Clinical Risk Management in NDS

NES DIGITAL SERVICE
NHS EDUCATION FOR SCOTLAND
"You're all going to die."
“Our engagement highlighted the need for easy access to information at the point of care in a timely fashion. The Expert Panel highlighted the importance of being able to access and use information at the point of care, and went further in emphasising the need for this also to help drive and develop learning and knowledge.”

Scottish Government, 25 April 2018
“It is no longer acceptable in this age that our health service is still using multiple incompatible systems and various platforms. In all our work we have heard repeated concerns around data sharing and interoperability. Nurses, pharmacists, allied health professionals, social care services, primary care services, prison health services and more all highlighting the fact they do not have timely access to relevant health records.”

Scottish Parliament Health and Sport Committee, 1 February 2018
1. Clinical data at the point of care
2. Common architecture to allow for innovation
3. Data at scale for research and quality
WELCOME TO THE NDS
HELPING GET THE RIGHT DATA IN THE RIGHT PLACE AT THE RIGHT TIME.
BUILDING INTUITIVE PRODUCTS FOR CLINICIANS, CARE WORKERS, AND CITIZENS

WHAT IS NDS?

We are a new team, working to improve how your medical information is managed so that it is available to you, when you need it, safely and securely. We think you should be able to do things like book appointments, get test results, manage your medication and renew prescriptions.

To make this happen we will work very closely with people who work in health and care services and people like you who use those services. We will start small. How we work is important. We believe that in the same way as the doctors and nurses of the NHS have developed new treatments that cure disease and improve the quality of our lives, the NHS can develop its own technology.

In the next few months we will be establishing ourselves as an organisation and begin to work on one or two priority projects. We are recruiting. Watch this space.

https://nds.nes.digital/
An open domain-driven platform for developing flexible e-health systems

- Platform Approach
- Comprehensive Semantic Framework
- Semantic Scalability
- Platform-based economic ecosystem
- Prevents lock-in
- Customer retains control of the data
- Way for clinical experts to be involved

https://www.openehr.org/

https://www.openehr.org/resources/white_paper_docs/openEHR_vendor_independent_platform.pdf
https://openehr.org/
Clinical Safety in NHS Scotland

• No H&SC Act 2012
• Joint approach via
  • SCIMP
  • Scottish Government eHealth Lead
    • Ian Thompson (ian.thompson@gov.scot)
  • NHS National Services Scotland Clinical Informatics
    • BISHOP, Iain (NHS NATIONAL SERVICES SCOTLAND) (iain.bishop@nhs.net)
• 77 trained - mix of CSO and CSE

• Encouraging a culture of safety

• Medical Device Regulation
  • Medical Devices Unit - http://www.medicaldevicesunit.org/
Clinical Safety in NDS

• Clinical Leads CSO trained
  • Me, Steve Baguley, Sam Patel
• Professional requirement
• New organisation
• Culture and process
• Documentation
• Education

16 - Whether you have a management role or not, your primary duty is to patients. Their care, dignity and safety must be your first concern. You also have a duty to the health of the wider community, your profession, your colleagues and the organisation in which you work.

https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/leadership-and-management-for-all-doctors/working-with-colleagues#paragraph-16
Clinical Risk Management Processes

- Following mostly DCB0129
- Evolving process
- Aligning to MDR
- Agile

Contents
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2  Review of these processes ........................................................................................................................................ 4
3  Definitions ................................................................................................................................................................. 4
3.1 What are the requirements for systems and product specialists relating to clinical safety? ..................................... 4

9 Documentation
9.1 Clinical Risk Management Files
9.2 Clinical Risk Management Plan
9.3 Hazard Logs
9.4 Clinical Safety Case Report
9.5 Incident Management Log
Lessons

- Implementation
- Manufacturer vs deployment
- Components
- Compliance team
- A living document

