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National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines

Evaluation of label adherence to single use and reusable hollowware containers used in the operating room – Report 2

August 2012



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This paper is available on the Commission web site at www.safetyandquality.gov.au.

National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines

Evaluation of label adherence to single use and reusable hollowware containers used in the operating room (Report 2)

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1. Introduction

The Australian Commission on Safety and Quality in Health Care (the Commission) is responsible for maintaining the *National Recommendations for User-applied Labelling of Medicines, Fluids and Lines* (the *Labelling Recommendations*) described at <http://www.safetyandquality.gov.au/our-work/medication-safety/user-applied-labelling/>. The Commission also identify and reduce national barriers to implementation.

Implementation is an evolving process and *Labelling Recommendations* issues referred to the Commission's advisory groups are recorded in the *Labelling Recommendations Issues Register* on the Commission web site at <http://www.safetyandquality.gov.au/our-work/medication-safety/user-applied-labelling/>

IR8 from the labelling Recommendations Issues Register considers the labelling of containers on the perioperative sterile field.

Labels may be difficult to remove from stainless steel and other reusable hollowware containers used in operating rooms. This would render such containers unsuitable for reuse.

Jurisdictions advise the Commission that stainless steel and other reusable containers are used in preference to disposable containers in a high proportion of health facilities in Australia. Thus, it is a requirement that labels may be removed entirely after use.

The *Labelling Recommendations* specify 'peel off' labels are used for container labels on the perioperative sterile field. Identification of medicines in containers on the sterile field is mandatory. Therefore, the ability to remove 'peel off' labels from reusable containers used on the perioperative sterile field supports the continued use of reusable containers.

The Commission engaged health services to evaluate sterile labels and adherence to reusable containers in the perioperative area to establish viability of container reissue. Report 1 (April 2012) documents the evaluation of labels from 3 suppliers to establish the potential for these labels to be removed from reusable plastic or stainless steel containers after exposure to 3 fluids frequently used in the perioperative sterile field
<http://www.safetyandquality.gov.au/wp-content/uploads/2012/02/Evaluation-of-label-adherence-to-reusable-hollowware-in-the-operating-room-April-2012.pdf>

Subsequent to this evaluation a trial undertaken at Calvary Wakefield Hospital (CWH) in South Australia tested the use of pre-printed labels in the perioperative sterile field. The labels were well accepted for the identification of medicines and fluids removed from their original container.

<http://www.safetyandquality.gov.au/wp-content/uploads/2012/02/Evaluation-of-pre-printed-labels-on-perioperative-sterile-field.pdf>

The April 2012 evaluation of label adherence to reusable hollowware containers was replicated to establish if the CWH labels are suitable for use on reusable containers. Sterile labels from 3 additional manufacturers were evaluated alongside the CWH label set.

2. Aims

To evaluate the performance of sterile labels with regards to: a) label adherence; and b) label residue on the surface of hollowware containers over time.

3. Methodology

St Vincent's Hospital, Sydney conducted the evaluation in August 2012 following a request from the Commission to replicate the evaluation described in April 2012 (Report 1) with sterile labels used in the trial at Calvary Wakefield Hospital. In addition, 3 further sets of sterile label products were evaluated for label adherence and residue.

The evaluation was conducted in an empty operating room with recommended ranges for air temperature and humidity and with standard air flows (Figure 1).

The setup procedure used for the 2 hour and 4 hour testing replicated the four table setup with a table for each of Control, Contrast, Sodium Chloride and Water with 2 sets of 3 containers (stainless steel, plastic reusable, plastic disposable) on each table (Figure 1).



Figure 1
Example of table setup/procedure for evaluation of sterile labels

One table per solution with two sets of containers. Three containers per set (stainless steel, plastic reusable, plastic disposable)

The >16 hour testing was conducted one week later using a one table setup: 1 table with four sets of containers (Figure 2).



