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VALUE study: a protocol for a qualitative semi-structured interview study of IVF add-ons use by patients, clinicians and embryologists in the UK and Australia

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ABSTRACT

Introduction For couples undergoing assisted reproduction, a plethora of adjuncts are available; these are known as 'add-ons'. Most add-ons are not supported by good quality randomised trial evidence of efficacy, with some proven to be ineffective. However, estimates suggest that over 70% of fertility clinics provide at least one add-on, often at extra cost to the patient. This study has three aims. First, to undertake a survey of in vitro fertilisation (IVF) clinics in the UK to ascertain which add-ons are being offered and at what cost. Second, to undertake qualitative semi-structured interviews of patients, clinicians and embryologists, to explore their opinions and beliefs surrounding add-ons. Third, to review the interpretation of the Human Fertilisation and Embryology Authority traffic light system, to better understand the information required by IVF patients, clinicians and embryologists when making decisions about add-ons.

Methods and analysis All UK IVF clinics will be contacted by email and invited to complete an online survey. The survey will ask them which add-ons they offer, at what cost per cycle and how information is shared with patients. Semi-structured interviews will be conducted in the UK and Australia with three groups of participants: (i) fertility patients; (ii) clinicians and (iii) embryologists. Participants for the interviews will be recruited via social media channels, website adverts, email and snowball sampling. Up to 20 participants will be recruited for each group in each country. Following an online consent process, interviews will be conducted via video-conferencing software, transcribed verbatim and data subjected to inductive thematic analysis.

Ethics and dissemination Ethical approval has been granted by the Universities of Sheffield, Bath Spa and Melbourne. Findings will be published in a peer-reviewed journal and disseminated to regulatory bodies in the UK and Australia. A lay summary of findings will be shared via Fertility Network, UK.

Strengths and limitations of this study

- VALUE is the first study to explore, through in-depth, semi-structured qualitative interviews, the driving factors behind the use of in vitro fertilisation add-ons by patients, clinicians and embryologists.
- Early and in-depth patient and public involvement was used to ensure the study's acceptability, use and relevance to the target population.
- Purposive sampling in two different healthcare systems, encompassing both private and state funded fertility services will be conducted to capture a wide range of patient, clinician and embryologist experiences.
- We will mitigate the risk that interviewees adjust their responses in light of interviewers being medical professionals working in fertility, by training interviewers and highlighting their neutrality at the start of the interview.
- Recruitment via social media may limit the recruitment to a particularly motivated, engaged and media literate group of participants.

INTRODUCTION

Undergoing fertility treatment can involve physical, mental and financial stress, with patients often desperate to explore any options which might confer greater chance of treatment success. Over recent years there has been an increase in medical and non-medical in vitro fertilisation (IVF) treatment adjuncts available; these are commonly known as 'add-ons'.[1]

The UK regulatory body for assisted reproduction, Human Fertilisation and Embryology Authority (HFEA) describes add-ons as 'optional extras you may be offered on top of your normal fertility treatment, often at an additional cost. They're sometimes emerging techniques that may have shown some promising results in initial studies, or they may have been around for a number of years, but haven't necessarily been proven to improve pregnancy or birth rates'.[2] In some

cases, add-ons have become 'routine practice', with costs embedded into the fertility package fee as opposed to being charged in addition. For example, embryo incubation using time-lapse technology is routine in some centres, and is optional in others.[3]

Assisted reproduction is a fast-paced area of medicine, with growing demand for treatment, accompanied by rapid innovation.[4] There is growing recognition from the assisted reproduction community of the paucity of evidence surrounding the use of add-ons, most add-ons are not supported by good quality randomised trial evidence.[2 4 5] There has been much speculation and interest in the driving forces behind add-ons' popularity, both factors of supply (IVF clinics offering or advertising add-ons) and demand (IVF patients requesting add-ons).[6–9] However, thus far, there has been no research specifically focused on why patients, clinicians and embryologists opt to offer or use them. There is a lack of research into the views of these groups, particularly surrounding their interpretation of evidence of efficacy of add-ons, and information sources for decision-making about their use.

