

Article

Development and Introduction of the Risk-Sentience Auxiliary Framework (RSAF) as a Robust Enabler to the ISO 31000 and ISO 31010 for High-Risk Environments

Jerry Selvaseelan

Risk and Quality Advisor, Health Service Executive (HSE), Community Healthcare Organisation-7,
Oak House, Millenium Park, Naas, Kildare, Republic of Ireland; jerry.selvaseelan@hse.ie/jerryot@gmail.com;
Tel.: 00 353 45882527/00 353 85 8287384

Abstract: The aim of this Irish study was to develop, implement and evaluate a new auxiliary risk management framework and process to serve as an enabler to the global ISO 31000 [5] risk framework and ISO 31010 processes [38]. This framework has been designed particularly for use within high-risk environments and those characterized by volatility, uncertainty, complexity and ambiguity (VUCA). The key objective was optimization of structured sharing and grass-root management of all available risk-information which have assessed potential to develop into a future identifiable risk. The author introduces new risk terminology including risk-sentience, risk-sentience information and risk-sentience management. The process involved development of the Theory of Risk-Sentience (ToRS), Risk-Sentience Auxiliary Framework (RSAF) and a risk-sentience management process referred to as LUOMEAR (Learning from Uncertainties, Others Mistakes, Experiences and Anecdotal Reporting). Manchester Patient Safety Framework (MaPSaF) [32], SWOT analysis and a newly developed Risk-Sentience Fertility Checklist were used to conduct pre and post-trial evaluations. The findings include positive adjustments in safety culture components of commitment to quality, communication and team-working around safety issues, access to evolving risk-information and efficient sharing and management of recorded risk-information with potential to develop into a future identifiable risk. Recommendations are made for more extensive applications of both the proposed auxiliary risk framework and process within high-risk sectors to further explore its effectiveness and scope.

Keywords: uncertainty management; risk management; safety; ISO 31000:2009; ISO 31010:2009; risk management framework; risk-sentience; safety culture; risk culture

1. Introduction

It would be considered a rational argument to state that the focus of organizations possessing either pro-active or generative safety culture would be on early and robust risk management, rather than by merely prioritizing incident management processes post-occurrence of incidents. However, such an argument would be based on the presupposition that it is generally acceptable to wait for the prospect of an event or uncertainty to evolve into the form of an identifiable risk before effectively addressing it. However, within the context of high risk and volatile environments (eg. counter-terrorism, oil rigging, complex surgery etc.) this waiting period of inaction could be the incubation stage of rapidly evolving risk-information which could potentially result in severe and long-lasting consequences. The question arises then, can evolving risk-information be better addressed at grass-root level even prior to becoming an identifiable risk? It has also been observed in organizations that risk management procedures fail to achieve complete buy-in from non-management workers due to a variety of reasons: ineffective communication from senior management, difficulty in establishing a risk-based work culture or uncertainty over reasons why

they should participate in risk management processes [1]. While the senior management employee's role is clearly established within the ISO framework, the role of non-management employees is not specified at all. Furthermore, the absence of personal values and ethics within the ISO framework, though they are recognized to have a bearing on risk-perception [34, 35] gives credence to the possibility that the framework has further scope to be improved on. The ISO 31000: 2009 which sets out the global best-practice standard in organizational risk management appears to have covered several aspects of efficient risk management in theory. In practice however, it has been open to debate whether its approach relating to the concept of uncertainty is appropriate [2] (p.p 5-8), and whether the potential for achieving buy-in and feeling of ownership of the risk-management process within the non-management employee category is realistic within this framework. According to the ISO 31000, risk is defined as the effect of uncertainty on objectives [6]. With uncertainties being identified as the singular causative factor for all risk, it would be a reasonable expectation that addressing uncertainties would feature prominently within the core ISO framework, but that is not the case. It is worth reflection that uncertainties and other risk-information which can be addressed are only those which we are made aware of, indicating the vital need for a robust process to obtain such evolving information on an ongoing basis.

The aim of this study was to develop, implement and evaluate a new auxiliary risk management framework and process to serve as an enabler to the ISO 31000 framework and ISO 31010 processes. This was envisaged to occur by optimizing structured sharing and management of all evolving risk-information which had identified potential to develop into a future risk, with secondary objectives of improved safety culture and engagement from non-management employees within the auxiliary risk-management process. The context of this study was in a community Occupational therapy department within a major Irish public health service organization which had adopted the ISO 31000 and ISO 31010 risk standards. The community occupational therapists included in this study were exposed frequently to issues of high-risk such as pressure ulcer development, serious incidents relating to use of hoists/ wheelchairs and complex seating assessments, all within the context of lone working in the community.

2. Literature Review

An extensive literature review was conducted to ascertain the current schools of thought in relation to global risk management strategies, frameworks and processes. This information was utilized to develop and design a supplementary risk-framework and process by building on the experiences and critique of the current ISO 31000 risk framework.

2.1 Managing uncertainties in risk management

Some challenges relating to ISO 31000's handling of the concept of uncertainty are based on prominent author Frank Knight's analysis within his seminal work '*Risk, Uncertainty and Profit*' in 1921. He established the foundational differences between uncertainty and risks by pointing out that while in the case of risks the distribution of outcome in a group of instances is known, for uncertainties it is impossible to form a group of instances as the situation dealt with is unique to a high degree. He differentiated risk as measurable uncertainty with objective probability and uncertainty as immeasurable uncertainty with subjective probability [6]. However, this opinion is not embraced by all as some believe that many uncertainties are measurable, although some are not [7]. Over the past nearly 100 years since Knight arguably established these classic distinctions between risk and uncertainty, these two sibling factors appear to have merged dangerously close to each other, with these terms even used interchangeably within the context of risk management [8] (p. 75).

In 1961, Ellsberg added the concept of ambiguity within the specific context of establishing subjective probability, by suggesting that the quality of information (amount, type, reliability and unanimity) has a direct bearing on our confidence in the knowledge we utilize to establish subjective

probabilities [9]. Combining the works of Knight and Ellsberg, John Prpic summarized the key differences between risk and uncertainty and defined risk as a situation where the probability and impact estimates of an event are objectively known, and the confidence in the quality of the information used to construct these estimates is very high. He further defined uncertainty as a situation where the probability and impact estimates of an event are subjectively determined, and the confidence in the quality of information used to construct these estimates varies from low to high [2]. But as the ISO definition points out, the crucial determinant in identifying uncertainty is its potential to eventually lead to an effect on objectives, thereby causing a risk. However, this does not seem to be captured within Prpic's definition. Moreover, Hillson points out that not all uncertainties are relevant within the context of risk management except the uncertainties that matter, which is that on occurrence, will have either a positive or negative effect on objectives. The remaining uncertainties are irrelevant and do not need to be addressed under risk management [10] (pp. 6-7).

Combining the knowledge base mentioned, the author proposes an inclusive definition of risk as a situation where the probability and impact estimates of an event are objectively known, the confidence in the quality of the information used to construct these estimates is high and where there is a mandatory effect (positive or negative) on objectives. The author further proposes that uncertainty be defined as a situation where the probability and impact estimates of an event are subjectively concluded; the confidence in the quality of information used to construct these estimates is highly variable, and has confirmed potential to become a risk only when its occurrence will have an effect (positive or negative) on objectives. These definitions highlight that not all uncertainties result in a risk. Due to these established differences between risk and uncertainty, there could be an opportunity for introduction of uncertainty management capable of identifying and managing several sources of uncertainty which give rise to and shape our perceptions of threats and opportunities. Such a strategy would need an uncertainty identification process with more open-ended, neutral description of factors, facilitating a less constrained consideration of response options [11].

