NHS
Greater Manchester
Integrated Care

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Private & Confidential
Elizabeth Wheeler
Assistant Coroner for Cheshire
Cheshire Coroner's Court
Museum Street
Warrington WA1 1JX

Sent by email to: [redacted]

Dear Elizabeth

Re: Regulation 28 Report to Prevent Future Deaths – Mr. Alan Crabtree

Thank you for your Regulation 28 Report dated 20th of February 2026 regarding the sad death of Mr. Alan Crabtree. On behalf of NHS Greater Manchester (NHS GM), we would like to begin by offering our sincere condolences to Alan's family for their loss.

Thank you for highlighting your concerns during the inquest, which concluded on the 26th of January 2026. On behalf of NHS GM, we apologise that you have had to bring these matters of concern to our attention, and we recognise it is very important to ensure we make the necessary improvements.

During the inquest, you identified the following causes for concern:

1. **The dose regime referred to in the "Shared Care Guideline for Oral Methotrexate in Rheumatological Conditions in Adults" does not reflect current practice and the initial dose recommended is a sub-therapeutic dose.**

The Shared Care Protocol (SCP) includes a section that explains how methotrexate doses should be managed once a hospital specialist has started treatment. It sets out a range of doses that may be used, starting at a lower dose and increasing gradually over time. The protocol states that methotrexate should be prescribed at 7.5–25 mg once weekly according to hospital instructions, with an initial dose of 5–15 mg once weekly, titrated upwards by 2.5–5 mg every 2–6 weeks according to response, with a typical maintenance dose up to 20 mg per week, and in some circumstances up to 25 mg per week. The protocol also specifies that only 2.5 mg tablets should be prescribed, which is a recognised national safety measure intended to minimise the risk of dosing errors with methotrexate.

The dose range described in the Shared Care Protocol is consistent with information contained within the Summary of Product Characteristics (SmPC) for Methotrexate, which describes typical dosing ranges for rheumatoid arthritis and states that dosing should be adjusted gradually in order to obtain an optimal therapeutic response. This approach is designed to allow clinicians to balance effectiveness with

safety. Methotrexate is a powerful medicine, and starting at a lower dose helps reduce the risk of serious side effects, particularly in people who are older, frail, or who have kidney or liver disease.

The dosing range described in the protocol also reflects earlier national rheumatology guidance available when the document was developed. For example, the 2008 guidance from the British Society for Rheumatology and British Health Professionals in Rheumatology for the prescription and monitoring of non-biologic disease-modifying antirheumatic drugs describes a typical methotrexate dose range of 7.5–25 mg once weekly, with an initial dose of 5–10 mg once weekly, increasing by 2.5–5 mg every 2–6 weeks until the disease is stabilised. The dosing range described in the Shared Care Protocol, therefore, allows specialist doctors to adjust treatment based on the individual needs of each patient.

It is important to note that within the shared care model, methotrexate treatment is initiated and titrated by the specialist rheumatology team, and the starting dose is a specialist clinical decision made in consultation with the patient. This decision takes into account multiple factors, including disease severity, comorbidities, renal function, age, and the overall treatment strategy. Methotrexate may also be prescribed in combination with other disease-modifying antirheumatic drugs (DMARDs) as part of the overall management plan for inflammatory arthritis, and therefore, the starting dose and titration schedule may be adjusted by the specialist clinician to reflect the overall therapeutic regimen.

There has been a recent update to specialist guidance to methotrexate monitoring, following publication of the British Society for Rheumatology guideline in 2025. National medicines information resources, including guidance published by the Specialist Pharmacy Service, have not yet fully updated their publicly available monitoring guidance to reflect these newer recommendations. In response to these developments, a review of the monitoring requirements within the Shared Care Protocol has already been scheduled, and the dosing wording will also be reviewed as part of the next update of the protocol to ensure alignment with contemporary rheumatology practice and national guidance.

Overall, the Shared Care Protocol provides a framework that ensures methotrexate therapy is initiated, dose-optimised, and monitored under specialist supervision, with clear safety safeguards and structured monitoring arrangements in place before prescribing responsibility is transferred to primary care.

The concerns raised by this report have highlighted that some Shared Care Protocols have passed their planned review dates. NHS Greater Manchester has addressed this by the implementation of immediate and long-term actions.

Immediate actions:

- Formally recognise the risk associated with out-of-date SCPs at the system level via a risk register.
- Introduce regular reporting through existing governance routes, including Greater Manchester Medicines Management Group (GMMMG) and GM Clinical Effectiveness Group (CEG).
- Add a statement to the GMMMG website to clarify when protocols have passed their review date and are awaiting formal review.
- Continue to make urgent safety-related amendments through existing clinical governance processes where required.
- Prioritise review of those protocols considered to present the greatest clinical risk.
- Preparation and dissemination of a ‘7-minute briefing’ to share the learning from this issue across the GM health care sectors, including primary and secondary care and community pharmacy teams.

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Long-term plan:

- Develop and implement a formal process for risk rating and prioritising review of all out-of-date SCPs.
- Establish clear ownership, responsibilities and timescales for coordinated review and updating of overdue protocols.
- Embed the SCP review programme within the NHS GM Pharmacy and Medicines Team with a responsibility for clinical guidance, including SCP's workplan.
- Maintain oversight through the NHS GM Pharmacy and Medicines Team with routine progress updates to GMMMG.
- Strengthen assurance arrangements so that shared care protocols are reviewed in a timely way and future backlog risk is reduced.
- Ensure there is a robust communication mechanism to inform all involved and to maintain future knowledge of any improvements.

