Co-funded by the Erasmus+ Programme of the European Union
2018-1-IE01-KA202-038820

Operational Risk: Implementing Open Norms (ORION)

Intellectual Output 4 (IO4) Report October 2021
Implementation Framework

Authors:
Nick McDonald, Natalie Duda, Rabea Morrison (SCL); Derek Ross, Rebecca Vining (TCD); Pernilla Ulfvengren (KTH); Daniele Baranzini (ERG); Vassos Lappa, Thomas Demosthenous (KTC)

Table of Contents

Executive Summary

Concept: The ORION Implementation framework establishes a link between learning and doing; training should lead to implementation case studies to develop and enhance effective safety management. At an organisational level, the competence and knowledge of staff in their different roles should make it possible to implement effective programmes to manage risk, safety and system improvement. Information about these interventions and their impact is gathered as organisational knowledge. Over time, this knowledge accumulates and much can be shared across a Community of Practice (CoP). This system knowledge forms the basis of a new best practice; it further enhances the competence of staff together with the organisation's capability to improve more effectively, reliably and with much greater strategic impact.

Needs: The ORION Implementation framework seeks to fill important gaps in risk and safety management: compliance with regulatory requirements does not ensure being able to manage system performance in a proactive way; as improvement in quality and safety is prone to failure, the system does not significantly change over time. An effective solution to these persistent endemic problems must exert leverage on critical transformational mechanisms. A set of needs were identified which demonstrate that the solution to the problems of safety management and change implementation is not simple. They place the development of information and transformation of system knowledge at the core of the solution. Developing and applying this knowledge requires new specialised competencies. Learning at individual and organisational levels have to go together.

The Mindful Governance Model put forward some basic principles including the Obligation to Act concept: applying this concept clearly indicates that even an experienced organisation has difficulty in identifying the important risks in complex operations, cannot easily engage in generating effective solutions, and experiences a lack of viable and verifiable pathways for implementing change.

Development: The ORION Advanced Risk Management training course expounds the concept of Mindful Governance of Operational Risk and supports its implementation through practical project work using the ARK platform. Within an operations management framework, the course aims to build the capability to analyse the risk in complex operations and devise solutions, using and analysing diverse sets of data, managing the risk in implementing those solutions, and building a strategic capability to manage risk at system level.

Infrastructure: The Advanced Risk Management programme is supported by the ARK platform. This has been developed as a knowledge-rich software system for managing risk and change. The methodology starts with needs or problem formulation, then supports development of a solution, integrates solutions through planning and preparation, implements the solution in operations (work system) and validates the actual outcome. The ARK Platform is used to build and maintain a unified knowledge graph of risks and projects. This will *create a new, unified risk evidence base* unknown in existing, highly siloed safety systems that emphasise manual risk analysis. When these processes are in place over many projects it will be possible to conduct semi-automated multi-project analysis and distillation of best practice from shareable, privacy-aware knowledge bases based on Linked Data.

Implementation: The ORION training and ARK platform were deployed in a set of case studies on infection prevention and control (IPC) in the context of COVID-19; These were conducted in a hospital, a clinical unit and an ambulance service, under the auspices of the ARK-Virus project, with training and training evaluation supported by the ORION project. The activity so far has focused on the analysis of the problem and identification of solutions. The main advance has been in developing a fuller and richer understanding of risk and engagement of different points of view. The trials have not yet moved to the planning and implementation phases of the projects. There are good prospects for evidence development and CoP developing best practice. The initial results are encouraging in terms of the active engagement of participants using the ARK Platform to address the complexity of the operational system.

The ARK platform is currently in the first phase of operational trials of its prototype, supported by ORION training. The platform is progressively meeting the identified needs. Trial evaluation shows that the training and platform combination are effective in engaging users in developing rich and relevant projects. The trial also identifies issues for development. Thus, the solution is not complete but is in line with users' needs.

Sustainability: There needs to be a viable pathway to deliver the solution. The goal of a mindful organisation, supported by a mindful knowledge system is not yet implemented but the first steps have been taken. The ORION training programme has been developed and beginning to deliver Professional Competence. The ARK platform prototype has been developed and is undergoing further development. It is beginning to support the Organisational Capability to implement interventions and to gather organisational level knowledge about initial projects formed and to be continued. There is a commitment to develop System-level Knowledge across the Community of Practice. There is a development and delivery roadmap going forward leading to a sustainable solution. This includes the production of the Advanced Risk Management course as part of TCD's on-line training programme, further building the Community of Practice, supported by ORION training, leading in time to ARK commercialisation, supported by ORION training.

Impact: The impact so far is evident in the initial knowledge base arising from the IPC projects and the development of effective and committed implementation teams. Looking further ahead the impact will be measurable through a contribution to best practice standards for practical infection prevention and control initially in the context of COVID-19, and then in a wider IPC context. Engagement with regulatory agencies will seek to embed these best practice principles within regulatory guidelines. The ORION Implementation Framework will also contribute to a next generation governance model of safety and risk management.

This development trajectory of the ORION Implementation Framework is laid out in Figure 1, below.

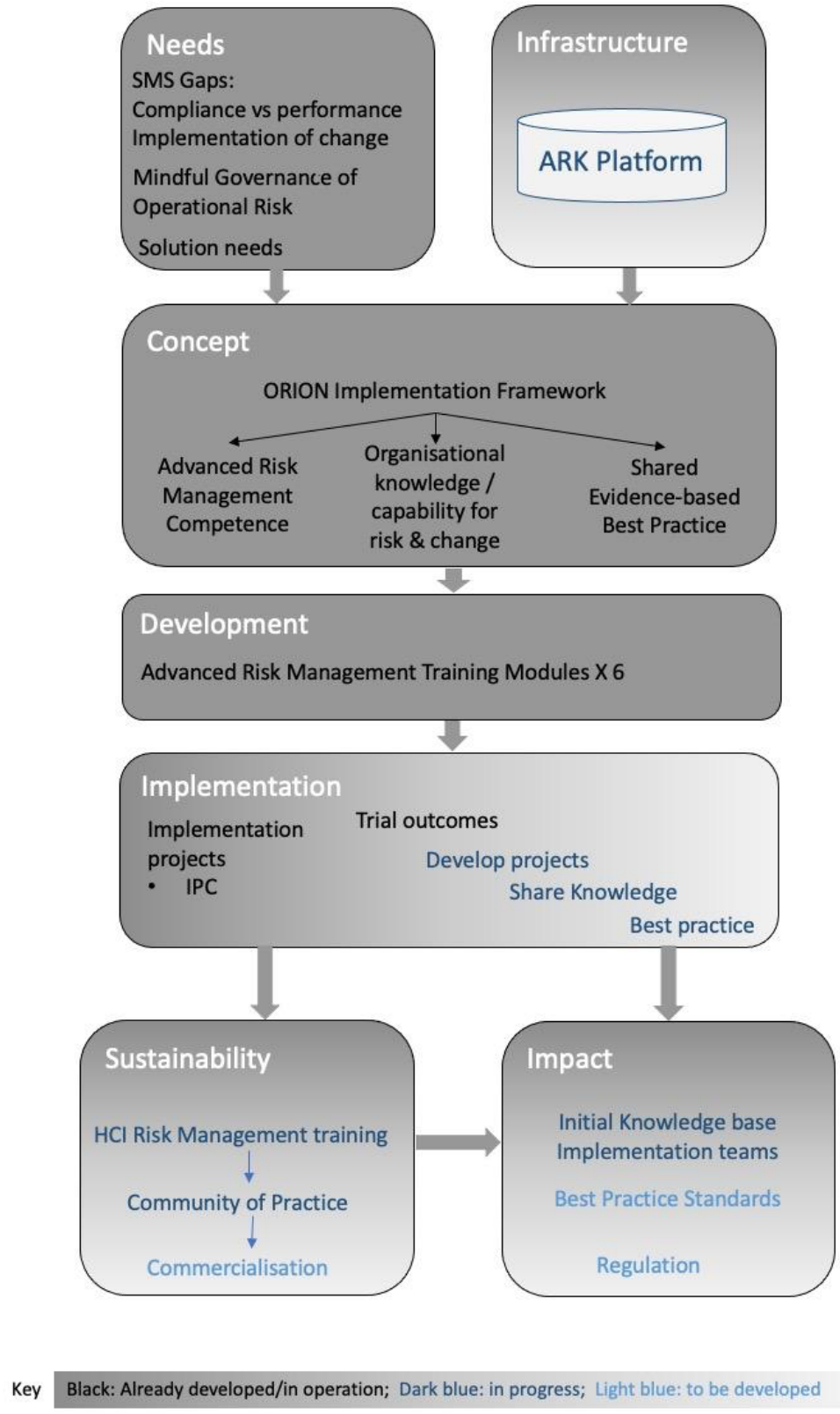

Figure 1: ORION Implementation Framework Development Trajectory

Acknowledgements
The ORION Consortium would like to thank the Associate Partners for their contribution to the ORION Project: Dublin Fire Brigade, Dublin, Ireland; SAS Airlines, Stockholm, Sweden; TUS Airways, Larnaca, Cyprus; Skylink Services, Larnaca, Cyprus; San Rafael Hospital, Milan Italy; and Association of Ambulance Physicians, Izmir, Turkey.



The Operational Risk: Implementing Open Norms (ORION) project is co-funded by the Erasmus+ Programme of the European Union.

