Patient safety in the peri-operative period: Is the implementation of an evidenced based checklist a sustainable method of improving patient safety?

Introduction

In the United Kingdom over eight million operations were carried out in 2004 alone (more than one operation for every seven inhabitants) with a mortality estimated at 20 000 – 25 000 patients. [1-2] The peri-operative period, encompassing pre-operative assessment, surgical and anaesthetic interoperative care and postoperative recovery therefore represents a significant area of risk to patients, and whilst peri-operative errors represent the minority of healthcare 'adverse events' (injuries arising from care itself) reported in the hospital environment, they produce disproportionately more morbidity and mortality than errors in other areas. [3]

The true rate of peri-operative adverse events is difficult to determine for a number of reasons, including the lack of a standard definition of 'adverse event' or consistent national method of reporting these. Compounding this is a consistent failure in documentation. However, current estimates suggest this figure lies between 6.9% – 33% of all surgical admissions. [4-6] This finding is worsened by the fact that around 50% of these events appear preventable. [7]

Adverse events are most commonly attributed to drug errors, surgical site infections or procedural complications. However, the interaction between other factors such as pre-operative nutrition and assessment, the time of surgery, grade of surgeon and anaesthetist, fluid management and peri-operative monitoring is complex and contributes significantly to peri-operative safety and hence mortality. [8-9] Thus for varied, mostly modifiable, reasons, it is clear that patients in the United Kingdom currently experience a sub-optimal standard of care.

In addition to the negative impact on patient care, peri-operative complications are a significant resource burden within the NHS. Surgical site infections for example, one of the most common peri-operative complications, have been estimated to cost an average of £959 to £6103 extra per patient (dependant upon the type of surgery), with the majority of this cost (circa 90%) attributable to increased length of stay. [10-11] Other costs not considered as part of these figures for example rescheduling procedures, additional treatments and increased primary care burden probably place the true cost much higher. [12] Considering that a high proportion of these adverse events are preventable it is consequently straightforward to make the case for improving peri-operative safety on an economic level in addition to improving standards of patient care.

However, given the complex nature of the peri-operative period, including involvement of different clinical specialities within the same environment and numerous critical steps performed under time and resource pressure, identification of any one single area for improvement is difficult.

One approach to facing the challenges of improving peri-operative safety is that recently taken by the World Health Organisation (WHO). Over a period of three years a team of nearly 100 experts systematically reviewed the available evidence exploring the interaction between the complex set of factors contributing to peri-operative mortality on a worldwide level. The end result, the WHO Guidelines for Safe Surgery, was published in 2009. [13] This document sets the minimum standards for performing surgery, and concludes that the necessary approach to improving patient safety is one that that ensures effective and consistent team communication, creation of and adherence to local policies and participation in national surveillance and quality improvement systems. Following on from this report an evidence-based checklist has been produced. This checklist has been rolled out across operating theatres throughout NHS hospitals in the United Kingdom as of February 2010.

This essay explores the findings of the World Health organisation, including the rationale for the WHO surgical checklist and its impact on peri-operative safety, and then proceeds to discuss whether introduction of a surgical checklist in the United Kingdom can result in a sustainable increase in peri-operative safety.

Safer Surgery Saves Lives – the WHO Surgical Safety Checklist

In 2007 the WHO 'Safer Surgery Saves Lives' project was set up with the aim of improving the safety of surgery worldwide. This culminated in the publication of the WHO 'Guidelines for Safe Surgery' in 2009. Although it is easy to assume, initially, that these findings are relevant only to the less economically developed countries from which part of the data came, on further consideration many of the key findings from this project have particular relevance to the United Kingdom.

Firstly, there is a paucity of accurate surveillance of adverse surgical errors in all countries involved in the study including the United Kingdom. Without this data it is difficult to audit existing interventions and hence identify areas for improvement. Secondly, existing evidence-based practices that increase safety are not used reliably. Compared to other countries participating in the study the United Kingdom is resource-rich. However, similarly to some of the less economically developed countries available interventions are not used consistently. One example relevant to the UK is prophylactic antibiotics regularly either missed or administered at incorrect times. [14] In the UK this is not due to lack of resources, but instead a failure in the system in which clinicians work. Thirdly, and perhaps of paramount importance, is the increasing complexity of the peri-operative period. Numerous critical steps are performed by different healthcare professionals, often simultaneously, all of which have the potential for significant error. There is also a high level of unpredictability (for

example that seen in emergency theatres) and a necessity to perform at all times of day. Compounding this, surgical 'teams' tend to work as independent entities. [15] A lack awareness into the challenges faced by other members of the team, at what point, and who is responsible for certain tasks is a recognised cause of peri-operative complications. Just one of many common examples is confusion over whether the anaesthetist or operating surgeon is responsible for ensuring prophylactic antibiotics are given. [16] These factors contribute to a standard of peri-operative safety that is currently unsatisfactory.

