



Human
Fertilisation &
Embryology
Authority

State of the fertility sector

2018/19

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Executive summary

We regulate by setting standards and inspecting against those standards to ensure that patients and donors have access to safe, ethical and effective treatment. What we find on inspection and the response of the clinic determines the length of the licence we award, or the conditions we might place on the licence.

We regulate a unique area of healthcare in the UK where more than half of all treatments are privately funded, although the position varies across the four nations. Our regulatory activity applies to all clinics, whether part of an NHS trust, a private sector group or a standalone clinic.

The 'State of the fertility sector' report is our annual sector-wide regulatory publication. This year's report shows that the quality of care in fertility clinics across the UK is improving, while the number of treatment cycles continues to rise. The majority of clinics are performing well and over half of clinics inspected had fewer areas of concern compared to their previous inspection.

Executive summary

Since our last report, we've seen improvements in clinic and quality management, which includes the safe use of equipment, as well as the processing and traceability of eggs, sperm and embryos.

We also confirmed this year, that in 2017, we saw the sector achieve our 10% multiple birth target for the first time. This is a huge step forward for patient safety and the result of joint working between us, clinics and professional bodies.

But this report also highlights areas where we need to see improvements. This includes areas such as quality management, medicines management, infection control and consent.

We believe that improving compliance requires clinic leaders to ensure staff have the right resources and training. They should work as a team to deliver high-quality care to every patient, partner and donor.

This report is an important part of our work with clinics to continuously improve the standard of care and safety for the benefit of patients. We expect the sector to make improvements in the identified areas of concern.

Executive summary

We recognise that modern medical practice is complex and incidents do happen. While the proportion of incidents to treatment cycles remains very small, any incident is of concern, and for the patients involved, sometimes traumatic. We investigate all serious incidents and work with the sector to learn from them.

We are concerned about the small increase in cases of ovarian hyperstimulation syndrome (OHSS), which occurred in less than 0.3% of all fresh cycles. Although this is a very small proportion, OHSS is a potentially serious side effect of IVF and we have strengthened our requirements on clinics to inform patients of the risks, and to improve the management of any adverse reactions.

Patient feedback is an important measure that we use to help improve clinics' performance. We expect clinics to encourage patients to give feedback on their experience via the [Choose a Fertility Clinic](#) function on our website. This enables others to look at the clinic through users' eyes, as well as through our inspection reports.

About UK fertility clinics

- There are 134 fertility clinics in the UK.
- About 80% of clinics are given a four-year licence, indicating good overall compliance.
- Two-thirds of clinics are standalone. The rest are owned by 10 private clinic groups.

Figure 2: UK clinics in 2018/19, by licence type

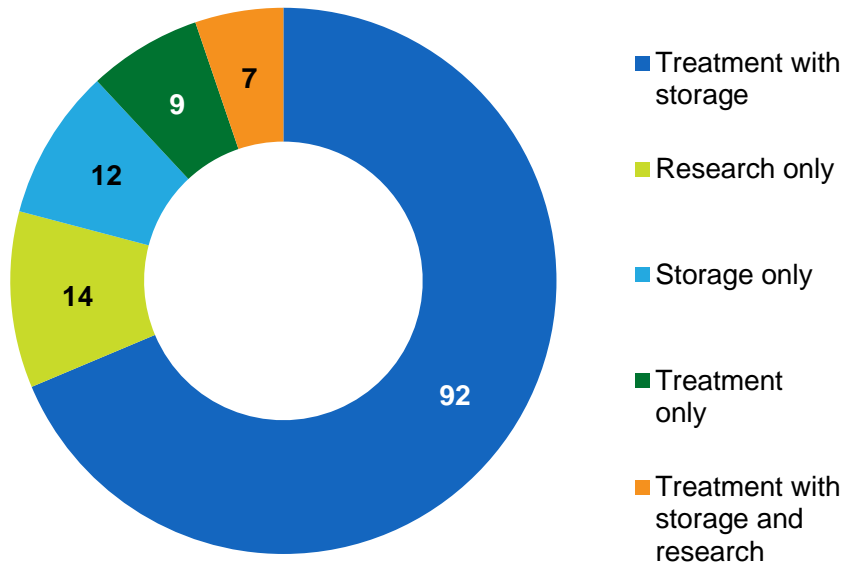
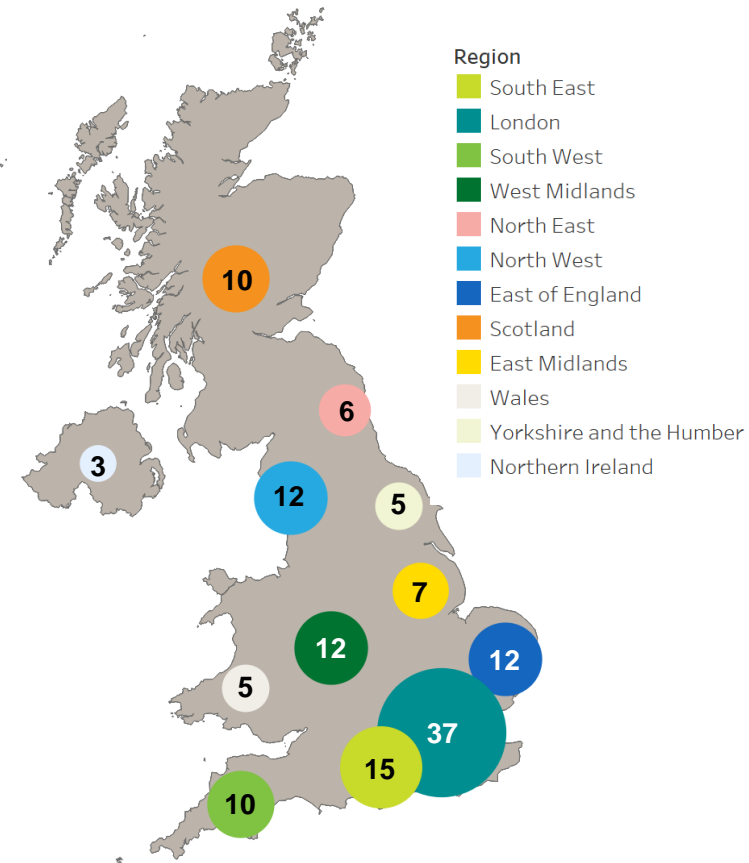


