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Trust-level fisk identification guidance

in the NHS east of England 2

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Abstract. 9

- BACKGROUND: In healthcare, ranges of methods are used to improve patient safety through risk identification within the scope 10
- of risk management. However, there is no evidence determining what trust-level guidance exists to support risk identification in 11 healthcare organisations. This study therefore aimed to determine such methods through the content analysis of trust-level risk 12 management documents. 13
- METHOD: Through Freedom of Information Act, risk management documents were requested from each acute, mental health 14 and ambulance trust in the East of England region of NHS for content analysis. Received documents were also compared with 15
- guidance from other safety-critical industries to capture differences between the documents from those industries, and learning 16 points to the healthcare field.
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- RESULTS: A total of forty-eight documents were received from twenty-one trusts. Incident reporting was found as the main 18
- method for risk identification. The documents provided insufficient support for the use of prospective risk identification methods, 19 such as Prospective Hazard Analysis (PHA) methods, while the guidance from other industries was extensively promoted such 20 methods. 21
- CONCLUSION: The documents provided significant insight into prescribed risk identification practice in the chosen region. 22
- Based on the content analysis and guidance from other safety-critical industries, a number of recommendations were made; such 23
- as introducing the use of PHA methods in the creation and revision of risk management documents, and providing individual 24 guidance on risk identification to promote patient safety further.
- 25
- Keywords: Healthcare risk management, risk identification, patient safety, health policy 26

1. Introduction 26

- Medical errors constitute one of the most important challenges in healthcare, harming thousands of 27
- people around the world every year [1-4]. Recent studies showed the high rate of errors affecting patient 28
- safety worldwide [5-11]. For instance, Walker et al. [12] reviewed a number of studies from a range of 29
- countries, and concluded that the adverse event rate ranges from 3% to 17%. All the figures, from around 30
- the world, indicate that improvements need to be made to healthcare systems to enhance patient safety. 31

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To help accelerate improvement in patient safety, healthcare organisations are advised to monitor their care delivery processes, identify errors, and investigate their links to hazards and risks. In order to address the latter challenge, risk identification is used as the main approach to support the process of finding,

recognising, and describing risks within the risk assessment process [13].

Risk identification is one of the key approaches in investigating possible linkages between hazards and errors, affording healthcare organizations an important means to substantially reduce errors [14]. Using a range of tools and methods, the aim of robust risk identification is to compile a comprehensive list of risks within the scope of risk management. Risk identification plays a vital role in the risk management process, since control mechanisms are far less likely to avoid or decrease the effects of unidentified risks [14–17].

While the literature indicates that retrospective approaches, such as incident investigation, have most 42 often been used to identify risks in healthcare [18-20], there are only a few resources available that 43 discuss current risk identification practices in healthcare further. While the report on Prospective Hazard 44 Analysis (PHA) produced by Ward et al. [20] analysed current PHA practices in the healthcare field, 45 another study by Card et al. [21], described a content analysis of the risk management strategies, policies, 46 and procedures used, particularly focusing on trust-level risk evaluation and risk control. However, there 47 is no evidence determining what trust-level guidance exists to support the risk identification process in 48 NHS trusts. 49

To help understand this, a content analysis was conducted of risk management documents from the trusts in the East of England (EoE) region of the NHS. As Ward et al. [20] suggested, the analysis of such documents can be helpful for gaining a significant level of insight into current prescribed risk identification practices.

The primary aim of this analysis was to understand what support is provided by trust-level policies, procedures, and strategies, to help healthcare staff to identify patient safety risks. This study, therefore, attempted to provide a better under-standing of the recommended risk identification practice in selected trusts. A brief comparison with the guidance of other safety-critical industries was also conducted to examine the possible differences between risk identification documents used in healthcare trusts and those of other industries, and learning points to healthcare field.

60 **2. Methods**

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In order to obtain risk management-related documents, a Freedom of Information (FOI) request was sent to each acute, mental health, and ambulance trust in the EoE, on 26 February 2013. Similar to the requests sent by Card et al. [21] earlier, the trusts were asked to provide the following documents:

1. Your organisation's current Risk Management Policy (or nearest equivalent, *e.g.*, Risk Assessment Policy)

- 2. Your organisation's current Risk Management Procedures (or nearest equivalent, *e.g.*, Risk Assessment Procedures)
- In addition to the documents above, the trusts were also asked to provide any other relevant documents (*e.g.*, plans, checklists, strategies, procedures, policies, etc.) potentially containing details on hazard/risk identification with respect to patient safety.
- The documents obtained from the trusts were analysed to identify what guidance informs the risk
- ⁷¹ The documents obtained from the trusts were analysed to identify what guidance informs the fisk identification process, and to determine specific risk identification methods and tools used. To this end, the following questions were asked regarding each document:

- Which risk identification tools and methods are mentioned in the documents?
 - Are the methods mentioned presented positively, neutrally, or negatively?
- Is there direct or indirect pressure on trusts to conduct retrospective or prospective risk identification
 by using specific tools and methods?

