

Lessons from the sentinel event casebook

Medication error

A routine blood test on a patient being treated with Clozapine a medication used in mental health, detected low white blood cells, (neutropenia/agranulocytosis) a known potential side effect of Clozapine. This leaves the patient extremely vulnerable to infections. The haematologist recommended that: the patient be taken to the hospital emergency department for urgent medical review; to cease clozapine until further notice; the patient's temperature should be closely monitored and Granulocyte Colony Stimulating Factor (GCSF) should commence to increase white blood cell production. This information was emailed to the mental health team and communicated to mental health and emergency department triage staff.

The patient presented and was assessed by ED staff late that day. Neither the resident nor the registrar ordered GCSF or antibiotics and there was no contact with the haematologist. Neither clinician identified the situation as an urgent medical issue. The consultant psychiatrist did not want the patient returned to community treatment so organised for admission to the acute psychiatric ward and clozapine was ceased.

On day 3 the patient developed a temperature. IV antibiotics were commenced, the patient was transferred to an acute inpatient unit and monitoring continued. Blood cultures did not identify a causative organism.

Ten days later the patient developed hypotension and tachycardia and was transferred to ICU with septic shock. Medications and treatment were given including GCSF and inotropes. The patient died the following week from sepsis and multi organ failure.

What were the major contributing factors in this case?

- Communication breakdown between referring haematologist and ED staff.
- Severity of presenting condition not recognised by ED staff
- Inappropriate admission to Mental Health unit when medically unwell
- Failure of communication between treating teams
- Absence of Clinical Management Guidelines for management of clozapine induced neutropenia/agranulocytosis

How did the health service address these issues?

- Development of a clinical guideline on the management of drug induced neutropenia and agranulocytosis, including admission criteria
- Patients with a mental health history presenting with agranulocytosis to be admitted to a medical bed (with psychiatric support services made available)
- Introduction of a standardised clinical communication tool for use between treating teams
- Increased role for the Clozapine program coordinator for mental health patients requiring an acute medical admission

Does your health service have a standardised communication system for use between units?

Are staff in your ED alert to the possible side effects of clozapine?

Are your ED staff aware of the clozapine monitoring systems and the clinical guidelines for drug induced agranulocytosis?

System improvement recommendations

- Emergency Departments to have Clinical Guidelines for the management of drug induced neutropenia and agranulocytosis, including admission criteria
- Drug induced agranulocytosis should be managed as a medical emergency not a mental health issue
- Clozapine related incidents should be reported to Adverse Drug Reaction Advisory Committee
- The TGA should require clozapine monitoring systems/registries to include monitoring guidelines for myocarditis and cardiomyopathy (in line with the TGA's recent black box warning) including schedule for echocardiograms.

Background

Clozapine Product Information includes a recent additional boxed warning (black box warning) alerting prescribers to significant risk of serious adverse reactions – myocarditis and cardiomyopathy.

The TGA requires that all patients taking clozapine are enrolled in a registry and monitored regularly, to detect the development of neutropenia and agranulocytosis. Current systems do not include monitoring guidelines for myocarditis and cardiomyopathy, which are also known side-effects of clozapine.

In Australia the systems available are;

- CPMS Plus – Online resource to assist with initiating, monitoring, managing and educating patients about schizophrenia and clozaril.
- Clopine Connect®
 - for prescribers of Clopine® to record baseline and ongoing results on use of Clopine® in clinical practice
 - system for regular monitoring and recording of white blood cell counts and neutrophil counts for all patients receiving Clopine® to reduce the risk of patients developing agranulocytosis or neutropenia

Procedures involving the wrong patient or body part

A patient was admitted for a procedure to remove a lesion on his tongue. On waking after the surgery he told staff that the operation had been done on the wrong side of the tongue. The patient was returned to theatre and the correct lesion was removed. Both lesions were found to be benign. The patient did not know that he had more than one lesion on his tongue. The patient showed the lesion to be removed to the nurse and she documented that "correct patient, correct site, correct procedure" had been confirmed. The site could not be marked and the specific location of the lesion on the tongue was not relayed to the anaesthetic

Lessons from the Sentinel Event Casebook continued...

nurse during handover in the anaesthetic bay. The surgeon did not see the patient before the operation.

What were the major contributing factors in this case?

- Preadmission forms did not identify multiple lesions
- Preoperative questionnaire included site but not side of operation
- Failure of communication between the nurse who completed the preoperative patient checks and the anaesthetic nurse
- The “Time out” protocol was not followed as the surgeon was not present and the precise procedure site was not identified

How did the health service address these issues?

- Preadmission questionnaire amended to include prompt for patient to confirm procedure site and side
- Clinical handover processes to be standardised to include verification of correct patient, correct site, correct procedure
- The consent form amended to include procedure site and side, including a diagram for regions with multiple lesions, e.g. tongue, breast, face
- Surgeon must be present for “Time out” process
- “Time out” protocol to include asking the patient the procedure site and side, and ensuring their answers are consistent with the consent form

Do your surgical consent forms include procedure site and side?

Do your surgical teams perform “Time out” before the patient is sedated?

Is there regular audit of the “Time out” process?

For surgery where the procedure site cannot be marked, how do your surgical teams confirm specific location of the “correct site”?

Coroner’s recommendations

Coroner’s case 3575/05.

The Coroner investigated the death of an 11 year old boy who presented to Emergency with back pain and vomiting. The boy was admitted and a number of tests conducted including x-rays, blood and urine tests. The boy was kept in Emergency overnight with on-going monitoring and support for his deteriorating condition and

was admitted to a ward the next morning. The boy had gastroenteritis-like symptoms and later developed a rash. The doctor advised the family that the patient likely had meningococcal meningitis but that he would need to do a lumbar puncture to confirm this. After the lumbar puncture the patient developed neurological symptoms, started fitting and went into respiratory arrest. A transfer was arranged to the Royal Children’s hospital however the patient did not recover. The Coroner found that death occurred from “Respiratory arrest precipitated by a lumbar puncture”.

The recommendations of the Coroner in this case are:

1. That where hospital guidelines read “lumbar puncture is not usually necessary and is generally contraindicated, especially in patients with altered conscious state or coagulopathy. If needed, an LP can be performed once the patient is stable”; consideration be given to changing the wording so that the words “altered conscious state or coagulopathy” are substituted with the words “altered conscious state or coagulopathy or the development of a rash of any description”.
2. That all hospitals, clinicians and treaters review their instructions and guidelines in the light of the circumstances and findings in this case and the strong views expressed within the Coroner’s report.

Victorian Health Incident Management System (VHIMS)

The Incident Information System project has been re-named the Victorian Health Incident Management System (VHIMS), and will concentrate on improving quality through incident management. To date the following outcomes have been achieved:

- A clear set of definitions relating to clinical incident management.
- Establishment of a standardised incident severity rating (ISR) methodology.
- Development of a standardised incident classification model based on World Health Organisation’s International Classification for Patient Safety (WHO IC4PS).
- Development of an incident data set that formally defines the clinical incident information to be collected and the associated data collection methodology.

The development of a comprehensive taxonomy and data set specification is completed and will be distributed to public hospitals.

Auditor General of Victoria – report on patient safety in public hospitals.

The Auditor General of Victoria has released a report on patient safety in public hospitals.

www.audit.vic.gov.au/reports_publications/reports_by_year/2008/20080528_patient_safety.aspx

There were four recommendations from this report, all of which related to current programs within the DHS.

1. Recommendations from the review of the DHS Quality and Safety Branch – These recommendations have been implemented.
2. Clinical Governance Framework - The Statewide Quality Branch engaged KPMG to undertake a review of clinical governance in Victoria and assist in determining future directions in relation to governance of patient safety and quality in healthcare.

The objectives of the project were to:

- Evaluate the implementation and effectiveness of the current Clinical Governance strategy.
- Advise the Department of Human Services on options for Clinical Governance in Victoria, based on the evaluation findings and a review of national and international Clinical Governance practice.
- Develop a Clinical Governance Framework for Victoria.

The final project report is available for review at: www.dhs.vic.gov.au/__data/assets/pdf_file/0011/232022/Final-Report—clinical-governance-in-VictoriaFINAL.pdf

3. VHIMS – The Incident Information System, (now known as VHIMS) project is currently underway.
4. Performance Measurement – The department is developing a program measures framework to be included as part of the Statement of Priorities (SoP). A new set of performance indicators associated with Australian Health Care Agreements include a number of quality indicators that are currently in development. The department is contributing to this list of indicators. The department also funds and participates in a number of external registry projects aimed at measuring quality of care, including cardiac surgery and intensive care. The data from each registry is subject to review with feedback mechanisms in place. Many of these will be further developed through the clinical governance framework.

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