

Changes to cryoprecipitate doses: Implications for Massive Haemorrhage Protocols



N SAFETY NOTICE 032/24

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Content reviewed by:	NSW Blood Management Clinical Advisory Committee; Clinical Lead Transfusion Stream NSW Health Pathology; Chief Health Officer Strategic Programs Branch
Distributed to:	Chief Executives; Directors of Clinical Governance; Director, Regulation and Compliance Unit
KEY MESSAGE:	The transition to split apheresis cryoprecipitate units may lead to underdosing, especially during critical bleeding episodes. This change requires Massive Haemorrhage Protocols (MHPs) to be updated at sites using large-dose apheresis cryoprecipitate. These facilities must manage this change to ensure correct dosing and mitigate clinical risks.
ACTION REQUIRED BY:	Clinicians and pathology providers
REQUIRED ACTION:	<ol style="list-style-type: none"> 1. Distribute this safety notice to all relevant staff, committees and departments where cryoprecipitate is held, prescribed and administered, and include this Safety Notice in relevant handovers and safety huddles. 2. Undertake a local risk assessment and incorporate the below recommendations to manage this transition. 3. Ensure a system is in place to document actions taken in response to this Safety Notice. 4. Escalate any concerns to: CEC-BloodWatch@health.nsw.gov.au 5. Report any incidents associated with the changes to cryoprecipitate doses via the local incident management system (e.g., ims+). 6. Confirm receipt and distribution of this Safety Notice within 7 days to: CEC-BloodWatch@health.nsw.gov.au
DEADLINE:	18 December 2024
We recommend you also inform:	Directors, Managers and Staff of: <ul style="list-style-type: none"> • Blood Management Committee • Surgical, Anaesthetics, and Emergency Departments • Nursing/Midwifery Services • Medical Services • Pathology Transfusion Services
Website:	https://www.health.nsw.gov.au/sabs/Pages/default.aspx http://internal.health.nsw.gov.au/quality/sabs/index.html
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N SN:032/24

Situation

From January 2025, Australian Red Cross Lifeblood (Lifeblood) will replace large-dose apheresis cryoprecipitate and cryo-depleted plasma with split apheresis components. This change is due to the discontinuation of a key consumable and has been approved by the National Blood Authority (NBA) and Therapeutic Goods Administration (TGA).

The planned shift to split apheresis cryoprecipitate poses a clinical risk for sites using large-dose apheresis cryoprecipitate and may lead to underdosing. Where required, facilities must review and update Massive Haemorrhage Protocols (MHPs) to align with the new product configurations. Without these updates, patients with massive haemorrhage may not receive adequate fibrinogen replacement, leading to poor clinical outcomes.

Sites that do not currently use apheresis cryoprecipitate are not immediately affected by this change. However, all sites should prepare for this transition, to ensure continuity in clinical practice.

Background

The split apheresis cryoprecipitate units will match the volume and dosing of whole blood-derived cryoprecipitate, requiring more units compared to large-dose apheresis products. Lifeblood have provided guidance on dosing specifications to help facilities adapt local protocols. See Lifeblood communication in the further information section.

Lifeblood customer letters have been issued with detailed advice. NSW Health Pathology are making the necessary changes to laboratory information systems to accommodate these changes.

Assessment

- Where large-dose apheresis cryoprecipitate is used, there is a risk of under-dosing patients, especially with critical bleeding, once these changes take effect.
- Urgent updates are needed to align policies and procedures, particularly MHPs, with the new product specifications.
- There is a patient safety risk if clinical teams are not aware of these changes.

Recommendations

1. Sites using large-dose apheresis cryoprecipitate must urgently update MHPs to reflect the new Lifeblood product specifications and work with local pathology laboratories to confirm dosing requirements.
2. Develop local communication strategies to support these changes.
3. Ensure effective oversight of these changes by blood management committees and other relevant governance groups.

Further information

Australian Red Cross Lifeblood – Cryoprecipitate and cryodepleted plasma – a change is coming: <https://www.lifeblood.com.au/news-and-stories/health-professionals-news/cryoprecipitate-and-cryodepleted-plasma-change-coming>