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**PATIENT SAFETY AND CLINICAL  
GOVERNANCE**

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## **Abstract**

### **Purpose**

The purpose of this Working Paper is to advance critical debate in relation to a very critical issue in current healthcare management – namely ‘patient safety’. This is currently a very high profile issue. In its various guises such as clinical governance, integrated governance and healthcare governance the question of avoiding or at least minimising harm to patients is attracting a huge amount of attention. Considerable resources especially within the acute sector are allocated to the problem. But, despite the systematic attention, progress in healthcare compared with certain other sectors is slow and mistakes continue to occur. Hospital acquired infections and clinical errors have become a matter of acute public concern. Evaluations of the health service are critically influenced by adverse judgements on this dimension of care.

### **Approach**

In this article, we draw primarily upon relevant literature in order to make sense of our recent empirical research in 8 acute hospital trusts in the UK. The analysis, however, is relevant to healthcare systems around the world.

### **Findings**

We reveal how the massive investment in systems, service improvement mechanisms and clinical government regimes may not in themselves be enough. One reason why they may not be enough is that there can be a problem of gaining acceptance and legitimacy. Staff may see such managers as ‘policing’ and ‘interfering’. There is then the danger of a vicious circle – more control but less effective control because of a feeling of alienation. The policing element is at best a final safety net not the prompt for improvement. We then identify 6 barriers and each is accompanied by a recommendation for its resolution.

### **Implications**

There are a number of implications for practice and for systems reform which stem from our analysis. Two main recommendations stand out: they need to be handled together. First, the traditional model of the autonomous professional needs to be challenged by subjecting clinical practice to shared clinical governance procedures. Second, and simultaneously, there is a need to attend to underlying values. There is a need to revisit the issue of underpinning values so that clinical values and system-wide/managerial values are congruent rather than separate or even in conflict. At this point, governance and leadership should come together.

## **Introduction**

Mistakes, errors, accidents, mishaps, serious untoward incidents, adverse events and so on are recurrent and costly in many industries. In health services they are especially problematical because of their potential for serious outcomes for patients. But healthcare is not unique in this regard, other critical industries such as nuclear power generation, commercial aviation and railways also carry high risk and high public exposure when things go wrong. In the USA, the Institute of Medicine's report 'Crossing the Quality Chasm' concluded:

'Healthcare today harms too frequently and it routinely fails to deliver its potential benefits. . . . tens of thousands of Americans die each year from errors in their care, and hundreds of thousands suffer or barely escape from nonfatal injuries' . . .The current system cannot do the job. Trying harder will not work. Changing systems of care will' (Institute of Medicine Committee on Quality in Health Care 2001: pp 1-4)

The rate of 'Adverse Events' has been estimated at 7.5 per cent of acute hospital admissions in Canada and 10.8 per cent in a study of two London teaching hospitals. In the latter, 48 per cent of these events were judged to have been 'preventable' (Vincent and Neale 2001; Baker and al. 2004). Adverse events were defined in these studies as 'unintended injury or complication that results in disability . . . death or prolonged hospital stay that is caused by health care management'.

Quantifying the number of adverse incidents is itself inherently problematic. A higher reported rate may be a healthy indicator of open reporting, an apparent low rate may simply result from a culture of under-reporting.

Often, the first reaction to adverse events is to look for someone to blame. The question: “Whose fault was it?” springs readily to our minds. While individual error and failure may not, and should not, necessarily be dismissed out of hand (we all as individuals do carry certain responsibilities for our actions), there are many circumstances where there are endemic and systemic failures which make errors and mistakes far more likely to happen. There is thus merit in attending to the source of such system-based errors and trying to engineer these out of the system or at least reduce them to the absolute minimum. High reliability organizations focus on ensuring that the system as a whole can anticipate the worst without each individual having to live in a state of high anxiety (Reason 2000).

### **Underlying sources of problems**

‘Sources’ of errors can be divided between: immediate triggers - e.g. sudden multiple calls on a nurses attention, versus longer-term more enduring source (e.g. understaffing; poorly planned procedures; inadequate supplies; and so on.

