Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

DRIVING IMPROVEMENT THROUGH INDEPENDENT AND OBJECTIVE REVIEW

Independent Healthcare Inspection (Announced)

London Women's Clinic (Cardiff)

15 September 2015

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Introduction

Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of all health care in Wales.

HIW's primary focus is on:

- Making a contribution to improving the safety and quality of healthcare services in Wales
- Improving citizens' experience of healthcare in Wales whether as a patient, service user, carer, relative or employee
- Strengthening the voice of patients and the public in the way health services are reviewed
- Ensuring that timely, useful, accessible and relevant information about the safety and quality of healthcare in Wales is made available to all.

HIW inspections of independent healthcare services seek to ensure services comply with the Care Standards Act 2000 and requirements of the Independent Health Care (Wales) Regulations 2011 and establish how services meet the National Minimum Standards (NMS) for Independent Health Care Services in Wales[1].

This report details our findings following the inspection of an independent health care service. HIW is responsible for the registration and inspection of independent healthcare services in Wales. This includes independent hospitals, independent clinics and independent medical agencies.

We publish our findings within our inspection reports under three themes:

- Quality of patient experience
- Delivery of safe and effective care
- Quality of management and leadership.

[1] The National Minimum Standards (NMS) for Independent Health Care Services in Wales were published in April 2011. The intention of the NMS is to ensure patients and people who choose private healthcare are assured of safe, quality services. http://www.hiw.org.uk/regulate-healthcare-1

Methodology

This inspection was undertaken jointly with the Human Fertilisation and Embryology Authority (HFEA). The report is based on evidence gathered by both organisations.Due to the confidential and sensitive nature of this service HIW did not speak with individual patients on this occasion. During the inspection we gathered information from a number of sources including:

- Information held by HIW
- Interviews with staff and registered manager of the service
- Examination of a sample of patient records
- Examination of policies and procedures
- Examination of equipment and the environment (joint with HFEA)
- Information within the service's statement of purpose, patient's guide and website
- Patient questionnaires (joint with HFEA)

At the end of each inspection, we provide an overview of our main findings to representatives of the service to ensure that they receive appropriate feedback.

Any urgent concerns that may arise from an inspection will be notified to the registered provider of the service via a non-compliance notice[2]. Any such findings will be detailed, along with any other improvements needed, within Appendix A of the inspection report.

Inspections capture a snapshot on the day of the inspection of the extent to which services are meeting essential safety and quality standards and regulations.

[2] As part of HIW's non-compliance and enforcement process for independent healthcare, a non compliance notice will be issued where regulatory non-compliance is more serious and relates to poor outcomes and systemic failing. This is where there are poor outcomes for people (adults or children) using the service, and where failures lead to people's rights being compromised. A copy of HIW's non compliance process is available upon request.

Context

London Women's Clinic (Wales) Ltd is registered to provide an independent hospital at 15, Windsor Place, Cardiff CF10 3BY. The service provides day patient fertility services for adults. The service was first registered on 3 September 2012.

The service employs a staff team which includes two consultant doctors, three embryologists, five nurses, 1 counsellor and two administration assistants. A range of services are provided which include:

- In vitro fertilisation (IVF)
- Intra-cytoplasmic sperm injection (ICSI)
- Intrauterine insemination (IUI)
- Donor eggs, donor sperm (from UK egg banks)
- Egg and sperm freezing
- Counselling sessions
- Support group
- Surrogacy

Healthcare Inspectorate Wales (HIW) completed an announced inspection to the service on 15 September 2015. This inspection was joint with the HFEA.

Summary

We saw that the service was designed, developed, reviewed and implemented to ensure that patient's rights and their freedom to make choices was promoted and respected. We found that the views of patients were sought and taken into account when reviewing and improving services. There was clear involvement with patients when planning their treatment and a counselling service was offered routinely to support patients' physical and mental welfare.

