Executive Licensing Panel - minutes

Centre 0037 (Glasgow Royal Infirmary) Interim Inspection Report

Monday, 11 April 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Paula Robinson (Chair) Jessica Watkin Anjeli Kara	Head of Business Planning Policy Manager Regulatory Policy Manager
Members of the Executive	Dee Knoyle Ian Brown	Secretary Head of Corporate Governance
External adviser		
Observers		

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

1.1. The panel noted that Glasgow Royal Infirmary, centre 0037, has held a licence with the HFEA since 1992. The centre provides a full range of fertility services.

1.2. The panel noted that the centre's licence is due to expire on 31 December 2017.

1.3. The panel noted that the inspection took place on 1 December 2015.

1.4. The panel noted that the centre provided 1323 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 October 2015. In relation to activity levels this is a large centre.

1.5. The panel noted that HFEA-held register data for all treatments, in the year to 31 July 2015, showed the centre's success rates, in terms of clinical pregnancy rates, were in line with national averages with one exception:

- for ICSI in women over 37 years, the clinical pregnancy rate was significantly greater than the national average.

1.6. The panel noted that in 2015, the centre reported 41 cycles of partner insemination with no clinical pregnancies. The national data for this year has yet to be analysed.

1.7. The panel noted that HFEA-held register data for the year ending 31 July 2015 showed the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 16%. This represented performance that was not likely to be significantly different from the 10% maximum multiple live birth rate target for this period.

1.8. The panel noted that at the time of the interim inspection on 1 December 2015, four major areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has implemented three recommendations and has committed to fully implementing the outstanding recommendation.

1.9. The panel noted that the inspectorate recommended the continuation of the centre's treatment and storage licence.

2. Decision

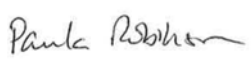
2.1. The panel noted the interim inspection report and the PR's response to this report and had no serious concerns.

2.2. The panel had regard to its decision tree and was satisfied that the centre was fit to have its treatment and storage licence continued.

3. Chair's signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature



Name

Paula Robinson

Date

20 April 2016

Interim Licensing Report

Centre name: Glasgow Royal Infirmary
Centre number: 0037
Date licence issued: 01/01/2014
Licence expiry date: 31/12/2017
Additional conditions applied to this licence: None
Date of inspection: 01/12/2015
Inspectors: Dr Andrew Leonard (Lead); Mrs Gill Walsh, Mrs Polly Todd
Date of Executive Licensing Panel: 11 April 2016

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of a short notice inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. For 2015-2017 the focus of an interim inspection is:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers, and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel (ELP) with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

The inspection team recommends the continuation of the centre's licence.

The ELP is asked to note that recommendations for improvement are made in relation to four major areas of non compliance as follows:

The PR has implemented the following recommendations:

'Major' areas of non compliance:

- The PR should review the quality management system (QMS) to assess whether there are barriers to the implementation of learning from guidance provided by the HFEA and other sources, and to the performance of effective audits against regulatory requirements.
- The PR should ensure the nitrogen generator and the quality of the nitrogen it produces are validated.
- The PR should ensure that effective consent to legal parenthood is obtained.

The PR has given a commitment to fully implement the following recommendation but some actions remain outstanding:

'Major' areas of non compliance:

- The centre should review its medicines management practices for compliance with legal and professional body requirements.

Information about the centre

The fertility clinic at Glasgow Royal Infirmary has held a licence with the HFEA since 1992.

The centre provides a full range of fertility services.

The centre provided 1323 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 October 2015. In relation to activity levels this is a large centre.

The centre's current licence was varied in October 2015 to reflect a change of PR.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Pregnancy outcomes[1]

HFEA held register data for all treatments in the year to 31 July 2015 show the centre's success rates, in terms of clinical pregnancy rates, are in line with national averages except for ICSI in women >37 years, where the clinical pregnancy rate is significantly greater than the national average.

In 2015 the centre reported 41cycles of partner insemination with no clinical pregnancies. National data for this year has yet to be analysed.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

HFEA held register data for the year ending 31 July 2015 shows the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 16%. This represents performance that is not likely to be significantly different from the 10% multiple live birth rate target for this period.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activities were observed in the course of the inspection: egg collection; embryo transfer. All of the procedures observed were witnessed using an electronic witnessing system in accordance with HFEA requirements.

