University Hospitals Birmingham
NHS Foundation Trust

Executive Office of the Chair and Chief Executive
[redacted]

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Monday 20th December 2021

For the attention of Rebecca Ollivere
Assistant Coroner for Birmingham and Solihull
Birmingham Coroner's Court
50 Newton Street
Birmingham

[redacted]

Dear Ms Ollivere,

Inquest touching the death of Christopher Collinson
Response to Regulation 28 Report to prevent future deaths

I write in response to the Regulation 28 Report made by you following the Inquest touching the death of Mr Collinson which concluded on 26 October 2021.

University Hospitals Birmingham NHS Foundation Trust (the Trust) has carefully considered the concerns raised within your report to prevent future deaths, which relate to the potential for delay in patient assessment and secondary checks when selecting medication and we would respond as follows.

Potential for delay in patient assessment

At the time of Mr Collinson's admission to AMU, patient records at Birmingham Heartland's Hospital (BHH) were predominantly paper based. Within AMU clinicians were expected to confirm their assumption of clinical responsibility for the care of a patient by logging in to a system which provided a list of all the patients on the ward at that specific time.

In this case, the junior doctor who took on Mr Collinson's care, logged on to the electronic system assuming responsibility for reviewing Mr Collinson and then proceeded to look for Mr Collinson's paper records in order to review them and assess him. The doctor became distracted looking after another sick patient and unfortunately did not remove their name from Mr Collinson's record on the electronic system. This was interpreted as completion of clinical assessment of Mr Collinson by other clinicians in AMU which led to the delay in Mr Collinson's clinical assessment and management.

Following Mr Collinson's admission, the above process has been updated and we have rolled out our in-house electronic system, PICS to BHH. PICS has been in use in AMU at BHH since July 2021. PICS provides a paper-free electronic patient record system that allows for simultaneous access and entries to the record of a single patient by multiple clinicians. With PICS, it is easy to access and review patient records at any time. To ensure patients are seen without delay, there are time markers on the system which indicate when patients have been waiting to be seen for a period of time without progression. This allows

those co-ordinating care to see clearly which patients are waiting to be seen and are not progressing. The system highlights those patients who are not progressing in 'red' which highlights that there has been too long a delay and this can easily be seen by the co-ordinators.

As the notes are now electronic, it is very easy for staff to identify what has actually been done, what it outstanding, with clear makers, as referred to above, where patient care has not progressed.

PICS allows for a quick visual summary of patients who are awaiting assessment thereby reducing the risk of delay in assessment.

We are confident that with the use of PICS in BHH, the possibility of unfortunate incidents similar to those surrounding the care of Mr Collinson has been minimised.

Secondary check within electronic prescribing system

The Trust currently has 2 electronic prescribing medication administration (EPMA) systems. This is a result of the merger of Heart of England Foundation Trust with UHBFT which had a different EPMA system in place. Work is already underway to implement a single system which will be in place across all of our sites by the middle of 2022. The system in place at BHH during Mr Collinson's admission was 'JAC', a commercial EPMA system which had been in use for many years.

Within your report you state that "the Doctor prescribed a prophylactic dose of Enoxaparin rather than the therapeutic dose which she had intended to prescribe. The reason for this was that the electronic prescribing system is a drop-down box with confusing tables to select the medication."

To provide some context, Mr Collinson was prescribed a single dose of enoxaparin, the dose of which was lower than that indicated for treatment of venous thromboembolism. The patient died soon after admission. He had been seen 11 days earlier in primary care with what in hindsight appears to have been symptoms of a DVT.

The doctor who had prescribed the medication accepted that the incorrect dose of enoxaparin was as a result of human error. This was also the finding of a carefully conducted internal investigation.
The prescription required a choice to be made of the correct dose according to indication and patient weight as shown in Fig 1 below.