8 Responsibilities of key personnel
8.1 Assignment of lead CSO

Each health IT system must have a named lead CSO. This CSO will:
- Agree and maintain the clinical risk management plan for the application. This will be the default plan as described in this document unless otherwise specified.
- Ensure that clinical risk management activities are completed in accordance with the plan.
- Review and approve clinical safety documentation associated with the health IT system including the Hazard Logs.
- Review the contents of the risk management file, ensure that the clinical safety case report is complete and approve the clinical safety case report summary statement for each phase and release.
- Recommend the approval or otherwise of releases from a safety perspective for the health IT system.
- Throughout the health IT system's lifecycle respond to any queries or concerns raised by development teams, sponsors, end users and other stakeholders relating to the safety of the system.
- Be responsible for ensuring clinical risk analysis of any incidents identified by post-deployment monitoring is completed and maintained via the hazard log.
### Recommended Summary Plan for Emergency Care and Treatment

#### Personal details

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full name</td>
<td></td>
</tr>
<tr>
<td>Date of birth</td>
<td></td>
</tr>
<tr>
<td>Date admitted</td>
<td></td>
</tr>
</tbody>
</table>

#### Summary of relevant information for this plan (see also section G)

- Indicating diagnosis, communication needs (e.g., interpreters), and treatment/communication aids, if any.
- Serious outstanding planning documents, where to find them (e.g., Advance Decision to Refuse Treatment, Advance Care Plan). Also include known wishes about organ donation.

#### Personal preferences to guide this plan (when the person has capacity)

- How would you describe your values for your loved one(s) that you would like to keep in mind (e.g., religion, family, personal preferences)?
- Values, if any, particularly important to you.
- Personal preferences, if any, that you would like to keep in mind.

#### Clinical recommendations for emergency care and treatment

- Focus on non-pharmacologic treatment as per guidance below.
- Focus on pharmacologic treatment as per guidance below.

- Further provide goal-directed specific interventions that may or may not be invasive or critically important (e.g., antibiotics, oxygen, support, blood products).

#### Capacity and representation at time of completion

- Does the person have sufficient capacity to participate in making the recommendations on this plan? 
  - Yes
  - No
  - Unknown

- Do they have a legal proxy (e.g., a written attorney, power of attorney, guardian)?
- Yes
- No
- Unknown

#### Emergency contacts

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
<th>Telephone</th>
<th>Other details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GP</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consultant</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Specimen Copy - Not for Use
<table>
<thead>
<tr>
<th>Section</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Personal Details</td>
<td>Completed</td>
</tr>
<tr>
<td>2. Summary of relevant information for this plan</td>
<td>Completed</td>
</tr>
<tr>
<td>3. Personal preferences to guide this plan</td>
<td>Completed</td>
</tr>
<tr>
<td>4. Clinical recommendations for emergency care and treatment</td>
<td>Completed</td>
</tr>
<tr>
<td>5. Capacity and representation at this time</td>
<td>Completed</td>
</tr>
<tr>
<td>6. Involvement in making this plan</td>
<td>Completed</td>
</tr>
<tr>
<td>7. Clinician signatures</td>
<td>Completed</td>
</tr>
<tr>
<td>8. Emergency contacts</td>
<td>Completed</td>
</tr>
<tr>
<td>9. Confirmation of validity</td>
<td>Completed</td>
</tr>
<tr>
<td>10. Emergency view</td>
<td>-</td>
</tr>
</tbody>
</table>

2. Summary of relevant information for this plan.

- Coronary artery disease.
- Previous heart attacks.
- Prostatic Hypertrophy. Long Term Catheter.
- Prone to fluid overload with hospital admission.
- Prone to delirium associated with urinary tract infections.

Including diagnosis, communication needs (e.g. interpreter, communication aid) and reasons for the preferences and recommendations recorded.

Details of other relevant planning documents

Details of other relevant planning documents and where to find them (e.g. Advance Decision to Refuse Treatment, Advance Care Plan). Also include known wishes about organ donation.
ReSPECT
Creating individualised recommendations for a person’s clinical care in emergency situations

