

Inspection Report

11 and 12 October 2021



Kingsbridge Private Hospital

Type of Service: Independent Hospital (IH) Kingsbridge Private Hospital 811-815 Lisburn Road Belfast BT9 7GX

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www.rqia.org.uk

Assurance, Challenge and Improvement in Health and Social Care

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

Registered Manager: Ms Sarah Marks
Date manager registered: 10 December 2013
Number of registered places:
22 inpatient beds
11 day beds
Following variation application this will
change to 24 inpatients (to include 2 ICU
post-cardiac surgery beds and day case
beds will reduce to 5).
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2.0 Inspection summary

An announced inspection was undertaken to Kingsbridge Private Hospital (KPH) on 11 and 12 of October 2021. The inspection was carried out by a team of RQIA care inspectors and an estates inspector who were accompanied by two inspectors from the Care Quality Commission (CQC).

In December 2019, Mr Mark Regan, Responsible Individual, submitted a variation to registration application in respect of Kingsbridge Private Hospital. This variation application proposed to convert a day ward into a two bed intensive care unit (ICU) facility to support both intensive care and high dependency care for post-operative cardiac surgery patients. It is planned that this unit will care for a specific lower risk group of patients over the age of 18 years old. KPH will only offer five cardiac surgical procedures, aortic valve replacement (AVR); coronary artery bypass graft (CABG); mitral valve replacement (MVR); atrial myxoma and adult atrial septal defect (ASD).

With the advent of the Covid -19 pandemic the application was not actively pursued by KPH until December 2020.

The purpose of the inspection was to assess compliance with the legislation and minimum standards including Guidelines for the Provision of Intensive Care Services (GPICS)¹ and review the readiness of the establishment associated with the variation to registration application. Additionally, any areas for improvement identified during the last care inspection were reviewed.

This was the first time an independent sector provider, in Northern Ireland, has come forward to register a critical care service. In order to advance this application the need to source knowledge and skills in this area was recognised by RQIA. In view of Northern Ireland's (NI's) small population and the limited number of clinicians with relevant expertise, it had been challenging to source local advice from professionals who were suitably independent. RQIA recognised that support and assistance from outside of NI would be required to progress the variation application. RQIA engaged with the CQC who agreed to provide this support and advice to RQIA. CQC staff acted in an advisory capacity to RQIA. The advice and assistance provided by CQC inspectors and a CQC national professional surgical advisor (cardiac surgeon) was drawn from their experience of registration of similar service types and the potential safety and quality issues that have arisen in such services during the period they had been registered with CQC.

Prior to the inspection an extensive and robust mapping exercise was undertaken of information submitted to RQIA by the KPH. The aim of this exercise was to examine compliance with the GPICS standards. Additionally, RQIA held a number of meetings with KPH senior management and clinicians for the purpose of discussing safety assurances of this proposed service.

The variation to registration application has also been reviewed by a RQIA pharmacy inspector and a RQIA finance inspector.

In a separate registration matter, in July 2021 RQIA became aware that the entity that operates KPH changed. KPH were informed there was a requirement to register the new entity as a priority. A fully completed registration application was received by RQIA on 22 September 2021 and following a detailed review of the application and the required supporting evidence, the registration under the new entity was granted on 6 October 2021. However RQIA are still awaiting confirmation that the controlled drugs (CD) licence is in the name of the current entity. The KPH management confirmed that the licence had been granted by the Department of Health (DoH) and they were actively engaged with DoH regarding expediting the written evidence on this matter. An area of improvement has been identified to provide RQIA with written confirmation from the DoH of the final approval of the CD licence for the new entity.

This inspection focused on a number of key areas: safe staffing levels; recruitment and selection procedures; practicing privileges; infection prevention and control (IPC) and decontamination procedures; environment; equipment; consent; the cardiac surgical patient care pathway and assurance of service quality.

Each area was assessed by inspectors to determine if KPH have satisfactory systems and process in place to deliver the proposed cardiac surgical service safely for patients.

There was evidence of good practice concerning staff recruitment; infection prevention and control (IPC); the management of cardiac surgery patients throughout the care pathway; arrangements for ICU care and governance system.

¹ https://www.ficm.ac.uk/sites/ficm/files/documents/2021-10/gpics-v2.pdf

No immediate concerns were identified regarding the delivery of front line patient care.

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.

A wide range of staff and management were interviewed in person or via a video conferencing platform, these included the responsible individual; the registered manager; the medical director who is also the lead anaesthetist for the proposed ICU; the clinical services manager; the postanaesthesia care unit (PACU) manager which includes the ICU facility; a cardiac surgeon; a cardiac anaesthetist; an IPC external advisor; the clinical equipment lead; a resident medical officer (RMO); the clinical educator; the estates manager; a human resources officer; a ward sister and a deputy ward manager.

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).

4.0 What people told us about the service

This variation of registration application relates to a proposed cardiac surgery service with intensive care provision and this service is not yet operational. Therefore there were no patients who had experienced the service present during the inspection. It was confirmed that KPH will ensure that the views of cardiac surgery patients' will be included in their patient survey mechanisms. Post-operative cardiac surgery patients' views will be actively sought as part of future inspections.

