Unannounced Interim Inspection Report

Date of Inspection: 18 March 2010
Length of inspection: 5 hours
Inspectors: Mim Glenn (Lead) and Sarah Brain

Inspection details:
The report covers the pre-inspection analysis and the unannounced visit and information received between the date of the last inspection on the 29 April 2008 and 18 March 2010.

Date of Executive Licence Committee: 15 July 2010

Purpose of the Inspection report
The purpose of the inspection is to assess whether centres are complying with the HF&E Act 1990 (as amended), the HF&E Act 2008 and the Code of Practice version 8 (CoP) to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence interim inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Authority's Executive Licensing Panel which makes the decision about the continuation of the centre's licence.

Centre details

Centre Name	The Woking Nuffield Hospital
Centre Number	0144
Licence Number	L0144/11/b
Centre Address	Victoria Wing Shores Road Woking Surrey GU21 4BY
Telephone Number	01483 227859
Person Responsible	Andrew Riddle
Licence Holder	Caroline Lewis
Date Licence issued	21/10/1997
Licence expiry date	31/10/2011
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Recommendation to the Executive Licensing Panel:

This was a randomly selected unannounced interim inspection of the centre. A small number of centres are randomly sampled in this way for quality assurance purposes.

There were a number of areas of non compliance identified at this inspection. Some of these were in the process of being remedied at the time of inspection, having been identified by the centre as areas of practice requiring improvement following completion of a Self Assessment Questionnaire (SAQ):

- The Standard Operational Procedure (SOP) does not include the procedures staff are to follow when witnessing the disposing of fresh material when not needed for treatment or storage.
- The witnessing SOP does not include the need to cross-check at all stages of clinical and laboratory procedures with identifying information in the patient's medical records.
- There was no indication that Quality Indicators (QI) or audits in relation to witnessing had been undertaken.
- The time of witnessing is not consistently recorded in patient medical records in that the name and status of the individuals performing and witnessing the activity are not included on the documentation.
- There was no SOP for staff to follow on how to obtain consent.
- The centre was not maintaining a summary log of cases in which multiple embryos have been transferred to patients' who met the criteria for single embryo transfer in the format set out in Directions 0003.
- The SOP relating to withdraw consent to the storage or use of gametes and embryos does not state that the request to withdraw consent is required in writing.
- The multiple birth minimisation strategy does not make reference to Gamete Intra Fallopian Transfer (GIFT) and Zygote Intra-Fallopian Transfer (ZIFT),
- A risk assessment of the various areas where patients' records are stored had not been undertaken.
- A risk assessment of the various areas where Cryopreservation dewars are stored had not been undertaken.
- There was no SOP in place for submitting data to the HFEA in compliance with the requirements of Directions 0005
- The centre has not established quality indicators relevant to the submission of data to the HFEA or undertaken an audit in the last two years
- The centres patient information leaflet 'Parental responsibility' did not reflect the new legal parenthood provisions which came into effect in April 2009.

Subsequent to the review of the draft report the PR has provided evidence that all of the recommendations outlined above have been implemented.

The following areas of non-compliance were also identified:

- There was no written evidence presented to demonstrate that staff have had their competency to performance their designated tasks assessed;

- The centre's counsellor was not able to demonstrate that she had achieved British Infertility Counselling Association (BICA) accreditation.

Subsequent to the review of the draft report the PR has given assurances that recommendations in relation to these areas of practice will be add addressed within the prescribed timescales and the lead inspector will continue to monitor implementation of these recommendations.

The inspection team recommends the continuation of the centre's licence without additional conditions.

Updated actions since the centre was inspected on 18 March 2010

Since the inspection, the centre has provided evidence that the following recommendations with the respect to these have been implemented

