Renewal Inspection Report

Andrology Hammersmith Hospital
0080

Date of Inspection: 7th October 2008
Date of Licence Committee: 15th December 2008

Centre Details

Person Responsible	Dr. Kevin Lindsay
Nominal Licensee	Dr Richard Chapman
Centre name	Andrology Hammersmith Hospital
Centre number	0080
Centre address	South Corridor, Area C/FR30, Hammersmith Hospital, Du Cane Road, London, W12 0HS
Type of inspection	Renewal
Inspector(s)	Bhavna Mehta Wil Lenton
Fee paid	Renewal fee due 28/02/2009
Licence expiry date	28/02/2009
NHS/ Private/ Both	NHS

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About the Inspection:
This inspection visit was carried out on 7th October 2008 and lasted for 6 hours.

The purpose of the inspection is to ensure that centres are providing a quality service for patients in compliance with the HF&E Act 1990, Code of Practice and to ensure that centres are working towards compliance with the EU Tissue and Cells Directive 2004/23/EC. Inspections are always carried out when a licence is due for renewal although other visits can be made in between.

The report summarises the findings of the licence renewal 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 Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:
How well the centre is organised
The quality of the service for patients and donors
The premises and equipment
Information provided to patients and to the HFEA
The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements or conditions that need to be imposed.
Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.
Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

Where recommendations are made the HFEA will provide details of what needs to be addressed but not how they should be carried out as this is the responsibility of the Person Responsible.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk .

Brief Description of the Centre and Person Responsible

The Andrology unit at the Hammersmith hospital provides storage of sperm for patients who are undergoing treatment that may impair their fertility. The unit also occasionally provides the same service to patients seeking short-term storage of sperm when undergoing fertility treatment. The laboratory is also contracted to carry out diagnostic sperm testing.
The centre is open five days a week between the hours of 09.00 – 12:00 or by appointment for urgent sperm cryopreservation.
The former Hammersmith Hospitals NHS Trust and St Mary's Hospital NHS Trust have merged into a new Imperial College NHS Trust. The Andrology unit is now part of the Imperial College Healthcare NHS Trust.
The Andrology unit plans to enter into an agreement to carry out sperm processing for an IUI centre (St Mary's) but this has not yet been finalised and no patients have been treated. The centre also has links with the West Middlesex University Hospital.
The person responsible (PR) has been in post since 1995. He is suitably qualified and experienced to carry out the role of PR.

Activities of the Centre for the time period from July 2007 to February 2009

The centre is licensed for processing of gametes, storage of sperm and the procurement and distribution of gametes.

Summary for Licence Committee

The Andrology Unit at the Hammersmith Hospital is a small unit providing a service to patients wishing to store sperm before undergoing treatment that may impair their fertility. The unit currently stores more than estimated 34,000 semen samples.

The unit has appropriate premises, suitably qualified and experienced staff and adopts appropriate laboratory procedures.

Improvements should be considered relating to the following:

- Payment of HFEA fees in accordance with Licence Condition **A.16.3**
- Training logs to clearly show that the individual demonstrated performance of tasks in accordance with **Licence Condition A 10.11**
- Ensuring an effective means for communicating information to staff in accordance with the Code of Practice **S.6.2.13**
- Review of documents in accordance with Code of Practice **S.5.2.5 (a).**
- Update staff training to ensure contemporaneous witnessing in accordance with **G 13.1.1**

The inspection team support the variation of the Centre's licence from the current to include Insemination.

