AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

TRIM 80949

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

Evaluation of standardised medicine syringe labels in interventional cardiac catheter and radiology laboratories

12 November 2013

Suggested citation

Australian Commission on Safety and Quality in Health Care 2013, *National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines: Evaluation of standardised medicine syringe labels in interventional cardiac catheter and radiology laboratories,* ACSQHC, Sydney.

Acknowledgment

Many individuals and organisations have freely given their time and expertise to support the development of this document. The Commission acknowledges and appreciates the willing participation and contribution by all staff in the cardiac catheter laboratories of St Vincent's Health Melbourne, St Vincent's Private Hospital, Melbourne, Greenslopes Hospital and Royal Adelaide Hospital, together with the radiology suites of St Vincent's Hospital, Darlinghurst and Prince of Wales Hospital, Randwick. This paper is available on the Commission web site at www.safetyandquality.gov.au.

Table of contents

1. Background

The high incidence of error and serious patient harm from injectable medicines is a national patient safety issue. Developing and implementing consistent user-applied labelling of injectable medicines and fluids, and the devices used to deliver them, was identified as a national patient safety priority.

In 2010, Australian Health Ministers endorsed the National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines (the Labelling Recommendations)[1] for use in Australian health services. The Australian Commission on Safety and Quality in Health Care (the Commission) developed and maintains the Labelling Recommendations. The Commission also identifies and reduces national barriers to implementation of the Labelling Recommendations.

The Commission convenes a specialist advisory group, the Labelling Recommendations Reference Group (LRRG), to advise it on maintenance and implementation of the Labelling Recommendations. Implementation across the full range of health services can present issues which require consideration by the LRRG and result in changes to the Labelling Recommendations and which are reflected in the Labelling Recommendations Issues Register.[2]

The anaesthetic labelling standard

While the Commission's Labelling Recommendations standardise user-applied labelling of injectable medicines and fluids in all clinical areas, there was a pre-existing standard which standardises user-applied labelling of medicines in syringes used during anaesthesia. The International Standard ISO 26825:2008 (*Anaesthetic and respiratory equipment: User-applied labels for syringes containing drugs used during anaesthesia – colours design and performance*)[3] colour codes labels according to medicine class and applies in parallel with the Labelling Recommendations in perioperative settings.

ISO 26825:2008 is described as the anaesthetic labelling standard throughout this document.

The Labelling Recommendations address the same patient risk for all circumstances other than those addressed by the anaesthetic labelling standard.

(Note that ISO 26825:2008 supersedes the Australian/New Zealand Standard (AS/NZS 4375: 1996 User-applied labels on syringes containing drugs used during anaesthesia. [4])

2. Introduction

The National Recommendations for User-applied Labelling of Medicines, Fluids and Lines (Labelling Recommendations) require identification of injectable medicines removed from the original container.

During implementation of the Labelling Recommendations, it became apparent that a wide range of pre-printed labels of different colour and wording were in use in interventional cardiology and radiology settings but with no clear standardisation of the labelling or the practice.

In a closed practice environment, and where the identity of the patient and patient care team are beyond doubt and recorded, user-applied labelling requires at least the medicine name but does not require patient and operator details unlike in open practice environments.

Examples of user-applied labelling in closed practice environments include:

- medicines in syringes used during anaesthesia where the anaesthetic labelling standard is applied
- the perioperative sterile field where pre-printed labels with medicine name (and concentration) are used.

Perioperative settings

Pre-printed labels were evaluated in perioperative settings in 2012. While cardiac catheterisation laboratories (CCL) are similarly organised to perioperative areas, CCLs differ in two main respects:

- The cardiologist manages the majority of medicine administrations at the same time as performing a clinical procedure.
- Both these tasks are often required to be undertaken in low light conditions allowing for simultaneous review of angiography.

The user-applied labelling solutions developed for perioperative settings provide some guidance on labelling solutions for CCLs but are not directly applicable.

Current practice in interventional cardiac and radiology settings

Many cardiac catheterisation laboratories and interventional radiology suites already use pre-printed medicine line labels developed locally. However, there is no established standard for pre-printed medicine syringe labels in these settings.

Cardiac catheterisation laboratories and interventional radiology suites follow protocols using the same sets of medicines which make it possible to establish pre-printed label sets for medicine identification.

Therefore the Labelling Recommendations Reference Group (LRRG) recommended evaluation of a pre-printed label set using anaesthetic labelling standard colour coding because:

- colour coding according to medicine class (as in the anaesthetic labelling standard) is widely accepted in cardiac catheterisation laboratories and interventional radiology suites
- appropriate standardisation can improve patient safety especially for staff moving between health disciplines and services.

This report details the evaluation of pre-printed labels for cardiac catheter laboratories and radiology suites and the particular requirements of those settings with low light levels in these procedure rooms.

3. Aim and objective

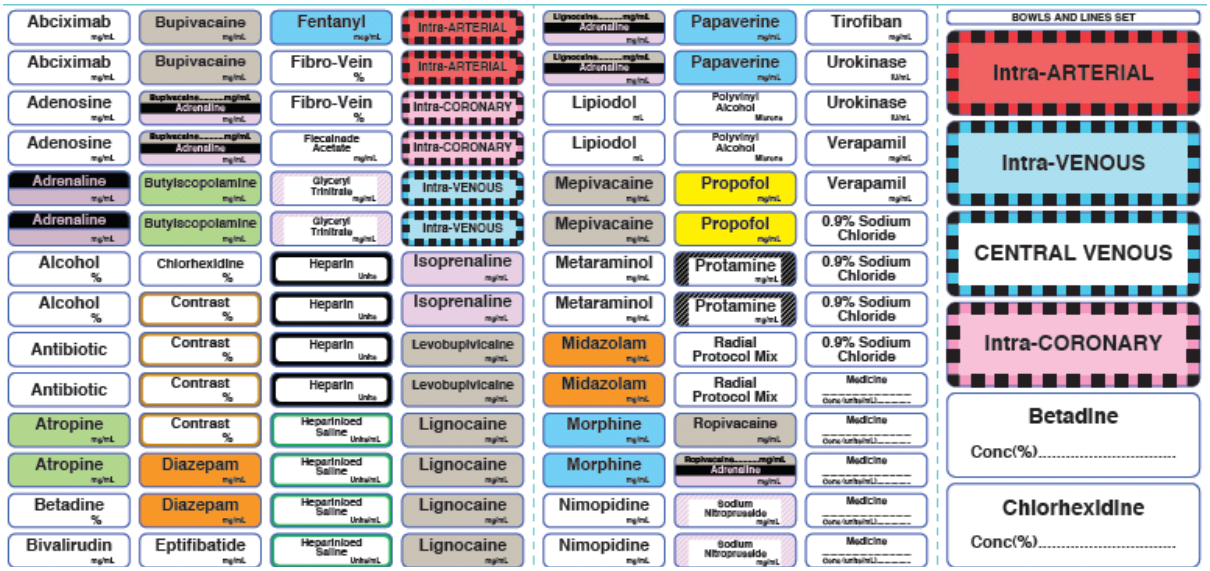
The aim of the study was to evaluate standardised pre-printed medicine syringe labels, based on anaesthetic labelling standard colours and formatting, for use on cardiac catheterisation laboratory and radiology suite sterile fields.

The objective of the study was to develop advice on implementation of the Labelling Recommendations for health services and health professionals in relation to cardiac catheterisation laboratory and radiology suite sterile fields.

4. First label set evaluation

A set of pre-printed labels for medicine containers (principally syringes) was evaluated firstly in a single cardiac catheterisation laboratory and subsequently, following modification, in four cardiac catheter laboratories and two radiology suites.

Figure 1: The first label set evaluated at St Vincent's Hospital Melbourne.



4.1 Methodology

The first label set (see Figure 1 above) was evaluated as a suitable tool for identifying medicines and fluids on cardiac catheterisation laboratory (CCL) sterile fields. The evaluation was conducted by staff at St Vincent's Health Melbourne in October and November 2012. The label sheets were either included in procedure packs or individually packaged and sterilised.

A follow up evaluation form (at Appendix 10.1) was completed for each morning or afternoon list.

The label set was created by a label supplier based on the following requirements:

1. Use of colour on medicine labels for containers (e.g. syringes) should comply with the anaesthetic labelling standard. Labels for medicines in the miscellaneous category of the anaesthetic labelling standard (such as 0.9% sodium chloride) should be printed black on white.
2. Label quality must be such that labels remain intact through sterilisation and retain integrity throughout the procedure.
3. Labels should be in accordance with the anaesthetic labelling standard on the advice of the Labelling Recommendations Reference Group and in accordance with Issue 14 of the Labelling Recommendations Issues Register.

4.2 Results

Collated and analysed evaluation forms provided the following findings:

- The name of the medicine was very small in some cases e.g. heparinised saline and glyceryl trinitrate.

- Concentration was not completed. For each medicine only one concentration is in use at any one time in any one facility. Sterile pens are not generally available.
- The number of medicines and fluids on the same sheet was proportionate to the range of items used in the CCL.
- Label selection became easier over time as staff understood the labels were in alphabetical order and became familiar with the label set.
- There were too many labels coloured black on white.
- There is insufficient distinction for anticoagulant medicines. In particular, heparin with a black border is inadequately distinctive from other miscellaneous medicines and too closely aligned with heparinised saline.
- Heparinised saline and saline are used interchangeably for flush and yet heparinised saline is more closely aligned with heparin.
- Glyceryl trinitrate and sodium nitroprusside are not clearly distinguishable as a class with only a hatched violet border.
- Contrast as a generic term is not sufficiently precise.
- Antibiotic is useful as a generic term. A wide range of antibiotics are available for use but only one antibiotic will be given in any one procedure.
- Metaraminol is a vasopressor and should be coloured violet.
- Nimodipine and verapamil are hypotensives and should be colour coded similar to glyceryl trinitrate.
- Radial Protocol Mix is a variable term.
- Label surface tends to disintegrate during longer procedures.
- Three medication errors were recorded. In all three cases, the cardiologist intended to administer heparinised saline. However, glyceryl trinitrate was given in error. Measures were taken to stabilise patient and no harm resulted. The error occurred with two different operators in three different teams.

4.3 Recommendations

The following changes to the label set were recommended in the first evaluation report:

- Increase the point size for the medicine name. Some medicine names are sufficiently large e.g. abciximab and adenosine. Others, such as heparin and flecainide, are considered too small.
- Remove concentration. This confers no benefit and its removal will allow for increased font size of medicine names.
- Introduce a colour associated with anticoagulant/antiplatelet medicines, including the following: abciximab, bivalirudin, eptifibatide, heparin, tirofiban and urokinase.
- Keep the green border (PMS 356) for heparinised saline.
- Hypotensive class e.g. glyceryl trinitrate and sodium nitroprusside: completely colour labels violet with a violet stripe border.
- Identify contrast media by name.
- Remove radial protocol mix label. Consider how to label syringes with multiple mixes.
- Ensure label integrity is retained for the duration of the procedure.

5. Label revision

5.1 Agreement on label set for second evaluation

Evaluation of the first label set resulted in recommendations for change to the pre-printed label set for use in CCLs.