Tucker and Edmondson’s study (Tucker and Edmondson 2003) of nurses found these common ‘types’ of errors and problems:

1. missing or incorrect information

2. missing or malfunctioning equipment
3. waiting for a resource (another person or some material object)
4. missing or incorrect supplies
5. simultaneous demands on their time
6. incorrect actions (or inactions) by the nurses
7. errors made by others
8. unnecessary execution of tasks

Tucker and Edmondson suggest a distinction between errors and problems – e.g. problems carry ‘less stigma’ than errors but the conceptual distinction seems blurred so we explore both forms of failure. The implications are mainly the same.

The main finding was that in seeking to cope with these problems nurses mainly sought to find a ‘patch’ solution – i.e. to produce a pragmatic, spur of the moment practical resolution. The nurses natural reaction was to find a short term fix, they worked around the problem (e.g. taking linen supplies fro other wards etc). This first order problem solving while sometimes ‘gratifying’ for the nurses, served to obscure the system failure as well as having knock-on effects (e.g. in the other ward).

Learning opportunities were missed. Consequently, in ‘saving time’ on this ‘one occasion’ there was an increased chance that the same or similar problem would re-occur and thus require repeated quick fixes which cumulatively wasted much more time than would a more fundamental resolution of the source of the problem.

This report on research among nurses argued that the source of problems were: overstretched work regimes, too few staff, culture of blame, independent professional

and the obstructions stemming from a 'craft' model. These different reasons fall into two main categories – staffing and culture. The latter was seen to be based on a set of assumptions built around the idea of the individual practitioner – that is the professional model. This model has in many respects served the practice of medicine well over many years. But this model of working is vulnerable in that it does not emphasise the identification and systematic removal of the causes of failures or near misses. Individual nurses tend to have little time for second-order problem solving, thus there is a need for some appropriate second-order support. *Second-order problem-solving* requires much more conscious effort and investment of front-end time in order to save time and risk at a later date.

The nurses in the study were hardworking and dedicated and yet still encountered repeat problems which limited organisational learning. Why was this so? The reasons identified in the study were:

1. Individual vigilance: norms of taking personal responsibility for practical problem-solving; coping. Encouragement of solve problems individually. Perceived as competent if not asking for help.
2. Nursing units were designed to maximise individual unit efficiency. In effect measuring efficiency by using the wrong variables. Thus the nurses could be working at full stretch and by one measure thus being super efficient but in reality be busy doing the wrong things or resolving repeat problems and doing re-work.

3. Empowerment of individuals and teams may paradoxically take management support out of the system. Too much unit self-sufficiency and self-dependency.

All this individual effort can be at the expense of overstretch and burn-out. This takes time to occur and meanwhile the potential for effort spent on *second order problem* solving would be reduced even further.

It is notable that the above analysis is confined to the practice level. But governance problems are traceable beyond the practice level. For example, even when problems are notified the alert may be ignored by higher tiers – as appears to have happened in the BP Texas explosion. But beyond this, it could be argued that the tone is set at the highest reaches – most notably by the trust board. And even beyond the trust board there is potential confusion and dilution arising from the reporting of Significant Untoward Incidents to multiple bodies: the Healthcare Commission, Monitor, the SHA and the PCTs. We return to these broader points later.

### **Prescriptions**

The essence of the Tucker and Edmondson recommendations – culture change, drawing attention to problems and trying to trace their source and pattern, double-loop learning, etc could arguably be regarded as a restatement or even re-discovery of the tenets of TQM and other quality related movements. Techniques such as systematic measurement, systematic error reduction, and the use of cause-effect diagrams could be rediscovered and redeployed.

By implication, we can add to their list while also benefiting from the fact their study was hospital based. For instance, one aspect the article does not pick up on is the potential for improvement by monitoring error statistics and working to drive them down – i.e. the target of zero defects. (That by implication suggests a mind-shift from immediate quick-fix to a wider consciousness preventing defects in the first place and also of how the process and system as a whole could be improved). Once again however the issue of open-reporting is important here.