The authors of an international perspective paper report that measurement of uncertainty within risk assessment can be varied; subjective probability, non-probabilistic representations with interpretations as lower and upper probabilities, non-probabilistic representations with other representations such as degree of belief, degree of possibility, hybrid combinations of probabilistic and non-probabilistic representations and semi-quantitative approaches. They also suggest that where risk analysis of large uncertainties is conducted, probabilities may not reflect the knowledge or information available and recommend the need for an extended framework for risk assessment which reflects the separation that exists between the analyst and decision-maker [12]. The choice of the method of measurement of uncertainty would be dependent on which risk theory each risk-analyst adheres to. For example, adhering to the Theory of Statistical Decision of 1951, the analyst could treat all uncertainties as risks, evaluating them with a subjective probability measure [13], whereas following the logical-relationist theory of Keynes, one would consider uncertainties as a state in which it is impossible to attribute a reasonably definite probability to the expected outcome [14] (p. 31).

While sensitivity evaluation experiments on the measurement of subjective probability seem to suggest that numeric measures outperform other scales [15], in some situations single-valued probability is not considered adequate to represent uncertainty and non-probabilistic measures interpreted as lower and upper probabilities are seen as more appropriate [12] (p.1201). It has also been observed that certain uncertainties in scientific advice to policy-makers are not caused by probabilistic predictions, but could originate from a fundamental lack of understanding of new phenomena at or beyond the frontiers of present knowledge [16] (p.891). Concerning uncertainty management, apart from rational strategies (calculation of probabilities, weighing pros and cons etc.) and irrational strategies (faith, hope etc.), it has also been argued that the reality of human decision-making influenced by 'in-between strategies' which may have some features of rational (may rely on use of knowledge but not scientific knowledge) and features of irrational (influence of personal context, feelings or beliefs), including the use of trust, intuition and emotion is vital [17] (pp.439-450).

The identification of risks are not always straightforward as they can be a borderless phenomenon, cutting across boundaries such as sociotechnical, geopolitical, organizational, cultural, physical or health related across a range of tangible and intangible borders [18] (p.3). The post-modern reality of the transcending of risks further into known uncertainty, unknown uncertainty (where one is missing information that others may possess) and even unknowable uncertainty (where others also lack information about the probability and thus perceived to be in the same boat) would require a more perceptive framework to address uncertainties at its evolving stages. The distinction between the unknown and unknowable uncertainty is said to depend on the assumption that a subject makes about the availability of information [19] (p.136).

Prpic states, within the context of project risk management, that uncertainty should not be conceptualized as a dimension of risk but as a separate phenomenon that can and does occur simultaneously with risk, and that project risk management is in effect about the management of risk, uncertainty and information confidence. He aptly suggests adding an information-confidence element to the subjective estimates of probability and impact to drive uncertainty management and states that many such errors and omissions also exist in the ISO 31000 framework [2]. The perception of uncertainty depends on personal skills, intuition and judgement and though uncertainty cannot be eliminated, continuous reflective learning and information sharing can reduce it to manageable levels [8] (p.77). The explicit treatment and communication of uncertainty is stressed as critical to the credibility of risk assessments by the 1989 U.S National Research Council report which stated that risk messages and supporting materials should not minimize the existence of uncertainty and that data gaps and areas of significant disagreement among experts should be disclosed. It also recommended that some indication of the level of confidence of estimates and the significance of scientific uncertainty needs to be conveyed [20].

2.2 Limitations and deficiencies within the ISO 31000:2009 framework

The benefits of the introduction of the ISO universal risk framework designed to be applicable to all industries has been lauded and supported by several risk management experts and commentators [21,22,23,24,25,26]. However, there have also been a steady flow of authors pointing out several components within the framework which they identify as possible deficiencies [3,4,5,2]. The absence of principles relating to the importance of a staff development program and establishing a system to acknowledge employees who detect risks early are pointed as limitations, and suggestions include the possible use of subjectivity, intuition, past experiences and motivation to enable efficient use of this standard [4] (p.278).

2.3 Risk perceptions and the determinants of risk-taking behaviour

There are several factors which can influence the development of risk perception from childhood into adulthood. In a study involving 10-12 year olds, children were able to identify and relate to risks presented by linking it to their own personal experiences or an observation about others who were engaged in a similar activity like crossing at an intersection, using a sharp knife etc. [27]. Risk-taking behaviour is said to be influenced by characteristics of the person, the situation and whether affect is involved, and also the '*who and when*' interact relating to the familiarity with a risk domain [28]. People with higher risk-perception as adults have a higher intention to engage in risk-reducing strategies, and a person who is more willing to take risks will have a lower subjective perception of risk. Empirically supported key determinants of risk-taking behaviour in children were identified as individual characteristics including age, sex, behavioural attributes, experience with activity, personal values and temperament, family/parent factors including socialization and teaching practices, parent modeling, style and attributes, sibling effects, socio-situational factors including persuasion influences, observational influences and situation-driven motivations.

The literature review thus reinforces the perspective that the foundational differences between the concepts of risk and uncertainty may not be fully appreciated within the ISO 31000 model. Also, there appears to be a valid case for the introduction of a dedicated uncertainty management component within the risk management framework, and where numerical probabilities are not

appropriate as an uncertainty measure, non-probabilistic measure with upper and lower probabilities may be necessary. Information sharing is identified as the key to manage uncertainties, and credibility given to the suggestion that '*information confidence*' may need to be added to the subjective estimates of probability and impact concerning uncertainty management. Deficiencies within the ISO framework have been identified from various quarters, with further need for organizational staff members to be involved within the risk process in early detection of risks and further training programs. Furthermore, risk-perception is said to be directly impacted by risk attitudes and the key determinants of risk-taking behaviour have been identified from social developmental research. These factors would have immense potential to be harnessed together to create a powerful tool for uncertainty identification.

3. The Theory of Risk-Sentience (ToRS)

While a healthy organizational safety or risk culture requires early and effective identification of risks, the author observed a difficulty in organizational staff applying this in everyday practice. There appeared to be a process missing in the sequence of effectively identifying evolving risks.

Sentience is a term which appears to have no universally accepted definition [30], with some defining a 'sentient being' as someone who has the ability to evaluate the action of others in relation to itself or third parties, to remember its own actions and consequences, to assess risks and benefits, to possess degree of feelings and awareness [31]. The term 'sentience' is generally considered as the ability to feel, perceive, or experience subjectively. It has also been defined as the ability to evaluate the actions of others in relation to itself and third parties, to remember some of its own actions and their consequences, to assess risk, to have some feelings and to have some degree of awareness [36]. The author introduces a new risk terminology referred to as 'risk-sentience' and defined as *the ability to perceive, feel or experience subjectively the positive or negative deviation as a result of uncertainty on objectives*. This is hypothesized to develop by a continual process involving sharing of uncertainties (unknown probability of occurrence), other's mistakes, experiences (personal and others) and anecdotal reporting of events. For example, children develop their risk-sentience relating to crossing a road from a complex amalgamation of information weaved naturally together from the following: their doubts on how to cross safely, hearing their friend's experience or mistakes relating to crossing roads, their own past experience, and their parents or school teachers warning them of potential dangers. It is also proposed that safety or risk-culture will not be easy to cultivate in an organization until its precursor risk-sentience, being a natural and innate skill, is well-watered and nurtured first.

While uncertainty has been defined as the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood, risk is defined as the effect of uncertainty on objectives [5]. The effect referred to is a deviation from the expected – positive and/or negative. A cumulative analysis would thus infer risk is a result arising only in the situation where there exists a deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood which causes a positive or negative deviation from an objective. But there appears to be a missing component, as there also is in existence emerging risk-information which may not have identifiable deficiency in reference to the currently available knowledge pool and the likelihood that its own effect could cause a positive or negative deviation from an objective may be a reasonable certainty.

