Surgical Never Events should never happen...

by Jane H Reid

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Surgical procedures are intended to save lives and improve the quality of life, however omissions in essential practices (system and human error) contribute to unsafe surgical care, and cause significant harm to patients. For centuries it was believed that patients’ co-morbidities and the surgeon’s technical competence were the key determinants of surgical outcome; it is only within the last decade that the relationship between failure to follow safety procedures, sub-optimal team work, poor communication and clinical outcomes has been appreciated (Vincent et al 2001). Recognition of the interdependencies for good surgical outcomes owes much to safety oriented research focusing on interpersonal behaviours and cognitive performance, the science of ‘human factors’, and the route cause analysis (RCA) of surgical harm.

It is now acknowledged that, while most things are done for most patients most of the time, process failures, cognitive impairment/human error, and less than optimal teamwork result in inconsistencies of care and adverse outcomes. A Never Event is defined as: ‘A serious, largely preventable patient safety incident that should not occur if the available preventative measures have been implemented by healthcare providers’ (NPSA 2010a).

The scale and typology of surgical harm common to the world’s health systems was first identified in 2004, due to returns to the World Health Organisation (WHO) and data analysis from some 54 countries. It was calculated that, of an estimated 187 million major procedures conducted worldwide per annum, 3-16% resulted in major complications and with disturbing death rates (Weiser et al 2008).

Of equal concern based on earlier examination of two western health systems, it was determined that nearly half of the reported adverse events were preventable (Kohn et al 1999, DH 2000).

In response, the World Alliance for Patient Safety initiated the WHO’s second Global Patient Safety Challenge: Safe Surgery Saves Lives (WHO 2008), and launched the Safe Surgery Checklist in July 2008. Modelled on checklists used in aviation, the WHO checklist consolidated many of the essential safety checks that were already regarded and evidenced as best practice in many countries. The hypothesis that structured communication and attention to a series of standardised essential checks can reduce Never Events and surgical site infection to improve patient outcome, is proven (Haynes et al 2009). However the WHO checklist’ ‘5 Steps’ is still far from routine for every surgical patient.

Mainstreaming the process for standardisation in UK hospitals has been subject to many practical challenges (Vats et al 2010, Patient Safety First 2010).

This paper will explore why, despite the promotion of recommended safety interventions to mitigate surgical harm, surgical Never Events continue to occur. It explores in particular the reasons why staff may fail to implement the best practices asked of them.

Context

Committed to improving patient safety in England and Wales, the National Patient Safety Agency (NPSA) has captured and analysed data relating to surgical harm through the National Reporting and Learning Service for many years. Data analysis and distillation of poor practice compared with best, has resulted in the NPSA regularly publishing guidance notes, toolkits and alerts.

Following the WHO’s launch of the checklist, in July 2008, standardisation and ‘care bundles’ were integrated into the design of patient safety campaigns across the UK. Sensitive to WHO guidance that the checklist should be adapted to suit health systems, the campaigns promoted plan-do-study-act cycles (Langley et al 2006) and local testing. Working with early adopter sites, Patient Safety First (England) quickly identified briefings and de-briefings as vital adjuncts to the Sign In, Time Out, Sign Out stages of the WHO checklist, observing that local adaption to care pathways enhanced clinical leadership and commitment to local improvement. It was from this work that the ‘5 Steps to Safer Surgery’ grew (Patient Safety First 2009a). In January 2009, the results of a six country evaluation of the checklist was published (Haynes et al 2009), the weight of the evidence prompting the NPSA to issue an alert requiring all trusts to conduct the WHO Safe Surgery Checklist for every surgical patient (NPSA 2009).

With the endorsement of a coalition of professional associations and Royal colleges, the checklist and 5 Steps enjoyed a high profile across the NHS. The messages of 1000 Lives (Wales), the Scottish Patient Safety Programme and Patient Safety First reached hundreds of hospital boards and thousands of front line staff. Local ‘conversations’ were encouraged, the benefits of standardisation...
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explored and coalitions of clinical managers and clinical leaders fostered, releasing energy and commitment to deliver better outcomes for patients.

What worked?

A survey of English trusts in September 2009, to specifically assess the impact of the first year of Patient Safety First, identified that about one in five trusts were making good progress with 40% commenting positively that the campaign was helping them in their efforts; yet a great many trusts had considerable progress to make if they were to deliver the requirements of the NPSA Alert by February 2010 (Patient Safety First 2009b).

In March 2010, trusts were required to respond to the Department of Health’s Central Alert System (CAS) detailing their progress; all reported that they were implementing the checklist in line with requirements and were compliant with the NPSA (2009) alert. This situation represents a continuing reliance on self-reported compliance versus sustained improvement, evidenced over time.