In addition to the documents provided by the trusts, the following guidance was also reviewed to determine whether there are any relevant learning points that can be borrowed from other safety-critical industries:

- Hazard Identification Guidance Note from the National Offshore Petroleum Safety and Environmental Management Authority (NOPSEMA) [22]
 - Hazard Identification Guidance from the European Commercial Aviation Safety Team European Strategic Safety Initiative (ECAST/ESSI) [23]

There are much other guidance could be borrowed from other safety-critical industries to compare with healthcare documents. However, these two documents were chosen for their particular treatment of hazard/risk identification providing comprehensive knowledge of different tools and methods from the petroleum and aviation industries.

3. Results and analysis

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A total of forty-eight documents, including risk management policy, procedures and strategies, were received in reply from eighteen acute trusts, two mental health trusts, and one ambulance trust (n = 21). Most of the documents indicated that it is important for trusts to develop and promote policies and procedures that provide guidance to practitioners and managers in risk decisions. It was stated in many of

procedures that provide guidance to practitioners and managers in risk decisions. It was stated in many of
 these documents that such policies and procedures are available to all staff, at all levels in the organisations.
 Hence, it is expected that all staff have a part to play in identifying and managing risk, by being aware of
 and following the trusts' policies, procedures, protocols, and guidance.

With respect to fundamental definitions, the documents used both hazard identification and risk identification terms interchangeably. In most of the documents, the definitions of *hazard* and *risk* were provided, but only a few documents showed examples of these terms and the relationship between hazard and risk. In general, the review showed that very little advice was given regarding how to identify risks, despite the list of tools and methods described and (briefly) mentioned, in contrast with other industries' hazard identification guidance.

The documents provided showed that most trusts recognised the importance of suitable and sufficient 102 risk assessment in managing risks. Hence, most documents mentioned the importance of having a sys-103 tematic and proactive approach to identifying and assessing risks. Again, in most of the documents, risk 104 management was defined as a proactive approach that aims to identify, assess, prioritise, and manage 105 risk, in order to minimise its negative consequences. It was also specifically shown that risk identifi-106 cation is an ongoing and proactive process, and is the responsibility of all staff organisation-wide. In 107 some documents, it was also emphasised that all staff members are encouraged and supported in taking a 108 proactive role in identifying a comprehensive list of sources of risk and events that might have an impact 109 on the achievement of objectives and the continuity of service delivery. The documents also showed that 110 there are many means of identifying risks within any given organisation and circumstances, and the type 111 of assessment may suggest a preferable method. Regardless of the method chosen, the documents often 112 recommended being systematic. In addition, one document also highlighted the importance of identifying 113

No	Tools and methods	n	No	Tools and methods	n
1	Incident Reporting	21	18	Risk Profiling Exercises	5
2	Risk Register	21	19	Observation	5
3	Complaints	20	20	Whistle-blowing	4
4	Claims Reporting	20	21	Backlog Maintenance	4
5	Audit	20	22	Training	4
6	Near miss reporting	17	23	Hazard/ Safety/ Alert Notices	3
7	Issues Raised Through the Board	15	24	Unions	3
8	National Reports	15	25	Trigger Lists	3
9	External audit/ inspection	14	26	Brainstorming	3
10	RCA	13	27	Grapevine and Intuition	2
11	Patient and Staff Survey	11	28	Exit Questionnaires	2
12	New Legislation	11	29	The Health Check Self Assessments	2
13	Safety walkabouts	8	30	Risk Identification workshops	2
14	Checklists	7	31	Lean Analysis	1
15	Coroner Reports	6	32	Information Governance Toolkit	1
16	Benchmarking	5	33	SWOT analysis	1
17	Media	5	34	PHA methods (in total)	0

 Table 1

 Risk identification tools and methods determined in the documents

both possible latent organisational management failures and sharp-end failures, or adverse events, in a
 systematic way.

