



Centre for Innovative Human Systems (CIHS)





ARK Virus: Access Risk Knowledge platform for mindful governance of infection prevention and control risk

Final Stakeholder Report 23 May 2022





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Executive Summary

ARK-Virus has deployed novel socio-technical systems analysis (STSA) risk governance methods via the ARK Platform in O1, a large 1000-bed urban academic teaching hospital, O2, a large urban fire and emergency medical services (EMS) provider, and O3, a private renal dialysis service. This report includes an overview of ARK's risk mitigation project-based approach to governing risk that links organisational change to risks, evidence and analysis. The ARK trials for managing infection prevention and control (IPC) projects during covid in January-April 2022 resulted in improvements and evaluations of the ARK platform and a set of guidelines for IPC in emergency situations being produced (Appendix C). The ARK platform and mindful governance approach was found to add value by the organisations and follow-on projects are planned. However the level of training required to use the platform remains high and the usability for non-specialist staff is limited. This study showed the emerging central role of data governance methods and tools to enable whole organisation and multi-organisation patient quality and safety systems built on a mix of qualitative and quantitative data sources.

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1. The ARK-Virus Project

ARK-Virus studied novel risk governance methods for infection prevention and control (IPC) by deploying the Access-Risk-Knowledge (ARK) software platform in three healthcare providers. ARK guides users in a structured socio-technical analysis and governance of a clinical system: identifying and quantifying risks, developing and implementing risk mitigation projects while linking the analysis, risks and project progress to evidence. Users and stakeholders are supported by report generation, visualisations and flexible navigation of the linked risks, projects, analyses and evidence. ARK supports data governance best practice with extensive metadata and a data catalogue of evidence like datasets and publications. ARK uses privacy by design for controlled sharing of evidence between organisations. In parallel, a Community of Practice (CoP) has been developed, which connects ARK users from different healthcare organisations to facilitate inter-organisational learning and collaboration. The goal of ARK-Virus is to build a socio-technical infrastructure to support organisations in designing, implementing, and governing knowledge-based solutions to complex problems.

Since May 2021, ARK has supported infection prevention and control (IPC) risk management projects in O1 and O2. O2 focused on PPE compliance for reduced COVID-19 transmission in the workplace (non-clinical areas), while O1 focused on mapping and improving existing data relating to the prevention and control of all healthcare-acquired infections (PCHCAI). O3 has participated in the CoP and is in the early stages of a project on patient personal protective equipment (PPE) compliance for reduction of COVID-19 transmission within the unit. Three trials took place, in which participants used the platform and provided feedback to drive ARK improvement (Appendix B).

This report focuses on the findings of the third trial (January-April 2022). Section 2 provides an overview of risk mitigation projects, sections 3-4 synthesise the trial findings and the guidance for IPC practice in emergencies, and Section 5 discusses conclusions and next steps.

Key Terms, Acronyms and Concepts¹

ARK Platform	Access Risk Knowledge software platform, https://openark.adaptcentre.ie/
ARK Project	A risk mitigation project addressing a specific risk managed by ARK Platform
ARK-Virus	A SFI-supported project to develop novel risk governance methods
Context	Wider circumstances of the system (project or risk) - See Appendix A
CoP	Community of Practice in mindful risk governance using ARK platform
СМО	Context, Mechanism, Outcome: An analytic triad of the features of a system
	which critically influence outcomes
Cube	Comprehensive realist STSA for mindful governance of risk - See Appendix A
ERM	Enterprise Risk Management
IPC	Infection prevention and control
Mechanism	The way in which something is transformed, produced, circulated - Appx. A
01	A large 1000-bed urban academic teaching hospital
02	A large urban fire and emergency medical services (EMS) provider
03	A private renal dialysis service
Outcome	The end product of a purposive activity (results of the mechanism) - Appx. A
PCHCAI	Prevention and control of healthcare-acquired infections
Project Stage	An ARK project is organised as a sequence of stages: Problem, Solution,
	Plan, Implement, Verify See Appendix A
STSA	Socio-technical systems analysis

¹ A more complete terminology is defined on the ARK website in both human and machine readable formats, see <u>https://openark.adaptcentre.ie/Ontologies/ARKRiskTerminology/index-en.html</u>

2. Risk Mitigation Projects in ARK

ARK uses risk mitigation projects as the central organising concept for risk governance. Each project addresses a specific risk. The projects are organised around a sequence of five stages: Problem, Solution, Plan & Prepare, Implement, and Verify & Embed. This forms a basis for iterative, structured analysis and project tracking to enable management of both the original risk and the associated risk due to the process of change. At each project stage, ARK structures the analysis in the following way (Figure 1):

- An assessment of the risk and the value (both potential loss and gain) of the project.
- A Cube STS analysis, a tool that prompts users with questions to help them plan and execute organisational change projects. The Cube STSA links goals, actions, and outcomes to operational processes, drawing upon both explicit and implicit knowledge to build a rich picture of a complex system.
- A Context-Mechanism-Outcome analysis, which synthesises the findings of the Cube under three headings: what happens (outcome), how it happens (mechanism), and the conditions under which it happens (context).
- Linked evidence (i.e., infection rates, IPC protocols, PPE compliance rates, etc.) which is linked to specific parts of the analysis to support the analysis and conclusions.

Projects are used to drive change and address risks through this evidence-linked analysis that helps organisations uncover and evaluate risks and mitigations to prioritise activities.

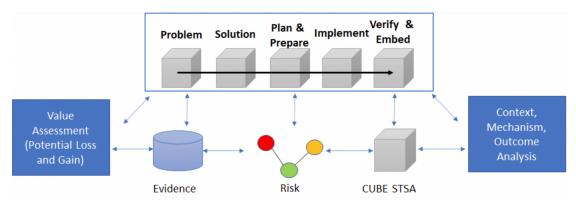


Figure 1: ARK Risk Mitigation Project Phases with Linked Risks, Evidence and Analysis

3. ARK Virus Trial 3 Results

Trial 3 (Jan-April 2022) sought to sustain good practice in IPC and to transfer that across the healthcare provider by conducting a case study of IPC using ARK for IPC risk governance in three different healthcare organisations in the context of the COVID-19 pandemic. Each organisation selected a key IPC issue to explore: O1 focused on data infrastructure relating to IPC generally, while O2 and O3 focused on PPE compliance for reduction of on-site transmission of COVID-19. We studied both IPC and the implications of using the ARK platform for governing IPC risk in the organisations.

