Duty of Candour

Threshold Review Group

Review of definitions

January 2014

Contents

Introduction

At the second meeting of the Duty of Candour Review Group it was agreed that the group required further information, in particular, on the different classifications related to patient safety incidents.

The aim of the paper is to inform the group of current thinking via patient safety literature, and national and international policies related to patient safety classifications. In addition it provides further information on being open, open disclosure found as a result of this review. It is hoped that this information will generate discussion which will lead to making a decision in relation to the threshold level at which the **statutory duty of candour** should be applied

Methodology of review:

- A search of national and international policy related literature and research related to; patient safety definitions, classification systems and grading
- A search related to oversight bodies internationally responsible for classifying, capturing and analysing patient safety incidents
- A search related to systems that have attempted to improve communication, openness, transparency and open disclosure with patients and the public

Thanks go to the following for their valuable insight:

- Patient safety and risk experts including Paul Downes at Salford Royal
- Frances Healey and Donna Forsyth at NHS England and members of the National Reporting and Learning System (NRLS) team

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Summary

This review has found that organisations and individuals in the NHS are not all talking the same language, and there is inconsistent use of the same definitions, terms and terminology in relation to patient safety across the NHS in England at all levels from the centre to the frontline. Over the last decade there has been a vast array of different guidance for NHS organisations to classify and grade their patient safety incidents which has resulted in limited consistent understanding.

If we want to be candid first we need to identify what we are being candid about. This needs a good reporting culture and a good reporting system; neither of which exist across the whole of the NHS.

A number of studies have now compared the findings from reporting systems with assessments of harm to patients using systematic case record review. For example, the study by Sari et al, who carried out a classic case record review and compared the findings with locally reported incidents. Results showed that the routine reporting system implemented in a large hospital missed most patient safety incidents that were identified by case note review and detected only 5% of those incidents that resulted in patient harm. From this and other studies we know that incident reporting systems are very poor at detecting all patient safety incidents. On average, most studies have found that reporting systems **only detect 7–15% of all incidents**.

A reporting system requires a good classification system for the different levels of harm which should be set up for the purpose of learning. If the system is going to be used for accountability and candour as well as subject to sanctions then it is vital that the definitions are consistent, valid and reliable; that they are **beyond doubt**. Measures of patient safety – just as with all kinds of information and data need to be both valid and reliable. However, we do not have definitions that are beyond doubt and are highly unlikely to do so across the spectrum of harm.

Incident reporting is dependent upon a safety culture that is open and fair and 'just' in which the reporter is supported when things go wrong. There remains in particular pockets of the NHS a propensity to blame individuals rather than a commitment to learning through the systems approach to analysing error and incidents. Reporters fear the blame and punishment. There is a concern that the statutory duty of candour will increase this fear.

Any guidance should stress the importance of 100% compliance with the 'being open' framework which applies to all levels of harm and is concerned with informing patients of any type of harm as part of the natural course of the care provided. Open disclosure policies have been increasingly adopted in a number of countries. In the US JCAHO has mandated open disclosure as part of its accreditation policies in 2001. In the UK the NPSA developed a Being Open Policy in 2005; while not mandatory it was considered so through the use of a Patient Safety Alert in 2010. However evidence suggests that both the US and the UK have failed to achieve full compliance. In Canada, the Canadian Patient Safety Institute produced guidance and apology legislation has been enacted in four provinces. Most Australian states and more than 30 U.S. states have enacted similar laws.

The published literature is sufficiently vague in relation to informing patients, stating that 'patients should be informed when they have been harmed', and 'all patients should be receive an apology if

they have been harmed'. The authors do not clearly define what they mean by harm and what level of harm and what level of response should be provided. This therefore creates confusion and widespread inconsistency in implementation. Equally staff do not feel that the support, knowledge and training that underpins being open or open disclosure has yet been fully developed.

The potential time involved as a result of extending the statutory duty of candour to either moderate or all other levels of harm could be huge. Experts suggest a need for a proportionate level of response. At one end of the scale, openness and honesty might only require a 10 second acknowledgement of a minor problem and a simple apology. At the other end it could involve multiple meetings over several months or even years.

The solution has to be clear and stand up to legal scrutiny. One possible solution is to set the threshold for the statutory duty in terms of outcome; i.e. death and permanent harm to patient(s) and not to attach the duty to incidents grade i.e. severe, or moderate or low. This may also mean that the duty is less reliant on incident reporting systems as a way of detecting the incidents that require candour.

Section One: Definitions, terms and terminology

Classifying objects can be difficult, but classifying incidents is even more so. Careful thought about the purpose of a taxonomy or classification system is necessary to develop one that works to achieve that purpose. Patient Safety Incidents as a term was first used by the National Patient Safety Agency in 2004 (Seven Steps to Patient Safety). Prior to this the most common term used was adverse event.

In the NHS in England guidance and grading terms has been issued by the Department of Health, the National Patient Safety Agency, the Care Quality Commission (and its predecessors), Strategic Health Authorities and Primary Care Trusts. NHS Trusts themselves have also developed their own internal guidance and grading.

With the abolition of the National Patient Safety Agency, Strategic Health Authorities, and Primary Care Trusts the responsibility for issuing ongoing guidance rests with NHS England and the Care Quality Commission.

With regard to examples of the different grades Annex A provides 'text book examples' kindly provided by Frances Healey, Senior Head of Patient Safety Intelligence, Research and Evaluation in the Patient Safety Division, NHS England. Annex B provides the definitions and grades issued by the National Patient Safety Agency which are supposed to be the nationally agreed definitions.

Frances has also carried out an analysis of a random sample of 100 moderate harm incidents. Clearly a different random sample would inevitably get different numbers, as 100 drawn from tens of thousands is obviously subject to variation, but it does allow a general sense of the types of incidents reported as moderate and their likelihood of already being known to the patient.

Of the random sample of 100 incidents reported to the NRLS as 'moderate harm' during 2013 from all care settings:

- 5 do not appear to be patient safety incidents (e.g. safeguarding issues where the harm was unrelated to healthcare)
- 7 were unlikely to have caused moderate harm (reporters appear to have over-graded because of concern for potential for harm)
- 74 were types of harm where the patient would clearly be 'automatically' aware. These were:
    a. 36 pressure ulcers
    b. 19 falls
    c. 3 incidents of self-harm
- 16 other miscellaneous types of harm that would be known to the patient (e.g. pain due to failed epidural)
- 4 would not have been automatically known to patient, but had clearly been disclosed already (e.g. a diathermy burn to patient's back during surgery)

- 5 were infections which would have been known to the patient, but where disclosure may have been needed about nature of infection (e.g. diarrhoea due to c diff)
- 5 would need disclosing to the patient, but unclear if this had happened yet, and in most cases would have been unfeasible at time of reporting (e.g. hypoglycaemic episode after insulin infusion not monitored closely enough, patient currently too unwell from underlying condition for conversation)

Note: The proportion of pressure ulcers might at first glance look surprisingly high but the vast majority of pressure ulcers need to be graded moderate (more than 'first aid' which is the definition of low harm but less than permanent impairment/disability which is the definition of severe harm) whilst other types of harm like falls are distributed over no harm, low harm, and so on.

There are a number of challenges related to classifying and grading incidents which have been sited in the literature. These are described in **Section Two**.

Section Two: Challenges related to classifying patient safety

The literature on incident reporting is extensive and includes information on developing a safety culture, the importance of leadership, integration of information systems, the benefits and barriers to reporting and different types of mechanisms for identifying things that go wrong, how to design incident reporting systems to maximise learning, and the importance of feedback.

The main challenges to achieving a robust patient safety system are set out in the following section.

Complexity

The challenge that the classic concept of an incident leading to one specific outcome is exceptionally rare. The patient outcome could be entirely due to natural disease progression, or there may be errors of omission or commission ranging from the miniscule to the multiple and serious. Even with regard to the death of a patient it is possible that the incident only contributed in as little as 1% to the patient's death.

Subjectivity

The grading of patient safety incidents is subjective. Incidents are classified by in the main junior staff or staff with limited training. They may be classified by a clinician and then reclassified by a patient safety or risk manager to match the organisation's definitions. Whoever classifies them does so by using their individual knowledge, clinical experience, type of expertise, previous experience of a similar incident, personal bias, outcome bias, confirmation bias and hindsight bias. The grading from severe to moderate and low harm is subject to multiple variables and biases. Consider the following scenarios.

Patient suffers a DVT

> Scenario 1. No risk assessment and no prophylaxis = duty of candour is clear
>
> Scenario 2. Risk assessment carried out, one dose of prophylaxis given one hour late on one day = what is the clinician being candid about, did this lead to the DVT?

