Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

Quality Check Summary

London Women's Clinic, Cardiff

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Findings Record

Our Approach

Healthcare Inspectorate Wales (HIW) undertook a remote quality check of London Women's Clinic, Cardiff as part of its programme of assurance work. London Women's Clinic is a registered provider of adult day patient fertility services, including In vitro Fertilisation (IVF) and is licensed by the Human Fertility and Embryo Authority (HFEA). Their main laboratory and clinic facility is situated in Cardiff with a further clinic available in Swansea and regional centres across England.

HIW's quality checks form part of a new tiered approach to assurance and are one of a number of ways in which it examines how healthcare services are meeting the Care Standards Act 2000, Independent Health Care (Wales) Regulations 2011 and other relevant regulations. Feedback is made available to service representatives at the end of the quality check, in a way which supports learning, development and improvement at both operational and strategic levels.

Quality Checks are a snapshot of the standards of care within healthcare settings. They are conducted entirely offsite and focus on three key areas; infection prevention and control (IPC), governance (specifically around staffing) and the environment of care. The work explores arrangements put in place to protect staff and patients from COVID 19, enabling us provide fast and supportive improvement advice on the safe operation of services during the pandemic. More information on our approach to inspections can be found here.

We spoke to the Responsible Individual and Clinic Manager on 17 January 2021 who provided us with information and evidence about their setting. We used the following key lines of enquiry:

- How are you ensuring that all patients (including vulnerable/at risk groups) are able to access services appropriately and safely? In your answer please refer to both the practice environment and processes to enable patients to access appointments
- What changes have you implemented in light of COVID-19 to ensure infection prevention and control standards are maintained?
- How has the clinic and the services it provides adapted during this period of COVID-19?

Environment

During the quality check, we considered how the service has designed and managed the environment of care to keep it as safe as possible for patients, staff and visitors. We reviewed recent risk assessments and questioned the setting on the changes they have made in response to COVID-19 to maintain safety and patient dignity.

The following positive evidence was received:

In response to the COVID-19 pandemic and on the advice of the HFEA, fertility treatment was suspended on the 15 April 2020. On the 1 May 2020 the HFEA announced fertility clinics could re-introduce fertility treatments if carried out in a manner that minimised the spread of the virus to patients and clinic staff.

In line with the HFEA code of conduct the clinic in Cardiff has an appointed responsible individual who is responsible for ensuring license activities are conducted in line with regulatory frameworks and the Human Fertilisation and Embryology Act 1990 (as amended). The responsible individual is a consultant who works on site in the Cardiff clinic.

The responsible individual provided us with evidence and verbal assurance that changes had been made to the environment and standing operating procedures (SOPs) in response to the pandemic to ensure the health, safety and well-being of patients and staff.

We were provided with a series of comprehensive up to date SOPs, policies and pathways including:

- COVID Adapted Re-induction Competency Policy
- IPC SOP
- Patient testing pathway
- Health and well-being policy
- Risk Assessment SOP
- Preparing for a future pandemic

A review of the COVID-19 Adapted Re-induction Competency Policy dated May 2020 indicates this is a management tool used to document the process by which staff were made aware of the procedures introduced in response to the pandemic. It also provides them with the skills to perform tasks including donning and doffing, use and disposal of personal protective equipment (PPE). In addition this policy provides staff with guidance on the fitting and use of masks and respirators.

We were provided with a patient information leaflet that informs patients that the clinic now staggers appointments to enable social distancing. We were informed that consultations and counselling sessions are conducted on the telephone or by video link to reduce risk of cross contamination and transmission of the virus.

We were provided with documented evidence of COVID-19 codes of conduct for both staff and patients with a focus on health, safety and well-being in response to the pandemic. The codes of conduct provide guidelines on the precautions individuals must take to ensure the safety of themselves and others. The staff code of conduct provides individuals with the clinic requirements for social distancing, interaction with colleagues, hygiene, PPE and the procedure to take if they display COVID-19 symptoms. The patient code of conduct provides clear guidelines on COVID-19 screening, attendance at appointments, hand hygiene and face coverings.

