

RESEARCH

'It all depends on why it's red': qualitative interviews exploring patient and professional views of a traffic light system for *in vitro* fertilisation add-ons

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Abstract

In vitro fertilisation (IVF) add-ons are techniques, medicines, or procedures used in addition to standard IVF with the aim of improving the chance of success. The United Kingdom's IVF regulator, the Human Fertilisation Embryology Authority (HFEA) developed a traffic light system to categorise add-ons as either green, amber, or red, based on results of randomised controlled trials. We undertook qualitative interviews to explore understanding and views of the HFEA traffic light system among IVF clinicians, embryologists, and IVF patients across Australia and the United Kingdom ($n = 73$). Overall, participants were supportive of the intention of the traffic light system; however, many limitations were raised. It was widely recognised that a simple traffic light system necessarily omits information which may be important to understanding the evidence. In particular, the red category was used in scenarios that patients viewed as having different implications for their decision-making, including 'no evidence' and 'evidessnce of harm'. Patients were surprised at the absence of any green add-ons and questioned the value of a traffic light system in this context. Many participants considered the website a helpful starting point, but desired more detail, including the contributing studies, results specific to patient demographics (e.g. <35 years and >35 years), and inclusion of more options (e.g. acupuncture). Overall, participants believed the website to be reliable and trustworthy, particularly due to the Government affiliation, and despite some concerns regarding transparency and an overly cautious regulator. The limitations of the traffic light system could be considered in any future updates to the HFEA website and others developing similar decision support tools.

Lay summary

In vitro fertilisation (IVF) add-ons are medical procedures or technologies that may be used in addition to standard IVF. They are usually used with the aim of increasing the chance of pregnancy and live birth. However, most add-ons have not been studied in high-quality clinical trials so it is uncertain whether they are beneficial. The UK's IVF regulator developed a traffic light system for add-ons. They label them red, amber, or green, depending on whether there is evidence the add-on increases the chance of having a baby from IVF. We interviewed IVF patients, IVF doctors, and embryologists about the traffic light system. Overall, many people thought it was a reliable and trustworthy resource – however, many problems

were identified. People generally thought the system was too simple and didn't give enough information, it had limited detail about the number and types of studies included, and some important add-ons were missing, such as acupuncture.

Keywords: ▶ IVF add-ons ▶ risk communication ▶ traffic light ▶ evidence

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Introduction

In vitro fertilisation (IVF) 'add-ons' are extra procedures, techniques or medicines, added to standard IVF protocols, usually with the aim of increasing the chance of a successful outcome. Many 'add-ons' are now available; these include procedures that clinics or clinicians consider to be non-essential and may be separately charged, or they may be included in standard care, such as time-lapse imaging of embryo development. Other examples include endometrial scratching, hyaluronic acid containing culture media for embryo transfer (EmbryoGlue™), and pre-implantation genetic testing for aneuploidy (PGT-A). Most IVF add-ons are not supported by good-quality evidence demonstrating an increased likelihood of live birth (Armstrong *et al.* 2019, Kamath *et al.* 2019, Lensen *et al.* 2019). Despite this, IVF add-ons are widespread. In the UK, 74% of people undergoing IVF used add-ons and over 80% of Australian IVF patients reported to have used at least one add-on (Human Fertilisation and Embryology Authority 2018, Lensen *et al.* 2021).

Many IVF patients look for information online to inform their IVF-related treatment decisions, with IVF clinic websites being a primary resource (Human Fertilisation and Embryology Authority 2018). The reliability and quality of information on these websites are variable; many exaggerate possible benefits and omit information relating to risks and costs (Spencer *et al.* 2016, van de Wiel *et al.* 2020, Galiano *et al.* 2020, Lensen *et al.* 2021). A recent UK-based study reported that over 30% of IVF clinic websites claimed add-ons such as assisted hatching and timelapse imaging of embryos improved the chance of implantation or pregnancy (van de Wiel *et al.* 2020). A similar study in Australia reported that descriptions of add-ons are frequently accompanied by claims of benefit (77% of the time), which are not quantified or supported by published research (Lensen *et al.* 2021).

The Human Fertilisation and Embryology Authority (HFEA), the IVF regulator in the UK, launched a traffic light system in 2017 with the aim of providing a trusted and robust resource to inform patients about the evidence-base for IVF add-ons (<https://www.hfea.gov.uk/treatments/>

[treatment-add-ons/](#)). They rated add-ons green if there was more than one high-quality RCT demonstrating the add-on to be effective and safe, amber if evidence was conflicting, and red if there was no evidence the add-on was effective and safe. This traffic light system appears to have been developed and launched with little evaluation or consultation with IVF patients, and it is, therefore, unclear whether IVF patients understand the information, including the traffic light labels, and whether patients and professionals perceive the information as relevant and helpful to their decision-making. The provision of quality information is a key dimension of high-quality patient-centred care in IVF (Dancet *et al.* 2011). The experience of being uninformed or misinformed about IVF treatment options and decisions has led to patients regretting or feeling resentful about their IVF treatment (Lensen *et al.* 2021). Such emotions contribute to the substantial psychological burden IVF patients experience, especially following IVF failure. It is critical to ensure that information is understandable to IVF patients and relevant to their treatment decision-making.

