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3rd August 2022

**Your Ref 16192**

**Prevention of Future death report following Inquest concluding 17.6.22 into the Death of Mr Donald Gore**

Dear Mr Fox,

I am writing to reply to the documents sent to us recently relating to the above-named deceased patient and subsequent inquest:

1. Regulation 28 Report to Prevent Future Deaths dated 17th June 2022
2. Findings of Facts dated 17TH June 2022

In section 5 of the Regulation 28 you have stated the following:

Coroners Concerns

"*During the course of the inquest the evidence revealed matters giving rise to concerns. In my opinion there is a risk that future deaths will occur unless action is taken. In the circumstances it is my statutory duty to report to you.*

*The MATTERS OF CONCERN are as follows.-*

*The evidence demonstrated that the General Practitioner to whom Mr Gore first presented with symptoms on 3.11.17 did not read the alert regarding the risk of Mycobacterium Chimaera infection contained in his GP records, entered in March 2017 further to a letter sent to the practice by the cardiac surgery department.*

*The investigation in response to this is summarised in a document headed "Proforma for completion at SEA/ adverse incident meeting" dated 14.11.19.*

*My Concerns are –*

1. *The investigation in response to this incident summarised in that document-*
a) *Does not conform to the usual detail and format of such investigations (eg Root Cause Analysis), and*
b) *Appeared inadequate;*

[redacted]

*(In addition the investigation and document, or even their existence, were not disclosed to the coroners office despite three GP statements/ reports from your practice being requested and provided in the preparation for the inquest, only being revealed in the course of oral evidence from the GP during the course of the Inquest). "*

We were saddened to learn of the death of Mr Gore on the 24th August 2019. We have taken this matter extremely seriously and had commenced actions immediately after the inquest and before the Regulation 28 was issued.

These are the actions taken and details of plans to take forward.

**Action to address the concern regarding management of the alert and prevention of future alerts being missed by General Practitioners**

1. The surgery has reviewed the SEA carried out on the 14th November 2019. At that SEA, it was identified that the warning letter had been coded in the medical notes, in part of the medical records called "active problems". There was also a coded entry on the main consultation page. The structure of medical records is complex. The surgery uses Emis which is widely used in many GP practices. The key action identified at the SEA in 2019, was to use an additional place for these sorts of warning letters. which may make them less easy to miss. This additional location is a pop-up message facility on Emis, where free text messages can be recorded. It pops up a message on screen when someone goes into records and the user has to actively click to get beyond it to do anything on the medical records. The discussion at the SEA meeting on the 14th November 2019 was that the pop ups can get overused and that they can then become such long messages that this becomes counterproductive. However, the conclusion of the discussions at the SEA were that the pop ups should be used for such alerts, even where, as in this case, the risk was expressed as very low. (See the Root Cause Analysis which calculates that only about 1:5,000 patients who have heart valve replacement or repair surgery will go on to develop infection. As at May 2022 there have been only 120 worldwide cases of M Chimaera reported. In the UK there have been 49 cases reported. Sadly 33 of these have died)

2. Since the Regulation 28 has been issued, the surgery has conducted an audit of all pop-up messages. This took place on Friday 2nd July 2022. This shows that the pop-up system instigated in November 2019, following the SEA, are being used. We have checked that the pop-up messages currently in place have been actioned appropriately. We accept however, that this system needs to be strengthened. We are at an advanced stage of drafting and implementing a SOP to detail exactly how these warning alerts will be recorded on medical records to standardise practice. We are guided by the literature regarding these infections. Our Root Cause Analysis identified that of the 49 cases identified in the UK, one case took 12 years for the infection to occur. The "Active problem" field includes a feature where the entry will move to another field called "Dormant Problems". The field entry will default to dormant unless this is actively changed and another time is entered. The SOP will detail that all entries will need to remain in the "Active Problem" field indefinitely.

