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

Stakeholder Report
11 December 2021

ST. JAMES'S HOSPITAL DUBLIN . IRELAND

Beacon Renal

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Executive Summary

The ARK-Virus project is developing novel risk governance methods via the ARK Platform, using the CUBE socio-technical systems analysis (STSA) methodology for managing risk. It develops a shared evidence base of COVID-19 IPC (Infection Prevention & Control) compliance data and explores the impact of embedding ARK-based mindful governance in healthcare organisations. ARK-Virus has supported an IPC project in St James's Hospital (SJH) and Dublin Fire Brigade (DFB) since May 2021. Beacon Renal (BR) has also participated in the community of practice (CoP). Participants (*n*=7) in each organisation were asked to trial the platform within their organisation and then take part in a combination of risk management and platform use workshops (training), focus group discussions and informal CoP meetings.

The overall IPC outcome (table 1) was: increased engagement of staff/stakeholders; reduced HCAI transmission and impact on service delivery; CoP facilitates collaboration and project synthesis. Five key benefits of the ARK Platform were reported (see 2.2): expands risk management by forcing users to consider less obvious elements of IPC, such as the social, cultural, and sense-making aspects of the CUBE; supports transparency; builds evidence both by making implicit knowledge (such as that of risk and safety experts) explicit and by linking evidence from a diverse array of data sources; engages stakeholders; shares knowledge.

The next phase of ARK-Virus (to May 2022) will continue building an infrastructure that supports organisations in engineering, implementing and governing knowledge-based solutions to complex Socio-Technical Systems problems.

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Acknowledgement: This work was supported by Science Foundation Ireland through COVID Rapid Response programme grant number 20/COV/8463 and the ADAPT Centre for Digital Content Technology (www.adaptcentre.ie) [grant number 13/RC/2106_P2].

1. The ARK-Virus Project

This report is designed to brief stakeholders on the ARK-Virus project, summarise the trial results so far, solicit feedback and increase impact. The ARK-Virus project (Figure 1) is developing novel risk governance methods via the ARK Platform, using the CUBE socio-technical systems analysis (STSA) methodology for managing risk, to develop a shared evidence base of COVID-19 IPC compliance data and to explore the impact of embedding ARK-based mindful governance in healthcare organisations.