Aim

Qualitative interviews were undertaken with IVF patients, embryologists, and IVF clinicians to explore their understanding and views of the HFEA traffic light system, including perceived comprehensiveness, trustworthiness, and relevance to their treatment decision-making.

Methods

We followed the methodology outlined in our published protocol (Armstrong *et al.* 2021). The interviews were part of a parent project exploring the motivations and barriers to IVF add-on use (Armstrong *et al.*, under review).

Design

Qualitative semi-structured interviews were undertaken and analysed using an inductive thematic approach.

Patient and public involvement

We undertook extensive patient and professional involvement with IVF clinicians ($n=4$), embryologists ($n=4$), and patients ($n=5$) who provided input into the study design including the development of the interview schedule, plain language summary, research advertisements, study website, and recruitment strategy (Armstrong *et al.* 2021). This feedback resulted in several changes to the study design including splitting the patient interview into two separate sessions.

Participants and sampling

We included IVF clinicians, embryologists, and IVF patients (with IVF experience in the last 3 years, but not in active treatment) who lived in either Australia or the United Kingdom. These two countries were selected to provide both a local and an independent view of the traffic light system while avoiding possible complications of privacy legislation from data collection of subjects overseas to the research team. We applied framework sampling which increased diversity, ensured a mixture of public and privately funded patients, professionals working in public and private settings, level of professional experience, and geographical spread across both countries.

Participants were recruited via professional organisation mailing lists (e.g. the British Fertility Society), social media advertising, an established (In)Fertility Research Panel (<https://medicine.unimelb.edu.au/school-structure/obstetrics-and-gynaecology/research/fertility-panel>, accessed 16 March 2023), and subsequent snowballing. Interested people completed an expression of interest form online and were subsequently contacted to determine eligibility and arrange an interview. Recruitment continued until data saturation was reached as agreed by the research team. All participants were offered either a £30 love2shop voucher or a \$50 supermarket voucher for participation.

Interviews

Participants received a study information sheet and completed an online survey to capture relevant demographics and establish eligibility prior to the interview. Semi-structured interviews were conducted (by EV, LC, SA, and SL) remotely using video-conferencing software (Google Meet, Teams, or Zoom) between January and May 2021. Participants were requested to visit the

HFEA traffic light website to familiarise themselves with the content, prior to the interview. The interview questions explored participants' thoughts about the webpage and the use of a traffic light system, including the meaning they assigned to each traffic light label, the lack of green add-ons, the focus on evidence from randomised controlled trials (RCTs) reporting live birth, and how useful they viewed the content for decisions in their own practice or (hypothetical) decision-making (Supplementary File 1, see section on [supplementary materials](#) given at the end of this article). The audio was transcribed verbatim by a professional transcribing service and de-identified prior to being uploaded to Dedoose™ to facilitate qualitative analysis.

Analysis

In preparation for analysis and throughout the interviews, the coding team (DW, EV, SA, and SL) immersed themselves in the interview data through repeated reading of the transcripts. A senior qualitative researcher (EW) double-coded 12 transcripts and reported high agreement. After initial code development, codes were combined into themes and subthemes and discussed and debated throughout the development of the coding tree.

The interview and coding teams had varying personal and professional experience with fertility services, and IVF add-ons specifically. We recognised the role of existing opinions and perceptions in this research and employed several strategies to maintain research credibility including the acknowledgement of personal opinions and viewpoints among the study team and the inclusion of research team members with little or no exposure to IVF research (EW, DW, and LC).

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Results

Participant characteristics

A total of 154 people expressed an interest in participating (55 clinicians, 60 embryologists, 38 IVF patients, and 1 other). Of these, 68 (25 clinicians, 27 embryologists,

and 16 IVF patients) did not respond to a request for the completion of a demographics form to establish eligibility. Of 86 people completing the demographics and eligibility form, 10 were ineligible (clinicians based outside Australia and the UK (1), ineligible occupation (geneticist – only clinicians, embryologists, and IVF patients were eligible) (1), out of clinical practice for >2 years (2), not being willing to be recorded (1), unable to schedule a date for interview (4), or withdrawing consent (1)) and a further three did not respond to emails to schedule an interview.

