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NHS Trust

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PRIVATE & CONFIDENTIAL

Mr Edwin Buckett
Assistant Coroner for Inner North London
St Pancras Coroner's Court
[redacted]

Dear Mr Buckett

RE: Regulation 28 Prevention of Future Deaths Report: Norman Joseph Pirie

I write in response to your Regulation 28: Report to Prevent Future Deaths, dated 18 January 2019. Your concerns are related to device selection in Endovascular surgery.

The Royal London Hospital, Barts Health NHS Trust, has been a vascular surgery hub for over 20 years, throughout which it has adhered to the required governance processes. In recent years, vascular technologies have evolved, resulting in more endovascular and fewer open surgical treatments. In response to this, we have a dynamic infrastructure to allow an equivalent fluidity in our governance processes to ensure patient safety remains our paramount concern. Models of vascular practice encourage working within networks to centralise expertise and infrastructure. The Vascular Society, GIRFT (2018)[1] and a recent Vascular Surgery Service Specification (2017)[2,3] describe operational aspects of practice to influence best practice that is safe for patients. The Vascular Unit at Barts Health NHS Trust adheres to all of these standards of practice.

Endovascular (EVAR) technologies have changed management of Abdominal Aortic Aneurysms (AAA), having shown it to have a 30 day mortality of 1.8%[4]. There is strict guidance on AAA threshold for treatment; the shape of AAA for EVAR; and patient fitness from evidence produced nationally[3] and internationally over the last 25 years. The low 30 day mortality means it is a desirable option in the less fit patients who would otherwise have no option for treatment. Over the years, the technology has been cautiously extended in more complex situations including patients with less suitable anatomy as defined in the instructions for use (IFU) of endografts. There are many studies that demonstrate that EVAR can be performed safely in high-risk patients with unfavourable neck anatomy using commercially available endografts, and that such patients are capable of achieving mid-term outcomes that are comparable to those achieved in patients with suitable anatomy.[5]

Current practice:
Once the diagnosis of AAA has been made and the case has been referred to vascular surgery, it is discussed in the weekly Multi-disciplinary Team Meeting (MDT):

- Computed Tomography (CT) angiogram findings are discussed between Vascular Interventional Radiologists and Vascular Surgery Consultants.
- Discussions centre broadly around the choice of open surgical and endovascular options, or conservative management.
- Some discussion can be around particular technical solutions within those treatment modalities. Some of the more complex cases are also reviewed outside of the MDT to further assess the more complex technical solutions. We always look for solutions with devices within their IFU. We will consider other options if no IFU compliant device is available, including no intervention and open surgery. However, non IFU treatment remains a possible solution in certain scenarios based on clinical judgement, using our own institutional experience and the plethora of available literature.
- Outcome of discussion is recorded in the patient's electronic clinical record (CRS).
- The outputs of the MDT are then set up e.g. Outpatient clinic review, High risk pre-assessment, book for intervention, other investigations and return to MDT

Final management:

- Intervention (Open or Endovascular)
- Surveillance (with view to future intervention)
- No intervention

In Mr Pirie's case:

- A (usually benign, Type 2 endoleak) backflow of blood from a branch of the aorta back into the aneurysm sac was causing progressive expansion of the aneurysm and a low risk attempt at endovascular embolization of this vessel had not been successful.
- Mr Pirie was closely monitored until the aneurysm had expanded to the point where it was now leaking around the side of the stent at the proximal seal with a sac size of 90mm and 4mm increase in 4 months. This made him extremely high risk for rupture within a short timeframe due to the lethal triad of absolute size of the aneurysm; the mechanism of increase (Type 1A endoleak) and rate of expansion.
- A re-intervention was offered in this context, as when the aneurysm were to actually rupture, his mortality would be in the 90%-100% range. Even then, his re-intervention was delayed due to a further deterioration in his fitness, resulting in a cardiologist assessment and stratification as substantial risk for the endovascular procedure as discussed with the patient directly and confirmed by letter

- For all of the above reasons, although the procedure was performed on an elective list, the risk of the procedure was presented as high; but not as high as treating conservatively without a procedure.
- Given Mr Pirie's anaesthetic assessment, the alternative possible repair options - Fenestrated Endovascular Aortic Repair (FEVAR) and open surgery – were known to be too high risk given the complexity of both.
- The use of EVAR devices outside of the IFU is an accepted practice. The literature presented at the inquest was submitted to support this (attached). Extensive literature can be found on this.
- The concern of using devices outside of IFU is one primarily of longevity of seal.
- In Mr Pirie's case, given the above, the options were only those that were undertaken or no intervention at all. Given the institutional and world experience, there was no undue concern that the device would not deploy because of the given angulation.

Proposal

We feel that our processes are generally robust and in keeping with the other vascular institutions across the country. However, on reflection, the communication can be enhanced by the following:

- We will implement steps to improve the pathway around points of communication between clinicians, GP and the patient.
- We will institute a separate planning meeting outside of the MDT. Here the nuanced technical discussions on the type of stent and manufacturer can be expanded.
- We will move to joint planning meetings between IR and Vascular surgery consultants so that the issues of IFU can be discussed formally. This will enable longer joint discussions around particular devices and their suitability, based on IFU, and durability.
- The results of the planning meeting will then be fed back into the MDT.
- Where no IFU compliant option is available, we will re-discuss in the MDT to consider other options, i.e. no intervention or open surgery. However, non IFU treatment remains a possible solution in certain scenarios particularly urgent and emergency cases. While it is natural for the manufacturers to point out any deviance from Instructions For Use in the event of device failure, it is our opinion, based on our clinical experience of the peer-reviewed published body of evidence, that increased angulation of the aorta is unlikely to have been a factor in the failure of the device to deploy in this case
- The decision will be recorded in the patient's Clinical Record. The patient and GP will be notified with an output from the MDT.

- Discussion around this MDT outcome will be undertaken with the patient in the outpatients setting. The patient will receive an explanation regarding the available treatment options and the risks and benefits of each. If an endovascular solution outside of IFU is proposed, this will be made clear to the patient and the discussion recorded.

Thank you for bringing your concerns to my attention. I trust that you are assured I have taken them seriously and investigated them appropriately.

Yours sincerely

Alistair Chesser
Chief Medical Officer
Barts Health NHS Trust

CC:
Simon Harrod, Medical Director, Royal London Hospital
Legal Team, Barts Health NHS Trust

References:

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2. Specialised Vascular Services. NHS England 2017
3. Top tips' for reconfiguring Vascular Services 2018
4. Endovascular versus Open repair of Abdominal aortic aneurysms. The UK EVAR trial Investigators. N Eng J Med 2010; 362:1863-1871
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