A Baby at All Costs? Exploring the Use and Provision of Unproven Adjuvant Treatments in the Context of IVF

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Abstract

The year 2018 marked 40 years since the birth of Louise Brown, the first baby born as a result of pioneering in vitro fertilization (IVF) treatment. Since then, advances have seen a wide range of reproductive technologies emerge into clinical practice, including adjuvant treatments often referred to as IVF “add-ons.” However, these “optional extras” have faced growing criticism, especially when they have often come at additional financial cost to the patient and have little evidence supporting their efficacy to improve pregnancy or birth rates. Despite this, according to the latest national patient survey by the Human Fertilisation and Embryology Authority, three quarters of patients who had fertility treatment in the United Kingdom in the past two years had at least one type of treatment add-on highlighting the growing demand for these interventions. This article uses a psychosocial perspective to consider the motivations behind patient and clinician behavior along with the wider societal and economic factors that may be impacting upon the increase in the use of adjuvant treatments in fertility clinics more widely. It suggests the reasons fertility patients use unproven “optional extras” are complex, with interpersonal, psychological, and social factors intertwining to generate an increase in the use of IVF add-ons.

Keywords
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From the latter half of the 20th century, the landscape of reproductive medicine changed. The first baby born using in vitro fertilization (IVF) methods in 1978 heralded the start of a new era of assisted conception that has since provided the opportunity for many individuals to have the baby and family much longed for.1-3 However, IVF has not been without criticism, particularly concerning the potential outcomes that could arise from scientific intervention in human development and the ever-growing commercialization of the treatment.4

Recently, the field of assisted conception has once again been at the center of controversy, this time regarding the use and provision of IVF add-ons and adjuvant treatments. The emergence and increased use of these “optional extras” has catalyzed a public debate about their place within the wider commercial landscape of assisted reproductive technologies (ARTs).

The growing demand for these therapies was demonstrated by data generated from the latest Human Fertilisation and Embryology Authority (HFEA)’s national patient survey, which found that between 2013 and 2016, 66% of patients who had fertility treatment in the United Kingdom in the past two years had undergone at least one type of treatment add-on, with this increasing to 74% between 2016 and 2018.5 The most common were clinical techniques such as endometrial...
scratch, embryo glue, time-lapse imaging, and reproductive immunology tests and treatments to name a few.\textsuperscript{6}

However, the ethical and moral implications of selling these treatments when the evidence supporting their efficacy to improve pregnancy or birth rates is limited have been voiced. In 2016, a BBC documentary highlighted the increased tendency for UK fertility clinics to offer a range of these additions to a standard IVF cycle, often at considerable cost to the patient/s.\textsuperscript{7} As with most IVF in the United Kingdom, the NHS does not fund these treatments; so, they increase already expensive treatment costs by hundreds or even thousands of pounds.

The matter was raised in the BMJ in 2016 by Carl Heneghan and colleagues from the Centre for Evidence-Based Medicine at the University of Oxford, who criticized the lack of evidence for many interventions offered in UK fertility centers.\textsuperscript{8} Following publication of this article, the UK regulator introduced a “traffic light” system, which uses the colors red (no evidence of safety or effectiveness), amber (less clear evidence), and green (there is at least one randomized controlled trial [RCT] that provides clear evidence to support the use of the specific add-on treatment), to conclude that currently none of the treatment add-ons assessed were rated as green and therefore, none should be recommended for routine use.\textsuperscript{9}

Against a backdrop of growing use, and scrutiny about their efficacy, the question remains: Why do patients choose to use add-ons? In the first instance, it is important to remember that this phenomenon is not unique to reproductive medicine. Tensions between conventional medicine (considered rooted in scientific enquiry and underpinned by a strong evidence base) and alternative/complementary medicine (where the underpinning scientific evidence is not/less proven) have existed for many years.

To explore the reasons behind the use of add-ons necessitates taking a psychosocial perspective. The field of ARTs allows the opportunity to examine the science-society nexus and to understand the interplay of several issues intertwined with biological reproduction, such as gender, and emotional, legal, political, and financial factors.\textsuperscript{1} The aim of this article therefore is to explore the reasons why patients may be choosing treatments which have a less clear evidence base. Using a psychosocial perspective, we consider the motivations behind patient and clinician behavior along with the wider societal and economic factors that may be impacting upon the increase in the use of adjuvant treatments in fertility clinics.

### Providing Hope and Choice

One possible explanation for the demand for add-ons lies in understanding the hope that these treatments provide when perhaps previous conventional interventions have failed. In the case of IVF, while it can be a successful treatment for some patients, unfortunately, the majority of patients will experience treatment failure.\textsuperscript{10,11} The experience of infertility can lead to distress— influencing the individual not only emotionally in the short term but also their sense of identity and expectations for the future.\textsuperscript{3,12,13} Therefore, engagement with reproductive technologies can be viewed as an attempt to overcome these crises. However, this engagement can carry a high price, both emotionally and financially—with IVF requiring a great investment of time, and both physiological and psychological resilience.\textsuperscript{14}

In terms of fiscal investment, the myriad of options for alternative and additional fertility treatments not only funds a thriving fertility industry\textsuperscript{15} but also appears to offer choice when people may feel that they are running out of time and/or money. It also means that the experience of IVF in what may appear to be a context of limitless options can be characterized by a paradoxical combination of hope and choice. Sarah Franklin has suggested that IVF and its related technologies are “hope technologies,” because they offer a seductive solution to the enigmatic problem of infertility.\textsuperscript{1} In this context, clinicians become providers of hope, and this may, in some contexts, impede conversations about possible failure.\textsuperscript{16}

These mutually constituting trends mean that clinics may be increasingly likely to offer a range of treatment modalities to patients, who are willing to try them to achieve a successful pregnancy.\textsuperscript{3,17} The pressure for a clinician to “solve” the problem before them is great. Individual clinicians may disagree with these treatments, but reports have emerged of clinics feeling under pressure to offer them in response to patient demand and concerns that patients will go elsewhere if these alternative treatments are not offered.\textsuperscript{18} A recent article by Ernst states that desperation is one key reason why clinicians may offer unproven medical therapies to their patients, and some would argue that this is a more acceptable option when the condition is undiagnosed and therefore conventional medicine is less likely to work.\textsuperscript{19} Indeed, given that infertility diagnoses are often uncertain (31% of cases are diagnosed as “unexplained”) and that success with IVF remains relatively low at around 26.5% and appears to be plateauing worldwide,\textsuperscript{20} perhaps this explains why clinics are increasingly offering a range of unproven additional treatment options in a bid to improve the chances of a baby.

Hope has been conceptualized and operationalized by Snyder,\textsuperscript{21} who argues that its existence is essential as a psychological coping strategy. However, cognitive rules which govern the appropriateness of hope include such criteria as the goal being under some control and at the mid-range in terms of probability.\textsuperscript{22} Therefore, in the case of IVF treatment, where the probability of success is low, and the locus of control resides externally to those undertaking the process, it may be deemed that nurturing hope by offering additional treatments, in these circumstances, is considered inappropriate.

### Being Optimistic

It is also thought that optimism plays a role in the decision to pursue treatment. This over-optimism was found in the research of Miron-Shatz et al\textsuperscript{23} who reported that women aged 43 to 45 years who have a predicted IVF success rate of 5% reported their estimated success in their next cycle to be 49%. However, this disparity is not thought to be because these individuals lack information on success rates or do not have an understanding of the fundamental principles of probability. More likely is that those who engage in these
treatments make a conscious decision to choose to be optimistic about their chances, rejecting statistical data in favor of focusing upon individual future hopes as described earlier. However, dispositional optimism has been found to be significantly related to several aspects of reproductive health,24 which may lead to speculation that if those with higher neuroticism (linked to poorer reproductive health outcomes) are less likely to engage in fertility treatment, then those who are undertaking treatment can be assumed to be more optimistic generally—possibly making them more likely to reject negative probability information and focus instead upon the pursuit of individual goals.

