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.

Royal College of Physicians

Setting higher standards

Invited Reviews

Report of the invited service review to

Norfolk and Norwich University Hospitals NHS Foundation Trust

11 and 12 March 2021

Contents

1 Executive summary

Background

Norfolk and Norwich University Hospital Trust (NNUH) "the Trust" commissioned the Royal College of Physicians (RCP) Invited Reviews (IR) service following concerns raised about the cardiology department's use of drug coated balloons (DCBs) in the management of patients with coronary artery disease.

Percutaneous transluminal coronary angioplasty (PTCA) and stenting for coronary artery disease is a routine procedure widely used in the NHS for the treatment of a variety of cardiac conditions caused by narrowed or blocked arteries. Coronary stents have a substantial randomised control trial (RCT) literature to support their use – they are efficacious and complication rates are low. Even so, the recognised, albeit low risk, complication of stent thrombosis remains a concern, as does the long-term commitment to antiplatelet drugs following stent placement. Some researchers have evaluated the use of DCB technology as an alternative to stent placement, which delivers beneficial drugs to the arterial wall without the requirement for stent placement, potentially reducing the risk of stent thrombosis, and has the potential to limit the time required for antiplatelet drugs.

Currently, in the UK, DCB angioplasty is a recommended procedural treatment for in-stent restenosis, and in de novo coronary artery vessels <3mm diameter[1]. The Trust performs a very high number of cases with DCB technology without stent placement, which makes them a substantial outlier for DCB use when compared with other NHS cardiology departments. The reason for this outlier status is their use of DCB angioplasty in a much wider context, where there is limited data to support their use i.e. to treat de novo lesions in vessels >3mm in diameter, or in patients having ST elevation myocardial infarction (STEMI)[a].

Throughout this report, the use of DCBs outside of evidence and guidance-based practice is referred to as outside current European Society of Cardiology (ESC) guidelines[2] use of DCBs.

Concern about this outside current ESC guidelines practice was raised with the Trust executive, who after internal review, concluded that an external review of DCB practice was required. After discussions with the RCP Invited Review (IR) medical director, it was agreed that the terms of reference should include the combination of a clinical record review (CRR) of a broad range of cases using DCB, and a departmental service review (SR).

The specialist clinical reviewers included representation from the British Cardiovascular Intervention Society (BCIS) (Removed – identifiable information), an academic cardiologist, a consultant interventional cardiologist and a lay reviewer. The review was chaired by the deputy medical director, invited reviews (a consultant cardiologist) and supported by an invited review manager. They triangulated information from the following:

- a clinical record review of 16 cases (CRR); 12 randomly selected cases, and 4 index cases
- an extensive review of relevant documentation provided by the Trust and cardiology team
- interviews with a broad range of clinical and managerial cardiology and Trust wide staff conducted virtually on MS Teams over a two-day period (11 and 12 March 2021).

The clinical record review highlighted significant shortfalls in clinical care

The clinical record review of 16 cases in which DCB was used involved two independent reviews of each case by members of the clinical specialist review panel (see section 4.3) using a structured judgement

[a] STEMI is the medical term for a heart attack

review tool. Each case was then discussed in an MDT style meeting chaired by the deputy medical of IRs to agree on gradings for each phase of care as well as an overall agreed National Confidential Enquiry into Patient Outcome and Death (NCEPOD)[b]grading. This process is described in further detail in section 4.2 Approach to this review.

Out of the 16 cases, six were unsatisfactory, eight found room for clinical improvement and two had room for improvement with respect to clinical and organisational factors. All cases were not compliant with current best practice with outside current ESC guidelines use of DCB in STEMI, vessels >3mm in diameter, and left main coronary artery intervention.

Generally, for the outside current ESC guidelines use of DCB there was:

- little evidence for use of pressure wire[c] and intracoronary imaging[d] in cases that would benefit,
- limited documentation of multidisciplinary team (MDT) involvement,
- inadequate consent processes and lack of information provided for the discussion of appropriate cases at morbidity and mortality meetings (M&M),
- inadequate case reviews at departmental and Trust governance meetings.

Current arrangement for use of DCB angioplasty

Following consideration of the information provided, the specialist clinical reviewers were of the view that outside current ESC guidelines use of DCB angioplasty should cease at this time. If the Trust wish to continue the use of DCBs they should only be considered under the following circumstances (also outlined in our initial feedback letter dated 29 March 2021):

- In-stent restenosis[e],
- Vessels <3.0mm diameter,
- Vessels >3.0mm diameter if at least one of the following apply:

1) The patient is enrolled in a formal prospective research registry of DCB use with appropriate ethics and research and development (R&D) approval
2) The patient is enrolled in a formal randomised control trial (RCT)
3) The patient has signed a bespoke consent that clearly highlights the DCB use would be outside UK conventional and guideline-directed practice and has indicated specifically that this is their choice.

Adherence to these criteria will require ongoing monitoring by the Trust, to include a regular audit of circumstances where DCBs are used in vessels >3.0mm diameter, evidence of MDT discussion of those and consent of patients. Consideration should be given to asking BCIS for advice for seeking independent peer review of this.

MDT arrangements and documentation needs to improve

With respect to discussion of outside current ESC guidelines use of DCBs, the specialist clinical reviewers found little evidence of communication between colleagues within the appropriate MDT forum about the

[b] NCEPOD grading: http://www.ncepod.org.uk/grading.html
[c] A pressure wire is a device that can be used during coronary angiography to determine if a narrowing (stenosis) in one of your heart arteries (coronary arteries) requires further treatment
[d] Images taken of the heart to help with the diagnosis of heart disease
[e] Re-narrowing within a previously placed stent

clinical management and treatment options of patients. The CRR identified the need for better record keeping and discussion of these clinical cases.

Governance arrangements

Since its inception in 2009, the DCB programme at the Trust had not been supported by a robust governance framework. Encouraged by the interventional cardiology team's own experience with this technology, the DCB programme continued to develop outside current ESC guidelines and its use increased without clear lines of reporting and accountability. The review found an urgent need for a formal governance structure to be implemented to ensure that all aims, objectives and outputs of the programme are in line with Trust policy and best practice guidance. Going forward, the DCB practice as recommended by the specialist clinical reviewers needs regular appraisal not only within an open cardiology governance programme, but also at executive level, where the practice should remain on the risk register.

Standard operating procedures for DCB use

One example of the poor provision for arrangements of DCB expansion was the variation in outside current ESC guidelines use of DCBs across the interventional consultant cardiologists. Several staff were unaware of the newly developed standard operating procedure (SOP) for the use of DCBs for coronary angioplasty. There will need to be further revisions to the SOP to reflect the recommendations outlined in this report and that the document should be ratified by the Trust's appropriate NICE audit and policy committee and widely shared with all relevant members of staff.

Patient communication and consent for outside current ESC guidelines use of DCB

Another area of concern was a potential lack of open and honest communication with patients and their families with regards to outside current ESC guidelines use of DCBs. There was marked variability in the cardiology team's approach to consenting patients.

In order for DCB practice to be understood in a wider context for patients at the Trust, there needs to be updated patient information leaflets for DCBs and specific patient consent forms which, should be reviewed by BCIS to ensure external oversight.

Research and audit

The specialist clinical reviewers were provided with several published and unpublished data (some authored by the Trust's cardiology team). The overarching conclusions from these papers suggested that further RCTs are needed to inform the evidence base for using DCBs in coronary artery disease outside of current standard of practice. The specialist clinical reviewers agreed that there is a need to ensure the programme is enrolled as part of a prospective registry or RCT to contribute to the newly emerging evidence base whilst maintaining appropriate safety standards for patients at the Trust.

There were several research and audit specific improvements that need to be addressed by the Trust, these include outcomes reporting (including complications captured by the National Institute for Clinical Outcomes Research (NICOR) returns), as well as the presentation of research findings to the cardiology team and executive team. The review team were of the view that the link between research and development should be stronger to ensure all approvals are appropriately sought and follow a formalised process. These findings were informed by those outlined by the internal review conducted by the Trust in March 2021.

Working arrangements

The specialist clinical reviewers met an enthusiastic department, with generally good working relationships between colleagues. We were constantly reminded that the cardiology team were a cohesive and friendly

department where combined working for complex cases was encouraged. However, there are interpersonal difficulties that have arisen, partly because of the concerns raised that have led to this review. It is also clear from some colleagues, that they are not entirely comfortable about DCB practice, but do not feel empowered to challenge it. This might suggest that the culture could better promote transparency, support for those who raise concern and better organisational learning.

The specialist clinical reviewers wish to commend staff for their help and support in the co-ordination of this review. In addition to thanking staff for their frank and open way they engaged with the interviews to help inform the report findings and recommendations.

2 Overall conclusions

The following section reports on the review team's conclusions informed by the interviewee comments, documentation review and clinical record review (see section 6: Findings). The Terms of Reference can be found in section 4).

2.1 ToR 1: Clinical record review

Terms of reference 1 concerned the management of care of patients that had received DCBs outside current ESC guidelines and whether this was in line with national good practice, guidelines, and/or the views of a body of clinical professionals. Out of the 16 cases reviewed, four cases were selected because of concerns raised about the care provided (index), and the remaining were randomly selecting using a criterion provided to the Trust where DCBs were used instead of the more commonly used DESs.

Overall, the review team had concerns about all 16 cases (both indexed and random) and not just the index cases. They concluded that in all 16 cases, the use of DCBs was outside current ESC guidelines and that they would not have supported its use in any of the cases due to the lack of formal evidence to support its superiority and safety outcomes over DESs[f]. Therefore, the review team graded all 16 cases as either unsatisfactory (n=6), room for clinical improvement (in respect to either clinical factors n= 8 or both clinical and organisational factors n = 2)[g].

The review team were provided with the Journal of American College of Cardiology (JACC) DCB consensus document[3]. It provides recommendations summarising the historical background, technical considerations, and clinical indications for the use of DCBs. The article was co-authored by the DCB programme clinical lead. Although these are not international guidelines, standards of practice in the cases reviewed as part of the CRR fell short of this opinion piece (see section 6.1.3 Phases of care).

In cases where the review team believed that the patient outcome was possibly impacted by the intervention and where the cases fell short of the JACC DCB consensus document, these cases were graded as unsatisfactory (n=6). Based on the relatively small sample (16 cases), the review team could not comment on whether the outcomes were better or worse for patients that underwent DCB procedures outside current ESC guidelines. However, the review team did identify specific areas for improvement, examples include:

- the need for better diagnostic analysis pre-angioplasty treatment e.g. pressure wire studies, use of intravascular imaging, better-quality angiograms (criteria specified within the JACC DCB consensus document).
- better documentation regarding patient consent specific to the outside current ESC guidelines use of DCBs and the need for more honest engagement with patients about DCB use with patient-specific information.
- better documentation for the rationale of DCB use over best practice within MDT meeting notes.

Considering this, the review team were of the view that the Trust should set clear parameters for the DCB programme should they wish to continue. Suggestions for these are set out in section 3.1.1 Trust board - recommendation C (see recommendations: C and D). These conclusions are supported by findings from

[f] A drug-eluting stent is coated with a slow-release medication to help prevent re-narrowing (restenosis)from forming in a stent.

[g] Of note, some of the cases reviewed were within the timeframe of phase one, two and for part of the recovery phase of the pandemic.

section 6.1 Terms of Reference 1, Clinical record review and triangulated with findings from sections 6.2-6.5.

2.2 ToR 2: Processes in place to initiate DCB use

Terms of reference 2 concerned the robustness of processes put into place to initiate outside current ESC guidelines use of DCBs (outside of guidelines), the structure and funding of the DCB programme, commissioning arrangements, conflict of interest, and the ongoing monitoring of outcomes and effectiveness of treatment.

2.2.1 Initiation and development of the programme

This section concerns the governance framework to support the initiation and development of the DCB programme. Overall, the review team were of the view that since 2009, there has been limited reporting of the DCB programme into a formal governance structure and subsequently the accountability and responsibility for the programme has been unchecked.

The review team found that since its inception in 2009, the DCB programme grew organically but has continued to develop with limited oversight. For example, the programme has not been through a 'new technologies committee' nor had input or liaison with the Trust's 'NICE, audit and policy committee.' Therefore, the review team agreed that better and more robust Trust processes are put in place to maintain oversight of the programme from department to executive level. This would require a review of the current governance reporting, with a need to prioritise better links between the DCB programme and executive level Trust governance committees and/or sub-committees.

Considering the outside current ESC guidelines use of DCBs is not well supported by RCT evidence, the DCB programme has the potential to be high risk. There is an urgent need to ensure that the Trust have oversight of the DCB programme's aims, objectives and outputs and that the programme is included within the Trust risk register (see recommendations: G). These conclusions are supported by findings from section 6.2.2 Terms of reference 2: Initiation of DCB use. Further information regarding the overall conclusions specific to clinical governance meetings and arrangements are described in section 2.5. ToR 5: Quality of clinical governance arrangements.

2.2.2 Funding and conflict of interest (COI)

Terms of reference 2 also concerned the structure and funding of the DCB programme as well as any potential conflict of interest (COI).

Overall, the review team were of the view that there should be greater transparency regarding the involvement of the DCB manufacturer with the DCB programme, along with a review of the costs associated with DCB use.

The review team identified that the DCB programme lead receives research funding support relating to DCBs along with consulting fees by the DCB manufacturer. Moreover, there is a sponsorship agreement by the manufacturers to fund departmental research into the long-term outcomes of DCB. The Trust will need to decide whether there is sufficient transparency about any potential conflict of interest relating to the funding received from the manufacturer, and whether this relationship should be made clear to patients receiving this technology outside of current guidelines.

The review team also explored the cost of DCBs in comparison to stents, where DCBs are known to be more costly than stents. There were several members of the cardiology team who provided a justification that there were fewer long-term costs associated with DCBs due to the reduced number of complications compared to stents. However, this justification was anecdotal, not based on evidence and therefore cannot be applied to the outside current ESC guidelines use of DCBs. If the Trust wish to further explore whether

there is a cost implication associated with the use of the DCBs, they may explore the concept of a health economics/cost evaluation study comparing DCBs and DESs. This would help inform whether DCBs are more costly than the standard best practice intervention (DESs) (See recommendations: H). These conclusions are supported by findings in section 6.2.2 Funding arrangements.

2.2.3 Monitoring of outcomes

Terms of reference 2 concerned the ongoing monitoring of outcomes and effectiveness of treatment. Overall, the review team were of the view that the DCB programme leads have made good attempts to monitor and report outcomes through retrospective analysis. However, some of the concerns raised about the quality of the evidence to inform the effectiveness of treatment are valid and should be further explored.

The interventional cardiology team provided a substantial number of academic journals and data analyses as part of the documentation review. However, the review team were also informed of the discord among some staff regarding the robustness of the analyses and that the outside current ESC guidelines use of DCB is being practiced without 'gold standard' RCT evidence to support its use.

For example, the review team were informed that the Trust have better than expected outcomes with respect to their percutaneous coronary intervention (PCI) mortality outcomes from the BCIS national audit data. The DCB programme leads have interpreted these findings as evidence to support the safety profile of DCB use. However, there were several queries raised with respect the reliability of capturing complications following discharge, along with the need to explore further safety endpoints other than 30-day mortality.

Further to this, the review team found potential issues regarding the reliability of NICOR returns and recording complications associated with PCI. Having reviewed a series of cases and accompanying NICOR returns, there was some discordance between events that should have been reported to NICOR but were not captured on the NNUH local database (RCP 7, RCP 10, and RCP 14). This raised questions about the potential accuracy of the patient outcome data and rate of complications. This will need to be explored further by the Trust.

There is a need for increased externality and peer review of the analyses and outputs associated with the DCB programme, and this may be supported by registering the programme as part of an RCT or prospective registry. The conclusions reported within the academic journals (as part of the documentation review) recommended that although some research has demonstrated non-inferiority of DCBs to DESs in de novo lesions <3mm in diameter, further RCTs powered for clinical outcomes are warranted and in particular for in vessels >3mm where no RCT evidence exists. By the admission of the senior members of the DCB research team, it was accepted that outside current ESC guidelines use of DCB should only be conducted within a formal research trial (RCT or prospective registry) (see recommendations: C, D, E). These conclusions are supported by findings in section 6.2.3 monitoring of outcomes.

2.3 ToR 3: Use of DCBs in the treatment of coronary artery disease

Terms of reference 3 concerned the DCB current activity levels and outcomes, protocols and pathways, patient consent, MDT working, as well as internal reviews.

2.3.1 Protocols and pathways

Overall, the interviews and documentation review highlighted variation across consultants in their conventional and/or outside current ESC guidelines use of DCBs in coronary angioplasty. The review team identified that underpinning this variation, was personal experience and confidence in using DCB technology outside current ESC guidelines, but there was no formal documentation to guide indications for DCB use.

