

A system approach to Clinical Risk Management

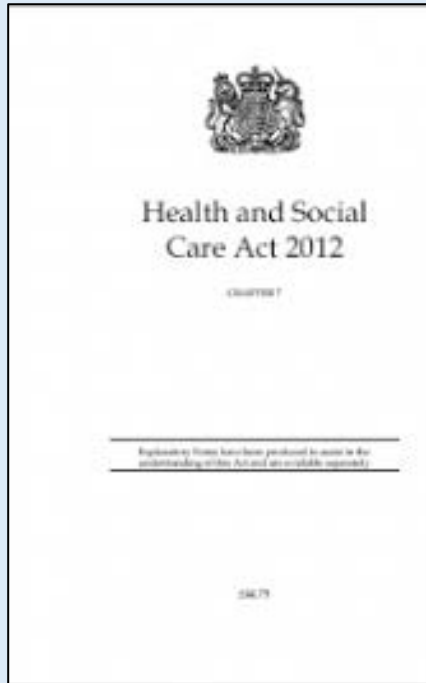
Primary Health Care Specialist Group Webinar

5th June 2024

Summary of session

- **The standards and documentation**
 - Often seen as a **compliance chore**
- **Organisational governance**
 - Who is responsible?
- **Organisations and systems**
 - The challenge of working in systems
- **A Clinical Risk Management model for systems**
 - **A case study**
 - **CRM as a transformation tool**

What is digital Clinical Safety?




DCB0129 

Document filename: DCB0129 Specification v4.2.docx

Directorate	Operations and Assurance Services	Project	Clinical Safety
Document Reference	NPFIT-FNT-TO-TOCLNSA-1792.06		
Director	Debbie Chinn	Status	Approved
Owner	Stuart Harrison	Version	4.2
Author	Sean White	Version issue date	02.05.2018

Clinical Risk Management: its Application in the Manufacture of Health IT Systems - Specification

DCB0160 

Document filename: DCB0160 Specification v3.2.docx

Directorate	Operations and Assurance Services	Project	Clinical Safety
Document Reference	NPFIT-FNT-TO-TOCLNSA-1793.05		
Director	Debbie Chinn	Status	Approved
Owner	Stuart Harrison	Version	3.2
Author	Sean White	Version issue date	02.05.2018

Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems - Specification

Digital Clinical Risk Management:

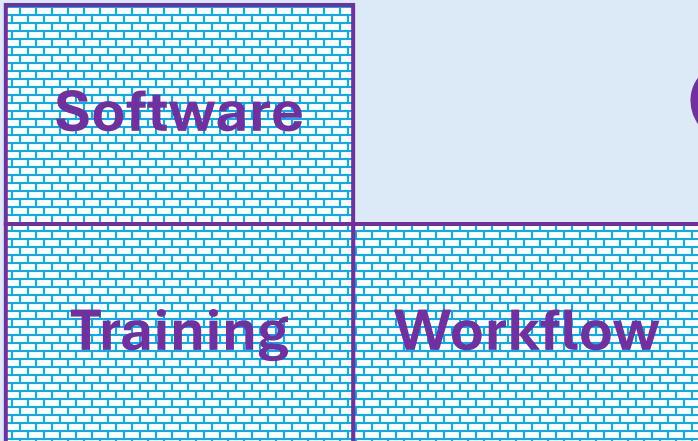
- Assures end users and risk owners
- In Health and Care Organisations (HCOs)
- That Digital Health Technology
- Is safe to be used
- To support clinical pathways
- Throughout the development of the product and the deployment lifecycle

Relevant documents from the English Standards

- **Clinical Risk Management System (or Approach*)**
 - How you approach clinical risk management as an organisation/project
- **Hazard Log**
 - A tool for capturing, analysing and monitoring hazards, risks and mitigations
- **Clinical Safety Case Report**
 - “... is the physical document that summarises all the key elements of the Clinical Safety Case and references all supporting material in a clear, comprehensible and concise format. It serves to communicate the Clinical Safety Case to the end users and Top Management but also where appropriate to other bodies such as regulators” (NHSD 2016. *Clinical risk management: its application in the manufacture of health IT systems – implementation guidance*)

DCB standards (England)

DCB 0129
Design and build



DCB 0160
Deploy and use
(and decommission)

The standards

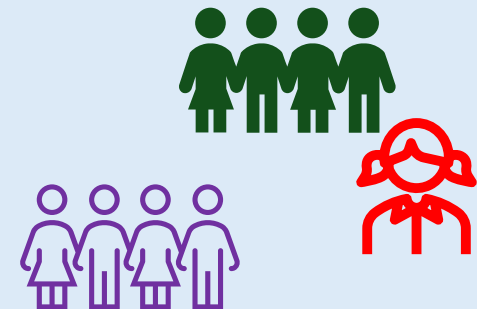
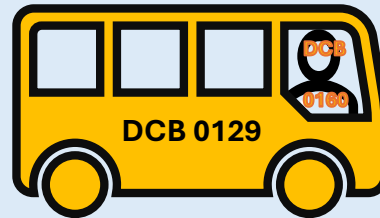
- **DCB 0129:** clinical risk management in the **manufacture** of Health IT systems



- **DCB 0160:** clinical risk management in the **deployment and use** of Health IT systems

