

The state of the fertility sector

2017-2018



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About this report

We are the independent regulator of fertility treatment and human embryo research in the UK. We aim to ensure that everyone who steps into a fertility clinic, and everyone born because of treatment, receives high quality care.

We do this by licensing, monitoring and inspecting fertility clinics and providing free, clear and impartial information about fertility treatment, clinics, and egg, sperm and embryo donation.

This 'State of the sector report' summarises what we have seen through our regulatory work during the 2017/18 year. It is our second such regulatory report and will become an annual publication.

The report is compiled from information gathered from our inspections throughout the year and also uses other sources of information including our Register of fertility treatments, incident reports and patient feedback mechanisms.

Executive summary

As the independent regulator of fertility treatment and research involving human embryos, our role is to ensure that high standards are met. We want patients and donors to have access to safe, ethical and effective treatment and have good outcomes. We assess how clinics achieve this against standards in our [Code of Practice](#).

The fertility sector is unusual when compared to almost all other elements of healthcare in the UK, as over 60% of patients have to pay for their own treatment. This changes the doctor-patient relationship and can lead to different expectations and demands.

Regardless of the source of funding for treatment, this report shows that most patients can expect that wherever they go for treatment in the country, they will receive the required standards of care.

The good news is that the basic requirements are being met, and often met well. Clinics are meeting essential standards and engaging with our inspectors when there are shortcomings. This should then lead to improvements in practice from one inspection to another.

There is much to celebrate:

- Standards met by clinics are generally very good. Over the past three years, there were no critical non compliances in 24 out of the 37 themes we look at when inspecting clinics. This means that across most areas, all clinics have effective processes to ensure that there are few (or no) critical failings. In six out of the 37 themes (16%), there have been no critical or major non compliances since 2014.
- At renewal inspections in 2017/18, two thirds of clinics met more standards when compared to their previous inspection. This shows that most clinics are effectively engaging with the feedback they receive upon inspection and work closely with our inspection team to improve and maintain the quality of their services.

There is, however, more to do:

- While most clinics meet the required standards to be granted a full four-year licence, we should not confuse the overall good performance with a sense that patients experience uniformly high-quality care.
- At 1 April 2018, the majority of licensed clinics (whether treatment, treatment and storage, or storage-only clinics) had a four-year licence and therefore had a five-star (the highest) rating. However, 11 clinics had a two, three or four-star rating due to concerns.
- The most common standards not met are in:
 - the use of approved equipment and materials
 - arrangements for the processing and transporting of sperm, eggs and embryos; for example, not documenting processes and their labelling and packaging
 - ensuring suitable practices, for example, the suitability of premises, equipment and the leadership and staffing team and ensuring clinical practices are of a high standard.

In this report we set out the steps that clinics need to take to improve and meet the required standards.

Our inspection team works with clinics to ensure their multiple births minimisation strategy is effective and progress is made towards reducing the rate of multiple births to the 10% target. Non compliances in this area have significantly reduced and the multiple birth rate from IVF now stands at 11%.

Incidents are rare but too many clinics still make the same mistakes more than once.

For some years now, we have made public the number and type of incidents reported to us. 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. There were 570 incidents in 2017/18 (a prevalence rate of just under 1% of all cycles (80,000) carried out).

Around half of all clinical incidents in 2017/18 related to patients developing ovarian hyperstimulation syndrome (OHSS). Of these, 52 patients were reported as having severe or critical OHSS. It's important to stress that the risk of OHSS is very low. However, we, want to ensure that the processes and systems for identifying, reporting and preventing OHSS are as rigorous as possible.

Patient complaints, though relatively few, are increasing but simple steps could greatly improve how they are dealt with:

- Patient concerns should be addressed promptly and thoroughly to provide support to the patient which is necessary for high quality care. Doing this will also resolve the issue, so it does not go on to become a full complaint requiring investigation. Clinics can improve by making their complaints process clear and accessible to patients and regularly asking for feedback throughout treatment.
- Patients can complain to us when they've exhausted their clinic's complaints process. In 2017/18, we saw a 21% rise in the number of complaints to us (86 complaints, up from 71 in the previous year). Many complaints begin with a seemingly small mistake on behalf of the clinic, often down to human error or miscommunication. Too many times we see the clinic is poor at responding and resolving the initial incident. This leads to a breakdown of trust and a poor quality of experience for the patient. Where we intervened, we enabled a dialogue between the patient and clinic to be re-established and better understanding between both parties.

Patients are increasingly confident in expressing their opinions and the majority are satisfied with the care they receive. They are generally pleased with the quality of care provided by their clinic, with 83% of those rating their clinic saying they would recommend it to family and friends.

Looking ahead, leadership is key to improving the quality of care. In the coming year, we will be focusing more on leadership within clinics and providing higher standards for patients. We will ask clinic leaders and their teams to also show us how they are improving services to better meet the emotional and support needs of patients and their partners. We want clinics to act in an ethically responsible way, for example, in their offering of 'treatment add ons' to patients and will check this on inspection.

This report compliments our other annual assessment, [Fertility treatment 2014-2016: trends and figures](#), which covers key information about the number and type of patients treated, the different treatments they had and the pregnancy rates for fertility treatment.

For the first time, this year we have also carried out a survey of fertility patients and their partners to get their views across a range of questions on how fertility treatments are delivered. This will be published alongside this report to help us, and all those who work in clinics, to further understand how patients can be supported and services adapted to meet their needs.

How we regulate

Background

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

Regulation ensures that practices are carried out to a certain standard, by qualified professionals, and that research on embryos is only done where there is a real need and in a way that is ethical.

Regulation in this context means making sure fertility clinics and research centres comply with the law and the rules and standards we set. All fertility clinics and human embryo research centres in the UK must comply with:

- the Human Fertilisation and Embryology (HFE) Act 1990 (as amended)
- the HFE Act 2008, and
- a number of related pieces of legislation.

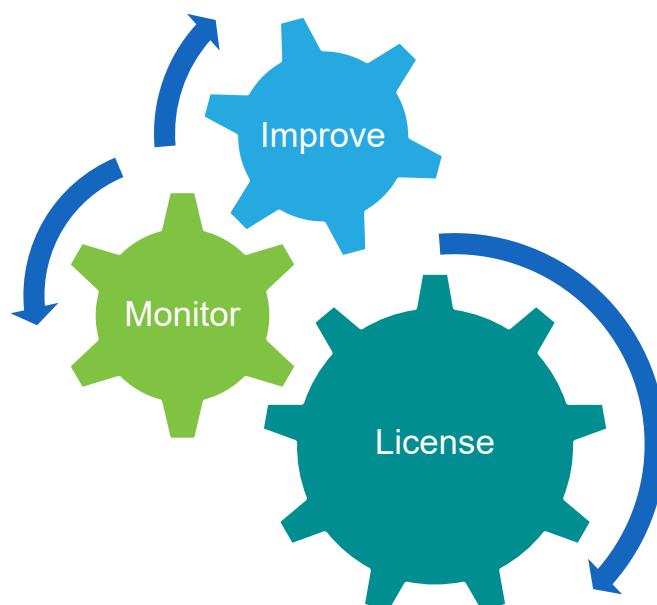
We provide guidance to clinics and research centres on how to meet the legal and policy requirements set out in our [Code of Practice](#).

What this means for clinics and research laboratories

Our inspections and ratings allow us to highlight those clinics that are delivering high-quality care and to recognise and act when we find poor care.

We regulate in three ways:

1. 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.
2. 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.
3. We operate an incident reporting system to ensure that clinics investigate any mistakes and that the whole sector learns from those mistakes.



Our Code of Practice

The legal obligations and our best practice standards are published in our [Code of Practice](#), which is organised into 33 standards of practice.

For the purposes of inspection, we sub divide some of these standards and inspect against a total of 37 'themes'. These themes are periodically updated to ensure they accurately reflect current legislation and best practice.

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.

Additional inspections are carried out for any number of other reasons, such as a risk-based inspection or for a variation of premises.

A licensing committee uses the evidence gathered on inspection, and from other sources like patient feedback, to decide whether 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. This is more focused on specific areas that we have selected as priorities; for example new requirements that need a closer look by us, checking previous findings have been addressed satisfactorily and investigating any trends in incidents reported or complaints. The licensing committee uses that evidence to decide whether the licence should continue.

Following any type of inspection, an inspector writes a report which identifies both areas of good practice and those which are non compliant and require improvement. The inspection report comments on the actions taken by the clinic to address areas of practice that require improvement and these are divided into categories: 'critical non compliance', 'major non compliance' and 'other non compliance'. The definitions of these are explained on p16.

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 the [Choose a Fertility Clinic](#) tool on our website.

Regulating a changing market

Fertility clinics operate in different ways, and in recent years the interaction between commercial organisations and the NHS is resulting in changes across the UK's fertility sector.

Recently, IVI from Spain, Virtus from Australia and FutureLife from the Czech Republic have all entered the UK market, while major independent organisations such as CARE Fertility, HCA, BMI and Nuffield are also operating fertility services.

These, and other private clinics, are operating in new ways with different models of delivery, which may include sharing resources, a quality management system, or being co-located.

This introduces new considerations for us, having previously operated in a sector of mainly stand-alone, clinical-led models, originally set up to deliver fertility services to a local population.

Many clinics are now looking for innovative and cost-effective ways to offer services. Consolidation across service providers can offer a route to doing this, particularly in the fertility sector where patient demand

outstrips supply, by achieving economies of scale, replicating clinical care, and having the opportunity to increase the scale of their services.

We do not have any regulatory powers over mergers or financial structures, but our role in ensuring high quality care for patients means that we are mindful of the potential positive and negative effects of consolidation on the services that patients receive. We will be keeping these market changes under review.

While consolidation can share risks and rewards across providers and has the potential to replicate high quality care for patients across the system; it inherently introduces the opportunity for poor care to be replicated and once established can be more difficult to change.

In addition, evidence from US healthcare markets shows that consolidation can reduce competition between providers, thereby increasing costs for patients. This may be a concern in the UK fertility market if some providers hold a monopoly position in any of the nations or regions across the UK. This may also result in financial or market challenges to the remaining smaller stand-alone providers who still aim to provide local fertility services, putting their viability at risk.

We will monitor the impact of this trend to ensure that the same high standards we have established to date are maintained and patients across the UK are able to access high quality care. However, in doing so, we recognise that different operating models may require new regulatory processes.

Observed changes and proposed approach

We have developed an informal typology of the various group structures in the current UK fertility market. These are not hard and fast categories and there is some fluidity between them.

- Federated model: autonomous role for the individual clinics (and lead clinicians), with central services provided with permission and where it makes sense to do so (eg, marketing, website, IT, purchasing).
- Location specific: involves a high degree of shared processes and functions.
- Franchise: consultant-led model within the independent hospital operating model, with high local autonomy and marketing and legal services provided at a central level only.
- Integrated model: based on a common operating system with a high degree of central control.
- Standalone clinics: based on how clinics have traditionally operated, with an autonomous role in all aspects of delivery.

We have met the challenges posed by the growth of group structures by piloting a new regulatory approach with some of the more integrated groups, reflecting the fact that groups take a variety of forms and are at different levels of maturity.

