Medication Safety and Quality

Clinical Excellence Commission

Nina Muscillo
Senior Manager Medication Safety

NSW Hospital in the Home Forum
23 March 2018

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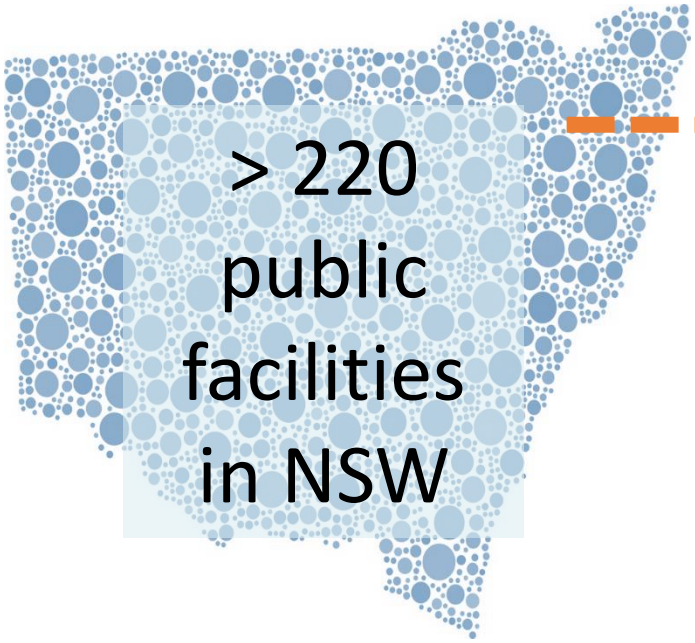
Use of medicines

- In excess of $700 million dollars spent on medicines each year in NSW hospitals



Approximately 28,000 medication incidents reported 2016/17

2016/17:
99 resulted in serious/major harm

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The extent of medication errors and adverse drug reactions throughout the patient journey in acute care in Australia

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Quality Use of Medicines and Pharmacy Research Centre, Sansom Institute for Health Research, University of South Australia, Adelaide, Australia

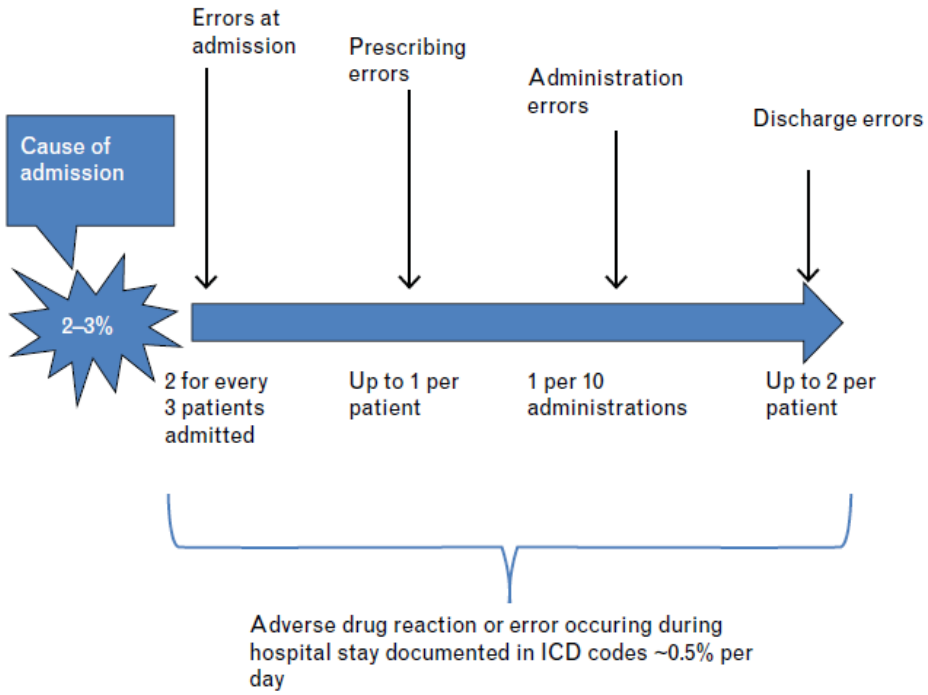

Figure 1. Medication-related problems including ADRs and medication errors during the hospital journey in Australia. ADRs, adverse drug reactions.

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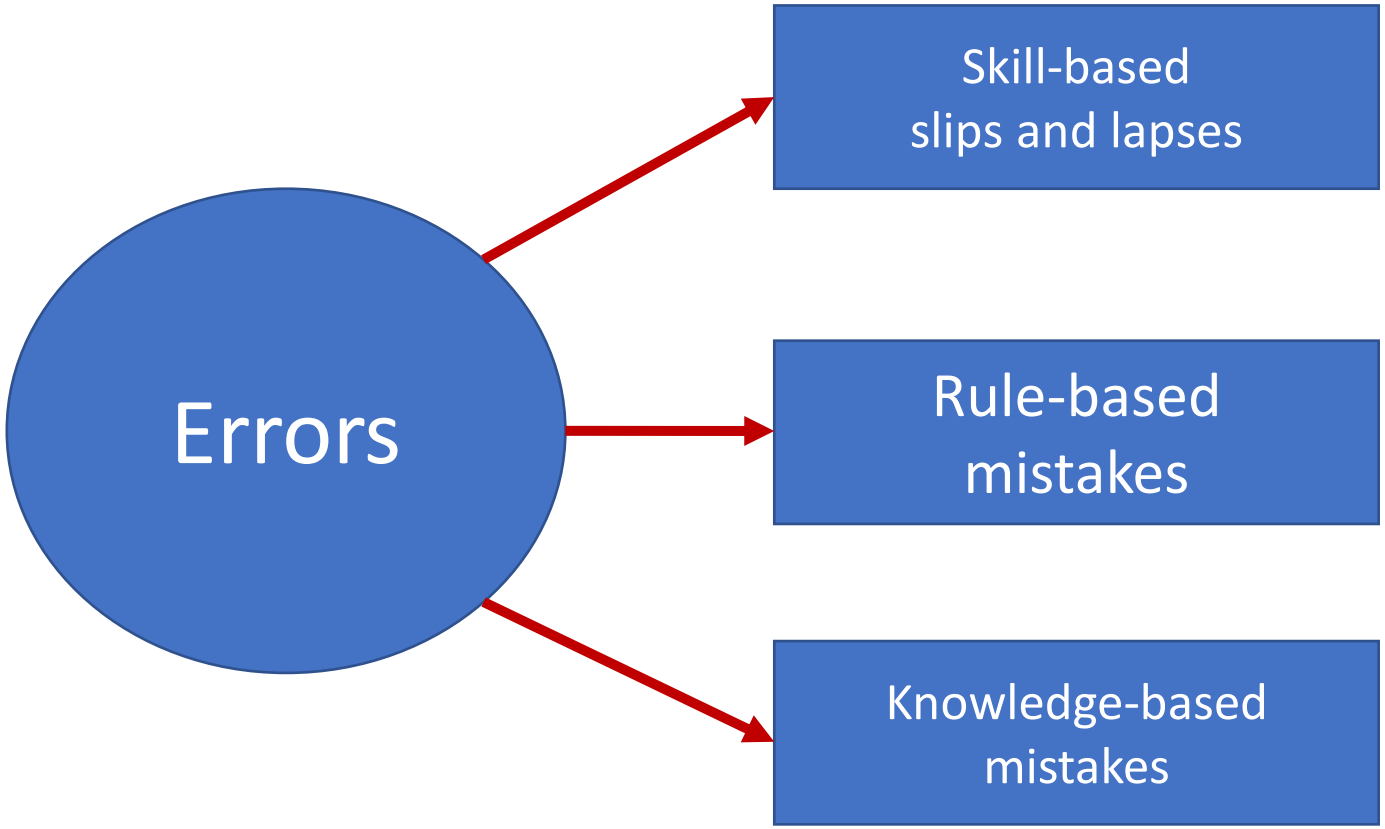
Three basic error types



