Policy

Directive: compliance is mandatory

User-applied labelling of injectable medicines, fluids and lines

Objective file number: eA837526
Policy developed by: Public Health and Clinical Systems
Approved at Portfolio Executive on: 18 August 2011
Next review due: 20 January 2020

Summary Labelling of injectable medicines, fluids and lines has been identified as a significant patient safety issue. This policy addresses the implementation of standardised labelling practices, as well as management of unidentified medicines or fluids

Keywords labelling, injectable medicines, fluids, lines, drug, medicine, IV policy directive

Policy history
Is this a new policy? **N**
Does this policy amend or update an existing policy? **Y**
Does this policy replace an existing policy? **N**
If so, which policies?

Applies to
All SA Health Local Health Networks
All SA Health Services
SAAS
Statewide Services

Staff impact All Clinical, Medical, Nursing, Allied Health, Emergency, Dental, Mental Health, Pathology

PDS reference D0240

Version control and change history

Version	Date from	Date to	Amendment
1.0	18/08/2011	28/02/14	Original version
2.0	28/02/2014	20/01/2016	Links and template updated
3.0	20/01/2016	Current	Updated in line with change from National Recommendations to National Standard

Government of South Australia
SA Health

User-applied Labelling of Injectable Medicines, Fluids and Lines Policy Directive

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Document control information

Document owner	Senior Specialist Pharmacist, Pharmaceutical Reform and Medication Safety, Medicines and Technology Policy and Programs, Public Health and Clinical Systems
Contributors	
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Document history

Date	Author	Version	Change reference
dd/mm/yyyy	<Position title, branch or directorate, division (no name)>	V4	Formally reviewed in line with 1-5 year scheduled timeline for review.
20/01/2016	Senior Pharmacist – Medicines Programs, Medicines and Technology Programs, System Performance and Service Delivery	V3	Reviewed and updated to reflect name change to National Standard for User-applied Labelling of Injectable Medicines, Fluids and Lines.
07/03/14	Senior Specialist Pharmacist, Pharmaceutical Reforms and Medication Safety, Medicines and Technology Policy and Programs, Public Health and Clinical Systems	V.2	Updated links and template
22/08/11	Senior Specialist Pharmacist, Pharmaceutical Reforms and Medication Safety, Pharmaceutical Services and Strategy, Public Health and Clinical Coordination	V.1	PE Approved version.

Endorsements

Date	Endorsed by
22/08/11	Director, Medicines and Technology Policy and Programs

Approvals

Date	Endorsed by
22/08/11	Chief Public Health Officer, Executive Director Public Health and Clinical Systems

User-applied Labelling of Injectable Medicines, Fluids and Lines Policy Directive

1. Objective

The SA Health User-applied Labelling of Injectable Medicines, Fluids and Lines policy is based on the National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines (*National Labelling Recommendations*) endorsed by the Australian Health Ministers in November 2010.

The *National Labelling Recommendations* were developed by the Australian Commission on Safety and Quality in Health Care (ACSQHC) based on the Australian standard AS 4940:2002.[2,3] The recommendations were reviewed and updated to the National Standard for User-applied Labelling of Injectable Medicines, Fluids and Lines[1] (*Labelling Standard)* in 2015 by ACSQHC. The *Labelling Standard* addresses the implementation of standardised practices for labelling of all injectable medicines, fluids and lines in clinical areas.

The User-applied Labelling of Injectable Medicines, Fluids and Lines Policy Directive aims to enhance safe medication practice and reduce the risk of error during the preparation and administration of injectable medicines in clinical areas.

The purpose of the policy directive is to enhance patient safety and reduce the risk of medicine related errors through implementation of the *Labelling Standard.*

- Labelling of injectable medicines, fluids and lines has been identified as a significant patient safety issue and is a recognised risk in the safe administration of injectable medicines.
- Patient harm including death from medicine related errors as a result of inadequate labelling has been repeatedly reported and is an issue across all health care systems in Australia and internationally.
- Clear, standardised labelling of injectable medicines and fluids by the user at the point of preparation and delivery should help to reduce the risk of medicine administration errors.

2. Scope

All SA Health employees, and persons who provide services on behalf of SA Health, involved in the preparation and administration of injectable medicines, fluids and lines in clinical areas must adhere to this policy directive.

This policy directive applies to all injectable products prepared in clinical or treatment areas and includes recommendations for labelling containers and conduits. This incorporates:

- all injectable medicines and fluids removed from the manufacturer's or hospital pharmacy's original packaging prior to administration
- all containers (for example infusion bags, syringes, jugs and basins) containing

medicines which leave the hands of the person preparing the medicine prior to administration (including flushes)
- all conduits (for example catheters and burettes) and lines for parenteral administration
- containers and conduits for any medicine or fluid in the peri-operative period where the Australian and New Zealand anaesthesia standard AS/NZ 4375[4] is not applicable.

3. Principles

SA Health is committed to the Quality Use of Medicines (QUM) and to enhancing safe medication practice in South Australia through implementation of standardised practices known to support high quality health outcomes.

4. Detail

The User-applied Labelling of Injectable Medicines, Fluids and Lines Policy Directive specifies that the requirements for label format, content and placement outlined in the *Labelling Standard* should be utilised to reduce the risk of patient harm from injectable medicines. The Standard outlines what should be labelled, what should be included on the label, standardisation of label colours according to route of administration, and where the label should be placed on the container. In addition, there are minimum requirements for labelling processes (see below under specific considerations).

The recommendations do not replace or obviate the need for other clearly defined quality and safety processes relating to the administration of injectable medicines and fluids.