- The PR has submitted evidence to demonstrate that two staff members are required to witness the disposing of all fresh material, when it is not needed for treatment or storage.
- The PR has submitted evidence to demonstrate that staff are aware for the need to cross-check at all stages of clinical and laboratory procedures with identifying information in the patient's medical records.
- The PR has submitted a Quality Indicators (QI) and Key Performance Indicators (KPI) policy, data that is to be collected monthly, a key performance indicator score sheet for 2010, the quality indicator data to be collected for 2010, once of which, Indicator Area 6. Witnessing to demonstrate that witnessing audits will be undertaken.
- The PR has submitted evidence in the form of a SOP for 'Staff signatures log for written medical records' and a pre populated blank staff signature log form, to demonstrate that staff now record their name, status, initials and signature on the staff signature log form which is retained in the patients medical records.
- The PR has submitted an SOP informing staff how to obtaining consent
- The PR has submitted evidence to demonstrate that a summary log of cases in which multiple embryos have been transferred to patients' who met the criteria for single embryo transfer in the format set out in Directions 0003 is being maintained.
- The PR has submitted evidence to demonstrate that when notification to withdraw consent is received that it must be in writing,
- The PR has submitted evidence to demonstrate that the SOP for multiple birth minimisation strategy has been up dated to include GIFT and ZIFT.
- The PR has submitted evidence that a risk assessment has been carried out of the areas where patients' records are stored, on the 6 May 2010, and no additional control measures are necessary.
- The PR has submitted evidence to demonstrate that so long as the controls that have been put into place and applied, employee exposure to liquid nitrogen is adequately controlled.
- The PR has submitted evidence in the form of a audit schedule, key performance indicators and audit tool for record keeping, to demonstrate that all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence are undertaken are audited annually if not monthly.
- The PR has submitted evidence in the form of a audit schedule, key performance indicators and audit tool for record keeping, to demonstrate that all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence are undertaken are audited annually if not monthly.
- The PR has submitted an up dated patient information leaflet for parental responsibility that would now appear compliant with the new legal parenthood provisions.
- The PR has provided assurances that the centre will submit evidence to demonstrate that assessment of all staff grade competencies has been completed by March 2011.

- The PR has provided assurances that he will submit evidence to demonstrate that the counsellor has achieved British Infertility Counselling Association (BICA) accreditation.

Details of Inspection findings

Brief description of the centre and its licensing history:

The Nuffield Health Woking Hospital's Assisted Conception Unit is based in the Victoria Wing, of the Nuffield Health, Woking Hospital, Surrey. It has a good history of compliance with no previous conditions on its licence.

The centre offers a complete range of assisted reproductive treatments, including ovulation induction, intrauterine insemination (IUI), in vitro fertilisation (IVF) and intracytoplasmic sperm injection (ICSI). The centre provides both NHS and self-funded treatments. Currently around 850[1] treatment cycles are carried out per year.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1 Jan 2009 to 31 Dec 2009*
In vitro fertilisation (IVF)	389
Intracytoplasmic sperm injection (ICSI)	253
Inter Uterine Insemination (IUI)	51
Donor Insemination (DI)	17
Zygote Intra Fallopian Transfer (ZIFT)	0
Gamete Intra Fallopian Transfer (GIFT)	0

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research	N/A

*These data were extracted from the HFEA register for the period 1 January 2009 to 31 December 2009. 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.

1. Focus of inspections for 2010-12

Witnessing
Evidence of how the centre demonstrates compliance with the requirement to double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process. The centre has in place a written SOP to be followed for witnessing practice (T33 (b)). This SOP specifies the witnessing steps to be carried out, both for clinical and laboratory practice (T71). Witnessing checks are carried out by two members of staff and are recorded in patients' medical records. An audit of three sets of patients' notes confirmed this (T71). A competence programme has been developed. This was provided at the inspection and was seen to include assessment of competence in carrying out witnessing (T15 (a)). The centre will be introducing the programme from April 2010 onwards.
What the centre does well.
What they could do better. In the course of the inspection three sets of patient records were audited and the inspectorate noted that the time of witnessing is not consistently recorded as required by CoP guidance note 18.7. It was also noted that the records do not record all the information required to meet licence condition T71, in that the name and status of the individuals performing and witnessing the activity are not included on the documentation. The PR should ensure that the patients' records contain all the information required under licence condition T71. The centre does however have a separate master list containing all staff names, and their signatures, but again does not list the status of the staff member (T71). The centre has an SOP for the disposal of frozen material which meets witnessing requirements (T33), but does not document the witnessing requirements when disposing of fresh material not needed for treatment or storage (T71). The centre should review the SOP to ensure that it includes the procedure staff are to follow when witnessing the disposing of fresh material as stated in licence condition T71 and recommended under guidance note 18.4(j). The Quality Manager was not available on the day of the inspection and staff were unable to confirm whether quality indicators and objectives relevant to witnessing have been established (T35). They were also unable to confirm or provide evidence to show that witnessing audits have been undertaken against compliance with protocols, regulatory requirements or quality indicators, in an independent way, during the last two years, or if findings and corrective actions have been documented (T36). The PR must ensure that audits of all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence are undertaken against compliance with protocols, regulatory requirements and quality indicators. These must be independently conducted at least every two years. Findings and corrective actions must be documented (T35 & T36).

Parenthood

Evidence of how the centre demonstrates compliance with the requirements in relation to legal parenthood.

The centre offers egg sharing and egg donation and provided donor insemination treatment in 2009.

Through discussion staff appeared to understood legal parenthood provisions which came into effect on the 1 October 2009 (T60, T61, & T62).

What the centre does well.

The centre has developed a form which lists the discussion points and information that patients are to be given during their consultation, this includes legal parenthood provisions.