It was noted that tubes used during egg collection are not labelled; albeit this has been risk assessed by the centre. Thorough cleaning and checks of the critical work areas are performed between egg collections as risk control measures to prevent mis-identification of

[1] The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2] The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

oocytes. The completion of these checks is not currently documented in patient records but the PR committed on inspection to ensure the checks will be documented in future.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

On inspection, the 'bring-forward' system was discussed with staff and storage records and audits thereof were reviewed. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out: patients attending for consultations were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

The Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff follow prescribed standard operating procedures (SOPs) and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: legal parenthood consent; witnessing; controlled drugs; CE marking and traceability; infection control.

The centre's procedures for auditing and acting on the findings of audits are partially compliant with requirements (see recommendation 1) because:

- a recent audit of medicines management practices did not identify non compliances with legal and professional body requirements, as noted elsewhere in this report;
- an audit of legal parenthood consent performed on inspection found some irregularities, discussed below in 'Legal parenthood' on page 7. These irregularities constitute non-conformances which should have been detected and corrected by checks by centre staff. Their presence suggests the corrective actions, implemented in response to the centre's audit of parenthood consents in October 2015, were ineffective.

We also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture then it is important that they act to review their practices when guidance is issued by the HFEA or

other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- the use of CE marked medical devices;
- the use of the most recently issued HFEA consent form versions;
- the centre's audits of legal parenthood consenting;
- the HFEA reports of adverse incidents from 2010-2012 and 2013;
- HFEA Clinic Focus articles regarding patient screening requirements and equipment failures;
- the presence of an effective bring-forward system to monitor gamete and embryo storage.

The centre has been partially effective in implementing learning from guidance from the HFEA (recommendation 1) because:

- the audit of legal parenthood consent performed in response to Chief Executive's Letter CE(14)01, issued in February 2014, was not performed in accordance with the audit methodology specified in the letter;
- the centre is not in all cases using the current versions of HFEA consent forms, which were released to centres by Chair's Letter CH(15)01 on 1 April 2015.

Medicines management

It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way.

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be partially compliant with guidance (see recommendation 2) because:

- out of date drugs had not been disposed of and were stored with drugs still in use;
- nurses label and dispense drugs as standard practice and the nurse dispenser is not identifiable on the drug label or packaging;
- nurses' training and competence assessment in providing drugs to patients could not be evidenced.

Infection Control

It is important that clinics have suitable arrangements in place so that patients experience care in a clean environment and to prevent patients and staff acquiring infections.

During the inspection, we reviewed infection control practices and found them to be compliant with guidance.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of the following medical devices was reviewed in the course of the inspection: all reagents and media used during gamete and embryo procurement and

processing; kits used to freeze and thaw embryos storage. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

During the inspection, no patients were available for inspectors to speak to about their experiences at the centre. Twenty patients have however provided feedback directly to the HFEA in the time since the last inspection in May 2014. Feedback was positive, with 15 of the individuals providing feedback giving compliments about the care received.

On the basis of this feedback and observations made in the course of the inspection, it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- maintains an effective system for responding to patient phone calls.

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

Information submitted by the centre in their self assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre, indicate that the centre is non-compliant with the following HFEA requirements:

- The nitrogen generator and the quality of the nitrogen it produces, which is used in the embryo culture incubators, have not been validated (see recommendation 3).

Compliance with recommendations made at the time of the last inspection

Following the change of premises inspection in May 2014, which reviewed all practices at the centre as well as the renovated premises, seven recommendations for improvement were made in relation to three major and four 'other' areas of non compliance.

The PR subsequently provided information and evidence that all of the recommendations were fully implemented within the required timescales.

On-going monitoring of centre success rates

Between 1 June 2014 and 31 October 2015, the centre received four risk tool alerts: one regarding success rates in patients aged <37 years undergoing ICSI, two regarding success rates in patients <37 years undergoing IVF, and one regarding high multiple pregnancy rates. The PR has responded and taken action appropriately in all cases.

Provision of information to the HFEA

Register data

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. This information is held in the HFEA Register.

The clinic is compliant with requirements to submit information to the HFEA.

