Interim Licensing Report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's

Centre name: Peninsular Centre for Reproductive Medicine
Centre number: 0005
Date licence issued: 01/03/2009
Licence expiry date: 28/02/2014
Additional conditions applied to this licence: None
Date of inspection: 10/10/2012
Inspectors: Ms Janet Kirkland MacHattie, Dr Andrew Leonard
Date of Executive Licensing Panel: 11/01/2013

Purpose of the report

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 an interim 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 2012-14 the focus of an interim inspection is:

- **Quality of service**: the quality of service provided by a centre, including its success rates and performance in reducing multiple births – the biggest single risk of IVF.
- **Patient experience**: it is considered crucial that the experiences of service users feed into any evaluation of a centre's performance.

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 with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

This report has enabled the inspection team to form a conclusion on the continuation of the centre's licence: The inspection team recommends the continuation of the centre's licence.

The team has made recommendations for improvement and these should be implemented within the time specified.

The Executive Licensing Panel is asked to note that there are recommendations for improvement in relation to no **'critical'**, eight 'major' and three 'other' areas of non-compliance or poor practice. Since the inspection, the PR has given a commitment to fully implement all of the following recommendations:

'Major' areas of non-compliance:

- The Person Responsible (PR) should ensure that witnessed checks are documented in a manner compliant with HFEA requirements.
- The PR should continue to gather and monitor patient feedback on their experiences of pain and/or discomfort during egg collection for the next three months.
- The PR should initiate quality indicator monitoring and review of key laboratory and clinical processes.
- The PR should ensure that all areas where confidential identifying information can be accessed are secure at all times.
- The PR should ensure that wherever possible CE marked medical devices are used.
- The PR should ensure that the treatment outcomes for partner intrauterine insemination (IUI) for 2011 are submitted to the HFEA immediately and that treatments are reported in line with the requirements of General Direction 0005.
- The PR should ensure that information given to patients, prior to their consenting to the use of their embryos in training, explains whether any information will be fed back to them or not.
- The PR should review audit procedures to ensure that they are robust and effectively audit compliance with regulatory requirements.

'Other' areas of practice that require improvement:

- The PR should ensure either that the tubes at egg collection are appropriately labelled and that transfers between tubes and dishes are witnessed or that the risks of the current practice of not labelling or witnessing is assessed and appropriate risk control measures are documented and implemented.
- The PR should consider gathering further focused feedback from service users to determine if there are opportunities for improving the patient experience.
- The PR should audit a sample number of patient and partner consents to disclosure of identifying information to researchers documented in patient records, against the consent decisions recorded in the HFEA Register, to determine whether the consent discrepancies between these sources noted on inspection are isolated occurrences or are more prevalent.

Information about the centre

The Peninsular Centre for Reproductive Medicine is located in Exeter and has held a licence with the HFEA since 21/05/1992.
The centre provides a full range of fertility services.

The centre provided 415 cycles of treatment (excluding IUI) in the 12 months to 31/07/2012. In relation to activity levels this is a small centre.

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.

Outcomes[1]

HFEA held register data for the year ending July 2012 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages with the following exceptions;

- clinical pregnancy rates following IVF in patients aged 16-37 years are below average at a statistically significant level;
- clinical pregnancy rates following ICSI in patents aged 16-37 years are below average at a statistically significant level.

See recommendation 3.

Multiple births[2]

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

In 2010/11 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 29%: this represented performance that was not likely to be statistically different from the 20% live birth rate target.

For the time period April 2011 to March 2012 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 26%: this represents performance that is not likely to be statistically different from the 15% live birth rate target.

While it is acknowledged that the centre's clinical multiple pregnancy rate indicates performance not likely to be different from the relevant targets, it is recommended that the centre review the current multiple birth rate minimisation strategy in consideration of the 10% live birth rate target that became effective on 01/10/2012.

[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.
[2] The HFEA use a conversion factor of 1.27 to convert the multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 2010/11 MLBR target of 20% is calculated as equivalent to a MCPR of 25%: the 2011/12 MLBR target of 15% is calculated as equivalent to a 19% MCPR.

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; thawing of embryos; sperm preparation; insemination. All of the procedures were manually witnessed and checks were made and documented in accordance with HFEA requirements, with some exceptions discussed below.

The inspection team was able to review witness check sheets that were present in the laboratory and in 10 sets of patient records provided by centre staff. From this we could conclude that accurate records of manual witnessing are maintained, with one exception discussed below.

The following non-compliances were observed:

- A witnessing check was observed to be documented prior to the check being performed;
- One witness check was seen to have been inappropriately documented in the audit of witness checks in 10 patient records);
- The tubes used during egg collection to transfer follicular fluid containing eggs to the laboratory were not labeled with patient identifiers, so the transfer of follicular fluid from the tubes to dishes could not be witnessed.This could lead to a risk of misidentification if unmarked tubes from one patient are inadvertently left in a critical work area when a second egg collection commences. To mitigate the risks, staff ensure that the eggs of only one patient are present within the procedure room and laboratory critical work areas at any time. These areas are cleaned after each egg collection and cleared of all tubes.

See recommendations 1 and 9.

Consent: Disclosure to researchers

A patient providing informed consent is one of the most important principles in healthcare. Since 1 October 2009, the HFEA has been able to release patient-identifying information held by the HFEA to researchers if patients give their permission. Patients are asked to give their consent to the disclosure of this information and this is recorded in their records and the HFEA is notified of their decision through the electronic data interface (EDI) system. It is important that the reporting through EDI is accurate so that patient information is not disclosed without consent.

The records of consent to disclosure to researchers given by 10 patients were reviewed in the course of the inspection. The consents were completed and reported to the HFEA accurately in seven of the records reviewed.
In three of the records reviewed, the patients had consented to disclosure but the EDI entry recorded that they had not consented to disclosure.
See recommendation 11.

Consent: To the storage of cryopreserved material

A review of the centre's records of consent to storage of gametes and embryos showed that all gametes and embryos currently in store are being stored in accordance with the consent of the gamete providers.

Staffing

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

Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out: patients were seen promptly on arrival; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

Patient experience

During the inspection visit we spoke to two patients who provided feedback on their experiences and we also observed interactions between centre staff and patients. A further 34 patients have provided feedback directly to the HFEA since the last inspection. Feedback was generally positive with 29 of the individuals providing written feedback to the HFEA commenting that they had compliments about the care they received, however, eight patients commented that they had complaints.

Feedback is gathered by centre staff from patients and staff and the results are analysed and acted on where appropriate. The inspector had the opportunity to review the patient feedback gathered by the centre from a further 12 patients.

Overall, whilst feedback was predominantly positive, negative comments were made regarding:

- difficulty contacting the centre by telephone;
- delays experienced by patients waiting for their appointment to commence.

See recommendation 10.

On the day of inspection it was observed that a patient undergoing egg collection experienced some discomfort. A small number of patients providing feedback to the HFEA also commented that that they had found the egg collection procedure uncomfortable. The PR informed the inspection team during the inspection that the clinician performing the egg collection was returning from a break in practice and that the centre was introducing a new method of pain relief for use in some cases.

This led the inspection team to be concerned whether the practices being used for egg collection were suitable and/or whether the individual performing egg collections was competent to do so. It is acknowledged that these concerns were based on a very small sample of patients' experiences but further information and reassurance was requested from the PR immediately post inspection. The PR subsequently provided the inspection team with a report of the sequence of events on the day of inspection and documentation relating to the monitoring of patients' pain and/or discomfort during procedures. The PR

assured the lead inspector of the competence of the medical team by providing a description of the assessment process and their experience of performing egg collections. The PR has also, since the inspection, reviewed the sedation/analgesic procedures and assured the inspector that egg collections have been performed by the clinician since the inspection without any adverse events or negative patient feedback.

The inspector acknowledges that the centre team were faced with a difficult situation on the day of the inspection and from observation and discussions with the team; they appeared to handle it with professionalism and with regard for patient safety, dignity and experience. In addition the PR has been pro-active in providing information regarding the protocols and procedures adopted by the team and verbal feedback regarding patient experience subsequent to the inspection.

See recommendation 2.

