



Human
Fertilisation &
Embryology
Authority

State of the fertility sector: 2016-17



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www.hfea.gov.uk

We are the UK's independent regulator of fertility treatment and research using human embryos. A world-class expert organisation in the fertility sector, we were the first statutory body of our type in the world.

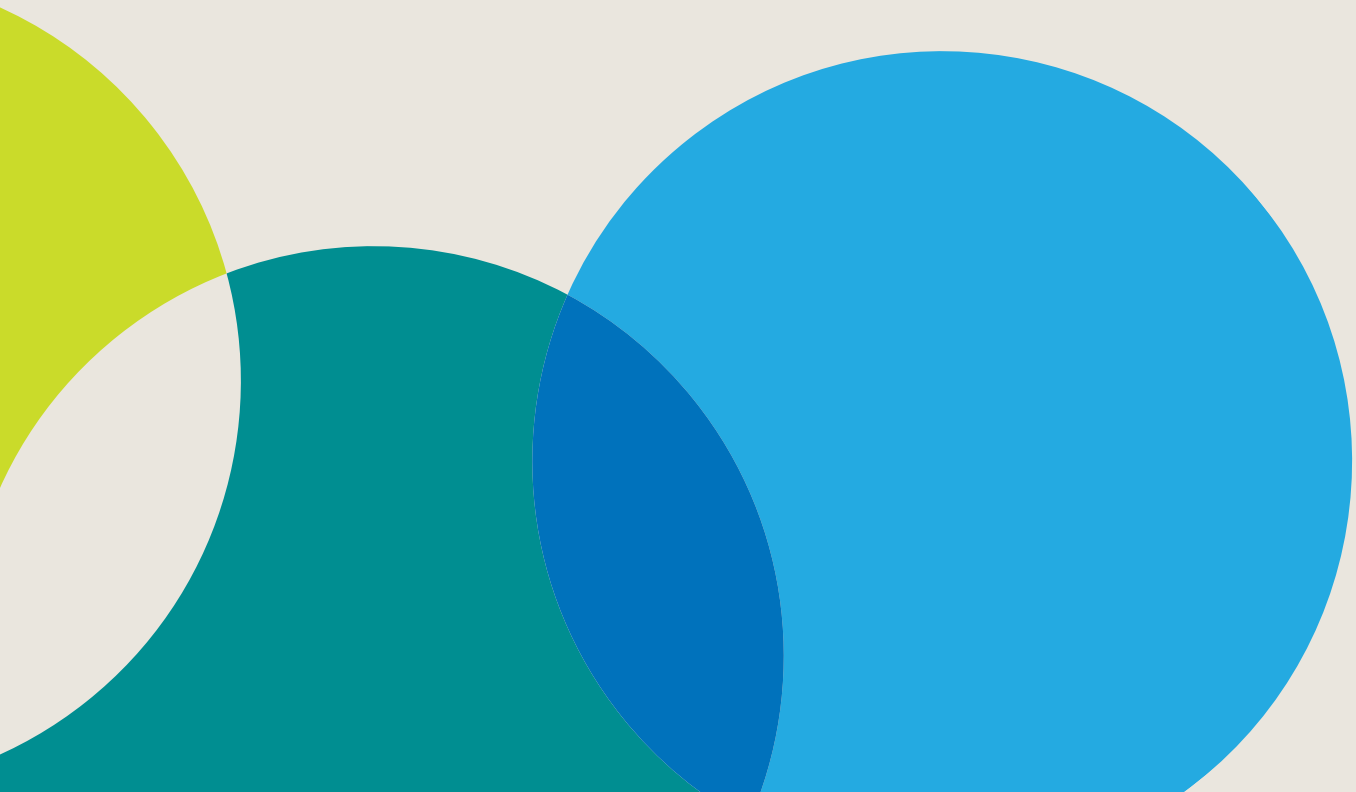


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Executive summary

Our vision for fertility services in the UK is high quality care for everyone affected by fertility treatment. We want patients and donors to have access to safe, ethical and effective treatment with good outcomes. We want them to be prepared for treatment and well supported throughout. And we want clinics to use data and other information to improve their performance for the benefit of their patients.



‘The state of the fertility sector’ report shines a light on how well the UK fertility sector is doing. In this new publication – bringing together previously separate reports on incidents, inspection findings and patient feedback – we show how fertility clinics and research laboratories performed in the financial year 2016–17. Analysing information collected through inspections, ongoing monitoring of outcome data, reported incidents and feedback from patients, we show the overall performance of the sector and of individual clinics.

So, what does it tell us? The report shows that fertility clinics perform very well on minimising multiple births: 86% of clinics have met our stretching target of no more than 10% multiple births. Working together, we have reduced the national multiple birth rate from 24% in 2009 to 11% today without reducing birth rates. This is a fantastic achievement which has increased the safety of IVF for mothers and their babies and reduced the burden on NHS ante- and neonatal services.

It also shows that clinics and laboratories perform well on compliance with our standards: 74% of clinics have a 5-star inspection rating and all 21 research licences show the highest level of performance. We have also seen slight improvements in incidents in clinics: the number of incidents as a proportion of treatments has reduced a little, as has the proportion of more serious incidents.

From the information collected in 2016–17, patients’ experience of care seems to be good, though the number of patients giving feedback was low. We have since redesigned our patient feedback systems and expect to be able to report on much richer and wider patient experience next year.

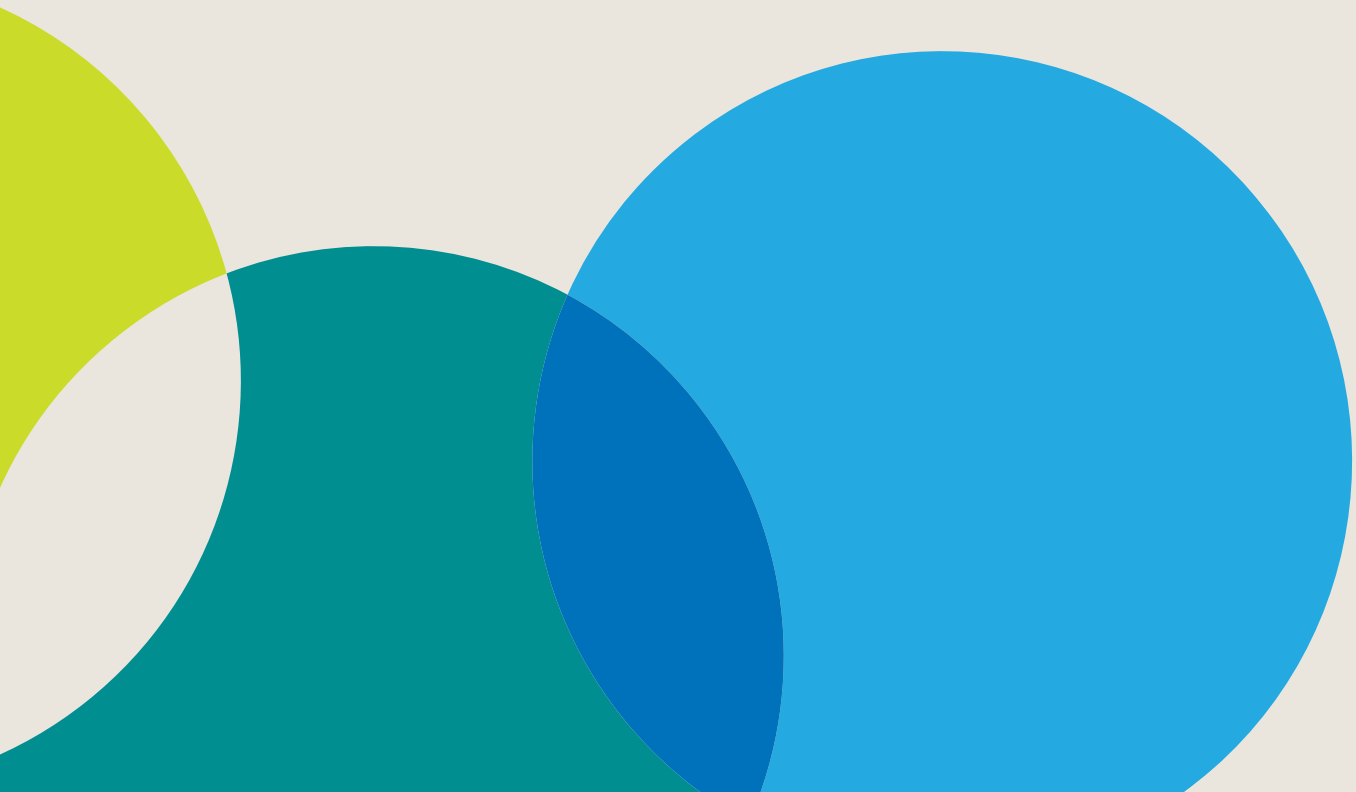
What have we learned from this? Despite overall performance being good, a small number of clinics need to improve their performance. We are focusing attention on those on less than a 5-star inspection rating and those which have not yet met the 10% multiple births target. We are also continuing to work across the sector to improve performance in key areas such as surgical procedures and quality management.

