AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

Review of the Incident Notification, Management and Analysis of Incorrect Dosing of Cytarabine of Acute Myeloid Leukaemia at Flinders Medical Centre and Royal Adelaide Hospital

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(amended)

Review Panel

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Executive Summary

1. Commencing from July 2014, the Central Adelaide Local Health Network (CALHN), through the SA Pathology Acute Leukaemia Subspecialty Team within the Haematology Directorate, put into effect a new protocol for chemotherapy treatment of patients with Acute Myeloid Leukaemia at the Royal Adelaide Hospital (RAH). The protocol contained an error, resulting in the dose of cytarabine being administered once daily over the course of the consolidation phase of the chemotherapy treatment instead of twice daily.

2. This report was commissioned by the Chief Executive of the South Australia Department for Health and Ageing (SA Health) to assess whether the action by the health services concerned after the error was discovered, complied with SA Health policies requiring investigation and report on the cause of the error; implementation of any recommendations to prevent it reoccurring and "open disclosure" to the ten affected patients and their families.

3. The error was uncovered on 16 January 2015 when a pharmacist at RAH was filling two prescriptions for chemotherapy for the same patient within the space of a few days from two different doctors with two different dosages for cytarabine. The pharmacist contacted the more senior doctor, the Deputy Director, Haematology and Bone Marrow Transplant Service, who confirmed that the correct dose was twice daily. On 19 January 2015 the doctor confirmed that the protocol was wrong and acted to have it amended. An email, which did little to highlight the error, was sent on 20 January 2015 advising the recipient group of cancer clinicians of the amendment to the protocol. The email went unnoticed by the clinicians at Flinders Medical Centre (FMC) who were also treating patients under the protocol.

4. SA Health, CALHN and Southern Adelaide Local Health Network (SALHN) guidelines on incident management and open disclosure require the reporting of an error in the SA Health Safety Learning System (SLS) and the assigning of a Severity Assessment Code (SAC). A SLS report was not made about the incident at this time, in direct breach of the guidelines. If a SLS report had been made with the appropriately applied SAC rating, the most senior staff of the CALHN would have been automatically alerted.

5. One pharmacist told the review that when the Deputy Director attended and the error was confirmed, he asked whether an incident report should be made in the SLS and left with the understanding that the Deputy Director would deal with this issue. The Deputy Director said her main focus at the time was amending the protocol and identifying the other affected patients at RAH. As her only contact with the SLS was reviewing incident reports made by nurses, she thought it was a system for use by nurses only.

6. The Deputy Director was unaware that the protocol containing the error had been adopted by the FMC when a consultant haematologist, working across both RAH and FMC for a time, suggested the FMC protocols reflect RAH protocols. None of the FMC clinicians who received the email notification registered the amendment to the protocol and an FMC patient was underdosed during his chemotherapy infusions over three days in late January 2015.

7. The consultant haematologist, still working across both RAH and FMC, was told of the error by another pharmacist when he attended his last clinic at RAH on 30 January 2015. He was also told that open disclosure with the RAH patients was being done by each patient's consultants. The consultant was about to see one of the affected patients and told the patient of the error during his routine clinic appointment. No report was made in the SLS.

8. The consultant next raised the issue during a consultants' meeting/ward round on 4 February 2015 at FMC with other haematology consultants and a pharmacist present. None of the clinicians present when the issue was raised made an SLS report. The review found that it was almost universal among clinicians that they were unaware of the Incident Management guidelines and had no training and experience using the SLS. The next day, 5 February 2015, the consultant told one of his FMC inpatients, who was alone, of the error in dosing. The patient's wife made a written complaint a few days later.

9. The issue came to the attention of the Head of Haematology Services at FMC during the next weekly consultants' meeting/ward round on 11 February 2015, after she had returned from leave. The Head of Haematology Services immediately recognised the seriousness of the issue, briefed her Chief Executive and other senior clinicians, including from RAH, and ensured incident reports were lodged on the SLS. She began arranging open disclosure to the patients who had not yet been told and involved senior clinical governance staff in the open disclosure process.

10. As awareness of the error spread, incident reports regarding the RAH patients were made on the SLS, rating the matter as SAC 1 – the most serious assessment which under the guidelines should trigger an intensive investigation. A senior project officer from SA Health emailed the Clinical Governance Manager SALHN and the Director of Safety, Quality and Risk at CALHN and asked whether there were any plans to do a single "cross border" investigation, which is specifically provided for in the SA Health Incident Management Policy. The manager at SALHN advised there were no such plans and no response was received from CALHN. No further action was taken by SA Health to pursue this. A single investigation should have been conducted and, if the guideline was followed, would have produced a report and recommendations which could have

avoided the divergent approaches taken at FMC and RAH to both investigation of the incident and open disclosure to the affected patients and their families.

11. FMC investigated the matter and, as a result, reviewed its existing protocols and tightened its already rigorous approval procedures. The FMC investigation was documented and entered on the SLS as required by the Incident Reporting and Management policy.

12. At CALHN, however, even though five SAC 1 incident reports were made on the SLS, there was no investigation as required by the guidelines. Although a brief to the Chief Executive SA Health on 19 February 2015 made some recommendations, the evidence that these had been implemented in any effective and systematic way was sparse at the time of a previous review of this matter by an independent panel led by the Chair of the Australian Commission on Safety and Quality in Health Care.

13. The issue was raised at the CALHN Quality and Governance committee meeting of 3 March 2015 by the Clinical Director Cancer Services. Despite the SLS SAC 1 reports the committee took no action to ensure that the requisite investigation or root cause analysis was conducted. This committee has overarching responsibility for ensuring good clinical governance in CALHN and its membership includes the most senior clinical and management staff of the CALHN including its Chief Executive and Director of Medical Services.

14. The failure to comply with clinical governance policies and guidelines by CALHN meant there was no comprehensive documentation of the action taken in response to the error. This resulted in briefings later requested by the SA Health Chief Executive being compiled on the basis of email requests and conversations with the staff involved. When taken together with the lack of accessible documentation of open disclosure, assurances given in briefings about what had occurred were not consistent with the experience of the affected patients.

15. Open disclosure was, on the whole, handled poorly, with little planning and without sufficient consideration of the impact on the patients that could reasonably have been anticipated. FMC was more active and better prepared after the involvement of the Head of Haematology Services. The efforts of CALHN in conducting open disclosure were very poor. The patients and families whose accounts were given to the review, found open disclosure to be insensitive and without the care and attention that the impact of the error on them warranted. The patients and families found that the support which may have been offered was not forthcoming without them having to fight for it. The legalistic approach taken by the health service insurer, SAICORP, which required patients to put their claims in writing with supporting evidence, confirmed for

the patients that the health service was more interested in protecting itself rather than caring for them. Their painful experience is set out in some detail in the report.

Findings

16. There was a serious failure of clinical governance at the RAH when an error in the protocol for the administration of chemotherapy to Acute Myeloid Leukaemia was confirmed on 19 January 2015 and it was ascertained that five patients had been incorrectly dosed. Responsible staff had little or no knowledge of the Incident Management guidelines and did not make an incident report in the SLS, which would have set in train processes which would have brought the error to the attention of more senior staff.

17. The method of notification of the error on 20 January 2015 to other concerned clinicians via a group email address, which was rarely read by the recipients, was an inadequate and ineffectual means of notification and resulted in no action being taken.

18. When the error was brought to the attention of a consultant visiting RAH from FMC on 30 January 2015, there was, again, no compliance with Incident Management guidelines. Further failures of clinical governance occurred when that consultant informed other clinicians and a pharmacist of the error during the consultants' meeting/ward rounds at FMC on 4 February 2015. No incident report was made on the SLS despite the guidelines requiring that serious incidents be reported within 24 hours.

