NHS England

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20 January 2025

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Dear Sir,

Re: Regulation 28 Report to Prevent Future Deaths –Aviva Otte who died on 2 January 2014. Yousef Al-Kharboush who died on 1 June 2014, Oscar Barker who died on 29 June 2014

Thank you for your Report to Prevent Future Deaths (hereafter "Report") dated 15 November 2024 concerning the death of Aviva Otte on 2 January 2014, Yousef Al-Kharboush on 1 June 2014, and Oscar Barker on 29 June 2014, and sent to the NHS England Regional Director for London. I am responding on behalf of the organisation in my capacity as National Medical Director but would like to assure you that the Medical Director for London has also been sighted on this response and has reviewed your Report. In advance of responding to the specific concerns raised in your Report, I would like to express my deep condolences to Aviva's, Yousef's, and Oscar's parents and wider families. NHS England are keen to assure the families and the Coroner that the concerns raised in the Report have been listened to and reflected upon.

I am also grateful for the further time granted to respond to your Report, and I apologise for any anguish this delay may have caused to the parents and families of Aviva, Yousef and Oscar. I realise that responses to Coroner Reports can form part of the important process of family coming to terms with what has happened and appreciate this will have been an incredibly difficult time.

The concerns raised in your Report were that:

1. There is no requirement for a section 10 exempt entity to report any of its findings to the MHRA or indeed to other Trusts or the industry in general if an adverse event occurs.
2. The current reporting structures (for a section 10 entity) involve reporting to NHS England and the Care Quality Commission (CQC) but the threshold or necessity for such reporting appears unclear and in essence, up to the Trust.
3. There may be times when section 10 entities reach conclusions which would assist the wider industry and help to assist both other Trusts and commercial organisations in assessing their own risks and improving the provision of highly specific medications to a group of vulnerable patients.
4. The same may also be true of commercial organisations but they have the power of the MHRA controlling and effecting recalls and actions and the wider dissemination of information.

My response to your Report has been informed by the Infection Prevention, Patient Safety and Pharmacy teams here at NHS England.

We note these tragic deaths occurred over ten years ago and can assure you that practice has changed since then. For example, sporicides (agents that kill harmful spores) are now widely used.

Risk management of TPN manufacturing in the NHS

We are aware that contaminated Total Parenteral Nutrition (TPN) poses severe risks to patient safety, including hospital infection outbreaks. These risks are particularly pronounced among vulnerable populations such as neonates, oncology patients, and those in critical care settings, where adverse outcomes from infections can be life-threatening.

Whilst TPN is a sterile intravenous solution that provides essential nutrition to patients unable to eat or absorb nutrients orally it is susceptible to contamination during its production, storage, or administration. Such contamination can lead to bloodstream infections (BSIs), sepsis, and nosocomial outbreaks. Factors contributing to these risks include inconsistent practices in aseptic preparation, improper handling, and breaches in storage protocols.

The risk of contamination of TPN can arise from multiple stages in its lifecycle, to include production, storage and handling and catheter management.

These issues are compounded in high-risk populations such as neonates, oncology patients, and those in intensive care units, where compromised immunity increases susceptibility to infections.

To mitigate against the risk of contamination several mitigations are put in place during the production, storage, distribution and administration of TPN.

To mitigate the risks associated with TPN contamination, a comprehensive approach is required:

- **Education and Training:** Healthcare professionals should be thoroughly trained in aseptic preparation techniques, proper storage protocols, and the early identification of contamination risks. Consistent education ensures safe and standardised TPN handling practices across all settings.
- **Adherence to Guidelines:** Compliance with national and international standards, such as NICE QS61, must be enforced to maintain the highest levels of care quality and patient safety.
- **Operational Oversight:** Regular audits and monitoring should be conducted to ensure adherence to established protocols. Enhanced oversight of TPN preparation and administration is particularly critical for high-risk patient populations to minimise complications and improve outcomes.

S.10 Exempt NHS Units – Guidance and effectiveness

The reporting structure for section 10 units is now much clearer following the publication of the NHS England » Assurance of aseptic preparation of medicines.pdf in March 2023, and replacing the previous guidance from 1997. This guidance …"applies to all NHS pharmacy aseptic facilities in England undertaking preparation of sterile medicinal products under Section 10 exemption to the Medicines Act 1968 (as amended)…". It is my understanding that a copy of this was previously shared with the Coroner. The document outlines the escalation processes for:

a) periodic quality audit findings,
b) ongoing monthly quality indicator and action plan monitoring,
c) serious patient safety incidents

NHS England commissions the NHS Specialist Pharmacy Service (SPS) to carry out quality audits of section 10 units through their regional quality assurance leads (RQAs) and to support Trusts in achieving the required quality standards in accordance with this guidance.

