

Packaging and labelling problems and solutions

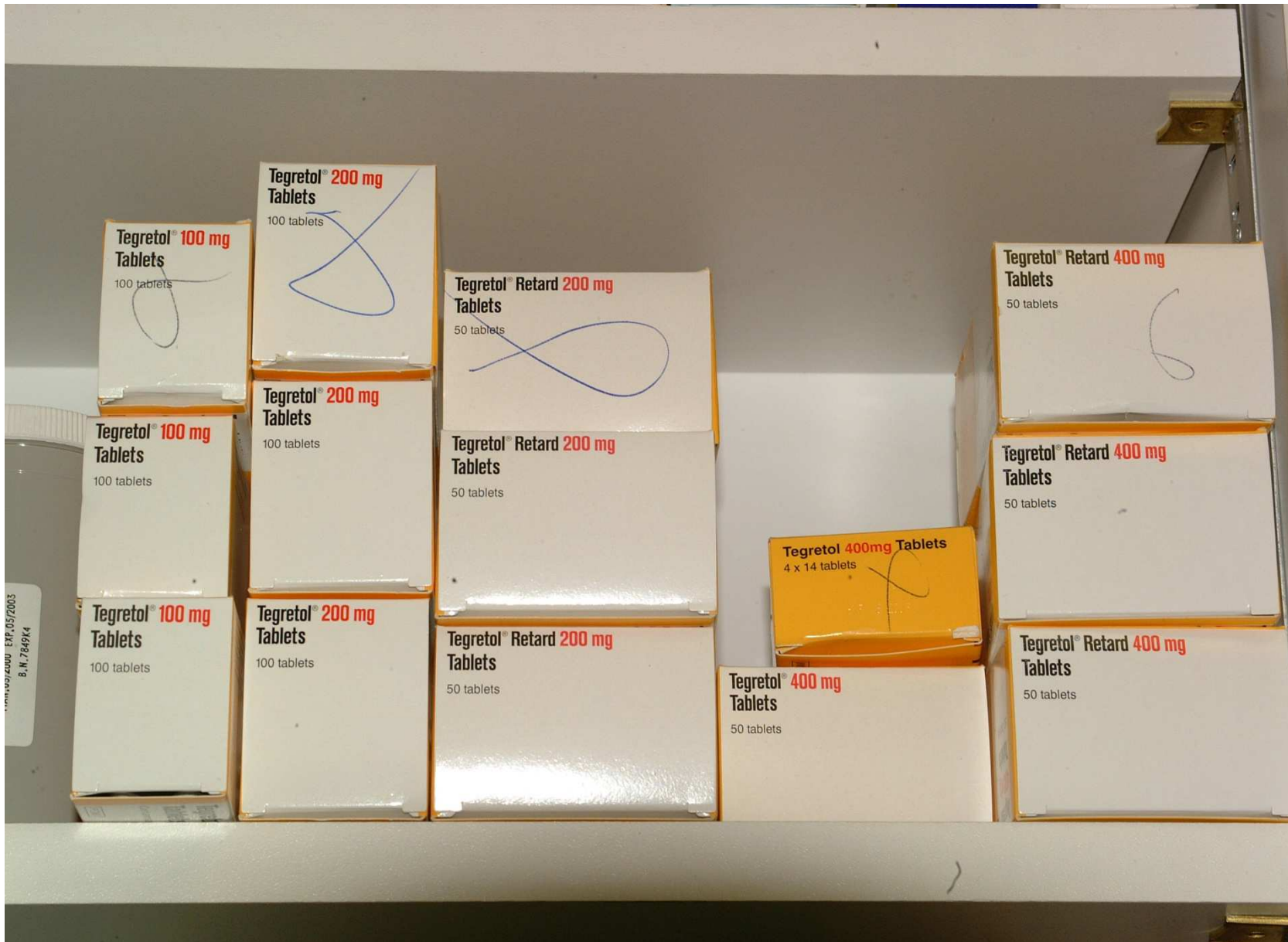
Ciara Kirke

Drug Safety Coordinator

Tallaght Hospital, Dublin, Ireland

Hospitals

- Drug administration - small part of a nurse's day; smaller part of a doctor's
- Human factors, system factors
- Huge number of drugs, limited familiarity
- Time pressure, interruptions, multiple tasks, miscommunication, handovers
- Independent double check
 - Packaging and labelling should help make it clear and easy to do the right thing