19. The failure of clinicians to comply with incident management and open disclosure standards and protocols is a serious breach of standards of care. The almost universal evidence of the clinicians involved at all levels of this matter was that they were not aware of the guidelines on reporting adverse events and had never received any instruction or training on their responsibilities. The review agrees that the health services did not provide sufficient education or explanation of system response or policies while evidence suggesting that some training was offered although on a voluntary basis with poor attendance.

20. It is disturbing that senior clinicians were not aware of their professional responsibility to report the adverse event. At the very least they should have made inquiries with the hospital management on how to discharge these responsibilities. *Good Medicine Practice: A Code of Conduct for Doctors in Australia - Medical Board of Australia (2014)* (the Code) sets out that "good medical practice involves complying with any reporting obligations that apply" to the doctor's practice and explains the responsibilities of doctors in the management of adverse events and open disclosure.

21. The error did not receive anything approaching concerted action until it was drawn to the attention of the Head of Haematology Services at FMC during the consultants' meeting/ward rounds on 11 February 2015. It was then ascertained that five FMC patients had also received incorrect doses. SLS reports were then made, although their classification at SAC 2 was based on a narrow reading of the guidelines. Taking into account all the circumstances, the SLS incident reports from FMC should have been rated as SAC 1.

22. When RAH was notified of what had happened at FMC an SLS report was finally made on 12 February 2015 and given a SAC 1 rating. Contrary to the guidelines, however, the incident was not investigated in the comprehensive and systematic way required. Although the issue was raised with the CALHN Quality and Governance Committee, consisting of the most senior staff in CALHN and charged with overall responsibility for clinical governance, the Committee took no action to ensure an investigation or root cause analysis was carried out as required by the relevant policy. This demonstrated a disturbing and indefensible failure in clinical governance by the Committee charged with overall responsibility to ensure good clinical governance in the CALHN. Such efforts as were made to examine what went wrong and fix it were mostly ineffective, and the failure to produce a report and recommendations compromised the implementation of a comprehensive solution, the open disclosure that was undertaken with patients and their families, and the quality and accuracy of reports to the Chief Executive SA Health.

23. The response at FMC, once the Head of Haematology Services became aware, was more comprehensive and systematic in addressing the adoption of the CALHN protocol containing the error to ensure it would not occur again. FMC complied with the SALHN Clinical Incident Reporting and Management procedure by reporting its investigation and remedial action in the SLS.

24. Open disclosure guidelines of SA Health and the health services are concise and consistent with the Australian Commission on Safety and Quality in Health Care's Australian Open Disclosure Framework (2013). The South Australian guidelines provide little practical guidance or assistance on how open disclosure should be conducted, though this is dealt with in sufficient detail in the Australian Open Disclosure Framework (2013). While better handled at FMC than RAH, the open disclosure that occurred in this matter was, on the whole, not well thought out or properly planned. In many cases it occurred when the patient was attending for their clinical care, alone and without notice. There was inadequate documentation of the process or planned follow up. Requests for further information by patients or their families were not responded to quickly and there was no process of reporting back to the patients and their families about changes that had been implemented. The support which should have been provided to the patients also suffered from a lack of planning, and was perceived by patients to be offered grudgingly only after they had to fight for it.

25. The issue of compensation was poorly managed with the health service insurer taking a legalistic approach requiring written claims by patients, foreshadowing a lengthy legal process. This compromised the effectiveness of open disclosure and contributed to the perception by some patients that the health services and SA Health were being defensive and covering up.

26. Although the SA Health Incident Management guideline makes provision for a single investigation where an incident crosses a number of different health services, this prospect was raised by a senior project officer from SA Health, but not pursued and each health service dealt with the matter separately. A single investigation should have occurred from the outset and may have avoided the inconsistencies in the responses of the two health services.

Developments within SA Health

27. It must be acknowledged that considerable work has occurred within SA Health since these events and the Marshall report of November 2015. Almost all of the clinical staff interviewed who, at the time, were unaware of the guidelines on incident reporting and open disclosure, reported that they had received, or were shortly scheduled to receive, training in both areas.

28. The review also met with the Director of Safety and Quality Public Health and Clinical Systems for SA Health who advised that a comprehensive review of relevant policies was well underway and provided a draft of the reviewed Patient incident management and open disclosure Policy Directive. The policy is far more comprehensive than the existing guideline and provides much more sophisticated and thoughtful direction on open disclosure. The review was also provided with a number of completed policies and associated documents which demonstrate that a great deal of thought and effort has been put into documenting a rigorous clinical governance framework for implementation in South Australian health services.

Recommendations

29. The terms of reference of this review ask it to make recommendations to the Chief Executive SA Health to assist in mitigating the risk of reoccurrence and responding to breaches of compliance. As such the review makes the following recommendations.

Recommendation 1:

The clinical governance processes and response at CALHN with respect to the management of this incident demonstrated a disturbing and indefensible failure in clinical governance by the Quality and Governance Committee charged with overall responsibility to ensure good clinical governance in the CALHN. CALHN should review its clinical governance framework, structures and procedures to ensure that they provide robust clinical governance.

Recommendation 2:

That the clinical and management staff who failed to comply with SA Health incident management and open disclosure policies complete as a matter of urgency training in these areas.

Recommendation 3:

The SA Health draft Patient incident management and open disclosure Policy Directive should be finalised and implemented as a matter of urgency, and the tools and associated documents referred to in the Policy Directive should be finalised and implemented as soon as possible.

Recommendation 4:

Implementation of the new clinical governance policies and tools be accompanied by a systematic and audited training program across all South Australian health services. The importance of this training, while self-evident, should be made clear and clinicians and managers exercise personal accountability to undertake the training.

Recommendation 5:

SA Health should develop an understanding and appropriate protocols with SAICORP to ensure that the issue of compensation is included sensitively as part of the open disclosure process, and that South Australian health services have the capacity to make reasonable and timely without prejudice payments to patients suffering from the impact of health service errors.

Recommendation 6:

The legislative provisions which operate to protect certain information from disclosure as currently applied to reports of the investigation, analysis and recommendations of incidents reported on the Safety Learning System are applied too broadly. This complicates open disclosure by making it an offence to provide such information as part of open disclosure and diminishes the usefulness of the Safety Learning System as a learning tool for clinicians who, if they do not appreciate its clinical usefulness, will be reluctant to use it. The currently wide application of the legislative provisions to incident investigation and the Safety Learning System should be reviewed so as to facilitate the provision of reasonable explanations to patients and their families as part of open disclosure, as well as to others with a legitimate interest, and to ensure that it fulfils its potential of providing feedback on adverse incidents to clinicians to improve clinical practice.

This review has not been concerned with any issues of individual culpability or misconduct but aimed to review systems and recommend improvements to them. The review has been advised that other inquiries are being conducted regarding individual responsibility.

Scope and Method of the Review

30. In November 2015, the Australian Commission on Safety and Quality in Health Care (the Commission) reviewed and reported on the incorrect dosing of cytarabine to ten patients with Acute Myeloid Leukaemia at the two hospitals in the *Independent Review into the Incorrect Dosing of Cytarabine to ten patients with Acute Myeloid Leukaemia at Royal Adelaide Hospital and Flinders Medical Centre* (Appendix One). The review panel, headed by Professor Villis Marshall AC (the Marshall review), found that the underdosing of cytarabine resulted from a series of significant clinical governance failures at the Royal Adelaide Hospital haematology unit.

31. Although largely concerned with the cause of the incorrect dosing, the Marshall review also found that certain clinical staff did not comply with SA Health incident management and open disclosure policies by failing to report the matter in the SA Health Safety Learning System (SLS); conduct timely and appropriate open disclosure with patients; and provide an immediate clinical response to the underdosed patients.