Legal parenthood

When a couple to be treated with donated gametes are not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly, or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent. In some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

In February 2014, HFEA Chief Executive's letter CE(14)01 required centres to audit their parenthood consenting practices to ensure their suitability, to report the findings of the audit to the HFEA and to respond to those findings. The centre provided the audit report to the HFEA within the required timeframe. The report indicated that the centre had no parenthood consent non conformances and no corrective actions were needed.

As part of the HFEA's ongoing activities relating to legal parenthood consenting, all PRs were asked in October 2015 to confirm that all relevant cases had been included in the original audit in 2014. During that review, the PR discovered that the 2014 audit had been a sample audit, i.e. it had looked at a randomly selected proportion of relevant cases, rather than at all relevant cases as was required by CE(14)01 (see recommendation 1).

In response, the PR immediately conducted an audit of all relevant cases since April 2009. This audit identified five cases where effective consent to legal parenthood was questionable. One case should have been identified by the 2014 audit, the other four occurred after that audit was conducted. Had the centre's audit in 2014 been robust, corrective actions may have been taken, avoiding the further four cases now identified.

Preventative actions (training sessions for staff who take consent; additional consent form checks; SOP revisions; quarterly audits of relevant cases) were implemented by the centre in response to the audit findings.

On inspection, the PR advised that centre staff had been liaising with hospital management and legal advisors regarding corrective actions, but that it was taking some time to clarify legal options and to co-ordinate all parties to attend meetings with the five patient couples affected by the consent issues. These meetings were planned for February 2016.

The inspection team emphasised the importance of informing the five patient couples affected without further delay and to consider how best to support them, since it was likely that discrepancies or uncertainties in legal parenthood consent could only be resolved by a court. The PR has now confirmed that the five patient couples met with representatives of the centre and hospital managers in the week 22 – 26 February 2016.

It is noted that the current PR was not in post during the 2014 audit. The PR in post at the time advised the inspection team that she was not directly involved in the audit and had assumed that it had been conducted according to the requirements specified in CE(14)01, i.e. that all relevant cases rather than a sample were audited.

To assess the current compliance of parenthood consenting procedures, 30 records of treatments with donor gametes in 2015 were audited by the inspection team. These treatments did not result in on-going pregnancies and were not included in the centre's audit in October 2015 however, irrespective of the outcome, effective parenthood consents should have been in place prior to treatment. The following discrepancies were noted (see recommendation 4):

- in one instance the person's date of birth was recorded instead of the date consent was given;
- in one instance the box to be ticked to confirm acceptance of legal parenthood was not ticked;
- in four instances the centre and/or patient number was missing from the area in the consent forms for completion by centre staff;
- out-of-date versions of the parenthood consent forms were sometimes used;
- the stickers printed with the patient or partner's name, date of birth and identifying number, affixed on consent forms to document the patient or partner details, was prone to being misprinted, such that in some cases characters were lost from the right hand edge.

These discrepancies may be considered minor but it is of note that a recent judgement handed down by the President of the Family Division of the High Court, was clear that where there are discrepancies or uncertainties in legal parenthood consent forms, legal parenthood can only be determined by a court.

Following the October 2015 audit, the PR confirmed that:

- preventative actions had been taken to provide assurance that staff are trained and competent to seek parenthood consent;
- mechanisms are in place to ensure compliance with consent requirements;
- audit plans to review parenthood consents are robust.

Three of the patient records with discrepancies in parenthood consents noted in the inspection team's audit, involved treatments which took place after the centre's October 2015 audit and the implementation of the preventative actions it recommended. The inspection team has concerns that despite these preventative actions, discrepancies in legal parenthood consenting have still occurred (recommendations 1 and 4).

