The Leeds Teaching Hospitals NHS
NHS Trust

Contact: [redacted]
Date: 17 April 2015
Our ref: [redacted]

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Ms Melanie J Williamson
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West Yorkshire (Eastern)
Coroner's Office
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Dear Ms Williamson

INQUEST TOUCHING THE DEATH OF LEXIE LOUISE HARRISON (Deceased)

I refer to your correspondence of 20th February 2015, received on 27th February, regarding the inquest touching the death of Lexie Louise Harrison and the Regulation 28 Report to Prevent Future Deaths in respect of this case.

I can confirm that the contents of your Regulation 28 Report have been shared with the relevant staff to enable us to provide you with a comprehensive response.

We have considered the contents very carefully and the responses to the matters of concern you have raised in the report are detailed below.

In your report you highlight that

(1) *Birmingham Children's Hospital NHS Foundation Trust has a policy in place and/or guidelines dealing with paediatric endoscopy procedures for the banding of an oesophageal varix/oesophageal varices ("the procedure"). Neither Sheffield Children's NHS Foundation Trust nor Leeds Teaching Hospitals NHS Trust has such a policy and/or guideline. Both of the latter Trusts have undertaken the said procedure for many years.*

The management of **bleeding** oesophageal varices is a medical emergency and each of the three Paediatric Liver Centres in the UK (Leeds, Birmingham and London) have guidelines for the management of this emergency. As you will recall, the Leeds version of these guidelines was produced in evidence at the Inquest and includes recommendations about resuscitating the child; when to use antibiotics; when to pass a Sengstaken tube; the need to go to theatre for the oesophageal varices to be banded by a trained operator and, the post-operative management of the patient which included the use of an acid suppressing agent (omeprazole) and an antacid (sucralfate).

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Chairman Dr Linda Pollard CBE JP DL **Chief Executive** Julian Hartley

The Leeds Teaching Hospitals incorporating: Chapel Allerton Hospital, Leeds Dental Institute, Leeds Children's Hospital, Seacroft Hospital, St James's University Hospital, The General Infirmary at Leeds, Wharfedale Hospital, Leeds Cancer Centre

These guidelines are very similar to those used in both London and Birmingham and we have shared the Leeds guidelines with our referring Trusts including Sheffield Children's Hospital.

However, Lexie underwent **prophylactic** banding of her varices i.e. banding before they had bled. Currently there are no national guidelines for this procedure in children. The procedure is well established in adult practice and evidence has been produced in adult practice that it decreases the risk of spontaneous oesophageal bleeding. From 2006, the three Children's Liver Centres in the UK undertook a study to try to assess the benefits of prophylactic banding of oesophageal varices in children. [redacted] from Birmingham was the chief investigator for this study. Of the 65 children recruited to the study only 22 had varices large enough to be randomised into the banding or non-banding arms of the study. Results were assessed after at least 6 months follow up and 3 of the 10 children randomised to no banding did bleed, whereas 1 of the 12 children randomised to prophylactic banding bled a week after an elective banding episode. The numbers in this study were too small to provide evidence for the efficacy of prophylactic banding, although it was felt that that the procedure was well tolerated. This study is published in abstract form.

Following this study, the Birmingham Team has elected to offer prophylactic banding to any children with significant portal hypertension and found to have large oesophageal varices at endoscopy. They apply the same conditions as in the study which graded oesophageal varices as small - occupying less than a third of the radius of the oesophagus during maximum insufflation; moderate - occupying between a third and two thirds of the radius of the oesophagus; and large - occupying greater than two thirds of the radius of the oesophagus. As in the study only those with large oesophageal varices would be banded.

In Leeds, following considerable deliberation of the evidence available, the clinical team concluded that they should only offer prophylactic banding to children over 10 years of age who are found to have large varices. They felt that the evidence base is very much adult literature and therefore they can justify applying that to children over 10 years of age but should await further evidence before applying this management to younger children. In King's College Hospital, London, they do not undertake prophylactic banding at all in children.

There is no written protocol describing how to perform a banding procedure although it is described in textbooks. Trainees are taught this procedure as part of their education towards a certificate of completion of training in Paediatric Hepatology and in Paediatric Gastroenterology.

Point 2 of your report raises concerns that:

(2) *There is no standardisation of practices, (either locally or nationally), adopted by Consultants when undertaking the said procedure, by reason predominantly of there being no national policy and/or guideline in relation thereto.*

You have listed a number of points that a national policy or guideline should address namely:

(a) *Precise definitions of the grades of oesophageal varices;*
(b) *Which grades of varies should be subject to banding and which should not;*
(c) *Those patients who are deemed suitable for placing on a banding programme and those who are not;*

(d) *Once a patient is placed on a banding programme, the assessment process to be adopted prior to the said patient undergoing each procedure;*
(e) *Post endoscopy care, for example, the administration of sucralfate, frequency of basic observations;*
(f) *The steps to be taken to properly assess for and manage variceal bleeding, for example, the immediate use of antibiotics;*
(g) *The circumstances in which a Consultant is deemed to be competent to undertake the procedure alone or with supervision.*

The Leeds team have advised me that the standardisation of practices is to be discussed at the UK Paediatric Liver Steering Group which includes representatives from the three UK Paediatric Liver Centres and a representative of the Paediatric Gastroenterology Centres with an interest in hepatology.

Currently the three UK Paediatric Liver Centres have agreed to take part in an International study which asks the Centres to recruit patients following a surveillance endoscopy to each Centre's normal management i.e. no prophylactic banding; prophylactic banding in certain age groups; and prophylactic banding in most children. The centres will be required to keep a database of the outcomes of these procedures to get a better understanding of the efficacy and safety of prophylactic banding in children. This is not a randomised study but is deemed to be the only way to recruit large numbers of children.

In response to part (a),(b), (c) and (d) the definitions of oesophageal variceal grading is always subjective; hence there is a variety of grading scales in both adult and paediatric practice. However, there will be an agreed grading scale for the International study referred to above and this will be shared with all Centres. Photographs will be taken at endoscopy to standardise the grading. The results of this study should help clinical teams to make recommendations about who should be put forward for prophylactic banding; which grades of varices should be subject to prophylactic banding; and what the risks are of inducing bleeding by prophylactic banding.

In relation to parts (e) and (f), post-operative care is the same whether the patient undergoes prophylactic banding or banding after bleeding, and the Leeds team will follow their current guidelines as for management of bleeding varices.

Turning to point (g), all trainees specialising in Paediatric Hepatology are trained to band oesophageal varices during their National Grid training. Trainees in Paediatric Gastroenterology are trained in upper GI endoscopy and in the recognition of oesophageal varices. Some of these trainees will also elect to be trained in banding of oesophageal varices. These procedures are not common outside the three Liver Centres. However, it is often important that a Paediatric Gastroenterology service is able to band oesophageal varices in an emergency situation. To feel confident to be able to do this, these consultants would need to maintain their skills.

The assessment of competency in interventional endoscopy is under discussion at a national level within the Paediatric Gastroenterology and Hepatology College Specialty Advisor Committee, within the Royal College of Paediatrics and Child Health.

Thank you for bringing these matters to my attention. I do hope that this response has assured you that the Trust has given careful consideration to the matters of concern you have raised.

I note that you have shared your report with [redacted] of the British Society of Paediatric Gastroenerology, Hepatology and Nutrition. It would be very helpful to us if, in due course, we could be provided with a copy of their response.

If I can be of any further assistance please do not hesitate to contact me.

Kind regards.

Yours sincerely

Chief Medical Officer

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