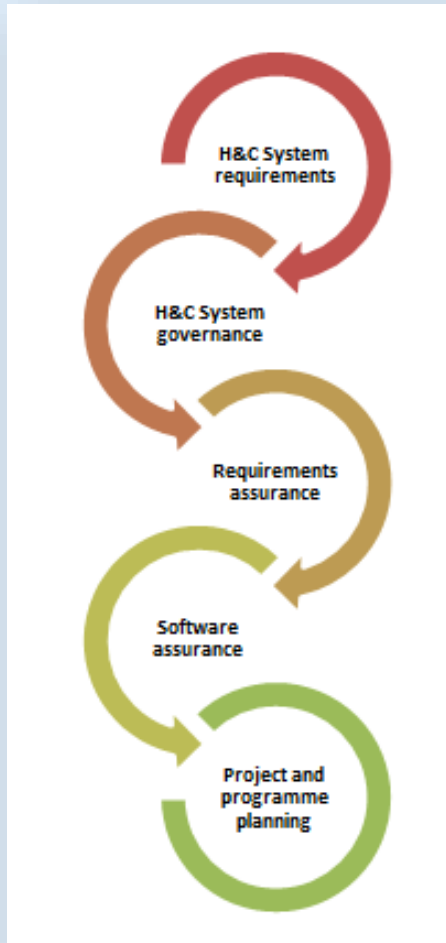


The journey



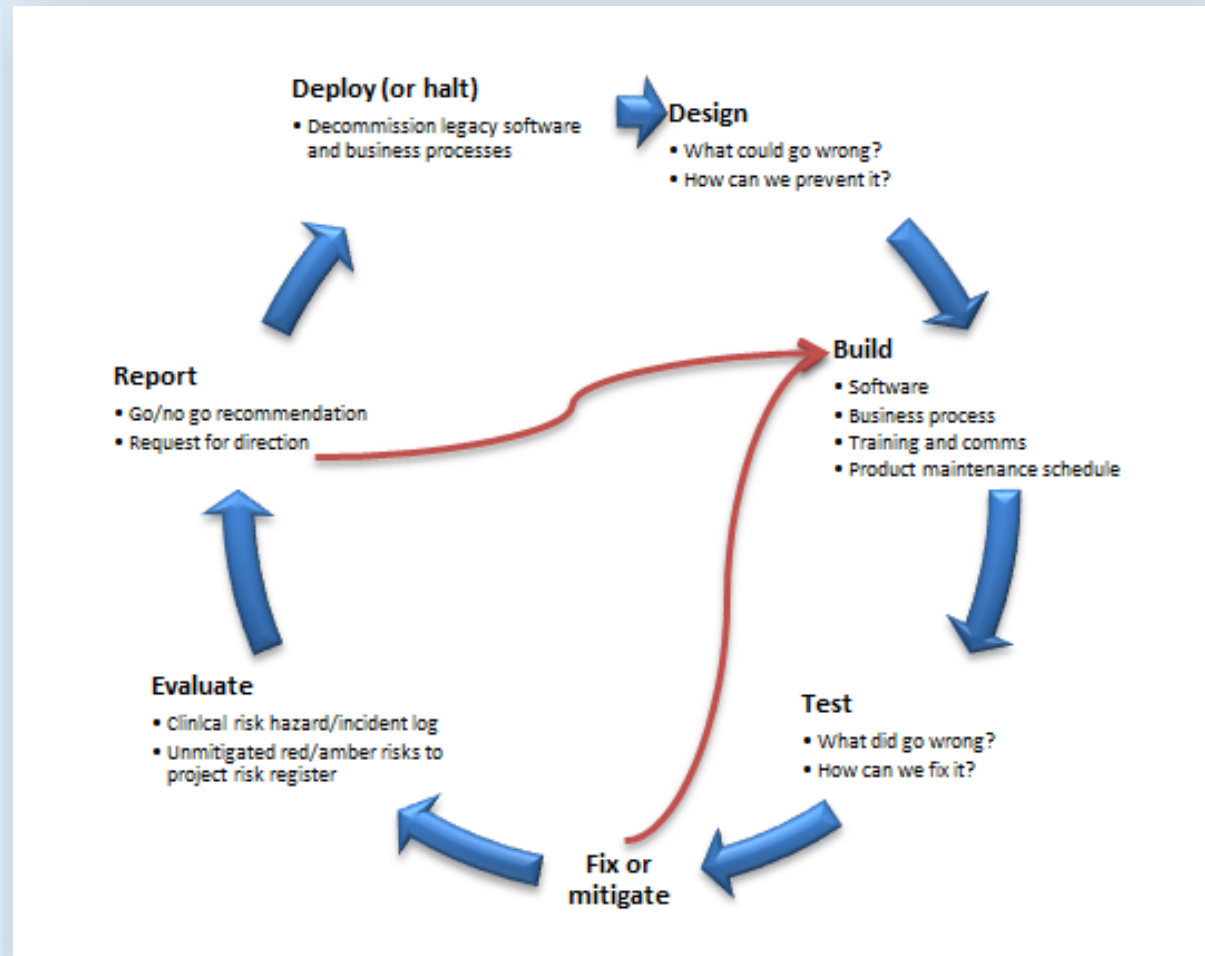
CRM as part of the assurance **lifecycle** for Health and Care software assets (Maggie Lay 2021)