32. In June 2016, the Chief Executive SA Health requested the Commission conduct a more intensive review of the governance and management processes in the two hospitals following discovery of the adverse event, including its notification in the SLS; the assessment of the severity of the incident; the investigations into the cause that were undertaken and the process of open disclosure.

33. The full terms of reference are attached to this report (Attachment 1).

34. The review was conducted as follows:

    - SA Health provided specific documentation requested by the Commission including SA Health policies and guidelines, internal documents, reports and emails from SA Health, Central Adelaide Local Health Network (CALHN) which manages the Royal Adelaide Hospital (RAH) and SA Pathology, and from Southern Adelaide Local Health Network (SALHN) which manages Flinders Medical Centre (FMC).

    - This documentation was reviewed, further documentation was requested and a series of questions prepared and sent to individual clinicians and staff who were identified for interview. Unfortunately, a number of key staff were unavailable for interview, having resigned and left South Australia.

    - Patients were contacted and asked if they wished to contribute to the review. Of the four who consented, two were too ill to participate at the time, and two were interviewed by the Commission. The Commission also received and reviewed written submissions provided by a number of patients and their families to a Parliamentary Committee inquiry that was then underway.

- The review interviewed 11 clinicians and staff members of the organisations involved.

- A draft report was prepared and provided to SA Health to ensure the accuracy of material and provide procedural fairness to relevant people. Extensive submissions were received which contributed to the accuracy of the final report.

The Clinical Governance Framework – policies and procedures for incident management including open disclosure

SA Health

35. SA Health, CALHN and SALHN each have documented policies on how adverse incidents should be managed. The principal SA Health document is a policy titled "Incident Management Guideline incorporating Open Disclosure Response". It was approved in October 2011 and substantively amended in June 2012 to incorporate incident reporting on the SLS, and was due for review in March 2015.

36. This guideline provides that all South Australian local health networks (LHNs) should have in place "procedures or instructions" that ensure reporting, review and open disclosure of incidents. At paragraph 1.7 it notes that "all incidents where a consumer was or could have been harmed should be reported into the Safety Learning System". Adverse incidents must receive a Severity Assessment Code (SAC) when entered into the SLS. The most serious is coded as SAC 1, grading down to SAC 4, the least serious, and the guideline provides a matrix to help determine the appropriate SAC rating. All SLS reports have a manager, or reviewer, assigned who must consider and confirm or amend the SAC rating that has been applied by the person who made the incident report.

37. The policy requires that each LHN configures the SLS so that there is automatic notification of incidents to key staff members depending on the SAC rating. Part 4 of the guideline requires the incident manager to confirm that SAC 1 events, the most severe, are escalated to the Chief Executive Officer of the health service. SAC 1 incidents are also required to have a "Level 1 Open Disclosure response" and the nomination of an "appropriate Open Disclosure Facilitator" by the LHN.

38. SLS reports have the capacity for entry of details regarding the review and analysis of the cause of the incident, contributing factors or how it could have been prevented.

According to the guideline, this part of the incident management module is an authorised quality assurance activity under section 64 of the *SA Health Care Act 2008*. Section 66 of that Act provides that such information cannot be disclosed to any person, court or agency, with severe penalties for so doing. The SLS reports for the ten patients involved in this matter that were provided to the review included no information as to how the matter was managed, investigated or disclosed; nor any SLS records verifying that the investigations and other actions required by policies were undertaken The identities of the reporters and managers of the reported incidents were also withheld by both LHNs as "prohibited information". The review put to both CALHN and SALHN that there were no such records on the SLS. CALHN did not object to this although the senior staff at SALHN advised that appropriate documentation of investigations and other action taken had been entered on the SLS consistently with the relevant policies. Supporting documentation was provided.

39. Section 7 of the guideline again refers to open disclosure and says that incidents assessed as SAC 1 or SAC 2 "will usually require a level 1 response in which case the Open Disclosure Facilitator will be notified". Section 8 deals with the level of investigation or review to be applied to incidents, and requires LHNs to provide appropriate policies, training programs and appropriately trained staff for the conduct of investigations, reviews and open disclosure.

40. Paragraph 8.4 notes that all SAC 1 incidents require "thorough investigation" and, if the incident "falls within the definition of an adverse incident" (which is not defined in the document) the investigation may be a root cause analysis "in which case any information gained as a result of this investigation will be protected from disclosure". If the incident is not defined as "adverse", an investigation "should still be conducted". The outcomes of any investigation should be documented and reported into the SLS and include recommendations. Incidents rated as SAC 2 have similar investigation and reporting requirements. Section 12 of the guideline requires that final reports must be uploaded into the SLS within 70 days of commencement of investigation for SAC 1 and SAC 2 "adverse" events. These reports are to be endorsed by the Chief Executive of the LHN and notified to the Department's sentinel events area via email.

41. Section 15 of the guideline deals with the management of incidents across different LHNs and provides for a single investigation that covers the whole of the incident. It specifies that the SLS reporting system should provide access to relevant staff from each LHN and that responsibility for "overseeing the management lies with the Directors Clinical Governance/Manager of Safety Quality and Risk [positions with the same essential responsibilities, albeit different titles] of the health services".

42. These positions should agree on which health service has primary responsibility for overseeing management of the incident and are responsible for deciding the

appropriate level of investigation; the preparation and distribution of reports and recommendations. The final paragraph notes that it may be appropriate for staff of each health service to conduct specific parts of the investigation separately "however, these should be co-ordinated and any final report should cover all components of the investigation."

43. Section 20 of the guideline contains a brief description of the essential elements of open disclosure – an expression of regret; a factual explanation of what occurred and the consequences; steps being taken to manage the event including the patient's ongoing care and support, and information on action being taken to prevent recurrence. It concludes that the opportunity should be provided for the patient to raise questions and obtain answers but "care should be taken not to release any information that is prohibited by legislation."

44. The only other document provided to the review on open disclosure was shared by the CALHN and consisted of a page entitled "SA Health Incident Management and Open Disclosure Policy Directive – Map of Documents". This document was not in existence at the time the underdosing occurred, and was produced as a work in progress at the time of this review with none of the documentary "tools" referred to, such as a Quick Guide to open disclosure; checklists of actions to take; a booklet for patients and Frequently Asked Questions yet produced.

Central Adelaide Local Health Network

45. As required by the SA Health guideline set out above, the CALHN has a guideline entitled "Incident Reporting and Management Guidelines", affective from March 2014. It largely mirrors the SA Health guideline in its general terms, but specifically to the LHN's reporting and management of incidents, makes Clinical Service Coordinators/Managers responsible for managing incident reports.

46. At paragraph 3.2.1 with reference to SAC 1 and SAC 2 rated incidents it says:

> *The CSC/Manager should notify the following staff - Relevant line manager; The Medical and Nursing Co-Directors and Risk Manager*
>
> *The relevant risk manager will confirm the SAC rating and provide a report in brief to the CALHN Director Safety, Quality & Risk, Chief Executive Officer (CEO), Chief Operating Officer (COO) and Relevant Executive*
>
> *An immediate investigation must be undertaken into all confirmed Sentinel events/SAC 1 and 2 events*

All confirmed Sentinel / SAC 1 events are reported to the Incident Review Panel (IRP) by the relevant Senior/Clinical Risk Manager.

47. The CALHN guideline contains no reference to incidents that may cross over or involve it and another health service (although there is a hyperlink to the SA Health guideline) nor any reference to open disclosure apart from two lines in paragraph 3.2 titled "Managing incidents" saying that the incident should be disclosed to the patient "as soon as practicable" and that effective clinical management includes "supporting patients, relatives and staff involved in an incident."