In November 2012, the Labelling Recommendations Reference Group, including representatives from the Cardiac Society of Australia and the Royal Australia and New Zealand College of Radiologists considered first evaluation recommendations. A second modified label set was agreed for both CCLs and interventional radiology suites and as the basis for a second evaluation.

5.2 Context for decisions

Labelling Recommendation Reference Group members considered further changes to the first evaluation label set in the context of pre-existing use of colour for medicines identification. The main issues for consideration were:

1. The written word is the primary identifier in all medicines identification. Colour can assist recognition but is always secondary to the written word.
2. Colour is used judiciously as a secondary identifier for medicine route in the Labelling Recommendations (see Table 1 below). It is derived from the pre-existing Australian standard for user-applied identification labels used on fluid bags, syringes and drug administration lines (AS 4940:2002)[6].
3. Colour is used as a secondary identifier for medicine class in the anaesthetic labelling standard (see Table 2 below).
4. Further integrating colours used in the anaesthetic labelling standard would only occur after careful consideration.
5. The Clinical Oncological Society of Australasia uses purple in association with the word cytotoxic for cytotoxic medicines[7].

5.3 Changes to first evaluation label sheet

A new colour was proposed for anticoagulant and antiplatelet properties acknowledging the high number of black on white labels and the need for differentiating those high risk medicines.

After considering existing standardised colours, green was selected to represent the anticoagulant class. Label artwork was developed for four full label sets, each using a different green in association with anticoagulants. The three types of green most closely matched were:

- Pantone Matching System (PMS) 3255
- PMS 3375
- PMS 3248.

The teal green (PMS 3255) was chosen to represent the anticoagulant class being the most differentiated from PMS 361 (enteral route) and PMS 367 (anticholinergic agents e.g. atropine).

Other colours considered and rejected were green PMS 344 (used for heparinised saline in the first evaluation), PMS 802, brown (PMS 153) and white reversed out of black.

Table 1: Labelling Recommendations colour coding for medicine route

Route	Colour	Pantone Matching System (PMS)
Intravenous	Blue	2985
Neural	Yellow	Pantone Yellow
Subcutaneous	Beige	723
Intra-arterial	Red	1787
Intra-gastric (Enteral) Used in AS 4940:2002 only	Green	361
Miscellaneous (other routes including intra-coronary) Used in the Labelling Recommendations only	Pink	806

Table 2: Anaesthetic labelling standard colour coding for medicine class

Medicine class	RGB colour	PMS	Medicine examples
Induction agents	Yellow	Process Yellow	Thiopentone, methohexitone, propofol, ketamine
Benzopdiazepines	Orange	151	Diazepam, midazolam
Benzodiazepine antagonists	Orange with white diagonal stripes		Flumazenil
Muscle relaxants	Flourescent red or warm red	Warm red/Flou-rescent red 811	Suxamethonium, d-tubocurare, pancuronium, atracurium, vecuronium
Relaxant reversal agents	Flourescent red or warm red with white diagonal stripes		Neostigmine, edrophonium, pyridostigmine
Opioids	Blue	297	Morphine, fentanyl, pethidine
Opioid antagonists	Blue with white diagonal stripes		Naloxone
Vasopressors	Violet	256	Adrenaline, ephedrine, phenylephrine, metaraminol
Hypotensive agents	Violet with white diagonal stripes		Sodium nitroprusside, glyceryl trinitrate, phentolamine, hydralazine
Local anaesthetics	Grey	401	Procaine, lignocaine, bupivacaine, ropivacaine
Anticholinergic agents	Green	367	Atropine, glycopyrolate
Anti-emetics	Salmon	156	Droperidol, metoclopramide, tropisetron
Heparin	White with solid black border (1 to 2 mm)		
Protamine	White with black diagonal stripe border (1 to 2 mm)		
Miscellaneous drugs	White		e.g. oxytocin, potassium chloride, antibiotics

Heparinised saline had been printed with a bright green border which was prompted by a client request of the label production company, Bard Australia. There was no logic beyond local preference for the colour association. Heparin diluted with saline, or heparinised saline, is used as a flush and must be clearly distinguished from full strength heparin. Heparinised saline is printed black on white and heparin black on white with a solid black border according to the anaesthetic labelling standard. If the anticoagulant class is allocated a colour, it follows that the border for heparinised saline is the same colour as that associated with anticoagulant class.

Introduction of another colour for anticoagulants in CCLs may have implications for:

- the anaesthetic labelling standard, the primary source of colour coding according to drug class
- the extension of the anaesthetic labelling standard for identification of medicines in dedicated continuous infusion lines
- angiography in areas other than the CCL.

6. Second label set evaluation

6.1 Methodology

The second label set (see Figure 2 below) was evaluated as a suitable tool for identifying medicines and fluids on cardiac catheterisation laboratory (CCL) and interventional radiology suite sterile fields. In addition, the trial evaluated label quality, acceptability and utility.

The evaluation was conducted by staff at the following facilities and with practice areas indicated:

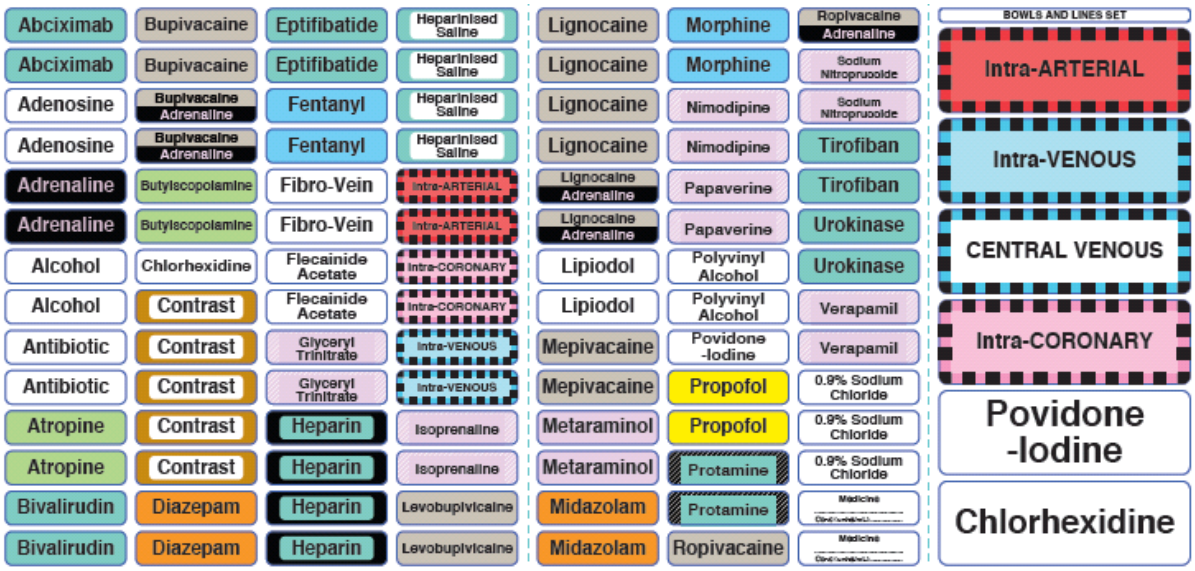
1. St Vincent's Health Melbourne (CCL)
2. St Vincent's Private Hospital Melbourne (CCL)
3. Greenslopes Private Hospital (CCL)
4. Royal Adelaide Hospital (CCL and electro-physiology)
5. St Vincent's Hospital, Darlinghurst (radiology suite)
6. Prince of Wales' Hospital (radiology suite).

The evaluation took place between April and July 2013. The label sheets were either included in procedure packs or individually packaged and sterilised.

The Commission funded label sheet artwork. The manufacturer, Bard Australia, revised the first evaluation label set accordingly and label sheets were produced. The label sets were provided in sterile custom procedure packs procured by each trial centre. The exception was the Prince of Wales Hospital which uses a different supplier for procedure packs. That hospital was supplied with individually packed and sterilised label sets for use alongside the procedure packs.

Education was made available to the nursing and medical staff about the draft standard medicine labels. Label sets were trialled for a period of four to six weeks depending on local circumstances. Staff were asked to complete an evaluation survey (at Appendix 10.2) following each list in which the draft national standard medicine labels were used. The survey included questions about the new label set including acceptability, ease of use, content and quality.

Figure 2: The second label set evaluated at six hospitals.



6.2 Second label set

The second label set was created by using the first evaluation label sheet and with the following details:

- All labels were coloured consistent with the anaesthetic labelling standard with the exception of anticoagulant drugs.
- Medicines in the anaesthetic labelling standard miscellaneous category (e.g. frusemide and 0.9% sodium chloride) printed black on white.
- All route labels were consistent with the Labelling Recommendations.
- All labels to use:
    - plain sans serif font
    - alphabetical order
    - text size as large as possible
    - lower case letters with an initial upper case letter.
- Label properties were as follows:
    - label size - 10 mm wide and 35 mm in length (small container labels) and 25 mm wide and 70 mm in length (large container labels)
    - font size – between 10 point (small container labels) and 16 point (large container labels)
    - liner - supercalendered glassine paper, 60g/m² in weight, 0.053 mm thick
    - facestock - supergloss, white, woodfree paper, 83g/m² in weight, 0.084 mm thick
    - adhesive - general purpose, permanent, rubber based with a with a peel adhesive strength of 980N/m
    - sterilisation method - ethylene oxide

The following changes were reflected in the label set:

- Anticoagulant labels were coloured teal green (PMS 3255)
- Heparin and protamine were coloured teal green (PMS 3255) and differentiated by a solid black border for heparin and a black hatched border for protamine (as specified in the anaesthetic labelling standard).
- Heparinised saline labels were coloured with a teal green border (PMS 3255).
- Concentration may be omitted because the label is applied to a small syringe and the low light conditions of the cardiac catheter laboratory require the point size used for the medicine name to be as large as possible.
- Full generic medicines names were used with no abbreviations and no brand names.
- No labels with medicine class names with the exception of antibiotics and contrast.

6.3 Participants

The trial of a standard set of pre-printed medicine syringe labels developed in accordance with the above was conducted in six centres (described in Table 3 below). A seventh centre, St John of God Hospital's cardiac catheterisation laboratory, withdrew at the outset and took no further part in the evaluation (see 6.4).

A: St Vincent's Health Melbourne is a tertiary public healthcare service providing a range of services, including acute medical and surgical services. The hospital has more than 5,000 staff and 880 beds in daily use across services. The Cardiac Investigation Unit has two cardiac catheter laboratories and undertake on average 60 cases per week.

B: St Vincent's Private Hospital, Melbourne is a 500 bed hospital with medical and surgical facilities. The Cardiovascular Care Centre has one vascular and 2 cardiac catheter laboratories and undertake on average 80 cases per week.

C: Greenslopes Private Hospital is a 676 bed private tertiary hospital with medical and surgical facilities. The theatre complex includes 3 cardiovascular suites undertaking on average 250-300 cases per month.

D: Royal Adelaide Hospital is a 650 bed public tertiary hospital with medical and surgical facilities. Cardiovascular services have 2 cardiovascular interventional units, an electrophysiology unit with a recovery room. On average 1600 diagnostic and undertake approximately 800 percutaneous coronary interventions per year.