The *Labelling Standard* includes recommendations for medicines administered via non-parenteral routes e.g. enteral, topical and inhalational routes.

4.1 Specific considerations:

Labelling in the peri-operative area

- Recommendations for labelling injectable medicines drawn up in SYRINGES for use during anaesthesia are addressed by 'The Australian/New Zealand Standard: User applied labels for use on syringes containing drugs used during anaesthesia (AS/NZ 4375).

Labelling processes

- Only one medicine at a time should be prepared and labelled before preparation and labelling of a subsequent medicine.
- Any medicine or fluid that cannot be identified (for example in an unlabelled syringe or other container) should be considered unsafe and discarded.

5. Roles and Responsibilities

5.1 Chief Executive, SA Health will:

- ensure SA public hospitals and health services are aware of and comply with this policy, User-applied Labelling of Injectable Medicines, Fluids and Lines.

5.2 Director, Medicines and Technology Programs Branch, SA Health will:

- ensure sufficient training and reference resources are provided/developed to assist SA public hospitals and health services implement the national recommendations

- review and update the policy as required.

5.3 Local Health Network Chief Executive officers will:

- delegate the day-to-day responsibility for complying with this policy to the relevant senior managers
- ensure the health services under their administration have systems in place to ensure appropriate user-applied labelling of injectable medicines, fluids and lines.

5.4 Executive Directors, Directors, heads of service/departments and other senior managers will:

- develop and implement local policies and procedures to ensure appropriate user-applied labelling of injectable medicines, fluids and lines
- promote and resource the implementation of the national standards into educational programs
- ensure that governance for the policy is established within relevant committees and information is disseminated to all pertinent clinical staff
- ensure appropriate and timely procurement of the labels necessary to comply with the implementation and maintenance of the policy.

5.5 All SA Health employees will:

- adhere to the principles and aims of this policy.

6. Reporting (if applicable)

SA Health hospitals and health services are required to report compliance with governance and systems for medication safety to the relevant accrediting body when undergoing the Accreditation Survey. Implementation of this policy will assist hospitals and health services achieve successful accreditation to Standard 4 Medication Safety by demonstrating:

- policies, procedures and/or protocols are in place that are consistent with legislative requirements, national, jurisdictional and professional guidelines
- action is taken to reduce the risk of adverse medication incidents.

7. EPAS Considerations

N/A

8. Exemptions (if applicable)

N/A

9. Associated Policy Directives / Policy Guidelines (if applicable)

- Accreditation Policy Directive
- Incident Management Policy Directive
- Incident Management Guideline Incorporating Open Disclosure Response
- Open Disclosure Policy Directive
- Patient Identification Policy Directive
- Patient Identification Guideline

- Spell it out: Standardised terminology, abbreviations and symbols to be used when communicating about medicines Policy Directive
- Spell it out: Standardised terminology, abbreviations and symbols to be used when communicating about medicines Standards

10. References, Resources and Related Documents

1. National Standard for User-applied Labelling of Injectable Medicines, Fluids and Lines - Copyright – The Australian Commission on Safety and Quality in Health Care. Accessed 18 January 2015 :

   http://www.safetyandquality.gov.au/our-work/medication-safety/safer-naming-labelling-and-packaging-of-medicines/user-applied-labelling/

2. User-applied identification labels for use on fluid bags, syringes and drug administration lines (AS 4949:2002). Sydney: Standards Australia International Pty Ltd; 2002.
3. User-applied identification labels for use on fluid bags, syringes and drug administration lines (AS 4949:2002) Amendment 1(2003). Sydney: Standards Australia International Pty Ltd; 2003.
4. The Australian/New Zealand Standard®: User-applied labels for use on syringes containing drugs used during anaesthesia (AS/NZS 4375).
5. National Standard for User-applied labelling of Injectable Medicines, Fluids and Lines. Implementation Support Materials.
6. SA Health *Labelling Recommendations* implementation pack.
7. Australian Commission on Safety and Quality in Health Care, National Safety and Quality Health Service Standards, September 2012
8. Australian Commission on Safety and Quality in Health Care, Safety and Quality Improvement Guide Standard 4: Medication Safety (October 2012), Sydney, ACSQHC, 2012

11. Other

N/A

12. National Safety and Quality Health Service Standards (if applicable)

National Standard 1 Governance for Safety and Quality in Health Care	National Standard 2 Partnering with Consumers	National Standard 3 Preventing & Controlling Healthcare associated infections	National Standard 4 Medication Safety	National Standard 5 Patient Identification & Procedure Matching	National Standard 6 Clinical Handover	National Standard 7 Blood and Blood Products	National Standard 8 Preventing & Managing Pressure Injuries	National Standard 9 Recognising & Responding to Clinical Deterioration	National Standard 10 Preventing Falls & Harm from Falls
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13. Evaluation of Performance and Compliance

N/A

14. Attachments (if applicable)

N/A

15. Definitions

In the context of this document:

- **conduit** means any line or device through which injectable fluids could be administered (for example; IV administration lines, epidural lines, catheters, invasive monitoring lines, burettes).
- **container** means any vessel holding a fluid that contains an active ingredient that is intended for injectable administration (for example; bags, syringes, bottles, jugs and basins).
- **flush** means to purge access devices (for example, cannulae) before and/or after injection of a medicine or between injections of different medicines.
- **injectable medicine** means a sterile medicine intended for administration by bolus injection, perfusion or infusion by any of the following routes: intravenous, intramuscular, intrathecal, intra-arterial, subcutaneous, intradermal, intravesicular, epidural, intravitreal, intrapleural and intraocular. This does not exclude other routes of injection.