However, we want to go beyond good compliance. Fertility services in the UK are unusual in that of the 76,000 treatments taking place each year, 60% are paid for by patients themselves. With many private providers, increasingly working in multi-clinic groups, fertility clinics compete for business, particularly in London and Manchester. This doesn’t necessarily affect the quality of services – private providers can have better systems and equipment – but it can mean that patients are prey to marketing techniques which draw false comparisons between clinics and attention to new treatments and technologies which are not yet proven to work.

Our own patient information and support services, including Choose a Fertility Clinic, are a crucial and independent antidote to this. However, rather than working around the statistics clinics produce, we want clinics to change their behaviour and the key to that behaviour change has to be leadership. Over the coming year, through a review of our Code of Practice and working with professional bodies, we will develop new guidance, training and other initiatives to improve the leadership in clinics, so that the performance of the fertility sector as a whole becomes ever better for the patients we all serve.

How we regulate

As the specialist regulator of fertility treatment and research using human embryos, we closely monitor services in this area to reassure patients and donors that the services they use are safe and effective.



We regulate in three ways:

- We issue a licence to operate to each clinic and laboratory and inspect them at least every two years to ensure that they meet their legal obligations and our standards.
- We monitor the performance of clinics on an ongoing basis and publish quality measures on our website to inform patients and help them choose where to have their treatment.
- We operate an incident reporting system to ensure that clinics investigate any mistakes and that the sector as a whole learns from those mistakes.

The legal obligations and our best practice standards are published in our Code of Practice, which is organised into 13 areas of practice. The obligations and standards fall into the following areas of practice, which we check against on inspection:

- staffing
- counselling
- information and consent
- multiple births
- welfare of the child
- embryo testing
- donation and surrogacy
- use of gametes and embryos
- research and training
- facilities and administration
- treating people fairly
- record keeping and other obligations
- mitochondrial donation.

How we license and inspect clinics and research laboratories

We are required by law to inspect each fertility clinic or research laboratory at least every two years.

Fertility clinics offering treatment or storage services have licences which are usually four years long. We carry out a ‘renewal’ inspection before the end of the licence to assess the quality of the service and compliance with the law and our guidance. A licensing committee uses the evidence gathered on inspection and from other sources to decide whether or not to grant a new licence. If the committee is concerned about the clinic’s performance and compliance, it can grant a shorter licence or add conditions to the licence. In rare circumstances, it may decide not to renew the licence at all, in which case the clinic must stop providing services.

We also carry out an ‘interim’ inspection mid-way through the licence. The licensing committee uses that evidence to decide whether or not the licence should continue.

We monitor research laboratories in largely the same way as treatment and storage clinics. However, research licences are awarded for specified projects and a laboratory might therefore hold more than one licence. Research licences are three years long, rather than the four usually granted to treatment and storage clinics. Interim inspections of research laboratories are also carried out mid-way through the licence and the findings considered by a licensing committee.

Following the inspection, the inspector writes a report which identifies both areas of good practice and those which require improvement. The inspection report comments on the actions taken by the clinic to address areas of non-compliance identified. Areas of practice that require improvement are divided into the following categories:

- Critical non-compliance – an area of practice which poses a significant risk of harm to a patient, donor, and embryo or to a child who may be born as a result of treatment services.
- Major non-compliance – an area of practice which:
 - poses an indirect risk of harm to a patient, donor, embryo or to a child who may be born as a result of treatment services;
 - indicates a major shortcoming from the statutory requirements;
 - indicates a failure of the person responsible to carry out his/her legal duties;
 - is a combination of several other areas of non-compliance, none of which on their own are major but which together represent a major area of non-compliance.
- Other non-compliance – a departure from statutory requirements or good practice, but not a major non-compliance.



The inspection report and a recommendation from the inspector is then considered by a licensing committee, after which the clinic is informed of the decision. The minutes of the licensing committee and the inspection report are published on the clinic's entry on Choose a Fertility Clinic.

Our target is to complete the process of preparing an inspection report, making a licensing decision and communicating that to the clinic within 70 days of the inspection.

70 days

our target from inspection to
new licence

Feedback from clinics about the inspection process

During 2016–17 we carried out 81 inspections, falling to four categories:

- 25 inspections to renew a licence
- 29 interim inspections of treatment and or storage clinics
- 6 ‘initial’ inspections of new clinics
- 21 additional inspections, six of which related to a variation of the licence and 15 because of concerns (four of which related to consent to legal parenthood).

We ask the person who holds the licence in each clinic or laboratory (known as the ‘person responsible’) to give us feedback about their inspection, including the pre-inspection process, the inspection itself and its impact, and the inspection report.

Around 30% gave us feedback in 2016–17. More than 90% of respondents were neutral or positive about the pre-inspection process, the inspection itself and the inspection report. Just over 85% were positive that their inspection had promoted improvements to the way they work.

Where respondents gave negative feedback, this focussed on the self-assessment questionnaire carried out in preparation for their inspection, the accuracy and clarity of their inspection report and the reasonableness of the timescale for the addressing non-compliances.

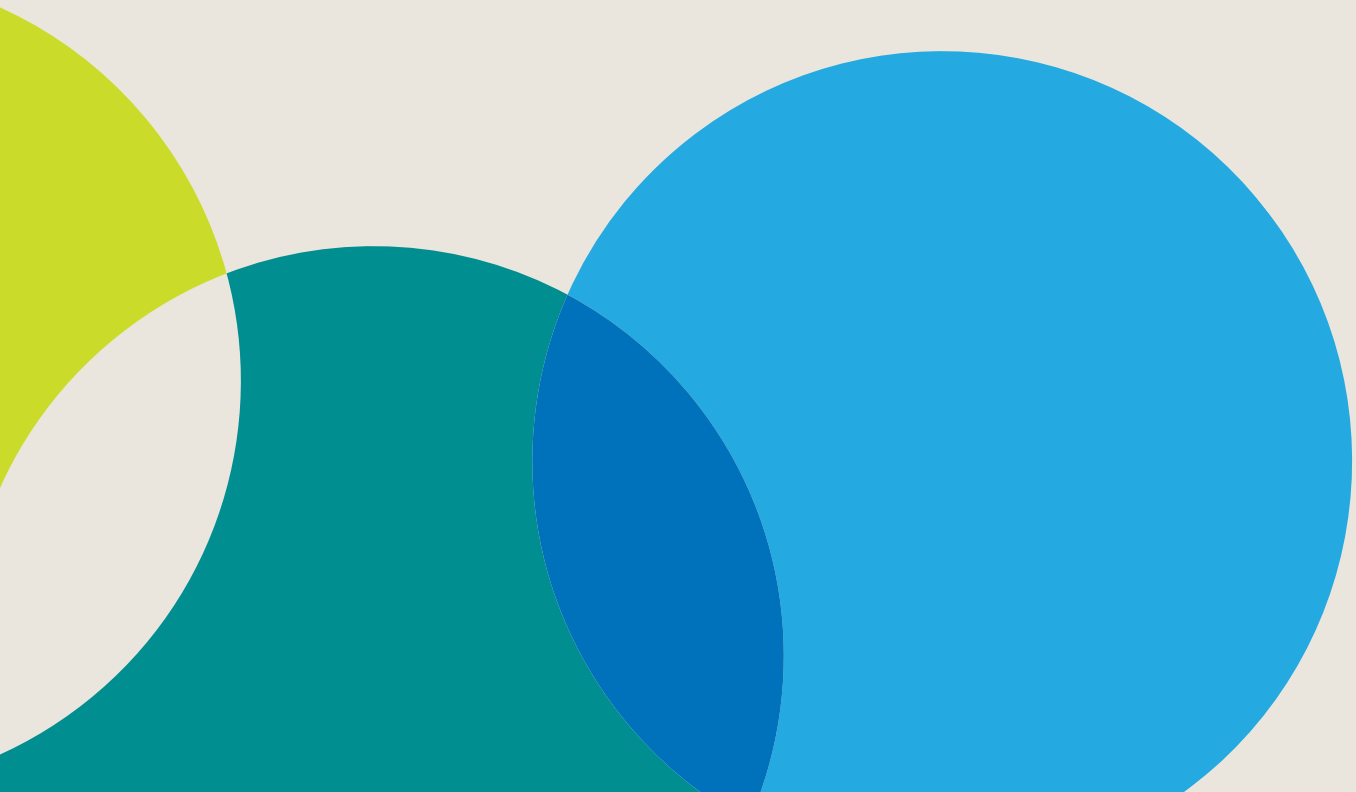
Overall, feedback suggests that our inspection process works well, the inspector’s assessments are seen as fair and their recommendations help clinics to improve.