2. The "Shared Care Guideline for Oral Methotrexate in Rheumatological Conditions in Adults" was produced in September 2017. Since then, the "Pharmacy First" scheme has come into effect. The guidance, therefore, does not reflect the changes in the relevant responsibilities between secondary care, GPs and community pharmacists leading to ambiguity as to what type of healthcare professional a patient should consult and potentially fatal delay in increasing methotrexate or commencing treatment for toxicity for the same.

The SCP was written in 2017, before the introduction of the Pharmacy First scheme, which expanded the role of community pharmacists in treating some minor conditions.

The SCP clearly advises patients taking methotrexate to seek medical advice if they develop symptoms such as sore throat or mouth ulcers, as these can be signs of serious side effects. Patients are directed to contact their GP or specialist team, who are responsible for their ongoing care and monitoring.

Community pharmacists are not part of the formal shared care arrangements for methotrexate prescribing and monitoring. While pharmacists play an important role in supporting patients, symptoms that may indicate methotrexate toxicity require assessment by the clinicians overseeing the patient's treatment.

As part of the planned review, NHS Greater Manchester will consider whether the guidelines could be clearer for patients about who to contact if they develop concerning symptoms.

This learning relates particularly to the importance of clear communication and the timely recognition of immunosuppression and its potential effects. While methotrexate is widely and appropriately used, the case has reinforced how critical it is that signs of possible infection or toxicity are recognised early and acted upon, and that patients know who to contact for advice.

Additionally, NHS GM has undertaken a review of the community pharmacy involvement in this case, in conjunction with NHS Cheshire & Merseyside ICB, where the community pharmacy involved is situated. We have linked with the regional pharmacy lead to share learnings and escalate to the national team regarding feedback on the pathway design for sore throat, and specifically around patients who are immunosuppressed. NHS GM is also liaising with the Community Pharmacy Greater Manchester (CPGM) to raise awareness across GM community pharmacies to share learning. This includes ensuring

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pharmacists delivering the Pharmacy First service are aware of local and national resources to support Pharmacy First consultations.

We have raised issues presented in the PFD at the March GMMMG and CEG meetings and agreed to monitor progress of the improvements through the updates to the groups and the organisational risk register.

The GMMMG and CEG are grateful for the improvement opportunities that have been identified and would like to formally acknowledge them, providing assurance that actions are being taken locally to address these areas. A review of the circumstances around out-of-date SCP was conducted and although the document had passed its scheduled review date, the clinical content remained aligned with current guidelines and standard clinical practice. Importantly, the patient was not managed under the SCP at the time of the incident, as they remained on a consultant-led titration regimen. It was concluded that the status of the SCP did not influence the patient's care and did not contribute to the patient's death.

We believe there is a clear need to provide feedback to NHS England, as the commissioner of the Pharmacy First Service, to highlight the wider challenges associated with the delivery of the service. The PDF report review has identified that the patient should not have been managed through the Pharmacy First Service, as they did not meet the eligibility criteria for this service. This highlights the need for strengthened pathway exclusions and clearer safeguards to ensure that patients with complex clinical needs or specialist oversight requirements are appropriately identified and excluded from Pharmacy First pathways.

We also recognise the need for further work with the Trust to better understand the Patient Information Leaflet (PIL) provided at the point of prescribing, including how it is selected, issued, and explained to patients. Ensuring that patients receive clear, accurate, and comprehensible information at the time of prescribing is an important additional safety net and may support earlier identification of risk or deterioration. NHS GM will be seeking assurance from providers that appropriate patient consultation is consistently undertaken when patients are commenced on new treatment.

We consider that addressing these challenges at both national and provider levels could help prevent similar incidents in the future. In addition, we are planning to develop a local 7-minute briefing to share further learning and reinforce good practice across relevant teams.

Thank you for bringing this matter to our attention.

I trust this information is useful. Please contact me should you require further information.

Best wishes

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Chief Medical Officer
Caldicott Guardian
NHS Greater Manchester

References:

- Summary of Product Characteristics, Methotrexate 2.5mg Tablets, Accessed at https://www.medicines.org.uk/emc/product/9945/smpc
- The British Society For Rheumatology, BSR/BHPR guideline for disease-modifying anti-rheumatic drug (DMARD) therapy in consultation with the British Association of Dermatologists, 2008, Accessed at: https://pubmed.ncbi.nlm.nih.gov/16940305/
- The British Society For Rheumatology, The 2025 British Society for Rheumatology guideline for the prescription and monitoring of conventional synthetic disease-modifying anti-rheumatic drugs, 2025, Accessed at https://academic.oup.com/rheumatology/article/65/2/keaf522/8322743
- Visser K. Katchamart W., Loza E., et al., Multinational evidence-based recommendations for the use of methotrexate in rheumatic disorders with a focus on rheumatoid arthritis: integrating systematic literature research and expert opinion of a broad international panel of rheumatologists in the 3E Initiative, Ann Rheum Dis Diseases 2009 Jul;68(7):1086-93, Accessed at : https://pubmed.ncbi.nlm.nih.gov/19033291/
- Specialist Pharmacy Service, Methotrexate monitoring, July 2021 (last updated Jan 2026), Accessed at: https://www.sps.nhs.uk/monitorings/methotrexate-monitoring/