

Executive Licensing Panel - minutes

Centre 0100 (Bourn Hall Clinic)

Renewal Inspection Executive Update

Tuesday, 21 April 2020

HFEA Teleconference Meeting

Panel members	Richard Sydee (Chair) Kathleen Sarsfield Watson Niamh Marren	Director of Finance and Resources Communications Manager Regulatory Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing Manager

Declarations of interest

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

The panel had before it:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Background

- 1.1. The panel noted that Bourn Hall Clinic is located on the outskirts of Cambridge and has held a treatment and storage licence with the HFEA since 1992. The centre provides a full range of fertility services including embryo testing. Other licensed activities at the centre include storage of gametes and embryos.
- 1.2. The panel noted that, following a renewal inspection in September 2019, recommendations were made in relation to four major and seven 'other' areas of non-compliance.
- 1.3. The panel noted that the renewal inspection report was considered by the Executive Licensing Panel (ELP) on 12 November 2019. At this meeting, the ELP 'noted that evaluations of corrective actions and audits, with regards to many of the non-compliances identified, were due for receipt by 18 December 2019 and 18 March 2020. The panel expected the centre to make significant progression in rectifying the non-compliances, requesting that a progress report is submitted to the Executive Licensing Panel (ELP) in 2020.'
- 1.4. The panel noted that the ongoing monitoring of post inspection actions, by the centre's inspector, has enabled a progress update to be provided for consideration.
- 1.5. The panel noted that the Person Responsible (PR) provided information in relation to the actions that were due for completion by 18 December 2019 and 18 March 2020. Eight out of eleven recommendations have been fully implemented and three audits of practice to evaluate the effectiveness of corrective actions remain to be completed.
- 1.6. The panel noted that, in March 2020, the PRs of the Bourn Hall group centres suspended fertility treatments across all their clinics in accordance with HFEA requirements and professional body guidance issued in response to the Covid-19 pandemic. In view of this the centre's inspector will liaise with the PR to consider an appropriate timescale for completing the audits taking into account the period of time where treatments are suspended as a result of the Covid-19 pandemic.
- 1.7. The panel noted that the Bourn Hall group's progress with implementing these recommendations was also followed up by the centre's inspector during the interim inspection of centre 0325 (Bourn Hall Clinic Norwich) in January 2020 and the renewal inspection of centre 0363 (Bourn Hall Clinic Wickford) in February 2020. The reports of those inspections will also be considered by ELP, at the current meeting.
- 1.8. The panel noted that progress in completing the remaining recommendation will continue to be monitored by the centre's inspector.

2. Consideration of Progress Update

- 2.1. The panel considered the papers, which included an executive update, inspection report, update on recommendations made in the report and licensing minutes for the last five years.
- 2.2. The panel noted the update on the implementation of the recommendations, made in the renewal inspection report.

3. Decision

- 3.1. The panel agreed that appropriate progress had been made by the centre to rectify the non-compliances identified at the renewal inspection, hoping the PR will continue working with the inspectorate to ensure the outstanding audits are submitted within an appropriate timescale.
- 3.2. The panel agreed that the centre's treatment (including embryo testing) and storage licence should be continued.

4. Chair's signature

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

Signature

A handwritten signature in black ink, appearing to read 'Richard Sydee', written on a light-colored background.

Name

Richard Sydee

Date

29 April 2020

**Executive Update for Executive Licensing Panel
21 April 2020**

Centre number	0100
Centre name	Bourn Hall Clinic
Person Responsible	Dr Michael Macnamee

Progress report following up on recommended actions relating to non-compliances identified at renewal inspection, as requested by Executive Licensing Panel

1. The Executive Licensing Panel met on the 12 November 2019 to consider the centre's application to renew their treatment (including embryo testing) and storage licence. The minutes recorded the following:

'**2.5** The panel noted that evaluations of corrective actions and audits, with regards to many of the non-compliances identified, were due for receipt by 18 December 2019 and 18 March 2020. The panel expected the centre to make significant progression in rectifying the non-compliances, requesting that a progress report is submitted to the Executive Licensing Panel (ELP) in 2020.'
2. The ongoing monitoring of post inspection actions by the centre's inspector has enabled a progress update to be provided in the table below. The actions that have been taken are noted in the 'Executive Review' column in [blue](#) text.
3. The PR provided information in relation to the actions that were due for completion by 18 December 2019 and 18 March 2020. Eight out of 11 recommendations have been fully implemented and three audits of practice to evaluate the effectiveness of corrective actions remain to be completed. In March 2020 the PRs of the Bourn Hall group centres suspended fertility treatments across all their clinics in accordance with HFEA requirements and professional body guidance issued in response to the COVID-19 pandemic. In view of this the centre's inspector will liaise with the PR to consider an appropriate timescale for completing the audits taking into account the period of time where treatments are suspended as a result of the COVID-19 pandemic.
4. The Bourn Hall group's progress with implementing these recommendations was also followed up by the centre's inspector during the interim inspection of centre 0325 (Bourn Hall Norwich) in January 2020 and the renewal inspection of centre 0363 (Bourn Hall Wickford) in February 2020. The reports of those inspections are also being considered by ELP together with this progress update.
5. Progress in completing the remaining recommendations will continue to be monitored by the centre's inspector.

Karen Conyers
Inspector

▶ **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 to a 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.

A major area of non-compliance is identified in the report by a statement that an area of practice is partially compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
<p>1. Donor screening As part of the centre's review of the group's practices in relation to the recruitment, selection and assessment of gamete and embryo donors the group's Medical Director has updated SOPs, incorporating the most recent professional body guidelines released in June 2019. The inspection team noted that these new SOPs which are not yet fully implemented do not capture all aspects of the professional body guidance such as asking sperm donors</p>	<p>The PR should ensure that the group's SOPs for donor recruitment, assessment, selection and screening procedures include all regulatory requirements and professional body guidance.</p> <p>The PR should review the group's SOPs to ensure that they include all regulatory requirements and professional body guidance and consider what actions can be taken to address the concerns regarding the number of documents that are not clearly</p>	<p>We will review all SOPs and Work Instructions relating to screening of donors with a view to simplifying the information so there are clear instructions for all staff and to ensure they include all regulatory requirements and professional body guidance. We will provide a summary report of the review by 18 Dec 2019.</p> <p>Any corrective actions will be implemented by 18 March 2020.</p>	<p>The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation.</p> <p>The PR has confirmed that all SOPs and 'Work Instructions' related to screening of donors will be reviewed to ensure that these include all regulatory requirements and address the concerns raised by the inspection team. The PR has confirmed that a summary of the findings of this review will be provided to the centre's</p>