A total of 73 interviews were conducted, including 24 patients (11 UK and 13 Australia), 25 embryologists (13 UK and 12 Australia), and 24 clinicians (11 UK and 13 Australia) (Tables 1 and 2). IVF patients were mostly female and in a heterosexual relationship. Patients had variation in IVF exposure and IVF add-on use, with most (23 of 24) having used at least one add-on during their IVF treatment. IVF professionals were mostly senior staff members with over 10 years of professional experience and had varying clinical approaches to offering and recommending IVF add-ons (Supplementary Table 1). The IVF professionals living in the UK were often familiar with the HFEA traffic-light website or had visited it before: 21 of 24 UK-based and 14 of 25 Australian-based professionals had visited it before. Among patients, 7 of 11 UK-based patients had visited the website previously, compared to only 2 of the 13 Australian-based patients.

Overview of findings

Overall, most participants were supportive of the purpose of the HFEA treatment add-ons webpage and the use of a traffic light system. Despite this, participants identified many issues with the implementation and interpretation of the traffic light labels, which were grouped into five themes and are outlined below (Table 3, Supplementary Table 2).

'Red is no, amber's a maybe, and green's a go'

'It all depends on why it's red'

The use of a traffic light system was attractive for its simplicity which was particularly appreciated by patients. Both professionals and patients interpreted the traffic light labels in the context of exposure to this system in other areas, such as health food labelling and road traffic lights. In this sense, green was understood as a recommendation to 'go' and red as 'stop'. Beyond this, many also overlaid the specific meanings of these labels as intended by the

HFEA, although had difficulty with the 'red' label which was viewed as 'a danger colour' as opposed to the intended 'no evidence of benefit'. Participants who read through the website description of the labels understood this was not the intention of this label:

"So I guess it would mean that they don't recommend it. My initial reaction was that it means it's unsafe and not to do it, but actually reading into it it's actually about the live birth rate not the safety-ness of it."
Patient, UK4

Despite superficial satisfaction with a simple rating system, it was widely recognised that such simplicity necessarily omits information which may be critical to accurate knowledge translation. Many IVF professionals were concerned that their patients would not appreciate the advantages and disadvantages of IVF add-ons when relying on a single traffic light label. This is summarised by one clinician regarding PGT-A

Table 1 Demographics of IVF patients.

	Interviews in		Total (n/%)
	UK	Australia	
<i>n</i>	11	13	
Gender			
Female	11	11	92%
Age (years)			
25–30	1	1	8%
31–35	4	3	32%
36–40	5	6	44%
41–45	1	3	16%
Relationship status			
Single	1	0	4%
In partnership	10	13	96%
Gender of partner			
Female	1	3*	16%
Male	10	10	84%
IVF/ICSI undertaken			
1–2 cycles	4	7	48%
3–4 cycles	6	3	36%
≥ 5 cycles	1	3	16%
Number of embryo transfers			
None	1	2	12%
1–2 transfers	3	4	32%
3–4 transfers	4	4	32%
≥ 5 transfers	3	3	24%
IUI (any number of cycles)	2	2	16%
Cumulative period undergoing fertility treatment (IVF/ICSI, IUI, OI)			
1–2 years	3	6	36%
3–4 years	5	4	40%
5 years or longer	3	3	24%

*Two are female partners of male participants.

ICSI, intracytoplasmic sperm injection; IUI, intrauterine insemination; IVF, *in vitro* fertilisation; OI, ovulation induction.

Table 2 Demographics of professional participants.

	Interviews in		Total (n/%)
	UK	Australia	
<i>n</i>	24	25	
Profession			
Clinician	11	13	49%
Embryologist	13	12	51%
Time working in assisted reproduction			
1–5 years	3	1	8%
6–10 years	5	5	21%
11–15 years	6	6	24%
≥ 15 years	10	13	47%
Senior embryologists (<i>n</i> = 25)			
Scientific director	6	3	36%
Laboratory manager	1	0	4%
Senior qualified embryologist	4	5	36%
Qualified embryologist	2	3	20%
Missing	0	1	4%
Senior clinicians (<i>n</i> = 24)			
Consultant (O&G) fertility specialist	7	12	79%
Staff grade fertility specialist	1	0	4%
Clinical fellow/trainee reproductive medicine	3	1	17%

“I mean particularly for things like PGT-A... PGT-A is so much more complex, you can't reduce PGT-A to that (laughs).” Clinician, Aus7

With only three possible categorisations (red, amber, and green), both IVF professionals and patients thought the system would be improved with further delineation ‘maybe you could have six categories instead of three’. This lack of granularity was particularly important for add-ons rated amber. While understanding this meant the evidence was ‘conflicting’, many participants wondered whether the add-on may have been ‘almost green’ or ‘almost red’, as highlighted by one clinician

