



# Clinical Safety in the manufacture and use of health IT systems

(or digital Clinical Safety)

FCI Clinical Safety SIG presentation

Maggie Lay



Joining the dots across health and care

# Who am I and what am I doing here?

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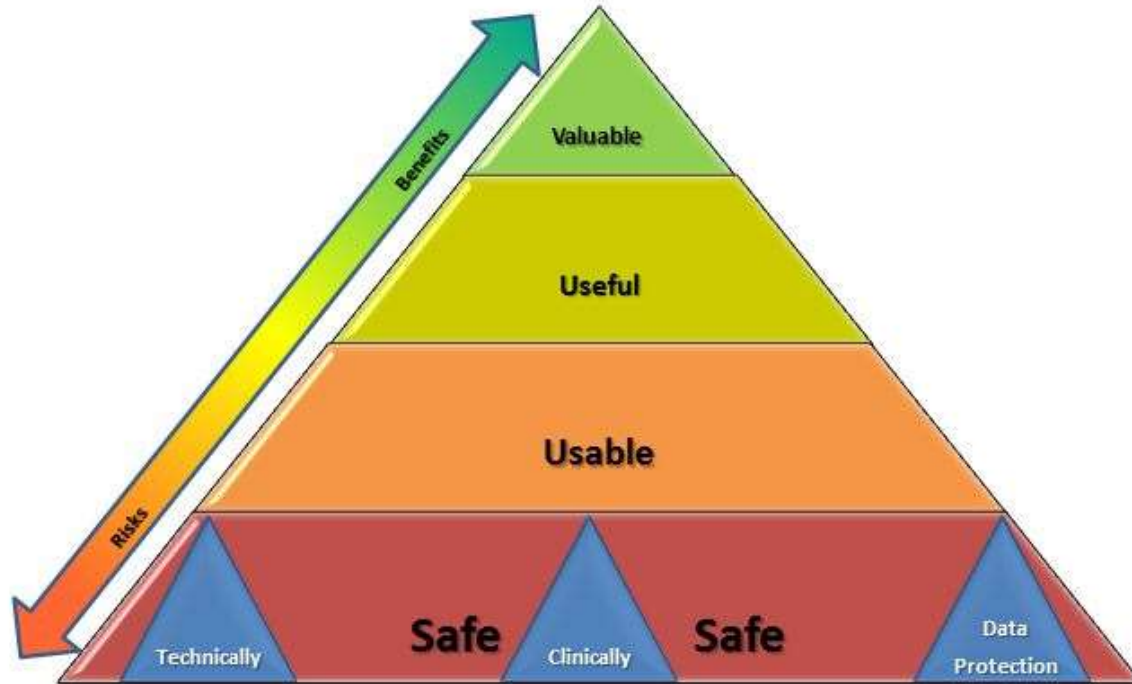
- Maggie Lay
  - Registered nurse
    - Predominately community
  - Clinical Informatics Lead and CSO for South Central and West CSU
    - Supporting CCGs, STPs, LHCRs, NHSE
  - Experience in shared records
  
- What I've learned about **digital Clinical Safety**
  - (aka Clinical Safety in the Manufacture of and Use of Health IT systems and unhelpfully shortened to Clinical Safety)
  
- An overview of the digital Clinical Safety work for Digital First Primary Care during COVID, incorporating Video Group Consultations



## What I've learned

# Digital Clinical Safety doesn't exist in isolation

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# It is a structured way of describing a clinical risk and its mitigations in terms that others will understand



It's **not** all about the risk

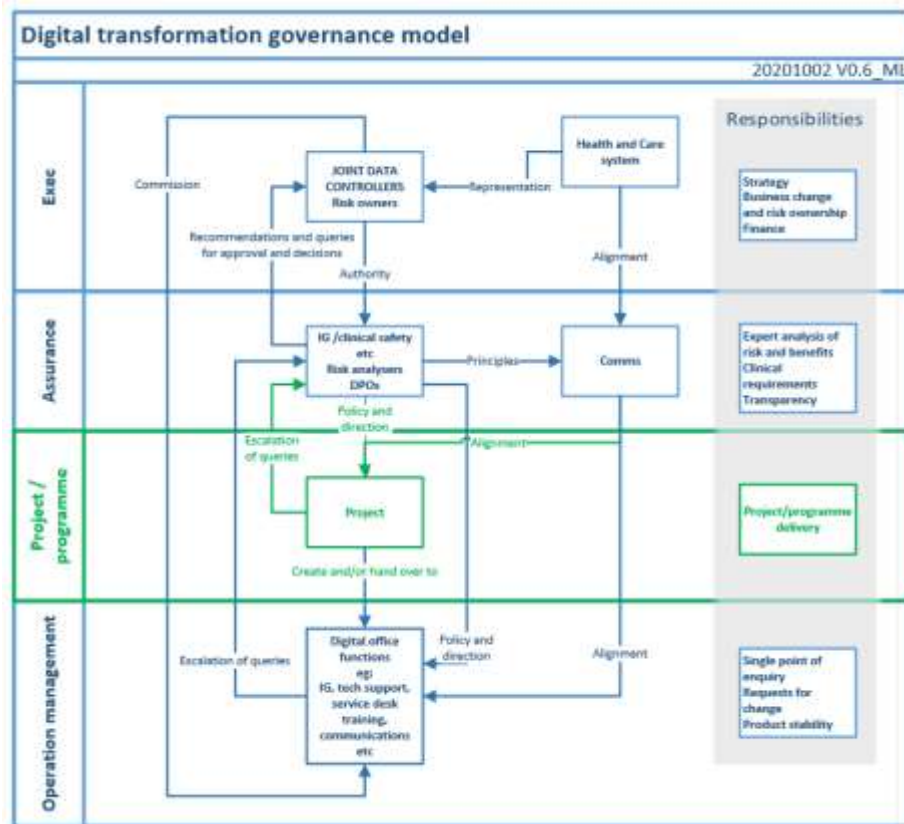
It's about the mitigations  
(and who is responsible for them)



It's **not** all about the software

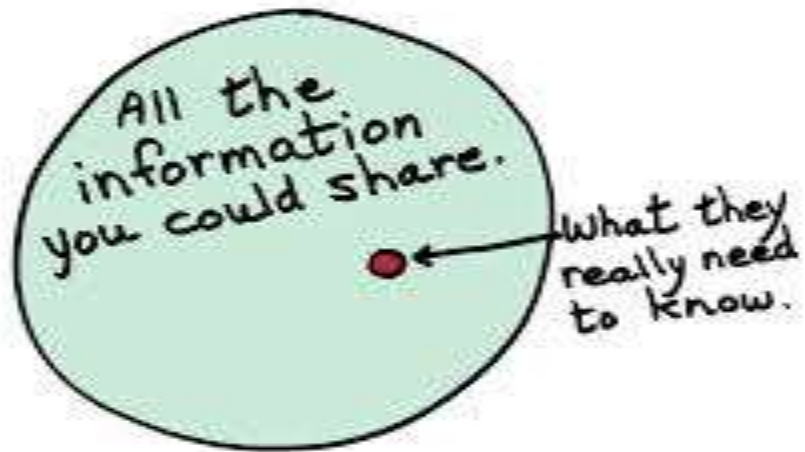
It's about the people who use it  
(and what it's for)

# It won't work without a governance structure



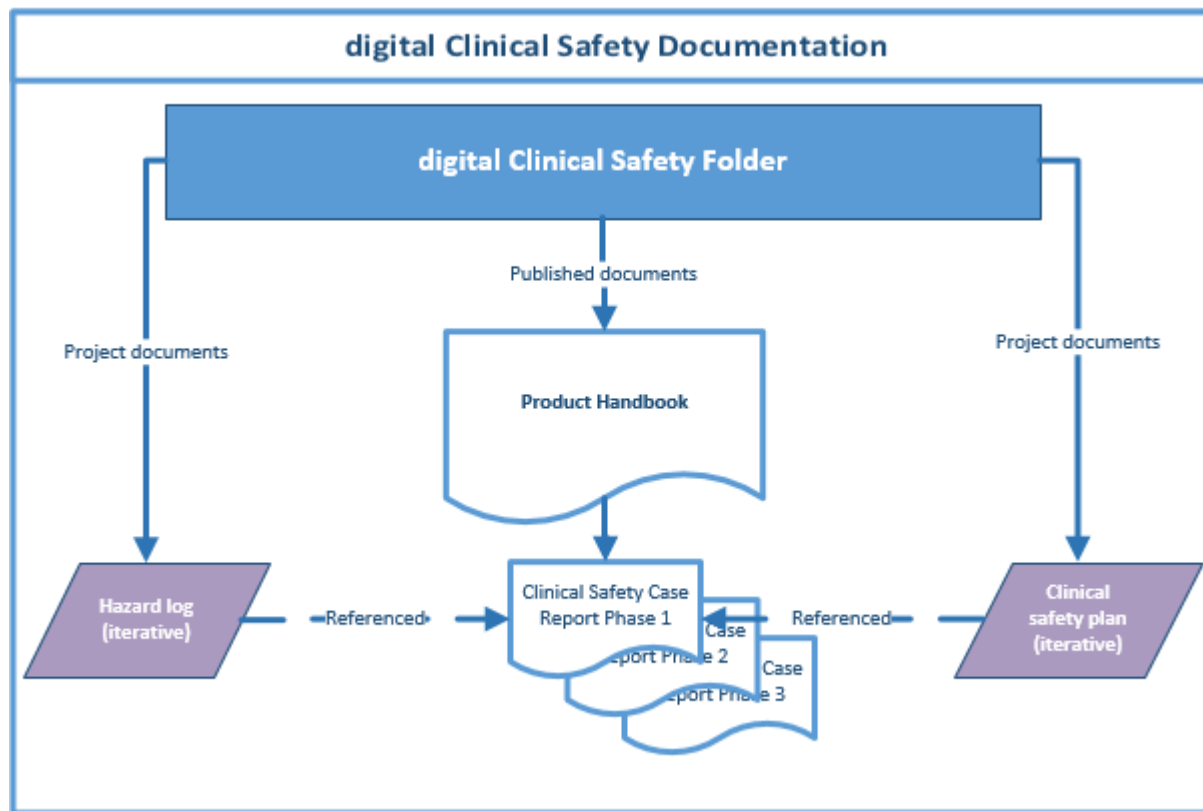
# It's not an exam question!

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So...