Project planning



05/06/2024

Project lifecycle



05/06/2024

Asset maintenance

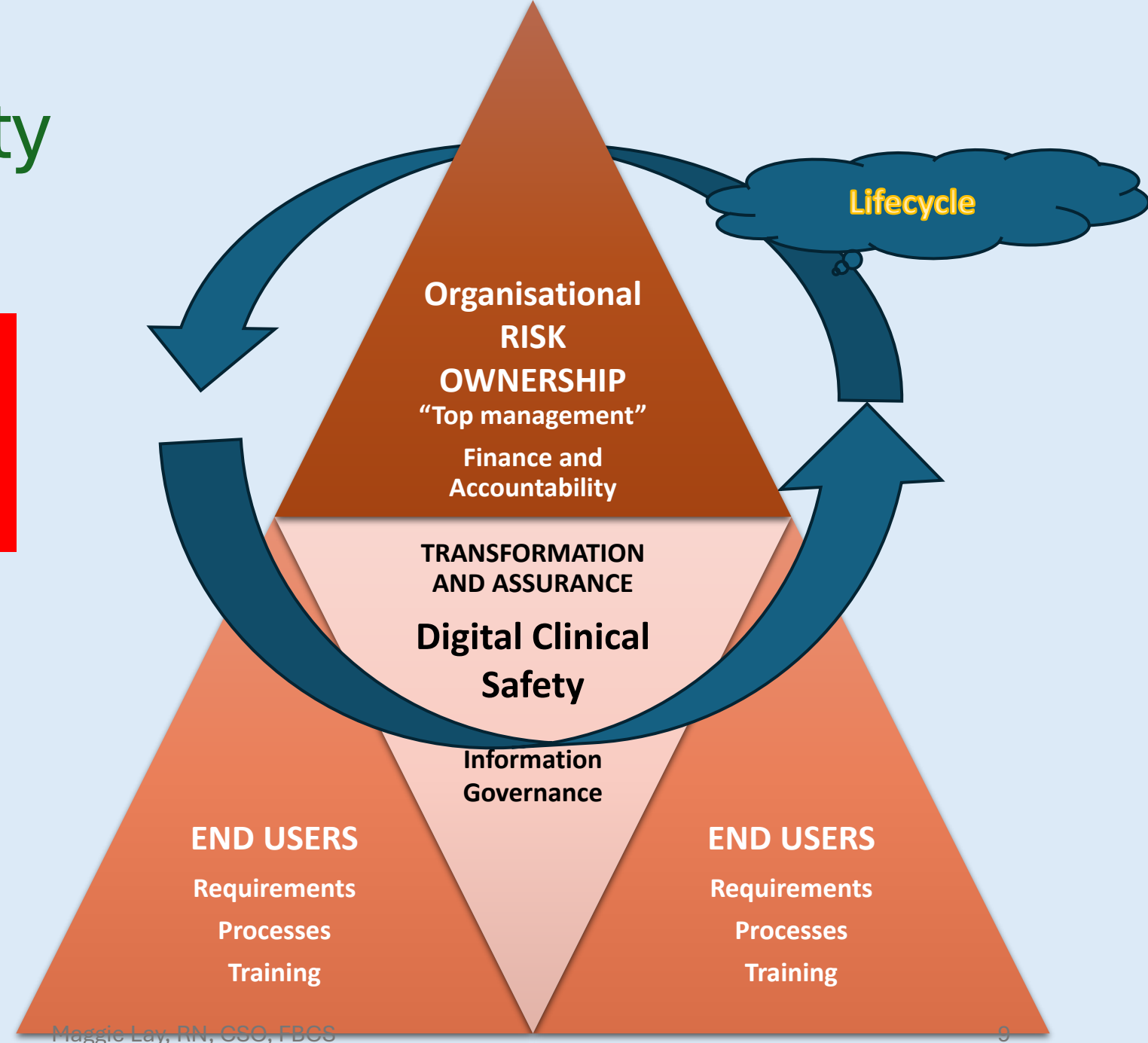


Digital Clinical Safety Governance

Every Health and Care Organisation is accountable

To its patients, its employees and its commissioners

And to bodies such as CQC



Triangles and circles



- **A triangle is an organisation**

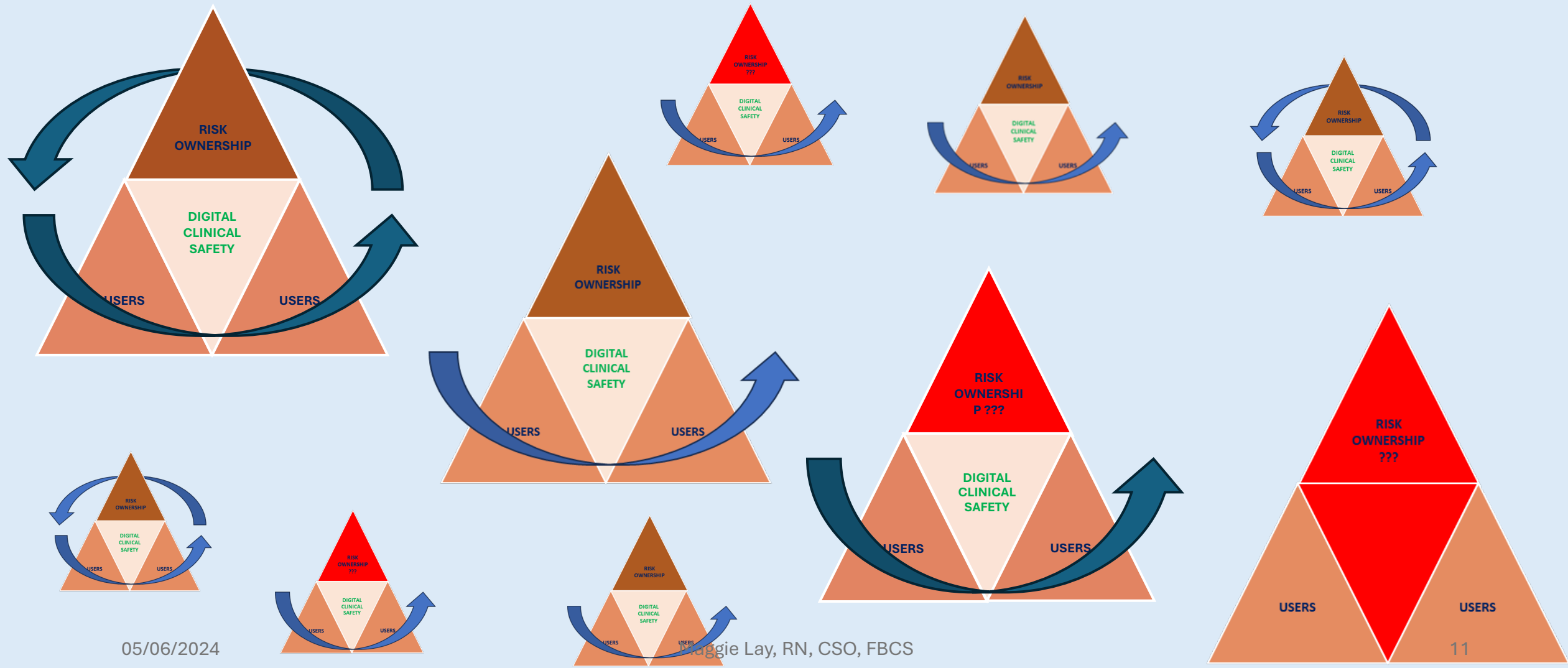
- It exists by statute
- It has its own governance structure



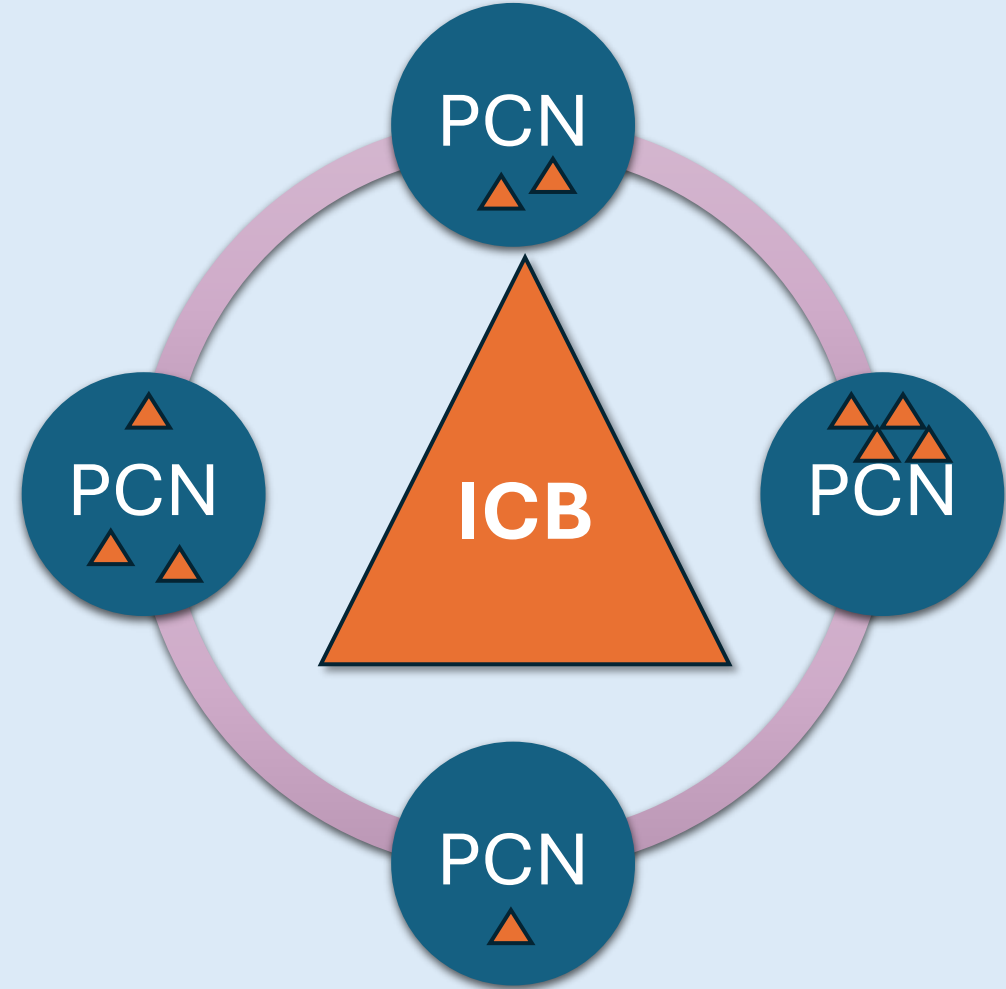
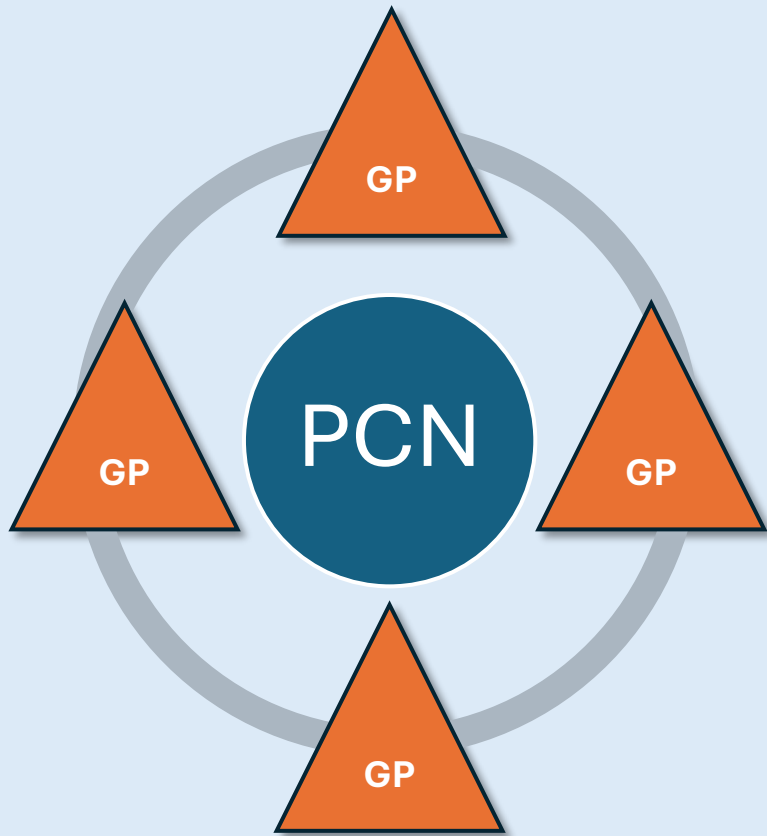
- **A circle is a system of organisations**

