

Independent Healthcare Inspection (Announced)

Centre for Reproduction
and Gynaecology Wales
(CRGW)

12 & 13 January 2016

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1. 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 Wales¹.

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>

2. Methodology

This inspection was undertaken jointly with the Human Fertilisation and Embryology Authority (HFEA). The report is based on the information gathered by both organisations. 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
- Conversations with patients and relatives
- Examination of a sample of patient records
- Examination of policies and procedures
- Examination of equipment and the environment
- Information within the service's statement of purpose, patient's guide and website
- HIW patient questionnaires.

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 notice². 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.

3. Context

Centre for Reproduction and Gynaecology Wales (CRGW) is registered as an independent hospital at Ely Meadows (Medi-Science Park), Rhodfa Marics, Llantrisant, CF72 8XL. The service provides day patient fertility services for adults. The service was first registered on 30 July 2010.

The service employs a staff team which includes four consultant obstetrician and gynaecologists, three fertility nurses, three nursing assistants, four embryologists, a practice manager and administration staff.

A range of services are provided which include:

- IVF (In Vitro Fertilisation)
- ICSI (Intracytoplasmic Sperm Injection)
- IUI (Intrauterine Insemination)
- Ovulation Induction and Intrauterine Insemination (OI/IUI)
- Egg donation
- Egg sharing
- Blastocyst culture
- Assisted hatching
- Embryo freezing
- EmbryoScope time-lapse imaging
- Sperm freezing
- Surgical sperm retrieval.

4. Summary

The evidence we found demonstrated that the service works hard to provide a patient centred service and are committed to making it the best possible experience for patients. The staff we spoke to were passionate about their work and cared a great deal for the patients they treated. There were opportunities sought by the service at the end of each treatment cycle where patient feedback was asked for and this information was used to shape and improve the service.

We spoke to some patients being treated by the CRGW and also obtained questionnaire feedback from seven other patients receiving treatment. Their comments were overwhelmingly positive about all aspects of the service.

Overall, HIW were assured that the Centre for Reproduction and Gynaecology Wales provides 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.

There were some improvements identified to the controlled drug record book and we have also recommended that the service revisit their current policies for safeguarding adults and laundry handling.

There was a stable team of staff working at the service and they were led day to day by the registered manager and responsible individual. Staff were encouraged to actively contribute ideas to the running of the service and we found that the registered manager and other senior staff worked hard to promote high quality care and treatment.

We identified the following areas for improvement during this inspection regarding – the method of recording patient treatment and clinical observations during invasive procedures. 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.

5. Findings

Quality of patient experience

The evidence we found demonstrated that the service work hard to provide a patient centred service and are committed to making it the best possible experience for patients. The staff we spoke to were passionate about their work and cared a great deal for the patients they treated. There were opportunities sought by the service at the end of each treatment cycle where patient feedback was asked for and this information was used to shape and improve the service.

We spoke to some patients being treated by the CRGW and also obtained questionnaire feedback from seven other patients receiving treatment. Their comments were overwhelmingly positive about all aspects of the service.

During this inspection, in conjunction with the HFEA, we were able to speak to some patients receiving treatment. We also left some questionnaires and seven were completed and returned to us. Patients were unanimously positive about the care and treatment they had received from staff at the CRGW and provided us with the following comments which they consented to us using in our report:

“Very kind clinic – put patients first!”

“Excellent, friendly staff. I feel well supported throughout my treatment.”

“The open day we attended was very well organised with just the right amount of information needed to make our decision. It was from this open day that we decided the clinic was the right choice for us.”

Citizen engagement and feedback (standard 5)

The service regularly reviews the quality and patient satisfaction levels of its service. At the end of every treatment cycle they provide, patient(s) are asked to complete a questionnaire. The staff told us that there is a good response to this and they commit to reviewing and analysing the results so that they can identify if there are any ways in which they could improve.

A variety of treatment information leaflets were also available for patients. These were treatment specific.