5.0 The inspection

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

Areas for improvement from the last inspection on 1 and 2 of December 2020				
	e compliance with The Minimum Care e Establishments (July 2014)	Validation of compliance		
Area for Improvement 1 Ref: Standard 16 Stated: First time		Met		

5.2 Inspection Findings

5.2.1 How does this service ensure that staffing levels are safe to meet the needs of patients?

Staffing arrangements for the provision of the proposed cardiac surgery service in KPH were examined across all staff disciplines. The senior management team (SMT) told us that the service will be delivered by a team comprising of:-

- one ICU lead doctor- consultant anaesthetist
- three ICU consultant anaesthetists
- six cardiac surgeons
- PACU lead nurse
- a team of ICU trained nurses
- clinical equipment technicians
- theatre staff experienced in cardiac surgery
- perfusionists
- ward nursing staff
- resident medical officer (ward level)
- radiographers on call
- physiotherapist with respiratory experience
- allied health professionals (as required)
- clinical nurse educator (providing an education programme to staff)
- IPC lead nurse (consultation)
- clinical microbiologist
- senior pharmacist and supporting pharmacists

Nursing

Examples of staff rotas were reviewed for the proposed ICU and at ward level. Managers described how they intend to staff the ICU for the duration of the patients stay in ICU/ high dependency unit (HDU) and at ward level.

It is planned that the patient will require to be cared for in the ICU for between 12 and 36 hours, following a medical assessment the level of care will step down to HDU level care with the patients then being assesses as ready for transfer to the surgical ward, 24 to 36 hours later. Eight nurses who work in the PACU team are ICU trained and two who are HDU trained will provide care to the patient whilst they are in the ICU/HDU.

Additional support can be sought from a bank of ICU nurses who currently work in the Royal Victoria Hospital (RVH) Cardiac Surgical Intensive Care Unit (CSICU). It was confirmed that there will be two ICU trained nurses and one supernumerary ICU trained nurse whilst the patient is being cared for in the ICU. There will be two HDU nurses (these nurse's may be ICU trained dependant on staff availability) and a supernumerary nurse (ICU trained) caring for patients when the patient's medical assessment indicates they require HDU level care. There will always be a patient nurse ratio of 1:1. These staffing levels are in keeping with the GPICS standards.

The decision to transfer the patient to the ward would be made following a ward round with agreement from the anaesthetist, surgeon and ICU nurse in charge. On the day of transfer to the ward, one of the HDU nurses on rota for the ICU/HDU will move with the patient to the ward to ensure continuity of care for the first 6 to 12 hours.

Ward nurses would then provide care to post cardiac surgery patients with a range of specialised nursing care needs. Whilst there are two ICU trained nurses working at ward level, the majority of nurses at ward level have no experience of caring for a post cardiac surgery patient. The state of readiness of this group of nurses to provide this level of care was not fully evidenced. Management confirmed that the clinical educator would be present on the ward to provide support and carry out onsite competence assessments. However, the position of the clinical educator is a part time position. The training and competence assessments for this group of staff in relation to caring for post cardiac surgery patients were in the very early stages and staff spoken with were unclear of their role and responsibilities in relation to post cardiac surgery patients.

The matter was discussed in detail with the SMT who told us that an additional ICU trained nurse will be rostered on the ward when post cardiac surgery patients are transferred to the ward until such times as the ward staff have successfully completed the training and competence programme for the care of post cardiac surgery patients. A revised rota for the surgical ward was submitted to RQIA following the inspection outlining these arrangements. In addition, a policy detailing the roles and responsibilities of staff involved in the pathway of care for the cardiac patient, was submitted. The SMT confirmed all staff would be made aware of the policy.

Training and competence is further discussed in section 5.2.3.

Medical

Staff rotas were reviewed and discussion with medical staff took place in relation to their understanding of medical staff cover.

Management described the medical cover as follows:

There will always be a dedicated ICU consultant anaesthetist in charge of the ICU/HDU. They will live in at KPH and be on the ICU rota whilst patients are in ICU/HDU and once discharged to the ward they will be on-call and able to be onsite within 30 minutes of being contacted. There will be a nominated lead ICU consultant in addition to this on call. The patient will remain the responsibility of the named consultant cardiac surgeon whilst at ward level. They must be able to be onsite within 30 minutes notice or have made clear arrangements for one of the other consultant cardiac surgeons to provide medical cover for their patients. The RMO will be on site at all times and will have clear channels of communication with the consultant cardiac surgeon and the lead ICU consultant anaesthetist.

During a discussion with a member of the medical staff it was noted that some confusion arose in relation to the arrangements for 24 hour cover for the ICU/HDU when a patient is present. This member of medical staff described on-call arrangements and not live in arrangements. This matter was fully discussed with the SMT who confirmed that an anaesthetist would be onsite for the duration of the patients stay in the ICU. Following the inspection, an email directing consultant ICU anaesthetists of this arrangement and a staff rota outlining this arrangement was submitted to RQIA. The arrangements should also be clearly outlined in the practising privileges agreements with the consultant ICU anaesthetists. Practising privileges agreements are further discussed in section 5.2.4.

Theatre staff

An experienced consultant cardiac surgeon will carry out the cardiac surgery with the assistance of a surgical scrub practitioner and a consultant cardiac/ICU anaesthetist. Bank theatre nurses with experience in cardiac surgery who are working in RVH cardiac theatres will be assisting in the surgery. KPH theatre nurses will also be present and will be upskilled in the theatre nurse's role for cardiac surgery.

Two perfusionists will be on site, one in the theatre with the patient and one in the theatre suite with a back-up bypass machine in a state of readiness should it be required.