85%

of clinics found the inspection useful

About the UK fertility sector

In 2016–17 over 75,000 cycles of IVF were carried out in 119 licensed fertility clinics across the UK. Most treatment offered at licensed fertility clinics is of good quality, delivered by trained professionals who have their patients' best interests at heart.

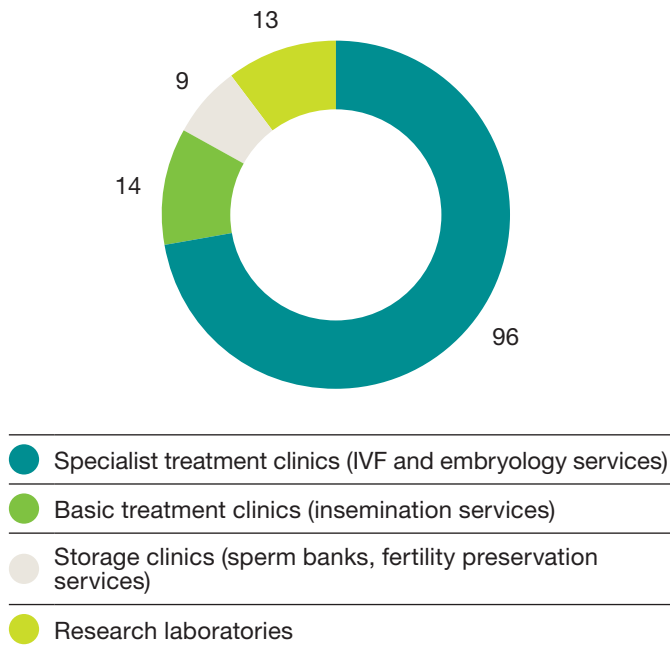


The circumstances in which that care is offered varies greatly: clinics vary considerably in size, in geographical location, in whether the service is provided by the NHS or in clinics wholly or partly owned by the private sector.

Types and number of clinics in the UK

At 31 March 2017, there were 132 licensed clinics and laboratories in the UK of the following different types:

Figure 1: Types of clinics and laboratories in 2016–17

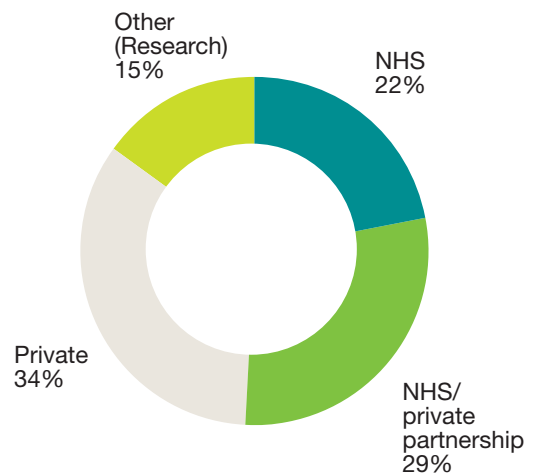


During the year, three clinics closed voluntarily and six new clinics opened.

There is a high proportion of self-funded treatment in fertility services, either in stand-alone private providers or in NHS services. Across the UK, around 60% of cycles are funded by the patient themselves. The proportion of NHS to self-funded cycles varies in the different regions, but this is mainly due to the concentration of private clinics in London and the South East.

The majority of clinics (34%) are privately owned, many of which are part of groups owning a number of clinics across the country. The second largest group of clinics (29%) are run by an NHS/private partnership where self-funded patients can access services through NHS institutions. NHS-only services make up just 22% of all clinics in the UK.

Figure 2: Proportion of NHS to private clinics



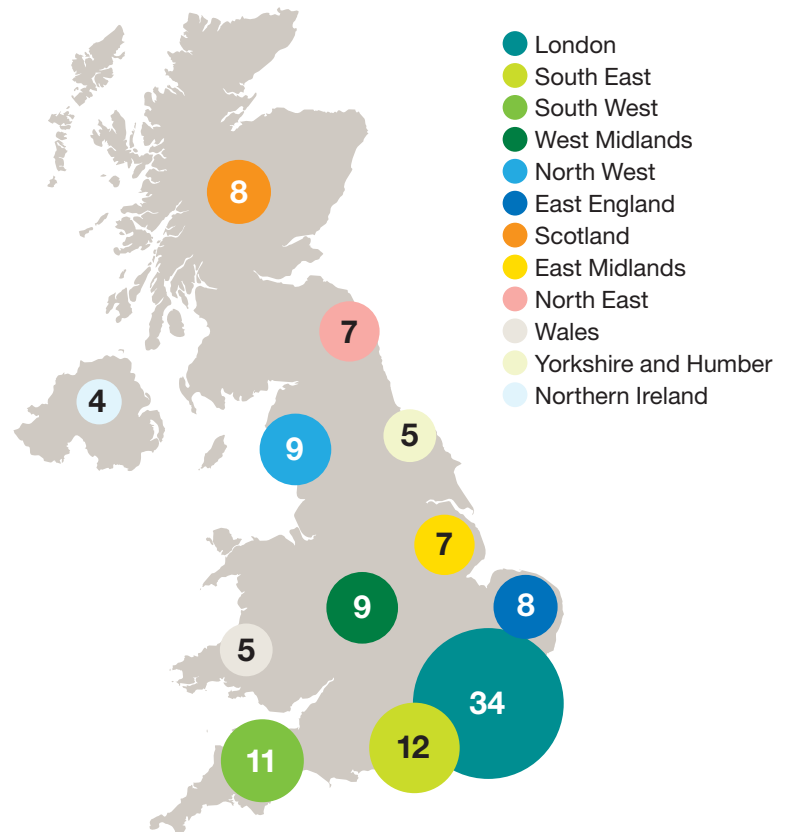
Location, size and type of clinics

Although treatment and storage clinics (excluding research) are geographically spread across the UK, a large majority are concentrated in London and the South East.

The size of clinics varies considerably. In 2016–17, the largest clinic provided 4200 cycles of IVF treatment whilst the smallest provided fewer than 100. The ten largest clinics (8% of all clinics) provided 26,700 cycles of IVF – 35% of all treatments.

Overall, the UK fertility sector provided treatment to around 60,000 patients. The vast majority of treatments were IVF (89%), with a small proportion being donor insemination (6%) and partner insemination (5%).