Figure 3: UK Clinics in 2018/19



Inspection findings

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The standards we expect

The Human Fertilisation and Embryology Act 1990 sets out our powers to inspect clinics to ensure compliance with the law.

- Our Code of Practice is organised into 33 topics across four key areas, for which we set best practice standards.
- We issue UK clinics and laboratories with a licence to operate and we inspect clinics at least every two years to ensure that they meet their legal obligations.
- On inspection, we look for areas of non compliance (NC), where clinics have failed to meet these expected standards and require improvements.

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.

What we inspect

The 33 topics in our Code of Practice are organised into four key areas. We analysed NCs in each of these areas to find out which have increased in number or severity. We focus on these so that the sector as a whole can learn lessons.

Clinic and quality management	Treatments and outcomes	Legal obligations and arrangements	Patient experience and engagement
<ul style="list-style-type: none"> ● Adverse incidents ● Equipment ● Premises and facilities* ● Procuring, processing, transporting gametes ● Research and training ● Record keeping ● Staff and PR ● Storage ● Quality management system (QMS) ● Welfare of the Child ● Witnessing 	<ul style="list-style-type: none"> ● Donor-assisted conception ● Donor recruitment ● Embryo testing ● ICSI ● Mitochondrial donation ● Multiple births ● PGD/PGS 	<ul style="list-style-type: none"> ● Consent ● Egg sharing ● Imports and exports ● Legal parenthood ● Obligations and reporting outcomes ● Payment for donors ● Third party agreements ● Traceability 	<ul style="list-style-type: none"> ● Complaints ● Counselling and patient support ● Confidentiality and privacy ● Information prior to consent ● Surrogacy ● Treating people fairly

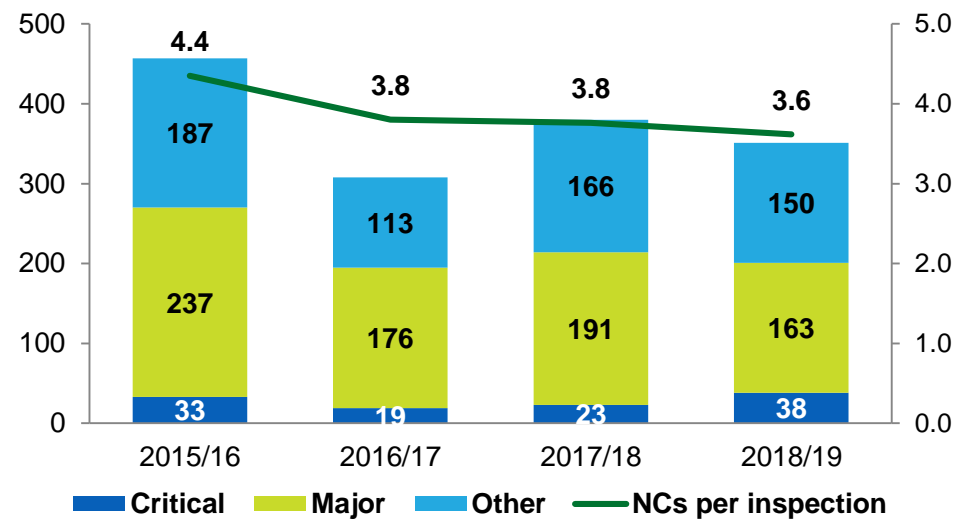
* This area is further divided into medicines management, infection control, and other premises and facilities aspects.