<u>Clinical Decision Support</u>

Clinical decision support exists within electronic systems to support clinical processes and to help clinicians to 'do the right thing'. Examples include allergy checking, assessment of interactions, critical pop-up alerts and evidence-based order sets. In the case of prescribing, an order set can provide rapid access to the most commonly prescribed dose, form, route and frequency of administration. It is recognised that this reduces the rate of execution errors, thereby improving patient safety. For example, in adult practice an order sentence might be 'Paracetamol 500mg tablets – 2 tablets – by mouth – four times per day'. Defaulting to the most common sentence promotes safe and effective prescribing.

Enoxaparin does not have a single prescribable dose because there is variation in dose and frequency according to patient weight, renal function and indication; (for example different daily doses and frequency for treatment or prophylaxis of venous thrombo-embolism). Using

paper, a prescriber has to make all these decisions themselves, often having to do a calculation of dosing according to a patient's weight to obtain the correct dose, a situation potentially prone to error. This risk is mitigated in different ways in different electronic systems however these all seek to incorporate knowledge of these variables, to then provide a prescription within an allowed safe range. For the JAC system, this is illustrated in Fig 1.

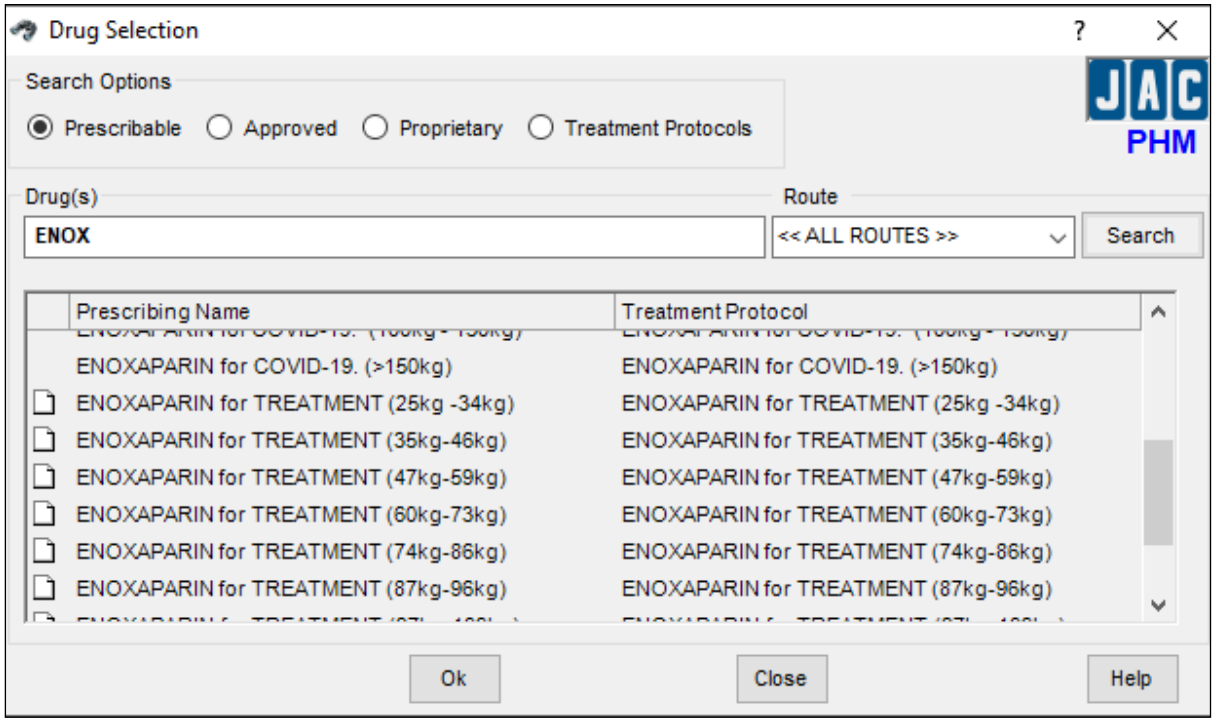

Figure 1: Enoxaparin treatment protocols within the JAC EPMA system

EPMA systems such as JAC, can assist by providing evidence-based options as illustrated In Figure 1, thus providing the correct dosage for the patient according to the determining variables.