Further, there may be some merit in taking it further upstream to re-engineering.

Tucker and Edmondson (Tucker and Edmondson 2003) suggest:

1. Management availability and support. Physical availability etc
2. An environment where it is acceptable to talk about failures and problems and risks. Psychologically safe environment to do so.
3. Evidence of management follow-through.

In addition, they recommend a shift in ‘desirable behaviour’ among employees. For example, the ideal employee instead of being someone who copes quietly might be someone who is constantly questioning and is even a ‘noisy complainer’ who frequently draws attention to problems and who therefore ‘runs the risk of being seen as someone who lacks self-sufficiency’ (p68). The heart of this point is the need to ‘reframe workers perceptions of failures from sources of frustration to sources of learning’ (p69).

But even the availability of service improvement and clinical government staff and systems may not in themselves be enough.

One reason why they may not be enough is that there can be a problem of gaining acceptance and legitimacy. Staff may see such managers as ‘policing’ and ‘interfering’. There is then the danger of a vicious circle – more control but less effective control because of a feeling of alienation. The policing element is at best a final safety net not the prompt for improvement. The role is often described as one of ‘influencing’, ‘supporting’, ‘guiding’, and ‘facilitating’. However, some Medical Directors seem to favour simple ‘direction’. But apart from these two – influence versus direction – there are alternative approaches based on systems theory. It is to a consideration of this that we now turn.

### **A microsystems perspective**

Nelson et al suggest that while all levels of healthcare need to be improved, a special focus on ‘microsystems’ can be justified (Nelson and al. 2002). Clinical microsystems are ‘the small functional front-line units that provide most health care to most people ... they are the building blocks of larger organizations’ (p473). Their study of 20 high performing hospitals found that certain characteristics (which they term ‘success characteristics’) were common: patient focus, staff focus, leadership of microsystems, a culture of microsystems, appropriate use of information and information technology and process improvement. The key feature seems to be the interplay and reinforcement between the main features – for example, appropriate leadership, with a patient focus, enabled by information and information technology, in turn driving

evidence based performance improvement. In total, the researchers infer the power of the underlying idea of the ‘microsystems’ – the engines which are best placed to deliver quality care. The prescription was to seek to replicate such microsystems and to provide them with the appropriate infrastructure support from the macrosystem level. (Nelson 2003; Nelson and al. 2003)

If the hospital ward as the microsystem much depends upon the quality of leadership in the ward. Some managers judge their ward level leadership as weak and they observe “Several ward managers take little responsibility when things go wrong. For example we have a huge issue with nursing documentation and the accurate completion of patient observation and assessment charts. Having tackled ward managers about it on several occasions the most common response is to say “well *I have told the staff about it...what more can I do? – I can’t make them do it*” faced with that kind of attitude it’s no wonder errors occur. Bring back Hattie Jacques!!!”

While the Tucker and Edmondson analysis helped move our thinking beyond the level of individual blame, the Nelson et al study helps move the analysis on further from simple task-level improvements to a system level of thinking. This latter is taken further by another study which probes more deeply the system barriers to healthcare improvement. We can now turn to that study.

### **System Barriers in Healthcare**

Alamberti et al (2005) explain why a ‘benchmarking’ approach to safety in high-risk industries is needed to help translate lessons so that they are usable and long lasting in

health care. They argue there are many benefits in emulating other industries such as civil aviation and nuclear power generation *but* that a simple adoption of the technical procedures will not be enough. These authors identify five successive systemic barriers currently prevent health care from becoming an ultrasafe system. We add a sixth. Each barrier in turn implies a recommendation if the barrier is to be reduced.

