King's College Hospital NHS
NHS Foundation Trust

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Mr Andrew Harris
Senior Coroner
Southwark Coroner's Court
1 Tennis Street
Southwark
SE1 1YD

Dear Sir

Response to Regulation 28 Report to Prevent Future Deaths: Edward Hearn (Deceased)

We write further to the above Report dated 8 May 2019 and detail the Trust's formal response below.

As a preliminary point, we note that in relation to the one matter of concern you raised in your Report and and which was directed to the Trust, you state that "…*it did not contribute to* [the] *death*" of the Deceased, on page 9 of your Judgment dated 8th May 2019.

Matter 1

The finding of a high globulin by a laboratory from a blood test in A&E was not followed up by either the laboratory or A&E department. It was not in College guidelines of tests, which required urgent notification. It was indicative of a fatal disease, which was not diagnosed for approximately another 4 months. I accept the professional opinion of the haematologist that this was a system failure, which is not acknowledged by the Trust. The laboratory suggested an additional action to have an automated comment but that would still not deal with the problem of reports returning to physicians in secondary care. Evidence was heard that there is inconsistency in laboratory repeating and alerting of clinicians even between hospitals in the jurisdiction, and insufficient evidence of a safe system within the Trust.

Trust response:

The Trust recognises that a raised globulin (a constituent of total protein, which itself was elevated) as a component of liver function tests (LFTs) was not acted upon following an inpatient medical admission with pericarditis in August 2017, and that multiple myeloma was diagnosed in December 2017, when the Deceased presented at the Trust.

It is however the case that there are multiple common causes for elevated protein, including dehydration, chronic inflammatory states, alcoholic liver disease,

autoimmune disease, amyloidosis (build-up of abnormal proteins in organs), infections, hepatitis B or C, HIV or AIDS, monoclonal gammopathy of undetermined significance (MGUS), and multiple myeloma.

The reason for the different laboratory practices of two of the Trust hospitals, the Princess Royal University Hospital (PRUH) and King's College Hospital (KCH), is that the critical difference between the PRUH and KCH, is that as the Institute of Liver Studies is located at KCH, the patient population treated by KCH has a high prevalence of HIV and hepatitis, and therefore a large portion of KCH patients will have a raised globulin level. Accordingly, carrying out extensive investigations on every sample with high total protein at KCH has poor clinical utility.

The poor clinical utility of such an approach is reflected by the fact that two similar size neighbouring NHS Trusts, Guy's and St Thomas' NHS Foundation Trust, and University College London Hospitals NHS Trust, do not perform routine globulin testing as part of the liver profile.

The Trust follows the Royal College of Pathologists' recommendations by telephoning out critical results to the requesting clinician or teams, 24 hours a day. Neither the recommendations in place at the time, '*Out-of-hours reporting of laboratory results requiring urgent clinical action to primary care: Advice to pathologists and those that work in laboratory medicine, November 2010*', nor the recommendations superseding that document, '*The communication of critical and unexpected pathology results, October 2017',* identify elevated total protein as a result that needs to be communicated to the requester as a critical limit.

The Emergency Department (ED) treating doctor did not note the raised total protein and globulin found on the sample sent on 12 August 2017. This case is being used to highlight to ED medical staff the importance of noting abnormal blood test results and ensuring appropriate follow-up (outpatient or GP). Work is also ongoing to highlight to clinical teams the importance of reviewing test results on inpatients daily. The Trust uses a system called 'Safety Net' to circulate key learning themes for clinical teams to be aware of. A Safety Net is being prepared in relation to raised protein/globulin and the association with multiple myeloma. The 'Screening Diagnostic Improvement Group' looks at systems to ensure that test results are reviewed promptly to reduce clinical risk. This Prevention of Future Deaths Report will be reviewed in that meeting to ensure that relevant actions are put in place to prevent a recurrence. The timetable for the above actions is from the time of writing (for the work with ED medical staff and highlighting to the clinical teams), whilst the Safety Net will be prepared by the end of August 2019. The Screening Diagnostic Improvement Group will meet on 19 August 2019, and this group's work remains ongoing.

We agreed that KCH and the PRUH standard lab comments to GP's for outpatient Biochemistry will be aligned. We plan to review the Biochemistry profiles that we provide to GP's and to implement these changes by the end of July 2019, (as the KCH and PRUH laboratories are currently part of a platform alignment project which requires significant IT support), with a view to standardising reporting across the Sustainability and Transformation Partnership. We plan to audit the number of referrals to the Plasma Cell Disorders service one year after instituting this change.

We trust you are satisfied with the response to the above matter of concern you have raised.

Yours faithfully

Legal Services