- It exists because people think it should.
- It has no formal existence or statutory structure
- It may develop Memorandums of Understanding to achieve shared objectives
- The organisations within it may choose to act unilaterally

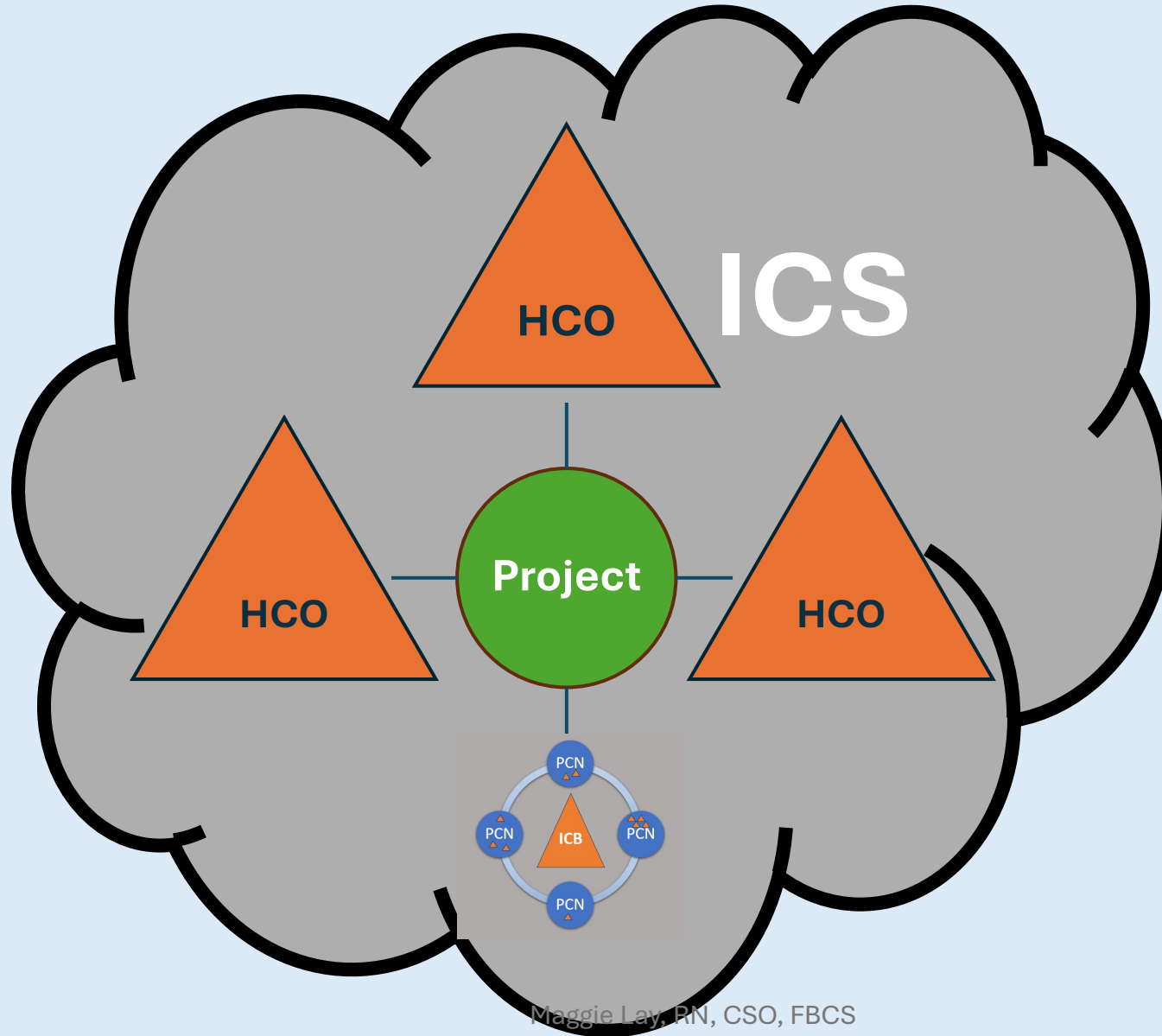
The system challenge



