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Professor David Anderson & Dr Owen Miller
Heads of Service
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16th March 2015

Dear Professor Anderson and Dr Miller

Many thanks for your extensive response to the 2011-14 NICOR data that showed a higher than expected early mortality for the Norwood procedure. Although your report also covered the outcome after pulmonary arterial banding procedures during the same period, we now know that this initial alert was attributable to data entry and coding issues and the outcome after this procedure is in fact within the expected range. This letter, therefore, only addresses the sections of your analyses which deal with the outcomes following the Norwood Procedure. It is very important to acknowledge that this was an 'alert (i.e. green flag)' rather than an 'alarm (red flag)' and we recognise this in our response.

The report from Evelina is extremely thorough and both the unit and the trust had clearly recognised a concern with Norwood outcomes at an early stage. Internal governance systems were excellent and had provided early warning, triggering an internal review – which is a credit to the team and part of good medical practice. Their recommendations in tightening up their inclusion criteria, strengthening their MDT processes and undertaking on-going surveillance are all entirely appropriate.

There is ***no evidence here to suggest that any further action needs to be taken***; however, we would make the following comments:

a) The proposed changes in protocol and selection appear entirely appropriate. However, given that most of the index cases would have fallen broadly within these categories, we would recommend that these changes in selection criteria are reviewed regularly to establish whether or not they are having an impact on outcomes.

b) Within the limitations of this format and the scope of this response, there is insufficient clinical detail of the individual cases to be able to make any further judgment on whether or not there could have been alternative strategies or management techniques that could have influenced outcome. If you wished to pursue a more detailed and objective assessment then we would recommend that Evelina commission an external review of the cases – either an invited peer review or through the Independent Review Mechanism of the Royal College of Surgeons. This is only our suggestion and not a requirement.

c) The response does not report individual surgeon outcomes. We recognise that the nature of such surgery is a team outcome, but it is important that individual operator outcomes are also monitored within the trust. The Evelina and relevant stakeholders need to be reassured that this alert is not related to the performance of a single surgeon. If Evelina do have a concern over individual performance then this should be declared through the Trust's internal governance mechanisms and a strategy taken to support and monitor his/her performance.

d) This procedure remains one of the highest risk and most complex procedures in congenital heart surgery, and this has to be borne in mind when reviewing the outcomes. Nevertheless, the cases that are described are not all in the highest risk sub-groups and many had several favourable physiological and anatomical features. It is important that this is not forgotten, just because this is a high risk condition. It is essential that the internal monitoring structure at Evelina continues to focus on the outcomes for this condition and seek further support or review if outcomes fail to improve. NICOR would be happy to assist in any way we can if further data analysis were required.

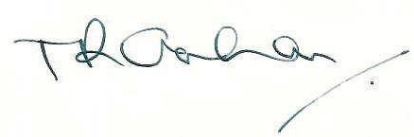
We would like to post your report on the NCHDA NICOR website to provide better context for this 'alert' line outcome. Please can you send to us a final analysis report which focusses solely on the Norwood procedure, and which you are happy to be published and made available by link to the NCHDA 2011-14 report, due out soon. This would of course exclude the Appendices which include individual patient details. You may wish to add information to your report following the comments listed here, particularly with respect to the third point.

Please contact us if you have any further questions, or concerns. We must emphasise the importance of continuing to maintain close surveillance of the real-time outcomes for congenital heart conditions in the interim between the annual NCHDA reports.

Yours sincerely,

Rodney Franklin, Clinical Lead National Congenital Heart Disease Audit, NICOR

Robin Martin, BCCA President



Tim Graham, SCTS President