In the ISO Guide-73, a risk source is defined as an element which alone or in combination has the intrinsic potential to give rise to risk [37]. The author suggests that uncertainty is not the sole potential owner to be a risk source as the ISO definition suggests, but can be so when combined with all risk-sentience information. The term 'risk-sentience information' is defined by the author as *all relevant emerging risk-information which may or may not have identifiable deficiency with reference to all available body of knowledge, and its likelihood that its effect will cause a positive or negative deviation from an objective includes a reasonable certainty, with the source of such information mainly originating from personal or others experiences, mistakes, anecdotal reporting and includes reports of uncertainties*. Risk-sentience management can be defined as *the process of management of all risk-sentience information, including*

uncertainties, with the core objective of preventing them from attaining the state of an identifiable risk. The theory of risk-sentience initially overlaps certain characteristics of a safety/risk culture within an organization, but then demarcates itself completely by going much further in its demand for developing an organizational consciousness which is able to pro-actively seek out and eliminate any uncertainties or evolving risk-information in an ongoing and robust manner.

4. The Risk-Sentience Auxiliary Framework (RSAF)

The Risk-Sentience Auxiliary Framework (RSAF) is thus a supplementary risk management framework to the ISO 31000, designed specifically for environments characterized by high risk and components of volatility, uncertainty, complexity and ambiguity (VUCA), incorporating aspects of effective management of both risk-sentience information and uncertainties with the core objective of preventing them from attaining the state of an identifiable risk. The RSAF framework developed (Figure-1) was specifically designed to serve as an auxiliary component to further supplement the efficiency of the current ISO framework, and not to undo or make impotent any of the components which constitute the organization's currently adopted risk management framework. The components identified for inclusion were non-management commitment and pro-active engagement, appropriate risk attitude and behaviour, continual risk-sentience development and strategy, transparent, anonymous and timely recording of risk-sentience data and blame-free culture to bad news and mistakes. Personal values and ethics were assigned the central position within the framework, to convey their influence as a key driver of the framework.

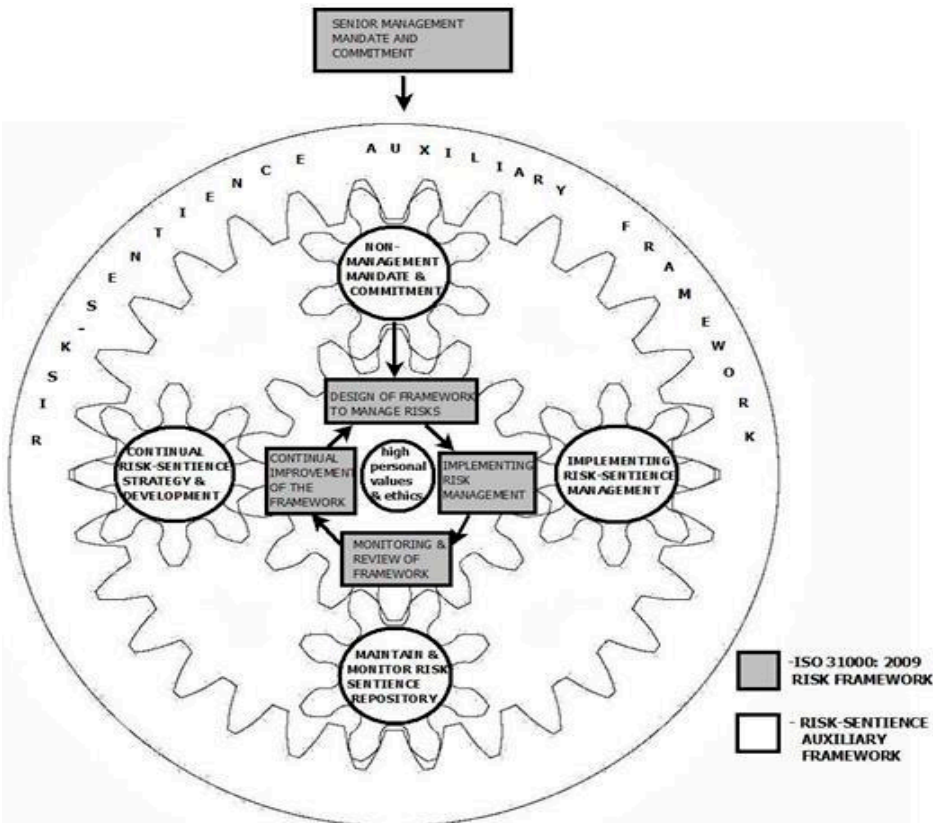


Figure-1: Risk-Sentience Auxiliary Framework

The framework was designed as a planetary cog-wheel system with high personal values and ethics as the sun and also conveying the interdependency of each of the risk-sentience components towards powering the ISO 31000 framework. The author aimed to design and develop a new risk-sentience management process aligned least 80% to key domains of empirically supported determinants of children's risk decisions. Three core domains of empirically supported determinants of development of risk awareness were identified as individual characteristics, family/parent factors,

and social-situational factors [29]. The new process designed was named as LUOMEAR (Figure-2) and consisted of the following components; learning from uncertainties, other’s mistakes, experiences and anecdotal reporting. As demonstrated (Table-1), 80% of the risk determinant components were successfully integrated into the LUOMEAR process.

Determinant factors	Points	LUOMEAR process	Points
<i>Individual characteristics</i>		<i>Learning from...</i>	
Age	1	Personal experiences	1
Sex	1	Personal experiences	1
Behavioral attributes	1	-----	0
Experience with activity	1	Personal experience	1
Personal experience & Values	1	Values & ethics	1
Temperament	1	-----	0
<i>Family/ parent factors</i>			
Socialization practices	1	Other’s mistakes	1
Teaching practices	1	+	1
Parent modeling	1	Personal experiences	1
Parenting style	1	+	1
Parenting attributes	1	Anecdotal reporting	1
Sibling effects	1		
<i>Social-situational factors</i>			
Oral-persuasion influences	1	Anecdotal reporting	1
Observational influences	1	Personal experiences	1
Situational motivations	1	Personal experiences	1
Total	15 (100%)	Total	12 (80%)

Table-1 Integration of risk-determinants into LUOMEAR

RISK-SENTIENCE MANAGEMENT PROCESS
(INCORPORATING UNCERTAINTY MANAGEMENT AND CORE DETERMINANTS OF RISK-TAKING BEHAVIOUR)

