Overview of Interventional Cardiology services at the Norfolk and Norwich, the Invited Service Review of the Cardiology service and the NNUH's re-review of clinical cases – July 2022

The Cardiology department at the Norfolk and Norwich University Hospital is a high-volume Percutaneous Coronary Interventions (PCI) centre undertaking over 1500 procedures per year. The outcomes for patients undergoing interventional cardiology procedures are very good, with low risk-adjusted 30-day mortality rates. These rates are significantly better than the National average (data from National Institute for Cardiovascular Outcomes Research).

Following concerns raised by a member of staff about the use of Drug Coated Balloons outside of accepted guidance, an in depth internal review was carried out which resulted in several recommendations, one of which was to seek an external review. The Trust requested the independent review from the Royal College of Physicians' (RCP) Invited Service Review (ISR) team. Due to the pandemic the ISR team conducted a virtual review which involved interviewing a number of multidisciplinary colleagues but did not provide individual Consultants an opportunity to present and discuss their decision making for their patients involved in the review.

The external review and the internal review acknowledge that there is a clear clinical rationale for using Drug Coated Balloons (DCB) rather than stents in individual cases and in particular situations. These are carefully defined in the recommendations we have agreed to action. There are concerns within the service about the potential long and short term issues associated with the use of stents. However, for assurance we continually monitor and report on long and short term outcomes for all out patients.

The ISR makes 14 recommendations, largely connected with governance processes, consent and patient information. We accept these recommendations in full. Most of the ISR's findings resonate with those that arose from the internal review. In response, we developed an action plan for the recommendations. Most have been implemented. The remainder are on track for delivery.

16 clinical cases were reviewed by the ISR team as part of the review and we have ensured all 16 have been thoroughly re-reviewed through our well established Serious Incident Group (SIG), which has formal Terms of Reference. This Group reviews internally reported incidents from across the Trust. These reviews included participation from Consultant colleagues across a number of specialities, the Deputy Medical Director, the Associate Medical Director for Quality & Safety, and the Associate Director for Quality & Safety, the Associate Director of Patient Experience & Engagement and the Serious Incidents and Family Liaison Officer.

Additionally, we have ensured a comprehensive review through the same process of a further 20 out of 36 patients who suffered from an acute vessel closure within 24 hours of an interventional cardiology procedure in the last 8 years. The Cardiology department reviewed the remaining 16 cases to ensure there were no other significant care or service delivery problems.

The internal reviews found that the many of these cases were complex, and there was evidence of discussion with, and or involvement of colleagues in the decision-making process in most cases (although these discussions were not always documented in the notes). In addition, in several of the cases there was evidence of discussion with colleagues at Papworth, the regional cardiothoracic centre. We found that the outcomes for patients in 13 of the 16 reviewed by the ISR team were very good or excellent. Of those, 3 of 16 case where the outcomes were concluded to be poor or very poor, duty of candour communications have been completed and the patient and or the family have been contacted. Of the 2 cases that the ISR team graded as having very poor care both had good long-term outcomes.

In terms of the patients concerned, the ISR review team graded 6 of the 16 cases as unsatisfactory and thought 2 of these had very poor care. They concluded that had it not been for the use of DCBs being outside of the accepted guidance at the time, they would have rated the care of 12 of the 16 as good.

Critically, the internal SIG review investigated the actual health outcomes for these 6 patients and concluded that they were excellent or good outcomes for four of the patients and poor for two. These two patients had already been through the SIG process prior to this additional review, the Consultants for these patients and the multidisciplinary team concluded that moderate harm was appropriate for each of these cases, with duty of candour applied in accordance with our SIG process and separate to this review.

Consultants from the cardiology team have fully acknowledged the findings of the internal and external review and formally applied duty of candour with the three patients where their care has been graded as poor. The team will communicate with appropriate patients about the review when providing ongoing care. The cardiology team have organised a helpline to allow patients or persons calling on their behalf to leave a message. A trained health professional will review the message and contact the caller within 72 hours to provide a personalised response to their enquiry and allay any concerns they may have from the report and its findings. The PCI leaflet and supporting information will be made available on the Trust Website for patients, their families and members of the public to access to respond to general queries.

We welcome the in depth review of our service and thank the ISR team for their very clear recommendations which will help us deliver improved quality of care for our patients.