The review team saw a recently published standard operating procedure (SOP) document for DCB use, and were of the view that it requires updating following the RCP report. The patient consent form and patient information leaflet for outside current ESC guidelines use of DCB also requires urgent attention and updating.

The review team raised concern about a logic gap between the interpretation of the consultants' experience of using DCBs, compared to the national evidence base to support the use of DES over DCBs. Therefore, the review team concluded there is an urgent need to ensure that evidence is used appropriately to inform the decisions to use the DCB technology.

2.3.2 Standard operating procedure

The review team were positive about the development of a new SOP for the use of DCBs in coronary angioplasty. Although, they recognised this was developed after the concern was raised about the programme and the commissioning of this review. The review team were of the opinion that the Trust had made some positive steps to develop a document that outlines a process for consenting patients, along with the explanation for DCB best practice. The review team also identified several amendments required to the document before it is widely circulated for use. For example, the review team would challenge some of the terminology as to when the SOP can be 'overridden,' and where to record 'clinical variation in practice.' The review team were unclear about the statement that highlights the document can be overridden by a consultant cardiologist for 'specific reasons.' The review team considered that interpretation of the term 'specific reasons' was ambiguous and should be clarified to avoid any potential patient safety concerns and should include mitigations such as clearly documented discussions at an MDT.

The review team also reported that 'the process to be followed' section does not always clearly identify where the clinical rationale for variation in practice should be documented. If the Trust wish to continue supporting the DCB programme (considering the suggested parameters of recommendation C), then the review team recommend that 'how' and 'where' the clinical rationale is reported should be clearly specified in the document i.e. within MDT meeting notes or patient notes.

The review team were unclear why the technical considerations outlined in the JACC DCB consensus document had not informed or been used as a reference to support some of the technical considerations within the SOP. For example, the consensus document emphasizes the importance of lesion preparation, use of fractional flow reserve[h] (FFR) and intravascular imaging, yet such technical matters were lacking in the cases reviewed as part of the CRR. The SOP should include the indication for such technology prior to DCB use.

Since there is variable evidence for outside current ESC guidelines use of the DCB technology, the review team would expect a degree of externality and review of the SOP. At present, the SOP has been developed by the interventional consultant cardiologists and ratified by the cardiology directorate governance board. The department may also consider updating the policy in line with recommendations from this report and then sharing with the appropriate NICE, audit and policy committee for review (see recommendation: J). These conclusions are supported by findings in section 6.3.3 protocols and pathways.

2.3.3 Patient consent

Patient consent was identified by the review team as an area for concern and this was informed by findings from the CRR (ToR 1) and service review (documentation and interviews specific to ToR 3 and ToR 5). The review team were positive about the Trust's recent progress towards developing a patient consent form specific to the use of DCBs. However, the DCB programme has been in place for some time and where the development of a new patient consent form is only recent (since the commissioning of this review), there are further limitations to the patient consent process. This includes wide variation across the department in

[h] Fractional flow reserve – a technique for evaluating flow through a narrowed artery

the staff approach to consent, along with the lack of awareness among staff members regarding the newly updated form and its use.

There was wide variation among staff in their interpretation of current DCB research findings, which influenced their consenting of patients. In many cases, there was little evidence of discussion about the variance of practice compared with other units. Therefore, the review team agreed that the consent process should be formalised, with a focus on objective information sharing. For example, if the Trust were to continue supporting the programme within the parameters of recommendation C, then the cardiology department should provide training to staff on how to consent patients best verbally. The information should ensure that patients are aware that the Trust are an outlier in their use of DCBs in the UK, what is considered standard best practice, and also to outline the research findings to support the decision to use the outside current ESC guidelines intervention.

If the Trust continue supporting the DCB programme (considering the recommendations proposed as part of this review), the patient information leaflet should be updated to include more information about current recommendations for angioplasty practice, with details about the current recommendations for DCB use. **It should be made clear to patients that they are receiving treatment outside of current guidelines and that understanding should be signed by the patient**. Once ratified by the Trust governance board, the review team recommend the patient consent form and patient information leaflet be shared with BCIS for their comments and feedback for external transparency (see recommendation: K). These conclusions are supported by findings in section 6.3.4 Patient consent.

2.3.4 Internal reviews

Overall, the review team agreed that the Trust had taken positive steps towards resolving the concerns raised with respect to the DCB programme. The internal review identified key concerns with a clear action plan that involved the development of a SOP, a DCB procedure specific consent form, patient information leaflet and external approval for these documents from the BCIS. However, the review team highlight that there is more to be done. There were some queries raised to the review team with respect to the criteria for the DCB activity to sit within research or service evaluation. The review team agreed that the R&D department review its criteria for these and may consider looking to external more robust research governance programmes for their independent advice (see recommendations F, G, I). These conclusions are supported by findings in section 6.3.5 internal reviews.

2.3.5 MDT meetings

Overall, as part of the documentation review and interviews, the review team were informed that within the cardiology department there was adequate and appropriate representation of colleagues and specialties to contribute to good MDT working. However, despite this, the CRR identified some cases where MDTs did not take place but may have benefitted from further discussion of alternative treatment options such as coronary artery bypass graft (CABG).

The review team found the MDT meetings to require improved communication between colleagues with respect to documenting the decision and rationale for the use of DCBs over stents. This MDT documentation was requested but not reported in any of the CRR cases reviewed (see recommendation: J). These conclusions are supported by findings in section 6.3.6 MDT meetings.

2.4 ToR 4: Quality of team working within the department

Terms of reference 4 concerned the quality of team working within the department with consideration given to clinical and managerial leadership, individual behaviours, interactions with members of the wider medical team and MDT working.

Overall, the review team were of the view that the cardiology department were a cohesive team with good working relationships. However, the review team identified areas for improvement such as empowering staff to openly discuss concerns and better information sharing.

2.4.1 Clinical leadership

The review team were informed of interpersonal difficulties within cardiology that have arisen since the DCB practice was challenged. Despite reassurance from many that the department was very collegiate, some of the interviewees (including consultants) described that they were not entirely comfortable about the current DCB practice, but did not feel empowered to express an alternative view. The review team felt that more could be done by the clinical leadership team to better support the critical appraisal of the research aims, objectives and outputs of the programme. For example, there were some concerns regarding the criticisms raised to inform this review, and the review team believe that challenges and limitations raised towards any research or service evaluation is useful for improvement purposes and impartiality. The review team suggest that the culture would benefit from better promotion of transparency and organisational learning and the cardiology governance meeting could be a platform for such discussion. Paramount is the support provided by the leadership team to staff who have concerns about the DCB practice.

Going forward, job plans will need to ensure adequate provision for leadership roles in clinical governance, as well as timetabled programmes that allow full attendance.

2.4.2 Raising and responding to concerns

The current concerns were raised approximately nine years after the DCB programme began between 2009-2012, and so it has taken considerable courage by colleagues for concerns to be highlighted. Throughout the development of the programme there has been little leadership oversight from a Trust executive level. More needs to be done by the Trust to bridge this gap if they wish to continue with supporting the DCB programme (see recommendations L, M). These conclusions are supported by findings from section 6.4.

2.5 ToR 5: Quality of clinical governance arrangements currently in place

Terms of reference 5 concerned the clinical governance arrangements currently in place to support and maintain oversight of the interventional cardiology service. This included audits, clinical incident reporting, reviews of morbidity and mortality and patient complaints/feedback.

2.5.1 Governance meetings

Overall, the review team were of the view that improvements to the governance meetings were needed to ensure appropriate sharing of information with respect to research, audit and morbidity and mortality.

The review team were provided with the recent governance meetings notes and noted that the standing agenda items for discussion at the directorate and cardiology governance meetings were appropriate and well considered. However, they found that the information recorded in some sections was incomplete with limited discussions regarding key aspects of the programme such as ‘research and audit,’ and ‘morbidity and mortality.’ For example, the cardiology department have contributed research output towards the DCB evidence base, yet the review team found limited evidence for this reported at the departmental and divisional governance meetings.

The review team were unclear about how the department utilise the governance meetings to regularly share the programmes findings, outcomes, challenges, and successes. Considering the outside current ESC guidelines use of this product, they were of the view that within the parameters of recommendation C there needs to be better communication and reporting internally of the programme’s aims, objectives and outputs (see recommendation N).

2.5.2 Morbidity and mortality meetings

The arrangements for morbidity and mortality meetings needs clarity. The CRR highlighted at least two cases which should have had M&M discussions, that were not forthcoming. There needs to be an agreement about which cases should be selected for such discussions to avoid the current perceived randomness of case choice. A criterion for cases to be discussed at the meeting would ensure that all cases are appropriately captured for discussion to learn from complications and embed learning within the department.

The review team were informed of the Trust serious incident group (SIG) meetings - the review team were of the opinion that the four index cases reviewed as part of the CRR should have been presented at such a forum, but were told that no cardiology cases were ever discussed. The SIG meeting notes were not made available for review. The review team would encourage that all cases associated with complications are reviewed formally and lessons shared within the department and appropriate Trust oversight meetings (see recommendation E, N). These conclusions are supported by findings in sections 6.1.3 phases of care and 6.5.4 morbidity and mortality.

3 Recommendations

Key for timelines for implementing recommendations:

> **Immediate (0-3 months)** – action should be completed within 3 months of receipt of either the initial ISR visit feedback letter 29 March 2021 or receipt of this report

> **Short term (0-6 months)** - action should be completed within 6 months of receipt of the ISR report

> **Medium term (6-12 months)** – action should be completed within 12 months of receipt of the ISR report. Planning for actions resulting from these recommendations should start as soon as possible.

> **Long term (12-24 months)** - action should be completed within 24 months receipt of the ISR report. Planning for actions resulting from these recommendations should start as soon as possible.

3.1.1 Trust board

A. The healthcare organisation should consider sharing this report with the regulator Care Quality Commission.

Short term (0-6 months)

B. This report should be considered by the Trust Board or relevant subcommittee and oversight of an action plan should be provided to a Non-Executive Board member to ensure these recommendations are successfully implemented.

Immediate (0-3 months from issue of this report)

C. If the Trust wish to continue the use of DCBs they should only be considered under the following circumstances:

- In-stent restenosis,
- Vessels <3.0mm diameter,
- Vessels >3.0mm diameter if at least one of the following apply:

    1. Patient is enrolled in a formal prospective research registry of DCB use with appropriate ethics and R&D approval
    2. Patient is enrolled in a formal randomised controlled trial (RCT) of DCB versus second or third generation drug-eluting stent
    3. Patient has signed a bespoke consent that clearly highlights the DCB use would be outside UK conventional and guideline-directed practice and has indicated specifically that this is their choice.

Immediate (0-3 months from issue of the initial feedback letter)

D. The above arrangements should be in place for no longer than a period of 6 months from the issue of this report, after which time it is expected that all patients deemed suitable for outside current ESC guidelines DCB use should either be enrolled in a formal prospective research registry or RCT. The Trust should monitor adherence to these criteria, in particular around issues of patient consent. Consideration should be given to asking the British Cardiovascular Intervention Society (BCIS) for advice for independent peer review of these recommendations. Please see recommendation K in relation to point 3.

Medium term (6-12 months)

3.1.2 Clinical record review

E. The cardiology department should review the findings from the clinical record review (CRR) and ensure that any key learning points are fed back to the cardiology department at the governance meeting to embed learning within the workforce. This should include a review of entries made to the NICOR database for cases where complications occurred (ToR 1).

Short term (0-6 months)

3.1.3 Initiation and development of the DCB programme

F. The Trust should reflect on the findings in relation to the set up and initiation of the outside current ESC guidelines DCB use. Consideration should be given to whether there is any learning to be taken from the use of new technologies and programmes of innovation across the Trust (ToR 2). As part of this reflection, it is recommended the Research and Development (R&D) department review its criteria for what is considered a research project as opposed to a clinical evaluation to ensure appropriate arrangements are in place at the start of a programme (ToR 3).

Short term (0-6 months)

G. The initiation and ongoing development of the DCB programme should be specifically reviewed and consideration given to the following:

- The cardiology team should approach either another department in the Trust or an external cardiology team with mature research and clinical governance structures in place to learn from how they best support new technologies or outside current ESC guidelines therapeutic use programmes. This would provide the opportunity for the cardiology leadership team to learn from and implement robust governance processes for the benefit of transparency, patient safety and accountability (ToR 2 and ToR 5).
- This should include a rolling audit program to monitor outcomes, issues of consent and appropriate reporting into executive level committees. There needs to be regular appraisal of the DCB programme, and the executive team should actively monitor this on a risk register (ToR 5).

Short term (0-6 months)

3.1.4 Funding and conflict of interest

H. In the interests of openness and transparency, potential conflicts of interest should be clarified by the Trust and members of the cardiology team, particularly in relation to research funding support and consultancy fees for staff, paid for by the DCB manufacturer. This relationship between the funder and Trust should also be made clear to patients as outlined in recommendation K (ToR 2).

If a potential conflict of interest is identified the following should be considered:

- Independence in the clinical decision making for using DCBs e.g. an independent chair in the MDT such as a non-interventional cardiologist.
- Independent and external review of programme outcomes.
- The Trust should consider a health economics cost evaluation study to compare the costs between DCBs and stents to provide an accurate evidence base to support the increased use of DCBs within the NHS setting (ToR 2).

Short term (0-6 months)

3.1.5 Monitoring outcomes

I. The cardiology team should take steps to improve their data collection and analysis processes in relation to the DCB programme. This should include:

- clarity over the submission of data to NICOR and other relevant databases for capturing data such as complications and re-intervention (ToR 2).
- the relevant approvals should be sought and application to a randomised controlled trial or prospective registry if the Trust wish to consider supporting the DCB programme and within the parameters outlined in recommendation C. The DCB safety data should also take into account primary and secondary endpoints other than mortality (ToR 3).
- the cardiology department should work closely with the R&D department to ensure that data capture protocols are agreed and shared between the two teams.
- the Trust should ensure there is externality and impartiality with respect to the management of the DCB programme data outputs. The Trust may consider ensuring that all research and evaluation outputs are peer-reviewed by an appropriate committee within the Trust, or externally (ToR 3 and ToR 4).

Medium term (6-12 months)

3.1.6 Protocols and pathways

J. As a priority the cardiology team should be required to update the DCB SOP. This is to ensure there is utmost clarity on how, when and where any variations in practice for use of DCBs are clearly documented.

As part of this revision to the SOP the following needs to be included:

- A requirement for all outside current ESC guidelines use of DCB to be discussed at an appropriate MDT and this should be recorded within MDT meeting notes and the patient's case notes.
- The JACC DCB consensus document should be used to inform the SOP with respect to the imaging guidance.
- The DCB in coronary angioplasty SOP should be reviewed by the appropriate governance committee.
- A clear policy on informed patient consent (see recommendation K).
- Ensure that any overriding decisions made to not follow the SOP are accounted for (ToR 3).

Consideration may be given to sharing the SOP with BCIS for their comment. Once finalised the SOP should be shared with all members of the cardiology department and wider members of the multidisciplinary team.

Short term (0-6 months)

K. There is an urgent requirement by the Trust and the cardiology team to ensure that patients being treated with DCBs outside current ESC guidelines are appropriately consented and informed with the use of an approved patient consent form and patient information leaflet.

As part of this the Trust should ensure

- That staff have appropriate training and an induction training on how to consent patients objectively, and that patients are aware that the Trust is an outlier compared to the rest of the UK and there is a current limited evidence base for this (ToR 3).
- the consent form and patient information leaflet be shared with BCIS and the NICE audit and policy committee for their review (ToR 3).

Immediate (0-3 months from initial feedback letter being received)

3.1.7 Teamworking and leadership

L. The Trust should reflect on the findings regarding oversight of the DCB programme (in line with recommendation G) consider reviewing its lines of accountability, reporting structures and escalation process for concerns (ToR 4).

M. The cardiology department should put support measures in place to ensure that staff who raise concerns about the programme are appropriately supported. The line management supervision time should allow for staff to openly discuss concerns (ToR 4).

Medium term (6-12 months)

3.1.8 Governance

N. There is a general need to improve the existing clinical governance processes which need to be made more robust. For example, this should include:

- ensuring the morbidity and mortality meetings take place monthly and involve members of the wider medical team, to include appropriate cardiac surgical expertise. These meetings should be job planned in the clinicians' schedules and attendance monitored and reviewed as part of the appraisal process (ToR 1, 4, 5).
- criteria for morbidity and mortality cases to be reviewed in these meetings, to include complications, readmissions and/or requirement for reintervention, as well as patient deaths. This would provide opportunities for learning to be shared and embedded across the cardiology team (ToR 5).
- processes in place for reviewing trends, sharing learning and measuring the success of actions arising (ToR 5).
- a clear Trust policy on the process for incidents and adverse outcomes to be reviewed at a serious untoward incident (SUI) level or root cause analysis (RCA) is also required (ToR 5).