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

From the information submitted by the centre in their self assessment questionnaire and from observations during the visit to the centre, the inspection team identified the following non-compliances:

- The PR has not submitted the IUI return for the year 2011 that was due to be submitted to the HFEA in February 2012 (see recommendation 6);
- On arrival at the centre it was noted that the door to the reception office was open. The reception was unmanned and patient files were clearly visible and accessible to unauthorised individuals (see recommendation 4);
- Information given to patients who consent to the use of their embryos in training does not include whether any information will be fed back to them (see recommendation 7);
- The centre reported in their self-assessment that they have audited how far procedures for witnessing and for the provision of information comply with the approved protocols, the regulatory requirements and quality indicators. The identification of non-compliances in the conduct of witnessing and information submission in the course of this inspection suggests that the centre's audit procedures are not robust (see recommendation 8).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2010 recommendations for improvement were made in relation to one area of critical non-compliance, four areas of major non-compliance and three 'other' areas of non-compliance.

The PR provided information and evidence that all except the following recommendation were fully implemented:

- the PR should ensure that wherever possible only CE marked medical devices are used (see recommendation 5).

On-going monitoring of centre success rates

In 2012, on the basis of success rate trend analysis, the centre was asked to review procedures for the provision of IVF and ICSI treatment to patients aged 16-37 years. The PR responded to the request but not within the time scale stipulated. During discussions at the time of the inspection, the PR explained what he believes to be the reason behind the reduced success rate and the actions taken to address it.

Discussions with centre staff highlighted that whilst some of the team were aware of the decline in success rates, the most recent laboratory and clinical quality indicator monitoring data the centre could provide was for 2010/2011. This data did not include any corrective actions or follow up. The lack of recent quality indicator monitoring data and its review is non-compliant with SLC T35 and raised a concern that the PR has not adequately investigated the HFEA alert regarding the centre's low success rates (see recommendation 3).

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out.

The centre generally has a good record of data submission and of compliance with regulatory requirements. However a significant proportion of their treatments are currently being reported late (see recommendation 6).

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 area 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.			

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
- 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. It was noted during observation in the laboratory that a witnessing check was documented prior to the check being performed (SLC T71). In addition, one witness check was seen to have been inappropriately documented in the audit of witness checks in 10 patient records (SLC T71).	The PR should ensure that witness checks are documented in a manner compliant with SLC T71. This should be implemented with immediate effect. The PR should review the centre's witnessing procedures and SOPs and implement any changes necessary to ensure that witnessing is compliant with HFEA requirements. Relevant staff should be provided with update training in witnessing procedures. A summary report of changes made to the SOPs and staff training provided should be submitted to the HFEA by 10 January 2013.	More detail of the observed witnessing shortcoming(s) would be helpful to address this. It is thought that the inspector may have misunderstood the procedure for the witness/ID check in theatre and on seeing it repeated (a 'double-check' is often performed) may have assumed it had not already been performed before signing. On the other hand it is possible the reference may be to the signing of an ICSI-insemination witnessing procedure that was signed immediately before performance of the procedure	The inspector acknowledges the PR's response. The scientific inspector did discuss his observations with the laboratory staff on the day of the inspection. The inspector is satisfied that witnessing procedures will be reviewed and looks forward to receiving the report of any changes made to the SOPs in addition to an update of staff training by 10 January 2013.

	The PR should ensure that an audit of witnessing is conducted within three months of the introduction of revised witnessing procedures. A summary report of the findings of the witnessing audit and any corrective actions and timescales for their implementation should be submitted to the HFEA by 10 April 2013.	and then again by the witness after the procedure. The witnessing procedures will be reviewed and a report submitted, with any necessary changes to SOPs, as requested. An update of staff training in witnessing is scheduled for December 2012.	
2. On the day of inspection it was observed that a patient undergoing egg collection experienced discomfort. A small number of patients providing feedback to the HFEA also commented that that they had found the egg collection procedure uncomfortable (SLC T2).	The PR provided assurance in relation to the competence of the staff member and the suitability of egg collection procedures immediately post inspection. It is recommended however that the PR proactively continues to gather and monitor patient feedback on their experiences of pain and/or discomfort during egg collection for the next three months. A summary report of the analysis of this feedback should be provided to the HFEA by 10 February 2013. If, during the monitoring of feedback, it becomes apparent that patients are experiencing unacceptable	Egg collection under anagesia/sedation is recommended by NICE. We have carried out thousands of such procedures and in the vast majority patients are comfortable and if necessary return for repeat treatment. Patients are warned that sometimes there may be complications that cause more pain than usual, however. We routinely collect patient feedback on discomfort and will comply with the request to submit a report by Feb 10th.	The inspector is satisfied with the PR's response and looks forward to receiving the summary report of patient feedback on their experiences of pain and/or discomfort during egg collection by 10 February 2013.