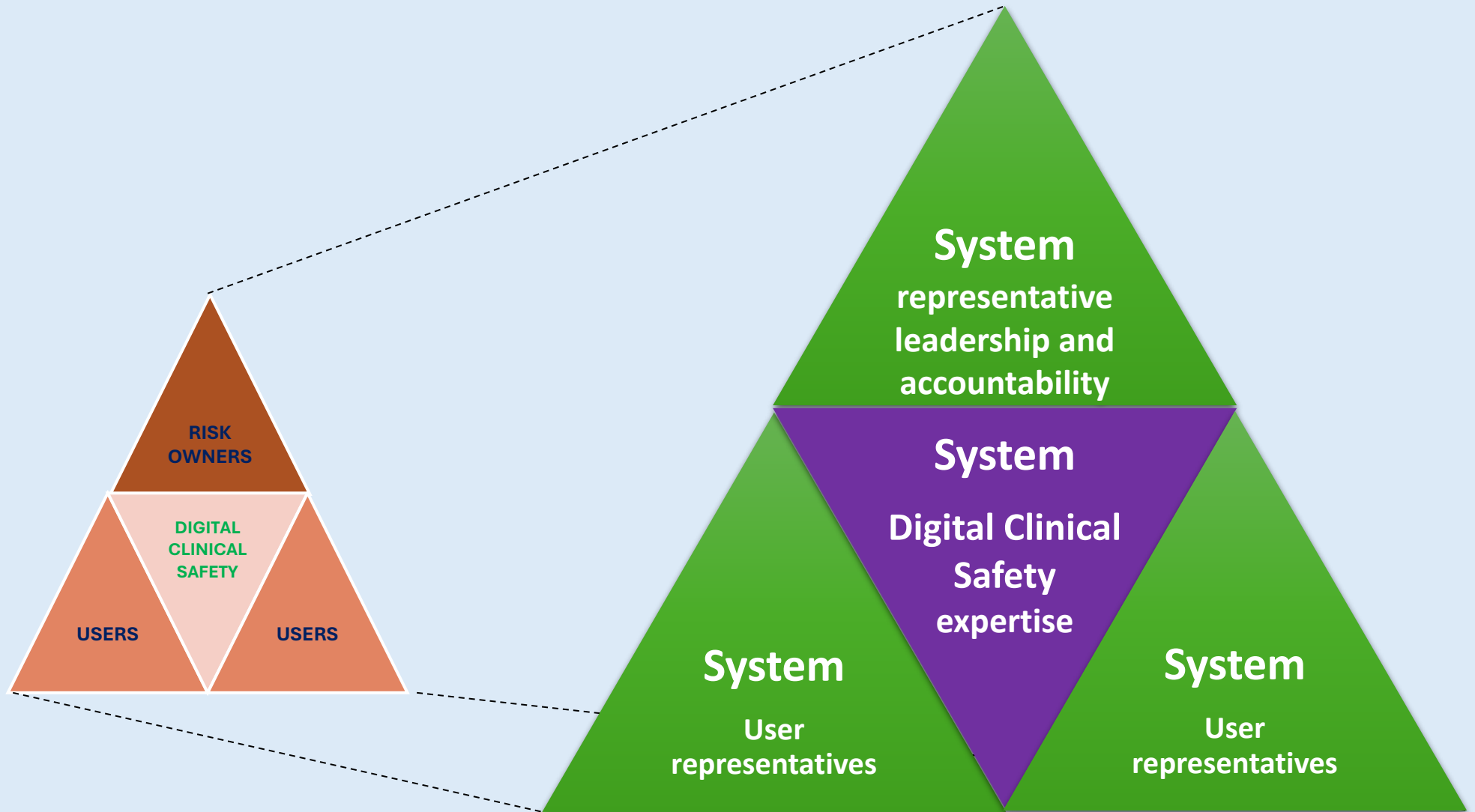
Primary Care systems



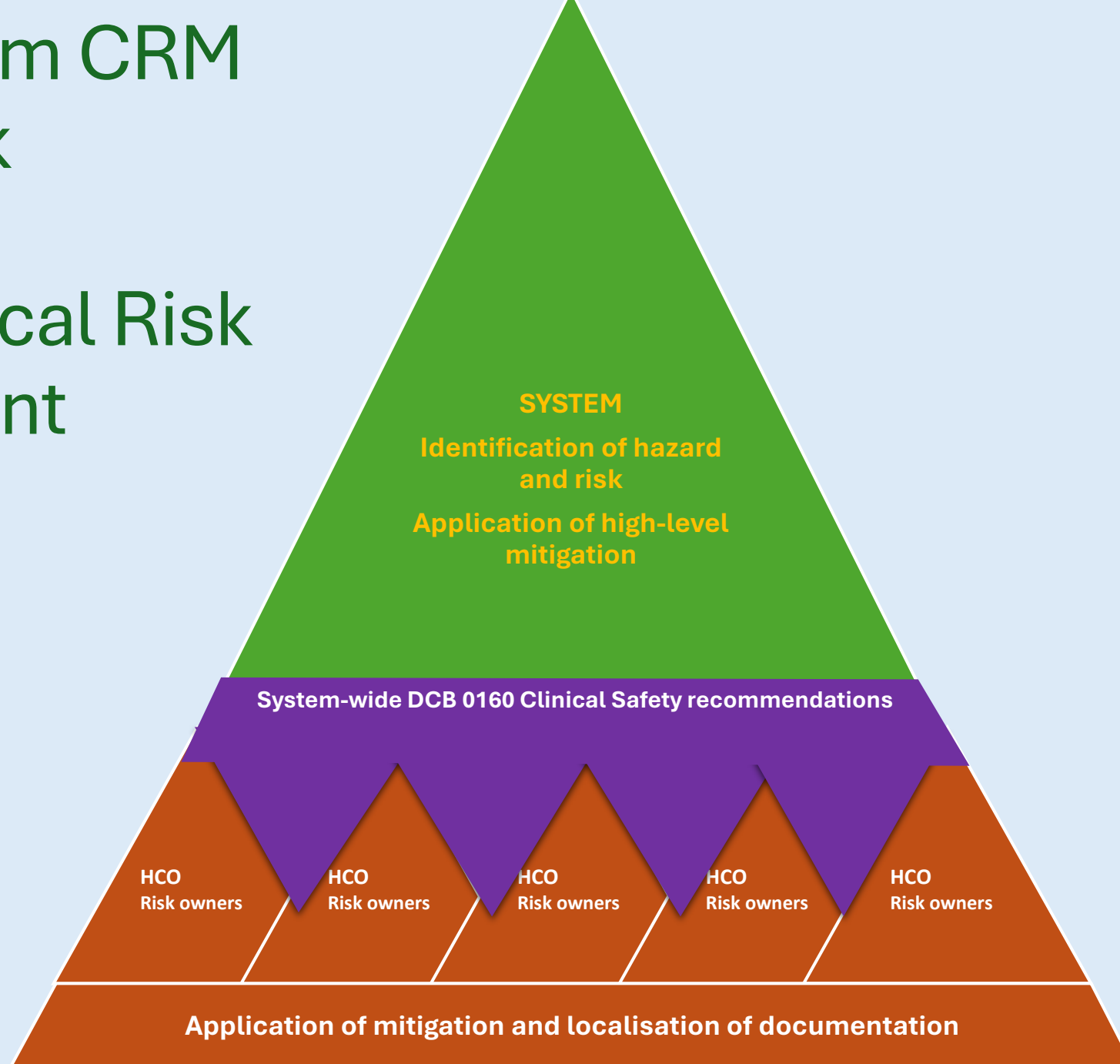
Integrated Care Systems



System-level Clinical Risk Management

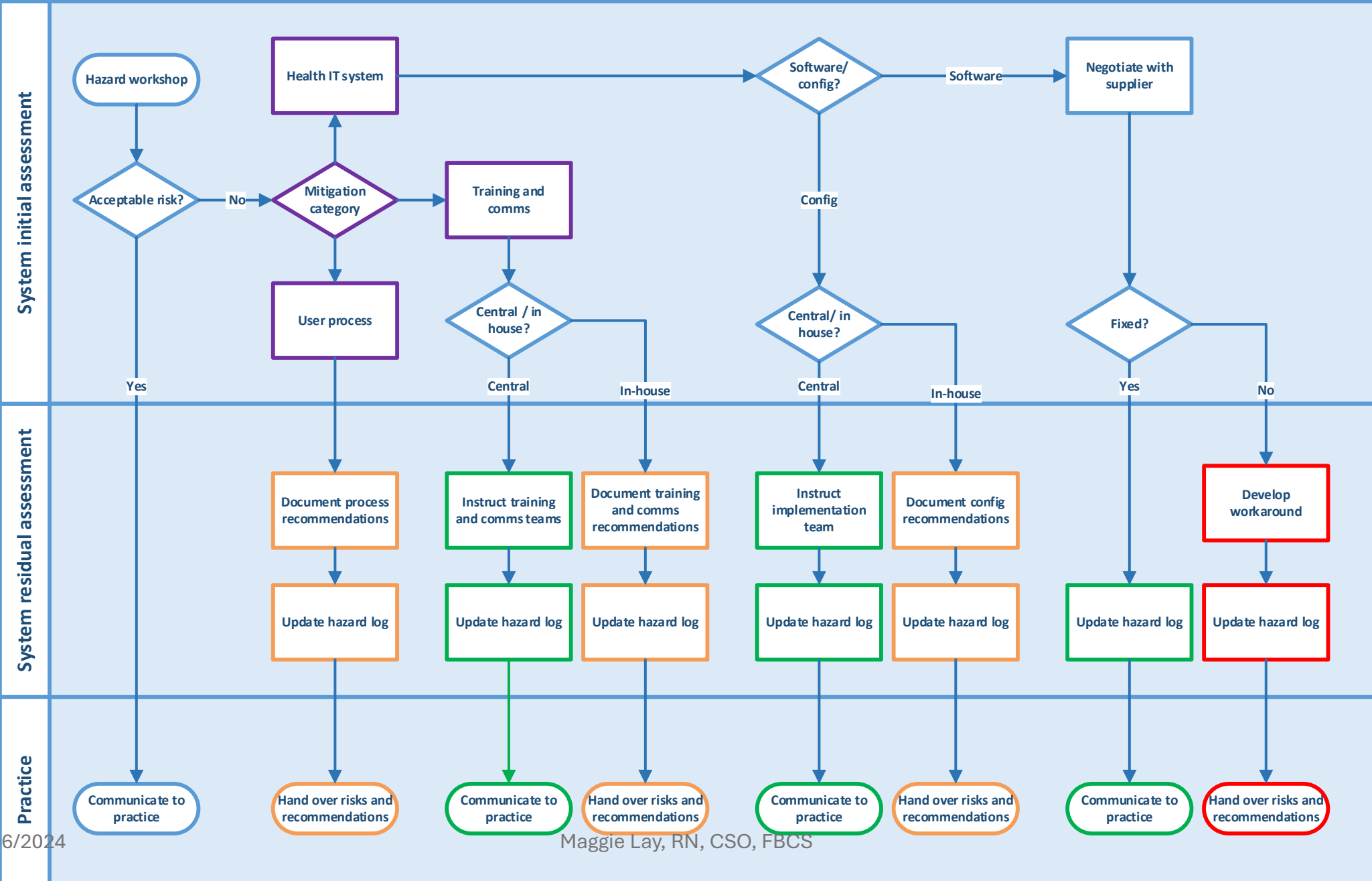


From system CRM to local risk ownership: a new Clinical Risk Management Approach*

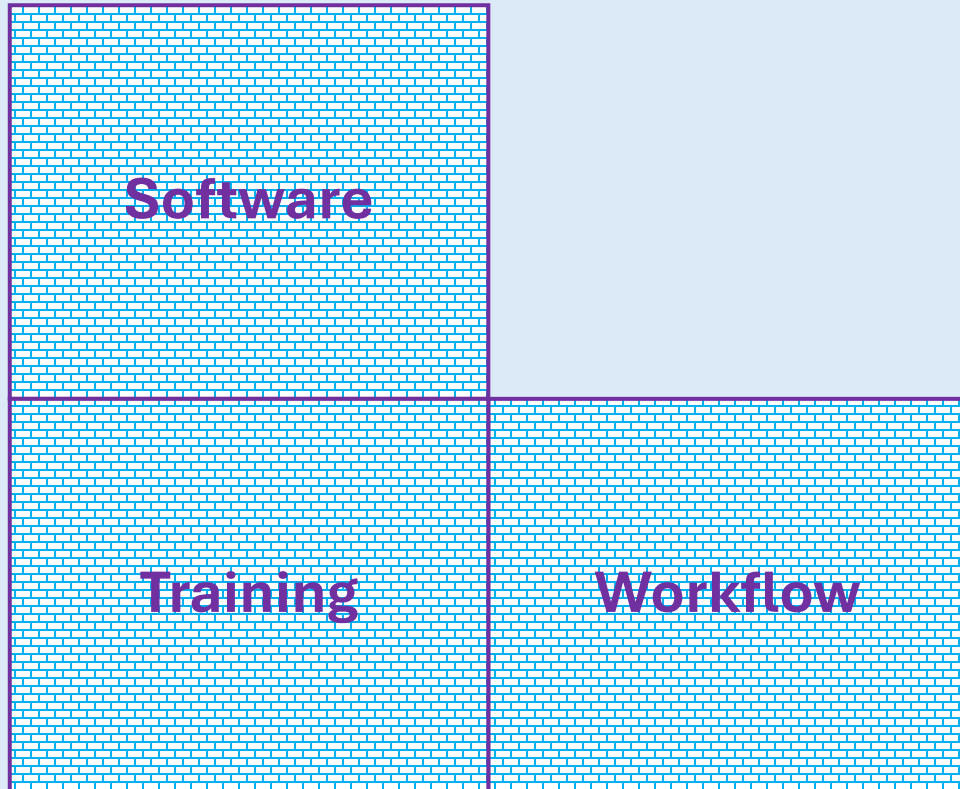


System-level risk assessment process for primary care

V0.1



Evidence of mitigation



Each HCO will need to be able to demonstrate to any appropriate party that it has applied mitigation in line with the system recommendations

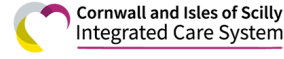
OR

that it has undertaken its own clinical safety assessment



England

NHS England — South West



Brave AI: a Case Study

Bering Limited

54 Portland Street, London, W1B 1DY
Company registered in England and Wales
Registration Number: 07415648
info@beringresearch.com
<https://beringresearch.com>

The South West Digital Neighbourhood Teams Programme

Vision

- Digitally enabled, data-driven, integrated neighbourhood teams delivering proactive, personalised care for every citizen in the South West.

Mission Statement

- To transform the experience of the citizens we serve and the workforce we support, by empowering integrated neighbourhood teams with the best use of digital technology and data.
- This programme of work is designed to contribute to the South West's strategic priority of being the most digitally enabled region in England.
- We need to respond urgently to the increasing needs of an older and ageing population - and a workforce spread across a large rural and coastal geography - leading the way for other regions as their demographics shift in the same direction.

Avoiding unplanned admissions by proactive care

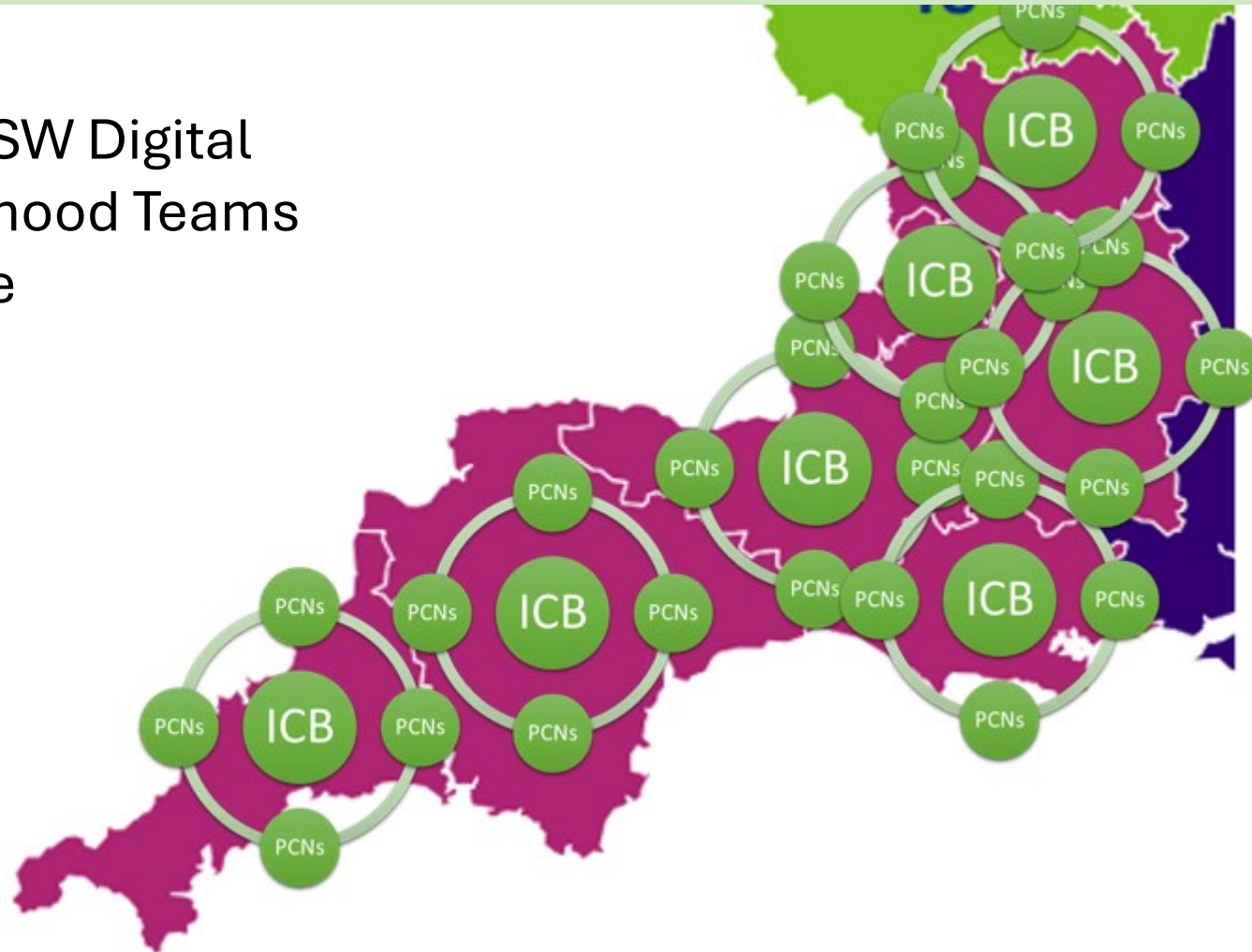
- The specification and procurement of a device which enables the identification of citizens at most risk of unplanned hospital admission is one of the aims of the DNP. The device chosen is **Brave AI**.