There is however little evidence to suggest that introducing an additional double-check into the individual prescriber's workflow improves patient safety. On the other hand, there is evidence of risks associated with introducing many more alerts. This is a consequence of alert fatigue discussed in more detail below.

There are exceptional situations in which an incorrect prescription is so immediately hazardous that a cross-check is made by another individual during the workflow. For example, this occurs for cytotoxic chemotherapy. However, for most medications, cross-checking by other individuals is displaced in time, occurring on ward rounds, in which prescriptions are repeatedly checked, over time, by different individuals.

Sociotechnical Issues, alerting and alert fatigue

Even though electronic prescribing systems with clinical decision support may include features that protect against individual error and thus enhance patient safety, they also have the potential to be confounded by new types of error. For example, dosing errors, such as 10-fold increases in dosing (additional 0 introduced into prescription) can be mitigated in various ways, including drop downs of allowed doses, or automated checking and

interruptive alerting against allowed dose ranges. As discussed above, dose variation within the allowed range is considerably more difficult to address. This can be mitigated by associating indication with the prescription (for example ENOXAPARIN FOR TREATMENT or ENOXPARAIN FOR PROPHYLAXIS). As this case illustrates even this cannot always prevent some types of slip error.

Not only does introduction of a double-check into the individual prescriber's workflow not necessarily reduce risk; there is a significant body of evidence that the addition of such alerting results in the phenomenon of alert fatigue. Alert fatigue is defined as a "condition in which too many alerts consume time and mental energy to the point that both important warnings and clinically unimportant ones can be ignored." It is well described in the literature; the term appears 14 times in the body of a recent report by the Health Safety Investigation Branch on electronic prescribing systems and safe discharge.

While alerts can change clinician decision making, as they increase there is progressive rise in the proportion that are over-ridden. For example, drug interactions often result in many clinical alerts; however these are overridden in nearly all cases (up to 95% in some studies). Overrides may be clinically appropriate, such as when a clinician deems the likely benefit of administering a medication to exceed the potential medication risks. In other cases, overrides may represent not carefully considered clinical decisions, but reflexive dismissals by clinicians who have become inured to the large number of alerts. This is particularly common in a situation in which a prescriber is invited to confirm the prescription just entered, as opposed to an interruptive alert that prevents prescriptions outside of allowed parameters. It is our view that there is therefore a high risk that introducing the suggested second check introduces so many alerts that high value alerts are inadvertently missed, whilst achieving no meaningful benefit. This is particularly the case when an EPMA already has significant design features to minimise the risk of error, in this case indication and weight.

Is a secondary check required?

When a prescriber picks from a list, they are performing an affirmative action. Introducing a new alert to say "are you sure you want to pick enoxaparin treatment for your patient" every time that this is prescribed will quickly lead to alert fatigue. The prescriber is very quickly not going to read the contents of the message and instead click 'yes' to get to the next action. (For context there are approximately 8000 prescriptions for enoxaparin every month across UHBFT. There are > 1 million drug administrations every month, all supported by carefully designed clinical decision support).

We believe that the balance of risk and benefit is against routinely introducing such a double-check step in the process of prescribing. This decision would be consistent with the current scientific literature and the collective approach of clinical safety officers responsible for the introduction and maintenance of EPMA. A selection of relevant references are attached to this response.

Based on the review of our systems and relevant literature, we are confident that the systems and processes that we have in place are sufficient to minimise risk to our patients. We are satisfied that our decision not to introduce an additional double-check step has been carefully considered and is consistent with the collective approach of those responsible for introducing and maintaining EPMA systems.

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I would like to assure you that the concerns raised within the Regulation 28 Report have been taken extremely seriously which I hope is demonstrated by our response above.

Yours sincerely

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Professor [redacted]
Chief Medical Officer

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