Annex 1

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the inspection team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical areas of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or 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.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
None identified			

‘Major’ area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or child who may be born as a result of treatment services;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties;
- which can comprise 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.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. The centre's QMS has failed to fully implement requirements and learning within: • Chair's Letters (14)01 and (14)02, and other HFEA communications, related to the audit of the process for collecting legal parenthood consent • Chair's Letter (15)01 concerning the use of revised consent form versions. The centre’s audit practices have failed to identify or fully correct non compliance and poor practice within medicines	The PR should review the QMS to assess whether there are barriers to the implementation of learning from guidance provided by the HFEA and other sources, and the performance of effective audits against regulatory requirements. Where barriers are identified, actions should be taken to remove them. The PR should provide a report of this review, including actions taken, to the centre’s inspector by 1 April 2016.	QMS underwent a full review in early 2015 with appointment of new Quality Manager in January 2015. Summary attached of 2015 QMS review and updates. Changes included: Introduction of fortnightly QM meetings to include: Datix incident reporting RBATs Clinic Focus KPIs Comprehensive audit schedule introduced November 2015	The inspection team notes the PR’s response, the actions taken and the documentary evidence provided by the PR. No further actions are required.

management and the documentation of legal parenthood consents. SLC T32.		(see attached). Further review of QMS performed following HFEA inspection December 2015 (see attached). Changes to be implemented from March 2016: HFEA/Regulation as a standing item on QM meeting agenda to discuss: RBATs Clinic Focus CE Letters Chairs Letters Directions Audit findings as a standing item on QM agenda (see template attached). All changes to practice or alerts from HFEA guidance or from audit findings to be disseminated to all staff via weekly MDT meetings and daily team brief with immediate effect. Medicines management had	

		not been audited prior to the HFEA inspection. A 'Supply of Medicines' SOP has been developed and audited (see attached). The preliminary Legal Parenthood audit was performed in Feb 2014 under the previous QMS. No non-compliances were identified and therefore no further action taken. The comprehensive LP audit performed in October 2015 highlighted five cases and these are currently being addressed. For all actions performed please refer to section 4 below.	
2. The nitrogen generator and the quality of the nitrogen it produces, which is used in the embryo culture incubators, have not been validated. SLC T24.	The PR should ensure the nitrogen generator and the quality of the nitrogen it produces are validated. A copy of the validation report should be provided to the centre's inspector by 1 April 2016.	Nitrogen generator validated to produce Nitrogen at >99.9% (certificate attached). Backup cylinder is medical grade (99.998%). Higher purity levels can be reached with nitrogen generator but will increase incubator oxygen recovery time and therefore not adopted. Incubators use oxygen sensors for gas mix,	The inspection team notes the PR's response, the actions taken and the documentary evidence provided by the PR. No further actions are required.

		therefore oxygen levels maintained at 5%. Any carbon impurities in the gas are removed by in-line HEPA filters.	
3. Practices used to manage medicines were not compliant because: • out of date medicines had not been disposed of and were stored with medicines still in use; • nursing staff label and dispense medicines as standard practice, rather than on an occasional basis, and the dispenser is not identifiable on the drug label or packaging. • nursing staff training and competence assessment in providing drugs to patients could not be evidenced. SLCs T2 and T12	The PR should review possible barriers to the timely disposal of out of date medicines and take action to remove them. The PR should arrange for a review of the practices used to dispense medicines, for compliance with legal and professional body requirements. Summary reports of these reviews including appropriate corrective actions, with timescales for implementation, should be provided to the centre's inspector by 1 April 2016.	Review of drug dispensing attached. Report from process and training audit for drug dispensing SOP (C-SOP-084) attached. A full review of medicines management practices by a senior pharmacist and nursing manager will be completed by 31 May 2016. It has been delayed because the staff needed to perform the review were unavailable. All staff made aware that two months prior to expiry, soon-to-expire controlled medicines should be clearly labelled, and separated from other medicines within the store. Pharmacy have confirmed they can be contacted two months prior to expiry of controlled medicines and will ensure prompt uplift of expired items.	The inspection team notes the PR's response, the actions planned and already taken and the additional evidence provided by the PR. The inspection team accept that the nursing staff training and competence assessment records for providing drugs to patients, were present at the time of inspection. The PR should advise the centre's inspector when actions have been completed to address concerns regarding the labelling of medicines. The review of drug dispensing provided by the PR documented the HFEA inspection team's findings and actions taken in response. The PR has advised that a fuller review of medicines

