Developing and Validating the Fertility Risk Detection Tool

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Introduction

The fertility rate of women and men has been declining in both developed and developing countries [1-6]. Around one in six couples is infertile [7, 8]. It takes couples 3.2 years to be diagnosed, a further 1.6 years before being assessed by a fertility specialist, and 2.2 years to get a baby [9, 10].

On one hand, the level and quality of the knowledge people have about their fertility health impacts their decision-making process in seeking a diagnosis and treatment [16-26].

On the other hand, assessing a patient's risk of infertility requires specific knowledge and consideration of multiple factors, including biological, hormonal, anatomical, lifestyle and environmental, that impact on a patient's and couple's reproductive ability.
General practitioners are often the first point of contact, however, don't always have access to adequate training in reproductive medicine to perform a detailed assessment and refer early to specialists [223]. There is also a vast array of clinical presentations and each patient   history is so specific and unique that assessing, managing and keeping track of each patient/couple unique factors is a complicated task [11-13].

Objective

To answer this problem, EFP developed the Fertility Risk Detection Tool (FRDT) aiming to help women and men:
- identify their fertility risk factors early,
- be better equipped to understand their diagnosis,
- and seek specialised medical assistance sooner

Method

An extensive literature review allowed us to draft the first version of the questionnaire. This was followed by expert validation where consultants in reproductive medicine were contacted (N=5) and asked to complete the FRDT, and to answer a questionnaire about the quality of the FRDT. They provided their opinion about the items' content, flow of the questionnaire, wording, and suggest improvements.

Interviews with patients who completed the questionnaire (N=16) were conducted to check the FRDT's comprehensibility, wording, inclusivity of the answer options, and relative appeal. Content analysis was conducted and improvements made to the assessment tool.

A total of 265 patients/couples had completed the final version of the questionnaire in July 2021.

Results

The FRDT questions related to **female health** include the following categories [14-120]: contextual questions, cycle and ovarian reserve, gynaecological history and health, genetic predisposition, intake of supplements, lifestyle choices and behaviours, environment.

- **Female health example-item:**

What is your level of Progesterone P4 (day 21)?*

*Progesterone belongs to a group of steroid hormones called progestogens. It is mainly secreted by the corpus luteum in the ovary during the second half of the menstrual cycle. It plays important roles in the menstrual cycle and in maintaining the early stages of pregnancy. It is shown as ng/ml.

- A *Haven't tested or don't know.*
- B *Less than 5 ng/ml.*
- C *Between 5 and 20 ng/ml.*
- D *Above 20 ng/ml.*

The FRDT questions related to **male health** include the following categories [121-222]: contextual questions, sperm and male health, genetic predisposition, lifestyle choices and behaviours, environment.

- **Male health example-item:**

What is your sperm progressive motility?*
*Sperm progressive motility refers to sperm that is moving forward.

- A *Haven't tested or don't know.*
- B *At least 32%.*
- C *Less than 32%.*

In total there are 90 questions. We were able to determine the weighting of each question, based on the relative size of factors' impact and frequency.

After answering to the FRDT, patients access the Patient Portal, which consists of an AI-driven dashboard, that processes their answers and allows patients to visualise their results in a meaningful way, as well as receive personalised care recommendations.
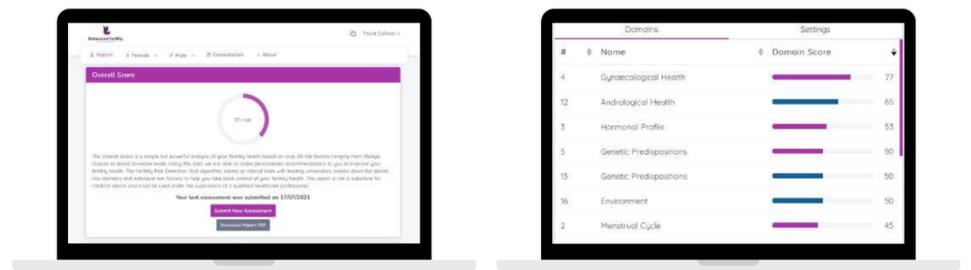
Apart from guiding patients, the FRDT can also assist clinics, physicians, consultants, and other medical professionals decide which treatment is most likely to give a specific couple a positive outcome, by providing a summary of information like overall assessment, diagnostics, risk factors, and need for emotional support.

Future research

In the future it would be interesting to investigate whether treatment outcomes are related to fertility risk factors. It would also be interesting to assess the use of Artificial Intelligence and Machine Learning as a way to predict treatment outcomes based on specific risk factors.