The HFEA have provided a website designed for patients regarding add-ons, with a traffic light rating of red, amber and green to denote the quality of evidence on efficacy and safety of use. However, there is little information about the utility of this system, and how patients interpret the different traffic light colours. For patients in Australia, there is no such similar patient directed website.

The practice of medicine rests open three main principles of ethics. First beneficence (the moral obligation to act for the benefit of others), second non-maleficence (requires that medical professionals prevent harm to the health and well-being of patients) and third autonomy (patients have a right to self-determination, or choices in their care). IVF add-ons raise an interesting ethical dilemma, given that add-ons have not been conclusively proven to make IVF more effective, or reduce the risk of harms, such as miscarriage. However, denying a patient's autonomy in opting to use add-ons may also be seen as unethical.[10] In order for autonomy to be executed, the patient must have informed consent, that is, an understanding of the potential benefits and risks of any given add-on.[11]

The VALUE study is important because it will help inform how patients, clinicians and embryologist weigh up the factors that relate to these three pillars of medical ethics when thinking about their experience of using add-ons. It will also explore what information is important to these three stakeholder groups when participating in informed consent. It is hoped that the information from VALUE will support caregivers to provide the best possible ethical care to their patients, and improve the quality of the informed consent process for patients to better support them in making informed decisions.

Aims

This study aims to first undertake a survey of IVF clinics in the UK to ascertain which add-ons are being offered and at what cost to the patient. Second, through qualitative semi-structured individual interviews of assisted reproduction patients, clinicians and embryologists, it will then explore the opinions and beliefs surrounding add-ons and any evidence for efficacy. Finally, the interviews will also be used to review the interpretation of information provided by regulatory bodies in order to optimise provision of information for these groups when making future decisions about IVF add-ons.

Objectives

1. Provide information on availability of add-ons in UK and the costs that are charged for them.
2. To understand how people make decisions about using or recommending IVF add-ons.
3. To understand where information about add-ons is sought, and to understand the role and importance of information such as safety and effectiveness when considering their use.
4. To explore participants' understanding and interpretation of the HFEA traffic light system for add-ons.

METHODS AND ANALYSIS

Study design

Part 1: UK clinic survey

A list of all licensed IVF clinics in the UK will be compiled using public data from the HFEA website.[12] Then, the medical director of each clinic will be contacted and invited to complete an online survey. The online survey will ask the following questions: (i) number of IVF and intracytoplasmic sperm injection (ICSI) cycles performed in year January 2019–January 2020; (ii) whether the clinic treats National Health Service (NHS) and/or private privates; (iii) which add-ons they offer at their clinic; (iv) the cost per-cycle to patients for the use of each add on; (v) whether written information regarding add-ons is offered, and the form of this information (ie, published by the clinic, or published by Industry) and (vi) whether any of the listed add-ons are included as part of an NHS funded cycle, or a private cycle (ie, are used routinely). The clinic survey is only taking place in the UK because a similar survey has already taken place in Australia.[13 14]

In order to improve the response rates, we will use an evidence-based strategy of survey recruitment. A prenotification email will be sent to the medical director 1 week prior to the survey opening outlining the survey and informing them that following completion of the survey they can choose to be entered into a prize draw for three £50 Love2shop vouchers. One week later the link to the survey will be emailed with a follow-up email at week 2. In week 3 or 4 we will send a further follow-up email and phone call to the clinic. In week 6 the survey will close and the prize draw winners announced. Those who complete the survey will be sent a follow-up email thanking them,

and asking if they would be happy to share their patient information leaflets on add-ons with us.