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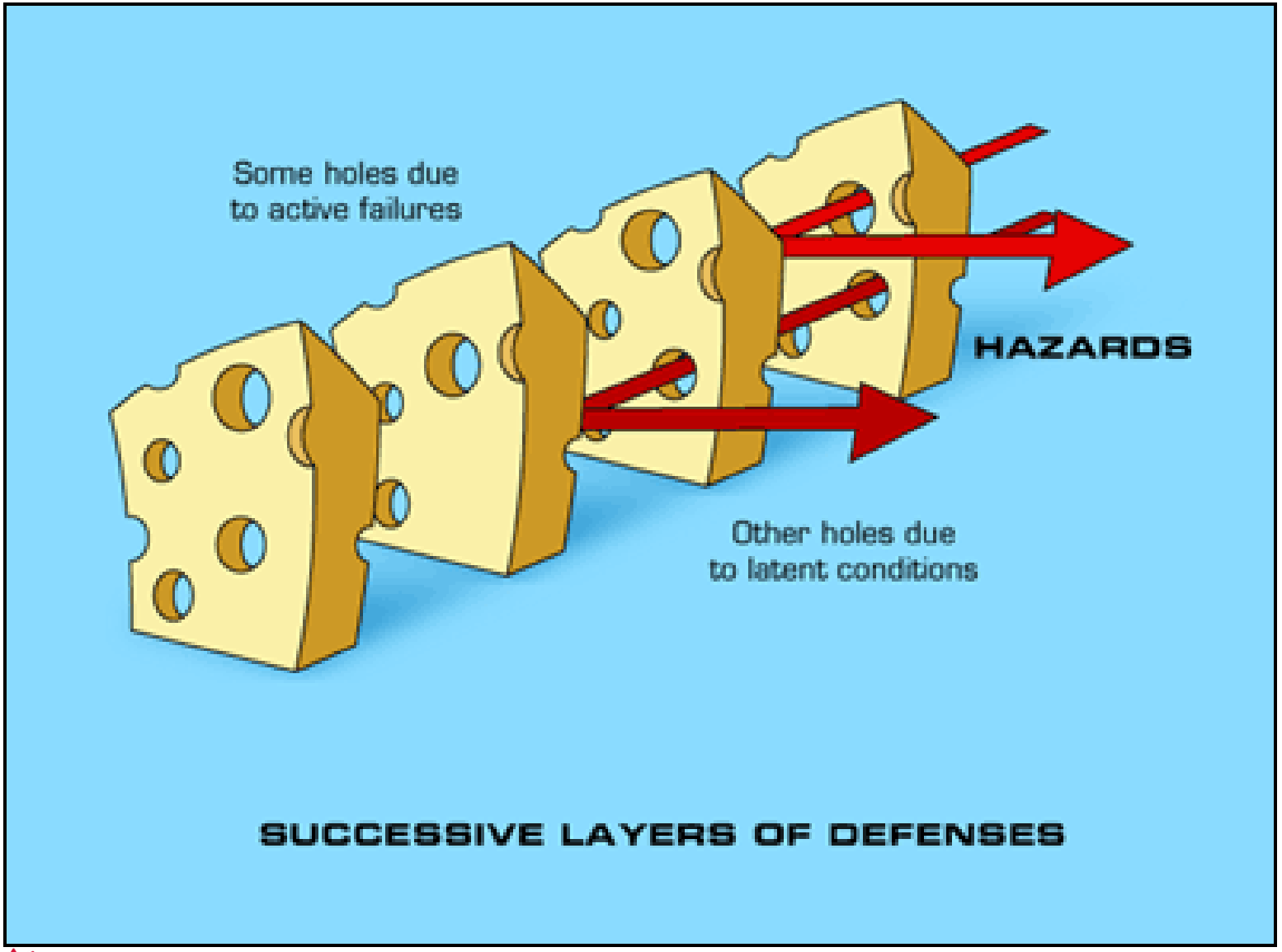
Errors happen when…

- You know what you're doing, but the actions don't go as planned (slips, lapses)
- You think you know what you're doing, but fail to notice something which should warn you of a potential problem (rule based error)
- You're not really sure what you're doing (knowledge error)

Some examples

- Nurse draws up 5 milligrams instead of 0.5 milligrams (a slip/lapse).
- Doctor prescribes correct dose (follows rule) but doesn't recognise this is dangerous in a patient with kidney failure (rule based error).
- Nurse does not recognise symptoms of bleeding and continues to administer anticoagulant (knowledge).



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Medication Safety and Quality

Purpose

- Support the safe and quality use of medicines
- Identify and respond to Medication Safety Risks
- Support facilities to improve local medicine-use systems

Key Priorities

- Medication Safety Self-Assessment
- Continuity of Medication Management
- High-Risk Medicines
- Venous Thromboembolism (VTE) Prevention
- Quality Use of Antimicrobials

Governance and assurance:
Secretariat to MSEAC
Co-ordinate MSAM team
Link to ACSQHC

Advisory role:
Ministry of Health
eHealth NSW
LHDs

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Medication Safety Expert Advisory Committee (MSEAC)

Peak state-wide committee that provides expert medication safety advice to the Clinical Excellence Commission and NSW Health

Functions include:

- supporting medication safety in the NSW health system
- identifying opportunities for state-wide system improvements relating to medication safety
- reviewing, developing and endorsing paper-based and electronic materials that will improve the safety of medicines use

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MSEAC actions…

- Review of NSW Health Policies, protocols, guidelines containing medicines.
- Endorsement of specialised state-wide paper medication charts.
- Review of Safety Alerts/Notices/Information.
- Advice on coronial recommendations.
- Advice to the Therapeutic Goods Administration, ACSQHC, other organisations.

Medication Safety Self Assessment (MSSA) – updated 2015

- Diagnostic tool
- A structured framework for assessing medication management systems and practices allowing systematic identification of specific areas of weakness
- Heightens awareness of characteristics of safe medication management systems
- Baseline data provides the foundation for a multidisciplinary effort to design and implement system improvements

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How MSSA facilitates system improvements: Rank Order of Error Reduction Strategies

Forcing functions and constraints

↓

Automation and computerisation

↓

Standardisation and protocols

↓

Checklists and double check systems

↓

Rules and policies

↓

Education / Information

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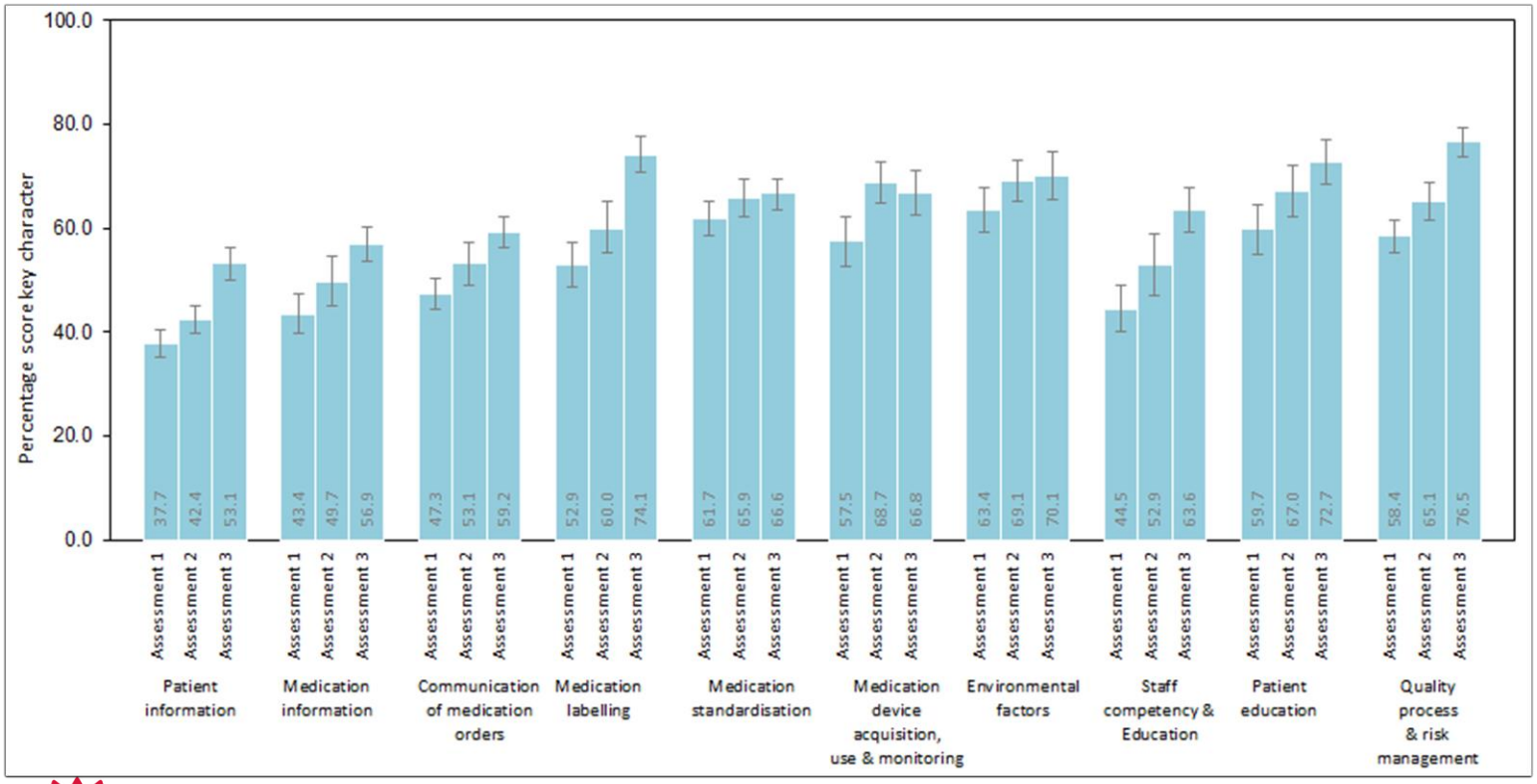
Three repeat assessments of 56 hospitals

Average percentage score of 10 key MSSA characteristics of the most recent 3 assessments between May 2007 to May 2017



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Continuity of Medication Management (CMM) Program

- Prevent unintentional changes in patients' medicines, and the harm that can result from these changes, by improving medication management when patients transfer between and within health care settings

- Focus 2017/18
  - Patient Friendly Medicine Lists
  - Supporting nursing and midwifery staff – Medication Reconciliation
  - Supporting LHDs/Specialty networks NSQHS standards

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Medication Reconciliation

- Improves communication of medicines information at transfers of care
- An internationally recognised strategy
- 4 steps
- Medication reconciliation processes are part of the NSQHS Standards (4.6, 4.8 & 4.12)

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Tools

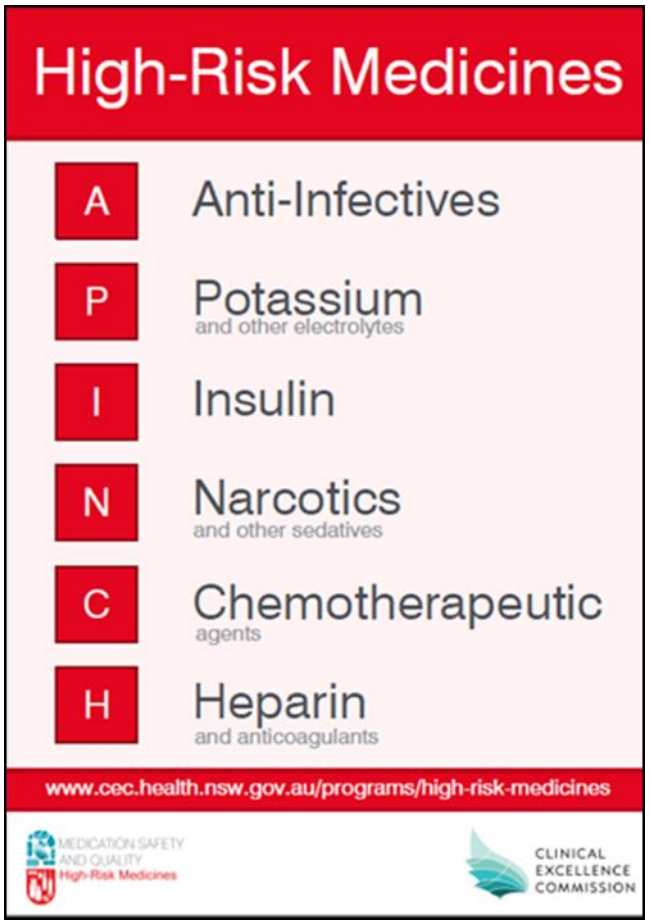
http://www.cec.health.nsw.gov.au/patient-safety-programs/medication-safety/continuity-of-medication-management/education

- Best Possible Medication History
- Medication Reconciliation
- HETI Online Courses
- ACSQHC Training Video

Safe management of High-Risk Medicines

- High-Risk Medicines are those that have a high risk of causing injury or harm if they are misused or used in error.

- Error rates with these medications are not necessarily higher than with any other medicines, but when problems occur, the consequences can be more significant.



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Focus 2017/18

- Anticoagulant medicines
  - Guidelines on perioperative management of anticoagulant and antiplatelet agents
  - Intravenous heparin protocol
- Working with HETI on Educational resources
  - Principles safe use high-risk medicines
  - HYDROmorphone
  - Anticoagulants
  - Opioids and sedatives
  - Insulin

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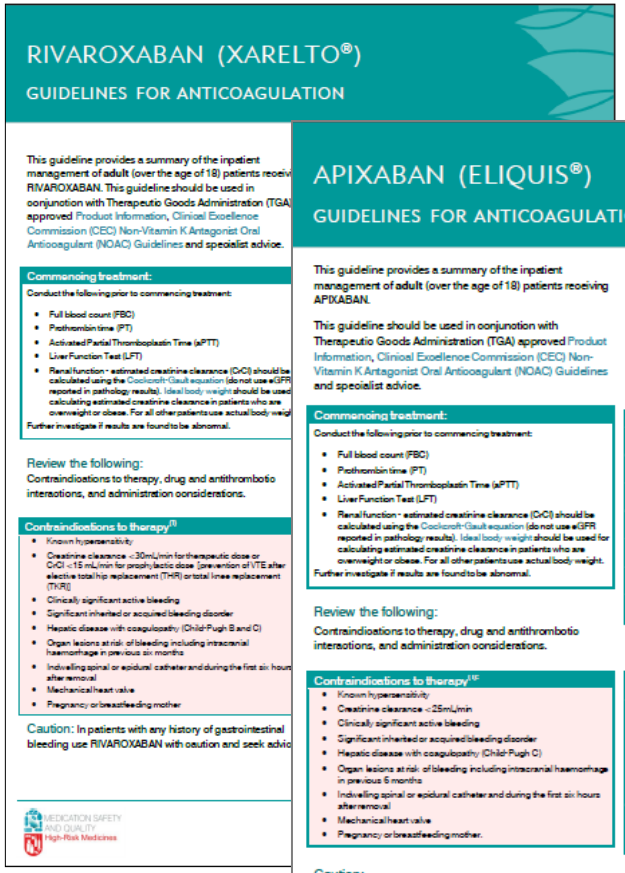
Types of incidents involving anticoagulants:

- Inadvertent duplication of anticoagulant therapy
- Mismanagement during the perioperative period
- Misinterpretation of monitoring tests
- Inadvertent omitted doses
- Misinterpretation of complex protocols
- Medications not recognised as anticoagulants

Examples of NOAC/DOAC resources


RIVAROXABAN (XARELTO®)

GUIDELINES FOR ANTICOAGULATION

This guideline provides a summary of the inpatient management of adult (over the age of 18) patients receiv RIVAROXABAN. This guideline should be used in conjunction with Therapeutic Goods Administration (TGA) approved Product Information, Clinical Excellence Commission (CEC) Non-Vitamin K Antagonist Oral Anticoagulant (NOAC) Guidelines and specialist advice.

Commencing treatment:

Conduct the following prior to commencing treatment:

- Full blood count (FBC)
- Prothrombin time (PT)
- Activated Partial Thromboplastin Time (aPTT)
- Liver Function Test (LFT)
- Renal function - estimated creatinine clearance (CrCl) should be calculated using the Cockcroft-Gault equation (do not use eGFR reported in pathology results). Ideal body weight should be used calculating estimated creatinine clearance in patients who are overweight or obese. For all other patients use actual body weig

Further investigate if results are found to be abnormal.

Review the following:

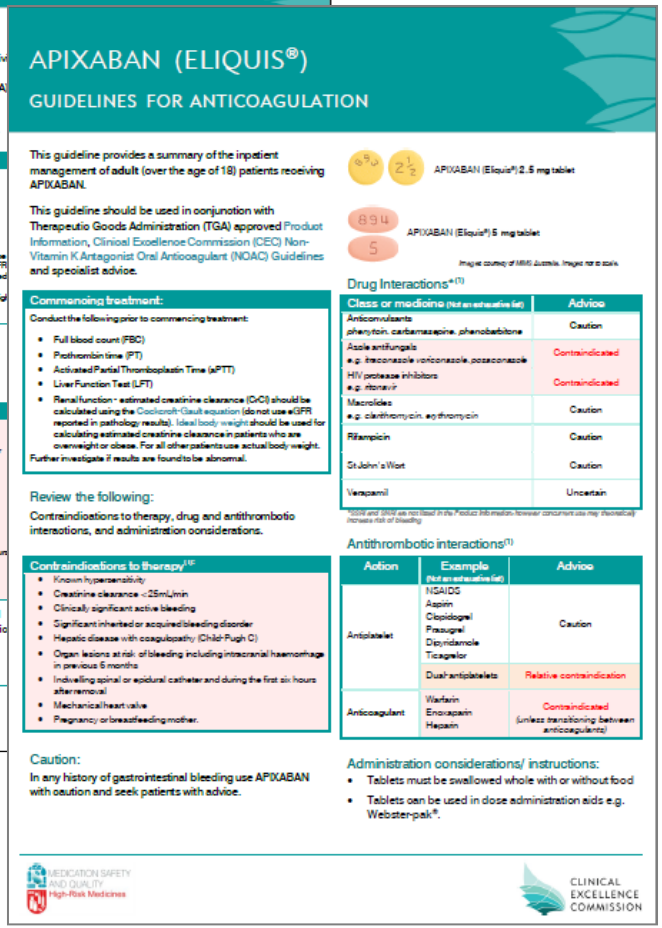
Contraindications to therapy, drug and antithrombotic interactions, and administration considerations.

Contraindications to therapy[1]

- Known hypersensitivity
- Creatinine clearance <30mL/min for therapeutic dose or CrCl <15 mL/min for prophylactic dose (prevention of VTE after elective total hip replacement (THR) or total knee replacement (TKR))
- Clinically significant active bleeding
- Significant inherited or acquired bleeding disorder
- Hepatic disease with coagulopathy (Child-Pugh B and C)
- Organ lesions at risk of bleeding including intracranial haemorrhage in previous six months
- Indwelling spinal or epidural catheter and during the first six hours after removal
- Mechanical heart valve
- Pregnancy or breastfeeding mother

Caution: In patients with any history of gastrointestinal bleeding use RIVAROXABAN with caution and seek advic

MEDICATION SAFETY AND QUALITY High-Risk Medicines


APIXABAN (ELIQUIS®)

GUIDELINES FOR ANTICOAGULATION

This guideline provides a summary of the inpatient management of adult (over the age of 18) patients receiving APIXABAN.

