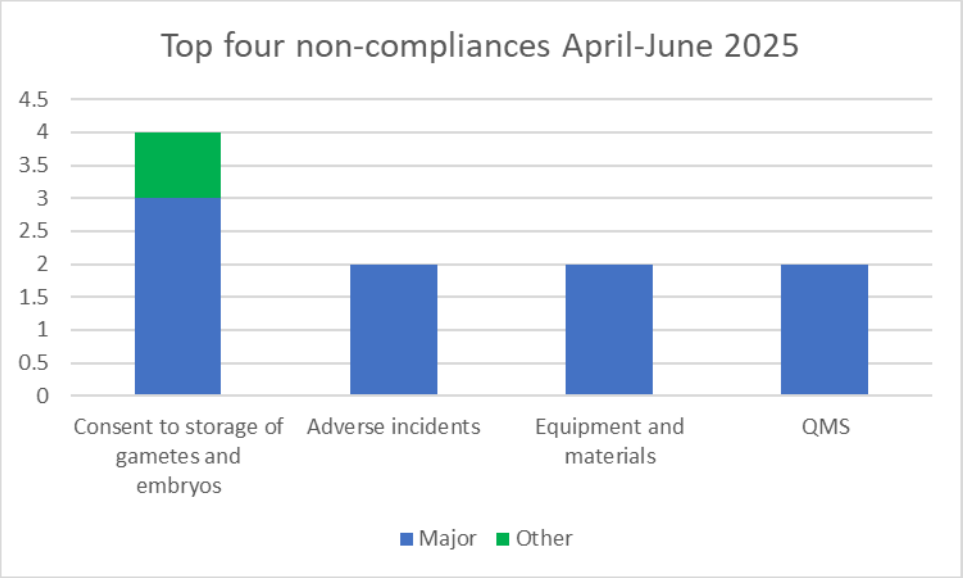
Clinical Governance Quarterly Update

This summary aims to provide:

- An overview of the four most common non-compliances between April and June 2025.
- A review of the critical non-compliances.
- A review of the four most common areas of non-compliances (major and other).
- A detailed insight into non-compliances to help centres improve compliance and prepare for inspections. The identified non-compliances in this report should be checked for in your own centre.

Findings

Graph 1 shows the four most common areas of non-compliance seen on inspections between April and June 2025 *(*16 inspections).



Definition of levels of non-compliance is detailed in Appendix 1.

Critical non-compliances

There were no critical non-compliances identified during this time period.

The four most common areas of non-compliance (major and other)

The main themes identified across the four most common areas of non-compliance are as follows:

Consent to storage of gametes and embryos

- Statutory notices had been sent to patients who had consented to less than 10 years of storage. Staff were incorrectly applying the consent renewal process to all gametes/embryos.

- Statutory notices had not been sent 12 months before the end of consent period in some instances.
- A copy of Statutory notices were not retained in the patient records, evidence that they had been sent was found elsewhere.
- Notification that embryo(s) may be removed from storage had been sent to a patient in error, this was not required until after the end of the consent period.
- Notice of Withdrawal of Consent form was sent before the consent renewal period had ended, this should have been sent as soon as possible after the end of the consent renewal period.
- Eggs were frozen on different dates; a statutory notice was not sent for one of the freeze dates.

Adverse incidents

- Reportable incidents and near misses had not been reported to the HFEA in line with incident reporting requirements.

Equipment and materials

- Semen collection containers for samples intended for use in treatment were not CE marked for their intended purpose.
- Laboratory equipment was overdue for servicing.
- There was no oversight of the equipment servicing schedule.

