Evaluation of the formal risk assessment practice in hospitals in England

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England**

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In England, hospitals routinely conduct a formal risk assessment practice to ensure the safety of patients and staff. However, although specific criticisms have been made on the practice, few investigated the formal risk assessment practice in the literature. This study investigates the risk assessment policies and procedures of one hundred hospitals in the English National Health Service (NHS) through content analysis. Findings revealed that hospitals provided varied descriptions of the terms risk and risk assessment. The concept of risk was often defined to be an undesired event, and risk assessment was often explained with the involvement of risk control step. Despite the variety in the descriptions of the risk terms, all hospitals recommended following similar steps to undertake risk assessments. Risk matrices- and therefore risk scoring – are at the heart of the formal practice, which increases the possibility of wrong risk prioritisation. This study provides several recommendations for the improvement of current guidelines by considering both Safety-I and Safety-II approaches.

Keywords: risk; risk assessment; patient safety

Introduction

Hospitals inhabit a wide range of risks (e.g. drug errors and poor equipment design) that might affect the safety of patients and staff and the quality of the health care services delivered (NPSA 2006; Woodward et al. 2004). It is, therefore, hospitals spent considerable efforts on safety and risk management (Simsekler et al. 2019; Vincent et al. 2017).

In England, hospitals have been encouraging their staff to undertake risk assessments (Sujan et al. 2017, 2016). They provide risk assessment policies or procedures, where the roles of hospital staff and the formal risk assessment practice are described, to guide their staff on risk assessment (NHS England 2015). However, alongside the successful risk assessment applications, hospitals have claimed to provide inadequate formal guidelines to express, analyse and evaluate risks. (Ward et al. 2010; Sujan et al. 2016; Abt et al. 2010; Abecassis et al. 2015; Eidesen, Sollid, and Aven 2009). The formal risk assessment guidelines have been claimed to provide unclear risk terminology and risk identification guidelines (Simsekler, Ward, and Clarkson 2018), inadequate guidance for the use of the risk assessment tools and techniques (Kaya, Ward, and Clarkson 2019a; Ward et al. 2010; Sujan et al. 2016), and inadequate guidance on risk control (Card, Ward, and Clarkson 2014).

Moreover, the risk assessment approach itself has been criticised. Currently, risk assessment guidelines in hospitals are built on focusing on “*how things go wrong*”. This is called Safety-I approach. In this approach, incidents are as a result of a causal chain of events. In the safety management literature, Safety-I approach has been claimed to be limited to manage safety in complex systems, as in healthcare (Sujan et al. 2019; Kaya, Ovali, and Ozturk 2019). To address such limitation, Hollnagel (2014) suggested

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3 focusing on “*how things go right*” in addition to “*how things go wrong*”, and called this
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5 approach as Safety-II approach. Safety-II approach supports the understanding of the
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7 interactions in complex processes and, in turn, responds to needs of the dynamic
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9 healthcare environment (Sujan et al. 2017; Sujan, Huang, and Braithwaite 2017). Thus,
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11 Safety-II provides an alternative way to the traditional risk assessment (Furniss, Curzon,
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13 and Blandford 2016).
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18 This study investigates the risk assessment policies and procedures of the English
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20 National Health Service (NHS) hospitals to evaluate the formal practice described for risk
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22 assessment. The potential contributions of this paper are two folded: to understand the
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24 formal risk assessment practice described and to provide recommendations for
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26 improvements by learning from the safety management literature.
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29 30 31 **Methods**

32 33 ***Data Collection***

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36 We collected risk assessment policies and procedures in place within acute hospitals in
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38 England. We sent a request to all acute hospitals in National Health Service (NHS)
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40 England (n=160) under the act of Freedom of Information (FOI) to obtain data on July
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42 11, 2016, by e-mail. We asked hospitals to provide their risk assessment procedure and
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44 policy (or nearest equivalent documents, e.g. risk management policy, strategy, procedure
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46 or guidance). In response, we obtained the data electronically.
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52 There is a legal obligation for hospitals to aim to respond to the FOI within 20
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54 working days. It is, therefore, in this study, data collection was halted after 35 days, and
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56 one hundred (out of 160) hospitals returned 142 documents. The response rate was 62.5
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58 per cent.
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Data Analysis

We conducted a content analysis of the procedure and policy documents to evaluate the formal risk assessment practice in English hospitals. The formal risk assessment practice was investigated by considering the concept of risk (i.e. risk and risk assessment definitions) and risk assessment process (i.e. process steps, techniques, and risk scoring).