3. Additionally, the surgery has completed a second SEA process on the 18th July 2022 regarding this incident. This is attached and has identified the following:

3.1 The need for a clear standardised approach to managing such warning letters. Ensuring the whole clinical team are aware of and using this new protocol.

[redacted]

3.2 Whole practice policy for clinicians that "active problems" field on medical records are routinely looked at when managing a patient.

3.3 Ensure the patient is aware of any secondary care warning letters and do not rely on secondary care sending out to patients. We will also directly send out communications to patients to make sure they have received the hospital warning, using text messaging, phone calls or letters.

3.4 Clinicians being aware of the symptoms of M Chimaera infection and to consider this where patients present- particularly with prolonger pyrexia, including considering that symptoms might not be present for up to 12 years after surgery.

4. The surgery has also emailed the Cardiology unit at University Bristol Hospital Trust, asking them for a complete list of all patients registered with this practice where they have sent other warnings about M Chimaera. This was requested on the 29th June 2022 and sent them a follow up e-mail on the 27th July requesting a progress report and asking when we might receive this information. This list has just been received and we are in the process of acting on it. We note that they appear to have changed their system of managing such warnings. It is no longer clear in the information they send to us if the patient has been informed, as they should have been by the hospital. We will review the whole list they have sent and feed back this and any other issues to them.

5. The surgery noted that the original warning letter sent by cardiology included web links to detailed information about Mycobacterium Chimaera. This detailed information has been sent to all GP's at the surgery to disseminate knowledge of this infection. This took place on the 15th July 2022.

**Action to address the concern regarding the investigation and that it did not conform to the usual detail and format of such investigations (eg Root Cause Analysis), and appeared inadequate**

1. The surgery is fully committed to openness and promoting a learning and improving culture. We have carefully considered the benefits of external scrutiny to help us see beyond any "organisational blind spots" and have appointed an experienced objective external GP and GP Appraiser, who has never worked for the surgery and has knowledge of local systems.

   He has:

- Reviewed the medical records and associated documentation and conducted a Root Cause Analysis.
- Reviewed our new SEA policy and reporting documentation.
- Reviewed the surgery's SEA conducted in November 2019
- Facilitated a second SEA event which took place on the 18th July 2022.

2. Undertaken a Root Cause Analysis – attached. This has included a detailed risk assessment showing how rare this infection is and has helped to identify actions for the surgery.

3. We have reviewed what our regulatory body- CQC- required in terms of investigation and managing incidents. This indicated that the main approach is SEA. GP mythbuster 3: Significant event analysis (SEA) - Care Quality Commission (cqc.org.uk) There is no specific mention of Root Cause Analysis on the website and this is not a technique which is generally used in general practice.

[redacted]

4. Reviewed our SEA process and documentation used in 2019. Our view and our external assessors view was that this did broadly meet CQC requirements. However, we accept that the content recorded was weak in terms of analysis, investigation, and outcomes.

5. Produced a new SEA policy and documentation process. CQC have been given a copy.
   We feel our new policy and documentation is robust and will result in a better investigation, including risk assessing, analysis, outcome, and written record.

6. The surgery has used this new system for the repeat SEA conducted on this case on the 18th July 2022. Attached. We will continue to use it for a further SEA meeting planned in August, where other SEA issues are being discussed. The practice board will then review at its meeting in August to assess if it is fit for purpose.

The surgery accepts there are always improvements to be made and we will engage actively with these.

**Concern that the SEA conducted in 2019 was not disclosed before the Inquest**

The specific concern is that "*the investigation and document, or even their existence, were not disclosed to the coroner's office despite three GP statements/ reports from your practice being requested and provided in the preparation for the inquest, only being revealed in the course of oral evidence from the GP during the course of the Inquest). "*

The surgery wishes to apologise that this document was not available and wishes to assure the coroner that this was in no way a deliberate intension but rather the result of several events. For the sake of openness and completeness we have fully documented these circumstances as follows:

*1.* The first report was requested by the coroner's office in a letter dated 12th September 2019. There was no indication of any concerns or criticism of the practice. We were requested to return this by the 10th October 2019. We did not conduct the SEA until after the report was requested. The SEA was carried out on the 14th November 2019. It was only as a result of the first request for a report that we discovered there were issues relating to the M Chimaera infection. In addition, this request for a report was the first notification we had received that this patient had died. The coroners court letter went on to say "*A post mortem examination has been carried out and the cause of death is currently unascertained pending the results of histology samples. On behalf of HM Senior Coroner, please may I request a detailed medical report regarding the deceased which will be read aloud at the inquest. This should cover in detail the deceased's medical chronology, recent contact with the surgery and details of any prescribed medication"*

2. The next communication from the coroner's office and dated 21st July 2021 said

*"The coroner has now reviewed the GP records and he has confirmed that the following GP's are to be given Interested Person (IP) status in the inquest:*

[redacted] *(re consultations on 3.11.17 and 10.11.17 and 5.12.17 and 21.12.17)*

[redacted] *(re consultation 13.11.17)*

*The coroner has requested that both GP's provide a statement within 2 months - no later than 15th September.*

[redacted]

*Please can you provide a copy of the letter the surgery received 15.3.17 (referred to in the report provided by GP, [redacted] – page 2 under 15th Mar) re mycobacterium risk. I attach [redacted] report for ease of reference.*

*Please also can you also provide a copy of the letter that was then sent to the deceased following receipt of the above letter – again this is referred to in the same para of the report of [redacted].*

*Please can this email be forwarded to Dr [redacted] so they are aware of the coroner's directions."*

In neither communication was there any information that led us to believe that there was criticism of the surgery. Both communications were very specific in the information requested. The second request named Dr's [redacted] as "Interested Persons". The surgery was never named as an "Interested Person".

As a locum who only saw the patient once, Dr [redacted] was not even aware of the SEA.

We did supply the SEA to the MPS on the 11th May 2022 after Dr [redacted] made MPS aware of it during a meeting held on the 10th May.

We have asked for MPS help in understanding why the SEA did not go into the information supplied to the coroner's office. They have advised us that the coroner determines the "Inquest Bundle". That the surgery was never named as an "Interested Person". That they too did not pick up the potential criticism. All parties felt that as Mr Gore was essentially under the care of secondary care for the last 20 months of his life, including coronary care that the surgery role in his care was very minimal.

We accept that this was a naïve mistake. We also accept that it is our responsibility, not that of MPS who are supporting us, and wish to apologise again for this omission and to further reassure the court that lessons have been learnt form this.

Additional information

The GP Partners, both at the time of the SEA held in November 2019 and those in the Partnership at the point of the inquest, have self-referred to the GMC and to PAG giving full details of the Regulation 28, the history, and the response of the surgery. The surgery has received a communication back from the Head of Professional Standards in the Southwest and chair the Performance Advisory Group (PAG). This states that a review has taken place with one of their clinical advisors and they are satisfied that this issue does not warrant any additional scrutiny from a professional standards perspective and the case will not go for further discussion at PAG. GP Partners are waiting to hear from the GMC.

The surgery has also had contact with our regulator, CQC, and shared full details of all aspects of this case. They too are satisfied and we will now share with them the more recent SEA conducted.

**Future Actions**

The surgery will undertake to share the learning from this incident to the wider Bristol Primary Care Community, via our Clinical Locality Monthly meeting, and also via the local DATIX system. DATIX is a Bristol, North Somerset and South Gloucestershire, whole system platform for reporting issues and for improving care across systems. We will do this by the 29th July 2022.

[redacted]

At an appropriate time in the future, we will contact the family of Mr Gore to apologise for our part in this sad and unfortunate event and to offer assurances about steps taken to prevent a further occurrence.

Yours Sincerely

[redacted]

[redacted]
**Practice Manager**

[redacted]

**Attachments:**

- New SEA policy
- New SEA recording documentation
- Root Cause Analysis
- SEA carried out 18th July 2022

[redacted]