Bowtie Analysis as a Prospective Risk Assessment Technique in Primary Healthcare

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EXECUTIVE SUMMARY

There is widespread interest in the healthcare community in implementing practical approaches to prospectively identifying and managing risk to patient safety. This is the second of two papers based on an assessment conducted by NHS Education for Scotland (NES) to review the potential value of the Bowtie Analysis method (BTA), which is in widespread use in the traditional high-hazard industries, as an approach to prospectively identifying and managing risk in primary healthcare. Previous work concluded that BTA can be readily applied to serious significant events in healthcare. Compared with alternative approaches, Bowtie Analysis is conceptually simpler, easier to implement, and need make no assumptions about the nature and causes of major incidents in a healthcare context. The present paper grounds the previous study in a wider theoretical context, and explores a number of issues affecting the application of Bowtie Analysis to healthcare. The paper proposes a method that can be used following a Bowtie Analysis to identify where to most cost-effectively focus effort to achieve the greatest improvement in the protection provided by the identified controls. There seems no reason why the conclusions shoud be limited to primary care only: the findings are likely ot have relevance across the healthcare communities.
INTRODUCTION

Primary healthcare (Box 1) relies on a wide variety of measures to control against the occurrence of events with the potential to impair the health and/or safety of patients. Variously referred to as “protective measures”, “safeguards”, “precautions”, “checks and balances” and so on, controls can be both formal and informal in nature. Formal controls in primary healthcare include assurance of the professional qualifications and licensing of health professionals, the use of clinical guidelines and protocols to support diagnosis and prescribing, and requirements for independent cross-checking of prescriptions, medications and recommended courses of treatment. Informal controls can range from expectations that clinicians or supporting staff - or even patients themselves - will notice errors or discrepancies in patient records, medication prescriptions and management system elements (such as checking of emergency drugs or equipment and compliance with regulatory obligations). They include expectations that key lessons from incidents will be accurately captured, shared and applied in future, and assumptions that service providers will not be unintentionally motivated or incentivised to cut corners or adopt unsafe practices.

There can be a very wide range of such formal and informal controls in primary healthcare. The importance of knowing what the key controls are, and managing them, is of course not new. In its guidance on assessing clinical risk, NHS England (2007) emphasized the importance of identifying and managing controls “For each hazard identified, it is important to decide whether...appropriate and sufficient controls or contingencies are in place to ensure that the risk is properly controlled”. (p.4). In healthcare, however, controls are rarely subject to formal scrutiny or assessment to determine either whether they are as effective as is believed, whether they are actually in place and functional, or under what conditions they can fail. External scrutiny in NHS Scotland would create significant political challenges, as GPs are independent contractors and manage their own ‘business models’. Primary healthcare is highly dynamic and interactive in terms of responding to demands and capacity issues, work pressure and workload can be heavy (Beasley et al, 2007; McKay et al, 2016; Bowie and Shelley, 2016). Staff generally have limited protected time or expertise to evaluate existing safety management systems or develop improvements. One example of where external assessment does take place however is in NHS England, where the
Care Quality Commission has a formal inspection and regulation role covering aspects of patient safety and avoidable harm.

By contrast, what are often described as the “high hazard” industries – such as nuclear power, chemical manufacturing, onshore and offshore oil and gas exploration, production and distribution, aviation, rail, and shipping — go to significant lengths not only to identify the hazards associated with their activities, but to ensure they have controls in place that are both sufficient and sufficiently effective and reliable to reduce risk to a level that is considered tolerable. In some cases that includes demonstrating that the risk has been reduced to a level that can be shown to be “As Low As Reasonably Practicable” (ALARP). The requirement to carry out such hazard analysis is embedded in regulation both in the UK as well as many other countries. Indeed, in some industries, organisations will not be able to achieve a license to operate unless and until such a demonstration is made to the relevant regulator.

**OBJECTIVES**

This paper is the second of two papers based on an assessment conducted by NHS Education for Scotland (NES) to review the potential value of the Bowtie Analysis method as an approach to prospectively identifying and managing risk in primary healthcare. The assessment identified and evaluated the controls that a sample of primary care professionals thought and expected would be involved in protecting against the risk of a potential primary care “Never Event”. McLeod and Bowie (2018, In press) reported on the details of the assessment and conclusions reached.

The McLeod and Bowie (2018) paper was intended for a clinical and risk management audience, demonstrating how the Bowtie Analysis technique could be applied to significant risk events in primary care but including minimal theoretical consideration. The present paper is intended for safety practitioners and academics: the purpose is to ground the study reported by McLeod and Bowie in a wider theoretical context, and to explore a number of issues affecting the application of Bowtie Analysis to healthcare that would be of limited interest to clinicians.

*Box 1. Characteristics of UK Primary Healthcare Context*
- Primary care professions (e.g. general medical practitioners, community pharmacists, optometrists) are independent contractors to the National Health Service typically working in small heterogeneous practice organisations.
- Relatively unbureaucratic bodies with a high degree of flexibility in how they choose to organise and operate their activities. Consequently, it is a lot easier to change their processes when compared with hospitals which are managed organisations with a relatively high level of bureaucracy and less freedom and flexibility in how they choose to organise themselves.
- Provide a “gatekeeper” role in authorising access to specialist care, hospital care and diagnostic tests.
- Around 90% of all patient healthcare interactions take place in primary care: over 350m patient consultations annually.
- Financed through general taxation and free at the point of delivery.
- Adverse events estimated to occur in around 2% of patient consultations (though research evidence is limited).
- Limited protected time for team-based safety-related learning and improvement.
- Prescription of medication – legislation and guidelines (Polypharmacy is one of the factors behind the high rate of medication-related patient safety incidents, mostly affecting the elderly.)
- General lack of robust technological solutions to reconcile test and radiological results returned to practices.
- Pressure and workload on clinicians can impact on human performance and safety via psychological stress, anxiety, fatigue and motivation. Impaired performance and time pressure can lead to missed diagnoses, incorrect prescriptions or poor treatment decisions.
- Patient management frequently involves both high complexity and high levels of coupling between elements of the healthcare system (Perrow, 1990\(^1\)).

\(^1\) The extent to which a system is complex or linear refers to whether the processes flow in a linear, anticipated fashion or unanticipated interactions between system elements that can have unanticipated consequences.
- Cultural inhibitions against researching and/or reviewing warnings in the presence of patients, compounded by cultural expectations that physicians will have ‘the answer’ during an in-person meeting.
- Patients often have pre-existing ideas about the answer to their conditions derived from friends, web searches, and/or ‘alternative therapy’ proponents. Can be effectively “shopping” for validation/access to a specific treatment. Physicians who contradict patients’ pre-existing ideas may receive negative feedback in surveys and external websites with significant career impact.

