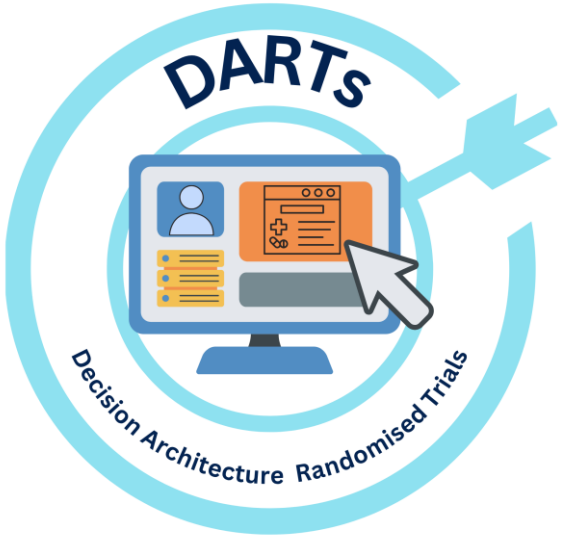
Developing and feasibility testing the first Decision Architecture Randomised Trial (DART) design



Presented by Clare Relton

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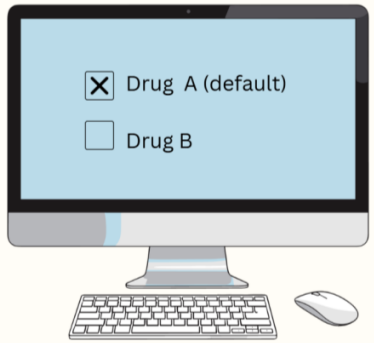
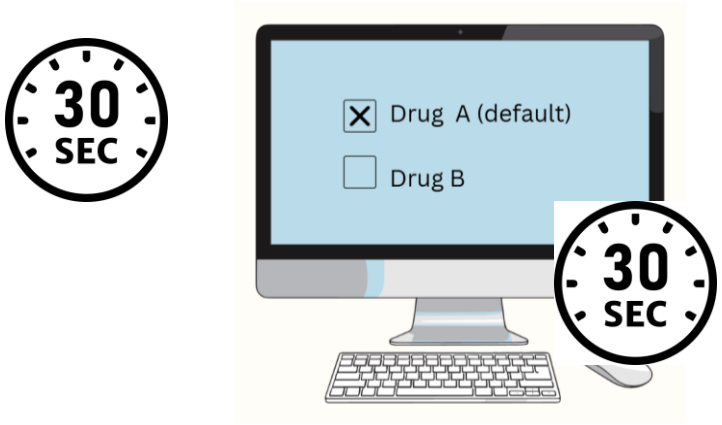
ICTMC 2026, Birmingham, UK

- 1.5mn NHS GP consultations daily
- 9 minutes

- ? Multiple medically approved, valid options that differ in effectiveness, side effects, recovery times, cost, long-term outcomes, lifestyle impact……
- EHR system presents prescribing choices



- Clinicians often choose the first option that appears on the screen



- EHR decision architecture presents prescribing choices
- Clinicians often choose the first option that appears on the screen (default)

Decision Architecture Randomised Trials

- Default option set randomly
- Nudges clinicians towards one option (can override default option at any time)
- Analysis uses instrumental variable framework

Development and feasibility testing

Analysis

Decision architecture randomisation: extremely efficient clinical trials that preserve clinician and patient choice?

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- Pilot DART
- Ethical acceptability

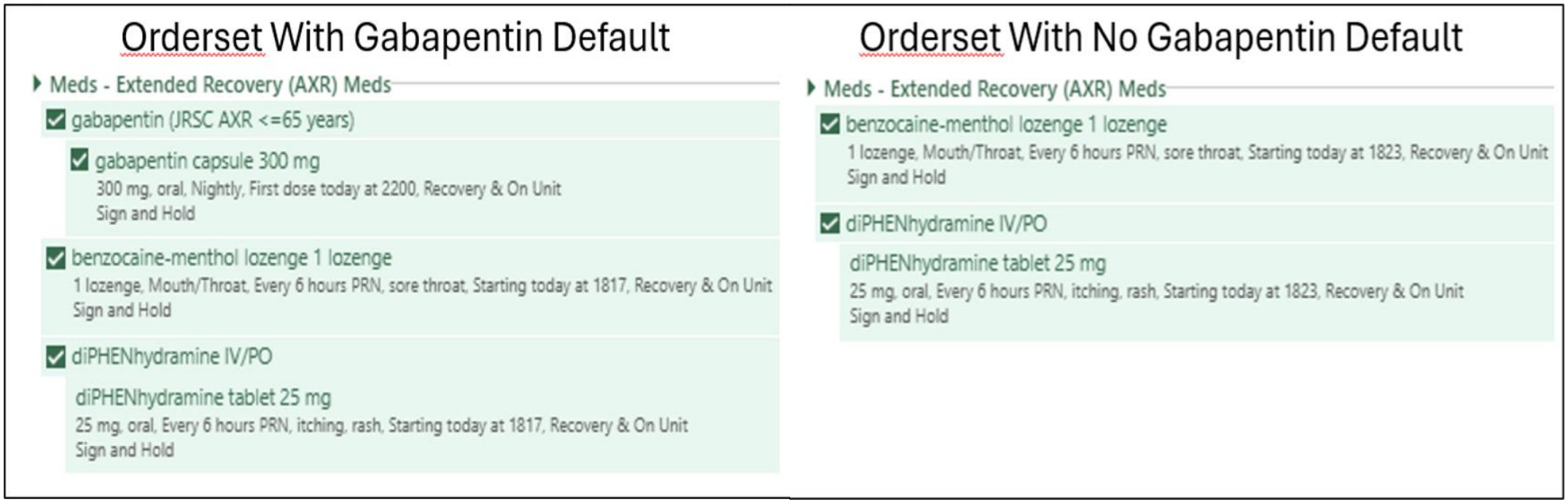
- Acceptability and implementation
- Public views on consent process