To synthesise learnings and to generate recommendations for IPC practice in emergencies, a trial synthesis report was created using the ARK platform by first creating a meta-analysis project linked to the healthcare organisation Trial 3 projects, risks, analysis and evidence (Figure 2). The full report created with ARK is included in Appendix D. The rest of this section provides the key points from each project stage.

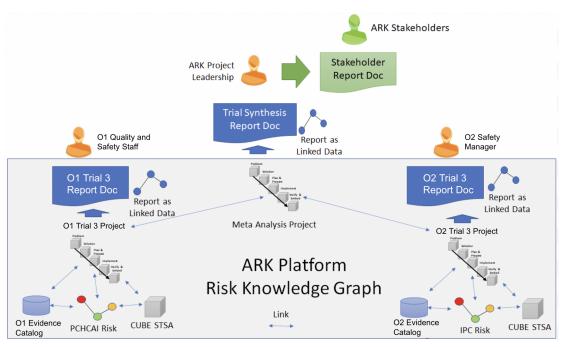


Figure 2: Creation of this Stakeholder Report from the Trial Synthesis Report and the Individual Healthcare Organisation Trial 3 Reports, Risks, Analysis and Evidence in ARK

Trial 3 Report Highlights

Each stage of the synthesis project is discussed in turn below. The next section provides a summary of the IPC guidance developed as a result of this trial and analysis.

Problem Stage: In Trial 3 there was a need to continue improving usability and utility of the ARK platform and to build on IPC lessons learned in previous trials. The key challenges were:

- Overwhelming amount of data or lack of data; for example, in O1, over 110 individual metrics are tracked relating to PCHCAI, while in O2, occupational health data is hard to access
- Data flows on IPC risk are not consistently linked to follow-up mitigation measures
- Lack of formal documentation of organisational rules and relationships in ARK model
- Communication within CoP good but complex to rest of the organisation, mechanisms for engaging with non-safety experts are under-developed
- A lack of protected time for engaging with ARK, combined with its difficulty of use and the time-intensive nature of ARK projects, led to a decreased engagement in O3

Solution Stage: A two-part solution was identified: to develop and deploy a new version of the ARK platform and to continue developing the CoP. ARK was deployed in each organisation to analyse the IPC problems and identify mitigation measures. In O1, this involves improving the monitoring, oversight, and continuous improvement of data relating to PCHCAI by applying data governance principles to analyse the data lineage of PCHCAI metrics; in O2 and O3 it involves reinforcing IPC control measures for COVID-19 PPE compliance through enhanced communication and supervision.

Plan and Prepare Stage: In preparation for the implementation stage, a new version of the ARK platform was developed (version 1.5) and a deployment plan was created with input from user organisations. Individualised support was made available to organisations, with accessible feedback channels so that issues and bugs could be addressed in real time. There was a strong focus on increasing the amount of evidence uploaded and use of the evidence

linking feature. Key mechanisms for IPC risk were identified, including the lack of unified data governance in O1 and need for social support areas (break rooms, etc) combined with pre-existing staffing issues in O2.

Implement Stage: Version 1.5 of ARK was successfully deployed in O1 and O2, and partially deployed in O3.

- To address the issue of data access, O2 combined explicit knowledge of COVID-19 infection and close contact rates among personnel with implicit knowledge of its impact on resources/service delivery and on areas of high infection risk
- To address the issue of data volume, O1 created a data lineage map of PCHCAI measures to create a new global view of PCHCAI monitoring data and direct future data analysis projects to determine the relative effectiveness of these measures
- Six months of data were gathered on patient PPE compliance in O3 and this was used to improve understanding of the problem/solution space
- An IPC practice in emergencies guidance document was generated (see Section 4)

Verify and Embed Stage: Feedback was sought from users and internal stakeholders, an assessment of how well the plan was fulfilled was conducted. These were the findings:

- In order to embed ARK, it must be integrated into existing organisational risk management frameworks. O1 has made progress towards this by making ARK a component of their Enterprise Risk Management (ERM) approach to PCHCAI, and have initiated a new data-driven IPC project, while O2 is deploying the platform in a major system infrastructure project.
- There is now a prospect of providing active, valid, and useful information that allows for more proactive risk management, whereas before the amount of data was overwhelming and prioritisation was difficult.
- Maturing the data governance of both risk and operational data in organisations and linking those datasets in meaningful ways is critical to integrated risk governance and ARK's evidence features help embed this.
- Training in advanced risk management and on the ARK platform needs to be streamlined.
- The platform usability has improved but is still below average on the simple usability scale (SUS) evaluation, indicating the platform is difficult to use even for domain specialists. Role-specific user interfaces as well as further population of the platform with completed projects will enable widening of the user base.

4. Guidance for IPC Practice in Emergencies

The experiences of the ARK-Virus Community of Practice and the Trial 3 synthesis were used to develop a set of guidance for developing a pandemic preparedness strategy in the context of Irish healthcare. Key items are listed here, the full guidance document is in Appendix C.