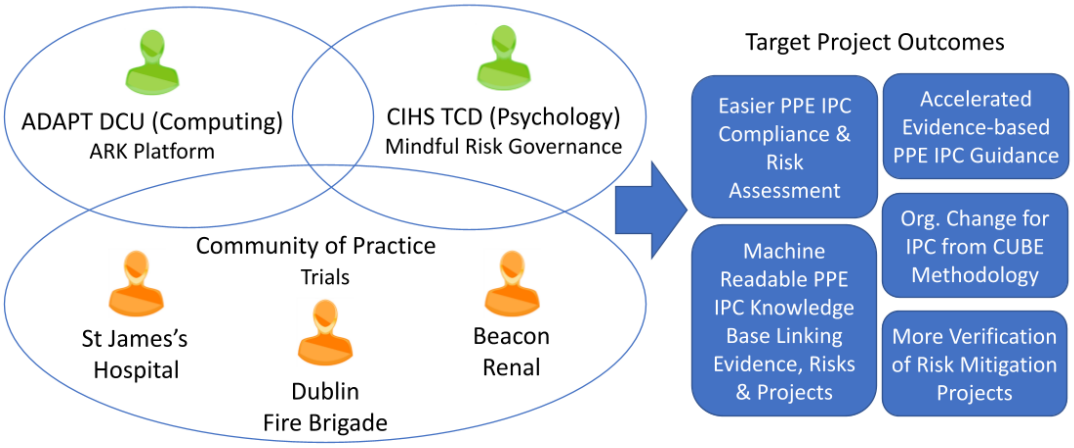

Figure 1: ARK-Virus Project Overview

ARK-Virus has supported an IPC project in St James's Hospital (SJH) and Dublin Fire Brigade (DFB) since May 2021. Beacon Renal (BR) 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. This report provides a brief description of key project concepts (§1.1), a synthesis of the completed projects (trials) from SJH and DFB in relation to IPC (§ 2.1), and also the CoP and the ARK Platform (§ 2.2). Finally, Section 3 describes next steps for the ARK-Virus Project. An appendix provides the full ARK Platform report of the synthesis. For the full individual project reports, see Appendix B (confidential) supplied as a separate document to the stakeholder committee members only (do not distribute). A publication in the Int. J. Environ. Res. Public Health containing extensive references, background and evaluation of the trials is also available[1].

1.1 Key Project Concepts

1.1a 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

[1] 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.

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 2). 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.

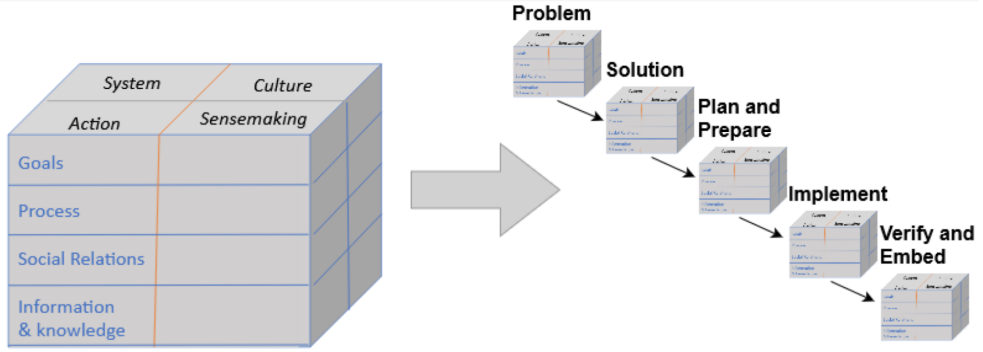

Figure 2: Dimensions of the CUBE and improvement project lifecycle

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.

1.1b The ARK Platform

The ARK Platform[2] 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 3). 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.