Pilot DART

Memorial Sloan Kettering Cancer Center

- Gabapentin vs No Gabapentin for patients undergoing mastectomy
- Effective? Safe?
- Treatment assignment influenced by patient level randomisation between order sets.
- Outcome - Morphine Milligram Equivalents (MMEs)

pcori



- Feasibility demonstrated
- 6 months and 600+ patients
- Strong nudge effect i.e. Most patients received the option in the order set to which they were randomised
- No workflow disruption reported

- Nudge achieved 85% separation in gabapentin use between order sets.
  - 14% (32/236) randomised to '**no gabapentin**' order set received gabapentin
  - 92% (255/258) randomised to '**gabapentin**' order set received gabapentin

Pilot DART - Consent for research

- DARTs closely integrated into EHR systems and routine prescribing decisions
- ***What level of information/ consent is indispensable?***

IRB agreed to waiver of consent

Impracticability - randomisation embedded into EHRs
Minimal risk - randomised between standard-of-care treatments
No adverse effect on rights and welfare - autonomy preserved
Significant social value - evidence for routine clinical decision-making

Pilot DART – Consent for research

- **Deliberative Democracy Sessions**
- Public (n=95) - surveys & facilitated group discussions.
- Majority (64%) supported waiving individual level informed consent for DARTs

- Themes
  - Nudges must preserve clinical autonomy
  - Notification that a DART was taking place preferred
  - Acceptability depends on comparators being similar, established treatments

BOWEL RESEARCH UK.

Colorectal Disease

TECHNICAL NOTE | Open Access

Addressing 'hard-to-fund' research questions in bowel research: Exploring the role of decision architecture randomised trials

Stephen J. Chapman, Carly Bisset, Hayley Fowler, Alice Murray, Jessica Banks, Judit Kovacs, Jim Tiernan, Julie Cornish, Susan Moug, Dale Vimalachandran, James H. Flory, Andrew Vickers, Clare Relton

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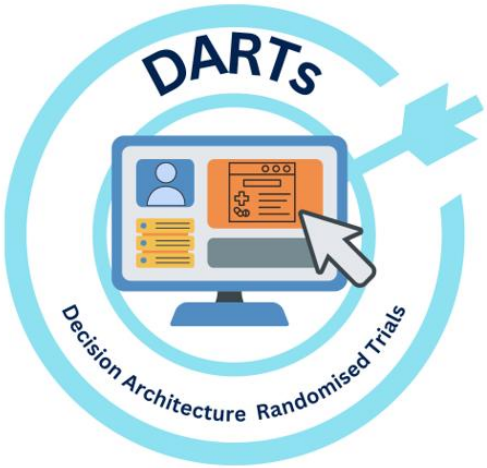
Exploring acceptability and implementation of DARTs

- Current status of EPRs (variation in capabilities)
  - Electronic survey of NHS Trusts
  - Industry providers and NHS EPR/digital team interviews
- Acceptability of DARTs (interviews and focus groups): Patients & Public, Clinicians, NHS managers, NHS IT professionals, Research nurses & delivery teams, RECs.
- RQs relevant to bowel disease amenable to DART methods
  - Consensus to generate priority list of questions & select one question to develop as 1st UK DART
- Developing publicly legitimate informed consent for DARTs
  - PhD study using deliberative democracy methods

Trials Methodology TMRP Research Partnership

- *Introduce randomised, indiscernible nudges*
- *Useful when treatment choice is influenced by order set design*



✓Patient and clinician choose freely

✓No disruption to patient care

✓Greater inclusivity

✓Reduced burden

✓Very low cost per patient accrued

Highly efficient, technology enabled trial design

Thank you

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DARTs

Decision Architecture Randomised Trials

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