This guideline should be used in conjunction with Therapeutic Goods Administration (TGA) approved Product Information, Clinical Excellence Commission (CEC) Non-Vitamin K Antagonist Oral Anticoagulant (NOAC) Guidelines and specialist advice.

APIXABAN (Eliquis®) 2.5 mg tablet

APIXABAN (Eliquis®) 5 mg tablet

Image courtesy of MIMS Australia. Images not to scale.

Commencing treatment:

Conduct the following prior to commencing treatment:

- Full blood count (FBC)
- Prothrombin time (PT)
- Activated Partial Thromboplastin Time (aPTT)
- Liver Function Test (LFT)
- Renal function - estimated creatinine clearance (CrCl) should be calculated using the Cockcroft-Gault equation (do not use eGFR reported in pathology results). Ideal body weight should be used for calculating estimated creatinine clearance in patients who are overweight or obese. For all other patients use actual body weight.

Further investigate if results are found to be abnormal.

Review the following:

Contraindications to therapy, drug and antithrombotic interactions, and administration considerations.

Contraindications to therapy[1,2]

- Known hypersensitivity
- Creatinine clearance <25mL/min
- Clinically significant active bleeding
- Significant inherited or acquired bleeding disorder
- Hepatic disease with coagulopathy (Child-Pugh C)
- Organ lesions at risk of bleeding including intracranial haemorrhage in previous 6 months
- Indwelling spinal or epidural catheter and during the first six hours after removal
- Mechanical heart valve
- Pregnancy or breastfeeding mother.

Caution:

In any history of gastrointestinal bleeding use APIXABAN with caution and seek patients with advice.

Drug Interactions*[1]

Class or medicine (Not an exhaustive list)	Advice
Anticonvulsants phenytoin, carbamazepine, phenobarbitone	Caution
Azole antifungals e.g. itraconazole voriconazole, posaconazole	Contraindicated
HIV protease inhibitors e.g. ritonavir	Contraindicated
Macrolides e.g. clarithromycin, erythromycin	Caution
Rifampicin	Caution
St John's Wort	Caution
Verapamil	Uncertain

*Azole and HIV as not listed in the Product Information however concurrent use may theoretically increase risk of bleeding

Antithrombotic interactions[1]

Action	Example (Not an exhaustive list)	Advice
Antiplatelet	NSAIDS Aspirin Clopidogrel Prasugrel Dipyridamole Ticagrelor	Caution
	Dual-antiplatelets	Relative contraindication
Anticoagulant	Warfarin Enoxaparin Heparin	Contraindicated (unless transitioning between anticoagulants)

Administration considerations/ instructions:

- Tablets must be swallowed whole with or without food
- Tablets can be used in dose administration aids e.g. Webster-pak®.

MEDICATION SAFETY AND QUALITY High-Risk Medicines

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DABIGATRAN (PRADAXA®)

INFORMATION FOR PATIENTS, FAMILIES & CARERS

DABIGATRAN (PRADAXA®)

환자와 가족 및 간호인을 위한 정보

KOREAN

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DABIGATRAN은 혈전 형성을 멈추게 합니다.

다른 어떤 약물 복용하실 경우에는 의사나 약사에게 알릴 필요가 있습니다. 복용 약으로는 처방전 없이 약국, 수퍼마켓 혹은 건강 식품점에서 구할 수 있는 비타민, 미네랄, 허브 보조제 혹은 허브 약품들을 포함합니다.

복용하는 모든 약의 최근 목록을 가지고 다니는 것이 좋습니다. 의료 경고 팔찌 착용을 고려해보십시오.

질병, 의료 및 치과 시술

사고를 당했거나 매우 아플 때 구급차와 병원 의료진에게 DABIGATRAN을 복용하고 있음을 알리십시오. 치료를 받기 전에 (병원 수술, GP 클리닉 혹은 치과에서의 가벼운 시술 포함), 의사 혹은 치과 의사에게 본인이 DABIGATRAN을 복용하고 있음을 알하십시오.

의사의 지시가 없이는 DABIGATRAN의 복용을 중단하지 마십시오.

DABIGATRAN은 어떻게 복용합니까?

캡슐을 통째로 삼키십시오. 음식과 함께 혹은 음식없이 복용할 수 있습니다. 복용 시간이 될 때까지 캡슐을 팩에 보관하십시오.

DABIGATRAN은 어떻게 보관합니까?

도제트 박스같은 투약 용량 보조팩은 사용하지 말아야 합니다. 30°C 미만으로 유지되는 시원하고 건조한 장소에 보관하십시오. 모든 약은 어린이의 손이 닿지 않는 곳에 보관하십시오.

DABIGATRAN (Pradaxa®) 75 mg 캡슐

DABIGATRAN (PRADAXA®) 110 mg 캡슐

DABIGATRAN (PRADAXA®) 150 mg 캡슐

실제 크기가 아님

MIMS Australia의 이미지 허가

캡슐 복용을 잊었으면 어떻게 해야 합니까?

만일 무릎 혹은 고관절 치환 수술 후에 DABIGATRAN을 복용한다면:

- 나머지 DABIGATRAN 캡슐을 다음날부터 같은 시간에 계속해서 복용하십시오.

만일 심박세동 (AF)이 있고 뇌졸중을 방지하기 위해 DABIGATRAN을 복용한다면:

- 다음 복용 시간이 6시간 이내에 있으면 놓친 캡슐을 복용하지 마십시오.
- 다음 복용 시간이 6시간 이상 이후이면 놓친 캡슐을 복용하십시오.

놓친 각각의 캡슐을 보충하려고 추가로 캡슐을 복용하지 마십시오. 만일 두 개 이상의 캡슐을 놓쳤거나 혹은 어떻게 해야할지 모른다면 즉각적으로 의사 혹은 약사에게 문의하십시오.

MEDICATION SAFETY AND QUALITY High-Risk Medicines

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DABIGATRAN (Pradaxa®) 75 mg capsule

DABIGATRAN (Pradaxa®) 110 mg capsule

DABIGATRAN (Pradaxa®) 150 mg capsule

Not actual capsule size

Images courtesy of MIMS Australia

forget to take a capsule?

taking DABIGATRAN following HIP REPLACEMENT surgery:

ue with your remaining DABIGATRAN les at the same time on the next day.

e ATRIAL FIBRILLATION (AF) and are ABIGATRAN for STROKE PREVENTION:

t take a missed capsule if it is less than 6 before the next capsule is due.

he missed capsule if it is more than 6 before the next capsule is due.

ke extra capsules to make up for missed capsules. If you miss more than one or if you are unsure of what to do, talk to tor or pharmacist immediately.