Figure 2.
Setup/Procedure for evaluation of sterile labels for >16hour

One table with four sets of containers (Control, Contrast, Sodium Chloride, Water). Three containers per set (stainless steel, plastic reusable, plastic disposable)

The following were evaluated:

A) Sterile labels from four companies

1. [StirlingFILDES (label production)/Bard (sterilisation) as used in the Calvary Wakefield trial]. Combination of pre-printed and abbreviated container labels. Sterile stock provided by company, sterilised by Ethylene Oxide;
2. [Mayo SP0068] Abbreviated container labels. Sterile stock provided by company, sterilised by Ethylene Oxide;
3. [Mermed] Pre-printed labels. Sterile stock provided by company, sterilised by Gamma irradiation;
4. [Big Green Surgical] Sterile stock provided by company, sterilised by Ethylene Oxide;
 - a. 'Standard' labels – pre-printed
 - b. 'EZ Peel' labels – pre-printed.

B) Materials - Hollowware containers made from one of three materials

- stainless steel;
- reusable plastic; and
- disposable plastic containers.

C) Solutions - Hollowware container surfaces dampened with one of three fluids

- water;
- sodium chloride; and
- contrast medium with a strong concentration (Iopromide 76.9 gm / Ultravist 370).

D) Three time periods

- 2 hrs;
- 4 hrs; and
- >16hrs.

E) Solvents available for removal of residue

- Alcohol wipes; and
- Eucalyptus oil.

F) Control

A Control set was evaluated for all time periods and for all labels and all container types to ensure that the labels were capable of remaining adhered to the hollowware surfaces when dry and to evaluate the amount of residue remaining on those dry surfaces. As for previous testing, the Controls had no solutions applied, the containers and labels were kept dry.

4. Results

4.1 Label adherence

All labels remained adequately adhered to all container surfaces (stainless steel, reusable plastic and disposable plastic) on the Control and all dampened surfaces (water, sodium chloride, contrast medium) for all three time periods (2 hrs, 4 hrs, and > 16 hrs).

A minor lifting at one corner was noted for:

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- Label 1 on the plastic reusable container dampened with contrast for the >16 hr time period.
 - Label 4b for stainless steel dampened with contrast in the 2 hr time period
 - Label 4b for the disposable plastic container dampened with contrast for the >16 hr time period.
- The labels were, however, still safely adhered and not at risk of falling off the containers.

4.2 Label residue

Label 1

- Easily removed leaving no residue from:
 - stainless steel Controls after 2 hours and 4 hours;
 - reusable plastic Controls and when dampened with water or Sodium chloride after all time periods;
 - reusable plastic dampened with contrast after 2 hours and 4 hours;
 - disposable plastic all Controls and when dampened with all solutions after all time periods.
- Minimal residue that was easily removed without using solvent from:
 - stainless steel dampened with Sodium Chloride after 4 hours;
 - stainless steel dampened with contrast after 4 hours and >16hours;
 - reusable plastic dampened with contrast after >16 hours.
- Residue that was easily removed with alcohol from:
 - stainless steel Control after >16 hours;
 - stainless steel dampened with Sodium chloride after 2 hours and >16hours.
- Too much residue remained on:
 - stainless steel dampened with water after all time periods;
 - stainless steel dampened with contrast after 2 hours.

Label 2

- Easily removed with no residue from:
 - all Controls for all time periods
 - stainless steel dampened with water for all time periods;
 - stainless steel dampened with Sodium chloride after 2 hours and when dampened with contrast after 2 hours and 4 hours.
 - reusable plastic for all solutions after all time periods;
 - disposable plastic for all solutions after all time periods;
- Minimal residue that was easily removed without using solvent from:
 - stainless steel dampened with Sodium Chloride for 4 hrs and >16hrs and
 - stainless steel dampened with contrast for > 16hrs.