This offers a range of benefits, both for us and clinics, and meets the requirement placed upon us to undertake our regulatory activity proportionately and efficiently.

About the fertility sector

Background

Key features of the UK fertility sector

Most clinics are specialist treatment providers (75% of providers are IVF treatment clinics).

Around 60% of treatment is funded by patients themselves.

The UK has a small embryo research sector (15 centres).

There were over 80,000 cycles of fertility treatment in 2017/18 and numbers continue to rise year on year.

Relative to areas of healthcare such as cancer or diabetes, the fertility sector is small. However, the issues that arise in relation to fertility treatment continue to prompt social debate and advances in clinical technology mean that treatment options and patient demographics continue to evolve.

Fertility treatment is delivered in both private and NHS-funded clinics and can be funded through a variety of mechanisms in each type of clinic (including publicly-funded treatment delivered in a private setting and privately-funded treatments delivered in a public setting).

A recent report estimated that the UK fertility market is worth £320million per year and is experiencing accelerating growth. The market has steadily grown in recent years, with volume growth around 3% per year.

This may be driven by the increasing age at which women start families, declining male fertility and greater social acceptance of fertility treatment as a route to having a family, especially for those who have delayed starting a family or who are in same-sex relationships.



Information about the outcomes of fertility treatment is in our annual [Fertility treatment: trends and figures](#) report.

Number of clinics

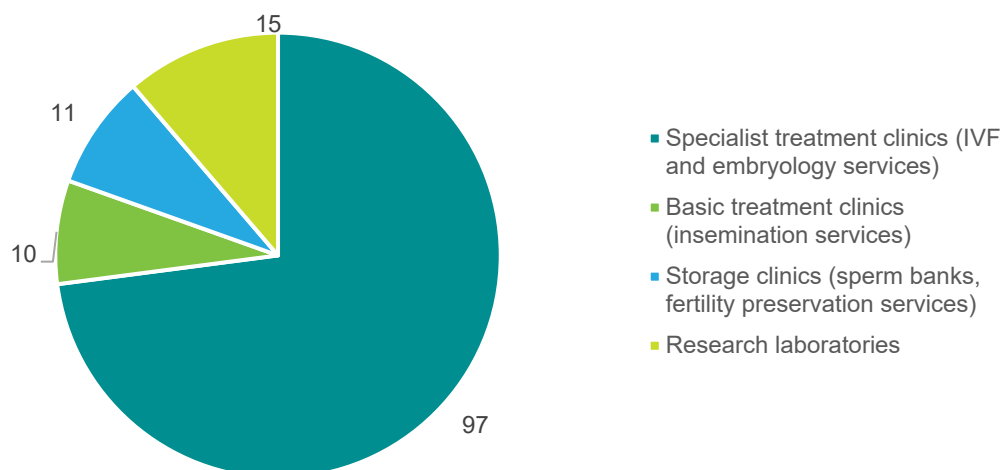
All clinics need a licence from us to provide fertility treatments, store eggs, sperm and embryos and carry out embryo testing. These services can be delivered using a range of licence types and the type of licence defines what type of activity can take place on the licensed premises.

The categories of licence we issue are:

- treatment and storage (and sometimes research) – for clinics offering IVF, ICSI and egg, sperm and embryo storage (74% of all licensed clinics)
- storage – for clinics offering just storage of eggs, sperm and embryos (8%)

- treatment – for clinics offering IUI and other basic fertility treatments which do not involve the creation or storage of embryos (8%)
- research – for centres who want to conduct research using human embryos (12%).

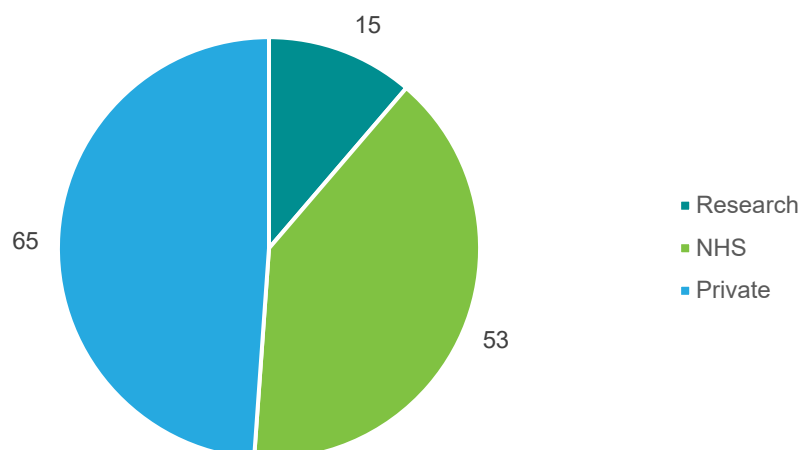
Figure 1: Number of licensed clinics in 2017/18



In 2017/18, there were 133 active licensed clinics. As noted earlier, an increasing number of clinics are operating in either formal or informal partnerships or 'groups'. Clinics providing treatment services as part of a group now represent 31% of the sector but deliver 39% of the market's IVF and DI treatment cycles. All consolidated clinics are privately funded.

Around 60% of fertility treatments are self funded, either in stand-alone private providers or in NHS services. However, the proportion of NHS to self-funded cycles varies across the different nations and regions of the UK and the concentration of private clinics in London and the South East does skew the national average.

Figure 2: Number of NHS and private clinics



NHS commissioning

Although regulation of fertility services is UK-wide, commissioning is devolved to the national level. In England, fertility services are commissioned locally, through clinical commissioning groups (CCGs) (with the exception of fertility services for those in the armed services). NHS-funded treatments can be commissioned from both NHS and private sector providers.

Commissioning in Scotland, Wales and Northern Ireland follows a different pattern. In Scotland, fertility services are commissioned by the 14 regional health boards, using a £12million central fund, from four NHS providers. In these services, clinical and social eligibility criteria are set centrally and patients are entitled to three full cycles of IVF.

In Wales, fertility services are commissioned centrally, according to a specialised commissioning policy. Clinical and social eligibility criteria are set centrally and patients are entitled to two full cycles of IVF.

In Northern Ireland, NHS services are offered at one provider in Belfast. Patients are entitled to one cycle of IVF, with only the fresh and one frozen embryo transfer included and there is a considerable waiting time to start treatment (18 months in November 2017).

The National Institute for Health and Care Excellence (NICE) has a clinical guideline which sets out the most cost-effective way for public bodies to fund IVF fertility treatment, but this is not mandatory. Access to the level of service set out in the NICE guideline is variable across England and we know that CCGs can pay very different prices for the same course of treatment depending on where they are and who they are commissioned from.

Although pricing and NHS commissioning do not fall under our regulatory control, we have stated publicly that we would like to see full implementation of the NICE fertility guideline in England, for reasons of social equity and cost-effectiveness in the use of public funds.

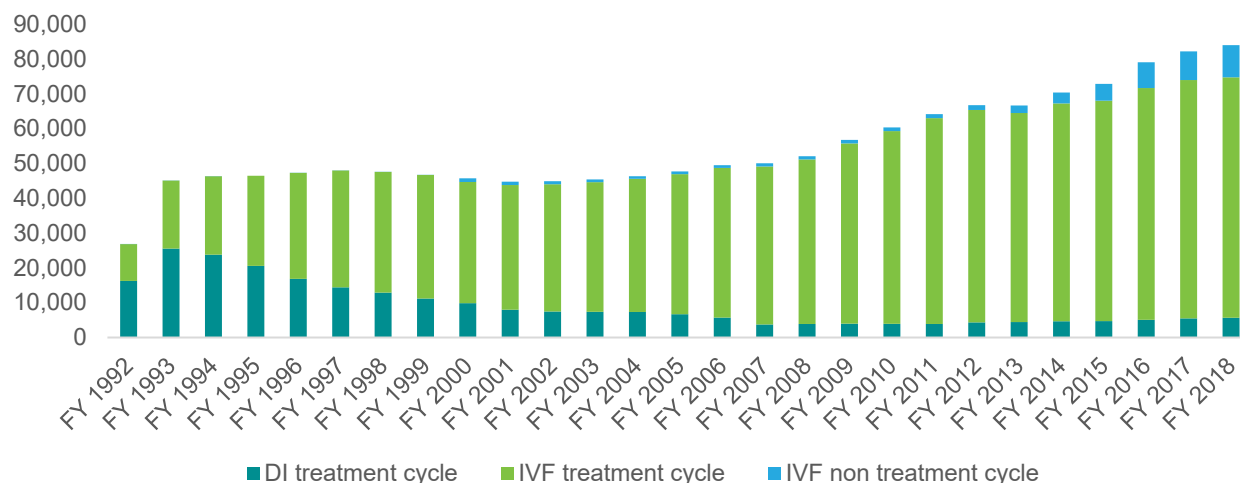
Number of fertility treatments and outcomes

Patients may use services in an IVF clinic for a variety of reasons, which can include standard treatment cycles (where the intention at the beginning of the cycle is to create, fertilise and transfer eggs in that cycle), or for 'non treatment' reasons, which can include other reasons for using an IVF clinic's services, such as storing eggs or embryos for future use or donating eggs or embryos.

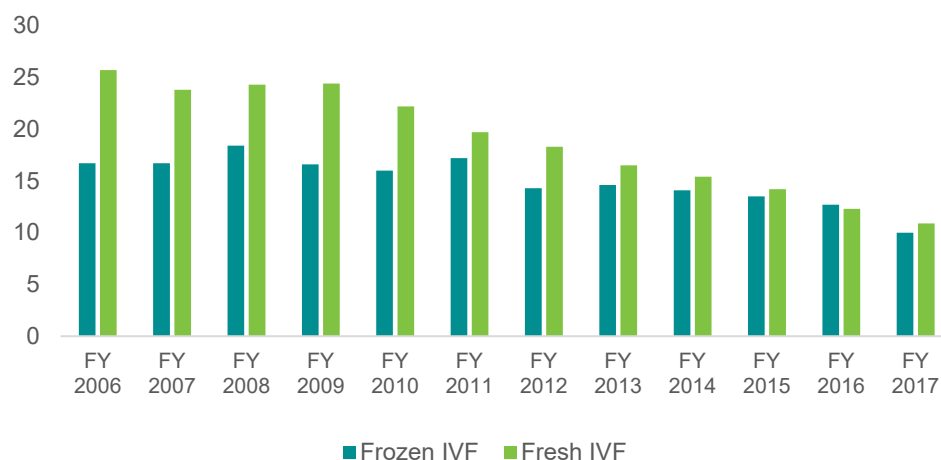
Of the 84,055 IVF and DI cycles in the UK in 2017/18, 83% were standard IVF treatment cycles, with DI accounting for just 7%. The number of DI treatments increased by 2.8% from the previous financial year, IVF treatments by 0.9%, and IVF non-treatment cycles by 12.2%. For the past five years, the greatest growth has been seen for non-treatment cycles.

Patients access fertility treatment services for a variety of reasons¹. The greatest percentage increase across the sector has been in the number of egg and embryo storage cycles, which have increased by 91% and 157% respectively since 2014/15, although the numbers of these cycles are still very small.