¹¹⁶ Despite the many statements recommending being proactive and systematic, however, it was found that ¹¹⁷ improvement of the risk identification process through retrospective analysis of incident reports is the main ¹¹⁸ tool used in the trusts. All trusts (n = 21) indicated the use of incident reports in identifying risks. After ¹¹⁹ incident reporting, the documents listed other common methods used — complaints, claims reporting, ¹²⁰ and audits (n = 20 for each). These were followed by near miss reporting (n = 17), national reports, issues ¹²¹ raised by the trust board (n = 15 for each), Root Cause Analysis (n = 13), and new legislation and patient ¹²² and staff surveys (n = 11 for each).

The documents provided showed very little evidence of the use of prospective risk identification tools. Safety walkabouts (n=8) were found to be the most commonly used proactive method supporting risk identification in the EoE region. This was followed by the use of checklists (n=7), observation (n=5), and brainstorming (n=3). In addition to these, several other methods were mentioned in the documents provided by the twenty-one trusts, and are listed in Table 1, below:

As can be seen in the last entry in Table 1, there was no evidence found that Prospective Hazard 128 Analysis (PHA) methods are used as part of the trusts' risk assessment processes. Moreover, there 129 was no evidence of system diagrams used to identify patient safety risks. Although the earlier documents 130 produced by Department of Health and NHS stated the need for implementing systematic risk assessment 131 and management through PHA approaches, such as Failure Mode and Effect Analysis (FMEA), Hazard 132 Operability (HAZOP), and Structured What-if Technique (SWIFT), in the NHS [24, 25], there was no 133 mention of such methods or direct reference to the use of such methods in the policies and procedures as 134 provided by the trusts. Analysis of the documents supported the conclusion that PHA methods have not 135 yet been embedded in trust-level policy and procedure documents. 136

Despite the lack of description of PHA tools and methods, a few trust documents did outline processes 137 that ensure a continuous and systematic approach to risk assessment followed throughout the organisation. 138 These processes, in general, allow for informed management decisions in the identification, assessment, 139 treatment, and monitoring of risk to minimise the hazards that threaten the organisations. For instance, two 140 trust docu-ments cited their adoption of the Australia/New Zealand risk management standard, which 141 is based on the ISO 31000 standard. However, as with the results of the earlier study [20], there was 142 no detailed information available on the construction and use of system descriptions as part of the risk 143 identification process. 144

Only limited information was presented in the documents addressing the extent to which hazards and risks should be identified. Some documents presented a comprehensive list of risks; one trust document, in particular, emphasised the importance of recording all possible risks without considering their likelihood or severity. This document showed that risks can be dynamic, continually changing according to the individual service user's circumstances; hence, the likelihood and severity of a risk can change over the course of time. It was therefore recommended that maintaining a brief record of all possible hazards is good practice, as well as helping to avoid superfluous details.

With regard to different tools and methods used in combination, again only limited information was 152 found in the documents provided. For instance, one of the trusts mentioned that a team of clinicians, 153 managers, and staff is assembled to create a profile of the trust at a particular time, using a variety of these 154 methods in combination, such as interviews, questionnaires, site visits, and facilitated group meetings. 155 The trust expected in this way that the ward manager or senior nurse within a given ward would assess 156 health and safety issues and clinical risk assessments as part of his or her speciality job role. Workers 157 who need support to undertake such assessments would also be supported with guidance, which shows 158 the use of a systematic process in risk assessment, supplied by the patient safety manager or the health 159 and safety risk manager. Although only a few documents exhibited the use of different risk identification 160 tools and methods in combination, the use of risk register systems seems to answer this need, at least 161 partially, by including all identified hazards and risks in one picture. 162

Risk register systems provide key features that help to understand whether the current risk identification 163 process is reactive or proactive. All the trusts (n = 21) indicated that they employ a risk register system, 164 a systematic form of documenting and recording identified risks and risk assessments. Comprehensive 165 use of risk registers, at a trusts-wide level, would enable a broader understanding of risk, allowing it to 166 be better addressed. It is suggested in many trust documents that all ongoing risks identified through risk 167 assessment should be recorded in the risk registers. Hence, consideration and documentation of the source 168 of the risks would be important in risk registers, as this would enable the trusts to identify which risks 169 have been identified by proactive and reactive tools; this might help workers understand whether risks 170 are better or more often identified reactively or proactively. Such systems can also shed light on whether 171 the risks recorded in risk registers relate to clinical, non-clinical, organizational, or financial issues. 172