<p>about their health and recent travel at each donation and the ensuring the appropriate frequency of some of the screening tests.</p> <p>The inspection team noted that there are a number of work instructions in development and whilst most of the required information was eventually found within these documents it was necessary to look at several of them to be able to gain the information needed. Further details as to the inspection team's concerns are set out in the body of the report.</p> <p>UK guidelines for the medical and laboratory procurement and use of sperm, oocyte and embryo donors' (2019).</p> <p>SLC T33(b)</p> <p><i>This has been graded as a major non-compliance as issues have continued to be identified in this area of practice since 2015; 0100</i></p>	<p>cross-referenced. A summary report of the findings of this review, including timescales for implementation of corrective actions identified should be provided to the centre's inspector by 18 December 2019.</p> <p>It is expected that the implementation of any corrective actions required are completed by 18 March 2020.</p> <p>Three months after the review the PR should audit practice to ensure any corrective actions taken have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 18 June 2020.</p>	<p>Three months after the review an audit will be conducted, a summary report will be provided by 18 June 2020.</p>	<p>inspector by 18 December 2019, and that any corrective actions required will be implemented by 18 March 2020.</p> <p>The findings of an audit to evaluate the effectiveness of any corrective actions taken in this area of practice due by 18 June 2020 is awaited.</p> <p>Further action is required.</p> <p>Progress update March 2020: The PR provided a summary of the findings of his review and an update on progress with implementing this recommendation in December 2019.</p> <p>Progress with these actions was reviewed by the centre's inspector during the recent inspections of two other centres in the group: 0325 in January 2020 and 0363 in February 2020. The reports of those inspections are also being considered by ELP</p>
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<p>(September 2015), 0325 (November 2018) and 0188 (May 2015 and May 2019).</p>			<p>together with this progress update.</p> <p>On 18 March 2020 the PR confirmed that relevant SOPs and related documents had been updated and issued.</p> <p>An audit to evaluate the effectiveness of any corrective actions taken in this area of practice was due by 18 June 2020. However, in view of the current suspension of treatment services due to the COVID-19 pandemic the centre's inspector will liaise with the PR to consider an appropriate timescale for submitting this audit.</p> <p>Further action is required.</p>
<p>2. Medicines management The following non-compliances related to the management of controlled drugs were identified during the inspection.</p> <ul style="list-style-type: none"> • During a procedure observed by the inspection team a box 	<p>The PR should ensure that the centre's practices for the management, use and safe storage of controlled drugs are compliant with regulatory requirements and best practice guidance.</p>	<p>We will review our practices and procedures relating to the use of controlled drugs. A summary report of this review will be provided by 18 December 2019.</p> <p>We have assessed the suitability of the location of the</p>	<p>The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation.</p> <p>The Executive notes that the centre have relocated the cupboard where controlled</p>

<p>of fentanyl (a Schedule 2 controlled drug) containing several ampoules was stored in an unlocked cupboard in theatre together with other non-controlled drugs.</p> <ul style="list-style-type: none"> • During a procedure observed by the inspection team, the controlled drugs register was completed by the nurse performing the sedation. The inspector noted that the nurse discarded the unused portion of the controlled drug, but this was not witnessed by the doctor who subsequently signed the register as having witnessed that discard. <p>The Misuse of Drugs (Safe Custody) Regulations (1973) section 5.</p> <p>Safer Management of Controlled Drugs; A guide to good practice in secondary</p>	<p>The PR should review the centre's practices and procedures relating to the use and safe storage of controlled drugs and investigate why the issues identified by the inspection team have occurred. The PR should also risk assess the suitability of the location of the cupboard where controlled drugs are stored. A summary report of the findings of this review, including timescales for implementation of corrective actions identified should be provided to the centre's inspector by 18 December 2019.</p> <p>Three months after the review the PR should audit practice to ensure any corrective actions taken have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 18 March 2020.</p>	<p>cupboard where the Controlled Drugs were stored. The cupboard has been moved to a secure area in the theatre complex.</p> <p>Three months after the review an audit will be conducted and a summary report provided by 18 March 2020.</p>	<p>drugs are stored to a secure area in the theatre complex.</p> <p>The findings of the review due by 18 December 2019, and of the audit to evaluate the effectiveness of any corrective actions taken in this area of practice due by 18 March 2020 are awaited.</p> <p>Further action is required.</p> <p>Progress update March 2020: The PR provided a summary of the findings of his review and investigation in December 2019. An audit to evaluate the effectiveness of corrective actions was submitted on 18 March 2020. No issues were identified.</p> <p>No further action is required.</p>
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<p>care (England) (2007) section 4.5.2, 4.5.4 and 4.11.1.3.</p>			
<p>3. Prescription of intralipid 'off label' During the inspection three records of patient's consent to treatment with intralipid treatment were reviewed and the following were noted. In one record the patient's signature was missing, in a second the consultant's signature was missing and in the third the patient's details and the staff witnessing signature was missing.</p> <p>The inspection team also noted that in one record the rationale and/or clinical indication for prescribing and treating patients with intralipids were documented as 'patient choice' and nothing was noted in the other two records. Whilst there was a record of the clinician's discussion on the use of intralipids with the patients there was no clear documentation of the rationale</p>	<p>The PR should ensure compliance with guidance for the prescription of intralipid 'off label'.</p> <p>The PR should review the centre's processes for the documentation of the rationale for the prescription of intralipids 'off label' and the recording of the consent of the patient for this treatment. A summary report of the findings of this review, including timescales for implementation of corrective actions identified should be provided to the centre's inspector by 18 December 2019.</p> <p>Three months after the review the PR should audit practice to ensure any corrective actions taken have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the</p>	<p>We will review our process for documenting the rationale for the prescription of intralipids 'off label' and the recording of the consent of the patient for this treatment.</p> <p>A summary report of the findings of this review will be provided by 18 December 2019.</p> <p>Three months after the review we will conduct an audit and a summary report will be provided by 18 March 2020.</p>	<p>The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation.</p> <p>The findings of the review due by 18 December 2019, and of the audit to evaluate the effectiveness of any corrective actions taken in this area of practice due by 18 March 2020 are awaited.</p> <p>Further action is required.</p> <p>Progress update March 2020: The PR provided a summary of the findings of his review and investigation in December 2019. As the timescales for implementations of some actions was March 2020 the centre's inspector agreed that the audit to evaluate the effectiveness of corrective actions should be provided by 18 June 2020. However, in</p>