PROSPECTIVE HAZARD ANALYSIS IN HEALTHCARE

Previous applications of prospective hazard analysis techniques in healthcare

The traditional high-hazard industries (which, it is worth noting, are heavily engineering-based) go to considerable lengths to ensure they understand the hazards and risks associated with their operations and are proactive in ensuring those hazards are under control and the associated risks are managed at an acceptable level. In many cases the need to be proactive is mandated by regulators or is accepted as standard good practice across the industry.

A variety of tools and techniques have been in widespread use for many years to identify hazards and risks, and to assess and demonstrate how those risks are controlled. Examples of the more widely used methods include Hazard Identification and Operability Studies (HAZID and HAZOP), Process Hazard Analysis (PHA), Failure Mode and Event Tree Analysis (FMEA), Layers-of-Protection Analysis (LOPA), and Bow-Tie Analysis, among others. There is a substantial literature covering such techniques, including expectations of industry regulators as well as good practice guidance published by standards bodies and organisations representing the interests of different industries (see for example Energy Institute, 1999; SAE, 2002; CCPS, 2015). The extent and depth of application of such tools varies across industries, with aviation and nuclear power probably being among the most rigorous and detailed in their use and assurance of such methods. Recent techniques, such as STAMP (Leveson, 2011) and FRAM (Hollnagel, 2012) are challenging the assumptions of linear cause-and-effect in the initiation and development of incidents in complex socio-technical systems that the more traditional techniques rely on.
Healthcare, by contrast, has, to-date at least, made little use of such prospective approaches to identifying and managing risk. A recent collaborative study between engineers, clinicians, and healthcare leaders (Royal Academy of Engineering, 2017) concluded that; “There is the potential for health and care improvement to benefit from the rigour of the engineering approach to systems…” and went on to identify one of the key areas where there is the potential for such benefit as being; “...risk management as a proactive process – the identification of possible opportunities for and threats to a system before they arise is more likely to lead to the delivery of robust and adaptable systems” (p.9).

In 2007, NHS England’s Patient Safety Agency published guidance intended to make the identification and assessment of clinical risk accessible to a broad population of health providers (NHS, 2007). Derived from general practice in risk assessment used in many industries, the guidance was designed to be as simple and practical as possible, avoiding undue complexity to encourage widespread use. For example, the guidance specifically advised users to “Keep risk assessment simple – do not use techniques that are overly complex for the type of risk being assessed” (p. 3). Such guidance is clearly well intentioned, though much research, as well as consideration of many incidents, demonstrates that there is considerably more psychological complexity to identifying risk than is generally realised. Apart from relying on hindsight and experience of what has gone wrong in the past – whether actual incidents or near misses - anticipating what might go wrong can demand a considerable degree of what has been termed “requisite imagination” (Adamski and Westrum, 2003; Fruhen et al, 2013). Despite the availability of such simplified guidance to conducting risk assessments, Wierenga et al (2009) noted that “…experience with systematic risk analysis is still scarce in healthcare…no risk analysis instrument exists that can be used to analyse and visualize risks, causes and consequences of potential adverse events in a prospective manner” (p. 664).

Ward et al (2009) conducted a major study to try to develop a “toolkit” of prospective methods for identifying and assessing hazards in healthcare in the UK. The study reviewed published guidance and standards at both national as well as local (i.e. NHS Trust) levels and conducted interviews with a range of health professionals, both clinical and non-clinical. Despite consistent guidance at national level about the importance of carrying out risk assessments and implementing risk management
systems, knowledge and awareness of methods for conducting prospective hazard analyses was found to be low. By far the most common and widely understood approach relied on the use of risk matrices based on judgments about the likelihood and consequences of different adverse events.

Ward et al did identify some specific cases where prospective methods such as HAZOP, SWIFT (Structured What-If Technique), Event Tree and Fault Tree Analysis had been either studied or applied in healthcare settings. A health-care specific form of Failure Mode and Effect Analysis (HFMEA) developed by the US Veteran’s Administration National Center for Patient Safety (NCPS, 2006) was identified as among the most widely used method. However, it was reported as being time and resource intensive and difficult to carry out the risk assessments.

Shebl et al (2012) explored the validity of the outputs of FMEA when it was applied to the prescribing, administering and monitoring of two antibiotics in a hospital setting. They evaluated four indicators of the validity of FMEA outputs: face, content, criterion and construct validity. Results showed that while face validity of the outputs (i.e. comparison of the process flow developed during the FMEA against real-world practice) was considered to be high, validity of the other three criteria were low. They concluded that “.FMEA’s validity is questionable and thus the absolute promotion of its use in healthcare may be inappropriate” (p.9.). Although Shebl et al did not specifically evaluate the HFMEA variant, they proposed that at least some of the problems they had found with FMEA would also apply to the HFMEA method. They did however see value in using FMEA/ HFMEA to aid multi-disciplinary teams mapping a process of care.

Ward et al (2009) also identified “Barrier Analysis” as a widely used “method” in healthcare, with many references to identifying barriers or defences against risk. However, there appeared to be little or no guidance or description of how a Barrier Analysis should be conducted or used. The National Patient Safety Agency includes what is referred to as a “Barrier Analysis Tool” within the suite of tools it makes available to assist in performing Root Cause Analysis Investigations of incidents. In reality, the NPSA’s Barrier Analysis tool is no more than a table to document existing barriers/controls or defences and to perform a simple assessment of them and how they might be improved. Further, the tool is a reactive, as opposed to a prospective
approach, based on learning from incidents after they have happened, rather than focusing on prevention.

Commenting on the difference between the extensive, routine and often highly detailed use of prospective risk assessment methods in high-hazard industries and what is likely to be needed for use in health care, Ward et al (2009) noted that:

“These methods and approaches have been developed in order to support the control of risks that are already very highly defended… Consequently, it has become very important within the nuclear industry and other high-hazard industries to be able to understand the contribution to risk from a broad range of potential failures… Within healthcare, the probabilities of adverse events are not as low, and hence the visibility of those events and of the performance of the defences and barriers against them is greater. This may permit risk assessment within healthcare to avoid the need for the significant levels of granularity applied within the nuclear industry” (p.38).

Recognising differences both in the culture and established practices in safety management between healthcare and high-hazard industries, and therefore the type of approaches to prospective risk analysis that are likely to be appropriate for use in healthcare, Ward et al also noted that:

“Within healthcare there is a less sophisticated approach to assessment of the tolerability of risk….hence the principle objective of risk assessment within healthcare tends to be to ensure that the nature of the risk is understood, and hence that qualitative approaches to risk reduction can be identified and considered.” (p. 39).