Quarterly unit status overview reports are routinely sent to NHSE Regional Chief Pharmacists (RCPs), the NHSE Chief Pharmaceutical Officer and CQC Medicines Optimisation. This achieves a cross sector sharing of s.10 exempt manufacturing and ensures the CQC have awareness of any high risk failings or serious incidents. This notification/reporting is not a decision made at local level by an NHS body/Trust, but forms part of the SPS oversight and escalation in place. Following implementation of the new guidance, the first of these quarterly reports was received in Jul 2024. There is immediate escalation of high-risk failings or serious patient safety incidents to the relevant RCP in the first instance.

In general, any NHS Trust providing aseptic services under a section 10 exemption does not need to report to the MHRA as they're not licensed units. However, all incidents from these services will be reported via the current patient safety incident reporting route and into the NHS Learn From Patient Safety Events (LFPSE) system.

There is also an informal system in place to specifically monitor errors from NHS aseptic units – NAERS – National Aseptic Error Reporting System. This has been established by the Pharmacy Aseptic Service Group, a national specialist interest network, but this is not formally mandated and neither the group nor the system are formally connected to NHS process and governance.

Recently, there have been conversations between the NHSE hospital pharmacy team, SPS quality assurance lead and MHRA inspectorate about sharing trends from audit and inspection findings, and indeed both SPS and the MHRA shared findings at the last Quality Assurance and Technical Services in October 2024: Pharmaceutical Aseptic Services Group: Quality Assurance and Technical Services Symposium (QATS).

However, the MHRA has no regulatory role in section 10 units so a requirement to report to them would not follow the governance and accountability arrangements in the NHS, nor would such a reporting line be consistent with MHRA's scope of activity, given it does not have a mandate over s.10 exempt units.

The SPS quality assurance service issues a regular newsletter and holds virtual workshops and seminars for NHS staff to highlight risks and support in aseptic services. This does not extend to commercial manufacturers producing TPN, who can continue to seek guidance and input from the MHRA. The SPS is intended to connect NHS s.10 exempt pharmacies and share sector knowledge as part of continuous improvement and learning across that group.

With respect to effecting recalls and actions, the situation is different for section 10 units compared to units under MHRA control because for a section 10 unit any recalls or actions and patients affected would be managed entirely within their own organisation. Generally, products will have already been administered by the time a problem is identified, so recall prior to use is not relevant and the current MHRA Defective Medicine Report Centre (DMRC) would not have a role. Situation management will follow usual incident management and oversight arrangements for NHS trusts in the same way as any other serious internal incident would be managed, identifying causes for the incident and implementing recommendations and learning to mitigate the risk of recurrence where possible.

In relation to the 4th aspect of the PFD report captured above, the MHRA will have a role in licensed unit manufacturers investigating incidents and the MHRA may choose to amend their guidance as a result (as we understand they did following the investigation into the June 2014 outbreak).

Updated position – joint approach

In early December 2024, my colleagues from the Hospital Pharmacy Team met with the DHSC, MHRA, CQC and SPS to understand current arrangements (included above) and consider actions. There was general consensus that useful actions could include:

1. NHSE reviewing and updating the 2023 Assurance of aseptic preparation of medicines guidance to provide further direction on thresholds for reporting and escalation of concerns from section 10 aseptic units.
2. Development and implementation of a 2-way information sharing agreement between the MHRA and NHSE at organisational level to share learning from serious incidents related to aseptic medicines preparation/manufacture. Criteria would need to be established to prevent over-reporting but information relevant to stakeholders could be cascaded through existing MHRA and NHSE safety alert mechanisms.

NHS England is happy to undertake to update the Coroner on future actions arising from this.

It was noted at this meeting that for some time the MHRA and CQC have had a Memorandum of Understanding (MOU) in place between them for sharing information on matters of concern and that the independent sector also operates section 10 aseptic units that only the CQC have authority over as the regulator, i.e. no MHRA, SPS or NHS involvement or oversight. The communication MOU referenced as action 2 above, will therefore address the NHS s.10 exempt pharmacy production incident point in the PFD, but it will not capture any independent sector s.10 exempt units.

These remain subject to reporting to CQC in the same way as the NHS reports safety incidents, both of which then depend on the CQC sharing that information with the MHRA under the MOU.

I would also like to provide further assurances on national NHS England work taking place around the Reports to Prevent Future Deaths. All reports received are discussed by the Regulation 28 Working Group, comprising Regional Medical Directors, and other clinical and quality colleagues from across the regions. This ensures that key learnings and insights around events, such as the sad deaths of Aviva, Yousef and Oscar, are shared across the NHS at both a national and regional level and helps us to pay close attention to any emerging trends that may require further review and action.

Thank you for bringing these important patient safety issues to my attention and please do not hesitate to contact me should you need any further information.

Yours sincerely,

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National Medical Director