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:

Professor David Currow, Chief Executive Officer, Cancer Institute NSW and co-leader of the section 122 inquiry

1. In your opening statement to the committee you said:

   "The inquiry found Dr Grygiel's prescribing with these two particular drugs was not supported by evidence."

   What is the second drug you were referring to apart from carboplatin?

   Capecitabine

2. You stated 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 you referred?

   I refer the Committee to Question 1 (b) of the questions for Mr Paul Gavel, and his response.

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

   I refer the Committee to Question 1 (d) of the questions for Mr Paul Gavel, and his response.

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

   No.

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

   Yes.

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

   No.

   (f) Did your inquiry receive evidence that these cultural problems extended beyond just the cancer unit at St Vincent's to other departments in the hospital?

   No such evidence was given; the Inquiry was not asked to look at other Departments at St Vincent's.

3. 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"

      (a) Do you conclude that the balance of the evidence suggests that Dr Grygiel is wrong when he says that other Senior Clinicians knew before June 2015?

      (b) If not, do you conclude that the balance of the evidence suggests that Dr Grygiel is correct when he says that other Senior Clinicians knew before June 2015?

      (c) If not, what do you conclude?

As stated in its Final Report, the Inquiry was unable to corroborate Dr Grygiel's statement about others being aware of the practice.

A dose of 100 mg carboplatin is not necessarily a flat dose of 100 mg carboplatin. As noted in the Report, there are patients for whom 100 mg carboplatin would be the personalised dose. By contrast, the Inquiry went to considerable effort to identify people for whom the dose was not a personalised dose.

Regardless of whether anything was known prior to June 2015 and by whom, it is clear to the Inquiry that a fundamental change occurred in June 2015. From its clinical review, the Inquiry found that no patients received a flat dose of 100 mg carboplatin after June 2015.

4. With regard to the entry into RiskMan in 2012 you 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 of St Vincent's 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) Is it your understanding from the evidence your inquiry has received that the staff member manually completed the RiskMan document and sent it to their manager but that the manager never responded to it or that the entry by the staff member was never completed and submitted to management?

   The Inquiry's understanding is that the process for entering the incident into the incident information management system (IIMS) was never completed.

(b) Does the evidence of Mr Hall that it was the fault of the manager and not the staff member that the issue was never followed up conflict with your understanding?

See the answer to (a) above.

5. Did any staff members at St Vincent's raise any issues of bullying when interviews were conducted for your inquiry?

I refer the Committee to Question 2 of the questions for Mr Paul Gavel, and his response.

(a) How many people raised this issue?

I refer the Committee to Question 2(a) of the questions for Mr Paul Gavel, and his response.

(b) Did the bullying involve the staff member who tried to raise the issue in 2012?

I refer the Committee to Question 2(b) of the questions for Mr Paul Gavel, and his response.

(c) Did the bullying involve Dr Grygiel?

I refer the Committee to Question 2(c) of the questions for Mr Paul Gavel, and his response.

(d) Did the bullying involved Associate Professor Gallagher?

I refer the Committee to Question 2(d) of the questions for Mr Paul Gavel, and his response.

6. Specifically how many junior pharmacists, oncology nurses and junior doctors advised your inquiry that they had raised the issue of flat dosing with Dr Grygiel before June 2015?

Four. Several people indicated to the Inquiry that they were aware of the issue having been raised with Dr Grygiel by other people on multiple occasions.

(a) Did any staff indicate that they had raised the issue more than once?

Yes.

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

Four.

and

(c) On how many occasions in total were you given evidence that it was raised?

Three of the four people who indicated they had raised the issue more than once did not state precisely how many times they had raised it.

7. Other than Dr Cooper and Dr Dalley, was there anyone else that Dr Grygiel told your inquiry he had told about his flat dosing before June 2015?

There was no-one else Dr Grygiel told the Inquiry he had *told* about his off-protocol dosing; he did indicate he had discussed the matter with staff who had raised it with him.

8. In your evidence regarding how flat dosing was raised in June or July 2015 you stated that "there were several versions of this put to the inquiry. One was that it was a nurse working together in clinic with a medical practitioner. Another was that it was a medical practitioner seeing patients in consultation that raised concerns at that time."