Key Findings: Recommendations for IPC Implementation in Emergencies

- 1. Core operational processes: adequate personnel and physical resources at all times are critical to maintaining service delivery and allowing for resilience during a crisis.
- 2. Performance standards: evidence-driven standards should be in place ahead of a crisis so that organisations can monitor their IPC performance.
- 3. Quality and flow of information: mature data governance programmes should be in place so that in an emergency, data can be rapidly found and shared; communication channels need to be in place to transfer information and knowledge to the point of decision-making.
- 4. Situational awareness and informed decision-making: implicit and explicit knowledge must be leveraged to create a collective understanding of the situation; access to data is important, but equally important is knowledge about that data and its provenance, quality, and intended use.
- 5. Responsive risk governance infrastructure: a risk governance framework (such as ERM) that links clinical and operational data should be in place. The infrastructure must be flexible and responsive so that measures can be escalated or de-escalated.
- 6. Quality and consistency of task performance: in order to monitor and validate implementation of control measures, data are needed about the outcomes of interest (i.e., transmission rates). Feedback loops must be in place that generate information back into the system for continuous performance improvement.
- 7. Embedment within behavioural norms: maintaining strict control measures may be difficult, particularly in stages when the emergency is perceived as less severe; transparent and open communication foster trust that the measures are necessary, and enhanced supervision may be needed to reinforce them. A stronger culture of vigilance contributes to maintenance of control measures.
- 8. Quality of collaboration, training, and leadership: more intensive collaboration and increased social support within the organisation is needed during an emergency, particularly as staff roles may change. Personnel need to be trained in their new roles ahead of a crisis.
- 9. Trust and transparency: a high level of trust across the organisational hierarchy is needed, engendered by a trust that the data is of high quality and that organisational decisions are made based on an understanding of that high-quality data.
- 10. Shared understanding: a comprehensive system of communication and reciprocal feedback is critical to generate a shared understanding of a collective response to risk.

5. Conclusions

The ARK-Virus project has supported the first ARK operational trials with healthcare partners. These trials have evolved the ARK platform and initiated a reusable ARK knowledge base around IPC, clinical risk and linked evidence. ARK is becoming embedded in two of the partners' risk management systems with further adoption and engagement agreed. The potential value of ARK has been illustrated but further progress of the trial risk projects is required to establish the value of ARK in governing core strategic risks in the organisations.

The mindful risk governance methodology has increased in profile in the member organisations. Organisations have adopted the ARK platform five phase sequential approach to implement change and manage the associated risk. In one organisation the methodological scaffolding provided by ARK provided more formal identification of a potential loss and quantification of an identifiable gain in health and safety of personnel. Participants recognised the benefits and further potential of intra-organisational collaboration experienced by applying the holistic mindful governance methodology.

The CoP was valued by all participants and seen as instrumental in successful deployment of ARK, although it also had wider benefits in transfer of knowledge in IPC, AI, knowledge management and risk governance. Practitioner-researchers played a key role in realising the project given the data collection and analysis effort required. ARK usability needs further improvement, including the development of specialised interfaces and reports for specific operational staff.

This study showed the emerging central role of data governance methods and tools such as data catalogues, data dictionaries, metadata, data lineage models, to enable data location, integration, protection, sharing, trust, and quality. This is also essential to enable whole organisation and multi-organisation patient quality and safety systems built on a mix of qualitative and quantitative data sources.

Current sustainability measures and follow-on projects to ARK-Virus include:

- HEA-funded extension on cross-sectoral analysis of ARK in aviation as well as healthcare domains
- SFI ADAPT Centre Risk and Value research challenge to further develop ARK platform and perform a behavioural analysis of clinical time series data on PCHCAI in O1 i.e. an analysis of PCHCAI data/observations obtained through repeated measures over a set period of time
- SFI Discover project application on patient engagement with PCHCAI
- O2 risk project using ARK platform on a major national emergency communications infrastructure project involving significant organisational change

The project members are interested in engaging with new partners for further deployments.

Appendix A: ARK Project Overview (from first Stakeholder Report)

This appendix provides a rapid overview of the ARK-Virus project (Figure A1). The project is developing novel risk governance methods via the ARK Platform, using the CUBE socio-technical systems analysis (STSA) methodology for governing risk, to develop organisational COVID-19 IPC compliance and to explore the impact of embedding ARK-based mindful governance in healthcare organisations.

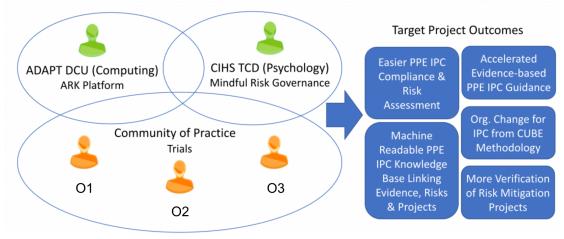


Figure A1: ARK-Virus Project Overview

ARK-Virus has supported an IPC project in O1 and)2 since May 2021. O3 has also participated in the community of practice (CoP), but has only completed the first stage of the project due to COVID-19 related resource constraints. Key project concepts are discussed below. A publication in the Int. J. Environ. Res. Public Health containing extensive references, background and evaluation of the trials is also available².

A.1 Key Project Concepts

A.1a The CUBE Approach to Mindful Governance of Operational Risk

The CUBE supports comprehensive STSA within a framework for mindful governance of operational risk. It engineers change, leveraging accumulated data from current and past organisational and operational activity. This data-driven approach to risk and change made it ripe for digitisation and connection to organisational data flows through the ARK platform. The CUBE enables a rich, multi-perspective, understanding of the system to be built around four domains: Sense-making, Culture, System and Action; and four system aspects: Goals, Process, Social Relations, and Information & Knowledge (Figure A2). This broad analysis is then focussed through identification of the critical outcomes (O), the key mechanisms (M) producing these and the context (C) in which these work. This CMO analysis then supports the assessment of risk and value and drives safety projects.

² 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.; Brennan, R. Evaluation of an Access-Risk-Knowledge (ARK) Platform for Governance of Risk and Change in Complex Socio-Technical Systems. *Int. J. Environ. Res. Public Health* 2021, *18*, 12572.

