**Agenda item 3.ii**

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| **Report to:** | **Board of Directors** | **Date: 2 February 2023** |
| **Report from:** | **Chief Nurse and Medical Director** | |
| **Trust Objective/Strategy:** | **GOVERNANCE: Patient Safety, Effectiveness of Care, Patient Experience and DIPC** | |
| **Title:** | **COMBINED QUALITY REPORT** | |
| **Board Assurance Framework Entries:** | **Unable to provide safe, high-quality care BAF numbers: 742, 675, 1511 and 1878** | |
| **Regulatory Requirement:** | **CQC** | |
| **Equality Considerations:** | **None believed to apply** | |
| **Key Risks:** | **Non-compliance resulting in poor outcomes for patients and financial penalties** | |
| **For:** | **Information** | |

## 1. Purpose:

The Medical Director and Chief Nurse would like to highlight the following items in addition to the Papworth Integrated Performance Report (PIPR) to the Board:

## 2. CQC IR(ME)R Inspection

Following the CQC IR(ME)R inspection that took place on 2nd November 2022, the Trust received two Improvement Notices on 14th November relating to:

IR(ME)R Regulations 2017 Regulation 6: Employer's duties: establishment of general procedures, protocols and quality assurance programmes; and

IR(ME)R Regulations 2017 Regulation 8: Employer's duties: accidental or unintended exposure.

The Trust was required to ensure compliance by 20th January 2023. On 16th January 2023, the Trust sent an action plan (Appendix 1 see reference pack) and evidence to the CQC confirming its compliance. As of 27th January 2023, no response has been received from the CQC.

The Final Report was sent to the Trust on 28th November, and included the following areas of improvement requiring an action plan to be submitted within 6 weeks of the date of the letter (9th January 2023):

| Regulation | Action Required |
|---|---|
| 6(5)(a)<br>Duties of the employer | The employer must ensure referral guidelines are available for cardiology. |
| 15 (2)<br>Equipment: general duties of the employer | The equipment inventory must contain all the information required in this regulation. |
| 17 (4)<br>Training | The employer must keep and have available an up to date record of all relevant training undertaken by all practitioners and operators. |

The Trust responded to the Final Report on 9th December 2022, offering clarification on areas that it believed were factually incorrect. The Action Plan relating to the report (Appendix 2 reference pack) was sent on 9th January 2023. The CQC confirmed receipt on 12th January 2023 and acknowledged that the action plan was 'good, with most milestones complete or almost complete'.

Ongoing actions are being progressed through Radiation Protection Committee, and Radiology and Cardiology Business Unit Meetings and the action plans are being monitored by QRMG.

**3. Surgical Site Infections (SSI) Q3**

The Trust continues to monitor SSI rates and whilst improvement was seen in Q2 (4.8%) reporting, Q3 rates have seen another increase (7.1%). The surgical site stakeholder group continues to meet bimonthly monitoring progress with improvement actions. An assurance dashboard together with a detailed action log is overseen by QRMG and Quality and Risk committee.

**4. Julie Quigley**

One of our colleagues, Julie Quigley, died peacefully on Saturday 14th January, surrounded by her family, following a long illness.

Julie worked at Royal Papworth Hospital from 2000-2022, having started as a staff nurse in our critical care team and progressing to become one of our nurse consultants.

During her time working here, she also held roles in resuscitation, clinical development and then in 2009 was given the opportunity to set up the ALERT Team which in her own words was a dream role for her, one that both challenged and gave her the determination to develop the advanced practice role within ALERT and show how this could benefit the Trust as a whole.

She was a wonderful nurse and an inspiration to so many. Always smiling, Julie was not just a colleague but a dear friend to so many at Royal Papworth, and support has been offered via the wellbeing hub and chaplaincy. Her funeral will be held on 31st January.

**5. Inquests**

**Two inquests were held in November 2022**

Mycobacterium abscessus inquest heard over 7 days and RPH was legally represented. This was in relation to two patients had undergone lung transplantation in the new hospital and subsequently acquired Mycobacterium abscessus and sadly died in 2020. The Trust declared an outbreak and a Serious Incident investigation was completed and extensive interventions focused on the hospital water, which was the most likely source of the infections.

Mitigations, such as point-of-use filters and enhanced water treatment remain in place and through regular testing we know that these measures have been effective in reducing the counts of mycobacteria at the Trust.

**Patient A**

**Cause of death –**

1a) Severe necrotising pancreatitis
1b) Antibiotic therapy for Mycobacterial infection
1c) Bilateral lung transplant for Chronic Obstructive Pulmonary disease

**Patient B**

**Cause of death –**

1a) Right pneumonia
1b) Non-tuberculous (Mycobacterium abscessus) mycobacteriosis

1c) Short telomere syndrome – associated chronic fibrosing lung disease (transplanted)
2) Antibiotic-associated Clostridium difficile colitis (treated)

**Coroner's Conclusion:**
Narrative conclusion **–** The Coroner concluded that both patients had died in part because of the acquisition of Mycobacterium abscessus or its treatment with antibiotics. However, the Coroner did not make any safety recommendations to the Trust in response to the clinical care provided.