Introduction

This report describes the development of the ORION Implementation Framework conducted as part of Intellectual Output 4 of the Operational Risk: Implement Open Norms (ORION) project. The ORION Implementation framework establishes a link between learning and doing; training should lead to implementation case studies to develop and enhance effective safety management. Information about these interventions and their impact is gathered as organisational knowledge. Over time, this knowledge accumulates and much can be shared across a Community of Practice (CoP). This system knowledge forms the basis of a new best practice; it further enhances the competence of staff together with the organisation's capability to improve more effectively, reliably and with much greater strategic impact. The findings of the ORION project are intended to be applicable to other contexts and sectors. It is also recommended that wider literature on SMS specific to sectors is considered to support the localisation of findings presented here.

Below a brief definition and description of the Safety Management System (SMS) is provided. Following this an overview of the ORION project and the focus of Intellectual Output 4 is presented.

What is a Safety Management System (SMS)?

The International Civil Aviation Organisation (ICAO) define a Safety Management System (SMS) as, "*a systematic approach to managing safety, including the necessary organisational structures, accountabilities, policies and procedures*," (ICAO, SMS Manual 4th edition, 2018). The overall aim of a SMS is to proactively and prospectively manage safety in order to minimise risks to system through the removal or mitigation of hazards. A SMS is based on an inclusive philosophy whereby each actor within a defined system actively contributes to safety. This is often achieved through communicating safety and relevant performance related issues through formal reporting systems. As ICAO state, "*safety management effectively implemented can lead to a documented, process-based approach to safety, as well as a better understanding of safety-related interdependencies and relationships*," (ibid). Therefore, the generation of knowledge about the system safety requires significant amounts of data to be elicited, managed and effectively analysed in order to establish a realistic understanding of the system as close to real time as possible. The resulting knowledge needs to be transformed into actions that uphold or enhance safety of the system for its members and users.

The ICAO SMS Framework is set around four components (also referred to as pillars of SMS).

- Safety policy and objectives:
    - Management commitment and responsibilities;
    - Safety accountabilities;
    - Co-ordination of emergency response planning;
    - SMS documentation.
- Safety risk management
    - Hazard identification;
    - Risk assessment and mitigation.
- Safety assurance:

    - Safety performance monitoring and measurement;
    - Management of change;
    - Continuous improvement of the SMS.
- Safety promotion:
    - Training and education;
    - Safety communication.

The ORION Project Overview

The Operational Risk: Implementing Open Norms (ORION) project has developed and implemented training to foster soft socio-technical skills for fully implementing and embedding a safety management system (SMS) and managing operational risk. ORION focuses on the skills needed to make the transition between fulfilling the formal requirements of a SMS and having a system that is fully embedded in normal operational practice so that it is fully part of the culture of the organisation, ensuring effective practice according the best practicable standards and delivering a high and constantly improving level of safety. This requires the skills and capability to productively address the systemic factors that influence and motivate people to behave in particular ways and to facilitate change. It also requires learning from others' experience.

The ORION project is co-funded by the Erasmus+ Programme of the European Union.

Objectives

The overall goal of ORION is to improve outcomes in the management of operational risk, across a wide range of risk-critical industries. Knowledge can also be utilized to contribute to a stronger economy and business model in the provision of safety related services across safety critical industries, and to promote a culture of sharing and learning from best practice in implementation among industry partners.

The aims of the ORION project are delivered through five objectives:
1. To design and develop training materials to support and facilitate implementation and embedding of SMS in norms of practice and effective management of risk in the operation.
2. The training can be delivered in short courses in the associate organisations. A common train-the-trainer programme leading to training in the ORION project Associate Partner organisations, each was directly supported by an ORION partner.
3. The training and support aims to result an implementation case study approach. This is intended to build and extend the knowledge base of evidence that links multiple implementation cases studies.
4. A validation programme starting with stakeholder needs and progressively verifying delivery on those needs and validate the project outcomes.
5. Utlising evidence on each of these activities to contribute to the development guidelines for open norms of best practice in the full implementation of SMS.

Background to the ORION Project

The background to the ORION project are framed around several complementary identified needs:

Implementing SMS and Managing Operational Risk

The Associate Partners of this project are in various stages of implementing SMS and integrating SMS with OHSAS. They need to achieve real value from this organisational effort. Embedding SMS requires building actual norms of behaviour and performance, reporting, implementing improvement.

Creating an evidence base

An empirically grounded evidence base of SMS implementation is lacking. While ORION is based on a wide range of research in certain industries (aviation, maritime, health, emergency services), there is a need to create a more comprehensive evidence base of what works in implementing SMS across a range of industries and regions.

Best practice guidelines

There are not many standards or much guidance as to how to implement and embed SMS. One good example of best practice guidelines comes from the Civil Air Navigation Services Organisation (CANSO) who published a Standard of Excellence in Safety Management Systems (SoE in SMS) and an associated implementation guide to support ANSPs (Air Navigation Service Providers) in their safety management. The CANSO SoE in SMS is compliant with ICAO Annex 19 (ICAO. Annex 19: Safety management. International Civil Aviation Organisation; 2013). This is largely a generic standard that is easily applicable to other industries. Level E of this standard is the highest level of implementation and embedding of safety practices that are shown to be effective. Another example is Transport Canada guidelines for both development and assessment of SMS in aviation. However, while there is a strong logic to these documents it lacks a solid evidence base from actual implementation.

Generate Open Norms

Overall, it is important to demonstrate what is possible in terms of good practice in SMS implementation across a range of industries. This then shows what could and should be normal. Creating open access to this evidence in implementation case studies begins to build open norms of how to progressively improve the real functioning of SMS in dealing with the pervasive intractable problems of operational risk.

Intellectual Outputs

The results of the ORION project are linked directly to the Intellectual Outputs and Multiplier Events that have been delivered through the project. Each of the Intellectual Outputs provide important results that are of value to the industries and sectors who are represented by the Associate Partners in the ORION project. These are described briefly below:

Intellectual Output 1 (IO1) SMS Maturity Assessment

Intellectual Output 1 provides a report synthesizing research evidence and best practice guidelines, together with an analysis of the current maturity level of Safety Management

Systems (SMS) in the Associate Partner organisations. This analysis will support the development of SMS Implementation Training.

Intellectual Output 2 (IO2) SMS Implementation Training

Intellectual Output 2 (IOS) provides an overall training design for train the trainers within the partnership as well as training SMS facilitators within the Associate Partners (including design of the facilitation and training to be offered by the facilitators in their organisations). This training includes developing an implementation case study approach. An initial training design and development activity occurred ahead of training events delivered to each of the Associate Partners that supported the full SMS implementation activity.

Intellectual Output 3 (IO3) SMS Implementation Validation

The purpose of Intellectual Output 3 (IO3) is to demonstrate how to undertake validation to provide confidence that the concept being developed and implemented meets the stated objectives in practice. Key activities of the validation tasks in ORION are to:

- Ensure the SMS needs are fulfilled.
- Iteratively verify and validate components and activities through stages of concept, design, implementation and operations during project.
- Feedback to various providers of progression according to requirements along the development stages.

Intellectual Output 4 (IO4) SMS Implementation Framework

The ORION Implementation framework establishes a link between learning and doing; training should lead to implementation case studies to develop and enhance effective safety management. At an organisational level, the competence and knowledge of staff in their different roles should make it possible to implement effective programmes to manage risk, safety and system improvement.

Intellectual Output 5 (IO5) SMS Norms of Practice Manual

Intellectual Output 5 (IO5) offers guidance on SMS Norms of Practice and consolidates lessons representing the core aspects of each of the previous outputs. This is designed to maximise transferability and impact by presenting in appropriate media the essential content of the ORION programme. This is innovative in providing concise evidence-based standards of good practice in SMS implementation, that are carefully designed to be easily transferable between organisations, across industrial and service domains, and spanning different regions. The SMS Norms of Practice provides a material report for the that can be used to support ORION SMS activities.

The Implementation Framework in ORION

The following is the specification for Intellectual Output 4 in the ORION workprogramme:

'*Best practice guidelines will consolidate the initial evidence base, the training designed and delivered, the case study reports and the validation exercise. This will draw out the lessons learned about implementation and to derive guidelines for best practice in implementation.*

'*The case study methodology here is highly innovative: it will be an adaptation of a methodology developed within The FutureSkySafety project and tested by Masters students (experienced professionals managing risk and change in major organisations). The adaptation will simplify the methodology to make it appropriate to the level of training and target trainees of ORION, without compromising its basic principles. Hence it becomes highly transferable between different users, different organisations and different industries. This is what enables the compilation of meta-analyses of multiple case studies. This in turn is the core of the impact of ORION - developing an evidence base based on multiple cases of implementation. The methodology is sufficiently powerful to take into account the points of comparability and difference between many cases.*

'Using the template each implementation associate will produce an implementation case study report, structured around the context, the activity and the outcomes of the implementation.

'The SMS Implementation Framework will be iteratively developed over a series of events beginning with a definition of the framework that will be populated as training and validation events are undertaken.'

There are three principles underlying the implementation framework in ORION:

1. Training in a practical requirement such as Safety Management should not just be a stand-alone pedagogical exercise but lead in some way to implementation of some initiatives to implement or enhance the management of safety.
2. The core issues arising from previous research and from IO1 concern challenges in the effective implementation of SMS. First in the organisational development that is necessary to ensure compliance with a complex regulation, and second in enabling that safety management activity to work together as a system to transparently demonstrate how to understand and improve the safety performance of the system.
3. Therefore, the training should be organised to stimulate implementation case studies to develop and enhance effective safety management in the relevant organisations.

Thus, the core specification of the ORION Implementation framework is establishing a link for each trainee or student between learning and doing.

This also works at an organisational level: the competence and knowledge of staff in their different roles makes it possible to implement effective programmes to manage risk, safety and system improvement. How does the system learn? It is necessary to develop a knowledge-base of evidence about practice in implementing risk and safety policies including improvement and impact. These three elements need to work in synergy to enable transformation at system level (Figure 2).