Medicine is not the first industry to face challenges relating to increasing complexity within a high intensity, high risk environment. It may however be one of the slowest to react to such changes.

The aviation industry has faced these difficulties since the earlier part of the last century. In 1935 during a trial flight a new Boeing Model 299 airplane crashed due to simple pilot error - neglecting to release the elevator lock during take-off. This was well publicised and the plane deemed "too much airplane for one man to fly". [17] Pilots were forced to acknowledge that their every day work had become too complex for any one human to reliably perform unaided. [18] Aviation checklists were developed and have been used consistently since. The aviation industry now quotes the risk per person flight as 4.1×10^{-7} despite the necessity to work in a highly complex, highly unpredictable, high stress environment. [19] This is in part due to the use of checklists and rigorous error-reporting and resolution cycles.

More recently there are specific areas of medicine which have shown dramatic increases in patient safety following the introduction of simple checklists. Within intensive care medicine simple steps for insertion of central venous catheters have been incorporated into a checklist. This resulted in a reduction in catheter-related infections by two thirds within three months of implementation. [20]

In line with the general principles employed in devising risk-reduction strategies in other industries and fields of medicine, the WHO generated a surgical safety checklist. The 19 item checklist was designed to address the problems in peri-operative safety discussed previously, with the brief that it should be concise, clear, verbal, collaborative and integrated into existing systems. It includes a team discussion at three key points. Before induction of anaesthesia ('sign in') the team confirms identity, surgical site marking, allergies, anaesthetic concerns and estimated blood loss. Before skin incision ('time out') the entire team are introduced, anticipated critical events are reviewed by the surgeon, anaesthetist and nursing staff, sterility and prophylactic antibiotics are confirmed and imaging is displayed if appropriate. Before the patient leaves ('sign out') the swab count is confirmed,

procedure name and necessity of specimen sample is confirmed and any equipment issues are addressed. [13]

Heynes *et al* trialled this checklist in eight hospitals within countries with different levels of economic development. Their prospective study comparing adverse events pre and post checklist implementation was designed with a sample size calculation to detect a 20% reduction in complications (at 80% power and P <0.05). The rate of complications dropped from 11.0% at baseline to 7.0% after introduction of the checklist (P <0.001) with a total in-hospital rate of death reduction from 1.5% to 0.8% (P = 0.003). Although the authors claim high-income country mortality fell from 0.9% to 0.6% the study did not have enough power to detect this (P = 0.18), however when only high-income countries were included in the multivariate analysis a statistically significant fall in complications was demonstrated. [21] These results are striking and suggest the WHO checklist may play a key part in improving peri-operative safety within the UK.

Based on the results of Haynes *et al* the UK National Patient Safety Agency (NPSA) issued an alert that a modified version of the checklist should be completed for every patient who has a surgical procedure in the England and Wales from February 2010 onwards. [22] An NHS evidence evaluation of the impact of this intervention suggests that in addition to improving patient care there are many other financial and organisational benefits to implementation. [23] This 'added value' is attributable to a number of factors. Initially, there is an obvious reduction in healthcare costs if adverse events are reduced. With adverse surgical events estimated to cost the average NHS hospital trust over £2 million a year in increased length of stay alone, a reduction in complications of 30% (that seen by Haynes *et al*) could save an average sized NHS trust hospital over £600,000 per year. Additionally, implementation of the surgical safety list has shown a reduction in 'never events' (serious safety incidents which the Department of Health say should never occur with the correct safeguards in place) such as wrong site of surgery. [24] These are costly to the NHS not only in terms of reputation but also financially – litigation due to surgical error is estimated to have cost £3.7 billion in the period of 1995 – 2009. [25] Finally, and least discussed in the literature so far, is the positive impact on operating theatre efficiency. Time for pre-and post-operative briefings resulted in greater prioritisation of theatre lists, fewer delayed starts and less unnecessary cancellations. One teaching hospital increased the average number of patients treated from 3.5 to 4.5 per 8 hour operating session – an opportunity saving of £386,800. [23] In addition equipment costs were lowered due to unnecessary last-minute transport and reduced wastage due to incorrect equipment being chosen.