¹ These reasons, as recorded on our database, include donation, egg and embryo storage, egg sharing, egg storage, embryo storage, IVF treatment and donor insemination.

Figure 3: Trends by type of fertility treatment

Multiple births

Figure 4: IVF multiple birth rate trend 2006-2017

The main health risk of fertility treatment is a multiple birth. We have worked with clinics and professional and patient organisations to reduce the multiple birth rate and promote elective single embryo transfer as the most appropriate treatment option for most women. As a result, the rate of twin pregnancies has decreased while the birth rate has been maintained.

We set a maximum multiple birth rate target of 10% and report on this target at every inspection. We allow clinics to develop their own 'multiple births minimisation strategy' for reducing their multiple birth rate to meet that target. Clinics can choose the approach that suits their practices and patients.

The multiple birth rate from IVF has reduced from 26% (fresh eggs) and 17% (frozen eggs) in 2005/6, to 11% (fresh) and 10% (frozen) in 2016/17. This is a reduction of 54% (fresh) and 40% (frozen eggs).

Our inspections

We inspect clinics to renew licences every four years, with an interim inspection after two years, so the number of renewal and interim inspections varies from year to year. In 2017/18, there were a total of 101 inspections. The majority of those were for IVF clinics.

Figure 5: Number of inspections by type

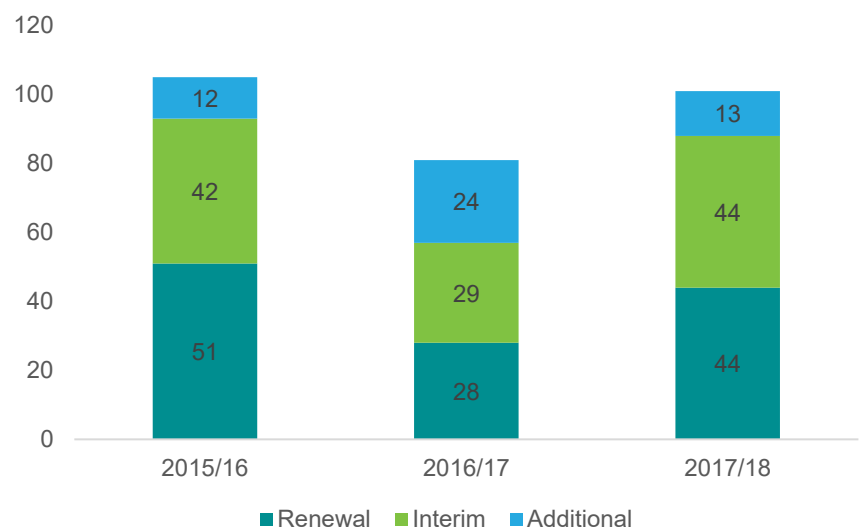
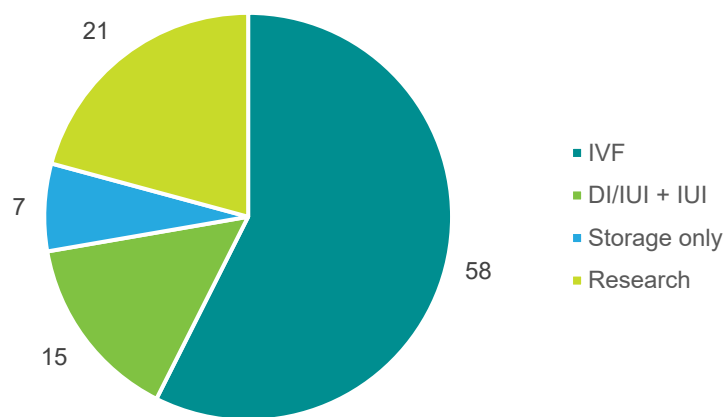


Figure 6: Number of inspections by clinic activity in 2017/18



Quality of service and compliance

This section looks at the overall level of compliance in all licensed clinics and laboratories during 2017/18, as assessed through inspection and monitoring.

Overall performance of treatment and storage clinics

Key findings about the quality of UK fertility sector

The fertility sector is operating at a generally high standard.

In 2017/18 we found 380 non compliances: 23 critical, 191 major and 166 other.

Progress has been made in the areas of witnessing, multiple births and third-party agreements.

Improvement is needed from clinics to follow appropriate consent procedures and have an effective quality management system.

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 on 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 1 April 2018, the majority of treatment, treatment and storage, and storage clinics had a four-year licence and therefore had a five-star rating. This shows that the fertility sector is operating at a generally high standard.

The table below shows the licence length, reason and associated star rating, as well as the number and proportion of clinics to which they applied as at 1 April 2018.

Licence length	Reason	Star rating	No. clinics ²	% licences
4 years	The most compliant clinics about which we have no significant concerns.	★★★★★	96	82
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).	★★★★	10	9
2 years	New clinics on their first licence (which therefore have no compliance history to draw on, with an interim within one year).	No rating – marked as ‘new clinic’	10	9
	Clinics granted a two-year licence due to concerns raised during the inspection process.	★★★	0	0
1 year	Applied because we have serious concerns about the clinic and wish to see progress before granting a new licence.	★★	1	0
Temporary (normally 3 months)	Applied either because of an unresolved legal dispute or administrative errors.	Rating from the clinic’s previous licence	0	
	Applied because we have serious concerns about the clinic and wish to see progress before granting a new licence.	★	0	

² A total of 118 clinics operated during the 2017/18 period but some closed during this time. This table shows a point in time at 1 April 2018, when 116 clinics were operating.

What we know from inspections

Rates of non compliance

Across all inspection types (renewal, interim and additional), in 2017/18 there were 380 non compliances observed: 23 critical, 191 major and 166 other.

While any non compliances are to be regretted, it is important to put these figures in context. Over the same period, there were 84,055 cycles of IVF treatment, IVF non-treatment³ and DI cycles. This suggests an overall compliance rate of 0.5% (or one non compliance in every 200 cycles).

Another way of looking at the issue is to identify the average number of non compliances found on each inspection. In 2017/18 we found, on average, 5.7 non compliances at each renewal inspection, 2.7 at each interim inspection, and one at each additional inspection – details of the split between critical, major and other non compliances can be found below.

In this report, we show findings relating to renewal and interim inspections separately because the interim inspection process is more focused and covers a smaller number of aspects of the Code of Practice.

This means we expect to see smaller numbers of non compliances, on average, at interim inspections compared to renewal inspections.

Renewal inspection rates

In 2017/18, at renewal inspections, there were 250 non compliances (a reduction of 14% from last year). This included:

- 11 critical non compliances (reduction of 22% from last year⁴)
- 125 major non compliances (reduction of 20% from last year)
- 114 other non compliances (reduction of 5% from last year).

Types of non compliances

Critical non compliance: an area of practice which poses a significant risk of harm to a patient, donor, 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 (PR) to carry out his/her legal duties, or
- 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.

³ Patients may use services in an IVF clinic for a variety of reasons, which can include standard treatment cycles (where the intention at the beginning of the cycle is to create, fertilise and transfer eggs in that cycle), or for 'non treatment' reasons, which can include other reasons for using an IVF clinic's services, such as storing eggs or embryos for future use or donating eggs or embryos.

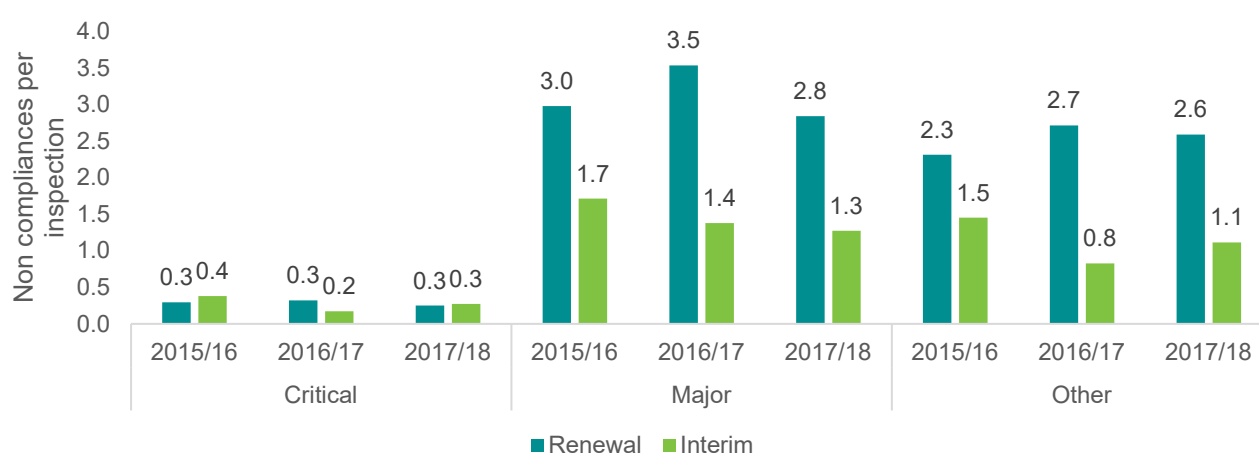
⁴ The number of inspections we carry out each year varies because clinics' licences start at different times, so comparing the performance of the sector from one year to the next is difficult, so we adjust for the number of inspections carried out each year by referring to the 'rates' of non compliances per inspection. This equates to the number of non-compliances observed per financial year, divided by the number of inspections per financial year.

Interim inspection rates

In 2017/18, at interim inspections, there were 117 non compliances (an increase of 11% from the previous year). This included:

- 12 critical non compliances (increase of 58% from last year⁵)
- 56 major non compliances (reduction of 8% from last year)
- 49 other non compliances (increase of 35% from last year).

Figure 7: Trend in non-compliance rates



Where standards have been met

There are many clinical practice and process standards which all clinics have consistently met. Looking at performance since 2014, we have identified no critical non compliances in 24 of the 37 themes we inspect against.⁶ This means that across most standards, all clinics have effective processes to ensure nothing critical goes wrong.

Since 2014/15 all clinics have been fully compliant in relation to:

- Embryo testing – which ensures that embryos are only tested for serious genetic conditions and transferred where it has been authorised by us, and testing has not been used for sex selection or social reasons.
- Information about ICSI – which ensures that patients are provided with appropriate information about the risks and that appropriate clinical protocols are used for recording the use of, and reasons for, using this procedure.
- Consent to disclosure – which ensures that patients have the right to decide what identifying information should be disclosed and to whom.

⁵ In 2016/17, there were five critical non compliances relating to consent (1), premises and facilities (2), incidents and complaints (1), and QMS (1). In 2017/18, there were 12 critical non compliances relating to consent (3), premises and facilities (5), QMS (2), import and export (1) and staff (1). The figures have been adjusted by the number of inspections carried out each year to calculate a percentage change over time.

⁶ The Code of Practice has 33 standards. For the purposes of inspection, we sub divide some of these standards and inspect against a total of 37 'themes'.

- Egg sharing – where patients who are already having IVF donate some eggs to the clinic in return for free or discounted treatment (a 'benefit in kind'), this is done ethically only for patients who are medically suitable with appropriate benefit in kind provided and full information given.
- Medical gases – which ensures that such gases are stored and used in accordance with professional safety standards (this is categorised under premises and facilities).