Patient suffers a stroke

> Scenario 1. Patient left very disabled but would not have been quite so disabled if they had got the right treatment slightly sooner = duty of candour is clear
>
> Scenario 2. Clinician had stopped prescribing Warfarin for a patient with atrial fibrillation because they had repeated falls, they die of a stroke. However a 'reasonable body of clinicians' would have said this was the right thing to do. What is the clinician being candid about, was this the wrong action to take?

Defining Harm

Defining harm is a particularly difficult issue in healthcare. As stated separating harm due to healthcare from that of the illness is the first issue. One person's level of harm will not necessarily be another's. Incidents are generally graded according to actual harm, however some are graded according to potential harm i.e. a patient falls and is bruised as a result, actual harm low – potential harm severe or even death as the patient could have hit their head and suffered permanent brain damage as a result. Also harm may be gradual, it may initially thought to be temporary and then become permanent and vice versa. Side effects and complications are not considered harm events and there are blurred boundaries and confusion across ALL levels of harm and not just between severe harm and moderate harm.

Serious Incidents

In some respects there is an artificial or unhelpful separation about certain incidents. These include serious incidents (formerly known as serious untoward incidents) and never events. Severe harm, death and never events are subsets of 'serious incidents'. The impact of defining some incidents as serious incidents or never events shifts the emphasis from a learning perspective to one of governance and accountability. This also has the unintended effect of restricting the focus to a narrow range of patient safety issues. Additionally, patient perceptions of serious differ from healthcare professionals.

Serious incidents have had a separate approach in terms of reporting not only to the NRLS but also through the Strategic Executive Information System (STEIS) to (then primary care trusts and strategic health authorities) NHS England. There is a national framework for serious incidents which sets out the systems and process associated with serious incident reporting, serious incident review, quality and safety surveillance groups and risk summits and so on. This is currently being updated by NHS England and the most up to date version is dated March 2013 published by the then NHS Commissioning Board.

CQC-registered organisations are required to notify CQC about events that indicate or may indicate risks to compliance with registration requirements, or that lead or may lead to changes in the details about the organisation in CQC's register. They are required to report serious incidents as defined in CQC's guidance, *Essential Standards of Quality and Safety*. Most of these requirements are met by reporting via the NRLS, who will forward relevant information to CQC. The exception is for independent sector providers and primary medical service providers who must report serious incidents directly to CQC. They can also report to the NRLS. These requirements are set out in Annex C.

Incident outcome versus contributory and causal factors

Patient Safety Incidents most often result from a complex interaction of contributory and causal factors. There is a complex relationship that exists between incident type (in terms of outcome) and contributing factors:

- The same incident or circumstance may be perceived as an incident or a contributing factor, depending on the context, circumstance or outcome

- An incident always has a set of contributing factors
- An incident can be a contributing factor to the origin or development of another incident
- Some contributing factors cannot be incidents in their own right:
    - For example, if a patient with atrial fibrillation on warfarin got up at night to go to the bathroom, and slipped and fell resulting in no discernible harm, the patient safety incident would be considered a no harm incident and the incident type would be categorised as a patient accident / fall
    - If this patient had been found the following morning unrousable on the floor, then it is likely that the patient safety incident would be considered a harmful incident and the incident type would be regarded as clinical management. The fall would be considered a contributing factor involving staff factors, work environment factors, and organisational / service factors

Incident Reporting

Formal Department of Health guidance on untoward incident reporting was first issued in 1955. Since then, the first attempts to develop system wide patient safety classifications started in Australia in 1997 with the launch of the Australian Incident Monitoring System (AIMS) to monitor anaesthetic incidents and in the mid 1990s with the University of Texas Southwestern developing a Medical Event Reporting System (MERS) for transfusion incidents. In the UK the NHS Executive issued guidance on risk management in 1993 and the requirement for a comprehensive clinical incident reporting system was set out in the risk management standards issued by the NHS Litigation Authority in 1995.

Over the last decade patient safety classifications have become more refined. *An organisation with a Memory* published by the Department of Health in 2000 was the first to describe the nature and scale of the problem. This document was the report of an expert group on learning from adverse vents in the NHS, Chaired by the Chief Medical Officer. This defined an adverse healthcare event as 'an event or omission arising during clinical care and causing physical or psychological injury to a patient'. The Government's response to this report, *Building a Safety NHS,* heralded the set up of the National Patient Safety Agency and the new national reporting and learning system.

In a review undertaken in 1999 for the expert group;

- a fifth of all NHS Trusts did not have a reporting system covering the whole organisation
- less than half provided specific training on risk management or incident reporting
- less than a third provided guidance to staff on what to report
- a third did not require clinicians to report unexpected operational complications or unexpected events

Consequently there was no standardised, operational definition of 'adverse event' which was easily understood by all NHS staff' and rates and types of reporting varied widely. The report called for

unified mechanisms for reporting and analysis when things go wrong. Its recommendations included the creation of a new national system for reporting and analysing adverse health care events.

Over the last decade if we were to re-run the review undertaken in 1999, we would probably find improvements in that;

- all NHS Trusts now have a reporting system covering the whole organisation
- all provide specific training on risk management or incident reporting however the level of training could be a simple 15 minutes at induction
- all provide guidance to staff on what to report as part of the individual organisations risk management policy

However we would probably also find that there were still areas that need improvement as not all clinicians report unexpected operational complications or unexpected events, there is still no standardised, operational definition of 'patient safety incident' which is easily understood by all NHS staff' and rates and types of reporting still vary widely.

Coverage

Incident reporting systems capture operational and managerial incidents as well as incidents related to patients and staff. Separating harm incidents that are 'organisational harm' from 'patient harm' will be required in order to understand which incidents require candour.

Most incidents reported relate to acute care, most are reported by nurses and most relate to events that happened rather than omissions of care. There remains limited reports from primary care, in particular general practitioners. There are limited reports in relation to true near miss incidents.

Bias

The reporting, analysis and investigation of patient safety incidents is subject to known biases including outcome bias, hindsight bias and confirmation bias. What if any affect will this have on the duty of candour?

Section Three: NHS Definitions

This section describes the main definitions used by the NHS in England.

Doing Less Harm

Prior to the development of the National Patient Safety Agency and the National Reporting and Learning System a draft document, *Doing Less Harm*, was published by the Department of Health. The reason why this is included here is that this document was disseminated to all risk managers across the NHS in England and was used by many of them to form the foundations of the risk management systems that remain today.

An adverse patient incident was defined as 'any event or circumstance arising during NHS care that could have or did lead to unintended or unexpected harm, loss or damage'. Harm was defined as 'injury (physical or psychological), disease, suffering, disability or death'. In most instances, harm was considered to be unexpected if it was not related to the natural cause of the patient's illness or underlying condition.

There was no guidance within the document related to informing patients or their families and carers.

The tables are found in Annex D.

The National Patient Safety Agency

The National Patient Safety Agency set up on 2001, issued national definitions for classifying harm in England (and Wales) in 2004 in its guidance *Seven Steps to Patient Safety*. This was published to support the roll out of the National Reporting and Learning System (NRLS).

The taxonomy developed for the National Reporting and Learning system was developed with the purpose of learning and not in setting thresholds for mandatory reporting or any other mandatory activity. It was also never intended to be the single source of harm.

Step Four defined a variety of terms including 'Patient Safety Incident' in an attempt to create a common language for reporting and learning from harm.

Step Five provided guidance on communicating and information patients and the public. It included detail of the Being Open framework and policy prior to the issue of the national patient safety notice in 2005.

Step Six provided guidance on investigating incidents.

Health and Safety Executive

The Health and Safety Executive in the UK has a system for reporting Health and Safety incidents using the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) which are updated on a regular basis. RIDDOR is the law that requires employers, and other people in charge of work premises, to report and keep records of:

- Work-related accidents which cause deaths
- Work-related accidents which cause certain serious injuries (reportable injuries)
- Diagnosed cases of certain industrial diseases; and
- Certain 'dangerous occurrences' (incidents with the potential to cause harm)

In 2013 there were changes to simplify the reporting requirements in the following areas:

- The classification of 'major injuries' to workers is being replaced with a shorter list of 'specified injuries'
- The existing schedule detailing 47 types of industrial disease is being replaced with eight categories of reportable work-related illness
- Fewer types of 'dangerous occurrence' require reporting

There were no significant changes to the reporting requirements for:

- Fatal accidents
- Accidents to non-workers (members of the public)
- accidents which result in the incapacitation of a worker for more than seven days

Further details are found in Annex E.

Local classifications

Every NHS organisation is expected to have a serious incident policy and a risk management policy which describes the way they collected and classify risk and incidents. As described earlier there has been differing guidance from national organisations, regional organisations (previously SHA serious incident policies) and commissioners (such as PCT serious incident policies) that have confused and led to the variety.