We were informed that patients, partners and donors are screened for COVID-19 prior to any treatment. Patients undergoing oocyte/sperm retrievals and embryo transfers[1] receive a COVID-19 RT-PCR swab test[2] prior to booking the procedure. Screening and swab testing aims to identify presence of the virus, prevent transmission of the virus and protect the health and safety of those employed in and visiting the clinic. In addition we were assured that patients currently attend the clinic without partners/spouses to reduce the footfall in the clinic and prevent cross contamination of the COVID-19 virus.

The responsible individual assured HIW that posters providing guidance to patients on social distancing and hand hygiene were being displayed around the clinic with a view to providing education and information.

We were provided with evidence dated 12 November 2020 that identified the clinic operates an infection control audit tool that enables a comprehensive environmental audit of the premises. The outcome of this particular audit was positive with evidence of management review citing only a small number of minor improvements.

We were provided with details of clinic risk assessment tools and recent risk assessments completed in response to the COVID-19 pandemic. The risk assessments identified a review of a number of risks and a documented mitigation against the each risk. Risk assessments noted the number of patients attending treatments had been adjusted to reduce the footfall in the clinic with a view to reducing any transmission of the virus. In line with this minimum safe staffing levels had also been introduced. A risk assessment was also completed to mitigate against a shortage of PPE. Clear guidelines were recorded on the ways in which the clinic agreed to source, order and secure delivery of PPE in line with government guidance.

We were provided with a copy of a blank customer complaint communication form and were informed of the process by which complaints and concerns are administered, reviewed and

[1] An in vitro fertilisation procedure to collect eggs and sperm
[2] COVID-19 swab test to detect viral infection

concluded. In addition we were provided with an example of a complaint that evidenced management review and resolution.

We were informed patients are treated with privacy and dignity and consent is obtained prior to all treatments and procedures. A chaperone is offered and doors are closed during consultation and ultrasound scans. Privacy curtains and patient alarms are fitted around examination couches and a paper sheet is placed to cover private body parts during ultrasound scans. No unnecessary personnel or observers are allowed to enter without permission from the patient during theatre or any other invasive procedure.

We were informed that the clinic has CCTV facilities in place for security purposes. These are fitted around the building and in the lobby and operate 24 hours a day.

The following areas for improvement were identified:

We were provided with the findings of a patient survey of fertility counselling services dated 23 November 2020. 95 patients were asked to contribute to this survey and 19 responses were received. Overall the feedback was positive however HIW noted that there were responses that expressed dis-satisfaction with some aspects of the counselling service. No action was taken to address the concerns other than a re-audit planned for January 2021. HIW recommends action is taken to review the findings of the survey and document the action that will be taken to address concerns raised by patients.

Infection prevention and control

During the quality check, we considered how the service has responded to the challenges presented by COVID-19. We considered how well the service manages and controls the risk of infection to help keep patients, visitors and staff safe. We reviewed infection control policies, cleaning and hygiene regimes and access to training.

The following positive evidence was received:

We were provided with evidence that the clinic completes weekly hand hygiene audits. A recent audit indicated staff were 100% compliant with the requirements of hand hygiene and hand washing. We were provided with evidence that confirmed the clinic were displaying posters around the clinic to educate both staff and patients on hand hygiene.

We were informed that an alcohol based anti-bacterial hand gel is available throughout the clinic and clinic facilities are cleaned on a daily basis. In addition clinical areas and laboratories are deep cleaned on a monthly basis.

We were provided with a copy of the IPC and COVID-19 PowerPoint presentation compiled by the Lead IPC Nurse. This was presented to staff after the clinic had re-opened in May 2020 and aimed to provide a comprehensive overview of the COVID-19 virus and its impact on the clinic and provision of fertility treatment.

We noted that staff and patient COVID-19 codes of conduct provide guidelines on social distancing, hand hygiene, a clean environment, PPE and identification and disclosure of viral symptoms, all aimed at managing and minimising the risk of infection and transmission.