Quality Management System

- Actions following audit findings were overdue.
- Audits were not completed for several areas of practice.
- ‘Legal parenthood’ and ‘consent’ standard operating procedures (SOPs) did not reflect current practice.
- No SOPs in place for the provision of information or confidentiality.
- Findings were made in an audit but were not included in the conclusions or associated with corrective and preventative actions.
- Scope of record keeping audit was not robust as it was not considered how and by whom the patient/donor had been reliably identified nor if there was a record of any clinical and laboratory data and results of tests carried out.
- Process for document review was not robust e.g. quality manual recently reviewed but contained outdated and inaccurate information and referenced staff who no longer worked at the centre and treatments that were no longer offered at the centre.
- Actions from previous inspection were not fully implemented therefore three non-compliances identified at the last inspection, reoccurred at the most recent inspection.
- Instructions for collection and delivery of semen sample for IUI form required the signature of the gamete provider or the gamete provider’s partner, but if the gamete provider’s partner

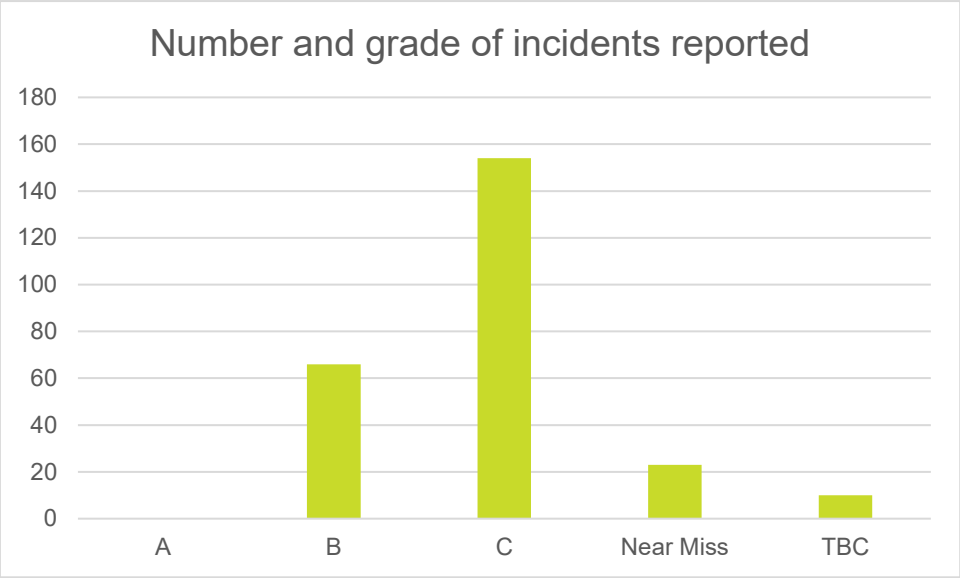
dropped off the sample, then the gamete provider would not have been required to confirm if the sample was theirs.

- Witnessing SOP stated that when a home produced sample is dropped off at the centre, the details should be countersigned by a member of staff, but there was no section on the form to record this event therefore concerns raised that witnessing step would not be documented.

Incident Findings

This summary aims to provide information relating to incidents and complaints for the time period 1 April 2025 – 30 June 2025

Graph 2 shows the number and grade of incidents reported.



NM = near miss; TBC = grade not yet confirmed.

Definition of grades is detailed in Appendix 2.

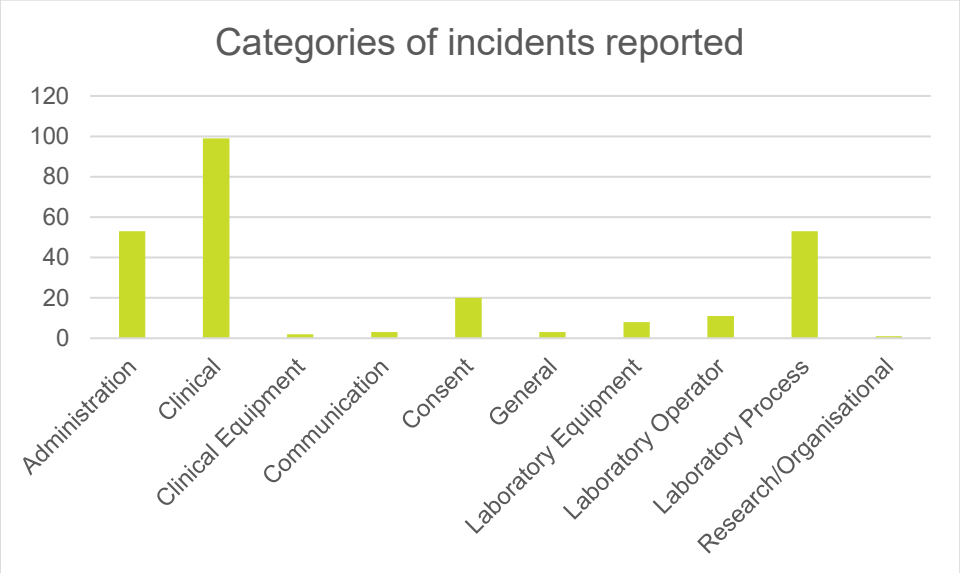
There were 284 incidents reported to the HFEA:

- 0 grade A
- 66 grade B
- 154 grade C
- 23 near misses
- 10 grade not yet confirmed

There were also 31 incidents that were reported to us but were classed as ‘not an incident’. Examples of these include: ectopic pregnancy that was identified by the clinic; adverse birth outcome but not genetic in nature; hospital admissions but not OHSS related, and no interventions required.

Our advice remains that if you are unsure of whether an incident is reportable to us, it is always best to report.

Graph 3 shows the breakdown of the categories of incidents reported. Incidents classed as 'not an incident' (n = 31) have not been included.



Description of incident categories is detailed in Appendix 3.

Of all the incidents reported, the largest proportion were clinical (99) and administration (53).

Examples of some of the types of incidents reported are as follows:

Clinical:

- There was no documentation of a patient's vaginal pack removal following egg collection. Patient contacted to ensure vaginal pack had been removed prior to leaving centre on egg collection day. The patient confirmed the pack was removed and therefore the notes updated to reflect this.

- It was identified by a nurse when scheduling a patient's treatment that they had been dispensed the incorrect medication during their mock cycle.

Administration:

- An email notification of a patient's treatment was sent to the patient's ex partner in error.

- Nurse emailed post egg collection summary to a patient. The patient had requested her partner be copied in. Nurse manually typed the partner's email in copy on the email, making a transcription error resulting in the patient's information being shared with an unintended recipient.

- Patient received an email for another couple who are in the process of completing their HFEA WCS forms. A copy of an email for them had been saved in the incorrect folder on centre's shared drive.

Consent:

- Intended parents (IP) had each been incorrectly issued SPP HFEA consent forms (Your consent to being the legal parent in surrogacy). The surrogate for the IP's was married, and therefore the surrogate's husband is recognised as the legal father of any resulting child born. The SWP form was also not issued or completed correctly. The IP's had not been informed that the forms they filled in were not applicable prior to the surrogate's FET treatment cycle.

- Couple donated embryos pre 2005 anonymously. The clinic used these anonymously donated embryos in treatment in in June 2007 and February 2008 (post transitional period). Incident discovered due to an OTR request.

- During a "Research & Training" audit, it was discovered that embryos created using donor sperm were used in training in accordance with egg provider`s consent but contrary to the (donor) sperm provider consent.

Laboratory equipment:

- Lab alarm system on dewars and incubators down due to lack of Wi-Fi. Lab used preventative measures until Wi Fi issues resolved (no harm to samples).

- An Embryoscope went into alarm mode early morning at a centre, but no SMS alert was received on the on-call phone (due to phone network issues in the area). The alarm was discovered when staff arrived on site three hours later. No harm occurred to embryos concluded after analysis of gas graphs.

Laboratory operator:

- At IVF fertilisation check it was noticed there were three oocytes with cumulus intact that had not been inseminated the previous day. Nine additional oocytes were inseminated normally.

- Loss of 1x vial of donor sperm (of four). Staff later noticed vial was left in Dilvac dewar flask.

Laboratory processes:

- Eggs were frozen for training in the afternoon of a fertilization check (rather than 48 hrs later). Upon thawing one egg showed 2PN. The embryologist who cryopreserved the eggs did not realise the 48 hrs post insemination requirement and followed instructions from the senior embryologist. The patient had consent to unfertilised eggs for training purposes (not training with embryos). The 2PN egg was therefore discarded.

- Embryo was warmed for a patient and immediately perished on entering the holding dish. The dish had been made incorrectly and had no oil overlay. Two embryos remain in storage.

- Egg was missed after egg collection (in wash dish). Egg was immature so would not have fertilised.

Patient Complaint Findings

Informal complaints:

There were 11 informal complaints referred to the HFEA, a few have been summarised below:

- The complainant is unhappy that their partner's day 1 scan was cancelled as the clinic is too busy to accommodate.
- Complaining about an IUI cycle performed in 2023.
- The complainant claims the clinic was not proactive in their efforts to investigate his wife's medical history or to address a prior miscarriage.

Formal complaints:

There was 1 formal complaint referred to the HFEA:

- Complainant alleges his ex-partner forged his signature re “withdrawing your consent to the storage of your own eggs, sperm and embryos consent form.” Upon further investigation of the complaint this was found not to be the case. The ex-partner had not forged a signature.

How complaints are categorised can be found in Appendix 4

Looking ahead

This report is designed to help you address areas of non-compliance as they emerge across the sector. If you have any suggestions on how we can improve this report, please let us know by contacting the Chief Inspector at: sharon.fensome-rimmer@hfea.gov.uk

Appendix 1: Levels of non-compliance

At inspection, a wide range of different areas are looked at before making recommendations to HFEA Licensing committees. There are three levels of non-compliance examined at inspection.

Critical

A critical area of non-compliance is an area of practice which:

- poses a significant risk of causing harm (or potential harm) to a patient, donor, embryo or to a child who may be born as a result of treatment services.

A critical area of non-compliance requires immediate action to be taken by the Person Responsible

Major

An area of practice which:

- poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services;
- indicates a major shortcoming from the statutory requirements;
- indicates a failure of the Person Responsible to carry out his/her legal duties;
- is a combination of several 'other' areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Other

An area of practice which:

- requires improvement (and which cannot be classified as either a critical of major area of non-compliance), but which indicates a departure from statutory requirements or good practice.

Appendix 2: How incidents are graded

Grade A: the most serious type of incident. They happen infrequently and examples may include a patient being implanted with an embryo that is intended for someone else, the death of a patient or an incident which affects a number of patients, for example, when a storage unit malfunctions.

Grade B: serious adverse events or reactions such as the loss of embryos for one patient, breaches of confidentially where sensitive personal data or data relating to more than one patient is sent to the wrong recipient, or when a piece of equipment malfunctions affecting the quality of a patient's embryos.

Grade C: adverse events or reactions such as one of many eggs rendered unusable during processing (for example the moving of an egg between dishes).

Near Miss: is an event that might have resulted in harm, but the problem did not reach the patient because of timely intervention by clinic staff or the patient, or due to good fortune. Near misses may also be referred to as "close calls" or "good catches."

Appendix 3: Incident categories

The table below shows incident categories

Category	Example
Resources/organisational	Theatre list cancelled or rearranged, impacting on patients.
Communication	Incorrect information given to patient regarding medication, resulting in an abandoned cycle.
Security	Break ins and/or theft of equipment from clinics.
Clinical equipment	Clinical equipment malfunctioning.
General	Adverse weather conditions causing flooding in a laboratory or clinical area.
Consent	Embryos removed from storage without the patient's consent.
Laboratory equipment	Most commonly equipment faults and failures e.g., dewar failure.
Laboratory operator	Dishes containing eggs or embryos knocked or dropped and failure to inject or inseminate eggs.
Laboratory process	Failure to follow laboratory protocols.
Administration	Breach of patient confidentiality.
Clinical	Hospital admissions due to ovarian hyperstimulation syndrome (OHSS) or a failure to follow clinical protocols e.g., incomplete screening prior to treatment.

Appendix 4: Categorisation of Informal and Formal complaints

Informal complaints are categorized as complaints that have not been raised with the clinic or complaints still going through the clinic's complaint process.

Formal complaints are complaints where the complaint has received a response from the clinic but remains dissatisfied. As well as complaints where the clinic has entered into an extensive dialog with the complainant and at the end of this process feel they have done all they can to resolve the complaint therefore advising the complainant to contact us. Complaints relating to an incident or complaints that flag up complex issues requiring further input from us are also classified as formal complaints.