The on call rota for returns to theatre will consist of a cardiac surgeon; anaesthetist; surgical scrub practitioner; two theatre nurses; a perfusionist and a technician. It was confirmed that the on call rota would be available and known by the ICU nurse in charge; the nurse in charge at ward level and the RMO.

Clinical Equipment Technicians

A clinical equipment lead has been appointed and during the inspection described the role of the clinical equipment technician. They are involved in the setup of clinical equipment for cardiac surgery in theatre with the exception of the bypass machine which is the responsibility of the perfusionist. The clinical equipment technician will sign off that the equipment is fit for clinical use and remain in the theatre area during surgery to support the surgical team with any equipment issues. The clinical equipment technician will set up clinical equipment in the ICU and remain in ICU for a period of time when the patient is transferred to ICU. The clinical technician will be on call while a patient is in ICU. It was confirmed that the clinical equipment lead is involved in recruiting additional clinical equipment technicians (clinical scientists) for KPH. The clinical equipment lead demonstrated a clear understanding of their role and responsibilities.

Physiotherapists

As stated a physiotherapist with respiratory experience will be available 7 days a week. It was confirmed the physiotherapist will attend ward rounds and governance and quality meetings. The senior physiotherapist has worked in the respiratory field and has extensive experience working in the Health and Social Care (HSC) sector ICUs as well as the RVH CSICU.

Allied Health Professionals

A speech language therapist, a dietitian and an occupational therapist will be available for consultation and advice as required.

Pharmacist

Management confirmed that a lead pharmacist and the pharmacy team will provide pharmacy support to the ICU. The lead pharmacist will be available for ward rounds in ICU.

It was confirmed that the lead pharmacist has completed a United Kingdom Clinical Pharmacy Association (UKCPA) Critical Care foundation course.

The management of KPH were requested prior to the inspection to contact UKCPA to seek advice on the course undertaken by the lead pharmacist, to establish if it equates the GPICS standards which outlines that the most senior pharmacist within a healthcare organisation who works on a daily basis with critically ill patients must be competent to at least Advanced Stage II (excellence level) in adult critical care pharmacy. SMT told us they have not yet received a response to this query.

A cardiac surgeon, who spoke to the inspection team, confirmed he has been directly involved in the development of the cardiac surgery service in KPH. He outlined that he will continue in that role which includes liaising with a senior pharmacist presently working in HSC ICU for additional expert advice and support.

Following the inspection KPH confirmed they had granted practicing privileges to a senior pharmacist presently working in a HSC ICU and would provide pharmacy support in line with the GPICS standards. It was noted that the pharmacy support was in line with the provision of cardiac surgery over the weekend. It is advised that the provision of pharmacy support cover is revisited if KPH extend the service into the core working week.

Clinical Microbiologist

A clinical microbiologist had been appointed by KPH and will be on call for expert advice and support as required. It was confirmed that whilst the patient is in ICU the clinical microbiologist will dial in to review the patient daily.

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

Recruitment and selection policies and procedures adhered to legislation and best practice guidance for the recruitment of staff. These arrangements ensure that all required recruitment documentation has been sought and retained for inspection.

A review of five personnel files of staff recruited in relation to the provision of a cardiac surgery service and discussion with a human resource officer, confirmed that new staff have been recruited as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005. There was evidence of job descriptions for specific staff roles. It was confirmed that professional registrations are checked as part of recruitment by the human resource department and annually thereafter by the staff member's line manager.

5.2.3 How does the service ensure that staff are suitably qualified and skilled to provide care to cardiac surgery patients?

It was confirmed that KPH has appointed a clinical nurse educator who is an experienced cardiac ICU nurse. The clinical nurse educator is responsible for the development and implementation of an education programme for all disciplines of staff involved in the post – operative care of cardiac patients.

The clinical nurse educator described using validated competency and assessment tools such as ICU –Critical Care Network Northern Ireland (CANNI) tools and cardiac tools to devise competency assessments for staff in ICU. It was confirmed that all KPH ICU nurses have undertaken a validated cardiology course.

The ICU staff have received induction training and orientation to the new ICU facility. ICU staff have undertaken cardiac advanced life support (CALS), intermediate life support (ILS) and advanced life support (ALS) training and completed all mandatory training.

The clinical nurse educator confirmed that a training needs analysis had been carried out for nurses at ward level in relation to caring for post-operative cardiac surgery patients and a training programme had commenced based on this analysis. However as stated previously, it was noted that there was limited evidence of the implementation of robust training and competency assessments for staff at ward level. It was requested that a training and competency framework for ward nursing staff be submitted to RQIA outlining clear timescales for implementation.

Following the inspection KPH submitted a ward cardiac competency and training matrix which included cardiac surgery specific competencies:-cardiac advanced life support (CALS) training; drain care and removal; rhythm recognition; pacing and telemetry; removal of pacing wires; discharge talk and making post discharge calls. This training and competency framework has to be implemented at ward level and will be facilitated by the clinical nurse educator. As discussed to facilitate safe care an additional cardiac ICU nurse will be rostered at ward level until such times as the ward level nursing staff are deemed competent in caring for a post cardiac surgery patient.

Consultant medical staff have declared competency in providing specialised cardiac surgery through a detailed competency framework which forms part of a review of qualifications and experience before they are granted practising privileges by the chair of the medical advisory committee (MAC).

