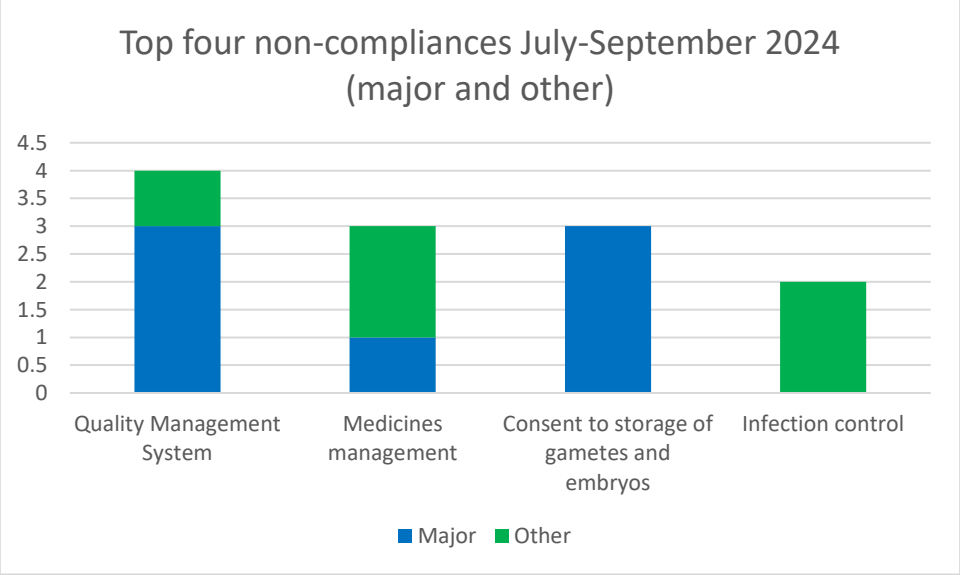
Clinical Governance Quarterly Update

This summary aims to provide:

- An overview of the four most common non-compliances between July and September 2024.
- 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 clinics improve compliance and prepare for inspections. The identified non-compliances in this report should be checked for in your own clinic.

Findings

Graph 1 shows the four most common areas of non-compliance seen on inspections between July and September 2024 (14 inspections, 1 rolled over from Quarter 3 October-December 2023).



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

Critical non-compliances

There was one critical non-compliance identified during this quarter; this was related to witnessing.

Witnessing

- There was no documented evidence that a witnessing check of the dish containing the embryo for transfer had been performed at the time of the procedure.

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:

Quality Management System

- Audits completed were not robust, this was seen at multiple clinics. For example, a storage of gametes and embryos audit was signed off as complete, but sections had been left blank or listed as unknown or 'to check.' The audit included patients who did not have any gametes or embryos in storage or did not identify discrepancies between the number of consenting years on the consent form and the number of years listed in the bring forward system. There were also incidences where the date of consent expiry recorded in the audit did not match the bring forward system or patient records.
- No reliable process in place to ensure information or guidance provided by the HFEA, or requests for action from HFEA, were relayed to ensure clinic staff were aware of legislative or regulatory guidance. Clinic focus articles had not been relayed to staff, who were unaware of changes to the law regarding posthumous storage of gametes and embryos who died before 1 July 2022. PR did not relay information to relevant staff and audit not conducted to determine if the change in law was relevant to patient samples in storage.
- Legal parenthood SOP audited but did not include current guidance or HFEA guidance that came into force before the date of review.
- Clinic had not audited how processes and activities comply with regulatory requirements or their own approved protocols and quality indicators.
- Routine re-audits not completed, seen at multiple clinics.
- Findings of audit not actioned.
- Audit for quality of counselling service not conducted.
- No quality indicators in place for record-keeping audits.
- Corrective action in audits was to remind staff which is not sufficient.
- Patient feedback not actively collected or analysed for significant amount of time.

Medicines Management

- Correction of entries not completed in accordance with legal requirements. This was noted at multiple clinics.
- Midazolam regularly used in operative procedures, but Flumazenil (used to reverse effects of Midazolam) was not stocked. Fentanyl also used in procedures and the reversal drug Naloxone had expired. Naloxone alternative found on the emergency trolley but sited away from theatre. Alfentanil in storage had expired. There was no evidence the expired drugs had been used in treatment.

Consent to storage of gametes and embryos

- Patients had not been sent statutory notices 12 months prior to the end of their consent period.
- Statutory notices regarding consent expiry had been sent to the patient couple but should have been provided separately to each gamete provider.
- Clinics are required to remove gametes from storage where storage is no longer lawful, following the end of the transitional period (30 June 2024). Several samples were in storage where there was no consent in place, a request to withdraw consent had been received or the patient had been deemed uncontactable. The PR was required to review patient records and sign off the disposal, but this had not taken place.
- The end of the consent to storage period had been calculated incorrectly by one day for gametes and embryos in storage. Patients had been informed of the incorrect date during the transitional period, but in one case, the clinic had corrected the consent expiry date in further communication with the patient but without an explanation in the accompanying letter to the patient.
- Consent expiry date calculated on the date of first storage, rather than the date when the Medical Practitioners Statement (MPS) was signed, therefore creating a difference of 18 months. Correct expiry date was explained to patient, but the clinic failed to assess whether the expiry date was determined correctly for other similar cases.