E: St Vincent's Hospital, Darlinghurst is a tertiary, public teaching hospital which provides acute care services to inpatients and outpatients from the local community, throughout the state and nationally. The interventional radiology in Medical Imaging undertakes on average 25 to 30 cases per week.

F: Prince of Wales Hospital. The Randwick Campus Medical Imaging Department provides imaging services to three co-located public tertiary referral facilities: The Prince of Wales Hospital, Sydney Children's Hospital and The Royal Hospital for Women together comprising over 800 beds. A broad range of medical and surgical services are provided including interventional neuroradiology. The interventional radiology suite undertakes over 2000 cases per annum.

Table 3: Trial centres and site coordinator contact details

Trial centre	Site co-ordinator contact details
St Vincent's Health Melbourne	Assoc Professor Andrew MacIsaacs, Director, Cardiology Services, Deputy Chief Medical Officer Ms Megan Leishman, Nurse Unit Manager, Cardiac Investigation Unit, (03) 9288 4671, **megan.leishman@svhm.org.au**
St Vincent's Private Hospital Melbourne	Ms Heather MacFarlane, Education Consultant, Cardiac Vascular Care, (03) 9411 7567, **heather.macfarlane@svpm.org.au**
Greenslopes Hospital	Ms Kris-Anne Mullany, Nurse Unit Manager, 07 3394 6701, **mullaneyk@ramsayhealth.com.au**
Royal Adelaide Hospital	Ms Barbara Copus, Catheter Laboratory Manager (08) 8222 4355, **barbara.copus@health.sa.gov.au**
St Vincent's Hospital, Darlinghurst	Assoc Prof Lourens Bester, Head of Interventional Radiology Ms Carolyn Graham, Nursing Unit Manager, Diagnostic Services Department, (02) 8382 2327 **cgraham@stvincents.com.au**
Prince of Wales Hospital	Ms Fiona Law**,** Clinical Nurse Consultant, Medical Imaging (02) 9382 8573, **fiona.law@sesiahs.health.nsw.gov.au**

The six trial centres used a range of non-standardised pre-printed medicine user-applied labels for syringes prior to the evaluation (Table 4). This range of labels did not comply with the Labelling Recommendations and there was no uniformity between health facilities for wording, colour or label specifications.

Processes for medicine administration also varied across the six centres (see Table 4 below).

Table 4: Processes for user-applied labelling of medicines in CCL and radiology

Trial Centre	Clinical scope and procedure packs	Personnel responsible for medicine preparation	User-applied label supply for trial
St Vincent's Health Melbourne	Coronary angiogram, percutaneous coronary intervention, cardiac structural procedures, pacing, renal denervation	Registered nurse	In procedure packs
St Vincent's Private Hospital Melbourne	Coronary and vascular diagnostics and interventions, cardiac structural procedures, coronary ablation.	Registered nurse	In procedure packs
Greenslopes Hospital	Vascular, coronary, pacemaker, electrophysiology	Registered nurse	In procedure packs
Royal Adelaide Hospital	Coronary angiogram, percutaneous coronary interventions, cardiac structural procedures, coronary ablation, electrophysiology	Registered nurse and occasionally proceduralist	In procedure packs
St Vincent's Hospital, Darlinghurst	Angiography, vascular, selective internal radiation therapy	Registered nurse	In procedure packs
Prince of Wales Hospital	Angiography, vascular	Registered nurse and occasionally radiologist	Individually sterile packaged

6.4 Pre-trial assessment of label durability

On the first trial day in the St John of God Hospital, labels disintegrated and became detached from the syringes in some cases. The trial was stopped and samples of labelled syringes were packaged and forwarded to Bard for analysis.

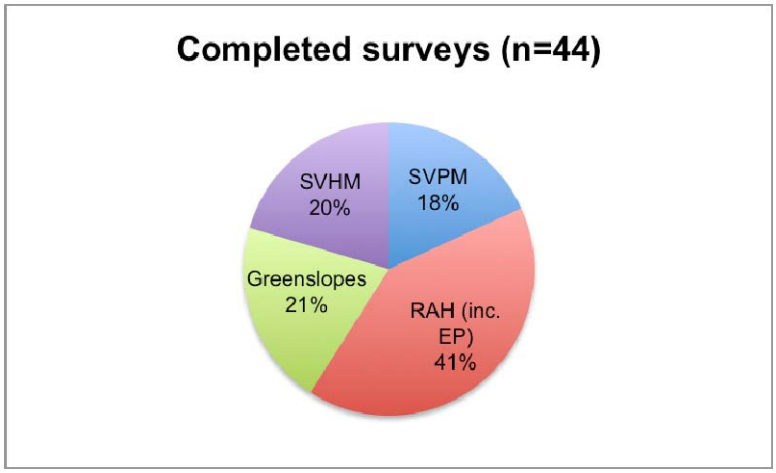
Bard confirmed label sets used the same materials including paper stock and glue as labels previously supplied on a commercial basis to cardiac catheter laboratories. Bard, the Commission and the Prince of Wales Hospital undertook independent bench top tests to assess durability of labels placed on syringes coming into contact with water. Wet labels did disintegrate if they were handled, in particular, labels with a white background.

Trial centres were made aware of the findings and only commenced the trial when they were confident the process of syringe labelling would ensure the labels remained intact. Moreover, if the labels started to disintegrate that these labels would be replaced.

6.5 Results of pre-printed label evaluation in the cardiac catheter laboratory

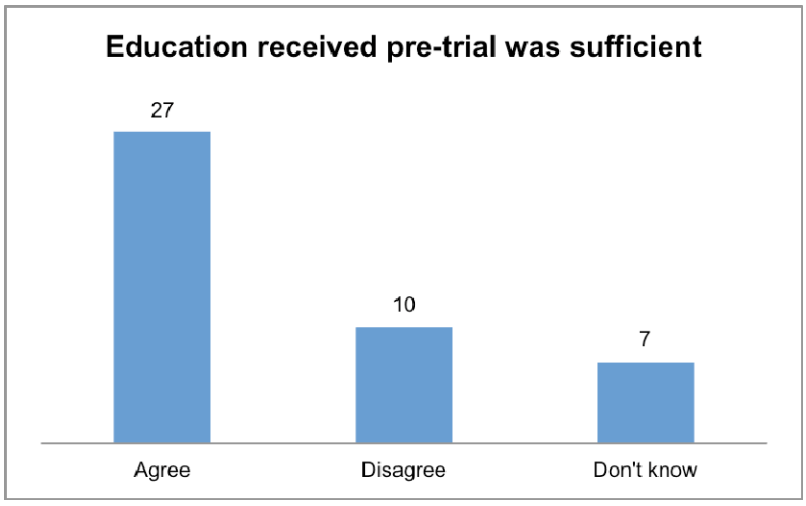
6.5.1: The four CCL trial centres submitted a total of 44 completed evaluation surveys. One survey was completed for each list (either morning or afternoon) by the respondent who had participated in the majority of cases during that session.

Figure 3: Completed surveys



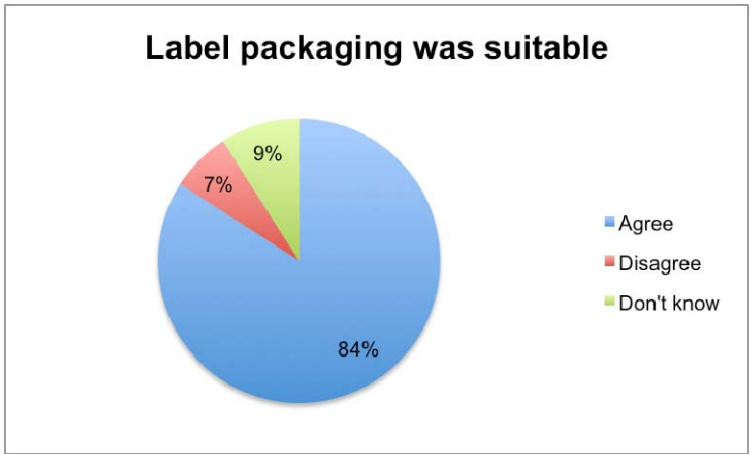
6.5.2: The education given prior to implementation of the syringe labels was sufficient in the majority (25%) of cases. Some respondents felt inadequately prepared to use the label set.

Figure 4: Pre-trial education



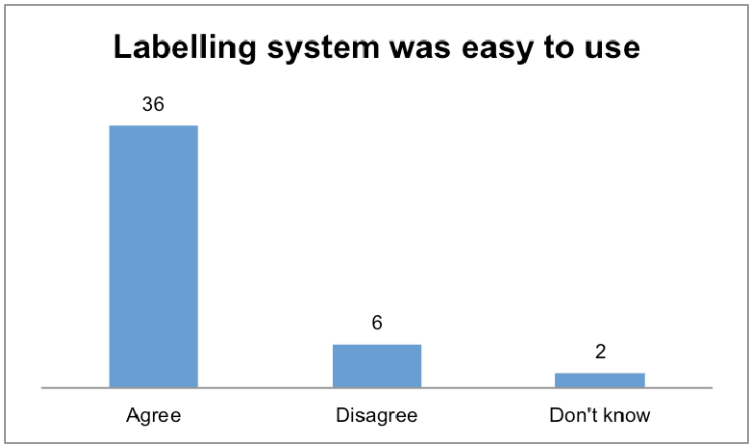
6.5.3: The majority of respondents thought the label packaging presentation was suitable for their requirements

Figure 5: Suitability of label packaging



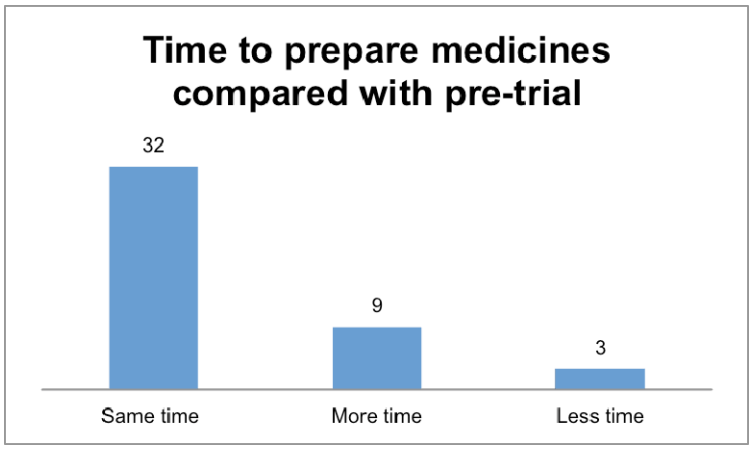
6.5.4: The majority of respondents (82%) thought the labelling system was easy to use.

Figure 6: Labelling system ease of use



6.5.5: There was agreement that the new labelling requirements did not alter the medicine preparation time.

Figure 7: Labelling time requirement



Labelling requiring more time than requested prior to introduction was attributed to unfamiliarity. In addition, labels were not previously available for all medicines. The time taken for preparation was expected to reduce as users became more familiar with label sets. It was also suggested that label selection time could be improved by reducing the number of available labels and repositioning the labels according to medicine class. A number of medicine labels were not required to be sterile and these confounded selection choice on the sterile field. Three respondents found medicines took less time to prepare, including a participant from St Vincent's Health Melbourne, when comparing the label set with that of the first evaluation label set.