Figure 3: Location of clinics



86,016

Total treatments

76,469

IVF treatments

4,051*

Partner insemination treatments

5,496

Donor insemination treatments

*Calendar year 2016

Leadership of clinics

Leadership is central to the delivery of high quality health services. The law requires that each clinic or laboratory has a ‘person responsible’ (PR) who is named on the licence and is responsible for meeting the conditions of that licence. The PR’s duties are:

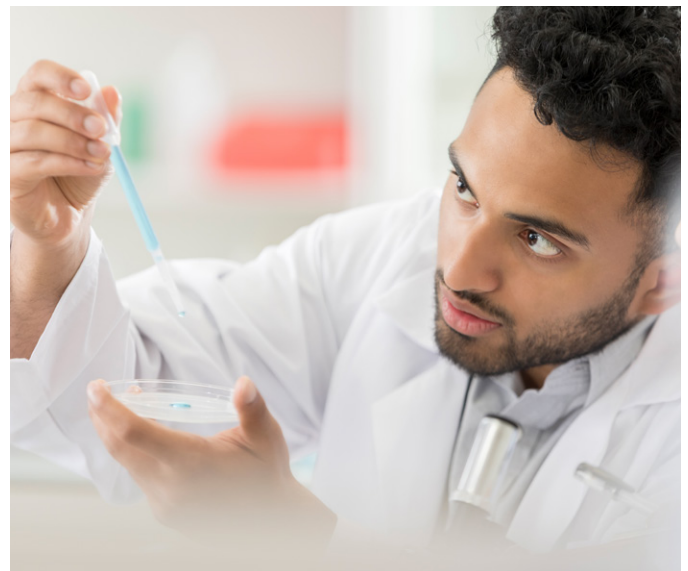
- maintaining and up-to-date awareness and understanding of legal requirements
- responding to requests for information and documents from the HFEA
- co-operating fully with inspections and investigations by the HFEA or other agencies
- informing the HFEA of any change to their professional registration.

Historically, the PR was often the lead clinician in a clinic. Today however, the role of PR is often held by a clinical scientist (embryologist or andrologist) or nurse.

The professional background of the PRs in treatment and storage clinics are:

- Doctor/consultant – 62%
- Nurse – 8%
- Scientist – 30%

Most PRs (56%) have taken on this responsibility in the last five years, whilst 44% have been a PR for 5–10 years.

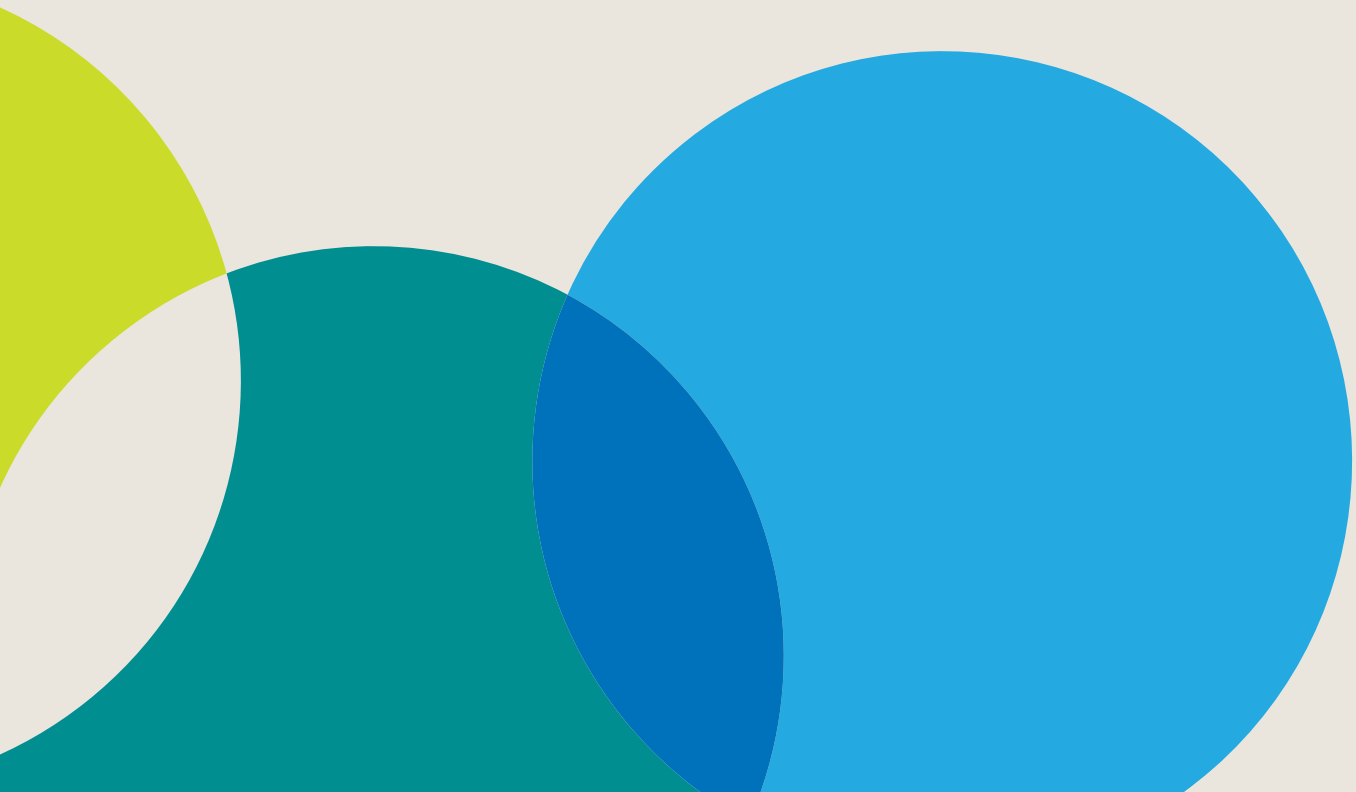


Key features of the UK fertility sector

- Most are specialist treatment providers (80% of service providers are IVF clinics).
- 60% of treatment is funded by patients themselves, whether in an NHS provider or a private clinic.
- The UK has a small embryo research sector (10% of all licensed entities).
- Treatment services are concentrated in London and the South East: they have 45% of patients and 39% of all treatment providers.
- A range of treatment services offered, though predominantly IVF (95%).
- Most persons responsible have a clinical background, though 30% are clinical scientists.

Quality of service and compliance

This section looks at the overall level of compliance in all licensed clinics and laboratories during 2016–17 assessed through inspection and monitoring.



Overall performance of treatment and storage clinics

Our top-line measure for the performance of fertility clinics is the length of the licence. We map the length of the licence to a star rating, which is published for each clinic in the Choose a Fertility Clinic section of our website. This allows patients to see the extent to which each clinic is complying with legal requirements and guidance.

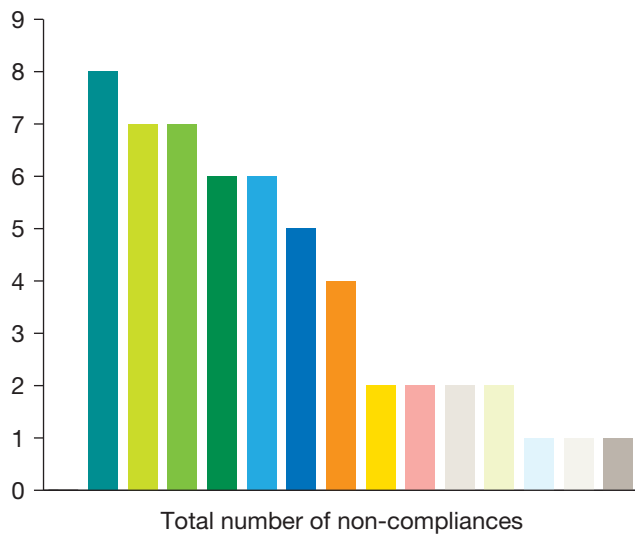
At 31 March 2017, the majority of our 119 treatment and storage clinics held a four-year licence and therefore had a five-star rating, showing that the fertility sector is operating at a generally high standard. The table shows the licence length, reason and associated star rating, as well as the number and proportion of clinics to which they applied in 2016–17.

Licence length	Reason	Star rating	No. clinics	% clinics
4 years	The most compliant clinics about which we have no significant concerns	★★★★★	86	74
3 years	Those clinics about which we have some concerns and therefore wish to carry out an interim inspection within one year (instead of two, as is normal)	★★★★	21	18
2 years	New clinics on their first licence (which therefore have no compliance history to draw on), with an interim inspection within one year	No rating – marked as ‘New clinic’	7	6
	Centres granted a 2 year licence due to concerns raised during the inspection process	★★★	2	2
Temporary (normally three months)	Applied either because of unresolved legal dispute or administrative error	Rating from the clinic’s previous licence	0	0
	Applied because we have serious concerns about the clinic and wish to see progress before granting a new licence	★	0	0

The areas of practice where clinics perform well

The chart shows 14 areas in which clinics generally performed well in 2016–17. On inspection, we found fewer than 10 instances of non-compliance in these areas, and very few critical non-compliances.

