RAPID-RT: Designing an inclusive study using real-world data to evaluate patient outcomes after radiotherapy

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1. Rationale for RAPID-RT

- Many patient groups (e.g. elderly, multimorbid) are under-represented in randomised control trial (RCTs), raising concerns about the generalisability of results
- Pragmatic trials, using real world data (RWD) offers the ability to conduct inclusive research and generate evidence on the impact of changes in clinical practice on patient outcomes
- The RAPID-RT study will collect RWD from patients receiving curative intent radiotherapy for stage I to III lung cancer at the Christie and develop a rapid learning methodology to evaluate the impact of changes in radiotherapy practice on patient outcomes (Figure 1)
- It will use the clinical exemplar of the introduction of a novel dose-limit to the base of the heart at the Christie in April 2023 for all patients with stage I-III lung cancer with curative intent. This was based on retrospective evidence that higher doses to this region reduce survival

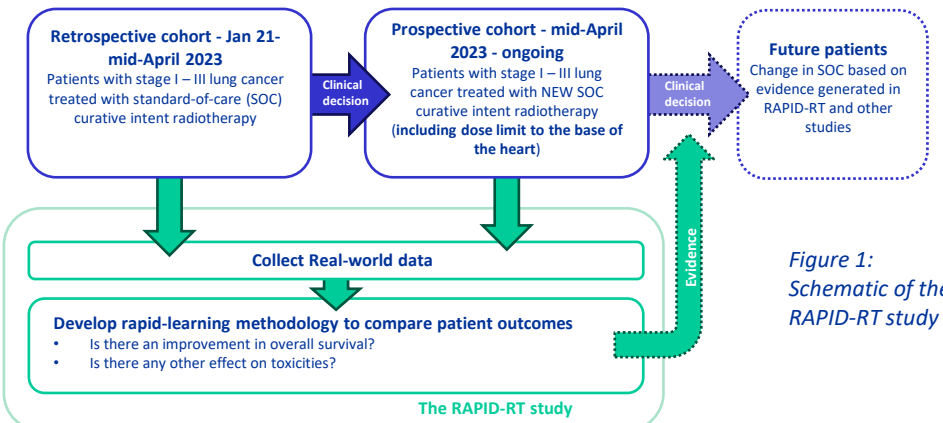


Figure 1: Schematic of the RAPID-RT study

2. Rapid-RT was co-designed with clinicians, patients, carers and members of the public

- Key priorities of the RAPID-RT team are ensuring:
  - ❖ Patients are fully-informed of why and how patient data is used
  - ❖ The study is inclusive, practical and acceptable to patients AND clinical teams

RAPID-RT has embedded patient and clinical engagement:

- Research team **includes 2 patient co-applicants and a patient advisory group** (n=8) who input into study design, review all patient-focused material and help with the dissemination of results
- **Focus groups with patients and clinicians** informed statistical design:
  - ❖ **All patients** should be included regardless of other factors
  - ❖ Patients prepared to accept increases in other severe toxicities if survival could be increased

  "I would be prepared to experience any level of side effects of the treatment no matter how severe so long as the process will allow me to live a longer cancer free life.'
  - ❖ Lung clinicians from across the UK agreed a >5% increase in survival would be significant and merit the study a success.
- Consent process chosen using a **Citizens' Jury**

3. What consent process is acceptable to ask patients to share their data?

- Used a 2-day Citizens' Jury to decide what consent process is appropriate
- 24 Jurors selected representing a range of demographics, with experience of living with or caring for someone with cancer, or a member of the public (Figure 2)

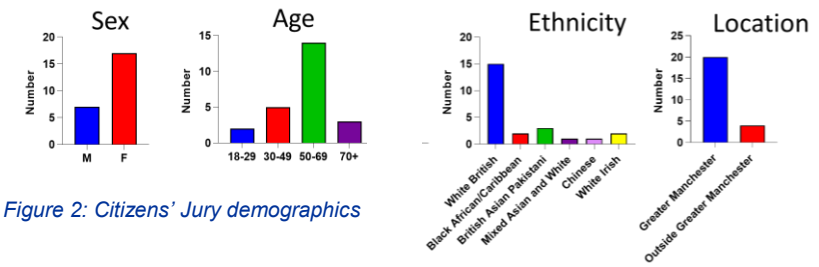


Figure 2: Citizens' Jury demographics

- The Jury were presented evidence on a variety of topics including:
  - ❖ How do we design research studies?
  - ❖ How does consent work?
  - ❖ Legal approvals needed for research studies involving people and their data
  - ❖ Patient and clinical practical experience of *opt-in* versus *opt-out* processes in RCT trials

Figure 3: Images from Citizens' Jury

- Jurors spent >160 minutes discussing in small groups and asking questions (Figure 3)
- Jurors were polled three times across the two days by secret ballot

The polls:

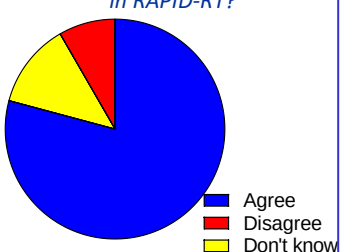
1)What consent process is appropriate for anonymised RWD use in RAPID-RT?

- ~80% voted for an opt-out approach

2) How should participants be informed about the study

- 100% of Jury members said face-2-face discussion with a doctor was essential
- 100% voted for a (short) participant information sheet
- Support for additional methods e.g. video

Figure 3: Results from poll "Is opt-out consent appropriate in RAPID-RT?"



4. Rapid-RT has recruited over 460 patients in 12 months

- RAPID-RT has **no exclusion criteria**, including all patients regardless of age, frailty and socioeconomically-deprivation
- >460 patients invited to take part since 3rd April 2023
- Only one patient has opted-out of data use showing the benefit of this approach
- Interviews with patients and clinical team indicate strong support for a simple consent process
- Patients recruited typically would be excluded from clinical trials (Figure 4)

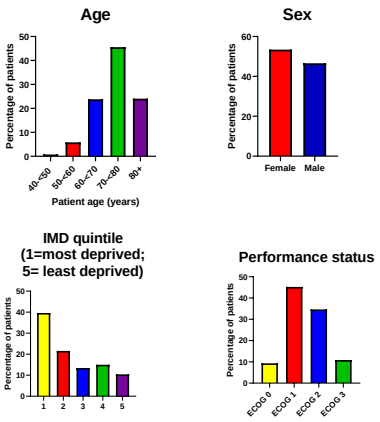


Figure 4: Demographics of patients in RAPID-RT

5. Conclusion

- RAPID-RT is an inclusive study, co-designed and run with patients and members of the public
- Including all patients means the results should be generalizable to the patients we treat
- Using a simplified opt-out approach is accepted and welcomed by patients and clinical teams
- Data collected during RAPID-RT is being used to develop a 'rapid-learning' methodology to analyse the impact of changes in standard-of-care on patient outcomes, providing a clinical exemplar of how prospective evidence can be used to improve future treatments
- Results generated will be continuously reported back to the clinical team, providing evidence to modify future patients care

Contact the team at rapid-rt@manchester.ac.uk

https://sites.manchester.ac.uk/rapid-rt/

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