We were informed that staff were receiving COVID-19 vaccinations at the time of the quality check.

The following areas for improvement were identified:

We saw evidence of a Cleaning and Decontamination policy that provided staff with guidance on responsibilities in relation to environmental cleaning and disinfection procedures. The policy had been implemented in June 2017 and indicated it was due for review in June 2019. HIW recommends clinic management review and update this policy without delay to ensure it reflects current policy and any changes made in response to the pandemic.

A review of infection prevention, COVID-19 and well-being policies identified London Women's clinic referred to the requirements of Public Health England (PHE). Given the service provider operates clinics in both Cardiff and Swansea, it is vital that policies and procedures reflect the requirements of Public Health Wales (PHW).

Governance / Staffing

As part of this standard, HIW explored whether management arrangements ensure that staff are suitable in their roles and are appropriately trained in order to provide safe and effective care. We reviewed recent risk assessments and questioned the setting on the changes they have made in response to COVID-19 to maintain safe practices.

The following positive evidence was received:

We were provided with a comprehensive responsible individual report dated February 2021 compiled in line with the Independent Health Care regulations (Wales) 2011, Regulation 28. In addition we were provided with an index identifying all policies, procedures and SOPs dated 2 February 2021.

We were informed that London Women's Clinic established a Coronavirus Action Committee with committee members assigned a portfolio of responsibility and reporting. Meetings are currently held on a weekly basis. Information discussed in the meeting is circulated to clinical leads in all centres. We were assured that committee members have regular contact with colleagues to share best practice.

We were provided with an up to date SOP outlining the procedure the clinic takes when administrating and managing adverse incidents, non-conformance and deviation. We were informed that the last incident recorded in the incident reporting book was dated 27 August 2019.

The responsible individual provided us with a detailed quality manual outlining organisational systems, facilities, staffing and approval for clinics.

We were informed that appropriate medication licenses are in place and are up to date with

an expiry date of November 2021. We were informed that Home Office checks have been undertaken in line with Independent Health Care regulations (Wales) 2011 and the clinic conforms with the criteria to safely store drugs.

We were informed the clinic provides virtual consultations to help maintain social distancing and reduce the footfall in the clinic. Mini teams comprising two members of staff have been created to minimise contact and maintain social distancing between staff and patients. Facilities in the clinic enable two patients to attend treatment at the same time in different consultation rooms. We were informed that staff rostering was agreed locally to enable safe continuity of service. We were provided with an example of staff rosters from the Cardiff clinic that confirmed the current staffing arrangements.

We were provided with an up to date copy of the Health Safety and Well-being policy. We were informed that staff have access to helplines and occupational health. We were informed that the clinic checks staff temperatures each day, regularly provides antibody tests and more recently staff have been receiving the COVID-19 vaccination.

We were provided with a record of staff appraisals dated November 2020. A number of appraisals were out of date however the responsible individual assured HIW that appointments had been made with staff to remedy this.

We were provided with an up to date Grievance procedure dated November 2020 providing staff with the formal process by which grievance and appeal is administered for any condition of employment.

We were informed that staff conduct a daily check of fire escapes, trip hazards, clinic corridors and electrical equipment on a daily basis. In addition the clinic fire alarm is checked weekly.

The following areas for improvement were identified:

Mandatory training records for clinic staff identified some areas for improvement. Training records reported compliance was less than 80% for information governance, manual handling, fire awareness and quality and diversity. In addition training records indicated three new members of staff had not received any mandatory training. We were informed that this was a direct result of the pandemic, clinic closure and staff furlough. The responsible Individual informed us that all mandatory training will be up to date by 30/4/21.

We were provided with a copy of the Practising Privileges SOP that appeared to be significantly out of date. The SOP was dated 5 May 2017 with a review date of 22 November 2017. We informed the Responsible Individual who referred this to London Women's Clinic Central Services to establish if an up to date version was available.

The Responsible Individual confirmed that London Women's Clinic do not have a staff escalation policy and this has referred this to Central Services for necessary action to be taken.

