SMARTT Critical Care Pathways
(Safe, Machine Assisted, Real Time Transfer)

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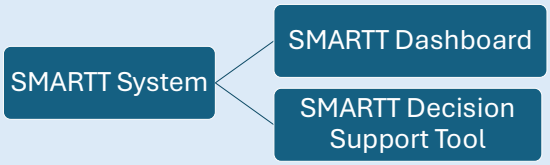
INTRODUCTION

- NIHR funded AI in Health and Care Award 2020
- Developed collaboratively
  - University Hospitals Bristol and Weston NHSFT
  - University of Bristol - Department of Engineering Mathematics
- **Aims**
  - Support prompt discharge decision when sufficiently recovered.
  - To coordinate discharge process when discharge decision made.



Problem

- Critical care demand is constrained, and demand is increasing.
- Significant clinician variation in discharge timing decisions.
  - 25% of patients stay too long, or not long enough.
- Prolonged admissions harmful to CCU patients and healthcare system.

CCU Patient Harm	System Harm
Ongoing invasive procedures.	Delay in admission when unwell.
Longer rehabilitation, delayed final discharge.	Elective operation cancelation.
Discharged outside normal hours.	Lost Revenue.

Background

- Proof of concept study (2018 C.McWilliams et al.) [1]
  - Random forest classifier and Logistic Classifier to predict successful discharges using routinely collected observations and demographics.
  - Limited to 18 clinical features.
  - Compared to established nurse-led discharge criteria.
  - Local Critical care (1870 patients), and MIMIC-III (7592 patients).

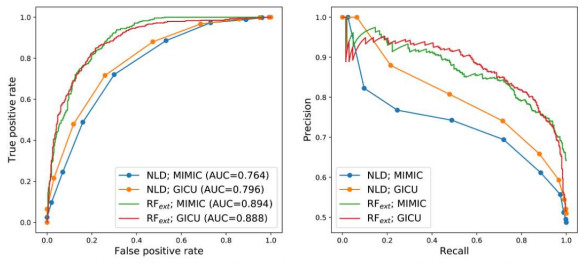
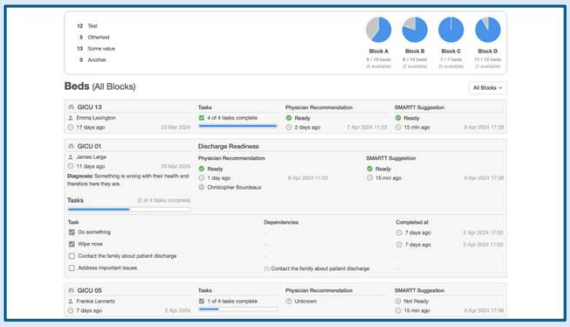


Figure 1 Performance of the nurse-led discharge criteria and random forest with extended feature set (RF$_{ext}$) evaluated on held-out data for a single train-test split. Left: receiver-operator-characteristic curves with associated area-under-curve scores. Right: precision-recall curves. AUC, area-under-curve; GICU, general intensive care unit; NLD, nurse-led discharge; RF, random forest.

SMARTT DASHBOARD

- Live display of patients assessed by team as being fit for discharge.
- Multi-item de-escalation checklist.
- Discharge location and bed allocation.
- Underpinned by wider process change project across Critical Care.



SMARTT Decision Support Tool

- Highlight patients that would benefit from clinical review as they may have recovered enough to be discharged from Critical Care Unit.
- Final algorithm currently under development
  - Clinical features expanded, larger patient data set.
- Planned shadow deployment Summer-Autumn 2024.
- Clinical risk assessment process to follow before any hospital deployment.
- Future interventional trial for evidence for medical device certification.

Regulatory Requirements

- **SMARTT Dashboard**
  - Not classed as a medical device under UK-MDR 2002.
  - Requires Clinical Safety Case
- **SMARTT Decision Support Tool**
  - If on the UK market - Class IIa medical device under UK-MDR 2002
    - Quality Management System (ISO 13485)
    - Medical Device Software Lifecycle process (IEC 62304:2006)
    - Application of risk management to medical devices (ISO14971:2019)
  - Requires Clinical Safety Case

Fellowship Outputs

- **Medical Device Documentation**
  - Report on SMARTT position in regulatory framework.
  - Planning path to commercialisation
  - Documenting standards targeted
  - Value proposition, Intended purpose statement
  - Drafting initial Quality Management System
- **Drafting Clinical Safety Case**
  - Mapping 'as-is' and 'to-be' flowcharts
  - Clinical Risk Management Plan
  - Clinical Safety Case Report
  - Hazard log
  - Planning Hazard ID workshop – planned Summer/Autumn 2024.

SMARTT Neonatal Proposal

- *Feasibility assessment of extension into Neonatal ICU.*
- **Problem**
  - Extreme preterm infants usually intubated and ventilated at delivery
  - No good quality evidence for when to transition to non-invasive support.
    - Spontaneous breathing trial
      - Pause ventilation on intubated baby and observe respiratory effort.
      - Low specificity of 62%, some studies < 50% [2]
      - Can have complications.
  - Previous studies using machine learning have shown improved performance on this baseline. [3]
    - Could be performed continuously on patient cohort.
- **Proposed Methods**
  - Using SMARTT infrastructure extract patient observations
    - 413 infants < 29 weeks gestation and <1250g at birth
  - Investigate MIMIC-IV to supplement dataset – 60,000 infants
  - Label extubation – exclude failed extubation due to secondary events.
  - Develop proof-of-concept machine learning model
  - If successful target NIHR i4i Product development award 2025.
- **Funding**
  - Awarded Topol Fellowship 2024
  - Applied to UH Bristol Research Capability Funding 2024
  - Targeting LEAP Twin Fellowship 2024

References:

1. McWilliams, C.J., Lawson, D.J., Santos-Rodriguez, R., Gilchrist, I.D., Champneys, A., Gould, T.H., Thomas, M.J., Bourdeaux, C.P., 2019. Towards a decision support tool for intensive care discharge: machine learning algorithm development using electronic healthcare data from MIMIC-III and Bristol, UK. BMJ Open 9, e025925. https://doi.org/10.1136/bmjopen-2018-025925
2. Shalish, W., Latremouille, S., Papenburg, J., Sant'Anna, G.M., 2019. Predictors of extubation readiness in preterm infants: a systematic review and meta-analysis. Arch. Dis
3. Natarajan, A., Lam, G., Liu, J., Beam, A.L., Beam, K.S., Levin, J.C., 2023. Prediction of extubation failure among low birthweight neonates using machine learning. J. Perinatol. 43, 209–214. https://doi.org/10.1038/s41372-022-01591-3

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