Southern Adelaide Local Health Network

48. The SALHN has a "Clinical Incident and Management Procedure" approved from July 2013. Rather than a guideline, the document is headed "CLINICAL PROCEDURE: Compliance is mandatory". The procedure is comprehensive concerning the responsibilities of staff to report incidents (including adverse incidents, which it defines) and the responsibilities of managers in determining the severity and the resultant investigation. The SALHN also has a separate and comprehensive guide to the practical use of the SLS.

49. On the type of investigation, analysis and reporting the results, the procedure relies directly on the SA Health guideline providing relevant hyperlinks. It also refers to the legislated privilege applying to information obtained during a root cause analysis and the privilege of such information entered in the SLS.

50. The procedure refers to open disclosure briefly at section 2.5 noting that SAC 1 and SAC 2 incidents will usually result in a level 1 open disclosure response. The review was provided with no other procedure or material from SALHN concerning open disclosure or what constitutes a level 1 or 2 response.

Discovery of the underdosing at Royal Adelaide Hospital and action taken

51. The Marshall review dealt with the circumstances under which an error was made in the new protocol for treatment of acute myeloid leukaemia patients which came into effect from July 2014. The Marshall review noted that there was no consensus on the optimum dosage of the chemotherapy drug, cytarabine, and that higher doses had resulted in moderate improvement in remission rates but also higher rates of death and disability due to the toxicity of the drug. The serious error in the new protocol halved the dose that was given before July 2014. The error in the protocol resulted in acute myeloid leukaemia patients after July 2014 receiving the newly set dose of the

cytarabine, over a course of infusions, once a day instead of what the protocol intended should be twice a day.

52. The error in the dosage of cytarabine was first noticed on Friday 16 January 2015 by the Pharmacist at RAH while examining a prescription for cytarabine in preparation for manufacturing the drug. The Pharmacist recalled processing a prescription a day or so earlier from a Registrar, dated 14 January 2015 for administration on Monday 19 January 2015, for the same patient for cytarabine once daily. The second prescription, prepared by the Deputy Director, Haematology and Bone Marrow Transplant Service on 15 January 2015 for administration on Monday 19 January 2015, was for dispensing the same dose of cytarabine to the patient twice daily.

53. The Pharmacist contacted the Deputy Director who confirmed that the correct dose was twice daily and the Pharmacist processed the prescription for medication on this basis. A call was made to production to cancel the earlier script written by the Registrar.

54. The Deputy Director said that she did not check the protocol on 16 January 2015 because both the author of the protocol and project officer responsible for managing protocols were not at work (although the protocol could have been accessed on the intranet). On Monday 19 January 2015, on coming to work, the Deputy Director and the project officer accessed the protocol and confirmed the error. The Deputy Director went to the clinic and told the patient that she was receiving the correct dose with the twice daily infusion but not that there had been an error in the protocol and that the patient had previously received half the correct dose.

55. The Deputy Director also met with the Pharmacist and Senior Pharmacist. According to the Senior Pharmacist, the three examined the protocol together and confirmed the error. The Senior Pharmacist said that he raised the issue of making an incident report in the SLS and said that the Deputy Director told him she would “sort it out”. The Deputy Director had no recollection of any discussion about reporting the incident in the SLS and denied saying that she would make an incident report. She said that her principal concern at the time was the safety of patients, determining whether other patients had been underdosed and correcting the protocol. The Pharmacist was not present at the discussion between the Senior Pharmacist and the Deputy Director of Haematology, but does recall being told by the Senior Pharmacist of his discussion with the Deputy Director about reporting the incident on the SLS. The Senior Pharmacist also said that he then informed the Acting Co-Team Leader of the incident and his discussion with the Deputy Director. The Pharmacist recalls being present at a discussion with the Senior Pharmacist and Co-Team Leader about the matter, but cannot recall the detail of the discussion.

56. The Senior Pharmacist also told the review that he had no previous training in using the SLS although he had used it as a reviewer of reports about minor matters but would not have known how to report a serious incident such as this. The Deputy Director said that she had also used the SLS as a reviewer of incident reports made by nurses in her area. She said that she understood the SLS to be a tool for nurses to report incidents, rather than doctors, and she did not know any doctors who used the SLS. Another senior clinician who spoke to the review confirmed that there was no induction process at RAH that covered use of the SLS and many doctors considered it a system used by nurses rather than applying to doctors.

57. The author of the revised acute myeloid leukaemia protocol, the Clinical Director, Haematology, SA Pathology, was overseas at the time this occurred. The Deputy Director, together with the project officer, amended the protocol to show the correct dosage of twice daily infusions and an email from the project officer was issued the next day, 20 January 2015, to a group email list. The Marshall review noted that the email did not highlight that the reason for the amendment to the protocol was a previous error, and that the email could have been read as a routine change of procedure.

58. The Deputy Director did not personally tell her immediate manager, the Head of the Clinical Haematology Service at RAH, who was included in the group email, nor did she directly approach any of the treating clinicians of other RAH patients who had been underdosed. The review was told by other recipients of the email that they receive high volumes of emails addressed to that group and rarely read them. The Deputy Director was not aware of this and told the review that she read all emails addressed to her. When asked why she did not escalate the notice by a more direct approach, she told the review that she did not feel it was her place and that the email was in the limits of her power, given her status. She also suggested that cultural factors contributed to her reticence. She said she thought it strange that there was no response to her email and was relieved when the issue came to the attention of her superiors around 11 February 2015.

59. The Clinical Director, Haematology, SA Pathology who was the author of the protocol found out about the error after he returned from leave on 27 January 2015. He told the review that he understood that the error had been corrected; that relevant clinicians had been notified by the group email; that procedures for adopting and implementing protocols were being reviewed and believed that the individual patients affected had been identified. He was unaware that the protocol was being used at FMC and thought that no further action on his part was called for. He also advised the review that he was not aware of the SLS and the need for incident reporting at that time.

Discovery of the error at Flinders Medical Centre and subsequent action

60. A consultant haematologist working part time at FMC was also working at RAH, so was consequently aware of the protocol that applied at RAH from July 2014. He persuaded FMC to adopt the protocol which agreed in the interests of consistency of treatment and making other trial treatments, which were dependent on patients being through the treatment in the protocol, available to the patients. The consultant haematologist, although working principally at FMC also attended RAH to conduct a clinic on Fridays in January 2015.

61. When attending the clinic at RAH on Friday 30 January 2015, the consultant was told by an RAH pharmacist about the dosing error in the protocol and that each of the RAH patients would be told of the error by their consultants. The consultant was due to see one of the five RAH patients who had been underdosed at the clinic that day and decided that he would tell the patient of the error. He told the review that the patient was by himself, in an outpatient room and attending for routine review. He said that the patient did not appear to be disturbed by the news and showed no outward signs of distress. The review was unable to contact this patient.

62. The consultant, having introduced the RAH protocol to FMC, was aware that it was in use there and at the consultants' meeting/ward rounds on Wednesday 4 February 2015 he raised the issue with other consultants and the FMC pharmacist. No-one present thought to make an incident report in the SLS at this stage. The consultant said that he was aware of a general responsibility to advise his seniors of serious incidents but had no knowledge at all of the SLS at that time, had never seen any SLS reports and was not aware of any policies requiring him to make an incident report.

63. The Director Clinical Governance of CALHN gave evidence that training in incident reporting and use of the SLS had been offered but it appeared to be on a voluntary basis and was poorly attended by clinicians.