Part 2: qualitative in-depth semi- Research Ethics approval was not required for the PPI interviews

Interview schedule design

The interview schedule was iteratively developed with our patient and public involvement (PPI) group and is underpinned by preidentified domains of interest within the academic and grey literature: (i) sources of information; (ii) the decision-making process and (iii) importance of evidence. The HFEA 2018 pilot national fertility patient survey[15] revealed important areas where information on add-ons is lacking including where patients seek information from, whether information on the efficacy, cost-effectiveness and side effects of add-ons is provided. Through our semi-structured interview design, we will therefore explore participants' personal experiences in deciding whether to use or offer add-ons. We will explore factors that are important to them in making this decision and their sources of information as well as explore how participants in the UK and Australia interpret the HFEA's traffic light system and its role to guiding decision-making around add-ons.[2]

Patient and public involvement

PPI has taken place to tailor the study design to ensure it is addressing important research questions and that the study materials are presented in a clear and understandable format. A 'study-focussed framework' will be supported, whereby two patients will follow the research cycle from initial PPI stages through to disseminating findings and achieving impact.[16]

The PPI process included patients, clinicians and embryologists with two PPI groups in both the UK and Australia. PPI sessions were conducted separately in the UK and Australia due to subtle differences in demographic questions. Due to concerns about a power dynamic between professionals and patients possibly preventing participants from feeling able to free express themselves[17] we held one focus group for patients in each location and a separate group for clinicians and embryologists. Participants were recruited through social media and engaged in an hour-long teleconference with other panel members and the research team. Each participant was provided with a draft set of interview questions ahead of the meeting and were asked to comment on them during the teleconference. In addition, they were asked to review the consent form, the information sheet and the study website. A series of questions about the coordination and practical running of the study were also posed.

The teleconferences were recorded following agreement from participants and followed strict General Data Protection Regulation (GDPR) guidance. Participants were offered either a £20 love2shop e-voucher or a $50 Australian supermarket voucher as a thank you for their time. All participants consented to being acknowledged in resulting publications.

Patients PPI

Two patient participants were sought in each country and patients were required to have undergone assisted reproduction (IVF or ICSI) in the past 2 years.

As a result of patient PPI, the wording of some of the qualitative questions was altered, and prompts were added where necessary. The panel felt that the patient interviews should be divided in two to enable time for the participant to browse the HFEA website prior to questions on this topic. The feedback was that asking the participant to familiarise themselves with the website during the hour-long interview was too stressful and would put the participant under undue pressure. The panel was in agreement that two shorter interviews were no more onerous or inconvenient than 1-hour long interview. In response to feedback, a table of 'commonly used terms' was added to the preinterview demographic questions (table 1) and the website was altered slightly to improve readability.

Embryologists and clinicians PPI

A minimum of two embryologists and two clinicians in each country were sought for PPI. Professional databases were checked to ensure that those taking part were registered doctors or embryologists delivering fertility treatment in the UK or Australia. In the UK, two embryologists and one reproductive medicine specialist doctor joined the teleconference, and a separate teleconference was undertaken with one other reproductive medicine specialist doctor due to clinical commitments. In Australia, one PPI panel was convened, consisting of two embryologists and two reproductive medicine specialist doctors.

As a result of PPI, the preinterview demographic questions were altered to accurately reflect clinicians' job titles and questions regarding ethnicity and religion were removed. Following panel input, the questions were reordered to improve the flow of the interview and the wording of some questions changed to remove any negative connotations towards add-ons. In addition, lay descriptions of add-ons were added to the website following feedback that this would enable patients to more easily identify which add-ons they had used or considered. This panel explained that part 1 and part 2 of the interview should not be split into two separate interviews for because it was too time consuming and may deter clinicians and embryologists from participating. The feedback was that being given the chance to look at the HFEA website prior to the interview would be preferable to being asked to look at it mid-interview. The study protocol has been altered to reflect these changes.