Overall levels of non compliances

There were 351 NCs in 2018/19 but the sector has become more compliant, as the number of NCs per inspection has been decreasing since 2015/16.

- The number of non compliances has decreased.
- The majority of non compliances occurred in the area of clinic and quality management (220 NCs).
- The slight increase in critical non compliances is in a small number of practice areas, which we focus on in this report.

Figure 4: Number of NCs, 2015/16 to 2018/19



What clinics are doing well

We see mostly compliant practice in the areas of treatments and outcomes (30 NCs) and patient experience and engagement (29 NCs). 61% of inspections found no NCs in these areas.

A number of areas have had improvements over the last years, showing fertility treatment is becoming safer:

- **Equipment and materials:** NCs fell from 41 in 2017/18 to 17 in 2018/19.
- There were five **sperm, egg and embryo processing** NCs last year (25 in 2017/18), with NCs relating to robustly tracing their transportation between clinics (**traceability**) falling to just two (nine in 2017/18).
- As the **multiple birth rate** reached our 10% target for the first time in 2017, related NCs have also continuously declined in recent years.

Where clinics could improve



Quality Management System (QMS)

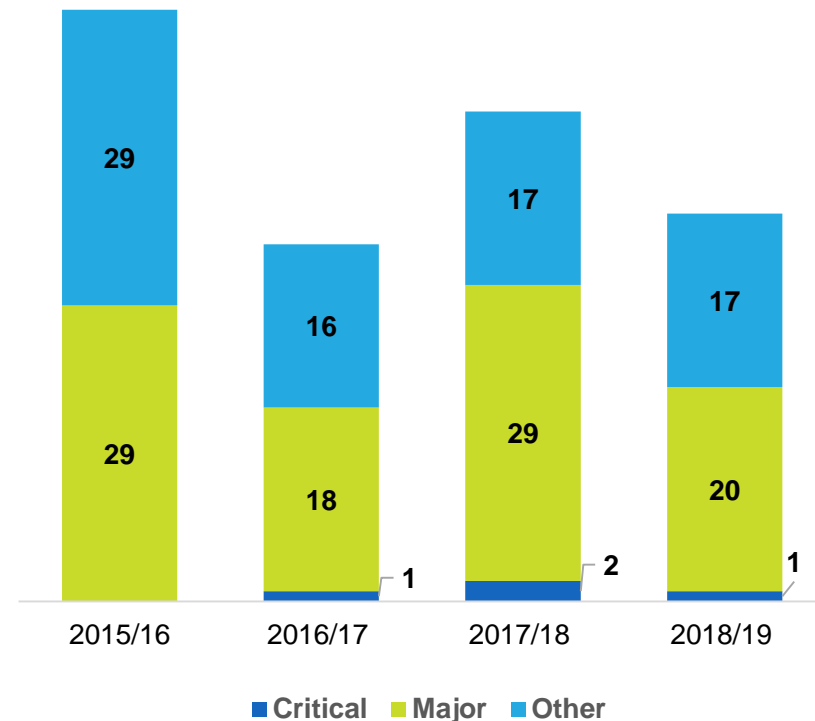
Overall, the largest number of NCs still relate to the QMS.

A good QMS ensures that clinical practice is continually monitored and improved. Clinics must:

- provide support and training for quality managers
- regularly review standard operating procedures
- have a thorough incident investigation process to include findings, corrective actions and learnings.

What we have done: bespoke workshops with clinics on best practice.

Figure 5: QMS NCs, 2015/16 to 2018/19



Medicines management

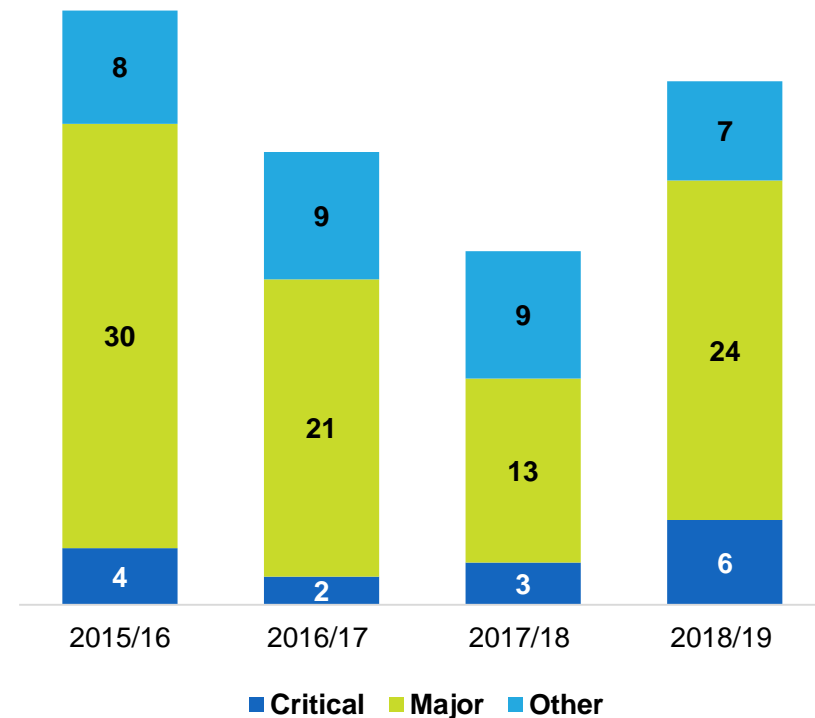
Medicines management NCs have increased, with more being classed as major and critical.