Delivery

- Brave AI will be deployed into 30 PCNs across the South-West of England in the first phase of a wider deployment.
 - Six PCNs have been chosen as 'Vanguard' sites; twenty four are 'Innovator' sites.

The Brave AI project

The NHSE SW Digital
Neighbourhood Teams
Programme




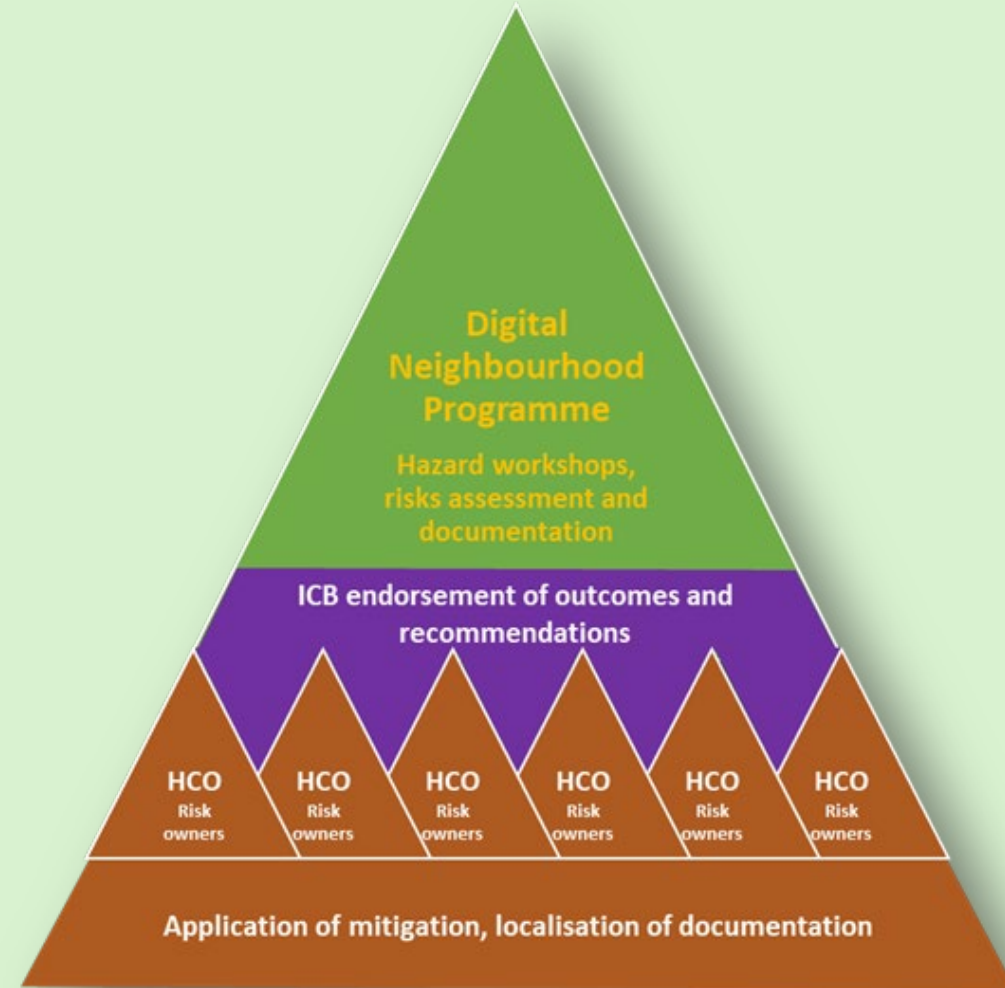
Regional Clinical Risk Management System

NHS
England
South West

**Digital Neighbourhoods Programme
Clinical Risk Management System
SW Region**

Published November 2023

Director	 Stephen Towell, Dir. Digital Transformation, NHSE SW	Status	Issued
Owner	SW Region	Version	1.0
Authors	Steve Roche, Maggie Lay	Version issue date	21/01/2023



Regional Hazard Log



Clinical Safety Hazard Log - Remote Health Management Programme (RHMP)			
Programme	Remote Health Management Programme	Document Record ID Key	
Prog. Director	Stephen Trowell (NHSE)	Status	Published
Owner	NHSE SW Region	Version	1.0
Author	Stephen Roche	Version Date	04/03/2024

Clinical Safety Hazard Log - Digital Neighbourhood Programme - SW MDT Proactive Care using Brave AI Risk

This Hazard Log template is amended from the NHS Digital template to specifically incorporate the requirement to hand over/communicate risks/mitigations to practices or PCNs from the ICB

Reference		Hazard Assessment				Initial Risk										Residual Risk										Owner	Status										
No.	Date Added	Hazard Description				Existing Controls				Initial Risk Assessment						Additional Controls						Residual Risk Assessment															
		Hazard	Effect	Harm	Possible Cause	HIT Design		User training and comm		User processes		Severity	Likelihood	Risk	Justification	Recommendation (where appropriate)	Category	Description	Evidence	Responsibility	Description	Evidence	Responsibility	Description	Evidence	Responsibility	Severity	Likelihood	Risk	Justification							
DH1881	5 6 7 28 29 30 31	Brave system is unable to connect to data generated or available	Users cannot access or update the Brave system or data generated or available	Missed or delayed implementation of practice interventions in primary care/secondary care/ hospital admission	Brave system error	Brave system data report error 31.03 availability						3	4	3		Recommendation - PCN/Practice to ensure they have full back processes in place - successful to transfer to practice usual identification methods																Practice / PCN	Risk status NOT YET communicated to practice / PCN				
						External access - password/username (user/brand)										3	3	3																	Practice / PCN	Residual risk NOT YET communicated to practice / PCN	
						Brave report not (upload/download) and completed prior to scheduled MDT discussion/working											3	3	3	Delegated needs to be completed in absence of a planned MDT - practice attention for data processing, results presentation, and for questions to be communicated from Braving to the MDT discussion	Recommendation - PCN/Practice to ensure they have processes in place to ensure timely upload/download in absence of MDT discussion														Practice / PCN	Residual risk NOT YET communicated to practice / PCN	
						User forgets login details	User must contact Braving user support team (see self-care options)	User guide in CRM already includes this process									3	2	6	No self-care users is required to be notified as legitimate (standard) by Braving																Programme	Risk status NOT YET communicated to practice / PCN
						Not enough registered general PCN/Practice, users with log in rights												3	2	6	Recommendation - PCN/Practice to ensure they have processes in place to ensure available trained staff																Practice / PCN

