NSW GOVERNMENT Health
Western Sydney
Local Health Network

07 August 2012

Labelling and Packaging Review Sub-committee
Therapeutics Goods Administration (TGA)
PO Box 100
Woden, ACT 2606

Re: **ALERT ON NEARLY IDENTICAL PACKAGING** FOR LIGNOCAINE HYDROCHLORIDE INJECTION 1% 50 mg in 5mL (Pfizer) AND HEPARIN SODIUM INJECTION 5000 units in 5mL (Pfizer).

To the members of the Sub-committee:

This is to bring to your **URGENT** attention an adverse event directly caused by near-identical packaging of the above-mentioned preparations.

The incident, which occurred on July 9, 2012, involved an 85 year old male patient who has been on home haemodialysis for seventeen years. During his dialysis at home, anticoagulation of the extracorporeal circuit is performed using a **patient prepared** solution of heparin administered by an infusion pump incorporated into the haemodialysis machine. This heparin solution is typically prepared by diluting ampoules of Heparin 5000units in 5mL with normal saline. To assist with cannulation of his arteriovenous fistula prior to performing dialysis, the patient also draws up a local anaesthetic solution from the lignocaine hydrochloride ampoule into a 1mL syringe. Supplies of Lignocaine and Heparin are supplied directly to the patient from the

Regional Dialysis Centre at Blacktown Hospital, which supports more than 100 patients on home haemodialysis.

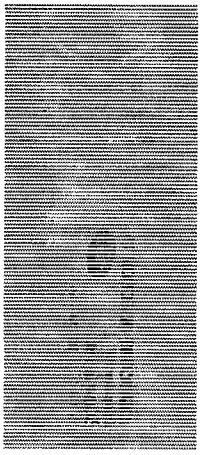
On the day of the incident, the patient inadvertently mixed one 5mL ampoule of Lignocaine Hydrochloride 1% with one 5mL ampoule of Heparin whilst preparing his anticoagulant solution. Haemodialysis was commenced but was complicated by clotting of the extracorporeal circuit on two occasions. It was only after the clotting of the second circuit that the error was discovered and haemodialysis was then ceased. No adverse effects were reported by the patient as a consequence of the inadvertent intravenous infusion of lignocaine, although clotting of the circuit led to the equivalent of 500mL of blood loss.

Although relatively safe when used within the correct dose and in the right anatomical route, lethal systemic reactions may occur from accidental intravascular administration of local anaesthetic agents [2, 3, 4, 5]. Systemic reactions involve the central nervous system and the cardiovascular system [2, 3, 4, 5]; generalised CNS depression and coma may arise from a sufficiently large dose, and respiratory depression may lead to respiratory arrest [2, 3, 4, 5]. Cardiovascular toxicity usually manifests itself as tachycardia and hypertension but with increasing toxicity, bradycardia and hypotension occur. Ventricular arrhythmias and cardiac arrest are known side effects[2, 3, 4, 5].

This incident highlights a critical safety concern that is in part related to the identical packaging of the heparin and lignocaine solutions used by the patient. This **issue demands urgent action.**

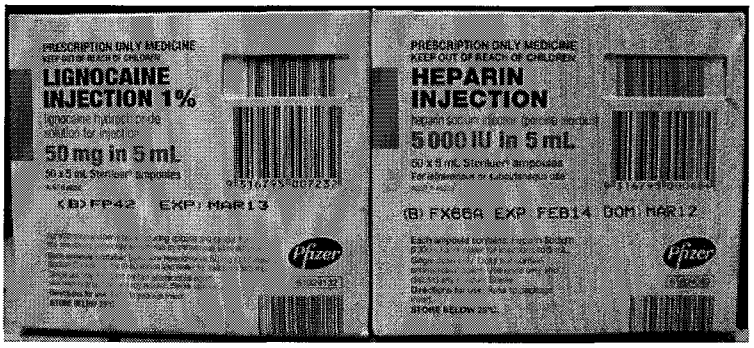
Our unit was supplied with Lignocaine ampoules which look nearly identical in packaging with the Heparin ampoules, as depicted below. Prior to a recent packaging change, the lignocaine ampoules were easily differentiated from the heparin as they were a different size and shape (round not rectangular base)-see images below. The current heparin and lignocaine ampoules are identical in size and shape and

differentiated only on the basis of their labelling. Whilst we have highlighted this issue to our patients, we are concerned that the ongoing use of these ampoules in patients on home haemodialysis may be complicated by a further potentially fatal incident. To date we have been unable to find an alternate source of heparin or lignocaine that are easily differentiated from one another on the basis of packaging.



Original packaging for Pfizer lignocaine showing different ampoule shape

Side by side comparison of the new lignocaine and heparin ampoules highlighting similarity in packaging



Side by side comparison of the lignocaine and heparin distribution boxes highlighting similarities in packaging

This is an issue which also affects in-patient and satellite dialysis centres due to their high usage of both preparations. Although medication checking protocols are in place and staff were alerted about the importance of storing Lignocaine and Heparin separately, the risks of medication errors and patient harm are imminent and they cannot be over emphasised enough.

This was acknowledged in the Report on the National Round Table on Safer Naming, Labelling and Packaging of Medicines (2011), to quote: "When manufacturers make a labelling or packaging change there is a risk that the change may lead to confusion with another product in the market, especially if the label or packaging is similar or the products are stored adjacent to one another on the pharmacy or ward shelves." Further it states: "A risk assessment should be undertaken when packaging changes are made and the consequences of the change considered prior to the release of the product."

We trust that this letter will facilitate a review of the packaging for Lignocaine and Heparin with a view to remedial action to mitigate current and future risks.

Signed,

Sr Maryann Nicdao	A/Prof Lukas Kairaitis	Prof Jeremy Chapman
Clinical Nurse Consultant	Director, Renal Medicine	Director,
Western Renal Service	Blacktown Hospital	Western Renal Service

References:

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3. Donald, M. J. & Derbyshire, S. (2004). Lignocaine toxicity; a complication of local anaesthesia administered in the community. *Emerg Med J 2004;21:249-250* doi:10.1136/emj.2003.00873

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