[2] https://openark.adaptcentre.ie/

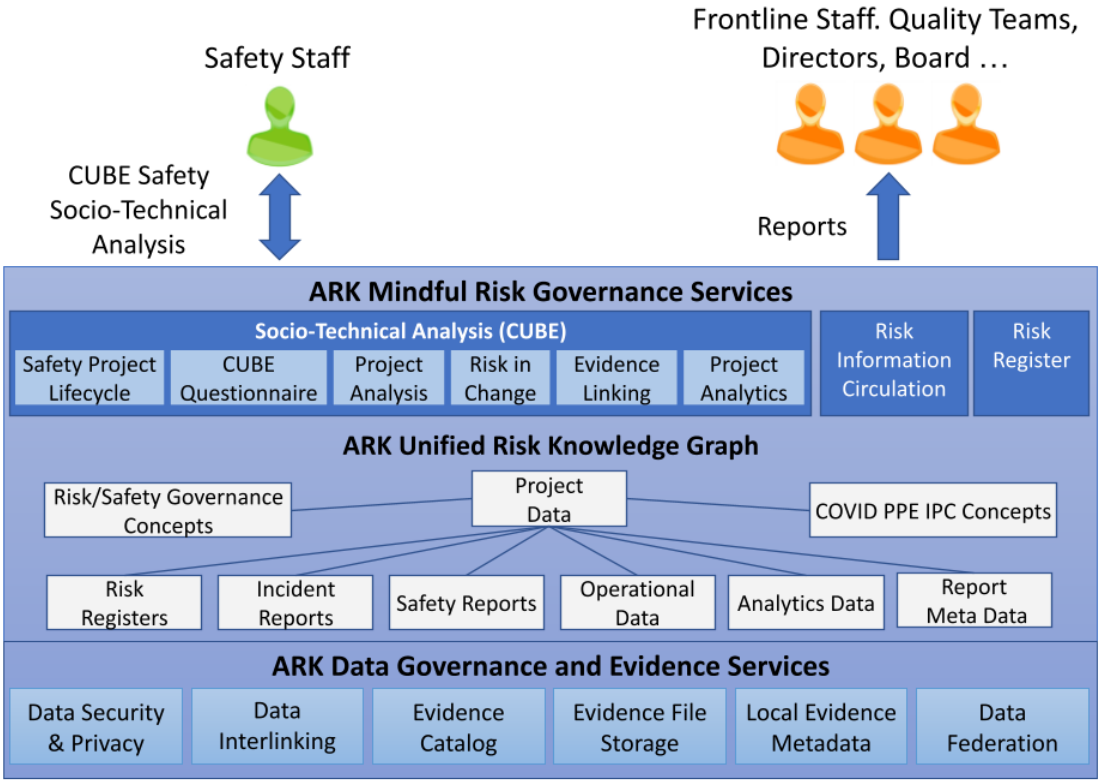

Figure 3: ARK Platform for the Mindful Risk Governance Framework based on Knowledge Graphs, Data Governance, Data Protection by Design, Metadata Management and Analytics

1.1c 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 principles, 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.

2. ARK-Virus Trial Synthesis

2.1 Trial Overview

The full ARK-Virus project (Dec 2020 - May 2022) consists of four development rounds: requirements, platform evaluation (trials) and evaluation driven enhancement. Participants (*n*=7) in each organisation were asked to trial the platform within their organisation and then take part in a combination of risk management and platform use workshops (training), focus group discussions and informal CoP meetings. The platform was rolled out to the CoP in May 2021. By Dec. 2021, the first three development rounds have been completed.

The COVID-19 pandemic has highlighted the need to rapidly translate emerging information into clinical practice to protect staff and patients, making information flow a key focus. Both SJH and DFB aimed to reduce healthcare associated infections (HCAI) transmission in the context of the pandemic, but within this common context SJH focused on reduction of HCAI transmission in clinical areas, while DFB focused on reduction of staff-to-staff transmission of COVID-19 in non-clinical areas.

2.2 Infection Prevention & Control

SJH and DFB selected their own problems to study following internal discussion; key considerations included priority and relevance of the problem and, more pragmatically, what could be reasonably achieved within the organisation. While the problem spaces were similar, different mechanisms were identified. *For SJH, this was the introduction of a multi-disciplinary (MDT) risk-based environmental hygiene assessment (EHA)*, while *for DFB this was compliance with and communication of social distancing and PPE procedures*. The CMO for each project phase is summarised in Table 1 below and the full project report from ARK can be found in Appendix A.

Table 1. Project Context, Mechanism & Outcome (CMO) at each Project Phase for Trial

CMO Element	Problem Phase	Solution Phase	Plan and Prepare Phase	Implement Phase	Verify and Embed Phase
C	HCAI trans- mission leads to patient and staff harm in clinical (SJH) and non-clinical (DFB) areas	Unchanged	Unchanged	Unchanged	Change to context for DFB: new guidelines on workplace close contacts mitigate impacts of workplace exposure on service capacity
M	SJH: to improve oversight, monitoring and continuous improvement in the Environment Hygiene element of the Hospital's prevention and control of HCAI (PCHCAI) programme DFB: high numbers of on-station close contacts	SJH: introduction of MDT risk-based EHAs DFB: expand and enhance communication of IPC procedures	SJH: piloting of EHA DFB: develop- ment of IPC data collection methods and expansion of communication channels	SJH: Solution partially implemented (pilot in 5 out of 55 clinical areas) DFB: Solution fully implemented	Continued implementation of MDT risk-based EHA (SJH) and collection of more evidence (DFB)
O	SJH: improvement in the Environment Hygiene element of the Hospital's PCHCAI programme. DFB: is needed to decrease HCAI transmission	SJH: pilot of MDT EHA DFB: rates of staff COVID-19 infection and IPC compliance	Enhance staff/ patient health and safety; maintain a high standard of service delivery; improve environment hygiene	SJH: good acceptance of new tool; risk generation; data integration DFB: high rates of compliance with IPC procedures re-established, routine IPC data collection implemented	Engagement of staff/stakeholders; reduced HCAI transmission and impact on service delivery; CoP facilitates collaboration and project synthesis