Regional Hazard Log – for localisation

Initial Risk Assessment				
Severity	Likelihood	Risk	Justification	Recommendations (where appropriate)
3	1	3		Recommendations - PCN/Practices to ensure they have fall-back processes in place - essentially to revert to previous manual identification methods
3	3	9		
3	3	9	Data upload needs to be completed in advance of a planned MDT review to allow time for data processing, results presentation, and for any issues to be communicated from Bering to the MDT	Recommendations - PCN/Practices to ensure they have processes in place to ensure timely extract/upload in advance of MDT discussions
3	2	6	No self-reset as user is required to be confirmed as legitimate (trained) by Bering	
3	2	6		Recommendations - PCN/Practices to ensure they have processes in place to ensure available trained staff



Risk							Owner	Status
User processes			Residual Risk Assessment					
Description	Evidence	Responsibility	Severity	Likelihood	Risk	Justification		
PCN/practice fall-back to usual patient identification methods and process		PCN/Practice	3	1	3		Practice / PCN	Risk status NOT YET communicated to practice / PCN
			3		0		Practice / PCN	Residual risk NOT YET handed over to practice / PCN
PCN/Practices run EPR export and Brave import activity in advance of MDT		PCN/Practice	3		0		Practice / PCN	Residual risk NOT YET handed over to practice / PCN
			3	2	6		Programme	Risk status NOT YET communicated to practice / PCN
Adequate staff numbers trained to cover sickness or absence		PCN/Practice	3		0		Practice / PCN	Residual risk NOT YET handed over to practice / PCN

Regio

Initial Risk Assessment				
Severity	Likelihood	Risk	Justification	Recommendations (where appropriate)
3	1	3		Recommendations - PCN/Practices to ensure they have fall-back processes in place - essentially to revert to previous manual identification methods
3	3	9		
3	3	9	Data upload needs to be completed in advance of a planned MDT review to allow time for data processing, results presentation, and for any issues to be communicated from Bering to the MDT	Recommendations - PCN/Practices to ensure they have processes in place to ensure timely extract/upload in advance of MDT discussions
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Risk							Owner	Status
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PCN/practice fall-back to usual patient identification methods and process		PCN/Practice	3	1	3		Practice / PCN	Risk status NOT YET communicated to practice / PCN
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			3	2	6		Programme	Risk status NOT YET communicated to practice / PCN
Adequate staff numbers trained to cover sickness or absence		PCN/Practice	3		0		Practice / PCN	Residual risk NOT YET handed over to practice / PCN

Regional Clinical Safety Case Report




Brave AI: DCB0160 Clinical Safety Case Report

SW Digital Neighbourhoods Programme Phase One

NHS England, South-West Region

Director	Stephen Trowell	Status:	Approved
Owner	NHSE Digital Transformation Team	Version:	v1.0
Author	Steve Roche – Programme CSO (NHS SCW CSU)	Version Issue Date:	19 th March 2024



Brave AI: DCB0160 Clinical Safety Case Report

14. Summary Safety Statement

Following the Clinical Risk Management activities described in this report, and considering the presented evidence, the Programme Clinical Safety Officer is satisfied the Brave AI system is:

- Clinically safe to proceed in the first phase of deployment as far as can be reasonably determined.
- This is based on the assumption that prescribed mitigation activity within this report is completed by PCNs ahead of any clinical application of Brave AI.

Each PCN remains ultimately responsible and accountable for its use of Brave AI and must be able to demonstrate it has applied mitigation in line with the Programme recommendations OR that it has undertaken its own clinical safety assessment.

The Programme cannot assure or approve mitigations outside of the recommendations described in this document.

PCNs which are considering alternative mitigations are encouraged to contact their ICB CSO, and/or the Programme CSO, for advice.

All open hazards as detailed in the Hazard Log and discussed above are deemed to be

- Of acceptably low risk when considering existing controls, or
- Anticipated to be at an acceptable risk level provided PCNs:
 - apply the recommended mitigations, and
 - evidence this in their Brave SOP, and
 - update and localise their Hazard Log to reflect this.

Risks on the Hazard Log are scored according to the current mitigation status, and therefore represent the current risk level.

The Programme Clinical Safety Officer will review the Clinical Safety Case prior to the next phase of implementation and will follow the same process as is detailed in this report.

CSCR - NHSE SW Region – Brave AI – Digital Neighbourhood Programme 33

1. BRAVE AI overview

Brave AI is a case finding and clinical decision support software solution provided by Bering. The software applies regular analysis and machine learning to specific primary care data sets to predict an individual's risk of an unplanned hospital admission over the following 12 months. Bering supports PCNs to interpret the predictions as part of clinical conversations and to make scientifically sound clinical decisions for proactive management and health promotion.

- The algorithm has been trained to predict:
 - Unplanned hospital admissions: the Brave Score
 - Encounters with GP practices: the Demand Score.

- The algorithm does not:
 - Provide the reason for the admission.
 - Predict other events or conditions such as death or frailty.
 - Predict social admissions.

- The algorithm is contra-indicated for use in emergency situations.

- In case of Brave system or data unavailability, existing MDT methods of patient identification should be used.

2. The [PCN Name] MDT overview

a. Purpose

The PCN MDT is looking to improve patient outcomes and operational efficiencies for the following cohort(s): Eg:

- Entire practice population
- Care home residents
- Frail elderly
- Learning disabilities

b. People

Professional resources available within the MDT (this will affect decisions about which interventions are achievable and likely to be effective)

3. Using BRAVE AI

a. Rules for cohorts

BRAVE AI searches the entire patient list. It does not search by cohort.

It is the responsibility of the PCN:

- *To agree the rules by which their cohort will be identified.*
- *To apply the necessary selection criteria to the BRAVE AI list.*

These rules will be agreed at preliminary meetings with Bering, who will provide assurance that the cohort(s) and selection criteria identified are scientifically sound.

They must be captured clearly here.

b. Creation of a patient list ahead of each MDT

Personnel (including date of training)

Frequency and schedule

Running searches

Applying filters

c. MDT Meeting processes

Reviewing Brave AI

Interpretation of Brave data

Collating with other sources of information

Identifying (and justifying) interventions

Capturing activities and interventions on the clinical record

d. Measuring effectiveness

A unique study will be devised between Bering and each vanguard and innovator PCN to measure the effectiveness of the cohorts, the selection criteria, and the interventions.

This should be summarised here.

Digital Clinical Safety (DCS)

The latest Digital Clinical Safety outputs have now been accepted and ratified by all seven ICB Clinical Safety Officers (CSOs) in the South West.

All documents are now on [the South West Digital Neighbourhoods Programme FutureNHS page](#) in the 'Digital Clinical Safety' section, including the 'Brave AI Standard Operating Procedure'.

Now the documentation is approved, the next stage (where this hasn't already happened), is for ICB CSOs to have conversations with constituent Vanguard and/or Innovator sites and distribute the documentation to them.

This will allow Practices/PCNs involved in this first phase of roll-out to consider their responsibilities relating to digital Clinical Safety in preparation for their go live dates.

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Feedback from the region

Clinical safety has been one aspect of the programme that I have had absolute faith in! The approach has been methodical, calm and has anticipated issues and addressed them with little (unnecessary) input from me. That we have a system wide log is also incredibly reassuring and gives consistency and depth to the work.

At first the task appeared completely daunting, but I must say I actually enjoyed this piece of work! This approach is a much more effective and efficient way to develop regional documents which are of a high standard for onward cascading.

The **Localised** SOP – for the journey



Questions

Maggielay@nhs.net

** The term Clinical Risk Management **Approach** is used in place of the term Clinical Risk Management **System** used in the Standards. We have found that it is more easily understood.*