“So, probably, you would need more shades of orange in a way.” Clinician, Aus12

Despite this, the amber rating was often perceived more positively than was intended, with participants viewing amber as applied when the evidence is promising but not strong, or not sufficient ‘yet’. This was summarised by an embryologist when explaining their interpretation of the amber label

“There has been some evidence that this add-on has provided a positive outcome in a treatment cycle. However, either the data set isn't large enough or more studies are required to replicate this outcome.” Embryologist, UK8

The red colour was also difficult to interpret because it conflated the concepts of safety and effectiveness into one label. It was therefore perceived to have multiple meanings: a risk of harm, no evidence of benefit for live birth, evidence of no benefit for live birth, or evidence of a reduced probability of live birth. Many participants viewed these as distinct scenarios and therefore wanted further information on why the add-on was labelled red.

“My ideal website would rate add-ons based on three criteria. Cost, risk and benefit... I think there is benefit in saying this is cheap, this is safe, but we don't have evidence of effectiveness... Or alternatively you say, this is expensive, this has significant side-effects, and we don't have evidence of effectiveness. I think there is a difference between these two, and that is not conveyed particularly clearly on that website.” Clinician, Aus8

“Yeah, I'd go back to my fertility specialist and ask him. And just say that it's rated red because it causes cancer. And I'll say, let's forget about that, I'm not prepared to take that risk. Or it's rated red just because it hasn't been tested or checked by whoever... then I'll say, yeah, I'm happy to proceed on that basis. It all depends on why it's red.” Patient, Aus7

Together these quotes highlight that the traffic light system, particularly the red label, is a ‘wide brushstroke’ and on its own is of limited help to the decision-making process.

‘It's not actually too relevant for me’

Both professionals and patients were unclear how helpful the website was to individual patients as the traffic light labels were generated based on evidence for the general IVF population. This was viewed as unhelpful by participants who often saw add-ons as being ‘patient-specific’ and recognised that ‘there are niches where add-ons do add value to patients.’ Embryologist, Aus13

“Because... there were randomised trials... I didn't know how old the people were that were involved with them. I didn't know if they had any pre-existing conditions, and so I think it was one of those things where I'd probably take it with a metaphorical pinch of salt and would talk to the specialists about it. And would probably try and do a little bit more of my own research on other websites. Because it seems like this is just something to break it down for the public, rather than something that's scientifically very accurate.” Patient, Aus11



Table 3 Themes and subthemes.

Theme/subtheme	Subtheme definition
Theme: 'Red is no, amber's a maybe, and green's a go' 'It all depends on why its red'	The traffic light system is simple but lacks nuance, resulting in one label having several possible meanings and complicating interpretation
'It's not actually too relevant for me'	The information is provided for the general IVF population and therefore excludes the possibility that there may be evidence in specific subsets of patients
'Who is making the decision?'	Participants placed different levels of trust in the website content, based on factors such as Government affiliation, tone, and (lack of) transparency about which individuals were responsible for assigning the labels
Theme: 'What kind of traffic light has no green?' 'A little bit shocked'	Confusion or surprise at the observation that none of the add-ons were rated green
'A bit too cautious'	Belief that the HFEA regulator has a very conservative approach to reviewing evidence and unwillingness to label add-ons as effective
No green – 'It defeats the purpose of having the traffic light system'	Lack of any green labelled add-ons seen to undermine the purpose of a traffic light system; converting an already limited three-label system into a two-label system, with a consequent focus on unproven options that was viewed as a negative position and failing to give patients the full perspective
Theme: 'It's a helpful starting point' 'Didn't really give as much information as I'd hoped for'	Participants desired more detail about the included studies, the combined evidence, and the explanation of how the evidence translated into the final rating
'I like to look at the bigger picture'	The current focus on randomised controlled trials reporting live birth was viewed as too narrow, and the website omitted other key information such as cost and specific add-ons
Theme: 'Use it to be informed' 'It's not gonna stop them'	Clinicians who don't routinely use add-ons are more likely to use the website and those who often offer add-ons are more likely to disregard it
'Which one's wrong? Website or specialist?'	IVF patients viewed the website as a trusted and supplementary resource to their IVF clinician, recognising the difficult conversation that may arise when the website and IVF clinician appear to have conflicting recommendations
'I just wish I'd known more about it'	Issues with lack of awareness of the website among IVF patients, and poor visual appeal and user experience
Theme: 'Would you like fries with that?' -	Term 'add-on' was viewed as carrying negative connotations including IVF clinics being exploitative. It was also viewed as trivialising a sensitive medical treatment, turning it into a cheap decision like whether to upgrade a take-away order. However, few alternative terms were considered any better except for 'options' which was broadly endorsed by all participants

'Who is making the decision?'