The DFB project resulted in a reduction in risk from high (20) to medium (12) and highlighted a key area of improvement for the system, which was addressing the issue of PPE compliance through expansion and maintenance of two-way

communication channels. In SJH, the residual risk was unchanged from the initial risk rating of medium (12) due to the pilot nature of the intervention. Gains were however made in relation to the following; there was a sense of ownership by all staff in relation to IPC on the ward; the new electronic risk-based EHA tool was deemed an acceptable tool to use by staff; use of the tool allowed for real time reporting to local and Directorate staff and automation of the assignment of tasks.
Users felt that the platform was well-suited to addressing IPC issues as it forced them to adopt a more systemic view of the problem at hand, assisted in keeping issues relevant to the organisation and led to staff acceptance of and feelings of ownership over the solution. Both organisations felt that these findings could have emerged without use of the ARK platform but that its use increased the efficiency and depth of the analysis at each project stage.

2.3 Community of Practice & the ARK Platform

Feedback on the ARK Platform was generally positive, with five key benefits reported:

- expands risk management by forcing users to consider less obvious elements of IPC, such as the social, cultural, and sense-making aspects of the CUBE.
- supports transparency by assigning responsibility for actions, keeping user logs, and tracking resources used throughout a project.
- builds evidence in two ways: by making implicit knowledge (such as that of risk and safety experts) explicit and by linking evidence from a diverse array of data sources; helps users to sift through a lot of different forms of data and clarify which gives evidence/support to arguments.
- engages stakeholders through the depth of analysis, inclusion of supporting evidence, and emphasis on addressing the social aspects of change.
- shares knowledge both within and between organisations, thus allowing for benchmarking and standardisation.

In later stages of the trial, a reporting feature was developed and tested within SJH and DFB. The reports delivered some additional benefits:

- support end-to-end coherence (and analysis) and clarity of workflow across a project by constructing a linear narrative.
- facilitate easier comparison between and synthesis of different projects by highlighting the most relevant knowledge.
- provide a ‘screenshot’ of progress, which contributes to a project portfolio that can be used to inform future projects.
- deliver greater emphasis on value as it encourages one to look at potential gains and losses through each cycle of the project.
- improve communication within and between organisations and stakeholder groups by presenting project findings in a more efficient and cohesive manner.

Project synthesis raises a range of issues to do with content, platform and methodology. For example, purely synthesising risk assessments is impossible given the differences in risk ratings based on factors such as organisational and project context or user judgement. Additionally, it can be difficult to account for differences in mechanism and context, even amongst projects with the same outcome. As seen

in Table 1, several project-specific CMO elements were unable to be synthesised. There is a need to further develop the ARK framework and CUBE to enable higher level synthesis of diverse projects and multi-project analysis.

Users reported challenges to fully participating in the ARK-Virus project, such as: time constraints, access to data and complexity of project concepts (i.e., use of highly technical language). These were offset by a high level of engagement from staff, the presence of insider researchers, support from the research team delivered through weekly meetings and support from other CoP members delivered through monthly plenary meetings. In fact, the CoP was seen to be one of the most important benefits of participating in the project, with the research activities themselves leading to the creation of shared knowledge between organisations.

3. Next Steps

The goal of the next phase of ARK-Virus is to continue building an infrastructure that supports organisations in engineering, implementing and governing knowledge-based solutions to complex STS problems. The next project stages will maintain and build this infrastructure through the following actions:

- Supporting the continuation of each organisation's project, as well as the expansion and embedment of the platform within the organisation.
- Continuously assess the platform's fulfilment of operational and technical risk management needs even as those needs are constantly evolving, and enhance the platform accordingly.
- Addressing data federation issues to enable privacy-aware sharing of information between organisations.
- Embedding advanced data driven and data governance approaches to risk and safety management within each of the collaborating organisations
- Linking multiple projects in a common knowledge base through machine inference and suggestion capabilities.
- Publishing a set of IPC best practice guidelines linked to evidence and worldwide Covid-19 data resources as machine readable Linked Open Data.