4 Introduction

Removed – identifiable information, medical director at Norfolk and Norwich University Hospitals NHS Foundation Trust (NNUH) contacted the Royal College of Physicians (RCP) in October 2020 regarding the use of drug coated balloons (DCBs) within the cardiology department. Removed – identifiable information discussed the review with Removed – identifiable information, medical director for invited reviews (IRs) at the RCP. It was agreed that a combined clinical record review (CRR) and service review (SR) would be undertaken virtually on MS Teams. The CRR consisted of a review of four index and 12 random cases. The SR comprised a review of Trust specific documentation and interviews with key staff and personnel on 11 and 12 March 2021.

4.1 Terms of reference for this ISR

The Royal College of Physicians (RCP) will provide an independent Invited Service Review (ISR) of the interventional cardiology services at Norfolk and Norwich University Hospital, a particular focus will be on the use of Drug Coated Balloons (DCBs) in the treatment of coronary artery disease (CAD).

1) To undertake a clinical record review (CRR) of 12 cases[i] of patients where Drug Coated Balloons were used in the treatment of coronary artery disease. The sample will include:

- 4 cases where specific concerns have been raised about outcomes linked with use of DCBs
- 8 randomly selected cases between June 2019 – June 2020
    - 4 where DCBs were used in the treatment of the proximal left anterior descending coronary artery (LAD)
    - 4 involving the use of DCB in angioplasty to the left main stem coronary artery (LMS).

The CRR enables the ISR team to assess the management of care, including identifying any avoidable risks, consent, multidisciplinary team working and record keeping. The purpose of this would be to gain a greater understanding of the pathways and protocols for use of DCBs in action. This will include taking into account whether the care is in line with national good practice and guidelines, and/or what would be considered by the view of a body of clinical professionals in a similar situation. The review team will independently review the cases before a meeting to discuss and agree on gradings of care. This will take place in advance of the visit.

2) To review the process followed for use of a treatment (DCBs) outside of national guidance and the robustness of processes put into place to initiate its use, structure and funding of the DCB programme, commissioning arrangements, conflict of interest, and the ongoing monitoring of outcomes and effectiveness of treatment. Consideration will be given to attempts made by the interventional cardiology team to share learning and outcomes more widely.

3) To review the use of DCBs in the treatment of coronary artery disease by the interventional cardiology team. This will include a review of current activity levels and outcomes, protocols and pathways, consent and MDT working. Consideration will be given to the concerns raised about mortality and outcomes and well as internal reviews of these matters. Consideration will also be given to whether the current practices are contemporaneous and comply with national and RCP guidance.

[i] The review team requested four cases where DCB had been used in the LMS, however, these were not made available for the clinical review meeting in February 2021 and subsequently four additional cases (RCP 13-16) were reviewed separately in April 2021 bringing the total number of reviewed cases to 16.

4) To review the quality of team working within the department and to give a view on whether this supports the delivery of high quality and safe care. Consideration will be given to clinical and managerial leadership, individual behaviours, interactions with members of the wider medical team and MDT working.

5) To evaluate the quality of clinical governance arrangements currently in place to support and maintain oversight of the interventional cardiology service to include a look at audits, clinical incident reporting, reviews of morbidity and mortality and patient complaints/feedback.

6) Highlight any new area of concern that arises during the ISR.

To make recommendations for the consideration of the medical director as to possible courses of action that may be taken to address specific areas of concern.

4.2 Approach to this review

The RCP consulted with the British Cardiology Society and British Cardiovascular Intervention Society (BCIS) who nominated specialist reviewers for the review team, as set out in section 4.3.

In advance of interviews with staff, the review team undertook a review of a series of cases. Each reviewer used a structured form adapted from the RCP National Mortality Case Record Review (NMCRR) programme[j] to independently examine all phases of care that the patient received. These were graded by the review team as **1 = very poor care; 2 = poor care; 3 = adequate care; 4 = good care, or 5 = excellent care**. The review team also used a grading system originally developed by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD)[k] to give an overall perspective on the quality of care provided. This considers both clinical and organisational care. The overall gradings were as follows: **good practice, room for improvement – clinical, room for improvement – organisational, room for improvement – clinical and organisational, unsatisfactory, insufficient information**.

Having independently reviewed the cases, the review team presented them at a virtual meeting on 19 February 2021 (12 patient case notes) and on 20 April 2021 (additional four cases of the LMS). The meeting was chaired by the deputy medical director for IRs and supported by the RCP review manager. Each case was considered in turn, the review team presented their views, followed by a 'confirm and challenge' discussion to agree the grading of phases of care and the overall care. In making judgements about the overall care provided to the patient, the review team considered national good practice and guidelines.

The documentation provided by the healthcare organisation was also examined for the insights it offered in respect of the terms of reference. The review team also held interviews with staff virtually, on MS Teams on 11 and 12 March 2021. Details of these have been included in section 8: Appendix 2: Documents received and reviewed.

The overall conclusions in this report are outlined in section 2 and represent a summary of the information gathered by the review team during the CRR, interviews and from the documentation submitted. The detailed findings are organised under the headings of the agreed terms of reference (section 6).

The information presented sometimes reflects the viewpoints of those individuals being interviewed and where this is the case it will be made clear; it will not necessarily reflect the views of the healthcare organisation, the RCP or its review team.

[j] NMCRR: https://www.rcplondon.ac.uk/projects/national-mortality-case-record-review-programme
[k] NCEPOD grading: http://www.ncepod.org.uk/grading.html

4.3 Invited review team

Name	Role
Removed – identifiable information	Removed – identifiable information /consultant cardiologist, Brighton and Sussex University Hospitals NHS Trust
Removed – identifiable information	Consultant cardiologist, Liverpool Heart and Chest Hospital
Removed – identifiable information	Consultant cardiologist, University Southampton NHS Foundation Trust
Removed – identifiable information	Consultant cardiologist, Guy's and St Thomas's Hospital
Removed – identifiable information	Lay reviewer
Removed – identifiable information	Review manager

5 Description of the service

The Norfolk and Norwich University Hospital NHS Foundation Trust provides acute hospital care for approximately 1,016,000 people in Norfolk and North Suffolk. The Trust has 998 adult and child inpatient beds, 31 inpatient wards, 154 day beds and 29 operating theatres[4].

The acute clinical services are provided across the Norfolk and Norwich University Hospital and Cromer Hospital sites. The cardiology department is located at the Norfolk and Norwich University Hospital site and cardiology in-patients stay is within the coronary care unit (CCU) or Kilverstone Ward.

There are 20 whole time equivalent (WTE) consultant cardiologists, including 10 interventional cardiologists that undertake PCI treatment including the use of DCBs. There are 10 WTE specialty registrars and two WTE Trust grade doctors. The nursing staff in the department consists of 1 WTE matron, 6 WTE sister/nurse managers and 17 WTE specialist nurse practitioners, there are 6 WTE trainee nurse assistants, 4 WTE advanced practitioners. The current consultant specialty on-call is – PCI 1:8 and non-PCI 1:9.

A full-service specification can be found in appendix 1 – service specification.

6 Findings

6.1 ToR 1: Clinical record review

A review of 16 cases of patients where DCBs had been used outside current ESC guidelines in the treatment of coronary artery disease; 4 index and the remaining randomly selected using a criterion provided by the RCP. As previously reported, of the 12 cases originally requested, the review team had asked for four cases where DCB had been used in the LMS, however, the cases provided did not meet these criteria. It was agreed to review these cases anyway but to also have an additional four cases where DCB had been used in the LMS.

6.1.1.1 Recommendations made in relation to this TOR: C, D, E

6.1.2 Overall rating for quality of care

Table 1. outlines the case details including the reason for selection, procedure and the overall NCEPOD grade, the following table 2, shows the breakdown of scores by the phase of care.

Of the 16 cases the breakdown of NCEPOD grades included room for clinical improvement n=8, unsatisfactory n=6 or room for both clinical and organisational improvement n=2.

The findings are described in detail in the section 6.1.3 Phases of care.

Table 1. Case details.

RCP case no.	Original reason for selection	Procedure (using DCB)	NCEPOD Grading
RCP 1	DCB – LMS*	Primary percutaneous coronary intervention (PPCI) to right coronary artery (RCA)	RfI – clinical
RCP 6	DCB – LMS*	PPCI to RCA (stent) and bystander circumflex (Cx) (DCB)	RfI – clinical
RCP 11	DCB – LMS*	Percutaneous coronary intervention (PCI) to obtuse marginal artery (OM)	RfI – clinical
RCP 12	DCB – LMS*	PPCI to RCA (DCB) and staged elective PCI to LAD (DES)	RfI – clinical

RCP case no.	Original reason for selection	Procedure (using DCB)	NCEPOD Grading
RCP 4	DCB – proximal LAD[l]	Elective PCI to LAD	RfI – clinical
RCP 5	DCB – proximal LAD	Elective PCI to LMS/ostial LAD	Unsatisfactory
RCP 8	DCB – proximal LAD	PCI to LAD (DCB) then restenosis at this site treated by DES	RfI – clinical
RCP 9	DCB – proximal LAD**	OM branch of Cx	RfI – clinical
RCP 2	Specific concerns	Elective PCI complicated by dissection of the left coronary artery	Unsatisfactory
RCP 3	Specific concerns	PCI to left Cx for acute coronary syndrome	RfI – clinical and organisational
RCP 7	Specific concerns	Staged complex LAD, PCI to RCA (DCB)	Unsatisfactory
RCP 10	Specific concerns	PCI to LAD complicated by acute thrombotic occlusion of DCB site, treated with DES	Unsatisfactory
Additional cases requested (to meet case criteria)	**Reason for selection**	**Procedure (using DCB)**	**NCEPOD grading**
RCP 13	DCB - LMS	PCI (DEB) to LMS and LAD	Unsatisfactory
RCP 14	DCB - LMS	PCI to LMS (DCB)	RfI – clinical and organisational
RCP 15	DCB - LMS	DCB to LMS following acute coronary syndrome presentation	Unsatisfactory
RCP 16	DCB - LMS	DCB to LMS, following POBA[m]/IABP[n] for STEMI	RfI - clinical
NB *DCB – LMS cases did not involve the LMS as requested; **DCB – LAD case did not involve the LAD as requested The cases presented above have been grouped by reason for selection based on the criteria provided. The index of cases was provided in this order by the Trust.			

The table below (table 2) provides a summary of the review team's agreed grading for each phase of care. Generally, the cases scored *adequate* or *poor* across all five phases of care (investigations and treatment, perioperative care, communication with colleagues, communication with patients and their family and clinical record keeping), however the phase that scored mostly *good* or *adequate* was 'clinical record keeping'.

Table 2. Phases of care – grading

Phases of care	Excellent care	Good care	Adequate care	Poor care	Very poor care
Investigations, treatment plan and implementation	-	-	RCP 4, 6, 9, 11, 12, 16	RCP 1, 3, 7, 8, 10, 13, 14, 15	RCP 2, 5
Perioperative care	-	-	RCP 2, 3, 4, 6, 9, 11, 12, 16	RCP 1, 7, 8, 10, 13, 14, 15	RCP 5
Communication - colleagues	-	RCP 9, 14	RCP 2, 3, 4, 6, 8, 10, 12, 15, 16	RCP 5, 7, 11,13	-

[l] LAD – left anterior descending artery
[m] POBA – percutaneous old balloon angioplasty
[n] IABP – intra-aortic balloon pump

Phases of care	Excellent care	Good care	Adequate care	Poor care	Very poor care
Communication – patients and family	-	-	RCP 6, 10, 11, 12, 16	RCP 1, 2, 3, 4, 7, 8, 9, 13, 14, 15	RCP 5
Clinical record keeping	-	RCP 1, 4, 9	RCP 2, 3, 5, 6, 7, 8, 10, 11, 12, 13, 15, 16	14	-

6.1.3 Phases of care

The following section outlines the key themes arising from the five phases of care; 'investigations and treatment', 'peri-operative care', 'communication with colleagues', 'interactions with the patient and their family' and 'clinical record keeping'.

6.1.3.1 Investigations and treatment

The review team graded the 'investigations and treatment' for all 16 cases, and the key themes are presented below.

In two cases (RPC 5 and RCP 7), the patient received DCBs to large vessels with a stenosis of 60-80%[o]. In one case (RCP 7) the review team were of the view that the treatment resulted in an avoidable complication. In all three cases (RCP 5, RCP7 and RCP 13) the clinical situation according to the JACC DCB consensus document should have prompted stent deployment and not DCB use. For example,

- RCP 7 was graded *poor care*. The patient received an elective angiogram and complex PCI to the long-calcified LAD (using two DCBs) and to the diagonal branch (using DCB) with a residual stenosis of 60-70%. An hour after the procedure, the patient experienced pain and ST elevation. The patient underwent an emergency angiogram where an acute occlusion was identified at the DCB site, this was successfully treated with two DESs. At the routine follow up the patient was pain free. The review team were unclear of the rational for using DCB in a patient with residual stenosis of 60—70% which according to the JACC DCB consensus document, should have prompted stent deployment. Further to this, the review team reported that a comprehensive angiographic study should have been undertaken to ensure that there was no significant vessel disruption. The review team were of the view that the complication could have been avoided if a stent was deployed in the first instance. These themes contributed to the overall NCEPOD – *unsatisfactory* grading.

- RCP 5 – was graded *very poor care*, due to the use of DCB to a large vessel with a stenosis of 80%. The patient received an elective PCI to the LMS/ostial LAD (using DCBs), at the end of the first procedure there was a significant residual lesion of greater than 50%. Following the first procedure, the patient was scheduled for and received a second procedure (an angiogram to check the ischemic vessels with a plan to perform PCI (with a DCB)). The patient was discharged and at their six-month follow up appointment was reported to be pain free. The review team were of the view that not all appropriate processes were followed in the management of this patient. For example, there was no evidence to demonstrate that during the first procedure the patient received intracoronary imaging (IC), a fractional flow reserve (FFR), or appropriate sizing of the balloons for the vessels. Further to this, after the first procedure there was a residual stenosis of 80%, which according to the JACC DCB consensus paper, should have prompted stent deployment. The review team were unclear about why a DCB had been used in a patient and did not meet the JACC DCB consensus document criteria. The review team were of the view that a stent should have been deployed in this patient due to the ostial location of the lesion, the LMS had been balloon injured, there was severe ostial disease at the end of the first procedure and that the long segment of

[o] Stenosis is a condition where a valve becomes narrowed.

disease in the LAD was left untreated. These themes contributed to the overall NCEPOD – *unsatisfactory* grading.

- RCP 13 was graded *poor care*, similar to RCP 7 and RCP 5, the patient underwent a procedure (DCB[p], PCI) to a large LMS artery, that was severely diseased with marked calcification. The review team were of the view that the statement within the notes Removed – identifiable information contributed to the poor management of this patient as more could have been done to discuss this patient within an MDT and offer debulking and stents and calcification management. The use of DCBs in this patient was also outside of the technical considerations of DCB delivery as reported in the JACC DCB consensus document. These themes contributed to the overall NCEPOD – *unsatisfactory* grading.

In three cases (RCP 2, 10 and 15) the use of DCBs in large vessels were associated with complications requiring an emergency procedure. For example,

- RCP 2[q] was graded *very poor care,* due to a complication which resulted in extensive dissection of the left coronary artery. The patient received an elective PCI to the LMS circumflex and LM-ostial circumflex (using DCBs). An emergency procedure was required to treat the resulting dissection of the coronary artery. This included treatment with DES, involving multiple bifurcations[r] and crush stent techniques[s]. The operators were able to achieve normal blood flow and check the result with intravascular ultrasound (IVUS) at the end of the procedure. The patient survived the complication with some left ventricular impairment. The review team found that this complication could have been avoided if the DES had been deployed in the first instance. Considering the involvement of the LMS during PCI the review team were of the view that the case should have been discussed at an MDT meeting. Further to this, the review team reported that there was no evidence of this case being presented for discussion at the morbidity and mortality meetings. These themes contributed to the overall NCEPOD – *unsatisfactory* grading.