<table>
<thead>
<tr>
<th>ReSPECT Sections</th>
<th>Status</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Personal details</td>
<td>Completed</td>
<td>07-Feb-2019</td>
</tr>
<tr>
<td>2. Summary of relevant information</td>
<td>Completed</td>
<td>07-Feb-2019</td>
</tr>
<tr>
<td>3. Personal preferences</td>
<td>Completed</td>
<td>07-Feb-2019</td>
</tr>
<tr>
<td>4. Clinical recommendations</td>
<td>Completed</td>
<td>07-Feb-2019</td>
</tr>
<tr>
<td>5. Capacity and representation</td>
<td>Completed</td>
<td>07-Feb-2019</td>
</tr>
<tr>
<td>6. Involvement</td>
<td>Completed</td>
<td>07-Feb-2019</td>
</tr>
<tr>
<td>7. Clinicians’ signatures</td>
<td>Completed</td>
<td>07-Feb-2019</td>
</tr>
<tr>
<td>8. Emergency contacts</td>
<td>Editing</td>
<td>-</td>
</tr>
<tr>
<td>9. Confirmation of validity</td>
<td>To Complete</td>
<td>-</td>
</tr>
<tr>
<td>10. Emergency view</td>
<td>Incomplete</td>
<td>-</td>
</tr>
</tbody>
</table>

8. Emergency contacts

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Telephone</th>
</tr>
</thead>
<tbody>
<tr>
<td>James Keddie</td>
<td>Legal proxy</td>
<td>(016977) 16163</td>
</tr>
<tr>
<td>Carolyn Cox</td>
<td>Friend</td>
<td>(01620) 126163</td>
</tr>
<tr>
<td>Geoff Carolyn D.</td>
<td>GP</td>
<td>(01492) 230201</td>
</tr>
</tbody>
</table>

Emergency contact

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal proxy</td>
<td></td>
</tr>
</tbody>
</table>

Telephone

Other details
1 Scope

RESPECT (Recommended Summary Plan for Emergency Care and Treatment) is a form of anticipatory care planning, as below.

From: https://www.resus.org.uk/respect/

“RESPECT is a process that creates personalised recommendations for a person’s clinical care in a future emergency in which they are unable to make or express choices. It provides health and care professionals responding to that emergency with a summary of recommendations to help them to make immediate decisions about that person’s care and treatment. RESPECT can be complimentary to a wider process of advance/anticipatory care planning.”

The output of the RESPECT process is a set of information items which are recorded on a RESPECT form. NDS is providing an application and some associated components to support the management of these plans electronically.

1.1 Clinical Scope

The application will enable the management of clinical information as defined in the RESPECT template available on Apperta Clinical Knowledge Manager: https://ckm.apperta.org/ckm/templates/1051,57,212

The application will allow users to manage RESPECT agreements for patients. These agreements will be available in part or in whole for use by authorised users to help them with provision of direct care to patients.

1.2 Usage scope

Initial deployment will be to a pilot in Forth Valley Royal Hospital Old Age Medicine Ward 11 for about 5 named clinicians. Usage thereafter will be extended as agreed on the outcomes from the pilot. Future users of the system are intended to be general practices, care homes and hospices, ambulance technicians and paramedics, care homes and patients. Available functionality may be constrained by user role.

1.3 Components

NDS will provide and maintain:

- An openEHR template and associated archetypes.
- An application to manage the information.
- Associated platform components and services including integrations with existing systems where required.

RESPECT Components
<table>
<thead>
<tr>
<th>Num</th>
<th>Hazard Name</th>
<th>Hazard Description</th>
<th>Potential Clinical Impact</th>
<th>Possible Causes</th>
<th>Existing Controls</th>
<th>Consequence</th>
<th>Likelihood</th>
<th>Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Add duplicate patient</td>
<td>Add new patient might not prevent adding of duplicates</td>
<td>Risk of duplicating ReSPECT agreement in conflict with others, looking at wrong form</td>
<td>No checks to prevent duplicates</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Edit function enabled on screen &amp; 5 patient select?</td>
<td>If edit function allows changes to key PID data outside of EMPI (or whatever) then risks of losing patient's unique ID and associated records</td>
<td>Wrong records selected, no records</td>
<td>Edit button enables too many unchecked changes</td>
<td></td>
<td>As above, this will be removed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Address / phone on patient banner</td>
<td>Misleading is Patient's or doctor's address??</td>
<td>Someone goes to the wrong house / users correspondence to wrong house / unable to check patient</td>
<td>User expectations</td>
<td></td>
<td>Minor</td>
<td>Low</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>Finish button</td>
<td>Risk that finish button on sections misleads users to think whole process is complete</td>
<td>User thinks agreement is published when it is not</td>
<td>Finish button does not make clear only applies to that section</td>
<td></td>
<td>Minor</td>
<td>Low</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>Slider for clinical recommendations</td>
<td>This should be a choice of two things, not a sliding scale - needs to be one thing or the other</td>
<td>You cannot have a 50/50 decision so will confuse and users in critical situations</td>
<td>That is not implemented in the wireframe correctly implying a sliding scale</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Maximize button</td>
<td>If maximize button hides patient context or sections then it could mislead users with respect to patient context or the stage in</td>
<td>Don’t know who patient is or forget wrong details added</td>
<td>Behaviour of maximize button?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>B</td>
<td>C</td>
<td>D</td>
<td>E</td>
<td>F</td>
<td>G</td>
<td>H</td>
<td>I</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Hazard</td>
<td>Date</td>
<td>Description</td>
<td>Initial Risk Rating</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>04-Jul-19</td>
<td>Section 4 default</td>
<td>None apparent, dependent on user behaviour and</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>04-Jul-19</td>
<td>Not saving capacity</td>
<td>This is a bug and not intended behaviour, should be fixed in</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>04-Jul-19</td>
<td>See also meeting minutes of 16th July in dev wiki, NDS internal</td>
<td>Process controls, but cannot be relied on</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>17-Jul-19</td>
<td>From the meeting minutes of 16th July in dev wiki, NDS internal</td>
<td>Process of agreement and completion. No validation or UI controls</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22</td>
<td>17-Jul-19</td>
<td>From the meeting minutes of 16th July in dev wiki, NDS internal</td>
<td>Only in process that agreement will be viewed again and by patient carer who may trap this if an error</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>23</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
=IF((OR(ISBLANK(I20),ISBLANK(J20))),"",VLOOKUP(I20,'Look Ups'!$C$3:$D$7,2,FALSE)*(VLOOKUP(J20,'Look Ups'!$A$3:$B$7,2,FALSE)))

<table>
<thead>
<tr>
<th>Likelihood</th>
<th>5</th>
<th>10</th>
<th>15</th>
<th>20</th>
<th>25</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almost Certain</td>
<td>5</td>
<td>8</td>
<td>12</td>
<td>16</td>
<td>20</td>
</tr>
<tr>
<td>Likely</td>
<td>4</td>
<td>8</td>
<td>12</td>
<td>16</td>
<td>20</td>
</tr>
<tr>
<td>Possible</td>
<td>3</td>
<td>6</td>
<td>9</td>
<td>12</td>
<td>15</td>
</tr>
<tr>
<td>Unlikely</td>
<td>2</td>
<td>4</td>
<td>6</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>Rare</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Severity Classification</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catastrophic</td>
<td>Death</td>
</tr>
<tr>
<td></td>
<td>Permanent life-changing incapacity</td>
</tr>
<tr>
<td>Major</td>
<td>Severe injury or major harm, medical intervention required, significant long term sequelae</td>
</tr>
<tr>
<td></td>
<td>Severe psychological trauma, medical intervention required, significant long term sequelae</td>
</tr>
<tr>
<td>Moderate</td>
<td>Moderate injury, medical intervention required, good recovery expected</td>
</tr>
<tr>
<td></td>
<td>Moderate psychological upset, medical intervention required, good recovery expected</td>
</tr>
<tr>
<td>Minor</td>
<td>Minor injury, first aid only, full recovery expected</td>
</tr>
<tr>
<td></td>
<td>Minor psychological upset, no medical intervention required</td>
</tr>
<tr>
<td>Negligible</td>
<td>Inconvenience, no harm to patients or citizens</td>
</tr>
</tbody>
</table>
Overflowing text in PDF

Description
Steps to reproduce
1. Add a ReSPECT form for a patient.
2. Add a line of more than 125 characters in section 2
3. Add more lines than allowed.
4. Add clinician with really long name.

Expected Result
I am prevented from adding more text than can be rendered in the pdf (and/or) The text is wrapped (and/or) truncated to fit in the box when pdf rendered.