Label 3

- Easily removed with no residue from:
 - stainless steel Controls and when dampened with water after all time periods;
 - stainless steel dampened with Sodium chloride after 2 hours and >16 hours;
 - reusable plastic Controls and when dampened with Sodium chloride after all time periods;
 - reusable plastic dampened with water or contrast after 4 hours and >16 hours;
 - disposable plastic Controls and when dampened with Sodium chloride after all time periods;
 - disposable plastic dampened with water or contrast after 4hours and >16 hours.
- Minimal residue that was easily removed without using solvent from:
 - stainless steel dampened with Sodium Chloride for 4 hours;
 - reusable plastic Control and when dampened with water or contrast after 2hours;
 - disposable plastic Control and when dampened with water or contrast after 2hours;
- Minimal residue that was easily removed with alcohol from:
 - stainless steel dampened with contrast after all time periods.

Label 4a

- The top layer of this label separated untidily from the all containers, for Controls and all solutions, and at all time periods.
- This label left uneven amounts of fibrous and tacky residue on all container surfaces.
- Neither of the solvents removed this residue adequately, either in isolation or in combination. Firm, persistent scraping followed by solvent might be effective however this would be slow, impractical and likely to damage the surface of the hollowware.

Label 4b

- Removed with no residue from:
 - all Controls for all time periods;
 - stainless steel dampened with water or contrast after 2hours;
 - stainless steel dampened with Sodium chloride after 2hours and 4 hours;
 - reusable plastic dampened with water after 2 hours and >16 hours;
 - reusable plastic dampened with Sodium chloride after all time periods;
 - reusable plastic dampened with contrast after 2 hours;
 - disposable plastic dampened with water or Sodium chloride after all time periods;
 - disposable plastic dampened with contrast after 2 hours and >16 hours.
- Minimal residue that was easily removed without using solvent from:
 - stainless steel dampened with Sodium chloride or contrast after >16hours;
 - reusable plastic dampened with contrast after >16 hours.
 - disposable plastic dampened with contrast after 4hours.
- Minimal residue that was easily removed with alcohol from:
 - stainless steel dampened with water after 4 hours and >16 hours;
 - stainless steel dampened with contrast after 4 hours;
 - reusable plastic dampened with water or contrast after 4 hours.

5. Evaluations

5.1 Label residue

See Figure 3 and Tables 1 to 5 to follow.



Figure 3. Label residue on containers dampened with water after 2 hours

No residue is seen on the left side of both the plastic bowls and the upper 2/3 of the jug after removal of Labels 2 and 3 from these positions.

On the right side of both the plastic bowls and the bottom of the jug, too much residue is seen after attempting to remove Label 4a from these positions.

Table 1: Removal of label 1 and any associated residue on hollowware following exposure to fluids for varying times

Materials, dampened surfaces and Time Periods			Label remained attached		Label removal			Comments	
			YES	NO	No residue	With Residue			
						Minimal residue easily removed	Removed with solvent		Too much residue
Stainless Steel	Water	2 hours	X				X	Eucalyptus ++ rubbing	
		4 hours	X				X	Eucalyptus ++ rubbing	
		> 16 hours	X				X	Eucalyptus ++ rubbing	
	Sodium Chloride	2 hours	X				X	Alcohol	
		4 hours	X			X			
		> 16 hours	X			X		Alcohol	
	Contrast	2 hours	X					X	Eucalyptus ++++ rubbing
		4 hours	X			X			
		> 16 hours	X			X			
Plastic (reusable)	Water	2 hours	X		X				
		4 hours	X		X				
		> 16 hours	X		X				
	Sodium Chloride	2 hours	X		X				
		4 hours	X		X				
		> 16 hours	X		X				
	Contrast	2 hours	X		X				
		4 hours	X		X				
		> 16 hours	X	X		X		Very minor lifting at one corner	
Plastic (disposable)	Water	2 hours	X		X				
		4 hours	X		X				
		> 16 hours	X		X				
	Sodium Chloride	2 hours	X		X				
		4 hours	X		X				
		> 16 hours	X		X				
	Contrast	2 hours	X		X				
		4 hours	X		X				
		> 16 hours	X		X				