A particularly interesting use of the concept of “safety barriers" in healthcare is reported by Mazur et al (2015) in the context of radiation oncology. Mazur et al report on an analysis of the event learning program (also known as the “good catch” programme) running in their department at the University of North Carolina. Based on an analysis of 560 events (including events reaching patients, near misses and unsafe conditions) reported by departmental staff over a nearly 2 year period, Mazur et al were able to calculate the utility of the various “safety barriers" built into their clinical processes (such as treatment planning and approval, Quality Assurance checks and treatment checks). By calculating the ratio of the number of events caught at each step of the processes to the number of events presented to that step, they were able
to put a numerical value on the performance of the safety barriers at each step. The ability to evaluate the effectiveness of their safety barriers in this way however was entirely dependent on the years of effort that had been put into developing a culture of Continuous Quality Assurance and learning in the department. It was also dependent on having an extremely clear process map of all of their clinical practices.

**BOWTIE ANALYSIS**

Perhaps the most conceptually straightforward and increasingly widely adopted technique used in high hazard industries to identify and evaluate controls against major adverse events is the method known as Bowtie Analysis (CIEHF, 2016, de Ruijter and Guldenmund 2016; CCPS, In press). The rapid growth in the use of Bowtie Analysis in recent years has been driven largely by the conceptual simplicity of the approach and the visual representation of the analysis, together with the availability of off-the-shelf and easy-to-use software tools. The UK’s Chartered Institute of Ergonomics and Human Factors (CIEHF) has recently published guidance on the basic elements of good practice in dealing with human and organisational factors in barrier management in general, and Bowties Analysis in particular (CIEHF, 2016). And the Center for Chemical Process Safety (CCPS, In press) has published the first generally agreed statement of what constitutes good-practice in conducting and using Bowtie Analysis in the global chemical and process industries.

Bowtie analyses are usually conducted based on some activity or operation where there is known to be the potential for harm. The diagrams prepared to represent the results of a Bowtie Analysis comprise a number of elements, as illustrated on figure one.
Figure one: Elements of a Bowtie Analysis

- Development of Bowtie diagrams are usually initiated by consideration of some activity or operation where there is known to be the potential for harm.
- Each diagram is associated with a specific hazard: i.e. something with the potential to do harm.
- For each hazard, Bowtie diagrams are developed for a single top event - one of the ways in which the hazard could be released. In principle, there can be multiple top events – and therefore multiple Bowtie diagrams - for a single hazard.
- Threats are events that, if they are not prevented from doing so, are likely to lead to the top event occurring.
- Barriers are the defences against the threat: on the left hand side of the Bowtie, they reduce the likelihood of the threat leading to the top event. On the right hand side, they prevent a top event, if it did occur, from leading to the consequences. Barriers can, in principal be comprised of both technical (i.e. engineered), and human elements.
- Degradation Factors are things that could cause a barrier to fail to do its intended job.
- Safeguards are things that are intended to prevent the degradation factors from interfering with the functioning of the barrier.

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2 Sometimes Controls on the left hand side are referred to as ‘Control measures’, while those on the right hand side are referred to as ‘Recovery Measures’
TYPES OF CONTROLS: BARRIERS AND SAFEGUARDS

In Bowtie Analysis, the term “barrier” refers to those controls that can be relied on to protect against the occurrence of major adverse events. The term is reserved for controls that have been assessed and assured as being sufficiently effective and robust: provided they are properly implemented and maintained they can be relied on to protect against major incidents – they are “barriers”. The Centre for Chemical Process Safety (CCPS, In Press) defines barriers as: “A control measure or grouping of controls that on its own can prevent a threat developing into a top event (prevention barrier) or can mitigate the consequences of a top event once it has occurred (mitigation barrier). A barrier must be effective, independent and auditable” (p.x) This is the way in which the term is usually used in Bowtie Analysis and is the way the term is used in this paper.

It is however worth noting that even in the oil and gas industry, which is sophisticated in terms of use of the concepts of barrier management, and Bowtie Analysis in particular, there are discrepancies in the way “Barriers” are defined and thought of. The Norwegian Petroleum Safety Agency for example (PSA (2017), who are among the most rigorous of any industry regulator in focusing on barriers in safety management systems, adopts a broader definition, where barriers include measures that cannot themselves prevent incidents, but play a role in identifying the development of potential loss situations (equivalent to the “Detect” functionality of Active barriers as described below). The PSA defines barriers as “A measure intended to identify conditions that may lead to failure, hazard and accident situations, prevent an actual sequence of events occurring or developing, influence a sequence of events in a deliberate way, or limit damage and/or loss”. (PSA, 2017 p.9). The PSA however does not specifically recommend Bowtie Analysis or any other technique for identifying and managing barriers: its use of the term “barrier” is therefore more general than the way it is used in Bowtie Analysis.

In Bowtie Analysis, barriers can be either Active or Passive. Active barriers must meet three capabilities: i) able to detect the existence of a threat, ii) able to decide what needs to be done, and iii) able to take the necessary action to block the threat. Passive barriers by contrast provide protection simply by their physical presence in a situation where a hazard exists.
Active barriers commonly rely on a number of different “elements” working together to deliver the functionality needed to Detect, Decide and Act. Barrier “elements” are individual components that all need to function as expected in order to achieve the functionality required of the barrier: none of the elements on their own is sufficient to achieve the barrier performance. A common example of barrier elements is the use of alarms. An alarm alone cannot provide barrier functionality. The barrier is achieved from the combination of the alarm enunciating and a competent person detecting and understanding the meaning of the alarm and then taking whatever action is appropriate: the alarm and human response together form the two elements comprising the barrier “alarm and human response”. To take another example, a condom on its own (once it is in place) would be an example of a passive barrier against sexually transmitted diseases and unwanted pregnancy. The real barrier is Active, comprising two elements working together: human (awareness of the need for protection – the Detect function - and making the decision to use one – the Decide function) and the condom (providing the actual physical barrier – the Act function).

At least three (Independence, Effectiveness and Assurance), and in some approaches to hazard analysis, six or more criteria need to be met for a control to be considered as a full barrier (CIEHF, 2016; CCPS, In press). Many widely used controls – and especially those that rely on people - cannot meet these criteria. Controls that do not meet barrier criteria, but nonetheless play an important role in protecting against incidents, are often referred to as “safeguards”; they are important – indeed, they frequently play a central role in safety management systems - but they cannot achieve the criteria required of full barriers. A key output from Bowtie Analysis therefore is clarity about what are the barriers in any hazardous situation in the full sense of being (at least), Independent, Effective and Auditable, and what are safeguards. Bowtie Analysis also brings understanding of what needs to be done to have confidence that intended barriers are actually in place and can be relied on to perform as expected when they are needed.