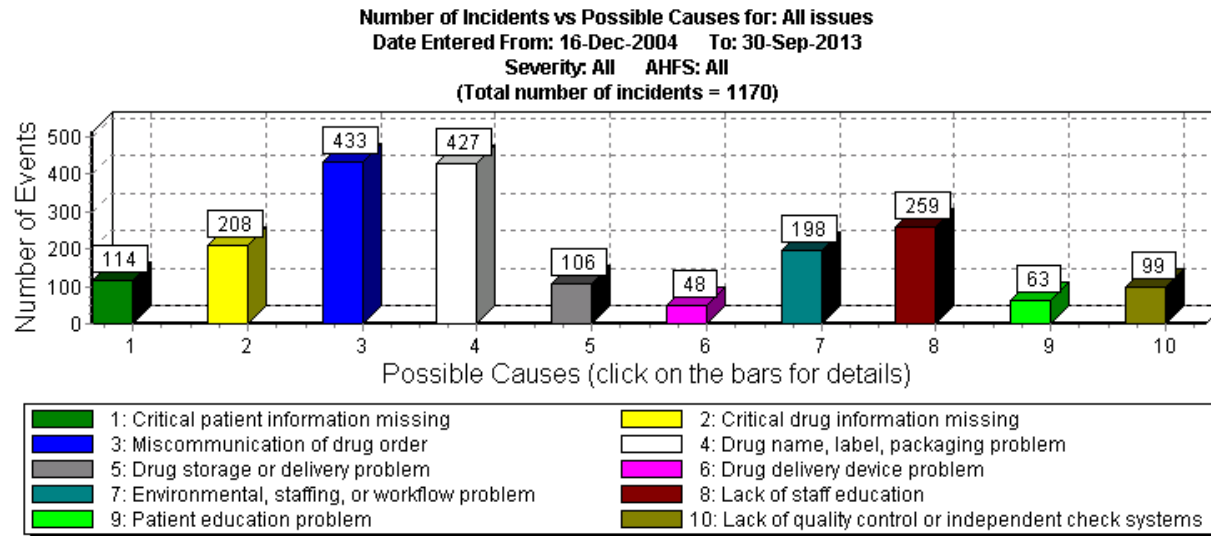


Similar packaging – easy to select wrong strength or formulation (Retard/not)

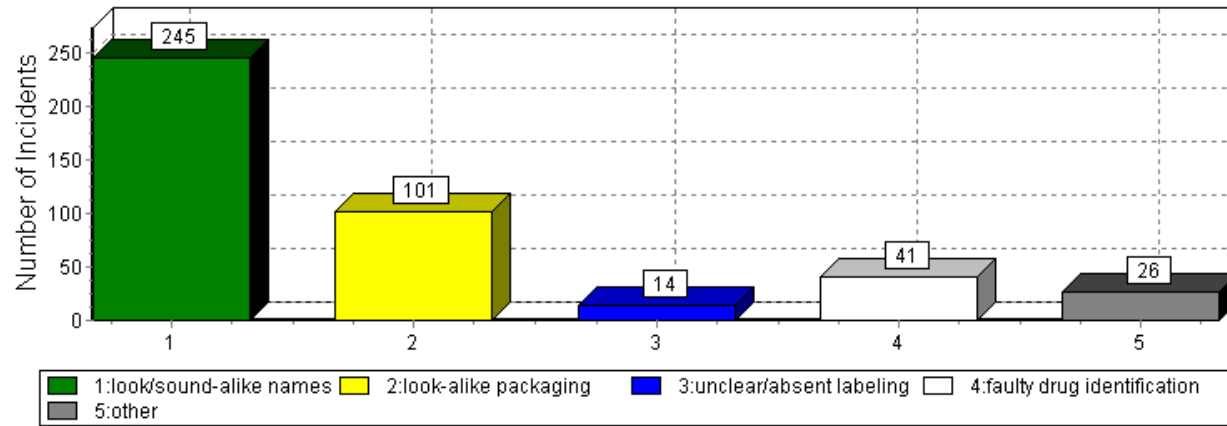


Strengths of same product looking very similar – 50mg, 75mg, 100mg

Contribution to reported incidents



Drug name, label, packaging problem
 Date Entered From: 16-Dec-2004 To: 30-Sep-2013
 Severity: AHFS: All
 (Total number of incidents = 427)



What have we achieved in Ireland?

- Notify manufacturers and regulators when errors occur relating to packaging and labelling
- Manufacturers – often respond with positive changes
- Regulators – enforce legal requirements, may support safety changes but not require







In our experience, EVERY product containing more than 1 mL which is labelled only with mg/mL, units/mL etc, results in patient overdoses.

Heparin Sodium
Solution for Injection or
Contraceptive for Subcutaneous Injection
Contains preservative

For intravenous use

10 vials

1.745E 100 units
5,000 units 10.5ml




Heparin Sodium
Solution for Injection or
Contraceptive for Subcutaneous Injection
Contains preservative

For intravenous or subcutaneous use

10 vials

1.745E 100 units
5,000 units 10.5ml



**Heparin Sodium
Flushing Solution**
for Maintenance of
Patency of Intravenous Devices
Preservative free

For flushing of devices only

10 ampoules

10 LU/ml
50 units 10.5ml



A tray containing 10 vials of Heparin Sodium Solution for Injection or Contraceptive for Subcutaneous Injection. Each vial has a red cap and a white label with blue and red text. The vials are arranged in two rows of five.



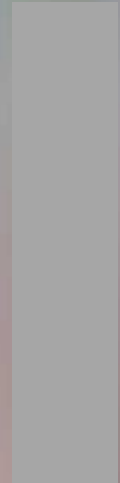
A tray containing 10 vials of Heparin Sodium Solution for Injection or Contraceptive for Subcutaneous Injection. Each vial has a blue cap and a white label with blue and red text. The vials are arranged in two rows of five.



A tray containing 10 ampoules of Heparin Sodium Flushing Solution. Each ampoule has a clear glass body and a white label with blue and red text. The ampoules are arranged in two rows of five.

Dalacin® C Phosphate
150 mg/ml

Concentrate for Solution for
Infusion or Solution for Injection
Clindamycin (as phosphate)



5 x 4 ml ampoulets

For intravenous use after dilution
or intramuscular use only



Dalacin® C Phosphate

150 mg/ml

Concentrate for Solution for
Infusion or Solution for Injection

Clindamycin (as phosphate)

600 mg/4 ml

5 x 4 ml ampoules

For intravenous use after dilution
or intramuscular use only

Pfizer

Education, alerts

Alert

To: All anaesthetists, anaesthetic nurses, theatre nurses
From: Aileen O'Brien, Shane Russell CNMs, [Anaesthetics](#)
Ciara Kirke, Drug Safety Coordinator
Date: 1st March 2010
Re: ***Similarity between ephedrine and morphine ampoules***

A new formulation of Ephedrine hydrochloride 30mg in 1mL is now stocked in Theatres and Pharmacy. This is because it is a licensed product. The previous, unlicensed, product is no longer available.



Ephedrine and morphine ampoules are now very similar in appearance.

- Take care to ensure you have selected the correct ampoule.
- Take care to return unused ampoules to the correct box.



Inaugural IMSN Conference 1st Oct 2010 -
'Networking for safety'

Safe Use of Sound-Alike Look-Alike Drugs SALAD

Gillian Oates



Briefing Document on
Sound-Alike Look-Alike Drugs (SALADs)

A better way

- Design in safety (NPSA series)
- Failure Modes & Effects Analysis
- Consult users (e.g. Med-ERRS)
 - BEFORE finalise packaging and labelling
- Respond rapidly and effectively to problems in use