# ...lets keep it simple...



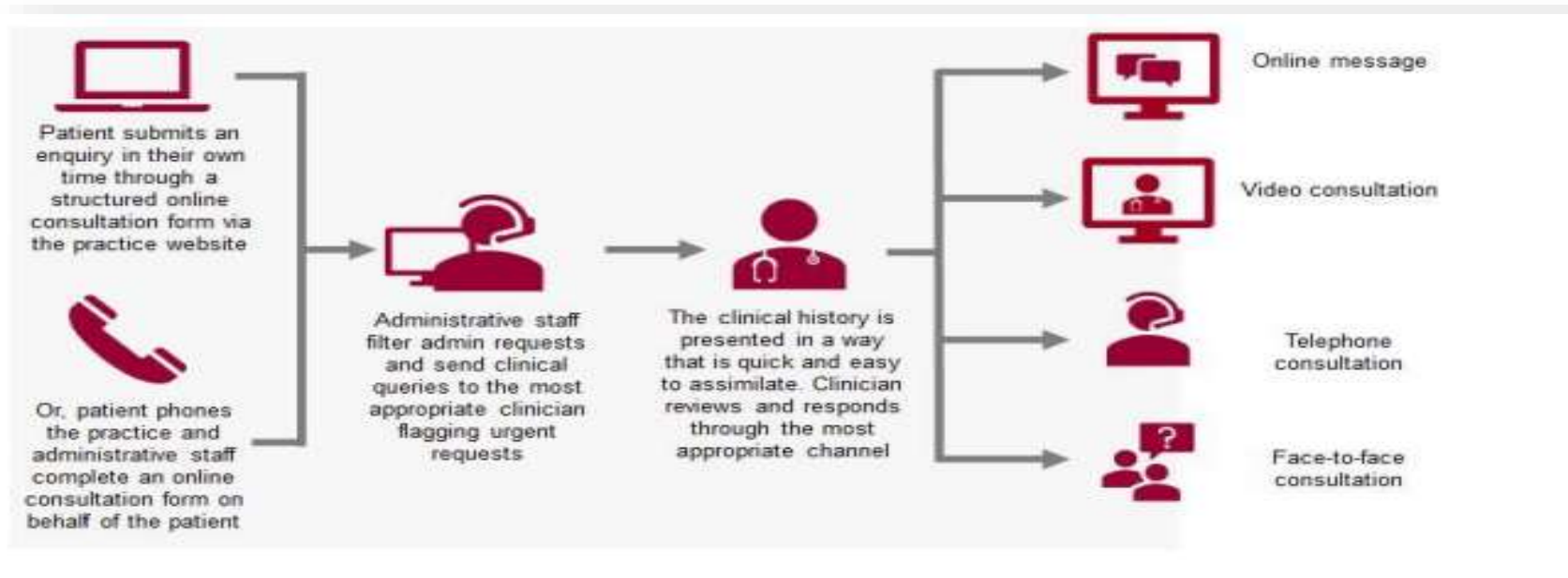




Rapid procurement of Online and Video Consultation software to facilitate

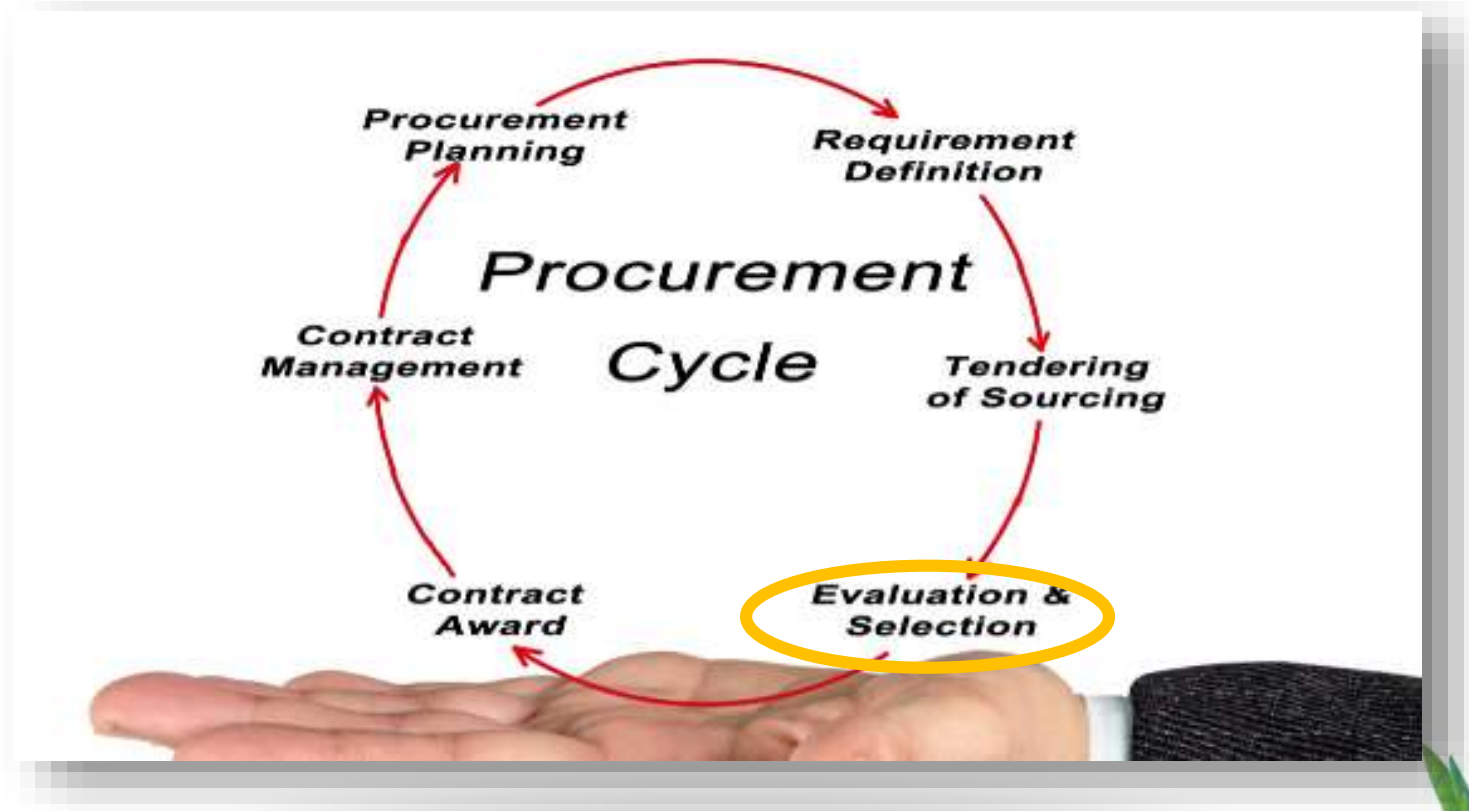
## **NHS England Digital First Primary Care Total Triage**