<p>for prescribing this 'off label' use of intralipids, and patient choice is not a clinical indication for its use.</p> <p>SLC T2 and Clinic Focus July 2015.</p> <p><i>This has been graded as a major non-compliance as issues have continued to be identified in this area of practice since 2015; 0100 (September 2015), 0325 (November 2018) and 0188 (May 2019).</i></p>	<p>centre's inspector by 18 March 2020.</p>		<p>view of the current suspension of treatment services due to the COVID-19 pandemic the centre's inspector will liaise with the PR to consider an appropriate timescale for submitting this audit.</p> <p>Further action is required.</p>
<p>4. CE marking</p> <p>The centre occasionally uses a product to activate sperm prior to ICSI treatment. This product is CE marked as an 'in vitro diagnostic' device but is being used as a medical device which is 'off label' i.e. for a purpose for which it was not appropriately classified.</p> <p>Where a centre is using a product as a medical device for which there is no CE marked alternative available, it</p>	<p>The PR should ensure that patients are provided with comprehensive information regarding the use of a product CE marked as an 'in vitro diagnostic' device being used as a medical device which is 'off label' i.e. for a purpose for which it was not appropriately classified.</p> <p>If the PR considers that there is no CE marked medical device available, or no other process using CE marked</p>	<p>We will ensure information relating to the use of this product is provided to patients and their consent to its use will be obtained. Copies of these documents will be provided by 18 December 2019.</p>	<p>The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation.</p> <p>The PR has confirmed that patients will be provided information about the product noted in the report, and their consent to its use will be obtained.</p> <p>Copies of the patient information and consent forms</p>

<p>is expected that appropriate information is provided to patients regarding the use of a non-CE marked product as a medical device (such as any possible risks associated with the use of this item) prior to use in treatment.</p> <p>SLC T30 and CoP 26.5.</p>	<p>medical devices can be used to activate sperm for ICSI, then he should ensure that patients are informed that a product not appropriately classified as a CE marked medical device is to be used.</p> <p>The PR should devise relevant patient information and consent forms relating to the use of this product and provide a copy of the documents to the centre's inspector by 18 December 2019.</p>		<p>relating to the use of the product due by 18 December 2019 are awaited.</p> <p>Further action is required.</p> <p>Progress update March 2020: The PR provided copies of patient information and consent forms in December 2019. Following further feedback from the centre's inspector, revised consent forms were provided in January 2020.</p> <p>No further action is required.</p>
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 **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.