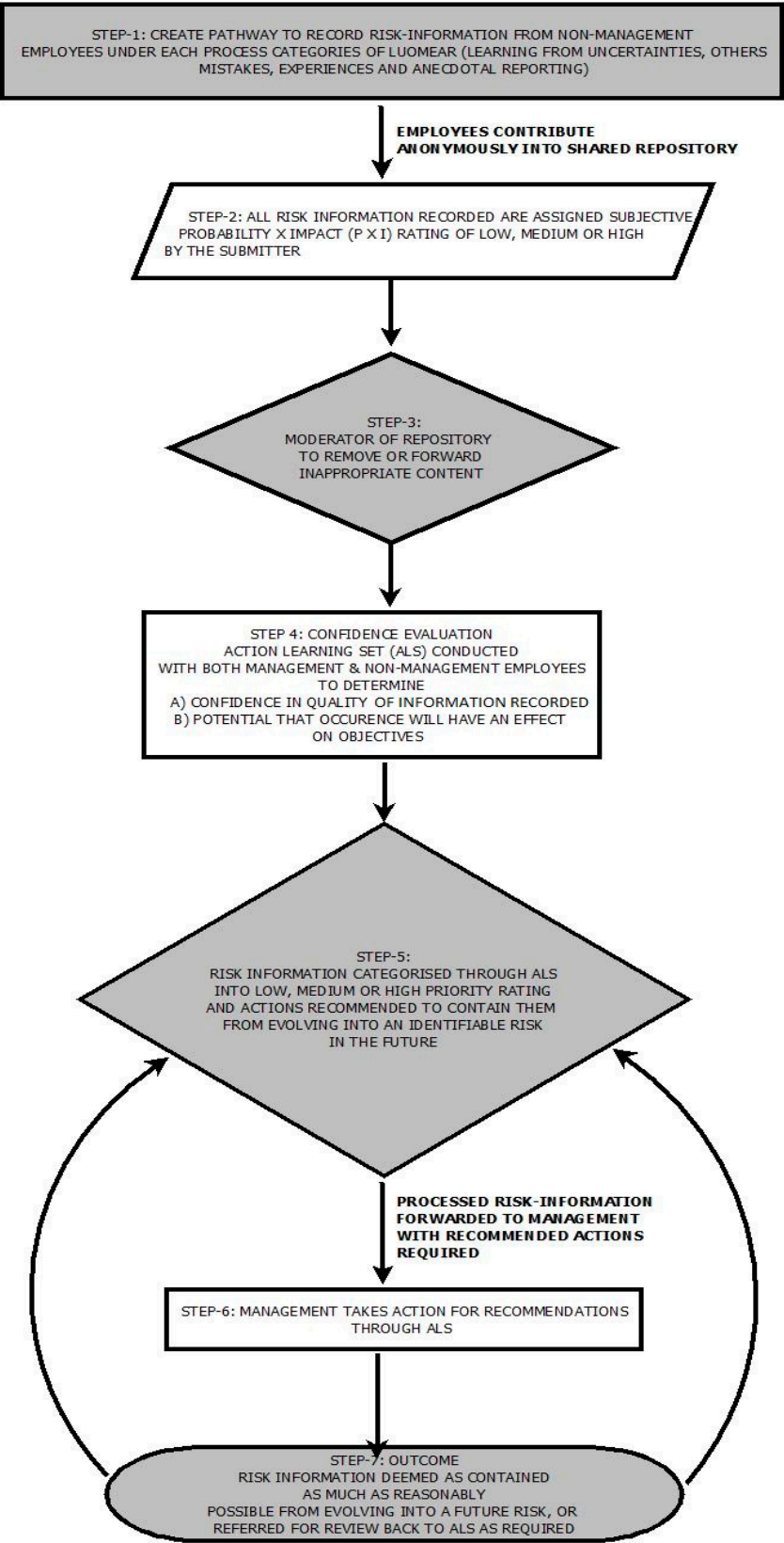


Figure-2: LUOMEAR – Risk-Sentience Management Process

The author also aimed to develop a Risk-Sentience Fertility Checklist incorporating key indicators of healthy risk culture. Four key indicators were identified as tone at the top, governance, competency and decision-making [33]. The Risk-Sentience Fertility Checklist (Table 3.1 and 3.2) was developed to serve as a health indicator of the level of risk-sentience culture within any organization or enterprise. Eleven of the eighteen statements forming the newly developed Risk-Sentience Fertility Checklist (Table-2) were aligned to the components of the risk culture model.

IRM Risk Culture	Points	Risk-Sentience Checklist	Points
Tone at the Top			
Risk leadership-Clarity of direction	1	Statement-2	1
Organisation response to bad news	1	Statements-3,6,7	1
Governance			
Clarity of accountability for managing risk	1	Statement-9	1
Transparency and timeliness of risk information	1	Statements-6,7	1
Competency			
Status, resources and empowerment of risk function	1	Statements-4,17	1
Embedding of risk management skills	1	Statements-1,12,15	1
Decision making			
Well informed risk decisions	1	Statements-11,12,13,14	1
Appropriate risk taking rewarded	1	Statement-5	1
Total	8	Total	8

Table-2 Integration of key risk culture indicators into Risk-Sentience Fertility Checklist

RISK-SENTIENCE FERTILITY (RSF) CHECKLIST
Yes = This is definitely the case in my institution (Score = 1)
? = Don't know, Maybe, or Could be partially true (Score = 0.5)
No = This is definitely not the case in my institution (Score = 0)

Statement	Yes	?	No
1) Risk Management is clearly recognized within the entire organization as a shared responsibility of each and every employee, and not just that of the senior/ risk management team.			
2) The organization has the leadership and openness to acknowledge its failures, to apologize for them, and to reassure that the lessons learned from past errors will help prevent their recurrence.			
3) After an adverse event, the senior management attempts to learn from it rather than try to attribute blame on the person reporting it.			
4) Staff from a wide variety of departments and levels (eg.porters) regularly attend meetings together related to risk management.			
5) Appropriate and prudent risk-taking behaviours are rewarded and encouraged and inappropriate behaviours challenged and receive sanction.			
6) There is a very transparent and risk-information flow within the organization with bad news rapidly communicated without any fear of blame.			
7) The organization always encourages anyone to raise safety concerns and risk issues. Messengers and whistleblowers are encouraged and rewarded, not dismissed or discredited.			
8) The organization relies on building trust and transparency with its workforce with full realization that a robust risk management reporting system will not survive without it.			
9) Accountability- each employee within the organization is fully aware of the risks for which they take full ownership and how to escalate risks which they have identified.			
10) Effective challenge- Alternate views, opinions and debates on current risk management systems and their effectiveness are encouraged and facilitated in an ongoing manner.			

Table-3.1 Risk-Sentience Fertility Checklist

Statement	Yes	?	No
11) A secure organizational database is present with collection of all identified risks (eg.Risk Register),with full access to all staff members and continuously updated.			
12) Access to evolving risk-information: All staff members are given full access to anonymously add valuable evolving risk-related information into the database without any fear of repercussions or blame.			
13) Experiences: Relevant personal experiences which have potential to evolve into risks have a dedicated system/process to be shared, discussed and addressed to prevent/ contain them developing into identified risks.			
14) Anecdotal Reporting: Third party reporting of evolving risks have a dedicated system/process to be shared, discussed and addressed to prevent/ contain them developing into identified risks.			
15) There is a robust, separate and ongoing non-management powered risk management process, which blends in without conflict to the senior management-driven mandate towards risk-management.			
16) Risk management is seen widely in the organization not as a top-down approach rather as a side-side approach with every worker equally valued and involved in this process.			
17) Risk management has a feeling of genuine ownership by most of the non-management staff members.			
18) High personal values and ethics are seen as the core drivers of an organizational Risk Management framework.			

INTERPRETING YOUR SCORE ON RISK –SENTIENCE FERTILITY

16 — 18	Excellent, but keep the learning on!
11— 15	Good, but don't get complacent
6 — 10	Developing, but needs more focus and planning
0 — 5	Primitive level, needs major policy changes!

GUIDANCE NOTES

Being a checklist, the scores are only indicators of what is working well and areas to develop on. The results are merely meant to be a focus-point to generate meaningful debate and discussion in improving the Risk-sentience culture within an organization.

Table-3.2 Risk-Sentience Fertility Checklist

5. Ethical approval and LUOMEAR process implementation

The participant pool was limited to all the Community Occupational therapy staff, excluding the department manager and the author. Royal College of Surgeons in Ireland (RCSI) Ethics Committee approval was received covering the entire scope of this study and data collection (RCSI Reference Number: REC 1162).

Overall, the five participants were required to participate in four different processes:

- (1) **Pre-trial evaluation:** Consisting of the Manchester Patient Safety Assessment Framework (MaPSaF) [32], SWOT analysis and Risk-Sentience Fertility Checklist with a total time commitment of an hour.
- (2) **LUOMEAR process (Figure-2):** The participants were also given the opportunity to trial the LUOMEAR computer program (Figure-3) which ran for a period of three months. The records created by the participants were categorized under: a) Uncertainties b) Other's Mistakes c) Experiences d) Anecdotal Reporting. Under each of the above classification they were able to add information under: 1) Category (eg. Identify as mistake/ experience etc.) 2) Brief description 3) Potential to develop into future risk- as low/ medium/ high. 4) Suggested solution/ how to address it. Electronic data collection by participants within LUOMEAR computer program occurred on an ongoing basis only during office hours and accessed through a secure shared drive.