Providing Solutions to Uncertainty

It is generally well accepted that uncertainty is inherent in all aspects of medicine,25 as Osler wrote (cited in Kim and Lee25), “medicine is the science of uncertainty and art of probability.” Maybe it is the uncertain nature of the technologies and the experience of disappointment and loss which is so common in both infertility and subsequent IVF treatment that allows hope to persist26 and leads both patients and clinicians to engage in more controversial reproductive technologies.10 Indeed, in a recent overview article considering the significance of uncertainty for understanding experiences within health care settings, Mackintosh and Armstrong suggest that clinicians and patients are mutually engaged in a range of strategies to overcome and limit the effects of uncertainty within medical encounters and systems.27

However, Ernst questions whether clinicians can solve one uncertainty, for example, unidentified diagnosis (in this case infertility), by introducing a further uncertainty, for example, unproven therapy (in this case adjuvant fertility treatment).19 A taxonomy to describe different facets of uncertainty in the context of medicine has been proposed by Beresford which distinguishes between technical uncertainty (i.e., uncertainty arising due to a lack of data/evidence), personal uncertainty (i.e., uncertainty arising in the doctor–patient relationship and the delivery of patient care), and conceptual uncertainty (i.e., uncertainty arising as a consequence of applying/using the data/evidence in routine care).28

In the case of IVF add-ons, it could be argued that there is much technical uncertainty, with an absence of RCT data demonstrating their effectiveness. However, even if there is a dearth of RCT data, is it reasonable, as proposed by Dhawale et al,29 to expect doctors to be able to determine with certainty which patients will have the best prognosis/outcome following an intervention? The challenges of undertaking RCTs of assisted conception techniques are well reported. The real possibility of being assigned to the “control” arm is a barrier to recruitment for patients who are self-funding and are investing financially and emotionally in the hope that this treatment will result in a successful pregnancy.30

The lack of data demonstrating the efficacy of add-ons, also by default, provides less evidence of the potential side effects. Given that there is a perception that alternative treatments come with less side effects, it is possible that the lack of RCT data could also be fuelling the use of add-on therapy, not reducing it, that is, conceptual uncertainty. For example, one group of highly contentious add-ons is treatment associated with reproductive immunology. These treatments have been rated as a red light on the HFEA traffic light system3—indicating that there is no evidence that they improve IVF success rates. According to the HFEA website, the possible side effect profile includes headache, muscle pain, fever, chills, low back pain, thrombosis, kidney failure, and anaphylaxis. Yet, confusingly, the evidence to support these side effects does not exist, and despite these factors, reproductive immunotherapy treatments are available at several UK IVF clinics, often at an additional cost.

Furthermore, it would be a misrepresentation to suggest that IVF patients rely only on the published findings of RCT studies to support their decision-making, when there are numerous other sources of influence. Increasingly, the use of the internet and social media have overtaken face-to-face interactions to provide information and create social support for those undertaking fertility treatments.31 Given the polarized media coverage which varies between ideas about “miracle cures” versus being “ripped off,” and concerns regarding irrelevant, unreliable, or misleading fertility-related information available on the internet,32 the lack of face-to-face contact is an issue of concern. Nevertheless, some might argue that since add-ons allow each IVF cycle to include a different set of options intended to incrementally increase the chance of a “take home baby,” these optional extras increase opportunities for tailoring, tweaking, and fine-tuning a patient’s treatment protocol.