Figure 2: Professional Competence, Organisational Capability, System Knowledge

What does this mean in practice? Let us explore these three elements with some examples, mostly from healthcare.

Competence and knowledge of staff: Savage et al. (2020) identify two contrasting styles of medical leadership: a virtuous cycle of management though medicine and a vicious cycle of medical protectionism. Characteristic of the virtuous cycle is an ability to see the wider picture, beyond one's own domain and hence an ability to see strategic challenges at system level. The vicious cycle of protectionism is motivated by clinical identity and professional objectives, rather than broader organisational goals. In the virtuous cycle, willing leaders continually improve their own management and leadership competencies, deploying participatory practices that cultivate medical engagement amongst staff. In the vicious cycle, disconnected leadership development efforts are seen to be irrelevant to the improvement of health-care. They argue that these two styles have differential implications across a wide spectrum of outcomes: quality of care; financial performance; staff satisfaction, retention, burnout & performance; IT adoption; and approval of reforms. A core objective of the ORION advanced risk management training is to support the development of this virtuous cycle of leadership.

Organisational management of risk and change: this virtuous cycle needs to be expressed through particular organisational interventions. Von Thiele Schwartz et al. (2020) propose 10 criteria (the Sigtuna principles) for the design, implementation and evaluation of such interventions. These include: engagement of key stakeholders; be aligned with organisational objectives; work with existing practices, develop organisational learning and evaluation; and transfer knowledge beyond the organisation. The ARK platform has been developed in parallel with the ORION project around a common concept concerning the analysis of risk in complex operational systems and the development and deployment of effective interventions (according to Sigtuna principles) to improve that risk profile. ORION training is critical to deploying that methodology which has been operationalised through the ARK platform.

Knowledge and evidence-base: This is the most innovative part of the ORION implementation framework, because here there is a significant gap in the current state of the art. For example, Mazzucato et al. (2014) report that the capability to develop and foster an ongoing learning framework to sustain the improvement and to generalise the approach to other parts of the system is often missing from even successful improvement initiatives. Such a learning framework must draw

on experience from past interventions in order to learn better ways to improve the system in all its complexity. The availability of this systematic organisational knowledge and evidence base continues to be a significant gap. An initial step towards addressing this gap was the development of a model of 'Mindful Governance of Operational Risk' (McDonald et al., 2019). A core feature of this model was addressing the flow of information in organisations around risk, safety and improvement, the synthesis of this information into usable knowledge and putting this into practice in improved interventions. It is this model (developed in the FutureSkySafety project) that is referred to in the ORION workprogramme (cited above). The second step in addressing the gap was the development of the ARK platform not just as a risk analysis and project support tool, but as a sophisticated knowledge engineering device that can synthesise the key characteristics of multiple projects. The ARK platform enables both a strategic overview and a grounded evidence-base upon which to develop best practice. The ORION Advanced Risk Management training takes the model of Mindful Governance of Operational Risk as a core organising principle in its curriculum.

This is the start of a long-term programme. The evidence needs to be built from practice in developing, implementing and recording interventions. The ARK platform is in its first operational deployment as a prototype in supporting these interventions; the platform has a further development trajectory. Both the rolling out of interventions and the platform development take time and resources. The ORION project represents a critical step in the first stage of this process: building the competence to intervene to change the operation; in order in turn to further develop the knowledge to enhance both the competence of staff and the systemic organisational capability do this more effectively, reliably and with much greater strategic impact.

Conceptual Background to the ORION Implementation Framework

The ORION Implementation framework seeks to fill an important gap in risk and safety management. This gap is illustrated by two related arguments:

- Having a Safety Management System in place does not guarantee that it is working effectively. There is thus a potential gap between compliance with regulatory requirements and actually being able to manage system performance in a proactive way.
- The evidence suggests that improvement in quality and safety is prone to failure, and that over time the system as a whole often does not significantly change. We will illustrate this below in relation to healthcare quality and safety improvement.

Pillars of Safety Management

Safety Management Systems (International Civil Aviation Organization, 2018) are built around four main pillars: Safety Policy and Objectives, Safety Risk Management, Safety Assurance, and Safety Promotion. This identifies the features of an SMS that need to be built to ensure basic regulatory compliance. However, it is less good as a metaphor for how the SMS should work as a system – four pillars do not make a house that provides shelter from the elements. Thus, how does this protective role of SMS actually work – it is not enough to seek assurance from compliance alone. Even more so, how can SMS provide a dynamic learning model of how to be safer even in an ultra-safe system (like commercial aviation)?

Capability maturity models of safety management, for example the Civil Air Navigation Services Organization (2015) model seeks to provide a conceptualisation of an SMS that is fully embedded in daily operations at all levels of the system, delivering tangible evidence of risk and verification of improvement. Unfortunately, there does not seem to be a simple progression from compliance with regulatory requirements to having a fully functional Safety Management System. This has given rise to considerable theoretical and practical controversy. Thus, Hollnagel (2015), from the perspective of Resilience Engineering, has argued that the 'conventional' reactive safety management system (labelled 'Safety I') has not worked and cannot work in a dynamic operational environment. This is because operational systems are inherently complex; they involve human decision-making and vulnerability, are self-organising in a way that is incompatible with planned implementation of change, and have 'emergent properties' which are highly situationally dependent. The alternative, 'Safety II', is based on developing a richer understanding of work as (actually) done, rather than 'as imagined', or officially should be done. Safety II invokes 'complex adaptive systems' to explain the emergent self-organising capabilities of social systems. This is a cogent critical analysis; however, its chief weakness is a lack of a practical model of how to implement this new approach to safety. For example, these 'self-organising capabilities' need to be fully engaged if complex systemic risks in operational systems are to be effectively addressed and organisations are to respond effectively, with 'resilience', to new and unexpected demands. How can this happen?

The ORION Implementation framework seeks to address this gap by building links between the four SMS pillars (see figure 3). Between the pillars of Safety Risk Management (on the one hand) and Safety Assurance (on the other) is a lot of work of implementation, mitigating risk in operations, improving the system through targeted projects, achieving strategic safety objectives. It is this work that can, in turn, make Safety Policy and Objectives more proactive, flexibly engaged with new and emerging issues and actively monitoring improvement. Joined up governance – different departments working together – enables the gathering of evidence that sustains strategy. This dynamic activity makes it possible to provide a new level of tailored and focussed support for operational performance, embedding good practice in everyday operations through Safety Promotion. These links are underspecified in the SMS regulation – but they are essential to a strategy for sustaining the SMS as a functioning system that is aware of the complex risks it faces, able to adjust to mitigate those risks

and thus able to purposely achieve is strategic goals to improve quality and safety, and, at the same time, sustaining a positive safety culture.

Thus, the concept of Advanced Risk Management is proposed as a way of overcoming the limitations of classic SMS and achieving a large part of the aspirations of Safety II. Advanced Risk Knowledge is the key innovation providing evidence-based insight not only into what needs to be changed but how to do it.

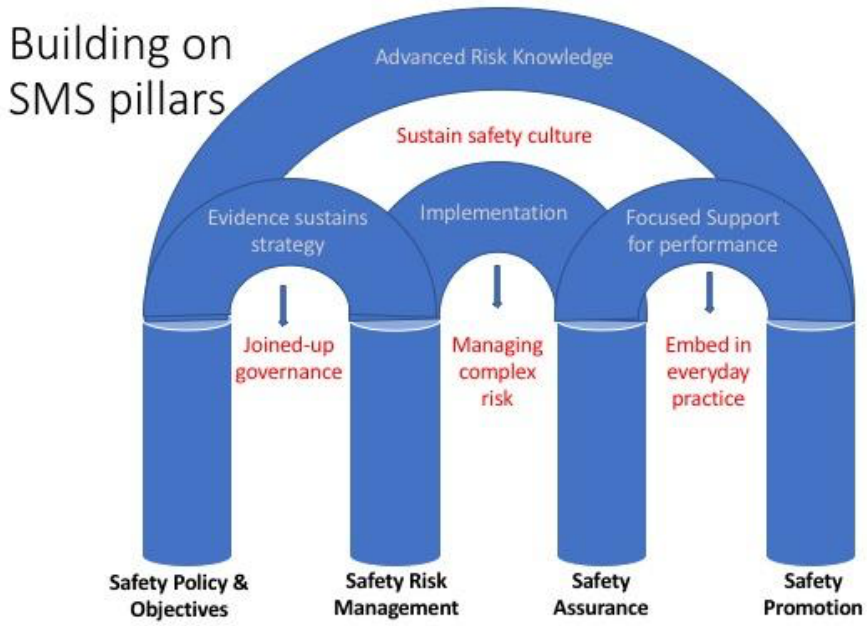

Figure 3. Building on SMS Pillars

The Challenge of Quality and Safety Change in Healthcare

One of the stark conclusions of many studies is the lack of substantial systemic change in quality and safety in healthcare provision over many decades (Institute of Medicine (US) Committee on Quality of Health Care [IOMCQHC], 2000, 2001; Organisation for Economic Co-operation and Development, 2020). The "To Err is Human" report first outlined the extent of patient harm in 2000 (IOMCQHC). More recently, the Lucian Leape Institute reported in a report on healthcare workplace safety that:

> "No other industry has more potential to free up resources from non-value-added and inefficient production practices than healthcare and no other industry has greater potential to use its resources to add value, promote health and relieve suffering" (2013, p.2).