Following discussion with a RMO and review of documentation, it was confirmed that the training and assessment of competency of RMOs to provide medical care to post-operative cardiac patients at ward level, was limited. It was requested that a formal training and competency assessment framework for RMOs be submitted to RQIA and implemented in KPH. Following the inspection KPH submitted to RQIA a 'Resident Medical Officer (RMO) competency self-assessment –cardiac surgery post-operative ward care framework'. This framework is completed and signed by the RMO. The competencies within are based around the four domains of the Framework for Appraisal and Assessment derived from Good Medical Practice (GMP) as outlines by the General Medical Council (GMC):

- Domain 1 Knowledge, Skills and Performance
- Domain 2 Safety and Quality
- Domain 3 Communication, Partnership and Teamwork
- Domain 4 Maintaining Trust

It outlines events specific to the management of post-operative cardiac surgical patients at ward level as follows:

- patient journey focussing on post cardiac surgery episode of care
- specific medications including anticoagulation
- epicardial pacing including rhythm interpretation and management of AF
- management of the deteriorating post cardiac surgery patient including resternotomy

The RMO may identify additional training and competence needs which will be highlighted to the medical director using an action plan.

The medical director will have final sign off on competency where additional training needs have been identified. The SMT confirmed this framework has been implemented in KPH. The role of the RMO is clearly outlined in the KPH cardiac surgical patients- roles and responsibilities policy which as stated was submitted to RQIA following the inspection.

The training and competence of staff involved in the provision of cardiac surgery in KPH have been strengthened as a result of this inspection.

5.2.4 Are practising privileges being effectively managed?

KPH has a policy and procedure in place which outlines the arrangements for the application, granting, maintenance, suspension and withdrawal of practising privileges.

Management and medical staff outlined the process for granting practising privileges and confirmed medical practitioners would meet with chairperson of the MAC prior to privileges being granted.

The practising privileges agreements for four consultant cardiac surgeons and a consultant cardiac/ICU anaesthetist and all supporting documentation were reviewed. They had been granted practicing privileges and others were noted to be in various stages of progress towards granting practising privileges. There was evidence of further information being sought from applicants to ensure compliance with the legislation and standards. It was noted that the scope of practice for the cardiac surgeons was outlined as 'cardiac thoracic surgery'. It was advised the scope of practice for each individual cardiac surgeon should include specific reference to the five cardiac surgical procedures to be carried out in KPH and which ones they have been granted practising privileges to carry out.

Following inspection, management submitted to RQIA a more detailed template for cardiac surgeon's practising privileges agreement that included the scope of practice and outlined the proposed five cardiac surgical procedures. The updated practising privileges agreement will identify which surgical procedures the cardiac surgeon has been granted practising privileges to carry out. It was confirmed that consultant anaesthetists practising privilege agreements will clearly specify the arrangements for ICU cover when patients are present.

It was confirmed practising privileges will be reviewed two yearly. An alert system is in place to highlight those due for renewal or those with any expired information such as professional indemnity insurance. It was confirmed there are robust follow up arrangements in place on this matter.

Appropriate measures are in place to manage practising privileges agreements.

5.2.5 How does the service ensure that it adheres to infection prevention and control and decontamination procedures?

This unit is categorised as an augmented care setting in line with the procedural paper for RQIA inspections in Augmented Care Areas.² Care that is designated as augmented is where medical/nursing procedures render the patients susceptible to invasive disease from environmental and opportunistic pathogens.

Future inspections of this area will be carried out using specialised Infection Prevention and Control Audit Tools for Augmented Care Settings. These audit tools will be used as an assessment framework designed to improve consistency in approach to clinical interventions and improve the quality and delivery of care and practice. The core elements of these tools were used to assess the unit during this inspection.

This unit was bright, spacious, uncluttered and in excellent decorative order. The standard of cleaning throughout the unit was excellent. Environmental cleaning guidelines were available which detailed guidance on routine cleaning, enhanced cleaning and terminal cleaning. An audit programme was in place for routine environmental cleaning. Cleaning schedules were available for domestic and nursing staff, detailing specific roles and responsibilities and cleaning frequencies.

Patient equipment including specialist equipment was newly purchased and clean. There was clear guidance describing the arrangements for the decontamination of equipment and plans were in place for the routine auditing of the cleaning, storage and replacement of equipment. All equipment is on a routine maintenance programme.

Hand washing facilities and a range of consumables were available to enable hygiene practices to be carried out effectively. Clinical hand washing sinks were clean, located near to the point of care and dedicated only for the use of hand hygiene. Clinical hand wash sinks were positioned appropriately to prevent splashing of patients, beds and equipment. All clinical hand wash sinks in the unit were in line with Health Building Note 00-09: Infection control in the built environment.³ Arrangements have been put in place to ensure that after hand washing, patients, visitors and staff use an alcohol hand rub.⁴ Sufficient supplies of PPE were available within the unit to facilitate standard infection control precautions and transmission based precautions (contact, droplet, airborne). Clear guidance on the donning and doffing of PPE was available.

Nursing staff demonstrated good aseptic non touch technique (ANTT) knowledge in the management of invasive devices. Quality improvement tools were in place to monitor ANTT compliance with invasive devices. Policies for the insertion and on-going management of invasive devices were available to guide practices. Systems have been put in place to monitor compliance with best practice in obtaining a blood cultures and assure that blood cultures are being collected with proper attention to aseptic technique.

Up to date antimicrobial guidelines were in place. Plans are in place to audit antimicrobial usage is in line with antimicrobial prescribing guidance.