Figure 4: Areas in which clinics generally performed well in 2016–17



- Procurring/processing/transporting gametes and embryos
- Incidents and complaints
- Traceability
- Witnessing
- Welfare of a child
- Multiple births
- Counselling
- Payment and fees
- Suitable practices
- Confidentiality
- Import and export
- Egg sharing
- Ethics approval
- Research and training

An inspector’s example of good practice: removing success rates from a clinic’s website

“Information provided on a clinic’s website is the first port of call for many patients. However, this information can be misleading, focussing solely on success rates, presenting success rates that are out of date, or favouring a subset of patients so that the results look good.

During the inspection process, we check that information on the clinic’s website is reliable and accurate, according to our best practice guidance.

One clinic’s website was found to be non-compliant with guidance at two consecutive inspections. So the clinic took a different approach on their new website, deciding to keep success rates out of their patient information. This is a positive step, encouraging patients to move away from seeing success rates as an indicator of how ‘good’ a clinic is. Information on the website is clear and includes a ‘patient care’ tab, providing information on counselling and patient support groups and a ‘jargon busting blog’, demystifying common terminologies used in fertility treatment.”



Areas of practice improving this year

The number of inspections we carry out each year varies because clinics' licences start at different times, so comparing the performance of the sector from one year to the next is difficult. However, adjusting for size and complexity, we can observe that there has been an overall improvement of the sector in relation to the following areas of practice.

Consent

Couples who are not married or in a civil partnership and are using donor sperm in their treatment must give consent to legal parenthood. However, over the past few years we have found errors in these consents in many clinics and some couples have had to seek a court order to rectify the situation. To make sure such mistakes are not repeated, we have held workshops for clinic staff, produced information for patients and been persistent with clinics where we identified concerns. Clinics – and professional bodies – now take consent to legal parenthood very seriously and are implementing additional checks to ensure compliance.

An inspector's example of good practice: recording marital status

“It is imperative that clinics accurately record the marital status of their patients, to ensure that the correct legal parenthood consent forms are completed. Very often, the marital status is difficult to determine when auditing records on inspection.

However, at one clinic inspected earlier this year, there was an information sheet in the front of each patient record, which contained the patient's demographic details. We were impressed that patients were also asked provide answers to the following questions:

‘Are you married or in a civil partnership?’
Yes/No.

‘If ‘Yes’, are you married or in a civil partnership to the person you wish to have treatment with or to someone else?’

This is good practice because it does not make the assumption that if a patient declares a married or civil partnership relationship, that they are married/civil partners to the person they present with for treatment.

This then allows the clinic to determine whether further consent is required, which could be missed in the absence of this enquiry, and prevents incorrect assumptions being made that the patient couple are married/civil partners to each other.”

Equipment and materials

Since 2014 we have required all clinics to use only 'CE' marked equipment. Before this time, clinics sometimes developed their own laboratory equipment (such as culture medium) in house, so they found it difficult to switch to sourcing CE-marked equipment for such specialist use. However, awareness and understanding in clinics has improved significantly and non-compliances in this particular aspect of equipment and materials area are now rare.

Surgical procedures

We took over the regulation of requirements around surgical procedures from the Care Quality Commission in 2014. These requirements include infection control, safeguarding, management of medicines and the surgical pathway. Whilst many clinics initially struggled with the requirements, we have worked with clinics to improve their performance. This has resulted in an increased awareness of the requirement to have a named safeguarding lead with a pathway to escalate concerns quickly. Most clinics have clear policies and an understanding on when and how to report safeguarding concerns. The need for an infection control champion in each clinic appears to be addressed well. The initial problems meeting these requirements were due to the building design, inappropriate floor covering that could not be cleaned properly in a clinical area or sinks and soap dispensers in theatres not allowing for elbow control to ensure hand hygiene standards were met.

Surgical procedures continue to have the highest number of non-compliances by guidance note; partly because it covers four areas and is the largest guidance note, and partly because of the need for more effective governance of controlled drugs and medicines at the clinics. Because medicines management is the main area of non-compliance within this guidance note it has been one of the key areas of focus this year to promote better supervision of the management and use of all medicines, which should equate to fewer non-compliances in the next inspection cycle.

Quality management

Since 2007, European legislation has required clinics to have a quality management system in place. This means that clinics have clear processes and procedures and continually monitor and improve them. Whilst the requirements were initially seen by many clinics as excessive, there is now good engagement in this area of practice, particularly around reporting, investigating and learning from incidents.

Witnessing

Failures in laboratory witnessing can have catastrophic consequences. Our requirements around witnessing ensure that the right eggs, sperm and embryos are used in the treatment of the correct patients. Although mistakes in this area have always been rare and compliance generally good, clinics have consistently worked hard to achieve compliance here. Most clinics use sophisticated electronic systems and those using manual processes have good witness procedures in place.

Non-compliances found on inspection

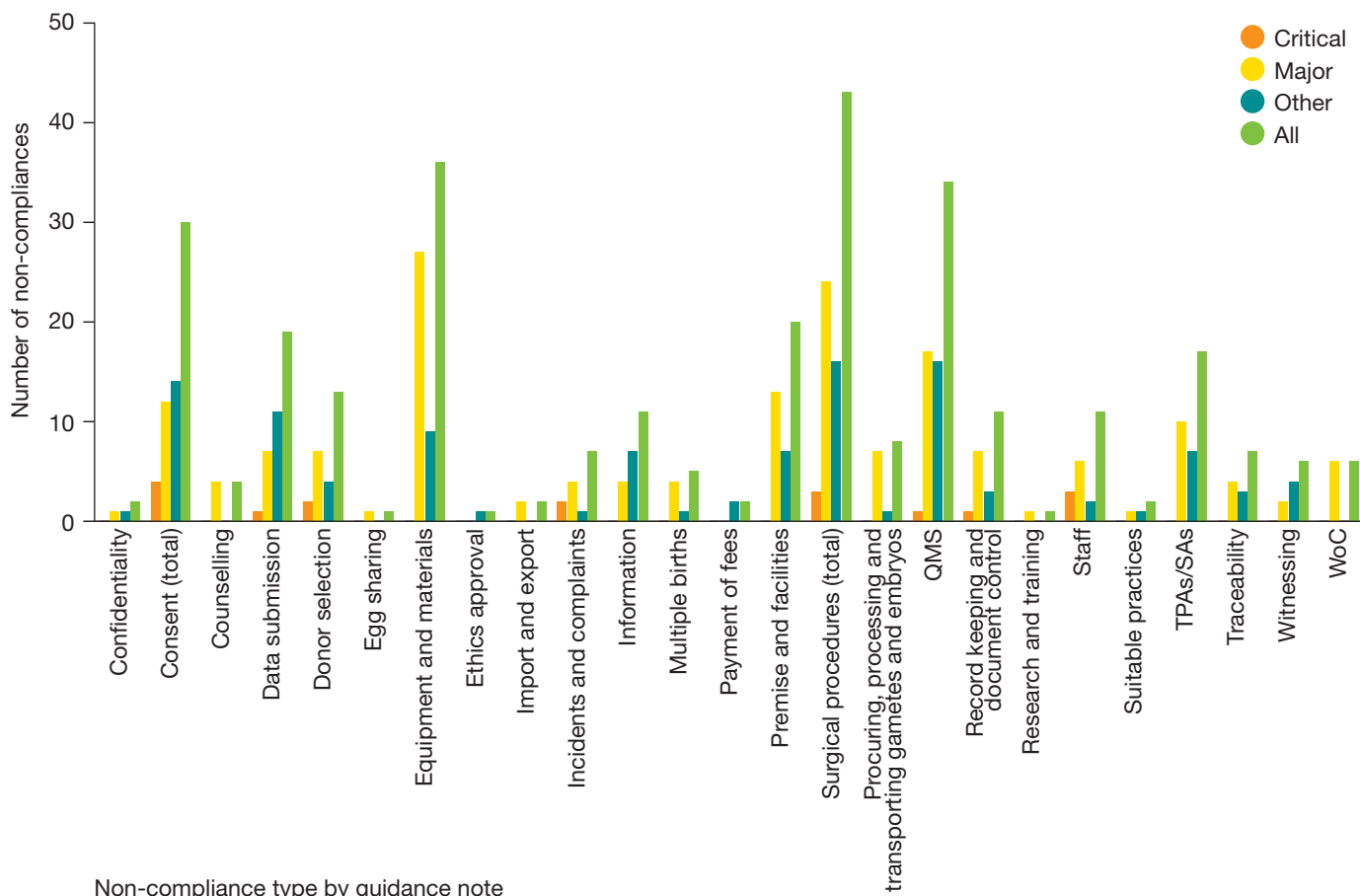
As the chart shows, the areas of practice where most non-compliances occur are consent, equipment and materials, premises and facilities, surgical procedures and quality management (QMS).