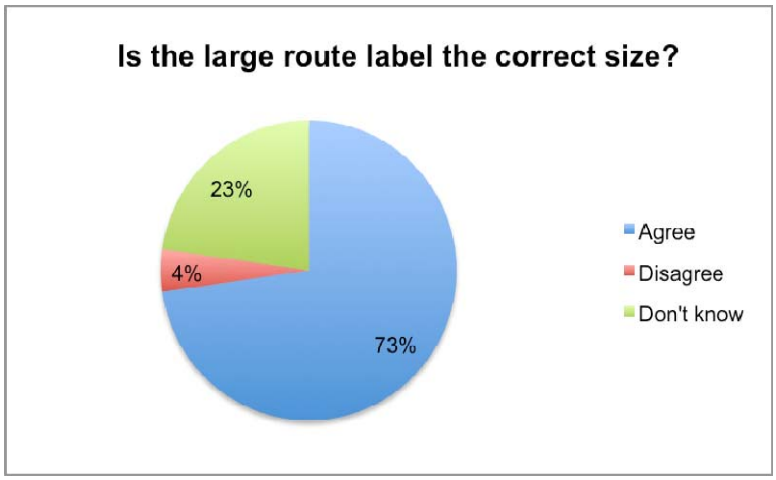
6.5.6 Route labels

6.5.6.1: Large intravenous route label

Figure 8: Large intravenous route label (below)

The size of the large route label was fit for purpose

Figure 9: Large intravenous route label size

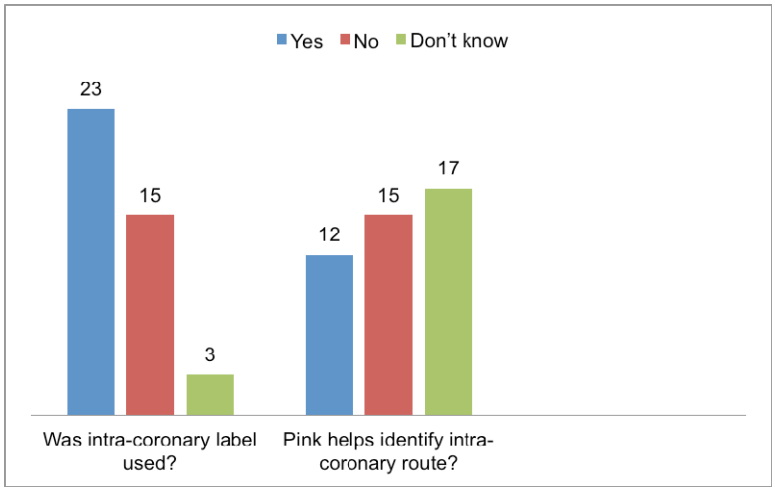


6.5.6.2 Large intracoronary route label: Pink colour associated with the large intra-coronary label was neither definitively helpful nor unhelpful.

Figure 10: Large intracoronary route label

The intra-coronary label was used by 23 of the 44 respondents. Three Royal Adelaide Hospital respondents reported using the intracoronary label. However, the intracoronary route was unlikely to have been used and this was either an error in data entry or labels had been applied in error.

Figure 11: Large intracoronary label utility and practicability (below)



The intra-arterial route may become the intra-coronary route as the guiding catheter enters the heart. Labelling was not changed during a procedure and the intra-arterial label was used for medicines administered via the intra-coronary route.

6.5.6.3: Small route labels

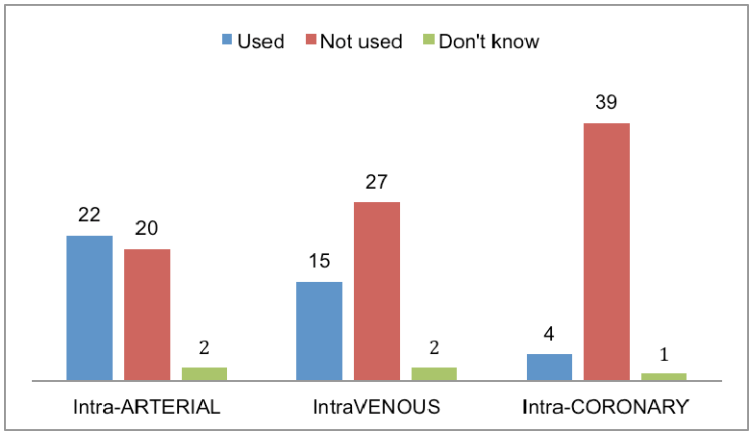
Figure 12: Small route labels

Some respondents required the intra-arterial and intravenous route labels (see figure 12 above).

Intra-arterial and intravenous route labels were placed back to back across the line to allow visibility from both sides of the line. It would be preferable to have slightly larger sterile line labels with a centre line marked and duplicate wording on both halves consistent with non-sterile line labels. The label may then be folded around the line and fully legible from both sides of the line.

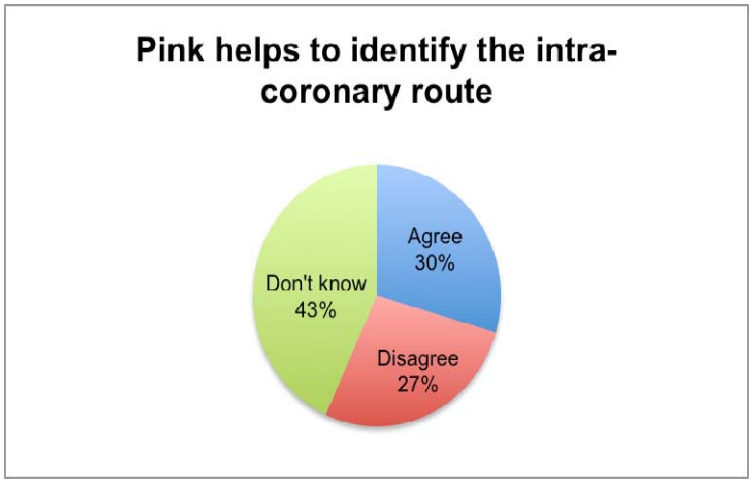
The small intra-coronary labels were infrequently used. The intracoronary route is used very occasionally. As for the large intra-coronary route label, the intra-arterial route may become intracoronary as the guiding catheter enters the heart and the intra-arterial label was selected for this line.

Figure 13: Small route label use



6.5.6.4: There was no clear indication that pink assisted identification of the intra-coronary route using the small intra-coronary labels

Figure 14: Utility of pink miscellaneous label colour



This correlated with results for the large intracoronary label (see 5.5.6.2).

6.5.7 Medicine/fluid labels

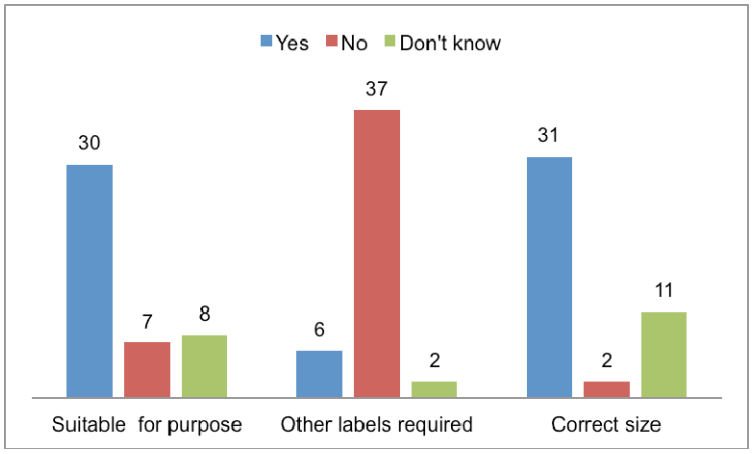
6.5.7.1: Large medicine/fluid labels (see Figure 15 below)

Figure 15: Large medicine/fluid labels example

The majority of respondents thought the large fluid labels were suitable for the purpose of labelling containers.

Additional large labels were required for medicines and fluids in bowls including 0.9%sodium chloride, heparinised saline and chlorhexidine alcohol. At the Royal Adelaide Hospital, povidone-iodine and chlorhexidine are placed in gallipots and ideally require labels between the two sizes.

Figure 16: Large medicines/fluid labels acceptability



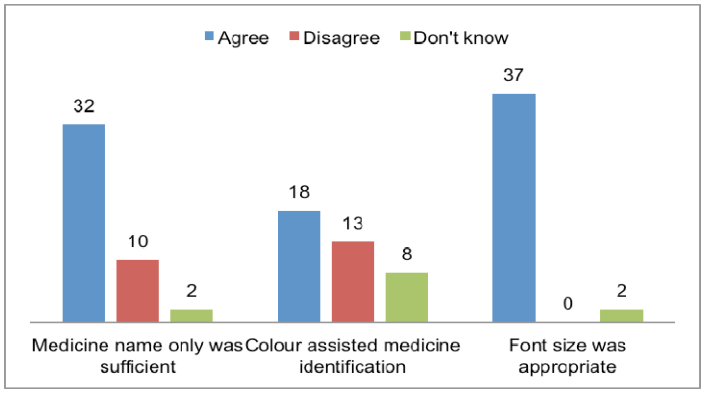
Only a few respondents indicated labels other than these included on the sheet were required (6 of 44). Suggestions included normal saline, heparinised saline, iodine and

chlorhexidine. There were no perceived issues with the large fluid label size with 25 of 44 respondents affirming the size was acceptable.

6.5.7.2: Small medicine labels

The majority of respondents (73%) agreed that only the medicine name was required on this label. Colour to assist identification was helpful in some cases but not in others. This may have depended on the label set in use prior to the trial.

Figure 17: Small medicine label acceptability

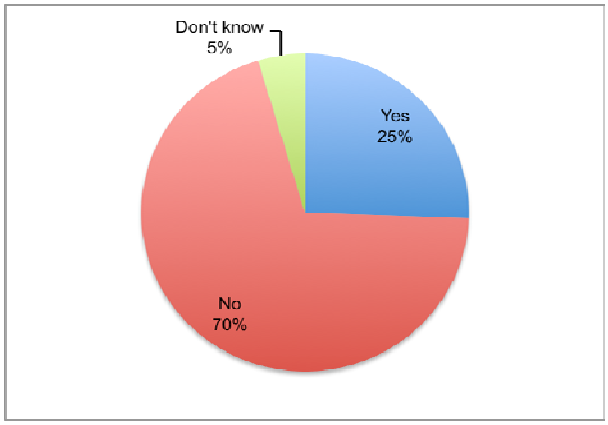


There was concern raised over the absence of a concentration prompt where a high risk of harm is associated with different medicine concentrations in use on the sterile field, e.g. adenosine, sodium nitroprusside and glyceryl trinitrate.

The four cardiac catheter laboratories recorded the labels used during the evaluation. Hospitals were also given the opportunity to review their requirements for sterile labels if the trial was conducted for longer (Table 5). A number of labels used in the CCL are not required to be sterile. These include atropine, fentanyl, flecainide acetate, isoprenaline, metaraminol, midazolam and morphine.