The Patient Safety Movement and the Quality Improvement (QI) movement in healthcare have been slow to achieve momentum in improving patient, staff and caregiver outcomes. In fact, Braithwaite et al. (2018) estimate that in healthcare organisations, nearly two-thirds of initiatives experience implementation failure. Even interventions with proven effectiveness fail to translate into meaningful patient outcomes--what the UK National Health System (NHS) refers to as the "improvement-evaporation effect" (Buchanan & Fitzgerald, 2007; Martin et al., 2011). The WISH foundation report that shying away from understanding complexity has led to the failure of the patient safety movement over the last 20 years to effect real change. They report that:

> "Despite notable examples of well-intentioned safety initiatives, healthcare researchers tend to consciously and narrowly focus on safety problems in isolation,

> rather than consider the problem as many interdependent systems at work. Efforts to date have been simplistic and myopic. Healthcare has taken some safety concepts from other industries but applied them superficially and independently of a comprehensive approach to creating high reliability" (Pronovost, et al., 2015, p.3).

The healthcare sector has widely adopted Lean, Six Sigma, and Lean Six Sigma as process improvement methodologies, which aim to empower staff to reduce waste by standardising practice (Jorma et al., 2016; Liker, 2004; Poksinska, 2010; Radnor & Osborne, 2013). While there are some positive associations between Lean adoption and performance indicators in individual case studies, overall evidence on the success of Lean is mixed (Flynn, et al., 2019; Shortell et al., 2018; Zibrowski et al., 2018). Considerable time and effort on implementation across the organisation are needed for Lean to be associated with gains in hospital performance, which are in turn mediated by the degree of system maturity, leadership commitment, daily management system use, and training (Shortell et al., 2018; 2021). The implications are that the problem may not be so much to do with Lean methodology in itself but concern the way in which Lean methodologies are implemented and embedded in the organisations that are using them.

Implementation in Aviation, Healthcare and Emergency Services

The ICAO SMS standard is a powerful international standard based originally on an ISO framework. For healthcare and emergency services, national standards prevail, again most often with reference to ISO standardisation. Despite these regulatory differences there are common problems in implementation. The issues cited above in relation to change in healthcare are not unique to that domain but can be seen across other domains including aviation and emergency services. A series of European Framework RTD projects over the last 20 years or so have explored the management of risk and change in the aviation operational industry (airlines, airports, air traffic control, maintenance, ground operations) – these include the projects HILAS, MASCA, PROSPERO and FutureSkySafety. Critical findings about the evolution of safety management and change implementation are reported in Ward et al (2010), Ulfvengren and Corrigan (2015) and McDonald et al. (2019), for example. One of the outcomes of that series of projects was the on-line Masters programme in Managing Risk and System Change run by the Centre for Innovative Human systems in Trinity College. Experience over the previous seven years of that course has demonstrated the commonality of these problems across a very wide range of industrial and service domains, from financial services, public services, defence forces, through transport, manufacturing and natural resources, to software development and software based services like gambling. The ORION Implementation Framework is a further initiative to build a practical capability to address the challenges of managing safety and improvement, empowering a wider cohort of users with potential application across a broader set of domains.

Gathering Needs in the Design of an Implementation Framework

It is clear from the above analysis that education, training and the resulting competence may be critical contributors to the resolution of this 'cycle of stability' in healthcare improvement, but on their own they will not be sufficient to exert leverage over the system. The concept of Mindful Governance of Operational Risk (McDonald et al, 2019) was developed as a way of operationalising a conceptual approach to mindful organising put forward by Weick (1995). Weick's approach argued for a set of general dispositions of individuals and collectively of organisations (e.g. preoccupation with failure, reluctance to simplify, sensitivity to operations). However, for 'mindful organizing' to occur there needs to be an actual flow, transformation and management of information, not just the right mindset.

This information flow needs to generate sophisticated knowledge about the particular system and about the dynamics of implementation and change. Such knowledge needs to be well grounded in a particular context, but generalisable across a range of different contexts. It needs to be based on real implementation experience recorded and analysed in a consistent way. Such knowledge needs to be capable of synthesis to produce a systemic account that can support strategic policy and common standards of good practice. This then provides the basis for improved leadership, planning, resource allocation and development. Additionally, if shared, it enables people to make sense of their own situation, understand their strengths and limitations and can form the basis of effective participation in change. Ultimately such knowledge can become embedded in the culture of the organisation as it becomes part of its everyday life and routines. Such a knowledge system has the potential to help reduce the uncertainty and high failure rate of interventions to improve the quality of the health system and to reduce the time it takes for successful systems of organisational transformation to become mature.

The development of the initial concept of Mindful Governance was accompanied by the development of practical tools for gathering narratives from operational staff and demonstrating methods for analysing complex patterns of operational data (Callari, et al., 2019; McDonald et al., 2019). Subsequently, development focus moved towards developing a platform to support implementation of change and improvement following the assessment of risk (Crotti Junior, et al., 2020; McKenna, et al., 2021). This also consolidated the realisation that the accumulated data from much organisational activity provided a core mechanism for engineering change – knowledge of what has happened in the past, engineered to support performing those complex organisational tasks in the present. The accumulation of knowledge depends on the application of Socio-Technical Systems Analysis (STSA) and risk assessment to all phases of intervention activity. Ultimately the goal is to leverage this accumulated knowledge strategically in order to improve the functioning of the target system as a whole.

The complexity of the design and development task for such a system is illustrated by the identification of a set of needs to be addressed. This process is described in more detail in McDonald et al. (2021) and briefly summarised here. A set of 15 needs were identified under 4 headings. The needs identified are as follows:

The first heading (Socio-Technical System Governance and Change) linked socio-technical system complexity with high level characteristics of successful strategic change. The needs identified were:

1. To encompass multiple interacting causes and consequences
2. To address non-linear relationships between variables
3. To understand and support the role of people
4. To monitor and enable self-organising tendencies of adaptation and change
5. To provide an adequate basis for action at strategic, improvement and operational levels.
6. To identify emergent characteristics from massed data from divergent sources

7. To sustain strategic coherence across a wide range of initiatives

The second section addressed core factors identified in the Relative failure of Quality Improvement and Lean Programmes:

8. Provision of training and education
9. Improvement processes embedded within normal management activity
10. Provide a systemic methodology for collecting evidence
11. Produce shareable knowledge within and between organisations

The third section drew on an analysis of gaps in Risk and Safety Governance

12. Provision of common organisational capabilities for development, improvement and change.
13. An integrated approach between risk, safety and Lean and other improvement approaches.

The fifth section concerned Data Governance

14. Data governance infrastructure to support system change
15. Privacy-aware data federation to enable the sharing of evidence

The exposition of these needs demonstrates that the solution to the problems of safety management and change implementation are not simple. They place the development of information and transformation of system knowledge at the core of the solution space. Developing and applying this knowledge requires new specialised competencies. Learning at individual and organisational levels have to go together.

Developing the ORION Implementation Framework

Safety Management is a set of activities and processes, which involves the collaborative action of diverse stakeholders – safety professionals, operational staff, management of operations, planning, senior managers and accountable managers. For this collaboration to work there needs to be an adequate basis for co-ordination and decision making at different levels of the organisation. The Mindful Governance Model put forward some basic principles underlying the effective functioning of such a system.

A sequence of activity occurs at three levels. At each level gathering information and developing understanding leads to appropriate action.

- Operations: the gathering of information from operations and feedback to operations
- Management of improvement: assessing risk and identifying mitigations leads to implementing and verifying improvement actions
- Strategic management: oversight over all operational and project risk supports initiating strategic programmes.

Action is motivated by three requirements – the importance of the problem, the effectiveness of the proposed solution and the viability of the pathway to implementation. For co-ordination to work effectively between key stakeholders in the process, these three conditions need to be satisfied for the effective transfer of responsibility to act from one person to another. Both parties to the co-ordination need to agree that the issue is sufficiently important (level of risk is sufficiently high); that there is a (potentially) effective solution (possibility of mitigation is strong); and that there is a viable pathway to implementing the solution (the risk in change is not too high). If these conditions can be fully satisfied, then it can be said that there is a compelling 'Obligation to Act'. It is this 'obligation to act' that seeks to guarantee effective action to fully implement the basic processes which underlie a fully effective SMS.

Table 1 below schematically illustrates the application of these principles in an organisational system. Table 2 illustrates the divergence between the ideal version of such a system and the actual state of the art in one of the ORION Associate partners. This organisation has a strong history in the development of safety management and had also been through significant change and restructuring. This means that the identified gaps are not due to the immaturity of systems implementation in the organisation – they are associated with underlying problems in SMS and change implementation. This is why the ORION Implementation Framework is necessary.

Table 1: ORION Implementation Framework

		Identify critical **important issues**	Identify clear and cogent **solutions**	**Clear pathway** to implement solutions
Systemic Risk profile (massed data, multiple sources)	Gather and analyse data about operation in focus	Understand system risk	Analysis points to *leverage*	Process for data acquisition, integration & analysis
	Feedforward risk information to those involved & get feedback on how risk is being managed	Generate risk information **for** operational & other staff	Indicate appropriate action	Processs for feedforward and feedback of risk information
Planned change (prioritised across multiple risks)	Prioritise key operational risks & initiate improvement actions	Synthesise & prioritise key risks from integrated analyses	***Solution:*** *Plan for maximum leverage to mitigate risk*	Process to move from solution to implementation?
	Implement improvement and verify outcomes	Understand the risks of implementation (risk in change)	**Link** solution to verifiable outcome	***implement*** *& verify solution*
Strategy (many business units, projects)	Strategic synthesis of operational and change risk	Global, dynamic overview of risk and evidence-based best practice	Overview of implementation effectiveness	Risk drives management of planning & performance
	Strategic decision & action	Integrated risk profile: operational, technical, strategic	Strategic decision supported by commensurable operational and commercial risk.	Risk guides strategic investment & innovation

Implementation Framework: Current State of the Art

ORION IO1 reports on a comprehensive training needs assessment. Using the material from IO1, the table below illustrates the state of the art in one of the ORION associate partners. This maps some of the practical issues that need to be addressed across the ORION Implementation Framework. It is easy to see that the systemic functional integration of system understanding leading to effective action is not fully realised at any of the three levels.

