Department of Health & Social Care

From Helen Whately MP
Minister of State for Care

39 Victoria Street
London
SW1H 0EU

020 7210 4850

Our Ref: PFD-1202428

Mary Elizabeth Hassell
HM Senior Coroner, Inner North London
St Pancras Coroners Court
Camley Street
London N1C 4PP

4 June 2020

Dear Ms Hassell

Thank you for your correspondence of 27 January 2020 to Matt Hancock about the death of Shanté Turay-Thomas. I am replying as my Ministerial portfolio covers Long Term Conditions, including allergies and I am grateful for the additional time in which to respond.

I would like to start by saying how very sorry I was to read of the circumstances around the death of Shanté. Her loss, at such a young age, must be extremely distressing for her family and loved ones and I offer my heartfelt condolences to them. I agree that it is essential that we learn from this tragic event to prevent future deaths.

Your report raises several serious matters of concern and has been sent to a number of health-related organisations at local and national level that have a role to play to ensure the safety of people with allergies. My reply will focus on the response to your concerns by national level organisations. However, I want to make clear that the failings relating to primary care and urgent unscheduled care services in north London as described in your report are unacceptable. I expect the NHS to thoroughly review the circumstances of Shanté's death and your findings and take robust action to put in place learnings to prevent such deaths from occurring again.

Departmental officials have made enquiries with the organisations to which you issued your report to understand the system-wide response to the matters of concern. I am assured that your concerns have been carefully considered. I will not repeat the detail of the responses you will receive which are the responsibility of others. However, I wish to highlight the actions being taken at a national level that are relevant to the concerns you have raised.

I welcome the action agreed by the Commission on Human Medicines (that provides expert, independent advice to the Medicines and Healthcare products Regulatory Agency (MHRA)) to convene an Expert Working Group (EWG) on Adrenaline Auto-Injectors (AAIs) that will provide independent clinical advice on matters relating to the safe and effective

use of AAIs, including several of the issues highlighted in your report such as AAI product labelling; training in the use of AAIs; and whether AAIs should be available to the market in dual packs as the norm.

In addition, the AAI EWG will help to inform a planned communication campaign being developed by the MHRA to raise awareness of the key messaging on the safe and effective use of AAIs. As you will know, the key messages are:

- The need for patients to carry two AAIs with them at all times; and,

- In cases of acute anaphylaxis, to administer a second AAI five to fifteen minutes after the first if there has been no sign of improvement.

It is vital that these messages are understood by patients, their carers' and healthcare professionals to prevent future tragedies.

As to whether dual packs of AAIs should be available as the norm, I note that all AAI brands in the UK are authorised to supply AAIs in single or dual packs. Companies are not required to market all pack configurations and at present, only Epipen is available to the market as a dual pack. The MHRA intends to write to the manufacturers of Jext and Emerade to encourage the marketing of dual packs.

While the MHRA agrees that the availability of AAIs in packs of two would support the aim of ensuring that patients always have access to two AAIs, there are important considerations, such as the need for flexibility. The MHRA will seek the expert advice of the AAI EWG on this matter.

On the emergency response to cases of anaphylaxis, I am advised that a clinical coding review, conducted in May 2019, led by NHS England and NHS Improvement (NHSEI), concluded that symptoms suggesting life-threatening anaphylaxis should receive a Category 1 response. This change came into effect for NHS Pathways (used by NHS 111 providers and around half of ambulance trusts in England) in October 2019 and equally applied to the Medical Priority Dispatch System (MPDS) used by other ambulance trusts. I am advised that NHSEI has oversight of both the NHS Pathways and MPDS clinical decision support systems and the NHSEI-led Emergency Call Prioritisation Advisory Group provides governance and approval of any change to clinical code sets.

In relation to NHS Pathways specifically, I am advised that there are established governance systems in place to capture, review and resolve issues relating to clinical coding (including from Prevention of Future Deaths reports); and to ensure latest clinical advice and guidance is reflected in call categorisation. Independent clinical scrutiny of NHS Pathways is provided by a National Clinical Governance Group that includes representatives of medical Royal Colleges.

The commissioning and management of general allergy services is a local matter. For most patients (around 95 per cent) allergic diseases can be managed by primary or other non-specialist allergy services with routine therapies. Approximately five per cent of patients with allergies require treatment in a secondary service, and of those, around

20,000 (0.1 per cent) require referral to a specialist centre. These specialist services are commissioned at a national level by NHSEI to an agreed delivery specification.

The National Institute for Health and Care Excellence (NICE) develops 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.

NIICE has published clinical guidelines in this area covering food allergy in children and young people under 19[1]; drug allergy[2]; anaphylaxis[3]; eczema[4]; and asthma[5]. In addition, NICE has produced a range of technology appraisals for drugs and interventions to relieve symptoms of these conditions as well as diagnostic assessment tools.