64. The consultant had other patients at FMC who had been underdosed and he decided to tell one of them about the error when he saw the patient the next day in hospital. The consultant said that the patient did not seem to be visibly upset when told of the error. The patient elected not to participate in the review.

65. The Head of Haematology Services at FMC had been on leave through this time and, although the group email sent by the Deputy Director from RAH on 20 January 2015 included her, she first found out about the underdosing at a consultants' meeting/ward rounds on 11 February 2015. She immediately recognised the serious nature of the incident and took swift action to brief the Chief Executive SALHN. The Clinical Director

Cancer Services CALHN became aware of the incident on 12 February 2015 initially verbally from the RAH Head of Pharmacy and subsequently when copied into an email from the Head of Haematology Services. The Head of Haematology at FMC also ensured that incident reports were made on the SLS, so far as the FMC patients were concerned.

66. The Head of Haematology Services at FMC determined that the severity rating for the incident would be SAC 2 and defended this decision on the basis that there was little evidence of actual consequence to patients evident at the time. As noted above, acute myeloid leukaemia is a virulent form of cancer with a high mortality rate and the optimum dosage of cytarabine is debatable. All of the underdosed patients were reviewed by FMC clinicians and it was difficult to determine whether the half doses given to patients had harmed them – harm being the crucial element to determining the severity of an incident. Based on the patients' condition at the time, it was determined that only two of the five should be offered the option of "catch up" doses of cytarabine. The classification of the error at SAC 2 was an underrating given the possibility that the under dosing may have not had the desired effect on restricting the patients' cancer meaning that harm may have been caused to them. This, taken together with the distress caused to the patients by the error should have raised the level of seriousness to SAC 1 classification.

67. Following contact by the Head of Haematology Services at FMC on 12 February 2015, the Clinical Director Cancer Services, who had previous experience in a clinical governance role, directed that an SLS report, rated at SAC 1, be made. This was done on 12 February 2015 with respect to one of the five patients from RAH with the other four reported in the SLS on 17 February 2015.

68. The Head of Haematology Services at FMC also reviewed the protocol approval system at FMC and developed a new procedure for the implementation of protocols including an extra checking process and face to face briefing of staff involved in administering the protocol. FMC also extended the rigorous process it used to implement protocols to those adopted from elsewhere. The Marshall review described documentation of FMC's revised protocol checking process as "comprehensive".

69. As noted above, the review was unable to view the relevant documentation on the SLS but was advised by the relevant staff at FMC that all investigations, findings and recommendations were entered onto the SLS in accord with the policy requirements.

Further activity at RAH following notice from FMC

70. The contact by FMC with RAH and the subsequent incident report entered in the SLS triggered email notifications to various senior staff including the CALHN Director of

Medical Services and the SA Chief Public Health Officer. This resulted in a request that a briefing be prepared for the Chief Executive SA Health which was co-ordinated by the Clinical Director Cancer Services and signed off by the Chief Executives of CALHN, SALHN and the Executive Director SA Pathology.

71. The brief noted the discovery of the error at RAH on 19 January 2015, that the protocol was corrected and uploaded the next day. It also noted that RAH was unaware the protocol was in use at FMC and did not discover this until contacted by FMC on 11 February 2015 when the matter was escalated. The brief noted that "while corrective actions were implemented when the error was [first] noted at the RAH this incident was not formally reported into the SLS" and while the reasons were still being investigated, it appeared that "the critical importance of reporting such incidents was perhaps not clear to some of those involved." Under the heading "Open Disclosure" it noted that five of the ten affected patients had been "contacted and counselled" and "the remainder would be informed over the next 10 days".

72. The brief did not hide, nor did it highlight, the failures to follow clinical governance procedures but gave the overall impression that appropriate investigation and remedial action in accord with the procedures was underway. The brief made recommendations for reviewing the care and future treatment of the ten patients based on expert advice and review of all current protocols by an independent clinician, it recommended the review of the governance of the protocol database hosted by SA Pathology and that medical officers at both sites undergo training on incident reporting and open disclosure. The briefing was noted by the Chief Executive SA Health on 20 February 2015.

73. The Clinical Director Cancer Services, who had a significant role in preparing the briefing to the Chief Executive, told the review that he received the signed brief back but no other information and remained concerned about what was being done. He emailed the Chief Public Health Officer on 3 March 2015 advising he would follow up the recommendations in the brief and asking whether "we need to do anything else". The Chief Public Health Officer replied that he had no feedback but had spoken to the then Chief Executive SA Pathology, who indicated that it "may do a root cause analysis", and asking if he knew whether this was happening. The Clinical Director Cancer Services responded that he would go ahead with taking action on implementation of the recommendations in the brief relevant to CALHN.

74. The Clinical Director Cancer Services told the review that he tabled the matter at the CALHN Executive Quality and Governance Committee and the minutes confirm that it was discussed at the meeting on 3 March 2015. The Quality and Governance Committee oversees the operation of the CALHN Incident Review Panel to which all SAC 1 events must be notified and which decides on the appropriate level of investigation. The

Clinical Director Cancer Services told the review that the Quality and Governance Committee did not convene the Incident Review Panel about the incident and, although he expected the Chief Executive would have authorised a root cause analysis investigation, he had no actual knowledge of what investigation, if any, was taking place. The minutes do record the issue being raised and some remedial action then underway, although there is no mention that the SLS incident reports had been rated as SAC 1 nor any discussion regarding conducting an investigation or a root cause analysis, as the Incident Report and Management guidelines required

75. Still concerned, the Clinical Director Cancer Services emailed the Head of Haematology Services at RAH, the Deputy Director, Haematology and Bone Marrow Transplant; and the Clinical Director, Haematology, SA Pathology advising that the recommendations in the brief to the Chief Executive SA Health had been "formally" signed off and that his responsibility would be around having oversight of the 'clinical service' recommendations in the brief.

76. The Director of Safety, Quality and Risk at CALHN had been advised of the SAC 1 SLS reports by her staff and raised the issue with the Director of Medical Services, who was the Secretary of the Quality and Governance Committee, by email dated 4 March 2015, noting that the issue was not on the agenda for the Incident Review Panel meeting that day and asking whether he would be raising it. The Director of Safety, Quality and Risk told the review that the Director of Medical Services did not respond to her email and she did not attend the meeting of 4 March 2015 but checked with her team who took the minutes and was told the issue was not raised. She said she remained concerned and continued to raise the issue with the Director of Medical Services in subsequent weekly meetings. She told the review that she repeatedly raised the issue of whether a root cause analysis should be conducted but the Director of Medical Services took the view that the issue did not warrant a root cause analysis. The Director of Safety, Quality and Risk told the review that only the Chief Executive CALHN or the Director of Medical Services could instigate a root cause analysis investigation. The Director of Medical Services had resigned his position and left South Australia before the review was commissioned so was not interviewed. The then Chief Executive CALHN had also resigned and could not be interviewed.

77. In the absence of an accountable high level investigation appropriate to a SAC 1 incident, there was no formal report to the Chief Executive CALHN. Consequently, there was no endorsement by the Chief Executive of any recommendations resulting from such an investigation nor any formal process for implementing them. The Marshall review (at paragraphs 110-126) had no confidence that any of the recommendations had been implemented at the time of its report in November 2015 and was sure that some recommendations, such as training in incident management and open disclosure had not been implemented.

