Fulford Grange
Micklefield Lane
Rawdon
Leeds LS19 6BA
Tel: 0113 380 3000
emishealth.com

9th March 2022

Ref: REGULATION 28 – 13 January 2022 [redacted]

Dear Mr Cohen,

With regard to the Regulation 28 report dated 13th January 2022 (the "**Report**"), we have reviewed and considered the circumstances relating to this very unfortunate incident.

Whilst we note that the failure to review the MRI scan report was not causative or related to Mr Busby's death, we treat such matters with the utmost seriousness and an internal review has been undertaken, focussing on the issues of:

1) **No flag attached for abnormal radiology results;**

2) **Inadvertent 'multiple clicking' of the 'file no comment' button in EMIS Web will result in the filing of more than one result if subsequent results are not flagged as abnormal.**

We would like to note the collaboration of North Cumbria Integrated Care NHS Foundation Trust ("the **Trust**") throughout this investigation.

1) **No flag attached for abnormal radiology results**

In relation to this issue, we reviewed the functionality available within EMIS Web and confirmed that it is working as designed, and as per NHS Digital specification. EMIS Web flags results based on the presence of a normal / abnormal clinical code (relevant to the investigation type) within the message received from the Trust's reporting system (in this case ICE).

In this case, the message containing the MRI result did not have a code which indicated 'normality/abnormality' for the MRI. The MRI report was tagged with a ReadV2 code "*56D – Other diagnostic radiology*" terminology code, which is not specific enough to provide any receiving system (in this case EMIS Web) with the relevant details to flag the report as abnormal and present the relevant warnings.

The Report further notes that the Trust had subsequently, unsuccessfully, attempted to add flags to all pathology and radiology results. The above explains why this action was not successful as it requires associated coded clinical terminology, rather than custom flags, for results from any source system.

Investigation by EMIS, in collaboration with the Trust, has determined that a local EMIS Web protocol to flag *56D*-coded terms would not be possible. EMIS Web does not have the ability to configure rule-based logic on a particular code or result type to drive the desired protocol alert.

The understanding of functional limitations of third party systems (ICE & Cris), reviewed as part of this investigation, is based upon information provided by the Trust during the investigation process.

The UK messaging standards for laboratory and radiology reports are currently based on EDIFACT specification which are some 20 years old. EMIS is aware that NHS Digital are currently building a modern set of FHIR messaging standards which, when implemented, will enable report level flagging of normal / abnormal findings which will significantly improve the safety of these messages; EMIS is collaborating with NHS Digital on these standards. There are no current timelines for introduction from NHS Digital.

2) Inadvertent 'multiple clicking' of the 'file no comment' button in EMIS Web will result in the filing of more than one result if subsequent results are not flagged as abnormal

The report states that the Trust, during the course of their investigation, determined that *"clicking more than once on the 'file no comment' button will result in the displayed result being filed, but will also result in filing of the next in the list if that result has no flag indicating the result is abnormal."*

In relation to this issue, we reviewed the functionality available within EMIS Web and confirmed that it is working as designed and in accordance with NHS Digital requirements and specification.

Within EMIS Web, there are two views that a user can select when undertaking *results filing* activities: 'Inbox overview' and 'Detailed overview'.

Inbox overview (dummy data screenshot shown below in fig 1) shows all report tasks in a list view including the date the report was received, the patient's name and the report type.

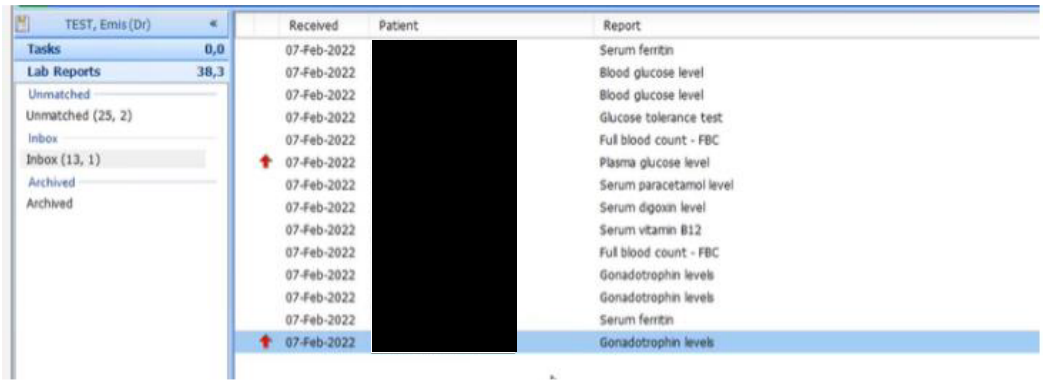

Fig 1

Within this view, it is **not possible** to inadvertently file multiple results through 'multiple clicking' of the 'file no comment' button, as the next result in the list is **not** automatically selected. The 'file no comment' button is not available again (after being pressed once) until the next result is selected manually by the user.

Detailed overview (dummy data screenshot shown below in fig 2) shows all report tasks in a list, and the full report is seen on screen (when one result is selected).