² Guidance and Procedural Paper for RQIA Inspections in Augmented Care Areas

³ HBN 00-09 - Infection control in the built environment

⁴ Water sources and potential Pseudomonas aeruginosa contamination of taps and water systems – Advice for augmented care units (including neonatal units caring for babies at levels 1, 2 and 3)

Up to date guidance on the management of Clostridium *difficile* infection and Methicillinresistant *Staphylococcus aureus* (MRSA), was available and known by staff.

The unit is a 2 bed open planned facility; there are no side rooms for isolation in the event of a patient identifying with an 'alert organism'. An alert organism, describes a microorganism that has the potential to cause harm and disease in individuals and which can cause an outbreak of infection in a hospital environment. In order to reduce transmission risk, a screening programme for infectious organisms prior to admission, was in place and staff had good awareness of all necessary transmission based precautions.

Plans for mandatory and non-mandatory surveillance of microorganisms were in place for the purpose of identifying trends, prioritising resources to improve patient outcomes and benchmarking performance against regional datasets. Surveillance data will be collected for catheter associated urinary tract infections, surgical site infections, invasive device associated blood stream infections and ventilator associated pneumonia. In addition, a process was in place for the mandatory reporting of alert organisms to the NI Public Health Agency.

It was confirmed that specialised IPC advice and support can be accessed from a dedicated infection prevention and control nurse independent advisor. An IPC steering group has been set up and meet on a quarterly basis to discuss IPC topics and identify areas for learning and improvement in practice. This group reports into the governance and quality teams and the MAC. Members of the group include: IPC nurse; microbiologist; CEO; lead nurse; general manager; IPC champions, departmental managers for domestic and environmental cleanliness manager.

The proposed management of IPC and decontamination systems were in line with best practice guidance and it was determined that appropriate actions had been taken in this regard.

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, businesses need to consider the risks to their clients and staff.

The management of operations in response to the COVID-19 pandemic were discussed with the SMT staff who outlined the measures that are taken by KPH to ensure current best practice measures are in place. Appropriate arrangements are in place in relation to maintaining social distancing; implementation of enhanced IPC procedures; and the patient pathway to include COVID-19 screening prior to admission.

The management of COVID-19 was in line with best practice guidance and it was determined that appropriate actions had been taken in this regard.

5.2.7 How does the service ensure the environment is safe?

A range of estates documentation was submitted to RQIA prior to the inspection, and was examined by the RQIA estates inspector as part of the approval process for the variation of registration.

The following was confirmed during inspection through examination of further relevant estates documents, a review of the ICU facilities and discussion with the KPH estates and facilities manager.

Design and Health Technical Memorandum (HTM) Standards

The conversion of the former day care ward into a two bed post-operative cardiac ICU accommodation was designed by a professional architectural consultant in compliance with Health Building Note (HBN) 04 02 Critical Care Units.

The engineering services installed to support the ICU were designed and commissioned by chartered mechanical and electrical consultant engineers, compliant with the following standards:

- Health Technical Memorandum (HTM 06-01) Electrical Services Supply and Distribution
- HTM 02-01 Medical Gas Pipeline Systems Part A
- HTM 03-01 Specialised Ventilation for Healthcare Premises Part A
- HTM 04-01 Control of legionella, hygiene, safe hot water , cold water & drinking water systems Part A
- HTM 05-02 Firecode. Fire safety in Healthcare premises

The Authorising Engineer commissioned to validate the building services compliance with the above listed standards, submitted confirmation that the accommodation and associated services were compliant on 3 August 2021.

Statutory Planning and Building Control approvals

Belfast City Council Building Control `passing of plans` and `completion of works` approvals were received, reference FP/2020/0983 B; final approval dated 26 April 2021

Specific planning consent was not required for the variation to registration application.

Fire safety

The facility fire risk assessment document was completed by the applicant's fire safety consultant on 20 July 2021. The fire evacuation policy was reviewed and amended by the facility fire safety consultant plus KPH estates and facilities manager on 8 October 2021.

This variation has been approved from an estates perspective.

It was determined that appropriate arrangements were in place to maintain the environment.

5.2.8 How does the service ensure there is safe equipment in place to meet the patient needs?

A range of clinical equipment has been procured to meet the needs of cardiac surgery patients in line with GPICS standards.

The clinical equipment for theatre and ICU was selected with the involvement of a cardiac surgeon, a consultant cardiac ICU anaesthetist, ICU nurses and the clinical equipment lead. It reflects where possible equipment used in the RVH cardiac theatre and ICU to allow for familiarity of use for staff involved.

It was confirmed that training on all equipment had been carried out for staff and competency on use was assessed. All equipment conforms to the relevant safety standards, and will be regularly serviced and maintained in accordance with the manufacturer's guidance. All equipment is new and is in warranty.

The clinical equipment lead responsibilities include ensuring that the equipment is audited serviced by the provider and is fit for use. All servicing and replacement has been embedded in the asset register. The clinical equipment lead will identify any issues that cannot be dealt with in house and will go through the facilities manager to ensure the equipment is appropriately serviced. Contracts are in place for the ICU equipment including servicing by appropriately qualified electro-biomedical engineering (EBME) support.

There are clear arrangements for the decontamination of equipment and staff confirmed they have received training on the decontamination of specific clinical equipment such as the transoesophageal echocardiogram machine.

It was noted the following equipment was in place, three ventilators; two bypass machines; telemetry; an emergency trolley; a cardiac advanced life support trolley and an advanced air management trolley. There is a blood gas analysis room within the ICU which is equipped with i-stat machines and a thromboelastogram (TEG). It was confirmed that training had been provided for staff in the use of equipment by the equipment company and the PACU manager.