IVF professionals and patients tended to perceive the reliability of the website differently. Many IVF patients spoke of the trust they placed in the website owing to the use of neutral language, government affiliation, and freedom from any ties with IVF clinics or companies. While the patients viewed the website as independent and fair, IVF professionals remarked on the lack of transparency regarding the individuals responsible for determining the traffic light labels.

"In order to do a Cochrane review... there should be absolutely no conflict of interest. So... it's quite rigid. But I am not clear as to what is their selection criteria.

It should be, you know, something similar. Because, otherwise, you can sway decisions." Clinician, UK7

Clinicians were generally sceptical of the potential biases and personal opinions of those on the scientific committee who were responsible for assigning the traffic light labels.

'What kind of traffic light has no green?'

'A little bit shocked'

Many IVF patients expressed surprise and strong emotions at the lack of any green-rated add-ons and the substantial number labelled red, particularly as red was

viewed as a strong or ‘damning’ judgement against the add-on. This was particularly evident where patients had used add-ons believing them to be supported by evidence of benefit.

“I found it a bit confronting... when you look at stuff that you’ve done or considered doing and you see that it’s red. I took it as a bit of a personal... I don’t know why, but I was just angry in a way... just annoyed, perhaps that I’d wasted time or money... why is it even offered?... They should’ve just been upfront and said: this is still really in the research phases.” Patient, Aus3

Some patients were confused at the availability of unproven add-ons at their IVF clinic and were upset they were recommended or offered these without having been informed that the treatments were experimental in nature.

‘A bit too cautious’

For some participants, the lack of green add-ons was viewed as a problem with how the traffic light system had been applied rather than with the traffic light system in principle. To be labelled ‘green’, add-ons needed more than one high-quality RCT demonstrating the add-on increases the live birth rate. For many, this was viewed as a very high bar, where one or two moderate-quality RCTs should be sufficient. Professionals believed that many of the add-ons were effective, at least in subgroups of patients.

“I don’t agree with it...we have developed methods where we do it safely. So, if an embryo’s hatching we take a couple of the cells from the outside the embryo... I find it really hard to believe patients that don’t have PGT have a higher chance of getting a live birth than patients that have it.” Embryologist, Aus1

Whether based on their own professional experience, their understanding of the literature or the lack of available evidence, many IVF clinicians and embryologists believed the add-ons they offered or used were effective, even if this position was not supported by high-quality evidence.

Many clinicians believed that the HFEA, as the regulator, were naturally overly cautious, which resulted in the labelling of all add-ons as either amber or red despite reasonable evidence of efficacy in some situations. This conservative approach was thought

to contribute to the overall vibe or tone of the website which was viewed as ‘negative propaganda’ by some. This is summarised by one clinician who believed the HFEA takes the position of being

“Deeply suspicious about each and every treatment that comes up and we do not classify anything as green.” Clinician, UK7

On the other hand, for some clinicians, the absence of green labels was a natural consequence of a website dedicated only to IVF add-ons, as treatments with established efficacy would generally be routine practice and ‘not an add-on anymore’.

No green – ‘It defeats the purpose of having the traffic light system’

Absence of green add-ons was considered confusing and counterintuitive, with one patient wondering if the website was still under development ‘maybe they’re just waiting to finally upload the green, I don’t know.’ Participants questioned the use of a traffic-light system when only two of the three available labels are in use.

“It defeats the purpose of having the traffic light system. If you’re not going to have anything or many things green, then don’t have a traffic light system.” Patient, Aus4

Many were concerned about the interpretation given the lack of perspective that results from only partial application of the traffic light system.

“I’d want to know what the green ones are, to be able to do a comparison, but if it wasn’t on there, which I thought was a bit strange, other than it said it was somewhere else on the website for you to look at, and it wasn’t obvious where it was.” Patient, UK7

Participants pointed out that patients are searching for treatment options that offer them hope; the possibility of an increased chance of having a baby. One clinician believed that the focus on a list of treatment options that were ineffective would have poor traction with most patients. This clinician likened the traffic light website to a different IVF-related website they viewed as a dismal failure

“It takes away all hope, and it doesn’t tell them what to do... they don’t want anything to do with that website, and they go to every alternative, other website; they won’t even look at anything on there.” Clinician, Aus9

The lack of perspective offered by green add-ons also introduced the possibility that patients would select amber add-ons as these were seen as better than red.