***Barrier 1: Performance and productivity focus***

When systems are geared either explicitly or implicitly to the attainment of high performance there may be a risk of trade-off in terms of safety. As the authors note, ‘The more audacious the expert the more risky the adopted strategies and the more frequent the adverse events’ (p 758). As most systems pass through the pioneering phase, comprehensive regulatory systems are put in place. But, perversely, there can then be dangers deriving from over-regulation. The authors instance flu vaccinations and blood transfusion policies which can have unintended consequences. For example, they suggest that safety restrictions on blood acquisition have led to reductions in the number of accepted blood donors. Thus in so far as this is the case there may be a trade-off between productivity and safety.

***Implied recommendation:*** Acceptance of limit on maximum performance.

***Barrier 2: Professional autonomy***

In nuclear power generation there has been a progressive reduction in the autonomy of professional engineers. There is, for example, a very robust reporting system of

near misses. There is an intensified approach to process improvement. In civil aviation, risk programmes have over the decades reduced the autonomy of pilots. There are numerous periodic checks on pilots. The improvement in the safety record of civil aviation has been admirable.

***Implied recommendation:*** The need to limit the discretion of workers. In health, cross-professional teams can be empowered to undertake collective checks. For example, before the start of surgery a team check could proceed in the same way as a cockpit check in an aircraft. A culture whereby individuals are enabled to challenge and to admit to issues threatening below normal performance risks can be generated. This is a highly controversial frontier of control in current healthcare practice in the UK. Already, there are a number of sources of national guidelines which in varying degrees curtail professional autonomy. These include, for example, guidelines from NICE. While some clinicians judge that these guidelines sometimes negatively impact motivation question clinical judgement, others (including many Medical Directors and clinical leads) feel that there is still too much scope for individual consultants to persist with traditional practices. Attempts to appeal to the evidence base for adjudication can be problematical if the statistics based on limited population sizes are too small. Under such circumstances, the influence of the insurers can be crucial. If insurers stipulate higher premiums for certain patterns of practice this can be a highly persuasive factor in shaping tolerance or otherwise for these practices (such as the number of minimum procedures required per surgeon per annum in order to maintain proficiency).

### ***Barrier 3: Craft worker mindset***

Even if the healthcare professional accepts limits to autonomy and accepts some team working, there may be a further barrier deriving from the craftsman self-image. This militates against standardised service and emphasis individuality and idiosyncrasy.

Where services such as anaesthesia have moved towards a renunciation of individuality their safety records have increased enormously.

*The implied recommendation is the curtailment of self-image as ‘craftsmen’ and a shift to more standardised conditions and procedures for activity.* While Alamberti et al refer to the ‘craftsman’ mindset this, in effect, suggests also a curtailment of the professionalised mindset. Once more, the classic ‘professional model’ which depended on individual integrity with a code of conduct and a professional institute is indicated as insufficient for the conditions of 21<sup>st</sup> century healthcare. The challenge will be to hold on to the best elements of that traditional model while bringing about appropriate amendments to it which reflect new conditions, new possibilities and new social expectations. One could add to this the point that system improvement necessarily involves something more than isolated improvements in episodes of care – some doctors may need to shift their sights from episode domains to the wider process of care. Those involved in clinical governance tend to argue that while they agree that such a shift is desirable, it is inhibited by the structures which continue to support medial specialities.

***Barrier 4: Overprotection of professionals***

Transparency of data and scope for public complaints bears down on unsafe practices; when systems reach certain levels of safety there may be even greater scrutiny and public pressure per untoward incident. A ratchet effect seems to kick-in: improvement increases pressure for even more improvement.

***Implied recommendation: system-level scrutiny and arbitration***

***Barrier 5: Complacency and the complexity of extant systems***

This barrier reflects the perverse effect of safety systems. These can become routine in a negative sense, taken for granted and ritualised. They lose their real relevance. People may neglect to complete forms properly and even if they do these forms may not be used and actioned. As regulations increase there is also danger of too many, and indeed even a danger of conflicting rules. The risk is that that layered safety systems become unwieldy and so potentially ineffective.

***Implied recommendation:*** the need for simplification. Periodic consolidation and removal of non-productive safety regulations.