The top priorities expressed by the CoP members are:

- Expanding use of the platform in the organisation (i.e., by adding more roles and divisions) and embedding the platform within organisational processes.
- Conducting more projects to build a broader IPC evidence base, and using the collected data to better understand the causal system impacting HCAI transmission.
- Continuing to build the collaborative relationships offered by the CoP.
- Developing a shared IPC knowledge base across the participating organisations to improve organisational approaches to IPC risk management.

In addition, the ARK-Virus consortium seeks further funding for a follow-on phase of development and deployment.

Appendix A: Full Trial Synthesis Report from ARK Platform

The following pages provide a synthesis report that was generated in the ARK platform based on expert analysis using the CUBE methodology, data from the final reports from SJH and DFB, and input from insider researchers from each organisation (DFB and SJH). As such this synthesis represents a CUBE analysis of the meta-project of deploying ARK and conducting the trials/IPC projects within SJH and DFB.

The report displays the following elements:

- Header information describing version, date of preparation, persons responsible
- Risk assessments for the initial risk, risk in change, and residual risk (not used in the synthesis report, see Appendix B for an example of reports with risk assessments)
- Value assessments at the start/end of the trial (potential loss and gain achieved)
- CMO for each project phase (Problem, Solution, Plan, Implement, Verify and Embed)
- Cube summary analysis for the project at the end (verify and embed phase) of the current trial period and project lifecycle
- Linked concepts from the ontologies
- Linked evidence (not used here, see Appendix B for an example of reports with linked evidence)

While the organisations have consented to allowing the synthesis report to be shared, they have been anonymised in the report for confidentiality reasons.

SJH & DFB Synthesised ARK Project Report

Add Concept

Infection Prevention and Control (IPC) | Risk Management | Healthcare-Associated Infection

Data Classification: Public

Report Title: ARK-Virus Trial 2 Synthesis Final Report

Report Compiler: Nick McDonald, Brian Doyle, Rebecca Vining, Marie Ward

Report Date: Fri Dec 10 2021

Distribution: ARK-Virus Stakeholder Committee

Project Title: ARK-Virus Trial 2 Synthesis

Project Owner: Nick McDonald, Brian Doyle, Rebecca Vining, Marie Ward

Project Version: 1.0.0

Project Description: Synthesis of findings from SJH, DFB, and Beacon Renal projects regarding implementation of the ARK Platform

Original Risk Rating: Unspecified Risk

Problem Stage - Risk Status: To be completed

Risk in Change Rating: Unspecified Risk

Implement Stage - Risk Status: To be completed

Residual Risk Rating: Unspecified Risk

Verify Stage - Risk Status: To be completed

Problem Stage - Potential Loss: Decreased capacity to deliver services due to staff COVID-19/HCAI infection. Fire service focused on staff to staff transmission within the workplace, while hospital focused on the Prevention and Control of HCAI and in particular clinical environment hygiene.

Verify Stage - Gain Achieved: Reduction of risk following implementation (high (20) to medium (9)) in fire service and maintenance of risk rating in hospital to reflect pilot status of intervention (medium 12)); both risks to remain open under continued monitoring. Staff acceptance of and feelings of ownership over the solution were noted. Additional action items for continued improvement of the solution were noted.

Problem Stage

Problem Stage - Context: Common context of COVID-19 pandemic, which has highlighted a need to rapidly translate emerging information into clinical practice in order to reduce/prevent HCAI transmission. Fire service focused on non-clinical areas (fire stations), while hospital focused on clinical areas (variety of hospital units).

Problem Stage - Mechanism: Fire service focused on staff-staff COVID-19 exposure/infection, especially during times of high community transmission; hospital focused on Prevention and Control of HCAI in general and introduction of a risk based environment hygiene assessment in clinical areas in particular.