Overall HIW were assured that London Women's Clinic provided patients with safe, effective treatment and care which was based on agreed best practice guidelines and complied with safety requirements. We saw that appropriate arrangements were in place to record and audit a range of practices within the service. However there were some areas of improvement identified which were required to meet the European Tissue Directive 2004 and the HFEA will be ensuring improvement in these areas.

There was some evidence that the clinic monitored its performance to identify where they could make improvements to patient treatment and care. Whilst we found regular audits had been carried out, there were no outcomes or identified improvements recorded from the audits. There were no concerns regarding staffing levels, recruitment, retention or training.

We identified the following areas for improvement during this inspection regarding – some areas of documentation, consent and safety checks. Whilst this has not resulted in the issue of a non compliance notice, there is an expectation that the registered provider takes meaningful action to address these matters, as a failure to do so could result in HIW taking action in accordance with our non-compliance and enforcement process.

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Findings

Quality of patient experience

We saw that the service was designed, developed, reviewed and implemented to ensure that patients' rights and freedom to make choices was promoted and respected. We found that the views of patients were sought and taken into account when reviewing and improving services. There was clear involvement with patients when planning their treatment and a counselling service was offered routinely to support patients' physical and emotional welfare.

Citizen Engagement and Feedback (Standard 5)

Prior to the inspection the HFEA distributed patient questionnaires with a view to gaining an insight into the patient's experience. Without exception all the responses made by the patients were complimentary regarding their experience at the service. However it was highlighted that some patients would appreciate more individualised information, this had not been identified in the clinic's internal audit of patients views. The service itself used Survey Monkey (an online survey program) to collect patient's views. We discussed with the registered manager the use of paper questionnaires so that patients who did not have access to the internet could still make their views known. The registered manager stated that the findings from the responses were discussed at staff meetings and any areas of concern were acted upon. Examples were given where changes had been made in line with patient requests.

We were also told that the clinic held monthly open days in Swansea and Cardiff for potential patients to visit and speak confidentially with staff.

Care Planning and Provision (standard 8)

We looked at the treatment records of people who use the service and observed how people were being cared for. We saw that patients were given choices and procedures / outcomes were explained. Care and treatment records were up-to-date and reflected each time a patient and their partner had attended the clinic for treatment or a consultation. Treatment plans (in the form of letters) and how patients were to take care of themselves were given to the patient at the end of the consultation. The required consent to treatment had been completed and a confidentiality form was completed in accordance with legal requirements.

Patient Information and Consent (Standard 9)

We saw that there was an electronic system for gathering personal and medical information from patients. During an audit of patient files, it was observed that any scanned documents did not have patient identifiers on each page and in some instances the history documented did not correlate with other records. For example it was noted on a history sheet that a patient had an allergy however this was not documented or addressed anywhere else in the records including in the pre-operative assessment. The inspection team could not be assured that all the documentation did in fact relate to that patient.

Improvement needed

The registered person needs to ensure that the welfare and safety of patients is maintained by individualised, clear and consistent documentation.

Consent, welfare of the child and confidential disclosure forms, which had been completed by patients, were discussed with the nurses before patients met with the consultant. The consent also stipulated the sharing of confidential information for reasons of audit or research. Although general consent was clear we found areas whereby more specific consent was unclear, for example the storage and disposal of gametes[3]. This approach needs to be reviewed to enhance and underpin patients' rights to dignity, privacy and respect.

Improvement needed

The registered person needs to audit records to ensure all patients have consented to the agreed arrangements for storage and disposal of gametes.

Dignity and Respect (Standard 10)

There were up to date privacy and dignity and equality and diversity policies available. The environment provided both open and private areas for patients and family members and/or accompanying supporters.

When we were shown around the clinic we observed that staff knocked on doors before entering and when people received clinical care there was an engaged sign on the door and/or the shutters on the glass observation panels of the doors were closed. This ensured patient's dignity and respect were maintained

[3] Gametes are reproductive cells (sex cells). Male gametes are sperm and female gametes are ova (eggs).