The Coroner issued a Prevention of Future Deaths (PFD) report to the Department of Health and Social Care (DHSC) about his concerns over a lack of guidance from Government to hospitals, around identifying and controlling the Mycobacterium abscessus and therefore a continuing risk of death.

**Patient C**
Patient underwent elective interventional left atrial appendage occlusion procedure at Guys and St Thomas Hospital in 2019. Procedure led by Royal Papworth Hospital Consultant Cardiologist (as agreed under specialist commissioning framework). Shortly following the procedure patient became unwell and found to have significant intra pericardial bleeding and haemodynamic instability necessitating emergency sternotomy surgery.

Exploration found a protrusion of the left atrial appendage device anchoring arm through appendage wall which was considered to be the source of bleeding. The left atrial appendage device was explanted and patient made a slow post operative recovery. Transferred to Royal Papworth Hospital for ongoing recovery. Two weeks after transfer, the patient's condition deteriorated rapidly and pulmonary embolus was suspected as the most likely explanation. Despite timely recognition of the patient's deterioration and treatment with full dose anti-coagulation, the patient sadly continued to deteriorate and died.

**Manufacturers examination of device:**
Examination of the explanted device showed a stabilisation wire to be bent and protruding from the left atrial appendage device. There was no evidence of left atrial appendage device manufacturing failure and no failure in the utilisation and deployment of the left atrial appendage device.

**Cause of Death**
1a) Pulmonary embolus
2) Left Atrial Occlusion, haemorrhage and repair mitral annular calcification

**Coroner's Conclusion:**
Narrative conclusion gave a factual detailed explanation of the procedure, complication, device finding, transfer to Royal Papworth Hospital, appropriate anticoagulation management and timely recognition of pulmonary embolus.

**Three inquests were heard in December 2022.**

**Patient D**
Patient with moderate to severe aortic stenosis and atrial fibrillation underwent aortic valve replacement and left atrial appendage excision. Coronary ostial obstruction recognised at time of operation and bypass grafts completed to try and address issue. Patient had complicated recovery in critical care requiring ECMO support which was weaned with an intra-aortic balloon pump and following removal of the IABP patient became hypotensive and could not be resuscitated.

**Medical cause of death**:
1a) Subendocardial infarction

1b) Malposition of prosthetic aortic valve
1c) Aortic stenosis

**Coroner's Conclusion**:
Narrative Conclusion – Patient died as a result of a known complication from necessary surgery (awaiting full record from Coroner's Office).

**Patient E**
Patient with extensive past medical history which included severe aortic regurgitation, coronary artery disease, spinal stenosis with chronic pain, obstructive sleep apnoea, bronchiectasis requiring home oxygen of 2-4 litres. Patient underwent an elective tissue aortic valve replacement and coronary artery bypass grafts. The surgery was uneventful and the patient was placed on the critical care ward for two nights for optimisation of pain management, then discharged to the ward. Patient's condition deteriorated and they had a cardiac arrest. Patient was transferred to Theatre and was placed on veno-arterial extracorporeal membrane oxygenation, continuous hemofiltration and mechanical ventilation for ongoing support and surgery was carried out to try to identify the source of the patient's internal bleeding. The patient's condition continued to deteriorate, despite treatment and intervention, and sadly died.

Meeting with family, surgeon and Clinical Governance held.

**Medical cause of death:**
1a) Small intestinal infarction and perforation
1b) Peri-operative myocardial infarction
1c) Aortic valve disease and ischaemic heart disease (operated on)
2) Previous myocardial infarction

**Coroner's Conclusion:**
Narrative conclusion gave a factual detailed account of the patient's medical history, treatment and deterioration following surgery. Post-mortem examination confirmed that the patient's death was due to a perforation of the small bowel. Small bowel ischaemia is a recognised complication of cardiac surgery.

**Patient F**
Patient with severe mixed mitral valve disease and a past medical history including moderate chronic obstructive pulmonary disease, hepatic cirrhosis secondary to Hepatitis B and Hepatitis C, rheumatoid arthritis. Admitted for mitral valve replacement surgery. On inspection, the mitral valve was found to have extensive calcification, retraction and thickening of the mitral valve leaflets, as well as extensive involvement of the sub valvular apparatus. Mitral valve replaced with VA ECMO support required, patient's clinical condition continued to deteriorate with significant bowel ischaemia from which they would not recover.

**Medical cause of death**:
1a) Multi-organ failure
1b) Atrioventricular dissociation
1c) Mitral valve replacement for rheumatic mitral valve disease
2) Chronic hepatitis C

**Coroner's Conclusion**:
Died as a recognised complication of appropriately indicated surgery.

The Trust currently have 110 inquests pending to be heard.

## 6. Recommendation
The Board of Directors is requested to note the content of this report.