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For clinicians

For patients

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Patient Safety Watch

Recognising bleeding in patients treated with intravenous heparin

PATIENT SAFETY WATCH

EDITION 3/16: Recognising bleeding in patients treated with intravenous heparin

WHAT SHOULD YOU DO

- Educate clinicians to consider retroperitoneal bleeding in anticoagulated patients who complain of acute back, leg or abdominal pain.
- Ensure local intravenous (IV) heparin protocols comply with the requirements of NSW Health Policy Directive, *High-Risk Medicines Management* (PD2015_029).
- Assess and ensure compliance with local heparin protocol requirements, including aPTT monitoring and dose adjustments based on aPTT results.
- Provide appropriate education and training to all junior medical officers (JMO) and nursing staff who manage IV heparin.
- Ensure compliance with NSW Health Policy Directive, *Recognition and Management of Patients who are Clinically Deteriorating* (PD2013_049).
- Implement an agreed mechanism for communication between teams when more than one team is providing care.

CASE 1

A 73 year old female patient with a past history of chronic renal insufficiency presented to an Emergency Department of a tertiary facility with a one week history of shortness of breath without cough or fever. An electrocardiograph revealed the patient was in atrial flutter. She was commenced on medications for heart rhythm control and an intravenous (IV) heparin infusion and was admitted to a cardiovascular ward for monitoring. Further investigations revealed pulmonary emboli and the treating team considered a plan for long-term anticoagulation.

The cardiology trainee and junior medical officer (JMO) reviewed the patient on the morning of day 7 when she was complaining of severe left femoral pain and difficulty mobilising. Examination revealed pain on palpation in the left lower quadrant of the abdomen and lower groin area, leading to a differential diagnosis of femoral deep vein thrombosis or incarcerated femoral hernia. Plans were made for an inguinal ultrasound and doppler scan of the groin. The patient required oxycodone and paracetamol for pain relief throughout the day.

A medical officer reviewed the patient in the evening when she again complained of leg pain and dizziness on ambulating. During the early hours of the following morning, she called the nurse complaining of ongoing pain. At that time, she appeared clammy. Clinical observations revealed a temperature of 33.7°C and a heart rate of 122 beats per minute (Yellow Zone criteria*). Her blood pressure was unable to be recorded. There was a delay of 15 minutes before a Rapid Response call was initiated. When the Rapid Response team arrived the patient was drowsy but rousable. A blood sample was taken and IV fluids were administered. An abdominal x-ray was attended which suggested an abdominal mass. A short time later, the patient deteriorated further and became unresponsive. Cardiopulmonary resuscitation attempts were unsuccessful.

A review of the pathology results revealed a grossly supra-therapeutic activated partial thromboplastin time (aPTT) and a decreased haemoglobin level.

It was identified that the aPTT result documented on the heparin chart on the previous day was in fact incorrect as the patient did not have an aPTT test attended that day.

RCA INVESTIGATION

The RCA team identified that a retroperitoneal bleed was not considered as a possible diagnosis by the medical officer when the patient complained of left groin and left lower quadrant pain. The severity of the patient's pain was not communicated by the cardiology trainee to the advanced trainee who may have considered a diagnosis of retroperitoneal haematoma. Furthermore the Admitting Medical Officer (AMO) was not advised of the pain until the Rapid Response call made. The RCA team identified that members of the cardiology team changed during the patient's admission due to term rotation and suggested the

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Patient safety
looking • learning • acting

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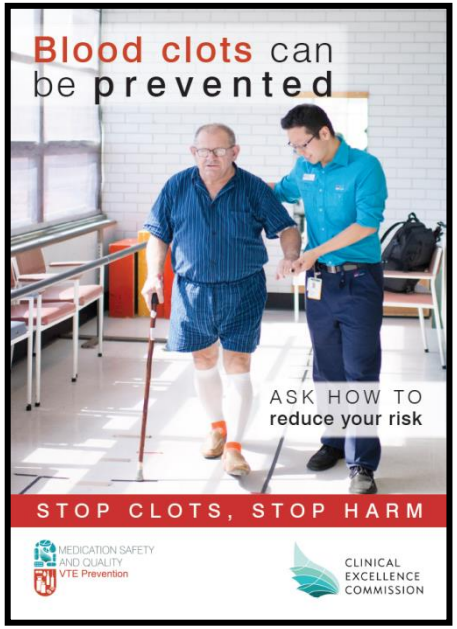
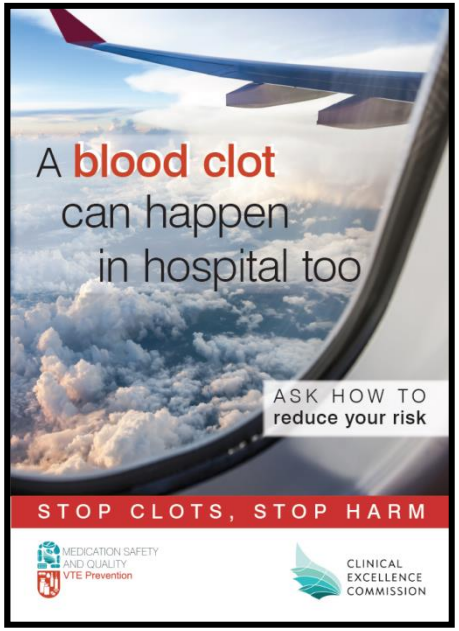
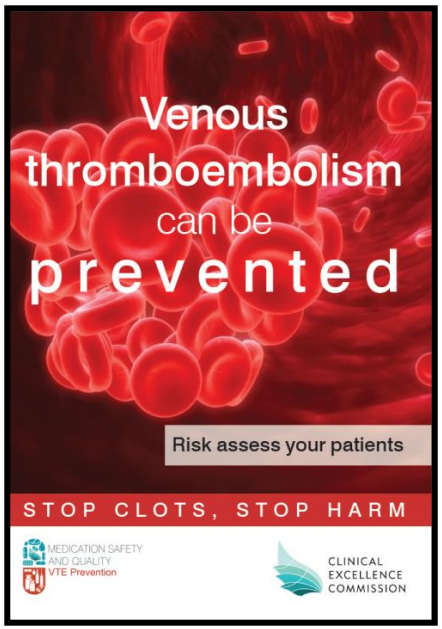
Venous Thromboembolism (DVT & PE) Prevention

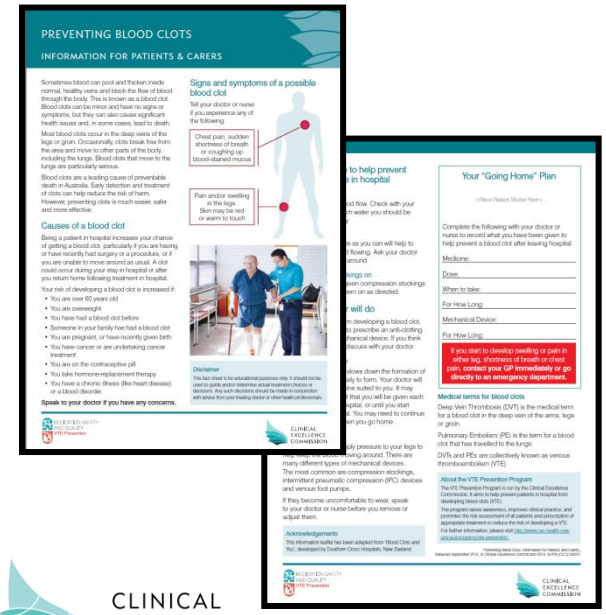
- Hospital Acquired Complication
- Majority (70%) preventable
- Complex clotting vs bleeding risk
- Risk assessment and appropriate prophylaxis
- Focus 2017/18
  - Patients discharged from ED with lower limb injuries
  - Electronic VTE Risk Assessment Tool and prompts