Clinics must ensure that:

- medicines records in controlled drug registers and patient files are clearly completed and up to date
- access to controlled drugs is in accordance with national guidance
- staff have appropriate knowledge of the legal requirements for the safe custody and handling of controlled drugs.

What we will be doing: We require PRs to create a culture that promotes good medicines management practice. We will also work with other health regulators to ensure that our guidance is aligned.

Figure 6: Medicines management NCs, 2015/16 to 2018/19



Infection control

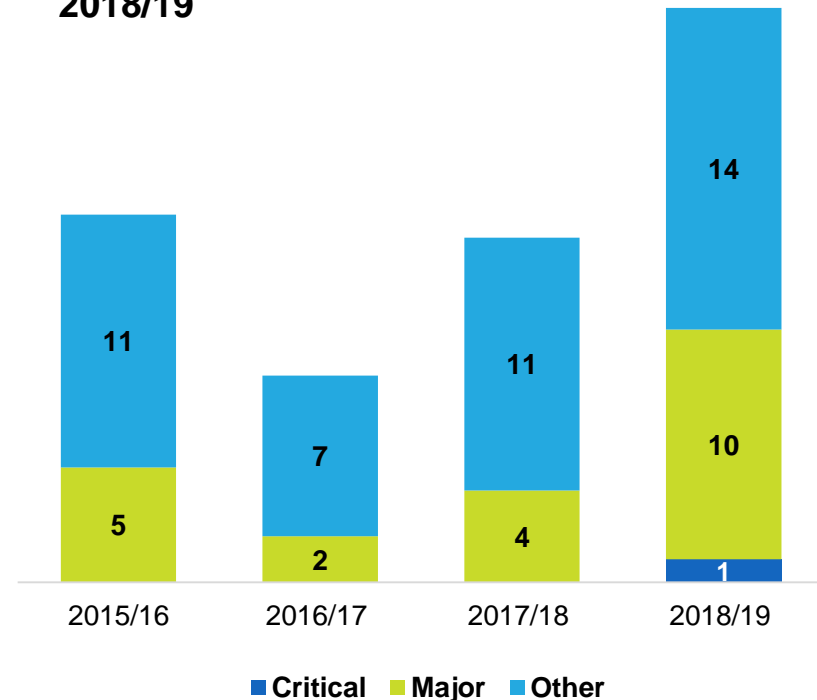
Infection control NCs have increased. One was classed as critical (none last year) and 10 were classed as major (four last year).

We saw an increase in clinics with a combination of infection control issues. Clinics must ensure they:

- have a proper waste management system in place
- implement clear cleaning schedules
- only use wipeable equipment and furniture and launder linen regularly
- keep sharps bins closed when not in use.

What we will be doing: encourage a culture of ownership for best practice at clinic level.

Figure 7: Infection control NCs, 2015/16 to 2018/19



Legal parenthood consent

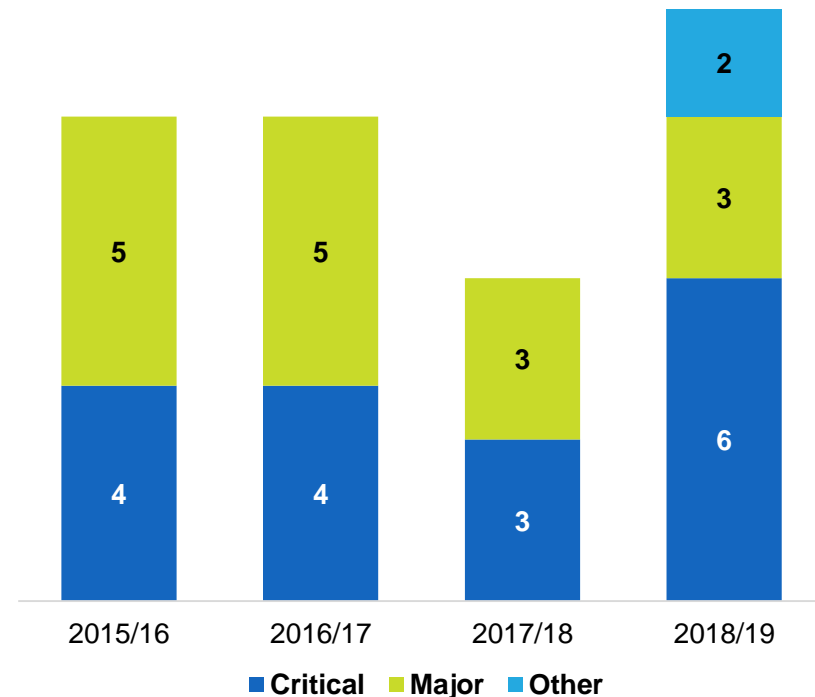
Despite small numbers, we've seen more legal parenthood NCs. There were four more critical NCs than last year.