	levels of discomfort, then the PR should notify the HFEA immediately and take appropriate action to ensure patient safety and comfort are protected.		
3. The centre has received one HFEA Risk Tool alert relating to outcomes in 2012. The PR did not respond to the alert in the proposed timescale. It became apparent in the course of the inspection and subsequent follow up, that despite declining success rates for particular groups of patients the centre team could not provide evidence of recent laboratory or clinical quality indicator monitoring and review (SLC T35).	The PR should re-establish quality indicator monitoring and review of key processes. The results of the reviews and audits, with corrective actions if necessary, should be documented. A summary report including proposed corrective actions and timescales for their implementation should be submitted to the HFEA by 10 January 2013.	The inspectors were able to review 3-month rolling KPI charts during the visit, although these were behind schedule because we are reviewing our KPI procedures due to increasing complexity and variations in the range of patients and treatment services provided. We will endeavour to complete this review and submit a report as requested.	The inspection team did not review rolling three month KPI data. The most recent laboratory and clinical quality indicator monitoring data the centre could provide on the day of the inspection was for 2010/2011. The inspector looks forward to receiving the summary report including proposed corrective actions and timescales by 10 January 2013. The centre outcomes will continue to be monitored and the PR is encouraged to respond to any RBAT alerts received by the centre within the designated timescale.
4. On arrival at the centre it was noted that the door to the reception was open. The reception was unmanned and patient files were clearly visible and accessible to unauthorised individuals (SLC T44 and S.33A of the	The PR should ensure that all areas where confidential identifying information can be accessed or obtained are secure at all times with immediate effect. The PR should review the centre's procedures and SOPs	These findings are fully accepted along with full intent to comply with the recommendations. Immediate action taken has been: to inform the NHS Trust Governance Authorities; to speak directly to staff	The inspector is satisfied with the response and looks forward to receiving the summary report by 10 January 2013.

Human Fertilisation and Embryology Act 1990 (as amended)).	for restricting access to confidential identifying information and implement any changes necessary to ensure the procedures are compliant with HFEA requirements. Relevant staff should be provided with update training in confidentiality requirements. A summary report of changes made to the SOPs and staff training provided should be submitted to the HFEA by 10 January 2013. The PR should ensure that an audit of practice is carried out within three months of the introduction of revised procedures. A summary report of the findings of the audit and any corrective actions and timescales for their implementation should be submitted to the HFEA by 10 April 2013.	concerned; and to institute a new reporting system to flag if or when anyone finds the reception area open but unattended. Staff training includes annual updates on Information Governance requirements and an audit of the above measures will be submitted within the requested time frame.	
5. Some of the equipment used in the laboratory is not CE marked when it is known that there are CE marked alternatives (SLC T30). This was identified as an	The PR should ensure that, wherever possible, only CE marked medical devices are used, with immediate effect. A list of all critical equipment and consumables should be provided	We endeavor to use CE marked equipment wherever possible and believe we comply with this i.e. where CE marked equipment is not used it would be because we have been unable to find CE-	The inspector is satisfied with the response however it is the PR's responsibility to ensure that CE marked equipment is used wherever possible and therefore it is for him and his team to investigate and source

area for improvement at the last inspection.	to the HFEA. The list should indicate where products are not CE marked and the rationale for the use of the product.	marked alternatives. We believe this complies with the Code of Practice but if the inspection team are aware of any specific CE marked alternatives to any of the non-CE marked equipment in use we would be grateful for the information and happy to investigate them. The list of critical equipment and CE marking information will be provided as requested.	the equipment as required. The list requested should be submitted by 10 January 2013
6. The centre has not submitted their IUI treatment outcomes and a significant proportion of treatments are currently being reported late (General Direction 0005).	The PR should ensure that the treatment outcomes for IUI for 2011 are submitted to the HFEA immediately and that treatments are reported in line with the requirements of General Direction 0005 with immediate effect. The PR should review the centre's procedures and SOPs for submitting information to the HFEA and implement the changes necessary to ensure that information is submitted in compliance with HFEA requirements. Relevant staff should be provided with update training in the relevant requirements. A summary report	The IUI data has already now been submitted. We had a good record of IUI data submission when the paper forms were used and the recent lapse followed the change in procedure to the Data Portal. It is accepted that the SOP for this was behind, but the relevant SOP - which details the information to be added to the regular 'tasks' diary has been amended. Compliance with the recommendation is accepted. Further staff training shouldn't be necessary.	The treatment outcomes for IUI have now been submitted. The PR is reminded that this non-compliance also relates to the late reporting of other treatment cycles via EDI and that further action, as described, in relation to this is required. The PR is encouraged to ensure that treatments continue to be reported in line with the requirements of General Direction 0005 with immediate effect.

