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Integrated Care
NHS Foundation Trust

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11th August 2022

Private and confidential
To be opened by the addressee only
HM Coroner, Mr Chris Morris
Via Email

Dear Mr Morris

I am writing further to the inquest touching upon the death of Derek Holmes (who died on 2nd December 2021) which concluded on 20th June 2022 and the subsequent Regulation 28 Notice issued to the Trust. I hope to be able to build upon the issued raises within your report, and set out below my response. I have outlined these in order of the concerns raised.

Concern 1:-
Prior to the inquest the Trust acknowledged and shared with Mr Holmes' family and with Her Majesty's Coroner that the root cause analysis contained errors, which had been identified as part of the inquest preparation. As an immediate response to this, an addendum was added to the investigation report and a written explanation and apology to Mr Holmes' family was provided.

In response to the concerns raised, the Trust instigated an immediate strategy meeting with all the Divisional Directors to collaborate, assess and understand the actions required to address the issues raised. As a result, a number of key actions have been taken and are planned to strengthen and improve the root cause analysis investigation and quality assurance processes. These are listed here as two core themes; Training and Policy and process.

<u>Training</u>

Whilst basic training has been provided for Trust members of staff in incident management over the last two years and support has been offered, and comprehensive, individual and bespoke support has been provided to individuals completing investigations, the delivery of largescale comprehensive investigation training has been challenging in the context of Covid and the Covid response. The reasons for this are twofold; both in terms of the redeployment of key members of the corporate governance team to support clinical areas, and in terms of the ability of staff to attend, when the training is not mandatory.

The Trust recognise the importance of comprehensive investigation training to underpin the methodology and rigor that must be applied to this process. As such, the Trust are providing root cause analysis investigation training days which commence in September 2022, and

are also scheduled to run in October and November. Following these initial sessions, these are planned to continue through 2023. Each training sessions runs over the course of one full day with availability for key staff to attend each session.

This training will provide Root Cause Analysis training in line with national requirements. The course will offer a practical guide to investigations with a focus on systems-based patient safety investigation as proposed by the forthcoming National Patient Safety Incident Response Framework which emphasises the requirement for investigations to be led by those with safety investigation training and expertise, and with dedicated time and resource to complete the work. The course will provide staff with the key skills and knowledge that they will require to conduct an investigation effectively and accurately.

The training day contents will support staff through the seven-key stages to conducting a high-quality investigations and it includes; planning and managing investigations, interviewing staff, mapping and triangulating information, using appropriate analysis tools to establish contributory factors to ensure that comprehensive and accurate reports and action plans are produced.

The training has been targeted initially to key members of clinical and corporate teams who are likely to undertake root cause analysis or complaints investigations as part of their role. Once undertaken the Integrated Governance Team will hold a live register of staff who have completed root cause analysis investigation training. This is to ensure that on the commissioning of any new investigation, at least one member of the team have completed this training.

The Trust has used the case of Mr Holmes and subsequent learning to develop a seven minute briefing which has been shared widely across the Trust, to reemphasise the importance of triangulation and accuracy of data used within any investigations including root cause analysis and complaints.

Overseen by the Head of Investigations, Learning and Audit a resource tool kit for investigators has been reviewed an updated to include guidance on triangulation, factual accuracy and a data mapping tool which should be included as part of the investigation process. The tool kit will be provided to each investigation team on the commencement of a root cause analysis investigation.

Process and Policy

In regard to the errors identified within the root cause analysis, steps have been taken following the inquest of Mr Holmes to strengthen the process in which these documents are checked for quality and factual accuracy, with increased divisional ownership and oversight. The Safer Care Assurance Process has been revised to explicitly include the expectation for all investigations of this form to be reviewed and approved as an accurate account of the incident and learning by an appropriate Matron. Although it is not possible to completely remove the human factors which can affect this process, it is anticipated that this should reduce the opportunity for errors such as those identified in the root cause analysis document presented in relation to Mr Holmes.

In addition to this, the Safer Care Assurance Process also includes a caveat that the request for root cause analysis is reviewed by the Head of Nursing and Assistant Director of Integrated Governance should the patient die during the investigation process. This is intended to provide an opportunity to stop and reassess whether continuation of the enquiries is the most appropriate cause of action, or whether an additional or more comprehensive form of investigation is required.

Prior to the inquest of Mr Holmes, I had instructed a review of the Trust's Incident Reporting and Incident and Complaints Investigation Policy. This was in the context of Patient Safety 2, as information and resources become available to inform the Trust approach. The learning from this inquest has further informed the quality assurance process. The review and update to the Policy has been undertaken by the Head of Investigations, Learning and Audit and Head of Nursing for Professional Standards and Assurance, overseen by the Assistant Director of Integrated Governance.

The policy builds of the principles of good compliant handling that have been recommended by the Parliamentary Health Service Ombudsman. This includes the Trust's approach to managing the complaints, responding to complainants and keeping people informed about the concerns that they raise. As part of this approach, learning will be disseminated across the organisation regarding the required methodology and how we respond and support people when they raise concerns. Ongoing monitoring of the policy will take place through local audits of informal concerns and formal investigations. This will support the completion of other investigations such as root cause analysis and use the same principles so that these can be communicated across the organisation, alongside learning from investigations.

As stated above, the Incident Reporting, and Incident and Complaint Investigation Policy is currently being reviewed alongside the NHS England Patient Safety Framework to ensure that this aligns. The Policy will outline the process for identifying, reporting, managing, investigating and learning from patient safety incidents, including Serious Incidents (SIs), Never Events, incidents which are notifiable under the Trust's Being Open Policy that supports Duty of Candour. The purpose of this review of policy is to support a systematic, compassionate and effective response to patient safety incidents; with a clear focus on learning and continuous improvement. This work will ensure accountability, compassion, openness and ownership of improvement and will provide a basis for local training and development. This policy will describe in detail the approach in place to ensure that the Trust is prepared for patient safety incidents so that staff understand what to do and how to behave when an incident happens. This will also include the Trust, Divisional and Directorate governance arrangements (including key organisational roles and responsibilities) to ensure an effective response.

The management and oversight of investigations, complaints and incidents, including time taken to conclude is undertaken in our Service Quality and Assurance Group, chaired by myself. As the operational forum for discussions regarding governance, effectiveness of and adherence to this policy will continue to be undertaken through this group, providing assurance through to our Quality and Governance Committee, led by Non-Executive Director members and to Trust Board.

Concern 2:-
The Trust acknowledge that the root cause analysis investigation for Mr Holmes missed the opportunity to include the wider factors present during his care and treatment at Tameside and Glossop Integrated Care Foundation Trust. We also acknowledge that although this was included within the complaints investigations which had been completed and shared with Mr Holmes' family, these had not been disclosed to Her Majesty's Coroner prior to or during the inquest.

Following the inquest I commissioned an external review of the complaint investigation relating to Mr Holmes, to provide an independent lens upon the findings and learning from the investigations completed by the Trust. The independent review concluded that the Trust had *"answered in detail all the concerns raised by the family in the letters they have submitted and has responded to them in a timely manner".* They also noted that *"that where the ICFT (Integrated Care Foundation Trust) have identified lapses in care during their investigations they have clearly apologised to the family and articulated the steps they have taken to share the learning with the teams involved and wider across the ICFT".*

May I take this opportunity to apologise that these documents were not disclosed to you as they should have been and that as such, opportunities were missed to provide you with a complete picture of the steps taken and information provided to Mr Holmes's family. This should not have happened and I am aware that the team have reflected upon this oversight outside of this process. I hope that the inclusion of this information from our third party review provides you with assurance. Further response to this concern has been organised into two themes; oversight and learning.

<u>Oversight</u>
Although the Trust review all cases of newly commissioned root cause analysis investigations to understand other investigatory processes which may be underway for the patient, this has been strengthened to include triangulation between the Head of Investigations, Audit and Learning and Head of Nursing for Professional Standards and Assurance. As part of this, a list of all new investigations commissioned as part of a complaints or patient safety process is shared with the Head of Nursing for Professional Standards and Assurance on a weekly basis for cross reference against ongoing root cause analysis which might be ongoing as part of our safer care processes. This should also support the identification of any patient deaths, prompting a case review as outlined earlier in this letter. While this process is in its early stages, this is supported by an automated report produced by the Ulysses Safeguard system which indicates patients who might have simultaneous processes ongoing.

The Trust has also introduced a bimonthly oversight meeting for triangulation of scheduled and new inquests with existing or newly instructed investigatory processes, with Head of Investigations, Audit and Learning, Head of Assurance, Compliance and Governance, Head of Nursing for Professional Standards and Assurance and Legal Services Manager, chaired by the Assistant Director of Integrated Governance. This process has sought to ensure the improved triangulation of current investigations and support early identification of any changes in status to the patient (such as their death) or delays in conclusion. Patient tracking list methodology will be used to inform this process and ensure that there is oversight of all learning activity associated with investigations and inquests.

The development of a clinical review process is ongoing at the time of preparing this response to ensure that all incident investigations, inquest statements and reviews undertaken as part of our learning from deaths process are assessed and considered cohesively before an inquest. This aims to ensure consistency across all streams of investigation and learning and will help provide an additional clinical check to ensure that any potential discrepancies are responded to, enhancing our approach to learning.

The documentation of oversight and Divisional approval of investigations has been amended and strengthened following the learning from Mr Holmes' inquest. The root cause analysis template has been updated to include evidence of review and approval by senior members of the Divisional operational, nursing and clinical leadership teams. It is proposed that any root cause analysis document will not be accepted for review at an assurance panel if this information is not completed. A process has also been introduced to undertake a quality assessment of investigations undertaken as part of our falls pathway. In this process, a member of the Safer Care Team will review the completed root cause analysis for accuracy against the clinical and nursing records prior to assurance panel. This is registered with the Trust clinical audit team and this will be identified at the point that the investigation is commenced.

Learning

The Trust has held a learning from complaints stakeholder event with senior leadership colleagues from across the organisation to review current processes for learning. This event reviewed the learning that had been identified in relation to complaints investigations and what was needed to strengthen and support the completion of investigations resulting from complaints. The Complaints and Concerns policy was reviewed and a number of additional actions were agreed such as updating informal learning and training on complaint investigations and writing a role description to support investigators. This includes ensuring that evidence reviewed as part of the investigation process is clearly referenced to ensure that there is oversight of this when completing responses.

The Trust are currently undertaking a comprehensive improvement project focused upon the Ulysses Safeguard system, which is the electronic risk management system used by the Trust .It is a system which allows for web-based reporting of incidents and safeguarding concerns, alongside system based operational management of complaints, incidents, claims, inquests, safeguarding and risk. It is also a platform which has the facility to recognise and acknowledge good professional practice known as 'Excellence reporting'. The improvement project aims to increase utility of this system, with standardisation of use and increased reporting functionality. This is intended to support teams in the Integrated Governance Unit, but also divisional colleagues in providing a single version of standardised reports and increasing ownership and understanding of processes which can be complex and running concurrently.

This project is ongoing and updates are provided on a monthly basis to the Service Improvement Group, chaired by the Deputy Chief Executive. One of the successes of the project is use of the web-based management of complaints, which allows divisional colleagues coordinating and undertaking complaints investigations to document their progress and record their findings or identified areas for learning in real time. This supports our ambition for the PALS and Complaints Team to provide timely and useful updates to complainants about the progress of an investigation as outlined earlier in this letter.

Part of this project is focused on the alignment of the different modules used and knowledge and skills of staff using the system. This has led to the development of the automated report which links ongoing investigatory processes for individual patients as referenced previously. This shows at a glance listed inquests for which a patient may also have open incident investigations, a complaint or safeguarding concern. This should support triangulation and minimise the risk of duplication or silo working. Alongside this, the Trust is also working with Ulysses to understand the potential benefits of accessing supplementary modules which would support learning and the coordination of theme or issue specific action plans or workplans.

Beyond this, to further strengthen internal processes, the Trust are undertaking training to support the development of staff. Witness statement training is being implemented Trust wide to help support those who have been approached to prepare statements. Clinical and nursing staff understand that they may be asked to provide a written report about their involvement in a patient's care. The training will accentuate that the statement is to focus on the facts relevant to death and is to be detailed and accurate. In order to maintain consistency, templates are being drafted to ensure structure is provided.

In relation to the issue raised relating to patient call bells, a safety checklist has been revised with an accompanying standard operating procedure intended to support the regular testing and checks of emergency equipment within all inpatient areas. This includes a daily check by operational staff of the call bell, oxygen and suction located at each bedside. This is overseen by a weekly assessment, recorded within the safety checklist. This is then auditable as part of assessments completed by members of the Safer Care Team for each area and reviewed as part of the Ward accreditation process. As this is a new process, this has been socialised with the divisional leadership teams to ensure their views and comments are considered in the implementation of this.

Finally, in response to your concerns regarding the referral process to another NHS Trust and the oversight of this. Enquiries have been undertaken and I understand that our current process is for the Trauma Coordinators to be copied into all referrals to an external or tertiary centre such as Wrightington, Wigan and Leigh NHS Foundation Trust by the clinical team. If a patient is accepted by the Acute Hip Team at Wrightington, Wigan and Leigh NHS Foundation Trust, a response to indicate this is provided along with a patient referral booklet, which is completed by the Middle Grade Doctor. This is returned and a copy is retained by the Trauma Coordinator until the patient is either transferred or treated locally.

Following consideration of the information provided, a response is provided by email from the Acute Hip Team with the plan to treat locally or transfer. If ithe plan is for transfer, then the Trauma Coordinator will commence the appropriate preparations required such as blood tests, an Echocardiogram or ECHO (if needed), Covid and MRSA swabs and anaesthetic review, sharing this information with the receiving organisation.

This process is recorded using a database and is pursued manually by the Trauma Coordiators on a daily basis for confirmation of an available bed and allocation of a theatre date. I am advised that as centres such as Wrightington, Wigan and Leigh NHS Foundation Trust receive referrals from across Greater Manchester, any changes or developments to this process would be led by them. However, it is considered that there is an opportunity for the Trust to further

develop and automate the electronic system used here, with the ability for the system to generate reports and notifcations based on days waited or pre-agreed markers.

Development of a system such as this is currently being discussed with our Chief Clinical Information Officer, who has developed our interactive Ward White Boards, to understand the possibilities of this and the scope for intgratioin with other existing systems used at the Trust to improve efficiency and patient outcomes. While this remains in its formative stages, I hope that this provides you with assurance of the Trust's commitment to innovation and development, while acknowledging that some improvement programmes require time and investment.

Concern 3:-
Your final concern was that the Trust did not revisit the level of harm following completion of the Root Cause Analysis Investigation. As you know, there may be occasions where the initial harm level for a patient following a safety incident is not fully known or understood at the time of completion of an investigation, such was the case for Mr Holmes. However, the Trust acknowledge that in cases such as this there is a need to strengthen the processes to ensure that this is a considered when final sign off of an investigation takes place. I hope that the steps introduced or reinvigorated to triangulate our processes has provided you with assurance of our commitment to improve.

To provide an additional safety net in this process, the Trust has also taken steps to amend and improve the triage system for newly listed inquests. In the context of the recent letter HM Senior Coroner received from Mr Richard Jolly of Weightmans LLP , in relation to the provision of our inhouse legal team, processes have been reinvigorated to ensure triage, review and instruction sent out to clinicians within seven days of the initial inquest request.

As part of the new process, a clinical review of the case and a review of any previous investigations is also performed at the outset where we are able, in order to identify any linked actions. This process would allow for the revisiting of levels of harm for individual incidents to ensure that this is appropriate, with advice from the specialist teams. There is also the addition of a full time clinical member of staff to support this process moving forward, and a more rigorous review system to capture potential delays. The Trust has started to implement this process ensuring communication is maintained with HM Coroner throughout.

It is acknowledged that all comprehensive investigations for which there is an inquest listed by HM Coroner remain in draft until the conclusion of this process in which the definitive cause of death is established. In this instance, the original incident may also remain open. This has been the Trust practice for many years as you may be aware, acknowledging that evidence from third parties or external partners may impact on the information understood on conclusion of the Trust investigation. This may in turn result in a reassessment of the harm grading.

I hope that this response has provided assurance that the Trust has taken your comments and concerns seriously and taken action to minimise the risk of such event occurring again. Should

you require any further information, please do not hesitate to contact me through the Legal Services Team on [redacted]

Yours sincerely,

[redacted]

Executive Director of Nursing and Integrated Governance