Around 20% of organisations use the national grading set by the NPSA set out in Seven Steps, some organisation use the grading set out in the NPSA risk matrix consequence scoring system; 1Negligible, 2 Minor, 3 Moderate, 4 Major, 5 Catastrophic.

In 2014 the situation has not yet been resolved with Clinical Commissioning Groups adding to the pile.

All local grades irrespective of where they originated are then subsequently mapped to the NRLS grades; no harm, low harm, moderate harm, severe harm, death.

Examples of local grading systems are found in Annex F.

The Health Foundation

The Health Foundation commissioned Charles Vincent and his team to explore the measurement and monitoring of patient safety in the NHS. Vincent defines patient safety as 'The avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare.' The report, *Measuring and Monitoring of Patient Safety* helpfully summarises a number of the challenging issues. The report provides ten guiding principles for safety measurement and monitoring described word for word below:

1. A single measure of safety is a fantasy

The search for simple metrics has at times led to claims that it is possible to use a specific measure, such as standardised mortality, as a generic indicator of safety performance. A hospital advertises its enviably low mortality rate in the front entrance and uses this information to claim that it is one of the safest organisations in the country. Can we trust this claim? Can any single measure give us the assurance that a healthcare organisation is safe? Boards and others responsible for safety sometimes search for the elusive single measure of safety that will enable them to sleep well because the single universal safety metric is within bounds. We believe that this is a fantasy – an understandable one but a fantasy nevertheless. In most organisations there are just too many different activities, too many different dimensions of safety and too many factors that influence safety. We certainly think that a great deal can be done to assure safety, but not that this can be encapsulated in a single measure. Worse, such a reductionist approach to measuring safety may have the consequence of making healthcare organisations less safe through providing false reassurance and complacency in the face of continuing hazards.

2. Safety monitoring is critical and does not receive sufficient recognition

Healthcare organisations use a variety of formal and informal approaches to elicit safety information that enables them to understand how frontline healthcare services are delivered. Timely action and intervention to thwart potential safety risks is the other key component of sensitivity to operations, which does not always fit well with rigid structures and management by committee. External regulators place considerable emphasis on monitoring harm and incidents, but the critical role of an organisation's approach to monitoring safety does not always receive sufficient attention. Time to walk, talk and watch is critical to monitoring and maintaining safety. However, this cannot be done if staff are burdened with administrative tasks and not empowered with the freedom and authority to monitor and intervene when necessary. Patients, carers and others play a particularly critical role in this regard both in monitoring their own safety and that of the wider safety of the healthcare system. Just like healthcare teams, patients and vigilance about the potential for harm. By learning from past events, by listening and perceiving, and by foreseeing future areas of risk, carers operationalise these dimensions of safety. They are an essential but all too often underused defence in preventing patient harm. It is also becoming increasingly apparent that patients and families provide some of the best and most pertinent warnings of deteriorating and dangerous organisations. While regulators struggle with intermittent visits and a lack of timely data, patients have immediate experience of poor or dangerous care. Generally speaking, healthcare has not captured the patient and carer role in safety and translated it into meaningful patient- and carer-centred safety metrics. Future work is needed in this area to ensure that what we are measuring is relevant to the people we serve.

3. Anticipation and proactive approaches to safety

Evidence from other industries has shown that safety measurement evolves over time and that there have been important differences between industries in the pace and path that this evolution has taken. Common to all industries is the recognition of the need to move away from an over-reliance on lagging indicators to a mixed model that combines both lagging and leading indicators. But where is healthcare in this evolutionary process? The case study evidence indicates that while healthcare organisations do not rely solely on reactive measures of safety further development of leading indicators in healthcare is needed. One of the notable findings from our case studies was that those organisations interviewed provided many fewer examples of 'anticipation and preparedness' metrics than metrics in the other four classes of safety information in our conceptual framework.

4. Integration and learning: invest in technology and expertise in data analysis

Safety information is fragmented both within NHS organisations and across the wider system. At a local level many organisations have an array of safety relevant information that consists both of formal intelligence and local intelligence from informal conversations and observation. Integrating this information at an appropriate level and in a usable and comprehensible format is probably the greatest challenge. Some of the healthcare organisations we interviewed had a much more evolved approach to safety measurement than others. Those with integrated data management capacity were able to collate safety information from many different sources in a timely way. Boards in these organisations recognised that carers create safety by intervening and thwarting potential safety issues. For instance, someone caring for a person with a serious mental health problem has to maintain constant investment in data analysts and information technology was essential in order to help clinicians collect and use information in a meaningful way. Such organisations had moved away from roles such as 'clinical audit facilitator' or 'unit risk manager' and introduced new roles for people with skills and expertise in the collection and use of safety and quality information within divisions and directorates. Investment in data analyst teams and automated data capture has enabled some organisations to collect and present safety data in formats that are accessible to clinicians, managers, executive and non-executive directors alike.

5. Mapping safety measurement and monitoring across the organisation

Safety measurement and monitoring has a number of dimensions and must, to some extent, be customised to local settings and circumstances. The assessment of other dimensions of quality, in particular clinical outcomes, necessarily varies between contexts: surgical outcomes are assessed in a different way from those in maternity or mental health. The same is also true for safety, even though in practice organisations tend to rely solely on generic safety indices such as incident reporting. In fact, in each clinical context we should be considering what kinds of harm are prevalent; what features of care must be reliable; and how we monitor, anticipate and integrate safety information. As we have seen, harm can take various forms and all different categories of harm must be considered. Assessing the reliability of key processes, behaviours and systems by sampling at defined intervals is also fundamental. All this information needs to be integrated at the different levels of the organisation and also set alongside wider quality and financial metrics. In this report, we have focused almost entirely on safety as this is the area in which there is most

confusion. However, safety cannot be assessed in isolation and must always be considered alongside the wider objectives and metrics of the organisation.

6. A blend of externally required metrics and local development

We have learned that safety measurement, and particularly safety monitoring, must be customised to local settings and local circumstances. This is not to advocate a free-for-all of locally derived metrics: there are many indices that can and should be agreed nationally or even internationally. But day-to-day monitoring, anticipation and preparedness are necessarily local activities, whether at ward or board Although our case study sites showed uniformity in terms of some of the external safety metrics they applied, there were also important variations across sites. Going forward it is important to remember that some types of metrics will be more or less appropriate to a given healthcare organisation, depending on the type of care setting and each organisation's culture and infrastructure. While recognising that some types of measures need to be standardised, we also need to balance the pursuit of standardisation of safety metrics with a recognition that there is not a 'one size fits all solution' where safety measurement and monitoring is concerned. The importance of this issue was raised by the paediatric and mental health case study sites which commented that one of their biggest challenges is inheriting safety measures originally designed in an acute setting that do not marry with their specific patient population.

7. Clarity of purpose is needed when developing safety measures

Healthcare can learn from other industries' experiences in being clear on the design, purpose and target audience for safety measures. Quality and safety dashboards often contain a myriad of red, amber and green metrics that are reviewed as one agenda item in a three-hour board meeting. Healthcare regulators, national agencies and commissioners of services need to consider the criteria for safety measures and be clear on the purpose of each measure. Specifically we need to ask the following questions.

Who is each safety measure being developed for?

How and in what context will the safety measure be used?

Is it measuring what it claims to measure?

Can this metric be used to reliably detect or demonstrate deterioration or improvement?

What untoward consequences will this metric have?

When safety measures are developed, healthcare regulators, national agencies and commissioners of services need to beware of perverse incentives leading to gaming and excessively complex or burdensome data collection. They also need to ensure that safety measures are tested in practice prior to implementation. An approach that looks promising to a regulator or a government department may in practice have a variety of unforeseen and unwanted consequences.

8. Empowering and devolving responsibility for the development and monitoring of safety metrics is essential

Other industries have recognised the need to empower managers, supervisors and operational staff to develop safety metrics suitable for their specific operations. In future healthcare regulators, national agencies and commissioners of services need to be flexible and allow clinical units to develop bespoke measures relevant to their clinical context. Similarly, healthcare managers need to have a flexible approach when developing safety measures. Enabling clinical units to adapt measures so that they are relevant to their specific clinical context is vital to avoid clinicians becoming disenfranchised. The nuclear industry has a goal-setting approach that devolves responsibility to demonstrate safety to industry companies. The current approach of some healthcare regulators is highly prescriptive, rather than goal setting. We need to move towards a goal-setting approach in which regulators and managers set goals and standards that require organisations to demonstrate that their care is safe but allow some flexibility in how this is achieved. Organisations need to be able to answer the question: 'is healthcare getting safer across your organisation and what measures do you have to show this?'