Indeed, lessons from marginal gains theory would suggest that patients choosing to use IVF add-ons may be making rational and sensible decisions in this regard. According to this theory, it is believed that when small incremental improvements are added together, significant improvements can be made. If fertility patients are already paying for one expensive round of IVF treatment, which has only a 26.5% success rate, then it would make sense to take additional small steps and pay additional money for an adjunct treatment in the hope that this may lead to a positive outcome. While evidence for the effectiveness of add-ons is not available in terms of RCT data, neither does it exist to the contrary. The alternative is that the failure of the standard IVF treatment would result in substantially more loss and financial recompense if the procedure had to be started all over again.

Dhawale et al29 explain that in a general context, patients may therefore be prioritizing different measures of success, more than simply relying upon the “clinical” markers of therapeutic benefit such as mean survival, etc. Instead, it may be the spread or variability of the potential effectiveness which is more greatly valued, such as the “hope” of a larger gain from choosing a particular treatment pathway.

The Role of Informed Treatment Decision-Making and Patient–Professional Relationships

The processes involved in patient decision-making and the communication that takes place between patient and
clinician may also help explain why patients choose to use and pay for IVF add-ons, something that Beresford refers to as “personal uncertainty.”

Despite their apparent popularity, definitive information about the provision and availability of fertility treatments generally is not publicly advertised. One survey of IVF patients in Poland found that a third of respondents reported that they learnt more about infertility from the internet than from the physician treating them. Despite the fact that the HFEA regulates UK clinics and reports on the success rates of IVF treatment, there is no way of knowing how many and which of these cycles involved an additional treatment, and thus, whether or not IVF success rates are improved by their inclusion. Moreover, there is additional complexity in regulating the use and success of add-ons when patients may choose to use more than one adjunct treatment and visit more than one provider to manage their own treatments. However, with their release of the traffic light system intended to rank add-ons, the HFEA does attempt to protect IVF patients from exploitation, as suggested by the following recent statement:

*We have been working with others to collaborate on a plan of action to improve the way in which treatment add-ons are offered in fertility clinics. It is the responsibility of all of us to ensure that innovation is encouraged with a clear evidence base, and patients are given transparent and relevant information about any treatments they are offered.*

From one perspective, it would appear that the uptake of IVF add-ons is based on mutual agreement, that is, in terms of both clinical recommendations and patient request/uptake. It could be argued that this apparent reciprocity aligns well with the model of patient-centered care and a shared model of decision-making, as a quality benchmark for the delivery of dignified care. This model of the doctor–patient relationship would suggest that the power between doctor and patient interaction is distributed more equally. This is in direct contrast to the traditional model of interactions between doctors and their patients, typically viewed as paternalistic, whereby patients are viewed as having no input into their treatment decision-making and remain passive in their healthcare. The discrete choice experiment into fertility care by van Empel et al. found that although pregnancy rates were reported to be more important to physicians, fertility patients assigned more value to patient centeredness and were willing to trade-off the higher probability of a successful pregnancy for a clinic that displayed patient centeredness. This suggests that although value is rightly placed on pregnancy rates, the importance of patient centeredness is perhaps being underestimated by fertility professionals. It could be assumed that the provision of IVF add-ons may be perceived by patients as a more tailored, individual treatment regimen and therefore increase their belief that their care is patient-centered. However, a lack of evidence about efficacy and possible commercial conflicts of interests—for example, where clinicians themselves may have invested financially in the development of the technique, or are shareholders in the clinic providing the treatment—raises questions regarding the extent to which patient-centered healthcare is being delivered. Studies also suggest that even when the principles of shared decision-making are evident within the clinical encounter, so that patients are fully informed and know their options and desired preferences, the balance of power still rests with the clinician,

suggesting that patients may ultimately act upon the advice and guidance of their doctor.