You will know from NICE's response to your report that information is already contained in the British National Formulary (BNF) and the BNF for children (BNFc) that two AAIs should be prescribed; that patients should carry two AAIs at all times; and the importance of training in the use of the particular AAI prescribed. Prescribers are expected to be alert to safety information in relation to the medicines they prescribe and to refer to the BNF and BNFc when making prescribing decisions with their patients. NICE will consider how it can make more clear in its guideline on *Anaphylaxis: assessment and referral after emergency treatment,* the advice that two AAIs should be prescribed and that patients should carry two AAIs with them at all times.

In relation to the training of primary healthcare professionals in the management of allergies, curricula and training is available through the relevant professional bodies (such as Royal College of Physicians and Royal College of General Practitioners (RCGPs)) and organisations, such as the British Society for Allergy & Clinical Immunology (BSACI), that provide educational, training and research resources. I am advised that NHSEI has undertaken to bring the matters of concern in your report to the attention of Health Education England (HEE) and the RCGPs to consider what action might be taken to strengthen training in this area and where possible, NHSEI will help to facilitate the uptake of any new guidance or resource.

We recognise the key role played in the wider primary care workforce by dietitians, to whom people with a variety of nutritional issues, including food allergies and intolerances, can be referred.

Last year, a system of Primary Care Networks (PCNs), each formed from different GP practices working together, was established across England. They are designed to bridge the historic divide between primary and community health services and provide an

[1] https://www.nice.org.uk/guidance/cg116

[2] https://www.nice.org.uk/guidance/cg183

[3] https://www.nice.org.uk/guidance/cg134

[4] https://www.nice.org.uk/guidance/cg57

[5] https://www.nice.org.uk/guidance/ng80

extended range of community-based services. PCNs are recruiting extra dietitians and other specialists, with funding being made available through an Additional Roles Reimbursement Scheme. The NHS Long Term Plan[6], published last year, has guaranteed a minimum investment of £4.5billion extra per year for primary medical and community care by 2023/24. On top of this, an extra £1.5billion has been committed to general practice over the next four years for growing the workforce by 6,000 doctors and 26,000 other staff.

In relation to accountability for allergies, my Ministerial portfolio covers long term conditions, including allergies and the provision of allergy services. Ministers are held to account by Parliament and that accountability is supported by several directorates within the Department of Health and Social Care that have relevance to policy on allergens. This includes primary care; population health; oversight of the Food Standards Agency (FSA); environmental hazards and NHSEI sponsorship. Although there is no single, named individual with oversight of all aspects of allergy policy, individuals and teams work closely together in the Department on all aspects of policy relating to allergies.

Following the reforms initiated by the Health and Social Care Act 2012[7], NHSEI is responsible for clinical policy and strategy in the NHS in England (including for allergies) and NHSEI is held to account through the annual NHS mandate[8]. NHSEI has a clinical reference group (CRG) for Specialised Immunology and Allergy Services[9], that provides advice on specialised services and commissioning policies and quality standards. The CRG is chaired by a consultant immunologist, specialising in clinical Immunology and allergy and expert clinicians are among the membership. I hope this provides assurance of the clinical leadership and policy oversight of allergy services.

Although not directly relevant to the matters of concern in your report, you may wish to note that as part of its food hypersensitivity strategy, the FSA, which is responsible for protecting the health of the public in relation to food, is exploring how it can build a better picture of allergic consumer experience. This includes exploring how to develop a reporting link that a range of stakeholders (e.g., consumers, businesses and potentially medical professionals) can use to facilitate the identification of emerging trends and where necessary, alert local authorities so that they can take appropriate investigative and enforcement action.

To support this project and increase the data available to the FSA on food-related cases of anaphylaxis, including deaths and near fatal incidents, the Department is working to identify means of access to relevant data sets so they can be included for analysis.

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[6] https://www.england.nhs.uk/long-term-plan/

[7] http://www.legislation.gov.uk/ukpga/2012/7/contents/enacted

[8] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/803114/accountability-framework-to-nhse-and-nhsi-2019-to-2020.pdf

[9] https://www.england.nhs.uk/commissioning/spec-services/npc-crg/blood-and-infection-group-f/f06/

Finally, I am aware that this is not the first time you have issued a Prevention of Future Deaths report following the inquest into the death of a child where there are concerns about the use of AAIs and the emergency response to cases of acute anaphylaxis.

I am assured that national health organisations are taking important action to ensure the safety and quality of health services related to allergies and my response has referred to some of that work. However, given the potential for systemic learning, Departmental officials have brought your concerns to the attention of the Healthcare Safety Investigation Branch (HSIB) that conducts independent investigations of patient safety concerns in NHS-funded care across England, to ask if it will consider the matters of concern in your report and whether these in part, or in whole, meet its criteria for national investigation. Due to the Covid-19 pandemic, HSIB's consideration of this referral will be conducted when the situation allows.

I am grateful to you for bringing these matters to my attention. I hope this reply is helpful.

HELEN WHATELY