	of changes made to the SOPs and staff training provided should be submitted to the HFEA by 10 January 2013.		
7. Information given to patients who consent to the use of their embryos in training does not include whether any information will be fed back to them (SLC T97).	The PR should ensure that information given to patients prior to their giving consent to the use of their embryos in training, explains whether any information will be fed back to them or not. A copy of the revised patient information should be provided to the HFEA by 10 January 2013.	The Patient Information sheet concerning consent to Training and Research will be amended and submitted as requested.	The inspector is satisfied with the response and looks forward to receiving a copy of the revised patient information by 10 January 2013.
8. The centre reported in their self-assessment that they have audited how far procedures for witnessing and for the provision of information comply with the approved protocols, the regulatory requirements and quality indicators. The identification of non-compliance in the conduct of witnessing and in information submission on inspection, suggests that the centre's audit procedures are not robust and do not effectively audit compliance with	The PR should review audit procedures to ensure that they are robust and effectively audit compliance with regulatory requirements. A summary report of the findings of the review and changes implemented to improve the audit procedures should be submitted to the HFEA by 10 January 2013.	Essentially this is a request for an audit of audit procedures. An initial review has already been conducted with an update to the 'general' clinical and other SOP document, which has been reviewed at a senior staff meeting on 14th November 2012. A report will be submitted by Jan 10th 2013 as requested..	The inspector is satisfied with the response and looks forward to receiving the summary report by 10 January 2013.

regulatory requirements (SLC T36).			

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non-compliance, but which indicates 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
9. The tubes used during egg collection to transfer follicular fluid from the procedure room to the laboratory, are unlabeled and are not witnessed when the follicular fluid is decanted into dishes (SLCs T71 and T101)	The PR should ensure either that the tubes at egg collection are appropriately labelled and that transfers between tubes and dishes are witnessed or that the risks of the current practice of not labelling or witnessing is assessed and appropriate risk control measures are documented and implemented. A summary report of any changes to procedures and corrective actions taken to mitigate risks should be submitted to the HFEA by 10 January 2013.	Amendments to the witnessing SOP will been made, to include witnessing of the check that clinical areas are clear of all tubes and dishes between procedures. This will be risk assessed and the report submitted as requested.	The inspector is satisfied with the response and looks forward to receiving the summary report by 10 January 2013.
10. Feedback from patients who have been treated at the centre in the time since the last inspection note the following: • difficulty contacting the centre by telephone;	The PR should consider gathering further focused feedback from service users to determine if there are opportunities for improving the patient experience. If it is determined that patients do	We have already taken note of feedback relating to communication difficulties on occasion, although for the most part believe feedback to be good. We have responded by exploring the introduction of	The inspector acknowledges the PR's response and is confident that the centre team will continue to receive and act on patient feedback. This will be the subject of on-going monitoring.

• delays experienced by patients waiting for their appointment to commence.	experience delays in their treatment then this can be indicative of staffing shortages and the PR should consider reviewing staffing levels.	a new and innovative procedure for email communication, for example. A copy of an information/consent form relating to this was submitted in initial feedback following the inspection. It should be noted, however, that we have also received a complaint that patients are being provided with too many requests for feedback.	
11. An audit of consent to disclosure to researchers given by 10 patients was reviewed in the course of the inspection. In three of the records reviewed, the patients had consented to disclosure but the EDI entry recorded that they had not consented to disclosure.	The PR should audit a sample number of patient and partner consents to disclosure of identifying information to researchers documented in patient records, against the consent decisions recorded in the HFEA Register, to determine whether the consent discrepancies between these sources noted on inspection are isolated occurrences or are more prevalent (SLC T36); The audit report should be submitted to the HFEA by 10 January 2013.	The PR had not been given the opportunity to respond to this non-compliance as further details were required to complete the audit. Following discussion with the PR he has agreed with the actions required and timescale.	The inspector is satisfied with this response.