Table 2: State of the Art in ORION

	Can the data gathered identify the critical important issues?	**Is there a capability to identify clear and cogent solutions?**	**Is there a clear pathway towards implementing those solutions**
Gather & analyse operational data	Data on its own does not identify the key issues - most of it is 'green' and does not point to critical issues. Oversight of suppliers is a challenge.	Not enough time to be proactive. Reactive approach predominant.	Too many reports to be easily dealt with; yet reporting needs to be improved in some sections. A combination of statistical & operational expertise is needed.
Feed risk information to operation & get feedback	It is not clear how well safety bulletins represent operational concerns		NOTAMS & bulletins issued. Each person's responsibility to read and sign. Top down without feedback
Prioritising operational risk & initiate improvement	It is difficult to assess what initiatives would bring best value.	Safety does not generate change. Risk management of change initiatives is beginning & spreading	Lean and SMS are separate. Confusion between 'change management' and 'management of change'
Implementation and verification	Planning for implementation is weak	Need to address effectiveness of implementation	Lack of continuity of implementation. Need to document what is done. Mitigations take too long
Strategic synthesis of operational and change risk	Safety policy document should be more alive. How to manage a gigantic library of hazards?	Need to go further and find evidence	We do not work together enough. We need to reach higher levels of the organisation

This reinforces the importance of the Obligation to Act concept: this example clearly indicates the difficulty of identifying the important risk in complex operations, the consequent problem in generating effective solutions, and the lack of viable and verifiable pathways for implementing change.

Advanced Risk Management Training

The ORION Advanced Risk Management training course outlines the whole concept of Mindful Governance of Operational Risk and supports its implementation through practical project work using the ARK platform. Within an operational management framework the course aims to build the capability to analyse the risk in complex operational systems, using and analysing diverse sets of data, managing the risk in implementing solutions, and through all this to build a strategic capability to manage system risk.

The ORION Advanced Risk Management training objectives are as follows:

- To understand – to be able to describe and discuss the concepts of Advanced Risk Management, including the achievements and limitations safety management systems; socio-technical approaches to operational systems, operations management and the management of change; the assessment of risk in operations and in the processes of change; the use of data analytics in proactively assessing risk; the strategic management of risk and evidence-based governance.
- To apply - to interpret these concepts in relation to their own organization or other organisations with which they are familiar; and to identify strengths and weaknesses and opportunities for improvement both at operational level and in management systems and processes.
- To analyse – to use the Cube socio-technical analysis to analyse a particular situation or circumstance.
- To evaluate – to use the CMO framework (Context, Mechanism, Outcome), Risk assessment, Risk in Change assessment to assess the risk.
- To create – to initiate a new project focusing on risk and/or change using the ARK platform.

The target audience primarily concerns safety and risk managers and those with managerial responsibility for implementing improvement and change in any industry or service. A second target are senior managers responsible for strategic decision making and the strategic risk profile of the organization. A third target are those with regulatory responsibility for safety, risk or quality of service. The programme includes an introductory module plus five training modules as follows:

1. SMS Maturity Assessment
2. Operational risk and organisational hazard
3. Proactive risk management
4. SMS Data Analytics
5. Monitoring and Measurement for safety assurance
6. Organisational Change and Strategy

Module 1 includes basic organisational capabilities derived from STS and engineering principles. Module 2 introduces the CUBE and initiates discussion of setting up systemically resourced projects. The third supports the management of advanced data analytics. The fourth discusses the joint performance management required in a joined-up management combining Lean and risk management measurement and monitoring. The last module consolidates a whole system approach linking change and strategy. The modules are provided as a web-based course with live sessions to discuss and initiate a project.

Advanced Risk Knowledge Generation – the ARK Platform

The Advanced Risk Management programme is supported by the ARK platform. This has been developed as a knowledge-rich software system for managing risk and change. Modules 2 and 5 of the training guide the user in detail in using the ARK Platform methodologies to analyse complex problems, assess risk, propose, plan and implement solutions, and analyse the risk in change. The ARK platform is thus a core component of the ORION training. It provides the mechanism for project implementation.

At the core of the platform is a methodological framework for analysing complex socio-technical systems (the Cube). The CUBE framework has been developed over several years across numerous programmes of research in aviation and healthcare safety (Corrigan et al., 2018; McDonald, 2015; McDonald, et al., 2018; McDonald, Morrison, & Grommes, 2006; Ulfvengren & Corrigan, 2015; Ward et al., 2010) in order to leverage STSA in support of organisational change.

The ARK platform methodology starts with needs or problem formulation, then supports development of a solution, integrates solutions through planning and preparation, implements the solution in operations (work system) and validates the actual outcome. As in most Systems Engineering, this is an iterative process, rather than sequential. For example, in the design stage a solution may be unfeasible due to lack of resources, and hence the team must backtrack and discuss priority of needs or requirements for change. Each stage of the lifecycle evaluates the conditions for achieving a certain outcome and the mechanism that delivered the outcome. At all stages there are links to diverse types of data that are relevant to the analysis. At each stage, the CUBE methodology supports a systemic analysis that feeds into a Context-Mechanism-Outcome model (Pawson and Tilley, 1997), which is linked to a focused risk assessment. This risk assessment has an evolving role at each stage of a project. The following briefly summarises the main functional aspects.

Operationally, the CUBE consists of a 96-item questionnaire which guides safety experts in identifying, assessing, and classifying risks, as well as planning, executing, and evaluating risk mitigation actions. The CUBE is built around four domains: System, Culture, Action, and Sensemaking. Figure 4 shows the interplay between these domains and how they interact with each other to form the STS.

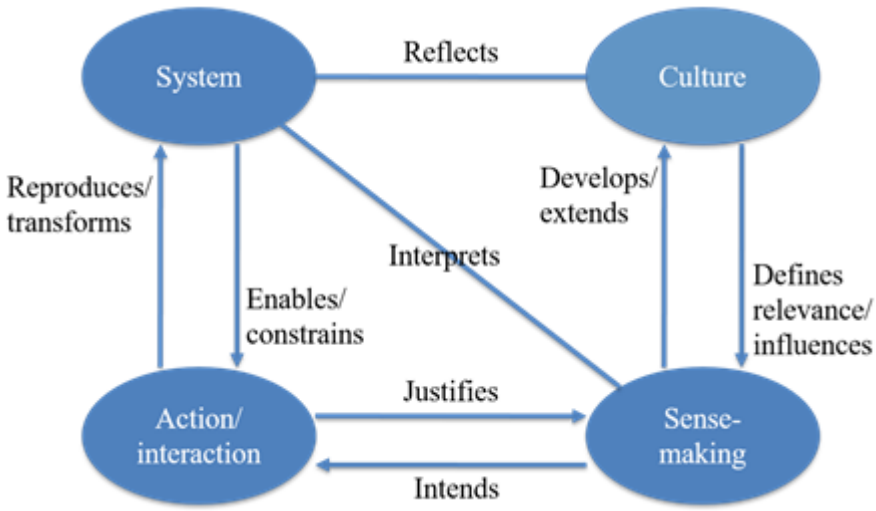

Figure 4. Domains of the CUBE Framework for STSA

The CUBE is further divided into four system aspects: Goals, Process, Social Relations, and Information & Knowledge. Figure 5 shows the sixteen dimensions of the CUBE framework.

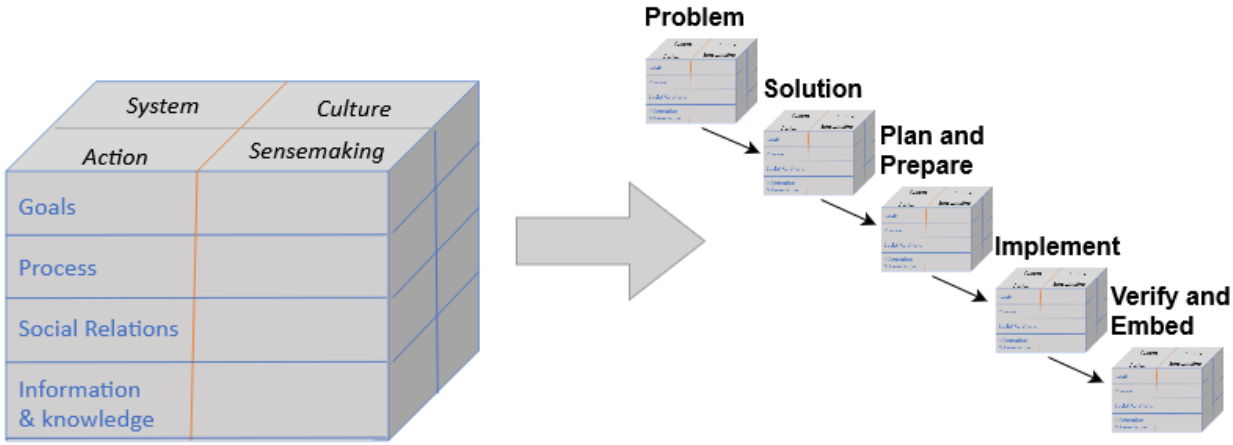

Figure 5. Dimensions of the CUBE

Figure 6 illustrates the evolution of risk through the phases. An initial risk assessment can be imported to the ARK platform from an external risk register. That will become further assessed and amended using the CUBE and other associated evidence. The solution stage supports a derivation of that risk - the projected risk, given the implementation of the solution. The Plan and Implementation stages introduce a new risk—the Risk-in-change (RiC)—projected at the plan stage, actual at the implementation stage. Finally, the Residual risk is the actual risk remaining after implementation.

