The Regulation and Quality Improvement Authority

Inspection Report

26 January 2022

In-Ovo Fertility Clinic

Type of Service: Independent Hospital (IH)
Fertility Services and Assisted Conception
Address: Unit 1,189 Airport Road West, Portside Business Park, Belfast, BT3 9ED
Telephone Number: 028 9620 7100

Information on legislation and standards underpinning inspections can be found on our website https://www.rqia.org.uk/; The Independent Health Care Regulations (Northern Ireland) 2005 and the Minimum Care Standards for Independent Healthcare Establishments (July 2014)

1.0 Service information

Organisation/Registered Provider: In-Ovo Fertility Clinic Limited **Responsible Individual:** Dr Efstathios Diakos	**Registered Manger:** Ms Melanie Stanton **Date registered:** 17 September 2020
Person in charge at the time of inspection: Dr Efstathios Diakos	
Categories of care: Independent hospital (IH) Prescribed techniques or prescribed technology: establishments providing in vitro fertilisation techniques PT (IVF) Private doctor (PD)	
Brief description of how the service operates: In-Ovo Fertility Clinic is registered as an independent hospital (IH) with prescribed techniques or prescribed technology: establishments providing in vitro fertilisation techniques PT (IVF) and private doctor (PD) categories of care.	

2.0 Inspection summary

An unannounced inspection was undertaken to In-Ovo Fertility Clinic which commenced with an onsite inspection on 26 January 2022 from 10.00 am to 5.20pm; followed by a request for the submission of information electronically.

The purpose of this inspection was to assess progress with any areas for improvement identified during and since the last inspection and to examine a number of aspects of the establishment from front-line care and practices, to the management and oversight of governance across the establishment.

A multidisciplinary inspection methodology was employed during this inspection and the inspection team met with patients; various staff members; reviewed care practices; and relevant records and documentation used to support the governance and assurance systems.

It was determined that staffing levels and morale in the establishment were good; with evidence of good multidisciplinary team working and open communication between staff. Staff feedback was positive; they told us that they were happy, well supported and that there were good working relationships throughout the establishment.

Staff were observed treating patients with dignity and were respectful of patients' right to privacy and to make informed choices.

No concerns were identified in relation to patient safety, and the inspection team noted areas of strength, particularly in relation to the delivery of front line care.

The arrangements for governance and managerial oversight within the establishment were reviewed and this provided assurance concerning the overarching governance structure.

Examples of good practice were evidenced in respect of: staffing; recruitment and selection of staff; safeguarding; the provision of assisted conception services; the management of a medical emergency; medicines management; the management of the patients' care pathway; communication; records management; clinical and organisational governance; engagement to enhance the patients' experience and the maintenance of the environment.

Six areas for improvement have been identified. One area for improvement was identified against the regulations in relation to staff training and five areas for improvement have been identified against the standards in relation to: ensuring the registered manager has an annual appraisal undertaken; dating policies, procedures and protocols when issued, reviewed or revised; reviewing the standard operating procedures (SOP) for COVID-19 in accordance with current guidance; developing a more robust infection prevention and control (IPC) audit programme; and reviewing the storage of bedlinen in accordance with best practice guidance.

3.0 How we inspect

RQIA is required to inspect registered services in accordance with legislation. To do this, we gather and review the information we hold about the service, examine a variety of relevant records, meet and talk with staff and management and observe practices on the day of the inspection.

The information obtained is then considered before a determination is made on whether the establishment is operating in accordance with the relevant legislation and minimum standards. Examples of good practice are acknowledged and any areas for improvement are discussed with the person in charge and detailed in the Quality Improvement Plan (QIP).

In response to the COVID-19 pandemic we reviewed our inspection methodology during the 2020/21 inspection year and considered various options to undertake inspections. The purpose of this was to minimise risk to patients and staff, including our staff, whilst being assured that registered services are providing services in keeping with the minimum standards and relevant legislation. Having considered different inspection methodologies a decision was taken to undertake multidisciplinary blended themed inspections. The blended methodology includes an onsite inspection and electronic submission of additional documentation to be reviewed remotely by the inspector. As the COVID-19 pandemic is ongoing a decision was taken to continue with this inspection methodology during the 2021/22 inspection year. The onsite component of our inspection was completed on 26 January 2022 by three care inspectors supported by Dr Mark Evans, RQIA's Adept Fellow and an RQIA pharmacy inspector. The onsite inspection team examined a number of aspects of the In-Ovo Fertility Clinic services as outlined in section 2.0 of this report.

Prior to the inspection we reviewed a range of information relevant to the establishment. This included the following records:

- notifiable events since the previous care inspection
- the registration status of the establishment
- written and verbal communication received since the previous care inspection
- the previous care inspection report
- the returned QIP from the previous care inspection

At the onset of this inspection In-Ovo Fertility Clinic was provided with a list of specific documents requesting items to be reviewed remotely in respect of the maintenance of the premises and grounds. These items were to be sent electronically to our estates inspector on or before 1 February 2022 for review remotely.

Formal feedback of the inspection findings was delivered to the In-Ovo Fertility Clinic senior management team on 9 February 2022 during a Zoom teleconference.

4.0 What people told us about the service

The inspection team had the opportunity to speak with patients during the inspection who stated that they had experienced a very high standard of care delivery and were very pleased with all aspects of the services they received.

Staff provide satisfaction surveys to patients following their treatment and findings are shared through their governance structures. A review of a recent patient satisfaction report demonstrated that In-Ovo Fertility Clinic pro-actively seeks the views of patients and their partners about the quality of care, treatment and other services provided. Patient feedback regarding the fertility service was found to be very positive in respect to all aspects of care received and reflected staff deliver a very high standard of care.

Staff were invited to complete an electronic questionnaire. No completed staff questionnaires were submitted following the inspection.

All staff spoken with during the inspection spoke about In-Ovo Fertility Clinic in positive terms. Staff spoke in a complimentary manner regarding the senior management team and the communication and support they have provided.

5.0 The inspection

5.1 What has this service done to meet any areas for improvement identified at or since the last inspection?

Areas for improvement from the last inspection on 22 July 2020		
Action required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005		**Validation of compliance**
Area for Improvement 1 **Ref:** Regulation 19, Schedule 2 (as amended) **Stated:** First time	The responsible individual shall ensure that all recruitment documents as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 are in place for any new staff member prior to commencing work in the clinic.	Met
	Action taken as confirmed during the inspection: This area for improvement has been assessed as met, further detail is provided in section 5.2.2.	

5.2 Inspection findings

5.2.1 How does the establishment ensure that safe staffing arrangements are in place to meet the needs of patients?

Staffing arrangements were reviewed and it was confirmed that there are appropriately skilled and qualified staff involved in the delivery of services. This includes Dr Diakos, two consultant anaesthetists, embryologists and registered nurses who have completed specialist qualifications and can demonstrate competency in fertility treatments.

Staff spoken with confirmed that induction programmes were in place appropriate to the roles and responsibilities within the establishment and induction records in respect of recently appointed staff had been retained.

A system was in place to monitor all aspects of ongoing professional development and a record was retained of all training and professional development activities. A review of records identified that all staff had undertaken training in keeping with RQIA training guidance and legislation with the exception of IPC training. A review of the IPC training records evidenced that staff IPC training was not up to date and also not all relevant staff had received aseptic non-touch technique (ANTT) training. However, on 25 February 2022 Ms Stanton provided copies of training certificates which verified that all relevant staff had completed ANTT training.

An area for improvement has been made against the regulations to ensure all relevant staff undertake IPC training in keeping with RQIA training guidance.

Procedures were in place for appraising staff performance. Staff confirmed that appraisals had taken place, however it was identified that Ms Stanton had not yet had an appraisal undertaken. This was discussed with Ms Stanton and assurances were given that the annual appraisal would be undertaken in respect of the Ms Stanton during February 2022. An area for improvement has been made against the standards in this regard.

It was noted that nursing staff did not regularly receive professional/clinical supervision. Supervision is an important part of professional development and it was advised that nursing staff should have supervision in line with their professional regulatory body; legislation and minimum standards. This was discussed during feedback and assurances were provided that this would be an area of further developmental support for all nursing staff moving forward.

Discussion with Ms Stanton and review of documentation identified that arrangements were in place to check the registration status for all clinical staff on appointment, for example: medical practitioners with the General Medical Council (GMC) and nursing staff with the Nursing and Midwifery Council (NMC). It was evidenced that for medical practitioners, their registration status and professional indemnity continues to be monitored during the renewal of their practising privileges agreement which occurs every two years (further in section 5.2.10). It was also identified that a robust system for ongoing monitoring of the professional body registration status of all clinical staff and the arrangements for monitoring the professional indemnity of all staff was in place.

Discussion with staff confirmed there are good working relationships. Staff spoke positively regarding the establishment, felt valued as members of the team and confirmed they were supported by management.

It was evidenced that sufficient staff were in place to meet the needs of patients.

5.2.2 How does the establishment ensure that recruitment and selection procedures are safe?

The arrangements in respect of the recruitment and selection of staff were reviewed.

A review of the policy and procedure for the recruitment and selection of staff found that the policy was in accordance with legislation and best practice guidance.

A number of staff had been recruited since the previous inspection. A review of a random sample of four personnel files of newly recruited staff evidenced that all the relevant information as listed in Regulation 19, Schedule 2 of the Independent Health Care Regulations (NI) 2005 had been sought and retained. It was determined that the previous area of improvement made against the regulations, as outlined in section 5.1 has been met.

Hepatitis B vaccination is recommended for clinical staff as it protects them if exposed to this virus. It was identified that a system was not in place to ensure that relevant members of the clinical team have received this vaccination. This was discussed with the Ms Stanton who confirmed that current clinical staff would have their Hepatitis B immunisation status assessed at the earliest opportunity.

A staff register was available to review which was up to date and included the names and details of all staff who are and have been employed, in keeping with legislation.

Robust recruitment and selection procedures were in place to ensure compliance with the legislation and best practice guidance.

5.2.3 Are the arrangements in place for safeguarding in accordance with current regional guidance?

The arrangements in respect of the safeguarding of adults and children were reviewed.

Staff spoken with were aware of the types and indicators of abuse and the actions to be taken in the event of a safeguarding issue being identified.

Review of records demonstrated that all staff had received training in safeguarding adults as outlined in the Minimum Care Standards for Independent Healthcare Establishments July 2014. Review of records demonstrated that Dr Diakos and the Ms Stanton as safeguarding leads, have completed formal training in safeguarding adults in keeping with the Northern Ireland Adult Safeguarding Partnership (NIASP) training strategy (revised 2016) and minimum standards.

Policies and procedures were in place for the safeguarding and protection of adults and children at risk of harm that fully reflect the regional policies and guidance documents. The policies included the types and indicators of abuse and distinct referral pathways in the event of a safeguarding issue arising with an adult or child. The relevant contact details were included for onward referral to the local Health and Social Care Trust should a safeguarding issue arise.

It was confirmed that copies of the regional guidance documents entitled ‘Adult Safeguarding Prevention and Protection in Partnership’ and ‘Co-operating to Safeguard Children and Young People in Northern Ireland’ were available for staff reference.

The service had appropriate arrangements in place to manage a safeguarding issue should it arise.

5.2.4 Does the establishment adhere to best practice guidance concerning the management of patients undergoing fertility treatment?

In-Ovo Fertility Clinic is licensed with the Human Fertilisation and Embryology Authority (HFEA), the UK’s independent regulator for the fertility sector. In-Ovo Fertility Clinic has held a Treatment and Storage license with the HFEA since 2020 and provides a full range of fertility services.

A range of treatment protocols were in place for the management of patients receiving assisted conception services which have been developed and agreed by all professionals within the establishment. It was identified that the protocols examined did not include review dates. This was discussed and an area for improvement has been made against the standards to ensure that all policies, procedures and treatment protocols for the management of patients receiving assisted conception services have been dated when issued, reviewed or revised.

The protocols for the prevention and management of ovarian hyper stimulation syndrome (OHSS) have been written by the lead clinicians, a review of these protocols demonstrated that they were evidence based and in line with best practice.

It was confirmed that written protocols are in place for the close monitoring of patients, in order to avoid unnecessary complications including multiple pregnancies.

An elective single embryo transfer (eSET) protocol was in place. It was confirmed that the eSET protocol sets out the number of embryos that can be placed in a patient in any one cycle and this protocol complies with the HFEA code of practice. The protocols and procedures were discussed with the staff who demonstrated detailed knowledge on the matter.

It was confirmed that the establishment have a procedure for indelible labelling of material for individual patients to ensure the unique identification of a patient's material and the checking and recording of all stages of treatment.

There was evidence that there is suitable counselling regarding treatment and outcomes and there was documentation to reflect this. Staff confirmed that patients and their partners are treated with respect, dignity and compassion. We observed a number of limited interactions between staff and patients that confirmed this approach.

A daily multidisciplinary clinical meeting takes place attended by Dr Diakos, registered nurses and members of the embryology team, to decide and agree patient treatment plans,discuss the management of patients and any recommended changes to treatment plans would be discussed and agreed at these meetings.

A review of a selection of patients' clinical records found that all records were well completed and clearly outlined the patient pathway.

It was identified that a laboratory audit programme was under development. A monthly witnessing audit is carried out to ensure compliance with the HFEA code of conduct. As the service has now been operational for over one year a cryostorage audit is under development and will be implemented on a rolling programme basis.

Discussion with staff and review of relevant policies and procedures evidenced that In-Ovo Fertility Clinic were adhering to HFEA best practice guidance.

5.2.5 Is this establishment fully equipped and are the staff trained to manage medical emergencies?

The arrangements in respect of the management of medical emergencies were reviewed.

The policy for the management of medical emergencies reviewed was in keeping with best practice.

A review of medical emergency arrangements evidenced that emergency medicines were provided in keeping with the British National Formulary (BNF), and emergency equipment as recommended by the Resuscitation Council (UK) guidelines was retained.

A record of all emergency medicines and equipment is attached to the emergency trolley and a written record is retained of the daily and monthly checks carried out by a designated member of staff.

Staff spoken with demonstrated knowledge and understanding of managing resuscitation and other medical emergencies and were aware of the location of medical emergency medicines and equipment.

A review of training records confirmed staff have received basic life support training, nurses have received immediate life support training and anaesthetists have advanced life support skills.

Review of the arrangements to manage a medical emergency identified that staff were suitably trained and appropriate medicines and equipment were in place to manage a medical emergency.

5.2.6 Are arrangements in place to minimise the risk of COVID-19 transmission?

COVID-19 has been declared as a public health emergency and we all need to assess and manage the risks of COVID-19, and in particular healthcare settings need to consider the risks to their patients and staff.

The management of operations in response to the COVID-19 pandemic was discussed with the staff; and application of the current best practice guidance. The SOP for COVID-19 entitled Treatment Commencement Strategy issued on 8 June 2020 was very comprehensive and directly related to the provision of an assisted fertility service. However, this SOP had not been reviewed in line with changing best practice guidance. A risk assessment which clearly outlined COVID -19 risks within the clinic was not in place. An area for improvement has been identified against the standards to review the SOP for COVID-19 and carryout a COVID-19 risk assessment to ensure both are in accordance with current best practice guidance.

There is an identified COVID-19 lead and arrangements were in place to ensure the clinic is regularly reviewing COVID-19 advisory information, guidance and alerts.

Staff confirmed that they had completed COVID-19 training and it was advised that it would be beneficial to consider staff undertaking refresher/update training on COVID-19 in line with current guidance and arrangements.

The management of operations in response to the COVID-19 pandenic was discussed with staff. Staff were knowledgeable and aware of current best practice guidance. COVID-19 measures were in place throughout the patient pathway to minimise the risk of transmission.

5.2.7 Does the establishment adhere to IPC best practice guidance?

The arrangements for IPC procedures throughout the establishment were reviewed to evidence that the risk of infection transmission to patients, visitors and staff was minimised. The clinic had an overarching IPC policy and procedures in place. As stated previously a Covid-19 SOP was in place which is required to be reviewed.

A tour of the premises was undertaken and the establishment was found to be clean, tidy and uncluttered. Overall, the equipment was clean, free from damage and in good repair. However, clean bedlinen was stored in large zipped bags on the floor in the clinical office area. This is not in keeping with best practice and an area for improvement has been made against the standards in this regard.

Cleaning records were completed and up to date. As previously discussed in section 5.1 it was identified that that staff IPC training was not up to date and an area for improvement has been made in this regard.

Clinical hand washing sinks located in each consulting room and other clinical areas were clean. Hand washing sinks were found to be used for hand hygiene practices only and a hand hygiene poster was displayed close to each sink. Staff were observed carrying out hand hygiene in accordance with best practice.

Social distancing screens were in place at the reception desk and hand sanitisers were readily available for staff and patient use throughout the clinic. PPE was readily available in keeping with best practice guidance. No reusable medical devices are used in the clinic and staff confirmed that contracts are in place to launder uniforms/scrubs and bedlinen.

Waste management arrangements were in place and clinical waste bins were pedal operated in keeping with best practice guidance.

A colour coded cleaning system was in place and staff were aware of best practice guidance in this regard.

An IPC audit dated 9 February 2021 was reviewed. It was comprehensive however, no further IPC audits were available to review. It was identified that a range of IPC audits had not been carried out on a regular basis in keeping with best practice. An area for improvement has been made against the standards to develop a more robust audit programme on all aspects of IPC within the clinic in keeping with best practice.

In the main, the arrangements in place to adhere to IPC best practice guidelines were satisfactory. The further development of IPC specific audits will further strengthen the current arrangements.

5.2.8 Does the establishment adhere to best practice guidance concerning the management of medicines, including controlled drugs?

A range of treatment protocols was in place. There were regular clinical review meetings held, attended by Dr Diakos, the registered nurses and members of the embryology team at which treatment plans for patients and the medicines being prescribed were agreed and patient outcomes discussed. There were also daily clinical meetings to discuss the management of patients and any recommended changes to treatment plans were discussed and agreed at these meetings.

There was suitable counselling regarding treatment and outcomes and documentation to reflect this. Patients were provided with information regarding their treatment and the medicines prescribed by Dr Diakos and registered nurses; this included detailed advice on the purpose of the medicines, how to administer them at home and any potential side effects. This information was given verbally, in paper form and electronically. Any changes to treatment were communicated to patients both verbally and electronically and records were maintained. The electronic clinical recording system in use included prescriptions.

Only medicines used in theatre and recovery, for example, analgesia, sedatives, local anaesthetics, antibiotics and emergency medicines, were held in the clinic. Systems were in place to manage the ordering of these medicines and to ensure adequate supplies were available. Medicines were prescribed by Dr Diakos and any medicines prescribed for use at home were obtained directly by patients from a pharmacy supplier in England. Where top-up prescriptions of fertility medicines were required, a private prescription, signed by Dr Diakos, was issued to the patient and an arrangement was in place with a local pharmacy to stock and dispense these medicines promptly.

The medicine records reviewed were legible and well maintained to ensure that there was a clear audit trail.

Medicines were stored safely and securely and in accordance with the manufacturer's instructions.

The staff spoken with demonstrated a robust knowledge of medicines management policies and procedures. These were readily available for staff reference.

Arrangements were in place to audit the management of medicines. Evidence of this activity was maintained. This included a quarterly controlled drugs audit, a review of patient records at the end of each clinic and stock level and date checking for the medicines held in theatre.

There were incident reporting systems in place for identifying, recording, reporting, analysing and learning from adverse incidents and near misses involving medicines and medicinal products. No medicine related incidents had been reported or identified since registration.

Satisfactory systems were in place for the management of controlled drugs. A recent HFEA report had highlighted some issues with the maintenance of the controlled drugs register. The controlled drugs register had been maintained in a satisfactory manner since this report was issued. A controlled drugs audit had been conducted in July and November 2021. A named nurse is now responsible for checking that a good standard of record keeping is maintained in the controlled drugs register.

Satisfactory arrangements were in place for the destruction of controlled drugs, with denaturing kits available for this purpose.

5.2.9 How does the service ensure the environment is safe?

The management of the premises component of this inspection was completed remotely. The management of the establishment were provided with a checklist of estates related records and certification required to be submitted to the estates inspector for review.

This information included service records and certification relating to the maintenance and upkeep of the building and engineering services along with all relevant risk assessments.

All the requested documentation was submitted in a timely manner. Following the inspection it was confirmed that the maintenance of the building and engineering services was in line with current codes of practice, best practice guidance and is carried out by a range of specialist contractors. Engineering services inspected included:

- Fire detection & alarm system
- Emergency lighting installation
- Portable fire-fighting equipment
- Fixed Electrical installation and portable appliance testing
- Gas Safe certification
- Emergency electrical backup generator and equipment

The fire risk assessment was undertaken and is reviewed annually by a risk assessor who is included on an independent register of fire risk assessors approved by the 'Fire Risk Assessment Competency Council'. The fire risk for the premises was assessed as being 'Tolerable'.

The risk assessment for the control of legionella bacteria in the premises hot and cold water systems was undertaken by a suitably accredited water safety company, and suitable control measures were found to have been implemented and are being maintained.

The premises specialised ventilation systems and medical gas systems are serviced in accordance with the current best practice guidance, and suitable validation is undertaken in accordance with the current HFEA guidance. Records and validation reports were submitted for inspection.

All areas of the premises were found to meet patient's needs.

5.2.10 Are robust arrangements in place regarding clinical and organisational governance?

Organisational governance

Various aspects of the organisational and medical governance systems were reviewed and evidenced a clear organisational structure within In-Ovo Fertility Clinic. Dr Diakos is the responsible individual and the only private doctor working in the clinic. He is supported by Ms Stanton as the registered manager and registered nurse.

In-Ovo Fertility Clinic has a Board of Directors that includes Dr Diakos as the clinician and one other non-clinical member. The Board of Directors meet quarterly and this meeting is also attended by a legal representative. It was suggested that Dr Diakos forms links with other clinicians who work in fertility clinics either in Northern Ireland (NI) or in the United Kingdom (UK). Dr Diakos confirmed that it is his intention to commence multi-disciplinary meetings with a named fertility clinic in England to strengthen the medical governance systems already in place.

Discussion with staff and a review of records evidenced that staff meetings take place every month and minutes were available to review. Staff confirmed that daily meetings also take place and are attended by Dr Diakos, Ms Stanton, the anaesthetist, the embryologists and nursing staff.

A sample of minutes from meetings were reviewed. These evidenced that the governance structures were functioning well to provide a level of assurance to the Board of Directors.

Staff working in different roles within the establishment confirmed that there were good working relationships and that management were responsive to any suggestions or concerns raised.

Where the business entity operating an assisted fertility service is a corporate body or partnership or an individual owner who is not in day to day management of the service, unannounced quality monitoring visits by the registered provider, or person acting on their behalf, must be undertaken and documented every six months; as required by Regulation 26 of The Independent Health Care Regulations (Northern Ireland) 2005. Dr Diakos, Responsible Individual, is in day to day charge of the service, therefore unannounced quality monitoring visits are not required.

Clinical governance

A team of Dr Diakos, two consultant anaesthetists and embryologists who have specialist qualifications and skills in fertility treatments work in In-Ovo Fertility Clinic. Dr Diakos is considered to be the only wholly private doctor as he no longer holds a substantive post in the Health and Social Care (HSC) sector in NI and is not on the General Practitioner's (GP's) performer list in NI. Review of Dr Diakos details confirmed there was evidence of the following:

- confirmation of identity
- current GMC registration
- professional indemnity insurance
- qualifications in line with service provided
- ongoing professional development and continued medical education that meets the requirements of the Royal Colleges and GMC
- ongoing annual appraisal by a trained Medical Appraiser
- an appointed Responsible Officer (RO)
- arrangements for revalidation

Dr Diakos had completed training in accordance with RQIAs training guidance for private doctors and is aware of his responsibilities under GMC Good Medical Practice.

All medical practitioners working within the establishment must have a designated RO. In accordance with the GMC all doctors must revalidate every five years.

The revalidation process requires doctors to collect examples of their work to understand what they're doing well and how they can improve. Experienced senior doctors (called Responsible Officers) work with the GMC to make sure doctors are reviewing their work. As part of the revalidation process RO's make a revalidation recommendation to the GMC. Where concerns are raised regarding a doctor's practice information must be shared with their RO who then has a responsibility to share this information with all relevant stakeholders in all areas of the doctor's work.

The current arrangements supporting medical appraisal and revalidation with an RO for all consultants working in the establishment was discussed. It was confirmed that the consultant anaesthetists who work in In-Ovo Fertility Clinic hold a substantive post in HSC and complete their annual appraisal and medical revalidation through their employing organisations which are either local HSC Trusts or other HSC organisations.

Practising Privileges

The only mechanism for a clinician to work in a registered independent hospital is either under a practising privileges agreement or through direct employment by the establishment.

Practising privileges can only be granted or renewed when full and satisfactory information has been sought and retained in respect of each of the records specified in Regulation 19 of The Independent Health Care Regulations (Northern Ireland) 2005, as amended.

A policy and procedural guidance for the granting, review and withdrawal of practicing privileges agreements was in place.

The two consultant anaesthetists are the only medical practitioners with a practising privileges agreement in place. A review of the medical practitioners' practising privileges records confirmed that all required documents were in place. It was confirmed that one of the Board of Directors is responsible for ensuring practising privileges agreements are updated every two years.

A review of the oversight arrangements of the granting of practicing privileges agreements has provided assurance of robust medical governance arrangements within the organisation.

Quality assurance

It was evidenced that arrangements were in place to review risk assessments, a risk management register is maintained and reviewed with the directors on a regular basis. Staff also told us that they are actively encouraged to contribute to the review of the risk register.

Arrangements were in place to monitor, audit and review the effectiveness and quality of care and treatment delivered to patients at appropriate intervals.

The results of audits are analysed and actions identified for improvement are embedded into practice. If required, an action plan is developed and embedded into practice to address any shortfalls identified during the audit process.

A system was also in place to ensure that urgent communications, safety alerts and notices are reviewed and where appropriate, made available to key staff in a timely manner.

The Statement of Purpose and Patient's Guide were kept under review, revised and updated when necessary and available on request.

The RQIA certificate of registration was up to date and displayed appropriately and current insurance policies were in place.

Notifiable Events/Incidents

A robust system was in place to ensure that notifiable events were investigated and reported to RQIA or other relevant bodies as appropriate.

A review of notifications submitted to us since the previous inspection demonstrated that a system was in place to ensure that notifiable events were investigated and reported to RQIA, HFEA or other relevant bodies as appropriate within a timely manner.

Ms Stanton advised that any learning from incidents would be discussed during the daily and monthly meetings to ensure the dissemination of learning to all staff. Ms Stanton advised that there was a process in place for analysing incidents and events to detect potential or actual trends or weakness in a particular area in order that a prompt and effective response can be considered by the senior management team at the earliest opportunity. An audit would be maintained, reviewed and the findings presented to the directors during their quarterly meetings.

Complaints Management

A copy of the complaints procedure was available in the establishment and was found to be in line with the relevant legislation and Department of Health (DoH) guidance on complaints handling.

Staff told us that a copy of the complaints procedure is made available for patients/and or their representatives on request and staff demonstrated a good awareness of complaints management.

It was confirmed that no complaints had been received since registration. Ms Stanton advised that any complaints received would be investigated and responded to appropriately to include details of all communications with complainants; the result of any investigation; the outcome and any action taken. Information gathered from complaints will be used to improve the quality of services provided.

Overall, the governance structures within the establishment provided the required level of assurance to the senior management team and Board of Directors.

5.3 Does the service have suitable arrangements in place to record equality data?

The arrangements in place in relation to the equality of opportunity for patients and the importance of staff being aware of equality legislation and recognising and responding to the diverse needs of patients was discussed with several members of the team.