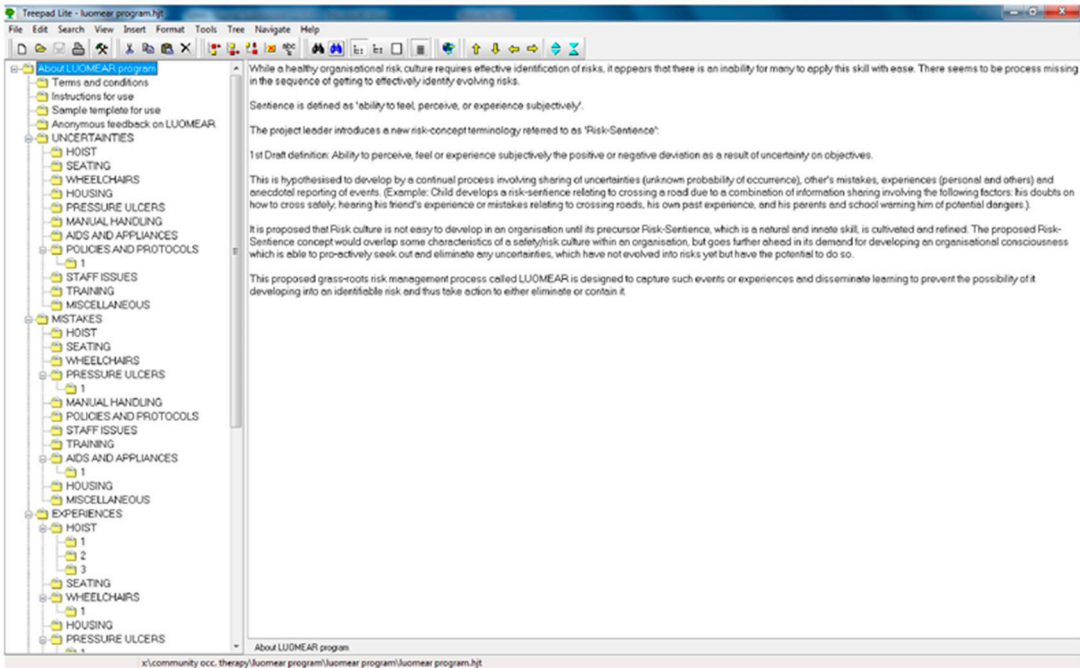


Figure-3: Screenshot of 'About LUOMEAR' page from pilot trial

The author customized the LUOMEAR repository computer program using free tree-based database software available on the internet. Terms and conditions were developed within the LUOMEAR program to ensure that the scope and purpose of the project was understood and strictly adhered to by the participants, and to limit inappropriate content being submitted into the computer program. At the end of the trial period, a total of 14 separate records were created by the participants.

- (3) **Action learning Sets:** Two half-hour Action Learning Sets (ALS) meetings were held during each monthly staff peer-support meeting. In each peer-support meeting within the 3-month period, each ALS session included a participant reading out anonymously submitted risk-sentence information. The ALS group members, who included both participants and non-participants, subjectively rated their confidence in the quality of the information recorded and assigned a rating of low, medium and high potential to evolve into a future identifiable risk through collective agreement. A recommended action was formulated by the group and forwarded to the department manager for action if required; otherwise, the learning from the records was disseminated within the group.
- (4) **Post-trial evaluation:** Consisted of the Manchester Patient Safety Assessment Framework (MaPSaF), SWOT analysis and Risk-Sentence Fertility Checklist with time commitment of an hour.

The project had been deliberately designed to limit identification of participants and ensured collection of anonymous electronic and hand-written data, with identifiable components limited as much as reasonably possible. During pre-trial and post-trial evaluation only computer typed or 'tick' responses on paper was collected, and during the three-month trial of the LUOMEAR program only anonymous electronic data was collected. All written data was scanned and uploaded into a secure and encrypted RCSI Ethics Committee drive, while electronic data was directly stored into the same drive for period of 5 years in compliance with the RCSI Ethics Committee requirements. Data collected in the study site was reviewed by the designated gatekeeper and the hard copy of the data collected, once scanned and stored in RCSI Ethics Committee secure drive, was destroyed through the organization's secure shredding disposal system. The total time commitment required from each participant was approximately 3 hours over a period of 5 months, excluding the individual time involved in their separate contributions into the program in creating anonymous records. After the

pilot implementation and evaluations, the author liaised with the department manager and discussed the improvements evidenced through the collected data. It was agreed that the actions recommended from the ALS sessions relating to the records created through the LUOMEAR process would be addressed through formal procedures as appropriate.

6. Evaluation

The system evaluation involved pre and post-trial completion of 3 tools; the MaPSaF (Tables 4.1 and 4.2), SWOT analysis and the Risk-Sentence Checklist (Tables 5.1 and 5.2). Risk-sentence information were recorded from all the available categories of LUOMEAR as follows: One record relating to policies and protocols in the category of *Uncertainty*, two records relating to pressure ulcer prevention and prescription of aids /appliances recorded under the category of *Mistakes*, seven records relating to hoist assessment and prescription, wheelchairs, pressure ulcers and aids and appliances recorded under the category of *Experiences* and four records relating to pressure ulcers, aids and appliances, hoist assessment/ prescription and manual handling recorded under the category of *Anecdotal reporting*. Action was either initiated or completed for twelve of the fourteen risk-sentence information records created within the LUOMEAR process, thus containing their potential from developing further into an identifiable risk. The potential for two of the risk-sentence information records to develop into a future identifiable risk were assessed as within acceptable levels, and action was confirmed as unnecessary by the department manager. A significant and direct outcome of the trial was the development and implementation of a new departmental policy relating to the half-yearly review of potentially high-risk medical equipment.

MANCHESTER PATIENT SAFETY FRAMEWORK (MAPSAF) - PRIMARY CARE EVALUATION DATA COMPILATION

1.Commitment to quality					
	A	B	C	D	E
Pre-trial (Team)	2	0	1	1	1
Post-trial (Team)	0	1	1	2	1
Pre-trial (Organisation)	0	1	3	1	0
Post-trial (Organisation)	0	2	2	1	0

2. Priority to patient safety					
	A	B	C	D	E
Pre-trial (Team)	0	0	2	1.5	1.5
Post-trial (Team)	0	1	0	2	2
Pre-trial (Organisation)	0	1	2	1.5	0.5
Post-trial (Organisation)	0	2	1	0	2

3.Perception to causes of patient Safety Incidents & their identification					
	A	B	C	D	E
Pre-trial (Team)	0	0	4	1	0
Post-trial (Team)	0	0	1	4	0
Pre-trial (Organisation)	0	0	4	1	0
Post-trial (Organisation)	0	0	2	3	0

4. Investigating patient safety incidents					
	A	B	C	D	E
Pre-trial (Team)	0	0	2	2.5	0.5
Post-trial (Team)	0	1	0	4	0
Pre-trial (Organisation)	0	0	4	0.5	0.5
Post-trial (Organisation)	0	0	2	3	0

5. Organisational learning following a patient safety incident					
	A	B	C	D	E
Pre-trial (Team)	0	0	3.5	1.5	0
Post-trial (Team)	0	0	3	1	1
Pre-trial (Organisation)	0	0	4.5	0.5	0
Post-trial (Organisation)	0	0	2	3	0

Table 4.1 MaPSaF Data Compilation

6. Communication about safety issues

	A	B	C	D	E
Pre-trial (Team)	0	0.5	3.5	1	0
Post-trial (Team)	0	0	2	2	1
Pre-trial (Organisation)	0	1.5	3.5	0	0
Post-trial (Organisation)	0	1	3	1	0

7. Personnel management & Safety issues

	A	B	C	D	E
Pre-trial (Team)*	0	0	3	1	0
Post-trial (Team)	0	0	2	3	0
Pre-trial (Organisation)	0.5	0.5	2	2	0
Post-trial (Organisation)	0	1	0	3	1

[*- One participant did not apply a rating for team patient safety culture in this evaluation by error]