Evaluations from the inspection

Topic	No Improvements required	Some Improvement required	Significant Improvement required
1. Organisation		✓	
2. Quality of the service		✓	

3. Premises and Equipment	✓		
4. Information	✓		
5. Laboratory and clinical processes		✓	

Breaches of the Act, Standard Licence Conditions or Code of Practice:
The table below sets out matters which the Inspection Team considers may constitute breaches of the Act, Standard Licence Conditions and/or the Code of Practice, and their recommended improvement actions and timescales. The weight to be attached to any breach of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee;-

Breach	Action required	Time scale
The centre took 92 days to pay the HFEA renewal fee. This is a breach of the **Licence Condition A.16.3** (In consideration of the grant of the licence (or its variation to designate the individual named in this licence as Person Responsible), the Person Responsible agrees that he will pay to the Authority any additional fee, as defined in section 16(6) of the Act, within 28 days of the date of the notice of such additional fee. **A.16.3)**	The PR should 1. review whether there are barriers to the prompt payment of HFEA invoices 2. take steps to ensure the fees are paid within 28 days.	To be monitored at the time of the next inspection
Some policy documents and procedures are reviewed on a 24 month cycle. This is a breach of **S.5.2.5 (a).** (The Centre shall establish a Documented Procedure to control all documents (internally generated and from external sources) required by the Quality Management System. This procedure shall ensure that **S.5.2.5 (a)** documents are regularly reviewed, revised as required, dated and re-approved promptly by authorised personnel. NOTE: Review, revision and re-approval should be conducted at a frequency that ensures that they remain 'fit for purpose'. The maximum interval between reviews should be twelve months.	The PR and Quality Manager to ensure that 1. all documents are reviewed every 12 months. 2. all SOPs to have effective document control and be subject to regular review in accordance with S.5.2.5 (a).	To be monitored at the time of the next inspection
Training files were reviewed at inspection and found to be in order	The PR should ensure that it is documented that each individual	To be monitored at

except for one file where the competency log did not show how the individual had demonstrated confidence in the performance of their designated tasks. This is a breach of **A 10.11.**	has demonstrated confidence in the performance of their designed tasks	the time of the next inspection
The batch numbers for freezing media had not been recorded in some patient records reviewed in the course of the inspection.	The PR should ensure that documented procedures for the management of equipment and materials that include: traceability of any materials that come in contact with gametes or embryos are implemented in compliance with S.6.4.3.	Procedures to be implemented immediately.

Non-Compliance

Area for improvement	Action required	Time scale
Witnessing was not carried out contemporaneously.	The PR should ensure that staff comply with the centres own witnessing standard operating procedures to ensure that the checking of identification of samples and patients/donors, and witnessing of these checks, should be recorded at the time the clinical and laboratory procedures) take place in compliance with the requirements of G.13.2.1.	Immediately

Recommendations

Area for improvement	Action required	Time scale
None		

Changes/ improvements since last inspection

Recommendations	Action taken since last inspection
Provision of an out of hours service for responding to damage or failure to storage vessels	SOP in place. An out of hours service operates between three staff members on a rota basis.
Monitoring and control of air quality in the laboratory	SOP in place. A monthly monitoring test of operational and background air quality of the class 2 cabinet is carried out.
Witnessing protocols and protocols and procedures for the transfer of gametes to other premises.	SOP in place. This specifies the key steps to be taken. Two internal audits have been carried out by the unit and staff training needs identified. An audit of patient records at this inspection identified that witnessing requirements of the CoP are still being breached.
Formalisation of contingency plans to accommodate fluctuations in workload and staffing levels	The centre has a policy for minimal staffing numbers and there is an understanding between staff so that individuals will change other commitments to meet demand.. In addition, the centre has recently employed a full time receptionist.

Continuing development and implementation of quality management procedures	These continue to be developed The unit has recently successfully been re-assessed for CPA accreditation. In addition, the unit uses the findings of their internal audits to improve the service. More recently, the PR has persuaded the trust's Clinical Programme Group director to set up a Tissue Governance Committee to oversee the regulatory needs for the laboratories within the trust's new structure (which includes this unit).
Continuing development of third party agreements	It is acknowledged that the centre has made significant effort to establish agreements but that the process has been hindered by poor response from some third parties. The PR has told the inspectorate that he has contact details for each third party agreement and documents that show that third party agreements are now in place.