We discussed the need to consider the provision of information to patients in Welsh and English and other languages as necessary. Other formats such as easy read font and audio may also need to be given consideration depending on the needs of

the patient population. We were told that so far there have been no requests or need for the service information to be provided in any other manner. The registered manager agreed, however, that it would be a good idea to review this and engaging with their patients for feedback on this would make this review even more beneficial.

Care planning and provision (standard 8)

We sampled a number of patient records between during the inspection, which were all electronic. However, some of the information had been completed on paper and then scanned on to the electronic record. Whilst we found that generally, all the required information was there, sometimes the two methods being used together meant that it could be difficult to locate everything that was relevant. Staff using the documents every day will obviously be familiar with where they store information, however there is a risk that if they need to be revisited in future they will be hard to navigate. We advised that they review the use of their electronic system to ensure that there is no information missing, whatever format the records take.

Patient information and consent (standard 9)

Obtaining consent from patients going through fertility treatments is a key part of the process. We discussed this with staff and were assured by their knowledge and understanding of consent and the complex legal issues that relate to fertility treatment. We concluded that their knowledge was sufficiently in depth to ensure they would do their utmost to handle this process as sensitively and carefully as possible to ensure that patients understand the breadth of legalities surrounding fertility treatment.

We advised that the consent process could be strengthened further by creating some written protocols setting out the process and referencing legal considerations; these would be particularly useful to support instances where patients may change their decision, or where staff consider that they need to reconsider their decision.

Improvement needed

Review the current consent policy to ensure that there is reference to how staff should respond to possible changes in patient consent which may happen at any stage during the treatment process.

Dignity and respect (standard 10)

The main waiting area at the service is large and open but there is a small waiting area away from this which could be used if patients prefer. There are numerous clinic rooms and a large conference room, one of which is often available and can be used if patients need privacy. During our visit, we noted that patients were arriving and being seen quickly, there did not seem to be long periods of waiting.

The more invasive treatments that are carried out by the service are carried out in a different part of the building away from the main reception and waiting area, therefore giving further privacy.

Communicating effectively (standard 18)

There is a large variety of patient information available online on the service's own website. There were also paper information leaflets at the service for patients to take away with them. Staff explained to us that their patients tended to be well informed about treatment options before coming to them. They give tailored treatment information leaflets depending on the recommended and chosen course of treatment for each individual.

The information documents required by the regulations (statement of purpose and service user guide) were available in paper form at the service. The documents were combined into one and were detailed and informative; we advised the registered manager to update the document and to review it against the regulations to ensure that it is fully compliant. We did not explore whether or not the statement of purpose, or the content within it is made available to all patients but in accordance with the regulations, the registered manager should ensure that it is. The service managers should consider whether this could usefully be added to their website providing another method for easy access.

Delivery of safe and effective care

Overall, HIW were assured that the Centre for Reproduction and Gynaecology Wales provides 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.

There were some improvements identified to the controlled drug record book and we have also recommended that the service revisit their current policies for safeguarding adults and laundry handling.

Safe and clinically effective care (standard 7)

We found that treatment and care was based on agreed best practice guidelines. The service is consultant led and includes medical staff with additional specialist training specific to this area of work. There are also three highly trained fertility nurses who have additional skills and can undertake some of the clinical procedures, including scans.

During invasive treatment at the service, we saw that the records were being completed directly onto electronic notes. Whilst in principle this is a good idea, it was not in a format which was tamper proof and it did not allow for a full audit trail of any changes or additions to the records that may at any point be made. We were concerned by this finding and raised it immediately. The staff were receptive to our findings and agreed that this was unsafe record keeping. They developed a solution to remove the risk which they were going to start using with immediate effect. We were assured with the action taken by the service to address this matter.

Safeguarding children and safeguarding vulnerable adults (standard 11)

The staff we spoke to had in depth knowledge of the specialist safeguarding considerations relating to their area of work. This included legislation concerning welfare of the child.

We recommended that they could improve their adult safeguarding knowledge and policies by giving further consideration to general safeguarding principles, rather than just those associated with their specialist area of work. We discussed this and suggested that they should consider speaking to other fertility services to see how they manage the confidentiality and data handling requirements that they must adhere to.