8. Staff education and training about safety issues

	A	B	C	D	E
Pre-trial (Team)*	0	0	2	1	1
Post-trial (Team)	0	1	2	2	0
Pre-trial (Organisation)	0	0	3	2	0
Post-trial (Organisation)	0	0	4	1	0

***- One participant did not apply a rating for team patient safety culture in this evaluation by error.**

9. Team working around Safety issues

	A	B	C	D	E
Pre-trial (Team)	0	2.5	1.5	1	0
Post-trial (Team)	0	1	1	2	1
Pre-trial (Organisation)	0	1	3	1	0
Post-trial (Organisation)	0	1	2	2	0

Table 4.2 MaPSaF Data Compilation

RISK-SENTIENCE FERTILITY CHECKLIST - COLLECTED DATA

Statement		Yes	?	No
1) Risk Management is clearly recognized within the entire organization as a shared responsibility of each and every employee, and not just that of the senior/ risk management team.	Pre-trial	2	2	1
	Post trial	5	0	0
2) The organization has the leadership and openness to acknowledge its failures, to apologize for them, and to reassure that the lessons learned from past errors will help prevent their recurrence.	Pre-trial	1	3	1
	Post trial	2	3	0
3) After an adverse event, the senior management attempts to learn from it rather than try to attribute blame on the person reporting it.	Pre-trial	2	2	1
	Post trial	3	2	0
4) Staff from a wide variety of departments and levels (eg.porters, doctors) regularly attend meetings together related to risk management.	Pre-trial	0	2	3
	Post trial	1	3	1
5) Appropriate and prudent risk-taking behaviours are rewarded and encouraged and inappropriate behaviours challenged and receive sanction.	Pre-trial	0	4	1
	Post trial	3	2	0
6) There is a very transparent and risk-information flow within the organization with bad news rapidly communicated without any fear of blame.	Pre-trial	2	3	0
	Post trial	2	1	2
7) The organization always encourages anyone to raise safety concerns and risk issues. Messengers and whistleblowers are encouraged and rewarded, not dismissed or discredited.	Pre-trial	2	3	0
	Post trial	3	1	1
8) The organization relies on building trust and transparency with its workforce with full realization that a robust risk management reporting system will not survive without it.	Pre-trial	1	4	0
	Post trial	3	2	0
9) Accountability- each employee within the organization is fully aware of the risks for which they take full ownership and how to escalate risks which they have identified.	Pre-trial	2	3	0
	Post trial	2	2	1
10) Effective challenge- Alternate views, opinions and debates on current risk management systems and their effectiveness are encouraged and facilitated in an ongoing manner.	Pre-trial	0	2	3
	Post trial	1	3	1

381

382

Table 5.1 Risk-Sentience Checklist – Collected Data

Statement		Yes	?	No
11) A secure organizational database is present with collection of all identified risks (eg.Risk Register), with full access to all staff members and continuously updated.	Pre-trial	1	3	1
	Post trial	3	2	0
12) Access to evolving risk-information: All staff members are given full access to anonymously add valuable evolving risk-related information into the database without any fear of repercussions or blame.	Pre-trial	0	1	4
	Post trial	3	2	0
13) Experiences: Relevant personal experiences which have potential to evolve into risks have a dedicated system/process to be shared, discussed and addressed to prevent/ contain them developing into identified risks.	Pre-trial	0	4	1
	Post trial	3	2	0
14) Anecdotal Reporting: Third party reporting of evolving risks have a dedicated system/process to be shared, discussed and addressed to prevent/ contain them developing into identified risks.	Pre-trial	0	2	3
	Post trial	3	2	0
15) There is a robust, separate and ongoing non-management powered risk management process, which blends in without conflict to the senior management-driven mandate towards risk-management.	Pre-trial	0	3	2
	Post trial	1	3	1
16) Risk management is seen widely in the organization not as a top-down approach rather as a side-side approach with every worker equally valued and involved in this process.	Pre-trial	0	1	4
	Post trial	0	4	1
17) Risk management has a feeling of genuine ownership by most of the non-management staff members.	Pre-trial	1	3	1
	Post trial	0	5	0
18) High personal values and ethics are seen as the core drivers of an organizational Risk Management framework.	Pre-trial	1	3	1
	Post trial	0	5	0

INTERPRETING YOUR SCORE ON RISK –SENTIENCE FERTILITY

Yes = This is definitely the case in my institution (**score = 1**)
? = Don't know, Maybe, or Could be partially true (**score = 0.5**)
No = This is definitely not the case in my institution (**score = 0**)

16 — 18	Excellent, but keep the learning on!
11— 15	Good, but don't get complacent
6 — 10	Developing, but needs more focus and planning
0 — 5	Primitive level, needs major policy changes.

Table 5.2 Risk-Sentience Checklist – Collected Data

7. Discussions

The Manchester Patient Safety framework (MaPSaF) data analysis recorded positive variances in the safety culture components of commitment to quality, communication about safety issues, and team working around safety issues with progress into the pro-active and generative safety culture levels (Figures 4,5,6). It is to be noted that some participants chose to assign the T (Team) score across two culture components and in a few cases did not assign a score. Considering the 3-month implementation of this pilot trial, this positive, yet modest shift is notable. Due to participant error during the pre-trial evaluation, the rating of personnel management and safety issues and staff education and training about safety issues could not be analyzed.

The post-trial SWOT analysis revealed the benefit themes realized by the participants in employing the RSAF framework and process were blame-free learning, positive learning experience and ease of use. The weakness themes were identified as too much data, security of data and subjectivity of information which could potentially lead to misinterpretation of results. The themes under opportunities were identified as possible potential to develop further, potential game-changer for future risk management and it's adaptability for multi-disciplinary teams. The possible threat themes were identified as poor buy-in from staff, increased work-load and the possibility that some managers may not be open to receiving feedback.