During our inspection we observed the interaction between staff and patients who attended the service that day. We observed one patient and her partner leaving, as we arrived and saw that a nurse accompanied them to the reception area where a member of the reception team spoke with them and checked that further appointment times were convenient and offered them choice around available time slots. The general atmosphere was friendly and welcoming.

Communicating Effectively (Standard 18)

We were given a current copy of the Statement of Purpose and Service Users guide. These are documents which set out the terms of the service offered, the staff team, a review of the service and the outcome of engagement with patients. Both contained the required information.

There were only a small amount of posters and leaflets displayed to inform people about the different treatments and options that the clinic offered. We discussed this with the registered manager who told us that a 'Welcome pack' was sent to prospective patients which contained the relevant details. We were given a sample pack and the contents confirmed the information was current, offered guidance on choice of treatment, costs and how to raise a concern, should the need arise.

Delivery of safe and effective care

Overall HIW were assured that London Women's Clinic provided patients with safe, effective treatment and care which was based on agreed best practice guidelines and complied with safety requirements. **We saw that appropriate arrangements were in place to record and audit a range of practices within the service. However there were some areas of improvement identified which were required to meet the European Tissue Directive 2004 and the HFEA will be ensuring that the clinic will improve in these areas.**

Safe and Clinically Effective Care (Standard 7)

We found that treatment and care was based on agreed best practice guidelines. The service was consultant led, however any prescribed treatment was subsequently checked by two nurses prior to administration. Information leaflets were given to patients with regard to their individual treatment after each consultation. The HFEA shared specialist information with HIW which identified that there were some areas which were of concern such as witnessing of some clinical procedures, ensuring that pre-attendance screening was undertaken by accredited practitioners and within set timescales and clearer documenting of some clinical procedures. More detailed information can be obtained from the HFEA website (www.hfea.gov.uk).

Safeguarding Children and Safeguarding Vulnerable Adults (Standard 11)

The service had an up to date safeguarding policy and procedure in place. We were informed that there had been no safeguarding concerns or incidents to date and/ or within the last few years. Staff had received training in safeguarding.

Infection Prevention and Control (IPC) and Decontamination (Standard 13)

There were schedules in place for cleaning and there were contracts with regard to clinical waste and facility maintenance.

Medicines Management (Standard 15)

We saw that there were robust systems in place to reduce the potential for any medicine error. Only nurses had access to the code for the medicine cabinet and this code was changed regularly (i.e when any staff left the service). There were effective medicines management policies and procedures available. There was a system in place whereby two nurses checked the controlled drugs twice daily and an external accountable officer from a sister service visited to audit the controlled drugs. There was an electronic ordering and stock inventory facility which was checked weekly. We checked the process for dispensing medication for patients to take home and found that the system was safe, however the patient information leaflet enclosed

within each box needs to be manufacturer specific. This would ensure that the patient had the correct manufacturing information if there was a suspected reaction to the drug.

Medical Devices, Equipment and Diagnostic Systems (Standard 16)

There were maintenance contracts in place with regard to equipment. Comprehensive daily machine diagnostic check records were available. We saw that the anaesthetic machine was checked daily by the nurses but there was no signature to confirm that this had been undertaken. We were also notified by the HFEA that the laryngoscope on the emergency trolley did not have a battery and was therefore unusable.

Improvement needed

The registered person needs to ensure that staff sign that appropriate checks have been undertaken which includes checking that equipment is fit for use.

Dealing With Concerns and Managing Incidents (Standard 23)

We discussed raising a concern with the registered manager and were told that formal complaints were referred to the head office in London. However where possible they would try and deal with any concerns/complaints at a local level and this would be with the lead consultant. There was a system to record details of any investigation, outcome and action taken. There was also a system for evaluation of concerns and incidents. We looked at one on-going concern and saw that responses were timely and met with the company's complaint policy and procedure. The complaint policy was not easily available (although it was in the Service User guide) and we discussed adding this to the "Welcome Pack" and to make it visible in the reception area.

