [Patient]

Make sincere personal apologies, not what looks like a standard letter from the chief executive. [Perioperative nurse]

Access to a solicitor and no rubbish spouted about 'can't discuss due to patient confidentiality' poppycock [ODP].

Domain 7 - Institutional and individual accountability

This domain concerns accountability. Relationships of trust create an obligation on professionals to give an explanation of their actions. In addition, misconduct (deliberate wrong doing or wilful negligence) in a trusted role should incur sanction. These principles hold true across many professions, from healthcare to policing to accountancy to law, and so on. When care goes wrong, people expect professionals to discharge the obligation to render an account, or accept sanction when appropriate. Organisations that accept accountability willingly, and enforce it consistently, reinforce trust in the professions and organisations.

*Honesty and candour, support, rectification of problem if possible.
My friends' first child was born with the cord round his neck. He died of anoxic brain injury. He and his wife had seen dips in foetal heart rate on monitor, but were told they were just neurotic doctors. They wanted a no blame process to protect other families and were assured by the chief executive this would happen. Then stories appeared in local paper indicating it was an ongoing problem. Trust would not accept liability for several years. [Surgeon]*

Chapter ten - Views on how to improve the learning from never events

The aviation industry commonly describes its knowledge of flight safety as having been bought with the blood of those injured in aviation accidents. Patients who suffer harm pay in the same currency. The views expressed in our consultation suggest that although there are beacons of good practice for others to emulate, the NHS could do more to change practice in light of what it learns from serious incidents.

In this chapter we present views from the consultation about current approaches to learning from serious incidents and suggestions for how to do it better. In the consultation, we asked how individual NHS trusts are enabling staff to learn from never events, what could be done to improve learning on a regional basis, and what could be done to improve national learning.

Establish a clinician patient safety lead for surgery in each trust who will be responsible for collating serious incidents and never events and for reporting a clinical analysis of them locally, regionally and nationally [Surgeon]

Learning within single organisations

It is apparent that there is huge variation in how effectively NHS trusts analyse the causes and disseminate the lessons of serious incidents.

Unfortunately we asked only about learning processes in NHS trusts, so we received no comments on how well private providers learn from events that occur when they treat NHS patients, or how they are sharing the lessons they learn with the wider service.

Some trusts are clearly working very hard to bring a wide range of staff into a learning process. Respondents referred to learning being shared via a quality improvement collaborative, clinical governance and audit events, multi-professional mortality and morbidity meetings, email alerts, patient safety boards in theatres and so on (as well as formal training, which we discuss further below).

We have: a Safe Surgery Group (multiprofessional) which reviews all incidents and cascades promptly to all staff (anaesthetists, surgeons, theatre staff); prompt 'first look' investigation of all high level incidents with information out to staff; use of roundtables as part of formal inquiry process; an internal patient safety newsletter. [Anaesthetist]

Newsletters, mandatory updates, case discussion, after action review, incident review groups [Other: professional working in patient safety]

Teamwork training and team observation. Open reporting of previous never events. Trust organised Theatre Safety Summit. [Anaesthetist]

However, in some trusts, it would appear that although there is a focus on learning from events the lessons are shared only (if at all) with the teams involved.

My trust does not offer any feedback or clinical analysis on serious adverse events, let alone never events, they simply count up how many are reported. [Surgeon]

Though never events are rigorously investigated and reported on in my trust, very little is ever fed back to enable staff to learn. [Anaesthetist]

The individuals who need to be involved in this learning are often not included in feedback. I believe that there is insufficient commitment from management to ensure that this is undertaken... In all these situations, feedback should be given on a personal and team level in a comprehensive way which identifies clearly what the issues were, where the breaches were, what happened and what the consequences were and additionally what the potential consequences might have been. Feedback, where provided is usually scant, non-informative and a tick box exercise. [ODP]

A similar theme arose in relation to 'naming and blaming' individuals. As we noted in our evidence review, most never events are a combination of systemic and individual failures. However, in some organisations, the message that is being sent is that the underlying disorder is individual failure to follow protocols, and the prescribed cure is individual vigilance. Other organisations appear to take the lesson of individual fault one step further, terminating the employment of those deemed at fault. The (no doubt unintended) message conveyed to some of our respondents was that they should simply 'keep their heads down'.

Regrettably, at my trust the joint response from the MD and Director of Nursing has been to remind clinical staff of their individual professional and personal liability for following protocols. Whilst this is not incorrect it makes clear that the priority for the organisation is to find fault with individuals rather than look and learn about the culture within and address latent issues contributing to the safety breaches. The Trust has yet to prospectively address accountability for theatre safety practices (the 'five steps to safer surgery'). [Anaesthetist]

How are individual NHS trusts enabling staff to learn from never events? Still sacking people who make them. Not really aware of any good practice. [Other medical practitioner]

Some respondents reflected on the impact of different approaches to implementing the learning from serious incidents.

Good: Debriefing the team, instigating change of practice and educating teams as to why the change has been instigated. Bad: telling people to double count swabs (following retained swab incident) which lasted for a month then vigilance returned to normal. [Anaesthetist]

Good stories [are shared]. But this does not change practice - unless it makes us adamant in protecting our practice. [Surgeon]

Strong leadership from consultant surgeons who take an interest in learning for all grades of staff leads to better teamwork. [ODP]

Not seen much where we worked, with a poor safety culture (critical incidents never reported by staff, as they felt they were ignored by theatre management). Change has only come after 10 years with a change of theatre manager. Good management matters. [Anaesthetist]

Training interventions were a frequently cited means of disseminating learning. Several respondents described having benefited from training offered by the Association for Perioperative Practice (AfPP). Others mentioned the introduction of skills drills in maternity care, a WHO Checklist training video, and training for perioperative staff in the interpersonal skills they need if they are to speak up effectively. From consultation responses, it would seem that some trusts are adopting an integrated approach that links training to system wide review of the causes of adverse events.

We require every directorate in the hospital to discuss every never event (even if it has not affected them) at governance meetings. We have had the AfPP come in to teach the theatre users (all - doctors, nurses, ODPs and HCAs) about theatre safety. [Surgeon]

[Trust] is working hard to introduce Trust Values and Behaviours to build a better culture. I spoke to health care assistants today about patient safety and when they said that they would never dare question I was able to point to the staff values and behaviours and say - you should not be bullied or put up with rude behaviour. [ODP]

Our trust has introduced team briefings at the start of lists - this improves team morale, it reduces hierarchy which enables staff to feel able to question things where they otherwise may not do... We have also received PACE training which is designed to give all staff the confidence and ability to question and challenge other staff members if they feel things are going wrong or if they feel help or assistance may be required before an emergency situation arises. [ODP]

This review of NHS staff experiences of the organisational response to serious incidents demonstrates that very good practice has developed in pockets within the service. The organisations 'getting it right' are therefore in a strong position to guide and support organisations that are currently doing less well.

Learning across regions

Responses to our question about what could be done to promote regional learning from never events elicited a common response, which was that people felt there was a tendency for any lessons learnt to remain confined to the hospitals concerned.

What could be done? A lot - regionally at the moment I am unaware of any steps. [Surgeon]

On the other hand, one leading perioperative practitioner and researcher questioned whether regional learning would be of value.

Why would this be helpful? You can report incidence on a regional basis but the learning and action needs to be taken at organisation level. Clearly the Royal College of Surgeons could use its regional structures to disseminate and share, but fundamentally clinicians need to engage with their peers and commit to improvement approaches at local level. [Patient safety expert]

Generally however, it was felt that greater openness between geographically co-located hospitals would be supportive of enhanced learning. This was thought to be especially so given that never events remain relatively rare, may not happen within individual organisations for some time, and always contain lessons for other organisations.

All never events, but particularly surgical ones are discussed at our regional Medical Directors forum every two months so lessons can be disseminated across all organisations. [Surgeon]

Need national / regional reports on trends and lessons learned in order to prevent a reoccurrence. Why reinvent the wheel if it works elsewhere? [Manager]

Suggestions for regional practice fell broadly into four classes: various forms of peer review, for which there appeared to be real enthusiasm; regional meetings; regional bulletins; and regional teaching (especially linked to existing regional training).

- Suggestions for peer review were reasonably common, and it would appear that in some areas (such as an existing South West collaborative) they have already been proving their value. Ideas included: peer review of theatre practice by local trusts; regional peer review of local investigations; external review of action plans by other trust safety leads; and regional un-announced visits from trust board members, royal colleges and other bodies but always with the presence of lay members.

- Suggestions for regional meetings were also frequently offered, and emphasised the importance of making these truly interprofessional involving healthcare students (medical, nursing, ODP and allied professions) and indeed patients and their representatives.

Regional interdisciplinary professional networks - need to allow the clinical professionals to be participating in these - not at the higher strategic management level. [Perioperative professional and patient safety expert]

East Midlands held a regional shared learning event on never events. Very beneficial as we learnt from each other's errors and shared actions. Share actions and improvements more widely - what has worked and why. [Foundation Trust governor/board member]

- Ideas for regional communications included reference to the MHRA style safety bulletins, and a regional theatre safety bulletin that would be sent directly to theatre departments.
- Training suggestions included frequent reference to teamwork and human factors training at regional level, inclusion of more safety related teaching in regional provision at specialty trainee level, and enhancing access to simulation training by providing this on a regional basis where facilities are not available locally.

National learning

In our final question on learning, we asked what could be done to improve learning on a national basis.

Very broadly speaking the comments fell into three categories, reflecting the three elements of our proposed strategy. Ordered by prevalence they were educate, standardise, and harmonise. We will, however, take them in the order in which we have discussed the elements in the report.

Large scale thematic reviews. Feedback on changes made elsewhere that have worked. Standard setting in response to national themes. [Manager]

Standardise

It is of note that many respondents chose to comment on standardisation when invited to reflect on what could be done nationally.

Why does each hospital have its own peri-operative process? Lack of uniformity makes it difficult for juniors who move to be familiar with protocols. [Surgeon]

Every theatre dept in the country needs clear guidance on standard procedures to ensure that there is a set standard that remains the same no matter which hospital you work in. Every theatre in every hospital should work the same and have standard procedures for all theatre checks done. [Perioperative nurse]

Develop guidelines from NICE. [Surgeon]

Adjust guidelines according to conclusions from previous events. [Anaesthetist]

Standardisation, in this hospital alone we have so many variations on a theme of WHO Checklist. A form must be produced centrally for all NHS hospitals to follow the exact same code of practice. [ODP]

Universal procedures so that staff moving area can follow practices. A breakdown of events delivered to all so that staff can evaluate their own practice. Universal training package covering basics. [Perioperative nurse]

Educate

The most frequent suggestion was for thematic reviews of the learning emerging from serious incidents. Receiving numerical data was not seen as helpful. Rather, what was sought was more in the way of a 'digest' of stories of monthly, quarterly or annual learning. It was suggested that this could be delivered in a number of ways with several practitioners referring to videos, such as the account of Elaine Bromiley's care¹⁵, having been useful to them. Similarly, reference was made to the value to the anaesthetic community of their SALG bulletin, and the usefulness of CORESS to surgeons. A number of respondents lamented the demise of the NPSA and the summaries that it had circulated in the past.

Collate all never events nationally and produce a series of reports, each one covering a theme. These should be published, AND distributed to all relevant staff groups. There is a tendency for 'surgical reports' to only go to surgeons, 'medical reports' to only go to doctors etc. These reports should be endorsed and supported by Medical Royal Colleges, Royal College Nursing and other professional bodies e.g. for ODP and hospital managers. [Anaesthetist]

Re-start/energise Patient Safety First as national point of focus for all to access info, resources, initiatives etc. Patient Safety First had succeeded in becoming a mainstream national resource used by all disciplines and levels. [Perioperative nurse, patient safety expert]

In addition to information needs being fulfilled through various media, respondents made suggestions that echoed those under regional learning. These include the need for nationally mandated core safety training, and cross sector support between successful and struggling trusts.

¹⁵The film 'Just a Routine Operation' has been widely used for surgical safety training in the UK.
<http://www.youtube.com/watch?v=JzlvgtPl0f4>

Human factors and error training in medical education compulsory. Human factors in all postgraduate training. Postgraduate national training updates for older senior doctors (who miss out on the younger trained generation). [Other medical practitioner]

*1) Mentoring scheme where trusts with an excellent record re never events can share good practice with trusts that are struggling
2) Further research into contributory factors re specific never events e.g. factors increased risk of retained swabs may include: number of sites operated on; whether sites use keyhole surgery or open surgery; amount of bleeding; patient weight etc. [Head of Patient Safety]*

Harmonise

Revalidation was viewed as a powerful tool by several of those on the taskforce. This view was shared by experts we consulted, as well as by those responding to the online consultation.

It is highly unlikely that a surgeon or anaesthetist does NOT experience an adverse event occurring to one of their patients in within a five year period (although possibly not a serious one and unlikely a never event) so the GMC could very reasonably ask every theatre clinician to describe the completed follow-up process to an adverse event each revalidation cycle. This would reinforce the responsibility for clinical professionals to get a meaningful response and change from their trust following an adverse event. It might possibly increase the frequency with which the role of responsible officer was delegated elsewhere due to conflict of interests. [Anaesthetist]

Publicise findings in a brief readable fashion. Must be read as part of revalidation. [Surgeon]

Finally, a respondent with specialist expertise in human factors raised the issue of the design of instruments, prosthetics etc.