Patients are required to sign the form at the end of the consultation confirming that they have received the information and the form is retained in the patient's notes. These signed forms were observed in the two sets of patients' notes seen on the day of the inspection.

What they could do better.

Although it appeared that staff interviewed during the inspection understood the new legal parenthood provisions, the centre's patient information leaflet – 'Parental responsibility', did not reflect the new provisions in relation to patients receiving treatment with donor sperm or embryos where the patients are not married or in a civil partnership. The leaflet recommends that these 'unmarried couples' should seek their own legal advice about the partner's rights and responsibilities in relation to the potential child who may be born as a result of the treatment. In October 2009 it became possible for these individuals to consent to legal parenthood and these provisions are laid out in sections 36, 37 and 38 and section 43, 44 and 45 of the HFE Act 2008.

The PR should review the centres leaflet to ensure that it reflects the new legal parenthood provisions (T63, T64 & T65). The PR should also assure himself that all staff fully understand the new legal parenthood provisions (T15).

Information about the cost of treatment

Evidence of how the centre demonstrates that it has introduced personalised costed treatment plans for all patients

During the course of the inspection a number of costed treatment plans were seen and discussed with centre staff. The plan details the main elements of the treatment proposed (including investigations and tests), the cost of that treatment and any possible changes to the plan, including the cost implications as suggested under guidance note 4.3 of the CoP. The patient and their partners also have the opportunity to discuss the plan before treatment begins.

What the centre does well.

The costing information seen on inspection was clear and considered to be easy to understand.
What they could do better. No areas for improvement in this area of practice were identified at the time of this inspection.

Patient consent to the disclosure of information, held on the HFEA Register, for use in Research
Evidence of how the centre demonstrates that it provides information to patients about the use of information, held on the HFEA Register, for use in research. Of the three sets of patient records reviewed at inspection all included consent to the disclosure of information for use in research. The staff demonstrated an awareness and understanding of the CoP requirements related to disclosure of information for use in research. HFEA consent forms and patient information sheets are accessible to all staff and are provided to patients at the initial consultation.
What the centre does well.
What they could do better. During the course of the completing the SAQ the centre identified that although staff are trained and their competency for obtaining consent is assessed, there was no written SOP for the processes to be followed when obtaining consent (T33 (b)). This was in hand at the time of the inspection and the centre has since sent an SOP to the inspectorate which staff are to follow when obtaining consent.

Consent issues in relation to the storage of embryos (including cooling off period)
Evidence of how the centre demonstrates compliance with the requirements relating to the withdrawal of consent to storage of embryos intended for use in treatment. Senior staff stated there had been only one occasion when a request to withdraw consent to storage of material. In discussion with staff they were able to demonstrate the requirements relating to the withdrawal of consent to storage of embryos intended for use in treatment, and of the cooling off period (T15).
What the centre does well.
What they could do better. The centre's SOP, documents the process to be followed in the event that someone wishes to withdraw consent to the storage or use of gametes and embryos. However it does not state that the request to withdraw consent is required in writing. The centre should review the SOP to ensure that it is compliant with Human Fertilisation and Embryology (HFE) Act 1990 (as amended), Schedule 3 'Variation and withdrawal of consent'.

Multiple Births

Evidence of how the centre demonstrates compliance with Guidance Note 7 of the Code of Practice relating to multiple births:

In compliance with Directions 0003, the centre has a documented strategy to minimise multiple births and conducts regular audits to assess progress in reducing the centre's multiple birth rate. During discussion with staff it was apparent that the centres is determined to lower its multiple birth rate and is looking at ways to increase the uptake of elective single embryo transfers (eSET). At the time of the initial consultation, patients are provided with written and verbal information on the risks of multiple births and are given sufficient time to consider the information prior to treatment. All patients confirm they have received this information by signing a form. In discussion staff stated that clinical staff discuss eSET with patients, following egg collection with patients who are likely to meet the eSET criteria.

Patients who meet the criteria for eSET, but request to have more than one embryo transferred are required to sign a form confirming they have had the opportunity to discuss and understand the risks of multiple pregnancies if more than one embryo is transferred. Three sets of patients' notes were reviewed on the day of the inspection and in one set of records it was evident that a patient who met the criteria for SET had decided to have a multiple embryo transfer. The patient record included a clear explanation of the reasons for transferring more than one embryo and the consent form in the patient record provided evidence that the patient had consented to a multiple embryo transfer and that she was aware of the consequent risks (Directions 0003).

Evidence seen at the inspection demonstrated that the centre is maintaining a summary log of every treatment cycle involving the placing in a woman of three embryos or four eggs in the format set out in Directions 0003. The log showed that during 2009, of the 72 treatment cycles involving the placing in a woman of three embryos or four eggs, only two sets of twins were conceived. All the patients were over 40 years of age.

