

Lay Persons Views on Current and Novel Methods of Fertility Assessment and Supporting Conception: A Qualitative Study

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Abstract

Background

There is an ongoing trend towards delayed childbearing; 1 in 6 couples suffer from subfertility. For couples needing IVF, one factor hindering advances in this area is lack of knowledge on in-vivo uterine conditions. A novel intrauterine sensor is currently under development to measure the intrauterine environment, as an innovative means of fertility assessment. Our study explored women's views of current and novel methods of fertility assessment.

Methods

A qualitative study was performed. A purposeful sampling method was used to recruit participants from public spaces within Southampton. Women were eligible if they were of reproductive age, planning a pregnancy, nulliparous and not undergoing clinical investigation/fertility treatment. Semi-structured interviews explored pregnancy planning, understanding and experiences of current/novel methods aiming to assess and improve fertility. Interviews were conducted until data saturation was reached (n=16). Inductive thematic analysis was performed.

Results

The main factors influencing the decision of when to 'start trying' were education, financial stability and relationship status. Pregnancy was seen as a 'physiological' event without the need for intervention. Participants lacked knowledge of fertility indicators and had limited knowledge of available products to assess fertility/support conception. Although participants generally perceived a novel intrauterine sensor as acceptable and valuable, the main concerns centred around invasiveness, safety and discomfort.

Conclusions

When developing a novel medical device, healthcare professionals should be aware of the user's knowledge and views at each stage. A clear added benefit over conventional methods is needed and addressing invasiveness, safety, and comfort may improve the acceptability of the device.

Background

Most adults have life plans which include having children, however, there is an ongoing trend towards delayed childbearing; 1 in 6 couples will have fertility problems at some point in their lives. There is an increasing exposure to a multitude of fertility compromising risks, including obesity, sexually transmitted diseases and increased maternal age (1), delay in health-seeking behaviours when fertility problems arise (2), and high discontinuation rates from fertility treatment (3, 4).

There are many products on the market available to couples, aimed to support fertility (e.g. ovulation kits, sperm motility supporting lubricants). Innovation has also led to a flurry of available methods of fertility

assessment, and the number of people who can benefit from these continues to grow. Although studies have assessed awareness, knowledge and perception of fertility amongst the general public (5, 6), medical students (2, 5) and healthcare professionals (7, 8), there is a paucity of research focusing on knowledge and views of fertility assessment tools.

Reproduction at older ages remains an area of major concern with ongoing challenges for assisted reproduction (9). For those who fail to conceive naturally, an important component of gamete handling in in-vitro fertilisation (IVF) is striving to mimic the in-vivo environment. One factor hindering advances in IVF is lack of knowledge on actual in-vivo uterine conditions, namely oxygen concentration, pH and temperature (10). The University of Southampton and VivoPlex Medical Ltd have developed an intrauterine device (IUD) with the ability to measure biophysical parameters of oxygen, temperature and pH as a novel method of fertility monitoring. This is a small battery-less device which can be inserted inside the women's uterus for a period of time (up to 7 days) with the aim of tracking the intrauterine environment in real time.

The two components of the system are a sensor assembly and a wearable assembly. The sterilized sensor assembly consists of a small, T-shaped, flexible device (Figure 1) (VivoPlex, University of Southampton) and an 'inserter' accessory that a clinician would use to insert the device. The sensor device uses sensing technologies designed to cause minimal disruption to the biochemical environment of the intrauterine space. The device is designed to replicate the format and dimensions of market leading contraceptive IUDs and therefore benefits from the long standing, positive clinical experience gained from intrauterine contraceptive devices as well as their good safety profiles and high customer acceptance. When inserted into the uterus, the device is dormant until it receives wireless electrical energy from the wearable device assembly (Figure 2) (VivoPlex, University of Southampton) worn by the patient. When powered, the device measures and communicates the measured parameters to the wearable device.

A common pitfall in the development of a new medical device is that the views of the healthcare professionals are sought and less focus is placed in identifying patient/user perspectives (11). Potential user's views on a novel method of assessing fertility is crucial prior to the development and delivery of clinical research trials. The main reason for lack of patient and public involvement is the limited availability of resources, namely time, money and labour (12). Users can be and should be involved in all four stages of the medical lifecycle; these are concept, design, testing and trials, and production stages (11). Potential users' knowledge and perception of fertility assessment tools at the 'concept' and 'design' stage can inform further stages of the novel device development, increasing the functionality, usability, quality and safety of the device (12, 13).