An 'other' area of non-compliance is identified in the report by a statement that an area of practice is 'broadly' compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
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<p>5. Infection control</p> <p>The inspection team noted that the flooring of the central corridor from the theatre area does not have any coving up the wall, the sealant was damaged in places and sections between theatre and the recovery area are carpeted</p> <p>Health Building Note 00-09: Infection control in the built environment (2013), sections 3.109, 3.110 and 3.115.</p> <p>CoP 25.19 and 25.20.</p>	<p>The PR should ensure compliance with infection prevention and control regulations.</p> <p>When responding to this report, the PR should provide an action plan with timeframes for implementation to address infection control observations described in this report.</p> <p>It is expected that the implementation of any corrective actions required have been completed by 18 March 2020.</p>	<p>Our premises and processes for Infection Control have been inspected by external agencies (including the HFEA at Interim and Renewal inspections) and are subject to regular internal audit. Where issues have been identified the necessary corrective actions have been taken. It is surprising that none of these previous inspections have raised the issues highlighted here. These will be addressed as part of our repairs and maintenance schedule for 2020. Given the scale of the requested alterations and the use of solvent based adhesives the timing of the works will have to be considered carefully.</p>	<p>The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation.</p> <p>The PR has confirmed that the issues highlighted by the inspection team will be addressed as part of the centre's 2020 'repairs and maintenance' schedule.</p> <p>The Executive acknowledges the PR's concerns regarding the use of solvent based adhesives within the centre and requests that an update on the proposed timeframes for implementation is provided by 18 March 2020.</p> <p>Further action is required.</p> <p>Progress update March 2020: <i>In March 2020 the PR confirmed that 'We have reviewed the costs, the potential impact on patients health (in particular the use of solvents) and potential risks if</i></p>
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			<p><i>the work was not completed. As a result we have decided to complete this work by the end of 2020.'</i></p> <p>The centre's inspector will continue to liaise with the centre to ensure implementation of this action by the end of 2020.</p> <p>No further action is required at this time.</p>
<p>6. Third party agreements During the inspection, three third party agreements currently in place at the centre were reviewed. These agreements did not include a condition that the third party, satellite or transport centre will meet the requirements of the relevant licence conditions and the guidance set out in the HFEA Code of Practice.</p> <p>One of the agreements with an overseas donor sperm bank included a statement that the donors are compensated '45 euros irrespective of actual</p>	<p>The PR should ensure that all agreements with third parties include a condition that the third party, satellite or transport centre will meet the requirements of the relevant licence conditions and the guidance set out in the HFEA Code of Practice.</p> <p>A plan for the completion of this action should be provided to the centre's inspector by 18 December 2019.</p> <p>The PR should investigate why the centre's processes for assessing and auditing third</p>	<p>We will review all third party agreements to ensure the requirements of the relevant licence conditions and the guidance set out in the HFEA Code of Practice are included. A plan for the completion of this will be provided by 18 Dec 2019.</p> <p>An investigation will be completed to determine why the information relating to overseas donor compensation was not identified during the review of the agreements and a summary of the findings will</p>	<p>The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation.</p> <p>The PR has confirmed that he will provide a plan for the completion of the centre's review of all third party agreements and a summary of the findings of the investigation by 18 December 2019.</p> <p>The Executive notes that the all overseas sperm banks, including those TCS which the</p>

