NSW Health

Intravenous immunoglobulin (IVIg) therapy: Documentation in the healthcare record

SAFETY INFORMATION 008/25

Issue date:	17 July 2025
Content reviewed by:	NSW Blood Management Clinical Advisory Committee
Distributed to:	Chief Executives; Directors of Clinical Governance; Director, Regulation and Compliance Unit
KEY MESSAGE:	Adverse reactions to IVIg are not uncommon and may require amendments to standard administration protocols to minimise risks of further episodes. E.g., premedication may be required. Australian Red Cross Lifeblood are a key partner in the authorisation of IVIg and source of expert advice in managing risks associated with IVIg. Patients may be administered IVIg in inpatient and outpatient settings, where variation exists in how IVIg therapy is documented and prescribed.
ACTION REQUIRED BY:	Clinicians
REQUIRED ACTION:	1. Table with the following groups: • Blood Management Committees • Drug and Therapeutic Committees 2. Distribute this Safety Information to all relevant clinicians and clinical departments to increase awareness of these risks 3. Include this Safety Information in relevant handovers and safety huddles. 4. Review local processes for documentation of adverse reactions to IVIg to ensure they comply with Policy Directive Blood Management PD2024_024. 5. Report all adverse reactions related to IVIg as per Policy Directive Blood Management NSW PD2024_024 (inclusive of the full brand name of the IVIg).
DEADLINE:	N/A
We recommend you also inform:	Directors, Managers and Staff of: • Immunology, Neurology, Haematology and Oncology services • Outpatient Services • Facility Electronic Medical Record (eMR) teams
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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Contact: Clinical Excellence Commission
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Situation

A recent serious incident identified opportunities for improvement related to documenting adverse events associated with IVIg and managing risks for subsequent infusions. There is a patient safety risk that clinical decisions about IVIg therapy may not be evident to all staff across all patient settings. For example: the requirement for a patient to be prescribed premedication before their infusion.

Following an adverse event to IVIg, treating clinicians may seek advice from other clinical teams and Australian Red Cross Lifeblood (Lifeblood), about strategies to minimise risks of further adverse events. These include product changes, different administration rates or whether to prescribe a premedication.

These discussions are not always documented well, nor easy to find within patients' healthcare records. Further, these discussions and decisions are not always reliably communicated across care teams, especially where care extends across both outpatient and inpatient settings.

Background

BloodSTAR is Australia's online system for accessing government-funded immunoglobulin (Ig) products. Lifeblood are responsible for reviewing and authorising Ig requests via BloodSTAR. Lifeblood Transfusion Medicine Specialist staff are available to respond to clinical questions to support Ig therapy.

IVIg is commonly administered as monthly infusions, typically in outpatient settings. Currently there is variation between facilities with electronic medical records (eMRs), including hybrid paper and electronic systems used across outpatient and inpatient settings. Adverse events to IVIg and subsequent prescribing of pre-medication are not uncommon. Reports suggest that these events aren't reliably documented as reactions, notified in ims+, or that appropriate alerts are routinely documented.

Assessment

The Single Digital Patient Record will address these risks across NSW Health facilities, but variation will remain in the system until this is fully implemented.

Recommendations

Facilities are to review local systems to ensure:

- patients who require premedication prior to IVIg are identified and processes are in place to ensure this is communicated between teams or during transfer of care.
- reliable processes for documenting the details and outcomes of conversations with external agencies

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Further information

1. Intravenous Immunoglobulin Replacement Therapy Infusion Rates and Adverse Reactions Guide (2024) Australian Society of Clinical Immunology and Allergy. Retrieved 5 May 2025 https://www.allergy.org.au/hp/papers/ascia-guidelines-ivig-infusion-rates-for-irt

2. NSW Policy Directive: Blood Management (PD2024_024)