Is healthcare getting safer?

Based on a seminar by Professor Charles Vincent, Imperial College, London presented in Cardiff, June 2011

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1000 Lives Plus - Improving care, delivering quality

1000 Lives Plus is the national improvement programme supporting organisations and individuals to deliver the highest quality and safest healthcare for the people of Wales.

Every health board and trust in Wales, together with universities, voluntary organisations and charities, other public sector services, and commercial organisations are involved in 1000 Lives Plus.

The programme is focussed on building capacity and sustaining and spreading improvements. It supports frontline staff across Wales through evidence-based ‘programme areas’ and provides clinical leadership through its Faculty. It is committed to engaging patients and students in improvement work and promotes an internationally-recognised quality improvement methodology.

1000 Lives Plus is underpinned by measurement to illustrate improvement, and facilitates collaborative working to test new methods and protocols. The central team supports senior managers and frontline staff to deliver the quality of care that every person needs, everywhere and every time.

For further information, visit www.1000livesplus.wales.nhs.uk

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Executive summary

“The story of patient safety is really about this million dollar question - can we be sure that, after all of this, patients are any safer?” - Charles Vincent

There is difficulty in ascertaining whether patients are any safer after the many patient safety campaigns that have been run internationally.

Patient safety research has shown that harm is not about isolated events and unusual, or even rare, occurrences. It is an endemic problem across all of healthcare in many countries. Recent studies in New Zealand, Canada, France, the Netherlands, and Spain all show harm rates of between eight and twelve per cent.

The lack of research on this topic is leading to disagreements, and possibly genuine conflict, between two categories of people: ‘evangelists’ and ‘snails’. Evangelists believe the urgency gives a moral imperative to action. Snails want to exercise caution and amass evidence before intervening.

However, analysis of high profile programmes and campaigns have shown inconclusive evidence that patients are generally safer. In certain areas safety has improved, and there have been some ‘successes’.

One success of patient safety campaigns is that safety is now ‘on the agenda’ for healthcare organisations, and is being taken seriously as an issue at every level, from board to ward.

There is also a growing understanding that systems and processes negate the technical proficiencies of clinicians. In addition, non-technical human factors, particularly around team working, are now recognised as vital elements in achieving successful outcomes for patients.

“A huge number of papers have been published about team behaviour, communication breakdowns, latent risk factors and so on. There has been a huge amount of progress in the general understanding of safety issues and it is now common parlance.” - Charles Vincent.

However, evaluating the impact of patient safety campaigns - and answering the question: ‘Are patients any safer?’ has been difficult. Healthcare organisations are not used to gathering data and senior leaders and managers are frequently working without useful data to hand. This is in stark contrast to the financial arm of healthcare, where there is abundant data and decisions can be made from an informed position.

Patient safety has to be reported to board members and senior leaders within organisations to ensure that problems are identified and addressed at the earliest opportunity.

The question of whether patient safety is getting safer can only be answered if organisations start measuring safety metrics. New campaigns or programmes need to prioritise measurement from the beginning to provide evidence that they have made a difference.

The sustainable changes that will ensure safer healthcare, and consequently safer patients, are due to system changes. But we will only know the system actually changes if we can measure the consequences of making these changes. The health service is not good at this. We continue to ask: “Where is the supporting data?”
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Introduction

Professor Charles Vincent is a world-renowned academic expert on patient safety, responsible for gathering the evidence that underpins much patient safety work - that 1 in 10 hospital in-patients will be harmed by the healthcare system and treatments they receive, and 1 in 300 patients will die as a result of their treatment¹.

In June 2011, Professor Vincent addressed an audience in Cardiff at the invitation of 1000 Lives Plus, the NHS Wales national improvement programme. The central theme of the evening was whether it was possible to establish if healthcare was safer as a result of the many improvement programmes in healthcare, not just in Wales but across the UK and globally.

This is a vital topic given the progression and development of ‘patient safety’ as a significant concern to the wider public, and to those working in the NHS. In the current climate of financial constraints and the need to give value for money, along with regular media reports of sub-optimal care affecting public confidence, knowing that the efforts to improve are having an impact is very important.

Professor Vincent began the session by saying he had been watching the patient safety activity in Wales (the 1000 Lives Campaign and 1000 Lives Plus) with admiration. “Many countries have tried similar things, but not in such a co-ordinated way.”

However, all countries are facing similar challenges and problems, even though ‘patient safety’ as a concept is evolving over time and taking slightly different forms and the challenges are changing.