Noteworthy: a survey of trusts one month later (Patient Safety First 2010), probing and pursuing greater detail, illustrated considerable variation in both approach and progress across the NHS. The review highlighted differences within trusts across hospital sites and between specialties, and when comparing organisations to one another.

Trusts reported:

- On average, the checklist was being used for about nine out of ten people undergoing surgery (89%). This ranged from 0 to 100% in different trusts.
- One third were using the checklist alone (33%), one third the checklist and briefings (32%) and one third the 5 Steps (the checklist, briefings and debriefings) (33%).
- About half of trusts had started implementation with one list or theatre and rolled out the checklist slowly (45%). More than one quarter began with a few theatres at a time (30%) and one quarter took a ‘big bang approach’ i.e. the checklist was introduced to all theatres across the trust at the same time (25%).
- About six out of ten trusts reported implementing a process, to measure any changes resulting from the checklist (64%).
- 53% of trusts said that they had used/were using small tests of change such as PDSA cycles, to adapt the checklist for local use.

Reported benefits of implementing the checklist included:

- Improved teamwork (77%)
- Improved safety (68%)
- Capturing more near misses (41%)
- Smoother and quicker procedures (35%)
- Improved staff morale (24%)
- Improved list start and finish times (11%)
- Reduced turnaround times (7%)
- Reduced reported stress (3%)
- Improved rostering lists (3%)
- Additional cases per list (1%)

Whilst commonly reported challenges hampering trusts efforts included:

- Negative clinician attitudes/lack of clinical buy-in or engagement (77%)
- Tendency to view the checklist as a tick box exercise rather than a tool to improve communication and teamwork (78%)
- Not seeing the checklist as a priority (37%)
- Not having enough time (37%)
- Lack of understanding of improvement methods (28%)
- The checklist was perceived to make things more difficult (12%)
- Lack of leadership support/managerial attitudes (9%)
- Lack of partnership between clinical and non clinical managers (9%)
- No resulting benefits (8%)

- Using a ‘big bang’ approach or requiring widespread implementation did not work (6%)
- Focus on reporting back to NPSA rather than engaging teams for local action (3%)

The factors regarded as supporting implementation comprised:

- Use of clinical champions and early adopters (76%)
- Enthusiasm of nurses in theatres (75%)
- Engagement of clinicians (62%)
- Applying the checklist in one area first (57%)
- Focus provided by Patient Safety First (55%)
- Executive leadership (37%)
- Using rapid improvement cycles e.g. PDSA (24%)
- Safety incident or Never Event (22%)
- Leadership walkrounds (14%)

This was reinforced in December 2010 with the publication of the NPSA’s Never Events Report for 2009/10 (NPSA 2010a). The report identified that of 111 reported Never Events, 57 events concerned cases of wrong site surgery. The report highlighted considerable variation in implementation effort and approach, and that the checklist / ‘5 Steps’ were far from embedded to realise discernable safety improvements for patients.

While the reported Never Events for surgery varied in body location, type of surgery and occurred across different trusts, each reinforced that teams were failing to execute what was required of them and that the Surgical Safety Checklist had not been fully implemented in all theatres, across all specialties at the time of the event. The WHO recommendations were not being followed at the time that the Never Event had occurred; team briefing and debriefing, for which there is an international evidence base was not common practice, and the ‘power’ and ‘personality’ of senior clinicians in several cases inhibited perioperative teams from implementing best practice.
The reason why negative behaviours pervade the NHS is in part because human beings are incapable of consistently following rules

Never Events can be attributed to systemic problems, such as poor leadership, poor team relations, failure to ‘performance manage’ disruptive and abusive behaviour, conflicting work pressures. However, the failure to learn from and act upon ‘near miss’ incidents, which is key to any change process, is the challenging question. Why do staff fail to do what is asked of them?

Those directly affected, the public at large and, crucially, the organisations in which the 57 Never Events occurred, will be seeking answers in order to effect the necessary improvements.

**Doing the right thing**

While patient safety campaigns galvanised action and commitment to ‘no avoidable harm, no avoidable death’, Ian Kennedy (Santry 2009) identified that harassment and bullying prevails in many organisational cultures, at both the system and individual professional level, and that this can inhibit staff who want to do the ‘right thing’.

The reason why negative behaviours pervade the NHS is in part because human beings are incapable of consistently following rules. In the absence of effective and proven systems, people routinely deviate from standard procedure to creatively manage changing situations in order to deliver organisational efficiencies (Amalberti et al 2006).