5.2.9 How does the service ensure that patients have a planned programme of care and have sufficient information to consent to treatment?

The cardiac surgery patient journey was examined, through discussion with key medical and nursing staff, review of the facilities, scrutiny of relevant policies/ procedures and care pathway documentation.

It was confirmed that there will be a clear selection criteria in place for KPH cardiac surgery patients. With the absolute exclusion criteria of patients under 18 years of age, weight must not be greater than 155kg and patient must not be pregnant. The selection criteria have a list of clinical conditions as contraindications for selection which are set out in a KPH Intensive Care Unit Criteria for Case Selection policy.

Referrals

Referrals for cardiac surgery will be through a HSC cardiac surgeon and the patient will have an already identified need for a specific cardiac surgical procedure which will be one of the five cardiac surgical procedures to be carried out in KPH. They may be self – funding patients or patients with health insurance cover.

Pre-admission

A detailed pre-admission assessment of the patient will be carried out jointly by a cardiac surgeon and a consultant cardiac anaesthetist. The case will then be presented at the weekly ICU governance meeting for consideration by the multi-disciplinary team (MDT). Taking into account the KPH selection criteria and the patient's fitness for surgery, a decision will be made if the patient is suitable for cardiac surgery in KPH.

Pre –operative assessment

If deemed suitable they will have an extensive pre op assessment and work up to ensure they are suitable for KPH enhanced cardiac surgery -cardiothoracic surgery care pathway protocol.

At the outpatient consultation the patient will receive an information booklet which includes information to help decision making and consent and waiting for cardiac surgery. The following is part of the pre-operative assessment (POA) arrangements:-

- POA two weeks prior to operation date
- the appropriate pre-operative assessment pathway is used
- during POA, prescription made out in advance for albumin
- date of operation to be confirmed
- date of Covid-19 screening to be confirmed as per KPH protocol. Patient advised to selfisolate as per KPH protocol
- date of Covid-19 screening to coincide with a date for outpatients for repeat group and screening, full blood count, international normalised ratio (INR), urea and electrolytes.

Scheduling Theatre/ Pre-operative care following admission

A cardiac surgeon who is involved in the development of the cardiac surgery service in KPH confirmed he will schedule the theatre list with the involvement of the consultant cardiac anaesthetist, theatre manager and PACU manager.

The following is the care pathway for the patient on admission:-

- the patient will be admitted either the night before or on the day of surgery to ensure that all markers are stable, and the patient is fit for theatre. A pre-operative assessment will be completed. The cardiac surgery care pathway, which is a MDT care pathway covering the patients journey from admission to discharge, will be commenced.
- the patient will be seen by the consultant anaesthetist and anaesthetic assessment is completed within the cardiac pathway.
- the consultant anaesthetist will order four units of packed red cells for delivery to the KPH that evening.
- the patient will have bloods taken for full blood count (FBC) / urea & electrolytes (U&E), group and crossmatch.
- the patient will be seen by the surgeon who will confirm there is no clinical change in the patient, consent obtained and any further questions answered.
- ward medicine Kardex will be commenced by RMO in relation to routine medications.
- the anaesthetist will advise regarding night sedation and any routine medications to be omitted.
- the cardiac surgeon will complete the thrombus/bleeding risk and will confirm any anticoagulation therapy required with the RMO.
- the patient will be advised to fast from food and fluids as per KPH protocol.

Intra -operative care

The patient is accompanied to theatre by a ward nurse, if sedative pre-med has been prescribed this will be in the bed. Theatre 3 has been identified for cardiac surgery as it is adjacent to the ICU facility. An anaesthetic nurse will meet the patient at theatre door and will carry out a detailed checklist. The patient will be in taken into theatre where a pre-operative health and safety equipment checks will be completed and recorded. A detailed cardiac theatre safety checklist will be carried out this includes the World Health Organisation surgical safety checklist and surgical pause. This will be recorded in the theatre section of cardiac surgery care pathway documentation. The operation will be carried out and the patient will be monitored throughout. The intra-operative documentation will be completed including a comprehensive anaesthetic record; details of skin prep; pacing wires used; chest wound drainage systems inserted; specimens sent to the laboratory; cardiac theatres check form (swabs; disposables; sutures/needles); cardiac theatre sterilisation details; cardiac theatre implant details; central venous catheter (CVC) checklist; fluid balance; critical care unit (CCU) medicine Kardex and a blood transfusion record, if required.

The surgical register will be completed. The operation notes are completed by the cardiac surgeon.

ICU care

Following the successful conclusion of surgery, the ventilated patient will be admitted to the ICU. The patient will commence the ICU component of the cardiac surgery care pathway. There will be a full handover from theatre team. The ventilator settings and position will be checked as per clinical technician set up. Staff will ensure that a peripheral line observation is in place and that all lines are labelled. They will ensure all lines; catheter; pacing wires; drains; delirium score are documented in the comprehensive ICU observation chart. The patient will be cared for on a 1:1 ratio by a trained ICU nurse. Nurse handovers will take place throughout the patients stay in ICU/HDU and ward level at 07.45 and 19.45 daily at the change of shift or when handing over breaks.

