The development of a fertility preservation decision aid to support teenage and adult women with cancer

Jones GL et al….and *on behalf of the Cancer, Fertility and Me study group).*

Fertility preservation and decision-making

Many women with a cancer diagnosis have to make time-pressured decisions regarding fertility preservation with specialist fertility services, whilst undergoing treatment of their cancer with oncology/haematology services.

Our recent narrative review exploring the factors which hindered women's decisions about fertility preservation after a cancer diagnosis suggested that many women do not feel well supported in making these decisions. Lack of specialist fertility preservation information and the timing of this information were found to be key factors. [1]

Similarly, a recent prospective, mixed-method study in Sheffield found that women with cancer wanted to receive specialist fertility information sooner, in the context of their cancer care, and *in advance* of seeing the fertility expert. They felt this would help them better prepare for the fertility decision and ensure they made the best decision for their future aspirations. [2]

Although there are many fertility preservation resources publically available for women with cancer, none have been developed for UK female cancer patients, and the two existing patient decision aids (ptDA's) are exclusively for women with breast cancer. [3]

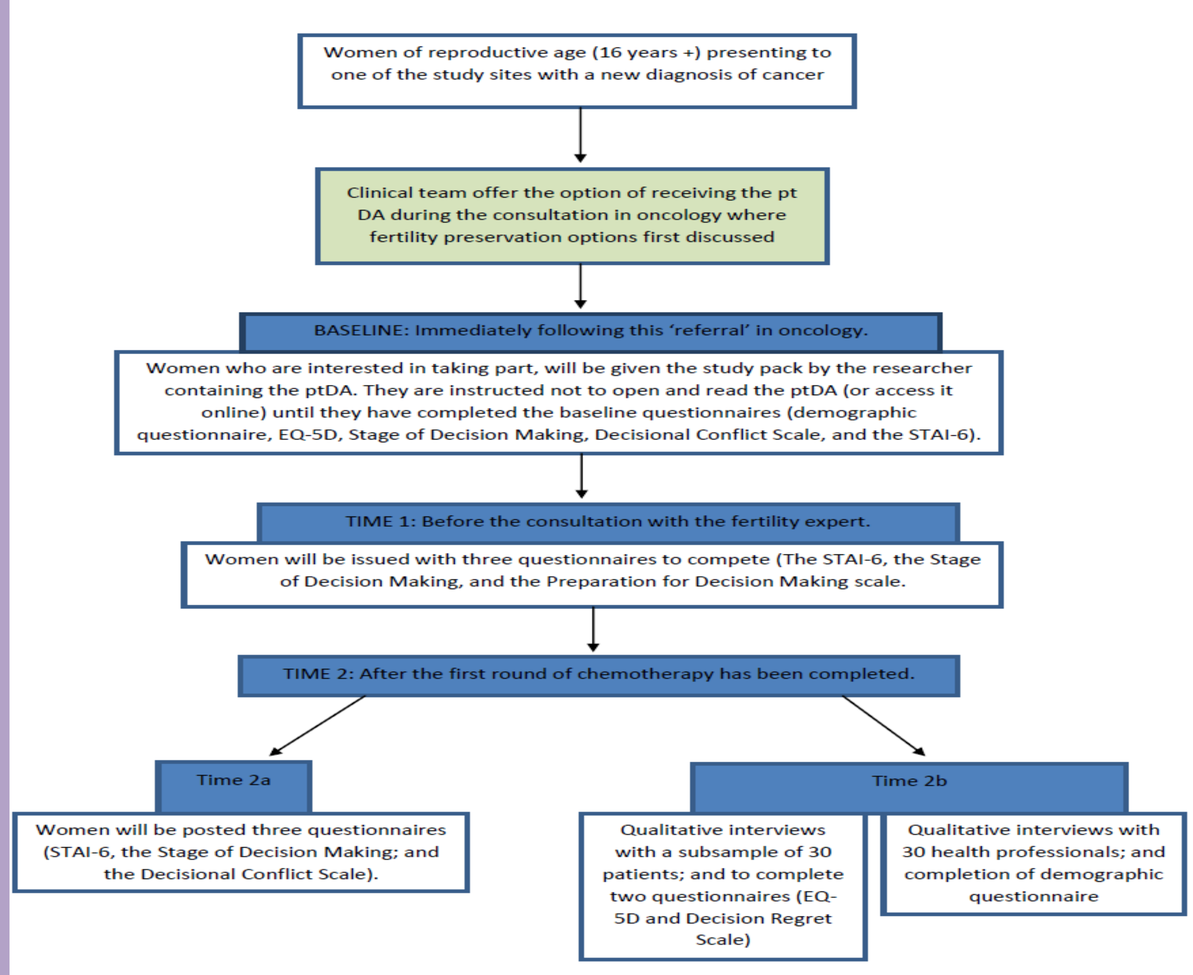
Design

A prospective, observational study using mixed-methods will be carried out across 3 stages, (table 1) to assess the ptDA's acceptability to women and professionals in usual cancer care and fertility service settings. Figure 1 shows the recruitment process, timings of the data collection and outcome measures to be used.

