Saving lives, Improving lives

NHS
Northern Care Alliance
NHS Group

Salford | Oldham | Bury | Rochdale | North Manchester

[redacted]
Chief Officer
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Telephone: 0161 206 3178

Ref: JS/SJB

Date: 11th April 2019

Dear Sir

Inquest touching the death of John Mellor

I write in relation to the above inquest which was held before you on 13 February 2019. Following the inquest you issued a Regulation 28 report. Box 1 of this report addresses it to Sir David Dalton, Chief Executive of the Northern Care Alliance Group ("NCA") (amongst others).

Firstly, thank you for bringing the concerns raised in the Regulation 28 report to our attention. I would like to take this opportunity to provide assurance to both you and the family that Salford Royal Care Organisation ("SRFT") takes the concerns raised very seriously and action has been taken to address these as detailed below.

As you are aware, Pennine Acute Hospitals NHS Trust ("Pennine Acute") was considered an Interested Person and witnesses from Pennine Acute gave live evidence.

You also heard evidence from SRFT by way of a single statement read under Rule 23. SRFT were not given Interested Person status at the inquest and therefore did not attend. SRFT would have welcomed the opportunity to give evidence to your inquest to explain the steps that had already been taken to address the concerns that you have raised. SRFT first became aware of the Coroner's concern following receipt of the Regulation 28 report.

I would like to take this opportunity to apologise to Mr Mellor's family that the inquest process has been extended through the Regulation 28 process.

Discussions have taken place with representatives from Oldham Care Commissioning Group ("CCG"), St Chad's Medical Practice and Pennine Care Foundation Trust. Cross-organisation learning has been shared and we are assured that there is now a robust

tracking system within SRFT for patients requiring Erythropoietin Stimulating Agents ("ESA") treatment and monitoring their bloods. Erythropoietin ("EPO") is a specific hormone that falls into the ESA drug group.

Regulation 28 concerns and response:

- **Systematic failure to ensure that blood tests are conducted, where required, for individuals under specialist, secondary care for renal failure. Failure to establish a shared care arrangements, or at least ensure that an organisation was identified in order to undertake blood sampling for drug monitoring is insecure and unsafe.**

Following discussions with the CCG, it is recognised that this is a Greater Manchester issue.

SRFT has looked at both immediate actions and long-term solutions to address the concerns raised and the lessons that have been learned will be shared with the Renal Patient Safety Committee which is a joint venture with the British Renal Society. The Renal Patient Safety Committee works closely with the Medicines and Healthcare products Regulatory Agency (MHRA) and NHS Improvement and aims to minimise avoidable harm to patients with kidney disease.

Immediate actions to assure patient safety

The wording of letters to patients has been modified to ensure the options available to them for arranging blood tests is very clear and a point of contact at SRFT is provided if the patient is having any difficulty. Patients may attend the renal clinics at Salford, Wigan, Bolton and Oldham for pre-arranged blood tests.

Prior to commencement of treatment, a letter is now sent to the patient's GP when the Renal Consultant is considering ESA treatment to make the GP aware of this and to ask if they are able to monitor the patient's bloods. A returns slip is included so that this can be completed and administrated efficiently. When SRFT are aware of the GP's position in respect of the patient's bloods, an appropriate blood monitoring plan is agreed with the patient at the time of the prescription of ESA. This method enhances the informed consent process for ESA treatment as the patients will have an understanding of the full implications of the monitoring required. SRFT's Electronic Patient Record System ("EPR") has been updated with a section confirming when a GP has responded in respect of monitoring. If no response is obtained from primary care, this is followed up by the renal clerical team.

Until SRFT receives a response from the GP, we assume responsibility for taking bloods to ensure that patients start ESA treatment when clinically necessary.
A Standard Operating Policy has been developed which describes the above process and the steps taken when a negative response is received, or when a response is outstanding. A copy of the Standard Operating Policy is attached.

In order to track all patients receiving ESAs, SRFT's EPR system has been updated to show when patients' blood results are due, and those that are missing and require follow up.
Prescribers have allocated time in their job plans for ESA monitoring and prescribing. The new EPR system always shows the most recent haemoglobin results for the patient.