What the centre does well:

What they could do better:

The centre from time to time performs Gamete Intra Fallopian Transfer (GIFT) and Zygote Intra-Fallopian Transfer (ZIFT), but the multiple births minimisation strategy does not reference GIFT or ZIFT. The centre should review the SOP and ensure that it includes GIFT and ZIFT (T33).

At the time of the inspection the centre was not maintaining a summary log of cases in which multiple embryos have been transferred to patients who met the criteria for single embryo transfer in the format set out in Directions 0003. Since the inspection evidence has been received by the inspectorate which demonstrates that a log is now being maintained in the format set out in Directions 0003.

2. Changes / improvements since the last inspection on 29 April 2008

Area for improvement	Action required	Action taken as evidenced during this inspection
Not all of the required witnessing steps are captured in the laboratory witnessing protocol.	Witnessing procedures should be reviewed in consideration of the Code of Practice guidelines at G.13. 29 July 2008.	The witnessing SOP is not fully compliant with guidance note 18.4 of the CoP, in that it does not include the need to cross-check at all stages of clinical and laboratory procedures with identifying information in the patient's medical records. The PR should review the witnessing SOP to ensure that it meets Guidance note 18.4 of the 8th CoP.
Not all staff training records reviewed in the course of the inspection showed evidence that competency had been assessed.	The competency of the personnel must be evaluated at appropriate intervals specified in the quality system. (A.10.9). To be monitored at the time of the next inspection.	Through discussion with staff and senior centre management, it was clear that staff undertake an annual joint review with their line manager. However no documented evidence was presented that staff have their competency to performance their designated tasks assessed (T15). The centre has developed a more formal competence assessment programme and will be implementing it as from April 2010 onwards.

Recommendations	Time scale	Action taken as evidenced during this inspection
Patient records are stored securely but over several locations, including in toilet areas off consulting rooms. This may result in notes being difficult to locate. The PR should assess whether there are any risks associated with the storage of records in different locations and take corrective actions to minimise and risks that are identified.	To be monitored at the time of the next inspection.	To comply with the recommendation in the last report, the PR should undertake an assessment of the risks of the areas where patients' records are stored and assess whether there are any risks associated with the storage of records in different locations. It is recommended that the PR seeks the advice of appropriately qualified individuals to advise him as to how to minimise the risks. Findings and corrective actions must be documented and corrective actions implemented. Licence Condition T17
Cryopreservation dewars are stored over several locations including the ensuite to a consulting room and in a room next to the reception area. The facilities are fitted with appropriate alarms and are secure. The PR should assess whether there are any risks associated with the location of the cryopreservation facilities and take corrective actions to minimise any risks that are identified.	To be monitored at the time of the next inspection. .	To comply with recommendation in the last report, the PR should undertake an assessment of the risks of the areas where Cryopreservation dewars are stored. It is recommended that the PR seeks the advice of appropriately qualified individuals to advise him as to how to minimise the risks. Findings and corrective actions must be documented and corrective actions implemented. Licence condition T17
The centre has a protocol in place for transportation of samples. However, the protocol is not fully compliant with the recommendations of Alert 21. Procedures for transfer of cryopreserved material should be reviewed in consideration of the recommendations of the Alert.	By 29 July 2008.	The evidence and information provided by the centre demonstrated that this recommendation has met recommendations of Alert 21. No further action is required.

3. Areas of concern

The analysis of the centre's self assessment questionnaire and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked during the inspection visit to this centre.

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
Guidance Note 2 Staff The SAQ states that the centre is 'almost compliant' in answer to the question 'is the centre operating with a full staff complement'.	During the course of the inspection centre staff clarified the reason why they had assessed themselves as 'almost compliant' in relation to operating with a full complement of staff. Around May/June 2009, the centre noted a drop in the number of patients attending for treatment. This was discussed and concluded that it was due to the state of the global economy at the time. At the same time two key members of the centre's staff went on maternity leave, nevertheless the centre appears to have been able to continue providing a safe service, without the need to employ additional staff. At the time of the inspection, senior centre staff informed the inspectorate that they anticipate an increase in treatments cycles in the near future and were monitoring activity levels closely, to ensure that the current staffing numbers are sufficient to accommodate the present level of treatment cycles safely.	At the time of the inspection the centre was compliant with licence condition T15 and the PR is continuing to assess treatment cycles to ensure they can be safely accommodated by the centre. Senior staff stated that before increasing patient throughput, the centre will undertake an assessment. The assessment will consider the centre's premises, equipment, staffing levels and the skill mix of staff members. Activity will then be adjusted according to the findings of the assessment. No further action is required at this time
Staff The SAQ states that staff were	At the time of the inspection no written evidence was presented to demonstrate that any staff, have	The PR should ensure that all staff in the centre are competent for the tasks they are required to perform.