Patient-targeted



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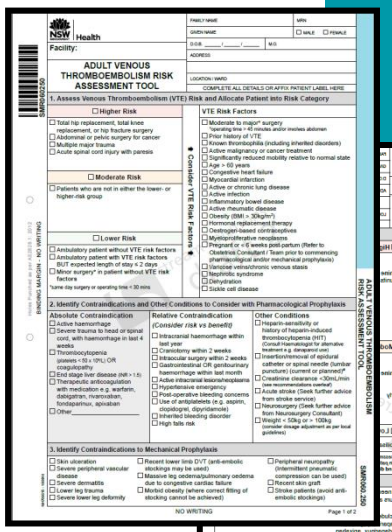

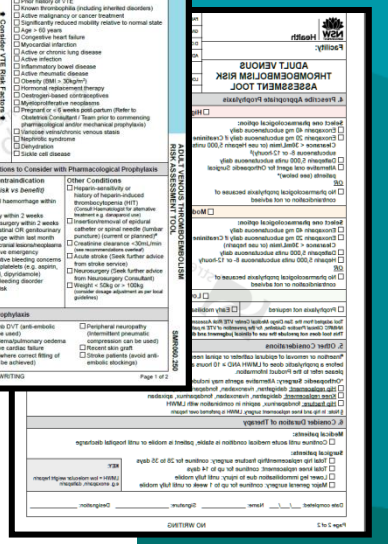

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http://www.cec.health.nsw.gov.au/patient-safety-programs/adult-patient-safety/vte-prevention

Quality Use of Antimicrobials in Healthcare Program

Purpose: to support NSW local health districts and networks in implementing and sustaining effective locally-owned AMS programs

- Focus 2017/18
  - Developing/identifying resources to support improved surgical antibiotic prophylaxis
  - Sharing resources to encourage timelier IV to oral antibiotic switch in children
  - Educational webinars to promote and support Antibiotic Awareness Week in NSW LHD/SHNs
  - Promoting use of quality improvement methodology to facilitate AMS projects in NSW hospitals

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Medicine shortages

- Increase in:
  - Number of drugs affected by shortages
  - Number of antimicrobial shortages
  - Number of shortages involving parenteral formulations
  - Duration of shortages
  - Resources and cost to manage shortages

- Impact to patients:
  - Care may be compromised, delayed or completely prevented
  - Suboptimal and delayed therapy for serious infectious diseases can compromise patient safety and result in poorer outcomes, including death
  - Possible harm due to unexpected or unmanageable side effects of alternative
  - Increased risk of harm from medication errors due to use of unfamiliar alternative

Reason for shortage = complex

- Increased global reliance on single manufacturers for active ingredients
- Manufacturing issues
- Discontinuation of a medicine
- Increased demand
- Regulatory issues
- Recalls
- Economic decision remove from market

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Managing shortages

- National
  - Therapeutic Goods Administration
    - Medicine Shortages Information Initiative
    - Regulation of Special Access Scheme and Section 19A
  - National Medication Shortage Working Party
- State
  - Model for Multi-Agency Management of Medication Shortages in NSW
  - Business Procurement Service (contract items)
- Local
  - Sponsors (manufacturers)
  - Wholesalers
  - Pharmacies

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Model for multi-agency management of medication shortages in NSW

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Agencies involved

Members of the Medicines Shortage Assessment and Management Team:

- The Office of the Chief Health Officer
- Chief Pharmacist Unit
- Business Procurement Services HealthShare
- Clinical Excellence Commission

Information gathering and communication:

- Expert Clinicians in the relevant field
- Clinical Networks, Agency of Clinical Innovation
- NSW Therapeutic Advisory Group and members
- Chief Executives and Directors of Clinical Governance

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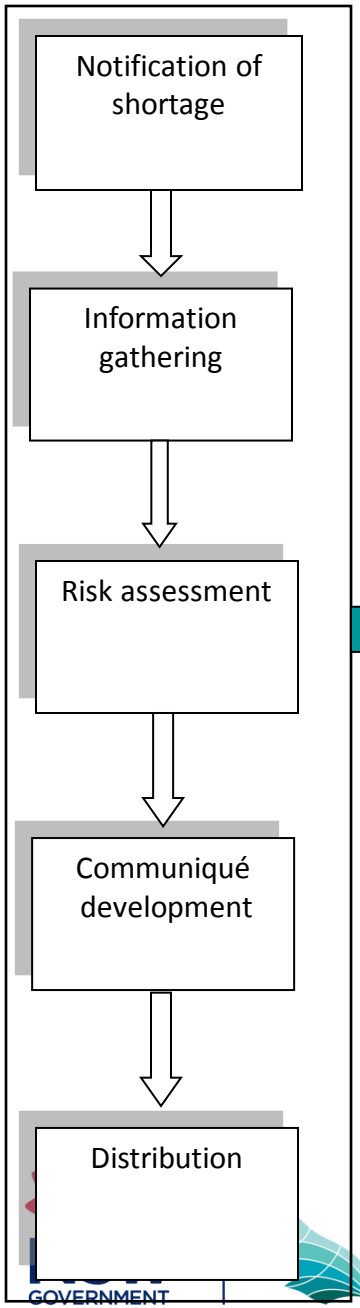
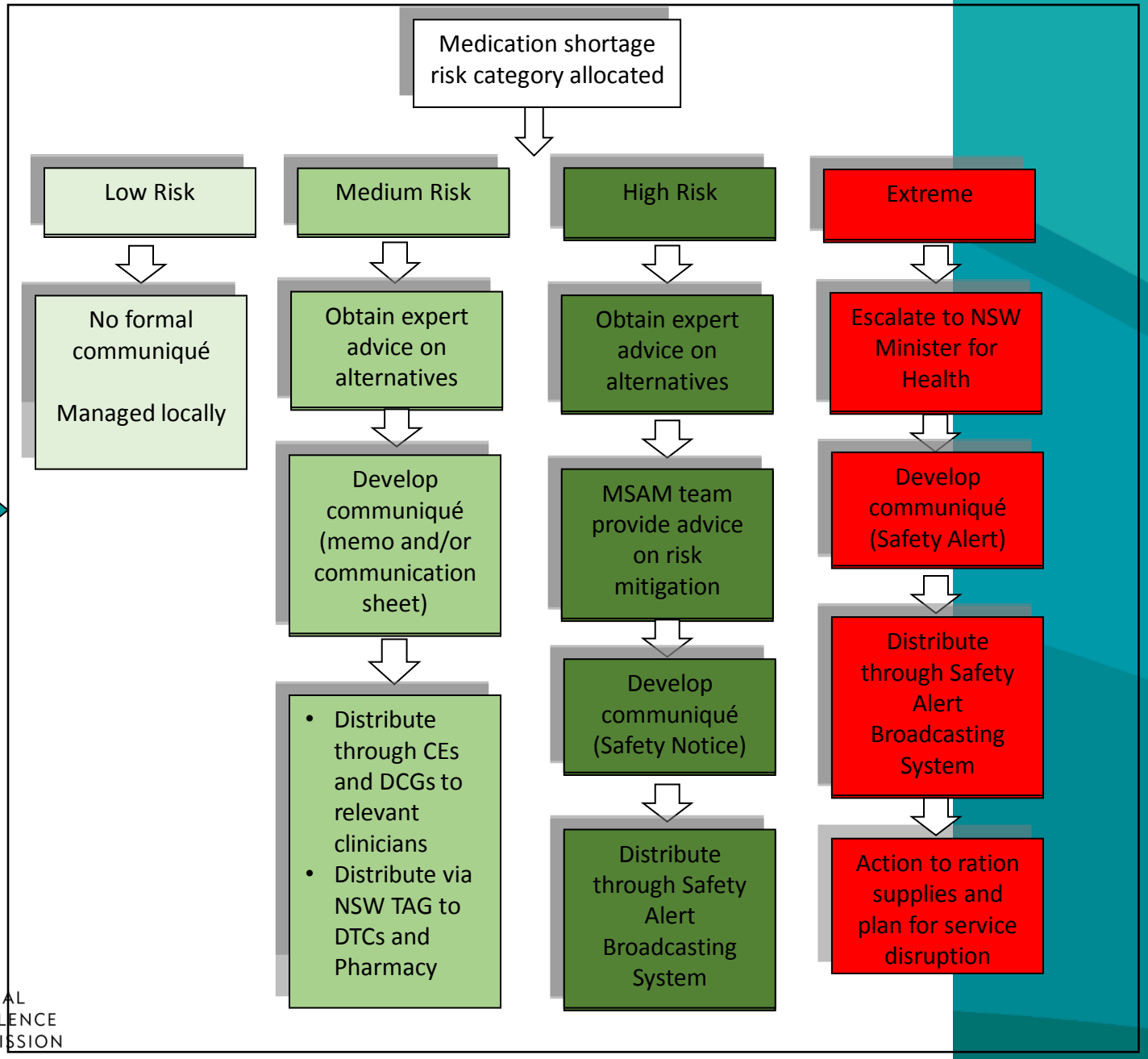
High Level Flow