Ethical Considerations

Ethics approval was granted on 5th April 2016 (Ref: 16/EM/0122) and Health Research Authority approval on 20th June 2016 (Ref: 194751). The protocol is also registered with clinicaltrials.gov (ID: NCT02753296).

Figure 1: Process Flow Chart for Stage 3 Evaluation Study



The 'Cancer Fertility and Me' project

The aim of the project is to develop a ptDA to meet this patient need and enable cancer and fertility services to support women's fertility preservation decisions following a diagnosis of *any* cancer type.

Our objectives are to:

1. Develop a ptDA for use by oncology/haematology teams to support teenage and adult women (16 years +) making fertility preservation choices.
2. Assess the face validity of the ptDA to teenage and adult women with cancer and oncology, haematology and fertility health care professionals.
3. Evaluate its acceptability (using both qualitative and quantitative methods) to:

a) women making fertility preservation decisions whilst planning their cancer treatment,

b) oncology, haematology and fertility health professionals supporting women's oncology and fertility treatment choices.

The ptDA

The ptDA uses guidance from the International Patient Decision Aid Standards collaboration [4] on balance of options, risk presentation, elicit values, use patient stories, enabling readability, and understanding illness.

The ptDA will structure information to encourage women to evaluate all decision options and their consequences in accordance with their values without bias, and to make a decision based on their trade-offs between these evaluations, i.e. to make a reasoned decision.

The aim is for women to receive the ptDA from their cancer health care professionals as part of usual care on diagnosis of cancer and before referral to fertility services.

The ptDA is being disseminated as both a leaflet and PDF on a website, and evaluated accordingly.

Table 1: The three stages of the Cancer, Fertility and Me study

Stages	Aims	Methods	Sample	Data Collection	Analysis
Stage 1: Development of the ptDA Nov 2015- Jul 2016	The ptDA is being developed with the Cancer, Fertility and Me steering group across two regional cancer (adult, and teenage and young adult services) and fertility centres in Yorkshire (Leeds and Sheffield)	Identifying the active ingredients of the ptDA.	Study team, steering group, oncologists, haematologists, fertility experts, decision scientists, relevant charity organisations and service user panels supporting this study.	Systematic review. Environmental scan. Iterative development process.	
Stage 2: Face Validity Jul-Sept 2016	To assess the face validity of the ptDA across stakeholders for attractiveness, comprehension, cultural Acceptability, self-efficacy and persuasion	Quantitative Qualitative	10 women (5 from each site). 10 health professionals (5 from each site) + Women and key health professionals from the relevant user groups and organisations identified by The Cancer, Fertility and Me steering group and systematic reviews. The same 10 women and health professionals + Additional women and key health professionals described above	LV questionnaire (comprising of 4 items taken from the QQ-10 and some open questions), and the Preparation for Decision Making questionnaire. Semi-structured telephone interviews.	Thematic analysis
Stage 3: Evaluation Sept 2016- May 2018	To evaluates the acceptability, feasibility and usefulness of the ptDA in clinical practice. The study design employs both quantitative and qualitative methods to evaluate the ptDA with a women and health professionals (figure 1)	Quantitative (baseline, time 1, time 2a) Qualitative (time 2b)	78 women (in total from both sites). 30 women and health professionals (in total from both sites).	EQ-5D, State Trait Anxiety Inventory, Stage of Decision Making, Decisional Conflict Scale, Preparation for Decision Making, Count data Semi-structured interviews, EQ-5D, Decisional Regret Scale	Paired sample t-tests to calculate mean change in scores from baseline to time 1 and from baseline to time 2. Framework analysis

Implications

- To the best of our knowledge, this research will develop the first, open access, evidence-based fertility preservation decision aid that is suitable for women of reproductive age (16 years +) and diagnosed with any cancer.
- The research will provide evidence of its acceptability and utility to women and healthcare professionals in usual practice across cancer and fertility care pathways.
- The research will provide evidence for the causal assumptions of its effectiveness and issues for implementation in usual care practice.
- This research will not provide evidence of its effectiveness on healthcare outcomes. However, our findings will provide the evidence to inform the study design for evaluating the effectiveness of this complex intervention on health outcomes in the future.

References

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