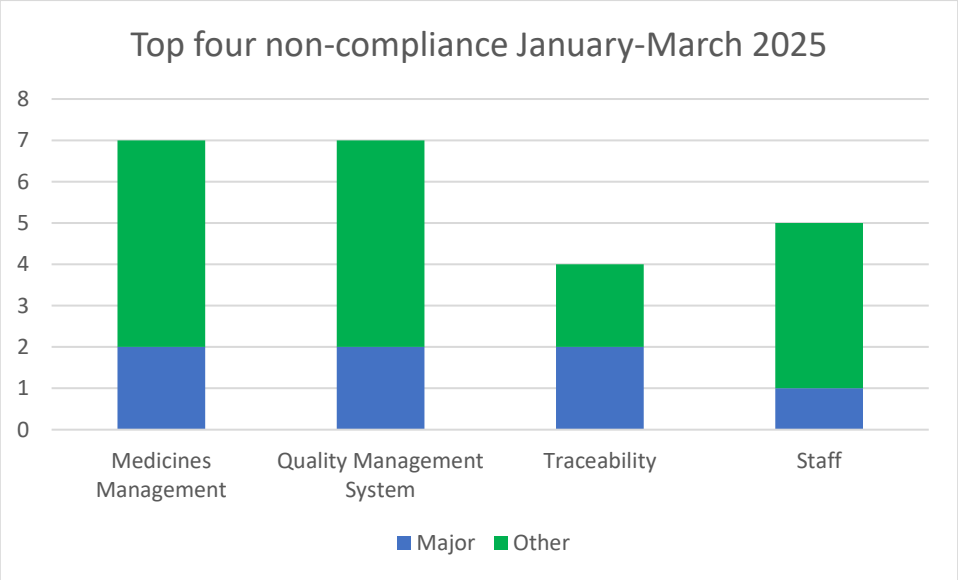
Clinical Governance Quarterly Update

This summary aims to provide:

- An overview of the four most common non-compliances between January and March 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 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 January-March 2025 (19 inspections, 2 inspections rolled over from the previous quarter October-December 2024, not including research inspections).



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

Critical non-compliances

There were two critical non-compliances identified during this quarter. The main themes identified within the critical non-compliances are as follows.

Consent to storage of gametes and embryos

- Embryos kept in storage after the due date for discard (no lawful consent in place).

Surrogacy

- Couple declined syphilis screening. Electronic system relied on flags for abnormal result. Staff took the absence of flag to mean that test had been carried out and was negative. Staff had not checked that all required screenings tests had been undertaken for this couple, and it was not clear if the reason for the couple declining the syphilis screening was explored or escalated.
- Intended Parent (IP) couples providing gametes had not completed infection screening questionnaires.
- A gamete provider had indicated that they practice MSM (men who have sex with men), but no rectal swabs were taken to screen for gonorrhoea or chlamydia as per professional body guidance.
- No evidence in the records of the gamete providers to indicate that Hepatitis A risk had been considered.
- Failure to complete a recent travel history form.
- The clinic identified corrective and preventative actions (CAPA) to take as a result of an audit; however, the root cause analysis was not robust and stated that 'surrogacy is a complicated process. Needs streamlining and simplifying.'
- No specific competency assessments in place for staff who facilitate treatment involving surrogacy.

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:

Medicines Management

- Controlled drug register (CDR)
    - Entries in the CDR had no name recorded next to the signature.
    - Unit of drug supplied not recorded
    - Group of entries recorded had one bracketed signature against drug supplied, rather than individual signatures against each action taken.
    - Entries crossed out, no footnotes accompanying errors and no double signatures from a nurse and an anaesthetist.
    - Theatre staff had pre-populated the CDR (with the wrong patient's details) before any patients had attended theatre. This practice goes against the Misuse of Drugs (safe custody) Regulations 2001 and not in accordance with professional standards of conduct for staff involved.
- Drugs that may have been required in an emergency were stored in the bottom of the locked resuscitation trolley. Key to unlock was attached to the trolley but this was not in accordance with UK Resuscitation Council 2021 guidance which states that resuscitation trolleys should not be locked or kept in locked rooms or cupboards.
- Two boxes of expired medication found locked in drugs cabinet in the theatre.
- Controlled drugs accountable officer (CDAO) not registered on the Care Quality Commission register of CDAOs.
- Seven out of nine staff members had not completed their medicines management training.