VALUE study eligibility criteria

Inclusion criteria

Patients

Adult women, men or couples (18+ years of age); who have undergone IVF or ICSI in the past 2 years (any number of cycles); publicly funded (NHS funded in the UK, or Medicare in Australia) or privately funded; using

Table 1 Table of commonly used terms

Term we use	What it stands for	Description of term
IVF	In vitro fertilisation	The process of stimulating the woman's ovaries, collection of eggs, mixing of egg/s with sperm to make embryos, incubation of embryos and replacement of embryos into the woman.
ICSI	Intracytoplastic sperm injection	The process described above, except instead of mixing the woman's eggs with sperm, a single sperm is selected to be injected into the egg.
A cycle of IVF or ICSI		One cycle of IVF or ICSI includes all the steps involved in IVF or ICSI described above, plus the replacement of any resulting embryos from that cycle (fresh or frozen transfer). A cancelled cycle, or a cycle where no embryos can be transferred both count as a cycle.
Embryo transfer		Embryo transfer refers to the process of replacing an embryo that results from an IVF or ICSI cycle. Embryo transfers can be single, where one embryo is transferred, or double, where two embryos are transferred. No matter how many embryos are replaced, these all count as *one* embryo transfer procedure.
Ovulation induction		The process of stimulating the ovaries to release an egg each month. This can be done using tablets such as clomiphene citrate, or injections. The couple conceive the baby through sexual intercourse.

ICSI, intracytoplasmic sperm injection; IVF, in vitro fertilisation.

either autologous oocytes and sperm, or donor oocytes and sperm; and who have considered using, or had used, one or more add-ons as part of their treatment.

Clinicians

Registered doctors involved in the care of patients or couples undergoing assisted reproduction. Doctors can be consultant fertility specialists, staff-grade fertility specialists or General Practitioners (GPs) who specialise in reproductive medicine and work in fertility clinics.

Embryologists

Registered embryologists involved in decisions regarding the assessment of embryos, who have direct interaction with patients or couples undergoing IVF or ICSI.

Exclusion criteria

Those who are non-fluent English speakers owing to the financial cost and logistics of arranging appropriate translation assistance during interviews. Those who are donating oocytes or sperm therefore undergoing assisted reproduction themselves.

Recruitment

In both countries, patient participants will be recruited via broad ranging social media advertising, including the websites and social media of patient support groups such as Fertility Network in the UK. Recruiting participants in this way aims to include those from a diverse range of socioeconomic and ethnic backgrounds and geographic locations. Additionally, this approach should include patients or couples who are at varying stages of their IVF experience, including those undergoing their first cycle, to those embarking on repeated cycles and those who have and have not experienced success from IVF.

Clinicians and embryologists will also be recruited via websites, newsletters and social media, but in this case with the assistance of professional bodies such The British Fertility Society and the Association of Reproductive and Clinical Scientists in the UK. The Fertility Society of Australia (FSA) will advertise the study in Australia. Recruiting in this manner enables sampling from a broad geographical range of clinicians and embryologists, working in different clinics, with difference practices.

Both patient participants and professionals may also be recruited using a snowballing technique, where at the end of the interview existing participants are asked to nominate others to be approached for participation. Snowball sampling is a valid technique for participant recruitment in qualitative research and allows researchers to reach populations who otherwise would have been hard to reach.

Interested participants in both the UK and Australia will be directed to the VALUE study website (www.value-study.org) where they can express interest in the study using the 'contact us' form embedded in the 'patient' webpage (www.valuestudy.org/for-patients) and the 'professionals' webpage (www.valuestudy.org/for-professionals). Researchers will then confirm eligibility and obtain informed consent via a secure online form, and schedule a time to undertake the interview (figure 1). A list of examples of add-ons is provided on the website, and has been published as online supplemental table 1.