“Because I read, it said they don’t put green on there. So, amber would say to me that it was more likely to be successful basically.” Patient, UK3

This was especially true for patients who were desperate to try something new which one clinician likened to the road traffic lights

“It’s rather like driving a car. If you come up to the traffic light, and you’re not prepared to stop, you’ll go through an amber light.... And if you’re really, really pushed, with caution, you’ll go through a red light.” Clinician, Aus1

‘It’s a helpful starting point’

‘Didn’t really give as much information as I’d hoped for’

While participants valued the information provided by the website, many desired a greater depth of information including the use of numbers to convey the magnitude of possible benefits and harms, details of the contributing studies in terms of their sample size and demographics, with some patients even requesting links to the original studies for further reading. Many participants desired an explanation for why each specific add-on was rated amber or red, including whether the evidence was leaning in favour or against the treatment option, in the case of amber add-ons.

“Well, I mean, maybe they should show that with those amber ones and list the studies and say tick, tick, tick, tick, and then a cross for whatever study. And the patient can be like, okay, well, eight studies found it was good and two didn’t get a good result, so they can weigh it up themselves a bit.” Embryologist, Aus7

While some explanation was available, this was often ‘hidden’ in the minutes from the relevant scientific meeting during which the scientific committee had reviewed the evidence and agreed upon a recommended rating.

“It wasn’t linked to studies... it seems they did hyperlink to... minutes from a meeting. And I thought no patient is going to want to go from reading about an add-on to reading about minutes of a meeting of, like, a medical group where the jargon probably is pretty inaccessible.” Patient, Aus11

‘I like to look at the bigger picture’

Participants were questioned about the scope of evidence being limited to RCTs reporting live birth. While recognising this represents the highest quality evidence, many remarked on the importance of other outcomes including pregnancy and miscarriage, especially when the goal of some add-ons is not to improve the live birth rate, such as PGT-A.

“The other one that’s difficult really is the PGS, because again, you know, if you’re taking a couple who’ve had repeated implantation failure and you end up finding out with PGS that they’re making abnormal embryos. Then, I’m sorry, but you are preventing them from having to go through repeated cycles with abnormal embryos. And, I just find that difficult that it’s not rated as something we could, we should be doing, other than as part of a research study.” Clinician, UK11

Many IVF clinicians discussed the possible utility of observational research, particularly when data from RCTs was limited. They also recognised that, especially for rare subpopulations which would be difficult to recruit, relying on RCTs would never provide an answer. These clinicians pointed to examples of IVF techniques which have been introduced and are undoubtedly beneficial, despite not being first subjected to evaluation in a clinical trial, such as embryo freezing and extended embryo culture.

“I think if you had an observational study that had a lot of patients in it... you’ve got to be able to say to, to the general public and to patients, there are some studies that are showing a tendency to a benefit, they are not as thorough perhaps as an RCT. But I don’t think they should be discounted.” Clinician, UK11

Lastly, many participants remarked on the omission of common IVF add-ons, including acupuncture, endometrial receptivity testing and NK-cell testing, which caused some patients to wonder if the website was incomplete. Specific information about safety and cost, which many viewed as important to the decision-making process, was also notably absent.

“What’s the price range that people are offered... so that people can be prepared for that. ‘Cause that, I mean, that’s a huge factor, is cost.” Patient, Aus10

Because the website was generalised to the IVF population and lacked sufficient detail of the evidence, especially tailored to each patient, the website was

viewed as a helpful ‘starting point’ but seldom seen as a comprehensive information resource.

‘Use it to be informed’

‘It’s not gonna stop them’

Clinicians were divided on the role the website played, or would play, in their professional practice. Those who believed strongly in evidence-based medicine described using the website to justify to patients or colleagues why they did not offer or recommend certain add-ons, or to ensure patients understood the lack of evidence before proceeding with an IVF add-on. Whereas clinicians offering add-ons routinely were considered unlikely to use the website, as described by two professionals:

“Doctors, they’re just going to do whatever they want to do and they won’t bother looking at this.”
Embryologist, Aus7

“Well, in Australia they probably won’t be in favour of the website because it’s, kind of, dictatorial, you know, amber or red. So it’s taking away individual choice.... Whereas this is a website that’s based quite a lot on so-called evidence-based medicine, which is not the way that most people practice their medicine.”
Clinician, Aus2

‘Which one’s wrong? Website or specialist?’

IVF patients generally found the website content and traffic light system to provide important information which would help their treatment decisions. Many viewed the website as an impartial and trustworthy resource which would supplement information from their fertility clinician. Participants believed the website would prompt patients to question their clinician if the information provided by the website differed with their advice or recommendation, and in doing so empower them to take control of their treatment journey.

“I think it would make a conversation with the clinic much easier because you could actually say to them, you know, you recommended this and actually it comes out as red, so why are you recommending that? I would change a decision based on what the website says, but it would create an awkward conversation. Because you’re then having to go in and say if you’ve been recommended one that’s been, that has a red traffic light, or even an amber, you’re then having to, um, have an awkward conversation with someone

who is supposed to be the professional to say, well, actually, I’m doubting your opinion.” Patient UK2

While patients regarded the HFEA website as a valuable tool to prompt a conversation or to facilitate further discussion with their IVF clinicians, they also recognised such a conversation could be difficult due to the power hierarchy of the doctor-patient relationship.