These areas of poor practice were evident in 2015–16, although none of the non-compliances in these areas were classified as a critical. Many of these are areas in which we saw improvement

during 2016–17, compared with the year before, showing that where there are non-compliances, there are fewer of them each year.

Compared to 2015–16, there was a slight increase in the number of non-compliances relating to incidents and complaints, third party and satellite agreements, record keeping and document control and welfare of the child. However, these increases are not significant and none of the non-compliances were classified as critical.

Figure 5: Non-compliances found on inspection



Non-compliance type by guidance note

The number of non-compliances according to clinic size and type

Looking at the most common areas of non-compliance in more detail, we see that there is no obvious correlation between the type of non-compliance and the size of the clinic. The chart in figure 6 shows non-compliances are fairly evenly distributed across large, medium and small clinics, and those offering insemination services. Storage clinics had no non-compliances relating to surgical procedures because they do not carry out treatment activities.

The severity of non-compliances according to clinic size and type

The severity of non-compliance also appears to bear no relation to the size of clinic and the type of service it offers. Figure 7 shows the number of critical, major, other and all non-compliances according to the size of the clinic and the service offered.

Of the 299 non-compliances identified in 2016–17 only 10 (3%) remained unresolved past the deadline. As a consequence, the inspections generated improvements in 289 areas of practice, demonstrating the effectiveness of the regime of inspection combined with a well-led and engaged sector.

Figure 6: The number of non-compliances according to clinic size and type

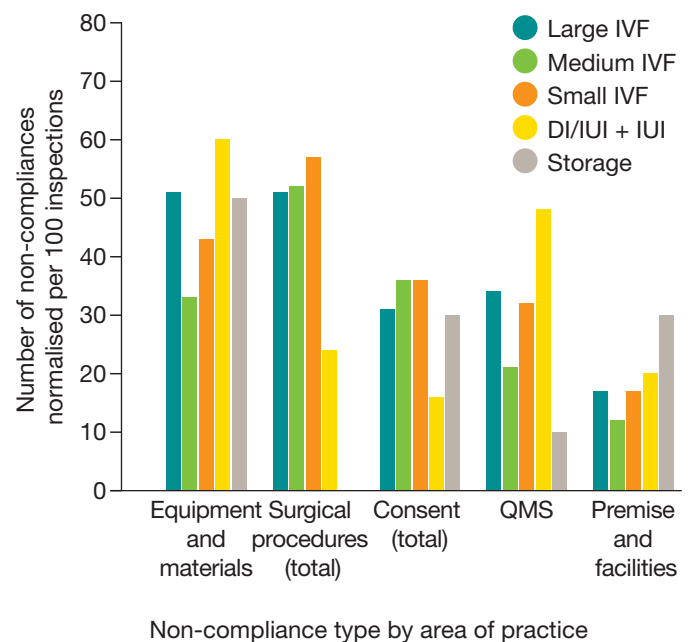
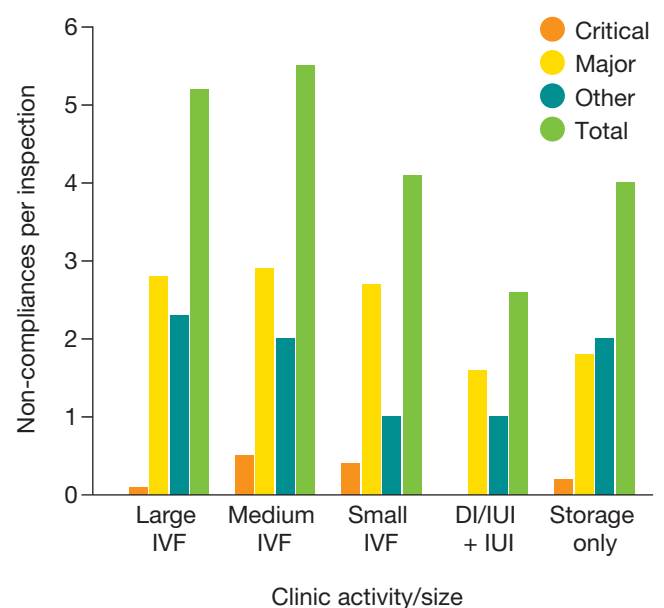


Figure 7: The severity of non-compliances according to clinic size and type



An inspector's example of good practice: infection control auditing

“One clinic asks their patients to do a hand hygiene audit on their staff when they are having their consultations. The patients are asked not to say anything to the person they are auditing but instead to observe whether the staff member:

- washed their hands before and after procedures;
- were bare below the elbow when washing their hands;
- was wearing any nail varnish.

This is an innovative way of conducting an audit. Usually, staff know when they are having a hand hygiene audit conducted as an auditor needs to be present to observe their hand hygiene practice. This doesn't always give a true picture of normal practice.

However, with the patients doing the audit, unbeknown to the staff member, a more accurate reflection of practice can be achieved. It also demonstrates to patients that the clinic takes infection control seriously.”

Performance of research laboratories

In the 2016–17 period, there were 21 licensed research projects held across 13 research laboratories. Eight of these are also treatment clinics. During 2016–17, we carried out four ‘renewal’ inspections of research laboratories and eight interim inspections.

Research laboratories have to meet fewer legal requirements and standards than treatment and storage clinics, and we tend to see high levels of compliance on inspection. Only three instances of non-compliance were identified on inspection. All 21 research projects are on a full-length licence of three years.

Key findings on quality of service and compliance

- Overall, clinics perform well against the legal requirements and our standards. 74% of clinics are on a full, four-licence and therefore have a five-star inspection rating on Choose a Fertility Clinic.
- Neither the type of service a clinic offers nor its size has a clear influence on the number of critical, major and other non-compliances found on inspection.

Area of focus: minimising multiple births

Multiple births are the single greatest risk associated with fertility treatment. However, they can be avoided without affecting the birth rate. Our campaign, One at a time, started 10 years ago and has raised awareness amongst patients and professionals about the risks associated with multiple births to ensure that as many women as possible have a healthy baby.



Multiple births can seriously harm the health of both the mother and her babies.