Here, we adopt a qualitative approach in order to explore (i) women's views and experiences of pregnancy planning, (ii) their views on currently available methods of fertility assessment/improvement as well as (iii) their views on the aforementioned novel intrauterine monitoring device as a method of fertility assessment. This study is important to inform clinicians and scientists involved in the development of

novel diagnostics or therapeutics in the field of reproductive medicine, and highlight the public/ potential user's views in methods designed to support conception.

Methods

Study design

A qualitative study design was used enabling us to capture rich data on a sensitive topic of fertility and pregnancy planning.

Patient involvement

Women who attended the local fertility centre open evening were involved in the design and conduct of this research. They were central to the design of the semi structured interview schedule which was used to perform qualitative research in this study.

Participant recruitment and screening

Recruitment took place between July 2016 and February 2017. A purposeful sampling method was used in order to capture a range of participant characteristics. Recruitment flyers were distributed and displayed in public spaces at the University of Southampton buildings, community areas, including bus stops, libraries and gyms across Southampton. We also distributed the recruitment flyers online via social media. Women who volunteered to take part in the study were eligible if they were aged 18-45 years, nulliparous, planning a pregnancy in the next 10 years and not undergoing clinical investigation/fertility treatment.

16 women took part in the study; the characteristics of the participants are summarised in table 1. The mean age of the women was 27.3 years (range 23-44 years, standard deviation 4.9 years). 68.8% (n=11) of the women were White British. The other 5 participants were Black Caribbean (n=1), Black British (n=1), Russian (n=1), Mixed (n=1) and Indian (n=1). 6.3% (n=1) had completed A-levels only, 68.8% (n=11) had completed an undergraduate degree, and 25% (n=4) had completed a Postgraduate degree. 18.8% (n=3) of the women were single, 55% (n=9) in a stable relationship or engaged, and 25% (n=4) married. 25% (n=4) of the participants were intending to try for a baby at some point, but not in the new few years. 62.5% (n=10) of the participants were intending to try for a baby in the next few years, but not actively trying right now. One participant (6.3%) was actively trying for a baby and one participant (6.3%) was actively trying for a baby and seeking help from a healthcare professional because of concerns with fertility.

Interviews

16 semi-structured interviews were performed. Interviews were conducted face-to-face between September 2016 to March 2017 by co-authors KYBN and MG. There were no pre-existing relationships between the interviewers and interviewees. The interviews were subdivided into four main sections: (i) demographic

information, (ii) pregnancy planning, (ii) knowledge and experience of products aimed at improving fertility and supporting conception and (iv) views on a novel IUD aimed at assessing and improving fertility assessment (please see Appendix A for interview schedule). Each interview lasted 30-60 minutes and were digitally recorded, Data analysis and recruitment ran concurrently with recruitment ceasing when data saturation was reached.

Data analysis

Participants' demographic data were summarised using descriptive statistics. Each interview was transcribed verbatim and verified for accuracy. We used a thematic analysis approach to data analysis (14); this is a technique that provides a robust procedure for extracting salient aspects of the data and organising it into coherent and meaningful themes. We used an inductive form of thematic analysis whereby the analysis was led by the content of the transcripts rather than pre-defined categories or theoretical frameworks. All transcripts were read for familiarisation and notes of initial possible codes were made. In the second round, the content was coded and themes and code structure was developed. It was used to develop coding manual and then used to apply codes to remaining transcripts. Initial coding was discussed and the next round of coding by a second coder was completed. Development of the coding manual (see Appendix B) and the initial analysis was carried out by KYBN and MG. These findings were discussed with LD, a health psychologist with qualitative research expertise and YC, a Professor and Consultant in Reproductive Medicine. Following the discussion and a few further iterations, a final model organising identified themes was developed.

Ethical considerations

This study received local University of Southampton ethics approval through Ethics and Research Governance Online (ERGO) (ERGO ID number 20758). The University Faculty of Medicine ethics committee has provided competent, rigorous and independent process for ethical review of this study. The study design and interview schedules have been reviewed, thus ensuring rigor and trustworthiness of our qualitative study. All participants gave written consent prior to being interviewed.