78. The Quality and Governance Committee is the overarching accountability mechanism for clinical governance in the CALHN. Its purpose, as set out in its terms of reference, "is to monitor quality and safety in CALHN; and make appropriate decisions, communicating these to appropriate staff". Its membership consists of the most senior clinical and management staff of the CALHN. On the date the Clinical Director Cancer Services raised the issue of the cytarabine underdosing at the Quality and Governance Committee, 3 March 2015, the attendance list shows the attendance of the Chief Executive CALHN, the Director of Medical Services and numerous other very senior staff representing the various services delivered across the CALHN. With respect to the underdosing error the minutes of the meeting record: "Chemotherapy protocol error identified. Ten patients received incorrect treatment. Five patients within CALHN and five within SALHN. Radiation Oncology Service now reporting incidents via the SLS database. Service is also implementing a modified surgical team safety checklist."

79. Although the matter was raised and discussed at the meeting, there is no indication that it was treated with any urgency and, more significantly, there was no further action by the Committee to ensure that the Incident Reporting and Management Procedure was followed; that the matter was formally referred to the Incident Review Panel; that a root cause analysis was conducted and appropriate recommendations made and implemented. This inaction persisted in the face of subsequent and continuing inquiries from the Minister, Chief Executive SA Health and others as public concern mounted. The failure by the primary clinical governance mechanism in the CALHN to ensure that its own policies were followed showed a breathtaking contempt for good clinical governance.

80. In the absence of compliance with the policy, there was no comprehensive investigation and consequently no accompanying documentation of remedial action and contact with affected patients and families. Subsequent briefings called for by the Chief Executive SA Health and the SA Minister for Health were compromised by the failure to properly investigate and document that investigation.

81. The issue arose again for the health services in May 2015, following approaches to the Chief Executive SA Health by patients and family unhappy about how they were dealt with. A brief to the SA Minister for Health was requested and coordinated by the Deputy Chief Executive, System Performance and Service Delivery, SA Health. The brief was requested on 7 May 2015 and submitted on 29 May 2015, after being sent back for clarification of issues. It is clear from the documentation provided to the review that information for this brief had to be sought from scratch. For example, the question of whether all of the ten patients had been contacted was sought by email and then telephone calls to each of the patient's treating clinicians to confirm that they had all been spoken to. On that issue, the brief said that all of the patients had been provided

with apologies and that the health services "have been providing ongoing support to the patients and their families as a part of their treatment". The issue of "support" is discussed further below but the health services and the patients had different understandings of what it meant.

82. On the question of what was being done to prevent a similar incident happening again, the brief advised, among other things, that "formal training has been provided to all haematology and oncology medical officers on the importance of incident reporting through the Safety Learning System and open disclosure". No such training had been provided at that time and the review could not ascertain how this came to be included in the brief. The lack of reliable documentation led to verbal advice on some issues and the misinterpretation of such advice may have led to the error. The effect on patients and the families, however, when their experience differed so much from the public statements of health spokespersons based on such briefings, was to shatter what little confidence the patients may still have had in the health services and in at least some cases, fuel the reaction that the health services were not disclosing the correct information to patients/carers and to the community..

Why wasn't there a single investigation into the matter?

83. As set out above, the SA Health guideline at section 15 deals with incidents that may occur and involve more than one health service. It sets out a sensible regime and appears to place management responsibility for such investigations with the Clinical Governance Directors/Directors of Safety, Quality and Risk within the relevant health services.

84. On 2 March 2015, following notice of the SLS reports regarding the patients affected, a senior project officer from SA Health Safety and Quality Public Health and Clinical Systems group emailed the Manager, Clinical Governance at SALHN and the Director of Safety Quality and Risk at CALHN saying; "I've been asked to find out if there is to be an aggregate (across sites) root cause analysis undertaken…". The Manager, Clinical Governance from SALHN emailed back the same day saying: "No plan to do this from this end" and the Director of Safety Quality and Risk from CALHN did not respond. The Director of Safety and Quality and Risk at CALHN told the review that, at the time, she was trying to clarify with the Director of Medical Services whether or not an investigation would be conducted. The question raised by the senior project officer was not pursued further by the SA Health Safety and Quality section.

85. The Head of Haematology at FMC told the review that she considered a single investigation would have been preferable and sought to engage with RAH and SA Health to that end. These approaches were informal however and appeared to gain no support.

86. A single high level investigation could have made recommendations promoting consistent clinical governance practice at both sites and assured the public that a serious and comprehensive approach had been taken.

The role of Clinical Governance and Safety, Quality and Risk staff

87. It is concerning that the senior clinical governance staff, charged under the SA Health Incident Management guideline with responsibility for managing a cross health service investigation, were not more active in pursuing that approach.

88. Clinical governance staff have a vital role in health services to ensure appropriate clinical governance systems and practices are understood and followed by all staff. They are also generally responsible for management of patient complaints and can bring a great deal of experience to handling sensitive situations and a more independent perspective than clinicians who may be involved in adverse events. In this matter, however, the Safety, Quality and Risk staff at CALHN had little influence in ensuring the Incident Management guideline was followed and, as they were not "invited" to assist with open disclosure to the RAH patients, played no part in it. The senior clinical governance staff at FMC were involved in managing the issues there from the time the Head of Haematology Services became involved on 11 February 2015.

Open Disclosure

89. The SA Health policy "Incident Management Guideline Incorporating Open Disclosure Response" has a very brief and rudimentary exposition of open disclosure at section 20. It calls for an expression of regret; a factual explanation of what occurred and the consequences; steps being taken to manage the event including the patient's ongoing care and support and information on action being taken to prevent recurrence. The respective policies of CALHN and SALHN provide little elaboration. Although an extensive suite of supporting documentation was planned by SA Health it was not in existence when the cytarabine underdosing was raised.

90. Almost all of the clinicians spoken to by the review who informed the patients of the error had no training or experience in open disclosure, had never heard of level 1 or 2 responses or an open disclosure facilitator. There is no reason to doubt that in conversations with the affected patients that they expressed regret for the error, explained the reason for it and the consequences as best they could.

91. It cannot be said, however, that open disclosure was effective. Although the review could not conduct a comprehensive survey that included all of the ten patients and their families, the two patients interviewed were not satisfied with the way the error was disclosed nor with the support offered to them. The review also received the

submissions of three other patients and/or their families to the Parliamentary Committee inquiry expressing their dissatisfaction. As no written record of each open disclosure was made, apart from an entry in the patients' medical record, there is no documentation to assist in determining how each disclosure was handled and the impact that it had on the patients and their families.

92. News of a chemotherapy medication error, on top of all of the emotional trauma of dealing with a particularly aggressive form of cancer, can reasonably be anticipated to induce a disassociative state, or shock, in the patient. In preparing for open disclosure it is important to consider whether the patient is likely to require the need of a support person. For the same reason it is important that a written record be made of the meeting and the conclusions recorded so that the patient can use it to recall what occurred. Such documentation also acts as a record for the health service.

93. Where the cause of the error is not yet known and/or action taken to remedy the error has not been completed, this should be clearly explained and offers made for further meetings where a more detailed explanation can be provided. A contact person from the health service should be nominated for ongoing contact with the patient, who is not a part of the ongoing clinical treatment team. The impact on the patient of the error should not be underestimated. As the Marshall review noted, some patients felt that the characterisation of the error as a "typo" diminished its importance and, they felt, the seriousness with which the health service was taking the issue.

94. The open disclosure in this matter, particularly the earliest cases, did not show any evidence of serious consideration of the likely impact on the patient and measures taken to mitigate it. . In one case, at RAH, the patient was told by a doctor with whom he had no therapeutic relationship in the context of a visit for treatment. He asked to see a consultant but remained upset after speaking to her. The patient then demanded to see the head of department, in this case the Clinical Director, Haematology, SA Pathology but was told that he was not available. The Clinical Director, who met with him about a week later, told the review that the patient's early interaction with the clinicians "was distressing for all concerned."