6.5.7.3: Generic medicine label

Figure 18: Generic medicine label use



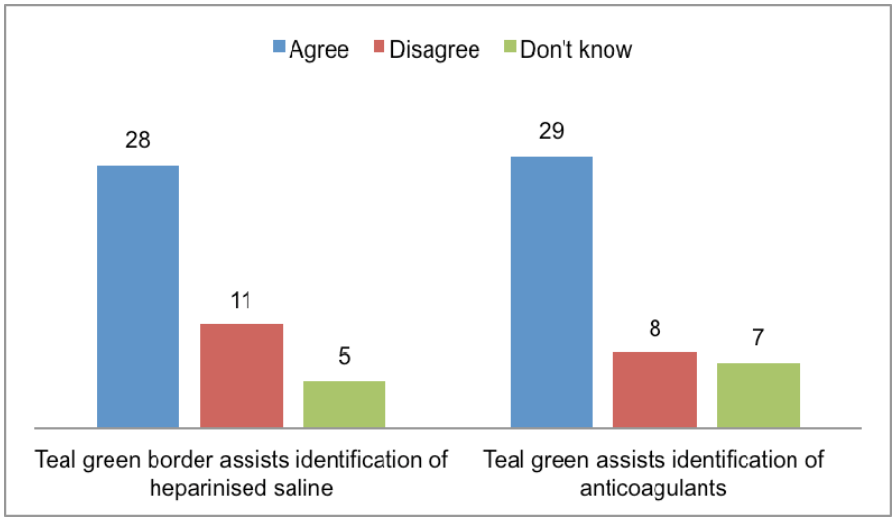
Generic label was used for radial protocol mix, chlorhexidine alcohol and urokinase.

6.5.8: Teal green associated with anticoagulants.

1. More respondents agreed that the teal green border on the heparinised saline label was helpful to assist identification than not.

2. The majority of respondents thought teal green was useful to assist identification of anticoagulants as a medicine class

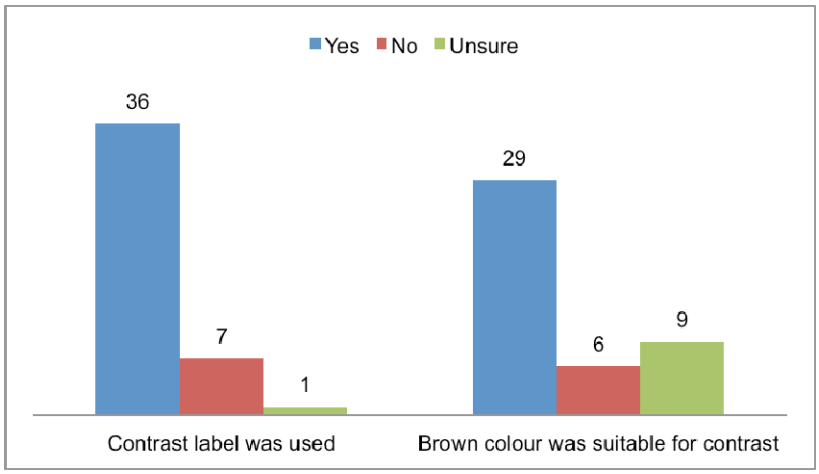
Figure 19: Anticoagulant colour coding acceptability



6.5.9: Contrast media labels. Contrast media were used and labelled in 29 of 44 lists. The majority of respondents found the brown border (see Figure 20 below) suitable for identifying contrast media.

Figure 20: Contrast media labels

Figure 21: Contrast label acceptability



6.5.10: Antibiotic label. The Antibiotic label was not used in the cardiac catheter laboratory.

Figure 22: Antibiotic label

One trial centre indicated the antibiotic label may be required for pacing cases.

Table 5: Medicine label use during the trial and a prediction of required sterile labels

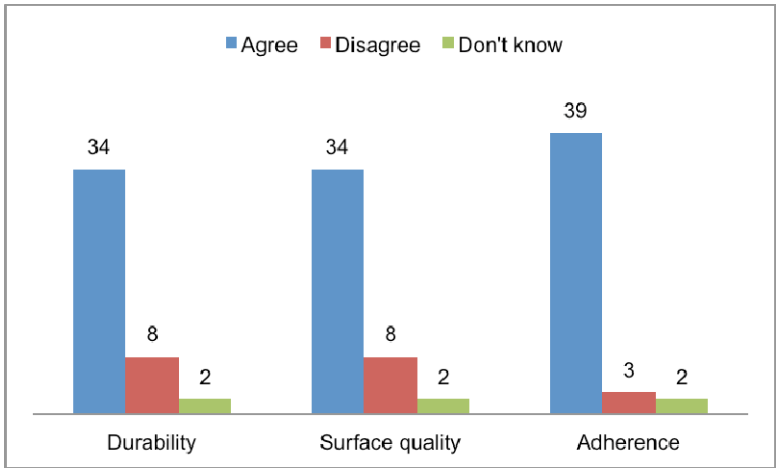
	Used				Required on sterile sheet			
Medicine	**RAD**	**SVHM**	**G**	**SVPM**	**RAD**	**SVHM**	**SVPM**	**Greenslopes**
Abciximab	√	√	√	√	√ (2)	√ (2)	√ (2)	√ (2)
Adenosine	√		√	√			√ (2)	√ (2)
Adrenaline	√	√						
Alcohol	√ (in error)				√ (2) (septal ablation)		√ (2)	
Antibiotic					√ (2) (pacemakers)	√ (2)		
Atropine	√	√	√					√ (2)
Bivalirudin					√ (2)	√ (2)		√ (2)
Bupivacaine	√				√ (2) (electrophysiology)	√ (2)		√ (2)
Bupivacaine/adrenaline	√					√ (2)		√ (2)
Cephazolin								
Chlorhexidine	√	√				√ (2)		
Chlorhexidine alcohol					√ (6)	√ (2)	√ (2)	
Contrast	√			√	√ (6)	√ (2)	√ (6)	
Fentanyl	√			√				
Fibro-Vein								
Flecainide acetate	√							
Glyceryl trinitrate	√	√	√	√	√ (6)	√ (4)	√ (6)	√ (4)
Heparin	√	√	√	√	√	√ (2)	√ (6)	√ (2)
Heparinised saline	√	√	√	√	√ (6 small) (2 large)	√ (6)	√ (6)	√ (4)
Isoprenaline	√		√					
Lignocaine	√	√	√	√	√ (2)	√ (2)	√ (2)	√ (2)
Lignocaine/adrenaline			√		√ (2) (pacemakers)	√ (2)	√ (2)	√ (2)
Metaraminol	√	√						
Midazolam	√	√		√				
Morphine	√	√						
Nimodipine								
Povidone-Iodine					√ (2)	√ (2)	√ (2)	
0.9% Sodium chloride	√	√		√	√ (2 small) (4 large)	√ (2)	√ (2)	√ (2)
Sodium nitroprusside	√				√ (2)		√ (2)	√ (2)
Urokinase (required not trialled)							√ (2)	
Verapamil	√			√		√ (2)	√ (2)	√ (2)
Verapamil/Heparin/glyceryl trinitrate (Radial protocol mix)					√ (2)		√ (2)	
Generic medicine label	√							√ (2)
Arterial route								√
Venous route								√

*Shading indicates sterile labels required across the 4 trial centres

6.5.11: Label quality

The labels demonstrated durability and surface quality was maintained in 77% of lists. Some labels disintegrated and required replacement where syringes were left in solution or came into contact with fluids during longer cases.

Figure 23: Label quality



6.5.12: Cardiac catheter laboratory label quality additional feedback comments

St Vincent's Private Hospital, Melbourne

- *The problem of label disintegration during longer procedures was noted with labels supplied prior to the trial and the trial labels.*
- *The unit performs both cardiovascular and vascular procedures. Staff work in both areas and a single sterile sheet of labels applicable to either area is preferred. Urokinase was required for vascular procedures.*
- *There are too many different kinds of stickers on the sheet never used on catheter lab.*
- *Colours are not bold or strong enough. Red, blue, yellow more effective, e.g. heparin red, lignocaine blue, contrast green, GTN white (colours traditionally used)*
- *More bright colours, no stripes required*
- *Able to identify easily, clearer than previous labels*
- *Adenosine too similar to saline label*
- *Labels, e.g. saline began to fray and dissolve when wet for long period of time*
- *Preparation fluids, povidone-iodine and chlorhexidine not used and not needed on table.*
- *Only require preparation solutions once. Then they should be discarded and not available for procedure*
- *Flush should have its own colour and different to adenosine, lipiodol, Fibro-Vein, chlorhexidine*
- *Most bowls are small and large fluid labels were not required*
- *Sterile pens are not generally available*
- *Consider including blank labels for medicines not on list*
- *Too many labels – difficult to find those needed*

St Vincent's Health Melbourne

- *The label sheet is useful for medicine reconciliation at the end of the procedure.*
- *The sheet is an improvement on the label sheet 1.*
- *Prefer heparin red, contrast green, lignocaine blue, GTN yellow.*
- *If heparinised saline syringe stays in the heparinised saline pot the label surface rubs off.*
- *Labels started to disintegrate when left in water or normal saline.*
- *Much clearer, bigger text, distinct colours.*
- *Many labels not used. Reduce labels on sheet.*
- *Need more GTN.*
- *Intra-coronary label have no relevance as drugs are given through multiple routes from the same syringe, e.g. GTN given intra-arterial and intra-coronary.*
- *Multiple medications use the same border and colour and are unsafe.*
- *Colour should not be used to identify medication over reading the label.*

Greenslopes Hospital

- *Had to look twice at the heparin and heparinised saline as they are the same colour.*
- *Using for the first time was disorientated.*
- *Bupivacaine and lignocaine are occasionally used in the same procedure. Both grey and not easy to identify.*
- *Suggest solid red for heparin, solid white for intra-coronary drugs, blue for lignocaine, green for contrast, yellow for atropine. New labelling terrible and prone to near misses.*
- *Heparin and anticoagulants should be black on red background.*
- *GTN used to be black and white and much easier.*
- *Route labels great for sheaths that remain in situ, e.g. after angioplasty (arterial access) and temporary pacing wire (venous). Makes it easy to recognise for staff who later remove sheaths.*
- *More GTN labels. Need 2 for each pot and syringe so a label is visible from every side of pot and syringe.*
- *Colours are often the same for different drugs – confusing.*
- *CCL lighting is always low and cardiologist focussed on screen. Different drugs with the same colour and pale striped artwork yet different actions and routes, e.g. isoprenaline and GTN are confusing. All medicines should have their own block colour.*
- *All similar decorative labels require reading which negates the need for any colours.*
- *GTN and verapamil mixes to prevent artery spasm use exactly same colour.*
- *Labelling in the same drug class does not help when wanting a specific medication.*
- *GTN same as sodium nitroprusside label.*
- *Heparin hard to identify quickly. Red would be preferable.*
- *Abciximab and bivalirudin are same colour but very different drugs.*
- *Bold, solid colours and a different colour for each drug much easier to use.*
- *Heparinised saline not used because too confusing.*
- *GTN picked up instead of heparin.*

