

Independent Healthcare Inspection (Announced)

Centre for Reproduction and
Gynaecology Wales, Swansea

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Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of healthcare in Wales

Our purpose

To check that people in Wales receive good quality healthcare

Our values

We place patients at the heart of what we do. We are:

- **Independent**
- **Objective**
- **Caring**
- **Collaborative**
- **Authoritative**

Our priorities

Through our work we aim to:

Provide assurance:

Provide an independent view on the quality of care

Promote improvement:

Encourage improvement through reporting and sharing of good practice

Influence policy and standards:

Use what we find to influence policy, standards and practice

1. What we did

Healthcare Inspectorate Wales (HIW) completed an announced inspection of The Centre for Reproduction and Gynaecology (Wales), Swansea on the 6 August 2019.

Our team, for the inspection comprised of two HIW inspectors, one acting as lead inspector and one clinical peer reviewer.

HIW explored how the service complied with the Care Standards Act 2000, requirements of the Independent Health Care (Wales) Regulations 2011 and met the National Minimum Standards for Independent Health Care Services in Wales.

Further details about how we conduct independent service inspections can be found in Section 5 and on our website.

2. Summary of our inspection

We found that the Centre for Reproduction and Gynaecology Wales (CRGW), Swansea had arrangements in place to promote the safety and wellbeing of patients attending the clinic.

This is what we found the service did well:

- Patients provided positive feedback about their experiences
- Arrangements to promote and protect patients' privacy and dignity
- The clinic was clean and tidy and arrangements were in place to reduce cross infection
- Good medication management processes in place
- Records checked were of a good standard stored chronologically
- Communication between management and staff was effective
- Staff had access to the training and guidance that they needed to undertake their duties.

This is what we recommend the service could improve:

- Ensure there is accessibility for all patients.

There were no areas of non-compliance identified at this inspection.

3. What we found

Background of the service

The Centre for Reproduction and Gynaecology (Wales), Swansea (the clinic) is registered to provide an independent clinic for consultations and treatment planning on all modern fertility treatments at Unit 4, Penllergaer Business Park, Swansea, SA4 9JH. The location is considered a satellite site of the provider's main facility in Llantrisant.

The clinic only provides day care services.

The clinic was first registered on 10 September 2018.

The clinic employs a staff team which includes two nurses, two receptionists. Staff from the Llantrisant site also work at this location if required.

A range of services were provided which included:

- Initial and follow-up medical consultations
- Treatment planning to include; down regulation scan appointments; follicular tracking scans; pregnancy scans; semen analysis.

Quality of patient experience

We spoke with patients, their relatives, representatives and/or advocates (where appropriate) to ensure that the patients' perspective is at the centre of our approach to inspection.

Patients provided positive feedback about their experiences of using services provided at the clinic.

We saw that arrangements were in place to promote and protect patients' privacy and dignity.

Arrangements were also in place for patients to provide their views on the services provided.

Prior to the inspection, we invited patients to complete a HIW questionnaire to obtain their views on the care and support provided by the clinic. Twelve questionnaires were completed by people who had been a patient at the clinic ranging from less than six months to five years.

Overall, patient feedback was positive and most patients rated the care and treatment that they were provided with as excellent.

Health promotion, protection and improvement

There was information available for patients to read and take away, both in leaflet form in the reception area and handouts given during consultations, on how they can take responsibility for their own health and wellbeing. The clinic also has a website detailing the services offered. However, there was no health promotion material relating to fitness, healthy living and mental health. We advised the clinic to consider providing information on these subjects.

Dignity and respect

Patients were asked in the questionnaires whether they agreed or disagreed with a number of statements about the staff at CRGW. All patients agreed that staff were always polite and listened to them. Patients also told us that staff were kind and sensitive when carrying out their care and treatment. Patients provided the following comments in the questionnaires:

“All the nursing staff that we have seen have been excellent. Also the reception staff are always very welcoming and friendly”

“Staff have always been friendly and willing to listen. Have never felt my concerns were unimportant”

There was a sign on display in reception to advise patients that there were rooms available should they need to have a confidential discussion. Information was also displayed informing patients of their right to have a chaperone present when seen by healthcare staff. The use of chaperones aims to protect both the healthcare professional and patient when the patient is examined by the healthcare professional.

During our visit, there were no patient appointments planned at the clinic. However, the sample of patient records checked showed that their dignity and respect was considered. We also saw that privacy curtains were provided around examination couches to maintain patients' privacy and dignity during consultations or when they were receiving treatment.

Patient information and consent

All of the patients who completed a questionnaire agreed that staff had provided them with enough information about their treatment. This included information about the different treatment options available and any associated risks, and information about the costs involved; a patient provided the following comment in the questionnaires:

“Lovely, caring staff, from start to finish. Lots of information given. Never too much trouble to tell you what's happening. Puts your troubles at ease. Clean, comfortable environment. Excellent - highly recommend!”

There was a statement of purpose and separate patients' guide as required by the regulations. These set out information about the clinic and included information about the services offered, how they could be accessed and the arrangements for consent to treatment. There was also an up to date written policy on obtaining valid patient consent. At the entrance to the first floor treatment rooms there was a display showing staff names and photographs. There was also further information about the staff on the clinic website¹.

¹ <https://crgw.co.uk/>

Patient records checked during the inspection showed that patients received good information about their care, that was easy to understand and given at the right time so they could make the choice that was best for them. At the initial discussion patients were given information on legal implications, counselling, clinic procedures and treatments. At the second visit the consent process is demonstrated and explained to patients; they then take the forms away with them to complete. Internet links were also given to independent web pages that helped the patients understand the process.

Staff we spoke with stated that patients normally make self-referrals. Following the initial visit, the clinic writes to the patient's GP to establish whether there were any issues that would affect treatment or the welfare of the child; the GP has a month to reply. Staff also confirmed that if there were any other concerns, such as diabetes, the diabetic team at the health board were contacted.

Staff we spoke with stated that patients were given a price list at the initial consultation and at first treatment / consent visit. At treatment planning meetings with the patient there was an itemised bill showing all the costs prior to treatment starting.

Communicating effectively

The majority of information provided in leaflet form and on the website was provided in English only. Arrangements should be made to provide further information in Welsh and to help staff make an 'Active Offer'². Language Direct³ was available to translate for patients whose first language was not English. Efforts should also be made to provide information in other languages and formats, taking into consideration the communication needs and wishes of patients using the clinic.

There was not a hearing loop available to assist those patients who were hard of hearing (and who wear hearing aids) to communicate with staff at the clinic. However, one was ordered whilst we were at the clinic. We saw pictorial signs

² An 'Active Offer' means providing a service in Welsh without someone having to ask for it. <http://gov.wales/topics/health/publications/health/guidance/words/?lang=en>

³ <https://www.languagedirect.org/>

were displayed to assist patients to find a suitable emergency escape route in the event of a fire.

Care planning and provision

As previously mentioned there were no patients at the clinic on the day of our inspection. Staff we spoke with stated that there were rarely delays in patients being seen at the clinic, but if there was, patients would be told about the delay. Given the number of patients that have been seen at the clinic and the staff available, there was more than enough staff to provide a safe service and to meet the needs of the patient.

Equality, diversity and human rights

The clinic had been open under a year and was in a modern two storey building. There was parking outside the building including a designated disabled parking bay. The ground floor entrance had a wide door with an accessibility button to enable the door to be opened automatically from both the inside and the outside. At the time of the inspection these buttons were not working, meaning that those who required assistance with the door could not easily access the building.

The downstairs had a large lecture room and an empty consultation room. We were informed this room would be used for patients who could not use the stairs, as there was no lift access to the first floor of the building. The first floor included a number of consulting and treating rooms with equipment, there were also empty consulting rooms and laboratory that were not currently being used.

Improvement needed

The clinic is to ensure that the necessary repairs are made to the accessibility buttons on the front entrance door.

Citizen engagement and feedback

The majority of patients that completed a questionnaire told us that they would know how to make a complaint if they were unhappy with the service provided at the clinic. There was a notice displayed in reception explaining to patients how to make a complaint, this included the relevant information. Additionally, the complaints process was described on the statement of purpose, patients guide and on the clinic's internet pages. There was also a poster from the Human

Fertilisation and Embryology Authority (HFEA)⁴ explaining how to contact them should there be a need.

We were informed that there had not been any complaints at the Swansea clinic. If any complaints had been received these would have been discussed at clinical meetings. If there was a specific member of staff mentioned, this would be summarised at this meeting.

Feedback on the clinic was carried out following treatment at the Llantrisant clinic. Results were compiled and reported in the clinical meeting. Currently, consideration was not given on the questionnaires to the Swansea clinic. This was because the majority of the treatments, and consequently the questions asked, were carried out in Llantrisant. The clinic stated that they would consider separating the feedback, based on where the patient had the initial consultation, in the future.

⁴ <https://www.hfea.gov.uk/>

Delivery of safe and effective care

We considered the extent to which services provide high quality, safe and reliable care centred on individual patients.

The clinic was clean and tidy and arrangements were in place to reduce cross infection.

There were good medication management processes in place and effective processes for checking the equipment being use.

A range of policies and procedures were available to ensure that staff were guided on the correct actions to take.

Records checked were of a good standard.

Managing risk and health and safety

Arrangements were in place to protect the safety and well-being of staff working at, and people visiting, the clinic. We found the clinic to be well maintained both inside and out. The treatment rooms were clean, tidy and organised. The clinic had a risk management policy in place. There were a number of risk registers in place, which were regularly updated, to ensure that any risks were managed appropriately. The risk registers included, fire safety, laboratory, legionella and clinical assessments. There was also a flowchart process noted for the management of risk.

Infection prevention and control (IPC) and decontamination

There were no major concerns given by patients over the cleanliness of the clinic; every patient who completed a questionnaire strongly agreed, in their opinion, that the environment was both clean and tidy.

Staff we spoke with outlined the cleaning schedules in place at the clinic. We saw copies of the current contract in place for the removal of clinical waste from the facility. We also saw that clinical waste was stored in a secure area whilst

awaiting collection. Sharps devices were used, but not intravenous cannulas⁵ and there were secured sharps disposal bins readily available. This helps reduce the risk of injury (to staff and patients) and cross infection from used sharps.

Personal Protective Equipment (PPE) was readily available for staff use. The hand hygiene facilities available were appropriate and sufficient for staff and patient use. This included a ten steps of hand hygiene poster available on the walls above sinks. We were informed that any infectious patients were referred to the Llantrisant site. Effective hand washing is important to promote infection prevention and control.

The scanners were decontaminated, using a three-part decontamination system for non-lumened medical devices⁶, according to the manufactures guidance. This comprised three wipes which in sequence perform the steps of the decontamination procedure. This meant that devices were effectively decontaminated and so promoted effective infection prevention and control.

Infection control was considered to be good and there was an up to date infection control policy available. There were regular audits of infection control that were seen during the inspection.

Medicines management

A written policy was available on the management of medicines used at the clinic. This included reference to the MHRA yellow card scheme.⁷ Staff we spoke with stated that medicines management was reviewed by a pharmacist on an annual basis.

There were no controlled drugs in use at the clinic. The medicines that were held at the site were stored safely and securely in a locked cupboard with the key to

⁵ Intravenous (IV) cannulation is a technique in which a cannula is placed inside a vein to provide venous access. Venous access allows sampling of blood, as well as administration of fluids, medications, parenteral nutrition, chemotherapy, and blood products.

⁶ <http://www.amityinternational.com/wp-content/uploads/2018/11/3-step-sloution-brochure.pdf>

⁷ <https://yellowcard.mhra.gov.uk/>

the cupboard kept in a key safe. There was a minimum amount of medicines used at the clinic

Records were maintained of medicines administered to patients and were of a good standard. These records showed that patients had been asked about known allergies to promote their safety and wellbeing prior to medication being prescribed / administered as part of their care and treatment. All prescribed medicines were scanned into the patient notes using a portable document format (PDF)⁸.

Safeguarding children and safeguarding vulnerable adults

The Register Manager was the main safeguarding lead, with the Consultant Embryologist deputising in their absence. Both had completed level three safeguarding training appropriate for the role.