The trend in non-compliance rates for renewal and interim inspections combined between 2014 and 2016, for each element of our Code of Practice, is set out in the appendix.

Where standards are not consistently met

As in any aspect of medicine, there are standards which clinics need to improve and this section describes them. The next section (learning from inspections) sets out what can be done by clinics and the HFEA working together (where necessary) to improve them.

Quality management system (QMS)

The standard where the highest number of critical and major non compliances were observed in 2017/18 concerns clinics' quality management systems (QMS). A QMS can be understood as a set of processes and procedures that clinics are required to have in place to continually monitor and improve practice – for example auditing practice; keeping procedure documents up to date, ensuring medicines are recorded and administered correctly, or that equipment is checked regularly.

Our inspection team have focused on these arrangements in the last year because if they work well, the QMS should drive greater quality of care and compliance with our requirements across everything that they do. Our focus on the QMS is having some effect given that most clinics' performance is improving in this area, but we still see deficiencies with too many clinics not embracing all aspects of the QMS requirements.

Consent

Consent is a cornerstone of the statutory scheme in the UK and the fact that we continue to find a small number of critical non compliances in the taking of consent is a concern. During the course of fertility treatment, patients may be required to consent to treatment, storage, donation, disclosing information and legal parenthood. Having effective processes when taking consent ensures that only the patients' (and partners' where relevant) wishes are acted upon. Consent is only valid if clinics provide all the relevant information and an opportunity to have counselling.

Consent to legal parenthood

The consent to legal parenthood standard has had high levels of critical non compliances in the past. This is particularly important when patients are using donated sperm or embryos in treatment and are not married or in a civil partnership. Legal parenthood consent is essential to enable the patient's partner to become the legal parent of any resultant children.

Following concerted effort by clinics, we are now seeing substantial improvements in this area. We do, however, see occasional breaches – such as transposing the patient's date of birth with the date of treatment. Even simple errors such as this can affect the legal parenthood of a parent to the child born, although the courts have now introduced a way in which such errors can be amended more straightforwardly. We expect all such instances to be reported to us as an incident (see the adverse incidents section) and are continuing to require clinics to have processes in place which can ensure that these complex consents are taken carefully.

Managing medicine (categorised with our assessment of premises and facilities)

Clinics are required to have arrangements for obtaining, recording, handling, using, and storing standard and controlled drugs in line with legal requirements and guidance. Our Code of Practice also requires clinics to keep accurate records that clearly set out the medication a patient is receiving. We are concerned about the number of non compliances in this area of practice. More information about this is in the 'medicines management (premises and facilities)' section later in this report.

Equipment and materials

Our Code of Practice requires clinics to only use validated equipment, to maintain and store this equipment to minimise hazard to patients and/or staff and to have appropriate procedures in place if something malfunctions. Rates of non compliances in this area remain stubbornly high and we have seen an increase in less serious, or 'other' non compliances this year.

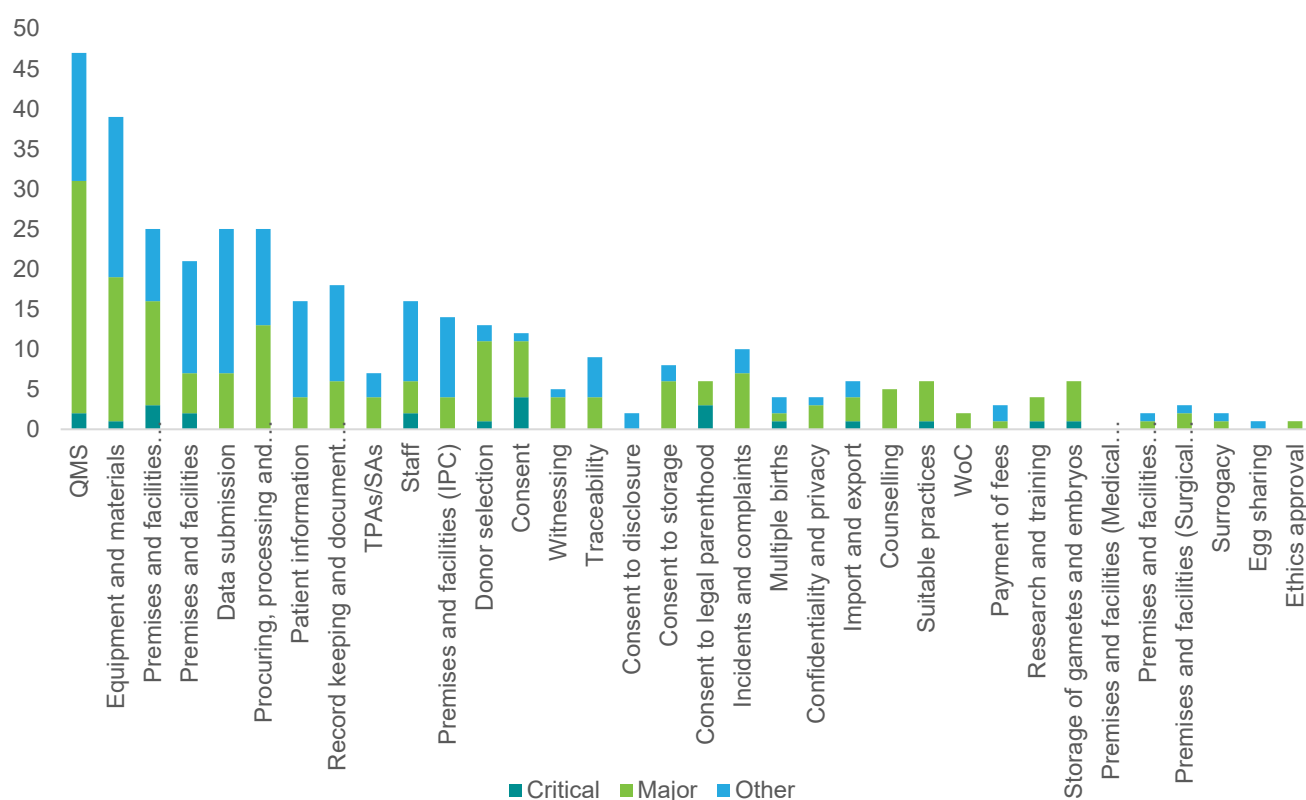
Procuring, processing and transporting of eggs and sperm

We require clinics to have a documented and appropriate system to ensure that all eggs and sperm are procured, processed and transported appropriately. Where we cannot see appropriate evidence of this, a non compliance is found and must be resolved.

Suitable practices

This theme covers a broad range of requirements, from the suitability of the premises and equipment, or the suitability of the leadership and staffing team, to the suitability of clinical practices (such as reducing multiple births or the quality management system). In 2017/18, we saw an increasing trend in critical and major non compliances in this area.

Figure 8: Number of non compliances in 2017/18 – all clinic and research centre types



Non compliances in research and storage clinics

In research and storage clinics, there are expected to be fewer, and a smaller range of non compliances because they do not carry out the full range of treatments and are subjected to fewer regulatory requirements.

Over the past three years, there were no critical non compliances in research clinics. Research clinic non compliances included consent to storage, ethics approval, patient information, and record keeping and document control.

Over the past three years, there were four critical non compliances in storage clinics, three of which related to consent. The most common critical and major non compliances over the past three years related to premises and facilities and procuring, processing and transporting of eggs and sperm (three observed).

How inspections improve clinic standards

Comparing clinics year by year

A way of considering whether our inspection regime is effective is to compare the number and types of non compliances identified at a clinic's previous licence renewal inspection with their most recent licence renewal inspection. While it is important to note that this is not always a like for like comparison as the requirements placed on clinics change over time, it does provide a reasonable benchmark against which to judge the effectiveness of our inspections.

Taking such a measure, of the 33 IVF treatment renewal inspections that took place in 2017/18, the compliance of 20 clinics showed an improvement overall, and one clinic's standard of compliance was about the same. However, the performance of 12 got worse.

The identification of non compliances is only the first stage of the improvement cycle. Following inspection, clinics are given an opportunity to make the necessary improvements where possible before the licence is granted.

A PR may also commit to an action plan which allows that the licence is granted subject to the required improvements taking place. The 12 clinics with more non compliances in their latest inspection than in their previous inspection were all granted a licence on the basis that the areas of improvement were rectified before the start of the licence, or shortly thereafter.

The evidence shows that the performance of most clinics has improved over time. However, this is not universal and more work must be put in by those clinics, and by our inspection team in monitoring the performance of those clinics, to guarantee the provision of higher quality care for all patients.

Learning from inspections

Inspections serve two primary purposes:

- they provide an assessment of the quality of services at a clinic at a particular time to enable a decision to be reached about whether the clinic should be licensed, and
- they provide an opportunity for learning.

To that end, we review the outcomes from inspections so that we can understand which areas are performing well, where we've seen improvement and where we still need to see improvement.

Areas of practice where clinics perform well

There has been real progress in areas which have historically been of a concern, such as witnessing. This shows that a sharper and more targeted inspection process, supported by clear communications and policy work, can have a real impact upon standards of treatment.

Witnessing

Our requirements on witnessing ensure that the right eggs, sperm and embryos are used for the correct patients. Mistakes in this area have always been rare and compliance is generally good.

Most clinics use sophisticated electronic systems to double check that the right embryos are selected and are checked again before use, though some still use manual processes and have good witnessing procedures in place.

Whatever the witnessing system, an inspection team reviews witnessing processes by observation of practice and/or discussion with clinic staff. They also review witnessing records, documented procedures and record sheets, and the clinic's own quality assurance activities relating to witnessing, to assess whether good witnessing procedures are in place.

We are pleased to see compliance in this area continues to improve and that clinics are motivated to get this right; rates of non compliances have declined by 69% since 2015/16 and have declined across all severity grades.

We identified witnessing as a key priority standard for inspection in 2016/17 due to the risks associated with non compliance. The inspection team noted that non compliances in this area are often due to documentation of witness checks and also noted that it's essential that the discarding of sperm, eggs and embryos is witnessed.

Multiple births

We continue to see improvement in areas relating to our multiple births policy. Our inspection team work with clinics on their multiple birth minimisation strategies to ensure that clinics meet our 10% target.

The rate of non compliance in this area has declined by 62% since 2015/16 overall (with a 74% reduction in critical and major non compliances), with a similar reduction observed for both interim and renewal inspections.

However, we shall continue to monitor this area closely. While many clinics have results close to the target, there are some where this is a way from being achieved.

Third party agreements

Third party agreements are vital to ensure the quality of additional services that are used by clinics and may cover areas of practice that are significant to the safety of patients and their sperm, eggs and embryos (for example, transport of eggs and sperm).

Some of the incidents we are informed about have third parties as a root cause and having robust and up-to-date third-party agreements, reflecting the latest evidence, is vital to ensure we minimise risks. In this area of practice, non-compliance rates have declined by 56% since 2015/16 and have generally declined across all severity grades for interim and renewal inspections.