Clearly, if the predicted improvement in peri-operative safety resulting from the WHO checklist is achieved and remains sustainable the benefits to both the patient and the NHS are significant. However, there are potential obstacles to this in current medical practice.

Obstacles to improving peri-operative safety and problems implementing a surgical safety checklist

Despite the WHO safety checklist being a cost-efficient and validated initiative it may still not have been fully incorporated in UK operating theatres. A study undertaken one month before compulsory implementation (January 2010) showed that from a sample of 44% of the UK's hospitals, from those in which the policy was not made compulsory 9% of hospitals did not use the checklist, and where the checklist was used senior theatre staff reported that certain tasks may be omitted including part or all of the surgical safety checklist. [26] Other studies have found similar problems – Vats *et al* discovered confusion over responsibility for the sign out checks which were frequently missed due to being at the most time–pressured part of the process, and found some checklists to be incomplete, hurried, dismissed (filled in without the information being present) or completed without key team members. [27] Haynes *et al* also admits the causes for the decrease in adverse effects seen in their pilot study of the WHO surgical safety checklist is probably multi-factorial. [21] Operating rooms in which the checklists were implemented underwent specific training and briefings beforehand and staff were aware of the participation in the trial. This is a documented study confounder resulting in overestimation of the treatment effect and is referred to as the Hawthorne effect. [28] There is no way to predict in operating rooms not participating in the study how staff will behave and what the true decrease, if any, in adverse events may be.

Compounding this is evidence that compliance with safety initiatives in healthcare diminishes with time once implemented, particularly where (a) benefits are not immediately apparent, and paradoxically, (b) in situations where safety increases, due to deviations in protocol felt to be less hazardous in a 'safe' system. [29] Therefore initial decreases in the rate of adverse events may not be maintained. This casts some doubt over whether implementation of a checklist is a sustainable long-term solution to improving peri-operative safety. However, if the checklist approach seems to work successfully in other industries why not in medicine?

There are several reasons why a checklist approach to safety may not be directly translatable to healthcare as it currently stands. Aviation is frequently compared to healthcare in discussions of safety systems and given as an example of the importance of checklists. However, aviation is an example of a 'high reliability organisation' (HRO), a system that runs based upon the idea that

appropriate organisational control can yield error-free results even when operating in hazardous and unpredictable environments. [30] It does this by embodying certain characteristics. These include a preoccupation with failure resulting in systems, procedures and attitudes in place to avert error, the use of intensive drills and training to ensure otherwise unfamiliar, rare yet potentially disastrous events are performed routinely, and an error reporting procedure that is not seen as seeking to blame but instead works to correct errors in the system. [31] The end result is an industry with a 'culture of safety' – one in which human error is seen as inevitable, but an adverse event is inherently preventable and represents a problem with the system in which staff are working. An overt preoccupation with safety empowers even the most junior members of staff to speak up and halt proceedings in the event of a credible safety threat. HRO's usually work within a hierarchical structure similar to medicine, however are flexible enough to quickly adapt in emergencies to allow all staff members to contribute to resolution.

When the use of checklists in aviation is analysed alone it has been found that up to half of checklists on airplanes are incorrectly completed due to interruptions and poor checklist design. [18] They play only one part of a complex safety net designed to catch errors based on the assumption that humans will make them and are not implemented to be foolproof. This is referred to as a 'systems' approach to safety.

Attitudes in medicine however are significantly different. Clinicians do not consider human error to be inevitable. [23] This is perpetuated within a 'person' approach to patient safety – one in which the focus is on unsafe acts; carelessness, negligence, forgetfulness, recklessness. [32] Attempts to improve peri-operative safety therefore focus on posters, new protocols, reminding, retraining, blaming, reprimanding – all based upon the assumption that the individual should be infallible and that anything less is unsatisfactory. One example of the effect of this is a study investigating medical professionals' attitudes to safety systems - 30% of nurses and doctors reported that they 'did not make errors'. [33] Whether this was due to staff believing this or feeling that this is the standard they should be attaining is in some ways irrelevant – either is dangerous to a safe organisation. Patient safety cannot be improved before the possibility for error is recognised. This sums up one of the single biggest obstacles to improving peri-operative patient safety in the long term.

It is therefore unsurprising that in a culture where errors are seen as personal failings that on an organisational level error reporting systems are poorly complied with and yield poor results. [34] In addition there is little motivation to report 'near-misses' resulting in opportunities to pre-empt disaster and correct system flaws being missed and the same errors perpetually repeated.

Furthermore, in a culture where clinicians see themselves as having to be infallible there can be resistance by some to completing checklists as part of routine clinical practice. There is little published on this phenomenon; however checklists may be seen as unnecessary, taking further time away from patient care or even undermining clinical knowledge. 'Checklist fatigue' is however a recognised phenomenon in healthcare especially where it is implemented alone and enforced from management without sufficient discussion with staff members who will be using the checklist routinely. [35]

Differences in attitudes and systems go some way to explaining why initiatives that improve safety in other industries may not show the same results in healthcare. Checklists work within aviation and other high reliability organisations not as single initiatives, but within a culture of safety as discussed previously. It is therefore likely that the WHO safer surgery checklist may not produce the peri-operative patient safety improvements initially demonstrated.

Conclusion

This paper has evaluated the impact of the WHO safer surgery checklist in the UK and has raised some key issues regarding its implementation, not with the policy itself but instead the culture of the organisation it is being used within.

The peri-operative period is undeniably a time in which there is high risk of adverse events causing unnecessary suffering to patients and placing unnecessary costs on healthcare systems. Few patients would feel 'safe' when told at the most conservative estimates one in seven will undergo harm during a procedure due to avoidable errors, and that many of these errors are unreported and therefore repeated. The National Confidential Enquiry into Patient Outcome and Death (NCEPOD) recently published a report on peri-operative safety supports this conclusion. [8] Although outside the scope of this essay its findings focus on failings in identification and care of high risk patients, and therefore it would be of benefit to explore separately how to use their findings alongside the issues raised here.

Their summary however is powerful and equally disturbing –

"...people die because we do not give them the level of care they are entitled to expect"

The World Health Organisation Safer Surgery checklist will undoubtedly contribute in some way to reducing errors in the peri-operative period, in the short term at least. However, evidence from safety interventions in medicine within a person-based safety culture suggests that compliance will

be a problem. Initially national monitoring of the use of the WHO checklist is required in the UK, as is further data on the reduction in complications to test real-world performance.

In the longer term the system of healthcare we work within needs to change. The ethos "do no harm" no longer applies to the individual – medicine is complex and we cannot alone ensure we do no harm. Instead we must operate within a safety culture similar to that of other industries. Key to this is the concept that errors are inevitable – we must seek to ensure clinicians work within an environment where this ethos pervades, where blame is secondary and errors are seen to be dealt with through changes to the system we work within. Frequently quoted in medical safety papers Alexander Pope encapsulates this perfectly – "to err is human". [36]

This shift does not seem an easy task in an environment where throughput is primary – the pressure to finish lists on time is recognised by all theatre staff. However, other organisations which rely on profit and throughput for survival still manage to put primary emphasis on safety – a culture of safety actually has significant cost benefits.

This shift in thinking needs to encompass all aspects of the peri-operative environment if it is to be successful. Whilst the WHO safety checklist has proved to be beneficial, the original 133 page report has recommendations that go far beyond this. These include many of the same findings as analysis of other HRO organisations shows is beneficial; systems for routine surveillance, team-work, drills for emergency procedures. It would be a catastrophe if the rest of these recommendations were to be lost in the shadow of one checklist, no matter how great the evidence for it is.

It must however be recognised that many operating theatres in the United Kingdom already implement some of these techniques. Indeed the author has personal experience of the introduction of routine theatre emergency simulation sessions with excellent feedback across nursing, anaesthetic and surgical staff. The WHO checklist may therefore have variable impact depending on the steps taken already towards a culture of safety. This discrepancy however still remains unsatisfactory. There must be a nationwide drive towards adverse event reporting and a blameless culture that seeks to resolve problems in the system rather than seek to resolve problems with the person. Only then can peri-operative safety be improved in a sustainable manner.

It is time for clinicians and managers to realise that medicine has become "too much plane for one man to fly".

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