Berkshire Coroner's Office
Reading Town Hall, Blagrave Street, Reading, RG1 1QH
[redacted]

Regulation 28: REPORT TO PREVENT FUTURE DEATHS (1)

NOTE: This from is to be used **after** an inquest.

REGULATION 28 REPORT TO PREVENT DEATHS

THIS REPORT IS BEING SENT TO:

1. **Secretary of State for Health and Social Care, 39 Victoria Street, London, SW1H 0EU.**
2. **UK Fatal Anaphylaxis Registry.**
3. **Medicines and Healthcare Products Regulatory Agency, 10 South Colonnade, London E14.**

2 CORONER'S LEGAL POWERS

I am Mrs Heidi J Connor, Senior Coroner for Berkshire. I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013.

3 INVESTIGATION and INQUEST

I conducted an inquest into the death of Alexandra Briess, which concluded on 15th December 2022. I recorded a Narrative Conclusion as follows:

Alexandra Briess underwent an uneventful tonsillectomy on 22nd May 2021. She suffered post-operative bleeding, and required further surgery. This was carried out on 30th May. During anaesthesia, Alexandra suffered a sudden deterioration and cardiac arrest. Despite extensive resuscitation efforts, she died at Royal Berkshire Hospital, London Road, Reading on 31st May 2021. Subsequent investigations have revealed that the most likely cause of her sudden deterioration was an anaphylactic reaction to Rocuronium. This was a drug she had not had before, and her reaction to it was unpredictable. Alexandra was a bright and well loved young woman, who had planned to study medicine herself.

Her cause of death was:
I a Anaphylaxis due to Rocuronium used during anaesthesia
I b Surgery to repair post operative bleeding 30th May 2021
I c Tonsillectomy 22nd May 2021

This Regulation 28 Report has been deliberately delayed, to allow for careful consideration of guidance to pathologists, police and coroners, and in order to

ensure the report is addressed to the correct recipients. Alexandra's family has been kept updated in this respect.

4 CIRCUMSTANCES OF THE DEATH

Alexandra was born on 3rd January 2004. She was 17 at the time of her death.

The key facts in this case are as follows:

- Alexandra had no significant past medical history.
- She underwent an uneventful tonsillectomy on 22nd May 2021.
- After returning home, she suffered post-operative bleeding and required further surgery.
- The second operation was carried out on 30th May.
- When the anaesthetic was administered on 30th May, Alexandra deteriorated suddenly and suffered a cardiac arrest.
- A large number of clinicians were involved in trying to assist Alexandra, but tragically, she died at the Royal Berkshire Hospital in Reading on 31st May 2021.
- There are no concerns about her clinical management.
- The most likely cause of her sudden deterioration was an anaphylactic reaction to Rocuronium, a drug which she had not had before.

5 CORONER'S CONCERNS

Background

This is not new territory. Several coroners have raised concerns similar to mine. Those listed below are simply the cases where coroners have sent Regulation 28 reports. There may well be others.

Previous cases include :

1. In the case of Shante Turay-Thomas (who I believe was 18 at the time of her death), the Senior Coroner for Inner North London stated:

> "*The issues within this Prevention of Future Deaths report are predominantly national issues, but I heard at inquest that there is no person with named accountability for allergy services and allergy provision at NHS England, or the Department of Health as a whole.*"

2. In the case of Robin Bousquet (who I believe was 14 at the time of death), the Coroner for Inner South London stated in a Regulation 28 Report to Prevent Future Deaths:

> *"In my opinion action should be taken to consider establishing a national reporting system which includes timely reporting to local authority and FSA and maintenance of a register of fatalities and their investigations, and consideration be given to investigating the feasibility of wider access to AAIs. I believe that the organizations would wish to learn of the circumstances of this death and are in a position to facilitate a collaborative process to mitigate or prevent future deaths."*

3. In the case of Ms Celia Marsh (who I believe was 42 at the time of her death), the coroner touched on many of the issues I will refer to in this report. She stated the following:

> "*Concerns were raised in relation to the immediate investigation into a suspected death from anaphylaxis, that the evidence obtained at this time, with the right approach, can be invaluable to preventing deaths, but that to achieve this, changes are required.*
>
> *In relation to the Food Standards Agency, the UK Health Security Agency, and the Department of Health and Social Care:*
>
> - *To establish a robust system of capturing and recording cases of anaphylaxes, and specifically, fatal and near-fatal anaphylaxis…*
> - *Such a system could involve, mandatory reporting of anaphylaxis presenting to hospital analogous to the current system for notifiable diseases… by registered medical practitioners have a statutory duty to notify the 'proper officer' at their local council or local health protection team of suspected cases of certain infectious diseases. An example of such a reporting system for anaphylaxis already exists in the State of Victoria in Australia, and allows for rapid alerts of serious cases to public health authorities to expedite investigation and evaluate public health risk."*

Alexandra's case

It seems clear to all coroners in these cases, and those involved in this area of medical expertise, that the only way to improve understanding and prevent or reduce future deaths is to gather information nationally and fund appropriate research.

Appropriate organisations already exist, and there is a lot of goodwill towards improving understanding in this area. It does however require national leadership and "joining up" of these organisations.

The matters of concern are as follows:

1. **I have tried to make my list of issues clear and succinct. Paragraph 2 below sets out the crux of this ongoing risk**.

2. **There is significant goodwill and desire to improve amongst numerous organisations involved in anaphylaxis work. What is lacking is national leadership and funding. In my view, consideration should be given to creating a leadership role and responsibility within NHS England to coordinate a national approach.**

3. As considered by other coroners before me, it should be mandatory to refer fatal anaphylaxis cases. UKFAR has indicated that they would be prepared to take on the role of receiving these reports (to avoid duplication for reporting clinicians), with the responsibility to forward the relevant information to other organisations such as the MHRA, where appropriate. Whilst my focus is on fatal anaphylaxis, inclusion of non-fatal cases would be a matter for the lead role to consider.

4. Gathering data and using this to research and reduce the risk of future deaths requires funding, and this should be reviewed.

5. Information sharing amongst the organisations referred to in this report should be straightforward. Confidentiality constraints are important, but not the same in the case of a deceased person as they are for a living person. I believe that a confidential advisory group has already started to consider this matter.

6. Consideration of including contact details for the UKFAR in algorithms used by doctors attempting to resuscitate patients – so that there is a clear requirement for referral to UKFAR in the event of an unsuccessful resuscitation. This is currently being considered by the Resuscitation Council UK.

For my part, I have taken the following steps to increase awareness in the work that

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I do :

1. I have taken responsibility for making my fellow coroners aware of the existence of UKFAR and circulated guidance to them to use in anaphylaxis cases.

2. The Royal College of Pathologists is reviewing their guidance, and I intend to circulate interim guidance which coroners can send to their pathologists, pending this more official guidance.

3. I will also send all coroners nationally a guidance note to use for their local police forces in gathering appropriate evidence at the scene of a likely anaphylaxis case.

6 ACTION SHOULD BE TAKEN

In my opinion action should be taken to prevent future deaths, and I believe your organisation has the power to take such action.

7 YOUR RESPONSE

You are under a duty to respond to this report within 56 days of the date of this report,
namely by 2 June 2023. I, the Coroner, may extend the period.

Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed.

8 COPIES and PUBLICATION

I have sent a copy of my report to the Chief Coroner and to Alexandra's family.

I have also sent this report to the following recipients, who have an interest in this matter:

[redacted], Director of Clinical and Service Development at the Resuscitation Council UK.

[redacted], Clinical Support Manager for Association of Ambulance Chief Executives.

[redacted], President of Paediatric Critical Care Society

[redacted], Honorary Secretary of Paediatric Critical Care Society.

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[redacted] President Royal College of Emergency Medicine.

[redacted], Deputy Medical Director at Learning from Patient Safety Events.

[redacted], National Medical Examiner Programme and Policy Lead.

[redacted], Lead Medical Examiner

[redacted], National lead for Designated Doctors for Child Health in Sudden and Unexpected Child Deaths.

[redacted], Permanent Secretary at DEFRA.

[redacted], Chief Executive Officer at Food Standards Agency.

[redacted], President of the Royal College of Pathologists.

[redacted], Chief Medical Officer, Royal Berkshire Hospital

I am also under a duty to send the Chief Coroner a copy of your response.

The Chief Coroner may publish either or both in a complete or redacted or summary form. He may send a copy of this report to any person who he believes may find it useful or of interest. You may make representations to me, the Coroner, at the time of your response about the release or the publication of your response by the Chief Coroner.

6 April 2023

Mrs Heidi J Connor
HM Senior Coroner for Berkshire