The visual display of a Bowtie diagram can imply that barrier identification is the end of the process. In reality it is only an intermediate stage. The analysis is not complete until degradation factors and safeguards have been identified and analyzed. Each barrier element can have its own degradation factors with the ability to degrade or defeat its ability to protect against a given threat. Safeguards are generally considered
as the controls that mitigate the risk posed by these degradation factors. And the risk associated with degradation factors can of course be protected by more than a single safeguard.

THEORETICAL BASIS OF BOWTIE ANALYSIS

There is confusion in the technical literature about the theoretical basis of Bowtie Analysis. Assumptions are frequently made, based on the visual structure of the representation, that Bowtie Analysis assumes a linear, event-driven model of accident causation. A type of model that leading thinkers have long argued are inadequate as a means of understanding the dynamics of modern complex socio-technical systems or the ways they can lead to losses (Perrow, 1999; Leveson, 2011, Hollnagel, 2012). The same arguments can apply to healthcare, both primary and secondary. Marks & Mazur (2015) et al for example, have assessed how the various processes used in the discipline of radiation oncology map onto the concepts of complexity and coupling that are at the heart of Normal Accident Theory (Perrow, 1999).

It is important for the purpose of this paper to recognise that, in adopting the concepts and structures of Bowtie Analysis, no assumptions are being made about the mechanisms and processes that lead to incidents in primary healthcare. This is one of the most significant differences between the use of Bowtie Analysis and techniques such as Failure Modes and Effects Analysis (FMEA) and Event Tree Analysis (ETA). FMEA, ETA and related techniques explicitly assume that adverse events can be modeled as a sequence of linear relationships and causal interactions between system elements. It can be argued that this is one of the principal differences that makes Bowtie Analysis more suitable for use in many healthcare settings than other formal hazard analysis techniques. This is particularly the case where there is both tight coupling and high interactivity between elements of the clinical context surrounding patient care (Perrow, 1990, Marks & Mazur (2015).

It is true that many users of Bowtie Analysis do subscribe to a traditional linear, event-driven model of technical systems and how they fail. It is also true that Bowtie Analysis has been used in ways that directly, indeed sometimes explicitly, aim to identify and assess barriers that are capable of blocking what is modelled as a linear chain of events between underlying “causes”, “human error” and top events (see, for example,
Wierenga et al., 2009; de Ruijter and Guldenmund, 2016). Such an assumption however is neither true nor necessary. Bowtie Analysis, and the understanding of barriers, failure mechanisms and safeguards that it can generate, is neutral in terms of any underlying model of accident causation. It need make no assumption about the mechanisms that might lie on the path between threats and the top events and consequences they can lead to. There is no theoretical reason why a Bowtie model should not be based on a STAMP (Leveson, 2011) or FRAM (Hollnagel, 2012) analysis. For example, if a FRAM analysis raised concern about resonance between functions in the financial services system (Sundström and Hollnagel, 2011), a Bowtie Analysis would identify controls capable of detecting signs of the developing resonance and intervening to dampen them. The threat in this instance would be the unwanted resonance between two or more of the functions. The analysis would also evaluate the quality of the controls to ensure they were capable of providing the protection expected, and would explore how they might fail.

Note also that the core Bowtie Analysis method does not include quantifying the likelihood of any barrier failing when it is needed. Some users of the technique have included quantifying the risk of barrier failure within Bowtie Analysis by combining a Fault Tree Analysis (on the left hand side of the top event) and an Event Tree Analysis (on the right hand-side). de Ruijter and Guldenmund (2016) discuss the difference between quantitative and qualitative uses of Bowtie Analysis. Neither the Centre for Chemical Process Safety (CCPS, In press) nor the Chartered Institute of Ergonomics and Human Factors (CIEHF, 2016) recommend using Bowtie Analysis to quantify the risk of barrier failure.

In summary, when it is done properly, Bowtie Analysis provides a rich understanding of the controls that are expected to be in place, how they can fail, and how they need to be implemented, supported and managed, without having to make any assumptions about the mechanisms or nature of accident causation in complex systems.

**PREVIOUS USES OF BOWTIE ANALYSIS IN HEALTHCARE**

To-date, there have been few published attempts to apply Bowtie Analysis to healthcare. The most comprehensive – although the least well documented - is a set of 17 example “inspirational” Bowties covering 10 patient safety topics in secondary healthcare (Janssen, Winters and Keetlaer-Qi, 2016). The example Bowties were
developed based on the safety themes in a Dutch project (called, in English, the ‘Safety Management System Safety Program’). The web-site describing the project to develop these Bowties however provides no detail of how the Bowties were developed, validated or used.

In their major review assessing risks in pharmacy, Phipps et al (2010) suggest that Bowtie Analysis has potential value through its incorporation of concepts drawn from a variety of risk analysis methods, including Root Cause Analysis, Failure Means and Effects Analysis and the ‘Swiss Cheese’ model of accident causation. Such a view however is based on using Bowtie Analysis in a way that assumes the kind of linear cause-effect relationship underlying incidents discussed in the previous section that many people argue are inappropriate to understanding how incidents occur in complex socio-technical systems such as primary healthcare.

Kerckhoffs et al (2013) reported the use of a Bowtie Analysis to assess risk associated with critical events in an Intensive Care Unit. Their aim was to identify those barriers that were already in place as well as potential additional barriers that could be implemented. In their study they defined hazards in terms of three situations in intensive care that experience had shown were regularly associated with critical incidents; transporting ICU patients around the hospital; unplanned extubation; and a general category of “communication”, selected due to its wide ranging importance for patient care and the anticipation that there would be room for improvement. Drawing on a multi-disciplinary team from nursing and medical staff, and using both face-to-face analysis and input by email, Kerckhoffs et al generated nine Bowtie diagrams covering these three hazardous situations. Their analysis identified a total of eighty-four “barriers” that were not currently implemented, and led to thirty-seven recommendations for improvements. With respect to the eighty-four missing barriers, they noted that “...these barriers were not thought of when protocols were composed or were not part of the usual care” (p. 158).

It is worth noting that Kerckhoffs et al did not use any quality criteria to what they considered as barriers: under the Bowtie terminology defined by the CCPS and CIEHF most if not all of the barriers Kerchoff et al identified would be better considered as safeguards. Nevertheless, their use of Bowtie Analysis was clearly thought to have led to improvements in patient safety in the ICU context.
Kerckhoffs et al. study included gathering feedback from members of the multi-disciplinary team involved about the usefulness and value of the Bowtie Analysis method. Team members especially valued the structured analysis and appreciated the multi-disciplinary approach and the ability to think “out-of-the-box” about potential new barriers. It was also noted both that the analysis needed significantly less time and effort than the alternative Healthcare Failure Mode and Effects Analysis (HFMEA) and that it could be conducted without bringing in a specialist external facilitator.

