

2019 review of treatment add-ons listed on clinic websites





1. Background

- 1.1. Patients undergoing fertility treatment at licensed clinics in the UK are often offered services in addition to their standard IUI, IVF or ICSI treatment cycle. These services are known as treatment add-ons and are offered on the basis that they improve the chance of having a baby. However, some treatment add-ons have varying levels of evidence to support their effectiveness and safety and, at times, this evidence can be contradictory. Add-ons are also frequently being offered to patients at a charge, which can vary greatly between clinics.
- 1.2. The HFEA has been concerned about treatment add-ons for some time and made two early policy interventions. The first aimed to improve the quality of the public information available on the evidence base. In 2017, the HFEA published traffic light ratings, agreed with its independent Scientific and Clinical Advances Advisory Committee (SCAAC), reflecting the published evidence from Randomly Controlled Trials (RCTs) of nine commonly offered add-ons. Two additional add-ons were added to this list in 2018 bringing the total number of reviewed by the HFEA to 11. Second, in January 2019 the HFEA agreed a consensus statement with 11 professional and patient bodies that set out a number of principles on the offering of add-ons with the aim of bringing about a culture change in the fertility sector towards more responsible innovation.
- 1.3. To get a better understanding of which add-ons are offered to patients and the price charged, in 2016 we gathered data on the 9 add-ons that were reviewed under the HFEA traffic light ratings system (together with DNA fragmentation which is listed in the additional information on our add-ons webpage). We repeated this review in 2018 with all 11 treatment add-ons review by the HFEA to assess whether there had been a change in the frequency or price of add-ons being offered on clinic websites. This 2019 review updates that work.
- 1.4. The information presented in this review provides a flavour of what was being offered to patients in UK fertility clinics in September 2019, but it is not the full picture. Information on websites may be outdated and not reflect the current cost or availability of treatment add-ons. Some clinics offer treatment add-ons as part of a package, so the individual cost of the treatment add-on is not available on their websites. And it is important to remember that the fact that a clinic offers a particular add-on does not mean that it is widely used.
- **1.5.** Further evidence on the uptake of treatment add-ons can be found in the survey of 1,017 patients that the HFEA conducted in 2018. This indicated that 74% of patients that had received treatment within the last two years had had used at least one treatment add-on.

2. Findings

How many clinics offer treatment add-ons?

- 2.1. As of September 2019, 136 clinics held licences from the HFEA to provide fertility treatments, store eggs, sperm and embryos and carry out embryo testing. Of these, 15 centres were only licensed to undertake embryo research and do not therefore offer treatment add-ons in a clinical setting. The remaining 121 treatment and/or storage centres form the basis of this review.
- **2.2.** The number of licensed treatment and/or storage clinics that offered treatment add-ons on their websites during each of the review years is set out in Table 1. From this we can see that the number of clinics offering add-ons on their website has decreased each year, from 78% in 2016 to 69% in 2018 and 64% in 2019.

Table 1: Number of licensed clinics offering treatment add-ons on their websites for 2016, 2018 and 2019

Licence Type	No. of centres (2016)	No. of centres offering add- ons (2016)	No. of centres (2018)	No. of centres offering add- ons (2018)	No. of centres (2019)	No. of centres offering add- ons (2019)
Treatment with storage	85	Data not available	93	75 (81%)	92	71 (77%)
Treatment only	13	Data not available	9	1 (11%)	9	1 (11%)
Treatment with storage and research	8	Data not available	7	6 (86%)	7	5 (71%)
Storage only	6	Data not available	12	1 (8%)	13	1 (8%)
Total	112	87 (78%)	121	83 (69%)	121	77 (64%)

2.3. The percentage of treatment and/or storage clinics websites that offer each of add-ons is displayed in Table 2. The add-ons reviewed is limited to the 11 add-ons under the HFEA traffic light ratings system and DNA fragmentation.

