The Regulation and Quality Improvement Authority

Inspection Report

1 May 2024

Ulster Independent Clinic

Type of service: Acute Hospital
Address: 245 Stranmillis Road, Belfast, BT9 5JH
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Information on legislation and standards underpinning inspections can be found on our website https://www.rqia.org.uk/

1.0 Service information

Organisation/Registered Provider: Ulster Independent Clinic Limited **Responsible Individual:** Ms Diane Graham	**Registered Manager:** Ms Diane Graham **Date registered:** 11 April 2007
Person in charge at the time of inspection: Ms Diane Graham	**Number of registered places:** Seventy
Categories of care: Acute Hospital (with overnight beds) - AH Acute Hospital, day surgery - AH (DS) Private Doctor - (PD) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers - PT (L) Prescribed techniques or prescribed technology: establishments using endoscopy - PT (E)	
Brief description of the accommodation/how the service operates: The Ulster Independent Clinic (UIC) provides a wide range of surgical, medical and outpatient services for both adults and children. The hospital is registered to accommodate up to 70 patients as in-patients or day surgery cases. The hospital has five theatres along with recovery units; a dedicated endoscopy suite; a one stop breast care clinic; a limited chemotherapy service; an x-ray department and magnetic resonance imaging (MRI) scanning; a pathology laboratory; and a range of consulting rooms. The in-patient and day surgery accommodation comprises of single en-suite rooms which are situated over two floors. The hospital also operates a Hospital Decontamination and Sterilisation Unit (HDSU) used to decontaminate equipment for use within the hospital.	

2.0 Inspection summary

An announced variation to registration inspection commenced on 1 May 2024, between 9.30 am and 5.00 pm by four care inspectors and an estates inspector. Department of Health (DoH) authorising engineers attended the inspection and reviewed the arrangements in respect of the HDSU. The inspection concluded on 24 May 2024 following the review of information requested by RQIA submitted following the on-site component of the inspection.

The inspection sought to assess a variation to registration application made by Ms Diane Graham, Responsible Individual (RI) and Registered Manager (RM) on behalf of the Ulster Independent Clinic (UIC) in respect of:

- The relocation of the HDSU suite;
- refurbishment of theatre four; and
- extension to theatre ancillary areas providing offices, additional storage space and a larger staff area.

This inspection was underpinned by the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003, the Independent Health Care Regulations (Northern Ireland) 2005, the Regulation and Improvement Authority Independent Health Care (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011, and the Department of Health, Social Services and Public Safety (DHSSPS) Minimum Care Standards for Independent Healthcare Establishments (July 2014).

There was evidence of good practice in relation to the governance systems in place to ensure robust oversight arrangements relating to the HDSU; the completion of annual appraisals and personal development plans identifying training needs; and the addition of an internal resuscitation trainer to provide staff training thus enhancing patient safety.

It was brought to our attention that theatre four was operational prior to the onsite inspection and the variation to registration application being approved by RQIA. This resulted in Ms Graham attending a serious concerns meeting on 15 May 2024 to discuss the circumstances under which theatre four returned to operational use prior to the variation to registration application being approved and to seek assurance that patient safety was maintained.

During this meeting Ms Graham confirmed that she had approved the recommissioning of theatre four and outlined that factors that influenced this decision. The circumstances under which a variation must be approved prior to a clinical area being operational were clarified at this meeting.

Following this meeting and review of supporting documentation submitted to RQIA following the inspection the variation to registration was approved, permitting the use of theatre four. As decontamination equipment was yet to be relocated to the new HDSU Ms Graham was advised that a further follow-up inspection would be undertaken to evidence that the outstanding actions to ensure the HDSU was ready to be operational had been have been completed.

Three areas for improvement have been made against the standards, one to fully implement the Department of Health (DoH) Authorised Engineer's requirements concerning the HDSU; one to identify a suitable area for staff to don and doff PPE until such times as the floor plan is redesigned to provide a staff gowning area and one to ensure decontamination equipment is validated following installation.

3.0 How we inspect

RQIA's inspections form part of our ongoing assessment of the quality of services. Our reports reflect how a service was performing at the time of inspection, highlighting both good practice and any areas for improvement.

It is the responsibility of the responsible individual to ensure compliance with legislation, standards and best practice, and to address any deficits identified during inspections.

Prior to this inspection a range of information relevant to the service was reviewed. This included:

- the registration status of the establishment;
- written and verbal communication received since the previous inspection;
- previous inspection reports; and
- the variation application, supporting documents, including plans.

Inspectors examined records in relation to the areas inspected and met with Ms Diane Graham, a theatre manager, HDSU/endoscopy manager and members of the estates team.

4.0 What people told us about the service

Views of service users and staff were not sought during this inspection.

5.0 The inspection

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

The Quality Improvement Plan (QIP) from the previous inspection on 18 April 2023, was not reviewed during this variation inspection and will be reviewed during a future inspection.

5.2 Inspection findings

5.2.1 Has the Statement of Purpose been developed in keeping with Regulation 7, Schedule 1 of the Regulations?

A review of the proposed Statement of Purpose (SOP) evidenced it reflected the key areas and themes as specified in Regulation 7, Schedule 1 of the Independent Healthcare Regulations (Northern Ireland) 2005. However, it did not include reference to the planned commencement of robotic assisted surgery, therefore consideration should be given to this in accordance with Schedule 1 (6). Ms Graham is aware that the Statement of Purpose should be reviewed and updated as and when necessary.

5.2.2 Has the Patient Guide been developed in keeping with Regulation 8 of the Regulations?

A review of the proposed patient guide (PG) evidenced that, in the main, it reflected the key areas and themes as specified in Regulation 8, Schedule 1 of the Independent Healthcare Regulations (Northern Ireland) 2005.

However, it did not include information for patients and other interested parties as to how a copy of the most recent RQIA inspection report could be obtained. It was also noted that it required further development to include reference to the robotic assisted surgery once this commences. Ms Graham is aware that the patient guide should be reviewed and updated as and when necessary.

5.2.3 Are there safe practices in place for surgical services?

Infection Prevention and Control (IPC)

The IPC arrangements were reviewed in relation to the refurbishment of theatre four which included the installation of a new laminar air flow system and ancillary areas to include equipment storage areas, staff rest room and offices.

Theatre four will be used for all types of surgery to include joint replacement procedures and for the newly introduced Robotic Assisted Surgery. Theatre four was found to be a spacious well equipped theatre. The laminar air flow ventilation system installed was in keeping with the requirements specified for laminar air flow. This ventilation system is designed to produce ultra clean air in the operating theatre and reduces the risk of contamination to open wounds. Theatre four comprises of a main theatre, a scrub area and preparation room. A sluice was located at the back of the theatre.

Theatre four was fully equipped and a new controlled drugs (CD) cupboard, medicines cupboard and drugs fridge were observed. As the cupboards were stocked, inspectors took the opportunity to review the CD record book. Some signatures were illegible and in some cases the staff member signing the CD record book had not printed their name as per policy. It was good to note that this had been identified in a recent internal audit and actions were in place to address the audit findings through the hospital governance structures. On review of the drugs' fridge temperature check log, it was noted that temperature checks were only recorded on days when the theatre had been operational. Daily fridge temperatures should be recorded to ensure the cold chain has been maintained.

Handwashing facilities and a range of consumables were available to promote adherence with effective hand hygiene practices. It was noted that the stainless steel sink in the scrub area had non touch taps. Cleaning schedules were in place and noted to have been completed. Hand gel dispensers were observed to be readily available. An issue with two of the hand gel dispensers was brought to the attention of the theatre manager who resolved the issue during the inspection. A small tear was noted on the mattress of the surgical trolley. This was discussed with the theatre manager who provided assurances that this would be addressed.

The sluice area was spacious with a number of high and low level storage options. Hand washing facilities were available as was a range of consumables. Personal protective equipment (PPE) stations were noted to be stocked. Disinfectant tablets were observed in an unlocked cupboard, which is not in keeping with control of substances hazardous to health (COSHH) guidance. This was brought to the attention of the theatre manager who resolved the issue during the inspection.

The sluice had a laundry chute linked to the new HDSU. The chute was not operational and signage was in place to reflect this.

At the back of the theatres complex there was a large area which had been identified for equipment storage. It was clean, spacious and remained empty and will be operational

following approval of the variation. The additional storage area will allow for better segregation and storage of equipment.

An IPC audit was carried out on 15 April 2024 which confirmed the finish and layout of the new areas met current standards. Evidence was provided that a deep clean had been carried out prior to theatre four being operational following its refurbishment.

Staffing

Review of the staffing rota and discussion with the theatre manager evidenced that there are sufficient staff who are suitably skilled and competent to work in the theatre. There has been no increase of staff as this had been a functioning theatre prior to the refurbishment.

Emergency/Resuscitation

There were no changes to the management of medical emergencies as a result of this variation to registration application. The resuscitation trolley was located in a central area in the main theatre complex and shared by all theatres. It was observed to be clean, fully stocked and a daily checklist in place.

Staff rest area and offices

The new staff area was an added benefit to the theatre complex. It was finished to a high standard and included a kitchen and seating areas. A fire blanket and fire extinguisher were observed to be available.

The new office areas were reviewed, one of the offices will be used as education room. IT equipment had yet to be installed. The second office will be shared with the theatre manager and the resuscitation trainer and resuscitation training equipment will also be stored in this office. UIC advised that they have their own internal resuscitation trainer (adults only) who had completed training through the Resuscitation Council (UK). This was in response to UIC staffs' ability to access training facilitated by external providers and will help maintain their compliance with this aspect of mandatory training. Both offices can be locked to restrict access.

Surgical Pathway

The surgical pathway remains unchanged with regards to the planning and scheduling of theatre lists. UIC has confirmed that theatre four has been identified as the theatre where the new robotic assisted surgery will take place for gynaecological procedures only. (see section 5.2.6).

A surgical register is required to be maintained for all procedures undertaken in theatres. On review of the surgical register associated with theatre four, it was noted that there had been surgical lists carried out following the refurbishment and prior to the approval of the variation to registration application.

As theatre four was operational prior to the variation to registration application being approved. Ms Graham was invited to a serious concerns meeting at the offices of RQIA on the 15 May 2024 to discuss the circumstances under which theatre four was recommissioned, prior to the variation to registration being approved.

During this meeting Ms Graham explained that as theatre four was an existing theatre that was being refurbished she thought that the decision to recommission theatre four could be made internally. Ms Graham confirmed that having considered the findings of the infection prevention and control audit; authorising engineer sign off; that the theatre had been deep cleaned and positive results of microbiological studies provided sufficient assurances for the recommission of the theatre. UIC did not consider that the variation to registration application had to be approved prior to the theatre being recommissioned. It was confirmed at this meeting that Ms Graham made the decision to authorise the use of theatre four. The circumstances under which a variation must be approved prior to a clinical area being operational were clarified at this meeting.

5.2.4 Is the premises fit for the purpose of providing safe and effective care?

Documentation was reviewed in relation to the design, commissioning and ongoing maintenance of the premises mechanical and electrical services. Discussion with the estates manager and estates staff demonstrated that suitable arrangements were in place for maintaining the environment in accordance with current legislation and best practice guidance. The following documents were reviewed:

- the planning and building regulations approvals;
- the fire risk assessment;
- commissioning documentation for the premises;
- fire alarm and detection system;
- emergency lighting installation;
- portable fire-fighting equipment;
- extension to fixed wiring installation;
- legionella risk assessment; and
- authorising engineer validation reports for the premises specialist ventilation systems, medical gases pipeline services, and decontamination services.

At the time of the inspection, the DoH Authorised Engineers discussed a number of requirements in relation to the HDSU facility. These were;

- pressure magnehelic gauge to be installed in the inspection assembly and packing (IAP) room;
- doors fitted with door interlocks should be adjusted to allow easy access;
- entry/exit to the steriliser loading/unloading dispatch area should be redesigned to accommodate a staff gowning room. This area will facilitate staff to don and doff PPE specific to the work task as well as outer clothing in preparation of leaving this area to re-enter HSDU and vice versa;
- confirm the lighting levels in the IAP room and wash area exceed 500 Lux;
- electrical socket outlets at the following locations should be replaced with ingress protection (IP) rated covered boxes:
    - sink unit areas for instruments & endoscope cleaning; and
    - behind ultrasonic cleaner.

A physical inspection of the alterations to the premises related to this variation, confirmed that the works had been completed to a high standard.

5.2.5 Are there safe practices in place for HDSU services

Governance, oversight and leadership

The unit was managed by a HDSU/Endoscopy manager supported in their role by two HDSU supervisors reporting directly to the theatre manager. There were nine permanent staff who currently work within the existing HDSU and they will move to the new HDSU when it has been approved for use.

UIC also receives support and specialist advice from two external consultants;

- an Authorised Engineer (AE) Decontamination; and
- an Authorised Engineer (AE) Medical Gases, Ventilation and Electrics.

The Estates Manager advised that decontamination audit results are routinely shared with the AE for Decontamination for review and comment.

There was evidence of a comprehensive audit schedule specific to the HDSU. The Quality and Education Department (Q&E) supports HDSU staff with the completion of audits and contributes to the UIC bi-annual management meetings and UIC's audit report. The audit reports form part of the overall governance information reviewed by the Governance Committee and in turn the Chair reports to Clinic's Board of Directors.

It was noted that a system was in place to ensure that incidents, accidents and notifiable events were investigated and reported to RQIA or other relevant bodies as appropriate.

A suite of policies and procedures to provide guidance for staff were contained within the HDSU/Endoscopy Quality Manual, revised April 2024. They were available to staff in both hard copy and on the hospital's intranet. The unit manager stated they reviewed these policies every three years as a minimum or following publication of best practice guidance. The manual for example contained information on: the organisational structure, service plans, untoward incidents, traceability and environmental monitoring.

The HDSU currently in use is registered with the British Standards Institution and operates a Quality Management System which complies with the requirements of ISO 13485.

HDSU staff meetings are bi-annually and the HDSU manager stated that dissemination of key information is provided to staff at daily briefings. There were no records of these meetings maintained. To further strengthen governance structures the HDSU manager was advised that a note of these bi-annual meetings and daily briefings should be maintained.

It was confirmed that the decontamination equipment in the existing HDSU would be relocated to the new HDSU. An area for improvement has been made concerning the validation of this equipment following installation. As previously discussed a follow-up inspection will be undertaken to the HDSU when it is ready to be operational.

Staff Training and Competence Assessments

The induction programme did not include assessment of staffs' competencies, however, the manager stated that staff did not progress through the induction programme until they demonstrated they were competent.

Two staff files were reviewed and it was noted that evidence of competency assessments was not included in the identified personnel files. This was discussed at the inspection feedback and the Q&E team member agreed they would review and amend the current induction booklet to include competency assessments. There was evidence of annual staff appraisals to include the identification of additional training needs and personal development plans.

It was identified that an external company had been appointed to undertake environmental cleaning in the HDSU. Records to evidence that the external staff had completed training and competency assessments were not available for review. A training matrix to include the names of the staff trained, the course title and date completed was submitted following the inspection.

Ms Graham stated the recently appointed Authorised Person for Decontamination attends the Regional Decontamination Working Group meetings as a means to ensure they remain updated.

Environment and Infection Prevention and Control

The new ancillary areas reviewed as part of this variation to registration were found to be finished to a high standard with a range of storage units and support areas such as staff changing rooms, staff tea room and manager's office. It was noted there were no shelving in place in a number of storage rooms including the endoscope store, domestic store and the COSHH storage cupboard. This was discussed with senior management staff who agreed that some actions remained outstanding to ensure the areas could be operational. It was confirmed that some pieces of equipment and storage would be relocated from existing store rooms to the new store rooms. Following the inspection evidence was submitted to RQIA that storage had been relocated and signage added to the identified COSHH cupboard in the HDSU.

It was noted that access to the HDSU was controlled by a swipe card system at the external door to ensure no unauthorised entry. However, there was an internal stairway to the HDSU which could be accessed by all staff. To ensure no unauthorised access to the HDSU using this stairwell it was suggested that signage should be displayed. Following the inspection evidence of this was submitted to RQIA.

The HDSU had hand washing facilities and a range of consumables available to promote adherence to effective hand hygiene practices. Supplies of personal protective equipment (PPE) were available. However, it was noted that hand hygiene options (hand washing basins, hand sanitiser) and PPE were not readily available in all areas of the HDSU. This was discussed with Ms Graham and it was advised that an IPC audit for the HDSU should be undertaken with a focus on the provision of hand hygiene facilities and availability of PPE throughout the department. Following the inspection, a IPC audit with action plan was submitted to RQIA. One of the actions was to ensure that hand hygiene options were available in all relevant areas of the HDSU.

As discussed in section 5.2.4, the DoH AEs recommended the entry/exit to the steriliser loading/unloading dispatch area should be redesigned to accommodate a staff gowning room.

An area for improvement against the standards has been made to identify mitigations that can be put in place to allow staff to don and doff PPE without having to exit and re-enter the HDSU until such times as a staff gowning are has been developed.

Planned cleaning schedules were reviewed and included daily and weekly tasks which will be carried out by staff.

During the serious concerns meeting held on 15 May 2024 Ms Graham was advised that a follow-up inspection will be undertaken to ensure that all outstanding actions relating to the HDSU have been completed prior to the new HDSU becoming operational.

5.2.6 Robotic Assisted Surgery

As discussed in section 5.2.3 above UIC have confirmed that this new innovative surgery will be undertaken in the newly refurbished theatre four for gynaecological procedures only. This type of surgery is less invasive for patients and should result in less pain and shorter length of hospital stay.

One consultant has completed simulated training facilitated by the Royal College of Surgeons and the supplier of the equipment. This consultant has a mentor and is continuing with their training by carrying out a set number of surgical procedures/cases under the direct supervision of their appointed mentor.

The arrangements for the consultant surgeon's practicing privileges agreement and training record were reviewed and noted to comply with legislation and best practice guidance.

A team of staff have received training specific to the use of the new specialist equipment and procedures to be undertaken to support the surgeon. The theatre lists will be planned in advance to allow for the allocation of appropriately trained and competent staff. The specialist equipment was stored in a separate store within the theatre complex.

5.2.7 Outcome of variation application

The variation to registration application to relocate the HDSU; refurbish theatre four and extend the theatre ancillary areas to include offices; additional storage/staff areas has been approved from a care and estates perspective. As discussed, a further follow-up inspection will be undertaken once all outstanding actions to ensure the HDSU is ready for operation have been completed.

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.

	Regulations	Standards
Total number of Areas for Improvement	0	3

Areas for improvement and details of the Quality Improvement Plan were discussed with Ms Diane Graham, Responsible Individual (RI) and Registered Manager (RM), as part of the inspection process. 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 and The Minimum Care Standards for Independent Healthcare Establishments (2014)	
Area for improvement 1 **Ref: Standard 21.8** **Stated: First time** **To be completed by:** **1 August 2024**	The responsible individual must fully implement the Department of Health (DoH) Authorised Engineer's requirements, as outlined in section 5.2.4 of this report. **Ref: 5.2.4**
	Response by registered person detailing the actions taken: All requirements have been met and inspected with the exception of the Area for improvement 2 detalied below.
Area for improvement 2 **Ref: Standard 21.8** **Stated: First time** **To be completed by:** **1 August 2024**	The responsible individual shall ensure there is a suitable temporary area to be used by staff to don and doff personal protective equipment (PPE) until such times as a staff gowning area has been developed. **Ref: 5.2.5**
	Response by registered person detailing the actions taken: Work on the staff gowning area has commenced but has been delayed due to supply issues - we will advise when this work is complete.
Area for improvement 4 **Ref: Standard 21.9** **Stated: First time** **To be completed by:** **12 September 2024**	The responsible individual must ensure that all decontamination equipment installed in the HDSU is validated following installation. **Ref: 5.2.5**
	Response by registered person detailing the actions taken: All equipment has been validated and approved by the Clinic's Authorising Engineer (Decontamination)

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

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