Actual Result
I can add as much text as I want.
The rendered text breaks the bounds of the text boxes as defined on the pdf form.

Beyond right and lower bounds of box
<table>
<thead>
<tr>
<th>Num</th>
<th>Hazard Name</th>
<th>Hazard Descipt</th>
<th>Potential Clinical Imp</th>
<th>Possible Cause</th>
<th>Existing Control</th>
<th>Severity</th>
<th>Likelihood</th>
<th>Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>39</td>
<td>Wrong patient's data copied to new patient's record</td>
<td>Information completed in the ResPECT sections for one patient will be copied to a new patient's ResPECT sections when a new patient is selected from 'search'</td>
<td>Information provided that is not applicable to that patient. Wrong actions undertaken.</td>
<td>Bug</td>
<td>Only limited by explanation and process</td>
<td>Catastrophic</td>
<td>Likely</td>
<td>20</td>
</tr>
<tr>
<td>40</td>
<td>Loss of patient context on refresh in browser</td>
<td>If the user refreshed the browser window then the patient browser details display 'null' as values, although the content of the ResPECT sections persist. It is unclear under which record, if any, the data is stored.</td>
<td>Information recorded against unknown or wrong patient</td>
<td>Bug</td>
<td>Only limited by explanation and process</td>
<td>Catastrophic</td>
<td>Likely</td>
<td>20</td>
</tr>
</tbody>
</table>
This is a TEST system. Do NOT use patient data.

Home

Go to patient

CHI number

Go

Test Patients

2406034497
Summary of relevant information for this plan

General information
Including diagnosis, communication needs (e.g. interpreter, communication aids) and reasons for the preferences and recommendations recorded.

Relevant planning documents
Details of other relevant planning documents and where to find them (e.g. Advance Decision to Refuse Treatment, Advance Care Plan). Also include known wishes about organ donation.
<table>
<thead>
<tr>
<th>Name</th>
<th>Hazard Name</th>
<th>Hazard Description</th>
<th>Potential Clinical Implications</th>
<th>Possible Cause</th>
<th>Existing Control</th>
<th>Rating</th>
<th>Risk</th>
<th>Leverage on</th>
<th>Origin</th>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>45</td>
<td>String lengths constrained to available text on PDF</td>
<td>Text will be written over the PDF section making text unreadable or meaningless, as on the PDF information, if not available</td>
<td>Unclear management instruction, wrong treatment</td>
<td>Process only</td>
<td>Moderate</td>
<td>Assigned</td>
<td>Certain</td>
<td>Risk</td>
<td>Leverage</td>
<td>15</td>
<td>22-Jan-2023 - Design choices need consideration and agreed.</td>
</tr>
</tbody>
</table>

| Section 4: CRI Recommendation - arrow key vs arrow | | | | | | | | | | | |
| 32 | There is a risk that the user selects the wrong CRI choice because they may use the down arrow to scroll the view, and this changes the selection on the radio button control for CRI choice. | Wiring choice made could lead to wrong clinical procedures | 4a. Currently designed if button is clicked, it has expanded choice of radio button with the arrow keys. | Only in process that agreement will be viewed again and by patient carer who my hear this if an error | Major | Possible | 12 | 22-Jan-2023 - Stil open. To be resolved. |

| Section 4: CRI Recommendation - risk of selecting wrong option in no confirmation step or prompt | | | | | | | | | | | |
| 33 | There is a risk that the user selects the wrong CRI choice and then saves the selection without noticing | Wiring choice made could lead to wrong clinical procedures | There is no check to the user to confirm the choice they have made. | Only in process that agreement will be viewed again and by patient carer who may hear this if an error | Major | Possible | 12 | 22-Jan-2023 - Still open. Design options being considered. |

- Comments
- Dates
- Linkage
- Filters and sorts
- Numbering
- Excel???

