

Select Committee on Off-Protocol Prescribing of
Chemotherapy in New South Wales

Off-protocol prescribing of chemotherapy in New South Wales

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Terms of reference

1. That a select committee be established to inquire into and report on off-protocol prescribing of chemotherapy in NSW including at St Vincent's Hospital, St George Hospital, Sutherland Hospital, Macquarie University Hospital and clinics at Orange and Bathurst, and in particular:
 - (a) the efficacy of electronic prescribing systems, and their capacity to stop or limit off protocol prescribing of chemotherapy,
 - (b) the value of a potential new patient information sheet on dose adjustment for patients and caregivers information,
 - (c) the process and systems around informed consent for all medical interventions, including chemotherapy,
 - (d) the capacity of the NSW Health system to have all notifiable cancer patients in New South Wales overseen by a Multidisciplinary Cancer Care Teams, and if this may prevent off-protocol prescribing,
 - (e) St Vincent's Hospital capability to comply with relevant NSW Health Policy Directives and Guidelines, particularly Open Disclosure Policy (PD2014_028) and Incident Management Policy (PD2014_004),
 - (f) the NSW Health Code of Conduct and specific programmes within NSW Health and St Vincent's Hospital, in relation to staff raising concerns about the practice of clinicians, and other breaches of the Code of Conduct.
2. That the committee report by 19 May 2017.

The terms of reference were referred to the committee by the Legislative Council on 11 August 2016 and the reporting date was extended from March 2017 to 19 May 2017.¹

¹ *Minutes*, NSW Legislative Council, 11 August 2016, pp 1050-1054 and 22 February 2017, p 1399.

Committee details

Committee members

The Hon Paul Green MLC	Christian Democratic Party	<i>Chair</i>
The Hon Bronnie Taylor MLC	The Nationals	<i>Deputy Chair</i>
Mr Jeremy Buckingham MLC	The Greens	
The Hon Daniel Mookhey MLC*	Australian Labor Party	
The Hon Trevor Khan MLC	The Nationals	
The Hon Natasha Maclaren-Jones MLC	Liberal Party	
The Hon Walt Secord MLC	Australian Labor Party	

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* The Hon Daniel Mookhey MLC has substituted for the Hon Courtney Houssos MLC from 9 February 2017 for the duration of the inquiry.

Chair's foreword

Getting a diagnosis of cancer is a moment of crisis for any individual, when their world explodes and nothing feels like it will ever be the same again. In that moment the individual becomes a patient and places their life in their doctors' hands.

A key theme of the inquiry has been trust – the profound trust that cancer patients and their families place in their treating clinicians and also in their hospital. Every patient must be able to trust that their doctor is acting within the bounds of reasonable care, with their consent. They must also be able to trust that if their doctor's actions are called into question, their hospital will act quickly to inform and protect them.

Our inquiry has found that St Vincent's Hospital did not live up to the trust that patients placed in it. It is abundantly clear to the committee that the hospital's failures in identifying the issue and responding to the allegations of off-protocol chemotherapy prescribing were substantial, multifaceted and prolonged. The hospital's key failures were that it did not escalate numerous concerns raised by staff in a reasonable timeframe; it did not understand the seriousness of the issue; it failed to grasp the imperative to act quickly; it failed to communicate with patients effectively, and to support them appropriately. The failure to engage external expertise to illuminate the clinical significance of the problem at an early stage was pivotal. And, as the hospital has recognised, its actions only served to compound patients' distress. Therefore, the committee is unable to discount the possibility of a cover-up.

St Vincent's Hospital is now setting about rebuilding the trust of patients and the community. It has acknowledged its many failures and publicly apologised for them. The committee accepts its leaders' assurances that they take responsibility for what occurred and are leading a process of cultural change to ensure that it does not happen again.

There was a consensus among inquiry participants that clinical guidelines and protocols for prescribing chemotherapy treatment are necessary, but they must also allow for flexibility for the individual patient. The committee heard that cancer treatment is not recipe book medicine, but must be customised to the needs of each patient. Doctors possess the expertise to make these judgement calls with the consent of patients, but where their judgements go beyond reasonable limits, it is important that effective safeguards be in place.

There are four pillars to this report, which run as themes throughout the chapters on St Vincent's Hospital, other hospitals and the broader health system: organisational culture and training; multidisciplinary teams; informed consent; and incident reporting and management. The committee is confident that concerted efforts on each of these pillars – in individual hospitals and across the health system – will deliver safeguards against future off-protocol prescribing of chemotherapy. More positively, they will also help build quality, holistic care.

I thank all inquiry participants including those who shared their personal patient and carer stories and the doctors and hospital administrators who were forthcoming in the face of direct questioning. From our perspective as a parliamentary committee, the public interest is well served by shining a light on what has gone wrong and providing a considered way forward.

I thank my committee colleagues for their hard work and their commitment to understanding and improving the cancer treatment system across the state. While the impetus for the inquiry was a scandal in a particular hospital, I feel confident that we together have made a positive contribution to the broader health system. I also thank the committee secretariat for their hard work and professional support.



Hon Paul Green MLC
Committee Chair

Finding and recommendations

- Finding** **82**
 That St Vincent’s Hospital Sydney failed to prevent and to respond effectively to the off-protocol prescribing of chemotherapy that occurred in the hospital. However, it has since taken responsibility for these failures and is addressing them appropriately.
- Recommendation 1** **95**
 That the Western NSW Local Health District:
- ensure that its review of medical specialist outreach service arrangements encompasses all of the Western NSW Local Health District, with a strong focus on fly-in fly-out medical specialists
 - establish proper governance structures to ensure fly-in fly-out medical specialists are subject to the same safeguards as locally based clinicians.
- Recommendation 2** **107**
 That the Cancer Institute NSW:
- ensure that, in the interests of transparency, all evaluations of the outcomes for patients who received an off-protocol flat dose of 100 mg carboplatin or reduced dose capecitabine be independently evaluated and published, subject to patient confidentiality
 - keep the affected cohort of patients informed as to the capacity of the evaluation dataset to shed light on their health outcomes
 - continue to monitor and assess the morbidity and mortality rates of the affected patient cohort and compare and contrast with expected ranges until at least 2022.
- Recommendation 3** **108**
 That the NSW Ministry of Health, in the interests of transparency and building the community’s trust in the health system, publish the results in detail of its audit of public cancer patients, subject to patient confidentiality.
- Recommendation 4** **134**
 That the Cancer Institute NSW examine whether, beyond allowable individualised dose adjustments, a model for oversight of significant variations to chemotherapy protocols should be adopted statewide.
- Recommendation 5** **135**
 That the Cancer Institute NSW ensure that all local health districts and specialty health networks have a functioning oncology management information system in place by early 2018.
- Recommendation 6** **135**
 That the NSW Ministry of Health and Cancer Institute NSW develop and implement an action plan to ensure that all people diagnosed with notifiable cancer in New South Wales have their care overseen by a multidisciplinary cancer care team that includes all relevant medical, nursing, pharmacy and allied health staff.

Recommendation 7**137**

That the NSW Ministry of Health and the Cancer Institute NSW undertake and publish a review of best practice in multidisciplinary cancer care teams that considers the evidence about:

- the benefits of ongoing team oversight of individual patients
- the role of the team with respect to oversight of chemotherapy dosing decisions
- team membership
- whether clinician attendance should be compulsory.

The review should then form the basis for NSW Health policy in respect of multidisciplinary cancer care teams across New South Wales.

Recommendation 8**138**

That NSW Ministry of Health:

- continue to build the capacity of all health professionals to fulfil their ethical and legal obligations with regard to informed consent
- with the Cancer Institute NSW, implement further strategies to empower patients to fully exercise informed consent.

Recommendation 9**138**

That the NSW Ministry of Health implement improved patient consent procedures which include 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
- when consent is obtained after a non-eviQ plan is recommended, patients are provided with information about the proposed protocol, including the clinical rationale for it, and a completed patient consent form is scanned into the patient information system.

Recommendation 10**138**

That the NSW Ministry of Health ensure that all key clinical staff are educated in expectations regarding valid informed consent.

Recommendation 11**139**

That the NSW Ministry of Health consider establishing a system of independent patient advisor-advocates in hospital cancer services, based on the official visitor model, as a means of empowering patients.

Conduct of inquiry

The Select Committee on Off-Protocol Prescribing of Chemotherapy in New South Wales was established by resolution of the Legislative Council on 11 August 2016.

The committee received a total of 115 submissions and 10 supplementary submissions from a range of stakeholders. A list of submission makers is contained in appendix 1.

The committee held five hearings at Parliament House on 31 October 2016, 1 November 2016, 29 November 2016, 24 February 2017, 31 March 2017 and one hearing in Orange at the Ex-Services' Club on 2 November 2016. A list of witnesses can be found in appendix 2.

Inquiry related documents are available on the committee's website, including submissions, hearing transcripts, tabled documents and answers to questions on notice.

Procedural issues

The committee resolved to issue a summons for Dr Brett Gardiner, former Director of Clinical Governance at St Vincent's Health Network, to give evidence in response to a request from his legal representatives. Dr Gardiner's lawyers were concerned that, without a summons, Dr Gardiner would not be protected from legal action that may stem from breaching confidentiality obligations.

The position of the Legislative Council is that a summons is not required to protect a witness from legal or other repercussions that may stem from breaching confidentiality obligations. This protection is provided by virtue of a committee hearing being a parliamentary proceeding with the consequent rights afforded under article 9 of the *Bill of Rights 1689* and section 12 of the *Parliamentary Evidence Act 1901*. Nevertheless, the committee took the view that issuing a summons would provide a level of reassurance to the witness and proceeded in that manner.

Chapter 1 Background

This chapter provides an explanation of key terms and concepts in chemotherapy treatment, chemotherapy treatment protocols in New South Wales, a brief summary of the events leading to the establishment of this inquiry, an overview of the section 122 inquiry initiated by the Secretary of the NSW Ministry of Health² and a brief description of the current investigations underway at the Health Care Complaints Commission and Medical Council of New South Wales.

What is chemotherapy?

1.1 Chemotherapy treatment is the use of drugs to damage and destroy cancer cells. Chemotherapy drugs are cytotoxic, meaning ‘toxic to cells’, and work by damaging cells as they divide. Traditional chemotherapy drugs, sometimes known as ‘non-targeted’ drugs, damage all cells; cancer cells divide more rapidly than most normal cells and are therefore most affected by chemotherapy. Some normal cells, including hair follicles, bone marrow, and cells inside the mouth or bowel also divide rapidly and so people undergoing chemotherapy treatment may experience damage to these cells for the duration of the treatment.³

What is the purpose of chemotherapy?

1.2 Chemotherapy is administered for a range of purposes in the treatment of cancer; the choice of drug and dosage rate will be adjusted according to the chosen purpose. Chemotherapy can be administered on its own or in conjunction with other treatments. Typical chemotherapy treatments include:

- **Curative chemotherapy** - Curative chemotherapy aims to cause the cancer to reduce or disappear (go into remission)
- **Neoadjuvant and adjuvant chemotherapy** - Chemotherapy may be administered with other treatments such as surgery or radiotherapy to improve the effectiveness of those treatments. Neoadjuvant chemotherapy is delivered before other treatments to reduce the cancer. Adjuvant chemotherapy is delivered after other treatments to destroy any remaining cancer cells.
- **Maintenance chemotherapy** - After initial chemotherapy has achieved remission of the cancer, maintenance chemotherapy may be given for months or years afterwards to prevent or delay the cancer returning.
- **Chemoradiation** - Chemoradiation is chemotherapy administered concurrently with radiation. Chemotherapy given for this purpose has the effect of sensitising cancer cells to radiation, increasing the efficacy of the radiation treatment.
- **Palliative chemotherapy** - It may not always be possible to achieve remission of a cancer, however palliative chemotherapy can assist in controlling the cancer’s growth

² The NSW Ministry of Health was formerly known as the NSW Department of Health and is referred to interchangeably as NSW Health.

³ Cancer Council Australia, *Understanding Chemotherapy*, August 2016, pp 8 and 33.

and stopping its spread for an extended period of time or by shrinking a tumour that is causing pain and other symptoms, with the goal of improving quality of life.⁴

How is a course of chemotherapy treatment chosen?

- 1.3** Clinicians treating people with cancer usually work as part of a multidisciplinary team to devise an individual treatment plan for each patient. The plan will specify whether a patient receives surgery, chemotherapy, radiation treatment or a combination of these. Medical oncologists within the multidisciplinary team will make treatment decisions in relation to the prescribing and administration of chemotherapy.⁵
- 1.4** In New South Wales there are established standardised treatment protocols and clinical guidelines for the administration of chemotherapy treatment. The treatment protocols and guidelines are evidence-based and peer-reviewed, drawing on state, national and international resources.⁶

Clinical guidelines

- 1.5** Clinical Practice Guidelines for use in New South Wales were developed by the United States' National Comprehensive Cancer Network and include recommendations on prevention, diagnosis, treatment and supportive care to optimise patient outcomes. The guidelines provide specific directions on which chemotherapy treatment to choose. The guidelines document evidence-based, consensus-driven approaches and are used in conjunction with treatment protocols when developing individual patient treatment plans.⁷

Treatment protocols

- 1.6** New South Wales has established evidence-based treatment protocols which complement the Clinical Practice Guidelines by providing information on optimal administration of chemotherapy once a treatment plan has been established.⁸ Protocols are based on the best available published evidence from clinical trials and describe:
- the treatment schedule (drug name, drug doses and the way the doses are to be calculated, the number and frequency of the doses, how the drugs are administered)
 - any tests required before, during or after treatment
 - possible side-effects
 - situations where it may be appropriate to change doses, dose intervals or choose another chemotherapy protocol altogether.⁹

⁴ Cancer Council Australia, *Understanding Chemotherapy*, August 2016, pp 9 and 23.

⁵ Submission 49, NSW Ministry of Health, p 5.

⁶ Submission 49, NSW Ministry of Health, p 5.

⁷ Submission 49, NSW Ministry of Health, p 6.

⁸ Submission 49, NSW Ministry of Health, p 6.

⁹ NSW Ministry of Health, *Inquiry under section 122 of the Health Services Act 1997: Off-protocol prescribing of chemotherapy for head and neck cancers*, Final report, 31 July 2016, (hereafter section 122 inquiry final report), p 7.

How are treatment protocols accessed by clinicians?

- 1.7 Treatment protocols accepted for use in New South Wales are provided on eviQ, an internet-based cancer treatment resource launched in 2009. The eviQ protocols are based on the best and most comprehensive evidence available at the time they are established and are reviewed periodically to ensure their content reflects the latest evidence.¹⁰
- 1.8 While a large number of accepted treatment protocols for particular cancers may be available on eviQ, it does not provide guidance on which protocol may be best for an individual patient. For example, there are 26 head and neck cancer protocols on eviQ. Different protocols may have equal efficacy, and oncologists often become expert at delivering two or three different protocols for a particular cancer and anticipating their side effects.¹¹

How is a chemotherapy dose determined?

- 1.9 As noted earlier, chemotherapy can be used for a number of different purposes when treating cancer and the type of chemotherapy treatment chosen for the individual will vary according to the purpose that chemotherapy is being administered for the particular cancer type, the stage of the cancer and individual patient characteristics such as age, gender and comorbidities.
- 1.10 Determining the appropriate individual chemotherapy drug dosage rate involves considering the treatment protocol for the chosen drug and administering the chemotherapy drug within a therapeutic range that balances the anti-cancer effect of the drug with adverse side effects.¹²

Therapeutic range

- 1.11 The therapeutic range (or therapeutic window) of a drug is the dosage range in which the drug will have a beneficial effect without causing significant adverse side effects. Chemotherapy drugs have a very narrow therapeutic range. Administering a chemotherapy drug in too small a dose will lead to reduced efficacy, allowing normal cells to survive without killing cancer cells. Administration of a chemotherapy drug at too high a dose will lead to increased toxicity, killing not only cancer cells but also too many normal cells, leading, in extreme cases, to death.¹³ The therapeutic range of chemotherapy drugs is reflected in chemotherapy treatment protocols.

Dosage adjustment

- 1.12 After considering and selecting a treatment protocol, clinicians may individualise treatment by adjusting the dosage according to a patient's age, health, height, weight and other factors such

¹⁰ NSW Ministry of Health, *Inquiry under section 122 of the Health Services Act 1997: Off-protocol prescribing of chemotherapy for head and neck cancers*, Interim report, 31 March 2016, (hereafter section 122 inquiry interim report), p 6.

¹¹ *In camera* evidence, Dr David Bell, Senior Medical Oncologist, Northern Cancer Institute, 31 October 2016, pp 6-7. Evidence published by resolution of the committee.

¹² Section 122 inquiry final report, p 6.

¹³ *In camera* evidence, Dr Bell, 31 October 2016, p 1.

as gender and ethnicity.¹⁴ After treatment has commenced clinicians may further modify subsequent doses if, for example, a patient has an adverse reaction to the drug.¹⁵

- 1.13** Many patients in New South Wales receive individualised chemotherapy treatments that vary from published treatment protocols, however, this variation is appropriate and essential.¹⁶ Variation from treatment protocols should always be discussed with the patient and recorded in the patient's medical records.¹⁷

Off-protocol prescribing of chemotherapy

- 1.14** Off-protocol prescribing of chemotherapy is considered to occur when treatment varies significantly from published treatment protocols and is not supported by evidence, when doses are not personalised to an individual patient, or when the justification for a dose variation is not clearly documented or communicated to patients.¹⁸

How are chemotherapy drug doses calculated?

- 1.15** The following calculations are found in treatment protocols for chemotherapy drugs in New South Wales:
- **Area under the curve (AUC)** – AUC chemotherapy drug dosing is calculated according to a function of an individual's age, gender, body weight and renal function.
 - **Body surface area (BSA)** – BSA calculates the surface area of an individual using a formula relating to weight and height.
 - **Flat dosing** (or fixed dosing) – Flat dosing prescribes the same dose irrespective of an individual's personal characteristics such as weight. The newer class of targeted therapy drugs are dosed using flat dosing.¹⁹

Which chemotherapy drugs are relevant to this inquiry?

- 1.16** **Cisplatin** – Cisplatin is a platinum based drug used to treat a wide range of cancers. Cisplatin has a number of strong side effects including nausea, vomiting, and damage to kidneys, nerves and hearing. Cisplatin is considered the first drug of choice when treating head and neck cancers because it has the most evidence of efficacy when used in combination with radiotherapy. Cisplatin doses are calculated using BSA and renal function.²⁰

¹⁴ NSW Ministry of Health, *Inquiry under section 122 of the Health Services Act 1997: Prescribing of chemotherapy*, Report on patients treated at Western NSW Local Health District, 16 September 2016 (hereafter section 122 inquiry Western NSW Local Health District report), p 9.

¹⁵ *In camera* evidence, Dr Bell, 31 October 2016, pp 11-12.

¹⁶ *In camera* evidence, Dr Bell, 31 October 2016, p 9.

¹⁷ Section 122 inquiry final report, p 7.

¹⁸ Evidence, Professor David Currow, Chief Executive Officer, Cancer Institute NSW, Chief Cancer Officer NSW, Chair of Section 122 Inquiry, 31 October 2016, p 2.

¹⁹ *In camera* evidence, Dr Bell, 31 October 2016, p 3.

²⁰ Section 122 inquiry final report, p 10.

- 1.17 Targeted therapy** – Newer cancer treatment drugs are targeted, acting only on specific genes or proteins within cancer cells. Targeted therapy drugs are prescribed using flat dosing and are often used in conjunction with chemotherapy or radiotherapy. For example, the targeted therapy drug cetuximab is prescribed as the second choice for patients who are not able to have cisplatin in combination with radiotherapy.²¹
- 1.18 Carboplatin** – is a platinum based drug developed ten years after cisplatin. Carboplatin has less severe side effects than cisplatin, although carboplatin is more toxic to bone marrow. Carboplatin is considered the third drug of choice when treating head and neck cancers and is generally prescribed when patients have previously been treated with cisplatin or are not able to tolerate cisplatin. Carboplatin doses are calculated using AUC.²²
- 1.19 Capecitabine** – is an oral chemotherapy drug. Capecitabine is the key drug for use in adjuvant chemotherapy for colorectal cancer and is also used in the treatment of metastatic colorectal and breast cancers. Capecitabine doses are calculated using BSA.²³

The events leading to this inquiry

- 1.20** In mid-2015 concerns were formally raised with management of St Vincent’s Hospital that Senior Medical Oncologist, Dr John Grygiel, was prescribing carboplatin as a chemotherapy or chemoradiation agent at a flat dose rate of 100mg to head and neck cancer patients. Dr Grygiel’s prescribing practice was not in line with published treatment protocols for prescribing carboplatin as either a chemoradiation or chemotherapy agent in head and neck cancers and did not take into account the age, gender and renal function of patients – factors usually used to calculate carboplatin dosage. Concerns were also raised that the flat dose prescribing practice may have ‘resulted in a potential increase in tumour recurrence.’²⁴
- 1.21** St Vincent’s Hospital initiated an internal investigation into the flat-dosing prescribing practice in August 2015, then an external review commenced in November 2015, concluding in February 2016.²⁵ At no time in the course of these investigations did St Vincent’s disclose to affected patients or their families that the chemotherapy they had received was an off-protocol dose.²⁶

²¹ Section 122 inquiry final report, p 10.

²² *In camera* evidence, Dr Bell, 31 October 2016, p 3; section 122 inquiry final report, pp 10-11.

²³ Section 122 inquiry Western NSW Local Health District report, pp 8-9.

²⁴ Answers to questions on notice, St Vincent’s Health Australia, 23 December 2016, p 10, quoting email from Dr Brett Gardiner, Director Clinical Governance, St Vincent’s Hospital, to senior clinicians, 5 August 2016.

²⁵ Section 122 inquiry final report, p 20.

²⁶ Section 122 inquiry final report, p 5.

- 1.22** Most affected patients at St Vincent's Hospital first learnt that their chemotherapy treatment was off-protocol through the ABC television current affairs program, *7.30*, which aired a story on off-protocol prescribing of chemotherapy treatment in South Australia and St Vincent's Hospital on 18 February 2016.²⁷
- 1.23** St Vincent's Hospital began the process of informing affected patients and their families the day that the story was aired. The following day the Secretary of the New South Wales Ministry of Health launched an inquiry into the matter under section 122 of the *Health Services Act 1997* and the matter was referred to the Health Care Complaints Commission and Medical Council of New South Wales for investigation.²⁸
- 1.24** The section 122 inquiry initially focussed on Dr Grygiel's treatment of patients at St Vincent's Hospital but was later expanded to include prescribing practices in Western New South Wales Local Health District (LHD) and its predecessor, where Dr Grygiel had practiced oncology as a 'fly-in fly-out' medical specialist between 1989 and 2012.²⁹ The section 122 inquiry published three reports of their investigation and made a number of recommendations discussed later in this chapter.
- 1.25** Dr Grygiel also practiced oncology at Macquarie University Hospital between 2010 and 2012, however, as a private facility Macquarie University Hospital is not a relevant public health organisation for the purposes of section 122 inquiries. Patient incidents that occur at a private hospital are reportable incidents under section 20L of the *Health Administration Act 1997*. NSW Health's private healthcare branch is monitoring the response of Macquarie University Hospital in responding to Dr Grygiel's prescribing practices.³⁰
- 1.26** The section 122 inquiry examined Dr Grygiel's prescribing of chemotherapy between 2006 and 2015 and found incidences of off-protocol prescribing of chemotherapy in metropolitan Sydney and regional and rural New South Wales. This raises a number of questions including those concerning:
- the effectiveness of clinical governance frameworks in place at those institutions
 - whether clinical governance principles and practices associated with those frameworks were followed - both before and after the discovery of off-protocol prescribing practices
 - clinical governance as it relates to visiting medical officers
 - incident management policies
 - informed consent

²⁷ Section 122 inquiry final report, p 25. Two ABC *7.30* programs were broadcast, the first on 18 February 2016, and the second on 23 February 2016: see *7.30*, ABC, 'Up to seventy cancer patients under-dosed during treatment at Sydney hospital', Matt Peacock, 18 February 2016, <http://www.abc.net.au/7.30/content/2015/s4409507.htm>; and *7.30*, ABC, 'Inquiry launched into St Vincent's Hospital chemotherapy dosage scandal', Matt Peacock, 23 February 2016, <http://www.abc.net.au/7.30/content/2015/s4412339.htm>.

²⁸ Section 122 inquiry final report, p 5.

²⁹ Section 122 inquiry Western NSW Local Health District report, p 3.

³⁰ Evidence, Ms Karen Crawshaw, Deputy Secretary, Governance, Workforce and Corporate, NSW Ministry of Health, 31 October 2016, p 21.

- the appropriateness of St Vincent's Hospital's response in communicating the issue to affected patients.

1.27 These questions were an important focus for the committee's inquiry and thus are addressed in detail in the chapters that follow. The following sections provide an explanation of the terms clinical governance, incident management, open disclosure and informed consent.

What is clinical governance?

1.28 Clinical governance describes a systematic approach to maintaining and improving the quality of patient care within a health system.³¹

1.29 All public health facilities in New South Wales have a common clinical governance framework in place. Local health districts and specialty networks each have a Clinical Governance Unit with responsibility for developing and monitoring policies and procedures to improve patient safety and clinical quality.³²

1.30 An effective clinical governance framework provides safeguards to protect against incidents that could seriously affect the health and safety of patients. While no clinical governance framework can completely prevent an adverse event occurring, where such events do occur clinical governance frameworks provide for the appropriate response by an organisation to an incident. In New South Wales clinical governance units oversee the risk management of patient safety and clinical quality and report any concerns to the Chief Executive for action. Action might include internal and external investigations, referral to the Health Care Complaints Commission, or other appropriate agency.³³

What is incident management?

1.31 A clinical incident is any unplanned event which causes, or has the potential to cause, harm to a patient.³⁴ Incident management forms part of the clinical governance framework and describes the reporting and response process that takes place after a clinical incident has occurred.

1.32 The NSW Health *Incident Management Policy* applies to all public health staff in New South Wales and sets out steps that must be taken in response to any incident including: identification, notification, investigation, and analysis.³⁵

³¹ NSW Health, *Clinical Governance* (October 2014), <http://www.health.nsw.gov.au/mentalhealth/cg/Pages/default.aspx>

³² NSW Health, *Corporate Governance & Accountability Compendium* (December 2016), <http://www.health.nsw.gov.au/policies/manuals/Documents/corporate-governance-compedium-section5.pdf>

³³ NSW Health, *Corporate Governance & Accountability Compendium* (December 2016), <http://www.health.nsw.gov.au/policies/manuals/Documents/corporate-governance-compedium-section5.pdf>

³⁴ NSW Clinical Excellence Commission, *Clinical incident management*, <http://www.ccc.health.nsw.gov.au/clinical-incident-management>.

³⁵ NSW Health, *Incident Management Policy* (10 February 2014), http://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2014_004.pdf.

What is open disclosure?

- 1.33** Open disclosure is a process of communication between health care staff, patients and/or their support persons who have experienced a patient safety incident. A patient safety incident is any unplanned or unintended event which could have resulted, or did result, in harm to a patient. Open disclosure ensures that communication is open, honest, empathetic and timely.³⁶ The NSW Health *Open Disclosure Policy*, based on the *Australian Open Disclosure Framework*, applies to all public health services in New South Wales.³⁷
- 1.34** The five essential elements of open disclosure are:
- an apology
 - a factual explanation of what happened
 - an opportunity for the patient to relate his or her experience
 - a discussion of the potential consequences
 - an explanation of the steps being taken to manage the event and prevent recurrence.³⁸
- 1.35** The open disclosure process is beneficial for patients because it provides them with the opportunity to make decisions about further treatment, may assist in restoring trust, and may provide assurance that steps have been taken to ensure the same event does not happen again.³⁹
- 1.36** The open disclosure process is beneficial for health care providers because it provides for an environment where patient safety incidents may be reported without attribution of blame. In addition, lessons learnt from patient safety incidents may assist in developing strategies to prevent further incidents.⁴⁰

What is informed consent?

- 1.37** Informed consent is a person's voluntary decision about medical care, made with knowledge and understanding of the benefits and risks involved.⁴¹
- 1.38** As part of their duty of care, health professionals must provide such information as is necessary for the patient to give consent to treatment, including information on all material risks of the proposed treatment.⁴²

³⁶ NSW Clinical Excellence Commission, *Open Disclosure*, <http://www.cec.health.nsw.gov.au/incident-management/open-disclosure>.

³⁷ NSW Health, *Open Disclosure Policy* (2 September 2014), http://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2014_028.pdf.

³⁸ NSW Clinical Excellence Commission, *Open Disclosure Handbook*, p 14.

³⁹ NSW Clinical Excellence Commission, *Open Disclosure Handbook*, p 19.

⁴⁰ NSW Health, *Open Disclosure Policy* (2 September 2014), p 2, http://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2014_028.pdf.

⁴¹ Medical Board of Australia, *Good Medical Practice*, March 2014, p 9.

⁴² Australian Law Reform Commission, *Equality, Capacity and Disability in Commonwealth Laws, Informed consent to medical treatment*, May 2014, p 228.

1.39 Doctors have a legal duty to warn a patient of a material risk inherent in a proposed treatment. A risk is material if a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is aware that the particular patient, if warned of the risk, would be likely to attach significance to it.⁴³

NSW Health policy

1.40 In New South Wales it is mandatory for all clinicians who work within public health organisations to comply with the NSW Health policy *Consent to Medical Treatment – Patient Information*. Under this policy, no operation, procedure or treatment may be undertaken without first:

- adequately informing a patient of the operation, procedure or treatment
- obtaining a patient's consent for the operation, procedure or treatment.⁴⁴

1.41 The policy notes that patients must be provided with sufficient information about the condition, investigation options, treatment options, benefits, possible adverse effects or complications, and the likely result if treatment is not undertaken, in order to be able to make their own decision about undergoing an operation, procedure or treatment.⁴⁵

1.42 While the law does not require patient consent to be obtained in writing, the NSW Health policy states that written consent is to be obtained for the following procedures and that the written consent should form part of the patient's medical record:

- all operations or procedures requiring general, spinal, epidural, or regional anaesthesia or intravenous sedation
- any invasive procedure or treatment where there are known significant risks or complications
- blood transfusions or the administration of blood products
- experimental treatment for which the approval of an ethics committee is required.⁴⁶

The section 122 inquiry

1.43 As noted earlier, under section 122 of the *Health Services Act 1997* the Secretary of Health may inquire into the administration, management and services of any public health organisation. St Vincent's Hospital, as an affiliated health organisation under the *Health Services Act*, is treated as part of the New South Wales public health system, and is subject to the provisions of the *Health Services Act*.

⁴³ Evidence, Ms Karen Crawshaw, Deputy Secretary, Governance, Workforce and Corporate, NSW Ministry of Health, 31 October 2016, p 30 and *Rogers v Whitaker* (1992) 175 CLR 479 .

⁴⁴ Consent is not required where immediate treatment is necessary to save a person's life or prevent serious injury where the person is unable to provide consent. NSW Ministry of Health, *Consent to Medical Treatment – Patient Information*, January 2005, p 5.

⁴⁵ NSW Ministry of Health, *Consent to Medical Treatment – Patient Information*, January 2005, p 5.

⁴⁶ NSW Ministry of Health, *Consent to Medical Treatment – Patient Information*, January 2005, pp 6-7.

1.44 On 19 February 2016 the then Secretary of the New South Wales Ministry of Health, Mary Foley, initiated an inquiry into issues arising from the dosing of cancer patients under the care of Dr John Grygiel which were not in accordance with eviQ protocols, at the Kinghorn Cancer Centre, St Vincent's Hospital, from June 2012 to June 2015 ('the incident').

1.45 The initial terms of reference were that the inquiry was to:

1. Review the adequacy and/or timeliness of the response to the incident including:
 - (a) the assessment and management of the clinical risk to the patients identified as directly affected by the incident
 - (b) the actions put in place to address or mitigate risk to other patients going ahead and to avoid a recurrence
 - (c) compliance with the relevant NSW Health Policy Directives and Guidelines dealing with managing and reporting clinical risks, in particular:
 - *Incident Management Policy*
 - *Open Disclosure Policy*
 - *Complaint or concern about a Clinician – principles for action*
 - *Complaint or concern about a Clinician – Management Guidelines*
2. Review the application of the *Cancer Institute eviQ Protocols* and any other standardised evidence based protocols at St Vincent's Hospital in relation to Dr John Grygiel's patients, and systems in place at the Hospital for monitoring application of the *eviQ Protocols*
3. Consider and identify any organisational issues or practices that may have impacted on the adequacy or timeliness of actions or compliance with policies
4. Identify any systemic learnings arising from the section 122 inquiry in relation to points 1, 2 and 3 above and any areas for improvement in policies, procedures or practices operating at St Vincent's Hospital or more broadly
5. Provide a report on progress to the Secretary by 31 March 2016, including any interim recommendations or recommended changes to the scope of this Terms of Reference
6. Provide a final report on a further date, as directed by the Secretary.⁴⁷

⁴⁷ NSW Ministry of Health, *Inquiry Under Section 122 of the Health Service Act 1997, Terms of reference*, <http://www.health.nsw.gov.au/Hospitals/Pages/cancer-patients-inquiry.aspx>.

- 1.46 On 4 April 2016, following a recommendation from the section 122 inquiry team, the inquiry terms of reference were extended to include:
- cancer patients treated by Dr Grygiel at St Vincent’s Hospital from 2006
 - cancer patients treated by Dr Grygiel at Western NSW LHD from January 2006
 - consideration of information provided to patients directly affected by the incident in consenting to treatment by Dr Grygiel, and the impact on those affected patients and their families.⁴⁸

The inquiry team and process

- 1.47 The inquiry was undertaken by a team comprising: Professor David Currow, Chief Cancer Officer and Chief Executive Officer of the NSW Cancer Institute (Co-leader); Dr Paul Curtis, Director Clinical Governance, Clinical Excellence Commission (Co-leader); Dr Tina Chen, Medical and Scientific Advisor, Cancer Information Analysis, NSW Cancer Institute (Member), and Mr Paul Gavel, Director Workforce, HealthShare NSW (Member). The team also received clinical input from an expert panel with members from the fields of medical and radiation oncology, clinical pharmacology and oncology pharmacy.⁴⁹
- 1.48 The section 122 inquiry team conducted their investigation by interviewing current and former staff and patients and families affected by the incident, seeking written responses to questions and obtaining documents from St Vincent’s Hospital and Western NSW Local Health District, and reviewing clinical records of affected patients.⁵⁰

Findings

- 1.49 The inquiry team delivered three reports:
- an interim report on 31 March 2016
 - a final report on head and neck cancer patients on 31 July 2016
 - a final report on patients treated at Western NSW LHD on 16 September 2016.⁵¹

St Vincent’s Hospital

- 1.50 The section 122 inquiry found that between 2006 and 2015, 129 patients at St Vincent’s Hospital, particularly head and neck cancer patients, were prescribed chemotherapy treatment by Dr John Grygiel that was off-protocol and not supported by clinical evidence. It also concluded that inadequate clinical governance, poor incident notification and management

⁴⁸ NSW Ministry of Health, *Inquiry Under Section 122 of the Health Service Act 1997, Terms of reference*, <http://www.health.nsw.gov.au/Hospitals/Pages/cancer-patients-inquiry.aspx>.

⁴⁹ Section 122 inquiry interim report, p 2.

⁵⁰ Section 122 inquiry final report, pp 3-4 and p 13.

⁵¹ The complete set of reports can be found on the NSW Health website at <http://www.health.nsw.gov.au/Hospitals/Pages/cancer-patients-inquiry.aspx>.

practices and a culture of conflict and mistrust within the oncology department at St Vincent's Hospital contributed to Dr Grygiel's off-protocol prescribing practices enduring for over a decade. The inquiry further found that when St Vincent's senior staff did become aware of the issue, there was a failure to communicate accurately and promptly with affected patients.⁵²

Western NSW Local Health District

- 1.51** In Western New South Wales, Dr Grygiel practiced as a 'fly in-fly out' medical oncologist in Orange and Bathurst between 1989 and 2012. The section 122 inquiry concluded that five patients in Western New South Wales received an off-protocol dose of carboplatin and 23 patients received significantly reduced doses of capecitabine.⁵³ The section 122 inquiry also found that in the Western NSW LHD there were governance issues relating to the management of cancer services, and no evidence of systems in place to ensure adherence to chemotherapy treatment protocols. However, the inquiry found that the LHD management did respond promptly and in the best interests of patients when they became aware of Dr Grygiel's prescribing practices.⁵⁴

Impact on patient outcomes

- 1.52** The section 122 inquiry noted that, on a population basis, it would be expected that off-protocol prescribing of chemotherapy puts patients at risk of higher rates of disease recurrence or death. However, the inquiry found that it is too early to determine any trends in recurrence or survival for the population of patients treated with off-protocol chemotherapy. Furthermore, the section 122 inquiry was not able to establish a causal link between receiving an off-protocol dose of chemotherapy and subsequent outcomes for individual patients.⁵⁵
- 1.53** The inquiry noted that many factors contributed to patient outcomes following cancer treatment; the disease could recur even with optimal treatment and, conversely, a patient receiving a lower dose may not have the disease recur.⁵⁶

Recommendations

- 1.54** The section 122 inquiry made a number of recommendations to address specific issues that arose in St Vincent's Hospital and the Western NSW LHD, and broader recommendations to all local health districts, the Ministry of Health and the Cancer Institute NSW. Recommendations made to St Vincent's Hospital and on a statewide basis are set out in appendix 3. All recommendations are discussed in the relevant chapters of this report.

⁵² The Hon Jillian Skinner MP, Minister for Health, 'St Vincent's Hospital Interim Report', *Media Release*, 5 April 2016.

⁵³ The number of patients found to have received an off-protocol dose of capecitabine may rise following the completion of a review of Pharmaceutical Benefits Scheme prescription records. Western NSW Local Health District, *Implementation of Recommendations – Six Month Report*, March 2017, p 7.

⁵⁴ Section 122 inquiry Western NSW Local Health District report, p 13.

⁵⁵ Section 122 inquiry final report, pp 15-16.

⁵⁶ Section 122 inquiry Western NSW Local Health District report, p 12.

Dr Kiran Phadke

- 1.55** Dr Kiran Phadke worked for 35 years as a medical oncologist and haematologist at St George and Sutherland hospital cancer services. Dr Phadke became part of this committee's inquiry following a media statement in early August 2016 by the then Minister for Health, the Hon Jillian Skinner MP, that linked Dr Phadke's treatment of patients with the prescribing practices of Dr Grygiel.⁵⁷
- 1.56** The committee received a large number of submissions regarding Dr Phadke and heard evidence from Dr Phadke and the South Eastern Sydney LHD, who carried out an investigation into his actions. Dr Phadke's treatment of patients in the South Eastern Sydney LHD is discussed in detail in chapter 7 of this report.

Other investigations

- 1.57** The NSW Health Care Complaints Commission and the Medical Council of NSW have important roles to ensure the integrity of the healthcare system in New South Wales. The Commission is responsible for investigation and prosecution of complaints while the Council's role is to remediate and monitor practitioners. All complaints or notifications about medical practitioners are jointly considered by the Commission and the Council.⁵⁸

Health Care Complaints Commission

- 1.58** The Health Care Complaints Commission is established by the *Health Care Complaints Act 1993* as an independent body with strong coercive powers to resolve, investigate and prosecute complaints about all health service providers in New South Wales. The Commission is currently conducting comprehensive investigations into both Dr Grygiel and Dr Phadke.
- 1.59** In terms of its investigation into Dr Grygiel, the Commission is examining the prescribing of chemotherapy for patients at a number of institutions across New South Wales and anticipates it will have completed its investigation by July 2017.
- 1.60** The investigation into Dr Phadke relates to his work as a haematologist and oncologist in South Eastern Sydney LHD. The Commission did not provide the committee with a timeframe for completion of their investigation into Dr Phadke; at the time of the public hearing the Commission was awaiting the provision of critical material from the South Eastern Sydney LHD.⁵⁹
- 1.61** At the conclusion of an investigation, the Commission may take a range of actions, including:
- referral of the complaint to a professional council

⁵⁷ The Hon Jillian Skinner MP, Minister for Health, 'Incorrect treatment of Southern Sydney cancer patients', *Media release*, 2 August 2016.

⁵⁸ Evidence, Dr Greg Kesby, President, Medical Council of New South Wales, 24 February 2017, p 11.

⁵⁹ Evidence, Ms Susan Dawson, Commissioner, NSW Health Care Complaints Commission, 24 February 2017, p 4.

- referral of the complaint to the Commission's independent Director of Proceedings for consideration of disciplinary action
- referral of the complaint to the Director of Public Prosecutions for consideration of criminal charges
- making comments and/or recommendations to a health organisation where there has been poor health service delivery and systemic improvements are required
- terminating the complaint and taking no further action.⁶⁰

1.62 The Commission informed the committee that its investigations into Dr Grygiel and Dr Phadke have raised a range of systemic issues for it to address including: mandatory reporting, informed consent, multidisciplinary teams, education and training and culture.⁶¹

Medical Council of New South Wales

1.63 The Medical Council of New South Wales is a statutory body established under the *Health Practitioner Regulation National Law (NSW) No 86a* and is responsible for ensuring all medical practitioners in New South Wales are fit to practice medicine by ensuring registered doctors maintain proper standards of conduct and competence.

1.64 If a medical practitioner is the subject of a serious complaint the Medical Council is empowered to suspend the doctor's registration or place conditions on their registration for the duration of the investigation into the complaint. The Medical Council will do this in circumstances where they consider it is appropriate to protect the health and safety of any person or is otherwise in the public interest.⁶²

1.65 Dr Grygiel is not currently practicing, however, he may work with conditions imposed on his registration by the Medical Council, including that he adheres to eviQ guidelines and practices under supervision and monitoring.⁶³

1.66 Similarly the Medical Council has imposed conditions on Dr Phadke's registration including that he work under supervision.⁶⁴

⁶⁰ NSW Health Care Complaints Commission, *Annual Report 2015-2016*, p 7.

⁶¹ Evidence, Ms Dawson, 24 February 2017, p 6.

⁶² Evidence, Dr Kesby, 24 February 2017, p 11.

⁶³ Evidence, Dr Kesby, 24 February 2017, pp 14-15.

⁶⁴ Evidence, Dr Kesby, p 16 and Murray Trembath, 'Cancer specialist Kiran Phadke thanks community after being cleared to return to work', *St George and Sutherland Shire Leader*, 13 April 2016.

Chapter 2 Dr Grygiel's off-protocol prescribing at St Vincent's Hospital

This is the first of three chapters examining off-protocol prescribing of chemotherapy at St Vincent's Hospital Sydney. This chapter focuses on the actions of Dr John Grygiel, while the next chapter focuses on the actions of the hospital itself after Dr Grygiel's prescribing was raised as a concern by a colleague in mid 2015. The third examines the hospital's actions in response to the section 122 inquiry.

First, this chapter sets out the section 122 inquiry findings in respect of Dr Grygiel's prescribing at St Vincent's Hospital. It then documents Dr Grygiel's perspective, most notably his rationale for his prescribing in respect of head and neck cancer patients. The chapter then details other key participants' perspectives on Dr Grygiel's actions and his justification for them.

Section 122 inquiry findings in respect of Dr Grygiel

- 2.1** As noted in chapter 1, the section 122 inquiry found that between 2006 and 2015, 129 patients at St Vincent's Hospital were prescribed off-protocol flat dose 100 mg carboplatin by Dr John Grygiel. Of these people, 103 were treated for head and neck cancer; the remaining 26 were treated for a range of other cancers. Of those treated with this flat dose, one half were aged 60 or less, and 51 per cent had comorbidities.⁶⁵ The last patients to receive an off-protocol flat dose 100 mg of carboplatin did so in June 2015.⁶⁶
- 2.2** According to the section 122 inquiry final report, several participants reported that Dr Grygiel justified his practice as he believed it could reduce toxicity and thus increase the rate of patients completing radiotherapy and radiosensitising chemotherapy, however, 'No evidence has been presented [to that inquiry] by Dr Grygiel, or found in the international peer-reviewed literature to support this contention.'⁶⁷
- 2.3** The report states that Dr Grygiel was asked during that inquiry whether he was 'aware of any published protocols or guidelines for 100 mg flat dose', and he replied 'no'. It further notes that 'the practice was not overseen by a human research ethics committee and no data were collected prospectively nor retrospectively to establish the net effect of this practice on patients' outcomes (benefits and harms).'⁶⁸
- 2.4** The inquiry final report documents a number of other conclusions concerning Dr Grygiel:
- While he stated that there were others who were aware of the practice, the inquiry was unable to corroborate that statement.⁶⁹

⁶⁵ NSW Ministry of Health, *Inquiry under section 122 of the Health Services Act 1997: Off-protocol prescribing of chemotherapy for head and neck cancers*, Final report, 31 July 2016 (hereafter section 122 inquiry final report), p 14.

⁶⁶ Section 122 inquiry final report, p 14.

⁶⁷ Section 122 inquiry final report, p 16.

⁶⁸ Section 122 inquiry final report, p 16.

⁶⁹ Section 122 inquiry final report, p 17.

- Dr Grygiel had a ‘proactive responsibility’ to advise his multidisciplinary team (MDT) colleagues that he was prescribing off-protocol and to explain the implications of what he was doing. However, there were conflicting accounts as to whether this occurred.⁷⁰

2.5 Professor David Currow, Chief Cancer Officer, NSW, Chief Executive of the Cancer Institute NSW, and Co-leader of the section 122 inquiry, advised the committee that the view of the expert panel that advised his inquiry was ‘very simply and consistently that this was off-protocol. This was so divorced, from the evidence ... This was off the radar’.⁷¹ He further noted that the external medical oncologist engaged by St Vincent’s Hospital formed the same view and advised St Vincent’s accordingly.⁷²

2.6 Professor Currow articulated the problem as not just about the use of a protocol, but also about Dr Grygiel’s discussions with patients and their families and his documentation of their consent. Noting that a clinician may vary anything if they sit down with the patient and family and explain what normal practice would be, what they are recommending, and why the variance, Professor Currow stated that the inquiry found Dr Grygiel’s practice wanting here as well:

Again I stress this is not simply about the protocol. This is about what is communicated, what is understood, and what is documented. You can, as a clinician, sit down with patients and explain that variance and, with their fully informed consent, move forward. That was the missing piece of this puzzle consistently in both the documentation provided to the inquiry and in the interviews with patients.⁷³

2.7 While the section 122 inquiry final report’s discussion of informed consent is limited, it is clear that when prescription is outside a protocol it must only be done in a research context, with ethics committee approval with clear processes of informed consent.⁷⁴ Consistent with this, the inquiry recommended that clinicians across New South Wales ensure ‘adequate informed consent for all medical interventions, including chemotherapy. If the clinician knows that his/her practice is outside accepted practice, there is a particular onus to draw this to the attention of patients in the process of providing informed consent, and to document this in the patient notes.’⁷⁵

2.8 In respect of discussions with patients about their treatment options, the report noted that patients’ chemotherapy was not so much discussed as advised:

Almost all of the patients and next-of-kin reported that they did not recall Dr Grygiel discussing chemotherapy drug options with them but rather that they were told by Dr Grygiel which chemotherapy drug was being recommended. Typically, Dr Grygiel was perceived as ‘the expert who knows best’ and the recommended treatment was not questioned. Interviewees indicated that they ‘trusted the advice of the expert’.

⁷⁰ Section 122 inquiry final report, pp 17 and 32.

⁷¹ Evidence, Professor David Currow, Chief Cancer Officer, NSW, Chief Executive Officer, Cancer Institute NSW, and Co-leader of the section 122 inquiry, 31 October 2016, p 19.

⁷² Evidence, Professor Currow, 31 October 2016, p 19.

⁷³ Evidence, Professor Currow, 31 October 2016, p 18.

⁷⁴ Section 122 inquiry final report, p 6.

⁷⁵ Section 122 inquiry final report, p 41.

Some family respondents indicated that they did not feel included in decision-making; nor did they feel comfortable questioning doctors, stating “if the doctor says it has to be done, then that’s OK”. Respondents reflected that they did not know ‘the right questions to ask anyway’ and had ‘complete faith and trust’ in Dr Grygiel as the doctor and professor. In reference to treatment recommendations, some patients mentioned that, in discussion with other doctors in the head and neck cancer multidisciplinary team, doctors other than Dr Grygiel informed them that “this is what the team said, this is what the team thinks is best”.⁷⁶

- 2.9** With regard to informed consent in respect of dosage levels, the section 122 final report states, ‘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.’⁷⁷

Dr Grygiel’s perspective

- 2.10** When he appeared before the committee in November 2016, Dr Grygiel stood firm in his view that he had done nothing wrong. While he expressed regret at the distress suffered by his patients as a result of the publicity around this inquiry,⁷⁸ he declined to apologise to patients and their families on the basis that there was no evidence they had not had the full benefit of carboplatin:

I do not believe that there has been any demonstration that a dose of 100 milligrams of carboplatin per week with radiotherapy is in any way inferior to any other dose that has been published. Under those circumstances, I do not believe that any patient has not had the total benefit of the drug ... I am saying that there is no loss of efficacy in the use of a 100 milligram dose per week of carboplatin with daily radiotherapy compared with higher doses. In fact, the lesser degree of side effects associated with the 100 milligram dose gives those patients a benefit.⁷⁹

- 2.11** Dr Grygiel advised that he had adopted the methodology of 100 mg flat dosing of carboplatin 12 years prior to the publication of the eviQ guidelines for head and neck cancers, that is, from 1985.⁸⁰ Asked for the evidence to support this treatment regime, Dr Grygiel referred to three published studies from 1985, 1989 and 2012:

The evidence starts in 1985 with the publication in cancer treatment reviews of research by the scientist Evan Douple, which demonstrated that for carboplatin and cisplatin very low doses were all that was required to sensitise cancer cells to the cytotoxic effect of radiotherapy. That was the first issue. Then there are the dose finding studies of Maria Jacobs and Mario Eisenberger published in 1989 in the *International Journal of Radiation Oncology, Biology and Physics*, which demonstrated a series of doses of carboplatin from 60 milligrams per metre squared, which in the majority of Australian patients would be around 100 milligrams per week. They were tested and

⁷⁶ Section 122 inquiry final report, p 23.

⁷⁷ Section 122 inquiry final report, p 24. Further analysis of discussions about dosage is provided on p 24 of the report.

⁷⁸ Evidence, Dr John Grygiel, Medical Oncologist, 1 November 2016, p 2.

⁷⁹ Evidence, Dr Grygiel, 1 November 2016, p 3.

⁸⁰ Evidence, Dr Grygiel, 1 November 2016, p 6.

the level of dosing went up to 400 milligrams per metre squared. The conclusion of the study demonstrated that there was no difference in terms of efficacy between the doses. More recently, in 2012, a paper was published about the utility of flat dosing carboplatin using 150 milligrams per week with radiotherapy versus radiotherapy alone. It showed a clear benefit from the combination of chemo/radiotherapy over radiotherapy alone with fewer side effects than for more conventional doses of carboplatin.⁸¹

- 2.12** Dr Grygiel asserted that he had devoted his career to the ethical treatment of oncology patients, that he had provided optimal clinical management for each of his patients, and had always been open and honest in his discussions both with patients and their families, and with colleagues, about proposed treatment.⁸² He then set out six points in defense of his actions:

First, the heart of my clinical practice has always been the best interest of each of my patients. Secondly, the most effective treatment is based on a combination of scientific evidence and clinical judgement. Thirdly, it is important to distinguish chemotherapy as a radiosensitiser and as a tumouricidal therapy. When treating head and neck patients it is intended as a radiosensitiser and not to kill cancer cells, which is the purpose of radiotherapy. Fourthly, the guidelines are important but the weight given to the guidelines depends on the level of scientific evidence behind them.

Fifthly, in the cases that have prompted this inquiry there is no evidence that the guideline dose would have led to a better outcome. Indeed, in many cases I believe it could have had a negative impact as it would have discouraged patients from continuing treatment. Cancer treatment is a complex process and there are numerous factors that need to be taken into account: the type of cancer and its stage; patient factors, including age, general state of health, and vital organ function; and co-morbidities. The purpose of treatment needs to be outlined as to whether it is curative in intent or palliative in intent. Lastly, the evidence of efficacy of treatment and the toxicity of treatment needs to be balanced. These factors are integrated to identify, if possible, the best choice in treatment before an ultimate agreement is reached between the patient and their family and the medical oncologists.⁸³

- 2.13** Dr Grygiel acknowledged to the committee that 100 mg of carboplatin per week does not appear in the eviQ guidelines promulgated by the NSW Cancer Institute.⁸⁴ His approach, he considered ‘was the least toxic, but equally efficacious practice’,⁸⁵ aimed at minimising toxicity and thus increasing the likelihood of the patient completing their radiotherapy.⁸⁶ He further explained the rationale for the choice of carboplatin over cisplatin, and for the flat dose:

The flat dose was, I suppose, a default. If you consider that the two choices of drugs are cisplatin and carboplatin, the evidence is—and it is a bias rather than strong evidence—that cisplatin is more effective than carboplatin ... the meta-analysis made the comment that any apparent advantage of cisplatin over carboplatin in terms of efficacy is lost at the age of 60. So a patient who is 60 or older gets no benefit and gets all the additional toxicity with cisplatin. Cisplatin is given to those people who are

⁸¹ Evidence, Dr Grygiel, 1 November 2016, p 2.

⁸² Evidence, Dr Grygiel, 1 November 2016, p 2.

⁸³ Evidence, Dr Grygiel, 1 November 2016, p 2.

⁸⁴ Evidence, Dr Grygiel, 1 November 2016, p 6.

⁸⁵ Evidence, Dr Grygiel, 1 November 2016, p 13.

⁸⁶ Evidence, Dr Grygiel, 1 November 2016, p 10.

under 60 and do not have comorbidities that prohibit its use. The distinction between the two levels of carboplatin is that if I felt a patient under 60 had significant comorbidities I would take them off the cisplatin dose, and the option was to have the area under the curve or a flat dose. Often the general condition of these patients was such that there was no real option.⁸⁷

2.14 In respect of his aim of reducing toxicity with a view to optimising patients' completion of radiotherapy, Dr Grygiel expounded:

One hundred milligrams was the dose that was most likely to enable these patients to get through combined chemotherapy and radiation treatment. It is very important to realise that in this treatment the dominant effect and the predominant benefit comes from radiotherapy. If you use carboplatin with radiotherapy in a dose of carboplatin that causes excessive toxicity, both treatments stop. If both treatments stop then the patient is at greater disadvantage. With the use of a flat dose, a 100-milligram dose, the toxicity coming from the chemotherapy is minimal and therefore the likelihood of completing six weeks and getting a full dose of radiotherapy is enhanced. If we look at the records at St Vincent's Hospital of the number of people who came off therapy because of toxicity, none of them came off because of chemotherapy toxicity.⁸⁸

2.15 Asked whether he believed that no patients were harmed as a result of his off-protocol treatment, Dr Grygiel asserted that he does believe this, on the basis that there has been no evidence of such harm: surveillance of the head and neck clinic's patients had indicated no evidence of change in recurrence rates.⁸⁹

2.16 Dr Grygiel further asserted that he had discussed his practice of flat dosing carboplatin with his supervisor at the time, Dr David Dalley, then Director of Medical Oncology at St Vincent's Hospital, in 2006 and again upon the latter's retirement in 2013,⁹⁰ such that 'we agreed that my dosing was adequate.'⁹¹ According to Dr Grygiel, their 2006 discussion concerned the evidence about effective dosing of carboplatin, in the context of Dr Dalley's membership on the inaugural committee setting carboplatin doses for head and neck cancer. According to Dr Grygiel, Dr Dalley had told him that the committee had great difficulty determining an optimal dose because of a lack of clear evidence one way or another for any particular dose,⁹² and that in this context, his preferred dosing was acceptable:

There is evidence that a lot of doses work. As a consequence of that discussion, there was never any indication from my boss that I should adopt the guidelines that had just been promulgated. The basis of that was that there was an agreement that there was no correct dose and that my treatments [of 100 milligrams of carboplatin weekly with daily radiotherapy] had not been in any way demonstrated to be inferior to any other ... it was agreed by Dr Dalley and I as a result of that conversation that there was clearly no compelling evidence to make a change.⁹³

⁸⁷ Evidence, Dr Grygiel, 1 November 2016, p 10.

⁸⁸ Evidence, Dr Grygiel, 1 November 2016, p 10.

⁸⁹ Evidence, Dr Grygiel, 1 November 2016, p 4.

⁹⁰ Evidence, Dr Grygiel, 1 November 2016, p 9.

⁹¹ Evidence, Dr Grygiel, 1 November 2016, p 12.

⁹² Evidence, Dr Grygiel, 1 November 2016, p 3.

⁹³ Evidence, Dr Grygiel, 1 November 2016, p 3.

- 2.17** Dr Grygiel also insisted that he and Dr Stephen Cooper, the radiation oncologist with whom he treated head and neck cancer patients, had discussed his dosing occasionally since the early 2000s.⁹⁴
- 2.18** With regard to patient consent, the committee asked whether he told all his patients and their families that their treatment deviated from accepted guidelines. Dr Grygiel responded that, ‘I explained to them that there were guidelines and I explained to them that I use lower doses ... In all cases I explained why I use lower doses’.⁹⁵ He also reported having provided ‘pretty well all’ of his patients with eviQ information sheets from the time the eviQ system was established at St Vincent’s Hospital in 2009.⁹⁶
- 2.19** Challenged as to why he did not conduct proper trials to substantiate his approach, Dr Grygiel responded that the benefit of this adjuvant therapy was so minor that an appropriate methodology would have required a sample size of around 5,000 patients on each arm of treatment, utilising an internationally cooperative approach. However, ‘most people in oncology doing research would want to spend that time, money and effort in finding something much better’ than investigating what would amount to an equivalence effect.⁹⁷ Asked whether he had ever sought to publish what he considered to be the best possible treatment for patients, or to compare notes with peer oncologists elsewhere in Australia or internationally, Dr Grygiel acknowledged that he had not.⁹⁸
- 2.20** Dr Grygiel also suggested to the committee that he was not the only doctor at St Vincent’s Hospital who had prescribed the dose of 100 mg of carboplatin.⁹⁹ The committee heard that the section 122 inquiry found that two other patients were prescribed 100 mg of carboplatin by other doctors, however these were based on a personalised calculated dose and not flat dosing in the way that Dr Grygiel had prescribed the drug.¹⁰⁰ Professor Currow subsequently confirmed that his inquiry received no evidence that doctors other than Dr Grygiel used flat dosing at St Vincent’s Hospital.¹⁰¹
- 2.21** The committee received a statement prepared by Dr Ian E Haines, Consultant Medical Oncologist and Palliative Care Physician,¹⁰² for Avant Law, acting on behalf of Dr Grygiel, based on Dr Haines’ review of the chemotherapy literature.¹⁰³ Dr Haines asserted that there is

⁹⁴ Evidence, Dr Grygiel, 1 November 2016, p 8.

⁹⁵ Evidence, Dr Grygiel, 1 November 2016, p 5.

⁹⁶ Evidence, Dr Grygiel, 1 November 2016, p 5.

⁹⁷ Evidence, Dr Grygiel, 1 November 2016, p 13.

⁹⁸ Evidence, Dr Grygiel, 1 November 2016, p 15.

⁹⁹ Evidence, Dr Grygiel, 1 November 2016, p 3.

¹⁰⁰ Evidence, Professor Currow and Dr Cheng, 29 November 2016, p 28.

¹⁰¹ Answers to supplementary questions, Professor David Currow, Chief Cancer Officer NSW and Chief Executive Officer, Cancer Institute NSW, received 28 November 2016, p 6.

¹⁰² Dr Ian Haines is an Adjunct Clinical Associate Professor in the AMREP Department of Medicine, Alfred Hospital, Melbourne, and a Senior Medical Oncologist and Palliative Care Physician, Medical Oncology Group, Cabrini Haematology and Oncology Centre, Monash University.

¹⁰³ Statement of Dr Ian E Haines MBBS FRACP FChPM, 4 May 2017, enclosed in correspondence from Ms Helen Turnbull, Special Counsel Professional Conduct, Avant Law Pty Ltd, to Chair, 5 May 2017. The committee received the statement in the final two weeks of the inquiry and was thus unable to explore the veracity of its contents with any other inquiry participants.

no evidence to indicate that flat dose 100 mg carboplatin provides inferior outcomes, particularly when given together with radiation therapy,¹⁰⁴ and that despite 30 years of international research and use of carboplatin, the most effective or appropriate dose to use in any patient is still not known.¹⁰⁵ Noting that the most important determinant of the outcome of chemotherapy for patients with locally advanced head and neck cancer is the completion of radiotherapy in the scheduled time, Dr Haines argued that it is vitally important to keep the chemotherapy dose low enough to prevent side effects that would delay radiation.¹⁰⁶ He further suggested that while most medical oncologists would simply follow the relevant eviQ guideline because it is an accepted protocol and conventional practice, this approach carries ‘the converse risk that some patients are being over-dosed with a toxic drug and put at risk of receiving a reduced and suboptimal treatment of radiation’, which is the primary and most important treatment.¹⁰⁷ In conclusion, Dr Haines stated that in his opinion, ‘based on all the available [but extremely limited] comparative dose efficacy clinical trial evidence ... Dr Grygiel’s regimen was carefully thought out, reasonable and in accordance with accepted medical practice.’¹⁰⁸

Others’ perspectives

- 2.22** The committee sought the perspective of a number of other inquiry participants about Dr Grygiel’s actions.

Dr Stephen Cooper

- 2.23** Dr Cooper asserted that he was not aware of Dr Grygiel’s flat dosing of carboplatin until the second quarter of 2015.¹⁰⁹ The committee challenged Dr Cooper as to how he could not have been aware of this, given his role as the radiologist whose treatment was intended to be made efficacious by the chemotherapy Dr Grygiel was prescribing. Dr Cooper responded that he understood the sentiment of this question, but that his non-awareness of the specifics of Dr Grygiel’s prescribing is consistent with standard practice in oncology, in which it is expected that highly trained specialist physicians do ‘the right thing to an appropriate level.’¹¹⁰ He explained:

Professor Grygiel was an appropriately trained, appropriately credentialed medical oncologist with some specialty expertise in head and neck cancer. When he wrote to me saying that he had used a drug that is consistent with the protocol, it is not normal course to specify the doses that he uses—it is just not done—and the expectation is not correct to say that it would be that he would write the dose. I do not go to the

¹⁰⁴ Statement of Dr Haines, 4 May 2017, p 1.

¹⁰⁵ Statement of Dr Haines, 4 May 2017, p 3.

¹⁰⁶ Statement of Dr Haines, 4 May 2017, p 5.

¹⁰⁷ Statement of Dr Haines, 4 May 2017, p 7.

¹⁰⁸ Statement of Dr Haines, 4 May 2017, p 7.

¹⁰⁹ Evidence, Dr Stephen Cooper, Radiation Oncologist, Genesis Cancer Care NSW, and Chair, Multidisciplinary Head and Neck Unit, St Vincent’s Hospital Sydney, 31 October 2016, p 56.

¹¹⁰ Evidence, Dr Cooper, 31 October 2016, p 57; see also p 58.

charts to see if he is actually giving a dose consistent with standard care. My expectation is that he will be using a schedule that is consistent with best practice.¹¹¹

2.24 Dr Cooper went on note that he had no way to monitor what Dr Grygiel was doing. He also expressed surprise that a greater level of scrutiny was not exercised within the medical oncology department, suggesting that in his own department there is a much greater awareness of clinician's decisions.¹¹²

2.25 For Dr Cooper, the key issue was not so much that Dr Grygiel was prescribing off-protocol, but whether the dose prescribed was outside the reasonable standard of care:

The sin is not to give a dose different to eviQ, but to the extent that there is a sin it is that that dose that is being prescribed is outside of the reasonable bounds of care.¹¹³

2.26 Dr Cooper told the committee that having subsequently interrogated the research evidence, he had concluded that Dr Grygiel's prescribing was not within the bounds of reasonable care because there was insufficient evidence to support it as standard practice:

I spent a lot of time trying to clarify that question in my own mind because I have a very high regard for John, and John had made a considered judgement that it was. In the course of my investigations I came to the conclusion that it was not within the spectrum of reasonable care.¹¹⁴

2.27 In the context of a detailed discussion about the research evidence in respect of carboplatin versus cisplatin, Dr Cooper suggested that while there was sufficient evidence to validate carboplatin as a reasonable drug to use, and that Dr Grygiel may have altered the dosage 'for good reasons', Dr Grygiel 'did not have the evidence to introduce it as standard practice.'¹¹⁵ Dr Cooper underscored the fault in Dr Grygiel not having disclosed to the multidisciplinary team his routine prescribing of flat-dosed carboplatin to a large number of patients, as well as his not having prospectively evaluated this treatment regime via a clinical trial.¹¹⁶

2.28 Notwithstanding these criticisms, Dr Cooper told the committee that he knew Dr Grygiel to be 'a deeply concerned and caring oncologist, who has always struggled to do the right things by patients' and observed, 'I have no doubt that what he has done has been, in his belief, the best thing for his patients'.¹¹⁷ He further stated that while he did not defend all of his former colleague's actions, he believed them to be 'in error rather than in mischief'.¹¹⁸

¹¹¹ Evidence, Dr Cooper, 31 October 2016, p 57.

¹¹² Evidence, Dr Cooper, 31 October 2016, p 61.

¹¹³ Evidence, Dr Cooper, 31 October 2016, p 58.

¹¹⁴ Evidence, Dr Cooper, 31 October 2016, p 59.

¹¹⁵ Evidence, Dr Cooper, 31 October 2016, p 61; see also p 62.

¹¹⁶ Evidence, Dr Cooper, 31 October 2016, p 61; see also p 62.

¹¹⁷ Evidence, Dr Cooper, 31 October 2016, p 56.

¹¹⁸ Evidence, Dr Cooper, 31 October 2016, p 56.

Dr David Dalley

- 2.29** The committee heard that in his interview with the section 122 inquiry, the former head of St Vincent's Medical Oncology Department, then Dr Grygiel's supervisor, Dr David Dalley, denied knowledge of Dr Grygiel prescribing off-protocol.¹¹⁹
- 2.30** Dr Dalley told the committee that while he was sure he would have discussed carboplatin used for radiotherapy with Dr Grygiel, he did not recall ever discussing the drug's dosage with him.¹²⁰ Indeed, Dr Dalley advised that he was first informed of the dosage of 100 mg and fixed doses by Professor Currow during the section 122 inquiry.¹²¹
- 2.31** Dr Dalley acknowledged that both he and Dr Grygiel shared concerns about the increased toxicity that combined chemo-radiation caused, and stated that given Dr Grygiel's significant experience as a medical oncologist, as a pharmacist and in the pharmaceutical industry, he would be surprised if Dr Grygiel used a low dose without evidence. He further stated that while he had recently become aware of two clinical trials using a fixed dose of carboplatin, both trials were small in scale and thus open to criticism.¹²² He told the committee, 'I think he firmly believed that low doses were sufficient.'¹²³ In addition, based on his understanding of the evidence, Dr Dalley proposed that it was 'impossible to determine, but it is unlikely' that the reduced, flat dosage resulted in harm.¹²⁴
- 2.32** Asked whether, in 2006 and again in 2013, he had authorised Dr Grygiel's flat dosage at 100 mg, Dr Dalley categorically denied this, and stated that while he and Dr Grygiel would have discussed concurrent chemotherapy [and radiation therapy], they would not have discussed dosage. He told the committee that from the time of preparing for the introduction of eviQ, dosage was expected to be in accordance with eviQ guidelines, and that 'everyone knew' that without sufficient evidence, '[t]here is no way that low dose fixed dosing carboplatin would have got through the committee' that determined what was adopted into eviQ.¹²⁵

St Vincent's Hospital representatives

- 2.33** The committee asked St Vincent's Hospital representatives if they knew why Dr Grygiel was prescribing off-protocol. Mr Toby Hall, Chief Executive, St Vincent's Health Australia, attested that he subsequently sought an explanation from Dr Grygiel, and could only take at face value his assertions that he was acting in his patients' best interests, based on his understanding of the evidence:

¹¹⁹ Evidence, Dr Paul Curtis, Director, Governance and Assurance, NSW Clinical Excellence Commission, 29 November 2016, p 29; correspondence from Professor David Currow, Chief Cancer Officer, NSW and Chief Executive Officer, Cancer Institute NSW, to Committee Chair, 22 December 2016, p 1.

¹²⁰ Evidence, Dr David Dalley, Former Head of Medical Oncology, St Vincent's Health Network Sydney, 29 November 2016, p 52; see also p 55.

¹²¹ Evidence, Dr Dalley, 29 November 2016, p 53.

¹²² Evidence, Dr Dalley, 29 November 2016, p 52.

¹²³ Evidence, Dr Dalley, 29 November 2016, p 57.

¹²⁴ Evidence, Dr Dalley, 29 November 2016, pp 52 and 53-54.

¹²⁵ Evidence, Dr Dalley, 29 November 2016, p 56.

I have spoken to Dr Grygiel to understand his treatment regime once this came to light and his explanation to me—and I have to believe that this is the case—was that he was doing this in the best interests of his patients. The cohort of patients that we are talking about are incredibly frail and carboplatin is poisonous to the body. All oncologists have to make a judgement about treatment in respect of “How much should I give a very frail patient” and essentially help them be cured versus damaging them. Now, that is quite an appropriate thing to think through from an oncology point of view. My question then was can you explain the evidence behind that because as an organisation we absolutely rely on having evidence-based treatment protocols. Dr Grygiel, at that point, explained that he believed he had read researched evidence that supported flat-dosing carboplatin for this type of head and neck patient, and he felt that that was the best treatment regime to avoid harm to these patients.¹²⁶

- 2.34** Mr Hall proposed that the strength of Dr Grygiel’s belief that there is evidence behind his treatment regime was likely to have been reflected in his communication with staff who had in the past raised concerns about his practice but not taken their concerns further (discussed further in the following chapter).¹²⁷ Mr Hall reported that nevertheless, he had not yet been provided with any evidence from clinical trials to justify Dr Grygiel’s dosing, and this being so, the onus was on Dr Grygiel to pursue his practices within a research framework, with ethics committee oversight, and patient consent. This did not occur.¹²⁸

Patients

- 2.35** The committee received confidential evidence from patients consistent with the section 122 inquiry’s observations that Dr Grygiel was not as thorough with obtaining consent as he should have been, nor as active in engaging patients in decision making as he might have been.
- 2.36** Of those patients and family members who made public or partially confidential submissions, a few commented on issues of informed consent and their understanding of the treatment Dr Grygiel prescribed them.
- 2.37** One family whose mother was treated by Dr Grygiel in the Western NSW Local Health District advised that a review of their case found no notes to indicate that their mother had a clear understanding of her treatment or prognosis. The patient’s son in law stated in his submission, ‘We believe that [our mother] was not given sufficient information to make informed decisions which has robbed her valuable time with her family’.¹²⁹ His wife, the patient’s daughter, also spoke of their family’s unanswered questions, whilst asserting her mother’s right to have been informed:

Mum believed she was getting the best care that was out there, she had faith in Dr Grygiel and believed he was giving her every chance to live, but with limited notes no one will ever know. He held her life in his hands and ... had no right to make decisions of dosage without discussing it with [her].¹³⁰

¹²⁶ Evidence, Mr Toby Hall, Group Chief Executive Officer, St Vincent’s Health Australia, 31 October 2016, p 45.

¹²⁷ Evidence, Mr Hall, 31 October 2016, p 45.

¹²⁸ Evidence, Mr Hall, 31 October 2016, p 45.

¹²⁹ Submission 94, Name suppressed, pp 1-2.

¹³⁰ Submission 103, Name suppressed, p 1.

- 2.38** Another woman from Western NSW treated by Dr Grygiel for breast cancer stated in her submission that with no previous experience of cancer she did not question her treatment regime. After later learning that other women treated for similar disease had had more cycles of chemotherapy, she raised her concerns with Dr Grygiel at a check up. However, she found his response – ‘Maybe we were just trying to be kind to you’ – evasive. She told the committee, ‘The above comment was all that Dr Grygiel would say. If there was some other reason why I could not have been given six doses I should have been told.’¹³¹
- 2.39** A patient who had colorectal cancer told the committee that following her surgery she attended an appointment with Dr Grygiel in Orange. After some delay, from his hotel room and without actually seeing her, Dr Grygiel prescribed her two Xeloda¹³² twice a day for 14 days, with an instruction to then wait one week and have a blood test on the sixth day, then attend her GP who would review her test results. Dissatisfied with her treatment, she applied to receive subsequent treatment in Dubbo and there was prescribed Xeloda at three tablets twice a day whilst seeing the oncologist every three weeks. She stated, ‘I thought how different this treatment was and could not understand why the dose was different’.¹³³
- 2.40** On the other hand, another submission author described how he had attended Dr Grygiel with his son, an actuary with a comprehensive understanding of statistics, risks and probability. Together, they had ‘a full and frank discussion including the surgeon’s report, the chance of reoccurrence, and the trauma and risk to my immune system of chemotherapy, and we decided to reduce chemotherapy to zero ... I am grateful to Dr Grygiel for helping us to decide to have no chemotherapy.’¹³⁴

Others

- 2.41** Others who, like Mr Hall, underscored that a doctor in Dr Grygiel’s position had a responsibility to pursue this line of treatment within an ethics committee approved research framework included Professor Stephen Ackland, Medical Oncologist and Director, Hunter Cancer Research Alliance. He asserted that ‘there should be, in a system, capacity to diverge from consensus and observe the effects of that divergence in the interests of the subject ... that should be done with discussion amongst colleagues, approval by whoever is in charge and everybody else in the team, and close observation of the effects of that change—if you can observe it.’¹³⁵ Professor Ackland explained the options for clinicians who wish to depart from accepted practice:

[T]here may be a scientific hypothesis for doing something that is outside of convention. In that circumstance there are two ways to go ... If it is an individual patient experiment then you have to go through a series of regulatory processes to obtain appropriate ethical approval for that individual patient—N=1—trial to be undertaken in your hospital, under appropriate supervision. If you think it is a bigger issue and you have a scientific hypothesis for a clinical trial then you have to write a

¹³¹ Submission 57, Name suppressed, p 1.

¹³² Xeloda is the commercial name for capecitabine.

¹³³ Submission 65, Name suppressed, pp 1-2.

¹³⁴ Submission 111, Name suppressed, p 1.

¹³⁵ Evidence, Professor Stephen Ackland, Director, Hunter Cancer Research Alliance, University of Newcastle, 1 November 2016, p 33.

protocol, submit it to a research ethics committee and make it a proper research study in a statistically justified cohort of 25, 30, 200 or 5,000 patients. [And before doing that t]here would need to be a degree of peer review to make sure that the individual physician's thinking was sound and evidence-based enough to proceed. Then there would need to be some regulatory oversight.¹³⁶

2.42 Professor Ackland's colleague, Professor Jennifer Martin, Chair of Clinical Pharmacology at the University of Newcastle, concurred, later suggesting that a clinician should be able to go 'outside the bounds of reasonable care' but that this should be under a research framework.¹³⁷ She argued that 'it really needs to go through a research ethics and governance process so that we can write it up and publish it at the end so that everyone else can understand what we have done and how much better or worse it is than the current protocol.'¹³⁸

2.43 One further inquiry participant, Dr Laurence J Denholm, framed the issue as a question:

A key question remaining for inquiry in this incident is whether or not there was, in effect, an unauthorised, informal and potentially illegal clinical trial of deescalated carboplatin chemotherapy by Dr Grygiel at St Vincent's Hospital without the informed consent of patients and whether other medical staff at St Vincent's were aware of this off-protocol experimental treatment of head and neck cancer patients by Dr Grygiel before August 2015.¹³⁹

Dr Grygiel's dismissal

2.44 Mr Hall advised that Dr Grygiel was dismissed from his employment with the hospital in August 2016 because of serious misconduct, having been on long service leave from February 2016.¹⁴⁰ He explained that the hospital waited until August to allow the section 122 inquiry to run its course:

We felt that it was important for the Currow inquiry to fully investigate what had happened. The Ministry announced that inquiry, Dr Grygiel essentially had retired from active practice at that point anyway and we said at the time that we would institute any review of staff involved once we had seen the finalised Currow inquiry. Once that finalised inquiry came in, the first step we took was obviously to talk to Dr Grygiel as to his employment with St Vincent's. We thought that was appropriate given the evidence from the inquiry, and particularly that some of the inquiry evidence did not align with internal information that Dr Grygiel had provided to the organisation.¹⁴¹

2.45 Mr Hall told the committee that Dr Grygiel did not receive a farewell remuneration package, but did receive a standard retirement package. He stated, 'In terms of the termination, there

¹³⁶ Evidence, Professor Ackland, 1 November 2016, p 31.

¹³⁷ Evidence, Professor Jennifer Martin, Chair, Clinical Pharmacology, University of Newcastle, 1 November 2016, p 34.

¹³⁸ Evidence, Professor Martin, 1 November 2016, p 33.

¹³⁹ Submission 95, Dr Laurence J Denholm, p 1.

¹⁴⁰ Evidence, Mr Hall, 29 November 2016, pp 33-34.

¹⁴¹ Evidence, Mr Hall, 29 November 2016, p 33.

has been no payment of any kind and, barring any outcomes of legal action, St Vincent's will strenuously avoid making any additional payments to Dr Grygiel.¹⁴²

- 2.46** In late March 2017, Dr Grygiel and St Vincent's Hospital settled an unfair dismissal case initiated by Dr Grygiel prior to the matter being heard by the Fair Work Commission.¹⁴³

Committee view

- 2.47** The committee has chosen not to comment in respect of Dr Grygiel's actions as we cannot in any way undermine the processes of the Health Care Complaints Commission investigations underway at this time, nor any future legal decisions that might arise from the investigations.
- 2.48** It is self evident that all medical practitioners should act in accordance with evidence based treatment protocols, and that every patient should be able to trust that their doctor is acting within the bounds of reasonable care. The committee's recommendations in chapter 8 are built on these principles.

¹⁴² Evidence, Mr Hall, 29 November 2016, p 34.

¹⁴³ David Marchese, 'Chemotherapy dosage controversy: Doctor John Grygiel settles unfair dismissal case', <http://www.abc.net.au/news/2017-03-24/chemotherapy-doctor-settles-unfair-dismissal-with-st-vincents/8382666>.

Chapter 3 St Vincent's Hospital's response to the allegations of off-protocol prescribing

There were many wonderful, skilled, ethical and caring people working at St Vincent's Hospital when this crisis occurred. Not just a few, but the majority. And yet the problem did occur.

Concerns expressed by junior staff were ignored, the interests of patients were ignored, mandatory reporting rules were ignored and ultimately there appears to have been an attempt at cover-up whilst correcting the situation, to avoid reputational damage ... It is critical to recognise that a decade of off-protocol chemotherapy prescribing was not the real problem, just a symptom of the problem. Off-protocol chemotherapy just happened to be the vehicle by which an underlying problem was revealed, but it might have occurred elsewhere.¹⁴⁴

This chapter examines St Vincent's Hospital's actions with respect to Dr John Grygiel's prescribing of off-protocol chemotherapy to head and neck cancer patients, from the point at which a senior clinician raised concerns about the prescribing in mid 2015, through to when the Secretary for Health initiated the section 122 inquiry on 19 February 2016.

The chapter begins with a list of the key individuals in the St Vincent's Health Network involved in the matter, then examines in detail the key areas in which St Vincent's Hospital's actions were found by the section 122 inquiry to be deficient. First, it explores how for ten years or more, concerns among junior staff about Dr Grygiel's prescribing were never formalised. Next, it documents how the concerns were eventually escalated and the various steps taken, from the perspective of those involved. The chapter then turns to a detailed analysis of the hospital's clinical governance response, including in respect of recognising the seriousness of the issue, incident management, the internal investigation and the external review. Next, the committee examines the hospital's disclosure to patients, and the related matter of how patients continued to be treated by Dr Grygiel and referred to him when the matter was under investigation. The chapter then considers whether there was an element of cover up in the hospital's handling of the matter. It concludes with an examination of the Chief Health Officer's awareness of the issue in late 2015, before the matter became public.

In each section the chapter notes the key findings and recommendations of the section 122 inquiry, then documents the perspectives presented during our own inquiry.

Key individuals

3.1 Dr John Grygiel is a medical oncologist with speciality expertise in head and neck cancer. Dr Grygiel joined St Vincent's Hospital in 1993¹⁴⁵ and practiced as a Senior Medical Oncologist, largely treating patients with head and neck cancers and a smaller number of patients with a

¹⁴⁴ Submission 95a, Dr Laurence J Denholm, p 4.

¹⁴⁵ Evidence, Dr Stephen Cooper, Radiation Oncologist, Genesis Cancer Care NSW and Chair, Multi-disciplinary Head and Neck Unit, St Vincent's Hospital, 31 October 2016, p 56.

range of other cancers.¹⁴⁶ He was head of the Head and Neck Cancer Clinic at St Vincent's Hospital from 2013 until his retirement in 2016.¹⁴⁷

3.2 The remaining individuals are listed in alphabetical order.

3.3 **Dr Stephen Cooper** is a Radiation Oncologist with a specialty interest in the treatment of head and neck cancers, and Chair of the Multi-Disciplinary Head and Neck Unit at St Vincent's Health Network Sydney. Dr Cooper works for Genesis Cancer Care NSW, which is contracted to provide radiation oncology treatment to St Vincent's Hospital patients.¹⁴⁸

3.4 **Dr David Dalley** was the Head of Medical Oncology at St Vincent's Health Network Sydney from 1983 until his retirement in December 2013, and Dr Grygiel's immediate supervisor until that time.¹⁴⁹

3.5 **Associate Professor Richard Gallagher** has worked at St Vincent's Health Network Sydney as a Head and Neck Surgeon since 1998. He is the health network's Director of Cancer Services and its Director of the Head and Neck Service.¹⁵⁰

3.6 **Dr Brett Gardiner** was the Chief Medical Officer and Director of Clinical Governance at St Vincent's Health Network Sydney between 2010 and 2016. Dr Gardiner left the hospital in June 2016.¹⁵¹

3.7 **Mr Toby Hall** is the Group Chief Executive Officer of St Vincent's Health Australia. St Vincent's Health Network Sydney sits within the larger St Vincent's Health Australia organisation.¹⁵²

3.8 **Associate Professor Anthony Schembri** is the Chief Executive Officer of St Vincent's Health Network Sydney, which includes St Vincent's Hospital Sydney.¹⁵³

Non-escalation of concerns

3.9 The committee learned that prior to the events of mid 2015, there had been a long history of staff raising concerns about Dr Grygiel's carboplatin prescribing but not formalising or escalating those concerns to a senior level. This systemic issue, that goes to the culture of St

¹⁴⁶ NSW Ministry of Health, *Inquiry under section 122 of the Health Services Act 1997: Off-protocol prescribing of chemotherapy for head and neck cancers*, Final report, 31 July 2016 (hereafter section 122 inquiry final report), p 14.

¹⁴⁷ Evidence, Dr John Grygiel, Medical Oncologist, 1 November 2016, p 6.

¹⁴⁸ Evidence, Dr Cooper, 31 October 2016, p 56.

¹⁴⁹ Evidence, Dr David Dalley, Former Head of Medical Oncology, St Vincent's Health Network Sydney, 29 November 2016, p 52.

¹⁵⁰ The Kinghorn Cancer Centre, *Clinical Care Staff*, <http://www.tkcc.org.au/richard-gallagher/>.

¹⁵¹ Evidence, Dr Brett Gardiner, Former Director, Clinical Governance, St Vincent's Health Network Sydney, 29 November 2016, pp 61-62.

¹⁵² St Vincent's Health Australia, *Our Executive Leadership Team*, <https://svha.org.au/home/about-us/svha-executive-leadership-team>.