Part of this evolution has been due to enthusiastic people driving forward the safety message with evangelical fervour, resulting in a wide number of patient safety initiatives. However, it’s hard to ascertain whether patients are any safer. “The story of patient safety is really about this million dollar question: Can we be sure that, after all of this, patients are any safer?”

Professor Vincent placed an emphasis on data, or the lack of it. “We treat patients using data. We wouldn’t dream of not using full blood tests and other diagnostic tools. But somehow we seem able to intervene in an entire hospital system without data.”

Everything must be tested to prove its effectiveness and efficiency, particularly in a ‘quality-centred’ healthcare environment, where effectiveness and efficiency are two prominent elements within the widely accepted definition of healthcare quality (as put forward by the Institute of Medicine²).

Evangelists and snails

The lack of research is leading to disagreements, and possibly genuine conflict, between two categories of people: ‘evangelists’ and ‘snails’. Professor Vincent used these terms that featured in a paper by Frank Davidoff about quality improvement and safety.

Davidoff uses developments in the 1970s when widespread screening programmes were introduced, as symptomatic of two viewpoints. There was a debate that centred on whether there was enough evidence of benefits to justify the quite considerable cost of establishing and running a screening programme.

This divergence in views is starting to develop in attitudes towards patient safety and quality improvement campaigns.

The difference between the ‘evangelist’ and ‘snail’ approaches, is seen in responses to situations: “the evangelist perspective suggests that under conditions of uncertainty it can be morally justifiable to: ‘Just do it, and learn as you go,’ while from the snail point of view, the more moral approach when faced by uncertainty is: ‘Look before you leap;' the difference between ‘action’ and ‘caution.’”

Why has this conflict arisen? Put simply, because quality improvement is less about ‘hard science’ and more about cultural change and influencing - social skills that are hard to evaluate using standard scientific methods. According to Davidoff:

“The emergence of a science of improvement within medicine in the last few decades has amplified the differences between the two epistemologies. The interventions in this data-driven, system-level discipline are designed to achieve appropriate, consistent and efficient delivery of established clinical measures by changing human performance. They are complex, generally consisting of multiple, reciprocally interacting elements. By design, they evolve over time in response to continuing feedback, and hence are intrinsically unstable. They are hard to standardise, since they are most effective when adapted to the local circumstances. Perhaps most importantly, they are inherently context-dependent. Healthcare improvement in this sense is therefore a hybrid discipline, primarily a science of social change, and secondarily a clinical or biomedical one.”

Further, “evangelists consider the snail demand for ‘hard’ proof of efficacy and safety as a precondition for putting a new clinical intervention into practice as morally unjustified precisely because obtaining ‘sufficient’ proof can delay and obstruct the actions seen as urgently needed to fix ineffective, inefficient, and sometimes harmful, or even lethal, existing care systems. Conversely, snails consider the evangelist insistence on implementing innovative medical procedures before their efficacy and safety are established as morally unjustified precisely because even reasonable-seeming interventions can waste scarce resources, introduce ineffective, inefficient and potentially even harmful changes in care, and generate serious opportunity costs.”

The snail point of view, therefore, “…reflects the palpable frustration of those who are convinced that introducing a healthcare intervention before its efficacy, safety and efficiency have been firmly established would be potentially wasteful, hence morally suspect.”

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Professor Vincent asked: “How do we marry these perspectives?” He framed his answer with introductions to three of his own papers, including the ground-breaking study in 2001 that established the commonly accepted ratio for harm occurring in advanced healthcare systems: one episode of healthcare-attributable harm in every ten hospital admissions and one death as a result of healthcare-attributable harm in every 300 hospital admissions4.

“The balance [between these viewpoints] is going to change over the years according to where we are and what we do… Patient safety has evolved from thinking isolated events and unusual, or even rare, occurrences to finding it’s an endemic problem across all of healthcare in many countries. Recent studies in New Zealand, Canada, France, the Netherlands, and Spain all show harm rates of between 8 and 12 per cent.”

**Patient safety - the beginning of a journey**

The harm rate of ten per cent that Professor Vincent established in 2000 was “publicised bravely” by the Department of Health in its publication ‘An Organisation with a Memory’5. This included an “ambitious target to reduce harm by 50 per cent”. The Institute of Medicine report ‘To Err is Human’6 was published in the same year, and contained similarly ‘ambitious’ aims. Five years after publication several papers were published analysing the impact and long-term effects.

Professor Vincent summed up the conclusions: “The consensus was that reporting systems are going well, there has been a culture change, awareness has been raised, accreditation created, and lots of other good things. But the papers are generally tentative about whether it’s really making a difference.”

Progress in patient safety can be seen, when viewed at different levels. Professor Vincent started by reviewing surgery as a discipline. “How do you explain outcomes? You can talk about patient risk factors, co-morbidities, the individual skill of the surgeon. These are all important factors. But they don’t provide a complete picture from a ‘systems’ point of view.”

“When talking to surgeons, nurses, and anaesthetists, certain subjects were in everyone’s conversation, for example teamwork. But you didn’t find those concerns reflected in the literature.

“We need to study teamwork, communication skills, even the environment of the operating theatre. Monitoring one operating theatre recorded that the door opens once a minute. That’s a terrible environment to do skilled work. If you were on an aeroplane and you saw the pilot’s door open once a minute, then you’d be terrified after about ten or fifteen minutes.”

“This has changed in the last few years. A huge number of papers have been published about team behaviour, communication breakdowns, latent risk factors and so on. There has been a huge amount of progress in the general understanding of safety issues and it is now common parlance.”

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“We also have specific interventions, such as the World Health Organization’s Safer Surgery Checklist. We have evidence for improvement – showing a reduction in errors and mortality through using it.”

“There are implications of doing this in a developed healthcare system. We might think we don’t need it. But in Holland a randomised control trial contrasted outcomes before and after introduction of the checklist. It reduced complications considerably. Holland is similar to our system here in the UK and the results are therefore informative to us.”

“We know that teamwork is important - we see it especially when things go wrong. A study in the USA shows team training on a large scale reduces surgical mortality. This was a controlled study - with very impressive methodology.” The end result was that team training doubled the impact on efforts to reduce mortality.

Professor Vincent was involved in the Safer Patients Initiative (SPI) organised by the Health Foundation. This was a “massive £4 million, two-year intervention. The target was reducing harm by 50 per cent.” It combined specific elements of change, for example interventions in critical care with “generic whole-hospital interventions such as medicines management and leadership.”

A large report on the SPI compared participating hospitals with non-participating hospitals: “Very little had changed between intervention hospitals and control hospitals. It wasn’t that nothing changed - infection was reducing, but it was changing everywhere.”

The Health Foundation has published its ‘Learning Report about the Safer Patients Initiative’ which shows that many key indicators of improvement were common between SPI hospitals and non SPI hospitals. “Rates of adverse events were similar between control and SPI hospitals over time.”

The Health Foundation conclude: “We cannot, therefore, confidently attribute the improvements that were achieved to the programme intervention alone... at the time of evaluation, differences between SPI sites and control hospitals were not statistically significant enough for quantitative improvements to be attributed to the Safer Patients Initiative.”

In listing what he considered should be recognised as achievements of the SPI, Professor Vincent included an ‘inspirational and important legacy’, but the key learning regarding impact was that ‘Simply getting basic clinical data and measures was a major challenge’ and ‘Measurement and evaluation’ proved problematic.

In conclusion, Professor Vincent stated that, “Yes, things are getting safer, but we don’t know why and we’re not sure it’s linked to this programme.” However the organisers of the SPI should be commended, “because they put in an evaluation and they stuck to it.”

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“The Safer Patients Initiative created huge enthusiasm, changed attitudes and taught a lot of important stuff. We learned many lessons, including the order in which to do things.”

Many campaigns seem to lack meaningful measures. “One campaign published the number of downloads of a measurement instrument - we have no idea of what actually happened but people had got the forms.” In Professor Vincent’s experience, “When I talk to people the big frustration is not having resources to really know and really evaluate.”

The Institute for Healthcare Improvement (IHI) sought to evaluate its 100,000 Lives Campaign in the USA, through studying risk-adjusted mortality over time, but this meant the only discernible change was after the figures had been through a risk-adjustment process. The change is not obvious in the raw data.

Wachter and Pronovost summed up the evaluation:

“Overall, we end our analysis of the science unable to fully understand what actually happened at the organizational and patient levels as a result of the campaign …. and concerned about what appears, to us, to be substantial bias in the methodology behind the reported “lives saved” numbers.

“Given the available resources, it was likely beyond the reach of the campaign to rigorously evaluate the results of the effort— but this is an argument for ensuring that large-scale campaigns possess the expertise and the resources to perform a proper evaluation, particularly when the implications of their results are so far reaching’.” 11

While Wachter and Pronovost’s conclusion illustrates the “snail perspective”, the message of the data has been replicated in France12, the USA again13, and a more detailed study from Holland14 all showed that safety had not improved in the past five years.

Of course, there are other variables in any time-bound study. Populations change, as do technology and treatments. These studies do not all separate out the ‘preventable events’, which is where the real safety issues lie, and show the standalone prevalence rates for them.

Professor Vincent’s own study of UK healthcare in 2008 contained the following:

- Standardised mortality was reducing.
- MRSA / C. difficile were “coming under control” - however there was not much information about them.
- In the Agency for Healthcare Research and Quality only one of the nine patient safety indicators was improving over time, the others were getting worse. (This may be due to better reporting.)15

12 Professor Vincent presented data gathered in France in2004 & 2009 study, which had been shared with him by Philippe Michel, Director, Regional Centre for Quality and Safety, Centre Hospitalier Universitaire de Bordeaux, France. This data is available in the Professor Vincent’s PowerPoint presentation held by 1000 Lives Plus.
14 Professor Vincent presented data provided by Cordula Wagner, Professor of Patient Safety VU University medical center and NIVEL and cited research by Maaike Langelaan. This data is available in the Professor Vincent’s PowerPoint presentation held by 1000 Lives Plus. The original data / source does not appear to be available in translation from the Dutch.
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- There was no data tracking medication errors over time. Different studies show rates of 4-6 per cent, but there is no trend information.

Important questions and elusive answers

In the second edition of his book, ‘Patient Safety’, published in 2010, Professor Vincent sums up the over-riding issue very neatly:

“Are patients any safer than they were ten years ago? The answer to this simple question is curiously elusive. While some aspects of safety are difficult to measure for technical reasons (i.e. defining preventability) the more substantive problem is that, for all the energy and activity, measurement and evaluation have not been high on the agenda... the available information is widely scattered and not easily accessible to clinical teams and managers.”

At the seminar, Professor Vincent elaborated on this: “It’s not that nothing has happened. But it takes a while to get to grips with it and see data change. There are lots of examples where got grip on certain issue. But it’s sensible to think about adverse events in the round and across whole system.”

“Certain things are system-wide, but ‘safety’ looks very different in intensive care, or the operating theatre or in care of the elderly. What you have to do to make a change will be different. The overall evidence of harm is not going to come from measuring isolated adverse events, but the aggregate of all these specific interventions.

“If you put a checklist in - a single kind of fix - you can expect results in relation to that one thing. If you want to change the whole system, it’s a bit different. We are often using a single issue approach, e.g. standardised mortality, when what we need is a more general approach. Hospital Standardised Mortality Ratio (HSMR) only reflects a small fraction of what’s going on - the number of people who die. It doesn’t measure pressure ulcers or other evidence of sub-optimal care. And it’s often used in a crude way.”

“Running a hospital you would want HSMR but only as one of 20 or 30 measures. It’s good to see decline over time, but its real use is as a flag to go and look for a problem. It’s useful to watch but not good measure of performance.”

“To reduce ‘disease’, you would have to identify all diseases then address each one and whether they are being reduced.”

While certain impacts have happened, for example in the reduction of Clostridium difficile incidence, “we’ve still not seen evidence of big change on large scale.”

“There is a naivety about what it would take to make changes in this way. The lesson from France and the USA is a message for all of us. But it’s not the message going out in national campaigns - that is ‘everything’s great’.”

“But as a patient I don’t care about the razzmatazz, I want to see that the health system is changing. Improvement work has been worthwhile. But it’s hard to say whether patients are any safer. I don’t want to know this as a researcher. I’d like to know it as a potential patient.”

The future of patient safety

Considering the difficulty in presenting conclusive evidence for improved safety, Professor Vincent proposed several ways that healthcare organisations could develop ways to gather evidence and use it to inform strategy and influence the day-to-day work of the organisation.

“We need to move beyond measuring adverse events - they are good for revealing problems, but for measurement it is all a bit loose. Incident reporting doesn’t show progress. Reporting is useful, but not necessarily for robust evaluation to see if things have improved.

“The way we think about safety has to change. More consideration needs to be given to the ‘dimensions of harm’ - for example in the care of the elderly, malnutrition, dehydration, and hospital-induced delirium needs much more attention.”

“Safety needs to be understood in different clinical contexts - we need to get a bit more sophisticated. The objectives of safety and means of achieving it are very different in pharmacy and emergency services. At the moment we have a blunderbuss approach, but techniques and measures need to be fine-tuned to fit their environment.”

“One problem for patient safety is that everybody is scattered and expertise is found all over the place. We don't have a critical mass of researchers and improvement people all in one place. We gather together doctors and nurses, but we probably need to look more widely and perhaps begin an institute of some description.”