Detailed Level Flow



Shortage Communication 2017

January	Azithromycin
January	Tigecycline
January	Dexmedetomidine
February	Glyceryl trinitrate
March	Metronidazole
March	Etoposide
April	Dantrolene
May	Piperacillin-tazobactam
June	Dilaudid oral liquid
June	Fentanyl
July	Piperacillin-tazobactam
October	Piperacillin-tazobactam

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Safety Alert 002/16

Vancomycin Intravenous preparations – Disruption to supply

8 December 2016

Distributed to:
- Chief Executives
- Directors of Clinical Governance
- Director Regulation and Compliance Unit

Action required by:
- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:
- Emergency Departments
- Intensive Care Units
- Infectious Diseases Physicians
- Cardiology
- Cardiothoracic surgery
- Orthopaedics
- Respiratory medicine
- Directors of Medical Services
- Directors of Nursing
- Directors of Pharmacy

Deadline for completion of action

12 December 2016

Expert Reference Group
Content reviewed by:
- Office of the Chief Health Officer
- Chief Pharmacist Unit
- Clinical Excellence Commission
- HealthShare
- AMS Expert Advisory Committee

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Internet Website:
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Intranet Website
http://internal.health.nsw.gov.au/quality/sabs/

Review date

June 2017

Background

All three suppliers (Pfizer/Hospira, Alphapharm and Sandoz) in the Australian market have depleted stocks. A return to normal stock levels is expected in February 2017.

Vancomycin intravenous infusion is used for the treatment of potentially life threatening Gram-positive bacterial infections (suspected or known to be resistant to first-line antimicrobials) including bloodstream infections due to methicillin-resistant *Staphylococcus aureus* (MRSA).

Oral vancomycin is not absorbed systemically and is NOT a substitute for intravenous vancomycin.

The affected products are:

Presentation	AUST R
DBL Vancomycin (as hydrochloride) powder for injection 500 mg	62603
DBL Vancomycin (as hydrochloride) powder for injection 1 g	62595
Vancomycin Alphapharm (as hydrochloride) powder for injection 500 mg	153438
Vancomycin Alphapharm (as hydrochloride) powder for injection 1 g	153439
Vancomycin Sandoz (as hydrochloride) powder for injection 500 mg	100021
Vancomycin Sandoz (as hydrochloride) powder for injection 1 g	100011

Further Information

Pfizer has a limited quantity on hand of 500 mg powder for injection in 10 vial packs for restricted supply. They are in the process of investigating alternate supplies.

Actions required by Local Health Districts/Networks

1. Distribute this notice to all stakeholders and all clinical departments.
2. Assess the current status of vancomycin intravenous infusion preparations available in each facility, ensuring all locations of stock are identified. Provide feedback on stock levels to Clinical Excellence Commission cec-medicationsafety@health.nsw.gov.au by **COB Monday 12 December 2016.**
3. Remove and quarantine stock from clinical areas where vancomycin intravenous infusion preparations are not routinely used.
4. Use alternatives to intravenous vancomycin (e.g. intravenous teicoplanin) where possible, depending on the infection and patient factors. Clinicians that are unsure about the suitability of alternative antimicrobials should seek advice from antimicrobial stewardship teams and/or infectious diseases/clinical microbiology services.
5. The National Centre for Antimicrobial Stewardship provides some advice on suitable alternatives. Their factsheet is available at: https://www.ncas-australia.org/news-and-events
6. Reserve vancomycin injection for indications that cannot be treated by other available antimicrobials, based on the advice of infectious diseases/clinical microbiology services, according to antimicrobial stewardship processes.
7. Ensure a system is in place to document actions taken.

Safety Alerts require immediate attention and action

IV vancomycin:

- Released Safety Alert
- Gathered information on stock levels in NSW LHDs/SHNs
- Liaised with distributors about hospitals in urgent need of stock
- Updated Alert to include information on S19A approved substitute

Other activities

- Review and analyse medication incidents
- Develop Safety Alerts/Notices
- Advice at State and National Level
- Supporting national initiatives
  - ACSQHC NSQHS standards
  - User-applied labelling
  - NIMC revisions
- MSQ Connect Newsletter
  - Available on-line
  - Via mailing-list

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New Areas

- Community Pharmacy Palliative Care Initiative
  - Support palliative care patients in the community
  - Improve access to palliative care medicines
  - Involvement of community pharmacists in palliative care teams
- Electronic Medication Management
  - Hybrid systems
  - Workflow/eMM integration
  - System/Design issue
  - Human factors
  - Hardware
  - Failure to perform task

The team

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Questions?

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