

## Incident Investigation Report -

<b>Summary Incident Description &amp; Consequences</b>	
Incident type:	Unit closure due to drop in CPR possibly due to nearby building works and laboratory contamination
Specialty:	Assisted Conception Unit (ACU) King's College Hospital
Effect on patient:	Treatment cancellations/delays/possibility of poor cycle outcome
Severity level:	Grade A
<b>Scope and Level of Investigation</b>	
Root cause analysis, HFEA visit x 2, review of laboratory conditions	
<b>Involvement and support of Patient and Relatives</b>	
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.	
<b>Chronology of events</b> - See table overleaf	
<b>Notable Practice</b>	
<ul style="list-style-type: none"> <li>• HFEA informed by telephone immediately after decision made to stop programme</li> <li>• Adverse incident report submitted in writing to HFEA by PR (attached)</li> <li>• Affected patients informed</li> <li>• Women's division and Chief Executive of Trust informed and involved in emergency planning</li> </ul>	
<b>Care and Service Delivery Problems (Themed and prioritised)</b>	
<ul style="list-style-type: none"> <li>• Emergency 3<sup>rd</sup> 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.</li> <li>• 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.</li> <li>• Free cycle offered to all patients identified to have had treatment during the affected period</li> </ul>	
<b>Contributory Factors</b>	
<ul style="list-style-type: none"> <li>• 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</li> <li>• No risk assessment carried out on the potential impact of the building works to other services in Mapother House</li> <li>• Insufficient air filtration system in the laboratory</li> <li>• Timescale of works and successive delays</li> <li>• Sudden drop in pregnancy rates possibly due to lab contamination</li> </ul>	
<b>Root Causes</b>	
<ul style="list-style-type: none"> <li>• 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</li> <li>• Duration and severity of building works</li> <li>• Insufficient air filtration system leading to potential contamination</li> </ul>	
<b>Lessons Learned</b>	
<ul style="list-style-type: none"> <li>• The importance of having a solid contingency plan, 3<sup>rd</sup> party agreement and productive relationship with another ACU.</li> <li>• The importance of an adequate air filtration system in the laboratory</li> <li>• Effective team work has been crucial to cope with this major crisis.</li> <li>• Improved communication between ACU and the leaseholders of the building and an agreement to be reached about warning timescales for this</li> <li>• ACU to be more proactive in investigating more thoroughly when informed of any potentially disruptive</li> </ul>	

work and to ask for detailed plans of work

### Recommendations

- Improvement of communication as above
- Purchasing of equipment to measure air quality in the lab
- Improvement of air filtration systems in the laboratory

**Action Plan** – see attached plan for the re-opening of the lab

### Implementation, monitoring and evaluation arrangements

- 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 [redacted] from [redacted] 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).

#### Remaining actions prior to re-opening

- Incubator and dewars alarms is to be fixed on 17/6, as since restarting the incubators it alarms but is not dialling out to the embryologists phones.
- Laboratory work and egg collections are currently undertaken by Guy's until alarm system works.

### Arrangements for sharing and learning

- 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
- HFEA to raise an alert for the Incident to be shared with other IVF units
- Incident communicated to the risk management department in the trust and incorporated into their risk assessments

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### Chronology of events

Date & Time	Event
July 09	Informed of works in department downstairs, due for completion Jan2010
15/09/09	Works beneath the ACU began
5-9/10/10	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	Yacoub Khalaf 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 Helier Hospital also re-directed to Guy's for treatment.
12/10/09	HFEA informed
19/10/09	Incident report submitted
19/10/09	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 Helier patients with support from nurses and embryologists from King's.
20/10/09	Management teams from Guy's and from King's met to agree on working plan.
14/10/09	All embryology work moved to Guy's Hospital ACU
13/11/09	HFEA incident visit
11/09-03/10	Investigations on causes of incident in the laboratory
31/01/10	Initial projected date for the end of the building works, submitted to successive delays
13/05/10	Actual end date of the building works, ACU plans to re-open on 14/06/10 if all tests in the lab are acceptable
15/05/10-11/06/10	Tests and validation in the lab in view of re-opening. Re-opening date delayed due to mouse embryos arrested development, troubleshooting implemented
10/06/09	HFEA inspection