'almost compliant' in being able to provide documented evidence of the assessment of their competence in the performance of their designated tasks (T15)	had their competency to performance their designated tasks assessed (T15). The PR was aware of this non compliance and had completed the self assessment questionnaire accordingly. The centre has since developed a more formal competence assessment programme for nursing and laboratory staff, which it will begin delivering as from April 2010 onwards (T15).	Training should be updated as required and when procedures change or scientific knowledge develops. The competency of the personnel to perform their designated tasks should be evaluated at appropriate intervals (T15).
Counselling The SAQ stated that although the counsellor was not accredited under the British Infertility Counselling Association (BICA), she could provide evidence of working towards accreditation through the BICA accreditation scheme.	During the course of the inspection the counsellor clarified the reason why she had assessed herself as 'almost compliant'. The counsellor is currently working towards BICA accreditation and will send a certificate verifying that she is working towards accreditation. She hopes to achieve accreditation by August 2010 (T15).	On the 24 March 2010 an e-mail was received confirming that she was awaiting a certificate verifying that she was working towards accreditation, and would forward this to the Executive once received. On 29 April 2010 an e-mail was received which contained evidence to demonstrate that the counsellor is registered with BICA for accreditation registration.
Premises and Facilities The SAQ states that the centre is 'almost compliant' in providing documented evidence of regular cleaning and disinfection of the premises (T26).	In discussion with staff and review of documentation, the centre was able to demonstrate that the laboratory is deep cleaned annually, weekly cleaning undertaken and documented. Spot audits are undertaken and findings and corrective actions have been documented.	The centre is compliant with licence condition T26 in relation to evidence of regular cleaning and disinfection of the premises. No further action is required at this time.
26 Equipment and Materials The SAQ states that the centre is 'almost compliant' in providing documented evidence that equipment with a critical measuring function is calibrated against a traceable standard if	At the time of inspection the PR considered this to be an area of non compliance and had completed the pre inspection SAQ accordingly. From discussion with staff and observation, the centre appears to be compliant with licence condition T24	The centre appears to be compliant with licence condition T24. No further action is required at this time.

available (T24).		
26 Equipment and Materials The SAQ states that the centre is 'almost compliant' in ensuring sterile instruments and devices used for the procurement of gametes and/or embryos and that instruments or devices used for the procurement of gametes and/or embryos are of good quality, validated and specifically certified and regularly maintained in accordance with licence condition T28.	At the time of completing the SAQ the PR felt that he could not state that he was fully compliant because the petri dishes used at the centre (and throughout the sector) were not CE marked. The company supplying the dishes have now gained accreditation.	The centre appears to be compliant with licence condition T28. No further action is required at this time.
30 Confidentiality and Privacy The SAQ states that the centre is 'almost compliant' in providing documented evidence of the receipt of training in maintenance of confidentiality (T15(a))	Currently, training in maintenance of confidentiality is incorporated with induction programmes for all centre staff. The centre has been developing a more formal competence programme and will be implementing it from April 2010 onwards. At the time of inspection the PR was aware of this non compliance, and had completed the pre inspection SAQ accordingly. Staff stated that all visitors, including staff from other departments within the hospital, are required to sign a confidentiality form when they visit the department. This included maintenance personnel.	The centre appears to be compliant with licence condition T15 (a). No further action is required at this time.
31 Record keeping and document control The SAQ states that the centre did not have an SOP in place for	Prior to the inspection the inspection team was informed, by registry that in the last year there have been only 3 errors recorded from this centre.	On 30 March 2010 an email was received from the centre with a copy of an SOP for submitting data to the HFEA in compliance with the requirements of Directions 0005.

the process to be followed when submitting data to the HFEA in compliance with the requirements of Directions 0005 (T33(b))	At the time of completing the SAQ the PR was aware of this non compliance, and had completed the pre inspection SAQ accordingly.	The centre appears to be compliant with licence condition T33 (b). No further action is required at this time.

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 require are given as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical are of non compliance is an area of practice which poses a significant direct risk of causing harm to a patient, donor or to an embryo. A critical area of non compliance requires immediate action to be taken by the Person Responsible

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
None identified at the time of this inspection.				Acknowledged	