		All other expiring medicines must be returned to pharmacy once highlighted at time of weekly check. C-SOP-084 amended and attached. Work ongoing with pharmacy department and external supplier to develop appropriate labels to allow ACS to provide overlabels for all medicines. Overlabels agreed to include: Patient details Medicine name and dosage Frequency Date of dispensing Dispensing staff name Proposal for new system expected mid-April 2016. Update will be provided to HFEA once proposal agreed. Nursing staff training and competency records were available at time of inspection. Training audit attached to confirm this.	management will be undertaken by 31 May 2016. The centre's inspector has discussed the reasons for delay with the PR and accepts they are unavoidable and that the PR is committed to ensuring dispensing practices are compliant with the law and professional body guidelines. The PR should provide the report of the review, with corrective actions and timescales for implementation, by 31 May 2016. Further actions are required.
4. An audit of parenthood consent forms by the inspection team found	The PR should ensure that the patients who provided parenthood consent forms	Q4 2015 Legal Parenthood audit attached.	The inspection team notes the PR's response, the actions taken and planned, and the

some discrepancies: • use of date of birth instead of the date of consent; • failure to tick the box confirming acceptance of legal parenthood; • omission of centre and/or patient number from the area completed by centre staff; • use of out-of-date versions of the parenthood consent forms; • the stickers printed with the patient or partner's details, affixed on consent forms, was prone to being misprinted such that characters were lost from the right hand edge. SLC T60.	identified with discrepancies, do not have further treatment unless appropriate and effective consent for parenthood has been provided. The PR should review the practices by which staff collect consent to legal parenthood and check the consent forms for correct and accurate completion. Corrective actions should be taken as necessary to ensure the compliance of these practices. A report of this review with corrective actions and timescales for implementation should be provided when the PR responds to this inspection report. The practices used to collect parenthood consent should be audited quarterly and reports of these audits should be provided to the centre's inspector until further notice. Further corrective and preventative actions should be taken, as necessary, until the practices are absolutely	A full review of the legal parenthood consenting process was performed between Oct and Nov 2015 following audit completed in Oct 2015. The following checks have now been implemented: Nurse completes consent forms with patients and checks forms for accuracy. Nurse co-ordinator double checks and confirms accuracy. Medical team check consents at time of scheduling. Scientific staff perform final check when reviewing case notes prior to treatment. The casenotes for all patients using donor sperm or donor embryos are therefore checked on four occasions prior to commencing treatment. Any forms with discrepancies are either amended or replaced prior to treatment.	documentary evidence provided by the PR. The inspection team notes that the PR has informed the HFEA regarding the centre's on-going actions concerning the five cases in which consent to legal parenthood is uncertain. These couples have all had meetings with centre staff and been provided with relevant information and support, and are deciding whether to take legal action to establish legal parenthood. The inspection team are reassured by the action that staff have been told to only use complete patient labels but the PR should advise the centre's inspector when complete patient labels are reliably being printed. The PR has provided a report of the legal parenthood audit, completed on 21 March 2016. It found no significant failings in legal parenthood consent forms. While the inspection

	reliable.	A summary of all changes implemented is attached. All amended SOPs attached. Staff training sessions performed November-December 2015 to raise awareness of new SOPs. New versions of consent forms introduced in April 2015 with an 'overlap' period of two months. All staff now aware that any consents completed post-June 2015 must use the April 2015 version. Administration managers aware of problem with patient stickers. Printers have been serviced and label supplier notified of misaligned stickers during manufacture. This is not isolated to ACS within GGC. ACS staff are aware that only stickers with full details should be used for patient consent forms. The discrepancies highlighted by the inspection team that took place immediately after	team take reassurance from this regarding the compliance of legal parenthood consenting at the centre, the PR should provide the next three quarterly parenthood consent audit reports to the centre's inspector so that the on-going effectiveness of the preventative actions taken can be assessed. No further actions are required beyond the PR providing the centre's inspector with the reports of the next three quarterly audits of legal parenthood.

		changes were implemented, were found to be during the transition period of staff training and SOP development in October and November 2015. No further change to practice required, however this will be reviewed with further audit findings. Next audit scheduled for March 2016. Results to be forwarded.	

‘Other’ areas of practice that requires improvement

Areas of practice that require improvement are any area of practice in which failings occur, which cannot be classified as either a critical or major area of non compliance, but which indicate a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
None identified			

Additional information from the Person Responsible