NHS
East Lancashire Hospitals
NHS Trust
A University Teaching Trust

Trust Headquarters
Royal Blackburn Teaching Hospital
Haslingden Road
Blackburn
BB2 3HH

30 June 2021

<u>PRIVATE & CONFIDENTIAL</u>

Dr James Adeley
HM Senior Coroner
Lancashire and Blackburn with Darwen

Sent via email only

Dear Dr Adeley,

Re: REGULATION 28 REPORT TO PREVENT FUTURE DEATHS –
Mr Frank Medley

Please find below response detailing the action taken or planned to address the matters of concern raised in relation to the above case. A narrative overview is provided as summary, followed by our detailed action plan with embedded evidence.

A core group has been established to oversee the implementation of this action plan led by the Associate Director of Quality and Safety, the Deputy Medical Director and Director of Nursing to ensure senior oversight of the issues raised. Please be assured that this group will continue to meet until all actions have been embedded as business as usual into Trust processes with clear reporting and monitoring processes in place.

MATTERS OF CONCERN

(1) The Trust has an ineffectual system to detect adverse outcomes where the patient is transferred to a tertiary centre for treatment and subsequently dies;

(2) The Trust's review of this case was seriously deficient in the following instances:

   a. At no point were members of the family spoken to for their views or concerns regarding the death up to and including the inquest.

b. The date of death was 14 July 2019. The Report was incomplete eight months later in March 2020 when it was suspended during the first Covid wave. The report was not completed before the inquest on 23 February 2021. This is not in accordance with NHS guidance;

c. The case was inappropriately allocated to a structured judgement review;

d. The "Summary of the Incident" contains substantial factual inaccuracies to such an extent that it is deeply misleading;

e. Mr Medley's death was due to complications of sepsis. The report failed to note that due to admission for query sepsis at the same hospital 11 days before, that:

    i. the EWS score was sufficient to trigger the septic shock pathway;

    ii. the nurse correctly identified that the septic shock pathway should be followed and drew this to the attention of "a doctor";

    iii. that due to the referrals taking place between specialties at this time the relevant speciality responsible for dealing with this issue cannot be identified and made no entry in the medical records (this raises similar issues to those concerns raised in the Regulation 28 report concerning Mrs Gillian McKinley at the same Trust);

    iv. that, despite the patient observations being readily available to the treating consultant orthopaedic surgeon the following morning and the nurse having documented the septic shock pathway should be activated in the notes, the consultant orthopaedic surgeon failed to note this both at the time and during the preparation of his witness statement for the inquest;

    v. the error was only detected by the Trust's Legal Services Department when preparing for the inquest 19 months after the event.

e. That the consultant physician responsible for Mr Medley's care appreciated that his symptoms constituted a medical emergency, that the MRI scan should be completed on 2 July 2019 but took no action himself to expedite the scan. There is no documented evidence in the medical records regarding junior doctor's attempts to expedite the scan;

g. The consultant physician responsible for Mr Medley's care after input from the neurologists on 3 July 2019 made no attempts to expedite the scan or to contact tertiary neurosurgical services;

h. On 2 July 2019 the treating clinicians suspected infective complications high in the cervical spine but only undertook a chest x-ray and blood cultures without considering sending a urine sample for analysis, considering an echocardiogram or OPG:

i. Mr Medley's scan should have been completed within 24 hours of request in accordance with NICE guidance, which was not cited anywhere in the report, and that the priority attached to the scan on 2 July 2019 placed Mr Medley in the lowest priority category when he should have been in the highest priority category. This mistake was repeated on 3 July 2019 when Mr Medley was placed in the middle priority category. There is no documentation as to any rationale for the priority allocation;

j. The scan when it was performed on 5 July 2019 was not a contrast scan necessary to accurately delineate foci of infection resulting in a further scan using contrast to be performed later that day.

k. That prioritisation of scans within the radiology department depended to a considerable extent on a personal attendance by clinicians at the department or speaking to radiologists rather than solely on clinical need;

l. There was insufficient senior clinical oversight of the conclusions drawn.

(3) The Department undertaking reviews of adverse incidents appears to operate independently from the Legal Services Department

(4) The delay in obtaining the scan was partly attributed to a lack of MRI scanner capacity. At the inquest the Trust could only provide conjecture as to whether or not alterations to scan capacity had made any difference to the time taken to obtain urgent scans

Radiology actions currently underway

Access to Diagnostic Imaging

In October 2020, ELHT commissioned two new Magnetic Resonance Imaging (MRI) systems on the Burnley General Teaching Hospital site. These scanners were replacement assets identified as part of the government initiative which aimed to replace all MRI systems over 10 years old. The initial intention was to replace the Philips MRI system at Burnley and the Trust owned asset at RBH. However, due to

increasing demand and the escalation of the COVID pandemic, these systems have remained operational.

The two new MRI systems at Burnley are now fully operational and plans are progressing to replace the oldest asset on the Royal Blackburn site. We are

anticipating that this will be finalised in the coming weeks with a view to commissioning of the new scanner before the 30th September 2021.

Following this, the second asset on the Blackburn site will also be upgraded; this is expected to be completed in late 2021. On the back of these two replacements, the service at ELHT will be second to none with state of the art MRI assets across East Lancashire.

The Radiology in patient dashboard has been developed using our business intelligence system and is currently used in key areas of the Trust. Roll out of the dashboard is progressing. The next steps are to demonstrate and share access to the dashboard at the Nursing & Midwifery Forum, Foundation Teaching and Clinical Leadership to accelerate roll out to the wards and clinical services.

Improving coordination and communication between wards and Radiology department

Radiology in-patient Co-ordinator/Navigator role was established in November 2019. This role has supported improved patient flow and communication between referring clinical teams and the radiology team. Cover is provided 52 weeks of the year by the Radiology Administrative function. A Standard Operating Procedure describing the functions of this role and the actions required by referrers to improve access and efficiency in radiology is being developed to support this function. Communications have been clarified to advise on the most appropriate manner for teams to access the In-patient Navigator. This is the route that teams will use to find out when a scan is planned and also to expedite imaging which has not yet been planned.

Clinico-radiological meetings were established in November 2020 and now occur twice weekly on Monday and Friday on AMU. It is intended that when possible, a third meeting will be provided on a Wednesday to provide better support through the working week. This development allows a forum in which difficult cases can be discussed and advice and guidance provided on the optimum imaging technique and/or interpretation of unusual report findings and has been a significant success; building improved relationships and communication between clinical teams on AMU and the radiology directorate. This meeting explicitly addresses the human factors highlighted in this case; ensuring that patient management is equitable regardless of the staff on duty and that clinical discussions can be held without personal attendance.

Reviewing the use of NICE guidance to inform prioritisation of referrals

The Internal Professional Standards (IPS) have been revised by the Radiology Directorate to support the requirements for imaging in this cohort of patients. The compliance with the standards are monitored weekly at the Radiology Performance

Meeting. Phase two of the Power BI dashboard development is to include the IPS for in-patient turnaround times. We are also working on a traffic light system which will demonstrate, at a glance, the average waits for radiology diagnostics supporting the need to expedite urgent imaging. The first draft of the traffic light system is now "live" on the radiology intranet site and is being validated prior to display in a more prominent area of the Trust intranet.

We are currently also reviewing the In-patient priorities applied at vetting stage by Radiology. It is anticipated that these will be time-based allowing a better understanding of the priority applied at vetting; aligned to NICE guidance for urgent imaging where stated. This will allow pressures within the system to be escalated so that clinical decisions can be made on how best to proceed.

Reviewing the appropriate use of contrast

Mr Medley's case was discussed at the Radiology Directorate Meeting on 19th March 2021 as evidenced by the minutes of this meeting. All decisions were viewed on the electronic system and the team consider the decisions made to have been appropriate based on the clinical evidence available at the time.

The MRI scan in question was vetted on 2nd July 2019 by a senior Consultant Radiologist and CRIS (Radiology Information System) records demonstrate that it was felt that the clinical question posed by the clinical team could be adequately answered by an MRI scan without the administration of contrast media. The referral was re-vetted the next day (3rd July 2019) by a second Consultant Radiologist who also agreed that contrast media was not required.

Following completion of the scan, a 3rd Consultant Radiologist provided the final report and it is evident that the clinical question had been suitably answered and a scan following administration of contrast media was not considered necessary. It was advised by the Consultant Radiologist who reported the scan that a CT Thorax, Abdomen and Pelvis was performed and this was requested on 6th July 2019.

Our Clinical Director has since confirmed that the department does not administer contrast media in cases where discitis or para-spinal abscesses are queried. The rationale for this is that these patients are commonly in significant pain and this lowers the tolerance of the scan owing to additional time taken to complete the

examination. Instead, we undertake additional sequences (STIR) which clearly demonstrate abscesses or discitis which is much faster. To summarise, it is felt that contrast media should generally only be delivered to improve lesion conspicuity in areas of low inherent contrast resolution or to characterise a lesion, which was not requested in this case.

Whilst the Lancashire Teaching Hospitals Consultant Neurosurgeon requested a scan with contrast media, it is presumed that this was due to the requirement to answer a different or additional clinical question. In such circumstances, we would be happy to provide a further scan with contrast media but it is felt that this has limited diagnostic utility.

As such, having reviewed this case again we are happy that the correct decision was made in providing a scan without intra-venous contrast media.

Action taken to strengthen and integrate and support the Trusts Legal Services

A weekly complex case coordination meeting has been introduced to enable early coordination with legal services and complaints team, to agree appropriate routes for investigation and ensure all families concerns are understood. This has enabled a full review of case currently listed for inquest and any potential delays or concerns regarding linked investigation processes. This complex case group coordinates all cases that cross divisions, are listed for an inquest, have an ongoing investigation of any kind (eg complaint/SJR/LeDeR) and ensures families are contacted by an allocated family liaison officer at as early a stage as possible.

The Trust's Legal team are currently advertising 2 additional solicitor posts and an inquest coordinator. Inquests attendance and statement writing training provided in partnership with Hempsons on 22nd June. Planned dates for a continued programme of training is awaited.

Divisions have taken responsibility for coordinating statements from clinicians in support of inquests, through their clinical governance teams. Statement management is now visible to all teams within governance; using the complex case meeting to escalate both statements required and outstanding, for action.

Follow up ME consideration of deteriorating pt transfers

You raised a concern re the lack of systems to follow up patients who once transferred go on to deteriorate in other Trusts. It has proved difficult to achieve this from a systems perspective. Achieving this is heavily reliant on the Trust being informed of a patient having unfortunately died, in a timely manner. Mr Medley's case has clearly demonstrated the impact of the absence of this system, but no Trust we have spoken to has been able to describe a standardised systematic approach to

achieving this when asked. Recognising the focus and role of the Medical Examiners, across all Trusts; our Lead Medical Examiner has asked the Regional Team to consider whether these roles could support with this issue. We await a response.

Whilst we recognise that Mr Medley's care was not reviewed until well after his death. The internal processes designed in line with the national guidance, did escalate the investigation from Structured Judgement Review to Root Cause Analysis appropriately. However this did not facilitate early learning, nor did it provide the family with adequate opportunity to discuss any concerns with our clinical team, which we regret.

Action taken to improve the Trust's Serious Incident Investigation processes

A full review and update of investigation process has been completed, in line with Patient Safety Incident Response Framework. Funding has been agreed in support of a proposal to develop a cohort of investigators and family liaison officers with allocated time, specific training and administrative resource to enable timely and thorough investigations. This team will report to the Assistant Director of Safety and Risk and work in partnership with the legal team to coordinate investigations and learning on behalf of the trust.

A full policy update is underway in line with the above mentioned proposal including new audit measures against investigation standards which will be monitored at Trust-wide Governance meeting.

A weekly Executive review of Divisional investigations due at SIRI Panel has been introduced from 21 April to monitor the quality of reports prior to submission. This aims to ensure that the quality of the investigation may be identified earlier and at a senior enough level to require any further improvements to be made without delaying the process or submission to your court. A pro forma for Serious Incident investigations, with a front sheet for sign off of each stage, has been developed in line with the National Patient Safety Strategy and PSIRF requirements; which prompts investigators to clearly link the problems, learning and recommendations to individual actions that are focused on preventing the same incident reoccurring. I understand a pilot version of this proforma was received favourably by one of your team at an inquest last week.

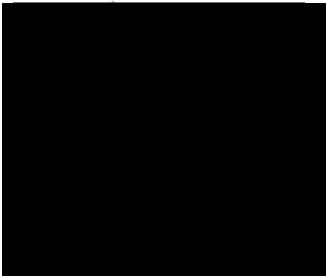
Future assurance monitoring

The action plan implementation will continue to be monitored at Trust Wide Quality Governance meeting and will report to the Quality Committee until all actions have been embedded as business as usual with monitoring processes in place.

The CCG and NHSE/I have been involved in the creation of this action plan and assurance on the implementation will continue to report to the Trust's monthly Quality Review meeting with the CCG.

Please do not hesitate to contact me with any questions or concern regarding the content of this response; we are keen to work with the Coroner to demonstrate our ongoing commitment to delivering the safest care possible for our patients.

Yours sincerely



Executive Medical Director & Consultant Urological Surgeon
East Lancashire Hospitals NHS Trust

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Appendix 1

Regulation 28 Action Plan with embedded documents

Matter of Concern	Objective	Evidence provided	Assurance process
The Trust has an ineffectual system to detect adverse outcomes where the patient is transferred to a tertiary centre for treatment and subsequently dies;	To identify opportunities to develop a network to support communication between hospitals following transfer of patients.	Lead Medical Examiner from ELHT has proposed that the Regional Medical Examiner group consider how this feedback mechanism might be established. Awaiting decision.	To be confirmed
The Trust's review of this case was seriously deficient in the following instances	To improve the timeliness, quality and oversight of the Incident Investigation process. Monitoring SIRIs completed within 60 day (not relevant for this case)	Complex Case Review (CCR) group established, coordinating investigations across open inquests, RCAs, complaints, SJRs and LeDeR reviews. CCR also monitors application of Duty of Candour, contact with families and allocation of Family	Weekly complex care meeting monitors and escalates outstanding or delayed investigations and contact /feedback with families Wednesday Exec SIRI review meeting will ensure all requirement of front sheet are

	Development of joined up pathway confirming which type of investigation should be considered and at which stage To ensure appropriate clinical senior oversight of SIRI prior to completion	Liaison Officers. Front sheet for all RCAs introduced ensuring all stages of investigation complete prior to sign off. Exec sign off meeting in place weekly, to oversee the quality of investigations and enabling SIRI panel to focus on coordinating and learning from action plans. Exec have agreed to fund a central team of lead investigators to work with Expert/Allocated Clinicians. Recruitment is due to start in July 21.	met and monitored, escalating to SIRI panel CCG SIRI Dashboard to continue to monitor completion of Duty of Candour
The Department undertaking reviews of adverse incidents appears to operate independently from the Legal Services Department	To ensure the legal team are integrated into decision making processes within the governance department.	Legal team are core members of Complex Case Group and inform all decisions made re management and prioritisation of investigations	Complex Case Group reports exceptions through divisional governance leads and SIRI panel

		Legal team are currently advertising 2 additional solicitor posts and an inquest coordinator. Monthly inquests update meeting established with Medical Director Inquests attendance and statement writing training provided in partnership with Hempsons on 22nd June. Planned dates for continued programme of training awaited.	
The delay in obtaining the scan was partly attributed to a lack of MRI scanner capacity. At the inquest the Trust could only provide conjecture as to whether or not alterations to scan capacity had made any difference to the time taken to obtain urgent scans	Development of improved communication pathway between ward and Radiology Department. (this also links to the previously described IP dashboard) Maintain turnaround time	Radiology IP Co-ordinator role established and operational. This Administrative function acts as a conduit between referring clinical teams and radiology Consultants in support of appropriate escalation.	Dashboard development complete. Roll out of system has commenced but not fully implemented." All referrals received are vetted/justified by a suitably trained Practitioner in

	for scanning of MRI IPs at or below 48 hours where possible Development of review of transfer out of hospital pathway which includes timeframes and responsibilities for follow up Implementation and embedding of NICE guidance into standard radiological practices Guidance on when and how to use contrast to be reconsidered. However, the vetting/justification of the scan in question did take place and it was felt that the clinical question could be adequately answered without contrast media.	Capacity & Demand exercise to support revised booking templates and access to IP scanning slots. Sharing of incident with Radiology Directorate team. Requirement to adhere to NICE guidance reiterated. Review of IPS for radiology at weekly performance meetings by radiology management team. Any actions required to improve performance are escalated each week. Consensus view on requirement for contrast media in clinical presentations such as this to be considered. Set up a biweekly radiology/AMU clinical meeting to discuss difficult cases, build	Radiology. Initial clinical urgency is based upon the clinical information documented on the referral/e-referral. Internal Professional Standards (IPS) to be reviewed to measure performance against IP turnaround time of less than 48 hours (currently measure at 12 and 24 hours for ED, Assessment units and standard IPs)

		interdepartmental relationships and knowledge sharing and teaching