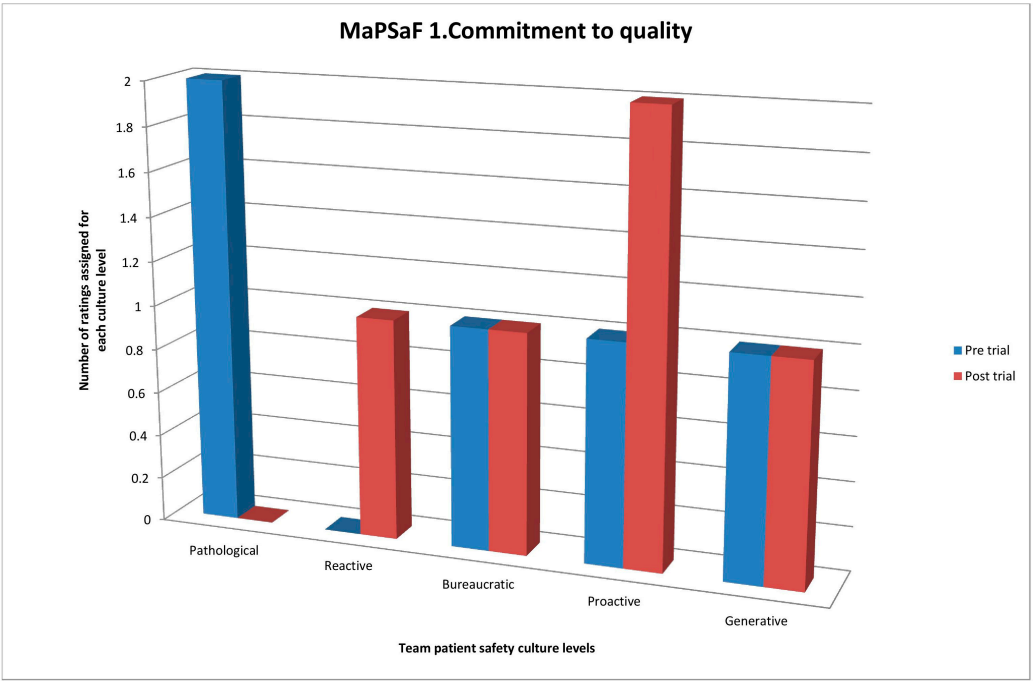


Figure-4 MaPSaF Commitment to Quality

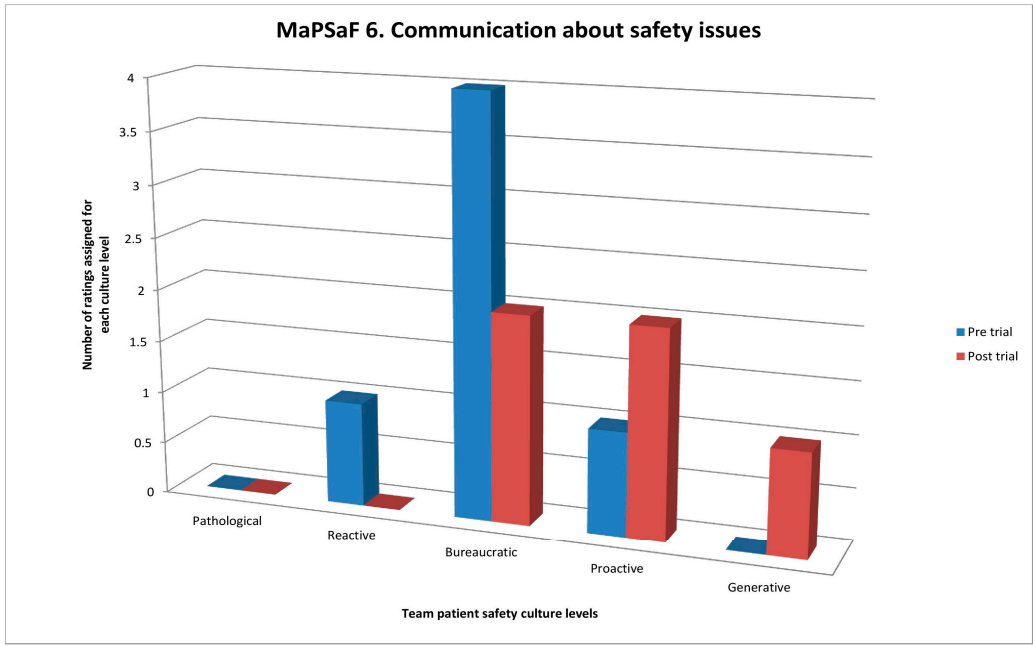


Figure-5 Communication about safety issues

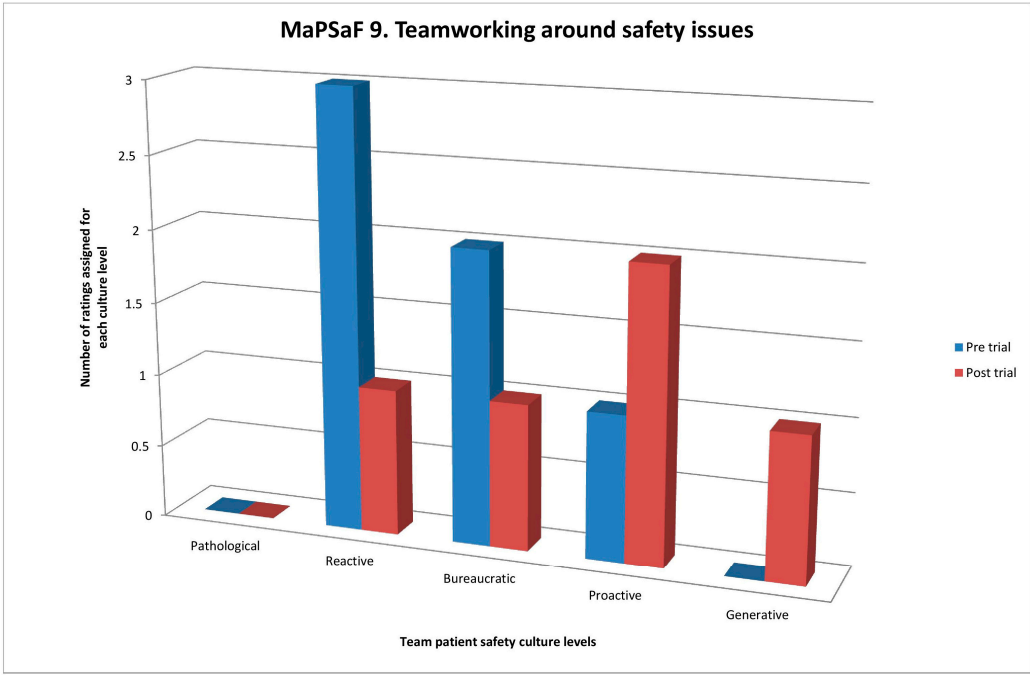


Figure-6 Team working around safety issues

The Risk-Sentience Fertility Checklist data analysis recorded improvements in risk management seen as a shared responsibility, building trust and transparency, accessing evolving risk-information, personal experiences/ anecdotal reporting having a dedicated process to be shared and addressed and in robust non-management powered risk-management process. Subtle improvements were recorded post-trial period in risk-management being perceived as a side-side approach rather than top-down approach, genuine feeling of ownership of risk management experienced by non-management employees and personal values and ethics being perceived as drivers of the risk management framework. While the newly developed checklist was designed merely as an indicator of the current risk-sentience culture within a specific organization, it would also be beneficial in facilitating thought and discussions on possible areas of improvement.

The improvements recorded by the participants highlight opportunities presented to high-risk environments in the area of risk-sentience information and uncertainty management.

8. Potential applications of the RSAF framework

The key strength of the RSAF and process at preliminary examination appears to be its concentrated ability to impact on the safety culture of the staff members within shortest possible timeframes. Also the ease of flow of risk-sentience information propelled by the anonymous component of the process appeared to encourage a more open willingness to share information without fear of blame or gossip. The scope of applying the risk-sentience management to contain evolving risk-information is potentially vast.

In the financial institutions sector, the LUOMEAR process sections under the main categories of Uncertainties, Others Mistakes, Experiences and Anecdotal Reporting could include credit, liquidity, interest rate, operational including mistakes and fraud committed by staff members, technology including those relating to power and equipment failures leading to data loss, product innovation, regulation and competition. In the education sector, the sections could include political interference, patronage networks, weak sector institutions, inefficient systems, governance, accountability and resource management. In the oil and gas sector, the sections could include political, geological, price, supply and demand and cost. In the insurance sector, the sections could relate to cost of capital and availability, tax and accounting changes, corporate governance, regulation, talent recruiting skills,

data security, reputational risk, macroeconomic trends, eurozone debt crisis and operational issues. In the retail sector, the sections could relate to consumer trends, regulation, general economic conditions, credit markets and availability of finances, labour, legal proceedings and competition and consolidation. In the energy sector, the sections could be compliance and regulation, climate policy and carbon pricing, commodity price volatility, managing planning and public acceptance of risks, talent, renewable subsidies, low-carbon technologies, economic shocks, political intervention and accessibility of capital. The applicability potential thus of the ToRS, the RSAF and the LUOMEAR within high-risk and volatile environments is said to be extremely high and needs to be aggressively exploited.

9. Limitations of the study

The participant pool was less than expected and was a key limitation of this pilot implementation. The clinical work-load held by the participants also affected their ability to contribute into the LUOMEAR repository on a regular basis and this could possibly be a future challenge when it is rolled out on a wider scale. There is also potential that the relevance of some of the risk-sentence records created could become obsolete due to time-related advancements in technology, work practices or changes in legislation and the possible need to invest in information technology (IT) infrastructure. However, such challenges will be similarly experienced by managers of conventional risk registers, who also require investment in IT and adequate time to administer, monitor and analyze the data collected.