“Boards have a lot of financial information but when it comes to safety, they don’t have data. It is impossible for them to monitor change. They therefore cannot review performance. They cannot target change. If they make changes they cannot know whether they have been effective. This is the same for all other levels of the organisation.”

“Safety initiatives are always happening in context of pressures on system. But unless you have serious data over time you can't begin to think about these things. What worries me is that hospital boards don’t have that data locally to see whether they are making progress.”

“Boards need to consider the kind of data needed. What are the big ticket items? But you need to tackle all areas of hospital, including routine low-risk operations. Also, put some measures in areas which have not usually been measured before. For example, in care of the elderly, where care is hugely variable, and the scale of minor adverse events is colossal as you’d expect with people with lots of co-morbidities.

“How can we run these institutions without this data? We wouldn’t run a hospital without financial data. Safety should be just as important to managers, executives and board members.”

“Safety and quality are aligned with clinical values and it’s odd that it’s been hived off into bureaucratic limbo.

“The shift we have to make is to professionalise safety and quality - make it a core of professional responsibility. Whether something is acceptable is critical. There will be no improvement until someone challenges the attitude. The shift to making something socially
unacceptable is possible - drink driving is a good example. Cultural attitudes are very different now towards drink-driving than they were in the 1960s and 1970s.”

“Safety is an aspirational thing. The reason to think about safety foremost is that it is fundamental. For a patient if you don’t get medication, or you develop a thrombosis, that’s not a ‘quality issue’ - you’ve been harmed!”

**Reflections from 1000 Lives Plus**

“Patient safety has not... addressed measurement sufficiently; this is now coming home to roost and seriously impeding progress. Safety and quality initiatives have not, in many cases, been evaluated in the same way as drugs and other major interventions (and nor, we might add, have most healthcare management or policy initiatives)... patient safety needs to reconnect with standard scientific methodology and epidemiological approaches and give measurement and epidemiology equal weight to understanding and analysis.” 17

To fully understand establishing the outcomes of change requires a robust measurement strategy. This continues to be an issue within the improvement work in Wales championed by 1000 Lives Plus. The commitment to developing a measurement strategy must remain integral in all attempts to reduce avoidable harm, to show whether improvement is occurring, or not.

There has been criticism of quality improvement initiatives, but this work does have a foundation in science and this science should be applied rigorously. All those engaged in healthcare improvement need to develop a respect for and a maturity in measurement that is currently lacking. 1000 Lives Plus must be confident in our discrimination between measures of outcome and process, while respecting them both.

It is not enough just to measure. The proverb: “You can’t fatten a cow by weighing it” points to the futile activity of just counting (measuring) without changing the system. Measurements can have unintended outcomes, as people may seek to ‘play the system’ to gain good scores at the expense of genuine quality, for example, by excluding certain cases that will drive down average quality scores from case-mix audits. Bureaucratic style measurements have often incentivised such behaviour, which has then impacted negatively on patient care and driven down quality.

We need to have effective, comprehensive and most importantly reliable implementation of the science of quality improvement, so that the outcomes of the underlying processes of improvement can be seen. The experience of staff involved in 1000 Lives Plus shows clinicians respond well to, and are incentivised by, a more explicitly scientific approach to management (hypothesis/action/outcome, or Plan, Do, Study, Act cycles) where run charts and driver diagrams are prominent.

Every intervention must have outcome measures attached to meet the legitimate demand to prove that outcomes have been effective. This takes time in itself, so sometimes the pressing need to respond to a ‘burning platform’ crisis situation requires change without totally fireproof evidence-based on outcomes.

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This requires trust on the part of the snails and integrity on the part of the evangelists. Trust that the outcomes of new interventions will be measured, and integrity in the prioritising of measurement and delivering evidence as quickly as possible.

Balancing the moral demands of the evangelists for action, and the equally valid demands for evidence from the snails means both ‘sides’ may end up dissatisfied. That is perhaps the surest evidence of a compromise - that neither side is totally happy. However, what unites both sides - a desire to see patient outcomes improve - will always be bigger than what divides them.

It is important that any patient safety improvement work can answer the question ‘Is healthcare getting safer as a result of what we’ve done?’ This is not an academic point, or matter of professional pride. It is, simply, seeking the best for the people and patients we serve and endeavour to protect from harm.

It is beholden on all those involved in improvement to establish the means of knowing whether their work is preventing unnecessary death, harm, suffering and grief. Being able to say with surety that healthcare is safer should be regarded as literally a matter of life and death.

For further reading and information


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