

WA MEDICATION SAFETY GROUP ALERT

Confusion between non-lipid and lipid formulations of injectable amphotericin

The National Patient Safety Agency of the NHS (UK) have published a Rapid Response Report¹ on the risk of confusion between non-lipid and lipid formulations of injectable amphotericin. This arose in response to two recent deaths and a number of reported "near misses" in the UK involving confusion between amphotericin formulations. WAMSG has examined incidents involving amphotericin reported to the WA AIMS system and, in the light of a number of WA incidents resulting from similar confusion², resolved to issue this alert.

The risk

The risk arises from the different dosage recommendations for the various formulations. Three formulations for IV use are available in Australia:

- amphotericin deoxycholate (Fungizone®) - up to 1.5mg/kg infused over 6 hours,
- liposomal amphotericin (Ambisome®) - up to 5 mg/kg infused over 1 hour, and
- lipid-complex amphotericin (Abelcet®) - 5 mg/kg infused over 1 hour.

Depending on the precise error involved, confusion between the different formulations can lead to either

- under-dosing and loss of therapeutic effect or
- over-dosing and toxic side effects.

The most significant (potentially fatal) risks to patients are concentration or rate errors with amphotericin deoxycholate leading to over-dosing.

Health services are requested to:

- Ensure this WAMSG Alert is brought to the attention of all medical, nursing and pharmacy personnel involved or potentially involved with the prescribing, preparation, supply and administration of amphotericin.
- Undertake an expedited risk assessment of amphotericin products and procedures with a view to taking action to reduce risks, particularly overdosing with amphotericin deoxycholate. As a guide to possible actions, WAMSG suggests that the following be considered:
 - When prescribing, communicating and dispensing amphotericin products use both the generic name and proprietary name: amphotericin deoxycholate (Fungizone®), liposomal amphotericin (Ambisome®) or lipid-complex amphotericin (Abelcet®). Where the formulation is not specified, the order should not proceed until the intended formulation is clarified.
 - The prescription should include dose/kg, the total dose required and the duration of the infusion.
 - Add a warning statement to any amphotericin guidelines or standard procedures to describe the risk.
 - Restrict the storage, dispensing and preparation of amphotericin products to pharmacy.
 - Differentiate or separate the storage of different formulations of amphotericin within the pharmacy.
 - Use cautionary labels on prepared material for infusion or another mechanism to alert staff about the risk of error given the various formulations and the variation in dose or infusion rate.

¹ Rapid Response Report 2: Risk of confusion between non-lipid and lipid formulations of injectable amphotericin Issued: 3 Sep 2007 http://www.npsa.nhs.uk/site/media/documents/2958_Amphotericin_Rapid_Response_Report_2_FINAL.pdf

² WA AIMS reported incidents involving amphotericin. There have been 45 AIMS reports involving amphotericin since 2001. Confusion between the different formulations accounted for 24 of these incidents including:

- 3 cases involving incorrect administration of amphotericin deoxycholate
- 1 case of incorrect administration of liposomal amphotericin which continued for 18 days (18 incidents)
- 1 case of infusion of amphotericin deoxycholate at the infusion rate for liposomal amphotericin (1 hour instead of 6 hours)
- 2 cases where incorrect labels were used, both indicating liposomal amphotericin instead of amphotericin deoxycholate.