Additional licence conditions and actions taken by centre since last inspection

None

Report of inspection findings

1.Organisation

Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of the findings from the inspection of the following areas of practice:

- Leadership and management
- Organisation of the centre
- Resource management
- Clinical governance
- Risk management
- Incident management
- Alert management
- Complaints management
- Contingency arrangements
- Establishment of third party agreements
- Meetings / dissemination of information
- Payment of licence/treatment fees

Areas of firm compliance
The leadership and management structures within this centre are well established. Those providing leadership have been in post for many years. The centre has arrangements in place for managerial cover in the PR's absence- the andrology quality officer and PR are not on leave or out of the department at the same time. The centre has an organisational structure with defined accountabilities and reporting relationships. A copy of the organisational chart of the centre was provided at inspection. As the former Hammersmith Hospitals NHS Trust and St Mary's Hospital Trust have recently merged under a new Imperial College NHS Trust, the organisation is presently in transition, in terms of the reorganisation associated with such large organisational changes. The standing instructions are to retain the status quo until the new structures come into existence. The PR and the Clinical Programme Group director have agreed to develop a Tissue Governance Committee to oversee the regulatory needs for the laboratories within this new structure. The centre has applied for central funding of 250K to the Trust on the basis of 'poor' fabric in terms of housing to improve the facilities and layout of the premises. As a primary licensed centre, the centre has links with the West Middlesex University Hospital (WMUH). The centre has formalised the contingency plans to accommodate fluctuations in workload and staffing levels, by developing a policy for minimum staffing numbers, so staff change other commitments to meet demand within the centre. A full time receptionist has recently been employed to relieve the laboratory staff of reception and administrative duties. Processes are in place for the identification, notification and investigation of incidents; incidents have been reported to the HFEA within prescribed timeframes and have been investigated and resolved. Investigations are carried out either internally or externally,

depending on the severity, to identify the 'root cause', leading to remedial action. The number of incidents logged since the last inspection in the centre's file matched the incidents record held by the HFEA. All staff are encouraged to report any anomalies they note on the basis of a no blame culture. HFEA alerts were displayed on the notice board.

The centre has a complaints policy in place and the procedure was displayed in the waiting room. The complaints file was reviewed at inspection. The centre has a three step process for evaluating patient satisfaction. At Trust level, all complaints are viewed seriously and active management of complaints is expected. Since the last inspection, the centre has received one complaint which has been resolved.

The PR has implemented changes as recommended in the 2007 Interim Inspection Report and continues to make improvements.

The Trust has two licensed centres; this and the other licensed Centre have an agreement to provide cryostorage contingency cover should either service require it.

Areas for improvement

Although the centre is now up to date with payment of HFEA fees, it took 92 days to pay the last renewal fee. This is potentially a breach of the Licence Condition **A.16.3**

Areas for consideration

Regular staff meetings are held and minuted, but at certain times of the year, such as peak holiday periods, the meetings are held on an 'ad hoc' basis. The staff are aware that they must examine the minutes of any meetings that they have been unable to attend. Minutes of meetings were reviewed in the course of inspection, but the last minutes on file were those for a meeting held in March 2008. **S.6.2.13** requires: The Centre shall have an effective means for communicating information to staff and receiving suggestions from staff. Records shall be kept of meetings and made available to all staff. PR was advised that the minutes of all meetings should be made available to all staff. The PR confirmed that meetings have been held since March and that minutes are held electronically and is to forward copies of minutes of meetings held since March 2008 to the inspectorate and make them available to all staff.

Executive recommendations for Licence Committee

The centre took 92 days to pay the HFEA renewal fee.
This is a breach of the Licence Condition **A.16.3**
(In consideration of the grant of the licence (or its variation to designate the individual named in this licence as Person Responsible), the Person Responsible agrees that he will pay to the Authority any additional fee, as defined in section 16(6) of the Act, within 28 days of the date of the notice of such additional fee. **A.16.3)**

Evaluation

Some improvements required

Areas not covered on this inspection

None

2. Quality of service

Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of the findings from the inspection of the following areas of practice:

- Quality management system
- Quality policy
- Quality manual
- Quality objectives and plans
- Quality management review/evaluation
- Feedback
- Document control
- Live birth rates

Live birth rates[1]
N/A as storage only centre.
Areas of firm compliance
Due to the recent restructuring of the Trust, the quality policy is being developed within the wider context of the Trust. The restructuring has created an air of uncertainty regarding the quality objectives and plans. However, the centre has a working quality manual and a quality manager is in place. The centre has implemented quality management procedures and is proactively developing these. The senior clinical scientist acts as the quality officer for the centre with support from the Trust quality officer. Information was provided by the PR that review of the QMS has included: • turn around times, • training effectiveness, • storage audits (rolling) and • witness audit. The PR also stated that the centre has a system for evaluating patient satisfaction; patient surveys are conducted and reviewed and complaints treated and managed. The PIQ details the outcome of the storage audits and shows that action has been taken in relation to non-conformities identified. At inspection, the PR explained that the witnessing audit had identified staff training needs. The centre has developed quality indicators for: • IUI outcomes, • sperm motility and concentration, • diagnostic testing turn around times and • complaints monitoring. This is work is ongoing.

Areas for improvement
The PIQ states that each policy and procedure is reviewed on a 12 or 24 month cycle, unless, an intermediate audit or risk analysis identifies a reason to change. The PR states that each document is given a version number based upon the date of issue. The documents are available on a shared drive and copies may be printed. Printed copies are working documents and only valid for the day as indicated on any printed versions. The documents produced by the PR both with the PIQ and at inspection showed that not all documents are reviewed at 12monthly intervals. The quality manual shows evidence of version control and review but this information is not necessarily transferred to the documents. This is potentially a breach of **S.5.2.5.** The inspectorate advised the PR of the HFEA requirement and that those documents that are reviewed every 24 months are potentially in breach of **S.5.2.5 (a).**
Areas for consideration
Executive recommendations for Licence Committee
The quality manual documents to comply with the requirements of the Code of Practice with regard to version control and review.
Evaluation
Some improvement required.
Areas not covered on this inspection
None

3. Premises and Equipment
Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of the findings from the inspection of the following areas of practice:

- Premises
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Staff facilities
- Storage of records

Areas of firm compliance
On the day of inspection the premises and facilities appeared well maintained and suitably equipped. However, to improve the building and use of space, the centre has made an application for to the Trust for 250K on the basis of 'poor' fabric in terms of housing. Patient notes are stored in a designated administrative office with controlled access, however, this office is presently located in another building some distance away from the centre. The PR informed the inspectorate that when the reorganisation of the Trust has been finalised, the administrative office will be moved to within the existing centre. Further, the PR stated that confidentiality of patient records is maintained by restricting access to staff within the unit, the IT network for storage of records is isolated and patients enter their own information onto the centre's database by completing a CD. When involved in treatment processes the couple, on arrival at the centre, present a document, which has embedded digital photographs of each partner and signed declarations indicating that these are an appropriate likeness. Copies of these are kept associated with each sample preparation. Some of the equipment in the laboratory is less than a year old and is covered by manufacturer's warranty. The older equipment is covered by maintenance service contracts. Evidence of maintenance was seen at inspection by way of last inspected dates and/or stickers on the equipment. The new equipment in the laboratory was CE marked and the PR stated that established equipment has been determined as fit for purpose by being regularly serviced and maintained. Temperature sensitive equipment is monitored and all equipment is serviced by appropriate external specialist engineers. Evidence of air quality monitoring in all relevant areas was provided in the PIQ and in the course of inspection. Air quality is monitored monthly; the results of the October 2008 testing indicated that the background air quality was assessed as grade D and grade C in the processing areas. Procedures have been implemented to ensure the traceability of consumables that come into contact with gametes.