The best third-party agreements are compliant with the [licence condition requirement of T111-T117](#) and other licence condition requirements relevant to the service provided. This ensures the third party knows what the service specifications are and enables the clinic to audit the service delivery effectively against those stated specifications.

Areas of practice which have shown some improvement

Equipment and materials and medicines management are below the standards we expect to see, but we have begun to see shifts in non-compliance rates towards the less severe 'other' non compliances over time. These areas form part of our focused interim inspection framework, so that clinics receive more frequent feedback on their performance.

While we do not expect to see improvements overnight, we do expect clinics to identify, report and learn from mistakes so that the sector improves. We will maintain our focus on these areas to monitor progress and continue our work with clinics through stakeholder engagement, the inspections process and supporting the sharing of best practice.

Equipment and materials

Clinics should use only media and consumables that have been CE-marked at a classification suitable for their intended purpose. Modifying existing devices (for example, adding calcium ionophore to culture medium) or using them 'off label' for purposes not intended by the manufacturer (for example, using a medium for a different purpose from that specified) can have safety implications.

Modification may also count as manufacture of a new device under the Medical Devices Regulations. If a clinic decides to modify an existing product or use a product 'off label', it should (as the 'manufacturer') complete a risk analysis and validation to ensure the product or process is safe. As part of our regulatory regime, we need to ensure that any changes to a different product are carefully sourced, monitored and implemented over time to minimise the risk of a detrimental effect on success rates.

The rate of critical and major non compliances in this area has reduced by 51% from 2015/16, but it remains too high (second highest non compliance overall for both interim and renewal inspections).

Clinics need to be aware of the requirements and not prioritise finance or convenience over sourcing appropriate products.

Medicines management (premises and facilities)

Medicines management was identified last year as an area where significant improvement is required. While the number of critical and major non compliances has reduced in renewal and interim inspections (by 35% and 55% respectively), an increase in 'other', less severe, non compliances has been seen during renewal inspections.

Disappointingly, it is still the case in 2017/18 that this area of practice is one with the highest rates of critical non compliances; there were three of these cases identified in the year.

Non compliances relating to medicines management often involve controlled drugs. These are not infertility drugs but drugs for sedating some patients during, for example, the egg collection procedure, with strict requirements placed on their use and control.

It is crucial that there is a safe 'chain of custody' so that such drugs are accounted for throughout their lifecycle from arrival at the clinic to prescription, use and/or disposal, so that they do not fall in to the wrong hands. Many clinics understand their responsibilities well but where we identify non compliance there are common themes:

- Poor record keeping in controlled drugs registers and patient records, which can include a failure to record the amount of drug administered, the time of administration, who has administered and witnessed the administration of the controlled drug, or illegible entries.
- Practitioners lack a knowledge of the regulatory and statutory requirements for the safe custody and handling of controlled drugs.
- Practitioners lack an understanding of the requirements of their own professional standards in relation to the management of medicines.
- There is a lack of practice oversight and knowledge from senior practitioners with a responsibility for medicines management.
- There is a lack of training and adequate assessment of competencies.
- Practice is not in line with the clinic's own standard operating procedures.

Clinics that do well in this area follow their professional and regulatory requirements through good governance, knowledge of regulatory and professional requirements and regular high-quality training. We have seen no evidence of any risk to patients from the various non compliances identified.

We are active in the Controlled National Drugs Group and have issued periodic updates to clinics. We also work closely with the Infertility Nurses Network to further emphasise the importance of improving performance here.

Areas of practice that need to improve

There are some areas of practice where clinics need to improve to ensure that patients and donors receive high quality services. It's important that clinics have sustainable and embedded systems to monitor their own performance over time; this will be vital in ensuring the sector continues to develop a culture of learning from experience.

Consent

There has been a small increase of 6% in the rate of critical non compliances relating to this and it is also the area with the highest rate of critical non compliance. Major and other non compliances in this area have remained the same since 2015/16. This is of concern.

Non compliances on consent vary, but many relate to consent to storage, which can be complex and sometimes difficult for clinics to manage. Clinics need to have a better understanding about the requirements and have robust processes for obtaining consent and managing eggs, sperm and embryos in storage.

It is clear to us that obtaining consent effectively is not given sufficient priority or time by some clinics. Getting it right first time must receive a greater focus in all clinics. Staff must understand the importance of

getting it right and frequent audit and training play an important role. It is a process that lends itself to 'check steps', where members of staff check consent has been completed properly at various stages of the treatment pathway as a basic requirement.

Due to the information that needs to be conveyed to patients, obtaining consent can be time-consuming. It is possible that, simply stated, some clinics set aside insufficient time to do things properly. Some clinics are investing in digital tools to support the information process, such as online portals for patients to absorb the information at home, and with the use of a quiz to ensure the patient has understood what a particular aspect of consent means to them. Electronic signature systems are also being introduced to minimise the potential for missing steps.

It's important to emphasise that nothing removes the responsibility of the PR in ensuring that the patient's consent is given appropriately.

Quality Management System (QMS)

The rate of critical and major non compliances relating to the QMS is the highest overall and for renewal and interim inspections individually. There has been a consistent increase over time (+13% and +36% for overall and renewal inspections). The number of 'other', less severe, non compliances relating to the QMS have decreased by 37%.

The role of a clinic's quality manager is vital in delivering a functioning and effective QMS and it is imperative that clinics provide training, skills and support to deliver this important function.

Although there is good engagement and the sector understands the importance of a quality management system, auditing and embedding learning well – so that it makes a difference – is difficult.

Clinics could improve in this area by focusing more on the quality of audits and learning, particularly on resource allocation. When auditing, it is important to carefully consider the scope and reasons for the main areas of focus so that targeted learning can come out and motivate clinics to continue their improvement cycle.

Factors contributing to high performing clinics

Generally, the features of clinics where there are few non compliances include:



A person responsible who is committed to attaining the highest standards of patient care and has time and a strong inclination to focus on compliance with all HFEA requirements.



Developing and retaining an experienced management team across the clinic who share the PR's commitment to patient care and the clinic or research centre's compliance, and all work together in a coordinated manner to deliver it.



Having access to the resources, both financial and human, to deliver high quality patient care and to address quality and compliance concerns when they are identified.



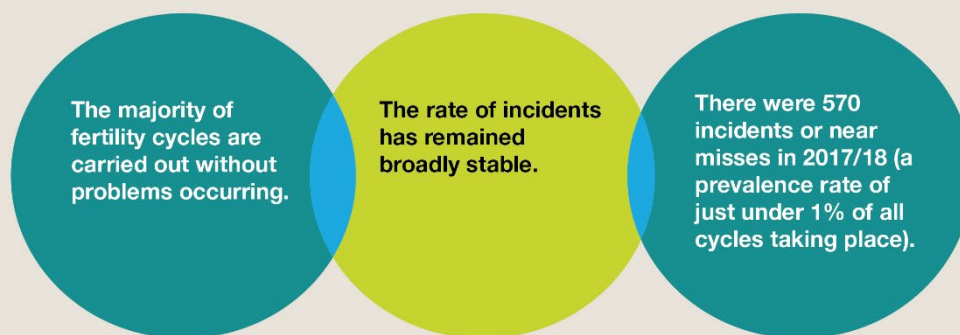
An appreciation for, and an understanding of, how to implement an effective quality management system.

Adverse incidents

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.

Background

Key findings from adverse incidents



The majority of fertility cycles (there were over 80,000 cycles in 2017/18) are carried out without any problems occurring. But, as in any hospital or clinical setting, mistakes can happen.

Most people understand that there are risks associated with all forms of healthcare, and equally expect that healthcare professionals take seriously the opportunities to learn from incidents where mistakes have happened.

We classify incidents that take place within a clinic as 'adverse incidents' or 'near misses'. Adverse incidents deemed serious must be reported to us within 12 hours and all other incidents or near misses within 24 hours.

We monitor the number and nature of adverse incidents and near misses. For any incident that occurs, we require the clinic to produce an incident report, so that we can determine if it has understood the 'root causes' of the incident and has started to think about how changes in practice could prevent a reoccurrence.

If we have concerns, or notice a pattern, we work with the clinic to identify what's going wrong, so improvements are implemented. Whenever there is a serious incident, we carry out an on-site inspection.

When we inspect clinics, we spend time understanding their approach to incident reporting, the quality of their analysis of the causes of an incident and, crucially, whether the learning has been embedded so that the potential for similar incidents happening in the future is minimised.

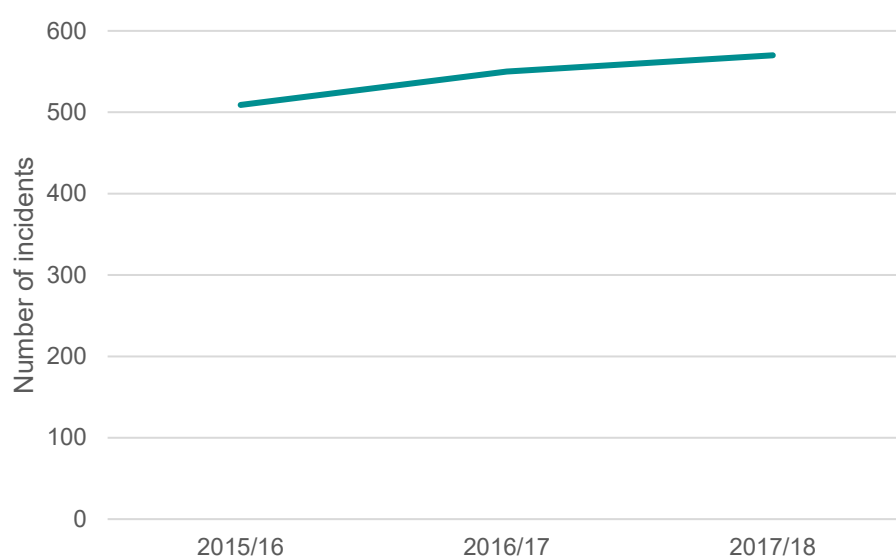
We also use our clinic website, Clinic Portal, to share learning from incidents to notify other clinics of potential issues with third-party providers and minimise the risk of an incident reoccurring.

Number of incidents

The rate of incidents has remained broadly stable over time. Although there is an increase in the number of incidents each year (an increase of 4.6% between 2016/17 and 2017/18), this reflects the increase in the number of fertility treatments performed in UK clinics.

In 2017/18, there were 570 incidents or near misses, which is a prevalence rate of just under 1% of all fertility treatments.

Figure 9: Incidents reported between 2016 and 2018



Severity of incidents

There were no grade A incidents in 2017/18. However, there has been an increase in the proportion of grade B incidents, with 41% classified as grade B in 2017/18, compared with 32% in 2016/17.

This is due mainly to more incidents relating to 'third party' factors and a greater awareness that such incidents must be reported.

For example, where a specific piece of equipment fails (and is subject to a product recall), any clinics using the equipment (or that batch of equipment) must report it. Similarly, where a third-party laboratory provides a service to a clinic and an incident takes place, this must also be reported by the clinic. All opportunities for learning to minimise reoccurrence must be seized.