But in addition, to the above five, there is a sixth barrier – the legitimacy or otherwise of audit and advice. Across numerous trusts, people working in these roles of service improvement and development often report difficulties in winning acceptance of their service. They may be perceived as ‘policing’ and ‘interfering’. Merely having

procedures and systems in place does not necessarily mean they are utilised, accepted and owned.

Clinical governance practitioners contend that safety regulations have become hugely cumbersome. There are it is suggested far too many regulators working in isolation from each other and each asking Trusts for the same information. On the other hand, attitudes to audit are changing for the better as clinicians have learned to use the data to support business cases and service development. But off-setting this, stand alone service improvement teams (SITs) are often seen as 'interfering'. SITs tend to be accepted if they are restricted to kick-starting the appetite for change. Others suggest they are time limited and should evolve into centres for best practice where teams can bid for their support to get some service improvement rather than have them taking the lead and in effect end up demanding corporately driven change.

### **Implications for Healthcare Governance**

Risks in health care environment are compounded by fact that health care is so varied and non-homogeneous. Some procedures are very safe and others are inherently risky. Further, healthcare is at least partly staffed by large numbers of relatively under trained staff and beginners. Excessive fatigue, overtime working, overloaded work schedules, diverse staff groups, under-systematised workflow planning and design are all potential sources of failure. One interesting possibility is that the shift to ambulatory care may be associated with increased risk.

The reaction to these sorts of characteristics has been the drive for specific committees and for named individuals to champion safety, quality and error elimination. But there may be a need for more than this: also needs to go beyond mere compliance and conformity. Evidence from other studies such as the initiative for a Patient Advice and Liaison Service also reveal that merely instituting structures and new roles does not guarantee effective organisational change or behavioural change (Buchanan, et al. 2005).

Overall, there is normally a corporate commitment to safety that is largely driven by substantially lower insurance premiums. However, at clinical team level, commitment to safety is often accorded a low priority when contrasted with corporate concerns to get patients in and out of the system as quickly as possible. Recent emphasis on financial balances and on lean service has resulted according to many clinicians in a 'conveyor belt mentality'. This in turn has it is said, 'fractured' the therapeutic relationship between nurse and patient. As one director of nursing commented:

The 'consumer' does not tug at the angels' heart strings. As a nurse I have no interest in customer care – I care deeply about the living, breathing patient and I will go to great lengths to make sure my patients are cared for as well as I can - but the 'consumer' turns me right off, frankly. The consumer has rights, will be demanding, will be watching my practice in case I get it wrong and will be wanting to sue if expectations are not met. That's not what I went into nursing for.

Many nurses now are unable to maintain the caring identity; an identity that is not enacted will decay. As one senior nurse argued: 'It is my belief that the caring

professional identity is decaying because nurses especially are prevented from enacting it. The caring professional identity is embedded in commitment to values of service, humaneness and altruism'. Increasing accountability for the patient will increase safety.

The accountable practitioner will ensure the patient receives optimum care e.g. receives medication on time, will be fed and watered, will be monitored, will be properly assessed, will be referred onto others where necessary. If the patient deteriorates the accountable practitioner will notice and respond. But as a senior nurse observed: "I've lost count of the examples I've come across where those very basic things have not been taken care of. So yes, we need to revisit values but I'm not sure there is the professional energy left to do that or the political will. What's left for the NHS in terms of patient safety is probably more and more policing".

As we noted above, there is certainly a need to avoid 'patching' behaviour. These committees may themselves institute their own forms of patching. There may be a temptation to use them for exchange of information, but need to look for opportunities for organisational learning – for double-loop learning. There is a need to embed them 'upwards' to the strategic level while also focusing 'downwards' into the culture and behaviour of clinical teams.

The revolution in Information & Communications Technology and the associated information systems also offer the potential for adding new powerful tools to help with the patient safety and quality of service agenda. Electronic Health Records and Personal Health records should in theory offer standardised and more complete and

timely information. Such information should enhance immediate care interventions and treatment and also post-hoc monitoring and evaluation of patterns. The increased capacity of modern health records to capture text is claimed to enable better clinical care. The easier accessibility by clinicians to notes, images, pathology results and the scope to order new diagnostic tests should all drive better and safer patient care.

