Department of Health & Social Care

From Nadine Dorries MP
Minister of State for Patient Safety,
Suicide Prevention and Mental Health

39 Victoria Street
London
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[redacted]

Your Ref: [redacted]
Our Ref: [redacted]

Mr Graeme Irvine
HM Area Coroner, East London
Coroners Court
Queens Road
London E17 8QP

03 June 2020

Dear Mr Irvine

Thank you for your letter of 12 March 2020 to Matt Hancock about the death of Mitica Marin. I am replying as Minister with responsibility for patient safety and I am grateful for the additional time in which to do so.

Please extend my most sincere condolences to Mr Marin's family and loved ones. I appreciate how distressing Mr Marin's sudden death must be to those who knew and loved him and we must do all we can to take the learnings from his death to prevent future deaths.

Your report explains that in a review of cases of delayed defibrillation conducted by the London Ambulance Service, a contributing factor was that the LIFEPAK 15 monitor and defibrillator was defaulted to manual mode, requiring the user to select the automatic external defibrillator (AED) mode when desired. You ask if future deaths could be avoided if the LIFEPAK 15 device was defaulted to the AED setting.

In preparing this response, my officials have taken advice from NHS England and NHS Improvement (NHSEI), the Medicines and Healthcare products Regulatory Agency (MHRA), the Association of Ambulance Chief Executives (AACE) and the London Ambulance Service.

The MHRA advises that it has not received any similar reports regarding the default settings of this model of defibrillator. Factory default settings have to cover a wide range of applications and are not suitable for all purposes. The LIFEPAK 15, used in hospitals and by ambulance staff, may be set up with different default settings, based on the intended use, for example as a clinical monitoring tool or an AED. Information on different set up options is provided with the device.

Professional organisations are best placed to determine the appropriate default settings according to their local protocols and intended use, taking into account available guidance.

You will know from the AACE's response to your report that in 2019, as part of a review of clinical practice guidelines, the advantages and disadvantages of manual and automatic modes for delivering the first shock to patients in cardiac arrest were considered. As a result, revised guidance was issued in June 2019 that acknowledged that while manual mode may be the preferred option for trained paramedics, the automatic mode may be preferable in other situations, for example, solo first responders in potentially stressful environments.

I am advised that the London Ambulance Service provides training to clinical staff on the importance of prompt defibrillation and, in October 2019, issued updated cardiac care guidance for staff making clear that in all cases of cardiac arrest, the LIFEPAK 15 should initially be switched to AED mode.

I understand that the London Ambulance Service has considered if changing the default setting of the LIFEPAK 15 to AED mode could improve clinical outcomes. The London Ambulance Service has decided, for reasons set out in its response to your report, that this is not practical for every-day use given the device's functionality as both a clinical monitoring tool and defibrillator.

In relation to future procurement of defibrillators, this is a matter for individual ambulance services. I am advised that the London Ambulance Service is looking to source devices that have in-built technology to negate the need for the user to actively select the mode of operation. I understand that such a device has not been located but that, where it can, the London Ambulance Service is encouraging manufacturers to consider this functional requirement for future models.

In the absence of such a design, it is of course important that ambulance services using devices such as the LIFEPAK 15 look to mitigate the risk of future incidents of delayed defibrillation and my officials have asked the AACE to make the concerns in your report known to ambulance services in England. I note the measures taken by the London Ambulance Service, including updated guidance to staff on managing cardiac arrest, human factors training and focused training for solo first responders.

Finally, my officials have drawn this matter to the attention of the MHRA and also Professor [redacted], the National Clinical Director for Heart Disease at NHSEI. Following discussion with clinical colleagues, Professor [redacted] has advised that the current default mode of the device being manual, rather than automatic, is acceptable having considered the rationale of the London Ambulance Service deliberations on this matter. Professor [redacted] has recommended that, if further monitoring and analysis of data shows continuing evidence of delays, consideration should be given to changing the default setting of the device and this advice has been shared with the London Ambulance Service.

I hope this response is helpful. Thank you for bringing these concerns to my attention.

NADINE DORRIES