- RCP 10 was graded *poor care*, due to an acute occlusion complication requiring emergency re-angioplasty and insertion of a DES. The patient was admitted with an anterior ST-elevation myocardial infarction (STEMI) and proceeded to PPCI, where they were treated with a drug eluting balloon (DEB) to the LAD and then discharged (on day two). The patient was readmitted within 24 hours with anterior STEMI, and LAD occlusion at the DEB site, subsequently the patient was then treated with a DES. The review team reported some concerns with the management of this patient particularly the under sizing of the balloon for the vessel. Moreover, although the TIMI III flow[t] was restored, the final images were suboptimal to determine adequacy of this result. Further to this, the electrocardiogram (ECG) on the following day of the procedure shows >50% resolution of the ST elevation. The review team were of the view that the complication could have been avoided if the patient was treated with DES in the first instance. These themes contributed to the overall NCEPOD – *unsatisfactory* grading.

- RCP 15 was graded *poor care*, following DCB to LMS the procedure resulted in significant residual stenosis and an LMS dissection. Further to this, there was no indication that the final result was

[q] Themes also identified in case RCP 7
[r] Multiple bifurcations - the point or area at which the vessel divides into two branches or parts
[s] Crush stenting technique - the "crush" procedure is a standard technique for providing stent deployment to both limbs of a bifurcation vessel
[t] TIMI Grade Flow' is a scoring system from 0-3 referring to levels of coronary blood flow assessed during percutaneous coronary angioplasty. 3 is normal.

checked with coronary imaging (IVUS). These themes contributed to the overall NCEPOD – *unsatisfactory* grading.

In five cases (RCP 4, 6, 9, 11 and 12) the DCB did not impact on the immediate outcome nor was associated with complications for example,

- RCP 4, 6, 9, 11 and 12 were graded *adequate care*; in all five cases there were no adverse outcomes or complications associated with the use of DCBs as reported in the clinical notes for these patients. However, the review team reported that the cases fell short of *good care* for the following reasons, the use of DCB was outside of the accepted indications for use, an inadequate assessment of the LAD (RCP 6), the patient left with a suboptimal angiographic result due to inadequate pre-dilation (RCP 11). RCP 16 was also graded *adequate care*, the patient received DCB to LMS after 10 days following a plain old balloon angioplasty (POBA)/ intra-aortic balloon pump (IABP) for STEMI, however although they experienced a dissection event post DCB with significant stenosis after a one year follow up the patient was stable. These themes contributed to the NCEPOD *room for clinical improvement* grading.

6.1.3.2 Perioperative care

Generally, cases were scored 'adequate care' for this phase and the key themes that underpinned the 'less than good care' grade include, the lack of evidence for pressure wires along with the potential incomplete management of care (during and after the DCB procedure).

In three cases (RCP 1, 8, and 14), there was no evidence for the use of a pressure wire in cases that would have benefitted for example,

- RCP 1 was graded *poor care*. The patient was admitted via A&E and received PPCI (using two DCBs), the patient was treated with 2x DCB after predilation with non-compliant and scoring balloons (3mm). The procedure was uncomplicated, and the patient was discharged (the following day) with a plan to follow up in three months. Four months after the follow up took place, the patient was admitted with chest pain via A&E with raised troponin. The review team were of the view due to the residual disease in LAD the patient should have been considered for invasive (or later non-invasive assessment). The patient was readmitted with raised troponin which the review team thought was a type 2 event. These themes contributed to the overall NCEPOD – *room for clinical improvement* grading.
- RCP 8[u] was graded *poor care*. The patient received a PCI to the proximal LAD (using a DCB. Subsequently the patient received a second and third procedure involving DCBs. The review team were of the view that if a pressure wire study had been undertaken at the first procedure, it could have potentially reduced the need for multiple follow up procedures. Further to this, if the proximal -and mid- LAD had been stented, there may have been less residual disease at the end of the third procedure. These themes contributed to the overall NCEPOD – *room for clinical improvement* grading.

In the cases graded *adequate care*[v], the review team reported good use of nursing bundles and the use of BCIS checklists before the procedures. The 12 cases fell short of good care, due to the decision to use DCBs outside of the recognised guidelines.

6.1.3.3 Communication with colleagues

[u] Theme also identified in RCP 14
[v] RCP 2, 3, 4, 6, 9, 11, 12

Across all 12 cases there was no documented evidence for the discussion of DCBs at MDT meetings. In one case there were no MDT notes provided (RCP 12,) and in in four cases, the review team were of the view that MDTs were not needed (e.g. RCP 3, 6, 8 and 9 took place within an emergency setting).

In the remaining six cases (RCP 1, 2, 4, 5, 7, 10, 11) there was limited documentation provided to support the rationale and decision-making process for DCBs between colleagues and this may have impacted on the care received. Further to this, there was limited discussion of cases at morbidity and mortality meetings (RCP 2 and 3).

For example,

- RCP 5 was graded *poor care*, the review team were of the view that due to the involvement of the LMS for PCI a discussion about coronary artery bypass grafting (CABG) would have been appropriate.
- RCP 7 was graded *poor care*, the review team reported that the first angiogram showed multivessel disease and so should have been reviewed as part of an MDT meeting to document the rationale for treatment.
- In cases that were graded *adequate care*, the review team reported evidence of appropriate interactions between colleagues. For example, in RCP 1 the review team were of the view that although the team should have raised the patient at an MDT to discuss revascularisation, there was evidence of appropriate and early involvement of communication with the cardiac rehab team (this prompted the *adequate* rather than *poor* grading). This theme was also seen in RCP 2 and RCP 10, the review team reported appropriate referrals where multiple teams were involved (again, this contributed to the *adequate* rather than *poor* grading).

6.1.3.4 Interactions with patients and their family

Across all 12 cases there was no evidence that the use of DCBs had been discussed with the patients or their families in the form of consent, patient information leaflets or as written formal correspondence.

- RCP 1, 2, 3, 4, 7, 8 and 9 were graded *poor care*, for the reasons described above.
- RCP 3 was graded *poor care*, the patient was a Removed – identifiable information who received a PCI to the dominant left circumflex artery (using DCB). The patient was discharged Removed – identifiable information and died four days later, the post-mortem showed atheroma[w] in the left circumflex and evidence of recent myocardial infarction (MI)[x]. There was evidence in the notes stating that the patient was unsure of treatment/diagnosis, Removed – identifiable information. The review team were unclear why the case had not been discussed at the M&M meetings considering the death four days after treatment in a young patient. These themes contributed to the *room for improvement – both clinical and organisational* NCEPOD grade.
- RCP 5 was graded *very poor care*, the review team raised several concerns regarding the operator decision to stop the first procedure and commit the patient to a second DCB procedure, without discussion of stent deployment. The review team were unclear about why there was no evidence in the notes to discuss the decisions with the patient at any stage.
- RCP 6, 10 and 11 were graded *adequate care,* the review team were of the view that majority of the patient care took place in an acute setting/emergency setting and therefore the communication was appropriate. There was evidence of good nursing communication with the family, however throughout all cases there was limited documented discussion regarding the

[w] Atheroma – a plaque, a build up of material in the inner layer of the wall of an artery.
[x] Myocardial infarction – commonly known as a heart attack.

outside current ESC guidelines use of DCBs which informed an *adequate* or *poor* rather than *good* grading.

6.1.3.5 Clinical record keeping

The 12 cases demonstrated either *good* or *adequate* clinical record keeping, for example,

- RCP 1, 4 and 9 were graded *good care*, the review team reported good documented in-patient stay, use of cath-lab checklists, well documented GP procedure reports and that the discharge summaries were comprehensive, along with appropriately recorded bundles.

6.2 ToR 2: Processes in place to initiate DCB use

TOR 2: To review the process followed for use of a treatment (DCBs) outside of national guidance and the robustness of processes put into place to initiate its use (6.2.2), structure and funding of the DCB programme (6.2.3), commissioning arrangements (6.2.3), conflict of interest (6.2.3), and the ongoing monitoring of outcomes and effectiveness of treatment (6.2.4). Consideration will be given to attempts made by the interventional cardiology team to share learning and outcomes more widely.

6.2.1.1 Recommendations made in relation to this TOR: C, D, F, G, H, I, J, K

6.2.2 Initiation of DCB use

6.2.2.1 Documentation review

i. Inception

The review team were provided with the document 'internal cardiology review' prepared by Removed – identifiable information, deputy medical director for Removed – identifiable information, medical director in March 2021. The purpose of the internal report was to review the concerns raised by a member of staff regarding the cardiology departments use of DCBs outside of current European guidelines. The document included two supporting appendices (Appendix T and Appendix U) they described how DCB use came about in the Trust (explained in this section 6.2.2.1. i. Inception), and how its use developed over time (explained in section 6.2.2.1. ii. Development of the programme).

Appendix T (of the documents we reviewed) highlighted that in 2009, the DCB technology was CE[y] marked and it was at this time the Trust began purchasing DCBs for use in patients within the cardiology department. Appendix U (of the documents we reviewed) described that in 2012, Removed – identifiable information and Removed – identifiable information attended a DCB educational meeting in Berlin. The meeting prompted Removed – identifiable information to undertake study leave to learn further techniques from the German centres with respect to DCB angioplasty. Upon Removed – identifiable information return to the Trust in 2012, it was noted that the learning from the German centres was shared with the Trust and subsequently, the use of DCBs 'grew organically'. The driving force for the increased use of DCBs was due to the concerns surrounding stent complications.

Appendix U (of the documents we reviewed) also noted that there was no robust system in place to support the DCB practice. The appendices reviewed did not report on any formal governance pathways to support its initiation or a process document to define DCB use. Further to this statement, the review team

[y] CE marked: By placing the CE marking on a product a manufacturer is declaring, on his sole responsibility, conformity with all of the legal requirements to achieve CE marking. The manufacturer is thus ensuring validity for that product to be sold throughout the EEA (https://www.gov.uk/guidance/ce-marking)

were not provided with evidence within the Trust documentation regarding the support from a 'new technology committee' or 'formal governance committee' to sign off on the initiation of DCBs at the Trust.

ii. Development of the programme

Since its inception in 2009, the 'internal cardiology review' document highlighted that there has 'not been a robust system in place to support DCB practice.' As reported in the document, DCB practice was initiated and used within the parameters of the European Society of Cardiology (ESC) guidelines and over time developed where DCB angioplasty has been used in a much wider context i.e. to treat de novo lesions in vessels >3mm in diameter, or also in patients having ST elevation myocardial infarction (STEMI).

Further to this, the review team found that there was no standard operating procedure (SOP) for the use of DCBs developed before 2020. Although, more recently developed, the review team suggested that there were several amendments required before the SOP is circulated for use (discussed in section 6.3.3 protocols and pathways).

6.2.2.2 Comments from interviewees

i. Inception

Triangulated with the information provided as part of the documentation review, several staff informed the review team of the background for the use of DCBs at the Trust. The review team learned that Removed – identifiable information joined the Trust in 2009 and in 2012 Removed – identifiable information visited centres in Europe to learn about the use of DCB technology. On Removed – identifiable information return, Removed – identifiable information pioneered the use of DCBs in coronary angioplasty within the Trust putting into practice the skills acquired from Removed – identifiable information time in Europe.

When asked about the driving force behind the rationale for pioneering DCB coronary angioplasty several staff described that it was driven by concerns regarding the increased rate of stent complications (i.e. stent thrombosis and duration of antiplatelet therapy). The review team provided challenge to whether DCBs were a suitable alternative considering the evidence was lacking, and several consultant staff were of the view that through experience, the Trust had developed a good evidence base to support DCB use and were continuing to contribute to this evidence base (the use of monitoring outcomes and effectiveness of treatment is described later in section 6.2.4).

ii. Development of the programme

Staff reported that since 2009 there was no clear governance pathway or processes to support the development of the programme. For example, the review team were informed that the outside current ESC guidelines use of DCBs for coronary angioplasty had not been through the Trust NICE, audit and policy committee.

The review team were informed that efforts had been made more recently (since 2015) to ensure that the appropriate research, ethics and governance approvals have been sought (described in detail in section 6.3.5 internal reviews).

6.2.3 Funding arrangements and Conflict of interest (COI)

6.2.3.1 Documentation review

i. Funding

The review team were provided with the document 'NNUH sponsorship & shortened lease agreement', an agreement between Removed – identifiable information and the Trust to utilise DCB treatment and to confirm its long-term benefits. Removed – identifiable information. The agreement supports the development of a DCB research centre at the NNUH.

6.2.3.2 Comments from interviewees

i. Conflicts of Interest

The review team were informed of a potential conflict of interest, in that, the DCB programme lead was receiving research funding support relating to DCBs along with consulting fees by the DCB manufacturer. Removed – identifiable information.

ii. Costs

Several staff reported that the cost of a DCB was more expensive than DES (~£450.00 vs ~£200 respectively). Some consultants provided the argument that the increased initial cost of the DCB was cost effective compared to stents as there were fewer long-term costs associated with DCB complications. However, when probed about whether there had been evidence to support this, the interviewees reported that this was anecdotal and based on experience.

6.2.4 Ongoing monitoring of outcomes and effectiveness of treatment

6.2.4.1 Documentation review

The review team were provided with the document 'internal cardiology review' March 2021 which included some discussions between colleagues about the concerns and justification to those concerns relating to the monitoring of outcomes and the effectiveness of DCB treatment. It was clear from the documentation that there was discord between certain staff regarding the robustness of the evidence base to support the DCB practice at the Trust.

For example, in documented meeting minutes from a discussion between cardiology colleagues in September 2020 there were concerns regarding the safety of using DCB angioplasty due to the poor-quality evidence base. The concerns raised were in relation to the evidence being retrospective, as part of non-blinded trials, discrepancies between the accuracy of analyses, and how these poor-quality analyses were being used to support clinical practice.

Examples of concerns raised with respect to DCB analyses included one that focused on the rates of mortality. In the 'internal cardiology review' document appendices, concern had been raised regarding a mortality analysis which showed an increase in 5-year mortality in the DCB group from an extrapolated Kaplan Meier curve[z]. However, this critique was disputed by another colleague in a separate documented letter which also featured as an appendix in the internal cardiology review. The colleague had challenged the quality of the analysis by showing that there was no difference between DCB and DES in mortality, but that age, CABG, stroke and diabetes were factors that affected the mortality rate and not the intervention (i.e. DCB). There was discord presented amongst the interpretation and analyses provided by the cardiology team and there was limited external and independent representation in the team to provide assurance and peer review to these analyses.

Further to this, the internal cardiology review document reported on some discord with respect to the internal auditing of the practice. It was documented that the cardiology team had been noted as a positive outlier (better than expected) with respect to their PCI mortality outcomes from the BCIS national audit data.

[z] Kaplan-Meier estimate is one of the best options to be used to measure the fraction of subjects living for a certain amount of time after treatment. In clinical trials or community trials, the effect of an intervention is assessed by measuring the number of subjects survived or saved after that intervention over a period of time. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3059453/)

However, challenge had been raised within the appendix of the internal cardiology review which conversely argued that the data was not stratified by DCB or stents and also there was no description about other endpoints such as re-infarction, target lesion revascularisation (TLR) or mortality >30 days, which some staff described as making the evidence unreliable. This prompted the view by some consultant cardiologists that there was a need to build up a bank of retrospective evidence to support the need for an RCT, before the RCT could be granted.

The internal cardiology review reported on varying support for the robustness of measuring the effectiveness for DCB use.

6.2.4.2 Comments from interviewees

Several interviewees were asked about the current monitoring of outcomes. There were varying accounts from staff regarding the quality of monitoring and reporting of outcomes, and the effectiveness of treatment. Most junior, non-consultant and some consultant grade staff reflected positively on the data analyses and data collection to inform the DCB programme. Several staff referenced the cardiology department as a positive outlier for BCIS mortality data and that the NICOR returns had not flagged any issues to patient outcomes (this is discussed in further detail in section 6.5.3 audits and incident reporting).

Triangulated with findings from the documentation review, the review team heard that data had also been monitored as part of a supervised research thesis, reporting on the following primary outcomes; major adverse cardiology events (MACE), a binary indicator of either death, myocardial infarction (MI) or target lesion revascularisation (TLR). The secondary outcomes included death, MI, target vessel revascularisation (TVR), TLR individually, also acute vessel closure and treated lesion/stent thrombosis which had shown non-inferiority of DCB with DES.

However, some consultant grade staff working within the service provided challenge to the quality of reporting and monitoring of outcomes. They suggested that some interpretation of the analyses and robustness of data collection was weak, particularly at reporting complications. The review team queried the process for identifying a patient who would receive a DCB, be discharged home and then return with a complication (following two or more days). There was variation in the response, some staff informed the review team that these patients would be captured, as they would be flagged by the Trust reporting system. Other staff informed the review team that the patients may be registered as a new event and that the complication may not necessarily be reported in connection with their initial procedure.

When challenged by the review team about what convinces the clinicians that the DCB vessels had a better outcome, many referred to their experience of practice at the Trust and that they (consultants) were working towards more comprehensive research. Some staff were of the view that there was currently not enough good quality research to justify the outside current ESC guidelines DCB treatment and the practice should be carried out within a formalised research setting to identify medium- and long-term outcomes.

