County Durham and Darlington NHS
NHS Foundation Trust

Executive Corridor
Darlington Memorial Hospital
Hollyhurst Road
Darlington, DL3 6HX
e-mail: [redacted]

Your Ref: [redacted]
Our Ref: [redacted]

5th September 2016

H.M Coroners Office
PO Box 282
Bishop Auckland
Co. Durham
DL14 4FY

Dear Mr Tweddle

I am writing in response to the Regulation 28 issued on the 15th July 2016. The content of the Regulation 28 has been given due consideration and an action plan put in place to reduce any risk of future harm of a similar incident occurring to patients in our care.

Mr Kane was a gentleman with a history of severe alcoholic liver cirrhosis (Child's C). Prior to his death, he had multiple episodes of complication from the liver cirrhosis requiring admission to the hospital for treatment. One of the main issues was development of fluid in the abdomen (ascites) which required regular drainage via insertion of an abdominal drain (paracentesis).

Mr Kane unfortunately passed away on the 3rd of January 2016 at 12:40pm.

An inquest was held on the 14th of July 2016. The events were recognised as complications of necessary medical intervention with the cause of death as

1a) Peritonitis

1b) Bowel injury following paracentesis for ascites

1c) Alcoholic liver disease including cirrhosis.

Prior to this Mr Kane had undergone 5 large volume paracentesis of which the first two were done with ultrasound marking. The subsequent procedures were done without any ultrasound marking and there had been no complications.

with you all the way

The complication from this procedure was reported on the hospital's safeguard system and a root cause analysis (RCA) was undertaken. The procedure was performed by the appropriate level of doctor who has previously been assessed and had achieved documented competency for the procedure. A written consent was obtained from Mr Kane, the procedure was appropriately documented and no immediate complication was noted. A post-procedural plan was left in place and the patient had his observations monitored appropriately. Unfortunately a perforation did occur which subsequently led to generalised peritonitis.

The national guidance on management of ascites from the British Society of Gastroenterologist was reviewed (Moore et al, Guidelines on the management of ascites in cirrhosis, 2006) and the followings were noted from its recommendations

- Therapeutic paracentesis is the first line treatment for patients with large or refractory ascites.

- Large volume paracentesis with colloid replacement is rapid, safe and effective

There is no mention of the role of ultrasound guidance in the placement of ascitic drain. The regional guidelines from the Gastroenterology Specialist Training Committee do not recommend the routine use of ultrasound for therapeutic paracentesis in liver cirrhosis.

The European guidance on the management of ascites from the European Association for the Study of the Liver was also reviewed (Gines et al, EASL clinical practice guidelines on the management of ascites, spontaneous bacterial peritonitis, and hepatorenal syndrome in cirrhosis, 2010) and the followings were noted from its recommendations

- Large volume paracentesis is the treatment of choice for the management of patients with grade 3 ascites.
- Large volume paracentesis is a safe procedure and the risk of local complications, such as haemorrhage or bowel perforation is extremely low.

There is no mention of ultrasound guidance in the management of the ascitic drain in this document.

The most recent guidance was published by the American Association for the Study of Liver Disease (B Runyon, Management of Adult Patients with Ascites Due to Cirrhosis: Update 2012). The followings were noted from its recommendations

- Serial paracenteses are a treatment option for patients with refractory ascites (Class 1, Level C)
- Although more serious complications (hemoperitoneum or bowel entry by the paracentesis needle) occur, they are sufficiently unusual (<1/1,000 paracenteses) that they should not deter performance of this procedure.

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- In recent years, new paracentesis equipment (eg. multihole, large-bore needle and a pump) have become available that may improve the ease and speed of therapeutic paracentesis.

With regards to the use of abdominal ultrasound, the guideline states "If the fluid is difficult to localise by examination because of obesity, ultrasonography can be a useful adjunct in locating fluid and visualising the spleen and other structures to be avoided."

The current departmental practice is in keeping with published guidance in that paracentesis is normally done at the bedside with ultrasound guidance only being undertaken when there are concerns such as the presence of previous surgical scars or uncertainty on the presence of ascitic fluid. Ultrasound is not used routinely in large volume paracentesis in patients with liver cirrhosis who have well documented ascites and have previously undergone paracentesis.

As NHS professionals the gastroenterology team have discussed the serious incident with their colleagues' at the British Society of Gastroenterology and clarified that their current practice does meet the standard of our professional body. They appreciate that the field is continually evolving and that the hepatology section of the British Society of Gastroenterology is reviewing the paracentesis service as a whole.

The current guidance does not recommend the routine use of abdominal ultrasound in managing large volume paracentesis. It describes the procedure as effective and safe with a very low risk of local complications. The decision on whether abdominal ultrasound may reduce the risk of complication is not supported by current evidence at the present time, and any change to the guidance in the future will be appropriately incorporated in the Trust's practice. Notwithstanding this, the Trust has recognised actions that need to be taken both in the short term and longer term.

Recommendations

1. To continue to provide a timely and safe service to all liver patients who require paracentesis in adherence to national guidelines. All trainees will be provided with a copy of the guidance.

2. Ensure that there is a clear audit trail of patients having undergone paracentesis within CDDFT. This will include the development of a proforma and database which will include

    i. Patient demographics
    ii. Date procedure performed
    iii. Clinician performing the procedure
    iv. Any complications during or post procedure

A lead person will be identified on the Acute Medical Units and Gastroenterology wards across CDDFT and a meeting will be held 3 monthly to reflect on the management of this patient cohort.

3. All procedures will be performed between the hours of 8am and 8pm so that any complications can be identified and escalated to a senior decision maker.

4. A patient information leaflet will be available to all patients at the time of giving informed consent which outlines the procedure and possible complications. This will aim to be in place by 1st September 2016.

Should you have any outstanding queries please do not hesitate to contact us again.

Yours Sincerely

Sue Jacques
CHIEF EXECUTIVE

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