Table 2: Percentage of licensed clinics offering each treatment add-on on their website

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Add-on	HFEA traffic light rating	Percentage of treatment clinics (n=112) offering add-on (2016)	Percentage of treatment clinics (n=121) offering add-on (2018)	Percentage of treatment clinics (n=121) offering add-on (2019)
Artificial oocyte (AOA)-calcium ionophore	Amber	1%	4%	3%
Assisted hatching	Red	59%	58%	51%
DNA fragmentation	N/A	32%	43%	39%
'Embryo glue'	Amber	25%	47%	55%
Endometrial scratching	Amber	60%	66%	66%
Freeze-all cycle	Amber	10%	14%	29%
IMSI	Red	n/a*	23%	23%
Intrauterine culture	Red	1%	1%	0%
PICSI	Red	n/a*	14%	12%
Preimplantation genetic screening (PGS)	Red	32%	49%	58%
Reproductive immunology	Red	18%	27%	30%
Time-lapse imaging	Amber	56%	59%	55%

- 2.4. Several points can be drawn from this data. There was a decrease in frequency for six treatment add-ons between 2018 and 2019. Of note, intrauterine culture, as of September 2019, was no longer offered on any clinic websites. There was an increase in the frequency of four treatment add-ons being offered on clinic websites. Two treatment add-ons had no change in offering between the 2018 and 2019 reviews.
- 2.5. The most common add-on listed was endometrial scratching, which was advertised by 66% of clinics that offer treatment add-ons on their websites. Endometrial scratching was also the most common add-on in both 2016 and 2018 (offered by 60% and 66% of treatment and/or storage clinics respectively). As of 2017 endometrial scratching has been rated as 'amber' by the HFEA's SCAAC, meaning there is a conflicting body of evidence for this add-on and further research is required

^{*} Intracytoplasmic morphologic sperm injection (IMSI) and physiological intracytoplasmic sperm injection (PICSI) were not included in the HFEA's 2016 treatment add-ons website review. These treatment add-ons were not added to the list of add-ons reviewed by the HFEA until 2018.

- 2.6. The 2018 HFEA patient survey also found that endometrial scratch was the most commonly used add-on by patients that had undergone fertility treatment within the last two years, with 27% of patients saying that had used it.
- **2.7.** 66% of clinics advertising treatment add-ons were privately managed, and 67% of the clinics that were privately managed were part of a group. The remaining 33% of clinics that offered treatment add-ons on their website were NHS managed clinics, and 4% of the NHS managed clinics were part of a group.
- 2.8. The most common treatment add-on offered at NHS managed clinics was endometrial scratching (offered at 73% of clinics) and the most common offered treatment add-on in private clinics was PGS (offered at 75% of clinics).

What do add-ons typically cost?

- 2.9. The consensus statement on the responsible use of treatment add-ons in fertility services agreed that, in principle, patients should not be charged extra to take part in research, including clinical trials. 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.
- 2.10. Despite this consensus, the evidence from this review suggests that patients are often charged an additional price to use treatment add-ons in their treatment cycles. This can either appear as a separate stand-alone cost or be incorporated into an overall package cost usually with a corresponding increase in price charged. The price of each treatment add-on can vary greatly been clinics.
- 2.11. 71 clinics that advertised treatment add-ons on their website included an estimated cost for an IVF treatment cycle. Of these, 56 clinics provide an estimation of the cost of a 'standard' IVF treatment cycle without any add-ons included, with an average price of £3,475 (the lowest advertised price was £2550 and the highest £4995). It is important to note the caveats around this number. Some of the treatment cycles on the lower end of the estimated costs were for natural or modified IVF cycles which involve the use of fewer drugs which should make treatment cheaper. Others did not include the price of medication or other expenses such as compulsory screening blood tests or consultation appointments. This sort of variation may give patients an unrealistic expectation of the price of an IVF cycle.
- **2.12.** 15 clinics listed time-lapse imaging, 'Embryo Glue' or assisted hatching in the cost of a standard package of IVF. It varied between clinics whether these packages included just one of the addons, a combination of two or all three. The average cost of an IVF package with these add-ons included was £3771 (n=15) compared to the average advertised price of £3474 (n=56) for an IVF cycle without these add-ons an average increase of £297.
- **2.13.** Some add-ons are offered in the form of an entire cycle package centred on the add-on, for instance the add-on freeze-all is always a cycle. This is summarised in Table 3.

