North Cumbria
Integrated Care
NHS Foundation Trust

[redacted]

04 December 2023

PRIVATE AND CONFIDENTIAL
Mr James Edward Thompson
HM Assistant Coroner for the Coroner Area of Newcastle and North Tyneside
Coroner's Office
Lower Ground Floor
Block 1
Civic Centre
Barras Bridge
Newcastle upon Tyne
NE1 8QH

[redacted]

Dear Mr Thompson

Re: North Cumbria Integrated Care's Regulation 28 Response and Action Plan Concerning the Inquest into the death of Mr Brian Moreton

I write following the inquest that you resumed on 21/09/2023 and 22/09/2023 into the death of Mr Brian Moreton at the Newcastle Upon Tyne Coroner's Court. You concluded that Mr Moreton sadly died on 06/05/2022 at the Freeman Hospital in Newcastle Upon Tyne with a medical cause of death of:

1a Cytomegalovirus Colitis and Invasive Aspergillosis
1b Treatment of Immune Checkpoint Inhibitor Colitis
1c Immunotherapy for Metastatic Malignant Melanoma

A Narrative Conclusion was recorded, together with a finding of Neglect.

During the inquest, you remarked on the candour of the North Cumbria Integrated Care NHS Foundation Trust ("the Trust") witnesses and their commitment to addressing any areas of concern. Notwithstanding this, the evidence identified a number of concerns that you felt may lead to future deaths if action is not taken by the Trust, and your statutory duty to issue a Regulation 28 Report to the Trust was therefore engaged. I was saddened to learn of the circumstances surrounding Mr Moreton's death and on behalf of the Trust, I wish to extend my sincere condolences to his family and friends.

I am grateful to you for raising your concerns to me. It is imperative to the Trust that safety issues are identified and rectified to ensure our services are safe and effective.

The Trust has undertaken a thorough review of Mr Moreton's care and the concerns raised within the Regulation 28 Report. A number of actions have been identified which will be implemented to address the concerns. These aim to prevent another safety incident (of same kind or similar kind) from occurring, and thus, prevent future deaths. I am grateful to you for the extension of time you have afforded to the Trust to ensure a robust review and response.

Please accept this letter as the Trust's formal response to the Regulation 28 Report. Each concern is addressed however may not appear in the same order as set out in the Regulation 28 Report. Please

find enclosed the Trust's corresponding action plan which incorporates the identification and embedding of all learning relevant to Mr Moreton's case, whether identified by the Regulation 28 Report or not.

Concerns 1 and 2

Evidence was heard that at the time of the inquest radiologists do not have access to a patient's medical notes and base their reporting on a summary document submitted by the department requiring imaging. The summary document in Mr Moreton's case was seen to be deficient in that it omitted his symptom of fever. It was heard in evidence a radiologist would need to telephone the department in question or go there to inspect the notes. Their awareness of a patient's condition is based on a telephone referral followed by a summary document which can be at odds with each.

It is of concern that the use of telephone referral system and summary could contain errors and the radiologist must rely on this information, with no quick way to inspect a patient's notes.

The inquest heard that referrals to Radiology for imaging were made electronically, in writing, on the ICE system. To ensure compliance with the Ionising Radiation (Medical Exposure) Regulations ("IRMER") 2017 and in line with the Trust's ICE User Guide for Radiology requests, the ICE system requires the referrer to provide the following details within the ICE referral:

- Patient demographics;
- Confirmation that the criteria for the imaging has been met;
- Referrer details including their name, role and contact details;
- Clinical details where symptoms, observations and past history should be recorded;
- Global clinical details. This an area where the referrer may type in any further information that has not been previously captured but it is limited in characters;
- How the patient will attend for their imaging;
- Priority of the imaging; and
- Location of where the results should be sent.

This ensures that for any requests for CT, MRI, or ultrasound scans, the Duty Radiologist has sufficient information from the referrer that the benefits of exposing the patient to ionising radiation outweigh the risks, and that this can be justified. The above details also subsequently assist the Reporting Radiologist to interpret and report on any imaging carried out, as they may not be the same practitioner as those justifying the imaging. The 'Clinical Details' box within the ICE system is a mandatory field, with unlimited free text, where the referrer ought to include anything of clinical importance to assist in the justification and interpretation of the imaging. Whilst the Trust's ICE Guide sets out that that symptoms, observations, and past history should be recorded within the clinical details box, it is the professional judgement of the referrer to make a decision on what is clinically relevant to the referral, to ensure the imaging is justified and the interpretation of it is meaningful.

The inquest heard that a whole body imaging CT scan for Mr Moreton was justified on 02/03/2022. The ICE referral requested that the imaging assess for progressive disease (due to his diagnosis of BRAF mutant metastatic melanoma and due to a re-staging CT already pending on ICE at that of his attendance to ED) and to rule out a bowel obstruction (due to the presentation that precipitated his attendance at ED). Mr Moreton's history and some symptoms were provided within the referral, however, it was accepted in evidence that the referral omitted to include the history of a fever and toxic megacolon was not identified as a differential diagnosis. The inquest further heard that had the referral included the symptom of fever, it might have altered the Reporting Radiologist's interpretation of the imaging.

At the time of Mr Moreton's admission, for urgent CT, MRI, or ultrasound scans, it was common practice within the Trust for the referrer to discuss the request with a Radiologist via the duty telephone line, to assist the Radiologist in making a decision as to whether the imaging could be justified. Discussions with the Radiologist were in addition to the written referral on ICE (i.e. one did not replace the other) and were not documented or electronically recorded. Furthermore and as aforementioned, it was not

guaranteed that the Radiologist, who justified the imaging, was the Radiologist who subsequently interpreted and reported on the scan. Hence why it was crucial for the referral on ICE to capture all clinically relevant information.

In August 2022, the Trust ratified a protocol, which sets out a clear referral flow chart for the authorisation of CT imaging for adults. If a CT scan is indicated, the patient must be reviewed or discussed with a senior decision maker within the referring team, and the referrer must make a written referral on ICE (as is the process for all imaging), with reference to who the senior decision maker is within the referral. If the request falls within the Rapid Radiology Request Pathway ("RRRP") criteria below, this can be discussed with a CT Radiographer without the requirement to discuss this with a Radiologist or the referrer:

- Unenhanced CT head
- Unenhanced CT cervical spine
- Unenhanced CT of the kidneys, ureters and bladder
- Trauma "Pan Scan" (head/neck/chest/abdomen/pelvis) – up to 150mls non-ionic contrast media
- Unenhanced localised CT to assess for fracture (thoracolumbar spine/pelvis/appendicular skeleton)
- Acute aorta – pre and post contrast of the full aorta with 100mls non-ionic contrast media
- CT pulmonary angiogram – post contrast scan with up to 100mls non-ionic contrast media
- "Surgical abdomen" – post contrast up to 100mls non-ionic contrast media

Furthermore, there is no longer the expectation or requirement for referrers to discuss referrals for any imaging with a Radiologist. Whilst the duty line is still operational for referrers, Radiographers and Radiologists to discuss any requests being made, it is process for a robust ICE written referral to be made, and it is on that basis that the majority of imaging requests are justified or rejected, either by a Radiographer or Radiologist (depending on the above criteria), without the need for further discussion.

If the protocol was operational at the time of Mr Moreton's admission and had malignancy not featured within his presentation, it is likely he would have met the RRRP criteria for a surgical abdomen CT, as the Emergency Department (ED) assessed that he had symptoms concerning for bowel obstruction. An ICE referral therefore would have been made and a CT Radiographer could have authorised this without the requirement to discuss this with a Radiologist or the referrer. However, a whole body imaging CT scan to assess for progressive disease and to rule out a bowel obstruction would not have met the RRRP criteria. An ICE referral therefore would have been made and a Radiologist could have justified or rejected the imaging on the basis of the written referral.

A referral should sufficiently transfer pertinent information between referrer and provider without loss of content or meaning. The protocol therefore intends to reduce the need for supplementary telephone discussions with a Radiographer or Radiologist, and instead emphasises the need for robust written referrals on ICE. This reduces the risk of the written and telephone processes being at odds with each other, makes it more efficient for the referrer and the Radiology Department, and ensures a decision on a patient's care pathway is made as timely as possible to inform the clinical plan. The protocol however also emphasises that advice can be sought or a request can be clarified between the referrer and Radiology Department utilising the duty line if needed.

The Trust recognises that if most requests for imaging are managed via written referral on ICE, there is a need to ensure that such referrals are robust. A robust referral should contain high-quality clinical information, which enables the Radiology Department to determine the most appropriate investigation or procedure to be selected, that takes into account patient safety, radiation exposure, and diagnostic value. It also provides a reason for the investigation through a clear diagnostic question that the referrer wants answering, to assist the Radiologist in the interpretation of results, minimising perceptual and interpretational diagnostic errors, and the subsequent completion of a pertinent and concise report.

An educational programme is therefore being developed, with support of the Trust's Education and Training Department, to provide a learning package for diagnostic referrals within the Trust (including

Pathology and Radiology requests). The package, available to all staff who have completed referral training, aims to provide examples of what a robust diagnostic referral looks like, and to highlight/emphasise:

- What mandatory fields need to be completed;
- The need for clear clinical information to be provided;
- The need to provide a differential diagnosis.

Such training would emphasise the need to include Mr Moreton's symptoms of fever and profound diarrhoea within the clinical details box on ICE, as a potential red flag for a complicating features of acute severe colitis.

The purpose of diagnostic imaging is to assist in the process of identifying or determining the etiology of a disease or condition, alongside the evaluation of a patient's history, physical examination, and review of laboratory data. Reaching a diagnosis provides a trajectory of treatment and an understanding of a patient's prognosis, and in some cases, may be useful for preventative treatments. However, in order to justify diagnostic imaging (to provide assurance that the benefits outweigh the risks) it is necessary to provide a differential diagnosis, which the imaging seeks to evidence or rule out. A differential diagnosis of query obstruction was included within Mr Moreton's ICE referral, but toxic megacolon was not considered as an explanation for his presentation during his admission.

The Radiology Department has therefore implemented an immediate change within the ICE referral system. The 'Clinical Details' box is now titled 'Order Clinical Details and Differential Diagnosis' and remains a mandatory, unlimited field. Whilst this new field within ICE alone would not necessarily give rise to a referrer or the Radiology Department identifying the presence of toxic megacolon in a similar presentation in the future, the field is a further prompt to the referrer to further analyse the patient's symptoms to really think about any potential diagnosis and ensure this is included within the ICE referral. This aims to reduce the rate of interpretational error. The absence or misrepresentation of a differential diagnosis carries the risk of the findings being interpreted as caused by a different condition (albeit with same or similar findings).

A standard operating procedure (SOP) is in the final stages of development for the management of inflammatory bowel disease (IBD), including the general management of acute severe colitis of all causes. The SOP includes red flag symptoms for acute severe colitis, and makes regular reference to the need for clinicians to be cognisant of high-risk features and devastating complications of severe colitis, such as toxic megacolon. The SOP provides education that toxic megacolon is characterised by radiographic distension of the colon often with fever, tachycardia, neutrophil leucocytosis and anaemia. Once ratified the SOP will be electronically accessible to all clinical teams via the Trust's Clinical SOPs intranet page. Therefore, any clinician encountering a similar presentation to that of Mr Moreton's, ought to refer to the SOP, which provides a step-by-step plan of care and a detailed section around presenting features, to help support assessment, diagnosis and management of IBD.

The introduction of the differential diagnosis box on ICE and the SOP supports the educational programme in highlighting what constitutes clear clinical information and red flags for a diagnostic referral in a differential diagnosis of IBD, which needs to be included within the ICE referral to assist in the justification and reporting of any requested imaging.

The inquest heard that Radiologists triaging and reporting on Mr Moreton's imaging on 02/03/2022 did not have access to the relevant records. The Trust has a number of Electronic Patient Records (EPR) across its services. Inpatient, outpatient and community care also utilise paper records. On attendance to the ED on 02/03/2022, Mr Moreton's records would initially have been in paper format, and later scanned to the ED's EPR, Symphony. Within the Trust, post-holders are only granted access to systems relevant to their role/service in line with the Trust's information governance policies. Furthermore, Radiology Departments are not an outlier and it is not common practice nationally within the NHS for Radiology staff to independently obtain information to assist them in the justification and reporting of imaging; the process is reliant on the information provided by the referrer. Therefore, Radiology staff did not have access to Symphony at the time of Mr Moreton's admission, and due to the operational

pressures within the Radiology Department, it would not have been feasible or considered normal practice for any Radiologist on shift to leave the department to speak to a referrer or review the EPR or paper records, within the referring department. Practice and operational pressures remain the same in November 2023.

The Trust recognises the benefits of fit-for-purpose digital tools and technologies designed to manage patient information and make it easily available for our staff and patients. As of June 2023, Symphony Paperlite has now been implemented in the EDs across the Trust's acute hospital sites and the Urgent Treatment Centres. Patient information in ED is now recorded directly onto Symphony, removing any paper records and the need for any specialism to have to attend the department to view the records. Digital transformation work is also underway to implement an EPR within the inpatient hospital setting. The EPR will replace some inpatient and outpatient paper records and legacy paper case notes will be digitised into a digital repository. The Trust's EPR project was launched in April 2023, but the process of procuring and implementing an EPR of the scale required for the Trust will take several years. The project anticipates the process of securing the funding to continue until Spring 2024, with phase one of the implementation to commence by March 2026.

Whilst it would not be commonplace for Radiology staff to access records in the process of triage or whilst interpreting and reporting on imaging, the Trust recognises that in exceptional circumstances, it may be of benefit. Radiology staff have therefore already been granted access to the Clinical Portal, which is an EPR and contains primary care information and past medical history. Access has also been granted to WebV, which is an inpatient EPR and provides access to a patient's pathology results, vitals/NEWS scoring and nursing assessments. The Trust is in the process of granting Radiology staff access to Symphony Paperlite, and access will also be granted to the new EPR once commissioned. A guideline needs to be produced on when records should be accessed in line with the Royal College of Radiologists.

Concern 3

The evidence also dealt with radiologists working in 2 hour triage shifts in a hectic environment where those clinicians receiving the referral seldom were the clinicians who carried out the imaging. The inference was the arrangement was susceptible to error.

The inquest heard that each Radiologist on shift was expected to cover the duty line for 2 hours as the expectation that referrers would discuss all requests for urgent CT, MRI or ultrasound scans with a Radiologist, resulted in the department receiving a large volume of calls. At the time of Mr Moreton's admission, only 2 Radiologists would be on shift with shared duties for managing the duty line and reporting on imaging. There was an expectation that Radiologists reported on all acute images performed during their 2 hour duty, within the same duty period. A re-staging scan, particularly for melanoma, is notoriously complex and ordinarily is afforded 14 days to report on. However, any imaging performed resulting from an ED referral, had to be reported within 2 hours (ideally under 1 hour). A combination of staffing, duty obligations and key performance indicators resulted in a poor physical environment, and created many interruptions to the Radiologists interpreting and reporting on, what were sometimes very complex presentations, similar to that of Mr Moreton's.

Since Mr Moreton's admission, the Trust has increased its staffing within working hours (Monday to Friday 09.00 to 17.00), to 3 to 4 Radiologists on duty per shift, with 1 Radiologist responsible for managing the duty line. A more flexible approach to what can and cannot be reported within an allotted two-hour acute reporting block has also been adopted. This frees up 2 to 3 Radiologists to focus on interpreting and reporting. There is less requirement for referrers to discuss their referrals with a Radiologist, demand from the duty line has lessened and the timescales by which the imaging is to be reported on. These improvements have therefore provided a safer environment for the Radiologists to operate within.

Radiology is provided by Everlight (external teleradiology service) out of hours (Monday to Friday 20.00 to 09.00 and 19.00 to 09.00 on weekends). During on-call arrangements (Monday to Friday 17.00 to 20.00 and weekends 09.00 to 19.00), 1 Trust Radiologist is on shift, but there is provision in place for

Trust Radiologists to seek support from Everlight if there is increased demand/pressure within the Radiology Department. The newer referral process outlined above is replicated out of hours and during on-call.

Operationally NHS Radiology Departments cannot guarantee that Radiologists who may have been involved in the justification of a scan, be the Radiologist who interprets and reports on it. With the reduction in the telephone duty system and the introduction of Radiographers being able to justify certain CT images, it is likely most referrals will be limited to what is documented on ICE. With the intended improvements to the quality of referrals being made by the educational programme and introduction of the differential diagnosis box within the ICE system and the IBD SOP, that the overall quality of information gleaned within the referral process will improve, and the involvement of more than 1 Radiologist will not give rise to errors within the arrangement, particularly now that the reporting environment is more productive.

The Trust however recognises that there may be occasions where referrers and the Radiology Department need to discuss a referral. As aforementioned, such discussions were not documented or recorded at the time of Mr Moreton's admission. The Radiology Department utilises RIS (radiology information system) which has the ability to document any relevant information, and each Radiologist has access to the system. Following Mr Moreton's death, Radiology staff have been reminded of situations where it might be appropriate to record information on RIS, particularly discussions during the justification process, which could be reviewed by the Reporting Radiologist, if the imaging was justified by another Radiologist.

Concerns 4, 7 and 8

Over the course of the inquest evidence was heard on a number of issues where information passed to and from clinicians involved in Mr Moreton's care was inaccurate and misleading.

Clinicians in Newcastle when asked for advice were under the impression treatment was working as it was mentioned his discharge from hospital was contemplated and this was not the case.

Overall I am concerned about the poor and misleading communications between clinicians, departments and Hospital Trusts on matters of vital importance to patient care.

The inquest heard that the Trust's treating clinical team were looking for signs of a gradual improvement in Mr Moreton whilst on biologic medicines. Mr Moreton's condition fluctuated but there was no overall improvement. The inquest further heard that in line with British Society of Gastroenterology guidelines, by days 13 and 15 of Mr Moreton's admission, alternative treatment should have been considered, as the absence of improvement would have been as equally concerning as Mr Moreton deteriorating. The Trust has therefore also considered whether the Trust's Stop the Line SOP, which was a live document at the time of Mr Moreton's admission, could have been utilised during his care. The SOP sets out that 'Stop the Line' is a patient safety alert system where any clinical activity ceases, for staff to question or seek clarity on the effectiveness of the activity, and to prevent harm to the patient from occurring. The spirit of the SOP could have been utilised to reassess Mr Moreton's care and consider an alternative approach in view of the absence of improvement. The Trust's daily ward round documentation incorporates a review of a patient's progress against the plan, and the need to confirm or revise escalation plans, if there a change is indicated. However, the Trust has considered 'Stop the Line' could be more prescriptive within the ward round templates to ensure the clinical team recognise where this SOP applies and utilise it. The ward round documentation will therefore be updated to reflect this.

In Trust policies and SOPs where handover and referrals feature, it is set out that staff are to utilise the standard communication structure/format of: Situation Background Assessment Recommendation (SBAR). An SBAR internal referral form has been in existence within the Trust for a number of years. NHS England sets out that the SBAR tool is one of the most well used, effective improvement methodologies to escalate a clinical problem that requires attention, or to facilitate efficient handover of patients between clinicians or clinical teams. The tool can be used in urgent or non-urgent

communications, verbal or written exchanges, in escalation and handover and in clinical and managerial environments. An SBAR communication should convey the following:

- Situation – who the referrer is, which patient the referral relates to, and what the concern is.
- Background – what the reason is for the patient's admission, the patient's medical history, and any relevant clinical details.
- Assessment – what investigations have been undertaken and what the referrer's clinical impression or concerns might be.
- Recommendation – what is being requested from the communication and the timescales involved.

Whilst staff are expected to utilise SBAR within handover and referrals, and is clearly referenced within various policies and SOPs, it would appear that this system has lost momentum within the Trust. SBAR is therefore being relaunched throughout the Trust and meetings are ongoing to determine how best to achieve this. Clinicians will be expected to utilise SBAR in any escalation of a clinical problem that requires attention, or to facilitate efficient handover, both internally and externally.

Where contact is made to a clinician or clinical team for advice via telephone utilising SBAR and advice is given over the telephone, the referrer will be required to email the advisor detailing the discussion, and then place a copy of this in the patient's records. This provides the advisor with the ability to clarify their advice if there has been any misinterpretation, and ensures the advisor is provided with a copy of the discussion, as they may not have access to the patient's records. This requirement will be rolled out within the SBAR relaunch.

The IBD SOP mandates joint care between general surgery and gastroenterology. Any clinician managing the care of a patient presenting with IBD will be required to refer to and follow the SOP, ensuring that necessary referrals to general surgery and gastroenterology are made. If a referral is made to either general surgery or gastroenterology, it is the responsibility of the service referred to, to ensure the involvement of the other service.

The Trust now holds joint biweekly IBD multidisciplinary team meetings (MDTs) between the internal general surgery and gastroenterology teams. A triweekly joint specialist IBD MDT between the Trust and Newcastle upon Tyne Hospitals NHS Foundation Trust has also been established since February 2023. An MDT, made up of a variety of specialists with an interest in IBD or gastroenterology, approach to the management of a patient's IBD, is recommended to provide optimised and personalised care, based on available professional expertise, infrastructure and funding, and helps to prevent errors in the delivery of care and avoid related harm to patients. The timing of MDT meetings happen on the aforementioned frequencies to ensure decision-making is not delayed, however, such discussions largely relate to complex, chronic IBD patients. Acute or emergency care decisions cannot not be delayed for timetabled MDTs, but should happen separately between relevant specialists. The introduction of the MDTs has improved working relationships and communication between the teams and Trusts, to ensure early referrals for specialist input in the management of a patient's care is sought, for patients who are acutely unwell and/or where urgent advice is required. Had the MDTs been in place during Mr Moreton's admission, he likely would have been listed for discussion in both MDTs and professional relationships would have been established to seek earlier input from surgical colleagues and specialists in Newcastle.

The Trust has also made changes to its on-call system during the working week to ensure there is both a dedicated colorectal and an upper GI surgeon of the week. While the conditions that both surgeons treat may sometimes overlap, it is a colorectal surgeon that specialises in the surgical management of IBD patients, and previous on-call arrangements meant that there was not always a dedicated colorectal surgeon available.

Concern 6

It was assumed Mr Moreton would be referred for a surgical opinion by ED department clinicians when in fact none took place.

The IBD SOP will ensure the involvement of both the general surgery and gastroenterology teams via referral from any service managing a patient with presenting IBD.

Once again, thank you for bringing your concerns to my attention. I hope that the above provides assurance to you, Mr Moreton's family, and the public, that the Trust has taken them seriously and appropriate action is being taken to prevent any similar future deaths.

I appreciate not all of the actions are yet implemented and I would be happy to provide updates on these in the future, should you require this. Please also let me know if you require clarity on any of the responses I have provided above.

Yours sincerely

[redacted]
Chief Executive