Legal parenthood consent is essential to enable the patient's partner to become the legal parent of any resultant children. Clinics must:

- always record marital status for all patients at the initial consultation
- ensure staff taking consent are clear on what forms should be completed and avoid redundant forms
- conduct thorough and regular audits with the tools we provide.

What we will be doing: launch a new push for staff understanding, and continue to promote our auditing tool.

Figure 8: Legal parenthood NCs, 2015/16 to 2018/19



Storage consent

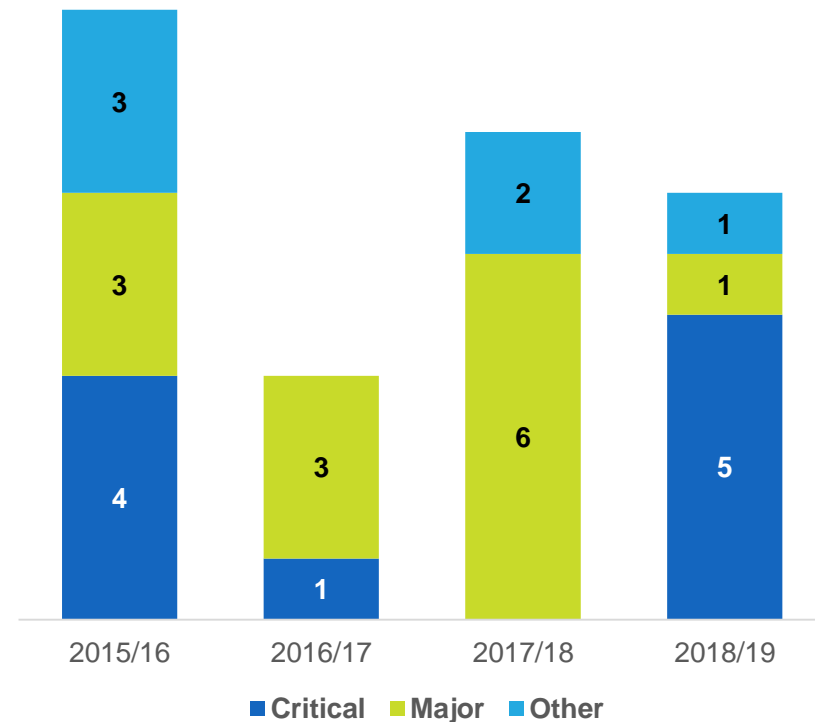
There have been fewer consent to storage NCs, but a higher proportion were classified as critical.

Clinics must ensure that they:

- conduct adequate audits of records relating to stored material
- fully understand the regulations and requirements governing statutory storage periods and their extension
- take robust action to address inconsistencies in storage records
- take complete records of storage consent and of decisions related to discarding at the end of storage.

What we will be doing: work with clinics to ensure legal requirements are clear, relevant and staff are aware of them.

Figure 9: Storage consent NCs, 2015/16 to 2018/19



Key learning points

Good compliance is achievable. PRs should be ambitious and provide leadership on high-quality care by:

- Committing to investing in quality managers and all staff so they have the right tools, skills and training to do a good job.
- Ensuring workload is managed efficiently.
- Taking ownership of areas of poor practice, even if it occurs in another area of a trust or clinic group.
- Ensuring staff are familiar with current professional guidelines.
- Undertaking robust audits which are essential for good compliance across all areas.
- Making sure that the information available to patients and donors is clear and transparent.
- Ensuring good processes are in place to allow consent to storage to be effectively managed.

Incidents

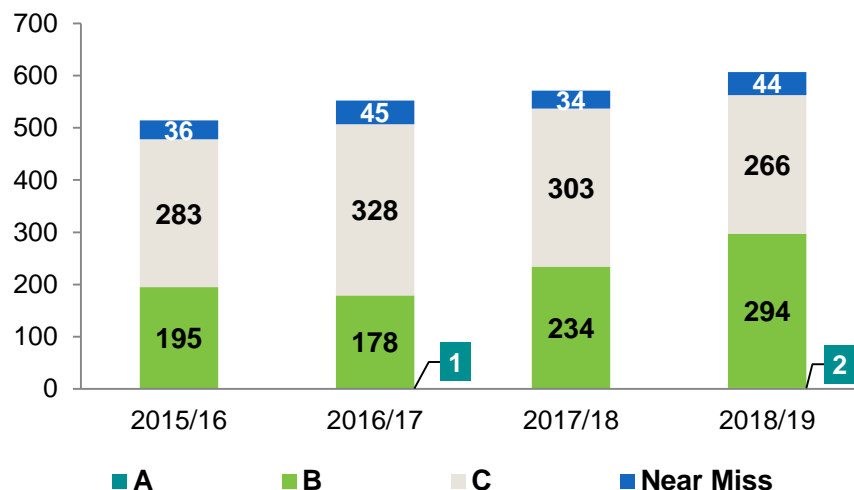
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Incidents are rare

The majority of treatment cycles (there were over 75,000 cycles in 2018/19*) are carried out without any problems occurring, but mistakes can happen.

- In 2018/19, there were 606 incidents reported to us (0.8% of all treatment cycles*).
- An increasing proportion of incidents are grade B and there were two grade A incidents.

Figure 10: Number of incidents by grade, 2015/16 to 2018/19*



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.

Near miss: an event not causing harm, but has the potential to cause injury or ill health.

*Based on provisional treatment cycle data for 2018/19

Clinics should learn from incidents

We take grade A and B incidents very seriously. We ensure clinics do everything to understand what went wrong and, crucially, that steps are taken to ensure that it does not happen again.

- Incidents fall into four broad categories: clinical (56% of grade A and grade B incidents); administration (18%); laboratory process, operator and equipment (15%); and other eg, consent and data protection (11%).
- Proactive reporting allows clinics to learn from incidents and ensures that changes can be made to prevent reoccurrence.
- We share learning and notify other clinics of potential issues. An incident in one clinic should lead to learning across others.
- The sector is becoming better at analysing incidents with tools such as root cause analysis, which leads to more actionable learnings.
- In the rare event of a grade A incident, it is thoroughly reported, investigated and action is agreed by our Licence Committee because of its potentially devastating nature.

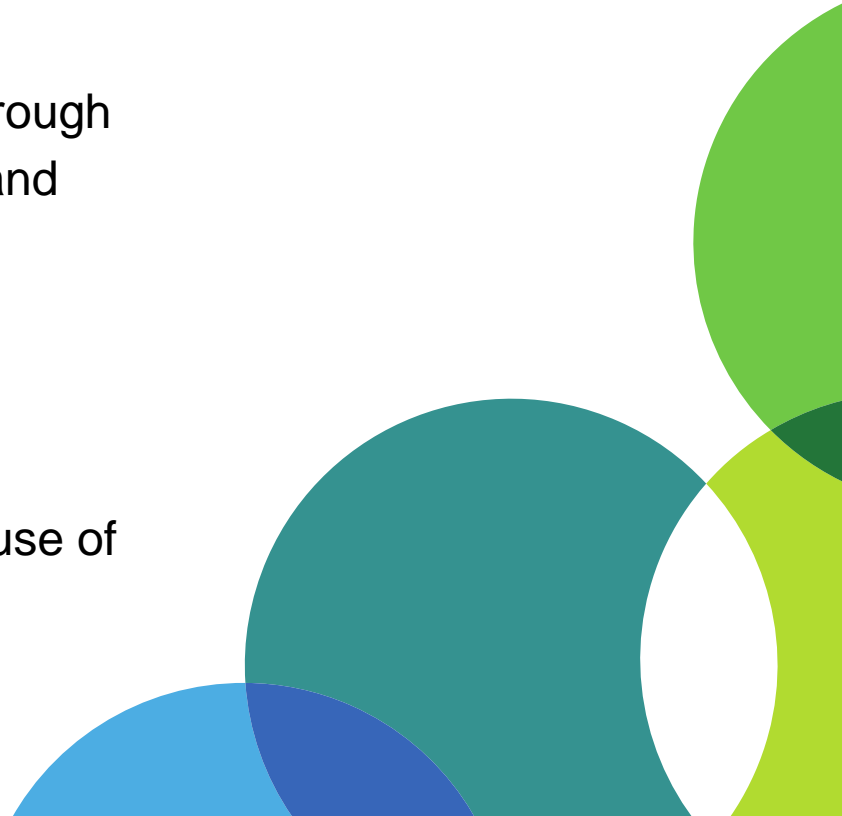
Grade A incident case study

Summary

- The donor sperm process was not verified by an embryologist at the point of preparing laboratory records, resulting in the wrong donor sperm being used.

Key learnings

- Ensure all sperm and eggs are assigned through an electronic patient management system and operating procedures are audited every six months.
- All staff trained on the electronic patient management system.
- Embryologists to review and pre-authorise use of all donor sperm.




Grade A incident case study

Summary

- The incorrect gas cylinder was delivered and connected, with embryos from several patients affected.

Key learnings

- Gas storage yard to be arranged to ensure specialist mixed gases are stored in separate areas and clearly labelled.
 - All cylinders delivered should be checked on arrival and signed over from the porter to the embryologists.
 - Ensure there is a procedure for attaching cylinders to the incubators, including a two-person check.
- 

Ovarian hyperstimulation syndrome (OHSS)

OHSS can be very serious and we have taken steps to improve the way that clinics advise patients of the risks and report incidents to us.