Table 3: Treatment add-ons offered to patients as a cycle

Add-on	HFEA traffic light rating	No. of clinics offering add-on cycle	Average cost (£)	Lowest cost (£)	Highest cost (£)
Freeze-all cycle	Amber	22	3704	3000	4945
PGS cycle	Red	6	8993	6460	9500
PICSI cycle	Red	1	4250	4250	4250
IMSI cycle	Red	1	4400	4400	4400

Table 4: Cost for treatment add-ons offered on clinic websites

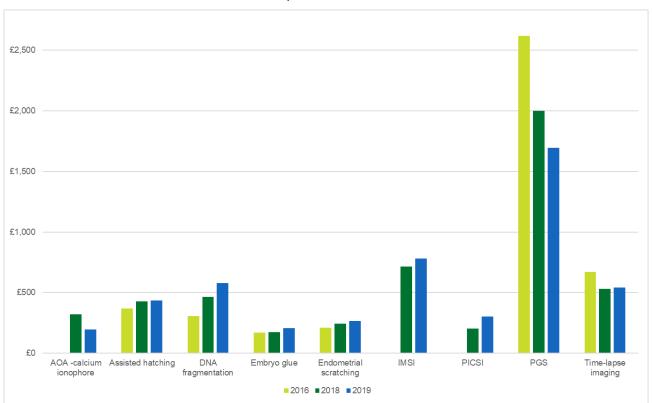
Add-on	HFEA traffic light rating (as of September 2019)	No. of clinic websites displaying a standalone cost for an add-on	Average cost (£)	Lowest cost (£)	Highest cost (£)
Artificial oocyte (AOA)- calcium ionophore	Amber	2	195	195	195
Assisted hatching	Red	32	434	130	615
DNA fragmentation	N/A	29	579	160	1125
'Embryo glue'	Amber	24	208	55	525
Endometrial scratching	Amber	49	264	115	1250
IMSI	Red	16	783	240	1855
Intrauterine culture	Red	0	0	0	0
PICSI	Red	8	303	100	900
Preimplantation genetic screening (PGS)	Red	36	1696	290*	2850
Time-lapse imaging	Amber	17	541	350	788

2.14. Table 4 shows the average costs identified for each of the treatment add-ons from the 69 clinics that display standalone costs on their website. In such cases, we assume that the patient will pay for the price of an IVF package and the price of an add-on is additional to the package (i.e. a standard IVF package cost of £3350 and a separate standalone cost of £475 for assisted hatching, would mean that the patient would pay at least £3825).

^{*} This price of £290 did not include essential expenses such as genetic consultation, biopsy and courier fees. When included this price comes to £1090 giving an unrealistic expectation of the price that a patient will pay for PGS.

- 2.15. Table 4 also demonstrates the high degree of variability in the price of add-ons within the sector. The largest percentage increase between the highest and lowest advertised price was for PGS at 883%. However, the lowest advertised price of £290 for PGS did not include essential expenses such as genetic consultation, biopsy and courier fees. When included this price comes to £1090. This gives an unrealistic impression of the price that a patient will pay for PGS.
- 2.16. The second largest percentage increase between the highest and lowest advertised price for a treatment add-on is embryo glue, at 855%. Unlike PGS this difference is not due to misleading prices on clinic websites but is a reflection of the variability in prices that patients can be charged for the same treatment add-on at different clinics.
- 2.17. Having now reviewed clinic websites on three occasions we are able to track the prices charged for add-ons over time. Figure 1 shows the change in the average costs for nine of the treatment add-ons over the previous review years. Of these, six add-ons increased modestly with DNA fragmentation showing the highest percentage increase between 2016 and 2019. The remaining three add-ons decreased in price, with AOA decreasing by the highest percentage from 2018 to 2019. It is also clear from this table that although the average price of PGS decreased markedly since 2016, it remains the most expensive add-on at over £1,600 on average in 2019.

Figure 1: Overview of the change in cost for each treatment add-on included in this analysis over 2016, 2018 and 2019.



2.18. Some treatment add-ons, like reproductive immunology, cover a variety of different treatments, with a wide variety of different prices charged, as Table 5 demonstrates.

Table 5: Overview of reproductive immunology treatment types offered

Reproductive Immunology treatment type	No. of clinics offering add-on	Average cost (£)	Lowest cost (£)	Highest cost (£)
Prednisolone	8	4	3	8
LIT	1	850	850	850
Intralipids	11	345	250	543
IVIG	4	1567	1500	1700
NK Cells	15	501	360	700

Are treatment add-ons available across the UK?