Results

There were nine key themes identified in the analysis. Figure 3 presents these themes and their possible inter-relationships. The themes 'stage of trying for a baby', 'knowing about my fertility' and 'best age' were linked to pregnancy planning. The themes 'time to ask for help' and 'fertility assessment tools' were linked to knowledge and experience of products aimed at improving fertility and supporting conception. 'New knowledge' and 'concerns' were linked to views on a novel IUD aimed at assessing and improving fertility assessment. Below, each theme is briefly described along with illustrative quotes from participants.

Fertility and conception

Stage of trying for a baby. Current stage of trying for a baby seemed to be central for women's opinions and experience regarding various aspects of fertility and conception. Women who had not started trying yet were more likely to assume natural conception and had limited knowledge about their fertility. Those who already started were more aware of fertility issues and appeared more likely to try various methods of fertility assessment, should they have problems conceiving naturally within certain timeframe (generally 6-12 months). Stage for trying for a baby seemed to be linked to participants' age and life stage and had impact on knowledge about fertility, fertility assessment tools, and their opinions about the novel device.

Knowing about my fertility. Generally, women described a low awareness of their own fertility as well as its indicators.

I don't think you can ever really know. I think it's very difficult to know if you're somebody who's very fertile or not fertile. [Participant 9]

However, some participants believed that they could draw conclusions about their fertility in the context of age, general health, having healthy lifestyle, lack of family history of fertility problems and lack of negative symptoms.

I think it would be really shocking if I couldn't get pregnant. I think I'm just assuming, naturally that I'm going to have no problems with it ... I consider myself a relatively healthy person, and Josh is a relatively healthy person and there has been, as far as I'm aware, no problems in our families. So, I think it would be a bit of a shock, and my opinion might change if I found out that I couldn't get pregnant, because I'm so desperate for children. [Participant 11]

Best age. The perceived 'ideal age' for trying to have a baby was much lower than the 'realistic age', which was often linked to having a stable relationship, career and financial situation.

Participants linked age to prediction of possible conception difficulties, as one of them explained: *I don't want my biological clock to run out [Participant 7]*. There was also a minority voice that there was no 'best age'. Some of the participants declared that age was one of the factors that would determine whether they sought medical help for trying to get pregnant.

Time to ask for help. Most participants saw conception as a 'physiological' process and that falling pregnant should preferably be achieved naturally. Self-help methods to enhance fertility known by participants included herbal/dietary supplements, having regular intercourse around ovulation time, and using acupuncture. Most participants did not know what their fertility chances were and were unsure when to ask for professional help.

But, yeah, in all honesty I wouldn't know whether or not (I'm fertile) unless we'd, you know, had that check before... [Participant 2]

I think I don't really know that much about that (my fertility). I think when I saw my gynaecologist, but it was a couple of years ago, he said that I'm healthy and should be okay. [Participant 4]

A third of participants said that they would seek medical help if they had been unsuccessful in conceiving after specific time (mostly one year or six months) of trying. Participants who had passed their perceived 'best age' or who have medical histories would consider seeking help much earlier, even before actively trying to conceive. The GP was the first person they would contact. Participants felt that intrusive tests are necessary only if fertility issues become apparent once the couple starts trying. There was also a voice that adoption may be an alternative option.

I mean I want a child in my life...but I wouldn't be averse at all to adopting... So, I would say within a year I'd be more likely to go down the adoption route rather than any kind of invasive methods. [Participant 11]

Fertility assessment tools. Participants' knowledge about available products to assess fertility or support conception was limited. Most of participants were not aware of commonly available methods of assessing fertility.

All I basically know is like old wives' tales and over-the-counter things, but I've never really taken that seriously. I don't know if that actually has any effect. [Participant 1]

Of the very few participants who mentioned ovulation kits, majority reported lack of knowledge regarding how they worked, but most knew that they played a role in assessment of ovulation time. A few participants used these kits or knew someone who had. Several participants mentioned ovulation apps, using the Internet sources, observing physiological changes over the cycle, or tracking cycles to determine the ovulation time and to enhance chances of getting pregnant. One of the participants' partners had used an off the shelf 'sperm count' kit. Others were aware of additional medical tests which may be available on referral to a fertility specialist.