   (a) Is it your understanding that the two medical practitioners you refer to are the same person?

   No.

   (b) Was that person, or one of those people Dr Cooper?

   I refer the Committee to the evidence given at the hearing of the Inquiry's decision not to identify individuals who provided information to the Inquiry, in order to ensure full and frank discussions.

   (c) If they were not the same person, who were they?

   They were two different medical practitioners.

   (d) Was the nurse the same person who made the RiskMan entry in 2012?

   I refer the Committee to the evidence given at the hearing of the Inquiry's decision not to identify individuals who provided information to the Inquiry, in order to ensure full and frank discussions.

9. In your evidence you stated that "my recollection is that there were four people who declined [to participate in your inquiry]".

   (a) Can you confirm that this is correct?

   Yes.

   (b) Did each of them formally decline, or did they just not respond to the request?

   Three formally declined; one person who initially agreed to be interviewed subsequently indicated they were seeking legal advice.

   (c) What reasoning was given for not participating in your inquiry by each of the 4 people who declined to participate?

   None of the four was currently employed by St Vincent's. One declined on legal advice, one was seeking legal advice and two simply declined.

   (d) How did each of the 4 people communicate to the inquiry that they would not participate?

   Two communicated through St Vincent's, one directly and one through their lawyers.

   (e) Did any of the three junior medical staff who declined work under Dr Grygiel?

   They were registrars who had worked with Dr Grygiel at some time on rotation.

(f) Was the senior clinician who declined to participate a member of Dr Grygiel's medical oncology department?

No.

(g) Was the senior clinician a current of employee of St Vincent's?

No.

10. You also gave evidence that "One of the people [who decline to participate] offered to answer some written questions. It was not felt that that would particularly aid the inquiry."

(a) Was this person one of the 3 junior medical staff or the Senior Clinician?

No.

(b) Why did your inquiry conclude that this would not aid the inquiry?

The evidence already provided to the Inquiry by the people interviewed was sufficient to provide a clear and consistent picture of the clinical governance and cultural issues that needed to be dealt with.

11. Did your inquiry interview Dr David Dalley?

Yes.

12. Did your inquiry interview Dr Stephen Cooper?

No.

13. In his evidence to the committee, Associate Professor Gallagher stated that the reason he continued to send patients to Dr Grygiel after becoming aware of the flat dosing was that "Unfortunately for me we had no other medical oncologist"

(a) Is it unusual in your experience for a public hospital to not be able to call on another medical oncologist if they have concerns about sending patients to the existing doctor?

From its clinical review, the Inquiry found that no patients received a flat dose of 100 mg carboplatin after June 2015. As such, Dr Gallagher was referring patients to a medical practitioner who had discontinued prescribing flat dose 100 mg carboplatin and was prescribing personalised doses of either carboplatin or cisplatin, as outlined in the Inquiry's report.

The nature of sub-specialist clinical practice generally, not just in cancer, is that often there will be only one sub-specialist in a particular sub-specialty, even in a large teaching hospital.

(b) Are you concerned that Associate Professor Gallagher chose to keep sending patients to Dr Grygiel even though he had concerns about his clinical practice?

See the answer to (a) above. The Inquiry was presented with no evidence of ongoing concerns, by any people interviewed, after the prescribing of flat dose 100 mg carboplatin had been discontinued.

14. 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) Did your inquiry receive evidence from Dr Gygiel that other doctors used flat dosing at St Vincent's?

    No.

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

    No. The two patients to whom I understand Dr Grygiel to be referring were patients of another practitioner who received carboplatin as a personalised dose that happened to be *calculated* at a dose of 100 mg.

    (c) Did your inquiry receive any evidence from anyone else that doctors other than Dr Grygiel used flat dosing at St Vincent's?

    No.

15. Did anyone provide evidence to your inquiry that senior clinicians who worked at hospitals other than St Vincent's were aware of Dr Grygiel's practice of flat dosing?

    The Inquiry was not provided with any evidence of this.

    (a) Did your inquiry ask 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?

    No-one was asked that question.

