

DECIDE-AI

Thematic Analysis

27.04.21

How to read this document

Two members of the research team (Myura Nagendran and Baptiste Vasey) performed in parallel an inductive thematic analysis on the open-ended answers to questions 1-4 and the general comment box in Round 1, using the NVivo software. Conflicts were resolved by consensus. For each theme identified, one of five actions was taken and is reported in the table here below:

- Do nothing – theme out of scope or not the primary focus of DECIDE-AI
- Do nothing – theme already covered in an existing item
- Add the theme to the provisory explanation of an item (not displayed to the participants at this stage)
- Add the theme to an existing item by modifying the item's wording
- Select the theme as a new item

Themes

| Themes identified | Action taken (updated list) |
|-----------------------------------|---|
| Algorithm | |
| Bias | Covered in item 25 |
| Malfunction/faults | Selected as new item 21c |
| Version | Newly included in item 9 |
| Description | Covered in item 9 |
| Development and validation | Covered in item 9 |
| Continuous learning | No action taken |
| Training data | Covered in item 9 |
| Safety | |
| Risk assessment | Covered in item 13a |
| Safety requirements | Covered in item 13a |
| Safety outcomes | Covered in item 21a |
| Hardware & software | |
| Description | Covered in item 10d |
| Connectivity | (see integration in IT infrastructure) Newly included in item 10d |
| System requirements | Added to item 10d provisory explanation |
| Health economic assessment | |
| Health economic assessment | No action taken - dropped after Round 1 |

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| Data security & confidentiality | |
| Data security | Covered in item 6b |
| Confidentiality | Covered in item 6b |
| Errors | |
| Case audit | Added to item 21d explanation |
| Causes | Newly included to item 21d |
| Consequences | Covered in item 21d |
| Error detection (by algorithm or human) | Newly included to item 21d and 21e |
| Occurrence rate | Covered in item 21d |
| Human errors | Selected as new item 21e |
| Error severity grading | Newly included in item 21a |
| Unexpected errors | Selected as new items 13b and 21b |
| Ethics | |
| Ethics | Selected as new item 16 |
| Reference standard | |
| Reference standard | Covered in item 11b provisory explanation |
| Human factors | |
| Agreement | Newly included in item 23a |
| Deviation from recommendation | Covered in item 23a |
| Clinician changing mind | Newly included in item 23a |
| Trust | Covered in item 23b |
| Device ergonomics | Added to item 23c provisory explanation |
| Workload and fatigue | Selected as new item 23d |
| System design and nudges | Added to item 19 provisory explanation |
| User experience - satisfaction - acceptability | Covered in item 23c |
| User interface | Covered in item 23c |
| Existing ISO norm | Added to item 26 provisory explanation |
| Human decision making process | No action taken |
| Usability | Covered in item 23c |
| Situational awareness | No action taken - dropped after Round 1 |
| Context of HF evaluation | Covered in item 14 |
| Time (to produce output/to task completion) | Covered in item 23c |
| Level of human control | Added to item 3 provisory explanation |
| Use cases | Covered in item 14 |
| Implementation | |
| Adherence | Covered in item 18a |
| Dose and reach | Covered in item 18a |
| Integration in clinical pathway | Selected as new item 10b |
| Impact on clinical pathway | Covered in item 18b |
| Integration in IT infrastructure | Newly included in item 10d |
| Implementation time | Added to item 10d provisory explanation |
| Decision support timing | Covered in item 10c |
| Access to additional information | Covered in item 10a |
| Intended use | Covered in item 3 |
| Algorithm threshold used | Newly included in item 10d |

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| Input data | |
| Data availability | Covered in item 10a |
| Pre-processing | Covered in item 10e |
| Data quality/missing data | Covered in item 10e |
| Data entry (user vs automated) | Newly included in item 10e |
| Similarity with in silico input features | Covered in item 9 |
| Type of data | Newly included in item 10e |
| Exclusion | Covered in item 8a and 10e |
| Interpretability and explainability | |
| Interpretability and explainability | Covered in item 23e |
| Iterative improvement | |
| Iterative improvement | Covered in item 19 |
| Legal & regulatory | |
| Regulatory framework | Covered in item 4 |
| Responsibility | Covered in item 10b |
| Algorithm output | |
| Presentation/clarity | Covered in item 10f |
| Clinical value or implications | Newly included in item 23e |
| Level of confidence | Added to item 10f provisory explanation |
| Storage | Added to item 10b provisory explanation |
| Output edit possibility | Added to item 10f provisory explanation |
| Patients | |
| Patient involvement | Covered in item 15 |
| Patient experience | No action taken - dropped after Round 1 |
| Communication of outputs to patients | No action taken - dropped after Round 1 |
| Clinical performance | |
| Diagnostic/accuracy metrics | No action taken |
| Assess assisted performance | Covered in item 20a |
| Context dependent | No action taken |
| Outcome - process measures | Added to item 11a provisory explanation |
| Outcome – adverse outcome | Selected as new item 21b |
| Outcome – clinical end goal | Added to item 11a provisory explanation |
| Outcome – surrogate outcome | Added to item 11a provisory explanation |
| Performance of worst case scenario | Added to item 13a provisory explanation |
| Stability | Newly included in item 21a |
| Reproducibility - generalisability | No action taken |
| Expected performance from in silico study | Covered in item 9 |
| Post-market surveillance | |
| Post-market surveillance | No action taken |
| Scale up feasibility | |
| Scale up feasibility | Covered in item 27 |
| Study design | |
| Study design description | Covered in item 7 |
| Representative clinical setting | Covered in item 10a |
| Representative patient population | Covered in item 17a |
| Statistics | Covered in item 12 |

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|------------------------------------|---|
| Sample size & power | Covered in items 8a and 8b |
| Cluster | Added to item 7 provisory explanation |
| Silent or shadow mode | Added to item 20b provisory explanation |
| Control | Covered in items 8b and 20c |
| Study termination (safety reasons) | Added to item 13a provisory explanation |
| Workflow & clinical pathway | Selected as new item 10b |
| Target clinical problem - task | Newly included in item 2 |
| Subgroup analysis | |
| Cases of disagreement | Added to item 22 provisory explanation |
| Cases of incorrect outputs | Added to item 22 provisory explanation |
| Clinician experience level | Added to item 22 provisory explanation |
| Condition present or absent | Added to item 22 provisory explanation |
| Implementation settings | Added to item 22 provisory explanation |
| Level of adherence | Added to item 22 provisory explanation |
| Level of chronicity | Added to item 22 provisory explanation |
| Patient subgroups | Added to item 22 provisory explanation |
| Low quality data | Added to item 22 provisory explanation |
| Users | |
| Characteristics | Covered in item 17b |
| Level of experience | Covered in item 17b |
| Training | Covered in item 8c |
| Learning curve | Covered in item 23d |