NSW GOVERNMENT Health

Safety Notice 003/13

Voluven and Volulyte (hydroxyethyl starch)

5 September 2013

Distributed to:

- Chief Executives
- Directors of Clinical Governance

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Clinical Directors
- Directors of Medical Services
- ICU Directors
- ED Directors
- Other relevant Clinical Areas

Expert Reference Group

Content reviewed by:

- Clinical Excellence Commission
- Agency for Clinical Innovation

Clinical Excellence Commission

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Background

Voluven and Volulyte (hydroxyethyl starch) is a synthetic colloid resuscitation fluid, used to treat and prevent hypovolaemia. Recent reports have indicated that the use of Voluven and Volulyte (hydroxyethyl starch) is associated with an increased risk of patients requiring dialysis and increased mortality when used in certain patient populations, particularly patients with sepsis. As a consequence the Therapeutic Goods Administration have issued the following warning:

Hydroxyethyl starch should not be used in patients with severe sepsis, renal failure including those requiring dialysis, severe liver failure, fluid overload, severe hyperchloraemia or hyponatraemia, patients with intracranial bleeding and in patients with known hypersensitivity to hydroxyethyl starch.

Health Professionals should be aware of the following:

- The use of hydroxyethyl starch should be discontinued at the first sign of renal impairment. The need for dialysis has been reported up to 90 days after use of hydroxyethyl starch.
- Bleeding disorders, greater than those explained by dilutional effects of volume replacement, have been noted with the use of these products. If coagulopathy is detected, use of hydroxyethyl starch should be discontinued.
- The use of these products in critically ill patients should only be considered if other therapies have failed, the lowest possible dose is chosen, and the benefits outweigh the risk.
- The Therapeutic Goods Administration is initiating a full inquiry into hydroxyl-ethyl starch solutions, Voluven and Volulyte, advising that it should only be used in low risk patients. Health professionals are asked to report any serious adverse events including cases of renal impairment or bleeding disorders associated with the use of hydroxyethyl starch to the Therapeutic Goods Administration.

Local Health Districts / Networks should:

- Determine if your LHD/LHN use Voluven and Volulyte (hydroxyethyl starch).
- Reassess the use of Voluven and Volulyte (hydroxyethyl starch) based on this warning.
- Disseminate this information to all relevant clinical units within your LHD/LHN.

Further information:

Safety Information from the TGA is available at
http://www.tga.gov.au/safety/ews-medicine-hydroxyethyl-starch-130709.htm

References:

1. Perner A, Haase N, Guttormsen AB, et al. *Hydroxyethyl starch 130/0.42 versus Ringer's acetate in severe sepsis*. N Engl J Med 2012;367:124-34.
2. Brunkhorst FM, Engel C, Bloos F, et al. *Intensive insulin therapy and pentastarch resuscitation in severe sepsis*. N Engl J Med 2008;358:125-39.
3. Myburgh JA, Finfer S, Bellomo R, et al. *Hydroxyethyl starch or saline for fluid resuscitation in intensive care*. N Engl J Med 2012;367:1901-11

Suggested actions by Local Health Districts/Networks

1. Ensure this safety information is distributed to all relevant staff.
2. Ensure a system is in place to document actions taken.