10. Conclusions and Recommendations

The author would recommend and invite more research in the area of uncertainty and risk-sentence management and the proposed RSAF's effectiveness in various other sectors incorporating risk management such as; security, engineering, energy, financial portfolios, project management, industrial process and public health and safety. Considering that the ISO global risk standard is still in its early stage of dissemination, there is immense scope and appetite within the international risk communities for a robust and comprehensive debate on its effectiveness in practice and to discuss any viable proposals and opportunities for improvement within the model. It is envisaged that the RSAF and process will maintain its relevance and applicability within the forthcoming second edition of ISO 31000 framework.

This pilot trial strived to highlight untapped opportunities by demonstrating with preliminary evidence that by utilizing the newly proposed RSAF and LUOMEAR process, the objective of grass-root containment of evolving risk-sentence information can be realistically achieved by halting or slowing their progress into an identifiable risk. The study has also demonstrated that the expected secondary benefits of the proposed framework and process could also be improved safety culture and increased non-management staff engagement in the overall risk-management process. Considering that our understanding of the concepts of uncertainty and risk and their effective management is a continuously evolving process, our vision should not be to merely adopt a globally accepted standard but to continually test and further enhance its efficacy with other combinations of evidence-based, innovative risk concepts embedded with effective scientific strategies.

Conflict of Interest: The author declares no conflict of interest. This study did not require or use any funding source.

References

- 1 Summerill, C., Pollard, S. J., & Smith, J. A. (2010). The role of organizational culture and leadership in water safety plan implementation for improved risk management. *Science of the Total Environment*, 408(20), 4319–4327.
- 2 Prpic, J. (2015). Project Risk Management Incorporating Knight, Ellsberg & Kahneman. Presented at the Prpic, J., (2016). Project Risk Management Incorporating Knight, Ellsberg & Kahneman. Proceedings of the 49th Annual Hawaii International Conference on System Sciences, Kauai, Hawaii, January.
- 3 Aven, T. (2011). On the new ISO guide on risk management terminology. *Reliability Engineering & System Safety*, 96(7), 719–726.
- 4 Lalonde, C., & Boiral, O. (2012). Managing risks through ISO 31000: A critical analysis. *Risk Management*, 14(4), 272–300.
- 5 ISO, I. (2009b). 31000: 2009 Risk management–Principles and guidelines. *International Organization for Standardization, Geneva, Switzerland*.
- 6 Knight, F. H. (1921). Risk, uncertainty and profit. *New York: Hart, Schaffner and Marx*.
- 7 McManus, H., & Hastings, D. (2005). 3.4. 1 A Framework for Understanding Uncertainty and its Mitigation and Exploitation in Complex Systems (Vol. 15, pp. 484–503). Presented at the INCOSE International Symposium, Wiley Online Library.
- 8 Perminova, O., Gustafsson, M., & Wikström, K. (2008). Defining uncertainty in projects—a new perspective. *International Journal of Project Management*, 26(1).
- 9 Ellsberg, D. (1961). Risk, ambiguity, and the Savage axioms. *The Quarterly Journal of Economics*, 643–669.
- 10 Hillson, D. (2007). When is a risk not a risk. *Project Manager Today*, 15–16.
- 11 Ward, S., & Chapman, C. (2003). Transforming project risk management into project uncertainty management. *International Journal of Project Management*, 21(2), 97–105.
- 12 Flage, R., Aven, T., Zio, E., & Baraldi, P. (2014). Concerns, Challenges, and Directions of Development for the Issue of Representing Uncertainty in Risk Assessment. *Risk Analysis*, 34(7), 1196–1207.
- 13 Savage, L. J. (1951). The theory of statistical decision. *Journal of the American Statistical Association*, 46(253), 55–67.
- 14 Nowotny, H., Scott, P., & Gibbons, M. (2001). *Re-thinking science: knowledge and the public in an age of uncertainty*. SciELO Argentina.
- 15 Haase, N., Renkewitz, F., & Betsch, C. (2013). The measurement of subjective probability.
- 16 May, R. (2001). Risk and uncertainty. *Nature*, 411(6840), 891.
- 17 Zinn, J. O. (2008). Heading into the unknown: Everyday strategies for managing risk and uncertainty. *Health, Risk & Society*, 10(5), 439–450.
- 18 Smith, D., & Fischbacher, M. (2009). The changing nature of risk and risk management: The challenge of borders, uncertainty and resilience. *Risk Management*, 3.
- 19 Chow, C. C., & Sarin, R. K. (2002). Known, unknown, and unknowable uncertainties. *Theory and Decision*, 52(2), 136.
- 20 National Research Council. (1989). *Improving Risk Communication*. Washington DC: National Academy Press
- 21 Baker, N. (2011). Managing the complexity of risk: the ISO 31000 framework aims to provide a foundation for effective risk management within the organization. *Internal Auditor*, 68(2), 35–39.
- 22 Dennis, N. (2013). Using the Risk Management Standard ISO 31000 to support Health and Safety. *Safety at Work*, 427.
- 23 Gjerdrum, D., & Peter, M. (2011). The new international standard on the practice of risk management—A comparison of ISO 31000: 2009 and the COSO ERM framework. *Risk Management*, (31), 8–13.
- 24 Gjerdrum, D., & Salen, W. (2010). The new ERM gold standard: ISO 31000: 2009. *Professional Safety*, 55(8), 43.
- 25 Neves, A. A. S., Pinardi, N., Martins, F., Janeiro, J., Samaras, A., Zodiatis, G., & De Dominicis, M. (2015). Towards a common oil spill risk assessment framework—Adapting ISO 31000 and addressing uncertainties. *Journal of Environmental Management*, 159, 158–168.
- 26 Purdy, G. (2010). ISO 31000: 2009—setting a new standard for risk management. *Risk Analysis*, 30(6), 881–886.

- 531 27 Bruce, B., Ungar, M., & Waschbusch, D. A. (2009). Perceptions of risk among children with and without
532 attention deficit/hyperactivity disorder. *International Journal of Injury Control and Safety Promotion*, 16(4),
533 189–196.
- 534 28 Figner, B., & Weber, E. U. (2011). Who takes risks when and why? Determinants of risk taking. *Current*
535 *Directions in Psychological Science*, 20(4), 211–216.
- 536 29 Morrongiello, B. A., & Lasenby-Lessard, J. (2007). Psychological determinants of risk taking by children:
537 an integrative model and implications for interventions. *Injury Prevention*, 13(1), 20–25.
- 538 30 Proctor, H. S., Carder, G., & Cornish, A. R. (2013). Searching for animal sentience: a systematic review of
539 the scientific literature. *Animals*, 3(3), 882–906.
- 540 31 Broom, D. M. (2014). *Sentience and animal welfare*. CABI.
- 541 32 NPSA. (2006). Manchester Patient Safety Framework (MaPSaF). Retrieved May 11, 2016, from
542 <http://www.nrls.npsa.nhs.uk/resources/?entryid45=59796>
- 543 33 IRM. (2012). Risk Culture under the Microscope: Guidance for Boards. Retrieved April 10, 2016, from
544 <https://www.theirm.org/knowledge-and-resources/online-resource-centre/enterprise-risk-management/risk-culture,-corporate-culture-and-ethics/risk-culture-under-the-microscope-guidance-for-boards/>
- 545 34 Slimak, M. W., & Dietz, T. (2006). Personal values, beliefs, and ecological risk perception. *Risk*
546 *analysis*, 26(6), 1689–1705.
- 547 35 Weber, E. U., Blais, A. R., & Betz, N. E. (2002). A domain-specific risk-attitude scale: Measuring risk
548 perceptions and risk behaviors. *Journal of behavioral decision making*, 15(4), 263–290.
- 549 36 Broom, D. M. (2006). The evolution of morality. *Applied Animal Behaviour Science*, 100(1), 20–28.
- 550 37 Guide, I. S. O. (2009). 73: 2009. *Risk management – Vocabulary*.
- 551 38 ISO, I. (2009). 31010: Risk management–Risk assessment techniques. *Event (London)*. Geneva.