Part of the complexity of shared decision-making is that the intentions behind patient decisions are emotionally and socially complex. Indeed, within the field of assisted conception, some authors report that decision-making around fertility treatments are based more on the feelings of loss and overwhelming desire for a child rather than relevant and sufficient information provision. Human judgment and decision-making has also been considered to be inherently flawed, with Prospect Theory stating that highly unlikely events are either ignored or over-weighted. Errors in rational decision-making are also exacerbated by the role of emotions and vividness. This has been identified and defined by Kahneman as “emotional framing,” so that the ways in which treatment options are communicated (e.g., in a positive or negative way such as “survival vs. mortality” and “life vs. death”) can lead to a cognitive bias toward that treatment, especially when the information has been framed in a positive manner.

Consequently, there is the possibility that health care professionals unknowingly bias patient decision-making in the way they communicate the risks and benefits of IVF add-ons. They may also bias patients toward uptake of these adjunct therapies, if the clinical encounter aligns more closely within the framework of a traditionally authoritarian doctor–patient relationship. It is important to remember that while those seeking IVF treatment are “patients,” they are also consumers of healthcare technology. In terms of treatment decision-making, the additional costs of IVF add-ons might be perceived as leading to a better-quality service/product and increased chance of becoming pregnant. Within the highly emotive context of infertility, it has been suggested that add-ons have created a “perfect storm” of exploitation. These factors may undermine the values of informed consent and shared decision-making.

### Patient’s Beliefs and Complex Motivations

Also “certainty,” driven by the data and evidence, may not be important for individuals and couples pursuing assisted conception techniques. It would be overly simplistic to assert that success rates are the primary considerations when patients choose whether or not to engage in fertility treatments. For example, consider “Compassionate Transfer,” defined by Riggan and Allyse, when frozen embryos are transferred into the uterus at an infertile time in the menstrual cycle, as an alternative to embryo disposition. This procedure is considered by many to be an unnecessary or even exploitative adjunct to fertility treatment; however, the authors argue that it can be an ethical extension of fertility care for certain patients and has the potential to be a
The Role of Commercialization

It has been suggested that one of the reasons for the expansion in such treatments rests in the profit margins they offer to an increasingly privatized and corporatized fertility sector. While concerns about the commercialization of IVF have existed for several years, something Marilyn Strathern refers to as the “enterprising up” of nature (in this case fertility), the introduction of add-ons presents a new set of questions regarding efficacy.

Concerns about the scientific and commercial legitimacy of add-ons have therefore led some commentators to argue that offering expensive and often unproven treatments is an exploitative practice. This use of unproven treatments is especially relevant in the context of IVF more widely, which in itself remains uncertain, and which often proceeds on a trial-and-error basis, especially where diagnoses are unclear.

A potentially more complex picture emerges when considering that recent evidence suggests some of these adjuvant treatments may in fact adversely impact upon IVF outcomes. An analysis of worldwide live birth rates between 2004 and 2016 reports that while the decline in birth rate may be the consequence of an aging demographic of women presenting at IVF clinics for fertility treatment, it also appears to coincide with the introduction of several IVF add-ons, undertaken in the process of embryo selection, mild ovarian stimulations, and cycle interruptions. If a link between add-ons and success rates is established, it would be IVF patients who would potentially suffer the consequences—both financially and in terms of their clinical outcomes, especially older women who are already at a greater risk for a poorer prognosis and reduced success rate.

Answering the question of why patients use add-ons may lie in understanding that they form part of a wider landscape in which the range of treatment options offered to patients continues to expand with clinics under pressure to attract an increased share of the market, as well as to meet demand from an increasingly diverse number of patient groups. In light of debates about increasing commercialization, authors have drawn our attention to the potential conflicts of interest which may be present when fertility clinics provide an ever-growing array of treatment options to patients, especially when they are unproven. Given the considerable financial gains to be accrued from the offer of additional treatments, authors have argued that there exists a growing tension between profit and care, whereby clinicians may need to balance the needs of patients with a motivation to increase revenue. While this is an important consideration, Mayes et al. alert us to the dangers of an overly simplified set of arguments about commercialization and conflicts of interest. They suggest that rather than seeing interests as a hierarchy, that we see them as an overlapping and intersecting web, whereby as we have suggested, both patients and clinicians are invested in successful treatment outcomes.

On a societal level, Pugh argues that the commercialization of childhood is revolutionizing the way that parenting is experienced. Pugh states that in the United States in 2004, $670 billion was spent on or by children, and contends that
this commodity consumption is shaping expectations of what parents should provide for their children, and how this cultural environment defines what it is to care and belong. These expectations of parenting could viably be transferred to consumer behaviors during pregnancy and thus, it may be argued that the marketing of fertility “addons” is an example of commercialization culture, even before conception occurs. Pugh describes those who engage with them as “neither dupes nor hedonists.”. Instead, the lived experience of inequality perhaps increases the urgency by those undertaking IVF to purchase additional add-ons (often at great sacrifice) in their strive to belong and join the world of parenthood.

In January 2021, the UK Government Competition and Markets Authority (CMA) released draft consumer law guidance for fertility clinics, due to come into effect in the following spring. This guidance documents the shift in thinking about users of these technologies from fertility patients to fertility treatment consumers. Therefore, it aims to increase the awareness of consumer rights in this area, especially around treatment add-ons where there is a limited evidence base and a potential opportunity for harm but also highlighting the need for better information provision for patients, especially in the early stages of treatment seeking.52

The Move toward “Boutique” Medicine

Add-ons also form part of a wider (but related) cultural change, which sees biomedicine increasingly individualized and personalized. For example, a wider shift toward tailoring in the personalization of drug treatments (via individual genomic sequencing) may be reconfiguring the way we imagine medical treatment more generally. This shift may lead to a reimagining in how treatments are provided and how medicine is organized.

In the context of a move toward a model of “boutique” fertility treatment, patients may behave more like customers and may demand increased “choice” over their treatment protocols. Patient expectations about appropriate levels of tailoring of their fertility treatment therefore need to be situated within this wider sociomedical context. Some social scientists have referred to these changes as part of the growing “responsibilization” of patients; a sociopolitical process in which individuals are increasingly instilled with a moral imperative to do everything possible to improve their (in this case, reproductive) health.53–55 In this context, patients are expected to engage in an increasing amount of “health work” and to take more responsibility for contracting their own health care. This is particularly true within an increasingly privatized model of healthcare in the United Kingdom. It has been suggested that increased choice coupled with the imperative for patients to act, ties into new discourses of medical hope whereby hope is directly and tied into new increasingly privatized model of healthcare in the United

Conclusion

The reasons fertility patients use unproven “optional extras” are complex, with interpersonal, psychological, and social factors intertwining to generate an increase in the use of IVF add-ons. Insights from the social sciences help explain some of the possible motivations behind patient and clinician behavior including hope, optimism, patient choice, addressing uncertainty, and avoiding possible future regret, along with the wider societal and economic factors such as commercialization and the move toward boutique medicine that may be impacting upon the increase in the use of unproven adjuvant treatments in fertility clinics more widely.

To support informed patient choice, recent moves from regulatory bodies to improve transparency about the effectiveness of these optional extras and to disclose the financial conflicts of both clinician and clinics is a positive step. However, greater understanding is needed about the extent to which IVF patients will prioritize this evidence over other forms of direct-to-consumer advertising (such as clinic websites, social media, peer recommendation, and forum posts). It may be that belief in these interventions, along with the marginal gains and hope these technologies provide in an area of medicine where uncertainty dominates, is the main motivation to try anything to achieve a positive outcome. IVF add-ons therefore need to be understood as part of this wider landscape in which patients are increasingly mobilized to contract their own care. It will be interesting to observe whether demand continues to increase for these treatments in light of the recent HFEA publication, on-going discussion about their legitimacy, and the emergence of new data suggesting some add-on treatments may actually adversely impact upon IVF outcomes. Only time and investment in future research will help us answer these questions more fully.

Conflict of Interest

None declared.

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