These improvements will provide assurance not only in respect of new patients who start ESA treatment, but also current patients. All patients currently receiving ESA treatment will be written to by the renal admin team by the end of May 2019 to establish whether they have experienced any difficulties in accessing appropriate monitoring. Patients experiencing difficulties will be managed in accordance with the agreed SOP.

Long-term plan
Patients under the care of SRFT renal services often do not live locally to the renal unit so if monitoring is required to be undertaken at SRFT, this is often not the best or most appropriate solution. Previously, there was no agreement or shared care protocol in place between SRFT and its CCG catchment primary care providers for the monitoring of bloods.

As above, following discussions with the CCG, it is recognised that this is a Greater Manchester issue. We are exploring via CCGs and the Greater Manchester Medicines Management Group the possibility of a Greater Manchester commissioned shared care protocol for monitoring of ESAs.

- **Responses or updates to referrals, as well as requests for tests in the community have not been communicated to primary care directly.**

A Rapid Review has been completed to ensure all lessons to be learned from this incident have been identified and to ensure the learning can be embedded.

The Rapid Review included a thorough review of the timeline of correspondence sent to Mr Mellor's GP. I apologise unreservedly on behalf of SRFT for any perceived shortfalls in respect of SRFT's communication to Mr Mellor's GP.

Going forward, GPs will be copied in to all correspondence to the patient, including correspondence advising the patient that they are due to have their bloods tested.

Next steps

I trust that this response provides assurance that lessons have been learned from this case and demonstrates the improvements that have been made to systems at SRFT.

I would like to conclude by once again apologising to Mr Mellor's family for the issues in his care that have been identified above and that the Inquest process has been extended through the Regulation 28 process. We would have much preferred to have had the opportunity to explain this in person at the Inquest. I would wish to offer my deepest condolences to Mr Mellor's family on their loss.

Please do not hesitate to contact me if you require any further information.

Yours sincerely

[redacted]

Chief Officer
Salford Royal NHS Foundation Trust
Northern Care Alliance NHS Group
Comprising Salford, Bury and Rochdale,
Oldham and North Manchester Care Organisations

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11 April 2019

Nicholas Flanagan
Assistant Coroner
Manchester Area
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The Phoenix Centre
L/Cpl Stephen Shaw MC Way (formerly Church Street)
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Dear Mr Flanagan

Re: John Mellor – DOD 3rd October 2018

Further to your Regulation 28 report of 14th February 2019 following the inquest into the death of Mr Mellor on 12th October 2018, I confirm that a full investigation into the matters you raised has been completed by the care organisations responsible for the care of Mr Mellor. I am now in a position to respond to the concerns raised into the circumstances surrounding the death of Mr Mellor. The matters of concern raised and the actions we will take to address these concerns are as follows:

1. **That there appears to have been a systematic failure to ensure that blood tests are concluded, where required, for individuals under specialist secondary care for renal failure. Individual patients, who may not be local to the specialist centre, will inevitably fail to have the appropriate assessments, care and treatment in the absence of a clear line of responsibility.**

2. **The failure to establish a shared care arrangement, or at least that an organisation was identified in order to undertake blood sampling for drug monitoring, is insecure and unsafe.**

3. **It is also concerning that responses or updates to referrals, as well as requests for tests in the community have not been communicated to primary care directly, with the sole reliance on a patient to pass vital documentation on to his primary healthcare provider.**

The investigation has highlighted a number of contributing factors within the care system which prevented Mr Mellor accessing the necessary service which is extremely regrettable. There was a

lack of systems and processes in place throughout the organisations to ensure follow up, escalation and effective communication between all agencies involved in Mr Mellor's care. The absence of a clear line of responsibility within the system was evident within the investigation and demonstrates the need for a clear shared care pathway with accountability for action to ensure that the patient receives the appropriate level of care.

In discussion with colleagues across the system it is apparent that there was no one individual taking responsibility for this gentleman's care, resulting in a level of assumption and an unnecessary and inappropriate level of responsibility placed on him and his family to be requesting blood tests. In both the case of the referral to the District Nursing Single Point of Access and the Primary Care team, it is clear that escalation of the issues to a more senior clinician may have altered the course of these events and allowed more timely action to be taken. This is something that has been identified by both the GP Practice and the District Nursing Team and forms part of the learning to prevent such occurrences in the future.

From a system perspective, there was a missed opportunity for Mr Mellor to have his bloods taken at the blood lounge at Royal Oldham Hospital whilst he was on the Oldham site for the clinic appointment. This generates learning about satellite clinics and the awareness of the team as to what services may be available locally that the clinic can tap into.

The review of the timeline of events with the GP Practice has demonstrated where gaps in communication have had a significant impact. The failure to copy the GP in to the communication out to Mr Mellor meant that whilst he was struggling to access a service to take his bloods, the GP was unaware that this was the case. When this was brought to light, there was an escalation within the surgery, however this was impacted by existing skills and capability along with annual leave arrangements. Unfortunately this was not communicated back to the GP themselves and the investigation clearly recognised this as a missed opportunity.

The CCG instigated a system call to agree actions going forward as a collective, some of which will be described in greater detail within individual organisational responses.

The actions being led by the Renal Team at Salford Royal Foundation Trust have been to put in place a standard operating procedure to communicate directly with GP's and ensure a response to any request for blood monitoring or any other service carried out locally. This will require a response from the local GP or provider before the treatment plan is confirmed. The Trust have confirmed that all correspondence with the patient will be copied to the GP. On a longer term implementation is the development of a shared care model – this has been described in a business case to Greater Manchester Medicines Management Group which will then go out to local commissioners.

The Pennine Care Foundation Trust District Nursing single point of access service have implemented a follow up system to make sure that there is a response from the GP practice following a referral. As a backup measure, where patients have been referred to another part of the system they are being told that should they encounter any problems they are to come back to the District Nursing Team who can then intervene on their behalf.

All staff within the GP practice are currently undergoing significant training in escalation and administrative processes. Common practice is for GPs to provide a phlebotomy service so that the patients care is close to home. Additional support has been offered by the CCG to ensure that all relevant staff are trained, up to date and competent to ensure that they can deliver this service.

Learning will be shared across the Northern Care Alliance (NCA) and communicated to Central Manchester Foundation Trust to ensure that shared care protocols are reviewed and that others can learn from the communication errors that occurred for Mr Mellor. Oldham CCG have been working

with the medicines optimisation team to identify all individuals who may be on (or fit the profile of) a shared care pathway. There have been 43 individuals identified that are currently receiving Epoetin or Darbepoetin. We have written to each GP practice to share the learning from this investigation and to ensure they have reviewed any patient that fits these criteria and that there is a robust monitoring process in place. NCA have also been asked to identify patients and escalate to CCG if they have any concerns.

We hope that this demonstrates that the CCG has robustly reviewed all aspects of the concerns raised within the Regulation 28 notice and provides assurances regarding the lessons learned and the actions taken to prevent reoccurrence in the future.

Please do not hesitate to contact us should you wish to discuss any further concern.

Yours sincerely

[redacted] MA MRCP MRCGP
Chief Clinical Officer & Deputy Accountable Officer
NHS Oldham CCG

Claire Smith
Executive Nurse
NHS Oldham CCG

NHS
Pennine Care
NHS Foundation Trust

9th April 2019

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Strictly Private and Confidential
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HM Assistant Coroner
H M Coroner's Office
The Phoenix Centre
L Cpl Stephen Shaw MC Way
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Dear Mr Flanagan

Re: John Mellor – DOD 3rd October 2018

I write following the Inquest of John Mellor. Your concerns after hearing all the evidence have been brought to my attention and I have subsequently reviewed the Regulation 28 letter issued to Pennine Care.

I am writing to respond to the concerns raised into the circumstances surrounding the tragic death of Mr Mellor. The matters of concern raised and the actions we will take to address these concerns are as follows:

- **That there appears to have been a systematic failure to ensure that blood tests are concluded, where required, for individuals under specialist secondary care for renal failure. Individual patients, who may not be local to the specialist centre, will inevitably fail to have the appropriate assessments, care and treatment in the absence of a clear line of responsibility.**

- **The failure to establish a shared care arrangement, or at least that an organisation was identified in order to undertake blood sampling for drug monitoring, is insecure and unsafe.**

- **It is also concerning that responses or updates to referrals, as well as requests for tests in the community have not been communicated to primary care directly, with the sole reliance on a patient to pass vital documentation on to his primary healthcare provider.**

I can confirm that a referral was received on 28/8/18 into the Oldham Single Point of Access (SPoA) for Adult Community Nursing from the Department of Renal Medicine at Salford Royal NHS Foundation Trust.

The SPoA is a central point of access via telephone or email which provides a gateway to a range of health services including Adult Community Nursing for patients, carers and

professionals. The service is delivered by nurses who triage and manage the referral process with the support of administrators.

The referral received did not arrive in the usual format as a recognised referral form and was more a letter. The letter did not contain all the relevant information required to triage effectively, for example it was not dated and did not detail if the patient was housebound which would assist in determining which team the referral would be allocated to. Additionally, the telephone number that was recorded on our Paris recording system for Mr Mellor was not in use and there was no patient telephone number documented on the referral therefore the SPoA requested an up to date contact number from the renal unit for the patient in order to arrange an appointment.

The Oldham Adult Community Nursing service provides care for patients who are housebound, either permanently or temporarily, requiring treatment in their own home. There is also a Treatment Room service based in clinics across the borough for those patients' not housebound but requiring District Nursing interventions. The service is commissioned to deliver a phlebotomy service to housebound patients only.

It was determined from the response received on 29th August 2018 from the Renal Unit at Salford Royal, confirming Mr Mellor's contact details that he (Mr Mellor) was not housebound. It was also identified through the Paris recording system that Mr Mellor was attending podiatry clinics most weeks therefore the referral was forwarded to the GP practice for blood pressure monitoring and phlebotomy (full blood count), via email, as is the correct process for the service. Had Mr Mellor been unable to self-administer his injection he would have been offered an appointment in Treatment Room clinics for his injection, blood pressure monitoring and full blood count as is the correct process.

Our records confirm, that the practice manager from Mr Mellor's GP practice contacted the West Cluster Integrated Community team (who are aligned to the practice) to ascertain if the recommendations from SPoA were correct; the duty nurse confirmed this to be the case and this decision was not questioned or contested.

No further contacts after 31st August 2018 were made to the Adult Community Nursing service in relation to this referral.

When Mr Mellor was contacted by SPoA on 31st August 2018, previous attempts to contact him on 29th and 30th August were unsuccessful, he was advised he was being referred back to his GP practice to undertake the blood pressure monitoring and phlebotomy - full blood count. An apology was given to Mr Mellor for the misunderstanding. The nurse contacted the surgery to advise of this conversation with Mr Mellor and confirm to the practice that the referral was forwarded to them by email on 29th August 2018 when it was identified the patient was not housebound.

Following the receipt of the Regulation 28 notice a meeting was arranged by the GP practice. The Cluster Lead and Senior Practitioner from the West Cluster Integrated Community team attended the meeting that took place on 25th February 2019. GP's, Practice Nurse, Practice Manager and an administrator represented the GP practice.

Both parties reviewed the information and timelines of events in regard to this referral to determine what collectively we would do differently if similar circumstances arose. It was determined that based on the information available the SPoA and District Nurses followed due process and acted accordingly. It was acknowledged at that time the practice did not have capacity to facilitate the full blood count although they were able to perform the blood pressure monitoring.

It was acknowledged that there was a lack of understanding from the practice administrator in relation to the differences between the SPoA and the cluster team; this was addressed in the meeting. Had the practice staff and cluster team discussed the case a resolution could have been identified. This could have included Mr Mellor attending Treatment Room for supervision of this injection alongside blood pressure monitoring and full blood count. Alternatively, it may have been possible to arrange for Mr Mellor to have his blood taken whilst he was attending his Podiatry appointments.