95. The patient, accompanied by his wife and daughter, met with the Clinical Director, Haematology, SA Pathology on 13 March 2015 and made a request for compensation although he considered that the health service should make him an offer rather than making him fight a legal claim. The Clinical Director put this request through health service channels which conveyed the advice of SAICORP, the health service insurer, that the patient should put his claim in writing. The Clinical Director told the review he thought this was "harsh". The patient later saw a lawyer and made a claim of $65,000. SAICORP countered with an offer of $5,000 on the basis that it was unlikely the patient could prove "harm" from the underdosing.

96. The Clinical Director told the review that although the issue of compensation was never again discussed between himself and the patient, he felt that there was mistrust in the therapeutic relationship after the way the compensation was handled. The patient's family, in a submission to the Parliamentary Committee's inquiry said that he was not offered any counselling during this time and outlines the devastating impact it had on him and his family. The patient succumbed to acute myeloid leukaemia on 22 November 2015.

97. Another patient who was interviewed by the review said that she was told of the error during a visit for treatment with no one accompanying her. She said "that the worst fact is you're so alone", that she couldn't take it in and they "rabbited on". The acute myeloid leukaemia had come back at that stage and she was focused on her future treatment. She told the review that there was no further contact until she received a letter dated 29 May 2015 sent to all FMC patients by the Chief Executive SALHN following requests from patients for something in writing. The final letter took some time to produce and had been vetted by lawyers. The Marshall review said the letter was "not empathetic, offered no comfort or additional information and may have been better not sent than arriving so long after the initial disclosure." The patient when interviewed by this review referred to "that bloody letter". She felt it was an insult - "it was so impersonal. I'd probably still have got the letter if I'd been dead."

98. Later, after agitation from patients came to the attention of the Chief Executive SA Health, directions were given for specific people from the health services to offer support to the patients. This patient told the review that she received a call and was asked what the health service could do to support her. She was living alone, with the acute myeloid leukaemia returned, and asked for a cleaner. She said the person at the other end of the phone laughed as though the request was out of the question. She was interviewed with another affected patient and both believed that support was offered only in response to the pressure after media exposure.

99. Another patient, not interviewed by the review, was told of the error on his own while in hospital on 5 February 2015. The consultant who disclosed the error told the review that the patient showed no visible signs of distress. His wife wrote to complain a few days later and another meeting was arranged for 16 February 2015. By this time, the Head of Haematology at FMC was aware of the issue and involved senior clinical governance staff in the meeting. Nevertheless, even though more care was taken with this meeting than previously, the patient's wife in a submission to the Parliamentary Committee inquiry said: "I don't think they realise the impact." After the meeting she continued to make requests for written information and had to follow up those requests as she received no response within a reasonable time. Her submission said that no assistance was offered until media exposure in August 2015. She recalled getting a call from a health service support person whom said she had been "told" to

offer support. She said she sought an apology from the person who was responsible for the error in the protocol but was told by the support person: "I'm not sure I can really influence that." On the effect the error had on the therapeutic relationship she said: "Trust went out the door once the incorrect medication was mentioned."

100. The other patient who spoke to the review received the incorrect doses at FMC over three days in late January 2015, after the error in the protocol was discovered at RAH but before FMC became aware. An open disclosure meeting was arranged with him on 17 February 2015 attended by the Head of Haematology Services, the treating consultant and senior clinical governance staff. The health service attendees who spoke to the review reported that the patient expressed his disbelief; said he was "gobsmacked" and that he had put his trust in them. The meeting then moved onto his future treatment and he was offered and subsequently had, "catch up doses" of cytarabine.

101. The patient also provided the review with an extensive submission he made to the Parliamentary Committee inquiry which chronicles in great detail his growing frustration and anger at the lack of support provided to him and his family and the lack of any meaningful advice, despite his inquiries, regarding investigations being undertaken to establish the cause of the error and what remedial action was being taken. He asked to meet with other affected patients and said this was vetoed by the Chief Executive SALHN.

102. The patient's ongoing interaction with FMC continued to fuel his growing sense that the incident was not being taken seriously by the health service. On 6 August 2015, he had another meeting with the Head of Haematology Services and discovered that she was a recipient of the group email of 20 January 2015 from RAH advising of the amended protocol but she was not aware of it until August 2015, confirming for him that no serious investigation was being undertaken. The Head of Haematology Services told the review that the issue of compensation was raised at this meeting and the patient was informed he should deal directly with the insurer in writing. Her impression was that it was at this meeting that the patient completely lost trust in the health service. She also told the review that she recognised the importance of compensation and made approaches that it be paid quickly but was unsuccessful.

103. As a result of his experiences, the patient began to approach the Chief Executive SA Health and the SA Minister for Health directly, the media and became a very public, and effective, campaigner and advocate for other patients.

104. The patient told the review that his experience, after being told of the dosing error, made him feel like nothing would be done to properly investigate it and properly support the affected patients. He said he felt that he was being treated like "an

embarrassment" to the health service and it would rather he go away. Even after his approaches to the Chief Executive SA Health resulted in care co-ordinators being appointed, they were slow to act and he needed to push them to do anything. Even then, he felt, some requests he thought reasonable were refused and he had to fight for them. Throughout this experience and the issue getting in to the media, he said that media statements and appearances by health spokespersons misleadingly implied the health services were being supportive and compassionate towards the patients, which deepened his mistrust, leading to his conviction that he was "in a sea of lies" and the health service was deliberately engaged in a cover up.

105. His experience with SAICORP, which took the approach that he should put everything in writing with supporting material, preferably with legal assistance, only served to confirm his growing belief that the health system was incapable of investigating itself and was misleading the public about the way it was treating the affected patients.

Findings

106. There was a serious failure of clinical governance at the RAH when an error in the protocol for the administration of chemotherapy to Acute Myeloid Leukaemia was confirmed on 19 January 2015 and it was ascertained that five patients had been incorrectly dosed. Responsible staff had little or no knowledge of the Incident Management guidelines and did not make an incident report in the SLS, which would have set in train processes which would have brought the error to the attention of more senior staff.

107. The method of notification of the error on 20 January 2015 to other concerned clinicians via a group email address, which was rarely read by the recipients, was an inadequate and ineffectual means of notification and resulted in no action being taken.

108. When the error was brought to the attention of a consultant visiting RAH from FMC on 30 January 2015, there was, again, no compliance with Incident Management guidelines. Further failures of clinical governance occurred when that consultant informed other clinicians and a pharmacist of the error during the consultants' meeting/ ward rounds at FMC on 4 February 2015. No incident report was made on the SLS despite the guidelines requiring that serious incidents be reported within 24 hours.

109. The failure of clinicians to comply with incident management and open disclosure standards and protocols is a serious breach of standards of care. The almost universal evidence of the clinicians involved at all levels of this matter was that they were not aware of the guidelines on reporting adverse events and had never received any instruction or training on their responsibilities. The review agrees that the health

services did not provide sufficient education or explanation of system response or policies.

110. It is disturbing that senior clinicians were not aware of their professional responsibility to report the adverse event. At the very least they should have made inquiries with the hospital management on how to discharge this responsibility. *Good Medicine Practice: A Code of Conduct for Doctors in Australia - Medical Board of Australia (2014)* (the Code) sets out that "good medical practice involves complying with any reporting obligations that apply" to the doctor's practice and explains the responsibilities of doctors in the management of adverse events and open disclosure.