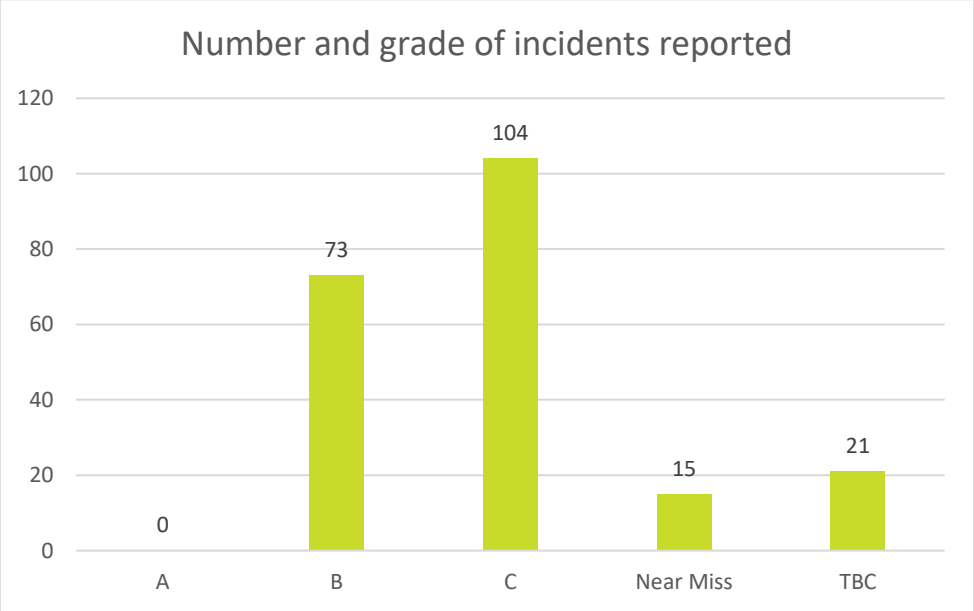
Infection control

- Stethoscope was kept on emergency resuscitation trolly and was visibly dusty.
- Several areas where the seal between the floor and the wall had broken down which was visibly dusty and contained a significant amount of debris.
- Records of cleaning and decontamination of premises could not be located.
- A sign on the door was not laminated therefore could not be wiped clean.
- Boxes of consumables and other equipment were on the floor in two rooms therefore the floor could not be adequately cleaned.
- There was a slow drip of condensation from the nitrogen generator, which was being collected in a bucket on the floor. The boxes also stored in this room could have become contaminated by the water.

Incident Findings

This summary aims to provide information relating to incidents and complaints between July to September 2024.

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.

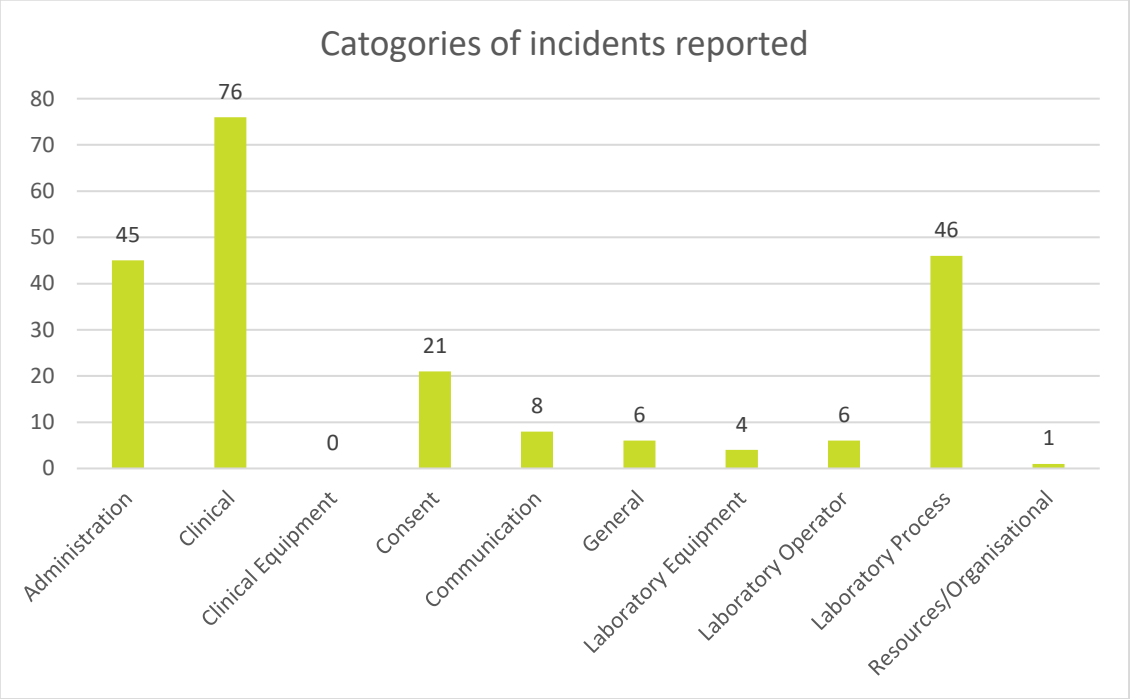
There were 213 incidents reported to the HFEA:

- 0 grade A
- 73 grade B
- 104 grade C
- 15 near misses
- 21 grade not yet confirmed (TBC)

There were also 30 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 however 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.

Gradings of incidents can change on receipt of further information and following publication of the previous quarterly clinical governance report.

Graph 3 shows the breakdown of the categories of incidents reported. Incidents classed as 'not an incident' (n = 30) have not been included.



Description of incident categories is detailed in Appendix 3.

Of all the incidents reported, the largest proportion were clinical (76) and laboratory process (46).

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

Clinical:

- Cases of severe OHSS.
- Hepatitis screening not completed prior to patient undergoing treatment.
- Fentanyl instead of Alfentanyl prepared and administered to two patients (no harm resulted in this error).
- Following a positive pregnancy test a patient was admitted to their local hospital with a swollen and painful left arm. Diagnosed with a left subclavian DVT and pulmonary embolism.

Administration:

- A patient's medical records were mistakenly sent to another patient. Records confirmed as still sealed and returned to unit.
- In house consent form containing patient identifying information sent to three other couples.
- A paper copy of procedure list containing six patient details left in a patient room.

- A patient received a copy of their IVF consultation letter following their appointment, however, in addition to their letter they also received a copy of another patient's IVF consultation letter.

Consent:

- Absence of effective cryostorage consent for three patients due to historical consenting platform errors.
- A patient had stored embryos created with donor sperm. However, the donor had only consented to IUI and not for the creation of embryos with their donations.
- Sperm samples were removed from storage and disposed when patient had requested samples to remain in storage.
- Embryos for one couple remained in storage although the couple had contacted the clinic several years ago to request that the embryos be donated to research.

Laboratory equipment:

- The Hospital Trust carried out a generator test and the clinic was not given advance warning. Power was not interrupted due to generator back up for essential equipment. However, possible power surge damaged the computer of one incubator and RI witness touchscreen tablet. Although incubator function intact, time-lapse function not accessible.

Laboratory operator:

- During an egg vitrification procedure, a dish containing four out of 11 patient eggs was knocked during a procedure and fell to the floor.
- The embryologist was returning the culture dish back into the benchtop incubator. The incubator lid fell on their hand and as a result the culture dish was dropped. Two embryos were not recovered.

Laboratory processes:

- Member of lab staff in training injected sperm into oocytes for the purpose of training in ICSI technique.
- Egg lost during pipetting in post denudation dish (several eggs remain for the patient).
- During sperm preparation, one of the electronic witnessing steps was missed. Identified and no harm to samples.
- During the thaw for a frozen embryo transfer it was noted by the thawing embryologist that the HSV straws had not been sealed. This should have been done during the vitrification event. Subsequently the first embryo did not survive the thaw, but the second embryo thawed successfully and was suitable for transfer.

Patient Complaint Findings

Informal complaints:

There were 12 informal complaints referred to the HFEA, a few have been summarised below:

- Complaint about medication prescribed for cycle (the complainant wanted a different medication prescribed for stimulation).
- Developed a painful bruise following a blood test. As well as feeling very upset over comments made about being encouraged to lose weight.
- The complainant did not understand one outcome of an egg collection could be "no eggs" or very few eggs collected.

Formal complaints:

There were six formal complaints referred to the HFEA:

- Complaint regarding clinical care was made in June 2023 and the complainant had not received a response.
- The complainant had made a formal complaint and remains dissatisfied with the response. Complaint about several communication issues including conflicting information provided by different members of the clinical team.
- Patient had complained to the clinic and was not happy with the response. The complainant felt not all their concerns had been responded to.

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 either contacting the Chief Inspector at: **sharon.fensome-rimmer@hfea.gov.uk** or the Inspections and Logistics Officers at: **amy.charles@hfea.gov.uk** and **susan.vaughan@hfea.gov.uk**

Appendix 1: Levels of non-compliances

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.

Category	Example
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 eg, 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 eg, 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.