Major area of non compliance

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

- which poses an indirect risk to the safety of a patient, donor or to an embryo through the procurement, use, storage or distribution of gametes and embryos, which do not comply with the centre's licence;
- 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	Reference	Action required	Timescale for action	PR Response	Executive Review
Witnessing The centre has an SOP for the disposal of frozen material which meets witnessing requirements but does not document the witnessing requirements when disposing of fresh material not needed for treatment or storage (T71).	Licence condition T33 & T71 Guidance note 18.4(j) of the CoP	The PR should review the SOP to ensure that it includes the procedure staff are to follow when witnessing the disposing of fresh materials as stated in licence condition T71 and recommended under guidance note 18.4(j).	Written confirmation to be submitted to the Inspectorate by 1 June 2010	laboratory SOP for disposal of fresh embryos and eggs. Laboratory form 7.1 and 7.4 Semenology submitted	The PR has submitted evidence in the form of extracts from their SOP and documentation to demonstrate that two staff members are required to witness the disposing of all fresh material, when it is not needed for treatment or storage. The lead inspector considers this response to be sufficient.
Witnessing The witnessing SOP is not fully compliant with guidance, in that it does not include the need to cross-check at all stages of clinical and laboratory procedures with	Licence condition T71 Guidance note 18.4 of the CoP	The PR should review the witnessing SOP to ensure that it meets guidance note 18.4 (j) of the CoP.	Written confirmation to be submitted to the Inspectorate by 1 June 2010	Laboratory SOP witnessing procedure submitted	The PR has submitted evidence to demonstrate that staff are aware for the need to cross-check at all stages of clinical and laboratory procedures with identifying information in the patient's medical records. The lead inspector considers this response to be sufficient.

identifying information in the patient's medical records.					
QMS Staff were unable to confirm whether quality indicators and objectives relevant to witnessing have been established or provide evidence that demonstrated witnessing audits have been undertaken against compliance with protocols, regulatory requirements or quality indicators, in an independent way, during the last two years, or if findings and corrective actions have been documented	Licence condition T35 & T36	The PR must ensure that audits of all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence are undertaken against compliance with protocols, regulatory requirements and quality indicators. These must be independently conducted at least every two years. Findings and corrective actions must be documented.	Confirmation that quality indicators and objectives relevant to witnessing have been established and an audit plan or schedule as to when these are to be undertaken should be submitted to the Inspectorate by 1 June 2010	Quality Indicators and Key Performance Indicators policy. Medical records audit tool submitted	The PR has submitted a Quality Indicators (QI) and Key Performance Indicators (KPI) policy, data that is to be collected monthly, a key performance indicator score sheet for 2010, the quality indicator data to be collected for 2010. The lead inspector is satisfied that these documents provided evidence that the centre has established quality indicators relevant to witnessing and plans to undertake relevant audits.
Witnessing It was noted that the time of witnessing is not consistently recorded as required by CoP guidance note 18.7 and that the records do not	Licence condition T71 Guidance note 18.7 of the CoP	The PR should ensure that the time of witnessing is recorded in the patients' records, in that the name and status of the	Written confirmation to be submitted to the Inspectorate by 1 June 2010	SOP Staff signature log for medical records. Medical staff signature log submitted	The PR has submitted evidence in the form of a SOP for 'Staff signatures log for written medical records' and a pre populated blank staff signature log form, to demonstrate that staff are now aware that they must record their name, status, initials and signature on the staff signature log form and a copy of this list to be

record all the information required to meet licence condition T71, in that the name and status of the individuals performing and witnessing the activity are not included on the documentation		individuals performing and witnessing the activity are included on the documentation			retained in the patients medical records. The lead inspector considers this response to be sufficient.
Staff There was no documented evidence presented to demonstrate the assessment of all staff competence in the performance of their designated tasks	Licence condition T15	At the time of completing the SAQ the PR was aware of this non compliance, and had completed the pre inspection self assessment questionnaire accordingly The PR should ensure that there is evidence is available to demonstrate that all staff have demonstrated competence in the performance of their designated tasks, and/or updated as required, it is documented in the individual staff	A plan showing timelines for completion of assessment of all staff should be submitted to the Inspectorate by the 27 May 2010	Audit of clinical competencies and competency programme for 2010 submitted	The PR has submitted evidence to demonstrate that an audit of staff competencies was completed in 2009. A statement within the evidence states that they have developed a more formal competence assessment programme for counselling, nursing and laboratory staff. It further states that these were implemented from April 2010 and that they would all be completed by March 2011. At the time of writing this report the centre had also begun work on consultant's competencies, which should be completed by May 2010 and implemented by June 2010. An index of all the competencies was also submitted. The lead inspector considers this response to be sufficient at this time and will review the staff training records at the next inspection.

		members training records.			