<p>loss of expenses' which would not be compliant with HFEA requirements for compensation of overseas donors.</p> <p>SLC T116. General Direction 0001.</p>	<p>parties did not identify the non-compliance with compensation arrangements noted by the inspection team. A summary of the findings of the investigation including whether any further issues have been identified and corrective actions with timescales for implementation should be provided to the centre's inspector by 18 December 2019.</p>	<p>be provided by 18 December 2019.</p> <p>The donor sperm bank was not included on our audit schedule, therefore this could not have been identified during that process. All overseas sperm banks are now included on the audit schedule and compensation information will be reviewed during those audits.</p>	<p>centres in the Bourn Hall group have an ITE, are now on the centre's audit schedule. Reports of those audits will be reviewed at future inspections in the group.</p> <p>Further action is required.</p> <p>Progress update March 2020: In December 2019 the PR confirmed that all of the group's third party agreements would be reviewed and updated by December 2020. Progress with this was reviewed by the centre's inspector during the inspection of centre 0363 in February 2020. The third party agreements for centre 0363 had been updated.</p> <p>The centre's inspector will continue to liaise with the group's 'Head of Quality Assurance' to ensure implementation of this action by the end of 2020. Progress in completing this will be followed up at the next</p>
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			<p>inspection of a centre in the group.</p> <p>No further action is required at this time.</p>
<p>7. Adverse incidents The centre had not reported one adverse incident relating to the quality and safety of gametes and embryos to the HFEA.</p> <p>SLC T118.</p> <p><i>This non-compliance has been graded as 'other' because the inspection team accepts that incident reporting and investigation at the centre is thorough and generally compliant.</i></p>	<p>The PR should ensure that all HFEA reportable adverse incidents and near misses are reported to the Authority.</p> <p>The PR should review all adverse incidents in the centre's incident register since the time of the last inspection in 2017 and report retrospectively to the HFEA any which fulfil the criteria of adverse incidents or near misses. This recommendation should be implemented by 18 December 2019.</p>	<p>We will review all adverse incidents since the time of the last inspection in 2017 and report any relevant adverse incidents retrospectively by 18 December 2019</p>	<p>The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation.</p> <p>The PR has confirmed that he will review all adverse incidents in the centre's incident register since the time of the last inspection in 2017 and report retrospectively to the HFEA any which fulfil the criteria of adverse incidents or near misses by 18 December 2019.</p> <p>Further action is required.</p> <p>Progress update March 2020: In December 2019 the PR confirmed that incidents reported by all centres in the group since 2017 had been reviewed and five incidents</p>

			<p>that should have been reported to the HFEA were identified. These have been retrospectively reported to the HFEA. The executive is satisfied that the incidents were investigated by the centre and appropriate actions taken as a result.</p> <p>No further action is required.</p>
<p>8. Confidentiality & privacy The inspection team had some concerns for the confidentiality and privacy of patients when they are in the recovery area. The curtains shared between adjacent bays did not close fully so it is possible to see patients in another bay. In addition, despite the radio being played in the background, the inspection team could clearly hear conversations taking place through the curtains.</p> <p>CoP 25.9 and 25.14.</p>	<p>The PR should ensure that he provides for the privacy, dignity and respect of all prospective and current patients and donors.</p> <p>The PR should provide an action plan with timeframes for implementation to address the concerns noted during the inspection by 18 December 2019.</p>	<p>Our Family and Friends test score is over 95% positive. Our patient feedback supports our care for their privacy and dignity.</p> <p>As this is a Nurse controlled recovery area it is good practice to have the curtains open whenever possible to enable the monitoring and observation of patients.</p> <p>The issue of inadequate curtaining to each of the bays will be addressed and an action plan for implementation will be provided by 18 December 2019.</p>	<p>The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation.</p> <p>The PR has confirmed that he will take actions to address the concerns noted during the inspection and provide an action plan with timeframes for completion by 18 December 2019.</p> <p>The Executive notes that a private room is used wherever practicable to carry out any sensitive discussions with patients.</p>

		<p>Where practicable all sensitive communication with patients in recovery are held in a separate room where conversations cannot be overheard.</p> <p>Given the nature of the recovery area general conversation between patients may be overheard.</p>	<p>Further action is required.</p> <p>Progress update March 2020: In December 2019 the PR confirmed that further actions had been taken to address the concerns noted on inspection, including reminding staff to ensure curtains are fully closed, and that wherever practicable all sensitive communication with patients are held in a separate room.</p> <p>No further action is required.</p>
<p>9. Consent to disclosure to researchers</p> <p>One discrepancy was found between completed patient and partner disclosure consents and the related consent data submitted for inclusion on the register in 10 patient files audited. The inspection team noted that the discrepancy was such that could pose a risk that the</p>	<p>The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register.</p> <p>The PR should confirm that the incorrect submissions identified have been corrected when responding to this report.</p>	<p>We have corrected the submissions identified.</p> <p>We will review our procedures to ensure the disclosure consent information supplied to the authority accurately reflects that given and recorded on the patients consent form. A summary of the findings will be provided by 18 December 2019.</p>	<p>The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation.</p> <p>The PR has confirmed that the incorrect submissions have been corrected and that he will review procedures to ensure that the disclosure consent information supplied to the Authority is accurate.</p>