16. Did anyone, other than Dr Grygiel, give evidence to your inquiry that they had raised Dr Grygiel's practice of flat dosing with anyone other than Dr Grygiel before June 2015?

    Yes.

    (a) Who?

    Two people indicated that a pharmacist had raised it.

    (b) On how many occasions?

    The Inquiry was told of one occasion.

    (c) Who was it raised with?

    The two people indicated it had been raised with a senior clinician. The senior clinician concerned indicated that no-one had raised it with him/her.

    (d) What was done about it?

    See (c) above.

17. In your evidence you said that your inquiry's report makes it clear that "There is a problem in culture, there is a problem in systems, there is a problem in clinical governance."

Do you think any individual, other than Dr Grygiel, is responsible for his flat dosing? If so, who?

No.

(a) Do you think 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?

No.

(b) Do you think 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?

Several meetings occurred in early August 2015. None of them sought content expertise from a medical oncologist. This was acknowledged as an error by St Vincent's.

18. Can you confirm whether there were any clinicians that you interviewed who gave evidence to indicate that they had raised concerns about flat dosing on more than one occasion?

See the response to 6(b).

19. In your evidence you stated that you only received documented evidence of one performance review for Dr Grygiel, in 2014.

(a) Did St Vincent's tell your inquiry that this was because no other annual performance reviews had occurred or that they simply could not find the documentation for any others?

I refer the Committee to Question 1 of the questions for Dr Paul Curtis, and his response.

(b) Did your inquiry ask Dr Grygiel whether any other annual performance reviews had occurred? If so, what did he say?

No.

20. 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?

The notification of *notifiable conduct* is a requirement of the Health Practitioner Regulation National Law (which is applied, with modifications, as a law of NSW by the *Health Practitioner Regulation (Adoption of National Law) Act 2009 (NSW)*).

21. Do you think there should be mandatory reporting by medical practitioners of unsatisfactory professional conduct built into law, as it is for drug use and sexual misconduct?

See the response to 20 above.

22. In your section 122 report you state that "Under clause 2.5.6 of the Incident Management Policy, St Vincent's Hospital should have consulted the Ministry of Health when they determined to go to external review… There is no evidence of this occurring." The committee has since received evidence that St Vincent's made contact with the Chief Medical Officer and yourself in November 2015 to consult you about going to an external review. Is this not evidence of consultation with the Ministry of Health which you were aware of when preparing your report?

This was not consultation and it would be incorrect to refer to it as such. The contact was "for information" to the Chief Health Officer that there had been a media inquiry. Consultation about an incident would occur through a formal written process, which would include a Reportable Incident Brief, followed up by a more detailed In-Brief.

23. On what date did Professor Schembri contact you in November 2015?

10 November 2015.

(a) What was discussed in this conversation?

That there had been media interest in an issue relating to chemotherapy, and that it was in hand. No details of the chemotherapy, the prescriber or the prescribing were discussed.

(b) What did you recommend St Vincent's do?

A recommendation was not sought.

(c) Did you recommend that St Vincent's conduct an external review?

See the response to (b) above.

(d) Did Professor Schembri tell you that ***you*** *[sic]* had had inquiries from Matt Peacock from the ABC about the issue? If so, how did you respond?

I was not provided with details about the media inquiry, only that there had been media interest.

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

There was no information to suggest that a Reportable Incident Brief was required.

(f) Did you recommend to St Vincent's that they not tell the Ministry formally about the issue?

No.

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

No. Nor was it mentioned in any of the material St Vincent's provided to the Inquiry in response to the Inquiry's detailed questions about the prescribing incident.

(h) Did you tell anyone in the Ministry about this conversation before February 2016 and if so who?

No.

24. Did anyone at St Vincent's make any other contact that you are aware of with the government or the Ministry, including the Chief Health Officer or yourself, prior to giving formal notice in February 2016?

No.

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

See the response to 24 above.

25. Did you tell the Ministry that you were aware of the issue at St Vincent's in November 2015 before

agreeing to complete the section 122 inquiry?

I was not given sufficient information in November 2015 to enable me to realise the incidents were connected.

26. Have you ever told Minister Skinner or her office that you were aware of the issue at St Vincent's in November 2015?

No.