Improvement plan

Setting: London Women's Clinic

Service: Independent Clinic

Date of activity: 17 January 2021

The table below includes improvements identified during the Tier 1 Quality Check, where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

Please note, all actions are expected to be complete within three months of the Quality Check and the final version of the Improvement Plan is to be submitted via Objective Connect once complete.

Reference Number	Improvement needed	Standard/ Regulation	Service Action	Responsible Officer	Timescale
1	We were provided with the findings of a patient survey of fertility counselling services dated 23 November 2020. 95 patients were asked to contribute to this survey and 19 responses were received. Overall the feedback was positive however HIW noted that there were responses that expressed dis-satisfaction with some aspects of the counselling service. No action was taken to address the concerns other than a re-audit planned for	Standard 5 Citizen engagement and feedback Regulation 19 and 28	No action was taken & re-audit planned as our regular counsellor was on sick leave and returned to work in February 2020. Hence the audit was not totally reflective of her performance. Patients received counselling from another counsellor and feedback of audit findings was given to the counsellor covering the sick leave. With small sample size of 19 patients, one dissatisfied or unhappy patient will result in the audit showing 5% dissatisfaction.	Clinic Administrator	31/05/2021

	January 2021. HIW recommends action is taken to review the findings of the survey and document the action that will be taken to address concerns raised by patients.		Although we can aim for 100% satisfied patients, this is not a realistic goal especially for counselling services. The re-audit will be completed at end of May 2021		
2	We saw evidence of a Cleaning and Decontamination policy that provided staff with guidance on responsibilities in relation to environmental cleaning and disinfection procedures. The policy had been implemented in June 2017 and indicated it was due for review in June 2019. HIW recommends clinic management review and update this policy without delay to ensure it reflects current policy and any changes made in response to the pandemic.	Standard 1 Governance and Accountability Framework Regulation 9 Standard 13 Infection, Prevention, Control and Decontamination Regulation 9 and 15	The Cleaning and Decontamination Policy is being updated	IPC Lead Nurse	31/03/2021
3	A review of infection prevention, COVID-19 and well-being policies identified the service provider referred to the requirements of Public Health England (PHE). Given the service provider has clinics in Cardiff and Swansea it is vital that policies and procedures reflect the requirements of Public Health Wales.	Standard 1 Governance and Accountability Framework Regulation 9 Standard 13 Infection, Prevention, Control and Decontamination	This has been updated	IPC Lead Nurse	Actioned

		Regulation 9 and 15			
4	Staff mandatory training records reported compliance was less than 80% for information governance, manual handling, fire awareness and quality and diversity. In addition training records indicated three new members of staff had not received any mandatory training. HIW recommends that all staff receive up to date mandatory training without delay.	Standard 25 Workforce Planning, Training and Organisational Development Regulations 20 and 21	Mandatory training is being organised. Date for completion ILS 08/04/2021 Infection control 18/03/2021 Other mandatory training will be completed by 31/05/2021 as we are having difficulties getting dates from providers.	Doctor Hemlata Thackare HFEA person responsible	31/05/2021
5	We were provided with a copy of the Practising Privileges SOP that appeared to be significantly out of date. The SOP was dated 5 May 2017 with a review date of 22 November 2017. HIW recommends this document is reviewed and updated accordingly.	Standard 1 Governance and Accountability Framework Regulation 9 Standard 25 Workforce Planning, Training and Organisational Development Regulations 20 and 21	This SOP is under review	QM Manager and Medical Director JDH	15/04/2021
6	The Responsible Individual confirmed that London Women's Clinic do not have a staff escalation policy. HIW recommends a policy is	Standard 1 Governance and Accountability Framework Regulation 19	Staff Escalation Policy is now in place	Operations Manager	Actioned

	drafted and approved without delay.				

The following section must be completed by a representative of the service who has overall responsibility and accountability for ensuring the improvement plan is actioned.

Name: Dr Hemlata Thackare

Date: 11.03.2021