Quality of management and leadership

There was some evidence that the clinic monitored its performance to identify where they could make improvements to patient treatment and care. Whilst we found regular audits had been carried out, there were no outcomes or identified improvements recorded from the audits.

Governance and Accountability Framework (Standard 1)

The responsible individual (person with delegated responsibility for the running of the clinic) and the registered manager were present on the day of the visit. Both were visible and approachable to patients and staff.

A range of monthly audits had been carried out, including infection control, documentation audit review and infection control.

HIW had not received any regulation 30/31 notifications. (These are notifications of any untoward incidents or events). Discussion with the registered manager indicated that staff were not aware of the need to report to HIW. We were then told of a medicine management incident which could have potentially resulted in harm to a patient (there was no harm). It was documented and reported appropriately within the organisational reporting structure but HIW were not informed.

Improvement needed

HIW must be notified of any allegation of misconduct which results in actual or potential harm to a patient.

Workforce Recruitment and Employment Practices (Standard 24)

Staff appraisals indicated that the current staffing team had a personal development plan to meet identified needs. Staff training was on-going within the clinic. There was no concern with staffing levels, recruitment or retention. There had been no use of agency nurses for many years. Anaesthetists were recruited via an agency and to maintain continuity for patients, the same staff were contracted on an on going basis.

Next Steps

This inspection has resulted in the need for the service to complete an improvement plan in respect of Quality of Patient Experience, Delivery of Safe and Effective Care and Management and Leadership. The details of this can be seen within Appendix A of this report.

The improvement plan should clearly state how the improvement identified at London Women's Clinic (Wales) Ltd will be addressed, including timescales.

The improvement plan, once agreed, will be published on HIW's website and will be evaluated as part of the ongoing inspection process.

Appendix A

Improvement Plan

Service: London Women's Clinic (Cardiff)

Date of Inspection: 15 September 2015

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
Quality of Patient Experience					
Page 7	The registered person needs to ensure that the welfare and safety of patients is maintained by individualised, clear and consistent documentation.	Reg: 23	Documentation will include patient identification on all documents created and stored. Alerts will be placed on file to maintain welfare and safety of patients. Audit will be conducted by January 2016 to review change of practice	Dr Hemlata Thackare, PR to HFEA	15.01.2016
Page 7	The registered person needs to audit records to ensure all patients have consented to the agreed arrangements for storage and disposal of gametes.	Reg 40(2)	The Laboratory team routinely audits records for consent to storage and disposal of gametes/embryos. Gametes/embryos are kept in storage beyond the consented storage period only under	Jeanette MacKenzie, Laboratory Manager	On-going and routine

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
			exceptional circumstances as disposal of gametes is a permanent and irreversible procedure. At the time of this report only one couple has embryos in storage without consent as they are in the 'cooling off period'. The HFEA is aware of this case		
Delivery of Safe and Effective Care					
Page 10	The registered person needs to ensure that staff sign that appropriate checks have been undertaken which includes checking that equipment is fit for use.	Reg 15(2)	Staff has been reminded to conduct appropriate checks with signatures to confirm equipment is fit for use. Checklist and forms revised to ensure this. Audit will be conducted in January 2016 to review change in practice	Ms Anne Fisher, Nurse Manager	20.01.2016
Quality of Management and Leadership					
Page 11	HIW must be notified of any allegation of misconduct which results in actual or potential harm to a patient.	Reg 30/31	This is duly noted for future action	Dr Hemlata Thackare PR to HFEA	immediate

Service Representative:

Name (print): **Ms Anne Fisher**

Title: **Nurse Manager and Registered Manager to HIW**

Date: **04.11.2015**