Abdi et al. (2016) also reported on a Bowtie Analysis conducted as a means of proactively identifying and managing clinical risks in intensive care. In their study, a multi-disciplinary team comprising physicians, nurses and management met 32 times over a period of more than 2 years. Bowties were developed for five hazardous situations in ICU: adverse drug incidents; ventilator-associated pneumonia; catheter-related blood-stream infections; urinary tract infections; and unplanned extubation. In order to provide a comprehensive assessment of the major risks in ICU, Abdi et al. adapted the basic Bowtie Analysis method to include risk assessment and prioritization. They focused heavily on human errors as threats.

Wierenga et al. (2009) adopted an explicit causation model in their assessment of the usefulness of Bowtie Analysis for the prospective analysis of risk in the medication process in a hospital setting in the Netherlands. Using a multi-disciplinary team of physicians, nurses and pharmacists, their study focused on three top events associated with medication: ‘wrong drug’, ‘wrong dose’ and ‘wrong administration’. The study was conducted in two hospitals, with nine, two-hour analysis sessions being held in each hospital. As well as identifying barriers, and assessing how they could be defeated or degraded, the study included a risk assessment (based on the existence of barriers, the number of barriers and the existence of degradation factors) and a prioritization stage (using a risk matrix to assess the frequency and seriousness of possible consequences). The study included gathering qualitative feedback from the participants on the use of the Bowtie method in terms of four criteria; applicability to healthcare; whether it gave comprehensible insight into the situation; whether it influenced awareness of the risk and motivation to address issues; and whether it was capable of identifying underlying systemic causes of potential adverse incidents. Learnings from the first hospital were used to improve the method used in the second hospital. Changes in the second hospital included focusing on fewer top events
considered to have the highest priority, and defining top events such that they were specific to the clinical process involved as well as the type of drug and patient involved.

Based on the learnings from their study, Wierenga et al recommended a twelve step process for carrying out a risk assessment using Bowtie Analysis in healthcare. The evaluation showed that with the changes made for the second hospital – making the top events more specific and focusing on what were assessed as the highest priority threats – the Bowtie method was well received and seemed well suited as a means of proactively assessing and evaluating risk.

In summary, although there have only been a few published previous uses of Bowtie Analysis in healthcare, feedback has been positive in terms of the ease of use and insight generated into what needs to be in place to mitigate risk of serious adverse events.

It is important to recognise that each of the reported applications to-date has deviated in important, and often significant, ways from what is considered good-practice in Bowtie Analysis in the traditional high hazard industries. Most importantly, the term “barrier” has been used loosely, and usually in a way that is synonymous with what the CCPS and CIEHF term “safeguards”: quality criteria that need to be met in high-hazard industries for something to be considered as a barrier (including, at least, Independence, Effectiveness and Auditability) have not been used. Rather, the term barrier has been used to refer to any form of activity or procedure that is thought or hoped to play some role either in preventing adverse events, or in mitigating the consequences of those events if they do occur.

Finally, previous uses of Bowtie Analysis have usually attempted to cover the full scope of prospective risk assessment, up to and including assessing and prioritizing risks. And they have usually been based on an assumption of linear causality between threats and adverse events.

ASSESSMENT WORKSHOP

McLeod and Bowie (2018, In Press) reported on a workshop conducted for NHS Education Scotland (NES) to assess the potential value of using Bowtie Analysis to proactively assess the controls against a ‘Never Event’ in primary healthcare. The workshop was attended by a sample of GPs, Practice Managers and NES clinical
educators and patient safety researchers and focused on one of the “Never Events” arising from previous NES work (de Wet et al, 2014): “Prescribing systemic oestrogen-only hormone replacement therapy for a patient with an intact uterus”.

McLeod and Bowie identified the three potential barriers on the left-hand side of the Bowtie (i.e. prior to the top event of the incorrect prescription being issued), two of them comprising multiple barrier elements:

1. Use of the electronic patient record system, comprising the elements;
   a. Electronic patient record system
   b. A system-generated warning specific to the Never Event
   c. Effective clinician response to the warning
2. Use of a local protocol, comprising the elements
   a. A protocol specific to the Never Event
   b. Clinician competence to understand and use the protocol
3. Clinician competence and experience.

There was a positive reaction to the workshop and a general consensus that primary healthcare could benefit by making use of the Bowtie Analysis method more widely. It was concluded that Bowtie Analysis provided a straightforward approach to engaging frontline care practitioners and managers in identifying and assessing the controls that are expected to be in place to protect against significant events, as well as how those controls can be degraded or defeated, and what is needed to protect against such degradation. The principal benefit of Bowtie Analysis was concluded to lie in the shared awareness and understanding of the nature and characteristics of barriers and the focus it brought on what is needed to ensure controls are implemented and supported in such a way that they are effective in providing the level of protection expected by the responsible authorities.

**ISSUES ARISING**

There are at least three important learnings arising from the McLeod and Bowie (2018) study that need to be addressed if Bowtie Analysis as a technique is to find a place as an effective prospective risk assessment technique in healthcare settings;

1. The nature of hazards in a healthcare context;
2. Defining and locating top events;
3. Prioritising the many potential degradation factors likely to be identified as having the ability to degrade or defeat barriers, and deciding where action can most effectively be focused to reduce the risk they can represent;

THE NATURE OF HAZARDS IN HEALTHCARE

Formally, Bowtie Analysis begins with recognition of the hazards that need to be managed in order for an enterprise to achieve its objectives. Often, hazards are fundamental to the purpose of the enterprise. In the oil and gas industry for example, it is the very flammable/explosive nature of hydrocarbons, as well as their chemical properties, that provides their commercial value. These hazards are unavoidable, and must be managed, not avoided or removed. The same is true of many of the hazards involved in healthcare, whether surgical intervention, the use of drugs or radiation therapy: managing them so the benefits are realised without harm to patients or others is fundamental to the function of healthcare. Other hazards, or hazardous situations, however, which do not provide benefit and are harmful (such as Never Events) exist as a potential unwanted consequence of the activities involved in healthcare when those activities deviate from what is planned and expected: they are unacceptable events that must be avoided. Of course, exactly the same is also true of all other industries: many of the hazards are associated with the way operations are carried out rather than being inherent to the value of the industry.

The term “hazard” is however used in Bowtie Analysis two quite distinct ways: either i) as something with the potential for harm (most usually a source of energy), or ii) as a situation or activity with the potential to cause harm. As the Centre for Chemical Process Safety defines it: “Within the bow tie methodology, the hazard is an operation, activity or material within an organization that has the potential to cause harm. (CCPS, In press, p.11). These two quite distinct uses of the term hazard can lead to confusion and, often, a lack of insight and clarity about the potential for loss. It is usually much easier to think in concrete terms about specific hazardous situations or activities, than it is to think more abstractly about the hazardous nature of the materials being managed. And, therefore, to identify the significant top events that represent the various ways control of those hazards can be lost with the potential for harm. Put another way, identifying situations or activities with the potential for harm is much
easier, makes less demand on foresight and “requisite imagination”, than identifying the hazardous energies or materials that exist in an operational situation does.

In healthcare, hazards will include such things as:

- Diseases, pathogens and processes leading to failure of organs, etc.;
- Sources of energy (chemical, radiation, heat, pressure) used in treatment and therapy;
- Medical procedures and other activities with the potential for unintended harm.

The hazard in the Never Event workshop reported by McLeod and Bowie (2018, In press) is the physiological/biochemical mechanism leading to the development of cancer of the womb.

So in its best practice usage in industry, Bowtie Analysis begins with recognition of hazards, and proceeds by defining top events where control of the hazard may be lost, and then identifying and evaluating the barriers that will be used to control the risks associated with the hazards. In their use of Bowtie Analysis to prospectively assess risk associated with critical events in an Intensive Care Unit, Kerchoffs et al (2013) followed the standard process and began their analysis by identifying three “hazards” selected because of their frequency of exposure or the extent of risk they represented. Two of these (use of transportation device and communications) were hazardous situations, while the third (unplanned extubation) is an event where control of the hazard is lost (i.e. it is a top event). None of them are hazardous material or energies as such.

Similarly, neither Wierenga et al (2009), in their prospective analysis of risk in the medication process in a hospital setting, or Abdi et al (2016), in their application of Bowtie Analysis to clinical risk in intensive care began by identifying hazards. Both studies by-passed identification of hazards and started by defining top events of interest. Wierenga et al defined top events as “..an unwanted event or error that takes place (e.g. an incident, a hazardous situation), but at that moment has not yet caused any harm or has not yet had any consequences”. (Wierenga et al, 2009, p. 665-6).

An important consequence of the initial focus on hazards as the theoretical basis for Bowtie Analysis is that, in principle, a single hazard can be associated with multiple
top events. There is therefore the potential to need to create multiple Bowties for each of the top events associated with a single hazard. Whether there is any value in investing the effort and resources necessary to produce such a comprehensive analysis clearly depends on the organisation, the context and the extent of risk involved. In most primary care situations, it is unlikely that any local practice will be in a position to devote the resources necessary to develop multiple Bowtie models for different top events associated with a single hazard. (Though such effort could possibly be justified at a national level, or perhaps at the level of professional bodies responsible for specific clinical disciplines).

It therefore seems that to be of most practical value in primary care settings, Bowtie Analysis should concentrate on situations or events that are of serious concern at the practice level. I.e. It should focus on specific hazardous situations, rather than attempting to abstract, or generalise to a wider set of potential top events that could be associated with the many potential sources of harm that inevitably exist in a healthcare environment. Indeed, it seems appropriate to follow the lead of Wierenga et al (2009) and Abdi et al (2016) and not attempt to distinguish between hazards and top events when performing a Bowtie Analysis. For use in primary healthcare, Bowtie analysis will often be most practical by identifying an event that is sufficiently serious and defining that event in sufficient detail that it can be analysed. Essentially, there will often be little practical value (though potentially a lot of unnecessary intellectual challenge and debate) in attempting to distinguish between “hazards” and “top events”.

**DEFINING AND LOCATING TOP EVENTS**

McLeod and Bowie (2018) adopted the selected Never Event “Prescribing systemic oestrogen-only hormone replacement therapy for a patient with an intact uterus” as the top event in their Bowtie. While equating the Never Event with the top event may seem obvious, it is worth reflection: it is not necessarily the case that Never Events should be equated with top events.

As a general principle, top events should be selected that lie as far to the left hand side of the bowtie model as possible (CIEHF, 2016). The rationale is that the further towards the left the top event is located, the more space, in terms of time and
opportunity, is created to detect and react to the top event before it leads to one of the identified consequences. There can also be also significant differences between the nature of the controls – including both the reliance on the competence, skills and the ability of the individuals involved to make judgments and take decisions in what can be stressful and time-critical situations - likely to be used on the left and right-hand sides of the top event. In practice though, top events need to be sufficiently serious in their own right that any competent and aware professional with the relevant responsibility (in this case GPs) would, if they knew about its’ occurrence, recognize its seriousness and intervene without having to be prompted.

So the desire to identify top events as far towards the left hand side of the model as they can be needs to be balanced against the need for top events to be sufficiently serious in their own right that there should be no doubt in the mind of anyone involved about the seriousness of the situation and the need for intervention if they do occur. They also, ideally, need to be clearly and unambiguously identified and clear and easy either for the available technology or any competent person who is in a fit state to detect.

There is a more fundamental issue with use of the term “top event” in healthcare. In Bowtie Analysis, the term top event refers to the moment in time when control over the hazard is lost. Historically, the term was derived from Fault Tree Analysis, where the unwanted event is visually located at the top of the page, with failures with the potential to lead to the event represented lower down. Apart from having an unnecessary implication that BTA assumes incidents in healthcare arise from underlying linear cause-effect failure sequences (as has been argued earlier in this paper), the term “top event” itself is unnecessarily obscure for use in a healthcare context. Better terms exist that are more widely used do not carry theoretical ‘baggage’, and are generally easier for healthcare practitioners to understand and relate to. The term “adverse event” for example, could be used as a more accessible alternative.

PRIORITISING DEGRATION FACTORS

Across the three top-level barriers identified in the workshop reported by McLeod and Bowie (2018), a total of over fifty different safeguards were identified as having a role
in protecting against the selected Never Event. Of these fifty safeguards, only four were identified as protecting against more than one degradation factor. These were:

- Learning from Significant Event Analysis;
- Feedback from Continuing Professional Development (which can both raise awareness of the risk, and improve local protocols);
- Ensuring local protocols/procedures have a dedicated local clinician owner;
- Having a programme in place to annually review the use and quality of local protocols.

The remaining nearly fifty different safeguards appeared to be specific to protecting against individual degradation factors. In addition, fourteen of the suggested safeguards were identified as being “aspirational”: they could, in principle, be used to protect against degradation of the barriers but were either not thought to be currently in use at all, or were not in widespread use. For the purpose of illustration, only the degradation factors and safeguards identified as being associated with the barrier ‘Electronic patient record system’ will be discussed further. These are illustrated on figure two and the details are summarized on table one.

Assuming for the purpose of discussion that the barriers, degradation factors and safeguards identified by McLeod and Bowie were valid, these results raise a major challenge of identifying where the primary health care system could most efficiently focus effort to provide the biggest impact in reducing risk of even the single Never Event analysed. Expecting any general practice to actively manage such a large number of safeguards for a single relatively rare event would clearly impose an intolerable burden on the front line primary care system. A method was therefore developed that could be used following a Bowtie Analysis to identify where to most cost-effectively focus effort to achieve the greatest improvement in the protection provided by the identified barriers and safeguards.

**PRACTICABILITY X IMPACT ASSESSMENT**

The suggested Practicality and Impact method involves three steps:

1. For each of the identified degradation factors, identify the level in the organisational structure (i.e. local practice, regional Health Board, NHS
Scotland, etc.) that is expected to take responsibility for ensuring that factor does not actually lead to failure of the associated barrier (or element(s)).

2. At that organisational level, assess the safeguards associated with each of the degradation factors in terms of a) the Practicality of taking action to either ensure that the identified safeguards will be effective, or to introduce some form of change that would provide the level of assurance sought, and b) the expected Impact that taking the identified action would be likely to have. The assessment of Practicality and Impact can be carried out by reviewing the four factors shown on table two. In each case, reviewers should decide which of the following statement applies:

- Agree (score 5)
- Somewhat Agree (score 4)
- Not Sure (score 3)
- Somewhat Disagree (score 2)
- Disagree (score 1).

Note that table two shows a suggested weighting factor associated with each of the statements. In the absence of clear evidence or rationale to weight any of the dimensions higher than others, the weightings have all been assigned a default value of 1. In principle however it would of course be possible to use the weightings to reflect differential priorities of each of the dimensions, where a rationale for such relative weightings existed.

By taking the product of the score associated with the level of agreement and the weighting factor for each factor, and summing across all four factors for that dimension, a single value can be achieved representing the relative assessed Practicality and Impact of taking action at the assigned organisational level to reduce the risk from that degradation factor.

3. Review the assessed Practicality and Impact scores across all of the degradation factors assigned to that level of the organisation. Degradation factors where both the Practicality and the Impact are assessed as being high are those that should be prioritised for action.
Figure two: Summary of degradation factors and their safeguards for the barrier ‘Electronic Patient Records System’

<table>
<thead>
<tr>
<th>Barrier</th>
<th>Elements</th>
<th>Degradation Factors</th>
<th>Responsibility</th>
<th>Safeguards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic Patient Records System:</td>
<td>Health records database</td>
<td>GP unaware of admin staff changes to patient records</td>
<td>Practice Manager</td>
<td>Procedure &amp; authorisation levels</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Written record of change</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Visible on-screen indication of change / removal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Training and awareness</td>
</tr>
<tr>
<td>IT-based system that holds patient records.</td>
<td>Records for new patient not up to date</td>
<td></td>
<td>Practice Manager</td>
<td>New patient checked within 2 months</td>
</tr>
<tr>
<td>Barrier includes alarms and prompts</td>
<td>Patient records incorrect or</td>
<td></td>
<td>GP</td>
<td>GP review</td>
</tr>
<tr>
<td>advising user of potential risks as well</td>
<td>incomplete.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>as clinician response to alarms.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>System warnings</td>
<td>Warning disabled by Practice</td>
<td></td>
<td>GP</td>
<td>Critical warnings locked in system</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Partners agreement</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Contract arrangements</td>
</tr>
<tr>
<td></td>
<td>Warning removed during software</td>
<td></td>
<td>NHS Board</td>
<td>Communication of critical modifications</td>
</tr>
<tr>
<td></td>
<td>upgrade</td>
<td></td>
<td></td>
<td>Management of software change process</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Communication of changes to local practices</td>
</tr>
<tr>
<td></td>
<td>Warning badly designed</td>
<td></td>
<td>Not analysed</td>
<td></td>
</tr>
</tbody>
</table>

3 Practice partners are always ultimately accountable. Responsibilities are delegated under the overall authority of the partners.
<table>
<thead>
<tr>
<th>Clinician response to alarms</th>
<th>Warning overload</th>
<th>NHS Board</th>
<th>Design of warning system</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Clinical warnings distinguished from cost-based warnings</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Warning prioritisation</td>
</tr>
<tr>
<td></td>
<td>GP</td>
<td>Record of justification for ignoring</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reflection on feedback of frequency of overrides</td>
<td></td>
</tr>
<tr>
<td>Normalisation / over-confidence</td>
<td>Clinician⁴</td>
<td>Significant event analysis and clinical practice audits (or other Quality Improvement initiatives)</td>
<td></td>
</tr>
<tr>
<td>Locum unfamiliar with practice IT system</td>
<td>Practice Manager</td>
<td>Locum induction training</td>
<td></td>
</tr>
<tr>
<td>Locum</td>
<td>Locum</td>
<td>Locum’s preparation pre-engagement</td>
<td></td>
</tr>
</tbody>
</table>

⁴ “Clinician” can include Practice nurse, pharmacist, GPs
Table two: Practicality and Impact Statements

<table>
<thead>
<tr>
<th>Practicality</th>
<th>Weighting</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ease of Implementation</strong></td>
<td></td>
</tr>
<tr>
<td>There are simple actions that are easily defined and can be implemented at this organizational level with little effort.</td>
<td>1</td>
</tr>
<tr>
<td><strong>Resources</strong></td>
<td></td>
</tr>
<tr>
<td>Little capital or resource requirement</td>
<td>1</td>
</tr>
<tr>
<td><strong>Stakeholders</strong></td>
<td></td>
</tr>
<tr>
<td>Few stakeholders who are under the direct command of the individual responsible for the safeguard.</td>
<td>1</td>
</tr>
<tr>
<td><strong>Change</strong></td>
<td></td>
</tr>
<tr>
<td>Requires little change from existing practice</td>
<td>1</td>
</tr>
<tr>
<td><strong>Impact</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Scope</strong></td>
<td></td>
</tr>
<tr>
<td>The action would also improve other Barriers or protect against other incidents</td>
<td>1</td>
</tr>
<tr>
<td><strong>Exposure</strong></td>
<td></td>
</tr>
<tr>
<td>Opportunities for the Degradation Factor to act across other threats are frequent and arise in many different situations with many different people</td>
<td>1</td>
</tr>
<tr>
<td><strong>Effectiveness</strong></td>
<td></td>
</tr>
<tr>
<td>There is confidence that the action would be effective and would have an impact quickly</td>
<td>1</td>
</tr>
<tr>
<td><strong>Risk reduction achieved</strong></td>
<td></td>
</tr>
<tr>
<td>The Degradation Factor is widely recognised as a risk that is not currently adequately controlled.</td>
<td>1</td>
</tr>
</tbody>
</table>

**EVALUATION OF PRACTICALITY x IMPACT RATINGS**

To evaluate the usefulness of the Practicality x Impact method, a second workshop was convened, attended by two of the same GPs as well as the patient safety researcher who took part in the original workshop reported by McLeod and Bowie (In Press). For the purpose of evaluation, the method was only applied to the degradation factors and safeguards for the barrier ‘Electronic patient records system’. Table three shows the consensus opinions reached for these assessments.

Although a total of eight degradation factors were analysed, covering twenty safeguards, to make the Pxl assessments it was found convenient in a few cases to group the safeguards and to evaluate them as a single potential intervention. For example, as shown on table three, the safeguards associated with the degradation factor “patient records incorrect or incomplete” were organised into two separate groups.
**Table three: Assessments of Practicality and Impact of implementing safeguards to manage risk from degradation factors identified for the barrier ‘Electronic Patient Records System’**

<table>
<thead>
<tr>
<th>Degradation Factor</th>
<th>Safeguards</th>
<th>Practicality</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Effort</td>
<td>Resources</td>
</tr>
<tr>
<td>GP unaware of admin staff changes to patient records</td>
<td>A: Procedure and authorisation level; Training and awareness</td>
<td>Agree</td>
<td>Somewhat Agree</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Records for new patient not up to-date</td>
<td>B: New patient records checked within 2 months</td>
<td>Agree</td>
<td>Somewhat Agree</td>
</tr>
<tr>
<td>Patient records incorrect or incomplete</td>
<td>C: Clinician review of record in presence of patient</td>
<td>Agree</td>
<td>Agree</td>
</tr>
<tr>
<td></td>
<td>D: Significant event analysis and clinical practice audits (or other Quality Improvement initiatives)</td>
<td>Somewhat Agree</td>
<td>Somewhat Agree</td>
</tr>
<tr>
<td>Warnings disabled by Practice</td>
<td>E: Critical warnings locked in system (assuming local IT admin control)</td>
<td>Agree</td>
<td>Agree</td>
</tr>
<tr>
<td>F: Critical warnings locked in system (assuming software change needed)</td>
<td>Disagree</td>
<td>Disagree</td>
<td>Disagree</td>
</tr>
<tr>
<td></td>
<td>G: Partner agreement;</td>
<td>H: IT contract arrangements between Practice and NHS Board</td>
<td>Warning removed during software upgrade</td>
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<tr>
<td>---</td>
<td>---------------------</td>
<td>-------------------------------------------------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td></td>
<td>Somewhat Agree</td>
<td>Agree</td>
<td>Disagree</td>
</tr>
<tr>
<td></td>
<td>Agree</td>
<td>Agree</td>
<td>Disagree</td>
</tr>
<tr>
<td></td>
<td>Disagree</td>
<td>Disagree</td>
<td>Disagree</td>
</tr>
<tr>
<td></td>
<td>Disagree</td>
<td>Not Sure</td>
<td>Disagree</td>
</tr>
<tr>
<td></td>
<td>Not Sure</td>
<td>Disagree</td>
<td>Disagree</td>
</tr>
<tr>
<td></td>
<td>Agree</td>
<td>Agree</td>
<td>Disagree</td>
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<td></td>
<td>Agree</td>
<td>Agree</td>
<td>Disagree</td>
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<td></td>
<td>Agree</td>
<td>Agree</td>
<td>Disagree</td>
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<tr>
<td></td>
<td>Agree</td>
<td>Agree</td>
<td>Disagree</td>
</tr>
<tr>
<td></td>
<td>Disagree</td>
<td>Not Sure</td>
<td>Disagree</td>
</tr>
<tr>
<td></td>
<td>Not Sure</td>
<td>Disagree</td>
<td>Disagree</td>
</tr>
<tr>
<td></td>
<td>Agree</td>
<td>Agree</td>
<td>Disagree</td>
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<tr>
<td></td>
<td>Agree</td>
<td>Agree</td>
<td>Disagree</td>
</tr>
<tr>
<td></td>
<td>Somewhat Agree</td>
<td>Agree</td>
<td>Disagree</td>
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<tr>
<td></td>
<td>Agree</td>
<td>Agree</td>
<td>Disagree</td>
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<td>Agree</td>
<td>Agree</td>
<td>Disagree</td>
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<td></td>
<td>Disagree</td>
<td>Not Sure</td>
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<td></td>
<td>Not Sure</td>
<td>Disagree</td>
<td>Disagree</td>
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<td>Agree</td>
<td>Agree</td>
<td>Disagree</td>
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<tr>
<td></td>
<td>Agree</td>
<td>Agree</td>
<td>Disagree</td>
</tr>
</tbody>
</table>
Consideration of figure three suggests that the most effective steps that could be taken to reduce the risk profile, and increase the strength of the barriers, would be achieved by implementing safeguards A and B i.e.;

- A: Procedure and authorisation level; Training and awareness;
- B: New patient records checked within 2 months.

Action to implement safeguards ‘C’ (‘Clinician review of records in presence of the patient”) and E (“Critical warnings locked in system - under local IT control”) were assessed as being the most practical measures that could be taken. The assessed Impact however was relatively low (with scores of 11 and 13 respectively out of a maximum of 20).

In contrast, while taking action to improve the design and implementation of automated warnings within the patient electronic record system (safeguard I) was assessed as having the highest Impact, it was considered as having low practicality as a mitigation.
measure (Impact score = 6), due to the many organisational and bureaucratic issues, stakeholders and commercial arrangements that would be involved in implementing the necessary change.

Finally, figure three indicates that relying on Locum's to ensure they have fully prepared themselves for work in a new GP practice (safeguard N) was considered to be both the least practical measure while probably having the lowest impact in reducing risk.

CONCLUSIONS

There is widespread interest in the healthcare community in implementing practical approaches to prospectively identifying and managing risk to patient safety. However, despite various studies and sources of guidance, to-date few approaches to prospective risk assessment have been demonstrated to be practical for use in a primary healthcare context.

A workshop conducted for NHS Education (Scotland) concluded that the technique of Bowtie Analysis, which is in widespread use in the traditional high-hazard industries, may be readily applied to serious significant events in healthcare. It also suggested that the method has potentially wide relevance as an approach to prospective risk analysis at all operational levels in NHS Scotland.

Compared with alternative approaches, Bowtie Analysis is conceptually simpler, easier to implement, and need make no assumptions about the nature and causes of major incidents in a healthcare context. Having identified threats that could lead to loss of control over potentially hazardous situations, Bowtie Analysis;

i. Identifies controls that can contribute to preventing the threat from leading to the unwanted events;

ii. Evaluates those controls to determine whether they are of sufficient quality to be considered as “barriers”

iii. Investigates how those barriers can be defeated or degraded, and what needs to be in place to prevent such degradation.
When it is done properly, Bowtie Analysis provides a rich understanding of the controls that are expected to be in place and how they need to be implemented, supported and managed.

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