Novel intrauterine sensor fertility device

The opinions about the device seemed to be impacted mainly by the current stage of trying for a baby and participants' knowledge about fertility assessment tools. Participants generally perceived an intrauterine novel device monitoring the womb environment as acceptable and potentially valuable in the fertility assessment. The majority of participants would only consider the device after a period of trying to conceive and had been unsuccessful, *"I guess it seems a bit drastic if you haven't tried to conceive yet because it's almost like an extra level of detail you don't really need to know"* [Participant 9]. As described earlier, participants felt that pregnancy and conception should ideally be 'natural'. 'Medicalising the process' is generally considered appropriate only when problems arise.

Concerns. Concerns about the novel device focused on discomfort, pain, safety and invasiveness. Participants were particularly concerned about pain and discomfort around the time of the device insertion and removal. Participants also felt that size of the device was important factor affecting acceptability. Participants preferred shorter durations of insertion, i.e. days rather than weeks/months, as

they felt that this would minimise the potential risks. Participants perceived increased acceptability if the procedure for insertion/removal was quick, was done in an outpatient setting and/or performed by a medical professional. As one participant said:

If it's not really having an impact on your life, it's not a big procedure, then I think that would be a lot more acceptable to women and their partners in that situation. [Participant 9]

Participants expressed a need to be reassured about the safety of the device and had concerns surrounding potential risks (e.g. infection, damage to the integrity of the womb) and risks to their future pregnancies/babies. Participants compared the device to an intrauterine contraceptive device and recognised that the proposed novel device was an *'invasive tool'*. They had concerns that the device (perceived as a *'foreign body'* by some), would *'interfere'* with physiology or translate to a higher degree of risk than other *'non-invasive methods'*. However, one participant felt that the nature of the device was *'less invasive'* than current methods of assessment:

"Well it's less invasive than an exam, I guess at the moment, the other option is to have a camera on a stick...having something (device) up there for a couple of days, you'll get a lot more information"
[Participant 16]

New knowledge

Participants expressed a need to understand/be reassured about the relative added benefit compared to conventional methods. The potential addition of *'new knowledge'* from this novel device was attractive and there was the expectation that the information obtained would complement current investigations, e.g. a blood test or scan. They were interested in the accuracy and the translational benefit of the result specific to the individual, particularly when there are problems with conception or maintaining a pregnancy. Interestingly, most participants did not grasp what factors the novel IUD would measure to determine the womb environment. Some suggestions included the *'thickness of the womb'*, *'damage to the womb'*, *'hormones'*, *'timing of ovulation'*, *'various chemicals'*, *'ph'* and *'temperature'*. Participants felt that measurement of the womb parameters by the use of the local device is more valuable.

It may be that if it's (the device is) inside, it's getting better readings and accurate results... maybe because it's in a specific area, you're looking at more specific information. [Participant 15]

Participants generally expected the results generated from the novel device to be interpreted, and translated to clinical relevance and then communicated to the couple by a doctor or medical professional. Participants were more likely to find the idea of the device acceptable and useful the device if obtaining new knowledge from the device was going to help with treatment decisions or options; they saw benefits or potentially more streamlined and personalised care.

I think if it could give accurate results and those results were helpful in solving problems that women had, I think it could be a good idea. [Participant 15]

It was evident that the decision whether or not to accept the use of the novel device was a balance between the perceived benefits and risks.

Discussion

This was the first qualitative study to explore how women think and feel about current methods of fertility assessment and supporting conception, as well as their views on a novel intrauterine method of fertility assessment.

This study showed how the acceptability of any fertility assessment method seems to depend primarily on the individual's experience of trying for a baby. The assumption that lack of negative health symptoms indicates lack of fertility issues and therefore no expectations of any 'problems with conception' may limit willingness to engage with any fertility assessment method at early stages of pregnancy planning. Willingness to try different methods appears to increase as women move from consideration stage, to the stage of actively trying for a baby. However, non-invasive or natural methods are still likely to be chosen over the more invasive ones. The latter has been linked to medicalisation of the conception process which was expected to occur naturally.

The low regard for fertility, presumed lack of difficulties in getting pregnant in the future and limited knowledge in fertility assessment all contribute to delay in seeking professional help. Other studies have consistently identified deficiencies in the knowledge of factors potentially impacting on women of reproductive age (15, 16). Women's willingness to accept fertility assessment methods may be low, especially before or at early stages of trying for a baby, regardless of the method's usefulness. The expectation of the ease of natural conception and their reluctance to accept fertility assessment methods may lead to advanced maternal (and paternal) age. Delayed childbearing is rarely a conscious choice and women are usually unaware of it, however, has been associated with poorer pregnancy outcomes as well as reduced chances of natural or assisted conception (17). Women tend to underestimate the role that age plays in fertility (15), and overestimate the abilities of assisted reproduction to compensate for the declining fertility with older ages (18).