While the patient is in ICU the medical cover will include the following:-

- the operating team will be on the premises for at least 1 hour after the last case is admitted to ICU. They must confirm with person in charge in ICU before they leave the premises.
- as stated previously there will be a live-in consultant anaesthetist 24 hours a day until the patient returns to the ward.
- there will be an on call cardiac surgeon and surgical team.
- a consultant surgeon will review the patient daily.
- a consultant anaesthetist will carry out twice daily ward rounds morning and evening whilst patient is in ICU/HDU.
- a daily MDT ward round will be carried out.

On day one post-operatively it will be hoped the patient will be extubated and the HDU section of the cardiac surgery care pathway will be commenced.

Transfer from ICU to ward level

On day two the transfer to ward checklist will be commenced. If a patient meets the KPH discharge criteria from ICU to the ward the patient will be transferred to ward level.

The decision to transfer to the ward will be made by the consultant anaesthetist and the cardiac surgeon. Patients will only be transferred to the ward between the hours of 08:00 and 18:00.

As stated previously an ICU/HDU nurse will move with the patient to ward level. In addition there will be an ICU nurse rostered for the duration of the patients stay and will provide direct care to the post cardiac surgery patient supported by ward level nurses. The patient will be located in a single bedroom which is spacious enough to accommodate a range of clinical equipment. It was noted that the two cardiac surgical patient rooms will be located on ward level one opposite the nurses' station. These rooms are also on the same floor as ICU and the cardiac theatre 3. The ward level section of the cardiac surgery care pathway will be commenced. The patient will remain on monitoring for 48 hours post discharge to the ward via telemetry link to the nursing station. There will be a MDT approach to care with physiotherapy daily input if required.

It was confirmed the medical cover at ward level will be a RMO will provide 24 hour live- in cover. The consultant surgeon will conduct a daily ward round with the RMO and nursing team looking after the patient on the ward. During this ward round the management decisions on the patient's continuity of care will be taken and documented in the cardiac surgery care pathway accordingly.

A consultant-to-consultant handover will take place should there be a change in the consultant in charge of the patient. This may be done in person or verbally. It was confirmed that the consultant surgeon and consultant anaesthetist will be contactable by phone and available to attend within 30 minutes following ICU/HDU discharge.

Discharge from KPH

There are clear discharge procedures in place and the patient will be deemed fit for discharge by the consultant cardiac surgeon. The discharge section of the cardiac surgery care pathway will be completed by the nursing staff and the RMO. This includes arrangements for providing the patient with written discharge information and education booklets; referral to the Health Education and Rehabilitation Therapy (HEART) team; GP letter; district nurse letter; drug information list; medication; warfarin booklet; patients own medication; outpatients review planned and details of how to contact the ward for advice or if concerned.

If required a referral may be appropriate to the psychotherapy and counselling service. A decision to make this referral will be made by the consultant cardiac surgeon in conjunction with the members of the MDT responsible for the patients' post-operative care.

It was confirmed following discharge patients will receive at least two follow up calls from suitably trained and deemed competent nursing staff who will conduct the calls in line with an agreed script which will be fully documented. Any concerns will be escalated to the RMO in the first instance who may then contact the consultant cardiac surgeon.

Post-operative cardiac surgery patients who do not follow the expected patient pathway.

It was confirmed if a patient in ICU is not deemed fit to transfer to the ward and continue to require to be cared for in an ICU, there will be adequately trained staff to support that patient. This type of patient may need a day or two longer to recover and will be successfully discharged to the ward following a short period longer in the ICU. The patient's ongoing plan of care will be discussed and recorded by the consultant anaesthetist and consultant cardiac surgeon.

For patients whose condition may deteriorate, the decision to return a patient to theatre or to the ICU will be made by the consultant surgical team (operating consultant anaesthetist and consultant surgeon). The anaesthetist will lead on these decisions whilst the patient is in the ICU/HDU and the surgeon will lead once the patient has been discharged to the ward. The RMO will take part in the day to day management of the patient whilst they are on the ward under the direction of the consultant surgeon and consultant anaesthetist. As stated previously there will be an on call surgical team who can be in the hospital within 30 minutes.

Whilst patients selected for cardiac surgery in KPH will be viewed as lower risk group, however, given the nature of the cardiac surgical programme, it is understood that a small number of patients may experience surgical complications. These patients may deteriorate quickly and on occasions require advanced therapies such as renal replacement therapy; advanced interventions relating to airway management; ventilation and cardiac assistance such as ventricular assist devices. It was noted KPH have a list of the triggers for transfer within the cardiac trigger to transfer to HSC from ICU post-operative policy.

The KPH transfer policy was also reviewed following the inspection and advice was provided on further developing this policy to reflect the detailed information provided on transfer by KPH.

It was confirmed that KPH have arrangements in place for the support of Northern Ireland specialist transfer and retrieval (NISTAR) team when transferring a critically ill patient.

It was confirmed that RQIA are facilitating ongoing discussions with the Belfast Health and Social Care Trust (BHSCT) in relation to establishing a memorandum of understanding (MOU) with KPH for the transfer of critically ill patients from KPH to a HSC ICU. KPH will further engage with the BHSCT on this matter and seek to offer assurances in order to reach an agreement. A MOU with the BHSCT is required to ensure safe and ongoing care for the critically ill post-operative cardiac patients in KPH. An area of improvement has been made on this matter.