There was an emphasis, in a few documents, on developing a positive risk and patient safety culture, to 173 promote awareness and understanding of the benefits of proactive risk management. One document, for 174 instance, indicated the need for a culture where risk management is integral to the everyday operation and 175 fully supports the trust's objectives. A few documents showed that trusts, by implementing appropriate 176 policies and procedures, help foster a culture of risk awareness, enabling staff to play an important role 177 in identifying and managing hazards and risks. Some trust documents emphasised various safety culture 178 terms, such as being open, just, and nonpunitive, reporting adverse events, and identifying hazards, as a 179 fundamental part of the work and role of all staff. In most cases, however, such terms were mentioned as 180 part of incident reporting, but not in the use of proactive tools. Only a few documents indicated everyone 181

in the trusts to be observant in identifying possible hazards and threats proactively, and being prepared
 to share their concerns about perceived hazards with other healthcare staff.

These results indicated that the trusts in the chosen region, in general, recognised the value of a 184 systematic approach to risk management, but the documents provided insufficient support for the use 185 of prospective risk identification tools and methods, as compared to the guidance available in other 186 safety-critical industries. While the analysis of incident reports was the main method reported in the 187 documents provided by the trusts, guidance from other safety-critical industries showed that those other 188 industries have invested extensively in prospective risk assessment tools, in addition to using incident 189 reporting. It was found that incident reports are used as a supplement to proactive risk identification tools 190 in other safety-critical industries. Such industries also reported that a number of tools and methods, such 191 as FMEA, HAZOP, and SWIFT, which have been used successfully and broadly, are more proactive 192 and systematic in the identification of hazards and risks than retrospective methods, such as incident 193 reporting. Moreover, they emphasised the value of using multiple methods in combination, and outlined 194 further information on the features of successful risk identification processes. However, as mentioned 195 earlier, such PHA methods have not been embedded in the healthcare settings described in the documents 196 provided, despite the importance of these tools as recognized by the NHS [24, 25]. 197

198 **4. Discussion**

It is accepted as a given that the documents provided by the trusts represent the standard, and to some 199 degree reflect the actual level of risk identification in practice. A number of studies were conducted by 200 analysing the policies and procedures, but there are some limitations on generalising the results of such 201 analysis, due to the data source (procedures and policies) and specific region (EoE). First, the consistency 202 in the policies and procedures received from the trusts limits the potential to make a definitive statement 203 about risk identification processes in the NHS. Second, this study analysed the documents from the East of 204 England (EoE) area of the National Health Service; the results might differ in other regions and countries. 205 It is therefore difficult to conclude to what degree the results in this study can be generalised beyond EoE. 206 As also mentioned in an earlier study [21], the analysis relied on the documents received from the trusts 207 in response to a freedom of information request — although these documents were provided by the trusts, 208 there might be other documents that might have been more relevant or might have discussed the trusts' 209 risk identification processes in further detail. Or, as suggested by Card et al. [21], healthcare staff who 210 work on healthcare risk management and patient safety might contribute to the risk management process 211 in ways not captured by the policies and procedures. As Card and colleagues also stated, the paperwork 212 required by the risk management process can be complete with no reference made to the relevant policies 213 and procedures, which implies that such documents might be largely or routinely ignored. Real-world 214 risk identification practices may therefore differ from the risk management policies and procedures that 215 putatively govern them. 216

A number of recommendations can be made, based on the document analysis and with the help of guidance from other safety-critical industries.

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• Introduce the use of PHA tools in the creation and revision of policy and procedure documents.

The value of the contribution of PHA methods to the overall risk assessment process has been pointed out in a number of studies [18, 26–28]. However, despite the utility of systems approaches, there is only a very slow and sporadic adoption of PHA methods in healthcare [29]. The low rate of adoption of