111. The error did not receive anything approaching concerted action until it was drawn to the attention of the Head of Haematology Services at FMC during the consultants' meeting/ward rounds on 11 February 2015. It was then ascertained that five FMC patients had also received incorrect doses. SLS reports were then made, although their classification at SAC 2 was based on a narrow reading of the guidelines. The classification of the issue at SAC 2 was justified on the basis that the "harm" suffered by the patients involved was unclear at that stage. Even on this basis, administration of half the intended treatment dose instead of the full dose could reasonably be assumed to have caused, ("or may have caused" to quote the guidelines) physical harm to the patients in that the progress of their disease may have been less affected by the smaller dose. This, together with the psychological and emotional distress to which the patients and their families were subjected as a result of the error, clearly made the error serious enough to be classified as SAC 1.

112. When RAH was notified of what had happened at FMC, SLS reports were finally made and given a SAC 1 rating. Contrary to the Incident Reporting and Management guidelines, however, the incident was not investigated in the comprehensive and systematic way required. Although the incident was reported to the CALHN Quality and Governance Committee on 3 March 2015 and it was aware that the incident had been reported in the SLS, the Committee made no effort to ensure that the matter was properly investigated and reported upon as required by the guidelines. This Committee is the overarching clinical governance body of the CALHN and is chaired by the Chief Executive. The failure of this Committee to ensure its own policies were followed demonstrated a breathtaking contempt for good clinical governance. Such efforts as were made by the CALHN to examine what went wrong and fix it were mostly ineffective, and the failure to produce a report and recommendations as required by the policy, compromised the implementation of a comprehensive solution; the open disclosure that was undertaken with patients and their families and the quality and accuracy of reports to the Chief Executive SA Health.

113. The response at FMC was systematic in addressing the cause of the error to ensure it would not occur again. Although this review believes the incident was underclassified at SAC 2, there was a systematic review of the adoption of chemotherapy protocols and substantial changes made to how they would be approved in future. FMC was also compliant with incident reporting and management and open disclosure policies once the Head of Haematology Services became aware of the error.

114. Open disclosure guidelines of SA Health and the health services are concise and consistent with the Australian Commission on Safety and Quality in Health Care's Australian Open Disclosure Framework (2013). The South Australian guidelines provide little practical guidance or assistance on how open disclosure should be conducted, though this is dealt with in sufficient detail in the Australian Open Disclosure Framework (2013). The early instances of open disclosure that occurred in this matter were not well thought out or properly planned. In most cases it occurred when the patient was attending for their clinical care, alone and without notice. The open disclosures by FMC once the Head of Haematology Services became involved were better managed and included the clinical governance staff. FMC, however, was hampered in dealing with its patients by the lack of any investigation and report by CALHN into the cause of the error in that it was unable to provide an adequate explanation to affected patients on the cause of the error. Although FMC's management of open disclosure was more professional that what occurred at CALHN, it is common to both sites that there was inadequate documentation of the process and lack of planned follow up with patients and families. Requests for further information by patients or their families were not responded to quickly and there was no process of reporting back to the patients and their families about any changes that had been implemented. The support which should have been provided to the patients also suffered from a lack of planning, and was perceived by patients to be offered grudgingly only after they had to fight for it.

115. The issue of compensation was poorly managed with the health service insurer taking a legalistic approach requiring written claims by patients, foreshadowing a lengthy legal process. This compromised the effectiveness of open disclosure and contributed to the perception by some patients that the health services and SA Health were being defensive and covering up.

116. Although the SA Health Incident Management guideline makes provision for a single investigation where an incident crosses a number of different health services, this prospect was raised by a project officer from SA Health, but not pursued and each health service dealt with the matter separately. A single investigation should have occurred from the outset and may have avoided the inconsistencies in the responses of the two health services as well as provided a more consistent approach to open disclosure.

Developments within SA Health

117. It must be acknowledged that considerable work has occurred within SA Health since these events and the Marshall report of November 2015. Almost all of the clinical staff interviewed who, at the time, were unaware of the guidelines on incident reporting and open disclosure, reported that they had received, or were shortly scheduled to receive, training in both areas.

118. The review also met with the Director of Safety and Quality Public Health and Clinical Systems for SA Health who advised that a comprehensive review of relevant policies was well underway and provided a draft of the reviewed Patient incident management and open disclosure Policy Directive. The policy is far more comprehensive than the existing guideline and provides much more sophisticated and thoughtful direction on open disclosure. The review was also provided with a number of completed policies and associated documents which demonstrate that a great deal of thought and effort has been put into documenting a rigorous clinical governance framework for implementation in South Australian health services.

Recommendations

119. The terms of reference of this review ask it to make recommendations to the Chief Executive SA Health to assist in mitigating the risk of reoccurrence and responding to breaches of compliance. As such the review makes the following recommendations.

Recommendation 1:

The clinical governance processes and response at CALHN with respect to the management of this incident demonstrated a disturbing and indefensible failure in clinical governance by the Quality and Governance Committee charged with overall responsibility to ensure good clinical governance in the CALHN. CALHN should review its clinical governance framework, structures and procedures to ensure that they provide robust clinical governance.

Recommendation 2:

That the clinical and management staff who failed to comply with SA Health incident management and open disclosure policies complete as a matter of urgency training in these areas.

Recommendation 3:

The SA Health draft Patient incident management and open disclosure Policy Directive should be finalised and implemented as a matter of urgency, and the tools and associated documents referred to in the Policy Directive should be finalised and implemented as soon as possible.

Recommendation 4:

Implementation of the new clinical governance policies and tools be accompanied by a systematic and audited training program across all South Australian health services. The importance of this training, while self-evident, should be made clear and clinicians and managers exercise personal accountability to undertake the training.

Recommendation 5:

SA Health should develop an understanding and appropriate protocols with SAICORP to ensure that the issue of compensation is included sensitively as part of the open disclosure process, and that South Australian health services have the capacity to make reasonable and timely without prejudice payments to patients suffering from the impact of health service errors.

Recommendation 6:

The legislative provisions which operate to protect certain information from disclosure as currently applied to reports of the investigation, analysis and recommendations of incidents reported on the Safety Learning System are applied too broadly. This complicates open disclosure by making it an offence to provide such information as part of open disclosure and diminishes the usefulness of the Safety Learning System as a learning tool for clinicians who, if they do not appreciate its clinical usefulness, will be reluctant to use it. The currently wide application of the legislative provisions to incident investigation and the Safety Learning System should be reviewed so as to facilitate the provision of reasonable explanations to patients and their families as part of open disclosure, as well as to others with a legitimate interest, and to ensure that it fulfils its potential of providing feedback on adverse incidents to clinicians to improve clinical practice.

This review has not been concerned with any issues of individual culpability or misconduct but aimed to review systems and recommend improvements to them. The review has been advised that other inquiries are being conducted regarding individual responsibility.

Attachment 1

SA Health

Terms of Reference

Title	Review of the Incident Notification, Management and Analysis of Incorrect Dosing of Cytarabine of Acute Myeloid Leukaemia at Flinders Medical Centre and Royal Adelaide Hospital
Scope	The objectives of the review by Australian Commission on Safety and Quality in Health Care are: 1. To review the incident management process associated with the incorrect dose of Cytarabine of ten patients with Acute Myeloid Leukaemia; including the process of notification, assessment of severity assessment(SAC), investigation and open disclosure, to ensure all were in compliance with SA Health Policy Directives: a. Timeliness of notification and initial severity assessment score (SAC) b. Appropriateness of investigation method and management of incident c. Open disclosure – seniority of clinician / team undertaking the process and follow up with patient / family d. Actions / recommendations taken to mitigate reoccurrence and improve service 2. To review the systems of governance and confirm that appropriate actions were taken throughout the process of investigation. 3. To make recommendation on findings to the CE to assist in mitigating the risk of reoccurrence and respond to breaches of compliance.
Responsibilities	Independent advisers to the review: Australian Commission on Safety and Quality in Health Care. Executive Support: Safety and Quality Branch Report to be provided to Chief Executive SA Health