Royal College of Obstetricians & Gynaecologists

Dr Simon Fox
His Majesty's Senior Coroner Area of Avon
The Coroners Court
Old Weston Road,
Flax Bourton
BS48 1UL

17 January 2025

Dear Dr Fox

Re: Lisa Gale - deceased
Your ref: [redacted]

Thank you for your Regulation 28 Report to Prevent Future deaths following the inquest into the death of Lisa Gale dated 12 November 2024.

This loss is a devastating tragedy for the immediate and the wider family, and the healthcare professionals involved. We would like to begin by extending our deepest and heartfelt condolences to Lisa's family for their profound loss.

This response has been developed following input from members of the RCOG Patient Safety Committee and Senior Officers of the College.

We recognise and respect the narrative conclusion from the inquest that Lisa died of natural causes subsequent to developing a rare but serious condition, Acute Fatty Liver of Pregnancy (AFLP).

We also recognise the matters of concern as outlined in your letter as follows,

1. Blood was taken for liver function test (LFTs) on admission before her condition was diagnosed.
2. Lisa's LFT's were grossly elevated (normal range in brackets)
    a. ALT 612 (10-50)
    b. Bilirubin 122 (<21)
    c. Creatinine 168 (45-84)
3. This was due to a potentially fatal condition AFLP from which she subsequently died.
4. Despite being grossly elevated, the results once obtained in the laboratory were not phoned through by the laboratory staff to the clinical staff.
5. This was because the Royal College of Pathologists guidelines for urgent reporting only provides for the same levels above 750 ALT, 300 for bilirubin and 354 for creatinine and does not provide for different reporting levels for those taken in pregnant women.

6. This is despite pregnancy specific conditions such as AFLP being potentially fatal at much lower levels of abnormal LFTs that those set currently by the Royal College of Pathologists.
7. As a result there was a delay in diagnosing her ALFP and starting appropriate treatment.

Following review of the Regulation 28 Report it's recognised that there are key themes identified here which the College has provided clarity on over the past few years through its various initiatives. These include development of clinical guidance and good practice papers recommending appropriate escalation of clinical concerns, multidisciplinary working and seeking timely advice from clinical experts especially in case of rare medical conditions. Lisa had developed a complication of pregnancy that is very rare. In such situations, it is essential that the wider multidisciplinary team including obstetric physicians, anaesthetists and intensivists are involved in care provision, especially when there are severely abnormal test results and/or clinical deterioration.

This case highlights the delay in diagnosis of the severity of condition, resulting from the laboratory not using pregnancy specific levels of liver enzymes for reporting of abnormal results. The guidelines from the Royal College of Pathologists *'The communication of critical and unexpected pathology results' (2017)* recognises that there are variation in results phoned and suggests that this should be set by local need. The RCOG will review the response from the Royal College of Pathologists following this Regulation 28 Report and ensure that this is appropriately communicated with its members and included within relevant clinical guidance.

The RCOG however, recognises that there is also an obligation for clinical teams requesting investigations to review the results in a timely manner, depending on the severity of the clinical condition. In the current digital era, laboratory results are available on clinical systems and these should be reviewed by staff caring for the woman. **Guidance on the clinician responsibilities is outlined in the GMC Good Clinical Practice 2009, NMC Code of Conduct 2008 and the BMA Acting upon electronic test results (updated in June 2024).** Individual trusts/organisations will have specific guidelines applicable to their electronic patient records and it is expected that these, in line with GMC and BMA guidance, would outline the responsibilities of the clinical staff and potential time scales expected. The RCOG feel that this responsibility lies at the organisational level and should be communicated to the NHS-England & NHS in the devolved nations.

There is no RCOG guidance on the diagnosis and management of AFL in pregnancy. This is due to the rarity of the condition and the requirement for early intervention by specialist teams should the condition be suspected. The College does provide an online learning resource outlining the key clinical features, investigations, differential diagnosis, and management options. This resource can be found at: Acute fatty liver of pregnancy Key elements of care relate to the early diagnosis and escalation to the multidisciplinary team which includes: haematologists, hepatologists, anaesthetists, intensivists and the local or regional liver units.

The RCOG emphasised the importance of escalation as a key priority in provision of safe care within its Each Baby Counts and the Avoiding Brain Injury in Childbirth Programmes. There are a number of resources available through the College to support Trusts in a Quality Improvement approach to improve escalation in clinical situations.

We are aware that you have written to the Royal College of Pathologists, and we would suggest that their guidance and the thresholds contained within *'The communication of critical and unexpected pathology results'* is reviewed and amended to take account of the needs of pregnant women.

The College's commitment firmly lies in improving maternity safety. This encompasses elevating care standards through clinical guidance and multidisciplinary training. The College strongly advocates the importance of the Trust's guidelines being aligned with national guidelines.

Thank you for bringing this to our attention. I hope this is a helpful response to this matter.

Yours sincerely,

[redacted]

[redacted]

CEO Royal College of Obstetricians and Gynaecologists