Written policies and procedures were available to guide staff on the action to take should they suspect abuse of children or adults who become vulnerable or at risk. These included contact details for health board and local authority safeguarding teams. Staff working at the clinic had completed safeguarding training to a level appropriate to their roles. Staff we spoke with were clear of their responsibilities in relation to reporting safeguarding issues.

Medical devices, equipment and diagnostic systems

We viewed the service contracts for the ultrasound scanners used at the clinic for diagnostic purposes. The documentation showed that the devices had been serviced by the manufacturer and safety checked to the manufacturers' guidelines. This helps to ensure that the scanners provide the user with accurate readings.

Safe and clinically effective care

Staff we spoke with stated that there were audits in place to monitor patient care, including record keeping audits. Staff were aware of the clinical guidelines

⁸ Portable Document Format (PDF) is a file format used to present and exchange documents reliably, independent of software, hardware, or operating system.

associated with their area of practice to ensure that there was safe and clinically effective care given.

Records management

There was a good standard of record keeping for the sample that we checked with records filed in a chronological order. The treatment protocols we reviewed explained the treatment required and medicines prescribed. This included a cooling off period for patients to further consider whether they wished to carry on with their treatment.

Records seen, showed that all decisions were discussed. Patients made the decision to go ahead following input from the professional team involved. Records were readily available for viewing following the correct level of access. Paper based notes were scanned into the system and the paper notes were destroyed.

Quality of management and leadership

We considered how services are managed and led and whether the workplace and organisational culture supports the provision of safe and effective care. We also considered how the service review and monitor their own performance against the Independent Health Care Regulations and National Minimum Standards.

Staff were able to describe their individual roles and responsibilities and told us they had access to the training and guidance that they needed to undertake their duties.

Staff also told us that they were aware of the management structure within the organisation and that the communication between management and staff was effective.

Governance and accountability framework

There were well defined systems and processes in place to ensure that the focus was on continuously improving the services. This was, in part, achieved through a rolling programme of audit and the established governance structure. This included nominated members of staff meeting regularly to discuss clinical outcomes associated with the delivery of patient care.

Staff we spoke with stated that there were good informal, day to day staff supervision and support processes in place. Staff also confirmed that they felt supported in their work by their manager and colleagues.

The clinic was in the process of changing the responsible individual so that the registered manager covered both roles. We were informed that the registered manager had intended handing over that role to the practice manager. However, a period of maternity leave meant that this had to be put on hold. The registered manager worked at the clinic on a regular basis and was on hand to support staff and to monitor the quality of the services provided.

There was evidence noted of regular meetings between the clinic and the main site. These meetings included heads of department, audit team and all staff meetings. The meetings are normally organised via Skype, a telecommunications application that specialises in providing video chat and voice calls between computers to enable all required personnel to be involved without travelling.

Dealing with concerns and managing incidents

Arrangements were described for reviewing significant incidents and sharing learning from these to promote patient safety and wellbeing. Significant incidents were formally reported and outcomes and lessons learnt shared with all staff members.

Non conformity reports were completed where minor errors are made, these reports were reviewed at monthly heads of departments meetings. This review examines how the actions can be addressed and fed back to the relevant team. Where there were major incidents such as a medical serious incidents (SIs), these were reported to the registered manager. Any SIs that related to the HFEA were reported via the Consultant Embryologist. No serious incidents had been reported in this clinic

Workforce planning, training and organisational development

Information contained within the staff files inspected demonstrated that staff had attended mandatory training and other training relevant to their roles. The clinic also maintained a training matrix for all staff so that any staff, who were out of date with their training requirements, could be identified easily.

None of the staff at the clinic had been employed for 12 months at the time of the inspection and therefore had yet to have an annual appraisal. When appraisals are due, staff we spoke with stated that nursing staff appraisals will be completed by the lead nurse and administrative staff appraisals will be completed by the practice manager.

The staff we spoke with on the day of our inspection were all able to describe their roles and how they contributed to the overall operation of the clinic.