Categories of incidents

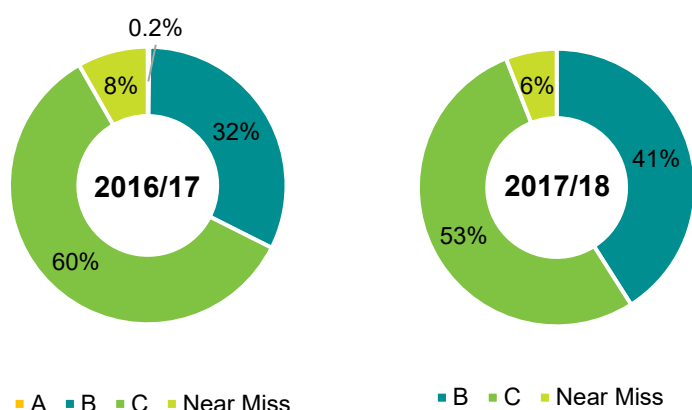
Grade A: the most serious type of incident which happen infrequently. These involve severe harm to one person, such as a death or being implanted with the wrong embryo, or major harm to many, such as a frozen storage unit containing embryos of many patients failing.

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.

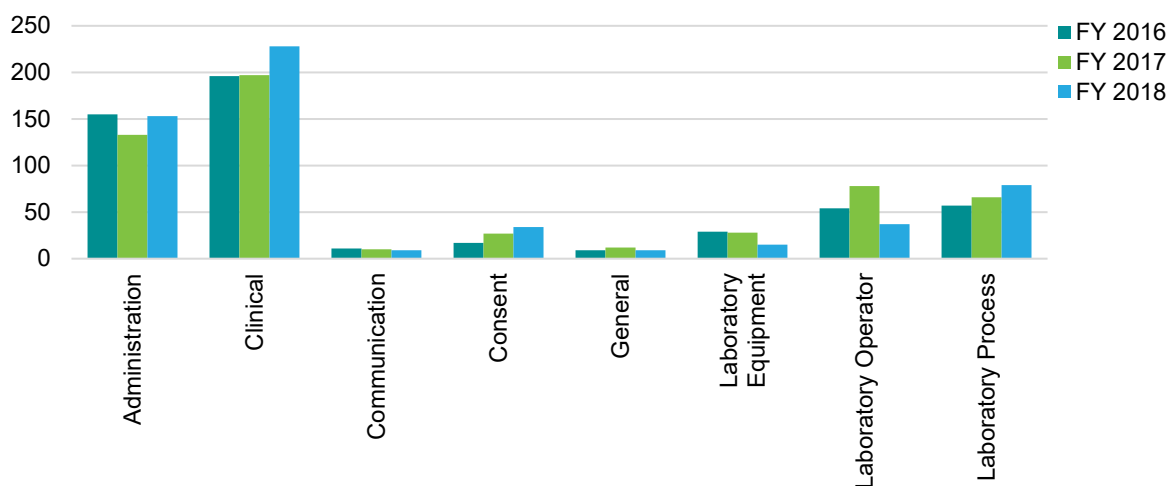
The number of grade C incidents decreased from 328 to 302 and the number of near misses also decreased from 44 to 34.

Figure 10: Incidents by severity



Categories of incidents

Figure 11: Incidents by common category and year



Clinical incidents are the largest category of incidents, making up 40% of all incidents last year and the number of grade B clinical incidents has almost doubled from 62 in 2016/17 to 116 in 2017/18. As outlined above, this is partly due to increases in reporting of incidents involving third parties.

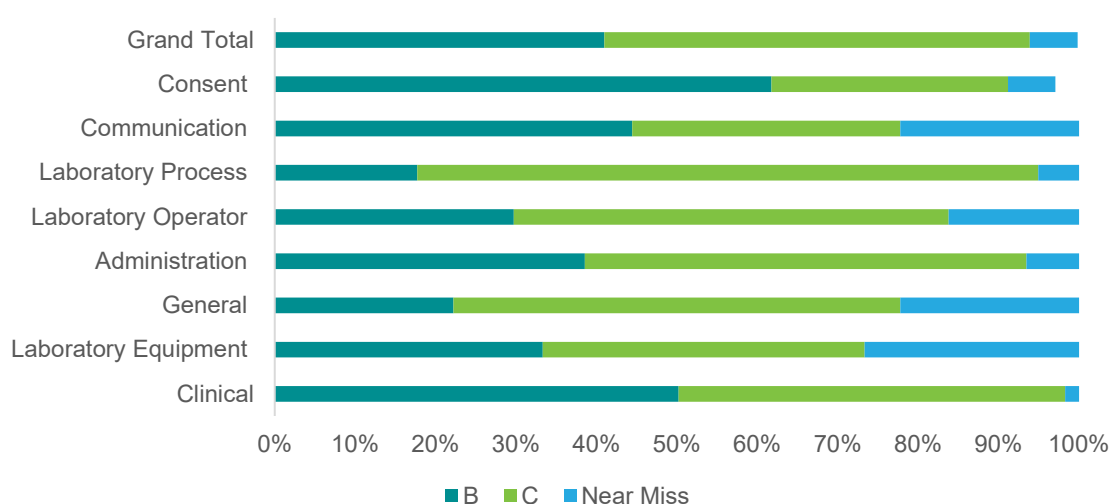
Only severe or critical OHSS should be reported to us as an incident. This year, we found that clinics have erroneously reported mild OHSS and other hospital admissions, such as ectopic pregnancies and pelvic inflammation, which are not classed as incidents. This is another reason we are seeing an increased number of incidents in the clinical incidents category. We have been working with clinics to rectify this. Find out more in the clinical incidents section below.

The second most common type of incidents are those categorised as 'administration', making up 27% of all incidents in 2017/18. These relate to administrative errors such as letters being sent to a wrong address, consent-related incidents and those involving laboratory processes.

The most common type of consent incident over the past three years relates to storage consent. We have seen a decrease in communication, laboratory operator, and equipment-related incidents in the last year.

Consent and clinical incidents are the most likely to be a serious grade B incident, whereas laboratory process and general incidents are likely to be the least serious or a 'near miss'. However, any adverse incident or near miss which is reported is important to review and learn from.

Figure 12: Proportion of each incident category by severity grade, 2017/18



Clinical incidents

Around half of all clinical incidents in 2017/18 related to patients developing ovarian hyperstimulation syndrome (OHSS). Of these, 52 patients were reported as having severe or critical OHSS.

Ovarian hyperstimulation syndrome (OHSS) is a potentially fatal reaction to gonadotrophin fertility drugs. It causes a woman's ovaries to grow large and painful and can lead to fluid leaking into their abdomen. Around a third of women have mild OHSS, which can normally be effectively treated at home with pain relief.

Few women will develop moderate or severe OHSS but, in very rare cases, OHSS can be life-threatening. We therefore require clinics to report all 'severe' and 'critical' cases of OHSS to us.

It's worth reiterating that the risk of OHSS is very low. To put these numbers into context, more than 80,000 treatment cycles are carried out each year.

Although the risk is very low, we have worked hard with partners across the sector to ensure that processes and systems for identifying, reporting and preventing OHSS are as rigorous as possible.

Some of the progress we have made over the past year includes:

- working with the NHS and confirming that clinics are not underreporting cases of OHSS to us

- revising and refreshing the information in our Code of Practice to make it clearer what cases of OHSS need to be reported as incidents and updating guidance regarding management protocols for the prevention of OHSS
- working with professional bodies to develop a bespoke form for reporting cases of OHSS to us
- working with professional bodies (such as the British Fertility Society and the Royal College of Obstetricians and Gynaecologists) to promote the specialised 'green top' guidelines and strategies for preventing and managing OHSS
- encouraging improved relationships between clinics and local hospitals
- encouraging improvement in post-treatment follow up of patients
- using inspections to check for underreporting of OHSS.

Other clinical incidents often involve suspected genetic conditions following the use of donor sperm or eggs, hospitalisation following egg retrieval or embryo transfer, or hospitalisation following ectopic pregnancies.

If patients have a live birth using affected sperm or eggs and the child has the genetic condition, patients must report this to us as a serious adverse reaction via our incident reporting system. We expect clinics to put an alert on the future use of the donor sperm and eggs and to support the patients affected.

If patients have a live birth using affected sperm or eggs and it is unknown if the child has the genetic condition, clinics still need to report this to us, and must notify the patients and support the patients/child to undergo genetic testing.

If there was no live birth using the affected donor sperm or eggs, clinics must put a block on their future and notify other clinics that have been supplied with that donor sperm/eggs.

Where hospitalisation occurs for a patient, this should be reported to us as an incident that requires hospital admission. We will then grade the incident, taking into account whether hospitalisation was as a direct result of fertility treatment.

Administrative incidents

Administrative incidents are usually data protection breaches, for example, when a letter or email is sent to the wrong address. There is a danger that some clinics view such mistakes as not serious. This is to misunderstand that such administrative failures can cause real distress to patients. Clinics must ensure they have robust data protection processes to prevent incidents of this type.

It is even more important for clinics to have effective data protection processes and procedures in place due to the implementation of the General Data Protection Regulations (GDPR) and Data Protection Act 2018.

These laws give people more rights over how organisations use their data and require them to be more accountable and transparent about how they use personal data. Our new Code of Practice includes information on clinics' responsibilities under this new legislation and advises that they review guidance on the [ICO website](#).

Incidents by clinic size

We know there is a relationship between clinic size and incident rate, with larger clinics tending to report more incidents. This could be expected because the more treatments clinics provide, the more chances there are for something to go wrong.

However, there are some clinics who report a disproportionately large or small number of incidents. This is not necessarily due to excellent or poor practice, as it may be that some clinics are more inclined to report incidents and embrace the lessons learnt from them.

We monitor reporting of incidents on a continual basis and incident data is contextualised and checked with other data so that each inspection considers the volume of reporting to provide the most comprehensive overview of clinic compliance.

Complaints by patients about their care

Background

Key findings from patient complaints



We take complaints seriously and work hard to resolve them. If patients are not happy with their experience, they should be able to make a complaint to their clinic.

Every clinic must have a complaints procedure which is adhered to in these circumstances. If patients have been through the clinic's complaints process and they are still not happy, they can contact us.

We provide guidance to clinics to follow when dealing with complaints by patients. We can review a complaint and assess the level of engagement and willingness by the clinic to resolve it.