- *Confusing in emergency situation when you have multiple syringes labelled with labels of same colour background.*
- *Labels shouldn't be put on flushes.*

Royal Adelaide Hospital

- *Radial protocol labels required. Don't need to identify differences between protocols.*
- *Radial protocol mix is routinely used for angiogram procedures. Radial protocol often contains verapamil 2.5mg/mL, glyceryl trinitrate 100 microgram/mL and heparin 2500IU/mL. However, the gylceryl trinitrate and heparin may change between procedures, e.g. angiogram and percutaneous coronary intervention. The generic label was used in the absence of a specific 'radial protocol mix' label and left blank as sterile marker pens were unavailable.*
- *Takes time to adjust to new labels.*
- *Unusable once they had fluid on them. Care must be taken to keep labels dry.*
- *Labels were not left in saline and did not come off.*
- *Labels could be more specific for our area.*
- *Don't route label intra-coronary. Need to specify drug name.*
- *Route labels should be double printed to be readable from both sides when folded.*
- *Route labels good for sheaths.*
- *Use of colour is good.*
- *You get used to identifying colour with a specific medication.*
- *Name should be identifying factor not colour.*
- *For a colour blind person font is more important.*
- *Do not adhere after they get wet.*
- *Iodine should be brown.*
- *The femoral venous line represents central venous access and is specifically labelled with a customised Femoral Venous Line label. This is a blue label based on the Labelling Recommendations minimum requirements for line labels with the addition of the wording 'Femoral Venous Line and the size (FG) of the line. The label is placed directly over the dressing covering the access port. A corresponding sticker with further details of reason for insertion, site of insertion and a contact number for further information is completed and placed in the notes at the time of insertion. The small sterile intraVENOUS line label provided is placed on the side arm of the intravascular sheath. A small central venous line label would have been used if available.*

6.6 Results of pre-printed label evaluation in radiology

6.6.1: Evaluation survey completion. The pre-printed labels were trialled in two interventional radiology units over four to six weeks. St Vincent's Hospital, Darlinghurst completed 22 evaluation surveys, one for each list. The nurse unit managers and supervisors at Prince of Wales Hospital interventional radiology each completed one evaluation survey as a summary of their findings during the course of the trial, returning three surveys in total. For this reason, combining the feedback from both hospitals will distort the findings in favour of one hospital so feedback for each trial hospital is presented.

6.6.2: The education given prior to implementation of the syringe labels was sufficient in all cases.

6.6.3: Packing and label presentation was suitable for St Vincent's Hospital, Darlinghurst in all cases. Prior to the trial Prince of Wales Hospital, Randwick used a set of labels individually packaged comprising 3 x heparinised saline, 3 x contrast medium, 1 x lignocaine 1% (Figure 1). The trial set of labels contained many more labels than required confounding the handling and label selection process.

Figure 24: Label set used pre-trial by Prince of Wales Hospital (supplied by Defries Industries)

6.6.4: All respondents at St Vincent's Hospital, Darlinghurst and one of the three respondents from Prince of Wales Hospital thought the labelling system was easy to use. The other two respondents from Prince of Wales thought the system difficult to use due to the large number of unrequired labels and the arrangement of labels in an alphabetical order rather than in drug families.

6.6.5: There was agreement that the new labelling requirements did not substantially alter medicine preparation time.

Labelling that took more time than that taken prior to introduction was attributed to unfamiliarity. The time taken to prepare medicines for these cases was expected to reduce as users became more familiar with label sets.

6.6.6: Route labels

6.6.6.1: Large intravenous route label. The size of the large route label was fit for purpose for all respondents at St Vincent's Hospital, Darlinghurst and one of the 3 respondents from Prince of Wales Hospital, Randwick. The other Prince of Wales respondents reported that the intravenous route label was too large for labelling lines. There was some confusion over the purpose of the route labels and if they were to be applied instead of a medicine label.

Figure 25: Large intravenous route label

6.6.6.2: Large intracoronary route label: The intra-coronary label (see Figure 26 below) was not used in either interventional radiology trial centre and therefore, participants were unable to comment on the acceptability including colour.

Figure 26: Large intracoronary route label

6.6.6.3: Small route labels. The small intra-coronary labels were not used in either interventional radiology trial centre. Respondents at the Prince of Wales Hospital, Randwick indicated that the route labels may have been used if they were separate from the medicine labels and easier to select. The intra-arterial catheters, including guiding and micro catheters must be distinguished.

Figure 27: Small route labels

6.6.7: Medicine/fluid labels

6.6.7.1: Large medicine/fluid labels, for example.

Figure 15: Large medicine/fluid labels example

All respondents from St Vincent's Hospital, Darlinghurst thought the large fluid labels were suitable for the purpose of labelling containers and the correct size. They did not see a need for any other large fluid labels.

Prince of Wales Hospital, Randwick interventional radiology use chlorhexidine swabs and did not require the chlorhexidine label. For povidone-iodine, one respondent was happy with the label size but others found the label too large for labelling the smaller gallipot used at preparation and thrown away prior to commencement of procedure.

6.6.7.2: Acceptability of small medicine label, for example.

Figure 28: Small medicine label examples

All respondents at St Vincent's Hospital, Darlinghurst and two of the three respondents from Prince of Wales Hospital agreed that only the medicine name was required on this label. However, one Prince of Wales Hospital respondent preferred concentration to be included citing the example of more than one concentration of lignocaine being used in the same procedure. In addition, the omission of concentration on the label for drugs used in anaesthesia was considered a retrograde step to existing practice. Anaesthesia and sedation are carried out in the interventional radiology unit. Anaesthetic labels colour coded and including a prompt for concentration are not required to be sterile and are readily available. Inclusion of anaesthetic labels on the sterile label sheet presents label selection error.

Colour to assist identification was helpful in the majority of cases. Two respondents at the Prince of Wales Hospital reported that the grey tint for lignocaine was unclear in low light conditions. Currently the unit currently uses a black on white label.

A large number of pre-printed labels were not required. Table 6 lists the extent of medicine label use and potential requirement for sterile pre-printed labels in the trial interventional radiology units.

Table 6: Requirement and potential requirement for pre-printed labels in interventional radiology

	Used		**Required to be sterile**	
Medicine	**SVHD**	**POWR**	**SVHD**	**POWR**
Abciximab			√	√
Cephazolin			√	√
Fentanyl	√			
Fibro-Vein			√	√
Heparin	√		√	√
Heparinised saline	√	√	√	√
Lignocaine	√	√	√	√
Lignocaine/adrenaline			√	
Midazolam	√			
Nimodipine			√	√
Papaverine			√	
0.9% Sodium chloride		√	√	√
Urokinase			√	
Verapamil	√		√	√

6.6.7.3: Generic medicine label

The generic medicine label was not completed in either trial centre.

6.6.8: Teal green associated with anticoagulants

All respondents agreed that the teal green border on the heparinised saline label was helpful to assist identification

The majority of respondents (96%) thought teal green was useful to assist identification of anticoagulants as a drug class.

6.6.9: Medicine or fluid group/class labels

6.6.9.1: All respondents in both trial centres used the Contrast label (see Figure 20 below) finding the generic term Contrast acceptable and the brown border suitable for identifying contrast media.

Figure 20: Contrast media labels

6.6.9.2: The use of the Antibiotics label was dependent on the interventional facility. All respondents at St Vincent's Hospital, Darlinghurst used the label to identify cephazolin. The Prince of Wales Hospital, Randwick respondents did not use the antibiotic label but suggested the antibiotic name should be specified.

Figure 22: Antibiotic label

6.6.10: Label quality

Labels were durable and surface quality was maintained for the majority of respondents (96%). St Vincent's Hospital, Darlinghurst reported label deterioration during a lengthy procedure for labels in contact with heparinised saline and contrast. Prince of Wales Hospital performed a bench top test of labels prior to trial commencement and found that all labels were durable with the exception of the contrast label which disintegrated when it became wet. The contrast label remained intact during the trial.

6.6.11: Interventional radiology additional feedback comments

- *The huge number of labels on test sheet may compromise label selection and the team feel uncomfortable with the availability of unnecessary labels on the sterile field. The majority of these medicines, e.g. fentanyl, midazolam, can be identified by anaesthetic non sterile labels readily available. Moreover, the trial labels do not have concentration and this is a retrograde step as the anaesthetic standard labels include a concentration prompt. Fentanyl and midazolam are likely to be given in different concentrations.*
- *Presentation of medicine labels should be according to drug class not alphabetical order. Small and large route labels should be grouped together separate from medicine labels.*
- *Label suitable for the cardiac catheter laboratory for CCL may not necessarily be suitable for the dual purpose of interventional radiology. A standard set for radiology would limit the label selection errors.*
- *Abciximab is not coloured with a colour associated with high risk.*
- *Grey for lignocaine does not stand out sufficiently.*
- *Place route and medicine labels apart and organise drugs according to class.*
- *Large fluid labels not used.*

7. Discussion

User-applied labelling with standardised pre-printed labels for medicines in syringes was well accepted. The label sets were easy to use and the presentation in custom procedure packs or individually packaged and sterilised was appropriate.

7.1 Label selection

No medicine selection errors were reported in relation to the labelling. There was little appreciable additional time taken to prepare medicines and where this was increased it was expected to reduce as staff become more familiar with the labels. In addition, some reorganisation of the label sheet so that medicines are listed according to class rather than alphabetically may improve label selection.

The range of labels covered the majority of medicines administered in cardiac catheterisation laboratories. The range was too extensive for radiology trial centres and confounded the label selection process. Additional labels were requested by CCL staff but were already on the label sheet.

7.2 Route labels

Both large and small route labels were suitable sizes. However, a label between the two sizes was preferred by Royal Adelaide Hospital instead of the large label for gallipots.

Intravenous and intra-arterial labels were used to label lines for these routes. In each case, two labels had to be applied back to back across the line to ensure the full wording is visible in any direction. This is consistent with line labelling across the labelling standardisation and labels with duplicate wording and a dividing fold line may be preferred.

Figure 29: Proposed new route labels with dividing fold for fixing over the line and visible from any direction.

The intra-coronary labels were infrequently used. The intra-arterial route becomes intra-coronary as the guiding catheter enters the heart and the intra-arterial label was selected to identify this line.

7.3 Medicine labels

The size of the text for the medicine name on the first evaluation label set was too small and difficult to read. The second evaluation label set used a larger font for the medicine name and omitted concentration. This was well accepted with the following exceptions:

- generic medicine names rather than brand names were not always recognised
- some respondents preferred concentration to be included. Indeed, lignocaine given in two strengths in the same case could not be appropriately labelled.

7.4 Use of colour

Colouring medicine labels according to medicine class as described in the anaesthetic labelling standard was a change in practice.

The nursing staff made alternative suggestions for colour changes which were inconsistent with the anaesthetic labelling standard. Staff may be unaware of the existing standard colour coding for anaesthetics and education and explanation of rationale and background may be helpful.

The application of colour coding according to medicine class, and the choice of colours applied according to the anaesthetic labelling standard, was better accepted as staff became more familiar with the coding. However, it is unclear whether resistance to the colour choices poses an ongoing risk of error.