‘I just wish I’d known more about it’

Despite many patients recalling spending a substantial amount of time on the internet seeking information about their IVF journey and add-ons, many had not come across the website (7 of 11 UK patients and 2 of 13 Australian patients had visited the website previously). Many Australian participants queried whether content on a UK-based website was applicable to Australia, and wondered why such a resource was not available locally:

“To be honest, I thought that there would be an Australian version by now.” Patient, Aus7

Patients recognised their lack of awareness probably resulted from a lack of publicity, advertising and IVF clinic endorsement of the website

“It almost feels like it needs to be interwoven with the clinic... there’s no point having amazing information if people don’t know about it.” Patient, UK2

Many participants were critical of aspects of the style, formatting, and language used on the website. For some, the website appeared to be written by researchers and the language was often inaccessible resulting in them feeling ‘bogged down’. Perceived lack of aesthetics and long scrolls of text, some of which was a repetition of content on other pages, resulted in many patients feeling unable to engage in or digest all of the information.

‘Would you like fries with that?’

Participants were divided on the use of the term ‘add-on’ to group together these optional procedures, techniques, and medicines. While participants generally appreciated that the term conveyed an aspect which is ‘additional’ or ‘extra’ to standard IVF, some likened this to the upsizing of fast-food ‘would you like fries with that?’ While for some this was a fair representation, others viewed this as ‘unprofessional’ and trivialising a complicated, sensitive medical treatment. While clinicians preferred more medical terms such as ‘adjunct’ or ‘adjuvant’ these were widely rejected by patients, many of whom were not

familiar with these terms. Patients instead preferred the term ‘option’ which conveyed the same sense of being ‘additional’ or ‘extra’ without the negative connotations.

Discussion

This is one of the first studies to explore the perspectives of IVF clinicians, embryologists, and patients of the HFEA’s treatment add-ons website which uses a traffic light system (red, amber, and green) to label add-ons, based on evidence from RCTs. While there was widespread support for the website, particularly among IVF patients, many important limitations were recognised, some of which have also been raised in recent qualitative studies in the UK (Perrotta & Geampana 2020, Perrotta & Hamper 2021, 2023, Iaconi *et al.* 2022). Key themes included an overly simplistic traffic light system that failed to convey sufficient detail about the level of evidence and the type of patients this applied to specifically. Many participants desired more information including greater detail of the relevant scientific studies, specific explanations for how this translated into the traffic light rating used in each case, and information about other outcomes such as pregnancy and miscarriage. Similar criticisms were raised by UK clinicians in recent interview studies, where the traffic light system was viewed as oversimplifying complex questions, and a sole focus on the outcome of live birth was viewed as a failure to provide the complete picture (Iaconi *et al.* 2022).

While many IVF patients viewed the website as an impartial source of reliable information, some professionals were concerned about a lack of transparency and an overly cautious approach to the review of the evidence. These professionals believed that the focus on high-quality randomised trials presented an unachievable standard and such a position was therefore not practical or relevant to their everyday IVF practice, where patient care is often based on evidence of lower quality. Those who don’t routinely offer add-ons supported the lack of green add-ons and used the website to guide or reinforce their practice, while those regularly offering add-ons viewed the website as overly cautious and with little practical implication or consequence for their service. These findings align with recent qualitative research which also reports a wide variety of approaches to evidence interpretation among IVF patients and professionals in the UK (Perrotta & Geampana 2020, Perrotta & Hamper 2021, 2023). Researchers of these studies described the professional divide as a tension between a science-first

vs patient-first approach, noting that proponents of the latter sometimes viewed evidence-based medicine as in conflict with their approach and viewed the traffic light system as unnecessarily dissuasive (Geampana & Perrotta 2022, Iaconi *et al.* 2022). However, a suggested flaw with these labels is the implication that those practicing evidence-based medicine are not offering a patient-centred approach or not acting in the best interest of their patients.

For patients in our study, while some were grateful to have an independent and reliable resource and were wary of being offered ineffective options, others placed great trust in their IVF clinician and their knowledge of their specific set of circumstances. Similarly, other researchers found patients were divided in their approach to evidence, while some preferred to delegate evaluations and associated treatment decisions to their doctor, others actively sought out scientific papers to inform their treatment decisions (Perrotta & Hamper 2021, 2023). Beyond these divides, the resulting lack of any green labelled add-on was widely perceived as problematic for multiple reasons, and many participants questioned the choice of a traffic light system if only two of an already small set of three labels were being utilised.