It is evident that Mr Mellor's ability to self-manage part of the treatment plan, (his injection) resulted in him not receiving the appropriate support to manage his condition safely and appropriately.

Following this incident and to ensure the learning is communicated, the Cluster Lead is meeting with SPoA staff to ensure that when referrals are forwarded to another provider that the patient is informed of the reason for this. Patients will also be advised to contact SPoA should any issues arise and SPoA staff will then escalate to cluster teams to resolve.

A 'lessons learned' poster is being developed to share across community services in support of this.

Oldham is entering phase 2 of integration having successfully co-located health and social care community teams around GP clusters to provide a whole system approach to delivering high quality care in a more joined up way and it is these closer working relationship and links between providers that will improve communication between members of the MDT.

I hope that the information provided offers assurances in relation to your concerns.

Please do not hesitate to contact me should you require any further information.

Yours sincerely

Clare Parker
Executive Director of Nursing, Healthcare Professionals & Quality Governance

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Mr Nicholas Flanagan
Assistant Coroner (Manchester North)

15 APR 2019

Dear Mr Flanagan,

Re: Inquest concerning Mr John Mellor (deceased)

Thank you for your letter of 14 February 2019 enclosing the Regulation 28 Report for the Prevention of Future Deaths in light of your investigation into the death of Mr Mellor. The report was also sent to [redacted] at Oldham Care Commissioning Group, [redacted] at North Care Alliance NHS Group and [redacted] at Pennine Care Foundation Trust in addition to St Chads Medical Practice.

Background

St Chads Medical Practice ("the Practice") contracts with the Oldham Care Commissioning Group ("the CCG") to provide primary care services to around 3000 registered patients within the immediate surrounding area. The Practice also provides some monitoring of medications prescribed within secondary care under a series of shared care agreements which are negotiated by the CCG with Secondary Care.

Prior to early 2018, the majority of the secondary care services provided to patients registered at the Practice would be through the Pennine Acute Trust, with some specialist care provided through Salford Royal NHS Foundation Trust. Renal Services were provided through Salford Royal NHS Foundation Trust, which had a satellite clinic at the Royal Oldham Hospital.

At the beginning of 2018 the Pennine Acute Trust and Salford Royal NHS Foundation Trust merged into the Northern Care Alliance ("the Trust").

Separate to this the Pennine Care Foundation Trust provides additional primary care support in the community, for instance the use of District Nursing.

In order to compile this response, we have discussed your report and the issues that arose at the inquest, not only within the Practice but also with the District Nursing Team and [redacted] at the CCG. As a result of those discussions various activities have been arranged by different bodies and this report seeks to identify those that are relevant to the Practice, rather than those matters that are concerns for the CCG and the Trust.

The Practice divided the concerns into three areas of urgency;

1. Red: Ensuring that there was no immediate risk to patients within the Practice and alerting the CCG

[redacted]

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2. Amber: Identifying where action should have been taken at the time
3. Green: Putting in place measures to prevent reoccurrence in the future

We have set out the steps taken by us in this regard below and enclosed a table which sets this out in more detail.

Ensuring that there was no immediate risk to patients
Ordinarily where Primary Care Services (GP Practices and District Nursing) are asked to arrange for ongoing monitoring for medication prescribed by secondary care, those medications are amber or green status drugs under the Greater Manchester Clinical Standards Board for Medicines ("GMMMG") Joint Formulary.

EPO (Erythropoiesis stimulating medication) is a red status medication under the Greater Manchester Joint Formulary (GMMMG). Red status medications according to GMMMG are *"for secondary or tertiary care initiation and long-term maintenance of prescribing."*

Amber status medications are described as *"drugs which are appropriate to be initiated and stabilised by a specialist in secondary or tertiary care, once stabilised the drug may be appropriate for responsibility to be transferred from secondary to primary care with the agreement of a GP and a formal 'shared care' agreement."* The GMMMG publish the approved shared protocols for those drugs on their website which include details such as dosage, baseline investigations, ongoing monitoring, who is responsible for the dose adjustments, drugs which must not be prescribed with the medication, criteria for shared care and the express responsibilities of the initiating clinician and primary care, amongst other criteria.

