

Emma Brown

Area Coroner for Birmingham and Solihull
Coroner's Court
Steelhouse Lane
Birmingham
B4 6BJ

By email to: [REDACTED], PA to HM Senior Coroner

[REDACTED]
Head of Health and Public
Services Sector
Engagement & Policy
Division
Health and Safety
Executive
Redgrave Court
Bootle
Merseyside
L20 7HS

Date: 19 March 2025

Dear Ms. Brown

NEVILLE MCKENZIE: PREVENTION OF FUTURE DEATHS REPORT

Thank you for your Regulation 28 report dated 24/01/2025, issued following the inquest into the death of Neville McKenzie. I am replying as the Head of HSE's Health and Public Services Sector.

I would like to express my sincere condolences to Mr McKenzie's family and loved ones.

Matters of concern

I understand that Mr McKenzie died at the City Hospital, Birmingham on 25/08/2024, as a result of a choking incident at Acorn Care Home (provided and run by 1st Care Limited) on 13/08/2024. During the inquest the Director of Operations for 1st Care Limited expressed the view that anti-choking devices could save lives in the event of choking incidents. Your report raises the concern that there is not wide knowledge of the availability of these devices in care settings and if more care homes had them it is likely that deaths from choking could be reduced.

In preparing this response, I have considered:

- the respective responsibilities of regulators in England when dealing with health and safety incidents in the health and adult social care sectors
- the regulation of medical devices.

Following consideration of these factors, I respectfully advise that HSE is not the appropriate regulator or policy lead to address this concern relating to anti-choking devices because:

- 1st Care Limited are a service provider registered with the Care Quality Commission (CQC), and therefore regulation of this and similar care providers falls under their enforcement responsibility
- anti-choking devices are medical devices for which the Medicines & Healthcare products Regulatory Agency (MHRA) are the UK regulator
- the Department of Health and Social Care (DHSC) are the government department that leads on health and social care policy and delivery in England.

These bodies will therefore be better placed to address your concerns about the use of anti-choking devices in health care premises.

To provide further clarification, I have set out below more detailed information on how health and safety incidents are regulated in the health and adult social care sectors in England and on regulatory responsibility in respect of medical devices.

Regulation in England of health and safety incidents in the health and adult social care sectors

In England, the regulation of health and safety in adult and social care sectors is shared between HSE/Local Authorities and the CQC. This is set out in a [Memorandum of Understanding \(MoU\)](#) that outlines each regulator's respective responsibilities.

In summary, in respect of patient safety:

- CQC is the lead inspection and enforcement body under the Health and Social Care Act 2008 for safety and quality of treatment and care matters involving patients and service users in receipt of a health or adult social care service from a provider registered with CQC.
- HSE/LAs (depending on the type of premises) are the lead inspection and enforcement bodies for health and safety matters involving workers, and patients and service users who are in receipt of a health or care service from providers not registered with CQC.

I draw your attention to Annex 1 of this MOU that gives illustrative examples of incidents where CQC take the lead (i.e. where the provider is registered with the CQC), including a patient/service user being seriously injured or dying as a consequence of choking.

As mentioned, 1st Care Limited are a service provider registered with CQC, and therefore fall under their enforcement remit.

Regulation of medical devices

MHRA are the regulator of medicines, medical devices and blood components for transfusion in the UK.

Anti-choking devices are classed as medical devices by MHRA, and they have published guidance on this issue: [guidance on anti-choking devices](#).

This agency's responsibilities include:

- ensuring medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and efficacy

- securing safe supply chain for medicines, medical devices and blood components
- educating the public and healthcare professionals about the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use
- enabling innovation and research and development that is beneficial to public health
- collaborating with partners in the UK and internationally to support the mission to enable the earliest access to safe medicines and medical devices and to protect public health.

Additionally, the Department of Health and Social Care (DHSC) are the government department that leads on health and social care policy and delivery in England. Its responsibilities include making sure that legislative and policy frameworks are fit for purpose. MHRA is an executive agency of DHSC.

I understand you have already copied your Regulation 28 report to the CQC as an interested party.

You may also wish to refer your concerns to MHRA who can be contacted at [REDACTED] and to DHSC, who have a dedicated inbox to receive coronial correspondence at [REDACTED].

Yours sincerely,

[REDACTED]

[REDACTED]

Head of Health and Public Services Sector