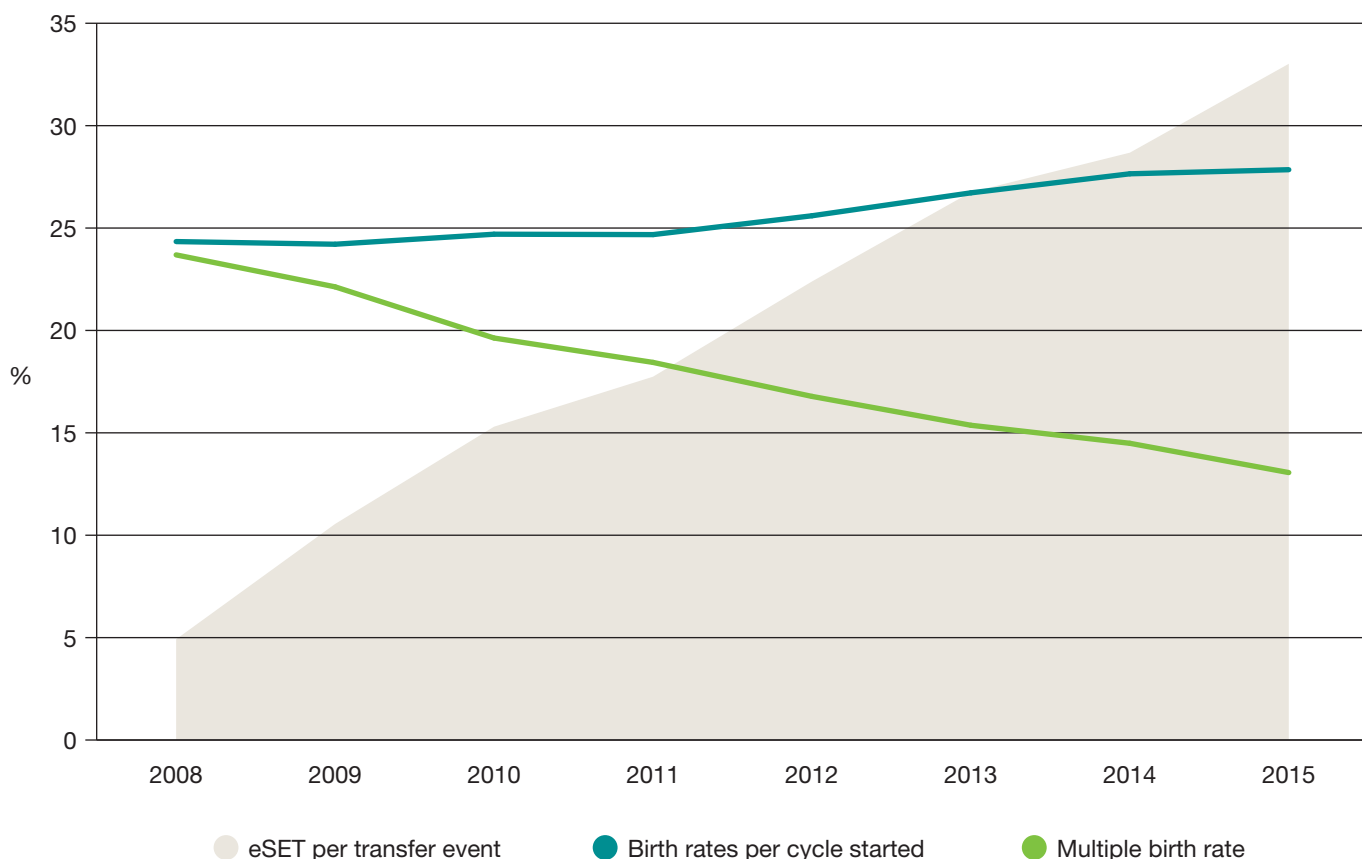
At least half of twins are born premature and underweight, which can lead to serious health problems and even death. Mothers are far more likely to have an early or late miscarriage if they are carrying multiple babies. And they are more likely to suffer from health problems such as high blood pressure, gestational diabetes, anaemia and haemorrhage than mothers of single babies.

When we started One at a time, one in four births from IVF were multiple births – 20 times higher than natural conception. Our aim is to get to one in 10 – and many clinics have reached that target already.

Multiple births national performance over time

Figure 8 shows the overall birth rate, multiple birth rate and rate of elective single embryo transfers (eSETs) since 2008. The multiple birth rate has decreased, as clinics have transferred fewer embryos. However, the overall birth rate has slightly increased, showing that eSET does not reduce the chance of having a baby. This is a fantastic achievement: our campaign and clinics’ positive response to it have resulted in a huge advance in the quality and safety of IVF services.

Figure 8: Birth rate, multiple birth rate, and eSET rate



Multiple births performance in individual clinics

We monitor closely individual clinics' performance against our standards and guidance, particularly whether they are reducing their multiple birth rate year on year and taking steps to reach the target of no more than 10% of all births being multiple births. The most recent national data shows that around 11% of IVF births are multiple births, showing that the sector has almost met that target.

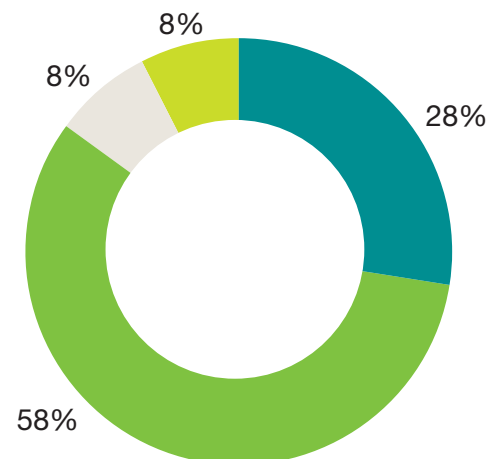
Figure 9 shows the proportion of clinics* that have achieved the different levels of performance in this area.

- 28% of clinics performed very well: they have met the target
- 58% of clinics performed well: they were likely to have met the target in 2016–17, but were either borderline or carried out too few cycles to be certain they met the target in a statistically reliable way
- 8% of clinics were monitored closely because they were at risk of failing to meet the target
- 8% of clinics were statistically above the target. There were 14 clinics in this category in 2015/16, but this reduced to six clinics in 2016–17. Inspectors are working closely with these clinics to help them to learn from their experience and make changes to their practice to reduce their multiple birth rate.

The reduction in multiple births over the past decade is a good news story for the role of regulation and for public health more generally. More women are getting pregnant and having a healthy singleton baby, exposing fewer women and their babies to the health risks associated with multiple pregnancy and birth.

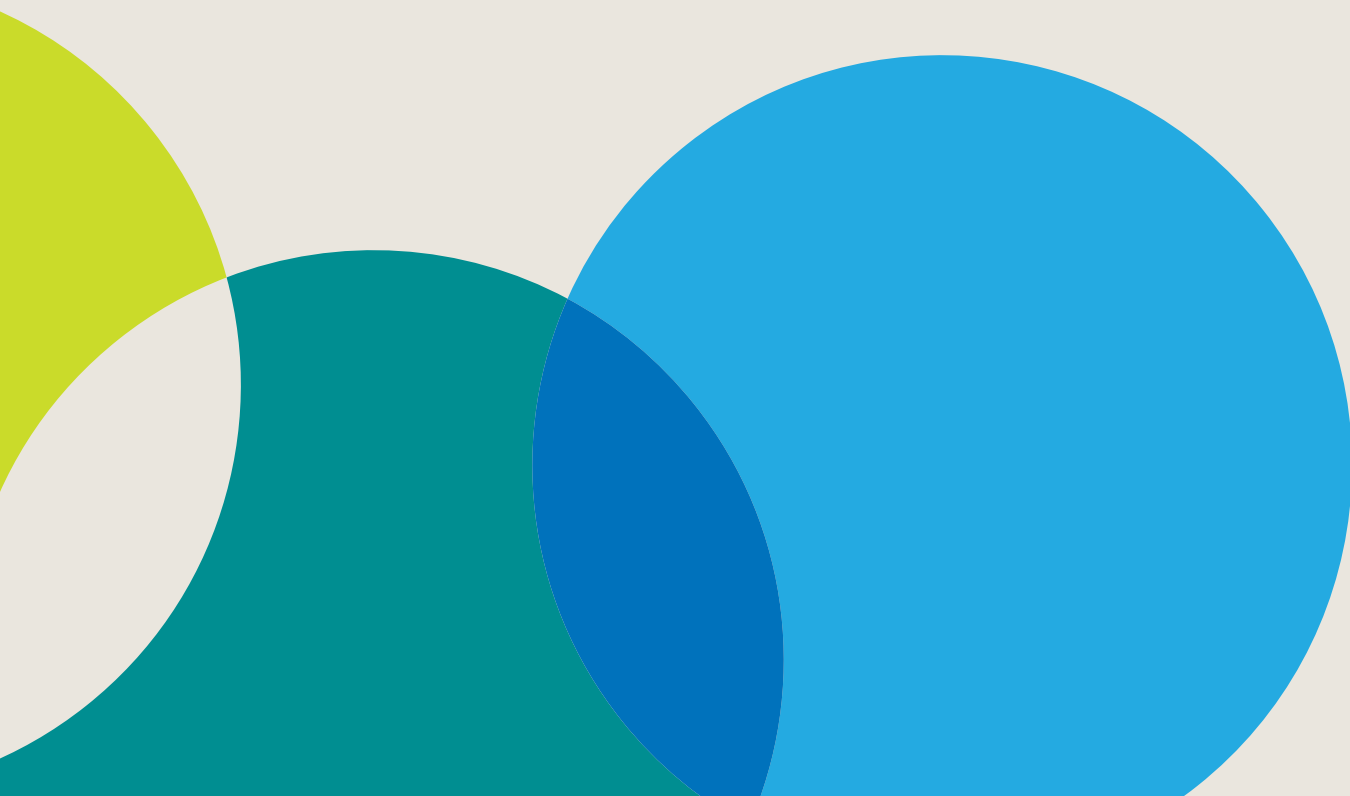
*Note: percentages may not total to 100% as each has been rounded to the nearest whole number.

Figure 9: Multiple pregnancy rates



Area of focus: learning from incidents

The vast majority of fertility treatment is carried out without any problems occurring. However, as in any hospital or clinic setting, mistakes can happen.



Whilst incidents are rare – they happen in around 1% of treatments carried out in UK fertility clinics each year – they are upsetting for both patients and clinic staff and can, in some cases, cause serious harm to patients.

We monitor incidents in clinics to make sure that everything is done to understand what went wrong and, crucially, to take steps to ensure that it does not happen again, whether in that clinic or another clinic.

How we classify incidents

We classify incidents in clinics into three grades of severity: A, B and C. We also hold information about ‘near misses’ in which only luck prevented an incident from occurring.

Incidents deemed serious must be reported to us within 12 hours of detection and all other incidents and near misses must be reported within 24 hours. We require this reporting to encourage a culture of openness, transparency and learning.

We monitor the number and nature of incidents and near misses and have a rigorous process for reporting, handling and investigating them. We do this to ensure that clinics understand the ‘root cause’ of the incident and have started to think about how they can change their practice to prevent a recurrence.

Grade A: involves severe harm to one person (such as a death, being implanted with the wrong embryo or birth of an affected child following genetic testing) or major harm to many (such as the failure of a frozen storage unit containing the embryos of many patients).

Grade B: involves serious harm to one person (such as the loss or damage of embryos for one patient) or moderate harm to many (such as sensitive personal data about more than one patient being sent to the wrong recipient).

Grade C: involves minor harm, such as one of many eggs being rendered unusable in the laboratory.

Incidents reported in 2016¹

Clinics reported 502 incidents and 38 near misses in 2016, a slight increase from those reported in 2015.

Type of incident	2016	2015
Grade A	1	0
Grade B	176	200
Grade C	325	267
Near miss	38	30
Total	540	497

Although there was an increase in the number of incidents and near misses in 2016, they have increased only slightly as a proportion of all treatments carried out in the year. In 2016, 76,500 treatments were carried out – a 6% increase from 2015 – whilst the number of incidents increased by 8.5%. Whilst the overall number in real terms has increased slightly, there has been a change in the severity of incidents, with a lower number of grade B incidents and a higher number of the less serious grade C incidents.

There was also a decrease in the number of severe or critical ovarian hyperstimulation syndrome (OHSS) cases reported. Categorized amongst the clinical incidents, the number of severe or critical OHSS cases in 2016 was 38, compared with 60 in 2015.

Although this decline is welcome, OHSS is a serious – and potentially fatal – condition and we want to reduce the incidence as much as possible. Recent media coverage has suggested that clinics are under-reporting severe and critical OHSS, particularly given figures collected through the NHS are higher than those reported to us. Although we would expect our OHSS figures to be lower because we only require information about the most serious cases, we are investigating this further. To date, we have found no evidence of under-reporting, but we are exploring this further, alongside work with professional groups to consider clinical management of OHSS.

Category ²	2016	2015
Administration	135	141
Clinical	207	198
Clinical equipment	7	2
Communication	9	8
Consent	24	18
General	11	10
Laboratory equipment	25	29
Laboratory operator	65	57
Laboratory process	68	52
Resources/organisational	2	1
Security	3	1

1 Calendar year 2016, rather than financial year 2016/17

2 Each yearly column contains figures that include the 'not an incident' category

Learning from incidents

There was one grade A incident reported in 2016. By their very nature, grade A incidents are difficult to predict and the incident reported this year does not illustrate a recurring theme.

The grade A incident in 2016 involved was the birth of a child with cystic fibrosis after the parents had been mistakenly identified as not being carriers of the condition. The investigation identified the following:

- The screening results report from the pathology laboratory was not properly read by the treating clinician, nor signed and transposed into the patient's medical record.
- There was no robust system in place providing evidence that reports are reviewed by the treating clinician or nurse before being filed.
- The clinic did not have a standard operating procedure to ensure that reports are allocated to the appropriate member of staff for review.

Learning from this incident, the clinic has made the following changes:

- A process for results management is now in place, incorporating receipt, assessment and action to be taken when abnormal results are received
- All abnormal results are reviewed by the treating clinician and arrangements made to discuss the meaning and implications of the results with the patient.
- A review of how abnormal results are reported by the pathology laboratory is in process (for example, highlighting abnormal results clearly).

As is our usual practice, a report of this incident was considered by the relevant licensing committee to ensure that all lessons from this sad event have been learned.

Supporting learning from incidents

On occasion, we see hurried and poor-quality incident investigation reports from clinics, suggesting the lack of a learning culture in the clinic. To address this, we ran six workshops during 2016–17 with individual clinics to improve their analysis of the root cause of incidents and encourage better incident reporting to us. We also ran a workshop on incident reporting and review for fertility professionals at the British Fertility Society conference on 21 June 2017.

An inspector's example of good practice: learning from incidents

“On inspection, one question that we focus on is whether the clinic learns from guidance published by us or other relevant sources. We expect clinics to constantly look for ways to be even better. Over recent years, we have published reports on incidents in fertility clinics. One reason for this is to maximise opportunities for clinics to learn from incidents to improve the quality of care they provide.

At one inspection in the summer, we saw a clinic that had gone to great lengths to make the most of our latest published report. Multi-disciplinary team meetings were held to go through the report in detail and ask themselves the question ‘could this incident happen here?’. They reviewed all of their own relevant procedures and as a result made changes to reduce risk. We thought that this was good practice and exactly our intention: learning from incidents that have happened elsewhere to ensure their own practices are as safe as possible.”

Area of focus: patient experience

It's important that patients have access to the best quality of care in clinics. Just as inspections drive up the standard of performance, we also use patient feedback, whether to clinics or directly to us, to improve fertility services.



Patient feedback on our website

We have introduced a new patient feedback process for 2017–18. Our new patient rating feature on Choose a Fertility Clinic allows patients and donors to give an experience rating which is published directly on the clinic's entry on Choose a Fertility Clinic.

This means that prospective patients can choose their clinic according to the experience of care, as well as other features such as birth rates and compliance with our standards.

We also encourage patients to send us further information about their experience of care, which is sent to the clinic's inspector. These comments – and the ratings themselves – are now used by the inspector to assess the clinic's performance in this area as part of the inspection process.

Patient feedback on inspection

We gather patient feedback through inspections in three ways:

- we talk to patients in the clinic on the day of inspection
- we encourage patients to complete the questionnaire via Choose a Fertility Clinic
- we look at the clinic's own patient satisfaction survey results.

Our inspectors use this information – and their discussion with the clinic staff – to determine whether the clinic respects the privacy of patients and donors, prepares and support patients through treatment and shows them empathy and understanding.

Although we have recently redesigned our approach to gathering patient feedback, integrating questionnaire feedback to inspectors with our new patient rating on Choose a Fertility Clinic, this report covers the previous year. Of the 21 treatment and storage clinic renewal inspections carried out in 2016–17, only one non-compliance out of 299 in total related to patient feedback.

During the year, inspectors spoke to 29 patients in the clinic and received 121 questionnaire responses. Feedback was generally positive, with 71% of questionnaire respondents giving compliments about the care they received and only 8% making negative comments. Of these, eight were from the one clinic which had a non-compliance relating to patient feedback.

With our new, integrated approach to gathering patient feedback now in place, we expect the number of patients and donors giving feedback to increase substantially in 2017–18, giving us greater insight into how clinics can support their patients through what is often a difficult and stressful treatment pathway.

