

Incident Investigation

0109

**Kings College Assisted
Conception Unit
25th June 2010**

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Executive Summary

The Compliance and Enforcement Policy (2008) states that Grade A incidents should be investigated by the centre and the Clinical Governance team. In order to reduce duplication the centre root cause analysis report has been reviewed and agreed by the Head of Clinical Governance and the Executive summary provides a brief overview of the incident and recommendations for the centre. The Incident Investigation report is being submitted to the Licence Committee as an Appendix to the Interim inspection report.

In October 2009 staff at the centre identified that there had been an unexplained fall in pregnancy rates across all age groups except for intra uterine insemination (IUI) treatments which were unaffected. This coincided with the start of significant building work on the floor below the unit. Although the air quality in the laboratory remained consistently within regulatory requirements the PR and consultant embryologist took the decision to stop egg collection, embryology and embryo transfer in the unit. The PR immediately informed the HFEA that they were invoking their contingency arrangement with a neighbouring HFEA licensed assisted conception unit at Guy's & St Thomas' Hospital NHS Trust (centre 0102). An incident report was then filed with the HFEA and a Management Review was held between the Head of Clinical Governance and the centre inspector. The Person Responsible submitted a detailed incident report in October 2010 and the decision was taken to monitor the situation as the risk to patients and embryo's was considered Low as activity had been transferred.

Between October 2009 and June 2010 the Head of Clinical Governance and the centre Inspector monitored the centre's progress. During this time the centre received four written complaints and three complaints were managed by the Trust Patient and Liaison team. The HFEA received one patient complaint/enquiry in December 2009 and a second complaint was received in April 2010. The second complainant was also part of an adverse incident reported by the centre in December 2010 and both complainants have requested a copy of the Investigation report once it has been to Licence Committee.

An Interim inspection was scheduled in 2010 and it coincided with the centre resuming IVF activity therefore the centre was asked to submit a root cause analysis report to be considered with the inspection report. (see below) The centre has undertaken detailed investigations to determine the cause of the fall in pregnancy rates and has concluded that the refurbishment work taking place within the building had a detrimental affect in the laboratory. The building work is complete and the centre believe they are now ready to resume a full programme of treatments.

It has been agreed that the centre will provide weekly updates to the centre inspector regarding pregnancy success rates.

Recommendation

Should the pregnancy success rates fail to achieve national average success rates the Licence Committee will be asked to make a decision regarding the continuation of Licensed activity.

Incident Investigation Report

Summary Incident Description & Consequences

Building work beneath the ACU began on 15th September 2009. The work initially consisted of the stripping out of 'soft' structures but soon moved on to the removal of internal walls with pneumatic drills.

The noise and vibration on the ACU increased such that during the week of 5 – 9 October the builders were approached and asked to stop earlier than their customary 4pm to allow ICSI to be performed.

The anti vibration table on which the ICSI equipment is placed could not cope with the vibrations being caused by the building work making ICSI impossible to perform. The builders did stop early on Friday 9th October but when asked to stop early on Monday 12th October they refused to do so.

An internal review of the outcome of patients who received treatment from 15th September performed on Monday 12th October demonstrated a poor pregnancy rate.

The contingency plan agreed with Guy's and St Thomas' NHS Foundation Trust was activated and patients were transferred there for treatment.

Incident type:	Unit closure due to drop in CPR possibly due to nearby building works and laboratory contamination
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Specialty:	Assisted Conception Unit (ACU) King's College Hospital
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Effect on patient:	Treatment cancellations/delays/possibility of poor cycle outcome
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Severity level:	Grade A
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Scope and Level of Investigation

Root cause analysis, HFEA visit x 2, review of laboratory conditions

Involvement and support of Patient and Relatives

- Affected patients communicated with by PR letter.
- Multiple discussions held with a number of patients by nurses explaining the reasons and consequences of their delayed treatment.

Chronology of events – see attached table

Notable Practice

- Affected patients informed
- HFEA informed by telephone immediately after decision made to stop programme
- Adverse incident report submitted in writing to HFEA by PR (attached)
- Women's division and Chief Executive of Trust informed and involved in emergency planning
- Free cycle offered to all patients identified to have had treatment during the affected period
- Emergency 3rd party agreement with Guy's Hospital ACU actioned and all egg collections, embryo culture, embryo transfers and freezes as well as surgical sperm collections transferred to Guy's.
- King's staff sent to Guy's to provide support with the extra workload: 1 nurse a day on King's egg collection days and 2 embryologists a day every day.