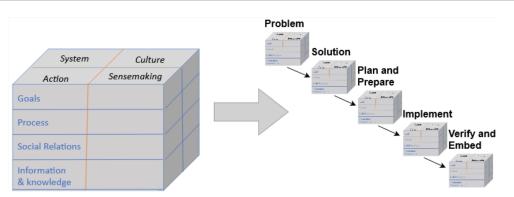


Figure A2: Dimensions of the CUBE and improvement project lifecycle

Risk management is operationalised in the CUBE methodology by process improvement projects to address risks. These start with problem formulation, then the development of a solution, integrates solutions through planning, implements designs in operations and validates the actual outcome. This is an iterative process. At each stage the context and mechanisms for achieving the outcome appropriate to that stage are evaluated as the CUBE, which consists of a questionnaire that guides safety experts in assessing and managing risks, is completed, stage by stage, including the risk in the change process itself.

A.1b The ARK Platform

The ARK Platform³ provides a way to embed the CUBE risk governance approach within the organisation. Safety experts are scaffolded through the process of linking risk analysis, CUBE analysis, evidence and project lifecycles to manage organisational change addressing risk. The unit of analysis is the change project. By populating a project on the ARK platform, users apply the CUBE to build a model of how to manage risk and change within a complex socio-technical system. The result is a supported analysis of a full change cycle that enables cross-project comparison. This builds shared organisational evidence on change management and leads to organisational learning and evidence-based strategic risk management.

ARK builds and maintains a unified knowledge graph of risks and projects that links available datasets on practices, risks and evidence (Figure A3). This bridges traditional qualitative risk evidence and quantitative operational or analytics data. 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. A privacy by design approach is taken and data governance principles are followed to ensure support for evidence linkage, classification and search.

³ <u>https://openark.adaptcentre.ie/</u>

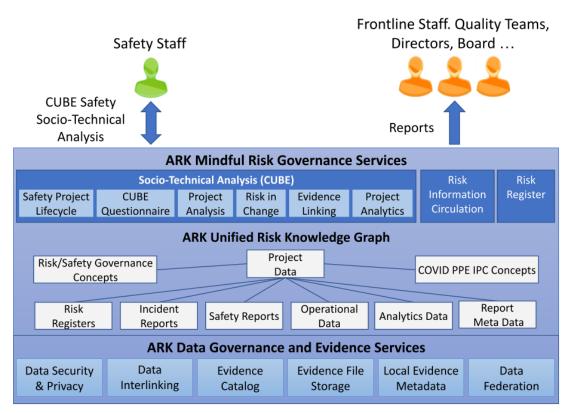


Figure A3: ARK Platform for the Mindful Risk Governance Framework based on Knowledge Graphs, Data Governance, Data Protection by Design, Metadata Management and Analytics

A.1c Trustworthy AI

The ARK platform is designed to support human-directed decision-making and implementation as part of an accountable governance framework. Data governance, data protection and confidentiality are key features of the design. It incorporates all these concepts of EU Trustworthy AI systems. The projects reported here were developed in line with the Sigtuna principles⁴, which provide criteria for the design, implementation and evaluation of healthcare interventions, including, engagement of key stakeholders, alignment with organisational objectives, working with existing practices, developing organisational learning and evaluation, and transferring knowledge beyond the organisation.

⁴ See <u>https://doi.org/10.1080/1359432X.2020.1803960</u>

Appendix B: Technical Features of ARK

Trial 1 (v 1.0)	 An evidence data catalogue, ARK Evidence, was created, using CKAN, in order to store evidence metadata and datasets in line with FAIR principles⁵. Evidence interlinking - users can create evidence links between the Project Analysis section of a project and a dataset in ARK Evidence. Concept tagging - users can classify data entered on the platform using concepts from a set of controlled taxonomies - the ARK Health Taxonomy, ARK Risk Taxonomy, HSE Adverse Incidents Categories and Subcategories Terminology, and the ARK Platform Taxonomy. Risk matrix based on the HSE risk assessment tool. Optional automated copying of data across project stages and risk assessments. Risk assessment data importation into an ARK project. Security features including user profiles, user profile approval processes, user data encryption, and data partitioning based on user organisation. Data classification - all data can be classified according to the Information Classification and Handling categories defined by the HSE, and the personal data types defined by GDPR.
Trial 2 (v 1.3)	 Automated report generation - reports can be automatically generated using the project data and published in PDF and HTML formats. Project Overview - the project overview feature provides data on the progress of the project stages, the completeness of the project, and a timeline of recent edits. Evidence interlinking - users can create more detailed links which describe the specific relationship between a given data field and an evidence dataset stored in ARK Evidence, and add rationale to an evidence link. Concurrency control - multiple users can work on the same project at the same time. Organisation dependent risk assessment form and risk matrix display.
Trial 3 (v 1.5)	 Project Comparison - the ability to compare project data within the same project or across different projects. The comparison tool provides a similarity score across project data fields based on text similarity, concept similarity and evidence similarity. Project interlinking - users can create hierarchical relationships between different projects on the platform. Automated concept suggestions - the platform uses the BERT natural language processing model to suggest concepts based on the text entered into the platform. Project analytics - provides graphical data on the most used evidence and most used concepts in a project. Project search filter which allows users to conduct keyword search within and among projects, and to filter results based on project stages, data fields, dates, and concepts. Evidence interlinking - users can interlink to external evidence sources outside of the ARK Evidence data catalogue. Report generation in RDF machine-readable readable formats.

⁵ See <u>https://www.go-fair.org/fair-principles/</u>

Appendix C: ARK-Virus Guidance on Implementing Infection Prevention and Control (IPC) in Emergencies

Introduction

This guidance arises from practical case studies on the implementation of infection prevention and control (IPC) measures in two healthcare organisations in the ARK-virus project. The project deployed the ARK (Access-Risk-Knowledge) platform for mindful risk governance, a software designed to support risk management in complex organisations through advanced socio-technical analysis and data collation. Fundamentally, it assists health and safety experts in analysing the system in order to draw evidence-based conclusions about causal links between risks, actions, and outcomes. Outlined below are a summary of the analysis and ten key recommendations for IPC pandemic preparedness.

Context:

Within the broad context of healthcare improvement, this guidance has a focus on preparedness for future emergencies, through the management of socio-technical risks. It is also relevant to the management of IPC risks in normal operations.

