

# **INDEPENDENT REVIEW INTO THE INCORRECT DOSING OF CYTARABINE TO TEN PATIENTS WITH ACUTE MYELOID LEUKAEMIA AT ROYAL ADELAIDE HOSPITAL AND FLINDERS MEDICAL CENTRE**

## **REVIEW PANEL**

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## Executive Summary

1. Over a period of six months [end July 2014– end January 2015], during the consolidation phase of treatment for Acute Myeloid Leukemia, five patients at the Royal Adelaide Hospital and five patients at Flinders Medical Centre received a daily dose of Cytarabine instead of a dose twice a day. This was the result of the Royal Adelaide Hospital’s Acute Myeloid Leukemia protocol containing the incorrect dose.
2. On 5 August 2015 the South Australian Minister for Health and Ageing and the Chief Executive of SA Health requested that an independent review be conducted.
3. The Terms of Reference of the review were to:
  - review the events and decisions that led to the incorrect dosing protocol being used
  - review the system of reporting incidents at the Royal Adelaide Hospital and Flinders Medical Centre, the process of investigation and open disclosure to ensure all were in compliance with SA Health policy directives
  - review the systems of governance and confirm that appropriate actions were taken throughout the process of investigation
  - review the appropriateness of recommendations made by Central Adelaide Local Health Network and SA Pathology in relation to said local investigation, including progress in actioning these recommendations
  - make recommendations on review findings to the Chief Executive to assist in mitigating the risk of reoccurrence and respond to breaches of compliance.

## Major Findings

4. The review panel found that under dosing of Cytarabine was caused by a series of significant clinical governance failures at the Royal Adelaide Hospital Haematology unit, including:
  - failure to follow routine clinical processes and procedures for the development, review and publishing of patient chemotherapy protocols
  - failure to advise patients that the chemotherapy protocol was a non-standard protocol that required approval from the relevant committee and informed patient consent
  - failure to provide adequate clinical supervision to nursing staff administering Cytarabine
5. Additionally, the review panel found that certain clinical staff did not comply with SA Health incident management and open disclosure policies by failing to:
  - report and lodge the incidents in the SA Health incident management system
  - conduct timely and appropriate open disclosure with patients
  - provide an immediate clinical response to patients who had been under dosed.
6. The review panel formed the view that the clinical conduct of certain clinicians demonstrated a lack of adequate knowledge, skill, care and judgment.

## Recommendations

7. The review panel makes the following recommendations:

**Recommendation 1:** That in view of the serious clinical governance failings identified by this review:

- failure to follow accepted practice whilst implementing a new non-standard clinical protocol;
- failure to seek and to be granted the approval of the relevant committee in relation to the introduction of a non-standard protocol;
- failure to report and lodge the incidents in the SA Health incident management system;
- failure to conduct timely and appropriate open disclosure with patients; and
- failure to provide an immediate clinical response to patients who had been under dosed,

the Chief Executive Officer of the Central Adelaide Local Health Network gives consideration to referring relevant clinicians to the Australian Health Practitioner Regulation Agency for review.

**Recommendation 2:** That the Chief Executive Officer Central Adelaide Local Health Network ensures staff fully understand their responsibility to act in accordance with SA Health policies, particularly incident management and open disclosure policies. That effort is made to ensure that the requirement to report all incidents into the Safety Learning System is clear and that open disclosure and incident management training is made available to all staff, including all medical staff.

**Recommendation 3:** That the Chief Executive Officer Central Adelaide Local Health Network implement a rectification plan to ensure that the appropriate governance frameworks are in place within SA Pathology and, in particular, the Haematology service provided to the Royal Adelaide Hospital. That this plan takes into consideration the recommendations made in the report “Governance of Clinical Services Conducted by SA Pathology Clinical Staff: A Review” Peter Brennan, Jeff Szer, June 2012 and the National Safety and Quality Health Service Standards related to Governance, Partnering with Consumers and the provision of patient centered care.

**Recommendation 4:** That the Chief Executive Officer Central Adelaide Local Health Network ensures appropriate processes and procedures for the development, review and publication and, where indicated, revision of chemotherapy protocols are developed and implemented that are consistent with the current evidence base. And that the resulting policies, procedures and protocols are understood and acknowledged by all relevant staff, are consistent with SA Health policies and procedures and are appropriately filed and stored.