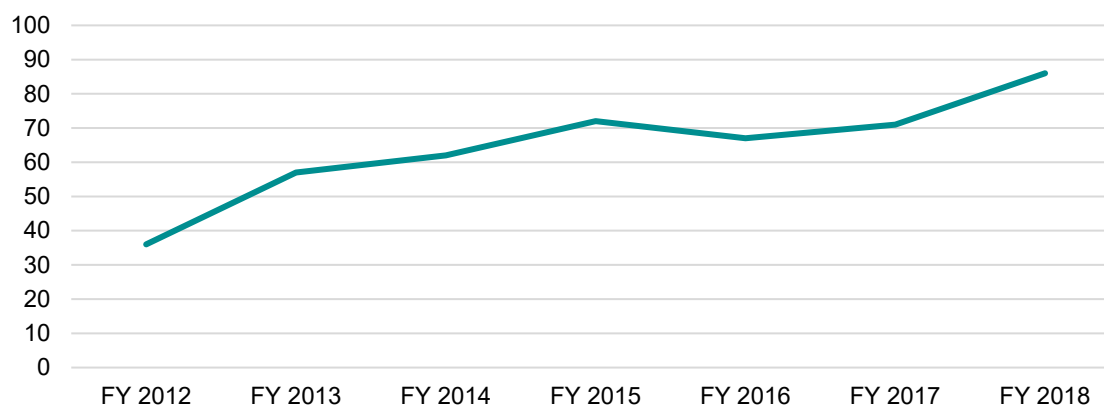
We can also consider whether there are wider regulatory issues or failings that necessitate some sort of intervention with the clinic. Unlike some other healthcare bodies, however, we do not have a specific statutory duty to investigate patient complaints. We keep a record of all complaints which help shape our planning for the inspection process.

Number of complaints

In 2017/18, we dealt with 86 complaints from patients who had been unable to resolve their complaint with their clinic, a 21% increase on the 71 received in 2016/17. This continues the upwards trend in the number of complaints that we receive and is attributable to several factors:

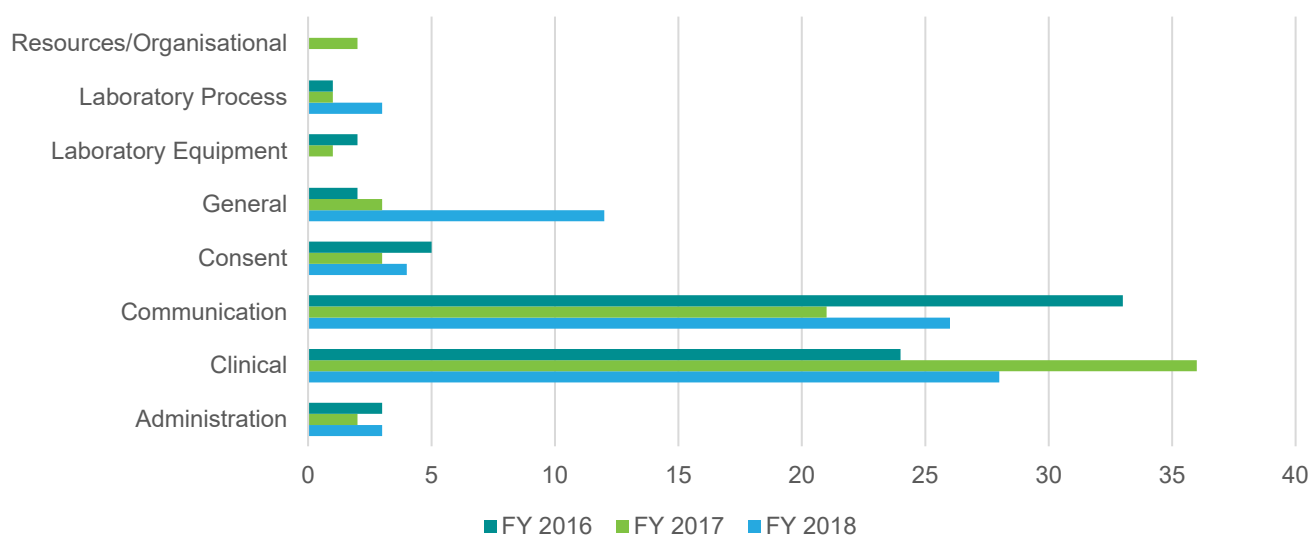
- a greater awareness of the HFEA
- a growing willingness by patients generally to complain, and
- an increasingly 'risk-averse' approach in dealing with complaints in some clinics, where the patient's concerns are not sufficiently at the centre of considerations.

Each year over 80,000 cycles take place in fertility clinics and the number of patients resorting to complaining formally to the clinic is low, and to us lower still. That said, the experience of the patients affected is very real and the impact on some can be very significant.

Figure 13: Complaints recorded over time

Complaint categories

Most complaints are categorised as either clinical (37%) or communication (34%) related. There has been a decrease in the number of clinical complaints (relating to concerns about clinical practice such as clinical procedures) and an increase in communication and general complaints.

Figure 14: Complaints by category

What we know about complaints

Many complaints begin with a seemingly small mistake on behalf of the clinic, often down to human error or miscommunication, such as a last-minute rescheduled appointment, an unexpected test or a change in treatment plan.

However, a common theme in many of the complaints that are referred to us (because the patient was unable to resolve it with their clinic) is that once the issue is raised, the clinic is poor at responding and

resolving the initial incident. This leads to a breakdown of trust and a poor quality of experience for the patient.

It is important that, if patients raise a concern, this is addressed promptly and thoroughly. This provides support to the patient, which is necessary for high quality care and to resolve the issue, so it does not go on to become a full complaint requiring investigation. Clinics can improve this process by making their complaints process clear and accessible to patients and regularly asking for feedback throughout treatment.

It is also essential that clinics communicate changes to treatment clearly and acknowledge if a mistake is made so a resolution can be sought with minimal disruption. During the year, where we have seen a breakdown of trust between clinic and patient, we have intervened, usually successfully, in enabling a dialogue and improved understanding between the parties.

We will also continue to check clinics' arrangements for dealing with dissatisfaction when it happens, and the steps taken by clinics to capture feedback from patients more generally. We have recently carried out a national patient experience survey, which we have published alongside this report, and will use the results to inform our work, including inspections, over the year ahead.

Patient feedback

Background

Key findings from patients feedback

In July 2017, we introduced the patient ratings function on the Choose a Fertility Clinic section of our website.

Around 1,500 patients have submitted ratings via the new system between July 2017 and March 2018.

The results from patient feedback so far demonstrate a broadly positive picture.

83% of patients would be extremely likely, or likely to recommend their clinic to friends or family.

Our 2017-2020 strategy places patients, donors and donor-conceived people at the centre of high quality care.

There is good evidence to show a positive association between the experience of patients and improved outcomes and patient safety. For this reason, patient experience, as measured by feedback, is one of several measures of performance that we, as the regulator, seek to explore and monitor.

A key part of this is ensuring patients' voices are heard during and after fertility treatment and that they are given opportunities to feedback on their experience of care.

Patient ratings

We introduced the patient ratings function on the [Choose a Fertility Clinic](#) section of our website in July 2017 to promote patient feedback. We wanted to ensure that the rating system was fair and robust, and, crucially, that it provided data that was helpful to us, clinics and patients.

The ratings system is entirely anonymous and optional and we encourage clinics to ask patients to fill in the short survey. It has two distinct elements:

1. A set of five questions, where patients rate their clinic in relation to whether they:
 - would recommend their clinic
 - felt treated with privacy and dignity
 - understood what was happening during treatment

Clinic spotlight

Uptake for the patient ratings function has been mixed, but one clinic stands out in terms of the amount of feedback received.

One clinic that was recently inspected explained how they provide tablet computers in the recovery areas for patients with links to the clinic's own patient feedback survey and to our patient rating system.

What is more exemplary is that all this feedback is actively acted upon. Any negative feedback that is a risk to the service is fed directly into the clinic's risk and opportunities register for immediate action.

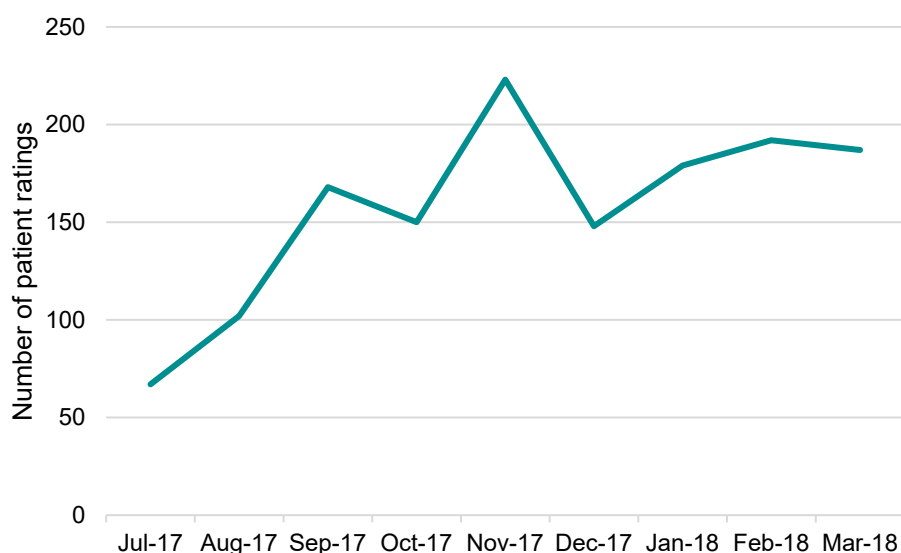
- felt treated with empathy and understanding, and
- paid what they expected (if they paid for treatment).

The responses are displayed on our website in the form of a star rating.

2. A free text feedback mechanism, which allows patients to make private comments directly to our inspectors.

Between July 2017 and March 2018, just under 1,500 patients used the patient rating system to rate their clinic and we hope that this will continue to increase as more patients become aware of the system. However, the take up among clinics varies greatly and we are now looking for all clinics to do more to encourage patients to provide feedback on the quality of treatment they received.

Figure 15: Number of patient ratings submitted by month

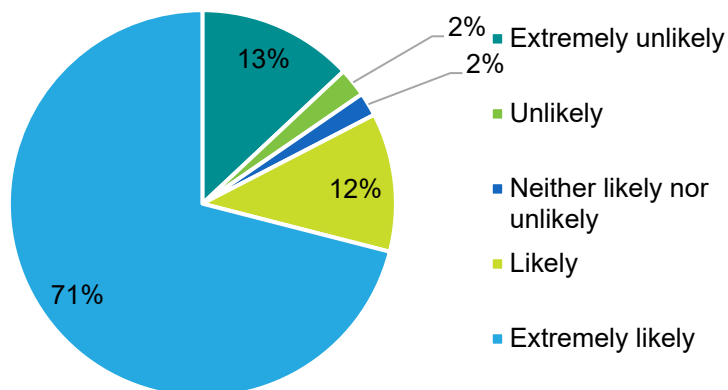


Summary of responses to Choose a Fertility Clinic patient ratings

The results from the patient ratings demonstrate a broadly positive picture. However, as always, more can be done and what is important is that clinics use the feedback from the patient ratings, as well as the feedback they receive from their own mechanisms, to improve their services.

