Co-producing a novel dynamic platform to facilitate informed consent in Cancer GENomic Testing (CoGenT)

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Background

- Genomic testing is characterised by an unprecedented degree of personal uncertainty and complexity.
- Patients may leave the consent process for genomic tests with limited understanding, inflated expectations, some confusion and uncertainty, and changing information needs and preferences over time (*Davies et al, 2020; Best et al, 2020).*

Aim

- To develop a novel online COnsent in GENomic Testing **(CoGenT)** intervention, comprising:
  - a **Dynamic Consent Platform (DCP)** and
  - **Question Prompt List (QPL)**

  about genomic research participation

- **Dynamic consent platform (DCP)**

  Online platform to provide clear, **layered** information, allowing patients to:
  - ✓ **Tailor** to needs/preference (e.g., less vs more detail)
  - ✓ Make and **document choices** among consent options
  - ✓ Review and **make changes** over time
  - ✓ **Communicate** with research team

  CoGenT DCP - adapted from CTRL (Haas et al, 2024)

Methods

Four stakeholder groups:

1. **Patients** who **have had** tumour molecular profiling
2. **Patients** who **have not had** tumour molecular profiling
3. **Family members / carers** of included patients
4. **Healthcare professionals** (clinicians + research co-ordinators)

Each participant invited to take part in a **series of 3 video interviews**.

Development of the QPL & DCP

Interview 1 N= 34	QPL Draft	**Interview 2** N= 22	DCP Prototype	**Interview 3** N=15
Aim: **Idenitfy information needs for QPL.** When considering tumour molecular profiling: - *What do people want to know?* - *What should people know or ask about?* - *Would a QPL be useful?* • Feedback on an existing DCP	Developed from content analysis of Interview 1 **Draft QPL** (questions + answers) Edited content for low literacy	Aim: **Feedback on QPL draft.** Interviewer shared screen, showing draft QPL (questions + answers). Participants provided feedback on *content, structure, wording.* Iterative revisions.	Develop DCP prototype Edited DCP content for low literacy	Aim: **Feedback on the DCP prototype.** Currently in progress Think-aloud feedback on DCP. Feedback to be used to further refine DCP.

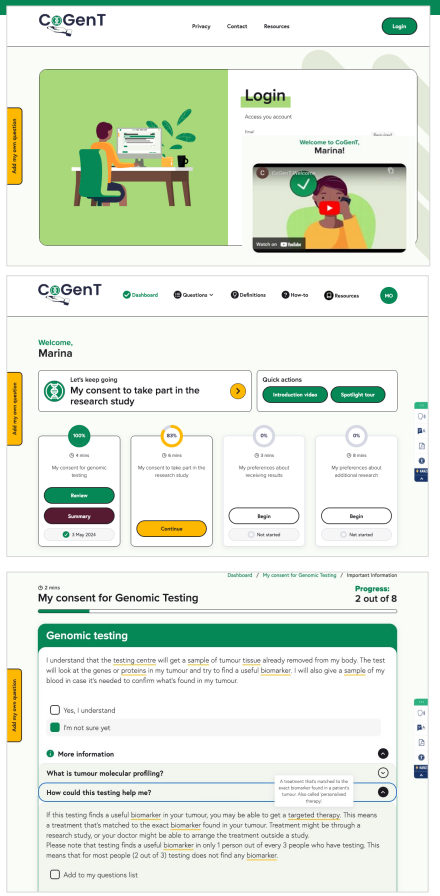
Results

- Participant information needs centred around the genomic testing process, namely results and implications, and research participation, which formed key sections of prototype DCP.
- **QPL feedback** was largely positive, resulting in **29 questions.** 3 sections:
  - *Tumour molecular profiling (7 Qs)*
  - *Results of tumour molecular profiling (13 Qs)*
  - *About the genomic research study (9 Qs)*

  Each question features brief general answers on which consent personnel can elaborate, if desired.
- The DCP was strongly endorsed, particularly its potential value to inform patients, enable them to indicate preferences, and identify where they need support.
- Participants emphasised the importance of optimising clarity, accessibility, and engagement in the DCP.

Conclusions

- The CoGenT intervention appears to be **valued by patients, clinicians, and research personnel.**
- In the next phase, **the acceptability, clinical feasibility, and potential effectiveness of the CoGenT intervention will be compared with usual consent processes in cancer genomic settings.**
- These evidence-based resources may guide consent **practices when genomic testing enters routine clinical care**.
- This work has the potential to **facilitate greater access to cancer genomic testing by ensuring consent processes meet the needs of all stakeholders.**



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