There was mixed feedback from the consultant and registrar grade clinicians regarding the need for further RCTs. Some staff were supportive of the need and others noted some of the logistical challenges associated with setting up an RCT. Some interviewees described challenges with securing funding and the need for a substantial baseline set of observational data before enrolling into a trial. There was a divide between some colleagues regarding the next stages for research and evaluation of outside current ESC guidelines DCB intervention.

6.3 ToR 3: Use of DCBs in the treatment of coronary artery disease

To review the use of Drug Coated Balloons in the treatment of Coronary Artery Disease by the interventional cardiology team. This will include a review of current activity levels and outcomes (6.3.2),

protocols and pathways (6.3.3), consent (6.3.4) and MDT working (6.3.6). Consideration will be given to the concerns raised about mortality and outcomes and well as internal reviews of these matters (6.3.5). Consideration will also be given to whether the current practices are contemporaneous and comply with national and RCP guidance.

6.3.1.1 Recommendations made in relation to this TOR: J, K

6.3.2 Current activity levels and outcomes

6.3.2.1 Documentation review

i. Current activity levels

The review team were provided with the individual operator numbers for consultants performing PCI with DCBs between 2015 and 2018 (Norfolk and Norwich DCB presentation summary - slide 10). A total of n=4625 PCI with DCBs were performed with large variation across operators (range 91 - 858 across five years). PCI 30-day mortality across operators in 2020 varied from 1.34% - 6.38% (across 10 operators) unadjusted.

ii. Current outcome data

The Trust provided the review team with a summary presentation that provided an overview of DCB activity levels and outcomes 'Norfolk and Norwich DCB presentation summary'. The presentation highlighted the following key findings:

Between 2016 – 2020, the NNUH cardiology team undertook n=4449 DCB procedures of which the top three presentations were for (acute coronary syndrome/unstable angina (ACS-UA/NSTEMI/convalescent STEMI (n=1292), followed by stable angina (n=1244) and ACS – primary PCI for STEMI (no lysis) (n=918). Across the five years, DCB was used mostly in the left anterior descending coronary artery (LAD) (30%, n=1334/4449), right coronary artery (RCA) (27%, n= 1201/4449), or coronary circumflex (22%, n=979/4449).

Of the 4449 DCB procedures, there were 156 peri-procedural complications (i.e. reported in the lab), the two most common were coronary dissection (n=66) and no flow/slow flow phenomenon (n=34). Thirteen were left 'blank' and 5 were 'unlisted'. Further, to these complications were n=114 in hospital events the top three included death (n=40), re-intervention PCI (n=24) and n=12 were reported as 'unlisted'.

The risk adjusted NNUH data for 2015-2018 showed that NNUH had a higher survival than expected by 2 standard deviations.

iii. Academic journal publications

The review team were provided with 16 articles developed by the NNUH cardiology department since 2018. Published research articles of randomised controlled trial data from external departments were also provided. In relation to the use of DCBs in coronary artery disease, the main conclusions reported by the NNUH cardiology team and the external departments were the need for a large randomised controlled trial comparing DCB to second generation DES in *de novo* coronary artery disease, with long-term follow-up. There was no good quality evidence to support the use of DCBs for coronary angioplasty in vessels >3.0mm or in other indications such as STEMI.

6.3.2.2 Comments from interviewees

The use of DCBs outside current ESC guidelines varied across the consultants, several consultants were asked about their outside current ESC guidelines use of DCBs and this ranged from 10%-90%. The variation in use was described by consultants as due to their own levels of confidence, the need for training and

based on the individual patient need. For example, some consultants described their approach would be to start out with the intention of using DCB as the default option and then depending on the vessel preparation they may use a stent instead. There were some consultants who were much more cautious in their approach to DCBs as they described feeling less confident and detailed the importance of appropriate training.

Some consultant staff also reported that they would use DCBs in younger patients so that they were not left with a stent, and the review team were informed of the low cumulative attrition rate in patients with a stent which was another justification for outside current ESC guidelines DCB use in the department. However, the review team posed challenge by asking whether there was evidence to show that DCB attrition was better than stented vessels and the response from interviewees was that there was no evidence to support this.

6.3.3 Protocols and pathways

6.3.3.1 Documentation review

The review team were provided with an SOP which provided guidance for the use of DCB in coronary angioplasty. The SOP was recently produced (in 2020) by the interventional cardiology team and ratified by the cardiology clinical governance team. No SOP was in place for use of DCB before this time. The SOP explains when and how DCBs should be used in line with best practice referencing the European Society of Cardiology guidelines on myocardial revascularisation, an update to the NICE guidance regarding the SeQuent Please balloon catheter for in-stent coronary restenosis and the BASKET SMALL 2 study (an open label randomised non-inferiority trial) and which states that DES or DCB should be used for in-stent restenosis, small vessel disease <3mm, high bleeding risk patients, and or bifurcation side branch. The SOP also reports the option of DCB (with specific informed consent only) in large vessels >3mm patient or operator preference with documented justification. However, there were no guidelines or supporting evidence referenced on the document to inform this practice. In addition to this, there was no clear justification for the rationale for using DCBs in large vessels. The rationale for the SOP reports that at times the guidance will be overridden by an interventional cardiologist for 'specific reasons.' However, the document did not include specific examples of when it would be appropriate to override the guidance.

The SOP further described that when the operator used DCB outside of its considered use (i.e. in large vessels) the document notes that informed consent was required, and for it to be based on patient or operator preference. The theme of consent is described and explained in detail in section 6.3.4 consent.

The document advises that any clinical rationale for deviation from guidance needed to be documented. However, there were no specific examples for when, how, or where the rationale should be reported.

The review team were also provided with the JACC DCB consensus document which reports on the use of DCBs in coronary artery disease. There were some clear technical considerations in the article including lesion preparation, FFR, intravascular imaging and DCB delivery. The review team noted that the use of DCBs in the clinical record review did not follow those outlined in the technical considerations of the JACC DCB consensus document for which the DCB programme lead was named author.

6.3.3.2 Comments from interviewees

Several interviewees were asked about the SOP for DCB use in PCI and feedback regarding the document was mixed. The review team heard from some consultants and other non-consultant grade staff that they were unaware of the SOP, some had not been informed of the SOP, others reported that it was in development (to be ratified) and not yet in use. Some consultants were more confident in their own ability to perform DCB angioplasty in varying situations and so reported that there were occasions when they would override the SOP and that this was also the same for the JACC DCB consensus document.

The review team heard varying accounts from consultants regarding their parameters for DCB use outside of the defined best practice. Some consultants suggested that their use of DCBs was the default option in all cases and that they would stent only if DCB was not appropriate. However, the rationale for not using stents in cases that would benefit was unclear. Other consultants were more conservative with their approach and would only use stents, as they felt that the evidence base was greater and that DCB outside current ESC guidelines use should only be considered by consultants that had been appropriately trained.

6.3.4 Patient consent

6.3.4.1 Documentation review

The review team were provided with the PCI consent form which had been updated in October 2020 to include specific consent for the use of DCBs (following the request made for this review). The consent form did not include a statement regarding current best practice guidance. There was no formal documentation specific to DCBs prior to this.

The SOP as mentioned previously outlines the stages at which to consent patients, however, there remained some subjectivity regarding the information that was verbally presented to patients as this was not documented.

The *PCI patient information leaflet* developed in January 2021 was approved by the Trust patient information forum (PIF), the leaflet described coronary angiography, PCI and also referred to the use of DCBs as an alternative practice (not standard practice), however there was limited information included about the evidence base for the use of DCBs outside current ESC guidelines.

The internal cardiology report identified patient consent as a major concern, and an area for improvement. It was reported that there was no formal patient consent form specific to DCB angioplasty until 2020. Patients had been undergoing outside current ESC guidelines treatment between 2009-2019 without a formal DCB specific patient consent form process in place.

Considering consent specific to ethics approval for collecting data the internal cardiology report concluded that all necessary approvals had been met, through the confidentially advisory group (CAG) and Caldicott guardian processes (this is explored further in section 6.3.5 internal reviews).

6.3.4.2 Comments from interviewees

The verbal and written consent processes varied among staff, some staff were aware of the formal DCB specific patient consent form and others were not.

Some non-consultant grade staff felt as though there could be more information provided at their induction to the cardiology department to include that the Trust are an outlier for DCB use, and to include detailed information about the current evidence base for DCBs outside current ESC guidelines.

Some non-consultant grade medical staff reported that there was good evidence to show the benefits of DCB use including outside current ESC guidelines, however they were not fully aware of the interpretation of the analyses or that these results were based on retrospective small sample data.

The review team were concerned to hear from consultants and nurses that some patients asked after a procedure why a stent was not placed. One member of staff reported that this made them reflect on their practice on the importance of consenting and appropriate information sharing with the patient.

Considering consent from research and development department with respect to using patient information, the head of research and development at the Trust was clear in that the approvals for

obtaining patient information had been through the appropriate channels. A few queries relating to appropriate approvals were raised to the review team reported in section 6.3.5 internal reviews below.

6.3.5 Internal reviews

6.3.5.1 Documentation review

The review team were provided with the document 'presentation to the interventional team' which outlines the findings of an internal review carried out by Removed – identifiable information, deputy medical director in March 2021. The five key concerns included, poor/inappropriate consent relating to DCB procedures (which was upheld), whether the DCB programme should have commenced as a formal research programme (this concern could neither be upheld or rejected), whether appropriate research processes were undertaken (upheld), whether patient safety has been put at risk as a result of using DCB outside of current guidelines (this concern could neither be upheld or rejected) and if there had been insufficient analysis (partially upheld).

The internal review found that the cardiology team did hold suitable R&D approval and ethical permission to collect patient level data and data from some external databases, these databases were not specified. However, considering this, a conclusion was made that urgent external expert peer review was recommended to address concerns properly and independently around the use of DCB in PCI. The issues around the databases that were being accessed led to the Trust developing a registry of registries in R&D and ensured that all registries and patient case series research would require R&D engagement and associated research approvals.

The internal review presentation proposed a clear action plan which involved the development of a SOP, procedure specific consent form, patient information leaflet, external approval for these documents from the BCIS, a reminder of the Trust's PRIDE values[aa], along with an external review of the department and the DCB programme.

The review team were also provided with some email correspondence where the following outcomes were reported as primary endpoints to be considered these include, revascularisation/ re-infarction, acute vessel closure rates, cost-effectiveness.

The internal review report also showed some outstanding queries that were upheld by the research and development department. These were raised during the RCP invited review interviews and followed up by way of email. The queries included:

- one with respect to the indications and contraindications of the Sequent Please Neo (a brand of DCB) information as described on the patient information leaflet
- three were in relation to whether certain DCB programme activity would be considered service evaluation or research

Although these queries were raised to the review team, it was not within the remit of the review team to address specific queries like those raised above as they fell outside the agreed ToRs. However, the review team agreed that there was limited evidence for criteria set out by the department with respect to their terminology of what is considered research and what is considered evaluation and these criteria should be addressed.

6.3.5.2 Comments from interviewees

The cardiology team at the Trust welcomed the internal review and many of the interviewees reported that it had brought about discussions for positive change, such as the development of a patient information

[aa] NNUH PRIDE values; https://www.nnuh.nhs.uk/about-us/the-trust/our-values/

leaflet, patient consent form and an SOP. The review team were also informed by consultant and non-consultant grade staff that they would welcome the recommendations in the review to improve their services to patients. Further information regarding the internal review is considered in section 6.4.3 Managerial leadership.

6.3.6 MDT meetings

6.3.6.1 Documentation review

The review team asked for MDT records (previous 2 years) and were provided with those for the time period October 2020 – December 2020. The record keeping was clear in documenting the clinician attendance, the MDT question to the team, the patients background, medications, investigations, previous MDT discussions along with the MDT outcome.

Although there was evidence of good record keeping and sharing of information in the MDT meeting notes provided as part of the documentation review, this was less evident in the cases reviewed as part of the CRR. Across all 16 cases reviewed as part of the CRR, there was no documented evidence for the rationale of using DCBs instead of stents within the MDT notes.

6.3.1.1 Comments from interviewees

The review team were informed that MDT meetings were held weekly, with good attendance from the department. However, some staff were of the view that more could be done by the department to formally record the discussions regarding the use of DCBs in patients.

MDT working was present with the surgical team at Papworth (2 surgeons every Friday at 1.30 for an hour). The surgeon interviewed was aware that their use of DCBs was higher than in other Trusts but was not aware of any increase in major adverse events or emergency surgical involvement required specifically for the use of DCBs. The surgeon reported a good working relationship between the two sites and mentioned that sometimes there could be issues with referrals but that this was a common challenge across many settings.

6.4 ToR 4: Quality of team working within the department

To review the quality of team working within the department and to give a view on whether this supports the delivery of high quality and safe care. Consideration will be given to clinical (6.4.2) and managerial leadership (6.4.3), raising and responding to concerns (6.4.4), individual behaviours (6.4.5), interactions with members of the wider medical team and MDT working (6.4.5).

6.4.1.1 Recommendations made in relation to this TOR: L, M

6.4.2 Clinical leadership

6.4.2.1 Documentation review

i. Job plans

The review team reviewed the job plans and specifically the time allocated for supporting professional activities (SPAs) for the service director, DCB programme lead, clinical governance lead, and clinical academic supervisors. Not all SPAs are listed below, only those concerning governance, clinical management, and research.

Service director

- Clinical governance 0.181 PAs (43 minutes per week)
- Clinical management 0.272 PAs (1 hour 5 minutes per week)
- Research CRN (2 hours per week)
- Research NHS funded 0.125 PAs (30 minutes per week)
- Director role 1.582 PAs (6 hours per week)

DCB programme lead

- Clinical governance 0.154 (30 minutes per week)
- Clinical management 0.428 (1 hour 43 minutes per week)
- Research NHS funded 0.625 (2 hours 30 minutes per week)
- Research supervision of PhD students 0.125 (30 minutes per week)

Clinical governance lead

- Clinical governance 0.141 (34 minutes per week)
- Clinical management 0.06 (14 minutes per week)
- Research CRN 0.250 (1 hour per week)

Clinical lecturer and supervisor

- Audit lead 0.250 (1 hour per week)
- Clinical governance 0.050 (12 minutes per week)
- Clinical management 0.20 (48 minutes per week)

6.4.2.2 Comments from interviewees

i. Clinical leadership

The review team were informed that the cardiology service director stepped down from their post in July 2020, a new cardiology service director was then appointed, and was in post at the time of this review (for a total of 8 months). The previous service director held the position for three years 2017-2020.

6.4.3 Managerial leadership

6.4.3.1 Documentation review

The review team were provided with the Trust wide organogram which showed that the chief of medicine reports directly to the chief operating officer. The service directors report directly to the chief of medicine (a consultant cardiologist).

The review team looked through the job plan for the chief of medicine and in particular the SPAs. Not all are listed below, only those concerning appraisals, clinical governance and management.

These included:

- Appraisal 0.25 PAs (1 hour per week)
- Clinical governance 0.203 (49 minutes per week)
- Clinical management 0.094 (23 minutes per week)
- Director role – chief of division 5.0 (20 hours per week)

6.4.3.2 Comments from interviewees

The review team wanted to further understand the levels of escalation within the Trust in relation to the concerns raised for this review. The review team were informed that the current medical director had been in post for two years, prior to the concerns raised as part of this review there had been no risks identified

or raised to the managerial leadership of the Trust. The review team were told by several staff that the DCB programme had continually reported 'good outcomes' and because the cardiology department had not been flagged up as a negative outlier by NICOR or BCIS they were not on the radar of the Trust or division wide risk register.

Some managerial staff were of the view that if the concerns had not been raised, it would be unlikely that there would have been an internal or external review. This raised concern within the management team considering the high-profile nature of the DCB programme.

Since the concerns were raised the executive level team underwent appropriate steps to conduct an internal review which then prompted the RCP external review to address these concerns.

Many staff had welcomed this external review as they reported that they felt it would bring about (and has already bought about) positive change including better processes for consenting patients and more information for patients in the form of patient information leaflets.

6.4.4 Raising and responding to concerns

6.4.4.1 Documentation review

The internal cardiology report documented accounts from clinical leaders, which described that colleagues within the cardiology department worked within a supportive environment. However, it also noted that there has been a divide within the department with respect to the interpretation of research results and analyses from the DCB programme and this had caused some tension within the department. In the report appendices there were details of discussions relating to concerns specific to the safety of patients undergoing outside current ESC guidelines use of DCB and the perceived inaccurate research analyses. The meeting notes reported that the discussions had to be stopped due to differences of opinion. There was little evidence of documented solutions or action plans reported as part of the discussion. There was no clear information about the support provided to those who raised concerns by the clinical leadership team.