<p>HFEA may inadvertently release patient identifying information to researchers without the patients consent.</p> <p>CH(10)05 and General Direction 0005.</p> <p><i>NB. The Centre's designated HFEA form returnee has been provided with the relevant patient and partner numbers so that the form data can be reviewed and corrected.</i></p>	<p>The PR should review the centre's procedures to ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on patient's consent forms. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 18 December 2019.</p> <p>Within six months, the centre should carry out an audit of records to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 18 June 2020.</p>	<p>We will carry out an audit of records and provide a summary report by 18 June 2020.</p>	<p>The findings of the review due by 18 December 2019, and an audit to evaluate the effectiveness of any corrective actions taken in this area of practice due by 18 June 2020 are awaited.</p> <p>Further action is required.</p> <p>Progress update March 2020: The PR provided a summary of the findings of his review and investigation in December 2019.</p> <p>An audit to evaluate the effectiveness of any corrective actions taken in this area of practice was due by 18 June 2020. However, in view of the current suspension of treatment services due to the COVID-19 pandemic the centre's inspector will liaise with the PR to consider an appropriate timescale for submitting this audit.</p> <p>Further action is required.</p>
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<p>10. Record keeping and document control A number of issues in relation to record keeping and document control were noted by the inspection team as detailed in the body of the report.</p> <p>SLC T46(e), SLC T46(f), SLC T46(c) and SLC T34.</p>	<p>The PR should ensure that proper records are maintained and that only current versions of documents are in use.</p> <p>The PR should review the issues noted in this report relating to record keeping and document control with a view to considering why these have arisen. A summary report of the findings of this review, including timescales for implementation of corrective actions identified should be provided to the centre's inspector by 18 December 2019.</p>	<p>We will review the issues noted in this report relating to record keeping and document control and provide a summary report by 18 December 2019.</p>	<p>The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation.</p> <p>The PR has confirmed that he will review the issues noted in this report relating to record keeping and document control and provide a summary of the findings of this review by 18 December 2019.</p> <p>Further action is required.</p> <p>Progress update March 2020: The PR provided a summary of the findings of his review and investigation in December 2019.</p> <p>No further action is required.</p>
<p>11. Fees Fees payable to the HFEA have not always been paid within the required timeframe.</p> <p>SLC T9d and CH (10)02).</p>	<p>The PR should ensure fees payable to the HFEA are made within the required timeframe.</p>	<p>The PR has secured agreement with the Bourn Hall finance department that future HFEA invoices are prioritised.</p>	<p>The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation.</p>

<p><i>This is noted as an issue across all centres in the group.</i></p>	<p>The PR should take appropriate action to ensure that all HFEA invoices are paid within the timescales specified by the Authority and advise the centre's inspector of these actions by 18 December 2019.</p>		<p>The PR has confirmed that future HFEA invoices are prioritised. This will be monitored by the centre's inspector and reviewed at the time of the next inspection of a centre in the group in late 2019/early 2020.</p> <p>No further action is required.</p> <p>Progress update March 2020: Progress with this was followed up by the centre's inspector during the recent inspections of two other centres in the group: 0325 in January 2020 and 0363 in February 2020. The reports of those inspection are also being considered by ELP together with this progress update.</p> <p>The executive notes that since January 2020 no further risk based assessment tool alerts in relation to finance have been issued to any of the centres in the Bourn Hall</p>
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			<p>group. The centre's inspector will continue to liaise with the PRs of the Bourn Hall group to ensure that HFEA invoices are paid within the timescales specified by the Authority.</p> <p>No further action is required at this time.</p>
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