Sampling strategy and size

Approximately 60 interviews will be conducted in both the UK and Australia (20 per participant group) and the collection and analysis of data will be done iteratively to consider when sufficiently robust codes and themes have been created.[18] A sample of n=20 per group has been based on similar studies,[18–22] however, it is recognised that deep analysis is more important than number of interviews and sample size will be determined by data

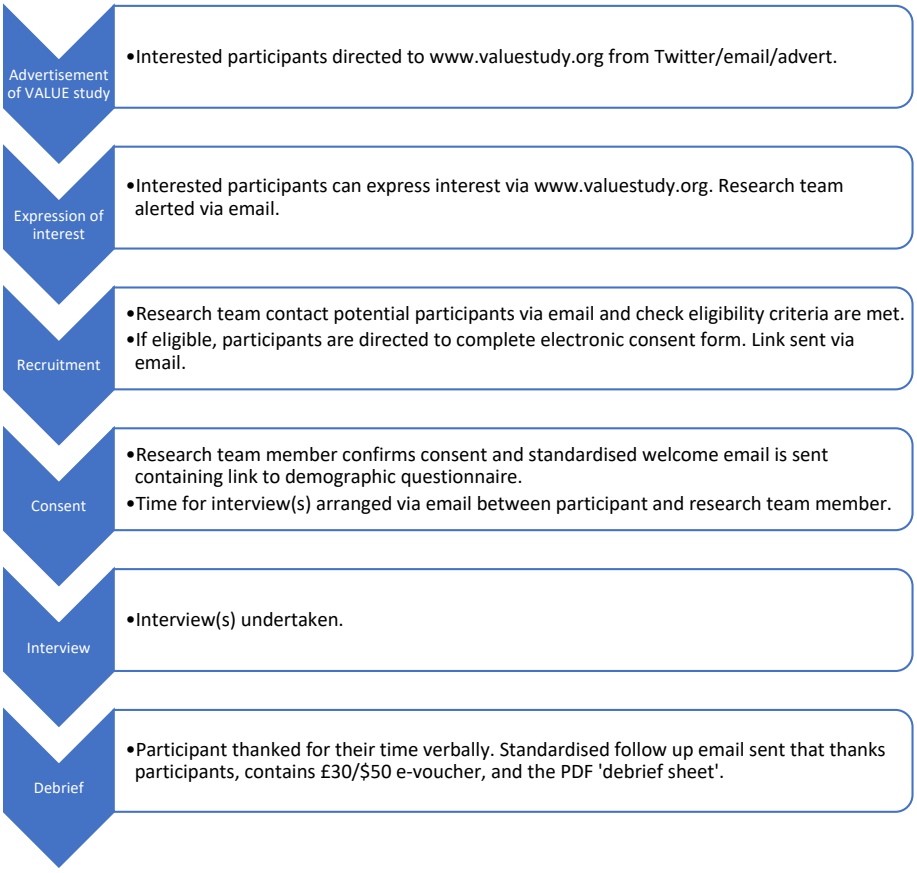

Figure 1 Flow of participants through the VALUE study.

saturation when no further themes are generated.[23] Couples who wish to be interviewed together will be considered as n=1 towards the sample size, however, if they wish to be interviewed separately, then they will be considered as two participants.

There will be purposive sampling within our inclusion criteria, to provide a variety of participants so that readers can assess transferability to a wider population of clinicians, embryologists and patients undergoing IVF.[23] The VALUE study aims to interview patients who have had government subsidised as well as privately funded cycles. It also aims to interview clinicians and embryologists working in the public and private sector and to include both senior and junior staff, the importance of which was highlighted by the PPI panel. Timely thematic analysis of the first 20 interviews will be undertaken and if an appropriate spread of patients and professionals has not been included, we will use a sampling framework for maximum variation for the next 20 interviews prior to consent stage (table 2).

There will be complete transparency with potential participants that we may not need to interview them depending on their answers, but that we appreciate their interest and time in getting in touch. We will explain that

Table 2 Framework sampling questions

Question	Patients	Professionals
Targeted questions to be asked prior to consent for potential interviewees if analysis of the first 10 interviews is suggestive of lack of diverse respondents.		
1	Please can we ask how many cycles of IVF or ICSI you have undergone?	Please can you share your clinical title?
2	Please can we ask whether you have received NHS funded or privately funded IVF or ICSI? Perhaps you have had both?	How many years have you worked in the discipline of reproductive medicine? (clinicians only)
3		Please can we ask whether you see and treat NHS funded or privately funded IVF or ICSI? Perhaps you treat had both? Please can you explain.

ICSI, Intracytoplasmic sperm injection; IVF, in vitro fertilisation; NHS, National Health Service.

their answers to these questions will not be recorded as part of the study.

Interviews

Interviews will be held remotely using video-conferencing software and will be recorded to aid transcription. Patients will be interviewed twice. First with nine questions, lasting approximately 45 min, following this they will be asked to review the HFEA website prior to the second interview of eight questions, lasting approximately 30 min. Clinicians and embryologists will participate in a single interview of approximately 60 min interview containing 15 questions. Interview schedule will not be made available until after all interviews have been conducted so as not bias responses from participants having seen the questions in advance of the interviews from this publication. However, they will be available on request after the interviews have been completed.

The interview will be conducted by members of the research team who have undergone training in conducting semi-structured interviews about potentially upsetting topics. At the beginning of the interview participants will be asked to try to avoid mentioning their names or those of IVF clinics or staff; although, the onus will be on the research team to fully anonymise subsequent transcriptions. Participants will be reminded that involvement in the research is entirely voluntary and that they can withdraw at any point during the interview. For clinicians and embryologists, they will be reminded prior to the interview that it is not a test of their clinical knowledge and that all information shared will be kept confidential.

Patients, clinicians and embryologists will be offered a £30 e-Gift Card for love2shop or a $50 Australian supermarket voucher as a thank you for their time. National Institute for Health Research recommend rewarding public participation in research and vouchers of this value are an appropriate thank you for their time.[24]

Transcription

Audio recordings will be kept on secure servers and will undergo transcription by a third-party confidential and secure password protected transcription service. Transcription of audio recording will be checked by the in-country research team to ensure that all identifiably data are removed and the transcript deidentified.

Analysis

The clinic survey data and demographic data from interview participants will be exported to a password protected Excel spreadsheet and will undergo descriptive analysis.

The interview data will undergo inductive thematic analysis to identify descriptive labels (codes) through repeated analysis. Codes will be used to group data into subthemes and further overarching themes to produce a complex account of data that is both rich and detailed and appropriate to purpose.[25] Thematic analysis covers a range of epistemological and ontological decisions; we will use it as a 'contextualist' method within a critical realist paradigm.[24 26] Thematic analysis is an appropriate framework to use for data collection and analysis as it enables a detailed account of data that is both descriptive and interpretive.[27] It can acknowledge how people make sense of their experiences as well as how broad social structures interact with these.[28] It should enable an overarching understanding of the experience of the three groups being interviewed in this study.

Analysis will begin with listening to interview recordings and reading each transcript many times to establish familiarity with the whole interview and become immersed in the data, noting initial interpretations. Initial codes (salient features) will be created, to arrange the data into meaningful segments. In the main analytic phase, different codes will be reviewed and combined to form broader themes. The first set of coding and themes will be reflexively considered until consensus is reached to define, name and exemplify all themes.

Reducing bias

We acknowledge that some of the authors of this study have been involved in the publication of evidence that does not support the routine use of IVF add-ons. Every effort has been made to be aware of this and mitigate it in the planning, execution and analysis of VALUE. The interview questions have undergone a robust PPI process, and were also subject to close scrutiny by the ethical review bodies at the Universities of Sheffield and Melbourne. Changes were made to the wording of questions as a result of feedback from these processes where there was felt to be any implied judgement. In addition, interviewers have undergone the planned training on undertaking qualitative interviews. Furthermore, double coding on a proportion of the interview data is being undertaken by Dr Wainwright, who was brought into the project as someone experienced in PPI and qualitative methods but who has not been involved in the publication of evidence that does not support the routine use of IVF add-ons.

Data protection

All data from the VALUE study will be stored securely on password protected encrypted servers. No hard copies of data will be kept. Demographic data, interview recordings and transcripts will be stored in the country of origin (UK participants' data will be stored at the University of Sheffield, and Australia participants' data will be stored at the University of Melbourne). Only deidentified interview transcripts will be shared between the UK and Australia sites and uploaded to form part of qualitative analysis on using secure password protected analytic application. All recordings will be deleted after the transcripts have been checked by the respective country's research team and are fully anonymised.

The VALUE study will not release anonymised transcripts for future research. This decision has been made in light of the sensitive nature of the topic and in response to PPI feedback which suggested that participants may

feel inhibited to speak openly due to the nature of their stories being potentially identifiable.

Ethics and dissemination

Ethical considerations

Research ethics approval was not required for the PPI phase of this study. In the UK, ethical approval has been obtained from the University of Sheffield (reference: 036268) and Bath Spa University (BSU-20-205) and in Australia ethical approval has been obtained from University of Melbourne (2057434.1). Participants will receive comprehensive information leaflets prior to the study and participants will undergo an online written consent process prior to interview with all participant information treated confidentially. Participants are free to withdraw from the study at any time.

Output and dissemination

Results will be published in a peer-review journal and disseminated to regulatory bodies such as the HFEA, The National Institute for Care and Clinical Excellence, the Victorian Assisted Reproduction Treatment Authority (Australia) and the FSA in order to help shape future information about IVF add-ons. A lay summary of findings will be shared with participants from our PPI panel, patients interviewed and via fertility UK to highlight results from the work to the wider public.

The VALUE study aims that rich qualitative data from this research will help improve communication of clinical impact of IVF add-ons to patients in future. It also hopes to analyse understanding and interpretability of a traffic light system in conveying information to patients and professionals, generating information which can be used to inform the use of the traffic light system in regulatory bodies in other countries.

Limitations

Recruitment via social media aims to facilitate purposive sampling of participants from different geographical locations, and different socioeconomic backgrounds. However, a significant limitation of this approach is that it may attract a particularly information technology literate, motivated group of individuals. One concern is that patient participants who are looking at fertility websites and social media outlets, may be more likely to be further into their fertility journey, and less likely to be undergoing their first cycle of assisted reproduction. We aim to ameliorate this by using a variety of social media outlets, plus websites and emails.

Researchers involved in VALUE have been involved in novel research that has thrown into question the rationale of the routine use of some add-ons. This involvement in research may be known to some participants, and one limitation is the risk that participants may alter their responses in light of this. The qualitative interviews have been carefully designed to demonstrate equipoise and to not introduce any form of value judgement.

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Contributors SCA will take the role of principle investigator. In the UK and Australia respectively, SCA and SL were responsible for applying for ethics approval. They planned and coordinated the local PPI and wrote the initial draft of questions for the semi-structured interviews. They will conduct the interviews, collate the results and be involved in the thematic analysis of results, and write up the results for publication. EV will be involved at all stages of the study. She was involved in the PPI and formulation of questions for the semi-structured interviews. EV will conduct the interviews and help in the thematic analysis of results. She will be involved in write up and editing of the drafts of the VALUE study for publication. EW will be the qualitative research expert for the study. She advised and participated in the PPI, helped with the methodological rigor of planning questions, and commented on ethics. EW will oversee the thematic analysis of results and edit drafts of the VALUE study for publication. CMF, AP, MP and AHB are experienced researchers who contributed to the design of the study. They will be involved in interpretation of results, as well as editing drafts of the study for publication.

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