6.4.4.2 Comments from interviewees

Several interviewees informed the review team of the cohesive and supportive environment and that there was good clinical leadership support in the form of weekly informal PCI meetings (every Thursday) where the consultants talked through what had worked well and what could have been improved on. Staff also described weekly M&M meetings to review deaths (every Friday) (the review team described the M&M meetings in detail in section 6.5.4 Morbidity and mortality). The staff also referred to clinical governance meetings as a formal forum to talk through governance related concerns. The review team were not provided with the notes from the informal PCI meetings and did not review these as part of the documentation review. However, it was unclear how concerns were dealt with on an individual basis. Triangulated with findings from the documentation review there was some unease, tension and difficulty between colleagues when describing a meeting that was held to talk through differences in opinion with respect to research analyses. There was no action plan or solutions identified following that discussion.

However, several staff reported that the way in which the issues were raised with respect to the DCB programme analyses and research could have been better. The review team heard from some staff that this had impacted on the working relationships and interactions between team members. Others reported that although there were differences in research opinion that this did not impact on day to day working and patient care.

6.4.5 Individual behaviours, interactions and MDT working

6.4.5.1 Documentation review

The review team were provided with the findings from the internal cardiology report document which included interviews with consultant cardiologists. Overall, the consultants were positive about interactions with their colleagues. However, concern had been raised about how the challenges to the DCB programme had come about.

6.4.5.2 Comments from interviewees

All staff within the department reported positively on their working relationships with their colleagues. The review team were informed of staff feeling supported and working within a good environment where colleagues often help one another. These comments were echoed across all levels of staffing, consultants reported that they often help and support one another through cases, nursing staff reported that the catheter lab nurses are also skilled as radiographers by having the dual role. However, as mentioned previously some staff were of the view that more could be done to support those who raise concerns.

6.5 ToR 5: Quality of clinical governance arrangements currently in place

To evaluate the quality of clinical governance arrangements currently in place to support and maintain oversight of the interventional cardiology service (6.5.2) to include a look at audits, clinical incident reporting (6.5.3), reviews of morbidity and mortality (6.5.4) and patient complaints/feedback (6.5.5).

6.5.1.1 Recommendations made in relation to this TOR: A, B, C, D, E, F, G, N

6.5.2 Clinical governance meetings

6.5.2.1 Documentation review

The review team were provided with minutes from the divisional governance meetings and the minutes from the cardiology governance meetings from 2020. The divisional governance meetings reported on standing agenda items including; patient experience, incidents, serious incidents (SI) management, never events, risks, quality and standards, safety alerts, audit and research, mortality reviews, workforce, items for escalation and any other business (AOB).The cardiology governance meetings followed a similar format with discussion of the action log, patient experience, incidents, information governance, risks, quality and standards, audit and research, items for escalation and AOB.

In both meetings there was limited reporting of the outcomes associated with the DCB programme within the audit and research sections of the agenda and the M&M agenda item. The review team were provided with several BCIS and NICOR data, along with abstracts and research articles developed by the cardiology department DCB programme, however these outputs were not included within the divisional governance meeting notes for information sharing or shared learning.

Further to this, as part of the clinical record review the review team judged four index cases (where specific concerns or complications had been raised), the minutes from the M&M meetings were requested where these cases had been discussed, however, it was confirmed that these were unavailable as they had not been discussed at M&M meetings.

There was limited documented evidence for sharing DCB programme outputs with other oversight committees within the department such as the ‘Clinical Safety & Effectiveness Governance Sub—Board’ or the ‘Clinical Safety and Quality Committee.’

6.5.2.2 Comments from interviewees

Staff gave varying descriptions of the clinical and departmental governance meetings. Some staff felt that improvements could be made to the cardiology clinical governance meetings such as a more robust root

cause analysis of complications associated with DCB use. Other consultant staff suggested that because there has been no formalised process for supporting the DCB programme at the Trust, other staff were keen to visit another centre to learn from their governance processes to help improve existing processes.

6.5.3 Audits and incident reporting

6.5.3.1 Documentation review

i. NICOR

The review team requested the NICOR returns from the cases reviewed as part of the CRR out of the 16 cases and found some discrepancies. In RCP 7 the patient required an emergency reintervention for STEMI (acute vessel closure), in RCP 10, the patient experienced readmission with STEMI within 24 hours (vessel occlusion), RCP 14 was readmitted 4 months later for negative troponin, RCP 15 experienced residual stenosis and an LMS dissection, and RCP 16 experienced a dissection event post DCB.

ii. Serious incidents (SIs)

The review team were provided with SIs from the cardiology department – there were a total of 1528 incidents from March 2018 – December 2020, 1309 incidents were specific to cardiology. Of these cases the review team selected the following categories in relation to the ToR; accidents or injuries (not slips or falls), admission discharge or transfer, communication, infrastructure incidents, medicine/device incident, medication error, patient documentation, treatment/procedures (n=664). Similar sub-categories were selected on the basis that they serve the purpose of the ToR. (n=234). The spreadsheet was then filtered by death, moderate harm, low harm and no harm and in each category the term PCI was searched. This identified 1 death, moderate harm = 0, low harm = 1. However, the review team could not find information of those cases graded as unsatisfactory having been reviewed as serious incidents

6.5.3.2 Comments from interviewees

i. NICOR

Several staff referenced that NICOR returns would have picked up or suggested that the DCB practice was unsafe by flagging to the Trust, but had not yet done so. Several staff therefore interpreted this finding as evidence to support the continued use of DCBs within the Trust, but others reported additional concerns as described in the section reporting outcomes section 6.2.4 monitoring of outcomes. The review team were also informed that the department have recently (in 2019) acquired permission to compare hospital data with the national dataset but until this point have been reviewing local data. In the three-year period 2015/2016-2017/2018 the department's outcomes were better than expected survival (at 2 standard deviation level), 30 days following percutaneous coronary intervention from the BCIS audit data.

ii. Serious incidents

The review team were informed about the serious incident group (SIG) meetings which aim to discuss those cases considered serious incidents. Staff reported that lessons were discussed and shared well to inform learning across the department. One staff member reported on a SIG meeting where all serious incidents were formally discussed, and learning was shared. The review team did not review the notes as part of the documentation review. There was also mixed feedback among staff regarding the criteria for cases selected for the SIG meetings.

6.5.4 Morbidity and mortality

6.5.4.1 Documentation review

The review team requested the M&M meeting notes for the cases specific to the CRR. However, the review team were informed that the cases had not been discussed at the M&Ms as they did not meet the criteria. The criteria for M&Ms was not documented but discussed by the interviewees below.

6.5.4.2 Comments from interviewees

Several staff had reported that M&M meetings during the COVID-19 period had not been prioritised. Before COVID-19, M&M meetings occurred regularly (once a week, every Friday). The review team were informed by staff that the time was not ringfenced within their job plans. When asked about the criteria for M&M meetings the responses varied but some staff explained that there was no specific SOP of what defined a case for the meeting, but that it was mostly operator choice to discuss the case or not and it was mostly cases of death or cardiac arrest within the cath-lab. There were no criteria explained that pertained to the morbidity criteria. Others reported that the complication was flagged on the database as a case for discussion at the meeting. In all some staff felt that there was no robust mechanism in place to support the decision to select a case for discussion at M&M meetings.

There was a view from some staff that the Thursday PCI meetings and the Friday M&M meetings could be more structured in their approach to ensure learning is shared and embedded.

6.5.5 Patient complaints and feedback

6.5.5.1 Documentation review

The patient complaints were provided for July 2018 to October 2020, there were a total of 74 complaints specific to cardiology. Of these, 4 were specific to admission, discharge and transfers, 12 were specific to appointments including delays and cancellations, 15 were specific to clinical treatment, 23 specific to communication, 12 specific to privacy dignity wellbeing, 3 specific to waiting times. There were no complaints documented specifically to DCB use.

6.5.5.2 Comments from interviewees

There was no concern among staff about patient feedback, majority of staff reported positively. One member of staff reported that there had been some concerns regarding delays to treatment and this was due to COVID-19 pressures.

7 References

[1] National Institute for Health and Care Excellence. *SeQuent Please balloon catheter for in-stent coronary restenosis [MTG1].* Review decision update. London: NICE, 2018. https://www.nice.org.uk/guidance/mtg1/documents/supporting-documentation-2 [Accessed 21 January 2022].

[2] European Society of Cardiology. Clinical practice guidelines https://www.escardio.org/Guidelines/Clinical-Practice-Guidelines [Accessed 21 January 2022].

[3] Raban V. Jeger, Simon Eccleshall, Wan Azman Wan Ahmad, Junbo Ge, Tudor C. Poerner, Eun-Seok Shin, Fernando Alfonso, Azeem Latib, Paul J. Ong, Tuomas T. Rissanen, Jorge Saucedo, Bruno Scheller, Franz X. Kleber, Drug-Coated Balloons for Coronary Artery Disease: Third Report of the International DCB Consensus Group. *JACC: Cardiovascular Interventions*, 2020, Volume 13, Issue 12, 1391-1402, ISSN 1936-8798. https://doi.org/10.1016/j.jcin.2020.02.043 [Accessed 21 January 2022].

[4] Care Quality Commission. *Norfolk and Norwich University Hospitals NHS Foundation Trust Inspection Report.* May 2019. https://api.cqc.org.uk/public/v1/reports/5177a186-27e6-4541-82ec-8803abd597d4?20210115065848 [Accessed 21 January 2022].

8 Appendices

8.1 Appendix 1: Service specification

Information request	Answer	Additional notes
1. Local information		
Catchment population and demographics	The Trust carries out nearly 1 million outpatient appointments, day case procedures and inpatient admissions annually.	
Number of sites providing specialty service	One	
2. Personnel numbers		
Staff supporting the specialty service	Substantive Medical & Dental Staff: Consultants WTE:20 Specialty Reg WTE:10 Trust Grade Dr WTE:2 Ass Practitioner WTE:1 Substantive Nursing Staff Cath Labs 1 WTE Matron/ Cath Lab Manager 1 WTE Cath Lab Lead Nurse 0.75 Governance/ Education Lead 9.45 B6 Nurse 26.18 B5 Nurse 5.61 B4 AP 1.67 B3 Senior Support worker 1.23 B2 support worker	

	CCU/ Kilverstone Ward 1 WTE 8a Matron 1 WTE B7 Senior Nurse 15.04 WTE B6 Deputy Sisters 33.72 WTE B5 Staff Nurses 21.04 WTE B2 HCA's Spec Practitioner WTE:2 Technician WTE:34 Assistant WTE:8 Support Worker WTE:1 Admin & Support Various Roles WTE:45 Honorary Medical Staff Consultants WTE:5 Spec Reg WTE:2 Trust Grade Dr WTE:3	
3. Details of on-call		
Consultant specialty on-call	PCI 1:8 NonPCI 1:9	
Consultant of the day/week	N/A	
Details of 'acute' medicine rotas	N/A	
4. Facilities and resources		
Number of specialty wards and inpatient bed	Kilverstone Ward and CCU	In general other specialty patients are rare (except during recent pandemic)
No. of ward rounds per week		Twice daily board rounds (Red to Green). Individual Consultants rounds twice per week.
Provision of in reach services		In-reach to ED/AMU/SDEC by on call SpR and Consultant
Subspecialty services including any tertiary services		Percutaneous Coronary Intervention 10 consultants Cardiac rehabilitation: 8 nurses + 2 physio Cardiothoracic MDT with Papworth : weekly via Teams. In-house urgent MDT with Papworth: daily as required by telephone.

		Complex PCI MDT: weekly Cardiac Rhythm Management Devices – 8 consultants EP – 3 consultants 4 nurse specialists (shared EP and Devices) Pacing MDT weekly EP MDT weekly Adult Congenital Heart Disease (level 2) / Maternal Cardiology / Pulmonary Hypertension 2 consultants + 1 GUCH MRI specialist 1 nurse consultant and 2 nurse specialists Weekly MDTs with GST and Barts. Heart Failure 1 specialist clinic (4 consultants) 3 HFNS in hospital Monthly MDT with community Imaging Echo (inc DSE and TOE) – 3 consultants CMR – 4 consultants (+ 3 radiologists) Weekly MDT Inherited Cardiac Conditions 3 consultants (+ visiting consultant geneticist and genetic counsellor) 1 nurse specialist (NB 1. Consultant numbers are not WTE. 2. Some consultants have multiple subspecialty interests, so there is double counting)

5. Activity numbers per year

Outpatients services	Number of outpatient clinics per month: please see reports Average number patients per clinics (new/follow up): please see reports Total number outpatients new/follow up (per annum): numbers/proportion face to face/non face to face: please see reports DNA rates: please see reports	
Inpatient services	Annual total inpatient numbers: see reports Readmission rates: see reports Average LoS: see reports	
Details of any specialty MDT meetings	Please see minutes	
6. Clinical governance		
Details of clinical governance assurance systems in place (at service level)	See structure charts	
Clinical audit meeting arrangements	Each area has a designated audit lead	
M&M meetings	See minutes	

Sample of attendance records, agendas and minutes for the above meetings.	Contained in minutes	
Complaints SI's and complaints	Number of complaints June 2019 to June 2020: 96 Number of Sis June 2019 to June 2020:	
Details of all recent audits undertaken	See audit presentation document	
Details of any quality improvement initiatives		
(Please list any other meetings that regular take place such as consultant meetings, business meetings etc)		
7. Junior doctors		
Details of junior medical staffing	See ESR report	
Copies of education programmes		
Feedback on quality on training - GMC trainee survey		

8.2 Appendix 2: Documents received and reviewed

Clinical record review	
12 sets of patient medical records including images	8 randomly selected cases, and 4 index cases of patients
Additional cases received and reviewed after service review	4 cases (where DCBs had been used in the left main stem)

Service review documentation	
Organisational level information	
Trust organisational structure	• 2021 Medicine Organigram • Executive structure chart • Management structure for annual report

Issues, concerns and actions taken	• Presentation to interventional team
Reports of other reviews / visits	• PLR Cardiology Getting it right first time (GIRFT) April 2019
Service specific information	
Consultants and members of the clinical and medical team	• Cardiology staff in post (11 February 2021)
Facilities	• Bed occupancy • Boarders • Current bed base • Flow – average LOS • Flow – Inpatient discharges
Site map of relevant service	• NNUH site map
Cover rota	• New rota (September 2020)
MDT arrangements	Surgical MDT 23 October 2020; 30 October 2020; 13 November 2020; 27 November 2020; 4 December 2020
Protocols, guidelines and pathways	• Acute Coronary Syndrome Care Guidance • Administration and or supply of Clopidogrel • Administration of Atropine Sulphate IV bolus • Admitting Patients Attending Cardiology Outpatients to Inpatient Areas • Adult Patients referred to a Consultant Cardiac Electrophysiologist suitable for consideration Standard Ablation • Angiography and Angioplasty in the Cardiac Cath Labs - LocSSIP – Cardiology • Assessment of Competence for_ Cardiac Specialist Nurse_Nurse Led Valve Disease Clinic in Cardiology OPD • BCIS Safe Surgery Integrated Checklist for Cardiac Cath Labs • Bereaved Relatives_Carers of the GUCH_ACHD population in Cardiology • Cardiac Physiologists undertaking the multi-skilled practitioner role within Cardiac Cath Labs • Cardiology and Interventional Procedures • Cardiology Cath Lab Competency Pack • Cardiology Outpatient Pre-assessment Clinics (Trust Protocol for) • CARE DOMAIN_ 4 Care Guidance for_ Temporary Pacing • Clinical Procedure transfer ongoing care IABP therapy from PCI Cath Lab to the Critical Care Complex • Coronary Angiography and Percutaneous Coronary Intervention (PCI) (Patient Information) • Day Case Percutaneous Coronary Intervention • Fasting Prior to Cardiac Catheterisation • Percutaneous Coronary Intervention (PCI) • Removal of Femoral Sheaths