Likewise, the same technology should enable management to analyse infection rates, bed use and care pathways in a manner which should ideally lead to better planned healthcare through for example, better theatre utilization, and other efficiency gains.

## **Conclusions**

Ideally, the commitment to patient safety is embedded and owned within each clinical practice area – that is, within each micro-system. In addition, the micro-systems will be supported as well as monitored by a system-wide set of structures, procedures and tools. In addition, the safety and clinical governance agenda will be inextricably intertwined with the service improvement agenda. Each element is important.

Monitoring on its own will be limited in its effects – there is always the danger of ritualistic conformity. At the same time, the objective is not to eliminate defects at the price of suppressing innovation. Rather, experimentation and creativity need to be part of the solution. The conditions under which experimentation and innovation occur will need to be subject to controls which extend beyond the normal delivery of routine care.

Learning from systems failure ought to be tackled by clinical standards, clinical governance, audit, compliance, service development, risk management, complaints,

etc as one unified objective. Avoiding the fragmentation that can accompany such specialist approaches is naturally one key challenge. Some trusts manage to do so far better than others.

Meanwhile, there is the ever-increasing external monitoring by a range of bodies - most notably, the Healthcare Commission, the National Litigation Authority, the GMC, Monitor and PCTs to name but a few. Such external scrutiny may lead to a minimalist, ritualistic, conformance-oriented approach amounting to little more than box-ticking. In addition, because of their number and because they each take a partial view, there are concerns about the extent of joined-up analysis of underlying key issues. At least occasionally, there is likely to be a need for system reengineering rather than a reactive, fire fighting approach.

There may be a need to return to a consideration of underlying values. One aspect of this is the extent to which service users are regarded as consumers or as patients. This question of values relates closely to a question of staff 'identity'. Do they orient themselves to 'caring' as a vocation in the traditional sense or to 'customer care'? And is one, in any sense, superior or preferable to the other? There may also be a need to revisit the issue of underpinning values so that clinical values and system-wide/managerial values are congruent rather than separate or even in conflict. At this point, governance and leadership should come together. But, if the Trust Board has an essential priority to meet financial targets as expected by Monitor, the focus on patient safety and quality of service may, possibly, become subsidiary. Thus, healthcare governance has to start at the top – with the Trust Board as a whole.

## References

- Amalberti, R., and Y. Auroy, (2005). "Five system barriers to achieving ultrasafe health care." Annals of Internal Medicine **142**(9): 756-764.
- Baker, G. R. (2004). "The Canadian Adverse Events Study." JMMC **170**(11): 1678-1686.
- Buchanan, D., S. Abbott, Bentley, J.Lancely, and A.Meyer, J. (2005). "Let's be PALS: User-driven Organizational Change in Healthcare." British Journal of Management **16**(4): 315-328.
- Institute of Medicine Committee on Quality in Health Care (2001). Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, DC, National Academy Press.
- Nelson, E. C. (2003). "Microsystems in healthcare: part 3 planning patient-centred services." Joint Commission Journal on Quality Improvement **29**(4): 159-170.
- Nelson, E. C.. (2002). "Microsystems in health care." Joint Commission Journal on Quality Improvement **28**(9): 472-493.
- Nelson, E. C.. (2003). "Microsystems in healthcare: part 2 creating a rich information environment." Joint Commission Journal on Quality Improvement **29**(1): 5-15.
- Reason, J. (2000). "Human error: models and management." British Medical Journal **320**: 768-770.
- Tucker, A. L. and A. Edmondson (2003). "Why hospitals don't learn from failures: organizational and psychological dynamics that inhibit system change." California Management Review **45**(2): 55-72.
- Vincent, C. and G. Neale (2001). "Adverse events in British hospitals: preliminary retrospective record review." British Medical Journal **322**: 517-519.

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