Limited knowledge of existing fertility assessment methods, tools and lack of understanding on how they may work contributes to lack of understanding on how the proposed novel device might help as a fertility diagnostic tool. This, in turn, may increase future users' anxiety and reluctance to use the device. Trials to confirm biocompatibility and safety of the device, as well as clearly stated conditions of its use (e.g. suspending trying to get pregnant for the time of assessment) would provide reassurance. This result is in line with exploration of usefulness of pre-IVF counselling, where providing technical explanations was one of its helpful aspects (19).

The invasiveness of the device can be a main barrier to its acceptance of our novel fertility assessment tool. Patients have been shown to be less accepting of invasive diagnostic methods in other conditions such as coronary artery disease and oesophageal varices (20, 21). Providing clear explanation about the benefits of the device and its advantages over other available methods seems to be crucial for women

when they are asked to consider using the novel IUD. Discussion of its indication, risk and benefits in the context of supporting successful conception is also essential.

Study implications

The study is the first to investigate the perception and acceptance of a novel intrauterine fertility monitoring device. It helped in understanding the context in which the decision to use the device would be considered by women. It also provided information about potential barriers to the device acceptance. The analysis of the interviews allowed formulation of recommendations for researchers and clinicians introducing the device to the patients in future research trials.

This study also demonstrated the usefulness of the methodological approach to elicit users' views in the specific context. This can guide the design of further studies exploring patients' experience in the subsequent stages of the device development.

Study limitations

Although the thematic analysis was performed by two researchers, the qualitative nature of this study means that the data gathered is likely to be subjective, and therefore lacks generalizability. Participants recruited to the study were similar in their socio-economic status and stage of pregnancy planning. Therefore, our population may not be a true reflection of the views of the general public.

Future studies should consider including women from a wider socio-economic background and those experiencing difficulties with getting pregnant to assess the acceptability of the method in wider population as well as in the subfertility population where the use of the novel device may seem more relevant.

Conclusions

Women in our cohort lacked awareness of fertility indicators, and presumed that they would conceive 'naturally'. In general, there was a limited understanding and experience of current methods of fertility assessment. It was apparent that a novel intrauterine method of fertility assessment was more accepted by women if they transitioned from a period of 'natural conception' to 'seeking professional help for conception'. When developing novel methods of fertility assessment, a clear added benefit over conventional methods is needed and safety, comfort and invasiveness need to be addressed. Future studies may assess the views of women who are suffering from reproductive failures, e.g. infertility or recurrent miscarriages as part of development of a novel medical device prior to clinical trials.

Abbreviations

IVF – In Vitro Fertilisation

IUD – Intrauterine Device

Declarations

Ethics approval and consent to participate

This study received local University of Southampton ethics approval through Ethics and Research Governance Online (ERGO) (ERGO ID number 20758). The University Faculty of Medicine ethics committee has provided competent, rigorous and independent process for ethical review of this study.

Consent for publication

Not applicable. Our manuscript does not contain data from an individual person. Participants of this study have provided written consent for publication of anonymised quotes from the interviews.

Availability of data and materials

Data are available upon reasonable request. Further anonymised qualitative accounts may be available upon reasonable request by emailing the corresponding author.

Competing interests

Professor Ying Cheong is a co-founder of VivoPlex Medical Ltd.

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Author Contributions

KYBN, MG, LD and YC designed the study. KYBN and MG recruited the participants, conducted the interviews and performed thematic analysis. KYBN and MG wrote the initial manuscript and all authors contributed to the final version.

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Tables

Table 1 Table of characteristics for each participant. In relation to the pregnancy plans, '1' is intending to try for a baby at some point but not in the next few years, '2' is intending to try for a baby in the next few years but not right now, '3' is trying for a baby and '4' is trying for a baby and seeking help from a healthcare professional due to concerns with fertility.

Participant	Ethnicity	Highest Education	Relationship status	Pregnancy plans
1	White British	Masters	In a relationship, living apart	1
2	White British	Masters	Married	2
3	White British	Undergraduate	Single	2
4	White British	Masters	Married	3
5	Indian	Undergraduate	In a relationship, living apart	2
6	White British	Undergraduate	Engaged	4
7	White British	Undergraduate	Married	2
8	Russian	Undergraduate	In a relationship, living together	2
9	White British	Undergraduate	Engaged	1
10	Mixed	A-level	In a relationship, living apart	2
11	White British	Undergraduate	Married	2
12	Black British	Undergraduate	In a relationship, living together	2
13	White British	Undergraduate	Engaged	2
14	Black Caribbean	Undergraduate	Single	1
15	White British	Masters	Single	2
16	White British	Masters	In a relationship, living apart	1

Figures



Figure 1

Prototype of the sensor device.



Figure 2

Design of wearable assembly.

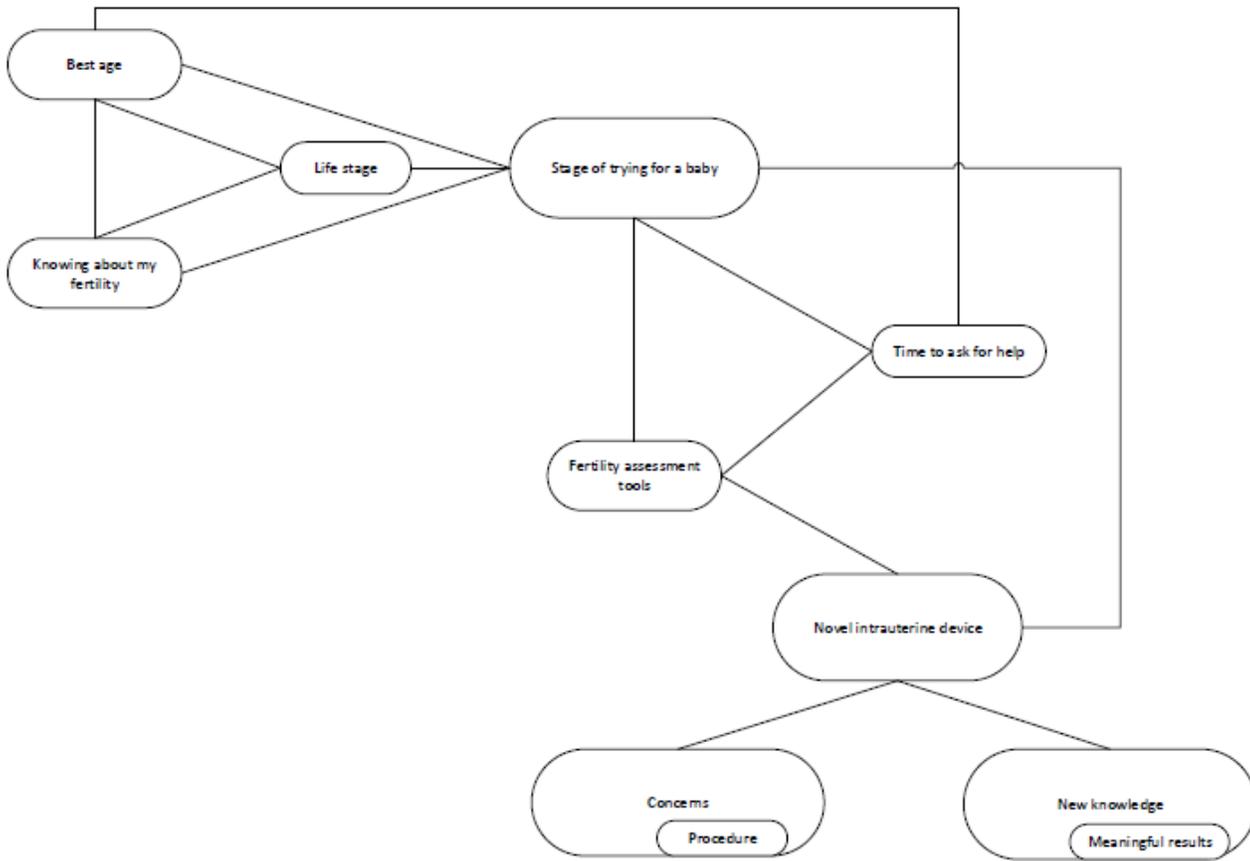


Figure 3

Model of themes identified in the analysis of interviews