Quality Management System

- Audits
    - Audit findings included 'observations' as opposed to non-compliances and as such, there were no corrective and preventative actions (CAPA) recorded to address the findings. CAPA not recorded or actioned.
    - Absence of a root cause analysis having been performed and corrective actions lacked detailed preventative actions.
    - The scope of the legal parenthood audit was not in accordance with the audit methodology guidance provided by the HFEA in April 2021.
    - Not clear how many records were audited.
    - No evidence that audits had been conducted within the required two years.
    - Audit of the multiple births minimisation strategy (MBMS) not effective as it did not consider any patient over the age of 38 years and no established quality indicators (Qis) for types of treatment.
    - The clinic's traceability audit did not include a representative sample of critical equipment audited.
    - Audit of counselling service did not include a QI for patient waiting times. Concerns that the clinic did not have a process in place to review the ongoing service provision and the patient experience.
    - Consent to IUI documentation not audited.
    - Audit identified a patient anaesthetic record had not been scanned into electronic record, original destroyed. No reliable check to ensure all required documents scanned onto electronic record before paper copy destroyed.
    - No formal process in place to document KPIs including addressing any anomalies in addition to documenting mitigating actions.
    - The clinic's blood glucose monitoring device not listed on the clinic's QM equipment database, nor was there evidence of the accuracy of the device having been tested at regular intervals.
- Issues related to SOPs and document control
    - SOP for medicines management was not reflective of the practice undertaken with regards to the preparation of controlled drugs (CD).
    - Third-party agreements beyond their review date and not evaluated to ensure the third parties met required standards.
    - Several active documents not controlled or subject to review as part of QMS, beyond review date or did not have review dates in electronic system.

Traceability

- Evidence not provided that all relevant data relating to anything coming into contact with the donor gametes, was recorded by the donor bank in Ukraine. This included batches of reagents/plasticware, and equipment used in each donor cycle.
- No record which centrifuge was used for the processing of patient and donor sperm for treatment purposes.
- Specific equipment used during processing was not recorded for traceability purposes or their specific use detailed in an SOP.
- Equipment traceability was not included in the clinic's traceability audit.
- Batch numbers incorrectly recorded.

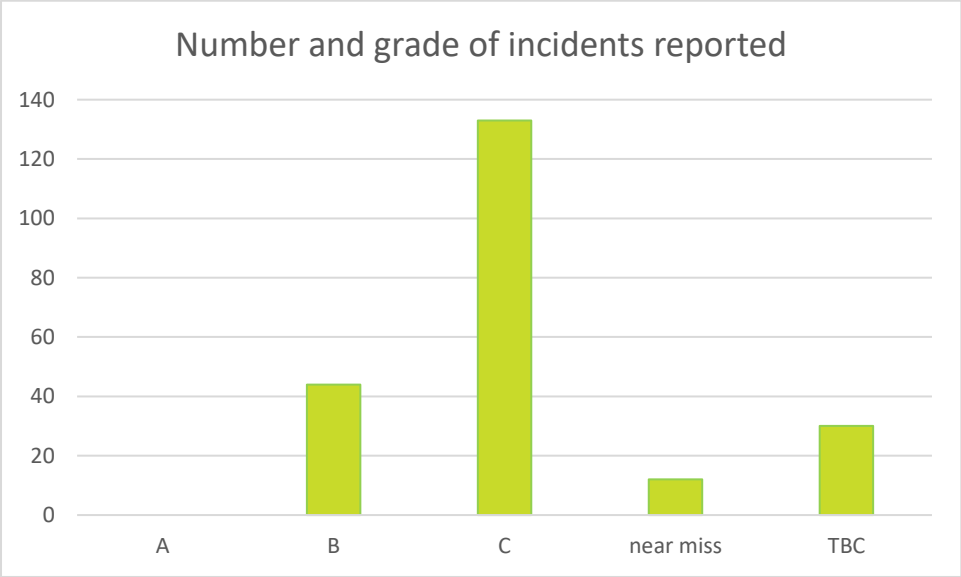
Staff

- Competency assessments for clinical staff were not robust, with particular reference to welfare of the child (WoC) assessments. No documented evidence of medical staff having had their competence assessed in relation to WoC.
- No documentary evidence of assessment of competence provided for multiple areas of practice.
- Documented evidence of training and competency assessment for the nursing team inconsistent. Staff training requirements and timeframes for these to be completed were not clearly outlined in any documentation provided.

Incident Findings

This summary aims to provide information relating to incidents and complaints for the time period 1 January 2025-31 March 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.

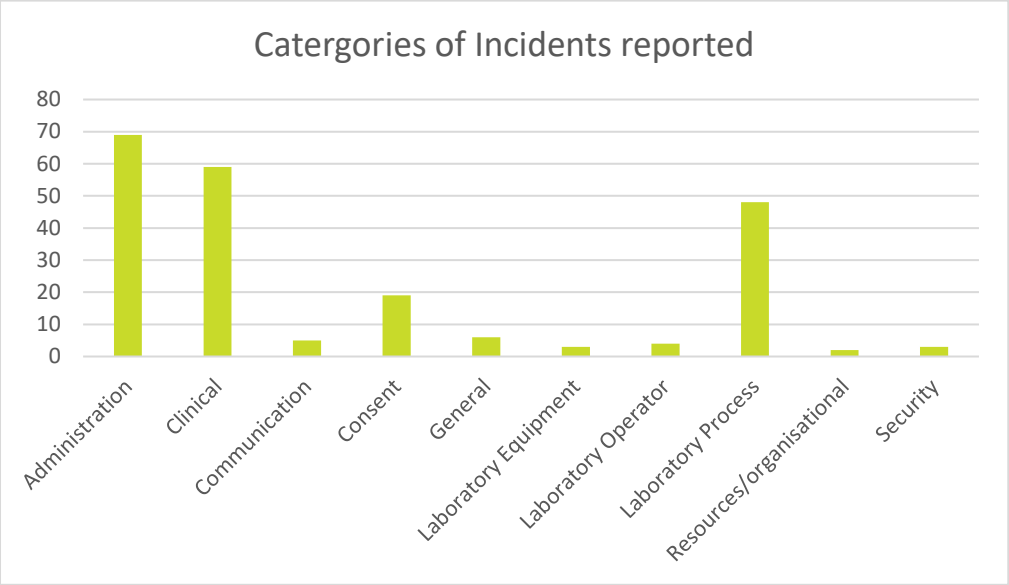
There were 219 incidents reported to the HFEA:

- 0 grade A
- 44 grade B
- 133 grade C
- 12 near misses
- 30 grade not yet confirmed

There were also 32 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 = 32) have not been included.



Description of incident categories is detailed in Appendix 3.

Of all the incidents reported, the largest proportion were administration (69) and clinical (59).

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

Clinical:

- A clinician omitted a GnRH antagonist from a patient's medication schedule. This however was rectified and prescribed, but the patient did not know when to take it. The patient subsequently did not start the antagonist at the correct time during stimulation'. This resulted in premature ovulation and the treatment cycle was abandoned.
- A patient was not aware of the correct number of co-codamol to take and accidently overdosed. This required attendance to A&E for further treatment.
- Patient suffered a bladder haematoma following egg collection.
- A donor was due to have chlamydia screen, but the donor did not attend, therefore screening was re-scheduled. At the donor's scan, it was identified follicular recruitment was sufficient for trigger and egg collection. On the day of egg collection, a positive chlamydia result was discovered.

Administration:

- An email with medical records of one patient was sent to another patient.
- Patient A received their letter following consultation. The envelope contained their own letter as well as letter of another patient (B).

- A blank WCS form was being uploaded onto the patient's portal by the lab team, however another patient's WCS instructions letter was uploaded instead.

Consent:

- Embryos being stored without valid consent. The 2022 storage updates have been incorrectly applied to patients who have embryos in storage created with donor gametes, resulting in embryos being stored without valid donor consent.
- RNE/RNG forms were sent to a number of patients with less than 10 years storage consent in error, when these patients should have been offered to reconsent on WT/MT. One of these patients completed an RE after her embryos expired their storage consent, as the centre were of the incorrect impression that she was in the 6-month window of the renewal period. Legal advice has been sought.
- Shared motherhood couple changed treatment from a fresh transfer to freezing embryos for the egg provider (and storing under her name) with a view to transferring later to the partner. The couple underwent treatment using a frozen embryo. It was realised after treatment that the PP and WP forms had been completed the wrong way round for shared motherhood as staff assumed the consents were for a standard FET cycle. The original legal parenthood forms were correct prior to treatment, but these were voided in place of new (incorrect) forms.
- Interim inspection at a clinic identified statutory notices were not always being sent in timely manner. Clinic's patient checks identified two patients where the RG statutory notice was sent late.

Laboratory equipment:

- The CO_2 monitoring system for both culture incubators in a clinic had malfunctioned. To ensure the laboratory staff still respond to any temperature alarms on the incubators, the CO_2 alarms have been temporarily taken off monitoring (and the on-call system).

Laboratory operator:

- Loss of several inseminated oocytes for one patient (9 embryos still available for culture). Staff noted during fertilisation check, that the media had largely evaporated due to no oil overlay being present. This had been missed during dish set up.
- During Vitrification procedure involving 2-stage "Equilibration" media (ES) and then "Vitrification" media (VS), 1 embryo was exposed only to the VS as the incorrect lid had been applied to the ES media bottle by another member of staff.

Laboratory processes:

- During the vitrification procedure an unfertilised egg was frozen in error. The 0PN was frozen in the same straw as a 2PN, so could not be immediately discarded.
- Several 2PN embryos (for one patient) frozen in error, rather than leaving in culture. Embryos thawed and culture resumed.
- Incorrect vitrification media placed into dish. This affected 2 patients and 1 egg donor.

Patient Complaint Findings

Informal complaints:

There were 9 informal complaints referred to the HFEA, a few have been summarised below:

- Complaint about various aspects of clinical care and the quality of embryos created with donor eggs. The complainants are refusing to pay for the treatment.
- Complainants wanted a specific treatment "add on" as well as a referral to a urologist, following their first unsuccessful cycle.
- The complainant was scheduled for a double embryo transfer, however due to a change in the clinic's policy this was changed to a single embryo transfer at short notice. The complainant has made a formal complaint, however the response from the clinic is now overdue.

Formal complaints:

There were 3 formal complaints referred to the HFEA:

- The complainants are unhappy that the cost of the ITE application was not explained to them prior to commencing treatment nor did if form part of their costed treatment plan.
- As the patient app was not updated the patient was not taking the appropriate amount of medication. Patient proceeded to an embryo transfer that unfortunately did not lead to a successful pregnancy. The complainants were waiting several months for an update from the clinic regarding a compensation package.

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 Officer 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.
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.