Only 1 patient provided feedback to the HFEA saying that the staff had been helpful and supportive and 'going out of their way to help me.'
Areas for improvement
None
Areas for consideration
The PIQ states that only 1 patient has used the counselling service that has been available since 1991. Two counsellors provide a continuous service; information, including a direct contact number, is provided to patients; information on the service is posted in patient waiting areas.
Executive recommendations for Licence Committee
Evaluation
None
Areas not covered on this inspection
Management of equipment and materials Staff facilities Counselling facilities

4. Information

Desired outcome: Information is relevant, clear and up to date for patients and the HFEA

Summary of the findings from the inspection of the following areas of practice:

- Information for service users
- Consent
- Welfare of the child
- Access to health records
- Provision of information to the HFEA register

Areas of firm compliance
Patients are given information at consultation for cryo-storage and use. A record that such information has been given is kept in the patient notes.
Areas for improvement
None
Areas for consideration
The patient information needs reviewing against the Code of Practice and needs expanding, with particular consideration to: procedure for withdrawal of consent (**G.5.2.1c**), costs (**G.5.2.1e**), risk of deterioration as a consequence of storage and potential risk of cross contamination (**G.5.10.1a**) and providing specific information appropriate to minors (**G.5.10.2**). It is acknowledged that this information may be provided verbally or otherwise, and if so, it is recommended that this is documented, if this is not already done.
Executive recommendations for Licence Committee
None
Evaluation
Areas not covered on this inspection
Welfare of the child Access to health records Provision of information to the HFEA register

5. Clinical, laboratory and counselling practice
Desired outcome: Clinical, counselling and laboratory practices are suitable and are provided by competent staff.

Summary of findings from inspection:

- Staff training and competency
- Clinical practice
  - Screening of donors
  - Three embryo transfer
- Laboratory practice
  - Procurement, distribution and receipt of gametes and embryos
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Coding/ identification of samples
  - Witnessing
- Counselling practice
  - Counselling audit
- Storage of gametes and embryos

Full time equivalent staff

GMC registered doctors	N/A
NMC registered nurses	N/A
Non NMC registered clinical staff	N/A
HPC registered scientists	5
Scientists working towards registration	2
Support staff (receptionists, record managers, quality and risk managers etc)	2
Counsellors	2

Summary of laboratory audit
The 2007/2008 audit report has been provided to the inspectorate. This shows that the centre has 34,389 samples in storage of which 27% were audited and appropriate action taken.
Summary of spot check of stored material
A sample storage system was demonstrated by the PR and embryologist and a spot audit was carried out and. One sample was tracked from the file to tank and vice versa and no discrepancies encountered. The laboratory notes are securely kept.
Areas of firm compliance
The Trust has a general induction policy and uses annual staff appraisals or individual performance reviews to ensure CPD. Staff are encouraged to join formal CPD schemes such as those run by the Royal College of Pathologists or Institute of Biomedical Sciences. The centre has audited its witnessing practices since the last inspection. The PR

explained that this audit has identified the need to provide further training to reinforce the practices learnt following the recommendations in the last report.

Each patient and sample are identified with a unique code. The centre has a documented procedure for witnessing.

The centre participates in the inter-laboratory and internal quality assurance process provided by the National Quality Assessment Scheme (NEQAS) and the PR confirmed that the centre has never received a 'poor performance' letter from the governing body. This is in addition to the centre's own quality process where the staff check and witness quality processes.

Gametes are stored in a laboratory, access to which is controlled. The 15 liquid nitrogen dewars are also secured by locks. Cryopreservation dewars are fitted with low nitrogen level alarms and the laboratory housing the cryo- dewars is fitted with a low oxygen monitor. This is connected to an external audio visual alarm system incorporating an auto dial system for out of hours alarms.

The implementation of the upgrade of the cryo-system to provide auto-fill controlled freezers is on going. The new vapour phase auto-fill cryotanks are replacing the 'old ' liquid dewar style tanks. The centre has invested in a new system of auditing stored samples that allows for 'auto-transfer' of data into an 'itemtracker' for all material stored in cryotanks. A high resolution photograph is taken of the unique bar code of 100 frozen samples, at a time, that are placed in a tray of liquid nitrogen. An optical reader reads the code on the photograph. It is hoped that this quicker system will reduce the risk of deterioration of stored samples during audit.