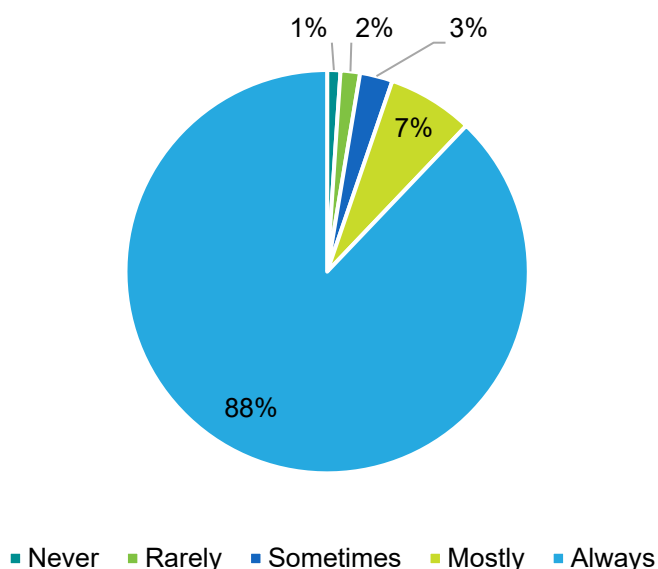
A clear majority of respondents said that they would recommend their clinic to friends or family (71% said that they would be “extremely likely” to do so and a further 12% said that they would be “likely”. 13% said that they would be extremely unlikely to recommend their clinic to friends or family.

Figure 16: How likely are you to recommend this clinic to friends and family if they needed similar care or treatment?



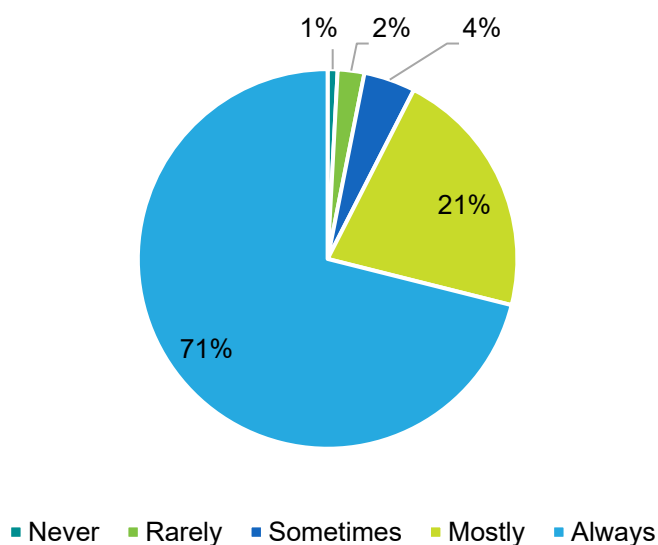
88% of respondents said they felt they were treated with privacy and dignity. Only 3% said they felt they were either never or rarely treatment with dignity and privacy.

Figure 17: To what extent did you feel you were treated with privacy and dignity?



71% of respondents said that they always understood what was happening throughout their treatment, which suggests clinics are doing a good job of providing accessible information to patients about their treatment. 3% said they never or rarely understood what was happening.

Figure 18: To what extent did you feel you understood everything that was happening throughout your treatment?



80% of patients reported that the empathy and understanding they received was excellent and 10% said it was good. 3% said that they considered it to be unacceptable and 3% rated it as poor.

Figure 19: What was the level of empathy and understanding shown towards you by the clinic team?

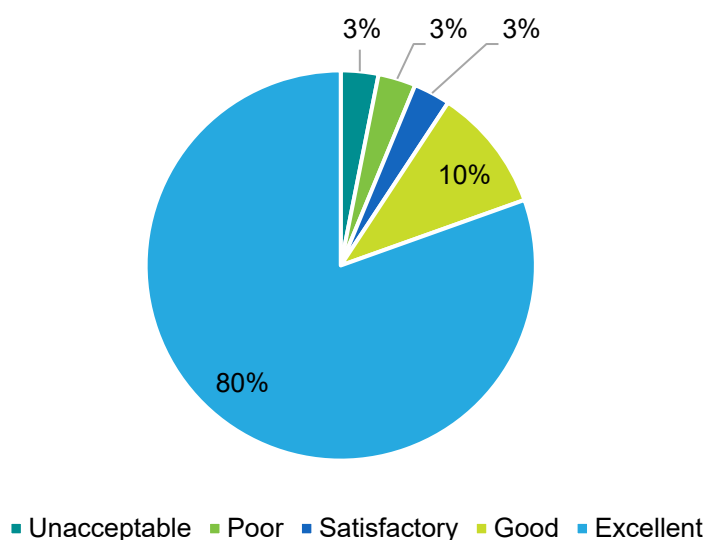
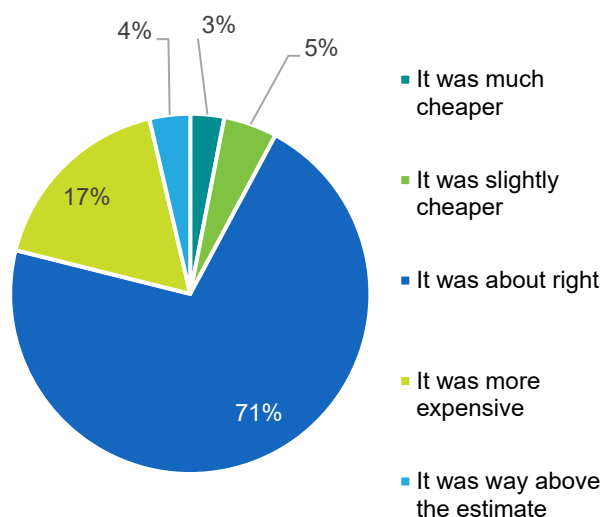


Figure 20: Did you pay what you expected?

71% of respondents said they paid what they expected for treatment. However, around 21% said that they paid more than expected. Around 8% paid less than they expected.

What patients are saying

What patients are saying about good practice

A thematic analysis of the open text responses confirms that clinic staff have a huge impact on patients receiving a positive experience. Where patients would strongly recommend their clinic to family or friends, the most frequent reasons include:

- staff being professional, caring and friendly, with lots of opportunities to ask questions; the most positive responses referred to staff at every level showing the same level of compassion, professionalism and care
- a feeling of involvement in treatment decisions
- a sense of being treated on a personal level.



What patients are saying could be improved

Where patients do not feel they would recommend their clinic to family or friends, the areas most often cited include:

- lack of organisation, inefficiencies or errors
- poor communication, particularly around treatment plans
- a lack of involvement in treatment decisions
- a lack of care and follow up.



The importance of ethical regulation

In the open text responses, there were several references to patients feeling their clinic was misleading them or acting unethically.

We are making clinic leadership a key priority for the forthcoming year to tackle these concerns head on and ensure clinics are provided with the tools and support to make ethical and clinically-robust decisions in the best interests of patients.

The feedback we receive through this channel informs what we focus on during inspection and we are committed to ensuring that patients receive ethical and transparent information about their treatment options.



Looking forward

Clinics across the UK continue to perform well against the basic regulatory standards we set, but there are challenges which we will continue to address. These include:

- ensuring our regulatory approach, particularly with new and expanding clinic delivery models, keeps pace with developments and remains effective
- tracking year-on-year improvements to ensure that our inspection system results in real change by engaging with clinics
- embedding changes from the new Code of Practice so that, as a sector, we can provide patients with timely and high-quality services
- ensuring that we highlight and recognise the high standards that clinics meet and we continue to promote a learning culture so that the existing areas of non compliance improve over time.

In 2019/20, we will focus our attention on the critical non compliances we find on inspection and will be alert to reducing the length of licence where appropriate.

Our work on leadership with PRs will mean that we look to each PR to demonstrate that they do not use inspection as a means of improvement, but are continually working to improve quality in their clinics.

Appendix: Trends in non-compliance rates

Figure 21: Trend in non-compliance rates (major and critical)

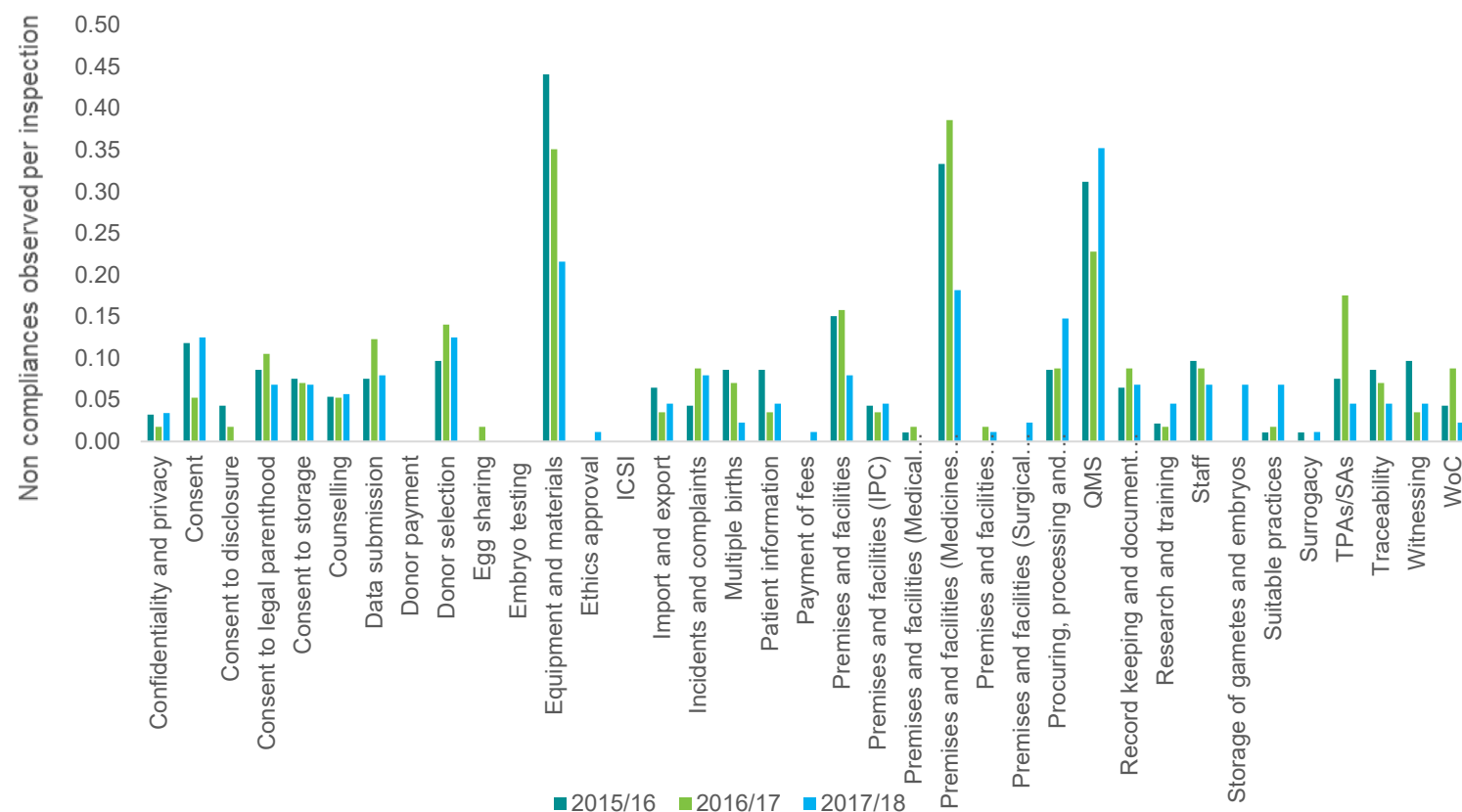


Figure 22: Trend in 'other' non-compliance rates