• Easily shared!
<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>23 May 2019</td>
<td>Demo system now available although needs confirmed as operational. A hazard identification review will be organised making use of the demo system following the ReSPECT team review meeting today.</td>
</tr>
<tr>
<td>4 July 2019</td>
<td>Internal review of application Migration hazard log to standard template</td>
</tr>
<tr>
<td>16 July</td>
<td>External wider review meeting with FVRH</td>
</tr>
<tr>
<td>24 July</td>
<td>Hazard assessment meeting including external stakeholders from FVRH</td>
</tr>
<tr>
<td>22 Jan 2020</td>
<td>Internal review meeting with Jonathan, Paul and Andrew looking at hazard log against new UAT environment.</td>
</tr>
<tr>
<td>29 Jan 2020</td>
<td>External hazard log review meeting</td>
</tr>
</tbody>
</table>
Discussion:

Note that focus was on open hazards with a risk rating of 9 or more.

Attendees are invited to review closed hazards and welcome to raise any questions that they may wish clarification on by contacting JW or PM. The group agreed that all closed issues remain closed at this time.

Hazard log issues:

#45: Possible controls for this issues were discussed with reference to an analysis provided by JW (Appendix A) looking at short and long term solutions. The group agreed that option 1 of that analysis was the preferred approach. This will limit the text to a specific number of characters to fit in the available space and design will provide user feedback as the user types to help guide their data entry.

#32 #33: Both these issues were considered to be best controlled by having a specific confirmation step for section 4 data, preference to have it at the end (before publishing)
NR-154

This document explains the options for mitigating Clinical Hazard 20 (NR-154). It outlines three potential solutions, explores user experience (UX) and clinical safety for each and recommends a preferred option.

Hazard Outline:

There is an interdependency between two questions in the Digital RESPECT Product. This exists because of the wording of the paper form.

Image 1 shows the questions on the paper form. Part 1 of question 5 asks a very similar question to question 6.

To ensure the application is clinically safe, users must be unable to select to answers that contradict themselves in the user interface. (Image 2 and image 3)

In order to implement this, we have appraised three options and made a decision.

This decision is being made for the trial in Forth Valley. It is possible to further iterate after the trial.

Image 1: Sections 5 and 6 on the paper RESPECT form

5. Capacity and representation at time of completion

- Does the person have sufficient capacity to participate in making the recommendations on this plan?
  - Yes / No

- Do they have a legal proxy (e.g. welfare attorney, person with parental responsibility) who can participate on their behalf in making the recommendations? Yes / No / Unknown

- If so, document details in emergency contact section below

6. Involvement in making this plan

- The clinician(s) signing this plan are confirming that (select A, B, or C, or complete section D below): (image)
  - A This person has the mental capacity to participate in making these recommendations. They have been fully involved in making this plan.
  - B This person does not have the mental capacity to participate in making these recommendations. This plan has been made in accordance with capacity law, including, where applicable, in consultation with their legal proxy, or where no proxy, with relevant family members/friends.
  - C This person is less than 18 (UK except Scotland) / 16 (Scotland) years old and has not been involved in making the plan (select 1 or 2, and also 3 in applicable or explain in section D below):
    - 1 They have sufficient maturity and understanding to participate in making this plan.
    - 2 They do not have sufficient maturity and understanding to participate in this plan. Their views, when known, have been taken into account.
    - 3 Those holding parental responsibility have been fully involved in discussing and making this plan.
  - D If no other option has been selected, valid reasons must be stated here. Document full explanation in the clinical record.

Image 2: Section 5 in the digital interface

Image 3: Section 6 in the digital interface
Agile

• Work with the team
• Awareness
• CSE / Product specialist
• Interval review – backlog sizing
• Fortnightly check in
• High risk awareness e.g. DNACPR
• Availability
Deployment

- End February
  - Some technical dependencies FVHB
- Clinical Safety Case
- Risk assessments score for pilot?
- Other controls
- Release authority
- Structured and unstructured post-release monitoring
Gaps (still to work out)

- Components
- openEHR content models
- CDR content governance
- Deploying organisations
- MDR alignment
What next

• Training
• Compliance
• Agile / Sprints
• Deployment
• CSO / CSE resource
• MDR
• Quality Management
• NHS NSS ISO 14971

• Ophthalmology
• ACP expansion
• Endocrine service
• Cancer care
• Device Registry
• ? Immunisations??