Colour coding according to medicine class results in multiple medicines printed with the same colour. This was raised as an issue by a minority of respondents.

The teal green introduced for the anticoagulant class, and used as a border for heparinised saline, reduced the number of black on white labels and was well accepted in most cases.

7.5 Label durability

One hospital reported label disintegration as the evaluation commenced and decided to cease participation. Following bench top testing which suggested labels may disintegrate on contact with fluid, the remaining hospitals progressed with the trial but acting with caution when labels contacted fluids. No further problems were experienced except in lengthy cases. Labels with less colour were more vulnerable to disintegration on contact with fluid over long periods compared with fully coloured labels.

8. Recommendations

The draft standard pre-printed medicine line labels were well accepted in interventional cardiology and radiology.

The following recommendations are made for user-applied labelling in interventional cardiology and radiology based on trial outcomes following review by the Labelling Recommendations Reference Group:

1. Label with a pre-printed label including the generic name of the medicine or fluid.
2. Concentration is not required. Concentration could be included. However, labels accommodating concentration may need to be slightly larger to retain font size and legibility of medicine name.
3. Only labels required on the sterile field should be included on the sterile label sheet (see Appendices 10.3 and 10.4).
4. Non-sterile labels compliant with the anaesthetic labelling standard should be available in procedure rooms (see Appendix 10.5).
5. Colour of sterile pre-printed medicine labels should be consistent with colour-coding in the anaesthetic labelling standard with the following exceptions:
    - antiplatelet agents/anticoagulants to be labelled with teal green (PMS 3255)
    - heparin to be teal green with a black border
    - protamine to be teal green with a black diagonal stripe border
    - heparinised saline to have a teal green border (PMS 3255)
    - contrast to have a brown border (PMS 471)
6. Colour of sterile route labels should be consistent with the Labelling Recommendations' colour coding according to route.

7. Route labels should be printed with duplicate wording and a dividing midline to wrap around lines.
8. An intra-coronary label is not required. It is appropriate to use the intra-arterial label even for lines that enter the intra-coronary space.
9. Contrast media may be labelled with the generic term contrast. No additional benefit is conferred by specifically identifying the contrast.
10. Antibiotics should be labelled with the generic medicine name of the antibiotic.
11. Size of label and font size should be such that the text is clearly legible:
    - In the trial font size varied between 10 point and 16 point
12. Labels must be produced using material that remains intact for duration of use:
    - In the trial label composition was as follows, noting that disintegration occurred in lengthy cases:
        - liner - supercalendered glassine paper, 60g/m² in weight, 0.053 mm thick
        - facestock - supergloss, white, woodfree paper, 83g/m² in weight, 0.084 mm thick
13. Labels must be produced with glue that ensures the label remains attached for the duration of use:
    - Trial labels were produced with a permanent, rubber based adhesive with peel adhesive strength of 980N/m

The number of medicine labels is not required to be as extensive as the number included on the trial label sheet, particularly in interventional radiology. The projected requirements of the test hospitals (see Table 5) indicate that health services should order pre-printed label sets with a smaller number of medicine labels consistent with local practice to optimise label selection. Example standard sterile label sets based on the outcomes of this evaluation are provided for cardiac catheter laboratories (see Appendix 10.3) and interventional radiology (see Appendix 10.4). Labels from the anaesthetic labelling standard should be available alongside the sterile packaged labels and suggested examples are provided in Appendix 10.5.

The benefit of standardising colour coding, both within and between organisations was endorsed as a positive outcome of this trial. Evaluation of the pre-printed labels for identification of medicines in interventional cardiology and radiology will continue to be monitored by the Commission working with the Labelling Recommendations Reference Group and reported through the *Labelling Recommendations Issues Register*.

9. References

1. Australian Commission on Safety and Quality in Health Care. (2010). *National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines*. Sydney: ACSQHC. Accessed 4 April, 2012 from www.safetyandquality.gov.au/our-work/medication-safety/user-applied-labelling/

2. Australian Commission on Safety and Quality in Health Care 2012, *National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines: Issues Register*, ACSQHC, Sydney. Accessed 20 August, 2012 from www.safetyandquality.gov.au/our-work/medication-safety/user-applied-labelling/issues-register/

3. International Standard. (2008). *Anaesthetic and respiratory equipment — User-applied labels for syringes containing drugs used during anaesthesia — Colours, design and performance*. ISO 26825:2008(E). www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=43811

4. Australian Standard. (1996). *User-applied labels for use on syringes containing drugs used during anaesthesia* (AS:NZS4375:1996). Sydney: Standards Australia International Pty Ltd, 1996.

5. Australian Commission on Safety and Quality in Health Care. *National Tall Man Lettering*: ACSQHC. Accessed 10 April, 2012 from www.safetyandquality.gov.au/our-work/medication-safety/national-tall-man-lettering/

6. Australian Standard. (2002). *User-applied identification labels for use on fluid bags, syringes and drug administration lines (AS 4940:2002)*. Sydney: Standards Australia International Pty Ltd, 2002.

7. Clinical Oncological Society of Australia 2008. *Guidelines for the Safe Prescribing, Dispensing and Administration of Cancer Chemotherapy*, COSA, Sydney. Retrieved January 21, 2013 from www.cosa.org.au/

10. Appendices

10.1 Evaluation survey label set 1

	Cardiac Catheter Laboratory Sterile Labelling Trial Evaluation	AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE
Week:	**Date:**	
Theatre:	**Scrub Nurse:**	

- In order to effectively evaluate the new **Sterile Label Set** and ensure the **Labelling System** meets the needs of the cardiac catheter laboratory it is imperative to review the label and process throughout the trial period.
- The labels are specifically designed to ensure easy and effective usage and you can actively participate in this process by completing one evaluation per list.
- Please evaluate the program using the following statements as guidance, circling the item that best indicates your level of agreement

1. The education given prior to the implementation of the labels and the labelling system was sufficient

a) Agree b) Don't know c) Disagree

2. The packaging of the labels was suitable for your requirements

a) Agree b) Don't know c) Disagree

3. The labelling system was easy to use

a) Agree b) Don't know c) Disagree

4. Was the time for preparation: (Circle Choice)

a) More than before
b) Less than before

c) No change in preparation time

5. If there was a time difference, what do you believe was the reason for the time difference?

A) Bowls and lines set (large labels) - route labels

For example, 

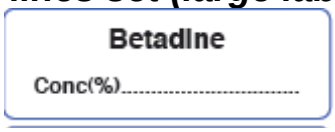
6. Was the Intra-CORONARY label printed on pink (indicative of miscellaneous route) appropriate?

Yes/No

7. For all route labels: Was the size suitable for the specified purpose?
Yes / No

8. If no, please indicate the preferred label size and why.

B) Bowls and lines set (large labels) - fluid labels

For example, 

9. Are the large Betadine and Chlorhexidine labels suitable for the specified purpose?
Yes / No

10. Would other large 'bowl and lines' labels have been useful? **Yes / No**

11. If yes, Please specify

12. For all fluid labels, was the size suitable for the specified purpose? **Yes/No**

13. If no, please indicate the preferred size and why.

C) Small labels – route, for example 

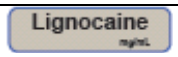
14. Was the Intra-CORONARY label printed on pink (indicative of miscellaneous route) appropriate?
Yes/No

15. Were the following route labels used
a) Intra-ARTERIAL **Yes/No**
b) Intra-CORONARY **Yes/No**
c) Intra-VENOUS **Yes/No**

16. Are any other small container route labels required?
Yes/No

17. If yes, please specify

D) Small labels – medicine and fluid (pre-printed)



18. The labels had sufficient information to allow for accurate identification of each medicine or fluid on the sterile field

a) Agree b) Don't know c) Disagree

19. For each medicine or fluid where (b) or (c) applies, list additional information required?

20. Where colour has been used was it useful for identification?

a) Yes b) No c) Undecided

21. Where colour is not useful please provide details

22. a) For heparinised saline; was the green border useful to assist identification?

Yes/ No

b) The green border is not in ISO26825. Is this colour associated with any other medicine in the CCL?

Yes/No

23. For each label not suitable, indicate the preferred colour (including black on white) and why.

24. Antibiotic labels.

Was this label used? **Yes/No**.

Please provide name of antibiotic

25. For the small labels used on the trial sheet please indicate if the font size is:

a) too small b) about right c) too large

26. Did you need to complete the concentration (i.e. mg/ml or %) for any of the pre-populated labels (i.e. any labels other than the "Abbreviated Container Label")?

Yes / No

27. If yes, which labels did you overwrite with concentration?

28. The labels were durable throughout cases **Yes/No**
The labels maintained their surface quality throughout case. **Yes / No**
29. If surface quality was compromised, explain what occurred and where possible identify solutions that came into contact with the label.
30. The label adhesiveness was effective and the label remained attached to the syringe or container for the duration of the case. **Yes/No** **31.** If the label did not adhere, give details of duration of adherence and medicines or fluids?

E) Small labels – generic medicine label (to be completed) 
32. Did you require the "generic "medicine label? **Yes/No**
33. If yes, please specify the container and contents that required identification with the generic medicine label.
34. If yes, please indicate which prompts were completed. **a)** Medicine **Yes/No** **b)** Concentration **Yes/No**
35. Any other comments?

F) Small labels – medicine and fluid (pre-printed)

Indicate which labels were used

Medicine	Used (tick)	Comment
Abciximab		
adenosine		
Adrenaline		
Alcohol		
Antibiotic		
Atropine		
Betadine		

Bivalirudin		
Bupivacaine		
Bupivacaine/adrenaline		
Butylscopolamine		
Chlorhexidine		
Contrast		
Diazepam		
Eptifibatide		
Fentanyl		
Fibro-Vein		
Flecainide Acetate		
Glyceryl trinitrate		
Heparin		
Heparinised saline		
Isoprenaline		
Levobupivacaine		
Lignocaine		
Lignocaine/adrenaline		
Lipiodol		
Mepivacaine		
Metaraminol		
Midazolam		
Morphine		
Nimopidine		
Papaverine		
Polyvinyl alcohol		
Propofol		
Protamine		
Radial protocol mix		
Ropivacaine		

Ropivacaine/adrenaline		
Sodium nitroprusside		
Tirofiban		
Urokinase		
Verapamil		
0.9% sodium chloride		
Medicine - generic		
Route	**Used (tick)**	**Comment**
Intra-arterial		
Intra-coronary		
Intra-venous		

☺ Thankyou for your time in completing this evaluation ☺

10.2 Evaluation survey label set 2

Cardiac Catheter Laboratory and Radiology Sterile Label Trial Evaluation Form	AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE
Week:	**Date:**
Unit:	**Completed by:**

- Aim: To evaluate the trial Sterile Label Set and ensure it meets the needs of the cardiac catheter laboratory or radiology suite
- Please complete one evaluation form per list
- Please answer the following statements, circling the item that best indicates your level of agreement