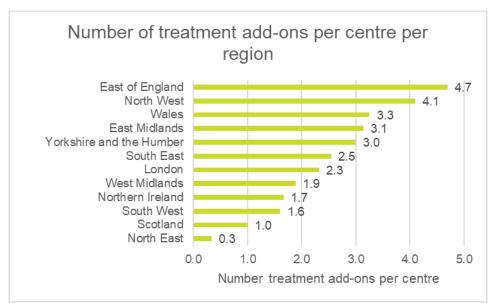
2.19. The availability of treatment add-ons varies across the UK. Table 6 shows the location of treatment and/or storage clinics and the numbers of those that offer add-ons. 87% of clinics that offer treatment add-ons on their website were located in England, with 27% of those in London.

Table 6: Distribution of treatment and/or storage centres around the UK

Country	UK Region	Number of treatment clinics	Number of treatment clinics offering add-ons
England	London	37	21
England	East Midlands	7	4
England	East of England	10	9
England	North East	6	2
England	North West	10	9
Northern Ireland		3	2
Scotland		9	4
England	South East	11	6
England	South West	10	6
Wales		4	4
England	West Midlands	9	6
England	Yorkshire and the Humber	5	4
Total		121	77

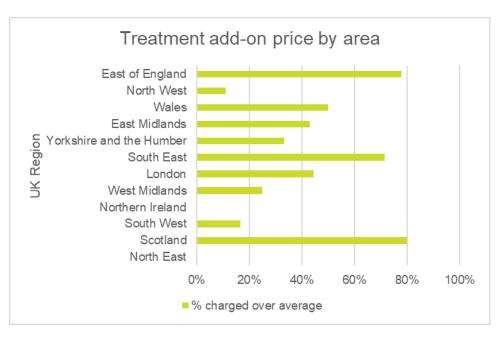
2.20. Figure 2 shows the average number of treatment add-ons offered per treatment and/or storage clinic by nation and region. It has been suggested that because London has the most clinics and the most competitive market this would encourage an environment where treatment add-ons are heavily advertised to create a competitive advantage. However, it is the East of England where we find the highest average number of add-ons per clinic.

Figure 2: Average number of treatment add-ons offered per treatment and/or storage clinic across the UK



2.21. The costs of treatment add-ons also varies by nation and region. Figure 3 shows the percentage of add-ons that were offered at above average cost. The East of England, as well as offering the highest density of treatment add-ons, also charges patients more than average. Clinics in Scotland, despite not offering many add-ons, charge patients more than average as well.

Figure 3: Proportion of treatment add-ons charged at above average cost by UK nation and region.

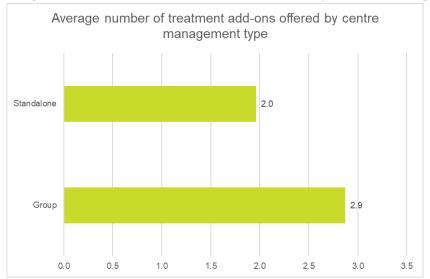


Do groups offer more add-ons than standalone clinics?

2.22. An increasing number of clinics are operating in either formal or informal partnerships or 'groups'. It has been suggested that standalone clinics were not able to offer as many treatment add-ons as clinics that were part of a group and that this would put them at a competitive disadvantage. It was

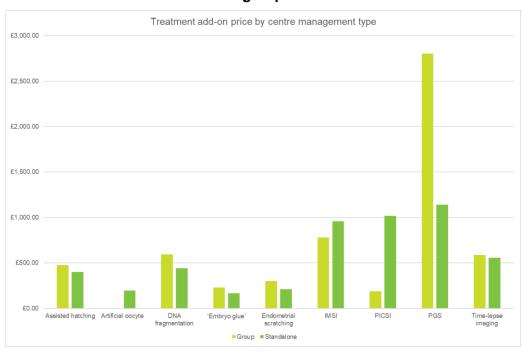
- also argued that standalone clinics were not able to afford the expensive equipment that is sometimes necessary to offer add-ons.
- 2.23. Figure 4 shows that, on average, clinics in a group did offer more treatment add-ons than those in standalone centres. However, these was a lot of variation in the number of treatment add-ons offered by different groups on their websites and in quite a few cases, standalone clinics did offer more treatment add-ons than clinic groups.