Why individual staff fail to deliver evidence based practices is a perennial challenge not only for the NHS but for virtually every industry. While the interdependence of system demands, capacity, risk assessment, individual judgement, organisational culture, and transparency can be examined, the reason for poor clinical engagement often lies at the door of the managers and leaders of the organisation who fail to engage the staff on whom they are dependant to deliver the necessary improvements. The reasons can be distilled to six broad explanations:

**Staff:**

- just don’t know
- don’t know how
- don’t want to do it

- are in a wrong position or role
- face an organisational roadblock
- face an ethical roadblock.

(Thomas 2010)

**Staff just don’t know**

A situation where staff ‘just don’t know’ illustrates an all too common communication problem. It owes much to assumptions: that staff have been told what or how they should do something, and that staff have understood what is required of them and have internalised the message, to inform future action.

Despite the publicity of the WHO Safe Surgery Saves Lives Campaign, the leadership effort of all the safety campaigns, and the support of the checklist by all perioperative associations, surgical and anaesthetic colleges, together with the communication efforts of individual trusts, it is conceivable that some information has simply bypassed some staff or that others have received mixed messages about what is required.

In an information rich world, and at a time when we enjoy sophisticated means of communication, we are reminded by the Marshall Institute (2011) that we must communicate seven times, seven ways.

Leaders and managers should support any change programme with a robust communication plan. They should regularly check that the target audience has received and understood the intended message, and that it has not been filtered and distorted as it has passed through the many levels of the organisation.

A simple test to assess if the checklist and the 5 Steps have been clearly communicated, received and understood, is to ask someone on the night shift, or a part time member of staff. A simple audit process is: if 5 people when asked cannot repeat back clearly what is required with regard to the 5 Steps, the organisation does not have fully engaged staff, or a reliable process.

**Staff don’t know how**

When it is identified that staff don’t know what, or how to do something, this illustrates a training problem (Thomas 2010).

It was envisaged by WHO that the checklist could be implemented relatively simply and that it offered an inexpensive solution to standardisation and improvement for patients (Gawande 2008).

The extent to which checklist implementation actually presented a negligible training demand on individuals and organisations, has largely depended on where organisations already were in their journey toward safety improvement.

Training needs analysis to support implementation of the checklist has varied considerably, as has the associated invested training response. A gold standard example was implemented at University College London Hospitals (UCLH) and delivered real progress. They took every theatre team through simulated scenarios in a ‘mock’ theatre, securing recognition and awards for excellence in education (Health Service Journal 2011).

The simulation experience at UCLH provided staff with a safe environment in which to practice the checklist, to reflect on their actions and behavior, and to inform future practice. While few organisations will have a resource similar to UCLH, securing opportunity for teams that work together to train together, is key to unlocking their potential and to delivering good team practices.

Campaign workshops were well attended, and toolkits, ‘how to’ guides and presentations continue to be downloaded reinforcing that we should never underestimate the training demands created by change.

**Staff just don’t want to do it**

This issue represents a motivation problem that stems from the fact that the individual or team are not personally driven to do what they should do (Thomas 2010).
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If we accept the premise that staff have the patient’s best interests at heart and generally go to work to do a good job, managers and leaders need to understand why some staff lack motivation in performing the 5 Steps, and/or are purposefully obstructive.

Goode et al (2002), focusing specifically on physician motivation, volunteer that those leading systems-level improvements often frame physicians as obstacles to improvement and fail to invest sufficient time in exploring their perspectives. Physician resistance to systems-based change can be routed in the concern that the change will interfere with the physician’s care of specific patients. Goode et al (2002) suggest that clear aims, detailed evidence, physician/manager collaboration, supportive education, and ensuring that the relationship of the planned change to physician regulation is clearly articulated, can get most physicians ‘on side’. Finally, they assert that the time invested in developing clinical engagement can lead to substantial improvements, particularly if medical societies and professional standard-setting bodies and interest groups work together, which was a purposeful strategy of Patient Safety First (Figure 1).

Maintaining motivation and understanding of what is required to improve team performance requires constant attention, given the levels of trainee rotation and staff turnover in operating theatres. Ensuring that the checklist is used for each patient in the spirit and manner intended is dependent upon leaders and managers re-visiting the basic beliefs of staff on a regular basis, continually assessing the behavioural change of teams, and encouraging and supporting staff with a variety of interventions (Kretzer & Larson 1998). Consistently reporting the impact of poor practice on patient care can be immensely powerful, focusing staff attention on what matters and where improvements can be made. Publishing local data, route cause analysis of Never Events and uncensored patient stories not only improves individual practice but also that of the team, through social/peer pressure to do better (Kelen et al 1991).
Patients are at their most vulnerable when they undergo surgery or procedures

Convincing people that the 5 Steps and the checklist are necessary demands strong leadership and visible support, led with commitment.

People with the capacity and energy to lead change, can be found at all levels of an organisation and should not be restricted to those traditionally recognised, such as the clinical director and theatre manager. Embedding the checklist is dependent on teams of professionals of all grades, whose power is fuelled by energy, passion and commitment, and who go to work every day recognising that the patient on the table could be their parent, child, relative, partner or friend.

It is not uncommon to find staff with positional power and/or status who fail to use their influence for any, or all of the reasons already cited. In an organisation as big as the NHS, there are occasions when staff are poorly selected and/or promoted, beyond their capacity for the job. Without necessary development and growth, such staff end up in the wrong position or role (Thomas 2010). They can become ‘a square peg in a round hole’ which neither they, nor the staff they manage, are happy with. If analysis of a Never Event uncovers a predisposition to poor leadership and/or management, or evidence of disruptive or unprofessional behaviour, then this must be tackled appropriately for the benefit of both patients and staff. Underperforming staff must be provided with the necessary support and development to make good any weaknesses/deficits over time and then reappraised. Effective performance management is one of the foundation stones to delivering successful change; ignoring problems simply dilutes commitment, energy and effort.

Organisational roadblock
In some cases, staff may fail to engage in what is asked of them, because they experience what Thomas (2010) describes as an organisational roadblock. Take the surgeon who is being asked to support pre-list briefings and repeatedly fails to show at 08.15am. Is s/he being deliberately obstructive, does this make him/her a laggard, or is s/he being asked to do something elsewhere in the building, in support of the patient pathway and ensuring timely discharges?

No matter how popular the checklist, or the evidence and enthusiasm staff may express, if organisational roadblocks get in the way, they need to be unblocked. Studies of patient flow and clinical activity/intervention, service redesign and estate reconfiguration can be crucial to freeing all staff to make the checklist happen.

The ethical roadblock
Finally, but not as a justification or defence for not performing the 5 Steps/checklist, is another issue that I have come across: the ethical roadblock. Thomas (2010) illustrates this with the scenario of a salesman objecting to being asked by his company to lie to a customer about the efficacy of a product, in order to hit his sales quota.

Thomas explains ethical conflict as arising when the supposed values of the organisation, or its leaders, clash with those of the individual.

Summary
The reasons why staff might not do what is asked of them with regard to the 5 Steps/checklist is multi-factorial.

The challenge to all of us is to implement, sustain and truly embed what is required. All staff need to be on side and fully committed. Without the commitment of every board, manager, team leader and team member, quality team performance cannot be consistently assured and Never Events remain a potential threat.

Patients should not be subject to a lottery; they deserve reliable processes, and failure to provide these is nothing short of unacceptable.

Seeing the ‘wood’ for the trees
The goal has never been to impose unnecessary routines on clinicians and practitioners, waste valuable operative time, compromise workflow patterns or create forced conversations. The aim of the 5 Steps is to integrate the WHO checklist in a way that suits list based care and enables teams to implement simple and efficient priority checks that also open up the lines of communication, build psychological safety and enhance teamwork.

Patients are at their most vulnerable when they undergo surgery or procedures. They place themselves totally in our care, trusting us to protect them from harm, for the time that they cannot protect themselves: a responsibility that should never fail to inspire us.

57 Never Events, means 57 failed and harmed patients.

In such cases patients are not the only victims. A great many staff associated with each case will have been distressed by the events that caused the patient harm. In some cases the staff involved may still be absent from work, due the associated emotional impact and stress; a loss to the service and to future patients in need of care.

57 Never Events indicate that we can never be complacent. Although 57 Never Events represent obvious and devastating failures, they also remind us that perioperative teams must attempt to minimise all minor errors in surgical care (Runciman et al 2000, NPSA 2010a). Although glitches and ‘near misses’ rarely cause direct patient harm, they occur in far greater numbers than is often acknowledged. They are stressful and distracting and impact on the overall performance of the team, reducing the efficiency of the list and increasing procedure costs.

With continuous attention to known barriers and challenges, the 5 Steps and the WHO checklist can be embedded, providing patients with safer surgical procedures and good clinical outcomes. Staff who support best practice know not only that they are doing the right thing, but also that they are contributing to the organisation’s overall objectives for patient safety, operational performance, reductions in waste and greater efficiency, all of which are necessary to meet the Quality, Innovation, Productivity
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and Prevention (QIPP) programme (DH 2010).

John Heywood an English playwright and poet, living 1497–1580, wrote ‘Rome was not built in one day’. The parallel for clinical practice is that patient safety is an improvement journey and never an end point.

For the sake of our patients, our desire for clinical excellence must always be far greater than our fear of failure, or our tolerance of mediocrity.

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