Care and Service Delivery Problems (prioritised)

- Unexplained drop in pregnancy success rates following the commencement of building work in the building occupied by the ACU.
- Unexplained impact on the King's patients when compared to St Helier patient results

Contributory Factors

- Failure of South London and Maudsley NHS Trust to communicate or provide sufficient information to King's or the ACU regarding the nature and scale of works to be carried out. **Communication**
- No risk assessment carried out on the potential impact of the building works to other services in Mapother House **Management**
- Insufficient air filtration system in the laboratory **Working Environment**
- Timescale of works and successive delays **Working Environment**
- Insufficient air filtration system leading to potential contamination

Working Environment

Investigation techniques

- Correlation analysis with different batches of media and disposables did not reveal any specific correlation, except for egg collection needles
- HFEA research about other units using the same batch of egg collection needles did not reveal any strong correlation between the batch used at King's and CPR. Batch of needles returned to supplier not to be used in the future.
- Analysis of the contents of the main filters was not carried out as the supplier could only identify the type of particle i.e. lead, carbon not the number per million and it was not cost effective to do this. Furthermore, this would not have told us the type of VOC in the air and whether its density in the air had increased during the time of the incident
- Discussions have been had with _____ from _____ and a decision made to test final laboratory conditions by growing mouse embryos in the lab
- Discussions held with the company that installed and services our current air filtration system (Artic Building Services) and upgrading of the current system installed with same particle size filtration as the CODA filters.
- Discussions took place with Exeter ACU but it was decided not to use the VOC meter for several reasons: no control value prior and during the incident, cost and time to arrange the training of one of the embryologists. The reliability of the measurements was also questioned by the CODA experts that came to discuss the potential purchase of CODA towers for the lab.
- Builders requested to use water based paint and glue wherever possible and decisions made with them based on the specifications of each product.
- Laboratory & theatres have had a 'deep clean', including walls and ceilings as well as all equipment using 7x, water and methylated spirits.
- Particle counter has been purchased and particle counts have been within acceptable levels in all areas.
- Settle plates have also revealed acceptable air quality

- Equipment has been turned on and appropriately validated with good results (e.g. incubators and fridges)

Mouse embryo assays

- Using a new flask of oil from the batch that was in use during September 2009 mouse embryos perished after developing to day 3 stage. In a subsequent sperm survival test all sperm died within 24hrs.
- Further tests were undertaken using BSA versus SPS as the source of protein and a new batch of oil versus no oil. After 5 days embryo development complies with manufacturers MEA SOP (80 % fully expanded blastocysts 96-108 hours in culture).

Conclusion

It has not been possible to isolate one specific root cause for the unexplained drop in clinical pregnancy rates. However the most significant factor was the

- Failure of South London and Maudsley NHS Trust to communicate or provide sufficient information to King's or the ACU regarding the nature and scale of works to be carried out. This would have allowed the ACU to undertake a risk assessment and proactively mitigate identified risks.

Lessons Learned

- The importance of having a robust contingency plan, 3rd party agreement and productive relationship with another ACU.
- The importance of an adequate air filtration system in the laboratory
- Effective team work has been crucial to cope with this major crisis.
- Improved communication between ACU and the leaseholders of the building and an agreement to be reached about warning timescales for this
- ACU to be more proactive in investigating more thoroughly when informed of any potentially disruptive work and to ask for detailed plans of work

Recommendations

- Improvement of communication (as above)

<ul style="list-style-type: none"> • Purchasing of equipment to measure air quality in the lab • Improvement of air filtration systems in the laboratory 			
<p>Monitoring and evaluation arrangements</p> <ul style="list-style-type: none"> • The pregnancy rates will be monitored on a weekly basis. • Air quality will be monitored • The centre inspector will be informed each week of progress 			
<p>Arrangements for sharing and learning</p> <ul style="list-style-type: none"> • Staff members constantly updated on progress and involved in decision making for both the investigations and the opening plan • HFEA thoroughly informed at all levels, and their input incorporated to plans • Incident communicated to the risk management department in the trust and incorporated into their risk assessments 			
Author	Mike Savvas,	Date	14/06/10
	Carmel Dodson-Brown		15/06/10

Chronology of events	
Date & Time	Event
July 09	Informed of works in department downstairs, due for completion January 2010
15/09/09	Works beneath the ACU began
5-9/10/09	Builders approached to stop early in the afternoons as noise and vibration made it impossible to carry out ICSI in the afternoons. Injection needle was visibly vibrating in spite of anti-vibration table. They only co-operate on one occasion.
12/10/09	Review of pregnancy data showed dramatic decline in pregnancy rate.
12/10/09	Programme stopped
12/10/09	Person Responsible approached and patients due for egg collection on the same week and the week after sent to Guy's for treatment. Transport IVF patients from St Heller Hospital also re-directed to Guy's for treatment.
12/10/09	HFEA informed
14/10/2009	All embryology work moved to Guy's Hospital ACU
Nov 2009 – March 2010	Investigations on causes of incident in the laboratory
19/10/09	Incident report submitted
20/10/09	Meeting held with the King's Divisional Manager and Nominal Licensee (Sarah Dawson) and ACU management team. Plans for future management of patients agreed. Patients affected by the building works to be offered another fully funded attempt. Guy's to provide treatment to half of our patients (5 a week) and St Heller patients with support from nurses and embryologists from King's. Management teams from Guy's and from King's met to agree on working plan.

31/01/2010	Initial projected date for the end of the building works, submitted to successive delays
13/05/2010	Actual end date of the building works, ACU plans to re-open on 14/06/10 if all tests in the lab are acceptable
15/05/2010 –	Tests and validation in the lab in view of re-opening. Re-opening date delayed due to mouse embryos arrested development, troubleshooting implemented
11/06/2010	HFEA inspection
10/06/2010	
14/06/2010	Investigation report submitted to HFEA
15/06/2010	Head of Clinical Governance edits report and returns to centre for comment – report to be included in Licence Committee papers for Interim Inspection