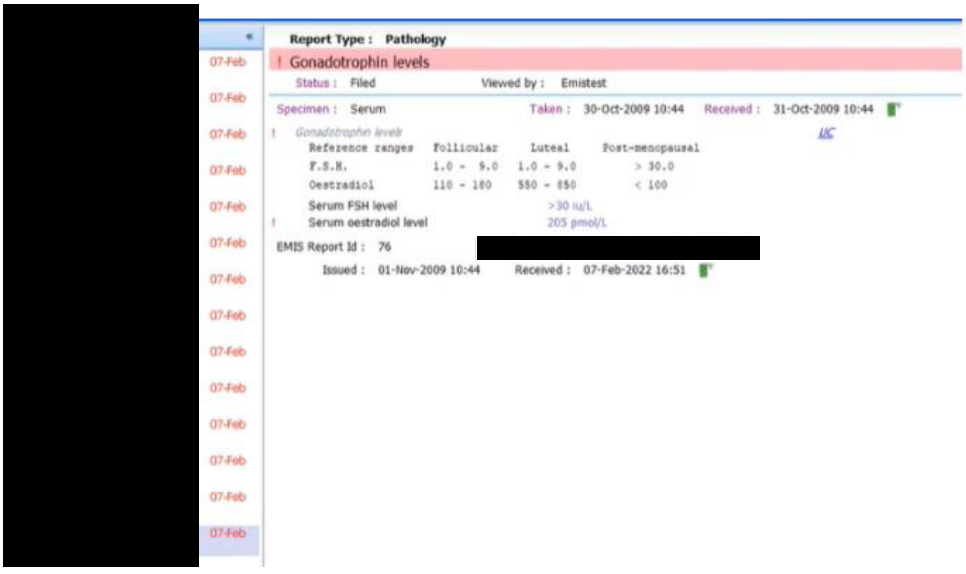

Fig 2

Within this view, after clicking the 'file no comment' button, the result in context **will** move down the list to the next available result. As another result is then in context, a user **can** click 'file no comment' again, and this may be done without the user reviewing the displayed report in appropriate detail.

The user therefore can click through any number of results in quick succession. If clicking fast enough, the system will not have time to load the result on screen before the user has clicked the 'file no comment' button again. The user therefore may not see the full report.

Irrespective of which method is used for *results filing* activities, it is important to note that filing actions do not remove the results from the user's screen. Results must be manually archived for this to occur. Results remain visible to the user and can be unfiled and re-actioned if needed. The system will indicate to the user which results have been filed by a green tick, meaning the user can re-review those results prior to archiving (as per dummy data screenshot shown below in fig 3).

Fig 3

A user can choose to archive using the 'archive' button on the EMIS Web ribbon or, when the user gets to the end of the results list, the system will suggest archiving, to which the user must apply a manual acceptance. Whichever method the user chooses to archive the results, they must click through a screen alert to confirm intended action (as per screenshot shown below in fig 4). It is important to note that the screen alert is defaulted to 'No' to prevent accidental clicking through.

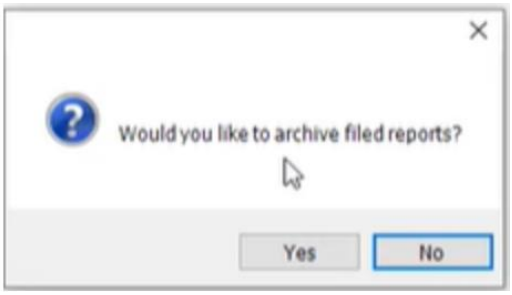

Fig 4

In terms of *results filing*, and against the information provided in the Report, our investigation shows that the system is working as expected and as per NHS Digital specification.

Conclusion

Based upon the information provided in the Report and the subsequent investigation, EMIS do not believe there are any software developments to be undertaken to mitigate risks relating to either of the issues raised in this case.

In respect of the **abnormal flag for radiology results**, EMIS do not believe that mitigation through EMIS Web development is plausible until emerging NHS Digital standards are implemented, given there are no clear identifiers on these types of results that would allow a system to differentiate between a normal or abnormal result.

In relation to any **inadvertent filing activity**, EMIS believe that there are sufficient failsafe measures within the system, alongside appropriate diligence from the user, to prevent such occurrence. It must be the responsibility of the clinician to review, file and subsequently archive results at a speed and with a level of diligence that fits the clinical nature of the results and the patient involved.

As a result of this case and your findings, EMIS is undertaking a number of actions to support our users in the prevention of future harm:

1. EMIS is reviewing and will update the EMIS Web Hazard Log and Safety Case to reflect these identified concerns; highlighting established system and training mitigations that can reduce the risk of future patient harm.

2. EMIS is reviewing training material relating to the filing of results, to include reference to those results that may require a more detailed review, such as radiology results – to prevent users becoming inappropriately reliant upon clinical decision support such as 'abnormal flags'.

EMIS will continue to review and investigate any cases of a similar nature, and review effectiveness of any current and ongoing mitigations.

EMIS have identified, during collaboration with the Trust, a number of operational improvements within their results management practices that the Trust could implement to improve patient safety. Additionally, EMIS will work with the Trust to modify local technical configurations to support the workflow. EMIS will support the Trust to implement these should they wish to.

We trust that the details outlined above are of help.

Finally, as a company, we work very hard to support health care services across the UK and patient safety is of paramount importance to us. We were saddened to read of the issues relating to this particular incident and we would like to pass our condolences on to the family.

If you have any further queries then please contact our Senior Clinical Director, [redacted] (via [redacted], in the first instance.

Kind regards

Dr [redacted]
Chief Medical officer, EMIS Group