Before undertaking the content analysis, the authors initially skimmed the documents and designed an Excel table to structure the data collection, and so to categorise data. Following that, the author (GKK) read all documents to extract the relevant data for each category (i.e. risk and risk assessment definitions, process steps, risk scoring and risk assessment techniques). While data analysis for some categories (e.g. risk assessment techniques) only required to list and count the number of the items in all documents, the categories such as risk definition required qualitative data analysis. The analysis involved coding, category development and thematic coding. Following that, the authors validated the findings through discussions and represented the results.

Ethical Considerations

Health Research Authority (HRA) approval was obtained to conduct this research study. The HRA approval comprised a review by an NHS Research Ethics Committee (REC) on behalf of the participating organisations. The REC reference for this study is 16/HRA/4955.

Results

The results of this study are represented under two categories: the concept of risk and the risk assessment process.

The concept of risk

The findings revealed a variety of definitions for the terms *risk* and *risk assessment*. 87 out of 100 hospitals provided a definition of *risk*. Among these definitions, the majority (63) defined risk as something being negative, including “*potential adverse event*”, “*threat to objectives*”, “*potential harm*” or “*potential harm, loss or damage*”. The remainder (37) described risk with neutral explanations, which may result in both positive and negative consequences, such as “*an event*”, “*uncertainty on objectives*” or “*an uncertain outcome*” (see Table 1).

Table 1 The description of risk by the number of hospitals

62 out of 100 hospitals described *risk assessment* on their policies and procedures. Risk assessment was frequently described as a process that involves risk identification, analysis, evaluation and control steps (see Table 2).

Table 2 The description of risk assessment by the number of hospitals

The risk assessment process

The findings showed that hospitals suggested using several different tools and techniques when undertaking risk assessments. Among these tools and techniques, risk matrices were at the core of the formal risk assessments. Table 3 lists all the tools and techniques, except the specific risk assessment forms identified in these documents (e.g. expectant mother, moving and handling, display screens, violence and abuse, infection control and lone working), and shows the applicability of these techniques in the risk assessment process. The decisions on the applicability of these tools on the risk assessment were made by reviewing the British Standards on risk assessment techniques (BSI 2010) in conjunction with discussions between the authors.

Table 3 Tools and techniques to support risk assessment based on reviewed documents

99 out of 100 hospitals provided 5 by 5 risk matrices to be used in the risk assessment. A score from 1 to 5 is assigned to each qualitative description provided for likelihood and consequence axes of the risk matrices. A risk score is measured by multiplying the likelihood and consequence scores. Hospitals recommended using multiple risk scoring types, including inherent (without considering existing controls), current (by considering existing controls), target (a level of risk being planned for) and residual (after the implementation of required actions) (see Table 4). Risk scores were designed to support decision-making about the level of management action (i.e. review frequency, action prioritisation, and responsibilities).

Table 4 Risk scoring types by the number of hospitals

Discussion

The findings from the content analysis shed light on the formal risk assessment practice that was described by hospitals in England.

Various hospitals provided different descriptions for the terms risk and risk assessment. The risk was often described as something negative (e.g. undesired events, harm and loss). The term risk in the patient safety context often refers to undesired events (e.g. pressure ulcers, falls, errors in prescription, delays in emergency care and the spread of infection) (Webster et al. 2011; NPSA 2010; Lago et al. 2012). The dictionary definition of risk in many languages also refers to something negative (e.g. danger and the possibility of damage and harm) (Aven 2012b). However, it is surprising that most of the hospitals described the risk assessment process outside the description of British Standards Institution risk management standards by including risk control step.

No matter how hospitals described the term risk or risk assessment, they all recommended following similar steps to undertake a risk assessment. The risk matrices and, so, risk scores were at the core of the formal risk assessment practice. This indicates inconsistency between the terminology and the practice described. Although it might be arguable that how to describe the terminology is not so important as long as risks are clearly defined and assessed in practice. It is essential to provide a consistent description of the risk terminology (Aven 2012a). The clear terminology supports for good communication among the members of healthcare staff, and, therefore, help undertake more effective risk assessments (Aven 2012a; Haimes 2009).

All hospitals recommended using risk scores by considering the likelihood and consequence scores. However, researchers criticised the use of the scoring mechanisms because they do not reveal the real value of the risk. As a result, it potentially leads to the wrong decisions made on the prioritisation of the risks and the use of resources to treat such risks (Vatanpour, Hrudey, and Dinu 2015; McElroy et al. 2016a). For example, the quantitative value of a risk score of 10 (a likelihood score of 5 and a consequence score of 2) might be lower than a risk score of 8 (a likelihood score of 2 and a consequence score of 4). Similarly, a risk with having a lower quantitative value might have a higher priority to be managed due to regulatory requirements. The safety management literature highlighted multiple factors to be considered when measuring the level of risk and making risk prioritisation decisions (Sujan et al. 2017; Kaya, Ward, and Clarkson 2019b; Cox 2008). The international standards, for example, encourage the consideration of the confidence in the determination of the level of risk, which can be through the consideration of uncertainty, the quality of the information used and the limitations of the analysis (BSI 2010, 2009). Moreover, the risk is suggested to be measured by considering the strength of knowledge (e.g. the assessor's knowledge and the availability of data). The

strength of knowledge supports the judgments made to measure the likelihood and consequence (Aven 2016; Veland and Aven 2015; Aven 2017).

As all hospitals used risk scoring, they represented the risk scores to analyse risks with the use of risk matrices. The findings showed that few hospitals suggested the use of comprehensive risk assessment tools and techniques in their documents. In the literature, it has been claimed that hospitals do not frequently use comprehensive risk assessment tools and techniques (e.g. FMEA) (Ward et al. 2010). Researcher; however, used such techniques and highlighted their potentials in practice in terms of better identification and analysis of the risks (McElroy et al. 2016b; Lu et al. 2013; Lago et al. 2012; Wreathall and Nemeth 2004; Simsekler et al. 2019; Sujan and Felici 2012). Studies found that such techniques provide a better understanding of the system to be assessed. Consequently, they support a more in-depth identification and analysis of the risks.

This findings from this study indicate that the criticisms of the risk assessment practice are also valid for the formal risk assessment practice described in English hospitals. However, the formal practice described in the guidelines can still be improved. Guidelines contribute to the improvement of practice if they are followed adequately (Mathews et al. 2018; Card, Ward, and Clarkson 2014; Simsekler et al. 2015; Eidesen, Sollid, and Aven 2009).

The formal practice described can be improved by providing a clear understanding of the concept of the risk and the risk assessment process. As the problems with risk scoring were at the heart of the criticisms, it might be suggested to require the involvement of multiple people when scoring risks. So, the assessors have to agree on the scores. This might then reduce the subjectivity in risk scoring. However, this suggestion would not address the criticisms of the definition of the risk (Aven 2012a, 2012b). Even

with minimum subjectivity in risk scoring, the risk scores would not reveal the real level of the risks. Hence, it can be advised to consider the strength of knowledge in addition to likelihood and consequence of the risks.

Moreover, hospitals can encourage the use of the various other risk assessment techniques (e.g. FMEA, Bow-tie and Functional Resonance Analysis Method (FRAM)) in line with risk matrices (Card, Ward, and Clarkson 2013), and provide sufficient training programmes to their staff for the effective use of such techniques. Several studies have already demonstrated the potential contributions of combining multiple tools and techniques. For instance, Manger et al. (2015) used Fault Tree Analysis (FTA) in conjunction with FMEA to assess risks in surface image-guided radiosurgery. They found that the assessment helped the team members understand the process, detect unrecognised failure modes and recognise several causes. Wierenga et al. (2009) applied the Bow-tie model for risk analysis of medication safety, and their study contributed to the determination of root causes of specific top events and the improvement of the safety awareness. Chatzimichailidou et al. (2017) compared the Bow-tie and Systems-Theoretic Accident Model and Processes (STAMP) approach to reduce the risk of surgical instrument retention and highlighted the strengths of each approach. However, such techniques require more time and skills to assess risks. Therefore, hospital management should clarify which risks to be assessed by the use of such techniques.