36. The education given prior to implementation of the labels and the labelling system was sufficient

a) Agree **b) Don't know** **c) Disagree**

37. The packaging of the labels was suitable for your requirements

a) Agree **b) Don't know** **c) Disagree**

38. The labelling system was easy to use

a) Agree **b) Don't know** **c) Disagree**

39. Was the time for preparation:

a) More than before **b) Less than before** **c) No change?**

40. If there was a time difference, what do you believe was the reason for the time difference?

Bowls and lines set (large route labels), for example,

41. For all large route labels: Was the size suitable for the specified purpose?

a) Yes **b) No**

42. If no, please indicate the preferred label size and why.

43. Was the Intra-CORONARY label printed on pink used?

a) Yes **b) No**

44. In the Labelling Recommendations, pink is aligned with all miscellaneous routes not specified. The colour is helpful to identify the intra -CORONARY route?

a) Agree **b) Don't know** **c) Disagree**

B) Bowls and lines set (large fluid labels), for example,

45. Are the large Povidone-Iodine and Chlorhexidine labels suitable for the specified purpose?

a) Yes **b) No**

46. If no, please specify alternative

47. Were other pre-printed large 'bowl and lines' labels required?

a) Yes **b) No**

48. If yes, please specify for which medicine/fluid they were required

49. For all large fluid labels, was the size suitable for the specified purpose?

a) Yes **b) No**

50. If no, please indicate the preferred label size and why.

a. Small route labels, for example

51. Were the following route labels used

Intra-ARTERIAL **a) Yes** **b) No**

Intra-VENOUS **a) Yes** **b) No**

Intra-CORONARY **a) Yes** **b) No**

52. In the Labelling Recommendations, pink is aligned with the miscellaneous route, i.e. routes with no specific label or colour. Pink is helpful to identify the intra -CORONARY route?

a) Agree **b) Don't know** **c) Disagree**

53. Are any other small container route labels required?

a) Yes **b) No**

54. If yes, please specify

D) Small medicine and fluid labels

55. The labels had sufficient information to allow for accurate identification of each medicine or fluid on the sterile field

a) Agree **b) Don't know** **c) Disagree**

56. For each medicine or fluid where (b) or (c) applies, list additional information required?

57. Where colour has been used was it useful for identification?

b) Yes **b) No** **c) Undecided**

58. Where colour is NOT useful, (b), please list medicines/fluids

59. For each medicine/fluid label not suitable, indicate the preferred colour (including black on white) and why.

60. For heparinised saline; was the teal green border useful to assist identification?

a) Yes **b) No**

61. If no, indicate preferred colour and why.

62. For anticoagulant drugs (Abciximab, Bivalirudin, Eptifibatide, Heparin, Tirofiban and urokinase), was the teal green border useful to assist identification? For example,

a) Yes **b) No**

63. If no, indicate preferred colour and why

64. Was the 'contrast' label used?

a) Yes **b) No**

Please provide contrast name(s)……
……

65. The 'brown' colour was suitable for association with contrast media

a) Agree **b) Don't know** **c) Disagree**

66. If disagree, (c), please give reason why and indicate preferred colour (if any).

67. Antibiotic labels.

Was this label used? **a) Yes** **b) No**

If yes, please provide name of antibiotic……

68. For the small labels used on the trial sheet please indicate if the font size is:

b) too small **b) about right** **c) too large**

69. The labels were durable throughout each case

a) Yes **b) No**

70. The labels maintained their surface quality throughout use

a) Yes **b) No**

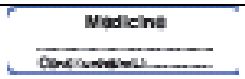
71. If surface quality was compromised, explain what occurred and where possible identify fluids that came into contact with the label.

72. The label adhesiveness was effective and the label remained attached to the syringe or container for the duration of the case

a) Yes **b) No**

73. If the label did not adhere, give details of duration of adherence and medicines or fluids?

E) Small generic medicine label



74. Did you require the "generic "medicine label?

a) Yes **b) No**

75. If yes, please specify the container and contents that required identification with the generic medicine label.

76. If yes, please indicate which prompts were completed.

Medicine **a) Yes** **b) No**

Concentration **a) Yes** **b) No**

F) Which small medicine and fluid labels were used?

Medicine	**Used (tick)**	**Comment**
Abciximab		
Adenosine		
Adrenaline		
Alcohol		
Atropine		
Bivalirudin		
Bupivacaine		
Bupivacaine/adrenaline		
Butylscopolamine		
Chlorhexidine		

Diazepam		
Eptifibatide		
Fentanyl		
Fibro-Vein		
Flecainide Acetate		
Glyceryl trinitrate		
Heparin		
Heparinised saline		
Isoprenaline		
Levobupivacaine		
Lignocaine		
Lignocaine/adrenaline		
Lipiodol		
Mepivacaine		
Metaraminol		
Midazolam		
Morphine		
Nimopidine		
Papaverine		
Polyvinyl alcohol		
Propofol		
Protamine		
Ropivacaine		
Ropivacaine/adrenaline		
Sodium nitroprusside		
Tirofiban		
Urokinase		
Verapamil		
0.9% sodium chloride		

Please provide any other information you feel may be useful

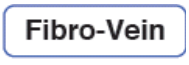
☺ Thank you for your time in completing this evaluation ☺

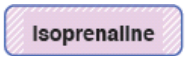
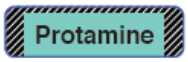
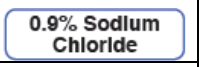
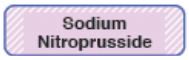
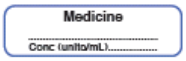
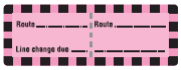
10.3: Example standard sterile label set for interventional cardiology

The following principles have been applied:

- Full drug names; no abbreviations; no brand names; no medicine class names
- Text size as large as possible
- A plain sans serif font
- Colour coding, stripes and borders according to anaesthetic labelling standard
- Black on white where no colour is specified in the standards
- Green (PMS 3255) for anticoagulant/antiplatelet medicines
- Either lower case letters with an initial upper case letter OR apply National Tall Man Lettering.
- Use route labels according to the *Labelling Recommendations*

Include only those labels that are required in your unit where possible to reduce the number of labels available and the potential for selection errors.

Medicine/s	**Anaesthetic labelling standard (ISO26825:2008) PMS colour**	**Proposed labels**
Abciximab	Anticoagulant/antiplatelet, teal green 3255	
Adenosine	B/W	
Adrenaline	Vasopressor, violet 256. Background -bold reverse plate letters within a black bar on the upper half of the label	 OR 
Alcohol	B/W	
Antibiotic (to be specified)	B/W	
Atropine	Anticholinergic, green 367	
Bivalirudin	Anticoagulant/antiplatelet, teal green 3255	
Bupivacaine	Local anaesthetic, grey 401	
Bupivacaine/adrenaline	Local anaesthetic, grey 401/Vasopressor, violet 256 bold reverse plate letters within a black background	
Chlorhexidine	B/W	
Contrast	Contrast, brown 471 border	
Eptifbatide	Anticoagulant/antiplatelet, teal green 3255	
Fibro-vein	B/W	
Flecainide acetate	B/W	
Glyceryl trinitrate	Hypotensive, violet 256 & white diagonal stripe	
Heparin	Teal green 3255 with black border (width between 1-2mm).	

Heparinised saline	B/W with teal green border, 3255	
Isoprenaline	Hypotensive, violet 256 & white diagonal stripe	
Levobupivacaine	Local anaesthetic, grey 401	
Lignocaine	Local anaesthetic, grey 401	
Lignocaine/Adrenaline	Local anaesthetic, grey 401/Vasopressor, violet 256 bold reverse plate letters within a black background	
Lipiodol	Contrast used as……	
Mepivacaine	Local anaesthetic, grey 401	
Nimodipine	Hypotensive, violet 256 & white diagonal stripe	
Povidone-Iodine	B/W	
Protamine	Black & white diagonal stripe border, teal green 3255	
Ropivacaine	Local anaesthetic, grey 401	
Ropivacaine/adrenaline	Local anaesthetic, grey 401/Vasopressor, violet 256 bold reverse plate letters within a black background	
Sodium chloride 0.9%	B/W	
Sodium nitroprusside	Hypotensive, violet 256 & white diagonal stripe	
Tirofiban	Anticoagulant/antiplatelet, teal green 3255	
Urokinase	Anticoagulant/antiplatelet, teal green 3255	
Verapamil	Hypotensive, violet 256 & white diagonal stripe	
Generic medicine	Medicine with concentration prompt	
Route	**Labelling Recommendations (PMS colour)**	**Proposed label**
Intravenous	Blue (PMS 2985)	
Intra-arterial	Red (PMS 1787)	
Intracoronary	Pink (PMS 806)	 Replace ‘route’ with IntraCORONARY

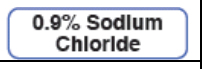
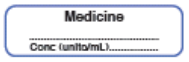
B/W = Black text on white background is used for drugs that fall into the miscellaneous category of the AS/NZS4375:1996 and ISO26825:2008 standards.

10.4: Example standard sterile label set for interventional radiology

The following principles have been applied:

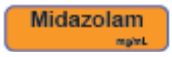
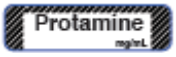
- Full drug names; no abbreviations; no brand names; no medicine class names
- Text size as large as possible
- A plain sans serif font
- Colour coding, stripes and borders according to anaesthetic labelling standard
- Black on white where no colour is specified in the standards
- Green (PMS 3255) for anticoagulant/antiplatelet medicines
- Either lower case letters with an initial upper case letter OR apply National Tall Man Lettering.
- Use route labels according to the *Labelling Recommendations*

Include only those labels that are required in your unit where possible to reduce the number of labels available and the potential for selection errors.

Medicine/s	**AS/NZS 4375:1996 and ISO26825 (PMS colour)**	**Proposed abbreviated container labels**
Abciximab	Anticoagulant/antiplatelet, teal green 3255	
Antibiotic (to be specified)	B/W	
Contrast	Contrast, brown 471 border	
Fibro-vein	B/W	
Heparin	Teal green 3255 with black border (width between 1-2mm).	
Heparinised saline	B/W with teal green border, 3255	
Lignocaine	Local anaesthetic, grey 401	
Nimodipine	Hypotensive, violet 256 & white diagonal stripe	
Povidone-Iodine	B/W	
Sodium chloride 0.9%	B/W	
Verapamil	Hypotensive, violet 256 & white diagonal stripe	
Generic medicine	Medicine with concentration prompt	

B/W = Black text on white background is used for drugs that fall into the miscellaneous category of the AS/NZS4375:1996 and ISO26825:2008 standards.

10.5: Example anaesthetic standard labels to be available in interventional cardiology and radiology (non sterile)

Medicine/s	AS/NZS 4375:1996 and ISO26825 (PMS colour)	Proposed abbreviated container labels
Adenosine	B/W	
Adrenaline	Vasopressor, violet 256. Background -bold reverse plate letters within a black bar on the upper half of the label	
Atropine	Anticholinergic, green 367	
Diazepam	Tranquilliser, Orange 151. Tall Man letters	
Fentanyl	Narcotic, blue 297	
Metaraminol	Vasopressor, violet 256	 (colour violet)
Midazolam	Tranquilliser, Orange 151	
Morphine	Narcotic, blue 297	
Propofol	Induction agent, Yellow, Tall Man lettering	
Protamine	Black & white diagonal stripe border, teal green 3255	 (colour teal green)