In addition there are three levels of green status medications which can be prescribed by primary care without a shared care agreement, they are those that have to be initiated in secondary care but require little monitoring, those that are prescribed following specialist medication requiring little monitoring and then drugs which can be instigated, monitored and reviewed within primary care.

Shared care agreements are negotiated between secondary care and the CCG. They are not matters that are usually negotiated between secondary care and an individual General Practice surgery. Where the Practice is individually contacted the appropriate guidance is "The Interface between primary and secondary care Key messages for NHS Clinicians and Managers" (July 2017).

The Practice should have alerted the CCG to the fact that they were being asked to arrange monitoring of a red status medication so that the CCG could liaise with secondary care and Medication Management. We wrote to the CCG on 11 February 2019 to notify them of this significant event and the upcoming Coroner's Inquest. Please find a copy of that letter enclosed with this response.

Following the Inquest a Practice audit was undertaken on 15 February 2019, which confirmed that there are no other patients at the Practice under the care of the Renal Team who are currently prescribed EPO or receiving monitoring. Please find a copy of that Audit enclosed with this response.

[redacted]

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During a telephone call with [redacted] at the CCG on 29 March 2019, the Practice was informed that we should not agree to the monitoring of red category medications and should notify the CCG urgently if asked to do so. The CCG are liaising directly with the Trust and also with Medications Management regarding this issue. At the request of [redacted] we have not written to the Trust and the CCG are liaising with them directly in relation to the issues identified by the Practice and by the CCG.

Identifying where improvements were required

The Practice undertook two separate investigations arising from JM's case;

1. An investigation into what had happened to the letter from the Renal Administrative Team at the Royal Salford Hospital to JM, when the Next of kin brought it to reception.
2. A Significant Event Analysis, which took place with input from the District Nursing Team on 25 February 2019.

One of the concerns raised by yourself was the potential for vulnerable patients to fall through the gaps of care between providers. The Practice has recently been inspected by the CQC (report not yet available) as part of that process the Practice has recently reviewed staff training in Safeguarding and the Practice's Safeguarding procedures and all staff members are up to date. We therefore did not undertake a further investigation into staff training in safeguarding but consideration of patient vulnerability was dealt with in the SEA and followed up during the clinical meeting on 18 March 2019.

A copy of the SEA is enclosed with this letter and the table sets out the findings and actions undertaken as a result of these investigations.

Steps taken by the Practice

The CCG have advised the Practice that if we are asked to accept responsibility for the monitoring of patients prescribed EPO by secondary care again we should not accept that responsibility. Whilst this reinforces that it was the right decision not to agree to undertake the ongoing monitoring that the Renal Team had asked JM to arrange, the Practice were concerned that our systems for escalating the concern within and outside the Practice were not as robust as they should have been.

The Practice has identified areas where staff required training, staff needed to be reminded of Practice Procedures or a Procedure needed to be put in place. This training and need is set out in the table enclosed with this letter, in the green section.

Training has been delivered through Practice meetings. The Practice holds weekly non-clinical meetings and fortnightly clinical meetings in addition to monthly Practice meetings for the whole of the Team. This training has been reinforced with follow up emails to all staff. The Practice has also scheduled reviews and audits to ensure that the changes have been effective and to identify any ongoing patterns of concern. Please see the enclosed table.

The Practice has updated the CCG with the findings from these investigations and the findings have been fed back to staff at the Practice. As mentioned above the CCG have requested that the Practice

[redacted]

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does not write to the Renal Team as they are going to correspond directly with the Trust regarding the issues raised in this case. We will continue to keep this matter under review and review our processes again once we receive further feedback from the CCG.

We hope that you find the information set out in the table attached useful and we would be happy to discuss these issues in more detail. Your office is welcome to contact Dr Gill on [redacted] to arrange a convenient time to discuss this matter further.

Yours sincerely,

[redacted]

[redacted]