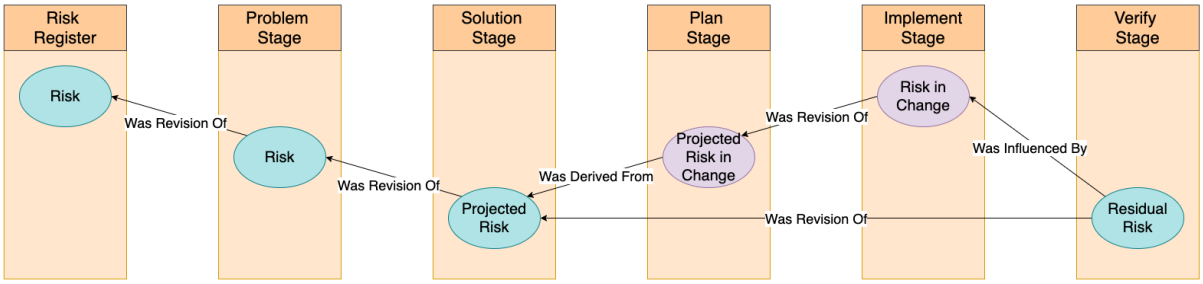

Figure 6. Transformation of Risk through Improvement Project Stages in the ARK Platform

The ARK Platform (Figure 7) is used to build and maintain a unified knowledge graph of risks and projects that links available datasets on practices, risks, and evidence. *This makes large-scale evidence collection and risk analysis more tractable* by transforming human-oriented quantitative risk information into structured, machine-readable data suitable for automated analysis, querying and reasoning. The ARK formal ontology is based on logical semantic models that enable text fields to be annotated with a taxonomy based on relevant domains: safety, healthcare, aviation, for example. This makes even highly specialised socio-technical risk analysis textual data amenable to machine processing. This will *create a new, unified risk evidence base* unknown in existing, highly siloed safety systems that emphasise manual risk analysis. When these processes are in place over many projects it will be possible to conduct semi-automated multi-project analysis and distillation of best practice from shareable, privacy-aware knowledge bases based on Linked Data.

The ARK data governance services support integrating siloed risk datasets, interlinking local knowledge to web-based sources, providing structured metadata about evidence, federating sensitive data from multiple organisations and enforcing privacy when converting local sensitive data to sharable evidence. Deliberative human control of safety analysis and recommendation is at the heart of the mindful governance methodology and the ARK platform. Nonetheless ARK aims at saving safety

experts time and effort with data aggregation, classification, ranking and structured mindful governance workflows.

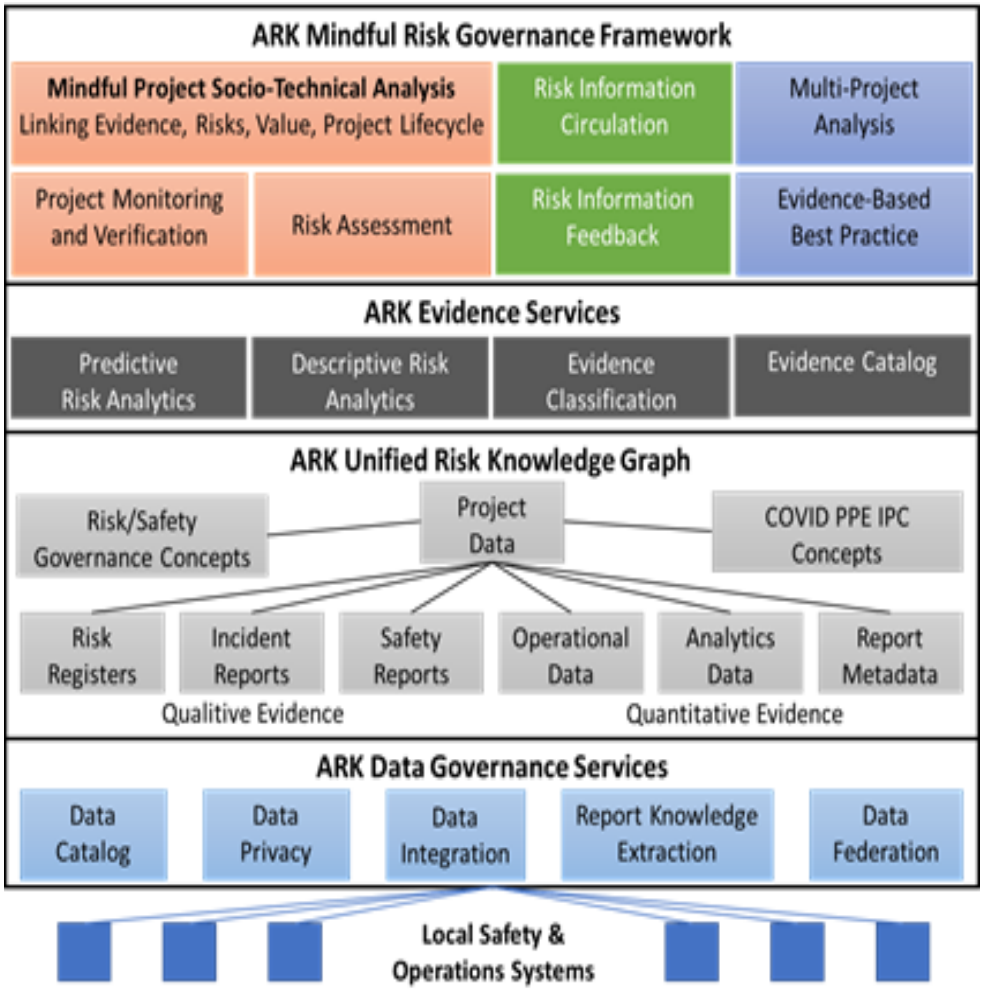

Figure 7. ARK Platform Mindful Risk Governance Framework.

Training & Implementation Trials: Developing Projects

The ORION training and ARK platform were deployed in a set of case studies conducted under the auspices of the ARK-Virus project, with training and training evaluation supported by the ORION project. The ORION training evaluation from this trial is reported in IO3. The relevant operational impacts of this trial are reported here also because they relate to the impact of the ORION Implementation Framework. The evaluation reported here is in terms of user engagement and organisational impact.

The ARK-Virus Project

The ARK-Virus Project is a collaboration between an academic team and a Community of Practice (CoP) which includes quality and safety staff from a large 1000 bed urban academic teaching hospital (inpatient and outpatient hospital services), medical staff from a private renal dialysis service (the largest specialised outpatient dialysis service in Ireland), and management staff from a large urban fire and emergency medical services (EMS) provider. The ARK-Virus project was designed to develop the ARK platform through the initiation and management of an IPC project in each of the three organisations. The development of these organisational projects was in line with the Sigtuna principles which provide criteria for the design, implementation and evaluation of specific interventions, e.g. engagement of key stakeholders; be aligned with organisational objectives; work with existing practices; develop organisational learning and evaluation; and transfer knowledge beyond the organization (von Thiele Schwarz, et al., 2020). The group of participating organisations was explicitly established as a CoP to share knowledge and experience in a way that would foster improved practice and contribute to best practice standards. Their diverse roles within the health system were seen to be an advantage in this.

Personal Protective Equipment (PPE) is a critical component of Infection Prevention and Control (IPC). Situationally aware risk management is critical to ensuring that PPE guidelines are understood, implemented and maintained. This is particularly relevant during the COVID-19 pandemic where it is vitally important to monitor PPE use to optimise its effectiveness in reducing the risk of virus transmission in healthcare settings. A key focus of the ARK-Virus Project is to develop a shared evidence base of PPE compliance data across the participating organisations. Using this data, the CoP can then conduct socio-technical risk analyses, via the ARK Platform, using the CUBE methodology. Effective COVID-19 IPC risk governance requires engagement from many actors across the entire healthcare organisation. This is also facilitated by the CUBE mindful governance methodology. Using the ARK Platform, users can link these safety improvement projects to supporting evidence such as datasets on IPC best practices, COVID-19 transmission data, and organisational IPC/PPE data. By putting the ARK Platform in place over many IPC projects across multiple organisations, it will be possible to collate the resulting best practice data into a shareable, privacy-aware, linked knowledge base. Development of this integrated evidence base is critical in optimising PPE effectiveness and in understanding the factors that influence PPE compliance.

Implementation Trial Evaluation

From June-August 2021, collaborators were given access to the platform and asked to initiate a risk management project relating to COVID-19 IPC. ORION Advanced Risk Management training was provided to support platform use and project development. Recorded presentations on Proactive Risk Management (Module 2) were provided and practical virtual workshops were conducted with participants. Collaborators aimed to complete the Problem and Solution Stages of their chosen project with the understanding that the remaining stages would be the focus of future trials. Over the course of the trial, each of the organisations used the platform to generate models of risk management of IPC. Members of the ARK-Virus and ORION research teams were available to liaise with the organisations and provide technical support as needed.

At the end of the three-month trial, platform users (*n*=7) from the three collaborating organisations took part in an online focus group and an anonymous survey (including training evaluation). The training evaluation is reported in IO3. The aim of the focus group was to evaluate user experiences from a technical and an operational point of view as well as to inform future iterations of the ARK Platform. All research ethics principles were adhered to including timely informed consent.
In the focus group, participants were asked to discuss a series of questions relating to their experiences using the platform and the CUBE methodology. Topics concerned what participants liked or disliked about the ARK Platform and the CUBE; as well as the usability and utility of both; the impact of the project on their organization; and operational requirements moving forward. Following the focus group, recordings were transcribed and thematic analysis was conducted independently by two members of the ARK-Virus research team. Preliminary results were presented to the users in a follow up meeting, giving them the opportunity to make corrections or additions. No changes to the themes were made as a result of this meeting, but the findings were discussed in further detail amongst the collaborating organisations.

Trial Results - Focus Group Feedback

Feedback from the workshop highlighted five benefits of the approach: expanding risk management, supporting transparency, building evidence, engaging stakeholders, and sharing knowledge. Overall feedback was positive regarding the platform's impact and potential, but there were a few shortcomings discussed as well. In addition to issues with the technical usability of the platform, users flagged two drawbacks: unclear workflows and lack of outputs.

Benefit 1. Expands Risk Management
Participants felt that interacting with the Cube framework and the ARK Platform promoted a broader awareness of risk management and implementing change by forcing users to consider the social aspects of change, culture, sense-making and communications. Users referenced the fact that implementation of a policy does not necessarily mean it has been enacted. There is a need to factor in how people interpret that policy, how it is understood or misunderstood, and whether it was enacted as intended. The approach also provides an integration pathway for combining risk assessment and improvement projects, which typically occur in different spaces within the organisation, in order to give what one participant describes as a "very rich governing picture". One organisation found that this perspective made the platform compatible with their Enterprise Risk Management approach and complemented existing risk assessment processes.

Benefit 2. Supports Transparency
The ARK Platform supports transparency by assigning responsibility for project roles and actions and by tracking the resources used throughout a change project from problem to verification. Users were interested in ways to improve this element of the platform.

Benefit 3. Builds Evidence
There has been extensive gathering of data on IPC and the implementation of guidelines in the three organisations, but much has not yet been uploaded to the ARK Platform due to delays in data protection agreements. The nature of the CUBE analysis makes it invaluable for producing evidence, for example by allowing users to translate safety managers' implicit knowledge and experience into explicit knowledge available for members of the team or organisation. Participants were interested in developing a repository of past projects as this leads to an improved understanding of issues over both time and place and thus enhances the spread and sustainability of change implementation.

Benefit 4. Engages Stakeholders

The ARK Platform has potential to effectively engage a wide range of stakeholders within the organization, due in part to the depth of analysis, inclusion of supporting evidence and focus on social aspects of change.

Benefit 5. Shares Knowledge

This trial demonstrated a high level of potential for constructive collaboration across the CoP. The focus group itself led to sharing of knowledge between organisations. There were many commonalities in experiences using the platform, observations of current impacts, benefits and drawbacks, and vision for future impacts and benefits. Further development of the CoP will allow for benchmarking and standardisation within and between organisations. Participants placed a high value on the ability to share not just data, but also knowledge, between organisations. They explained that this fulfils a need for shared knowledge on the application of standards and practices within healthcare, which is especially relevant for IPC.

Drawback 1. Unclear Workflow

The analysis components of the platform were appreciated for the richness and detail offered, but users noted that some of the sub-questions were abstract and difficult to relate to their own work context. Users need a road map to assist them in navigating around the platform as they work on a project. While a technical solution to the signposting issue will be implemented in future versions of the platform, this finding indicates that the training of users also should be enhanced to provide a greater understanding of progression through a project.

Drawback 2. Lacks Outputs

In the version of the ARK Platform used in the trial, no outputs (reports) are produced. This was identified as a significant drawback for participants throughout the trial in addition to during the focus group. Users suggested a reporting structure to link projects to the rest of the organisation. In this trial, much work has been done in terms of designing strategies for transforming the information contained in the platform into action; participants were pleased with the reporting feature currently under development for the next version of the platform and enthusiastic about contributing to the design of other output features.

Discussion

How far along the ORION Implementation Framework (as outlined in Table 1) have we progressed in this first phase? There has been extensive gathering of data on IPC and the implementation of guidelines in the three organisations, but not yet focused collation and feedback into the organisations concerned. The focus has been on the middle level of the Implementation Framework – improvement management. The activity has focused on the analysis of the problem and identification of solutions. The main advance has been in developing a fuller and richer understanding of risk and engagement of different points of view. The trials have not yet moved to the planning and implementation phases of the projects. There are good prospects for evidence development and CoP developing best practice.

Overall, each of the Advanced Risk Management training objectives (outlined on p. 15) was achieved to some extent. Throughout the course of the trial, the organisations were able to complete the ORION training and achieve a higher level of understanding of Advanced Risk Management, and subsequently apply the concepts in the context of their own organisation. Participants then initiated a risk project within the ARK platform and subsequently used the platform to analyse and evaluate the problem and solution states for the project.

The chief drawbacks for the organisations concerned the state of development of the ARK platform, which at the time did not contain worked out reporting formats and so lacked clear outputs from each stage (and this in turn is related to the navigation problems experienced). These developments are currently underway and will enable moving to the next steps of implementing solutions. This will be supported by further implementation of ORION training.

Performing a full STSA of risk and an associated corrective project using the CUBE methodology is time consuming. This was in part due to unfamiliarity with the user interface and the CUBE methodology; but it also reflected the deeper and richer analysis of risk that the CUBE invited - for example participants reported using the CUBE brought in considerations of culture, communications and sense-making that were not often considered before within the organisations. The process also encouraged wider participation in cross-functional discussion of tacit knowledge associated with specific roles within the organisations that participants reported had never been collected into one place before.

Competence and Training

The development and implementation of trial one was facilitated by having a broad mix of knowledge and experience of safety, risk and change amongst the collaborating organisations. The principle collaborator in each healthcare organisation had completed a masters in Managing Risk and System Change. Some others in the implementation teams and research organisations had a strong combination of education, research experience and professional knowledge of risk and safety in their particular domain. A small number of staff without this background were also involved. Despite the relatively high levels of experience amongst participants, however, both formal and informal feedback indicated that the training was viewed as highly advanced and somewhat complex—in some cases, it was viewed as more knowledge than necessary to complete an ARK project. Thus, while the ORION training objectives were achieved, there is more work to be done in terms of relating the conceptual aspects of the training to on-the-ground practice within each organisation.

The Advanced Risk Management training had a particular focus on linking training to implementation, using the ARK Platform as a vehicle to develop the projects, and helped extend participation to the wider implementation teams at the hospital and the fire service. As a result, each organisation had a relatively high level of competence to address the complexities of using the CUBE and ARK Platform to address the risk management of IPC in their organisation. As projects go into a wider implementation phase they will inevitably draw in more people, particularly on the operational side,

where the demands of implementation must be balanced against the continuing demands of normal operations. This will demand further training and facilitation support.

The pathway to implementation is in its early stages. Reported here is the first full implementation trial of a prototype platform still under development, supported by ORION training. These initial results are encouraging in terms of the active engagement of participants using the ARK Platform to address the complexity of the operational system. The next stages set out a challenging agenda. Moving from analysing problems and devising solutions to implementing those solutions and verifying the outcome will test the participating organisations: risks change over time and therefore priorities for implementation may change; wider participation of operational staff in the implementation phase will challenge the organisations and test the efficacy of the risk in change concept; further training will be needed.

The next trials will improve the outputs of the ARK system, improve its capability to manage multiple projects and integrate diverse sorts of evidence and actively support phases of implementation. Populating the platform will enable the development of the knowledge-based capabilities which will enable better support for the user in accomplishing individual complex tasks at the same time as building and synthesising a growing evidence base that supports risk governance at system level. This will increase the motivation to share evidence, to build better practice in common and to share with the wider healthcare community. This will require alignment of the platform configuration, data governance, and the organisation of the CoP and links with the wider healthcare community including regulatory and commissioning stakeholders. As it develops this will generate a need for new sustainable knowledge-based services to support a growing CoP.

This is designed to support a new virtuous cycle of knowledge generation, sharing and competence development, at least in part enabled by the ARK platform, illustrated in figure 8. This is the new version of the ORION Implementation Framework in which Advanced Risk Management training develops management competence; this stimulates the generation of organisational knowledge of risk and change through the development of implementation projects (and increases organisational capability). Many projects build a growing evidence base which supports an emerging best practice for effective system change. This then feeds into the further development of Advanced Risk Management as evidence-led training for system development.

Figure 8. The ORION Implementation Framework as a Virtuous Knowledge Cycle for System Development.

Next Steps

The roadmap towards realising this aspiration towards a knowledge-rich ORION Implementation Framework is as follows:

1. The immediate objective is to develop the existing projects further and extend the delivery of ORION training. This needs to be done in a flexible way to support project implementation and to be sensitive to the diverse levels of knowledge and understanding of different users.
2. The ORION training developed will become available as a regular on-line course delivered by Trinity College Dublin, through its Human Capital Initiative, contributing to Continuous Professional Development credits, and will contribute to an existing micro-credentialising system leading to Certificate, Diploma and Masters qualifications.
3. The ARK-Virus project development effort will build the resulting evidence base within each organization and then sharable between organisations in the Community of Practice. This will generate a common model of best practice in relevant areas of IPC. This best practice then becomes a resource for the ORION training. Evolving best practice is thus the keystone of developing professional competence.
4. Regulation and standards: there will be a focused engagement with regulatory and commissioning agencies, and professional associations, first at national level, then at European, and full international levels. The initial phase of this will be managed through the ARK-Virus project.
5. Commercialisation: A commercialisation programme has been initiated for the ARK platform since its development was fist supported by the Enterprise Ireland Commercialisation Fund. The ORION programme is a critical part of delivering a sustainable future for Advanced Risk Management and Advanced Risk Knowledge. It will help to gather a growing customer base as a sustainable Community of Practice. In turn this will continuously develop and extend the Knowledge base which is the key value of the enterprise. Currently, this programme is in a pre-commercial phase, but the next year of development and implementation will lead to the formation of a commercially sustainable partnership to continue delivery.

Conclusion

The need for the ORION implementation framework begins with a deep-seated systemic problem manifest in terms of persistent stability in the face of accumulating evidence of the need to change.

An effective solution must be proportionate to the scale of the problem in order to credibly exert leverage on critical mechanisms that potentially can transform the system. A set of needs for a capability to leverage system transformation were identified. To address these needs the ORION implementation Framework was based on the model of Mindful governance of Operational Risk. It is complemented by the ARK software platform which implements the core methodologies of the Cube STA, CMO, data & evidence, Risk assessment across the phases. Knowledge graph technology begins to build the knowledge base. ORION Advanced risk management training delivers the capability to implement the knowledge in system transformation. The ARK platform is currently in the first phase of operational trials of its prototype, supported by ORION training. The platform is progressively meeting the identified needs. Trial evaluation shows that the training and platform combination are effective in engaging users in developing rich and relevant projects. The trial also identifies issues for development. Thus, the solution is not complete but is in line with users' needs.

There also needs to be a viable pathway to deliver that solution. The goal of a mindful organisation, supported by a mindful knowledge system is not yet there but the first steps have been taken. Figure 2 above outlined the components of the ORION Implementation Framework: Professional Competence, Organisational Capability, System Knowledge. The ORION training programme has been developed and beginning to deliver Professional Competence. The ARK platform prototype has been developed and is undergoing further development and beginning to deliver the Organisational Capability. System Knowledge has been initiated with initial projects formed and to be continued. There is a development and delivery roadmap going forward leading to a sustainable solution. This includes ARK commercialisation, supported by ORION training, building a Community of Practice - forging a viable pathway.

These three conditions - important problem, effective solution, viable pathway - create a compelling 'Obligation to Act' to implement that solution in a verifiable way. The ORION project has played an indispensable role in setting this process in motion. The impact so far is evident in the initial knowledge base arising from the IPC projects and the development of effective and committed implementation teams. Looking further ahead the impact will be measurable through a contribution to best practice standards for practical infection prevention and control initially in the context of COVID-19, and then in a wider IPC context. Engagement with regulatory agencies will seek to embed these best practice principles within regulatory guidelines. The ORION Implementation Framework will also contribute to a next generation governance model of safety and risk management.

References

Braithwaite, J., Churruca, K., Long, J.C., Ellis, L.A., and Herkes, J. (2018) When complexity science meets implementation science: a theoretical and empirical analysis of systems change. *BMC Medicine, 16*, 63.

Buchanan, D. A., & Fitzgerald, L. (2011). Improvement evaporation: why do successful changes decay? *The Sustainability and Spread of Organizational Change*, 54-72. London, UK: Routledge.

Civil Air Navigation Services Organization. (2015). CANSO Safety Standard of Excellence in Safety Management Systems.

Crotti Junior, A., Basereh, M., Abgaz, Y., Liang, J., Duda, N., McDonald, N., and Brennan, R. (2020, 17 September). *The ARK platform: enabling risk management through semantic web technologies.* Presented at the 11th International Conference on Biomedical Ontologies (ICBO 2020). Bolzano, Italy.

Corrigan, S., Kay, A., O'Byrne, K., Slattery, D., Sheehan, S., McDonald, N., Smyth, D., Mealy, K., & Cromie, S. (2018). A Socio-Technical Exploration for Reducing & Mitigating the Risk of Retained Foreign Objects. *International Journal of Environmental Research and Public Health, 15*(4), 714.

Flynn, R., Rotter, T., Hartfield, D., and Newton, A.S. (2019). A realist evaluation to identify contexts and mechanisms that enabled and hindered implementation and had an effect on sustainability of a lean intervention in pediatric healthcare. *BMC Health Services Research 19*(1), 912.

Hollnagel E., Wears, R.L., and Braithwaite, J. (2015). *From Safety-I to Safety-II: A White Paper.* The Resilient Health Care Net. Published simultaneously by the University of Southern Denmark, University of Florida, USA, and Macquarie University, Australia.

Institute of Medicine (US) Committee on Quality of Health Care in America. (2000). Kohn, L. T., Corrigan, J. M., & Donaldson, M. S. (Eds.). *To Err is Human: Building a Safer Health System*. National Academies Press (US).

Institute of Medicine (US) Committee on Quality of Health Care in America. (2001). *Crossing the Quality Chasm: A New Health System for the 21st Century*. National Academies Press (US).

International Civil Aviation Organization. (2018). *Safety Management Manual* (4th edition).

Jorma, T., Tiirinki, H., Bloigu, R., Turkki, L. (2016). LEAN thinking in Finnish healthcare. *Leadership in Health Services, 29*(1), 9-36.

Liker, J. (2004). *The Toyota Way: 14 Management Principles from the World's Greatest Manufacturer*. New York, NY: McGraw-Hill.

Lucian Leape Institute. (2013). *Through the Eyes of the Workforce: Creating Joy, Meaning, and Safer Health Care.* Boston, MA: National Patient Safety Foundation.

Pawson, R., & Tilley, N. (1997). An introduction to scientific realist evaluation. In E. Chelimsky & W. R. Shadish (Eds.), *Evaluation for the 21st century: A handbook* (pp. 405–418). London, UK: SAGE Publishing.

Poksinska, B. (2010). The current state of Lean implementation in healthcare – literature review. *Quality Management in Health Care, 19*(4), 319-329.

Pronovost, P.J., Ravitz, A.D., Stoll, R.A., and Kennedy, S.B. (2015). Transforming Patient Safety: A Sector-Wide Systems Approach. Report of the WISH Patient Safety Forum 2015.

Martin, G. P., Currie, G., Finn, R., & McDonald, R. (2011). The medium-term sustainability of organisational innovations in the National Health Service. *Implementation Science, 6*(1), 1-7.

Mazzocato, P., Thor, J., Bäckman, U., Brommels, M., Carlsson, J., Jonsson, F., Hagmar, M., and Savage, C. (2014). Complexity complicates lean: lessons from seven emergency services. *Journal of Health Organization and Management, 28*(2), 266-288.

McDonald, N., Morrison, R., and Grommes, P. (2006, 10-13 September). *Knowledge space model – Human Factors and Operability.* Paper presented at the first CEAS European Air and Space Conference Century Perspectives. Berlin, Germany.

McDonald, N., Kay, A., Morrison, R., and Ryan, M. (2017). *How Automation may Transform the Ways in which Crew Manage Peak Workload and Incapacitation.* Presented at the ISAP International Symposium on Aviation Psychology. Dayton, Ohio.

McDonald, N., Callari, T.C., Baranzini, D., and Mattei, F. (2019). A Mindful Governance model for ultra-safe organisations. *Safety Science,* 120, 753–763.

McDonald, N., McKenna, L., Vining, R., Doyle, B., Liang, J., Ward, M.E., Ulfvengren, P., Geary, U., Guilfoyle, J., Shuhaiber, A., Hernandez, J., Fogarty, M., Healy, U., Tallon, C., and Brennan, R. (2021). *Evaluation of an access-risk-knowledge (ARK) platform for governance of risk and change in complex socio-technical systems.* [Unpublished Manuscript]. Centre for Innovative Human Systems, Trinity College Dublin.

McCaughan, C. (2019). *A study of how to effectively leverage incident investigations to better inform system safety.* [PhD thesis]. Trinity College Dublin.

McKenna, L., Liang, J., Duda, N., McDonald, N., and Brennan, R. (2021, 19-23 April). *ARK-Virus: an ARK platform extension for mindful risk governance of personal protective equipment use in healthcare.* Presented at The Web Conference, WWW'21. Ljubljana, Slovenia.

Organisation for Economic Co-operation and Development. (2020). *The Economics of Patient Safety: From analysis to action.* OECD and Saudi Patient Safety Center.

Radnor, Z.J. and Osborne, S.P. (2013). Lean: A failed theory for public services? *Public Management Review, 15*(2), 265-287.

Savage, M., Savage, C., Brommels, M., Mazzocato, P. (2020). Medical leadership: boon or barrier to organisational performance? A thematic synthesis of the literature. *BMJ Open, 10*(7):e035542.

Shortell, S.M., Blodgett, J.V., Rundall, T.G., and Kralovec, P. (2018). User of Lean and Related Transformational Performance Improvement Systems in Hospitals in the United States: Results From a National Survey. *The Joint Commission Journal on Quality and Patient Safety, 44*(10), 574-582.

Shortell, S.M., Blodgett, J.C., Rundall, T.G., Henke, R.M., and Reponen, E. (2021). Lean Management and Hospital Performance: Adoption vs. Implementation. *The Joint Commission Journal on Quality and Patient Safety, 47*(5), 296-305.

Ulfvengren, P., Corrigan, S. (2015) Development and Implementation of a Safety Management System in a Lean Airline. *Cognition, Technology & Work, 17*, 219–236.

von Thiele Schwarz, U., Nielsen, K., Edwards, K., Hasson, H., Ipsen, C., Savage, C., Abildgaard, J.S., Richter, A., Lornudd, C., Mazzocato, P., and Reed, J.E. (2020). How to design, implement and evaluate organizational interventions for maximum impact: the Sigtuna Principles. *European Journal of Work and Organizational Psychology, 30*(3), 415-427.

Ward, M., McDonald, N., Morrison, R., Gaynor, D., and Nugent, T. (2010). A performance improvement case study in aircraft maintenance and its implications for hazard identification. *Ergonomics, 53*(2), 247-267.

Weick, K.E. (1995). *Sensemaking in Organisations*. London, UK: SAGE Publications.

Zibrowski, E., Shepherd, L., Sedig, K., Booth, R., Sedig, K., and Gibson, C. (2018). A Qualitative Study of the Theory Behind the Chairs: Balancing Lean-Accelerated Patient Flow with the Need for Privacy and Confidentiality in an Emergency Medicine Setting. *JMIR Huan Factors, 6*(1), e11714.