- OHSS is a potentially serious side effect which some patients develop due to the drug treatment necessary for fresh cycles of IVF.
- No cases of critical OHSS were reported in 2018/19. In 2018/19, 156 cases of mild to severe OHSS were reported – less than 0.3% of all fresh cycles*.
- This is an increase from 135 cases reported in 2017/18. A new reporting form introduced in mid-2018 may account for this increase.
- Our Code of Practice requires clinics to advise patients about the risks of OHSS and what a patient should do if she feels unwell.
- Clinics are also required to work with local hospitals to ensure that any patient suffering from suspected OHSS is treated appropriately.

*Based on provisional treatment cycle data for 2018/19

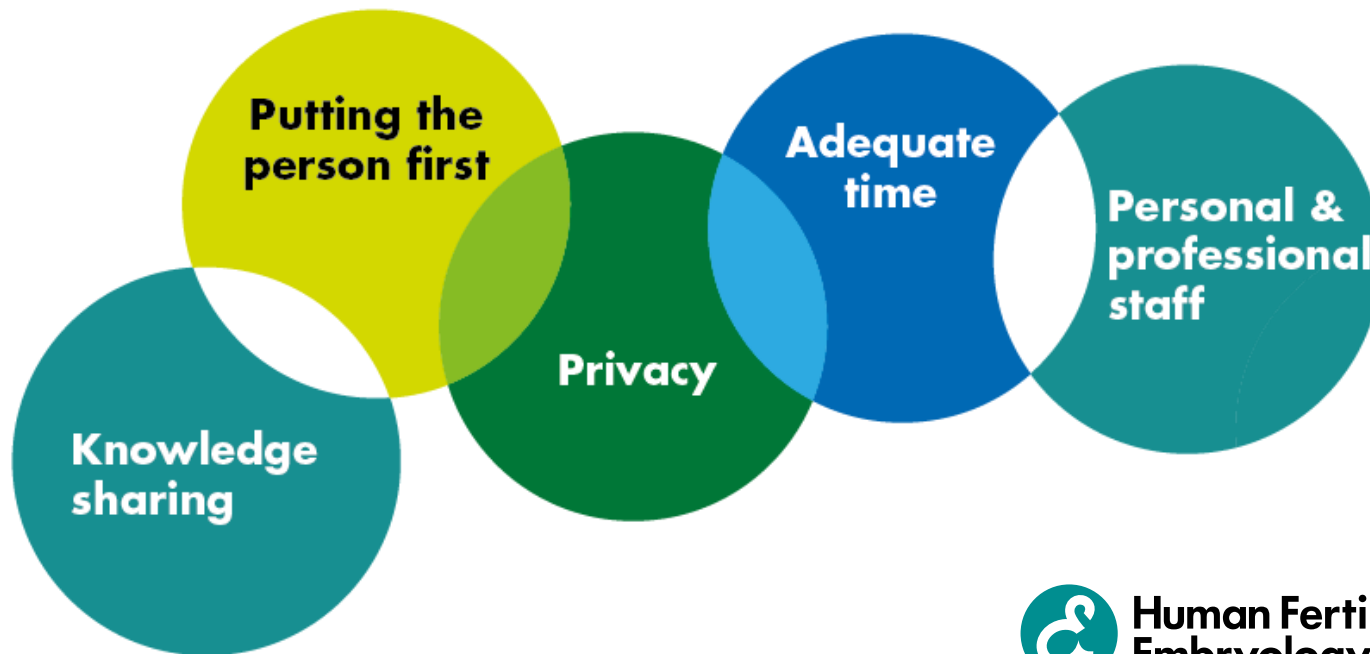
Patient feedback

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Patient feedback

We expect all clinics to encourage their patients to provide feedback using our [Choose a Fertility Clinic service](#).

- Almost 2,000 people have provided us with feedback.
- Approximately half of responses came from five clinics; we therefore focus on general learnings for improving patient experience.
- Patients tell us these are the most important areas for a positive experience:



Putting the person first

Echoing our 2018 [National fertility patient survey](#), being seen as a person was crucial for a positive patient experience.

- In some clinics, patients reported a sense of feeling like ‘just a number’.
- Patients felt a strong need for personalised care not a ‘one size fits all’ approach.
- Respecting a person’s autonomy and need for privacy and sensitivity was critical to a good experience .

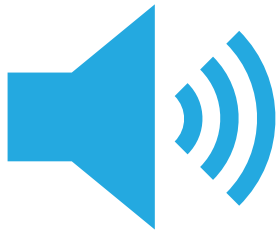
“I initially felt a bit uneasy at the beginning about the idea of injecting myself and as silly as it may sound of having a male doctor but I was made to feel so relaxed that neither were of any issue or importance once I had begun.”

“I felt like someone on a conveyer belt in this clinic”

Patient support resources

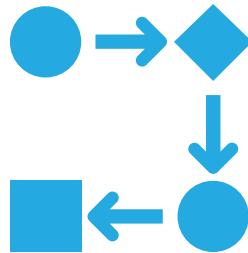
Many clinics already do an excellent job in supporting their patients, but this is not universal.