Mechanism:

For both normal operations and especially for emergencies, provision of resources and supply are critical. The information infrastructure is fundamental to data-driven decision-making which should be the core of Enterprise Risk Management, enabling a collective organisational response to emergencies, facilitating communication and feedback, and building transparency and trust in an effective response.

Outcome:

Overall system improvement should deliver better health outcomes; more efficient use of resources; enhanced service delivery; and better emergency response.

Goal:

The goal is to generate implementation guidance to achieve better health outcomes, more efficient use of resources, enhanced service delivery and better emergency response. An important functional objective is to establish the means of monitoring implementation and associated outcomes for patients and staff (ideally linking cause and effect). This should foster better communication and collaboration both across units within an organisation as well as to develop a strong cross-organisational response. It should enhance the value of participation and collaboration in a collective response.

Key Findings: Recommendations for IPC Implementation in Emergencies

- 1. Core operational processes: adequate personnel and physical resources at all times are critical to maintaining service delivery and allowing for resilience during a crisis.
- 2. Performance standards: evidence-driven standards should be in place ahead of a crisis so that organisations can monitor their IPC performance.
- 3. Quality and flow of information: mature data governance programmes should be in place so that in an emergency, data can be rapidly found and shared; communication channels need to be in place to transfer information and knowledge to the point of decision-making.
- 4. Situational awareness and informed decision-making: implicit and explicit

knowledge must be leveraged to create a collective understanding of the situation; access to data is important, but equally important is knowledge about that data and its provenance, quality, and intended use.

- Responsive risk governance infrastructure: a risk governance framework (such as ERM) that links clinical and operational data should be in place. The infrastructure must be flexible and responsive so that measures can be escalated or de-escalated.
- 6. Quality and consistency of task performance: in order to monitor and validate implementation of control measures, data are needed about the outcomes of interest (i.e., transmission rates). Feedback loops must be in place that generate information back into the system for continuous performance improvement.
- 7. Embedment within behavioural norms: maintaining strict control measures may be difficult, particularly in stages when the emergency is perceived as less severe; transparent and open communication foster trust that the measures are necessary, and enhanced support may be needed to reinforce them. A stronger culture of vigilance contributes to maintenance of control measures.
- 8. Quality of collaboration, training, and leadership: more intensive collaboration and increased social support within the organisation is needed during an emergency, particularly as staff roles may change. Personnel need to be trained in their new roles ahead of a crisis.
- 9. Trust and transparency: a high level of trust across the organisational hierarchy is needed, engendered by a trust that the data is of high quality and that organisational decisions are made based on an understanding of that high-quality data.
- 10. Shared understanding: a comprehensive system of communication and reciprocal feedback is critical to generate a shared understanding of a collective response to risk.

Footnotes and References

1 Data governance specifies a cross-functional framework for managing data as a strategic enterprise asset. In doing so, data governance specifies decision rights and accountabilities for an organization's decision-making about its data. Furthermore, data governance formalizes data policies, standards, and procedures and monitors compliance. - R. Abraham et al. <u>https://doi.org/10.1016/j.ijinfomgt.2019.07.008</u>

WHO. Communicating risk in public health emergencies: A WHO guideline for emergency risk communication (ERC) policy and practice. Geneva, Switzerland: World Health Organisation; 2020. [13 Feb 20]. Available from: https://www.who.int/risk-communication/guidance/download/en/.

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Appendix D: Trial 3 Synthesis Report from ARK Platform

The following pages provide a synthesis report that was generated in the ARK platform based upon the final IPC project reports from O1 and O2. The reports were synthesised by the ARK team and the results were verified by the participating organisations. While the organisations have consented to allowing the synthesis report to be shared, they have been anonymised in the report for confidentiality reasons.

The report contains the following:

- (1) Header information describing the title, persons responsible, project version, intended audience, and project description.
- (2) Risk assessments for the initial risk (before intervention), risk in change (risk including risk added by implementing the intervention), and residual risk (amount of risk remaining after conclusion of the project).
- (3) Value assessments at the start and end of the project (potential loss if nothing is done vs. gains achieved through implementing the intervention)
- (4) CMO synthesis of the STSA for each project stage under three headings:
 - (a) Outcome: impacts of interest, what happens
 - (b) Mechanism: how it happens
 - (c) Context: conditions under which it happens
- (5) Cube summary analysis for the project at the beginning (Problem) and end (Verify). The Cube is a 16-part analytic tool that supports domain experts in gathering and organising information about the system and the risk. Four system domains (functional system, activity, sensemaking, and culture) are analysed across four activity dimensions (goal, process, social relations, and information and knowledge). Specific prompts are asked at each intersection, the answers to which provide key information for understanding the risk, developing an intervention, and verifying the intervention's efficacy. The key elements of the Cube are summarised in the CMO (described above).
- (6) Evidence (documents, data, analyses, etc.) linked to different parts of the project to support the analysis and conclusions.
- (7) Linked concepts, keywords which are added by users and used to enable automated analysis by ARK.

ARK-Virus Meta-Analysis Project Final Report - Public

Add Concept	(i)	
Personal Protec	ctive Equipment (PPE) 🛞 Infection Prevent	ion and Control (IPC) 🛞 Risk Management 🛞
Staff 🚫 Ge	overnance 🛞 Healthcare 🛞 Data-Info	-Knowledge Cycle 🛞
Healthcare-Ass	ociated Infection 🛞 Patient 🚫 Outco	mes 🛞 Reporting 🛞 Feedforward 🐼
Data Classification		
Public 🗵	• (j)	
eport Title		Report Compiler
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RK-Virus Meta-An	Dts Project name	Rob Brennan, Nick McDonald, Rebecca Vining, Lucy McKenna

Project little	Project Owner
ARK-Virus Meta-Analysis Project	Nick McDonald, Rob Brennan, Lucy McKenna, Brian Doyle, Rebecca Vining, Marie Ward
Project Version	Project Description
1.0.0	A meta-analysis of Trial 3 of the ARK-Virus Project.
Original Risk Rating	Problem Stage - Risk
High Risk (16)	Status Monitor
Risk in Change Rating	Implement Stage - Risk Status
Medium Risk (6)	Monitor
	MONITOL

Residual Risk Rating	Verify Stage - Risk
Low Risk (4)	Status
	Monitor

Poorer staff health outcomes, leading to compromised service delivery. Poorer patient outcomes from patient infection; additional value lost in terms of longer length of stays, more complex care required, poorer patient experience, and added cost to the organisation. Without a strong socio-technical solution that enhances risk management capacity to control infection, negative health outcomes will continue.