# Total Triage is not just the software!



# Rapid procurement framework

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# 0129 – solution assurance

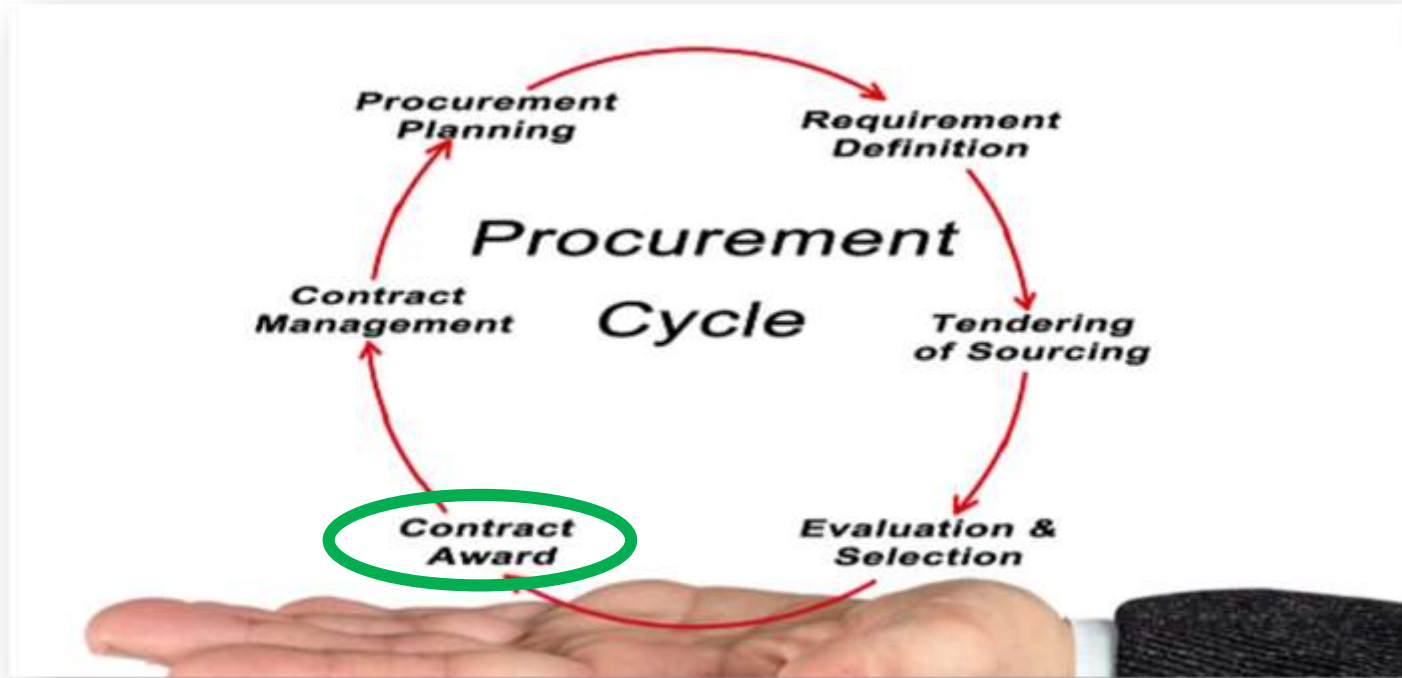
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- Documentation submitted?
- Documentation relevant?
- Documentation is not just NHSD templates?
  
- Documentation tells me:
  - What the CRM approach is
  - What they have done
  - What they have learnt
  - And what risks they are handing over to the deploying organisation



# Job done?

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Who will do  
the 0160?

The deploying  
organisations



# 0160 CRM activities

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## Hazard identification

- What if?
- Previous experience

## Mitigation identification

- System design
- Testing
- Training (and communications)
- Business process change
- **External resource and support (this needs a DPIA)**

## Risk evaluation

- Using the NPSA matrix
- **Clinical risks were hard to distinguish from IG risks**

## Hazard log



Microsoft Excel  
Worksheet

# And we wove it into something useful

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# A slide deck

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## Ownership and responsibilities

- Who needs to do what

## Summary of mitigations

- This is what needs to be done

## Classification of risk

- This is why

# VGC slide deck

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# And some tools

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- The latest iteration of the Hazard log
- An interim Clinical Safety Case report, handing over the initial risk
- Templates for:
  - a Clinical Risk Management System (currently known as a Product Handbook)
  - a Clinical Safety Case Report
- And:
  - A partially completed DPIA

# What happened next?

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<https://www.england.nhs.uk/gp/digital-first-primary-care/>