5.2.10 How does the responsible individual assure themselves of the quality of the services provided?

It was confirmed that there is a governance and compliance strategy and framework in place that includes the provision of cardiac surgery and ICU services. The SMT and staff spoken to demonstrated a good understanding of the governance arrangements and described the following:-

- data and audits from critical care will be collected and collated as defined by national guidelines and submitted to national registers as required. KPH will sign up to Critical Care Network NI, Regional Surveillance of Hospital Acquired Infections and the Cell Salvage Committee/Hospital Transfusion Committee. All cardiac surgery patient's data will be transmitted and recorded on the National Institute for Cardiovascular Outcomes Research (NICOR) data base as mandated by the Society of Cardiothoracic Surgeons of Great Britain and Ireland.
- all incidents and complaints will be handled via KPH electronic event reporting system and will be followed up with a full investigation, weekly discussion at management meetings and escalation as required, and reporting to RQIA as necessary.
- there will be a weekly ICU Governance and Quality Team meeting to begin with then monthly. The attendees will be the ICU lead consultant (chair); members of the surgical and consultant anaesthetic staff as appropriate; the PACU Manager; the nurse clinical lead; the clinical nurse educator and the clinical equipment lead (ICU). There may be other attendees as required for example the cardiac theatre coordinator; the lead perfusionist and lead cardiac ward nurse. The extra attendees will be invited as appropriate and when relevant to the patient discussions or areas of concern. These meeting will include reviews of audit; case discussions; new regulation; patient safety; incidents/complaints; education; training as well as mortality and morbidity. Any issues from this group will be escalated directly to the MAC as appropriate.
- ICU agenda items including audit, outcomes and IPC pertaining to critical care, will also be discussed at the monthly Local Quality Team meetings, IPC meetings and quarterly during MAC meetings. All action plans/minutes/learning at local level will cascaded to staff through departmental meeting as will MAC decisions.
- the monthly ICU governance quality meeting will serve as the MDT for the surgical; medical; ICU and nursing leads for service improvement. Additionally there will be daily/weekly MDT meetings/huddles for patient care.
- an intensive care meeting will be held monthly. This will be chaired by the group medical director. Composition of this clinical governance group will include a representative from the cardiac surgeons; cardiac anaesthetists/intensivists and roles listed in the governance strategy. The agenda for this meeting will include a review of all cases and include an analysis of any morbidity and mortality. The minutes of this meeting and the morbidity and

mortality analysis will be fed into similar agenda points at the group quality and MAC meetings which are held every three months. Learning points will be disseminated via the MAC meeting; communications from the group medical director; nursing leads and the clinical nurse educator. Any issues that require more urgent escalation will remain the responsibility of the group medical director.

• due to the size of the organisation the group medical director will be the lead for clinical governance. All governance will be considered by the ICU governance team and MAC.

Policies and procedures were available outlining the arrangements associated with the cardiac surgery service. Observations made confirmed that policies and procedures were indexed, dated and systematically reviewed on a three yearly basis or more frequently if required.

Mr Regan, Responsible Individual demonstrated a clear understanding of his role and responsibility in accordance with legislation. Information requested by RQIA has been submitted within the specified timeframes. It was confirmed that the statement of purpose and patient's guide are kept under review, revised and updated when necessary and available on request. They were reviewed as part of the registration process for the new entity and were found to be in accordance to legislation.

A new certificate of registration will be issued to Mr Mark Regan following the approval of the variation to registration application. Mr Regan was aware that the RQIA certificate of registration must be displayed in a prominent place.

Observation of insurance documentation confirmed that current insurance policies were in place.

5.2.11 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 management and staff.

6.0 Conclusion

Based on the inspection findings and discussions held we are satisfied that this service is providing safe and effective care in a caring and compassionate manner; and that the service is well led by the responsible individual.

The variation to registration application has been approved from an estates perspective. This variation is awaiting approval from a care perspective. Mr Mark Regan will be notified when the variation application has been approved.

7.0 Quality Improvement Plan/Areas for Improvement

	Regulations	Standards
Total number of Areas for Improvement	2	0

This inspection resulted in two areas for improvement being identified. Findings of the inspection were discussed with Mr Mark Regan, Responsible Individual and Mrs Sarah Marks, Registered Manager as part of the inspection process and can be found in the main body of the report.

7.0 Quality Improvement Plan/Areas for Improvement

	Regulations	Standards
Total number of Areas for Improvement	2	0

Quality Improvement Plan				
Action required to ensure compliance with <u>The Independent Health Care Regulations</u> (Northern Ireland) 2005				
Area for improvement 1	The Responsible Individual shall ensure the safe and ongoing care for post-operative cardiac patients in Kingsbridge Private			
Ref: Regulation 15(1)	Hospital (KPH) by establishing a memorandum of understanding (MOU) with the Belfast Health and Social Care Trust (BHSCT) to			
Stated: First time	include the arrangements for the transfer out of post-cardiac surgical patients to the BHSCT based on medical assessment.			
To be completed by: 12 January 2022	Ref: 5.2.9			
	Response by registered person detailing the actions taken : I can confirm that a signed MOU with the Belfast Trust is now in place. A copy has been forwarded to RQIA.			
Area for improvement 2 Ref: Regulation 15(6)	The Responsible Individual shall provide written confirmation from the Department of Health (DoH) of the final approval of the controlled drugs (CD) licence for the new entity.			
Stated: First time	Ref: 2.0			
To be completed by: 12 January 2022	Response by registered person detailing the actions taken: I can confirm that we are in procession of a CD license from the DOH. A copy has been sent to the RQIA of the same.			

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





The **Regulation** and **Quality Improvement** Authority

The Regulation and Quality Improvement Authority

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