9. Collaboration between regulators and the regulated is critical

In healthcare, one potential risk to the evolution of safety measurement is fragmentation of key safety information across multiple national and local stakeholders. The NHS has a number of regulators (unlike the aviation and nuclear industries where there is a single regulator) and numerous other government stakeholders who are custodians of safety information. The net effect of this fragmentation is that producing single source safety measurement reports that triangulate data from many safety metrics (like those cited for the oil and gas and mining industries) relies on the collaboration of a broad range of stakeholders. Furthermore, even if this collaboration were achieved, differences between local NHS organisations (for example, in the grading of harm on incident reports) would make meaningful benchmarking across organisations difficult. We also believe that the multiplicity of regulators in the NHS and the fragmented approach to regulation is potentially a threat to safety. Huge resources are consumed in meeting external demands to the detriment of the critical activities of monitoring, anticipation and, above all, improvement. Worse, equating safety with satisfying the regulators provides false reassurance and allows organisations to miss glaring safety issues simply because they fall outside the regulatory framework.

10. Beware of perverse incentives

Some types of measurement introduce perverse incentives that can lead to 'ticking the box' or behaviour that circumvents the original purpose of the safety measure. That is to say, certain safety measures create behavioural side effects where managers and operators demonstrate that they can meet a target, but they do so in a way that undermines the intended purpose of the measure. Where financial penalties are imposed if a healthcare organisation exceeds a threshold on a given safety indicator, this may promote under-reporting by clinical teams. In obstetrics, some health authorities have imposed a threshold target for perineal tears. If the target is exceeded, financial penalties are imposed. This type of performance management approach promotes under-reporting or encourages clinicians and hospital managers to focus on reducing one type of harm, as opposed to implementing a more holistic approach to measure, monitor and implement interventions for all potential types of harm.

Section Four: International Direction

This section describes international direction in relation to patient safety classification and open disclosure.

The World Health Organisation

The World Health Organisation (WHO) is developing an International Classification for Patient Safety (ICPS), a taxonomy for patient safety in order to promote greater standardisation of terminology and classification. The purpose of the ICPS is to enable categorisation of patient safety information using standardised sets of concepts with agreed definitions, preferred terms and the relationships between them. The WHO aims to complete this work in 2015.

The ICPS is not yet a complete classification. It is a conceptual framework for an international classification which aims to provide a reasonable understanding of the world of patient safety and patient concepts to which existing regional and national classifications can relate.

The tables and WHO conceptual framework can be seen in Annex G.

The Joint Commission on Accreditation and Healthcare Organisations

In the United States, The Joint Commission on Accreditation and Healthcare Organisations (JCAHO) developed a Patient Safety Event Taxonomy with five primary classification domains; impact, type, domain, cause, and prevention / mitigation.

The Joint Commission's activity includes the review of organisations' response to sentinel events. A sentinel event is similar to the NHS term 'serious incident' and is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and response.

The table of sentinel events is found in Annex H.

Canadian Apology Act

The Apology Act (2009) that came into force on allows individuals and public organisations to apologise for a mistake or wrongdoing without fear that the apology will be used adversely against them in civil court proceedings.

According to the Act, "apology" means an expression of sympathy or regret, a statement that a person is sorry or any other words or Actions indicating contrition or commiseration, whether or not the words or Actions admit fault or liability in connection with the matter to which the words or Actions relate.

This new dispute resolution tool provides that an apology made by or on behalf of a person in relation to any matter, does not constitute an admission of fault or liability by the person. Such an

apology is therefore not admissible in any civil, administrative proceeding or arbitration as evidence of the fault or liability of any person in relation to that matter. The Act is seen as part of a growing movement towards accountability and transparency in the Canadian health care system.

Australian Commission for Quality and Safety

The Australian Commission for quality and Safety Framework for Open Disclosure is similar to the NPSA's Being Open Framework however it has benefited from an update in 2013 and has some excellent flow charts. It also distinguishes between a low level response and a high level response depending upon the level of harm.

The Framework comes with multiple resources found at http://www.safetyandquality.gov.au/our-work/open-disclosure/implementing-the-open-disclosure-framework/

Denmark – Protection for the reporter

In 2003 Denmark created an *Act on Patient Safety* in the Danish Health Care System which included the requirement to report 'adverse events' and for those who report to be protected from discipline, as stated below:

- A health care professional, who becomes aware of an adverse event in connection with a patient's treatment or stay in a hospital, shall report such event
- Reports on adverse events, which may be attributed to specific individuals, may without the consent of the patient or the involved health care personnel be exchanged within the group of people who locally, within the county council will review the incident, and may be passed on to clinical databases and other registers where health information is recorded with a view to documentation and quality development within the patient safety area
- County councils shall not disclose information about the reporting health care professional's identity to anybody except relevant people reviewing the incident
- A health care professional reporting an adverse event shall not as a result of such reporting be subjected to disciplinary investigations or measures by the employing authority, supervisory reactions by the National Board of Health or criminal sanctions by the courts.

The University of Michigan's Early Disclosure and Offer Program

In late 2001 and early 2002, the University of Michigan (UMHS) changed the way its health system responded to patient injuries, applying what has become known as the Michigan Model and has since been described as an early disclosure and offer program. The UMHS' approach was designed to promote patient safety through the principles of honesty, transparency, and accountability.

The program was informed by two central observations:

- honesty is indispensable for safety improvement
- a short-term focus on financial risk impedes long-term improvement

The view of the disclosure and offer system includes:

- compensating patients quickly and fairly when inappropriate medical care causes injury
- communicating openly with patients about error(s)
- supporting staff vigorously when appropriate care has been provided
- reducing future injuries and claims through application of knowledge garnered through the discovery process

In 2013 the University of Michigan evaluation states that there are fewer claims; Kachalia and colleagues found in 2010 that the rate of new claims at UMHS has decreased from approximately seven per 100,000 patients to fewer than five. The rate of lawsuits has declined from 2.13 suits per 100,000 patients per month, to roughly 0.75. The median time from claim to resolution has dropped from 1.36 to 0.95 years.

Further information can be found at: http://www.uofmhealth.org/michigan-model-medical-malpractice-and-patient-safety-umhs

Section Five: Being Open – Open Disclosure

Informed Consent

Consideration will need to be given to the process of informed consent and whether it involves a discussion about patient safety and patient safety incidents as well as the information about the risks and benefits of a proposed therapy and allows the patient to decide whether the treatment and therapy will be undertaken.

An 'informed consent' is the consent of the patient after he has been fully informed, by the physician proposing the treatment or procedure, of the risks, benefits, and alternatives. Failure to obtain informed consent prior to surgery or administration of treatment may result in legal liability.

In law, the principle that a physician has a duty to disclose what a reasonably prudent physician in the medical community, in the exercise of reasonable care, would disclose to his or her patients about whatever risks of injury might be incurred from a proposed course of treatment, testing, or research. A patient, exercising ordinary care for his or her own welfare, and faced with a choice of undergoing the proposed or alternate treatment, testing, or research, or none at all, may then intelligently exercise judgment by reasonably balancing the probable risks against the probable benefits.

NPSA - Being Open

The framework and principles for Being Open were set out in Seven Steps to Patient Safety and then further developed into a Patient Safety Notice in 2005 followed by a Patient Safety Alert in 2010.

Seven Steps described the actions to take related to investigating incidents:

> No harm: Not usually contacted or involved in investigations
>
> Low harm: Discussions to be held between staff providing patients care and the patient / relatives or carers
>
> Moderate, Severe and Death: Higher level of response and the organisation's being open policy should be implemented

The guidance reiterates the following key requirements for openness and transparency:

- All healthcare is reliant on effective communication and information sharing. Saying sorry, providing detailed information about what happened, explaining what changes will be made to prevent a similar event in the future
- An apology has to be a genuine expression of being sorry for what has happened – the words 'I am sorry' should form part of the apology as a way of conveying genuine concern and compassion

- Informing patients when things go wrong should be a matter of common practice as part of the process of providing healthcare. It is a process rather than a single conversation and is essential in order to re-establish trust and confidence when things have gone wrong

- Being open and patient engagement should be promoted by those registering, regulating and commissioning healthcare together with those responsible for the training of healthcare professionals including the training for medical and nursing students

- When developing and implementing a policy for being open it should take into account that each patient and each patient safety incident is unique; it will require flexibility to ensure it is effective and meets the needs of each individual patient, their families and carers

Safety First

In 2006 the Department of Health conducted a review of patient safety in England which culminated in a report published in December 2006.

Recommendation 12 of Safety First stated 'All NHS organizations should develop and implement local initiatives to promote greater openness with patients and their families when things go wrong and to provide required support.' Professor Albert Wu was commissioned by the National Patient Safety Forum to conduct a review of the national guidance and programmes on 'being open' to identify barriers that prevent open communication with patients, to identify successful examples of local and international strategies to overcome those barriers, and to identify strategies that England might develop in the future.

Prof Wu suggested six options for future steps.

- (1) Patients: Local NHS organizations and other organizations treating NHS patients should have in place visible arrangements to ensure that all NHS patients are made aware about Being Open and what it could mean to them.

- (2) Clinicians: Local NHS organizations and other organizations treating NHS patients should identify three or more experienced clinicians ("three wise men or women") trained in Being Open to support fellow clinicians in dealing with adverse incidents and Being Open.

- (3) Patient Liaison Services: Local NHS organizations and other organizations treating NHS patients should have patient liaison services that support patients, including on the spot help to those in hospital, and work with clinicians to promote Being Open, thereby providing an alternative route to expressing concerns.

- (4) Boards of Directors: The Boards of Directors of local NHS organizations and other organizations treating NHS patients should ensure that Being Open is supported by non-punitive local policy, training for front-line health care staff, administrative and other relevant staff.

- (5) NHS Litigation Authority, Medical Defence Union & Medical Protection Society: NHS Litigation Authority, Medical Defence Union and MPS should review current practices to ensure that their staff provides unambiguous advice to health care staff on Being Open.

- (6) National Patient Safety Agency: The National Patient Safety Agency should consider a relaunch of Being Open, providing Being Open training to a broader group of health care staff, and convening a stakeholder meeting to develop strategies.

No harm and near misses and open disclosure

Guidance in the Australian Commission for Quality and Safety 'Open Disclosure Framework states that for no-harm incidents, clinicians must be certain that no harm has actually occurred. The only way to be certain of the absence of harm is to discuss the incident with the patient, their family and carers, which will require acknowledgement that an incident occurred. However it acknowledges that indiscriminate disclosure of near misses and no-harm incidents is not feasible.

In the case of a near miss or no harm incident that disclosure is discretionary based on whether it would be benefit the patient from knowing or whether a reasonable person would want to know about the circumstances. For example if a patient avoids being given a medication intended for someone else with a similar or identical name, although the medication was not given it may be prudent to discuss this kind of near miss to ensure the patient is aware of the risks in the future. Also if a patient is aware of a new miss an explanation may alleviate concerns and maintain trust.

The following questions can be used to guide such decisions.

> Will the distress or psychological harm of disclosing the information outweigh the benefit that could feasibly be achieved by disclosure?
>
> Will disclosure reduce the risk of future incidents?
>
> Will disclosure maintain patient, family and carer trust in the service?

Responsibility for incidents that originated elsewhere

An incident may have occurred in a practice or an organisation other than that in which it is identified. With an increasing proportion of care provided in the community setting, the mechanisms for responding to incidents that occurred elsewhere are important.

However there is very little guidance on how best to respond to this. The literature on the subject suggests the following good practice:

- Patients, their families and their carers needs come first; they should not be treated badly because either responsibility is not known or there is a dispute between parties
- The individual who first identifies the possibility of an earlier adverse event should notify the personnel responsible for clinical risk in their organisation
- The clinical risk personnel should establish whether the adverse event has already been recognised in the organisation in which it occurred and if the process of open disclosure has already commenced elsewhere and if any reviews or investigations are in progress
- If the open disclosure process has not already commenced in the other organisation, the process should be initiated after consultation, and in collaboration with the other practice or organisation.

- Individuals should be trained to talk to other colleagues as they are to talk to patients, their families and carers
- Ideally the healthcare provider or organisation involved in the patient safety incident should lead the disclosure process. The thorough clinical review of the incident and the disclosure process should occur, where possible, in the health service organisation where the incident took place
- Preferably representatives from both areas should work together

Section Six: Annexes

Annex A Examples of incidents per NRLS grade

'Seven steps' definitions of harm from patient safety incidents	Examples
No harm - Impact prevented: Any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care.	A healthcare assistant was about to give a normal diet to a patient who needed pureed food, but was stopped by a colleague just in time.
No harm - Impact not prevented: Any patient safety incident that ran to completion but no harm occurred to people receiving NHS funded care.	A patient in a community hospital was given another patient's medication in error. However, as the medication was aspirin and the patient had no contraindications, no harm resulted.
Low: Any patient safety incident that required extra observation or minor treatment (defined as first aid, additional therapy, or additional medication. It does not include any extra stay in hospital or any extra time as an outpatient, or continued treatment over and above the treatment already planned. Nor does it include a return to surgery or re-admission) and caused minimal harm, to one or more persons receiving NHS-funded care.	A patient's foot was caught in a wheelchair footplate when a porter was taking them to the discharge lounge. This caused a bruise. A patient had a reaction to antiseptic wash used on their skin and developed an itchy rash. They needed to take antihistamines for a few days.
Moderate: Any patient safety incident that resulted in a moderate increase in treatment (defined as a return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another area such as intensive care as a result of the incident) and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care.	A patient fell in an older people's mental health unit, and had a laceration to their forehead. They were transferred by ambulance to A&E where they needed one suture. A patient arrived for planned surgery but had not been given the correct advice to discontinue their Warfarin treatment. The surgery had to be postponed. A patient developed a small grade 2 pressure ulcer during an admission to treat an acute cardiac problem. Although they were now fully mobile, they need district nursing visits after discharge home to check and dress the ulcer until healing was complete two weeks later.

'Seven steps' definitions of harm from patient safety incidents	Examples
	A patient's DVT was missed by their GP. Because of the delay, they experienced increased pain and swelling and difficulty walking. When they contacted their GP again and the DVT was diagnosed, the late diagnosis meant they needed a short spell of inpatient treatment rather than outpatient management. A mother had significant post-partum haemorrhage after a difficult delivery, and there was some delay in obtaining blood for transfusion. She needed treatment in the high dependency unit for 24 hours before making a full recovery.
Severe: Any patient safety incident that appears to have resulted in permanent harm (directly related to the incident and not related to the natural course of the patient's illness or underlying condition and defined as permanent lessening of bodily functions, sensory, motor, physiologic or intellectual, including removal of the wrong limb or organ, or brain damage) to one or more persons receiving NHS-funded care.	An x-ray was taken when a patient had a chest infection. The x-ray report suggested there were signs of a possible lung lesion and the x-ray should be repeated once the chest infection was cleared. Through communication failures, this did not happen, and eighteen months later the patient was found to have lung cancer. Their chances of survival were believed to have been significantly reduced by the delay. An older patient fractured their hip in a fall. Given their age and other health conditions, they are unlikely to regain the mobility they had before the accident, and will need 24 hour care.
Death: Any patient safety incident that directly resulted in the death of one or more persons receiving NHS funded care. The death must relate to the incident rather than to the natural course of the patient's illness or underlying condition.	A patient on a mental health unit committed suicide after lapses in risk assessment and observation. An expectant mother who rang the maternity unit to report possible blood loss and reduced fetal movements was given inappropriate reassurance rather than asked to come for assessment. The baby was later stillborn.

Annex B National Patient Safety Agency Guidance

Term	National Patient Safety Agency Classification for Patient Safety
Clinical Risk	Patient Safety: The identification, analysis and management of patient related risks and incidents, in order to make patient care safer and minimise harm to patients
Adverse incident Adverse event Clinical incident Critical incident Medical error Clinical error Medical mistake	Patient Safety Incident: Any unintended or unexpected incident(s) that could have or did lead to harm for one or more persons receiving NHS funded healthcare Notes: To capture all levels of severity – low harm, moderate harm, severe harm, death Terms such as adverse, error, or mistake suggest individual causality and blame. Medical error in particular suggests the main cause is the medical profession Adverse events (AEs) are still used to describe medication incidents by a number of organisations
Sentinel event – used by the Joint Commission in the US Serious Untoward Incident Serious Incident	Patient Safety Incident: Any unintended or unexpected incident(s) that could have or did lead to harm for one or more persons receiving NHS funded healthcare Notes: The general definition was to be used with the level of severity graded as severe harm, or death however this didn't really take off as the vast majority of the NHS still uses the term Serious Untoward Incident or Serious Incident abbreviated to SUI or SI
Near miss, close call	Prevented Patient Safety Incident: Any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to patients receiving NHS funded healthcare Notes: Near miss was introduced into healthcare in the mid 1990s, having previously applied to accidents usually related to transport Applies to level of severity 'no harm' however the NRLS has a significantly large number of no harm incidents reported which in theory implies that there are a correspondent large number of near misses. In reality these are rarely the true definition of a near miss

Old terms	National Patient Safety Agency grading of patient safety incidents
None/ insignificant	No harm: impact prevented – any patient safety incident that had the potential to cause harm but was prevented resulting in no harm to people receiving NHS funded care impact not prevented - any patient safety incident that ran to completion but no harm occurred to people receiving NHS funded care
Low/minor	Low: Any patient safety incident that required extra observation or minor treatment (first aid, additional therapy, additional medication) and caused minimal harm
Moderate	Moderate: Any patient safety incident that resulted in a moderate increase in treatment (return to surgery, unplanned readmission, prolonged episode of care, extra time in hospital) and which caused significant but not permanent harm
Severe/major	Severe: Any patient safety incident that appears to have resulted in permanent harm (permanent lessening of bodily functions, sensory, motor, physiologic or intellectual, including removal of wrong limb or organ or brain damage)
Death/catastrophic	Death: Any patient safety incident that directly resulted in the death (related to the incident rather than to the natural course of the patient's illness or underlying condition) of one or more persons

Level of harm	Example of these as incidents
No harm Impact prevented	A patient is collected for theatre, as he is leaving the ward another nurse recognises that the wrong patient is in the bed and another patient with the same name should be taken – this is corrected – no harm caused A GP prescribes too much medication which is picked up by the dispensing pharmacist and the prescription is referred back to the GP
No harm Impact not prevented	Normal saline infused in two hours instead of four due to wrong setting of the infusion pump – no harm caused Patient given another patients medication – however the medication was identical to their own – no harm caused
Low harm	A patient trips and falls in the hospital corridor resulting in a wound which requires a dressing and extra observations for a few hours A patient receives a bruise from a 'towel clip' during surgery A patient is given one dose of an opiod related drug which leads to a mild reaction (vomiting and fatigue) – patient is known to react to a variety of medications – patient recovers after 24 hours
Moderate harm	Operation cancelled which leads to deterioration and a longer stay in hospital and recovery delayed Patient receives the wrong blood, the complications of which result in the need for treatment, extra stay in hospital and recovery delayed Patient receives opiods despite being allergic to them and suffers a significant reaction; their blood pressure drops and their condition deteriorates as they become drowsy and incoherent – additional treatment to raise their blood pressure is required, their stay is prolonged as a result
Severe harm	Perforation of bowel during surgery requiring colostomy and subsequent operations. Patient suffers hypoxia as a result of significant haemorrhage leading to brain damage Removal of wrong organ, wrong limb or operation on wrong site Patient suffers cardiac arrest as a result of an (known allergy) adverse reaction to medication resulting in brain damage A newborn baby with an inborn error of metabolism fails to be screened for phenylketonuria resulting in irreversible brain damage Patient incurs an extravasation injury (soft tissue burn) causing irreversible scarring and permanent damage to tendons in the hand
Death	Wrong blood transfused leading to multi-organ failure and a fatal cardiac arrest Patient allergic to penicillin administered dose which leads to severe anaphylaxis and a fatal cardiac arrest Patient with chest pains asked to wait in clinic / casualty – goes for a walk and suffers a fatal myocardial infarction in the car park

Annex C Reporting to the Care Quality Commission Regulations

The following sets out the requirements for English NHS trusts to inform the Care Quality Commission of the death of a 'person using the service'.

The NHS Trust must report the death of a 'person using the service' that occurred:

- While the service was being provided
- That was a consequence of the service being provided; and
- Was not caused by an illness or condition that was being appropriately treated

English NHS providers must submit notifications under 18F to the Care Quality Commission by sending them to the NPSA. They must not be sent to the Care Quality Commission direct. **Providers that are not English NHS trusts** - 18G All providers that are NOT English NHS trusts inform the Care Quality Commission without delay of ALL deaths of a person using the service where they die while receiving, or as a result of, the care, treatment or support provided by the service.

Regulation 16 of the Care Quality Commission (Registration) Regulations 2009 Notification of death of service user

(1) Except where paragraph (2) applies, the registered person must notify the Commission without delay of the death of a service user—

(a) whilst services were being provided in the carrying on of a regulated

activity; or

(b) as a consequence of the carrying on of a regulated activity.

(2) Subject to paragraph (4), where the service provider is a health service body, the registered person must notify the Commission of the death of a service user where the death—

(a) occurred—

(i) whilst services were being provided in the carrying on of a regulated activity, or

(ii) as a consequence of the carrying on of a regulated activity; and

(b) cannot, in the reasonable opinion of the registered person, be attributed to the course which that service user's illness or medical condition would naturally have taken if that service user was receiving appropriate care or treatment.

(3) Notification of the death of a service user must include a description of the circumstances of the death.

(4) Paragraph (2) does not apply if, and to the extent that, the registered person has reported the death to the National Patient Safety Agency.

(5) This regulation does not apply where regulation 17 applies.

Regulation 17 of the Care Quality Commission (Registration) Regulations 2009

Notification of death or unauthorised absence of a service user who is detained or liable to be detained under the Mental Health Act 1983

(1) The registered person must notify the Commission without delay of the death or unauthorised absence of a service user who is liable to be detained by the registered person—

(a) under the Mental Health Act 1983 ("the 1983 Act"); or

(b) pursuant to an order or direction made under another enactment (which applies in relation to England), where that detention takes effect as if the order or direction were made pursuant to the provisions of the 1983 Act.

(2) Notification of the death of a service user must include a description of the circumstances of the death.

(3) In this regulation—

(a) references to persons "liable to be detained" include a community patient who has been recalled to hospital in accordance with section 17E of the 1983 Act, but do not include a patient who has been conditionally discharged and not recalled to hospital in accordance with section 42, 73 or 74 of the 1983 Act;

(b) "community patient" has the same meaning as in section 17A of the 1983 Act;

(c) "hospital" means a hospital within the meaning of Part 2 of that Act; and

(d) "unauthorised absence" means an unauthorised absence from a hospital.

Regulation 18 of the Care Quality Commission (Registration) Regulations 2009

Notification of other incidents

(1) Subject to paragraphs (3) and (4), the registered person must notify the Commission without delay of the incidents specified in paragraph (2) which occur whilst services are being provided in the carrying on of a regulated activity, or as a consequence of the carrying on of a regulated activity.

(2) The incidents referred to in paragraph (1) are—

(a) any injury to a service user which, in the reasonable opinion of a health care professional, has resulted in—

(i) an impairment of the sensory, motor or intellectual functions of

the service user which is not likely to be temporary,

(ii) changes to the structure of a service user's body,

(iii) the service user experiencing prolonged pain or prolonged

psychological harm, or

(iv) the shortening of the life expectancy of the service user;

(b) any injury to a service user which, in the reasonable opinion of a health care professional, requires treatment by that, or another, health care professional in order to prevent—

(i) the death of the service user, or

(ii) an injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph (a);

(c) any request to a supervisory body made pursuant to Part 4 of Schedule A1 to the 2005 Act by the registered person for a standard authorisation, including the result of such a request;

(d) any application made to a court in relation to depriving a service user of their liberty pursuant to section 16(2)(a) of the 2005 Act;

(e) any abuse or allegation of abuse in relation to a service user;

(f) any incident which is reported to, or investigated by, the police;

(g) any event which prevents, or appears to the service provider to be likely to threaten to prevent, the service provider's ability to continue to carry on the regulated activity safely, or in accordance with the registration requirements, including—

(i) an insufficient number of suitably qualified, skilled and experienced persons being employed for the purposes of carrying on the regulated activity,

(ii) an interruption in the supply to premises owned or used by the service provider for the purposes of carrying on the regulated activity of electricity, gas, water or sewerage where that interruption has lasted for longer than a continuous period of 24 hours,

(iii) physical damage to premises owned or used by the service provider for the purposes of carrying on the regulated activity which has, or is likely to have, a detrimental effect on the treatment or care provided to service users, and

(iv) the failure, or malfunctioning, of fire alarms or other safety devices in premises owned or used by the service provider for the purposes of carrying on the regulated activity where that failure or malfunctioning has lasted for longer than a continuous period of 24 hours.

(3) Paragraph (2)(f) does not apply where the service provider is an English NHS body.

(4) Where the service provider is a health service body, paragraph (1) does not apply if, and to the extent that, the registered person has reported the incident to the National Patient Safety Agency.

(5) In this regulation—

(a) "the 2005 Act" means the Mental Capacity Act 2005;

(b) "abuse", in relation to a service user, means—

(i) sexual abuse,

(ii) physical or psychological ill-treatment,

(iii) theft, misuse or misappropriation of money or property, or

(iv) neglect and acts of omission which cause harm or place at risk of harm;

(c) “health care professional” means a person who is registered as a member of any profession to which section 60(2) of the Health Act 1999 applies;

(d) “registration requirements” means any requirements or conditions imposed on the registered person by or under Chapter 2 of Part 1 of the Act;

(e) “standard authorisation” has the meaning given under Part 4 of Schedule A1 to the 2005 Act;

(f) “supervisory body” has the meaning given in paragraph 180 (in relation to a hospital in England) or paragraph 182 (in relation to a care home) of Schedule A1 to the 2005 Act;

(g) for the purposes of paragraph (2)(a)—

(i) “prolonged pain” and “prolonged psychological harm” means pain or harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days, and

(ii) a sensory, motor or intellectual impairment is not temporary if such an impairment has lasted, or is likely to last, for a continuous period of at least 28 days.

Annex D Department of Health – Doing Less Harm

Table 1 Examples of 'adverse patient' incidents (Doing Less Harm)

Type	Example
General	Delay in diagnosis, wrong diagnosis or incorrect patient assessment Administration of the wrong drug, or incorrect quantity of the right drug Health records not available during a consultation Communication problems between patient and health care professional Health care associated infection Adverse drug reaction Defective medical device or medicines
Acute	Removal of wrong kidney Female patient with missed period and severe abdominal pain is not diagnosed as having an ectopic pregnancy. The ectopic ruptures and a massive transfusion in required Patient known to be allergic to penicillin but notes not checked and patient not questioned. Patient suffers respiratory arrest Examination of a patient's hand, which had been trapped in machinery, and nerve damage missed Blood specimen obtained for cross matching from the wrong patient. Subsequent transfusion of the right patient results in a massive reaction Urinary catheter infection
Mental Health	Patient absconscion Patient commits, or attempts to commit suicide or homicide Self harm
Ambulance	Delayed treatment, or delayed transfer to an appropriate Accident & Emergency unit Moving a road traffic accident (RTA) patient without appropriate assessment and immobilising the cervical vertebrae
Primary and Community Care	Dental extraction of the wrong tooth Large bleed following dental extraction on a patient on long term anticoagulant therapy Death of a dental patient under general anaesthetic Phenol burn to a patient's foot during removal of a toenail Childhood immunisation – injections given despite parents signing a consent form not agreeing to immunisation Unexpected death of a patient in a general practice surgery or clinic Anaphylactic reaction to immunisation Perforation of colon during a sigmoidoscopy Abnormal cervical smear results not notified to patient Insufficient specimen obtained when performing a cervical smear Incorrect repeat prescription for a patient on long term antihypertensives Prescription of medication where there are definite contraindications to medication the patient is already taking Incorrect dispensing of life threatening drug (pharmacist). Not picking up an eye condition such as glaucoma or a child's amblyopia (optician) Delay in diagnosis

Table 2 Grading of incidents in *Doing Less Harm*

Number	Description of harm / impact	Colour
1	None or near miss	Green
2	Minor	Yellow
3	Moderate	Amber
4	Major	Red
5	Catastrophic	Red

Table 3 Definitions in D*oing Less Harm*

Descriptor	Actual impact on patient(s)	Numbers (people)	Actual impact on organisation
Catastrophic	Death Including unexpected death of a patient whilst under the direct care of a health care professional Death of a patient on GP or health centre premises Suicide or homicide by a patient being treated for a mental health disorder Known or suspected case of health care associated infection which may result in death	>50	International adverse publicity Severe loss of confidence in organisation Extended service closure Litigation value >£1m
Major	Major permanent harm Procedures involving the wrong patient or body part Haemolytic transfusion reaction Retained instruments or other material after surgery requiring reoperation Known or suspected case of health care associated infection which may result in major permanent harm Rape Infant abduction	16-50	National adverse publicity Major loss of confidence in the organisation Temporary service closure Litigation £500k-£1m Increased length of stay >15 days Increased level of care >15 days
Moderate	Semi-permanent harm (up to one year) Known or suspected healthcare associated infection which may result in semi-permanent harm	3-15	Local adverse publicity Moderate loss of confidence in the organisation Litigation £50k to £500k Increased length of stay 8-15 days Increased level of care 8-15 days

Descriptor	Actual impact on patient(s)	Numbers (people)	Actual impact on organisation
Minor	Non-permanent harm (up to 1 month) Known or suspected healthcare associated infection which may result in non-permanent harm	1-2	Litigation <£50k Increased length of stay 1-7 days Increased level of care 1-7 days
None	No obvious harm	n/a	Minimal impact No service disruption

Annex E Health and Safety Executive

Table 7: Health and Safety Executives Definitions

Type	Description
Deaths	All deaths to workers and non-workers must be reported if they arise from a work-related accident, including an act of physical violence to a worker. Suicides are not reportable, as the death does not result from a work-related accident.
Major incident	A major incident is defined as a significant event, which demands a response beyond the routine, resulting from uncontrolled developments in the course of the operation of any establishment or transient work activity. The event may either cause, or have the potential to cause, either: Multiple serious injuries, cases of ill health (either immediate or delayed), or loss of life, or Serious disruption or extensive damage to property, inside or outside the establishment Events which, taken in isolation, may not warrant classification as major incidents, may do so when considered together. Significance is determined by the severity of the incident, the degree of public concern and the nature and extent of HSE's previous involvement with the duty holder(s).
Specified Injuries to report to RIDDOR	A fracture, other than to fingers, thumbs and toes Amputation of an arm, hand, finger, thumb, leg, foot or toe Permanent loss of sight or reduction of sight Crush injuries leading to internal organ damage Serious burns (covering more than 10% of the body, or damaging the eyes respiratory system or other vital organs) Scalpings (separation of skin from the head) which require hospital treatment Unconsciousness caused by head injury or asphyxia Any other injury arising from working in an enclosed space, which leads to hypothermia, heat-induced illness or requires resuscitation or admittance to hospital for more than 24 hours
Reportable dangerous occurrences	Dangerous occurrences are certain, specified 'near-miss' events (incidents with the potential to cause harm.) Not all such events require reporting. There are 27 categories of dangerous occurrences that are relevant to most workplaces. For example: The collapse, overturning or failure of load-bearing parts of lifts and lifting equipment Plant or equipment coming into contact with overhead power lines Explosions or fires causing work to be stopped for more than 24 hours.

Annex F Examples of local grading systems

Table 8 Ten examples of local grading

Example	Grading
Example: Mental Health	No adverse outcome / no injury Moderate Significant Severe Death
Example: Acute	Green Yellow Orange Red
Example: Acute	None Minor Moderate Major Catastrophic
Example: Mental Health	None / ho harm Low / minimal harm Moderate / short term harm Severe / permanent or long term harm Death caused by the incident
Example: Acute	Near miss No harm Minor / non permanent harm Moderate / semi permanent harm Major / permanent harm Catastrophic / death
Example: Acute	Insignificant / no harm Minor / minor injury / minor illness Moderate / moderate effect or serious injury but not long term Major / major injury leading to long term disability / incapacity Death / hospital closure / national adverse publicity
Example: Community	Low / no injury Minor / low minor harm recovery within 3 days Medium / moderate short term harm High / Severe permanent or long term harm Catastrophic / death
Example: Ambulance	None / negligible Low / minor Moderate Severe / major Catastrophic Death / catastrophic / death caused by the incident
Example: Acute	No adverse outcome Insignificant Minor

Example	Grading
	Moderate Major Unexpected patient death / catastrophic financial or organisational
Example: /Acute	None / no harm caused Low / Low, minimal harm, patient required extra observation or minor treatment Moderation / short term harm, patient required further treatment Severe / permanent or long term harm Death / caused by the patient safety incident

Annex G World Health Organisation International Classification for Patient Safety

Table 9 World Health Organisation International Classification for Patient Safety