While simple and apparently intuitive, the choice of the common traffic light system resulted in users applying existing understanding for these labels, such as their application in road traffic and nutritional labelling; meaning that did not necessarily align with the descriptions of these labels provided by the HFEA. The obvious interpretation of green as ‘go’ and red as ‘stop’ also conveyed a clear recommendation for or against the add-on. In this sense, the traffic lights were seen as recommendations rather than as simply conveying information about the evidence base. The red category covered many scenarios including no evidence of benefit and risk of harm. While this may be viewed as appropriate as the recommendation in both situations may be to ‘stop’ or avoid use of the add-on, participants recognised these situations as distinct. Many participants were willing to use an add-on with no evidence of benefit as long as it was safe - a position observed in other recent studies (Perrotta & Geampana 2021).

Informed decision-making in healthcare relies on patients making an accurate assessment of the risks and benefits in the context of their own personal values. Decision-aids and other decision-support tools usually aim to provide patients with relevant information to assist them in making value-concordant decisions, which have been demonstrated to increase decision satisfaction

and reduce subsequent regret (Stacey *et al.* 2017). This philosophy recognises that different decisions may be reached by patients with similar clinical profiles, due to differences in the values and preferences of different patients. Our findings suggest that the application of a traffic light system with associated recommendations to 'go' or 'stop', and little detail of the underlying evidence base and how this was translated into the traffic light label, may not provide patients with sufficient information to make an informed decision.

The traffic light system represents a form of evaluative labelling, the use of symbols or colour coding to convey meaning beyond simple text or numerical information. Such labels are widely used in areas such as consumer choice and nutritional labelling and have been demonstrated to improve knowledge translation and elicit behaviour change (Vermeir 2020). However, their use in healthcare as a decision-support tool is less well studied. Researchers have urged caution due to the risk of misleading or misrepresenting statistics and recommend pilot testing for understanding before implementation (Trevena *et al.* 2013). While little patient input appears to have contributed to the initial launch of the treatment add-ons website and traffic light system, the HFEA recently made several small modifications to the website based on user feedback, such as excluding the consideration of safety from the red label which now conveys effectiveness only. Although further large-scale changes are planned, these may not address all of concerns raised in this study, such as the inclusion of alternative and complementary therapies, provision of information about cost, and increased transparency regarding how data from studies are converted into each of the traffic light labels.

It is widely recognised that IVF patients invest substantial time in online searching aspects of their IVF treatment including the use of IVF add-ons. Information on IVF clinic websites has been shown to lack a strong evidence base, with unsubstantiated claims of benefit and omission of important information such as risk of harm and costs (Spencer *et al.* 2016, van de Wiel *et al.* 2020, Lensen *et al.* 2021). It is perhaps not surprising therefore that recent research suggests many IVF patients are not aware of the lack of evidence for the add-ons they use, despite reporting to place a high level of importance on scientific evidence of both safety and efficacy (Lensen *et al.* 2021). While patients place a high value on scientific evidence, and most IVF patients in our study viewed the traffic light website as a reliable and helpful resource, few had visited the website previously. This suggests that

awareness may be a key factor in ensuring patients have access to evidence-based information to inform their IVF add-on decisions.

Strengths and weaknesses

This was a large qualitative project exploring the perspectives of three key stakeholders (IVF clinicians, embryologists, and patients). Although we aimed for diversity in our sample and recruited patients with various levels of IVF and add-on exposure, seniority among professionals, and geographic spread across the two countries, we have limited representation from male patients or patients who did not use IVF add-ons. The research team have a strong research interest in IVF add-ons and RCTs. We made several efforts to minimise associated bias including using interviewers and coders without IVF or add-on experience (EW, DW) and embedding reflective practice into interview conduct and analysis.

Conclusion

The HFEA treatment add-ons traffic light system is perceived as a simple and helpful resource, which also has many significant limitations which impede its application. IVF patients and professionals need access to quality information that they consider relevant to their treatment decision-making. The traffic light system was found to be overly simplistic and greater granularity may be required to enable these groups to better understand the relevant components of the available evidence and therefore make value-concordant decisions. The limitations identified in this study could be considered in any future updates to the HFEA website and for any other groups planning to develop a decision support tool for IVF patients and professionals.

Supplementary materials

This is linked to the online version of the paper at <https://doi.org/10.1530/RAF-22-0136>.

Declaration of interest

The authors declare that there is no conflict of interest that could be perceived as prejudicing the impartiality of this study.

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Author contribution statement

SA and SL conceived the idea for the study. SA, SL, MP, EW, EV, AB, AAP and CF, were involved in the design of VALUE and publication of the protocol. SA, EV, SL and LC undertook participant interviews. Analysis was undertaken by SA, EV, SL and EW. SL wrote the initial draft which was edited by all authors. All authors approve the final version for submission.

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