Gain Achieved

Potential Loss

(1) ARK platform has been transformed from a prototype being productively used in strategically significant projects, engaging people and producing useful results. O1 is extending their project with specific data-driven sub-projects, while O2 is implementing a new communication infrastructure. Steps have been taking towards integrating ARK into the existing risk management infrastructure and influencing production of future guidance documents. (2) High levels of learning with regards to risk management, STS analysis, AI, and knowledge management for users of the platform - enhanced by intensified collaboration via the CoP. (3) Wider inter-domain collaboration with aviation is initiated in HEA supported project.

Problem Stage

Describes the 'as-is' situation and identifies aspects which may not be working as well as they could be, leading to potential damage, harm or other unwanted outcomes. Describes the relevant dimensions of the problem space.

Cube Summary

	Functional System	Activity	Sensemaking	Culture
Goal	What are the system goals? : To develop a new version of the ARK platform and deploy it across three participating organisations; to contribute to improvements in IPC risk governance in the user organisations; to continue developing the CoP; to expand the user base within each organisation	What are the key outcomes of the current situation and how are they measured? : Platform usability and usefulness (via qualitative and quantitative measures), involvement of the CoP organisations. Data is captured by each organisation with regards to IPC issue identified (PPE usage by personnel or patients, or general PCHCAI).	What are the objectives of key stakeholders? : The key objective is to improve health outcomes by preventing disease transmission. It is understood that through better risk management, this can be achieved.	What are the cultural values of people working in the organization? : High value placed on personnel/patient safety, and understanding of the importance of collaborating to ensure safety - resources are not always available to facilitate prioritisation however (i.e., time constraints, personne constraints, overwhelming amoun of data)
Process/Sequence	What are the key tasks & activities and how effective is the current sequence? : Current process works well enough, but could be streamlined. Evidence is handled primarily on an individualised basis, rather than integrated into a process. Greater collaboration between	What data and indicators are used to assess performance? : Transmission rates are tracked, but data is not yet fully integrated into a process for follow-up action. One organisation tracks a large amount of data (over 110 metrics), and prioritising by importance is the key	What is the quality of the tasks and activities being carried out? : Quality of tasks is generally good - the issue is integrating and transferring knowledge in a way that supports decision-making.	What are the norms of behaviour and everyday practice? : Staff are dedicated to reducing risk of HCA for patients/personnel. Organisations have varying degrees of how protocol-driven their practices are. Users are primarily risk/safety experts, and there is a high

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	divisions is needed. With regards to ARK, emerging issues and bugs must continually be addressed.	issue - another does not yet have easy access to the risk data collected.		level of trust in ARK as a method for improving risk management, however it is unclear how widespread this support is.
Social	What are the key roles and relationships (working with, reporting to)? : Each organisation involves users from a different division: quality and safety, management, or clinical.	How are roles and relationships documented and assessed? : Roles and relationships are known to the research team and documented within the organisation, but are not as of yet incorporated into the ARK platform.	What is the quality of leadership and collaboration? : Excellent leadership and high degree of collaboration. Sometimes, it is difficult to gather/distribute all data/information in advance of meetings.	What different professional groups/ subcultures work together? : Multiple divisions involved. All operational ranks (vertical collaboration) and structured interactions with other departments (horizontal collaboration) in one; horizontal collaboration between numerous divisions in the other. The third organisation's user base involves a user from the clinical division, who instructs clinical staff and communicates with other divisions as needed.
Information and Knowledge	Describe the flow of information that links people to their activity. : Feedback loops between research team and users via weekly meetings, monthly plenary meetings, and individualised support. Flow of information within each organisation is fairly fluid, with users in two organisations being based within the same unit/team. Communication to the rest of the organisation occurs via many channels, but could be formalised and streamlined. The third organisation has just one user, operating in the clinical space, and communication with safety staff is a challenge.	How is the quality of information , knowledge and information flow measured? : Qualitative information is collected, primarily informally, however there are few formal methods for assessing quality of information flow. One such method is having personnel tick a box to indicate that they have received and understood any new information.	What is the quality and flow of information like, with regards to enabling informed action? : ARK information flows are not yet linked to actions, but communication channels do exist within the organisations that can be used for enabling action.	Is there a shared understanding of what to do and how the system works? : Personnel have a high level of understanding of their role, however improvements could be made in terms of how their role relates to others and contributes to system functioning. There is a high level of understanding with regards to mindful risk governance between ARK users, but this needs to be better communicated throughout the organisation.

Problem Stage - Context

It is difficult to sustain good practice in IPC and to transfer that across the healthcare system. This issue was explored through the case study of IPC in three different healthcare organisations (O1, O2, and O3) in the context of the COVID-19 pandemic. Each organisation selected a key IPC issue to explore: O1 focused on data infrastructure relating to IPC generally, while O2 and O3 focused on PPE compliance for reduction of on-site transmission of COVID-19. The organisations participated in the ARK-virus project, which deployed the ARK platform for mindful risk governance in a CoP to address key IPC conerns. Trials 1 and 2 focused heavily on internal functioning of the platform and identification of the problem of interest, while Trial 3 (covered in this report) dealt with the first full implmentation of ARK as a strategy to address the identified problem. The core mechanism for improving risk management capacity in each of the organisations is to integrate a mindful risk governance approach, supported by ARK, into the existing risk management infrastructure.

Problem Stage - Mechanism

It is difficult to sustain highly effective IPC practice for the following reasons: (1) Organisations are not fully able to monitor and influence behaviour - systems and processes that support people to act in a certain way could be improved. (2) There is a large amount of data that is not being deployed in a timely way due to siloed information systems for different hospitals or providers and a lack of infrastructure for rapid data sharing between organisations. (3) Need to merge structured operational data and semi-unstructured risk management data. (4) There is a lack of common systematic approaches to risk management for all PPE users. (5) Lack of support for risk governance capable of analysing a dynamic and complex reality, anticipating potential failure and building resilience against it. (6) Difficulty in transforming data insights into relevant risk information for people on the ground and sharing this information with them in a timely way.

Problem Stage - Outcome

The ARK platform has been partially implemented to address the IPC problems identified in each organisation via the mechanisms outlined below, but negative impacts on health outcomes and service delivery have not been demonstrably mitigated. A solution is needed to map and improve data gathered relating to PCHCAI (01) and to increase PPE compliance (02 and 03).

Solution Stage

Describes a potential 'to-be' situation in which the problem dimensions are addressed with an effective solution or improvement. Identifies control measures that can prevent unwanted outcomes.

Solution Stage - Context

Unchanged from Problem Stage.

Solution Stage - Mechanism

ARK will be deployed in each organisation to analyse the IPC problems and identify mitigation measures. In O1, this involves improving the monitoring, oversight, and continuous improvement of data relating to PCHCAI by creating a data governance map; in O2 and O3 it involves reinforcing IPC control measures for COVID-19 PPE compliance through enhanced communication and supervision.

Solution Stage - Outcome

The solution should lead to improved health outcomes for staff and patients in each of the organisations. In parallel, the usability and effectiveness of the ARK platform will be improved.

Plan and Prepare Stage

Identifies the diverse activities required to achieve a desired goal and represent these in a plan. Preparation for the implementation of the plan.

Plan and Prepare Stage - Context

Significantly decreased engagement from the third organisation due to time constraints. O3 has users from operations, while O1 and O2 users are health and safety experts with protected time for engaging with the platform. Otherwise unchanged from solution.

Plan and Prepare Stage - Mechanism

The plan for implementation is to deploy the new version of the ARK platform within two of the collaborating organisations. Individualised and group (CoP) support will be provided, with accessible feedback channels so that bugs or other concerns can be addressed in real time. There is a focus on increasing the amount of evidence uploaded and use of the evidence linking feature, as this supports higher-level governance of the identified risks. Key mechanisms for IPC risk were identified, including the lack of unified data management technologies/systems in 01 and need for social support areas (break rooms, etc) combined with pre-existing staffing issues in 02. 01 will use ARK to complete a project on the data mapping intervention; 02, on the PPE compliance intervention. In 03, data gathering continues to be supported and the user base kept informed so that progress can continue at a later date.

Plan and Prepare Stage - Outcome

Generate sharable data and knowledge about COVID-19 IPC and related programmes. Develop initial lessons learned and guidance on the implementation of programmes on infection control. Evaluate implementation of an enhanced version of the ARK platform. Organisations involve the internal stakeholders relevant to implementation of their specific IPC intervention. Sustain CoP as a forum for learning and sharing experience.

Implement Stage

Implementation is the execution of a plan. To monitor implementation is to supervise and to continually check and critically observe; to determine the current status and to assess whether or not required or expected performance levels are being achieved; and adjust the activity as required

Cube Summary

	Functional System	Activity	Sensemaking	Culture
Goal	Does the implementation credibly sustain the new system's goals? : The goal of improving ARK was sustained, but this must be verified by user base. As of yet, there is no evidence of improved health outcomes. The user base has not yet been expanded, and one organisation did	What measures assess the solution value? : Improved performance of platform according to qualitative and quantitative feedback from users; production of useful IPC/risk guidance; feedback gathered to inform future development of the project	What are the actual goals and objectives of parties involved in implementation? : With addition of other staff in the organisations, there is perhaps an increased focus on practical outcomes (i.e., clear improvements in workflow and health outcomes).	What is the impact of the values of the organization and its members on implementation? :
Process (Sequence	not participate in deployment.			
Process/Sequence	No answer	No answer	No answer	No answer
Social	No answer	No answer	No answer	No answer
Information and Knowledge	No answer	No answer	No answer	No answer
Implement Stage - Cor	ntext			
Implement Stage - Cor Unchanged from plan	ntext			

Implement Stage - Mechanism

An improved version of the ARK platform was deployed in support of the two IPC interventions. Several research activities were also conducted: weekly CoP sessions, individual user support sessions, and plenary meetings. Feedback was collected from the CoP via a questionnaire and focus group discussion; this qualitative feedback was supplemented by metrics on usability, usefulness, and trust.

Implement Stage - Outcome

The new version of the ARK platform was successfully deployed in the two organisations, and remains partially deployed in the third. The CoP was further developed surrounding PPE for COVID 19 IPC and technology-supported mindful risk governance. Generation of evidence for new data governance, privacy, and analytics models and tools. In O1, increased oversight of PCHCAI data and presentation of an integrated dataset to relevant internal stakeholders, leading to increased support. Favourable health outcomes noted in O2 - increased compliance, decreased on-station transmission. Both organisations noted improvements in understanding of risk governance, in particular the social and cultural aspects of implementing IPC risk mitigation measures and the necessity to leverage both implicit and explicit knowledge in support of organisational change projects.

Verify and Embed Stage

Verification determines whether or not the outcomes of a project fulfills the requirements established during the solution stage, taking into account the quality of planning and implementation. A particular feature is embedded when it becomes a permanent and noticeable feature of the system or organisation

Cube Summary

	Functional System	Activity	Sensemaking	Culture
Goal	Do the solution outcomes fulfil the system goals? The Community of Practice (COP) users reported that using the platform allowed for the capture of both implicit and explicit knowledge along with relevant related evidence and the sharing of information and knowledge with other organisations. The platform supported learning about the quantity and complexity of risk management in an organisation and the scale of data used to measure and monitor risk. Goal is to provide guidance to do with implementation in relation to COVID-19 IPC and other risk projects.	Does evidence support the value of the implemented solution? Evidence from user evaluations indicate that using the ARK Platform had a positive impact on IPC risk management processes in the participating organisations. The platform also received passing usability scores.	How well do the outcomes fulfil the objectives of various stakeholders? : Risk and information management capacity was expanded in the two organisations, and the platform was improved and subsequently deployed successfully. Research team objectives were met to high degree. More data is needed to demonstrate a causal link between ARK and improved health.	How have the values of the solution been embedded in the cultural values of the organization? : Value of participation/collaborat is known/demonstrated, progress towards mindful risk governance within user base but needs to be expanded to wider organisation,
Process/Sequence	How effectively are the new processes functioning? : New processes have been helpful for leading	Has the new system met the performance standards set? : Yes, standards have been met in the two fully	How effectively has the implementation supported the required quality of human performance?	Have new practices become part of everyday routines? : Still in the early stages of

Information and Knowledge Are new System deployer First full complete platform been fu	re of roles and hships /enhance work done? : eements to dige-based inmaking via boment of inter- sational hships. Value by making elationships the sation more	Is there an improvement in the structure of roles and relationships? : Within the organisations, the groundwork has been laid for engagement of a wider range of roles, but improvements have yet to be demonstrated.	Have changes to the quality of collaboration and leadership created trust in the system and in its ability to deliver? : This trial has focused on primary users, though the organisations are working to move beyond this in two follow-on projects.	How have new roles and relationships become embedded in the activity of groups/subcultures? : Relationships have become embedded within CoP. Within the organisation, the focus is on implementation teams and generating mutual understanding
Knowledge system deploye First ful comple platforn been fu			These changes thus have potential to be embedded within the organisation in the future.	between them; in the future, relationships need to be expanded across the organisation and across healthcare more generally.
linked t amount data/ini There is better u	as fully ed and used? : Il projects eted on the m, ARK has Illy deployed in hisations and to extensive ts of formation. s a need to understand the g information	What indicators measure the appropriateness of the new information system to system functioning? : Data has begun being linked together, analyses done of complex risk and implementation aspects, concepts and ontologies being used	Does the quality of information and information processes support users' situation awareness and decision making? : Difficult to use for non-experts - more examples will help them use platform as a source of information, even if not becoming expert users Need to expand user base within each organisation to support real-time decision making	To what extent is there a shared understanding of how the system works? : Shared understanding within CoP, enhanced by their input into platform development which enabled reciprocal co- production of knowledge/understandin A shared understanding is being developed in terms of what can be achieved/vision for future use and development of ARK and mindful risk governance.

synthesise findings and determine learnings for ARK, risk governance, and the specific IPC issue addressed.

Verify Stage - Mechanism

At the end of Trial 3 another round of evaluation was conducted which included questionnaires, exploring the Lessons Learned from the CoP and from the ARK-Virus Project, the System Usability Scale and the Impact of the ARK Platform on IPC, and also a focus group feedback workshop. Additionally, a stakeholder meeting (and report) was planned, leading into an assessment of how well the platform was deployed and its usefulness to the organisation. Production of a report with IPC/risk management findings verifies the usefulness of the ARK platform.

Verify Stage - Outcome

Areas for improvement within the current IPC risk management system were identified, which fed into the guidance document "Practical Guidance on Implementing Infection Prevention and Control During Emergencies". ARK's usability and usefulness were improved over the course of the trial as according to metrics and feedback collected from users. Mechanism deployed for moving from highly confidential information to sharing of data within a CoP, which can in the future be extended to the national level.

Linked Evidence

Title	Evidence Link	Description	Evidence Rationale	Stage	Field
ARK-Virus Trial 1 Evaluation Results	obtains support from	ARK Platform user evaluation data collated as part of Trial 1 of the ARK-Virus Project.	Trial 1 user evaluation data	Verify and Embed Stage	Answer- Activity- Goal
ARK-Virus Trial 3 Evaluation Results	uses data from	ARK Platform user evaluation data collated as part of Trial 3 of the ARK-Virus Project.	Trial 3 Questionnaire data	Verify and Embed Stage, Problem Stage	Outcome
ARK-Virus Trial I Evaluation Results	obtains support from	ARK Platform user evaluation data collated as part of Trial 1 of the ARK-Virus Project.	Trial 3 user evaluation data	Verify and Embed Stage	Answer- Activity- Goal
ARK-Virus Trial 2 Evaluation Results	uses data from	ARK Platform user evaluation data collated as part of Trial 2 of the ARK-Virus Project.	ARK-Virus Trial 2 Questionnaire data	Verify and Embed Stage, Problem Stage	Context
ARK-Virus Trial Evaluation Results	uses data from	ARK Platform user evaluation data collated as part of Trial 1 of the ARK-Virus Project.	ARK-Virus Trial 1 Questionnaire data	Verify and Embed Stage, Problem Stage	Context
ARK-Virus Trial 2 Evaluation Results	obtains support from	ARK Platform user evaluation data collated as part of Trial 2 of the ARK-Virus Project.	Trial 2 user evaluation data	Verify and Embed Stage	Answer- Activity- Goal
Article, published in he nternational Journal of Environmental Research and Public Health, Jescribing the RKC Platform and its evaluation.	uses data from	https://doi.org/10.3390/ijerph182312572	Provides data from the Trial 1 evaluation of the ARK Platform.	Verify and Embed Stage	Context
Paper, presented at he 11th nternational Conference on Biomedical Ontologies ICBO 2020), fescribing the ARK Platform ts use of snowledge graph echnologies.	has evidence	http://ceur-ws.org/Vol-2807/paperM.pdf	This paper describes the ARK Platform, the CUBE ontology and the ARK taxonomies.	Problem Stage	Context

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Title	Evidence Link	Description	Evidence Rationale	Stage	Field
Demonstration paper describing the Access Risk Knowledge (ARK) Platform presented at the Web Conference 2021.	has evidence	https://doi.org/10.1145/3442442.3458609	This demo paper describes the ARK Platform and the ARK- Virus Project.	Problem Stage	Context



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