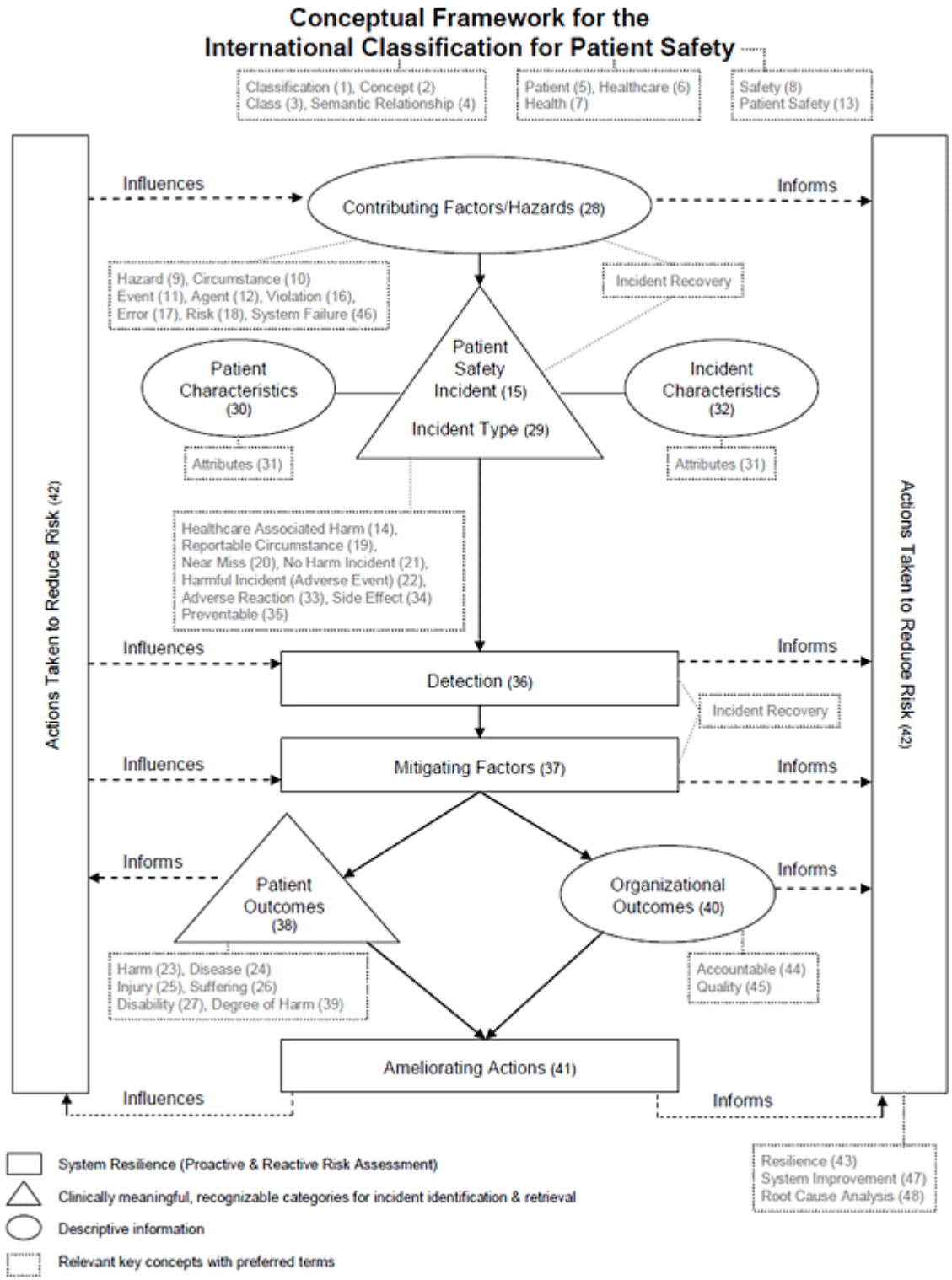
Term	Definition
Patient Safety Incident	An event or circumstance which could have resulted or did result in unnecessary harm to a patient. The use of the word "unnecessary" in this definition recognises that errors, violation, patient abuse and deliberately unsafe acts occur in healthcare. Certain forms of harm, however, such as an incision for a laparotomy, are necessary. Incidents arise from either unintended or intended acts. Errors are, by definition, unintentional, whereas violations are usually intentional, though rarely malicious, and may become routine and automatic in certain contexts
Harmful incident	A patient safety incident that resulted in harm to the patient. Replacing adverse event and sentinel event (e.g., the wrong unit of blood was infused and the patient died from a haemolytic reaction).
No harm incident	A patient safety incident which reached a patient but no discernible harm resulted (e.g., if the unit of blood was infused, but was not incompatible)
Near miss	A patient safety incident that did not reach the patient (e.g., a unit of blood being connected to the wrong patient's intravenous line, but the error was detected before the infusion started). Replaces 'close call'
Safety	Reduction of risk of unnecessary harm to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment.
Hazard	A circumstance, agent or action with the potential to cause harm. A circumstance is a situation or factor that may influence an event, agent or person(s). An event is something that happens to or involves a patient and an agent is a substance, object or system that acts to produce change.
Patient safety	The reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment.
Healthcare-associated harm	Harm arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury

Term	Definition
Error	Failure to carry out a planned action as intended or application of an incorrect plan. Errors may manifest by doing the wrong thing (commission) or by failing to do the right thing (omission)
Violation	Deviation from an operating procedure, standard or rule
Risk	The probability than an incident will occur. Both errors and violations increase risk, even if an incident does not actually occur
Harm	Impairment of structure or function of the body and/or any deleterious effect arising there from, including disease, injury, suffering, disability and death, and may be physical, social or psychological
Injury	Damage to tissues caused by an agent or event
Disease	A physiological or psychological dysfunction
Suffering	The experience of anything subjectively unpleasant. Suffering includes pain, malaise, nausea, depression, agitation, alarm, fear and grief.
Disability	Any type of impairment of body structure or function, activity limitation and/or restriction of participation in society, associated with past or present harm
Contributing factor	A circumstance, action or influence (such as poor task allocation) that is thought to have played a part in the origin or development, or to increase the risk, of an incident. Contributing factors may be external (i.e., not under the control of a facility or organisation), organisational (e.g., unavailability of accepted protocols), related to a staff factor (e.g., an individual cognitive or behavioural defect, poor team work or inadequate communication) or patient-related (e.g., non adherence). A contributing factor may be a necessary precursor of an incident and may or may not be sufficient to cause the incident.

Table 10 Descriptive Terms for categories of incidents and outcomes to use for investigations

Heading	Description
Incident Type	A descriptive term for a category made up of incidents of a common nature grouped because of shared, agreed features, such as "clinical process/procedure" or "medication/IV fluid" incident. Although each incident type concept is distinct, a patient safety incident can be classified as more than one incident type. An incident can be a reportable circumstance, near miss, no harm incident or harmful incident. A reportable circumstance is a situation in which there was significant potential for harm, but no incident occurred (i.e., a busy intensive care unit remaining grossly understaffed for an entire shift, or taking a defibrillator to an emergency and discovery it does not work although it was not needed)
Patient Type	A term to describe patient outcomes contains the concepts that relate to the impact upon a patient which is wholly or partially attributable to an incident. Patient outcomes can be classified according to the type of harm, the degree of harm, and any social and/or economic impact
Descriptive information	1. Patient characteristics; including patient demographics, the original reason for seeking care and the primary diagnosis 2. Incident characteristics; including information about the circumstances surrounding the incident such as where and when, in the patient's journey through the healthcare system, the incident occurred, who was involved, and who reported. 3. Contributing factors/hazards; including the circumstances, actions or influences which are thought to have played a part in the origin or development of an incident or to increase the risk of an incident human factors such as behaviour, performance or communication; system factors such as work environment; and external factors beyond the control of the organization, such as the natural environment or legislative policy. More than one contributing factor and/or hazard is typically involved in a single patient safety incident. 4. Organisational outcomes; including the impact upon an organization which is wholly or partially attributable to an incident. Organizational outcomes indicate the consequences directly to the organization such as an increased use of resources to care for the patient, media attention or legal ramifications as opposed to clinical or therapeutic consequences, which are considered patient outcomes.

WHO Conceptual Framework for the International Classification for Patient Safety



Annex H Joint Commission - Sentinel Events

Table 11 Sentinel event descriptions

Type	Description
Sentinel Event	Any event that has resulted in an unanticipated death or major permanent loss of function not related to the natural course of the patient's illness or underlying condition. A distinction is made between an adverse outcome that is primarily related to the natural course of the patient's illness or underlying condition and a death or major permanent loss of function that is associated with the treatment (including recognised complications) or lack of treatment of that condition, or otherwise not clearly and primarily related to the natural course of the patient's illness or underlying condition.
JCAHO List for Review	Suicide of any patient receiving care, treatment and services in a staffed around the- clock care setting or within 72 hours of discharge Unanticipated death of a full-term infant Abduction of any patient receiving care, treatment, and services Discharge of an infant to the wrong family Rape, assault (leading to death or permanent loss of function), or homicide of any patient receiving care, treatment, and services# Rape, assault (leading to death or permanent loss of function), or homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site at the health care organization Hemolytic (US sp) transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups) Invasive procedure, including surgery, on the wrong patient, wrong site, or wrong procedure Unintended retention of a foreign object in a patient after surgery or other invasive procedures Severe neonatal hyperbilirubinemia (US sp) (bilirubin >30 milligrams/deciliter) Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above the

Type	Description
	planned radiotherapy dose
Major permanent loss of function	Sensory, motor, physiologic, or intellectual impairment not present on admission requiring continued treatment or lifestyle change.
Not for review	Not for review are near miss or close call events - used to describe any process variation that did not affect an outcome but for which a recurrence carries a significant chance of a serious adverse outcome. Such events fall within the scope of the definition of a sentinel event but outside the scope of those sentinel events that are subject to review by The Joint Commission. Also not for review are: • Full or expected return of limb or bodily function to the same level as prior to the adverse event by discharge or within two weeks of the initial loss of said function, whichever is the longer period • Any sentinel event that has not affected a recipient of care (patient, individual, resident) • Medication errors that do not result in death or major permanent loss of function • Suicide other than in an around-the-clock care setting or following elopement from such a setting • A death or loss of function following a discharge against medical advice (AMA) • Unsuccessful suicide attempts unless resulting in major permanent loss of function • Minor degrees of hemolysis (US sp) not caused by a major blood group incompatibility and with no clinical sequelae (US sp)

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