There were no issues noted with the staff rotas and skill mix at the clinic. Appointments were pre-booked and the rota was staffed accordingly. The clinic also had the flexibility of staff from Swansea working in Llantrisant and vice-versa to ensure staff coverage and maintaining skills.

Workforce recruitment and employment practices

Workforce recruitment practices and procedures were being followed in line with regulations and standards. We viewed staff records and noted that the clinic had followed their procedures and undertaken relevant recruitment checks prior to staff starting in post. These included two references and checking the Nursing and Midwifery Council register for nurses to ensure they were registered. We also

saw evidence to confirm that each member of staff had undertaken a Disclosure and Barring Service (DBS) check as required by the regulations.

We noted that there was an induction policy for the clinic and that inductions had been completed for the staff at the clinic. In addition to there being an induction checklist covering working at the clinic in general terms, there were also specific induction programmes for qualified nurses and one for health care support workers. These inductions involved assessments on various aspects of fertility and care and competency frameworks that had to be signed off by a preceptor (teacher or instructor).

4. What next?

Where we have identified improvements and immediate concerns during our inspection which require the service to take action, these are detailed in the following ways within the appendices of this report (where these apply):

- Appendix A: Includes a summary of any concerns regarding patient safety which were escalated and resolved during the inspection
- Appendix B: Includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

Where we identify any serious regulatory breaches and concerns about the safety and wellbeing of patients using the service, the registered provider of the service will be notified via a [non-compliance notice](#). The issuing of a non-compliance notice is a serious matter and is the first step in a process which may lead to civil or criminal proceedings.

The improvement plans should:

- Clearly state when and how the findings identified will be addressed, including timescales
- Ensure actions taken in response to the issues identified are specific, measurable, achievable, realistic and timed
- Include enough detail to provide HIW and the public with assurance that the findings identified will be sufficiently addressed.

As a result of the findings from this inspection the service should:

- Ensure that findings are not systemic across other areas within the wider organisation
- Provide HIW with updates where actions remain outstanding and/or in progress, to confirm when these have been addressed.

The improvement plan, once agreed, will be published on HIW's website.

5. How we inspect independent services

Our inspections of independent services may be announced or unannounced. We will always seek to conduct unannounced inspections because this allows us to see services in the way they usually operate. The service does not receive any advance warning of an unannounced inspection. In some circumstances, we will decide to undertake an announced inspection, meaning that the service will be given up to 12 weeks' notice of the inspection.

Feedback is made available to service representatives at the end of the inspection, in a way which supports learning, development and improvement at both operational and strategic levels.

HIW inspections of independent healthcare services will look at how services:

- Comply with the [Care Standards Act 2000](#)
- Comply with the [Independent Health Care \(Wales\) Regulations 2011](#)
- Meet the [National Minimum Standards](#) for Independent Health Care Services in Wales.

We also consider other professional standards and guidance as applicable.

These inspections capture a snapshot of the standards of care within independent services.

Further detail about [how HIW inspects independent services](#) can be found on our website.

Appendix A – Summary of concerns resolved during the inspection

The table below summaries the concerns identified and escalated during our inspection. Due to the impact/potential impact on patient care and treatment these concerns needed to be addressed straight away, during the inspection.

Immediate concerns identified	Impact/potential impact on patient care and treatment	How HIW escalated the concern	How the concern was resolved
No immediate concerns were identified on this inspection.			

Appendix B – Improvement plan

Service: Centre for Reproduction and Gynaecology Wales, Swansea

Date of inspection: 6 August 2019

The table below includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
Quality of the patient experience				
The clinic is to ensure that the necessary repairs are made to the accessibility buttons on the front entrance door.	2. Equality, diversity and human rights	A Door bell has been placed on the door with a sign asking clients to press it for assistance in to the unit- so we are aware of people who need help into the clinic and also those who might need help to manage the stairs to reception	Amanda OLeary	Already done and in place
Delivery of safe and effective care				
No areas for improvement identified during this inspection on this theme.				
Quality of management and leadership				

Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
No areas for improvement identified during this inspection on this theme.				

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.

Service representative

Name (print): Amanda Oleary
Job role: Registered Clinic Manager
Date: 19/09/19