Interim Chief Executive, NHSI
National Medical Director
NHS England & NHS Improvement
Skipton House
80 London Road
London
SE1 6LH

Alison Mutch, Senior Coroner,
Manchester South
Coroner's Court,
1 Mount Tabor Street,
Stockport
SK1 3AG

11th November 2021

coroners.office@stockport.gov.uk

Dear Ms Alison Mutch

Re: Regulation 28 Report to Prevent Future Deaths – Mark Holden 26 February 2021

Thank you for your Regulation 28 Report dated 6 September 2021 concerning the death of Mark Holden on 26 February 2021. Firstly, I would like to express my deep condolences to Mr Holden's family.

The regulation 28 report concludes Mr Holden's death was a result of:
1a Pulmonary Embolus
1b Deep Vein Thrombosis, II Covid -19 Pneumonia

Following the inquest you raised concerns in your Regulation 28 Report to NHS England regarding:

1. The appointment with the GP was via telephone due to Covid. As a result, there was no examination of Mr Holden and no opportunity to identify the DVT which was present at the time of the telephone consultation.

Telephone consultations have been in use in general practice for many decades to help patients access medical advice and care quickly and conveniently. Where studies have been conducted, telephone triage has been shown to be safe. Telephone consultations are part of general practice training schemes.

The coronavirus (COVID-19) pandemic has brought about an unprecedented acceleration in the adoption of delivering NHS services remotely, and standard operating procedures were produced to ensure general practice is able to operate safely in this context. The relevant published version of the Standard Operating Procedure is here for reference which was iterated throughout the pandemic to meet changing needs and requirements since it was first published in March 2020.

These procedures make it clear that general practices and Primary Care Networks should triage patients remotely (to determine the right person and timeframe for managing the problem) in advance wherever possible to help prioritise patient care based on needs; and that clinicians should determine the most appropriate consultation method with the patient - telephone, video, online, face to face. This should be determined by taking into consideration

the patient's preferences, needs (including accessibility, privacy, capacity and communication requirements), clinical circumstances and currently, local risks of COVID-19.

In determining the most appropriate consultation method, considerations regarding patient safety, ability to make a satisfactory assessment, gain a sufficient understanding of the problem and whether information can be provided in a way the patient understands including assessing a patient's understanding of the advice provided should be factors in determining the most appropriate consultation method. If a particular concern did arise following a remote assessment or remote advice being given, then a decision could be made to move to an alternative approach, for example, face to face consultation or for remote advice to be followed up in writing or with the patient's permission with their carer.

Professional guidance published by the General Medical Council sets out high level principles of good practice expected of everyone when consulting and or prescribing remotely for patients https://www.gmc-uk.org/ethical-guidance/learning-materials/remote-prescribing-high-level-principles and guidance to support shared decision making https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent.

Additionally, guidance was developed jointly between NHS England and the Royal College of General Practitioners (RCGP) on Remote vs Face to Face: which to use and when? (November 2020) and RCGP now publish a range of guidance and learning materials on their Covid-19 Resource Hub .These resources underline the importance of ensuring patient safety, shared decision making and that an individual's needs are paramount.

Whilst we do not have all the clinical details regarding the circumstances of Mr Holden's discharge, we would ordinarily expect the discharge summary from the hospital to provide the GP practice with the details of their assessment including examination and investigations, and for advice to be given to the patient about safety netting. Safety netting is a routine part of clinical practice and explicitly sets out next steps to take for the patient in the event of a deterioration in their condition.

The joint NHS England and RCGP guidance (linked above), which is now in place, refers to the importance of 'safety netting'. Every GP practice must continue to provide face to face consultations alongside telephone, video and online consultations as part of making general practice as accessible as possible.

2. The D-Dimmer of over 10,000 did not trigger an alert on the Lorenzo electronic system due to how it was reported and the configuration of Lorenzo at that time at the Trust. The Trust have taken steps to change how the reports are input into Lorenzo to ensure a raised D- Dimmer such as this triggers an alert. It was unclear if that learning has been shared across the NHS to other trusts who use Lorenzo to ensure that alerts are triggered.

Due to the number of IT systems used across NHS organisations, investigation results are flagged in a variety of different ways. Many organisations incorporate third-party applications and non-technical processes to ensure relevant clinical staff are notified in a timely manner.

Whilst it remains the responsibility of clinicians to review the results of investigations they request, NHS organisations also have an obligation to ensure their processes and systems are safe. This requirement is outlined in Clinical Risk Management standards DCB0160. From your report, I understand that the trust in question has since taken steps to ensure abnormal results trigger alerts on the EPR system.

As a result of this Regulation 28 a Customer Safety Notice (CSN) has been produced and distributed to all impacted users of the Lorenzo system. This was issued on 21st September and has been communicated more widely within the NHS. An additional CSN was distributed on 24th September 2021 informs impacted users how to access a fix.

In addition, NHSEI's 'Digital First OCVC Clinical Safety Forum' was held recently and was attended by some digital suppliers. A point was raised as to whether an addition could be made to the triage tool, in which patients would be asked if they had sought healthcare advice in the previous 3-4 weeks (I understand that perhaps in this tragic case, Mr Holden had not volunteered this information and the GP may not have not asked).

It is NHSEI's understanding that the issue continues to be monitored by NHSX and NHS Digital in conjunction with the relevant manufacturers of the Lorenzo system and those IT systems connected to it.

3. The inquest heard that there will often be a raised D- Dimmer with Covid-19 and that in addition that there is an increased risk of clots with Covid-19. The evidence before the inquest was that the existing NICE guidance used by clinicians does not deal with the Covid-19 aspects/ recognised risks.

In November 2020, NICE published a COVID-19 rapid guideline on Reducing the risk of venous thromboembolism (VTE) in over 16s with COVID-19 (NICE Guideline 186). This guideline was in place at the time of Mr Holden's death and applied to all patients with COVID-19 pneumonia, covering pharmacological VTE prophylaxis for patients being treated for COVID-19 pneumonia in hospital and in the community.

NG186 has since been incorporated into NICE Guideline 191: COVID-19 rapid guideline on managing COVID-19 Overview | COVID-19 rapid guideline: managing COVID-19 | Guidance | NICE.

Thank you for bringing these important patient safety issues to my attention and please do not hesitate to contact me should you need any further information.

Yours sincerely,

[redacted]

Interim Chief Executive, NHS1
National Medical Director