Additional information from the Person Responsible
We understand that this was one of the first 'unannounced' inspections. Our understanding was that the focus would be on operational observation and the 'patient experience' rather than documentation such as SOPs, KPIs etc. Although of course all clinics should be prepared for a full inspection of any and every aspect of their practice at any time we might have been a little better prepared had we anticipated that these would form part of the procedure. There was discussion during the visit of our response to the HFEA alert regarding success IVF rates arising from the new 'risk tool'. Whilst a low success rate may indicate poor performance this is not necessarily the case. As part of our strategy to minimise multiple births we have recently introduced an innovative 'package' for 'gentle IVF' at what we beilieve to be exceptionally low cost. This is contingent on a commitment to single-embryo transfer but would be expected to result in a lower success rate, of which no account is taken in the 'risk tool'. We know our laboratory and clinical performance to be good from an audit of our eSET data, with a clinical pregnancy rate per cycle of over 30% in this group encompassing all age categories. We therefore have some concerns about the HFEA success rate 'risk tool', which we feel to be artificially created so as to try to provide enough data for statistical analysis but open to misunderstanding. This may drive clinics to poor practice (e.g. in patient selection and their non-IVF treatment algorithm) in efforts to 'correct' success rates that may be justifiably lower in some clinics than others for reasons of good rather than poor practice. Also, we are perplexed by the report of 'missing data' in relation to HFEA risk tool chart on the Data Portal. To the best of our knowledge all the data is complete and we would appreciate the opportunity to explore why it is thought that some data is missing. The CE marking system is based on self-reporting using a 'statement of conformity' by manufacturers or suppliers. The information available to us via third-party agreements when using non-CE marked items may be enough in theory for us to apply to CE-mark them ourselves. Ideally we would, of course, like to use third-party CE marked products and believe we do so wherever possible. It would be interesting and helpful to know whether we are alone in finding difficulty in sourcing those items in use in our clinic that are not CE marked.

HFEA Executive Licensing Panel Meeting

11 January 2013

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 2

Centre 0005 – (Peninsular Centre for Reproductive Medicine) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard, Head of Policy & Communications (Chair) Nick Jones, Director of Compliance Joanne Anton, Policy Manager	Joanne McAlpine

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that this centre has been licensed since 1992 and provides a full range of fertility services.

2. The Panel noted that the centre's current licence is due to expire on 28 February 2014.

3. The Panel noted that for the time period of April 2011 to March 2012 the centres multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 26%, and this represents performance that is not likely to be statistically different from the 15% live birth rate target.

4. The Panel noted that the centre was inspected in October 2012, and at the time of the inspection the Inspectorate identified no critical, eight major, and three other areas of non-compliance.

5. The Panel noted that since the inspection visit the Person Responsible (PR) has given a commitment to address the outstanding recommendations.

6. The Panel noted the tabled information that the PR had submitted to the Inspectorate on 7 January 2013, containing a summary of progress made to address the recommendations made at the time of the inspection. The Panel noted that the Inspectorate has been unable to review the standard operating procedures (SOPs) requested, due to IT problems. The Inspectorate has asked for this information to be re-sent and will review upon receipt, but is satisfied that the PR has responded to the recommendations documented in the interim inspection report and will continue to monitor the centres' progress.

7. The Panel noted the recommendations made by the Inspector, in particular those relating to pain management of patients undergoing egg collections, the security of confidential patient records and the reporting of IUI treatment outcome forms.

8. The Panel noted that the Inspectorate recommends the continuation of the centre's licence with no additional conditions.

Decision

9. The Panel endorsed the Inspectorate's recommendation to continue the centre's licence with no additional conditions, and endorsed the recommendations and relevant timescales within the report on those areas of non-compliance that remain outstanding.

10. Whilst the Panel noted the PR's comments made in response to the report, the Panel encouraged him to engage more constructively with

the Inspectorate and take a more proactive approach to addressing outstanding issues. In particular, the Panel urged the PR to address success rates, the reporting of outcomes to the HFEA, and the security and confidentiality of patient records.

Signed: Date: 31 January 2013

Juliet Tizzard (Chair)