	• Removal of Femoral Sheaths_ Adult Patients Undergoing Coronary Angiography- Percutaneous Coronary Intervention • Safe and effective flow of elective patients and inpatients requiring a procedure in the Cath Labs during COVID • SOP to allow the scrub nurse to be able to inject contrast medium during Angiography PCI EP • SOP covering sickness and unavailability of oncall team members while covering the PPCI service • SOP for recovering patients in Cath Lab • SOP for the Management of Equipment Failure in Angiography Suite by Cardiac Radiographers • SOP management of Yellow and Red pathway patients through CCU • SOP to allow unregistered Cath lab practitioners (uCLPs), to be second operator for Cath Lab procedures • SOP use of intravenous medications during procedures in the Cath lab • SOP Use of the Libel-Flarsheim Illumena Pressure Injector in Cardiology • Transfer of a patient requiring the use of an Intra-Aortic Balloon Pump • Warfarin referral, prescription and dosing chart for patients awaiting Cardioversion
Clinics that support the service	• Clinic utilisation (12 February 2021) • Outpatient activity (12 February 2021)
Appointment waiting times	• Outpatient referrals (12 February 2021) • Referrals report (8 February 2021) • Single PTL summary (12 February 2021)
Outcome data	• Activity data • Cancelled operations (31/01/20 to 31/01/21) • Diagnostics (12 February 2021) • Inpatient dashboard (02/08/17 to 31/10/20) • RTT performance (executive summary) (12 February 2021)
Mortality rates	• December 2020 NNUH Mortality report • DFI overview and deep dive (October 2020) • Mortality reporting (12 February 2021) • October 2020 NNUH Mortality report
Clinical team	
Job plans	• Removed – identifiable information • Removed – identifiable information • Removed – identifiable information • Removed – identifiable information • Removed – identifiable information • Removed – identifiable information • Removed – identifiable information • Removed – identifiable information • Removed – identifiable information • Removed – identifiable information

	• Removed – identifiable information • Removed – identifiable information • Removed – identifiable information • Removed – identifiable information • Removed – identifiable information • Removed – identifiable information • Removed – identifiable information
Appraisals	• Appraisal report
Clinical governance	
Assurance systems at Trust level	• Board reporting and accountability structure
Assurance systems at service level	• 2021 Medicine Organigram
Minutes and action logs of directorate and clinical governance meetings	Risk and governance meetings December 2019; June 2020; July 2020; August 2020; Divisional clinical governance meetings June 2019; July 2019; September 2019; October 2019; November 2019; December 2019; January 2020; February 2020; March 2020; May 2020 (draft and version 2); June 2020; July 2020; September 2020; October 2020 Cardiology governance June 2019; November 2019; September 2019; October 2019; February 2020; March 2020; May 2020 (draft); November 2020
M&M meetings	Minutes July 2020; August 2020; September 2020; October 2020 • Cardiology heart failure minutes (13 July 2020) • Cardiology M&M (7 August 2020) • PPCI M&M meeting (30 October 2020) • PPCI M&M meeting (4 September 2020)
Complaints, serious incidents and feedback on service	• Cardiology – claims • Cardiology – complaints • Cardiology - inquests
Recent audits	• Cardiology 2020-2021 audit report (December 2020) • Cardiology audit (February 2020)
Patient experience surveys	• Cardiology feedback (from June 2019 to June 2020) • PALS
Doctors in training	
Feedback on GMC trainee survey	• TA outlier post spec by Trust Board
DCB specific training	
Research governance, processes and protocols	• Percutaneous Coronary Intervention • Cardiology RD (October 2020)

	• NNUH sponsorship and shortened lease documents
Academic articles	• CV covering research items – Removed – identifiable information
Audit and outcomes specific to DCB	• April 2019 to March 2020 BCIS data • Report NOR (National Audit of PCI) Hospital report (from 1 April 2015 to 31 March 2018)
Information 04.03.21	
	• NICOR return
	• SOP – DCB angioplasty (version 1.4)
Presentation with embedded documents as attachments	• Embedded document from slide 14 • Embedded document from slide 15 - LMS • Embedded document from slide 15 – PCI • Embedded document from slide 19 – DATP • Embedded document from slide 19 – Daycase • ISR service review Norfolk and Norwich cardiology slides
Information 08.03.21	
Confidential not to be shared outside review	• Bifurcations vs non bifurcations DCB • DAPT DEB Abstract • DCB for stent thrombosis EuroPCR (29 January 2021) • DEB bifurcation review • EuroPCR abstract Spartan DCB LMS (February 2021) • EuroPCR abstracts innovation LBT got talent • STEMI denovo EuroPCR (29 January 2021)
DCB	• DCB 2015 booking form • DCB 2016 programme • DCB 2017 programme final • DCB 2018 programme • DCB V draft
Recent DCB work from group	• BCS day case DCB only angioplasty poster • Cardiovascular magnetic resonance stressing the future published version • DAPT DCB CCIJ 2019 • DAPT DCB ESC abstract 2018 • DAPT DEB 2021 abstract • Day case DCB audit published version • DCB DES high bleeding risk review – Interventional Cardiology (24 February 2021) • DCB PPCI book- see chapter 12 • DCB safety for EuroPCR (3 January 2020) • Diagnostic applications of USPIO for imaging myocardial and vascular inflammation • Drug Coated Balloon – only angioplasty for native coronary artery disease instead of stents • Endothelial dysfunction final • International DCB consensus report

	• Percutaneous coronary intervention in the elderly: are drug-coated balloons the future? (2018)
Research papers to support presentation	• Islam Y. Elgendy, MD et al. *Systematic review and meta-analysis: Clinical and Angiographic Outcomes with Drug-coated Balloons for De Novo Coronary Lesions: A Meta-Analysis of Randomized Clinical Trials.* Journal of the American Heart Association (October 2020) • Xue Yu et al. *Treatment of large de novo coronary lesions with paclitaxel-coated balloon only: results from a Chinese institute.* Clinical Research in Cardiology (volume 108, pages 234-243, 2019) • Tuomas T Rissanen et al. *Drug-coated balloon for treatment of de-novo coronary artery lesions in patients with high bleeding risk (DEBUT): a single-blind, randomised, non-inferiority trial.* The Lancet (13 June, 2019) • Raban V. Jeger, MD et al. *Drug-coated Balloons for Coronary Artery Disease.* Elsevier on behalf of American College of Cardiology FoundationBol (2020) • Bruno Scheller, MD et al. *Survival after Coronary Revascularization with Paclitaxel-Coated Balloons.* Journal of the American College of Cardiology (Vol 75, no. 9 2020) • Bruno Scheller, MD et al. *Bare metal or drug-eluting stent versus drug-coated balloon in non-ST-elevation myocardial infarction: the randomised PEPCAD NSTEMI trial.* Coronary Interventions (October 2019)
Retrospective review of data	• DCB STEMI analysis • Follow up regarding advice on DCB in Norwich (1 October 2020) • STEMI mortality
Spartan paper and supplements	• Ioannis Merinopoulos et al. *Long-term safety of paclitaxel drug-coated balloon-only angioplasty for de novo coronary artery disease: the SPARTAN DCB study.* Clinical Research in Cardiology (2 September 2020) • Supplementary figure 1 • Supplementary table 1 – Mortality rate of study groups
Supporting information for presentation	• Natasha H Corballis et al. *DCB birfurcations review for CCI.* • Ioannis Merinopoulos MD et al. *DCB for stent thrombosis Spartan ST study* • DCB vs DES for de novo LMS BCIS • Upul Wickramarachchi et al. *Effects of drug coated balloon angioplasty versus drug eluting stents in the management of acute and stable coronary artery disease of all vessel sizes: a propensity score matched analysis* (8 February 2021)
Thesis and supporting documents	• Upul Wickramarachchi et al. *Drug Coated Balloon-only Angioplasty in Chronic Total Occlusions, A UK Single Centre Experience.* BCIS (18-20 January 2017)

	• Upul Wickramarachchi et al. *Primary Percutaneous Coronary Intervention with Drug Coated Balloon (DCB)-only Angiplasty, First UK Experience.* BCS (18-20 January 2017) • Upul Wickramarachchi et al. *Drug Coated Balloon-Only Angiplasty in Left Main Stem Disease, A UK Single Centre Experience*. BCIS (18-20 January 2017) • Presentation slides: EuroPCR 2018 Bifurcations • Upul Wickramarachchi et al. Drug Coated Balloon-only Angipplasty in Chronic Total Occlusions, A UK Single Centre Experience. BMJ (17 April, 2018) • DCB angioplasty in small vessel vs large vessel coronaries. TCT abstract. Journal of the American Collect of Cardiology (vol 76, 2020) • Presentation slides: DCB-NNUH experience, by Removed – identifiable information • EuroPCR 2018 abstract bifurcations. DEB angioplasty for coronary bifurcation lesions (15 May 2018) • Presentation slides: EuroPCR 2018: DCB-only Left Main PCI by Removed – identifiable information • Presentation slides: EuroPCR 2017: DCB-only Angioplasty in Chronic Total Occlusions by Removed – identifiable information • EuroPCR CTO 2017 abstract (7 May 2017) • EuroPCR LMS 2017 abstract • ISR (in-stent restenosis) EuroPCR 2018 abstract • LMS 2017 ACI heart abstract: An analysis of 59,644 PCI cases in patients with previous CABG: is there a legacy effect of coronary perforation? BMJ (17 April 2018) • PPCI 2017 ACI heart abstract. BMJ (17 April 2018) • PPCI 2017 EuroPCR abstract: Primary PCI with DEB-only angioplasty (16 May 2017) • K.H. Mok et al. *Safety of bailout stenting after paclitaxel-coated balloon angioplasty* (17 November 2016) • Removed – identifiable information Thesis final (2020)
Documents received during the service review	
DCB presentations from Removed – identifiable information	Presentation slides: • DAPT DEB abstract • DCB – NNUH experience for September 2017 meeting • DCB for stent thrombosis EuroPCR (29 January 2021) • DEB Bifurcation Review • EuroPCR abstract Spartan DCB LMS (2 February 2021) • EuroPCR abstracts innovation LBT got talent • STEMI denovo EuroPCR (29 January 2021) Documents • STEMI denovo EuroPCR (29 January 2021) • EuroPCR abstract Spartan DCB LMS (2 February 2021)

From Removed – identifiable information*, associate medical director of research*	• Question 1 PIS for feasibility part macrophage inflammation phase A part 1 (18 December 2020) • Question 1 Protocol USPIO CMR in coronary intervention (18 December 2020) • Question 1 Sequent Neo Product Information • Question 2 Corbalis • Question 3 Merinopoulos • Question 4 Merinopoulus
Information from new concern raised	
Research and Development	• 19EE0075 Research Ethics Committee (REC) favourable opinion (25 July 2019) • Health Research Authority (HRA) approval letter (25 July 2019) • Confirmation of capacity and capability (17 July 2020) • Confirmation of capacity and capability part B (23 October 2020) • Integrated Research Application System (IRAS) application (3 January 2019) • Protocol USPIO CMR in coronary intervention (11 July 2019, version 4) • Protocol USPIO CMR in coronary intervention (18 December 2020) • Informed consent form feasibility phase A part 1 (18 December 2020) • Informed consent form for feasibility study phase A part 2 (18 December 2020) • PIS for feasibility part macrophage inflammation phase A part 1 (18 December 2020) • PIS for feasibility for macrophage inflammation phase A part 2 (18 December 2020) • Email dated 10 March 2021. From Removed – identifiable information; To: Removed – identifiable information. Subject: Removed – identifiable information • Protocol USPIO CMR in coronary intervention (18 December 2020) – pdf version • SeQuent NEO product information
Investigation report Removed – identifiable information	
	• Appendix T (v2) redacted noted from Removed – identifiable information • Appendix S redacted notes from Removed – identifiable information • Appendix U redacted notes from Removed – identifiable information • Appendix W redacted notes from Removed – identifiable information • Appendix X redacted notes from meeting with Removed – identifiable information • Cardiology report Removed – identifiable information review redacted (Removed – identifiable information)

	• Cardiology incidents Sis and SIG section (2019-2020)

8.3 Appendix 3: Interviews and visits to clinical areas

11 March 2021 (day 1)	
Pre-ISR meeting with key Trust personnel	Removed – identifiable information, medical director Removed – identifiable information, deputy medical director
Interview	Removed – identifiable information, chief of division for medicine and interventional cardiologist
Interview	Removed – identifiable information, service director and interventional cardiologist
Interview	Removed – identifiable information, previous service director and interventional cardiologist
Interview	Removed – identifiable information, senior clinical lecturer and interventional cardiologist
Group interview	Removed – identifiable information, clinical lecturer and honorary consultant cardiologist (imaging) and Removed – identifiable information, consultant cardiologist
Interview	Removed – identifiable information, interventional cardiologist (DCB programme lead)
Interview	Removed – identifiable information, interventional cardiologist
Interview	Removed – identifiable information, interventional cardiologist
Interview	Removed – identifiable information, general cardiologist (senior lecturer, academic consultant and professor of medicine)
Interview	Removed – identifiable information, interventional cardiologist

12 March 2021 (day 2)	
Group interview	Removed – identifiable information, database coding manager - IT team within cardiology (Removed – identifiable information) and Removed – identifiable information, cardiology project manager
Interview	Removed – identifiable information, interventional cardiologist (interventional cardiologist)
Group interview	Deputy divisional operational: Removed – identifiable information, tactical operational manager (cardiology and gastroenterology)
Interview	Removed – identifiable information, interventional cardiologist
Interview	Removed – identifiable information, associate medical director of Research, Ethics and Governance Lead(s)
Cardiology ward nurses/Group interview	Removed – identifiable information, sister in cardiology Removed – identifiable information Removed – identifiable information, sister and staff nurse in coronary care, inpatient ward and cath lab)
Radiographers/group interview	Radiographers
Cath lab nurses/group interview	Removed – identifiable information, lead cardiology rehab nurse; Removed – identifiable information, cath lab manager; governance education and audit lead; assistant practitioner; staff nurse in cath labs; staff nurse cath labs and lead nurse cath labs

12 March 2021 (day 2)	
Group interview	Physiologists working with the cardiology team; cardiology physiologists
Group interview	Removed – identifiable information
Interview	Removed – identifiable information, cardiac surgeon, Royal Papworth Hospital NHS Foundation Trust
Feedback session	Removed – identifiable information, deputy medical director Removed – identifiable information, chief of division

8.4 Appendix 4: Letter summarising initial feedback 29 March 2021

Removed – identifiable information
Medical Director
Norfolk and Norwich University Hospital NHS Foundation Trust

BY EMAIL ONLY

29 March 2021

PRIVATE AND CONFIDENTIAL

Royal College of Physicians: Norfolk and Norwich University Hospital NHS Foundation Trust, cardiology

Dear Removed – identifiable information,

I am writing following the Royal College of Physicians Invited Review of the interventional cardiology service at Norfolk and Norwich University Hospital NHS Foundation Trust on 11 and 12 March 2021. As you know we held this review visit virtually using Microsoft Teams and overall, we believe this worked well.

A substantial amount of information was gathered from the clinical record review (CRR), Trust documentation and interviews with staff. Using this information, in due course the review team will provide you with a final considered report which addresses the agreed terms of reference (ToR).

However, I wanted to ensure you had a written record of the preliminary feedback, and actions that we believe are necessary to ensure that patient safety is not compromised in the interventional cardiology service. This is based on the verbal feedback provided at the end of the two-day visit to Removed – identifiable information, deputy medical director and Removed – identifiable information, chief of division (medicine).

The review team wish to commend the staff we met during the review visit for the frank and open way they engaged with the review. We would also like to thank Removed – identifiable information and Removed – identifiable information team for their co- ordination and facilitation of the interviews and collation of information. We met several excellent staff who represented the Trust very positively, those who stood out to us included Removed – identifiable information, and the ward and catheter laboratory (cath lab) staff. Overall, all members of the cardiac team were universally professional and friendly.

Please see below the preliminary feedback:

Terms of reference (ToR) 1 – Clinical record review

This term of reference concerned the clinical review of 12 cases of patients who were selected as they had received drug coated balloons (DCBs), and in some cases had a complication. Full details of the cases and the judgements reached by the review team will be provided in the full report.

The review team used a structured form adapted from the RCP National Mortality Case Record Review (NMCRR) programme to independently examine phases of care that the patient received, in addition to a grading system originally developed by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) to give an overall perspective on the quality of care. Views were reached after a confirm-and-challenge meeting chaired by the deputy medical director of invited reviews on 19 February 2021.

Although four randomly selected cases were requested, where DCBs had been used in the left main stem, such cases were not included in the 12 cases returned to the review team. These were subsequently requested and will be reviewed separately and commented on in the final report.

Out of the 12 cases received, 4 were graded unsatisfactory, 7 had room for clinical improvement and 1 had room for improvement with respect to clinical and organisational factors. All the 12 cases were noncompliant with current best practice for the use of DCB's in STEMI, large vessels, and left main intervention (some cases demonstrated a lack of compliance with the recent JACC consensus document[28]).

Universally across the 12 cases there was limited documentation of multidisciplinary team (MDT) interaction to discuss the rationale for DCB use, limited evidence of patient consent specifically for DCBs and a lack of evidence for discussion of appropriate cases at the morbidity and mortality meetings (M&M). Generally, there was little evidence for the use of pressure wire and intracoronary imaging in cases that would have benefited.