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 good practice.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
Consent Although staff are trained and their competency for obtaining consent is assessed, there is no SOP for staff to follow when obtaining consent	Licence condition T33 (b)	At the time of inspection the PR was aware of this non compliance, had completed the pre inspection self assessment questionnaire accordingly, and one was being written.	Written confirmation to be submitted to the inspectorate by 30 April 2010	Acknowledged	**30 March 2010** The centre emailed a copy of its SOP for consenting patients which informs staff how to obtain consent. No further action is required.
Record keeping and document control At the time of the inspection the centre was not maintaining a summary log of cases in which multiple embryos have been transferred to patients' who met the criteria for single embryo transfer in the format set out in Directions 0003.	Directions 0003	The PR should ensure that a summary log of cases in which multiple embryos have been transferred to patients' who met the criteria for single embryo transfer is maintained in the format set out in Directions 0003.	Written confirmation to be submitted to the inspectorate by 30 April 2010	Acknowledged	**24 March 2010** E-mail received containing evidence that a log is now being maintained in the format set out in Direction 0003. No further action is required
Consent The centre's SOP, documents the process to be followed in the event that someone wishes to withdraw consent to the storage or use of	Human Fertilisation and Embryology (HFE) Act 1990 (as amended), Schedule 3 'Variation and	The centre should review the SOP to ensure that it states that the request to withdraw consent is required in writing.	Written confirmation to be submitted to the inspectorate by 30 June 2010	Laboratory SOP disposal of stored embryos or gametes submitted	The PR has submitted evidence to demonstrate that when notification to withdraw consent is received, that staff are aware that it must be followed up in writing.

gametes and embryos. However it does not state that the request to withdraw consent is required in writing.	withdrawal of consent'.				The lead inspector considers this response to be sufficient.
Multiple Births The centre from time to time performs Gamete Intra Fallopian Transfer (GIFT) and Zygote Intra-Fallopian Transfer (ZIFT), but the multiple birth minimisation strategy does not reference GIFT or ZIFT.	Licence condition T33	The centre should review the SOP and ensure that it included GIFT and ZIFT.	Written confirmation to be submitted to the inspectorate by 30 June 2010	Clinical SOP indications for eSET submitted	The PR has submitted evidence to demonstrate that the SOP for eSET has been up dated to include GIFT and ZIFT. The lead inspector considers this response to be sufficient.
Record keeping and document control Patient records are stored securely but over several locations, including in toilet areas off consulting rooms.	Licence Condition T17	In compliance with recommendations in the last report, the PR should undertake an assessment of the risks of the areas where patients' records are stored and assess whether there are any risks associated with the storage of records in different locations. It is recommended that the PR seeks the advice of appropriately qualified individuals to advise him as to how to minimise the risks. Findings and corrective actions must be documented and corrective	Written confirmation to be submitted to the inspectorate by 30 June 2010	Risk assessment of locations submitted	The PR has submitted evidence of a risk assessment carried out on the 6 May 2010, of the areas where patients' records are stored. The risk assessment identified no additional control measures are necessary and the risk rating was graded as 'low' No further action is required

		actions implemented			
Storage of gametes and embryos Cryopreservation dewars are stored over several locations including the ensuite to a consulting room and in a room next to the reception area.	Licence condition T17	In compliance with recommendations in the last report, the PR should undertake an assessment of the risks of the areas where Cryopreservation dewars are stored. It is recommended that the PR seeks the advice of appropriately qualified individuals to advise him as to how to minimise the risks. Findings and corrective actions must be documented and corrective actions implemented.	Written confirmation to be submitted to the inspectorate by 30 June 2010	Local risk management policy for safe handling and use of Liquid Nitrogen, Guidance for safe handling, storage, transportation and emergency procedures. Risk assessment submitted	The PR has submitted evidence in the form of a policy and procedure for safe handling and use of liquid nitrogen and a general risk assessment of the centre carried out on the 6 May 2010. A Control of Substance Hazardous to Health and Safety (COSHH) risk assessment carried out in March 2009 and again in March 2010, summarised the control that have been put into place and states subject to the controls being applied, employee exposure to liquid nitrogen is adequately controlled. The lead inspector considers this response to be sufficient.
Counselling The SAQ stated that although the counsellor was not accredited under the British Infertility Counselling Association (BICA), she could provide evidence of working towards accreditation	Licence condition T15(a)	Evidence should be available to demonstrate that the counsellor is currently working towards BICA accreditation and will send a certificate verifying that she is working towards accreditation.	Written confirmation that accreditation has been achieved to be submitted to the inspectorate by 30 September 2010	Acknowledged	On the 24 March 2010 an e-mail was received confirming that the counsellor was awaiting a letter verifying that she was working towards accreditation, and would forward this to the Executive once received.