- We introduced guidance to strengthen support to patients by staff, at all levels, in every clinic, and will start inspecting on this in October 2019.
- To help clinics improve the support offered to patients, we've developed new resources:



Podcasts

Listen to fertility counsellors speak about what good patient support looks like and hear clinics talk about best practice.



Patient Support Pathway

Read through easy to implement actions for all staff at every step of the treatment journey.



Good practice guidelines

Nine principles to help you provide your patients with the best support.



What others do

Find out what policies and practices other clinics have in place for emotional support.

Knowledge sharing

Fertility treatment has no guaranteed outcomes and knowing each step of the process helps patients to feel more in control.

- Patients wanted their doctors to give them information throughout treatment that was trustworthy and realistic.
- They also placed value on shared decision-making, and being given enough time to absorb new information.

“We were always kept well informed and told what was going on. Everything was explained to us before, in between and after treatments. Although I didn't always understand from the science side, I always trusted them.”

Personal and professional staff

A personable healthcare professional is important to patients

- Patients described good experiences as those where the care providers were both professional and appeared to take an interest in the personal journey of patients.
- People appreciated doctors and nurses who felt like they knew their case and history and offered a 'personal touch' to care.
- Where treatment was paid for privately, patients did not want to feel like it was a business transaction.

“Having always wanted children, and having failed IVF attempts before, there was so much empathy shown; even staff giving their own stories and the overall friendly nature of the entire environment.”

Adequate time

Patients mentioned “time” 312 times across 2,000 responses, so it was a key factor for how people felt about their treatment

- Feeling rushed or having to wait were important aspects constituting a bad experience.
- Although outside a clinic’s control, waiting time impacts patients’ fertility journeys: waiting to become pregnant and the ‘two-week wait’.
- Therefore, waiting times and being given time in appointments both play a role in how patients view their experience of care.

“Sometimes I felt appointments were a little rushed but I did get all of the information I needed.”

Privacy

Making sure all aspects of privacy are maintained is important to a positive patient experience.

- Patients expressed satisfaction with clinics that felt clean and professional but simultaneously made them feel ‘at home’.
- Patients commented frequently on the sound quality of the clinics, in terms of privacy.
- Patients felt they had private spaces where they could not be seen or see others, but frequently felt overheard or could hear others in treatment and waiting rooms.

“The area you are in for egg collection – the room is really small and you can hear everything about all the other patients. The clinic is in a small town; whilst I didn’t see any of the ladies, I knew all their names and histories.”

Complaints

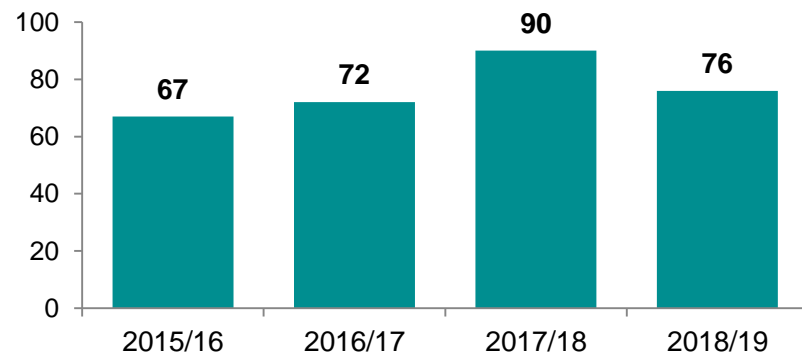
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Complaints

Patients can raise a complaint with us if they're unhappy with how a clinic has handled their complaint.

- There has been a decrease in the number of complaints, but those we are getting are complex in nature.

Figure 11: Complaints to the HFEA, 2015/16 to 2018/19



Learning from complaints

Clinics should take the opportunity to proactively engage with patients when issues and concerns first become apparent.

Clinics should ensure that they:

- talk to patients and proactively seek feedback
- proactively engage with complainants and listen to their concerns
- treat all complaints seriously and show the complainant due respect
- follow stated policies and keep patients up-to-date on response timelines
- tell patients what they will do differently as a result of the complaint, if relevant.

It's important to look at the big picture when dealing with individual complaints to identify wider concerns, issues and share learning across the organisation.

Looking forward

Clinics are generally performing well, but more needs to be done to achieve a consistently high standard of care for all patients. We expect clinics to make significant inroads on the identified areas for improvement and grade B incidents.

In the next year, we expect PRs to reflect on **leadership** and what they can do to achieve a culture change that puts a comprehensive understanding of patient care at the centre of all staff training and clinic processes.

To support this, we will be:

- inspecting on leadership and patient support from October 2019 to strengthen support to patients by staff, at all levels, in every clinic
- continue to encourage proactive reporting of incidents and best practice sharing
- review our inspection regime to ensure it keeps pace with developments.

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