Improvement needed

Explore safeguarding policies and ensure they are as robust and appropriate as possible considering the specialist area of work.

Infection prevention and control and decontamination (standard 13)

There was a system in place for cleaning and tidying the service. There were cleaning staff who cleaned all general areas within the service three times each week; this included the waiting area, entrance and toilets. All specialist areas (i.e. those used for treatment) were cleaned by the nursing staff.

One of the fertility nurses has some management responsibilities and it is her responsibility to monitor the standards of cleaning and ensure all areas are being properly maintained. Through the regular audits she carries out to check cleanliness, she had identified that the current cleaning hours were not sufficient to consistency maintain standards and as a result, the service were planning to increase the days that cleaning staff are employed for.

During the course of each day, it is the responsibility of all staff (although predominantly nursing staff) to top up patient areas, such as toilets, with toilet rolls and paper towels and to attend to any areas which need to be cleaned unexpectedly. We discussed this and advised the service to consider whether this is the most appropriate use of existing staff time and whether something such as an additional housekeeping role may alleviate some of this additional work and mean it is completed by more appropriate staff.

We looked at the areas where invasive treatment takes place and where patients are taken to recover after they have received anaesthetic or sedation. These areas were visibly clean, tidy and free from clutter. We did identify that all sinks used by clinical staff for hand washing should be designated as such, with appropriate soap dispensers and a no touch bin nearby for disposal of paper towels.

We saw that there was no appropriate area to dispose of any liquid waste, without the potential for contaminating clean areas. We discussed current procedures and the staff agreed to source an interim solution so that any liquid waste could be disposed of appropriately. In the longer term, the layout and sinks in the clinical room next to theatre may need to be reconfigured so that liquid waste can be disposed of without contaminating clean items and areas.

Improvement needed

Ensure that there are suitable facilities for the disposal of liquid waste and that these are positioned so that clean surfaces and equipment cannot be contaminated during disposal.

All laundry generated by the service (theatre scrubs, sheets and covers from patient treatment couches and recovery room beds) is washed and dried by staff during the day. There is a washing machine and tumble drier in a room on the ground floor of the service. There was a laundry policy which we saw and we also discussed the process with staff. Both the policy and the discussion we had assured us that they had given considerable thought to the way they safely handle the laundry. However, this task is done by staff in addition to providing patient care and whilst we acknowledged that it was being fitted in at times when staff were not caring for patients, we were not content that this was being done by the most appropriate staff members. We discussed the current practice at length and suggested that the whole process be reviewed. In the interim, we have advised the registered manager to explore a way to monitor the wash cycle to ensure that it reaches the required temperature for a sufficient length of time to ensure that decontamination of laundry is achieved.

Improvement needed

Review the current laundry management process; including ensuring the wash cycle is adequate. Inform HIW in writing of the outcome of this review, including any evidence which has informed the decisions made. If the current system is to remain, advise HIW in writing of who will do the laundry in future and whether ongoing calibration of the machine is possible.

Medicines management (standard 15)

We looked at the systems used by the service for ordering, storing, prescribing and administering medication. Whilst we found no evidence that there had been any issues as a result of the practices, we did find that a number of steps within the process could be improved:

The controlled drug record book was adequate but could be improved. We suggested some changes to the system used to record the medication at the point of administration, so that the total amount given and any wastage could be clearly and consistently identified.

Medical devices, equipment and diagnostic systems (standard 16)

There were maintenance contracts in place for all equipment. Comprehensive daily diagnostic check records were available for laboratory machines. The service had sought advice on the content of the resuscitation trolley to ensure that the equipment available was only what was necessary and within the competency of the staff. We found that staff had up to date training in basic life support, but did not have any higher level life support training. We suggested that they consider training some members of staff in additional life support skills.

Dealing with concerns and managing incidents (standard 23)

We saw that there was a log of all concerns, complaints and incidents. At the time of our inspection, none were active and all had been resolved.