Areas for improvement

Staff training files were reviewed at inspection and found to be in order except for one staff whose training log did not show how the individual had demonstrated confidence in the performance of their designated tasks. This is a breach of Licence Condition **A 10.11.** These logs should be signed off to demonstrate competency.

An audit of 5 patient records identified a further staff training need. In 3 of these files, traceability (batch numbers) of freezing media was absent although the witnessing was complete. In another file, the witness signature was missing. This suggests that witnessing was not carried out contemporaneously. This is potentially a breach of **G 13.1.1**
When this was discussed with the PR at inspection, he said that he would address this issue by providing further training.

Areas for consideration

None

Executive recommendations for Licence Committee

Staff training relating to witnessing procedures.
Training logs clearly show that the individual demonstrated performance of tasks.

Evaluation
Some improvement required.
Areas not covered on this inspection
Three embryo transfer Procurement, distribution and receipt of gametes and embryos

Report compiled by:

Name: Bhavna Mehta…….

Designation: Inspector…….

Date: 23/10/08……

Appendix A: Centre staff interviewed

PR

Appendix B: Licence history for previous 3 years

2007

A Licence Committee considered the centre's application to vary the licence in compliance with the EUTD on 2 May 2007. The committee agreed to vary the centre's licence pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007, subject to prompt resolution of the outstanding areas of non-compliance

2006

Unannounced inspection 3 April 2007.
Report not presented to Licence Committee.
Interim inspection 6 October 2006 (postponed from 28th September).
The interim report was considered by a Licence Committee on 30 October 2006.
The Committee agreed to issue a notice of proposal to vary the centre's licence to add the following condition:
· The centre must ensure that all storage dewars are fitted with low nitrogen level alarms fitted to an autodialler system by 1 March 2007.

2004

Interim inspection 9th November
Report considered by a Licence Committee 28 February 2006
The licence was continued without variation.

Appendix C: Response of Person Responsible to the inspection report

Centre Number……0080……
Name of PR……Dr K Lindsay……
Date of Inspection……7 October 2008……..
Date of Response……21 November 2008……

I have read the inspection report and agree to meet the requirements of the report.

Signed……Signed copy provided by email ……
Name……Kevin Lindsay ……
Date……21 November 2008……

1. Correction of factual inaccuracies
Please let us know of any factual corrections that you believe need to be made. We will make alterations to the report where there are factual inaccuracies.

None

2. Please use the space below to document any comments or additional information that you would like to be considered by a Licence Committee.

None

3. Please state any actions you have taken or are planning to take following the inspection with time scales

1. Organisational – The new Imperial College Healthcare NHS Trust continues to restructure taking into account the legacy Trusts of Hammersmith Hospitals and St Mary's Hospital. It is anticipated that the appropriate structures and host departments will clarify by the end of the financial year 08/09. Unfortunately the process of restructuring
contributed to late fee payments however this has not been a problem in
the past and should not be in the future.
2. Document review- The department has purchased Q-Pulse 5 as a document management programme which will allow an increase in the rigor of the current document control system. We are awaiting appropriate staff training.
3. As a CPA registered laboratory we use training logs to ensure competency and witness audit to ensure this is maintained. These will be reviewed as part of staff CPD and developed with NHS KSF profiles.
4. It has been agreed formally at the most recent staff meeting (11 November 2008) to introduce a separate traceability log to be updated with receipt of product supply rather than hand written in each activity record. This change will also reinforce the contemporaneous nature of witnessing. Witnessing has always been contemporaneous, however the records may not overtly demonstrate the case and further training has taken place. It is intended that we increase the frequency of witness audit to ensure all staff compliance.

We welcome comments about the inspection on the inspection feedback form, a copy of which should have been provided at the inspection. If you require a copy of the feedback form, please let us know.

Please return Appendix C of the report electronically to your inspector or in hard copy to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF