SELECT COMMITTEE ON OFF-PROTOCOL PRESCRIBING OF CHEMOTHERAPY IN NSW

Inquiry into off-protocol prescribing of chemotherapy in New South Wales

HEARING: SYDNEY, MONDAY 31 OCTOBER 2016

Questions for:

St Vincent's Health Australia

1. **In June 2015, what was the procedure at St Vincent's for determining if something was an incident which required implementation of the RIB or IMP protocols?**

   (a) What is the threshold for classifying something as a formal incident?

   (b) Does systemic departure by a doctor, regardless of the impact on patients, from dosage guidelines classify as a formal incident?

St Vincent's response

There are three relevant NSW Health policies for incident management that had been adopted by St Vincent's Hospital as at June 2015:

- GL2006_002 Complaint or Concern about a Clinician – Management Guidelines Policy (http://www0.health.nsw.gov.au/policies/gl/2006/GL2006_002.html)
- PD2014_004 Incident Management Policy (http://www0.health.nsw.gov.au/policies/pd/2014/PD2014_004.html)
- PD2007_075 Lookback Policy (http://www0.health.nsw.gov.au/policies/pd/2007/PD2007_075.html)

a) The severity assessment code from the Incident Management Policy (PD2014_004, Appendix B, pp.37-38) is used to determine the action required.

b) The severity assessment code from the Incident Management Policy (PD2014_004, Appendix B, pp.37-38) is used to determine the action required.

2. What changes to that procedure have been made since June 2015?

(a) When were these changes made?

St Vincent's response

The Hospital has reviewed its practices in relation to incident management as a result of the s122 Inquiry.

A key objective of the review has been to ensure the inclusion of content-specific expertise to determine the magnitude and impact of clinical incidents.

As a result of this review a number of key changes were implemented in June 2016:

- The seriousness of a clinical incident is confirmed by the Director of Clinical Governance. In confirming this determination, the Director of Clinical Governance is now required to ensure the immediate input of a Subject Matter Expert to ascertain the magnitude and impact of the clinical incident and what consequences should be anticipated.
- The clinical subject matter expert, to be included in any future incident reviews, will ideally be from outside the Hospital. This may include experts from other St Vincent's Health Australia hospitals, or from other health services or providers.
- The Director of Clinical Governance will review and formally appoint all investigatory team memberships to ensure a subject matter expert is included.
- The policies are now formally linked so that all future incidents that trigger the Lookback Policy must also be considered for relevance under the Incident Management Policy (and vice versa).
- All Severity Assessment Code 1 and 2 incidents are to be reviewed by a rapid response multidisciplinary team to determine: the requirement for Open Disclosure and who will complete the disclosure; the requirement for a Reportable Incident Brief; the type of investigation to be completed in accordance with policy; the proposed membership of the review team; and management of any immediate clinical risks.

3. When was it determined that Dr Grygiel's flat dosing was not a formal incident?

(a) Who made that decision?

(b) What changed at that point which meant that it was now classified as a formal incident?

(c) Was the decision not to characterise Dr Grygiel's flat dosing as a formal incident for many months consistent with how St Vincent's made other decisions on identification and classification of incidents before June 2015?

St Vincent's response:

Soon after the Hospital's senior executive became aware of the issue in early August, the then Director of Clinical Governance took the view that there was not enough information available at that time for the issues to be classified as an incident.

There was no decision made that it was 'not a formal incident' but rather that more information was required. The Hospital accepts that the process of gathering evidence and seeking external advice about this matter lacked urgency and took too long and has publicly apologised for this.

The Hospital accepts the finding of the s122 Inquiry that we misjudged the seriousness of this matter from the start, which impacted on all other aspects of our response.

St Vincent's Hospital generally performs well in how we respond to incidents in accordance with NSW Health policies.

In 2015, the NSW Ministry of Health Service Capacity Assessment Project (CAP) was undertaken aimed at reviewing Hospital governance processes throughout NSW following government reforms in 2011, which included the establishment of Local Health Districts and Speciality Health Networks with Governing Boards, new activity-based funding agreements and individual service agreements.

In its report, the NSW Ministry of Health reported that St Vincent's had considerable strengths in Network governance and stewardship, legislative compliance systems, risk management, internal audit, clinical governance framework, managing clinical incidents, open disclosure, and partnerships with organisations and the community.

The report also outlined that St Vincent's had rigorous processes in place to manage, monitor and report clinical incidents. All incidents were reviewed within 24 hours and open disclosure was initiated early. The Root Cause Analysis (RCA) process is well accepted and the implementation of recommendations is monitored until closure. RCA findings are discussed at formal governance committees, ward meetings, within stream levels and used for training purposes. St Vincent's was noted as having a Network approach to reviewing RCA findings and recommendations and undertaking clinical reviews where trends in non-serious incidents are noted.

However, we recognise that in the case of Dr Grygiel's off-protocol prescribing we failed to define the seriousness of the incident early on and this impacted on all aspects of our response. We have reviewed our incident management processes and practices as a result, and developed a new Incident Management Training program for managers which has been delivered to the St Vincent's Hospital Sydney Executive, Clinical Stream Directors, Clinical Stream Managers, Heads of Department, Department Managers and Senior Managers (over 150 staff). This program will be provided annually to capture new staff. In addition, it will be delivered as a refresher for existing staff every two years. Further information is provided in the St Vincent's submission to the Parliamentary Inquiry.

4. **Who's view was it that "because patients had received their correct surgery, they had received their correct dose of radiation and that this was a radiosensitising—so an adjuvant therapy—that it was not characterised as being a clinical incident at the time."?**

St Vincent's response

It was a collective view formed over the months following August 2015 based on advice from various team members and team discussions.

5. **On what exact date was Dr Grygiel's flat dosing characterised by St Vincent's as a formal incident?**

   (a) Who made that decision?

   (b) What happened then?

   (c) What date was a Reportable Incident Brief filed?

St Vincent's response

It was not characterised as a formal incident, which was a mistake.

6. On what exact date was the decision to contact patients made?

(a) Who made this decision?

St Vincent's response

On 7 August 2015, the Hospital Executive decided that open disclosure with the affected patients was appropriate and would be conducted.

However, it was decided not to begin contacting patients until further information was available including from the investigations into the issue, so as not to cause unnecessary distress from fractured or incomplete advice. We now recognise this was a mistake.

7. On what date did St Vincent's decide to conduct an external review of the issue of flat dosing?

(a) Who made this decision?

St Vincent's response

The decision to conduct an external review was made on 6 October 2015 by the Director of Cancer Services and Director of Clinical Governance.

8. **On what date did St Vincent's actually commission an external review of the issue of flat dosing?**

   (a) Was Dr Grygiel ever told about this external review?

   (b) If yes, on what date was he told and do you have any record of this communication and can you provide it to the committee?

   (c) Who else knew about this external review?

St Vincent's response

A search for an appropriate reviewer commenced in October and an external reviewer was initially approached on 9 November 2015. This reviewer subsequently declined the invitation and a second external reviewer was approached 11 December 2015.

(a) The Hospital is unable to confirm if and when the Director of Clinical Governance informed Dr Grygiel of the external review.
(b) As above.
(c) Senior officers at St Vincent's.

9. On what date did St Vincent's receive the results of the external review of flat dosing?

St Vincent's response

9 February 2016.

10. **Are you confident that Dr Grygiel always properly informed his patients about the risks and benefits of a proposed procedure, medication or dosage level and any changes that occurred along the way?**

    (a) Do you have documentary records to prove this?

    (b) Do you have documentary records which demonstrate that Dr Grygiel always sought the informed consent of his patients before deciding which medication and dosage to use?

St Vincent's response

St Vincent's Hospital expects all clinicians to comply with our informed consent policy. However, we accept the findings of the s122 Inquiry including those based on interviews with Dr Grygiel's patients.

St Vincent's Hospital has changed a number of processes to improve the information provided to patients including to formally document information provided in patient consent processes.

The existing practice at St Vincent's is that all patients are provided with a copy of the NSW Cancer Institute's eviQ chemotherapy protocol at education sessions ahead of their first treatment and when consent is obtained. Drug doses and frequency of doses, including the likelihood of variations that may need to be made, are also discussed at this time.

St Vincent's is now trialling an additional process to improve the information available for patients for whom a non-eviQ care plan is recommended. These patients are now provided with information in writing about their proposed protocol, including the clinical rationale for proposing an approved non-eviQ protocol. (Only eviQ or approved non-eviQ protocols can be prescribed through MOSAIQ™.) This document is then scanned into the patient information system as an accompanying document to formally record their consent to the variation.

11. Is it policy at St Vincent's to use the NSW Health model consent form to ensure that patients give informed consent to a procedure?

(a) If yes, how do you ensure doctors are using it?

(b) If no, what do you use instead?

(c) What other processes do you have in place to ensure that doctors properly inform their patients about the risks and benefits of the proposed procedure, any changes that may occur along the way and that they have a record of informed consent?

St Vincent's response

Yes.

(a) St Vincent's conducts an annual documentation audit to monitor consent.
(b) n/a
(c) The NSW Health Policy (PD_2005_406) Consent to Medical Treatment – Patient Information was adopted by St Vincent's when it was developed. St Vincent's also has a local protocol in place for Informed Consent (the Informed Consent Protocol). The protocol specifies the requirements and delegations for informed consent specific to St Vincent's and outlines the principles for informed consent that must be applied for any patient that is undergoing an operation, procedure, invasive investigation or treatment.

This policy and protocol applies to all medical treatment at St Vincent's, including chemotherapy. All patients receiving chemotherapy at St Vincent's require a signed consent form which outlines the nature of the chemotherapy to be prescribed as well as the material risks associated with the proposed chemotherapy that was discussed with the patient or person responsible.

As noted in response to Question 10, St Vincent's is now trialling a new additional process to improve the information available for patients for whom a non-eviQ care plan is recommended. These patients are now provided with information in writing about their proposed protocol, including the clinical rationale for proposing an approved non-eviQ protocol. (Only eviQ or approved non-eviQ protocols can be prescribed through MOSAIQ™.) This document is then scanned into the patient information system as an accompanying document to formally record their consent to the variation.

Training on informed consent is provided to all clinical staff at St Vincent's during orientation. Furthermore, our senior medical officer orientation program is being reviewed and will include education regarding St Vincent's expectations for valid informed consent.

12. **When was St Vincent's last audited under the national accreditation system and what were the findings regarding St Vincent's compliance with the requirement for doctors to ensure that patients give informed consent?**

St Vincent's response

In April 2016.

St Vincent's Hospital Sydney was found to have "satisfactorily met" (ie. the actions required have been achieved) the criteria relating to informed consent (Standard 1.1.8: Implementing processes to enable partnership with patients in decisions about their care including informed consent to treatment).

13. **Has St Vincent's completed recommendation 17 of the section 122 inquiry to prepare a new patient information sheet on dose adjustment of chemotherapy to allow patients and their caregivers to understand the rationale for it?**

    (a) If so, when was this completed?

    (b) If not, when will it be completed?

St Vincent's response:

Recommendation 17 of the s122 Inquiry was for implementation by the NSW Cancer Institute. However, St Vincent's fully supports this recommendation.

We have made changes to improve the information provided to patients receiving chemotherapy at St Vincent's.

The existing practice at St Vincent's is that all patients are provided with a copy of the NSW Cancer Institute's eviQ chemotherapy protocol at education sessions ahead of their first treatment and when consent is obtained. Drug doses and frequency of doses, including the likelihood of variations that may need to be made, are also discussed at this time.

St Vincent's is now trialling an additional process to improve the information available for patients for whom a non-eviQ care plan is recommended. These patients are now provided with information in writing about their proposed protocol, including the clinical rationale for proposing an approved non-eviQ protocol. (Only eviQ or approved non-eviQ protocols can be prescribed through MOSAIQ™.) This document is then scanned into the patient information system as an accompanying document to formally record their consent to the variation.

14. Would mandatory reporting by medical practitioners of unsatisfactory professional conduct reduce the risk of an incident like the flat dosing by Dr Grygiel not being picked up for 10 years?

St Vincent's response:

There are already mandatory reporting requirements for 'notifiable conduct' under the *Health Practitioner Regulation National Law Act 2009* (enacted under the *Health Practitioner Regulation National Law (NSW) No 86a*).

15. **Would St Vincent's support mandatory reporting by medical practitioners of unsatisfactory professional conduct?**

    a. **If so, will you make this a condition of employment in the future for all medical practitioners at St Vincent's?**

    b. **If not, why not?**

St Vincent's response:

There are already mandatory reporting requirements for 'notifiable conduct' under the *Health Practitioner Regulation National Law Act 2009* (enacted under the *Health Practitioner Regulation National Law (NSW) No 86a*).

Compliance with all aspects of the *Health Practitioner Regulation National Law Act 2009* is currently an expectation of employment for all medical practitioners at St Vincent's.

16. In what way did St Vincent's, in the words of Mr Toby Hall, "fail to live up to the high standards we set ourselves"?

St Vincent's response:

The mistakes made by St Vincent's Hospital have been articulated by the s122 Inquiry conducted by the NSW Cancer Institute. St Vincent's accepts the findings of the inquiry.

The final report of the s122 Inquiry can be accessed here:
http://www.health.nsw.gov.au/Hospitals/Documents/section-122-final-report.pdf

17. Why did St Vincent's "fail to appreciate the seriousness of the issue from the outset"?

St Vincent's response:

The mistakes made by St Vincent's Hospital have been articulated by the s122 Inquiry conducted by the NSW Cancer Institute. St Vincent's accepts the findings of the inquiry.

The final report of the s122 Inquiry can be accessed here:
http://www.health.nsw.gov.au/Hospitals/Documents/section-122-final-report.pdf

18. Why were St Vincent's internal and external inquiries into this issue not comprehensive or fast enough, as Mr Toby Hall has suggested?

St Vincent's response:

The mistakes made by St Vincent's Hospital have been articulated by the s122 Inquiry conducted by the NSW Cancer Institute. St Vincent's accepts the findings of the inquiry.

The final report of the s122 Inquiry can be accessed here:
http://www.health.nsw.gov.au/Hospitals/Documents/section-122-final-report.pdf

19. Which criticisms of St Vincent's was Mr Toby Hall specifically referring to when he said you "fully accept the criticisms of our hospital"?

St Vincent's response:

The mistakes made by St Vincent's Hospital have been articulated by the s122 Inquiry conducted by the NSW Cancer Institute. St Vincent's accepts the findings of the inquiry.

The final report of the s122 Inquiry can be accessed here:
http://www.health.nsw.gov.au/Hospitals/Documents/section-122-final-report.pdf

20. How have people in senior positions at St Vincent's taken responsibility for what has happened?

St Vincent's response:

St Vincent's executives, including the Hospital CEO and the Group CEO, have:

- Apologised to patients and families affected – and to all our cancer patients – for the distress caused. This apology has been provided directly to patients and their families, and publicly.
- Fully accepted the findings of the s122 Inquiry and agreed to implement all the recommendations.
- Engaged Professor Robert Thomas, Chief Cancer Advisor to the Victorian Government, to independently oversee and report on the Hospital's progress in implementing the s122 Inquiry recommendations at 3, 6 and 12 month intervals.
- The Group and Hospital CEO sit on the implementation steering committee, and the Hospital Implementation Working Group is chaired by the Hospital CEO.
- The Hospital CEO meets with NSW Health monthly to report on progress implementing the recommendations.
- Established two new clinical leadership roles at the hospital – a new Director of Medical Services, who will lead the hospital's medical workforce, and a new Director of Clinical Governance, who will be in charge of medical standards.
- Engaged an external and independent expert to assess the performance of relevant hospital staff in relation to this matter.

21. Can you please update the committee on your response to each of the Currow inquiry recommendations?

St Vincent's response:

St Vincent's progress implementing the s122 Inquiry recommendations as at October 2016 is contained in the 6 month implementation progress report, independently verified by Professor Thomas.

The full report was attached to the Hospital's submission to the Legislative Council Select Committee's Inquiry into off-protocol prescribing of chemotherapy in NSWand can also be accessed online at: https://svhs.org.au/home/newsroom/announcements/off-protocol-prescribing-chemotherapy-6-month-report

22. How are you "aggressively addressing the workplace culture that allowed this to happen"?

St Vincent's response:

St Vincent's Hospital Sydney is implementing a cultural change program in our Cancer Services to build a constructive culture of challenge.

This program of work involves:

- **New leadership and changes in key personnel** – In December 2015, we appointed a new Head of Medical Oncology and new medical oncologists.
- **Measuring staff engagement and satisfaction**
- **A facilitated restorative process** as recommended by the s122 Inquiry for a facilitated restorative process in Cancer Services.
- **Education and Training** including state-wide HETI education programs such as *Clinician Disclosure* and *Building a Safe Workplace Culture*.

In addition, St Vincent's is implementing new programs across St Vincent's Sydney Hospital and the St Vincent's Health Australia Group.

It's OK to Ask (St Vincent's Hospital Sydney)

In July 2016, St Vincent's launched a new campaign for staff *'It's OK to Ask'* to drive cultural change. The campaign aims to ensure patient safety is paramount through encouraging a culture of open dialogue between all staff which is based on mutual respect. The program is sponsored by, and reports to, the Hospital CEO.

'It's OK to Ask' features the following messages:

- St Vincent's fosters a culture of open dialogue between all staff which is based on mutual respect.
- Staff should not be afraid to ask questions of their peers, or raise concerns.
- There are specific avenues available to staff to escalate a concern.

Later in 2016, St Vincent's will roll out phase two of the *'It's OK to Ask'* campaign which will focus on patients and their families. Similar to the staff campaign, the message will be that anyone under St Vincent's care, including their carer or loved-one, has a right to respectfully seek more information or clarification about their treatment. The campaign will align with the Clinical Excellence Commission's REACH program.

Ethos – Inspired to Shine program (St Vincent's Health Australia – National)

The Ethos program aims to foster a culture that encourages feedback, addresses behaviour that undermines patient or staff wellbeing and embeds safe, respectful and professional behaviour so it is what we do every day. This program has St Vincent's Health Australia Board approval and is a priority program across the St Vincent's Group.

For further information about our cultural change programs, please see St Vincent's submission to the Legislative Council Inquiry.

23. Did St Vincent's fail to inform the Ministry until February as part of a cover up?

St Vincent's response:

No.

24. On what date was your new electronic medication system first introduced in the hospital and on what date was it in use across the whole hospital?

St Vincent's response:

St Vincent's implemented the MOSAIQ™ system into clinical practice in March/April 2015 as a booking and electronic clinical records system for cancer ambulatory care areas, with implementation of electronic prescribing of chemotherapy on 10 August 2015.

MOSAIQ™ is used specifically for cancer services.

25. Why specifically was Dr Grygiel's employment terminated?

St Vincent's response:

Dr Grygiel was terminated for serious misconduct.

26. On what date was Dr Grygiel's employment terminated?

St Vincent's response:

4 August 2016.

27. Why has no other person other than Dr Grygiel lost the job over this incident, despite the fact that the section 122 inquiry clearly found that "instead of acting in the best interests of the patients, the organisation's response to the issue was inadequate, drawn out, internalised and defensive"?

St Vincent's response:

Now that the s122 Inquiry is complete, St Vincent's has engaged an external expert to assess the performance of relevant hospital staff in relation to this matter. If further action is required, it will take place once the independent report has been received and examined.

We have also established two new clinical leadership roles at the hospital: a new Director of Medical Services, who will lead the hospital's medical workforce, and a new Director of Clinical Governance, who will be in charge of medical standards. The previous Director of Clinical Governance and Chief Medical Officer, Dr Brett Gardiner, left the Hospital on 10 June 2016.

28. Was Dr Grygiel encouraged by Associate Professor Gallagher to take early retirement to avoid a shit storm?

St Vincent's response:

St Vincent's Hospital was not aware of, or privy to, any such discussions. However, Associate Professor Gallagher has responded to this question in Question 8 directed to him.

29. **When do you expect the independent review of "the actions of all staff who were part of this process" to be completed?**

    (a) Will you make the results of this review available to the Health Ministry?

    (b) Will you make the results of this review available to this committee?

    (c) Will you make the results of this review available to the HCCC?

St Vincent's response:

We expect the independent review to be completed in early 2017.

We would be happy to provide the Committee and NSW Health with an update once the review is completed.

St Vincent's Hospital will take any necessary disciplinary action and/or reporting required as a result of the review.

30. Was Dr Grygiel ever informed that an external review of his performance was being conducted?

St Vincent's response:

The Hospital is unable to confirm if and when the Director of Clinical Governance informed Dr Grygiel of the external review.

31. Was Dr Grygiel exonerated by St Vincent's on 31 August 2015 as he has told the committee?

St Vincent's response:

Please see response to Question 7 directed to Associate Professor Gallagher.

32. On what dates was St Vincent's contacted by journalist Matt Peacock from ABC's 730 program between 1 June 2015 and 1 March 2016?

St Vincent's response:

Mr Peacock first contacted a St Vincent's nurse on 13 November 2015. St Vincent's Hospital responded to Mr Peacock on 17 November 2015.

Mr Peacock made subsequent contact with the Hospital in February 2016 prior to the airing of two ABC 7.30 stories on the issue in that month.

33. Was communication from Matt Peacock a factor in the decision by St Vincent's to commission an external review into the incident?

(a) If so, in what way?

St Vincent's response:

No. The decision to commission an external review was made in October, over a month before the first approach from the 7.30 Report.

The Hospital informed Mr Peacock of its external review in its first contact with him on 17 November 2015.

34. Was communication from Matt Peacock a factor in the decision to stop sending patients to Dr Grygiel?

(a) If so, in what way?

St Vincent's response:

No.

35. Was communication from Matt Peacock a factor in the decision to tell patients about the incident?

(a) If so, in what way?

St Vincent's response:

No.

As noted in response to Question 6, the Hospital had decided in August 2015 that patients would be informed.

At the time of the Hospital's first conversation with Mr Peacock about this matter on 17 November 2015, he was informed that the hospital would move to open disclosure with all affected patients at the completion of the external review.

The Hospital received the external review on 9 February. With that information in hand, it was agreed that the open disclosure process should start as soon as possible, and preparations had begun before 7.30 advised us they were planning to go to air.

It is very regrettable that we were unable to contact many of the affected patients and families before 7.30 went to air.

36. On what date were the first patients first told about the flat-dosing by Dr Grygiel?

(a) How many patients were told before the 18th February 2016?

St Vincent's response:

The open disclosure process commenced on 18 February 2016.

37. Is it satisfactory that Associate Professor Gallagher continued to refer patients to Dr Grygiel after issues of Dr Grygiel's prescribing practices were raised in June 2015?

(a) Is it concerning that he did so because "we had no other medical oncologist"?

(b) Why was St Vincent's unable to employ a different medical oncologist when issues of Dr Grygiel's proscribing practices were raised in June 2015?

St Vincent's response:

Dr Grygiel continued to treat patients while the issue was investigated. However, he ceased flat dosing in June 2015. He agreed to follow eviQ protocols and did so from June 2015. The MOSAIQ™ e-prescribing system was introduced in August 2015, which prevents any doctor from prescribing off-protocol without approval.

Please also see response to Question 14 directed to Associate Professor Gallagher.

38. On what date did Dr Grygiel stop flat dosing his patients?

(a) Does St Vincent's have any documentary evidence to prove this and can this be provided to the committee?

(b) How was Dr Grygiel told to stop flat dosing his patients?

(c) Do you have any record of this communication and can you provide it to the committee?

St Vincent's response:

Dr Grygiel's ceased flat dosing in June 2015.

(a) Our pharmacy records show that the last pharmacy order for 100mg carboplatin made by Dr Grygiel was on 5 June 2015. These records contain confidential patient information.

(b) At a meeting with the Director of Clinical Governance and Director of Cancer Services on 31 August 2015. Please see also response to Question 42.

(c) There were no records kept of the meeting.

39. Was there anyone at St Vincent's other than junior clinicians, junior doctors or pharmacists, who was aware that Dr Grygiel was flat-dosing with chemotherapy prior to June 2015?

St Vincent's response:

Not that the Hospital executive is aware of. Please also see response to Question 40.

40. Mr Hall gave evidence to the committee that "My investigations and the Currow investigations have found no evidence that senior management or clinicians knew." Given:

i. in your final inquiry report you state that "The practice [of flat-dosing] was widely known, and senior pharmacy and nursing staff should have known it was occurring";

ii. Dr Grygiel's evidence to the committee that Dr Dalley was informed in 2006 and again in 2013 and that Dr Cooper had known since the early 2000s; and

iii. the evidence of Dr Cooper where he said that "I find it surprising that those who worked in the medical oncology department did not have more insight as to what was going on" and "others must have known what was going on" and I find it hard to believe that other clinicians with whom he worked did not have an insight as to what he was doing"

Why has the evidence of Dr Grygiel that Dr Cooper and Dr Dalley knew been discounted by St Vincent's?

St Vincent's response:

The s122 Inquiry states (Paragraph 131): "Dr Grygiel's practice of prescribing an off-protocol flat dose carboplatin to many head and neck cancer patients remained unknown to senior hospital management until mid-2015."

The s122 Inquiry (Paragraph 66) was also "unable to corroborate" Dr Grygiel's evidence that there were others who knew about the practice.

Dr Dalley has advised St Vincent's Hospital that he was not aware of the practice and Dr Cooper provided evidence to the Committee that he was similarly not aware.

St Vincent's accepts the findings of the s122 Inquiry. However if there is any further evidence available to the Legislative Council Select Committee Inquiry , or to any other party, that senior Hospital staff or senior clinicians knew and did not escalate the issue, St Vincent's will consider this evidence and take any necessary disciplinary action.

41. Was Dr Dalley ever asked by St Vincent's if he knew about Dr Grygiel's dosage practices before June 2015?

(a) If so, what did he say?

St Vincent's response:

Dr Dalley has advised St Vincent's that he was not aware of Dr Grygiel's practice.

42. Was Dr Grygiel ever counselled by St Vincent's regarding his dosage regime?

(a) If so, when?

(b) If not, was the public statement that Dr Grygiel was "immediately counselled and placed under strict supervision" a lie?

St Vincent's response:

On 31 August 2015, the Director of Clinical Governance, Dr Brett Gardiner and the Director of Cancer Services, Associate Professor Richard Gallagher held a meeting with Dr Grygiel where he was directed to cease his flat-dosing and adhere to the eviQ dosing protocol for all patients.

43. Was the functionality of e-prescribing, which was turned on by the hospital in August 2015 according to Mr Prest, turned on in response to the concerns about Dr Grygiel's dosage practices?

(a) What date was it turned on?

St Vincent's response:

No. The Hospital was implementing MOSAIQ™ in Cancer Services independent of this issue.

The electronic prescribing functionality started on 10 August 2015.

44. Can you confirm that the over 1,500 documents that St Vincent's has submitted to Professor Currow for his inquiry are every document that was relevant to the inquiry?

(a) If not, why were some relevant documents withheld?

St Vincent's response:

Yes, to the best of the knowledge of the Hospital Executive.

45. Were staff of St Vincent's ever counselled on what to say or what not to say to Professor Currow when they were interviewed for his inquiry?

St Vincent's response:

No.

However, all staff were offered the opportunity to meet with a legal support person for general advice on their rights and responsibilities in regard to the Inquiry.

46. Does St Vincent's agree with the assessment of Professor Currow in his report that "instead of acting in the best interests of the patients, the organisation's response to the issue was inadequate, drawn out, internalised and defensive"?

(a) If yes, why did St Vincent's not act in the best interests of your patients?

St Vincent's response:

St Vincent's accepts the findings of the s122 Inquiry.

Our actions were guided by the information we had available at the time but we acknowledge that mistakes were made that have caused distress to our patients. We sincerely apologise to our patients and their families.

47. Was Dr Cooper interviewed by Professor Currow?

St Vincent's response:

Dr Cooper is not an employee of St Vincent's. However, we have been advised by Professor Currow that Dr Cooper declined to be interviewed by the s122 Inquiry.

48. Was Dr Dalley interviewed by Professor Currow?

St Vincent's response:

Yes. However for the Committee's information, Dr Dalley retired from St Vincent's in 2013.

49. Have Mr Gardiner and Dr Gallagher undergone the "comprehensive training program around the Ministry's incident management policy and protocols" that 150 of your senior managers have recently undergone?

St Vincent's response:

Dr Gardiner is no longer an employee of St Vincent's.

Associate Professor Gallagher has undertaken the training.

50. What does St Vincent's say to Dr Grygiel's evidence that there is medical research which backs up his assertion that flat dosing will not have worse outcomes for patients and that "when treating head and neck patients [chemotherapy] is intended as a radiosensitiser and not to kill cancer cells"?

St Vincent's response:

The s122 Inquiry (Paragraph 62) finds: "Dr Grygiel was interviewed by the Inquiry. At the interview, Dr Grygiel was asked whether he was 'aware of any published protocols or guidelines for 100mg flat dose?' to which he replied, 'No'. Further the practice was not overseen by a Human Research Ethics Committee and no data were collected prospectively or retrospectively to establish the net effect of this practice on patients' outcomes (benefits and harms)."

The s122 Inquiry also finds that in relation to the suggestions that off-protocol flat dose prescribing of carboplatin for head and neck cancer was justified because it could reduce toxicity and increase the rate of people completing radiotherapy and radio-sensitising chemotherapy: "No evidence has been presented by Dr Grygiel, or found in the international peer-reviewed literature to support this contention". (Paragraph 61)

St Vincent's accepts the findings of the s122 Inquiry.

51. How many people does St Vincent's understand raised the issue of flat-dosing with Dr Grygiel before it was raised in June 2015?

St Vincent's response:

The Hospital does not have this information.

52. How many cancer patients has Dr Grygiel seen in his time at St Vincent's hospital?

St Vincent's response:

Dr Grygiel was employed at St Vincent's for more than 20 years. It is not possible to collate a specific number of cancer patients that he has seen in this period.

53. How many patients did Dr Grygiel see from June 2015 until his employment was terminated?

St Vincent's response:

Dr Grygiel continued to treat eight patients in the affected cohort between June 2015 and February 2016, however he prescribed according to the eviQ protocol from June 2015.

54. Will St Vincent's commit to assess the treatment regimes of all of Dr Grygiel's patients through St Vincent's hospital, separate from the ministry's review of cancer patients?

St Vincent's response:

St Vincent's has commenced a complete review of the treatment regimes of all of Dr Grygiel's identifiable patients at St Vincent's since 2006 (when the eviQ guidelines were introduced).

The Hospital has fully cooperated with the s122 Inquiry. We are also participating in NSW Health's statewide review of cancer patients.

Further, any St Vincent's patient or family member can request a review of their case at any time.

55. Was the decision by Dr Gallagher to stop referring patients to Dr Grygiel in late 2015 consistent with the policy of St Vincent's or a decision he made on his own?

St Vincent's response:

Please see response to Question 37.

56. Did other doctors at St Vincent's continue to refer patients to Dr Grygiel after Dr Gallagher had stopped referring patients to him?

St Vincent's response:

Please see response to Question 37.

57. Professor Currow told the committee that "Dr Grygiel's practice was conducted in environments that had problems with culture, systems and clinical governance."

(a) What specifically were the cultural problems to which he referred?

(b) Did the cultural problems involve bully of junior staff by senior clinicians?

(c) Did the cultural problems involve bullying of senior clinicians by other senior clinicians?

(d) Were these cultural problems within the medical oncology department?

(e) Were these cultural problems between departments within the cancer unit of St Vincent's?

(f) Do these cultural problems extended beyond just the cancer unit at St Vincent's to other departments in the hospital?

St Vincent's response:

Professor Currow and the Inquiry team made a number of findings about culture which are set out in the s122 Inquiry Report. St Vincent's accepts the findings of the inquiry.

Prior to 2015, there were a small number of allegations of bullying in the Radiation Oncology Department which were investigated and appropriate actions taken.

We are implementing a cultural change program in our Cancer Services involving:

- **New leadership and changes in key personnel** – In December 2015, we appointed a new Head of Medical Oncology and new medical oncologists.
- **Measuring staff engagement and satisfaction**
- **A facilitated restorative process** as recommended by the s122 Inquiry.
- **Education and Training** –including state-wide HETI education programs such *as Clinician Disclosure* and *Building a Safe Workplace Culture*.

Further information about our cultural change program can be found in the St Vincent's submission to the Legislative Council Inquiry.

58. With regard to the entry into RiskMan in 2012 Professor Currow stated that "there was an entry into the incident information management system which was never actually submitted, so it was not a complete report in 2012" and "Someone had started to enter it and that was never completed"

The evidence of Mr Hall regarding this was that "there was a risk management notification from a member of staff. That is where a member of staff has a concern. They register it on the RiskMan database. It goes to their manager and their manager looks at it. The system was manual in those days. It was automated very shortly afterwards. There was no escalation process at that time to double-check that the manager responded to it. The manager thought she had responded to it and she had not. That was on the system and noted."

(a) Did the staff member manually completed the RiskMan document and send it to their manager but the manager never responded to it or was the entry by the staff member never completed and submitted to management?

(b) If the manager never responded to it, why was that?

(c) On what date was the entry made?

(d) On what date was RiskMan automated?

St Vincent's response:

The report was entered in the legacy RiskMan system on 29 February 2012, which included a manual posting system.

In a manual system, any staff member can enter a notification which then goes to a manager for review before being 'posted' by the manager. Only once a report is 'posted' does it get included in incident reports.

In this case, the notification was entered by the staff member but was never 'posted' by the Nurse Unit Managers. It is not clear why the notification was not posted by the Nurse Unit Managers, however there were two very similar notifications entered at the same time and the Managers may have thought they were duplicates. The other notification was posted.

The current RiskMan System which includes 'auto-posting' was implemented on 11 February 2013. Under this system, all notifications go into the consolidated incident reports automatically.

59. Have any staff members at St Vincent's raise any issues of bullying related the issue of Dr Grygiel's dosage practices? If yes:

(a) How many people have raised this issue?

(b) Did the bullying involve Dr Grygiel?

(c) Did the bullying involved Associate Professor Gallagher?

(d) Did the bullying involved Dr Cooper?

St Vincent's response:

No.

60. Specifically how many junior pharmacists, oncology nurses and junior doctors have raised the issue of flat dosing with Dr Grygiel before June 2015?

(a) Have any staff raised the issue more than once?

(b) If so, how many people raised it more than once; and

(c) On how many occasions in total was it raised with Dr Grygiel?

St Vincent's response:

The Hospital does not have this information as concerns were not escalated until June 2015.

61. Dr Grygiel gave evidence that "You must realise that maybe I am not the only person who uses those sorts of doses" and that he had reviewed "84 patients from the St Vincent's Hospital cohort, and two of them were not mine"

(a) Has St Vincent's ever been told by Dr Gygiel that other doctors used flat dosing at St Vincent's?

(b) Does St Vincent's have any evidence that other doctors used flat dosing at St Vincent's?

(c) Is it true that at least two of the patients who were flat dosed were not Dr Grygiel's?

St Vincent's response:

There are instances where clinicians other than Dr Grygiel prescribed 100mg of carboplatin as a personalised dose to treat cancers but which do not reflect a pattern of flat-dosing.

These records have all been provided to the s122 Inquiry who have not identified any pattern of flat dosing by any other St Vincent's medical oncologist. As Professor Currow made clear in his comments before the Committee: "Appropriate variation in prescribing is not only expected but essential. This means the dose is personalised."

62. Do you have any evidence that senior clinicians who worked at hospitals other than St Vincent's were aware of Dr Grygiel's practice of flat dosing?

(a) Have you asked any of the doctors who worked under Dr Grygiel but have since left St Vincent's whether they had told anyone at a hospital other than St Vincent's about Dr Grygiel's practice of flat dosing? If yes, what did they say?

St Vincent's response:

No (to both questions).

63. Did anyone, other than Dr Grygiel, raise Dr Grygiel's practice of flat dosing with anyone other than Dr Grygiel before June 2015?

(a) Who?

(b) On how many occasions?

(c) Who was it raised with?

(d) What was done about it?

St Vincent's response:

This question is not clear.

64. Is any individual, other than Dr Grygiel, is responsible for his flat dosing? If so, who?

St Vincent's response:

Dr Grygiel is responsible for his clinical decisions.

The Hospital has engaged an external and independent expert to assess the performance of relevant hospital staff in relation to this matter.

65. Is any individual or group of individuals is responsible for the flat dosing by Dr Grygiel not being detected by senior clinicians until June 2015? If so, who?

St Vincent's response:

The Hospital has engaged an external and independent expert to assess the performance of relevant hospital staff in relation to this matter.

66. Is any individual or group of individuals is responsible for the flat dosing by Dr Grygiel not being classified as an incident that triggered a reportable incident brief? If so, who?

St Vincent's response:

The Hospital has engaged an external and independent expert to assess the performance of relevant hospital staff in relation to this matter.

67. In his evidence Professor Currow stated that he only received documented evidence of one performance review for Dr Grygiel, in 2014.

(a) Is this because no other annual performance reviews have occurred?

(b) If yes, why not?

(c) If no, then why is there no documented evidence of other reviews?

St Vincent's response:

It is the Hospital's policy that senior medical staff undertake an annual performance review.

The former Director of Medical Oncology, Dr Dalley, has advised the Hospital that he did conduct annual performance reviews of Dr Grygiel. However, there is only one performance review for Dr Grygiel on record (2014). Dr Dalley retired from St Vincent's in 2013.

68. Is St Vincent's compliant with conducting annual performance reviews for all other staff specialists at St Vincents in the past 5 years?

(a) If not, why not?

(b) How many performance reviews for staff specialists have not been conducted by St Vincents in the past 5 years?

St Vincent's response:

St Vincent's is unable to confirm compliance rates for the past 5 years. At this time, records are paper-based and compliance is not reported.

St Vincent's Health Australia is implementing a new HR information system across the organisation in 2017. This system will fully automate all HR functions including performance management for staff specialists.

69. On what date did Professor Schembri contact the Chief Health Officer in November 2015?

(a) What was discussed in this conversation?

(b) What did she recommend St Vincents do?

(c) Did she recommend that you conduct an external review?

(d) Did you tell her that you had had inquiries from Matt Peacock from the ABC about the issue? If so, how did she respond?

(e) Did she recommend that you complete a reportable incident brief?

(f) Did she recommend that you not tell the Ministry formally about the issue?

(g) Are you aware of her telling anyone else about this conversation and if so who?

St Vincent's response:

Associate Professor Schembri contacted Dr Chant by telephone on 16 November 2015.

(a) Associate Professor Schembri advised Dr Chant that the hospital was seeking an external review of a cohort of our cancer patients.
(b) She asked Associate Professor Schembri to speak with the Chief Cancer Officer which he did.
(c) No, the Hospital had already made the decision to seek an external review.
(d) Associate Professor Schembri advised there was media interest.
(e) No
(f) No
(g) Associate Professor Schembri understands she advised Professor Currow.

70. On what date did Professor Schembri contact Professor Currow?

(a) What was discussed in this conversation?

(b) What did he recommend St Vincents do?

(c) Did he recommend that you conduct an external review?

(d) Did you tell him that you had had inquiries from Matt Peacock from the ABC about the issue? If so, how did he respond?

(e) Did he recommend that you complete a reportable incident brief?

(f) Did he recommend that you not tell the Ministry formally about the issue?

(g) Are you aware of him telling anyone else about this conversation and if so who?

St Vincent's response:

Associate Professor Schembri spoke with Professor Currow by telephone on 18 November 2015.

(a) Associate Professor Schembri advised Professor Currow that the hospital was seeking an external review of a cohort of our cancer patients.
(b) Proceed with review.
(c) No, the Hospital had already made the decision to seek an external review.
(d) Associate Professor Schembri advised there was media interest.
(e) No
(f) No
(g) Associate Professor Schembri is not aware.

71. Did anyone at St Vincent's make any other contact with the government or the Ministry, including the Chief Health Officer or Professor Currow, prior to giving formal notice in February 2016?

(a) For each instance, can you please provide details of who was contacted, who contacted them, what date this occurred and what was discussed?

St Vincent's response:

Please see responses to Questions 69 and 70.

72. Is it unusual for St Vincents to conduct an external review on an incident which is not deemed to be a formal incident?

St Vincent's response:

External reviewers are engaged by the hospital from time to time for peer review purposes and not always a result of a formal incident.

73. Should the patients of Dr Grygiel who were flat dosed and their families be compensated even though it will be very difficult to prove they had adverse outcomes due to the small number involved?

(a) If so, who should pay it?

St Vincent's response:

Any claim received by the Hospital will be given due consideration.

Questions for:

Associate Professor Gallagher, Director of Cancer Services, St Vincent's Health Network Sydney

1. **On what specific date did the issue of flat-dosing or under-dosing by Dr Grygiel first come to your attention?**

   (a) Who brought it to your attention?

   (b) How did they do so?

   (c) How many others were present at the time and who were they?

   (d) Do you have any record of this communication and can you provide it to the committee?

Associate Professor Gallagher's response:

I became aware of the issue of off-protocol dosing of carboplatin by Dr Grygiel in June 2015. I do not recall the exact date.

(a) Dr Stephen Cooper.
(b) I was approached by Dr Cooper and he asked me if I was aware that Dr Grygiel was not using the right dose of chemotherapy for treating our head and neck patients. I advised him that I was not aware and indicated that Dr Cooper should provide further information to support his concerns.
(c) There were no others present for this conversation.
(d) I am not aware of any record of this conversation.

2. **You gave evidence that it was raised by Dr Cooper with you on several occasions and you asked him to investigate further before you brought it to the attention of Mr Gardiner. Why didn't you tell Mr Gardiner immediately?**

Associate Professor Gallagher's response:

This is not correct and does not reflect my evidence that "when it came to my attention I brought it up with the Director of Clinical Governance".

When Dr Cooper raised it with me, I indicated that Dr Cooper should provide further information to support his concerns. However, I also raised the issue with Dr Gardiner following this initial discussion with Dr Cooper.

3. On what date were you convinced that the concerns of Dr Cooper were serious enough that they warranted bringing to the attention of Mr Gardiner?

Associate Professor Gallagher's response:

I raised the issue with Dr Gardiner following my initial discussion with Dr Cooper in June 2015. I do not recall the exact date however it was prior to 25 June 2015 (when I started a period of annual leave).

4. **On what date did you bring the issue of flat-dosing or under-dosing by Dr Grygiel to the attention of the director of clinical governance, Brett Gardiner?**

   (a) How many times was the issue raised with you before you decided to bring it the Mr Gardiner's attention?

   (b) How many times did you bring it to his attention before Mr Gardiner made the decision to have an internal review?

   (c) Why do you understand that you needed to bring it to Mr Gardiner's attention "on several different occasions" before he made the decision that there would be an internal review? Why was once not sufficient?

Associate Professor Gallagher's response:

(a) I raised the issue with Dr Gardiner following my initial discussion with Dr Cooper in June 2015. I do not recall the exact date however it was prior to 25 June 2015 (when I started a period of annual leave).

(b) I raised the issue with Dr Gardiner on several occasions.

(c) I cannot say. This question would be best directed to Dr Gardiner.

5. **Did you bring the issue of flat-dosing or under-dosing by Dr Grygiel to the attention of anyone else before Mr Gardiner made the decision to have an internal review?**

Associate Professor Gallagher's response:

Not that I recall.

6. What was the date of the MDT meeting in June 2015 at which Mr Hall asserts that the issue was raised?

(a) Who was present?

(b) What specifically was discussed with regards to Dr Grygiel's dosing practice?

Associate Professor Gallagher's response:

Cancer MDT meetings are held weekly. I do not recall which MDT meeting in June it was discussed in, however it was prior to 25 June (when I started a period of annual leave).

(a) My recollection is that present for the discussion were: Dr Grygiel, myself, Dr Cooper, Dr Chris Hughes and Associate Professor Ron Bova.
(b) Dr Cooper raised that he believed that Dr Grygiel was not prescribing standard doses of Carboplatin for head and neck cancer patients and challenged the practice.

7. Did you tell Dr Grygiel on 31 August 2015 that he had been exonerated?

(a) If not, why do you think he says that you did?

(b) If yes, why did you do so?

Associate Professor Gallagher's response:

No. I did not tell Dr Grygiel that he had been exonerated at any time.

(a) I cannot say. This question would be best directed to Dr Grygiel.

8. **Did you make a phone call to Dr Grygiel and ask him whether he would take early retirement?**

   (a) If yes, did you say to him that he should do this to avoid "a shit storm"?

   (b) If no, why do you think Dr Grygiel has asserted that you did?

Associate Professor Gallagher's response:

I was concerned that media coverage of the issue would be very damaging to Dr Grygiel's reputation. As such I offered advice to him as a colleague that he may wish to consider early retirement.

I did not ask Dr Grygiel to take early retirement. I was not acting on behalf of the Hospital and the Hospital executive were not aware of the discussion.

9. You gave evidence that "he was asked, he was told to change his practice". Which was it?
Was Dr Grygiel asked or was he told to change his practice?

(a) Who by and when?

Associate Professor Gallagher's response:

Dr Grygiel was told to change his practice by Dr Gardiner and myself on 31 August 2015.

10. Did you ever directly ask Dr Grygiel to change his practice of flat dosing patients?

(a) If so, on what date or dates did you ask him?

(b) Do you have any record of this communication and can you provide it to the committee?

Associate Professor Gallagher's response:

Dr Grygiel was told to change his practice by Dr Gardiner and myself on 31 August 2015.

I did not make a record of this discussion.

11. **Did you ever follow up with Dr Grygiel directly to ask whether he had changed his practice of flat dosing patients?**

    (a) If so, on what date or dates did you ask him?

    (b) Do you have any record of this communication and can you provide it to the committee?

Associate Professor Gallagher's response:

There was no need to follow up as I was aware the practice had ceased. The Pharmacist from the Kinghorn Cancer Centre had advised that Professor Grygiel had started using the EviQ protocol.

12. Did Dr Grygiel ever tell you that he would change his practice of flat dosing patients?

(a) If so, on what date or dates did he tell you this?

(b) Do you have any record of this communication and can you provide it to the committee?

Associate Professor Gallagher's response:

At the meeting on 31 August 2015, I understood that Dr Grygiel agreed with the direction from Dr Gardiner and myself to follow the guidelines.

13. Did you ever ask anyone else at the hospital to monitor Dr Grygiel's dosages?

(a) If so, who and when and what did they do about it?

Associate Professor Gallagher's response:

I was aware that Dr Grygiel's flat-dosing practice had ceased.

Further, the MOSAIQ™ e-prescribing system was introduced on 10 August 2015, which prevents any doctor from prescribing off-protocol without approval.

The Director of Pharmacy and Senior Oncology Pharmacists were aware of the concerns that had been raised and were members of the team overseeing the internal review into Dr Grygiel's dosing practice. I believed that pharmacy would have notified either myself or Ms Prest of any irregularities in prescribing practices.

14. On what date did you stop referring patients to Dr Grygiel?

(a) How did you communicate this to him?

(b) Do you have any record of this communication and can you provide it to the committee?

Associate Professor Gallagher's response:

I would like to clarify my evidence about referrals to Dr Grygiel. I have provided an overview below of the referral process for the treatment of head and neck cancer patients at St Vincent's.

All head and neck cancer patients at St Vincent's are discussed at the Head and Neck MDT and a recommendation is made for a treatment pathway for each patient.

For patients undergoing surgery, the surgeon would discuss the surgical pathology results with the radiation oncologist. If chemotherapy was to be considered, the radiation oncologist would then refer patients to the medical oncologist for their opinion. The surgeon did not refer patients to a medical oncologist.

For non-surgical patients, the surgeon is not involved other than as a participant at the MDT.

15. Can you be sure that no patients were given off-protocol doses of chemotherapy by Dr Grygiel after June 2015?

(a) If so, do you have documentary evidence to prove this and can you provide it to the committee?

Associate Professor Gallagher's response:

Yes. See response to Question 38 for St Vincent's Health Australia.

16. If there had been another medical oncologist available in June 2015 at St Vincent's would you have referred patients to that person instead of Dr Grygiel?

Associate Professor Gallagher's response:

Please see my response to Question 14.

17. Why did you not refer patients to a medical oncologist at a different hospital from June 2015 if you had concerns about Dr Grygiel and there was no other medical oncologist with the appropriate skills at St Vincent's?

Associate Professor Gallagher's response:

Please see my response to Question 14.

18. Did Dr Stephen Cooper ever suggest to you that you should stop sending patients to Dr Grygiel after June 2015?

Associate Professor Gallagher's response:

Please see my response to Question 14.

19. Have you ever asked Dr Dalley if he knew about Dr Grygiel's off-protocol proscribing practices before June 2015?

Associate Professor Gallagher's response:

No.

20. Did you ever question Dr Grygiel on his use of carboplatin rather than cisplatin?

Associate Professor Gallagher's response:

It had been discussed at Head and Neck MDTs over the years.

21. **Did any patients who you know to have been flat-dosed or under dosed by Dr Grygiel ever say to you that they wanted the highest dose possible or that they wanted the treatment that would give them the best chance of survival regardless of the side effects?**

Associate Professor Gallagher's response:

Not that I recall.

As a surgeon, my job is to discuss surgical treatments with my patients and support them pre and post surgery.

Surgeons would not generally discuss adjuvant chemotherapy dosage with their head and neck cancer patients. This would be a matter for the medical oncologist.

22. What did you mean in your evidence when you said that "The patients did not even know they were getting the dose"?

Associate Professor Gallagher's response:

I clarified in my evidence that the Committee would need to ask Dr Grygiel about that.

As a surgeon, I would not know first-hand what discussions were had between Dr Grygiel and his patients regarding their chemotherapy dosage, however I note the findings of the s122 Inquiry that "most of the patients and next-of-kin responded that they were not aware of the carboplatin dosage level used for their chemotherapy treatment while under the care of Dr Grygiel" (para 104).

23. In your experience did Dr Grygiel always obtain informed consent from his patients before determining their dosage levels?

Associate Professor Gallagher's response:

Please see my response to Question 22.

24. Did Dr Grygiel ever tell you before June 2015 that he believed that chemotherapy was only "intended as a radiosensitiser and not to kill cancer cells" when treating head and neck patients?

Associate Professor Gallagher's response:

Not that I recall.

Questions for:

David Faktor, Director of Media and Communications, St Vincent's Health Network Sydney

1. What was the exact date you were made aware of the issue?

Mr Faktor's response:

I was made aware of the issue in August 2015.

2. **Can you confirm that Professor Schembri was the person who first told you about the issue?**

Mr Faktor's response:

Associate Professor Schembri briefed me about the issue during a routine weekly catch-up.

3. **What were you told about the level of seriousness of the issue when it was raised with you by Professor Schembri?**

Mr Faktor's response:

From memory, I was told that there was an emerging issue involving one of our oncologists under-dosing some head and neck cancer patients with a specific chemo radio-sensitising drug. I was informed that an internal investigation was underway to determine the extent of the issue and whether his practices had impacted patient outcomes.

Questions for:

Ms Gabrielle Prest, Medicine Clinical Stream Manager, St Vincent's Health Network Sydney

1. **In your evidence you stated that "absolutely" you knew you had a significant problem developing in June 2015. Why do you think that this significant problem not classified as a formal incident by St Vincents?**

Ms Prest's response:

I was first made aware of the issue in the first week of August (specifically Wednesday 5th, ahead of the first joint meeting to discuss the matter on the 7th August) when reports of this off protocol dosing were being discussed with the Director of Clinical Governance.

At the time we needed to understand the extent and nature of the information and concerns raised. From the first meeting on the 7th August, the Director of Clinical Governance directed a plan of approach to conduct the internal review first. We very much appreciate that the full 'Look Back' Policy and procedure should have been followed at that time and that it be viewed as a formal incident.