We were told about the system for reviewing incidents which depended on the severity. For serious concerns and incidents, the issues would be reviewed immediately. All other incidents were reviewed at the next incident meeting – these take place twice a month.

Patient related incidents and non patient related incidents are all recorded on one log as the clinic managers want to be made aware of the full range of issues affecting the service, all of which ultimately could lead to a less positive patient experience if not addressed adequately.

Quality of management and leadership

There was a stable team of staff working at the service and they were led day to day by the registered manager and responsible individual. Staff were encouraged to actively contribute ideas to the running of the service and we found that the registered manager and other senior staff worked hard to promote high quality care and treatment.

Governance and accountability framework (standard 1)

We found evidence of strong team working at the clinic which was supported by the registered manager and responsible individual (both of whom are clinical consultants).

We spoke to a number of different staff members, all of whom were clear about their roles and responsibilities and also had confidence in being able to make suggestions about trying new ideas which might improve the way they work.

It was evident that there was clear leadership from the registered manager, responsible individual, one of the fertility nurses and consultant embryologist who form the management team responsible for overseeing the service. They had recently appointed a practice manager who will take on the day to day management of the service and be an additional key part of the management team.

The team were already auditing the quality of their work and held monthly quality meetings which they used to discuss policies, procedures and any arising issues which need to be addressed.

Workforce recruitment and employment practices (standard 24)

There was a stable staff team, many of whom had worked at the clinic since it opened. On the occasion when new staff were recruited, there were some pre employment checks carried out to determine their suitability to be involved in the work at the service. We saw an example of this and found that the procedures for obtaining references could be improved so that there are two written references for all staff members in accordance with the regulations. The registered manager agreed to address this.

All staff had recently been rechecked against the disclosure and barring list (DBS checks) in order to update their records.

There were records of training for each staff member and the approach of the registered manager was to support all staff through additional training relevant to their development. One member of staff was currently being supported through a

specialist master's degree qualification which would enable her to use additional clinical skills at the service once completed.

6. Next Steps

This inspection has resulted in the need for the service to complete an improvement plan in respect of the delivery of safe and effective care. The details of this can be seen within Appendix A of this report.

The improvement plan should clearly state how the improvement identified at Centre for Reproduction and Gynaecology Wales 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: Centre for Reproduction and Gynaecology Wales

Date of Inspection: 12 & 13 January 2016

| Page Number | Improvement Needed | Regulation / Standard | Service Action | Responsible Officer | Timescale |
|--|---|-----------------------------|----------------|---------------------|-----------|
| Quality of Patient Experience | | | | | |
| 7 | <i>Review the current consent policy to ensure that there is reference to how staff should respond to possible changes in patient consent which may happen at any stage during the treatment process.</i> | Regulation 9 / Standard 9 | | | |
| Delivery of Safe and Effective Care | | | | | |
| 10 | <i>Review current safeguarding policies and ensure they are as</i> | Regulation 16 / Standard 11 | | | |

| Page Number | Improvement Needed | Regulation / Standard | Service Action | Responsible Officer | Timescale |
|-------------|---|--------------------------------|----------------|---------------------|-----------|
| | <i>robust and appropriate as possible considering the specialist area of work.</i> | | | | |
| 10 | <i>Ensure that there are suitable facilities for the disposal of liquid waste and that these are positioned so that clean surfaces and equipment cannot be contaminated during disposal.</i> | Regulation 15/ Standard 13 | | | |
| 11 | <i>Review the current laundry management process; including ensuring the wash cycle is adequate. Inform HIW in writing of the outcome of this review, including any evidence which has informed the decisions made. If the current system is to remain, advise HIW in writing of who will do the laundry in future and whether ongoing calibration of the machine</i> | Regulation 15 / Standard 13 | | | |

| Page Number | Improvement Needed | Regulation / Standard | Service Action | Responsible Officer | Timescale |
|---|------------------------|-----------------------|----------------|---------------------|-----------|
| | <i>is possible.</i> | | | | |
| Quality of Management and Leadership | | | | | |
| | No improvements needed | | | | |

Service Representative:

Name (print):

Title:

Date: