Coroner for South London Area

South London Coroner's Office
2nd Floor, Davis House
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Tel [redacted]
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	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **1. [redacted], Chief National Medical Examiner, National Medical Examiner's Office, 6 Alie Street, London E1 8QT** **2. [redacted], Chief Executive, Medicines and Healthcare Products Regulatory Agency (MHRA), 10 South Colonnade, Canary Wharf, London E14 4PU** **3. [redacted], Interim National Director of Patient Safety, NHSE (National Patient Safety Committee), NHS England, Wellington House, 133-155 Waterloo Road, London SE1 8UG**
1	**CORONER** I am Andrew Harris, assistant coroner for the coroner area of South London
2	**CORONER'S LEGAL POWERS** 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** An investigation was opened on 28th November 2018 into the death of Mrs Ashana Charles on 20th November 2018 in Queen Elizabeth Hospital, Woolwich. The inquest was part heard in London Inner South by me as senior coroner on 13th February 2020. Following alarming evidence first heard in court, the pathologist recommended investigations and expert evidence that required international searching, which was not completed before I fell ill and retired from London Inner South. In December 2024 the case was transferred to South London. The resumed inquest concluded on 9th December 2025. The conclusion of the inquest was that she died from acute obstruction of small pulmonary arteries by

	cellulose fibres, which had embolised from inadvertently contaminated intravenous infusions at some stage of product preparation or administration. The source of fibres could not be identified, but the sudden death from embolism would have been prevented had a 1.2 micron filter been used in IV infusion, which was not standard practice at the time.
4	**CIRCUMSTANCES OF THE DEATH** Mrs Charles was admitted to hospital in September 2018 with weight loss and anaemia from severe immunosuppressed advanced stage AIDS. She improved on retroviral therapy and treatment of complications, including CMV colitis, but she had persistent diarrhoea and hypalbuminaemia requiring parenteral feeding. A Hickman line was inserted on 14/11, Ganciclovir was begun and IV antibiotics continued. At 22.30 on 19/11 IV feeding was begun with Nutriflex Omega Special, to which vitamins had been added by the manufacturer. The standard giving set normally used on the ward would have had an integrated 15-micron filter. There was no record of deviation from routine aseptic technique in administration. On the morning of 20/11, she was clinically improved on review; a hot feeling was sensed when medication was infused, but she had no temperature. At 13.55 her unexpected cardiac arrest was witnessed and CPR begun immediately. She was declared dead at 14.36.
5	**<u>CORONER'S CONCERNS</u>** During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths could occur unless action is taken. In the circumstances it is my statutory duty to report to you. The **MATTERS OF CONCERN** are as follows: 1. That no source of contamination could be identified due to the infusion set, filter, feeding bag and lines not being retained for forensic investigation. The pathologist Professor [redacted] gave an opinion that deaths that might be associated with IV feeding were probably underreported due to inadequate investigation. 2. [redacted], expert pharmacist and pharmaceutical regulator drew attention to a) The inconsistency at the time between US and European and UK guidance about use of filters in parenteral feeding (PN). b) Reference to filters for Omega Special by the drug manufacturer at the time indicating an appropriate filter "if one was used", but not its need or desirability or context of use, and the value of manufacturers and health providers integrating their approach to risk management. c) The use of 1.2 micron filter at the time was not standard practice, perhaps because of cost or operational reasons as the filter often led to blockages and delays in IV feeding. Now both that BNPG guidance and BBraun recommend the use of 1.2 micron filters on Omega Special label, but that does not give assurance that all PN and filter manufacturers issue the same guidance nor that their products are operationally consistent with guidance. d) Lewisham & Greenwich NHS Trust have begun to re-evaluate the use of 1.2 micron filters in PN feeding but the matter had not yet gone to its governance

	department but should do so next year. There was a need for those responsible for decision implementation in hospitals nationally to cross work with manufacturers and specialist bodies. e) Uncertainty whether the reported visual checks of PN products by batch rather than individually provided adequate safety assurance.
6	**ACTION SHOULD BE TAKEN** *Concern1:* The Chief Medical Examiner's attention is drawn to the opinion that medical examiners should be advised of the need to retain IV feed equipment for pathological investigation where there is an unexplained death within 24 hours of parenteral feeding. *Concern 2:* The MHRA and NHSE (National Patient Safety Service) are asked to consider whether the regulatory systems for production and administration of parenteral feeding need to be better integrated, with sharing of risk assessment data and consistent guidance.
7	**YOUR RESPONSE** You are under a duty to respond to this report within 56 days of the date of this report, namely by 6th February 2026. 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. Your response should be sent to: Clerk, [redacted] at [redacted]
8	**COPIES and PUBLICATION** I have sent a copy of my report to the Chief Coroner and to the following Interested Persons: [redacted] (husband), [redacted] (mother), Lewisham & Greenwich NHS Trust, BBraun Medical Ltd, and to the British Pharmaceutical Nutrition Group, who I believe may find it useful or of interest, and may also send them a copy of your response. I am also under a duty to send a copy of your response to the Chief Coroner and all interested persons who in my opinion should receive it. I may also send a copy of your response to any other person who I believe may find it useful or of interest. 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.
9	**11th December 2025** **Assistant Coroner Professor Andrew Harris**