Discussion and review of information evidenced that the equality data collected was managed in line with best practice.

6.0 Quality Improvement Plan/Areas for Improvement

Areas for improvement have been identified where action is required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005 and the Minimum Care Standards for Independent Healthcare Establishments (July 2014)

	Regulations	Standards
Total number of Areas for Improvement	1	5

Areas for improvement and details of the Quality Improvement Plan were discussed with Dr Diakos, Responsible Individual and Ms Melanie Stanton, Registered Manager, during a Zoom teleconference on 9 February 2022. The timescales for completion commence from the date of inspection.

Quality Improvement Plan	
Action required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005	
Area for improvement 1 **Ref:** Regulation 18 (2) (a) **Stated:** First time **To be completed by:** 26 February 2022	The responsible individual must ensure that all staff undertake infection prevention and control training as outlined in the RQIA training guidance. **Ref: 5.2.1**
	Response by registered person detailing the actions taken: The relevant staff has now completed their ANTT training and they are currently enrolled to complete IPC online training. This should be completed by the 29th of April.
Action required to ensure compliance with Minimum Care Standards for Independent Healthcare Establishments (July 2014)	
Area for improvement 1 **Ref:** Standard 13.9 **Stated:** First time **To be completed by:** 26 February 2022	The responsible individual must ensure the registered manager has an annual appraisal undertaken to review their performance against their job description and an agreed personal development plan. **Ref: 5.2.1**
	Response by registered person detailing the actions taken: An annual appraisal for the Registered Manager has been organised to take place on the 19th May 2022. This will be performed by Mr R Powe, Company Director of In-OVO Fertility Clinic.

Area for improvement 2 **Ref:** Standard 19.4 **Stated:** First time **To be completed by:** 26 February 2022	The responsible individual shall ensure that policies, procedures and treatment protocols for the management of patients receiving assisted conception services are dated when issued, reviewed or revised. **Ref: 5.2.4**
	Response by registered person detailing the actions taken: All Policies and SOPs are currently in review and as this process is ongoing a review date is now added to all of these documents.
Area for improvement 3 **Ref:** Standard 10.2 **Stated:** First time **To be completed by:** 26 February 2022	The responsible individual shall review the standard operating procedure (SOP) for COVID-19 and undertake a COVID-19 risk assessment to ensure both are in accordance with current best practice guidance. **Ref: 5.2.6**
	Response by registered person detailing the actions taken: The Responsible Person reviewed the Clinic's SOP for COVID-19 Treatment Commencement Strategy and taking into consideration the relaxation of measures taken in the UK and in Northern Ireland, it has been considered that there is no need for an update of the original COVID-19 risk assessment as the measures originally taken by In-OVO Fertility Clinic at the height of the pandemic will still remain in place. This will be reviewed if the UKHSA or the Department of Health-NI review their guidance and request an upscaling of the measures in the future.
Area for improvement 4 **Ref:** Standard 20.5 **Stated:** First time **To be completed by:** 26 January 2022	The responsible individual shall ensure that the storage of bedlinen is reviewed in accordance with best practice guidance. **Ref: 5.2.7**
	Response by registered person detailing the actions taken: A lockable Cupboard for the bedlinen has been ordered and should be delivered in the Clinic by the 15th of May in order for the bedlinen to be stored according to best practice guidance.
Area for improvement 5 **Ref:** Standard 20.7 **Stated:** First time **To be completed by:** 26 February 2022	The responsible individual shall develop a more robust audit programme to include all aspects of infection prevention and control (IPC) within the clinic in keeping with best practice. **Ref: 5.2.7**
	Response by registered person detailing the actions taken: A more robust IPC audit programme has been devised and it will be performed on a quarterly basis.

Please ensure this document is completed in full and returned via the Web Portal

The Regulation and Quality Improvement Authority

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7th Floor, Victoria House
15-27 Gloucester Street
Belfast
BT1 4LS

Tel 028 9536 1111
Email info@rqia.org.uk
Web www.rqia.org.uk
@RQIANews

Assurance, Challenge and Improvement in Health and Social Care