In line with the findings, the concept of risk assessment can also be questioned. In hospitals, processes are complex, and healthcare staff might need to make dynamic trade-offs to meet unpredictable demands and to deal with surprises (Braithwaite, Wears, and Hollnagel 2016; Fairbanks et al. 2014; Suján, Spurgeon, and Cooke 2015; Suján, Huang, and Braithwaite 2017). It is; therefore, guidelines can be redesigned by considering the

science behind Safety II (e.g. Functional Resonance Analysis Method) in addition to Safety I (e.g. FMEA). However, suggesting significant changes in the existing risk assessment practice might be challenging and arguable on the ground of their applicability in hospitals.

This study raised discussions concerning the formal risk assessment practice described in the documents. However, this study has limitations that should be mentioned. Firstly, this study assumed that the risk assessment policies and procedures (or nearest equivalent documents) are the guidelines to assess risks. Hospitals might have additional documents to guide their staff on risk assessment. However, the documents collected contain information in relation to the risk assessment practice, and the authors highlighted the purpose of their use when making the FOI request. Secondly, the non-response rate to the FOI request might have affected this study. The non-response rate would likely add more variety on the definitions given to risk terms. However, simultaneously, it would provide the same generic practice to assess risks.

This study yields insights into the formal risk assessment practice in English hospitals. The formal guidelines provided for the formal risk assessment practice have vulnerabilities to the existing criticisms made by researchers. The formal risk assessment practice; however, can be improved by learning from the safety management literature. Consequently, the improved guidelines would expect to contribute to the improvement of the practice in the front-line.

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Tables

Table 1 The description of risk by the number of hospitals

Risk Description	Number of Hospitals
Event	
Neutral (uncertain event) E.g. "An uncertain event, or set of events."	1
Negative (adverse event or unfavourable event) E.g. "An unfavourable event."	16
Impact on objectives	
Neutral (ISO risk definition) E.g. "The effect of uncertainty on objectives."	32
Negative (threat to objectives) E.g. "The threat that an action or event will adversely affect the Trust's ability to achieve its objectives."	9
Harm, loss or damage E.g. "Injury liability, loss or other negative occurrence."	25
Uncertainty of outcome E.g. "Uncertainty of outcome, whether positive opportunity or negative threat, of actions and events."	4

Table 2 The description of risk assessment by the number of hospitals

Risk Assessment Description	Number of Hospitals
The process of Identification	3

E.g. "A careful examination of what could cause harm to people or property."	
Identification and analysis	9
E.g. "The identification and analysis of relevant risks to the achievement of objectives."	
Analysis	7
E.g. "Consists of a combination of the probability of a perceived threat and the magnitude of its impact upon objectives"	
Identification, analysis and evaluation	15
E.g. "A systematic process of risk identification, risk analysis and risk evaluation."	
Analysis and evaluation	5
E.g. "The process of risk analysis and risk evaluation."	
Evaluation	2
E.g. "The process used to evaluate the risks and to determine whether controls are adequate."	
Identification, analysis, evaluation and control	21
E.g. "The process, by which an individual or organisation identifies, assesses and prioritises risks and, where appropriate, identifies additional controls and actions that will reduce the risk to a level which can be accepted."	

Table 3 Tools and techniques to support risk assessment based on reviewed documents

Techniques and Tools	Number of hospitals cited	Risk assessment process		
		Risk identification	Risk analysis	Risk evaluation
Audit	100	++	+	+
Risk Registers	100	+	+	+
Incident reporting	100	+	+	+
Heat map/ risk matrix	99		++	+
Root Cause Analysis (RCA)	52	+	+	+
Checklist	38	++		
Whistle blowing	33	+	+	+
Walk around/ walk about	29	++		
Horizon scanning	20	+	+	
Benchmarking	15	+	+	
SWOT	7	++		
Brainstorming	5	++		
PEST/PESTLE analysis	5	+		
Decision tree	3		++	
Grapevine/ intuition	2	+		
Lean analysis	2	+	+	+
Failure Mode and Effect Analysis (FMEA)	1	++	++	++
Bow-tie analysis	1		+	+
Event tree analysis (ETA)	1	+	+	
Fault tree analysis (FTA)	1	+	+	

++: Strongly Applicable, +: Applicable

Table 4 Risk score types by the number of hospitals

Risk Score Types				Number of Hospitals
Inherent	Current	Target	Residual	
+				5
	+			23
+	+			3
+	+	+		24
+	+		+	2
+		+		1
+		+	+	3
+			+	9
	+	+		14
	+	+	+	4
	+		+	11
+: Used				