Problem Stage - Outcome: Solution is required to ensure compliance with organisational IPC measures in order to decrease the incidence of COVID-19 (and other HCAI) infection in staff and/or patients. Fire service focused on compliance with PPE regulations, social distancing, etc, while hospital focused on environmental hygiene.

Solution Stage

Solution Stage - Context

Both projects occurred in the common context of COVID-19 pandemic, which has highlighted a need to rapidly translate emerging information into practice in order to reduce/prevent HCAI transmission. Fire service focused on non-clinical areas (fire stations), while hospital focused on clinical areas (variety of hospital units).

Solution Stage - Mechanism

Fire service: introduction of clear guidance and improve personnel understanding of how adherence to guidelines can enhance safety.
Hospital: introduction of a new risk based electronic tool for Environment Hygiene assessment used by an MDT (facilities, nursing, and operational/business staff).

Solution Stage - Outcome

Shift in outcome for fire service from measuring transmission to compliance with social distancing protocols. Hospital focus turned to introducing new risk based assessment for environmental hygiene involving multi-disciplines including facilitates, nursing and operational management.

Plan and Prepare Stage

Plan and Prepare Stage - Context

Both projects occurred in the common context of COVID-19 pandemic, which has highlighted a need to rapidly translate emerging information into practice in order to reduce/prevent HCAI transmission. Fire service focused on non-clinical areas (fire stations), while hospital focused on clinical areas (variety of hospital units).

Plan and Prepare Stage - Mechanism

guidance/expanding communication channels. Hospital focused on the pilot introduction of new electronic tool for Environment Hygiene assessment used by an MDT (facilities, nursing and operational / business staff).

Plan and Prepare Stage - Outcome

Enhance health and safety of all persons, patient or staff, entering the premises (staff, visitors, patients); maintain a high standard of service delivery; improve environment hygiene assessment practices.

Implement Stage

Implement Stage - Context

Both projects occurred in the common context of COVID-19 pandemic, which has highlighted a need to rapidly translate emerging information into practice in order to reduce/prevent HCAI transmission. Fire service focused on non-clinical areas (fire stations), while hospital focused on clinical areas (variety of hospital units).

Implement Stage - Mechanism

Fire service: communication channels established and maintained and data on transmission rates, close contacts, and staff isolating collected and monitored. Hospital: MDT (Facilities, Nurses, Operations and Business Managers) Environmental Hygiene Risk Based Assessments using an electronic tool.

Implement Stage - Outcome

Fire service: high rates of compliance with social distancing measures re-established, lower levels of COVID-19 transmission in the workplace and decreased number of work close contacts needing to quarantine. Hospital: from the results of the pilot implementation in 5 clinical areas (out of 55) benefits were gained from the following; a MDT carrying out the assessments - there was a sense of ownership by all staff in relation to IPC on the ward; the electronic tool was deemed an acceptable tool to use by staff; use of the tool allowed for real time reporting to local and Directorate staff and automation of the assignment of tasks.

Verify and Embed Stage

Cube Summary

	Functional System	Activity	Sensemaking	Culture
Goal	Do the solution outcomes fulfill the system goals? Yes, the goals were to; - reduce incident rates of COVID-19/HCAI transmission within the workplace in both clinical and non clinical setting. -reduce incident rates of close contacts to query/positive cases of COVID-19/HCAI in both clinical and non clinical setting. - maintain a high level and standard of service delivery for service users. - to improve oversight, monitoring and continuous improvement in the environment hygiene element of the hospital's PCHCAI programme (partial fulfilment as system piloted in 5 out of 55 clinical areas)	Does evidence support the value of the implemented solution? Yes both organisation have seen value gained from the implemented solution and have continued to monitor through data collection the sustainability of this gain.	How well do the outcomes fulfil the objectives of various stakeholders? -One of the organsiations has reported that the outcome is "Very well aligned with the objectives of the stakeholders" and has reported good engagement across the organisation. - the second organisation has reported that initial feedback in terms of outcomes from the process are positive. however this is an ongoing process with a need to further roll out the solution to more stakeholders across the organisation.	How have the values of the solution been embedded in the cultural values of the organization? good horizontal and vertical open channels of communication within the organisations which flow both ways have been key in embedding or giving impetus to embedding the solutions into the cultural values of the organisation.