through the BICA accreditation scheme.					On 29 April 2010 an e-mail was received which contained evidence to demonstrate that the counsellor is registered with BICA for accreditation registration. She has stated that she hopes to achieve accreditation by August 2010. The lead inspector considers this response to be sufficient.
Record keeping and document control The SQA states that the centre did not have an SOP in place for submitting data to the HFEA in compliance with the requirements of Directions 0005	Direction 0005 Licence condition T33 (b)	The PR should ensure that there is an SOP in place for submitting data to the HFEA in compliance with the requirements of Directions 0005 Prior to the inspection the inspection team was informed, by registry that in the last year there have been only 3 errors recorded from this centre.		Acknowledged	30 March 2010 An e-mail was received from the centre with a copy of an SOP for submitting data to the HFEA in compliance with the requirements of Directions 0005, was received. The centre would appear to be compliant with licence condition T33 (b). No further action is required at this time.
Record keeping and document control The SAQ states that the centre has not	HF&E Act 1990 (as amended) Schedule 3A (10)	At the time of completing the SAQ the PR was aware of this non compliance, and had completed the pre	An audit plan or schedule should be submitted to the inspectorate	Audit schedule including quality and	The PR has submitted evidence in the form of a audit schedule, key performance indicators and

established quality indicators relevant to submission of data to the HFEA or audited against compliance with the approved protocols, the regulatory requirements and quality indicators in the last two years	2006/86/EC, Appendix 1 F and T35 and T36.	inspection SAQ accordingly The PR must ensure that audits of all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence are undertaken in compliance with protocols, regulatory requirements and quality indicators. The centre must ensure that these are conducted independently at least every two years. Findings and corrective actions must be documented.	by 17 May 2010	key performance indicators. Medical records audit tool for 2010 submitted	audit tool for record keeping, to demonstrate that all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence are undertaken are audited annually if not monthly. The lead inspector considers this response to be sufficient.
The centres patient information leaflet – 'Parental responsibility', did not reflect the new legal parenthood provisions which came into effect on the April 2009	HF&E Act 2008 sections 36, 37 and 38 and section 43, 44 and 45 Licence condition T63, T 64 & T65 & T15	The PR needs to review the centres leaflet to ensure that it reflects the new legal parenthood provisions (T63, T64 & T65). The PR should also assure himself that all staff fully understands the new legal parenthood provisions (T15).	Written confirmation to be submitted to the inspectorate by 4 June 2010	Pt information leaflet - Legal parenthood / parental responsibility. HFEA discussion checklist submitted via email 27 May 2010	Following a review of the patient information leaflet – 'Parental responsibility' on the 27 May 2010, the inspectorate asked the centre to review the document again, as the information within the leaflet was still unclear to the reader. On 14 June 2010, an e-mail was received from the centre with an updated copy of the

					patient information leaflet – ‘Parental responsibility’ v5. Following the submission this version of the document, the centre would appear to be compliant with licence condition T63, T 64 & T65 & T15 No further action is required at this time.

Additional Information from the Person Responsible
I would like to thank the inspectors for the professional and courteous manner who attended this unannounced inspection, but as I am sure that you are aware on the day we had none of our senior members of staff initially present, two of whom did come in on days of leave. Maybe the license panel would like to bear this in mind as I feel if more senior members of staff are present at inspections the majority of issues identified on the day can be explained or amended as required. However myself and team found this inspection process very thought provoking and productive.

HFEA Executive Licensing Panel Meeting

15 July 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – item 4

Woking Nuffield (0144) Unannounced Interim Report

Members of the Panel:	
Peter Thompson, Director of Strategy & Information (Chair) Mark Bennett, Director of Finance & Facilities Carmel Dodson-Brown, Head of Clinical Governance and Patient Safety	Committee Administrator: Joanne McAlpine

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

The following papers were considered by the Panel:

- Papers for Executive Licensing Panel (45 pages)
- Supplementary Bundle in accordance with Direction 0008

The Panel also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings of the Authority's Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Direction 0008 (where relevant), and any other relevant Directions issued by the Authority;
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- Indicative applications guidance on the time period for which licences should be granted approved by the Authority on 21 October 2009
- Indicative sanctions guidance approved by the Authority on 18 March 2009
- Licence application and any relevant documentation

1. The Panel noted that this report is for an unannounced interim inspection and considered the papers that consisted of an inspection report and previous licence committee minutes.

2. The Panel noted that the centre's inspection was on 18 March 2010 for five hours.

3. The Panel noted that this was a randomly selected unannounced interim inspection of the centre; a small number of centres are sampled to provide greater quality assurance.

4. The Panel noted that there were a few areas of non-compliance identified regarding witnessing of patient records and updating of the multiple births strategy.

5. The Panel noted from the report that the cryopreservation dewars are stored at several locations. The Panel urged the PR to consider the risks associated with and take mitigating actions.

6. The Panel noted the inspectorate's recommendation that the licence should continue without any additional conditions.

<u>The Panel's Decision</u>

7. The Panel agreed to the continuation of the centre's licence with no additional conditions, and endorsed the inspectorate's recommendations and associated timescales.

Signed..Peter Thompson.....Date..26/07/10.
Peter Thompson (Chair)