fact sheet for health service organisations and clinicians

Conservation strategies and safety considerations during intravenous (IV) fluids supply disruption

Key messages

- The Therapeutic Goods Administration (TGA) has notified of a global shortage of intravenous fluids (IV), which will continue throughout 2025.
- To assist with supply disruption, the TGA has approved overseas-registered alternative IV fluids under Section 19A (S19A), of the *Therapeutic Goods Act 1989*.
- Some S19A alternative IV fluids will contain a larger volume of air than is typical for Australian registered products. There is a risk of air embolism when administering IV fluids without the use of in-line air detection.
- Apply principles for conserving medicines while maintaining safety, including: using the smallest possible volume of IV fluids for the required indication; regularly reviewing patients receiving IV infusions; and switching to alternative routes of administration where and when possible.
- Refer to the Australian and New Zealand College of Anaesthetists (ANZCA) <u>Fasting</u> Guideline and Guidance on sparing of intravenous fluid use for further guidance.

Purpose

This fact sheet has been developed by the Australian Commission on Safety and Quality in Health Care (the Commission) to assist health service organisations and clinicians with conservation strategies and safety considerations related to the disrupted supply of IV fluids in Australia.

IV fluids are essential when managing or correcting deficiencies in hydration and electrolyte imbalances. They are also used as diluents for delivery of compatible IV medicines.

The Issue

The TGA has advised of a global disruption to the supply of multiple IV fluid products. This is due to multiple factors including global supply limitations, unexpected increases in demand, and manufacturing issues. The shortage is particularly affecting multiple bag sizes of sodium chloride

0.9% and compound sodium lactate (Hartmann's solution) products. The TGA has been advised that supply will continue to be constrained throughout 2025.

To improve supply, the TGA have approved several overseas-registered alternative intravenous fluids under S19A. Updates and information on the approved products, are available on the TGA Section 19A approvals database along with the latest information on the IV fluid shortage.

Conservation Strategies

This factsheet draws from the general principles described in <u>Conserving medicines with a focus</u> on <u>medicines shortages</u>. For IV fluids the following should be considered where possible:

- Depending on local availability, use the smallest possible volume of IV fluids for the required indication. For example, if a 100 mL flush is required as part of a chemotherapy protocol, use a 100 mL bag instead of a 500 mL bag
- Use smaller bag sizes for slower rate infusions. For example, use a 250 mL bag for an infusion rate of 20 mL/hour or less, and reserve 500 mL bags for infusion rates of 21 mL/hour to 40 mL/hour
- Prioritise 500 mL sodium chloride 0.9% bags for use in priority settings (for example, with arterial lines, specialty infusion types)
- Ensure regular review of patients receiving IV infusions and switch to alternative routes of administration as soon as possible. Prioritise oral or enteral routes where clinically appropriate. For example, for administration of electrolytes, analgesia and antibiotics (particularly those with high bioavailability)
- Leverage existing strategies to assist with this change, such as:
 - Antimicrobial stewardship processes, IV to Oral Antibiotic Switch resources. See page 6
 - Regularly assess patients who may be suitable for oral hydration prior to the initiation or continuation of IV fluid therapy. Refer to local guidelines/protocols on oral rehydration.
- Review patients to ensure vascular patency, and vascular access devices (VADs) are flushed, locked and capped where possible. Remove VADs when not in use
- Avoid using IV fluids for non-IV administration including off-label use. For example, wound flushing, eye irrigation or as a weight on traction devices
- Reserve products such as glucose 5% solution for patients susceptible to hypoglycaemia.
 For example, women and children may be more susceptible to hypoglycaemia when fasting exceeds 24 hours
- Use 10 mL or 20 mL ampoules of sodium chloride 0.9% in place of small volume IV fluid bags, where possible. For example, to prepare medicines for use in a syringe driver
- Administer medicines via IV push injection rather than using infusions, wherever appropriate
- There may be circumstances where alternative fluid ampoules or IV fluid bags may be suitable for reconstituting or delivering IV medicines. For example, sterile water for injection ampoules instead of sodium chloride 0.9% ampoules for reconstitution purposes; or compound sodium lactate (Hartmann's) solution instead of sodium chloride 0.9% bags for administration via infusion and vice-versa. Refer to the <u>Australian Injectable Drugs</u> Handbook for information on compatibility of IV fluids
- Administer medicines by an alternative route where possible. Refer to instructions for each medicine for the most appropriate route, noting that central venous access devices may

have different recommendations to peripheral lines. Refer to Table 1 for additional information on specific population groups

- Apply robust governance and stewardship principles to the conservation and stock management of IV fluids, for example:
 - Ensure relevant practice changes are incorporated into policies, procedures and guidelines, and communicated to clinicians
 - Monitor adherence to existing conservation strategies
 - Limit stock levels held in clinical areas and conduct regular stock counts to inform escalations
 - Reduce minimum/maximum quantities for stock held in ward storage or imprest areas for the duration of the supply constraint.

Table 1. Information sources on the most appropriate route for the administration of medicines by population group.

Population	Reference for most appropriate route
Adults	Refer to the Australian Injectable Drugs Handbook.
Children (1 month – 16 years)	Subcutaneous and intramuscular administration in children is traumatic and should not be used unless clinically required or standard procedure. Refer to the Paediatric Injectable Medicines Handbook (PIMH) for more information.
Neonates (up to 28 days corrected age)	Retain standard practice when administering IV fluids and medicines. Refer to the <u>Australasian Neonatal Medicines</u> <u>Formulary</u> for guidance. The administration of antibiotics via IV push injection is not recommended in neonates.

Conservation strategies – surgical patients

- Limit IV fluids administered to surgical patients, wherever possible and clinically appropriate
- Minimise fasting in surgical patients to reduce need for fluid replacement
- Provide access to clear oral fluids up to two hours prior to surgery
- Implement evidence-based protocols in elective and selected emergency procedures, that
 minimise the need for intraoperative IV fluid administration. Refer to the Australian and New
 Zealand College of Anaesthetists (ANZCA) <u>Fasting Guideline</u> and <u>Guidance on sparing of
 intravenous fluid use</u> for further guidance
- Review the need for 'routine' IV infusions and avoid pre-emptive priming of IV giving sets
 prior to patient perioperative admission unless the requirement for IV fluid administration is
 confirmed
- Avoid excessive fluid restriction in patients undergoing major surgery. This can be harmful
 and lead to an increased risk of acute kidney injury and infection

Safety considerations

The <u>Principles for safe selection and storage of medicines</u> should be applied when using S19A alternatives. Some specific issues are outlined below, and Table 2 includes a list of other safety considerations.

Risk of air embolism

All bags of IV fluids contain varying amounts of air. There is a risk of air embolism when any IV fluid is administered without the use of an in-line air detection device. Some IV fluid products, particularly certain S19A alternatives, may have a higher risk of air embolism due to a larger volume of residual air within the bag than is typical for Australian-registered products.

It is important to raise clinician awareness regarding this issue. Prior to use, bags should be inspected for any differences in presentation. Any associated safety issues should be considered, with specific provisions for bags with larger than normal amounts of air. Take appropriate steps to mitigate the risk where administration without an in-line air detection is necessary.

All IV fluid products should be used in accordance with the manufacturer's instructions for use. NSW Health has published information on the <u>risk of air embolism when administering intravenous</u> fluids without in-line air detection.

Maintain best practice for injectable medicines

Refer to the Australian Injectable Drugs Handbook.

Irrigation fluids are **not** suitable for injection or infusion.

IV fluids should be in place for a maximum duration consistent with local procedures and guidelines, but not usually more than 24 hours.

Partially used or previously spiked IV fluid bags must **never** be re-spiked or reconnected to the same or another patient.

Ensure compatibility of the medicine with the selected diluent when administering medicines via the IV route and that the final concentration is within the acceptable range for administration/stability.

Some medicines interact with the composition of different types of plastics used for IV fluid bags. Consider the plastic type and its compatibility with medicines prior to changing between IV fluid bag products. For example, ciclosPORIN, TACrolimus and DIAzepam are incompatible with polyvinyl chloride (PVC).

Digital systems

Consider the need for an alert within electronic medication management (eMM) systems when prescribing IV fluids to alert clinicians to the disruption to supply.

Where appropriate, consider local configurations in eMM systems to enable preferential selection of order sentences/care sets that use lower volumes of fluids for IV administration.

Consider whether infusion pumps and other programmable devices may be impacted by any changes in IV bag volume/composition.

Table 2. Safety considerations when conducting a local risk assessment.

Safety issue	Consideration
Presentation	Consider the labelling language and whether translation is required. Consider the material(s) utilised to make the bag. For example: Polyvinyl chloride (PVC), plastic polypropylene and non-PVC.
Available volume(s)	Consider the available bag volume(s) and impact on patient administration.
Storage	Consider the use of additional signage on shelving or stock containers to assist with alerting clinicians to the disruption to supply at the point of use (for example, 'ALERT: CRITICAL DISRUPTION TO SUPPLY – consider alternate options available').
Other	Ensure pH range is suitable. Check for any excipients and any manipulation requirements for the port protector.

Useful resources

- About the shortage of intravenous (IV) fluids. Therapeutic Goods Administration (TGA).
 8 Aug 2024 [cited 14 Aug 2024]
- Guidance on sparing of intravenous fluid use. Australian and New Zealand College of Anaesthetists and Faculty of Pain Medicine (ANZCA). 01 Aug 2024 [cited 14 Aug 2024]
- <u>Fasting guideline</u>. Australian and New Zealand College of Anaesthetists and Faculty of Pain Medicine (ANZCA). [Accessed 14 Aug 2024 – Appendix 1 incorporated into single document updated 17 Dec 2024]
- Therapeutic Goods Administration (TGA) publishes medicine updates and information on approved products under Section 19A, on the TGA <u>Section 19A approvals database</u>
- Australian Commission on Safety and Quality in Health Care <u>guidance on conserving</u> <u>medicines within a focus on medicines shortages</u>
- eTG complete [online]. Melbourne: Therapeutic Guidelines Limited
- <u>Australian Injectable Drugs Handbook</u> [online]. Melbourne: The Society of Hospital Pharmacists of Australia (SHPA)
- Australian Medicines Handbook [online]. Adelaide: Australian Medicines Handbook Pty Ltd
- Australian Commission on Safety and Quality in Health Care <u>general information for</u> <u>prescribers and pharmacists</u> on how to manage antimicrobial shortages in acute and primary healthcare settings
- Australian Commission on Safety and Quality in Health Care <u>Principles for safe selection</u> and storage of medicines provides guidance on risk reduction strategies to address safe selection and storage of all medicines.

State and Territory safety alerts and guidance

- NSW Health: <u>Safety Alert 015/24 UPDATED Critical disruption to the supply of multiple</u> intravenous fluid bags (17 Oct 2024)
- Agency for Clinical Innovation (ACI) New South Wales: <u>Fact sheet: Preoperative fasting</u> (<u>Sip Til Send</u>) (15 August 2024)
- Clinical Excellence Commission (CEC) New South Wales: <u>Clinical recommendations for managing intravenous (IV) fluids shortage</u> (06 Aug 2024)
- Clinical Excellence Commission (CEC) New South Wales: <u>Risk of air embolism when</u> <u>administering intravenous fluids without in-line air detection</u> provides further information about the risk of air embolism when administering IV fluids without the use of in-line air detection
- Clinical Excellence Commission (CEC) New South Wales: <u>Intravenous (IV) fluid bags</u> International alternatives and associated safety considerations (06 Aug 2024).
- Clinical Excellence Commission (CEC) New South Wales: <u>Intravenous Fluids Stewardship</u> (IVFS) (06 Aug 2024)
- Safer Care Victoria: <u>Sip Til Send fluid fasting guidance</u> assists clinicians in managing fasting times for clear liquids for patients who are undergoing general anaesthesia and/or procedural sedation.
- Queensland Health: Patient Safety Alert 14/2024 Supply disruption affecting intravenous fluid products (09 Aug 2024)
- South Australia Health: <u>Medication Safety Alert 01/24 Critical disruption to supply of multiple intravenous fluid bags</u> (23 Jul 2024).

Antimicrobial stewardship processes – IV to oral antibiotic switch resources

A number of resources are available to guide IV to oral antibiotic switch:

- Therapeutic Guidelines Antibiotic. Guidance for antimicrobial intravenous to oral switch
- Australian Commission on Safety and Quality in Health Care: <u>Antimicrobial Stewardship in Australian Health Care</u> (2023) (See Chapters 3 and 20)
- Australian Commission on Safety and Quality in Health Care: <u>Antimicrobial Stewardship</u> <u>Clinical Care Standard</u> (2020)
- Clinical Excellence Commission (CEC) NSW: IV to Oral Antibiotic Switch
- Children's Health Queensland Hospital and Health Service: <u>Antimicrobial treatment: Early</u> intravenous to oral switch Paediatric Guideline
- South Australia Health: <u>IV to Oral Switch Clinical Guideline for Adult Patients: Can Antimicrobials S.T.O.P.?</u> (2023)
- Perth Children's Hospital: Children's Antimicrobial Management Program (ChAMP) Intravenous to Oral Switch Guideline.

Find out more

For more information, visit TGA Medicine Shortage Reports Database or contact the Commission at medsafety@safetyandquality.gov.au or call 1800 304 056.

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