Following the review of the additional four cases where DCBs had been used in the left main stem, the review team will decide if further case evaluation is needed.

Some of the cases in this review cause concern and are at odds with the data in the British Cardiovascular Intervention Society (BCIS) national audit, which does not identify Norfolk and Norwich as an outlier in terms of major adverse cardiac events following percutaneous coronary intervention (PCI). However, the review team identified that not all peri- and post procedural in-hospital complications were accurately recorded within the data submission to NICOR, and this requires further review by the Trust.[29]

The review team understand the passion for the DCB programme however, clearer indications and restrictions for use are required at this time and until there is further consideration of safety data and reassurance of outcomes. These restrictions should also remain in place prior to the issue of the final report by the RCP. Recommended criteria and suggestions for safety data to be captured have been set out below (see recommendations 1 & 4).

ToR 2 - To review the process followed for use of a treatment (DCBs) outside of national guidance and the robustness of processes put into place to initiate its use, structure and funding of the DCB programme, commissioning arrangements, conflict of interest, and the ongoing monitoring of outcomes and effectiveness of treatment.

Initiation for the use of DCB's

The review team found that in 2009 when the DCB practice was initiated, there was no governance put in place nor during its extension to other "off licence" uses ie outside of evidence and guidance-based practice such as in primary PCI and large vessels.

From the information provided by staff, the review team learned that DCBs were not taken through any form of new technology committee for approval and that there was no consideration of consent implications. Further to this, the review team were of the view that there was lack of clarity about the appropriate governance processes and appropriate allocation of responsibility for the same. As a result, since 2009 a Trust wide formal governance framework has not adequately supported the development of this "off licence" practice.

More recently research and development approvals have been sought, however these are not in place as yet. The review team were informed that the research governance at the Trust, compared to other more established research centres, is in its infancy. As the research unit develops, the review team consider that it will require further expert support of DCB specific research proposals and requests (see recommendation 3).

[28] JACC 2020;113(12):1391-1402

[29] Following the feedback session, the Trust informed the review team of a discrepancy in the NICOR returns document that had been shared. The review team will comment on this in the final report.

Conflicts of interest

The review team found a possible conflict of interest, in that, the DCB programme lead receives research funding support relating to DCBs along with consulting fees by the DCB manufacturer. The review team were informed that the manufacturer is also the Removed – identifiable information. Steps to clarify potential conflicts of interest are required for greater transparency (see recommendation 5).

Monitoring of outcomes

The review team recognise the recent efforts made by the academic teams to collect in-patient and follow up data for patients receiving DCB treatment. Removed – identifiable information and colleagues, with some external help have conducted various retrospective analyses, sometimes with propensity matching, to support the concept that their programme is safe and feasible - the review team were supplied with most of this research output.

The interviewees and documentation gathered for this review also showed that the main outcome data reports on mortality. The review team suggest that other safety events including complications and morbidity should be explored as part of the monitoring of outcomes and analyses. Applying for a prospective registry or randomised control trial may help support this.

Some interviewees reported that patient complications are captured solely by operator disclosure. The review team were of the view that this may be a limitation to reporting safety outcomes. Moreover, there was limited evidence for the discussion of complications and how learning is shared widely across the department which could also be improved. There is an urgent need for the Trust to review its reporting of safety measures (see recommendation 4).

ToR 3 - To review the use of Drug Coated Balloons in the treatment of Coronary Artery Disease by the interventional cardiology team. This will include a review of current activity levels and outcomes, protocols and pathways, consent and MDT working. Consideration will be given to the concerns raised about mortality and outcomes and well as internal reviews of these matters.

Variation of use

The use of DCBs among colleagues varied (from 10-90%) where some staff felt more confident than others in their own ability to use the technology. Although variation is expected between operators, there is limited guidance on the criteria for DCB use. The review team were of the view that because the use of this technology is outside of evidence and guidance best practice, it is necessary for the team to share a department wide criterion or standard operating procedure (SOP). A draft SOP document was received as part of the review, but the team were informed the document is not yet ratified. Considering this, staff should not feel pressured or coerced into using the DCB technique outside of the stipulated guidelines.

Consent

Consent for use of DCBs is a very real concern. There was wide variation across the staff with respect to how they consent patients. Some consultants reported that they verbally consented patients regarding their DCB practice, but the information provided to the patient did not always outline that the practice is outside of UK guidelines nor evidence based for certain uses (i.e. in large vessels). Non-consultant grade doctors in the unit reported that appropriate consent did not always occur and that there had been no formal induction to support the consenting process.

Since the initiation of this review a new consent form and patient information leaflet have been developed but the review team were informed that at present, these are not yet formally in use by all staff. There is an urgent need to address patient consent for DCB use (see recommendation 2).

ToR 4 - To review the quality of team working within the department and to give a view on whether this supports the delivery of high quality and safe care. Consideration will be given to clinical and managerial leadership, individual behaviours, interactions with members of the wider medical team and MDT working.

All the staff met during interviews were uniformly supportive of the department. The review team found that the cardiology team were a cohesive and friendly department who often helped each other with cases, and that combined working for complex cases was encouraged.

However, there are some interpersonal difficulties that have arisen partly because of the concerns raised for this review. Moreover, some consultant staff report that they are not entirely comfortable about DCB practice but perhaps do not feel empowered to challenge it. This might suggest that the culture would benefit from better promotion of transparency and organisational learning. Paramount to this, is the support for staff who raise concerns about the practice.

ToR 5- To evaluate the quality of clinical governance arrangements currently in place to support and maintain oversight of the interventional cardiology service to include a look at audits, clinical incident reporting, reviews of morbidity and mortality and patient complaints/feedback.

As described above in ToR 2 – there has been no robust governance structure in place, and the review team would suggest the Trust provide further assurance that patient safety incidents (other than death/cardiac arrest) have been captured, investigated and their learning disseminated.

This finding was supported by the cases chosen for review, where some chosen because of safety concerns were not subject to M&M processes, or other peer review.

In conclusion, the **immediate recommendations** are listed below. Further recommendations will be presented in the final report.

Immediate recommendations – implementation to start prior to the issue of the final report

1) At this time, if the Trust wish to continue the use of DCBs they should only be considered under the following circumstances:

    - In-stent restenosis,
    - Vessels <3.0mm diameter,
    - Vessels >3.0mm diameter if at least one of the following apply:

        1. Patient is enrolled in a formal prospective research registry of DCB use with appropriate ethics and R&D approval
        2. Patient is enrolled in a formal randomised controlled trial of DCB versus second or third generation drug-eluting stent
        3. Patient has signed a bespoke consent that clearly highlights the DCB use would be outside UK conventional and guideline-directed practice and has indicated specifically that this is their choice.

The Trust should monitor this and may wish to consider asking BCIS for advice for independent adherence to these recommendations.

2) There is an urgent requirement by the Trust to ensure that patients are appropriately consented and informed (with the use of an approved patient consent form and patient information leaflet) in line

with the recommendation 1 proposed above. In relation to recommendation 2, staff should have appropriate training and an induction on how to consent patients objectively.

3) The department should consider approaching either another department in the Trust or an external cardiology team with mature research and clinical governance structures in place to learn from how they support similar programmes. This would provide the opportunity to learn from and implement governance processes for the benefit of patient safety.

   The governance programme should support a formalised and robust reporting of incidents, learning and discussion at M&M meetings, and the development and implementation of a recognised SOP to support the use of DCBs.

4) The Trust should ensure that the DCB safety data takes account of more than just mortality data as an outcome. Steps should be taken by the research and development department to ensure that other outcome data is captured. Moreover, the Trust should ensure that there are accurate NICOR returns processes in place. Application to a randomised controlled trial or prospective registry may help support this.

5) In the interests of openness and transparency, potential conflict of interests should be clarified by the Trust, particularly in relation to research funding support and consultancy fees for staff, paid for by the DCB manufacturer.

I hope this letter is clear and helpful in summarising the review team's immediate feedback on these matters at the conclusion of the review visit. The team will now work to prepare and finalise the invited service review report, which will be sent to you in due course.

Yours sincerely,

Removed – identifiable information

Removed – identifiable information

Deputy Medical Director for Invited Reviews

8.5 Appendix 5: Additional comments on the factual checking letter

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18 January 2022

[redacted]
Deputy Medical Director for Invited Reviews
Invited Reviews Royal College of Physicians
Sent by email only

Dear [redacted]

Invited Review: Norfolk and Norwich University Hospital NHS Foundation Trust, cardiology

Thank you for extending the time to review the draft report for factual inaccuracies following the mislabelling of patient casenotes on our part, which caused undue confusion between the invited review team and our cardiology team.

Dr [redacted], [redacted] Cardiologist has re-reviewed [redacted] as RCP16 and has confirmed [redacted] patient presented with STEMI/Cardiogenic shock requiring IABP and POBA to LMS to restore flow. Staged DCB PCI to LMS, with good long term result. The patient remains asymptomatic from Cardiac perspective having survived a presentation associated with >50% mortality. The case was discussed on at least two occasions in the RPH: Norwich MDT where surgical intervention was turned-down in favour of PCI.

Dr [redacted] would like [redacted] original comments to remain, which explain the decision making process for this patient acknowledged. These are detailed below:

RCP16 - [redacted] the patient had a cadaveric renal transplant, was in cardiogenic shock and significantly impaired renal function, eGFR around 30, hence the bailout procedure conducted initially. The decision to avoid stenting the LMS was taken to avoid jailing the ostium of the circumflex. At that stage, the viability of the circumflex territory was unclear and it was believed to be essential to avoid stenting across the circumflex ostium until there was clear evidence of reversible ischaemia in the Cx Territory. Colleagues familiar with the practice of balloon angioplasty with DCB on a regular basis would be comfortable leaving a type B dissection such as in this case. The residual stenosis at follow up angiography is in the order of 25-30%. The report fails to mention the excellent positive remodelling that has occurred. The patient has subsequently been shown to have a viable circumflex territory, but no evidence of ischaemia, whereas the LAD territory, which the LMS subtends is largely non-viable. It was therefore felt that further optimisation of the LMS was not required at follow up.

Dr [redacted], [redacted] Cardiologist has re reviewed [redacted] as RCP 13. Dr [redacted] wished to point out that this patient was difficult to manage as there is no data on the best way to manage such patients. In Dr [redacted] opinion the patient's comorbidities and coronary anatomy limited any safe and effective treatment. The patient had a very high-risk PCI completed after being admitted with an ECG which suggested LMS or 3VD (both were since confirmed). As the patient's admission was during the height of covid,

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the MDT was undertaken in the cath lab, and due to being deemed as a high-risk PCI, was performed as a two consultant case, with Dr [redacted] in attendance as the second consultant. The patient's subsequent course was of a good recovery with well-preserved LV function on medical therapy with no more angina post-procedure. Dr [redacted] believes the fact that the patient had and still has inoperable terrible calcific coronary disease would suggest that the correct decision was made in this case. The patient is still alive and remains angina free 2 years later.

Dr [redacted] believes the comment about [redacted] is true based on the above, and [redacted] continues and has been linked to a combination of pulmonary fibrosis and recurrent fluid overload managed with dialysis.

Given the complexity of coronary disease and co-morbidities for this patient, it is felt that management for this patient is not fully covered by ESC guidelines or the consensus document. Dr [redacted] has requested, given the positive long-term outcome for this patient with a challenging presentation that this case be reclassified.

There was one final point the cardiology team wish to raise regarding the report, which we as a management team had not yet had opportunity to feedback, this is regarding the term ' off label'.

We believe 'off label' usually refers to using a product, device or a pharmaceutical agent outside its licensed indications. In accordance to the enclosed instructions for use document, we understand that the DCB devices have been used within their range of licensed indications. Therefore we would ask if it is possible to use the alternative term of 'outside current European Society of Cardiology (ESC) guidelines' instead as this would be more factually accurate within the report.

Yours sincerely

[redacted]

[redacted]
Deputy Medical Director

Enc: SeQuent® Please NEO Instructions for use

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SeQuent® Please NEO Instructions for use

Instructions for use

SeQuent® Please NEO

Contents of the sterile packaging
One SeQuent® Please NEO Balloon Catheter for the treatment of arterial occlusive disease. The balloon is coated with the agent Paclitaxel.
1 Flush cannula

CAUTION:
- The catheter is only sterile and non-pyrogenic if the package is not opened, damaged or broken. Sterilized with ethylene oxide.
- Please read instructions prior to using this device.
- For single use only. Re-use of single-use devices creates a potential risk for the patient or the user. It may lead to contamination and/or loss of functional capability. Contamination and/or limited functionality of the device may lead to injury, illness or death of the patient.

General product description / field of application
SeQuent® Please NEO manufactured by B. Braun Melsungen AG is a balloon catheter based on a rapid exchange design. SeQuent® Please NEO is a drug coated balloon catheter to treat occlusive arterial disease. SeQuent® Please NEO is designed to improve the lumen diameter and to reduce restenosis in native artery lesions. SeQuent® Please NEO can be used as an alternative to a conventional uncoated balloon. The superiority to reduce restenosis has been demonstrated for the treatment of in-stent restenosis and de-novo lesions in atherosclerotically narrowed arteries. The active drug coating is located on the surface of the balloon, which contains 3 µg Paclitaxel per 1 mm². The drug is embedded in a physiologically harmless and degradable delivery matrix (main component: Iopromide). The expansion of the balloon causes a surface contact of the coated balloon with those vessel segments which should be treated. This process allows the transfer of the drug into the vessel wall. Depending on the patient situation and vessel morphology the maximum balloon inflation pressure should be maintained in general for a period of at least 30 seconds. In cases where long lesions are treated (longer than the maximal balloon length available), the particular subareas should be treated only once with a SeQuent® Please NEO catheter.
The distal shaft (approx. 25 cm) consists of two lumina. The proximal section of the catheter is a single-lumen, stainless steel hypotube with a luer adapter connected to the balloon lumen. The two markers on the catheter shaft appear when the tip of the balloon-tipped catheter leaves the guiding catheter (brachial: 100 cm/femoral: 110 cm). A needle with a luer port is included for flushing the distal guide wire lumen. Two radio-opaque markers indicate the length of the cylindrical portion of the balloon. The balloon is protected with a removable sheath, which keeps the factory-made profile. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. The catheter has a hydrophilic coated surface at the distal shaft portion. Therefore, SeQuent® Please NEO offers superior gliding properties during intervention.

SeQuent® Please NEO is available in lengths of 10 mm, 15 mm, 20 mm, 25 mm, 30 mm, 35 mm, and 40 mm and in diameters of 2.0 mm, 2.25 mm, 2.5 mm, 2.75 mm, 3.0 mm, 3.5 mm and 4.0 mm.

REMARK: The enclosed clips are intended to store the catheter safely and save space in the sterile field. The clips should only be used at the proximal shaft (hypotube). The clips should not be used at the distal shaft.

CAUTION: Before the SeQuent® Please NEO balloon is inflated, the appropriate length and diameter must be matched to the length of the target lesion and the reference diameters.

Individual treatment
Before using SeQuent® Please NEO, the benefits and risks for each patient must be individually assessed. After establishing the patient exclusion criteria, the risk associated with anti-platelet therapy should be taken into account. Special consideration is required for patients with recent active gastritis or peptic ulcer disease (PUD).

Indications
- De-novo lesions (primary use in the case of stenoses or occlusions) including small vessels (small vessel disease (SVD))
- Restenosis after balloon- or stent-PTCA (ISR)
- Pre- and post dilatation during coronary stent implantation
- Acute or impending vascular occlusion

Contraindications
- Intolerance to Paclitaxel and/or the delivery matrix (main ingredient: Iopromide)
- Allergy to Paclitaxel and/or the delivery matrix (main ingredient: Iopromide)
- Severe allergy to contrast media
- Pregnancy and lactation
- Cardiogenic shock
- Hemorrhagic diathesis or another disorder associated with increased bleeding risk such as gastrointestinal ulceration, which restricts the use of platelet aggregation inhibitor therapy and anticoagulation therapy
- Treatment shortly after myocardial infarction with presence of intravascular thrombus or poor coronary blood flow
- Lesions not suitable for interventional treatment
- Patients with an ejection fraction of < 30 %
- Vascular reference diameter < 2.0 mm
- Indication for surgical revascularization
- Contraindication for whichever necessary accompanying medication
- Coronary artery spasm in the absence of a significant stenosis

Possible complications after balloon dilatation
Possible complications may include but are not limited to:
- Hematoma at the vascular access site
- Pseudoaneurysm
- Acute myocardial infarction
- Pulse arrhythmia
- Angina pectoris
- Arterial perforation or rupture
- Spasm of coronary arteries
- Death
- Cerebral circulatory disorders

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