Figure 4: Average number of treatment add-ons offered by centre management type



2.24. Figure 5 shows there was some variation in the price of treatment add-ons offered at standalone clinics and those clinics that were in a group. The largest percentages increase in price where found in PICSI, which cost 434% more in standalone clinics that those in a group, and PGS, which cost 146% more in centres that are part of a group compared to standalone clinics.

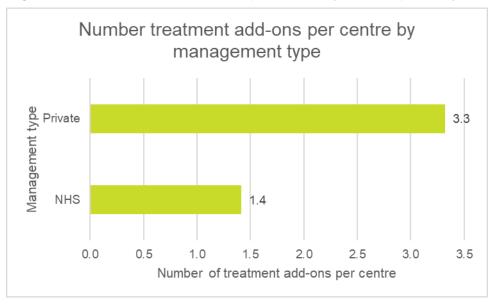
Figure 5: Average price of treatment add-ons in standalone centres and centres that were part of a group



Do private clinics offer more add-ons that the NHS?

2.25. Figure 6 shows the number of treatment add-ons offered per clinic for both the NHS and the privately sector. The evidence suggests that on average the private sector is more than twice as likely to offer add-ons than the NHS. This is due to a combination of perceived commercial advantage and NHS controls. However, some NHS clinics do offer add-ons as a 'bolt-on' option to a patient's NHS funded treatment cycle at an additional price. However, this is can be dependent on the local Clinical Commissioning Group (CCG) guidance in England and is often not well advertised on NHS clinic websites.

Figure 6: Average number of treatment add-ons per centre by NHS or privately managed centre.



3. Key messages

Treatment add-ons offered to patients

- Clinics continue to charge patients for treatment add-ons that the HFEA has identified as not having enough evidence to show that they are either safe or effective.
- The number of clinics offering add-ons on their website has decreased each year, from 78% in 2016 to 69% in 2018 and 64% in 2019.
- The is variability in the frequency that treatment add-ons are offered on clinic websites. The
 most common add-on listed was endometrial scratching, which was advertised by 66% of
 clinics that offer treatment add-ons on their websites. However, intrauterine culture, as of
 September 2019, was no longer offered on any clinic websites.
- There is a high degree of variability in the price of add-ons within the sector, however these
 prices can exclude essential expenses giving a misleading price to patients. For example, the
 lowest advertised price for PGS of £290 did not include genetic consultation, biopsy and
 courier fees. When included this price comes to £1090.
- It has been suggested that because London has the most clinics and the most competitive
 market this would encourage an environment where treatment add-ons are heavily advertised
 to create a competitive advantage. However, it is the East of England where we find the
 highest average number of add-ons per clinic.

- The costs of treatment add-ons also varies by nation and region. The East of England, as well
 as offering the highest density of treatment add-ons, also charges patients more than
 average. Clinics in Scotland, despite not offering many add-ons, charged patients more than
 average.
- On average, clinics in a group did offer more treatment add-ons than those in standalone centres. However, these was a lot of variation in the number of treatment add-ons offered by different groups on their websites and in quite a few cases, standalone clinics did offer more treatment add-ons than clinic groups.
- There was some variation in the price of treatment add-ons offered at standalone clinics and those clinics that were in a group.
- The evidence suggests that on average the private sector is more than twice as likely to offer add-ons than the NHS. This is due to a combination of perceived commercial advantage and NHS controls.

Limitations

- This review could only consider clinic websites which included a price list for treatments.
 Therefore, any clinic which did not have a price list on their website was recorded not offering
 add-ons, but this may not be accurate in cases where the clinic only provides prices on
 patient request or in person.
- Information on websites may be outdated and not reflect the current cost or availability of treatment add-ons. This review also only considers information within prices lists as displayed on clinic websites at the time of data collection, September 2019.
- Some clinics offer treatment add-ons as part of a package, so the individual cost of the treatment add-on is not available on their websites.
- The number of treatment add-ons offered on a clinic's website only reflects the availability of add-on to patients and the potential for them to be used in treatment, not the actual frequency of use.
- The HFEA has no powers to regulate costs or prices.

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