Department of Health & Social Care

From the Rt Hon Andrew Stephenson CBE MP
Minister of State for Health and Social Care

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Karen Dilks
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[redacted]

19 April 2024

Dear Ms Dilks,

Thank you for a copy of your Regulation 28 report to prevent future deaths, dated 26 January 2024, into the circumstances surrounding the death of James Atkinson. I am replying as Minister with responsibility for long-term conditions, including allergies.

Firstly, I would like to say how saddened I was to read of the circumstances of James' death, and I offer my sincere condolences to his family and loved ones. His loss at such a young age must be extremely distressing for them and I am grateful to you for bringing these matters to my attention. Please accept my sincere apologies for the delay in responding to this matter and I am thankful for the extension you have granted.

In preparing this response, Departmental officials have made enquiries with NHS England, to which you also issued your report. I am assured that your concerns have been carefully considered and I hope their response to you is helpful. I noted the extensive work of NHS England's Clinical Reference Group in particular, including the current review of the Specialist Allergy Service Specification, as well as the learnings and improvements implemented at the relevant practice and integrated care board.

My response will focus on the matters of concern relating to the need to educate, review and manage those who are diagnosed with allergies.

Under the GP contract, GP practices are required to provide a set of core services, termed essential services. They include the identification and management of illnesses, providing health advice and referral to other services during core hours, which are 8.00am–6.30pm Monday to Friday, excluding bank holidays. There is an expectation that GP practices review patient medication on a regular basis as part of these essential services and we expect commissioners to take action if services are not meeting the reasonable needs of their patients.

Medication reviews are, of course, particularly important for medicines provided on repeat prescriptions to confirm that the patient is taking their medicines as directed and check that medicines are still needed, effective and tolerated.

The General Medical Council (GMC), the independent regulator of all medical doctors practising in the UK, has issued ethical guidance for doctors on reviewing patients' medication, *Good practice in prescribing and managing medicines and devices*. The guidance is clear that doctors have a duty to ensure they are prescribing and managing patients' medicines appropriately, and that doctors must ensure that suitable arrangements are in place for monitoring, follow up and review. The guidance can be found at www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/reviewing-medicines.

Information is contained in the British National Formulary (BNF) that patients who are at risk for or have a history of serious allergic emergencies carry two adrenaline auto-injector devices (AAIs) at all times; on the importance of training patients and carers in the use of the particular AAI prescribed, as well as other advice aimed at patients and carers. The BNF is a joint publication of the British Medical Association and the Royal Pharmaceutical Society, and is accessible from the National Institute for Heath and Care Excellence's (NICE) website, with the relevant information available at https://bnf.nice.org.uk/drugs/adrenaline-epinephrine/.

Prescribers are expected to refer to information within the BNF to help inform prescribing decisions made with individual patients and carers. This expectation is also set out in *Good practice in prescribing and managing medicines and devices*, within the section entitled: '*keeping up to date and prescribing safely*' which can be found at https://www.gmc-uk.org/professional-standards/professional-standards-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/keeping-up-to-date-and-prescribing-safely.

As you will aware, NICE has developed evidence-based guidance to support clinicians in managing allergy and related disorders. Guidance is routinely subjected to an evidence surveillance exercise to establish whether an update is available. However, guidance will be reviewed and updated at any time if important new evidence comes to light.

NICE has published a clinical guideline, *Anaphylaxis: assessment and referral after emergency treatment (CG134),* and a quality standard on anaphylaxis (QS119). Both this guideline and quality standard cover care after emergency treatment for suspected anaphylaxis, including assessment and referral to specialist allergy services. That is, they begin at the point in the clinical pathway immediately after a health professional has started to manage a suspected anaphylactic reaction.

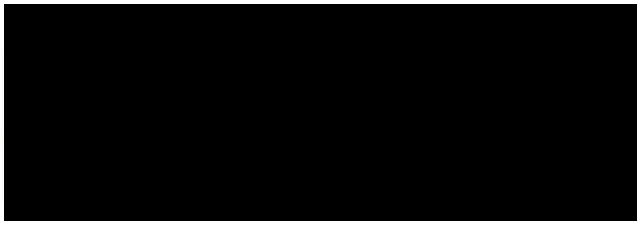
It is not clear from your report whether James had ever experienced an anaphylactic reaction before the one that caused his death. It is, therefore, unclear whether either CG134 or QS119 would have been directly relevant to the issues that contributed to his death.

In June 2023, the Medicines and Healthcare products Regulatory Agency (MHRA), with the support of allergy awareness advocates, launched a safety campaign to raise awareness of anaphylaxis and provide advice on the use of AAIs. As part of this campaign, a toolkit of resources was made available for health and social care professionals to support the safe and effective use of AAIs. Health and social care professionals were asked to use the materials to inform patients and caregivers what to do

if they suspect anaphylaxis and how to use AAIs. Details of the campaign and the resources can be found at https://www.gov.uk/drug-safety-update/adrenaline-auto-injectors-aais-new-guidance-and-resources-for-safe-use.

Finally, in June 2023, the British Society for Allergy & Clinical Immunology (BSACI) published *Adrenaline auto-injector prescription for patients at risk of anaphylaxis: BSACI guidance for primary care.* The guidance was developed to address key primary care clinical questions informed by current practice and known gaps in care from reported fatalities. It is intended to act as a resource and signpost to materials for primary care workers. The guidance is intended to assist in decision-making during consultations, especially around risk assessment, need for referral and prescription of AAIs, by simplifying the understanding and practice of prescribing for health professionals. This guidance can be found at https://www.bsaci.org/guidelines/primary-care-guidelines/adrenaline-auto-injector-prescription-for-patients-at-risk-of-anaphylaxis-bsaci-guidance-for-primary-care/.

I hope this response is helpful. Thank you once again for bringing these matters to my attention.



ANDREW STEPHENSON MP