such methods was particularly highlighted in the UK, where these approaches are not mandated [30]. In 223 order to shed light on issues impeding adoption, Ward and colleagues [20] listed the following barriers 224 to implementing PHA methods in the NHS: [1] availability and accuracy of data and information, [2] 225 complexity, [3] process variability, [4] current risk management practice, [5] the need to train specialist 226 facilitators, [6] availability of resources, and [7] culture. It was noted that it is not easy to adopt PHA 227 methods in healthcare organisations where such limitations exist. Recently, Potts and colleagues [30] also 228 identified three possible reasons why the healthcare industry has been slow to adopt PHA methods: [1] the 229 variety of methods makes it difficult to choose the most suitable method for a particular system assessed, 230 [2] the methods are resource-intensive, and [3] there is little evidence of their reliability and validity. In 231 addition to adoption issues, a number of concerns were raised about the validity and reliability of such 232 tools in healthcare contexts [31–33]. Potts and colleagues [30] stated that validation of PHA methods is 233 methodologically challenging, despite a few investigations proving their reliability. Beyond this, only a 234 few studies have highlighted the use of multiple reactive and proactive methods to successfully provide a 235 comprehensive view of risk in a given healthcare system [19, 30]. Potts and colleagues [30] also pointed 236 out that PHA methods should not be used in isolation in providing a comprehensive description. However, 237 there is no evidence in the healthcare literature of how well such an amalgamation, using multiple inputs 238 from both reactive and proactive risk identification approaches, can be demonstrated. These issues taken 239 together show that there is still a need to implement an improvement in risk identification, which will 240 contribute to the improvement of patient safety. 241

Further, healthcare industry needs to be careful in selecting and adapting risk identification methods 242 from other safety-critical industries, due to the implications of the differences between their natures. 243 Moreover, a number of requirements associated with the use of prospective risk identification tools, 244 such as the need for expertise, types of inputs and outputs, were highlighted in earlier studies [20, 29]. 245 Lyons [29] also emphasised that there is a lack of practical experience regarding use and selection of 246 prospective risk identification tools in healthcare. Further, it was noted that selected methods should be 247 made accessible by healthcare users and other users new to the system. Hence, Lyons [29] indicated the 248 need for initial guidance in supporting the selection of prospective methods, due to their large number 249 and complexity. This can possibly be accomplished starting with the definition of basic tools and methods 250 (such as structured brainstorming), or the current PHA Toolkit provided for the healthcare community 251 by Clarkson et al. [34]. 252

In addition to helping select appropriate PHA tools, potential integration between reactive and proactive 253 methods was also recommended in the PHA toolkit as an area needing further research [34]. Similarly, 254 the potential benefit of linking risk identification with incident reports was studied by Kessels-Habraken 255 et al. [19, 20]. There has so far been little work done, however, on the integration of such methods in 256 the healthcare research environment [19, 35]. As mentioned earlier, incident investigation and safety 257 walkabouts are the main risk identification techniques used in the healthcare setting [20]. The possible 258 use of current methods, with the support of prospective methods, might therefore improve patient safety 259 further. 260

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• Provide individual guidance on risk identification to accelerate improvement in patient safety.

The documents provided by the trusts showed that the trusts consider different types of risks, such as clinical risks, health and safety risks, information risks, project risks, operational risks, and financial risks. Hence, it was not easy to decide, through analysis of the documents alone, which specific tools and methods are particularly available for identifying patient safety hazards and risks. It can be said that different risk sources might affect each other. For instance, one of the trusts' documents stated that the

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trust does not separate clinical and nonclinical risks, as either could ultimately impact the delivery of 267 care and the achievement of objectives. Despite this, implementation of risk identification guidance in 268 which the specific focus is on patient safety risks can potentially promote risk culture, and awareness of 269 particular tools and methods. 270

It can be said that each risk identification method prescribed in trust-level documents may have 271 strengths. However, it is still an open question how adequately each method has been implemented 272 so far, and how well they have been integrated to create a comprehensive list of risks in complex health-273 care systems. Moreover, none of PHA tools have been extensively introduced in trust-level documents as 274 opposed to other safety-critical industries. Research recently conducted by Hudson et al. [36] highlighted 275 the need for healthcare organisations to adopt a new approach to identify and mitigate patient safety haz-276 ards by learning from the experiences of other safety-critical industries. The potential exists, therefore, 277 for improving the risk identification process by identifying the areas needing improvement within current 278 risk identification practices, and by studying the experiences of other safety-critical industries; therefore 279 introducing them in their trust-level guidance. 280

5. Conclusion

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The documents provided significant insight into prescribed risk identification practice from the acute, 282 mental health, and ambulance trusts in the chosen region of the NHS. As a result of the content analysis, 283 it was found that PHA approaches have not been introduced in trust-level documents compared to the 284 guidance from other safety-critical industries. It can be recommended that introducing PHA tools in 285 trust-level policies and procedures, and providing individual/specific guidance on risk identification may 286 provide sufficient support to encourage healthcare staff to identify risks to enhance improvement in patient 287 safety. 288

Conflict of interest 289

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