

The responsible use of treatment add-ons in fertility services: a consensus statement



Introduction

We in the fertility sector in the UK are concerned that many patients are being frequently offered, and charged for, optional extras to their treatment which claim to improve their chances of having a healthy baby. These additional therapies and techniques are collectively known as treatment 'add-ons'. They cover a range of interventions: genetic tests, drugs, surgery and equipment. Some add-ons have been around for many years, while others are more recent.

Treatment add-ons have entered clinical practice with the aim of improving the outcomes of fertility treatment. Offered responsibly, they can be a sign of healthy innovation in the fertility sector. However, there is currently no conclusive evidence that any of the add-ons offered in fertility treatment increase the chance of a pregnancy or live birth.

The growth in the use of add-ons in the UK is the result of several factors. The UK fertility sector is an intensely competitive market – unusually for healthcare in this country, approximately 60% of treatments are funded privately by the patients themselves and almost all NHS clinics treat a mix of privately-funded and publicly-funded patients.

Since information about add-ons is increasingly available online, many patients have strong views about the apparent advantages of a particular treatment add-on before they step into the clinic. Clinics report that this is the case and the first Human Fertilisation and Embryology Authority (HFEA) [national patient survey](#) confirms this.

This combination of patient expectation, market forces and a recasting of the professional-patient relationship in an online information age appears to be driving the supply, and demand for, treatment add-ons.

Practitioners have a duty of care to patients, which should separate pressure from patients and commercial interests from their best practice advice.

We believe that culture change is required, if the potential benefits of new treatments are to be offered responsibly. It's time to have an open and honest conversation about treatment add-ons. This consensus statement sets out the principles of responsible innovation which we believe should guide professionals in the UK.

Principles of responsible innovation

Wherever they go, patients deserve consistent, evidence-based treatment. Failing to provide this poses a significant risk to patient trust and to clinical innovation itself.

We have therefore agreed the following principles of responsible innovation. These principles give clinics the space to innovate, whilst also ensuring structures are in place to allow new treatment add-ons to be introduced through preclinical and clinical testing to confirm safety and efficacy.

1. Clinics should only offer treatment add-ons under the following conditions:
 - a) Where more than one high quality study demonstrates a treatment add-on to be safe and effective, clinics should continue to monitor their success rates and long-term follow-up data and report adverse incidents. Clinics should stop offering the treatment add-on to patients if concerns are raised regarding safety or effectiveness.
 - b) Where evidence of safety and effectiveness is limited or conflicting, clinics offering treatment add-ons should be open with their data to add to the evidence-base for the add-on.
 - c) Where there is no evidence to support safety and efficacy, treatment add-ons should only be offered to patients in a research setting with sound methodology and approval from a research ethics committee.
2. Clinics must provide patients with up-to-date information about the evidence base supporting the use of any treatment add-ons they offer. Information to be provided should be in line with the HFEA's Code of Practice guidance, given to patients before obtaining their consent and should include reference to the [HFEA website](#).
3. Patients must be clearly informed of the experimental nature of any treatment add-on which is offered, where there is no robust evidence of its safety and/or effectiveness.
4. Patients should not be charged extra to take part in research, including clinical trials.
5. Where patients are paying for their treatment, it may be appropriate to charge patients for the use of a treatment add-on if it has been demonstrated to be effective for their specific patient group or where incorporating the cost of providing the treatment add-on into a standard package would significantly increase the price of treatment for all patients.
6. Accurate and transparent declarations of financial or other interests are essential in discussion with patients and in publications and at meetings.
7. The fertility sector should continue to work together through its professional bodies to improve the standards of treatment by:

- a) Disseminating and promoting the principles raised in this consensus statement.
- b) Encouraging colleagues to adhere to these principles and providing training or events aimed at tackling the issues raised in this statement.
- c) Compiling the evidence for treatment add-ons with a view to publication and consensus around how add-ons should be offered to patients (the HFEA register may provide a means to enable interested clinics to aggregate their data collectively).

Context

This consensus statement is only one element of a range of initiatives designed to set standards and inform patients about the use of treatment add-ons in the UK. The signatory professional societies continue with related work outside of the statutory regime, on areas of treatment like recurrent miscarriage or fertility treatment abroad.

The HFEA has published information for patients on the most commonly offered add-ons, with a traffic light rating system giving a simple visual indication of the level of evidence supporting each add-on.

The HFEA has also tightened its guidance for clinics to require that any information provided to patients by clinics on the safety and effectiveness of any add-on explicitly references the HFEA website. The aim is to ensure that when this information is combined with detailed discussion with a healthcare professional, patients better understand the evidence supporting different treatments, and can make a fully informed choice.

The professional societies, through scientific meetings, educational events and publications, provide opportunities for clinics to present data and for practitioners to learn from each other's experience and research.

This consensus statement is designed to address treatment add-ons which are currently available to patients, as well as those under development. In future we envisage that new treatments or technologies under development will only be offered to patients outside of a research setting once safety and effectiveness have been demonstrated.¹

We want to move towards a more consistent and transparent approach to the use of treatment add-ons in fertility services. More high-quality research including Randomised Controlled Trials, meta-analyses, and follow-up of patients is needed. It will also be important to explore the challenges around financing research in the fertility sector.

The UK fertility sector should consider how such a framework might be developed and implemented following the publication of this consensus statement.

¹ The European Society of Human Reproduction and Embryology (ESHRE) has developed a tool for considering whether a new technology or treatment has sufficient supporting evidence to no longer be considered 'experimental'. The tool provides an example of a framework whereby new technologies or treatments are initially considered experimental. As the evidence base increases, the technology or treatment moves through an 'innovative' phase before finally being considered an 'established treatment'.

See: Provoost V, Tilleman K, D'angelo A, De Sutter P, de Wert G, Nelen W, Pennings G, Shenfield F, Dondorp W. Beyond the dichotomy: a tool for distinguishing between experimental, innovative and established treatment. *Human Reproduction*. 2014 Jan 15; 29(3): 413-7.

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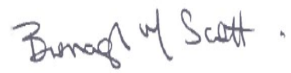
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