There must be a stronger relationship between the NHS and the companies that supply their instruments and components. There must be an understanding that those who supply the NHS must do so to a high standard, both of the implant but of the packaging/labelling. This would harden the resolve of the MHRA. [Researcher]

Maximising learning in a mixed health economy

The focus of our discussion here has been on disseminating learning across NHS organisations.

However, robust mechanisms for disseminating learning throughout a mixed public/private health economy may become increasingly important if commissioners take the opportunity to award more contracts to qualified providers.

The existence of a mixed health economy could also raise pressing issues as more interventional procedures with potential to be a source of never events take place outside of the traditional operating theatre environment.

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 <i>core generic processes for conducting surgical procedures in operating environments wherever they are located</i> . | 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 (<i>see Rec 10</i>). | 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 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. | |

NHS England Surgical Never Events Task Force Report

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| 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 (<i>see Rec 5</i>). | |
| 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. | <i>See also Recommendations 5, 10; and 45- 49.</i> |
| 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 | | | |
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| 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, 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. <i>(See also Rec 6)</i> |
| | 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. | <i>(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.)</i> |
| | 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. | |

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| 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 LETBs to ensure that knowledge and skills relating to national standards and clinical human factors are included in training of all perioperative staff. | 29 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 | | | |
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| For action by NHS England | 34 Data on SIs 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 SIs, disseminating information and notifying national standards review team. | | |
| For action by NHS Local commissioners | <i>See recommendations 35, 36, 37.</i> | | |
| For action by provider organisations | 38 When investigating SIs 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 <i>recommendation 35</i>). | 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 CNST discounts. | <i>See also recommendations 36, 37.</i> |

| SUNDRY MATTERS TO BE INCLUDED IN NATIONAL STANDARDS |
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| <p><i>NOTE: The scope of national standards is defined as ‘core generic processes for conducting surgical procedures in operating environments wherever they are located’.</i></p> |
| THEME 1 STANDARDISE |
| <p>46 All operating lists shall commence with a pre-list briefing at which all staff are present</p> |
| <p>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.</p> |
| THEME 2 EDUCATE |
| <p>48 Where appropriate national standards will make reference to provision of appropriate training an ‘acceptable means of compliance’.</p> |
| <p>49 Providers shall be responsible for ensuring that staff, particularly those trained outside the NHS national standards system, receive training in local standards.</p> |
| THEME 3 HARMONISE |
| <p>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.</p> |

Appendix 1 – Patient and professional stories in this report. Terms of reference. Membership and acknowledgements.

Patient and staff stories

The stories we have included in the report are derived from interviews with patients and professionals who have been involved in “never events”. Two patients and three professionals offered to take part in unstructured narrative interviews about their experiences to inform the work of the taskforce.

It is important to recognise that the stories we present here are stories of experience. They include perceptions and feelings as well as the ‘facts of the matter’. For professionals, the emphasis of the stories tended toward accounts of how an error occurred and why. For patients the focus was on how they were supported and treated in the aftermath. For both patients and professionals the events were traumatic and distressing.

Those involved have been assigned pseudonyms to protect confidentiality.

Terms of reference

The taskforce was a time limited group asked to investigate the reasons why surgical never events continue to occur and how to prevent them from happening in the future. The group used the following terms of reference:

1. Examine and clarify the reasons for the persistence of surgical never events in NHS Commissioned Services in England
2. Make recommendations for further interventions, policies, measures or other activities that will aim to eliminate the occurrence of peri-operative never events.
3. Specifically examine the effectiveness of the roll-out of the surgical safety checklist and its derivatives in the NHS Commissioned Services in England and make recommendations about how relevant checklists can further contribute to reducing surgical never events
4. Deliver the above to the patient safety domain of NHS England by 31 July 2013.

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Nick Toff and Bill Kilvington drafted the sample national and local standard.

The report was prepared by Suzanne Shale, who carried out the evidence scan

Fran Watts supplied content for chapter one, and Stephanie Russ prepared a draft of chapters four and five. Murray Anderson Wallace prepared the patient and professional stories and contributed to chapter nine. Edward Morris and Isabeau Walker commented on the first draft. Other members of the taskforce commented in detail on the final draft.

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Appendix 3 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.