Table 2: Removal of label 2 and any associated residue on hollowware following exposure to fluids for varying times

Materials, dampened surfaces and Time Periods			Label remained attached		Label removal			Comments	
			YES	NO	No residue	With Residue			
						Minimal residue easily removed	Removed with solvent	Too much residue	
Stainless Steel	Water	2 hours	X		X				
		4 hours	X		X				
		> 16 hours	X		X				
	Sodium Chloride	2 hours	X		X				
		4 hours	X			X			Very minimal
		> 16 hours	X			X			Very minimal
	Contrast	2 hours	X		X				
		4 hours	X		X				
		> 16 hours	X			X			very minimal
Plastic (reusable)	Water	2 hours	X		X				
		4 hours	X		X				
		> 16 hours	X		X				
	Sodium Chloride	2 hours	X		X				
		4 hours	X		X				
		> 16 hours	X		X				
	Contrast	2 hours	X		X				
		4 hours	X		X				
		> 16 hours	X		X				
Plastic (disposable)	Water	2 hours	X		X				
		4 hours	X		X				
		> 16 hours	X		X				
	Sodium Chloride	2 hours	X		X				
		4 hours	X		X				
		> 16 hours	X		X				
	Contrast	2 hours	X		X				
		4 hours	X		X				
		> 16 hours	X		X				

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Table 3: Removal of label 3 and any associated residue on hollowware following exposure to fluids for varying times

Materials, dampened surfaces and Time Periods			Label remained attached		Label removal			Comments	
			YES	NO	No residue	With Residue			
						Minimal residue easily removed	Removed with solvent	Too much residue	
Stainless Steel	Water	2 hours	X		X				
		4 hours	X		X				
		> 16 hours	X		X				
	Sodium Chloride	2 hours	X		X				
		4 hours	X			X			Very minimal
		> 16 hours	X		X				
	Contrast	2 hours	X					X	Minimal, Alcohol removed very easily
		4 hours	X					X	Minimal, alcohol removed very easily
		> 16 hours	X					X	Minimal, alcohol removed very easily
Plastic (reusable)	Water	2 hours	X			X			
		4 hours	X		X				
		> 16 hours	X		X				
	Sodium Chloride	2 hours	X		X				
		4 hours	X		X				
		> 16 hours	X		X				
	Contrast	2 hours	X			X			
		4 hours	X		X				
		> 16 hours	X		X				
Plastic (disposable)	Water	2 hours	X			X			
		4 hours	X		X				
		> 16 hours	X		X				
	Sodium Chloride	2 hours	X		X				
		4 hours	X		X				
		> 16 hours	X		X				
	Contrast	2 hours	X			X			
		4 hours	X		X				
		> 16 hours	X		X				

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Table 4: Removal of label 4a and any associated residue on hollowware following exposure to fluids for varying times

Materials, dampened surfaces and Time Periods			Label remained attached		Label removal			Comments
			YES	NO	No residue	With Residue		
						Minimal residue easily removed	Removed with solvent	
Stainless Steel	Water	2 hours	X				X	
		4 hours	X				X	
		> 16 hours	X				X	
	Sodium Chloride	2 hours	X				X	
		4 hours	X				X	
		> 16 hours	X				X	
	Contrast	2 hours	X				X	
		4 hours	X				X	
		> 16 hours	X				X	
Plastic (reusable)	Water	2 hours	X				X	
		4 hours	X				X	
		> 16 hours	X				X	
	Sodium Chloride	2 hours	X				X	
		4 hours	X				X	
		> 16 hours	X				X	
	Contrast	2 hours	X				X	
		4 hours	X				X	
		> 16 hours	X				X	
Plastic (disposable)	Water	2 hours	X				X	
		4 hours	X				X	
		> 16 hours	X				X	
	Sodium Chloride	2 hours	X				X	
		4 hours	X				X	
		> 16 hours	X				X	
	Contrast	2 hours	X				X	
		4 hours	X				X	
		> 16 hours	X				X	

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Table 5: Removal of label 4b and any associated residue on hollowware following exposure to fluids for varying times

Materials, dampened surfaces and Time Periods			Label remained attached		Label removal			Comments
			YES	NO	No residue	With Residue		
						Minimal residue easily removed	Removed with solvent	
Stainless Steel	Water	2 hours	X		X			
		4 hours	X				X	Minimal adhesive, easily removed with alcohol.
		> 16 hours	X				X	Minimal adhesive, easily removed with alcohol.
	Sodium Chloride	2 hours	X		X			
		4 hours	X		X			
		> 16 hours	X			X		Tore as removed, remainder easily removed
	Contrast	2 hours		X	X			Very minor lifting at one corner
		4 hours	X				X	Minimal adhesive, easily removed with alcohol.
		> 16 hours	X			X		Tore as removed, remainder easily removed.
Plastic (reusable)	Water	2 hours	X		X			
		4 hours	X				X	Minimal adhesive, easily removed with alcohol.
		> 16 hours	X		X			
	Sodium Chloride	2 hours	X		X			
		4 hours	X		X			
		> 16 hours	X		X			
	Contrast	2 hours	X		X			
		4 hours	X				X	Minimal adhesive, easily removed with alcohol.
		> 16 hours	X			X		
Plastic (disposable)	Water	2 hours	X		X			
		4 hours	X		X			
		> 16 hours	X		X			
	Sodium Chloride	2 hours	X		X			
		4 hours	X		X			
		> 16 hours	X		X			
	Contrast	2 hours	X		X			
		4 hours	X			X		
		> 16 hours		X	X			Very minor lifting at one corner

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6. General observations and comments

All labels remained adequately adhered to all materials (stainless steel, reusable plastic and disposable plastic) and all surface conditions (dampened surface: water, sodium chloride and contrast) for all three time periods (2 hrs, 4 hrs, > 16 hrs). The minimal lifting of labels observed with labels 1 and 4b was not considered significant as the labels remained securely in place.

Label 4a Big Green Surgical standard labels are sold as labels for use on disposable equipment and as such are not designed to be removed.

Label 2 and Label 4b could be removed swiftly leaving no residue. Label 3 required a slower, steadier technique to remove the label and achieve the same outcome. Provided this technique was used in the testing the same outcome of label and residue removal was achieved.

Labels 1 and 4a classified as 'Too much residue' required firm, persistent scraping in conjunction with solvents to effectively remove residue. However, this was very slow, impractical and possibly caused damage the surface of the hollowware.

7. Appendix 1: Labels evaluated

Label 1

Pre-printed label sheets evaluated in the perioperative area at Calvary Wakefield Hospital. Woodfree, gloss finish paper labels manufactured by StirlingFILDES and sterilised with ethylene oxide by Bard. The labels may be written on with water fast ink (outcome when exposed to individual fluids not guaranteed).

Label 2

Generic abbreviated container labels manufactured and sterilised with ethylene oxide by Mayo Healthcare.

Polypropylene facestock and permanent adhesive are one integral material which may be written on with water fast ink (outcome when exposed to individual fluids not guaranteed).

Label 3

Full Intravenous Use Only container labels printed with a resin overprint. Labels manufactured and sterilised with gamma irradiation by Mermed Australia.

Polypropylene facestock and permanent adhesive are one integral material which may be written on with water fast ink (outcome when exposed to individual fluids not guaranteed).

Label 4a

Pre-printed and generic abbreviated container labels manufactured and sterilised by gamma irradiation by Big Green Surgical (Xodus Permanent Labels).

Polyethylene facestock intended for use on disposable syringes with no fluid contact.

Label 4b

Pre-printed abbreviated container labels manufactured and sterilised by gamma irradiation by Big Green Surgical. Xodus E-Z™ Peel polyethylene facestock intended for use on containers exposed to fluids which may be written on with water fast ink (outcome when exposed to individual fluids not guaranteed).