Process/Seq	How effectively are the new processes functioning? Both processes are functioning effectively and providing solutions to the problems identified. The processes will require continued monitoring and in one organisation further roll out of the process across a wider section of the organisation structure to further assess its effectiveness.	Has the new system met the performance standards set? yes both systems have contributed to maintaining Infection Prevention Control standards	How effectively has the implementation supported the required quality of human performance? Both organisations have stated that engagement with the platform has created an awareness of the role of human performance in the effective implementation of a solution. Training, communication and clear guidance are perceived as essential elements in any solution implementation to build trust, engagement and consistency in the process and to prevent slippage back into old habits and processes.	Have new practices become part of everyday routines? Yes, the new processes have become fully embedded although in one organisation compliance 'slippage' has been noted meaning that continued communication about the processes is needed.
Social	Does the new structure of roles and relationships enable/enhance getting work done? Yes both organisations report increased engagement and collaboration with one organisation recognising the potential for future engagement with data driven improvements across diverse sections of the organsiation.	Is there an improvement in the structure of roles and relationships? Yes improvements in teamwork, collaboration noted in both organsiations with the reallocation of new roles and responsibilities also reported in one organisation.	Have changes to the quality of collaboration and leadership created trust in the system and in its ability to deliver? Trust is high but uncertain whether the project improved trust levels. May be easier to maintain trust in an organisational culture with a stricter chain of command where those involved in the change are trusted operational leaders within the organisation.	How have new roles and relationships become embedded in the activity of groups/subcultures? -One organisation has reported that roles and relationships have become embedded in group activities. -the second organisation needs further time to assess how increased workloads associated with the new process impact on the social and cultural factors within organisational teams and groups.
Information and Knowledge	Are new information systems fully deployed and used? - fully deployed in one organisation - fully deployed on a pilot basis in the second organisation across a sample section of the organisation with plans for a structured implementation across the wider organsiation.	What indicators measure the appropriateness of the new information system to system functioning? -infection transmission rates, HIQA national standards of service delivery/outcome measures.	Does the quality of information and information processes support users' situation awareness and decision making? Yes. ARK has improved the understanding of the complexity of the problem, thus improving the quality of information. Personnel have improved awareness of the relevant risks which can improve their situational awareness/decision-making.	To what extent is there a shared understanding of how the system works? Shared understanding has been enhanced by making implicit knowledge explicit through the Cube.

Verify Stage - Context

Change in context occurred for fire service - new protocol allowing asymptomatic, fully vaccinated close contacts to avoid isolation. Vaccine rollout (2 rounds fully completed, boosters in progress as of 3/12/21) also decreased incidence of COVID-19 within the community and the workplace. Hospital context remained clinical environments.

Verify Stage - Mechanism

Continued use of communication channels to support good information flow and monitoring/communication of IPC data. In hospital setting, the development of a more comprehensive framework reflecting HIQA national standards for PCHCAI taking a risk based approach; bringing disciplines together to carry out assessments, identify risks and taking action to improve; and use of an electronic tool to support the assessment and a platform to share results all facilitated improvement. The next phase would involve collection of further evidence in the fire service and contemporaneous analysis of the collected evidence in the hospital setting.

Verify Stage - Outcome

Decreased/minimised transmission of HCAI through successful implementation of the solution; staff engagement across organisation important for implementation/embedment, as is establishing two way lines of communication between all project stakeholders. Additional outcome of ARK-Virus was establishing the CoP, which has led to collaboration and potential for synthesis between organisations.

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FUNDED BY:

Ireland's European Structural and Investment Funds Programmes 2014-2020
Co-funded by the Irish Government and the European Union

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