



CONFIDENTIAL

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24 February 2022

Dear Ms Harkin

Re: Report to Prevent Future Deaths: Alfie Stone deceased

Thank you for your Regulation 28 Report to Prevent Future Deaths, dated 14 January 2022, bringing to my attention HM Coroner's concerns arising from the Inquest into the death of Mr Alfie Stone.

I would like to assure you that within the East Midlands Ambulance Service (EMAS) all matters related to patient safety are taken extremely seriously. Matters arising from Coroners' Inquests from which lessons can be learnt, including Prevention of Future Death Reports, are discussed within the Incident Review Group.

Coroner's Concerns

1. Apparent lack of training of paramedics in the use of buccal midazolam.

The paramedics administered rectal diazepam which was the treatment available within EMAS. Rectal diazepam is on the EMAS medicines formulary for the treatment of convulsions and is a recognised treatment within the UK ambulance service clinical practice guidelines, developed by the Joint Royal Colleges Ambulance Liaison Committee (JRCALC), who develop guidance for all ambulance services on behalf of the Association of Ambulance Chief Executives. This also aligns with recommendations from the National Institute for Health and Care Excellence (NICE). The NICE pathway for treating prolonged or repeated seizures in the community states:

Administer buccal midazolam as first-line treatment in children, young people and adults with prolonged or repeated seizures in the community. Administer rectal diazepam if preferred or if buccal midazolam is not available. (Available from <https://pathways.nice.org.uk/pathways/epilepsy> last updated 15 December 2021).

When buccal midazolam is available in the home as a medication prescribed by the patient's General Practitioner or hospital team, then EMAS paramedics can administer

this (where family/carer are unable to do so) according to JRCALC buccal midazolam guidance. This is a recent addition to EMAS JRCALC guidance which is available to EMAS staff to access as an 'App' on their phone, iPad or other electronic device. It is to be added to the EMAS Scope of Practice Policy to ensure clarity for paramedic staff that they can administer within EMAS guidance.

Buccal midazolam comes as a pre-filled oral syringe with the dose prescribed by the doctor according to the child's age. Each outer container has two or four doses and contains a patient information leaflet with clear instructions and illustrations as to how to administer a dose. Please see enclosed summary of product characteristics for Buccolam from medicines.org.uk (ENC). The buccal route will be familiar to paramedics as we administer other medicines by this route.

As registered healthcare professionals, paramedics are responsible for their own continued professional development according to standards of continuing professional development specified by the Health and Care Professions Council and so should ensure they are competent in the recognition of epileptic seizures and the treatments they can administer.

In the case of Alfie Stone, neither the Emergency Operations Centre (EOC) nor the attending responders were informed that buccal midazolam was available within the home for emergency treatment and so rectal diazepam was administered according to local and national guidance.

Following a review of the concerns raised in the PFD notice received on 19 January 2022, the concerns relating specifically to midazolam will be discussed at the Medicines Governance Group in February 2022 to assess the impact of adding buccal midazolam to the EMAS medicines formulary. The impact will consider treatment effectiveness, timely access to midazolam on Trust ambulances as it will need to be securely stored in a cabinet only accessible by controlled key access and it may take longer to access in an emergency (due to this being a Schedule 3 controlled drug within the Misuse of Drugs Regulations 2001) and alternative treatments.

The Medicines Governance Group will develop an action plan that will consider training for all staff who would access and administer buccal midazolam in an emergency, as well as staff who may need to access and administer buccal midazolam not supplied by EMAS but held at the patient's home or other facility.

Buccal Midazolam is on the agenda for the February Medicines Management Group, which is attended by senior Medical, Pharmacy and Quality leads. The intended timeline will be to start the process in April 2022, on the transition from our current anti-convulsant medication to Buccal Midazolam along with the legal processes we need to adopt to carry out this transition within the legal frameworks for this medication. The HM Coroner will be kept updated throughout this process.

- 2. No other form of oxygenation attempted such as bagging or the child being taken earlier to the ambulance to secure and deliver oxygen.**

In order to transport Alfie from his room down the stairs to the ambulance it would be technically challenging to ensure safe transfer and continual bagging of Alfie. EMAS accepts that it would have been beneficial to have maintained oxygenation via face mask during transfer to the ambulance from his bedroom. Following the outcome of this inquest, EMAS is keen to learn and embed lessons to ensure that all clinicians are reminded of the need to maintain oxygenation during the transfer of patients that are fitting. This will be covered in the bulletin stated below under question 3. to address seizure management, the HM Coroner will be provided with a copy of this bulletin when issued to our frontline staff.

3. No suction attempted, and the question was not asked of the parents as to whether the child had vomited.

When the crew arrived with Alfie he was conscious, alert and conversing. Whilst they were present Alfie started to fit, he did not vomit in the crew's presence and therefore there was no requirement to utilise the suction unit. However, as part of learning from events a clinical bulletin reinforcing a systematic approach to seizure management and aspiration will be developed to enforce best practice. The bulletin will be made available to the HM Coroner with an anticipated date of the 7 March 2022.

4. No evidence of training to the paramedics who attended and gave evidence, following an independent Serious Incident Report and its agreed recommendations.

As in point 1 above, EMAS provides rectal diazepam (and intravenous diazepam) for the treatment of convulsions and both are recognised treatments within the UK ambulance service clinical practice guidelines, developed by JRCALC, and within NICE guidance. Due to the discontinuation of diazepam rectal tubes 2.5mg, EMAS made a recommendation at its Medicines Governance Group in November 2021 to gather data and build a business case regarding a move to buccal midazolam, liaising with other Ambulance Trusts.

The business case will be brought to the Medicines Governance Group in April 2022. The aim would be to introduce buccal midazolam across EMAS within the next 6 to 12 months following appropriate review and oversight from the Clinical Governance Group. When midazolam is added to the Schedule 17 exemption list of the Human Medicines Regulations which is expected during 2022, this will speed up the governance and approval process.

In addition, the EMAS Trust Pharmacist is working with JRCALC and Specialist Pharmacy Service to ensure that neonates under the age of three months are included within the national patient group direction (PGD) and JRCALC guidance to enable treatment for those who do not have an epilepsy passport or treatment prescribed within the home who may present to emergency services with convulsive status epilepticus in the community.

The updated guidance, national PGD and learning from this PFD will also be shared across the Ambulance Pharmacists Network, a network of pharmacists from all

ambulance services within the UK. This will ensure learning is of benefit to patients across all ambulance services to avoid future harm.

5. East Midlands Ambulance Service not accepting the recommendation 3 within the report to carry and administer buccal midazolam when necessary.

Recommendation 3 of the Kettering report states: *“EMAS should audit training and competencies of first responders in administration of buccal midazolam in children experiencing prolonged seizures in line with Joint Royal Colleges Ambulance Liaison Committee (JRCALC) guidance”.*

At the time of the incident involving Alfie, EMAS did not have buccal midazolam within its medicines formulary. Therefore, at that time there was not a requirement to audit training and competencies of first responders in administration of buccal midazolam in children. Our clinical staff are trained to administer buccal medication, (patient’s own prescribed medication) therefore had buccal midazolam been available this would have been an option for the staff on scene.

I hope that the measures set out in this letter provide you with the appropriate level of assurance in relation to EMAS’ commitment to continuous improvement of services.

Please do not hesitate to contact me should you require any additional information, or any clarification, in connection with the above.

Yours sincerely




Chief Executive

Enc: Summary of product characteristics for Buccolam from [medicines.org.uk](https://www.medicines.org.uk)