¹⁵³ St Vincent's Hospital Sydney, *Our Leadership Team*, <https://svhs.org.au/home/about-us/our-leadership-team>.

Vincent's Hospital's Cancer Services stream, was a key focus for the section 122 inquiry, and in turn, was explored in our own inquiry.

The section 122 inquiry

- 3.10** An important finding of the section 122 inquiry was that individual staff members raised concerns 'on many occasions' about flat dosing of carboplatin with Dr Grygiel from at least 2005. However, each time clinicians accepted Dr Grygiel's explanation, and so did not act on the flat dosing as a clinical 'incident', even though the practice was outside protocol and no evidence supporting it was provided.¹⁵⁴ The inquiry's final report on St Vincent's Hospital states:

Failure by staff to recognise this prescribing as a clinical incident resulted in no incidents being reported in the St Vincent's Hospital RiskMan® [incident management] system. Therefore 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-2015.¹⁵⁵

- 3.11** The section 122 inquiry report further noted that the matter was also never escalated to an appropriate clinical expert.¹⁵⁶ Conceptualising the issue as one of organisational culture, as discussed in detail in the following chapter, the section 122 inquiry recommended that St Vincent's Hospital 'Revisit mechanisms for escalation of clinical concerns to ensure that key line managers are seen as crucial to the process of adequately addressing clinical concerns from junior nursing, pharmacy and medical staff'.¹⁵⁷

Evidence before the committee

- 3.12** The committee sought to interrogate the evidence before the section 122 inquiry about this ten year history of non-formalised concerns, in order to understand how this could have occurred, and what it revealed about the hospital at that time.
- 3.13** Professor David Currow, Chief Cancer Officer, NSW, Chief Executive of the Cancer Institute NSW, and Co-leader of the section 122 inquiry, advised the committee that a total of four staff, including junior pharmacists, oncology nurses and junior doctors told the section 122 inquiry that they had raised the issue of flat dosing with Dr Grygiel prior to June 2015, and that several people indicated that they were aware of the issue having been raised with Dr Grygiel on a number of occasions.¹⁵⁸

¹⁵⁴ Section 122 inquiry final report, p 28.

¹⁵⁵ Section 122 inquiry final report, p 28.

¹⁵⁶ Section 122 inquiry final report, p 31.

¹⁵⁷ Section 122 inquiry final report, p 37.

¹⁵⁸ Answers to supplementary questions, Professor David Currow, Chief Cancer Officer, NSW, and Chief Executive Officer, Cancer Institute NSW, received 28 November 2016, p 3.

- 3.14** In addition, two people indicated during the section 122 inquiry that a pharmacist had raised Dr Grygiel's practice of flat dosing with a senior clinician, however, the senior clinician concerned indicated that no one had raised it with him/her.¹⁵⁹ The staff member who allegedly raised it could not recall when they did so.¹⁶⁰
- 3.15** Asked specifically how many junior pharmacists, oncology nurses and junior doctors raised the issue of flat dosing with Dr Grygiel before June 2015, the hospital advised the committee that it does not have this information because the concerns were never escalated.¹⁶¹
- 3.16** Dr Grygiel acknowledged to the committee that perhaps five or six junior staff had raised concerns with him about off-protocol prescribing. He told us that he had explained to each of them why he did so, 'and they seemed to accept these explanations.'¹⁶² With regard to the registrars he supervised, Dr Grygiel told the committee that he would encourage them to use the guidelines to experience the toxicities that arose from the higher doses employed with the protocol's area under the curve formula,¹⁶³ that is, in accordance with the relevant protocol.
- 3.17** Asked whether prior to June 2015 anyone in the hospital was aware of the problem other than junior staff, Mr Toby Hall, Group Chief Executive Officer of St Vincent's Health Australia, stated categorically that endeavours to establish this found no evidence that more senior clinicians were aware:
- My investigations and the Currow investigations have found no evidence that senior management or clinicians knew. If anybody has that evidence they should come forward. As yet I have not been given that evidence from anyone.¹⁶⁴
- 3.18** Mr Hall acknowledged that the section 122 inquiry had discovered that there had been one entry in the RiskMan system in 2012 that should have been elevated to management but was not. He explained that the manual system that existed at that time had no escalation process to double check that the relevant manager had responded to it. The manager thought she had responded to it but had not.¹⁶⁵
- 3.19** Asked whether he accepted as credible that staff had raised concerns about underdosing by Dr Grygiel for 10 years without hospital management being aware that it was an issue, Professor Currow emphasised that this was the evidence his inquiry had received. He went on to explain the clinical context in which Dr Grygiel's prescribing occurred:

¹⁵⁹ Answers to supplementary questions, Professor Currow, received 28 November 2016, p 6.

¹⁶⁰ Evidence, Dr Paul Curtis, Director, Governance and Assurance, NSW Clinical Excellence Commission, 29 November 2016, p 29; see also correspondence from Professor David Currow, Chief Cancer Officer, NSW and Chief Executive Officer, Cancer Institute NSW, to Committee Chair, 22 December 2016, p 1.

¹⁶¹ Answers to supplementary questions, St Vincent's Hospital Sydney, received 28 November 2016, p 60.

¹⁶² Evidence, Dr Grygiel, 1 November 2017, pp 7-8.

¹⁶³ Evidence, Dr Grygiel, 1 November 2017, pp 4 and 8.

¹⁶⁴ Evidence, Mr Toby Hall, Group Chief Executive Officer, St Vincent's Health Australia, 31 October 2016, p 39.

¹⁶⁵ Evidence, Mr Hall, 31 October 2016, p 51.

I would hasten to add that there are three patient cohorts identified relating to head and neck cancers in the report. There are those who were administered cisplatin at a personalised dose; those who were administered carboplatin at a personalised dose; and those who were administered carboplatin at a flat dose off-protocol. That is important because, as you think about those staff rotating through in the case of medical staff, who perhaps are on a 10-week rotation, they will have seen patients treated with cisplatin, with carboplatin at a personalised dose and potentially carboplatin at a flat dose. If it was not escalated beyond that, their exposure to that clinically may indeed have been quite limited.¹⁶⁶

- 3.20** Responding to a suggestion that senior pharmacy and nursing staff knew about the problem, and told senior management, who ignored it, Professor Currow responded, ‘I do not have any evidence provided to the inquiry that supports that assertion’.¹⁶⁷ Professor Currow also underscored that the section 122 final report was not to be interpreted as laying the blame on junior staff, noting that it stated, ‘The practice was widely known, and senior pharmacy and nursing staff should have known it was occurring’.¹⁶⁸ Professor Currow then highlighted the section 122 inquiry’s findings and recommendations concerning problems with organisational culture, clinical governance and systems as key contributors to the context in which the failure to recognise and escalate the problem occurred, as well as the inquiry’s explicit criticisms of hospital and clinical leaders.¹⁶⁹ The issues of culture and leadership are discussed in detail in the following chapter.

How the events unfolded

- 3.21** A primary focus of both the section 122 inquiry and our own was how staff at St Vincent’s Hospital responded, at several stages, to the allegations raised in mid 2015 that Dr Grygiel was not prescribing in accordance with protocols. Set out below is a timeline of events. Next, we set out the evidence the committee received about how the allegations surfaced, discussion in the multidisciplinary team, the alerting of the Director of Clinical Governance then other senior hospital staff, and discussions with Dr Grygiel.

¹⁶⁶ Evidence, Professor Currow, 31 October 2016, p 5.

¹⁶⁷ Evidence, Professor Currow, 31 October 2016, p 16.

¹⁶⁸ Section 122 inquiry final report, p 17, quoted in evidence, Professor Currow, 31 October 2016, p 16.

¹⁶⁹ Evidence, Professor David Currow, Chief Cancer Officer, NSW and Chief Executive Officer, Cancer Institute NSW, 31 October 2016, pp 16 and 17; see also evidence, Dr Paul Gavel, Director, Workforce, Healthshare NSW, 31 October 2016, pp 16-17.

Timeline of events

From 2005	Concerns about chemotherapy dosing raised by individual staff members with Dr John Grygiel on a number of occasions. ¹⁷⁰
2012	An entry made in the St Vincent's incident management system regarding Dr Grygiel and flat dosing, but incident report never completed. ¹⁷¹
June 2015	Dr Stephen Cooper, Radiation Oncologist, informed Associate Professor Richard Gallagher, Director of Cancer Services, of his concerns with Dr Grygiel's prescribing. ¹⁷² Issue raised at a head and neck multidisciplinary team (MDT) meeting, where Dr Grygiel was asked to change his prescribing practices to align with eviQ protocols. Associate Professor Gallagher believes the prescribing practice did change from that time. ¹⁷³ Associate Professor Gallagher reports the concerns about chemotherapy dosing to then Director of Clinical Governance and Chief Medical Officer, Dr Brett Gardiner. ¹⁷⁴
5 August 2015	Dr Gardiner sends email to Associate Professor Anthony Schembri, Chief Executive Officer, and others regarding a potential issue relating to chemotherapy under-dosing of head and neck patients, suggesting a process of information-gathering take place with a view to conducting an external review. ¹⁷⁵
7 August 2015	Pharmacy, nursing and medical staff brief the Chief Operating Officer and Director of Clinical Governance/Chief Medical Officer at a meeting. ¹⁷⁶ Reportable Incident Brief (RIB) prepared for this meeting, but never sent to NSW Health. ¹⁷⁷ Initial internal investigation commenced. ¹⁷⁸
10 August 2015	MOSAIQ oncology information system implemented at St Vincent's Hospital. ¹⁷⁹

¹⁷⁰ Section 122 inquiry final report, p 28.

¹⁷¹ Evidence, Professor Currow, 31 October 2016, p 6; answers to supplementary questions, St Vincent's Hospital Sydney, received 28 November 2016, p 58.

¹⁷² Evidence, Associate Professor Richard Gallagher, Director of Cancer Services, St Vincent's Health Network Sydney, 31 October 2016, p 38.

¹⁷³ Evidence, Associate Professor Gallagher, 31 October 2016, p 37; evidence, Mr Hall, 31 October 2016, p 39. As noted later in this chapter, whether the issue was raised in the multidisciplinary team was disputed by Dr Grygiel.

¹⁷⁴ Answers to supplementary questions, St Vincent's Hospital Sydney, received 28 November 2016, p 74.

¹⁷⁵ Evidence, Dr Gardiner, 29 November 2016, p 61.

¹⁷⁶ Section 122 inquiry final report, pp 4-5.

¹⁷⁷ *In camera* evidence, Dr Gardiner, 29 November 2016, p 2. Evidence published by resolution of the committee.

¹⁷⁸ Answers to questions on notice, St Vincent's Hospital Sydney, received 23 December 2016, p 8.

¹⁷⁹ Section 122 inquiry final report, p 5.

31 August 2015	Dr Gardiner and Associate Professor Gallagher meet with Dr Grygiel to seek information as to the basis for his prescribing and to confirm that a review is being undertaken. Dr Grygiel confirmed he had changed his practice and would prescribe in accordance with the eviQ protocol. ¹⁸⁰
6 October 2015	Dr Gardiner, Associate Professor Gallagher and a radiation oncologist meet, prompting Dr Gardiner to confirm the need for an external review and to ask the Associate Professor Gallagher to enquire as to suitable reviewer. ¹⁸¹
November 2015	Associate Professor Schembri informs Dr Kerry Chant, Chief Health Officer, NSW Health, that St Vincent's Hospital will conduct external review. ¹⁸²
16 November 2015	Report of internal investigation provided to St Vincent's Hospital executive. ¹⁸³
24 November 2015	St Vincent's extends formal invitation to external reviewer. ¹⁸⁴
26 November 2015	External reviewer declines invitation. ¹⁸⁵
10 December 2015	Meeting of St Vincent's Health Board included a briefing on the concerns around flat dosing. ¹⁸⁶
11 December 2015	Second external reviewer approached. ¹⁸⁷
22 December 2015	St Vincent's external review commences. ¹⁸⁸
9 February 2016	External review report sent to St Vincent's Hospital. ¹⁸⁹
February 2016	Hospital notifies Ministry of Health after receipt of external review report and before informing patients. ¹⁹⁰ Dr Grygiel commences leave. ¹⁹¹
18 February 2016	ABC's 7.30 airs a report on the flat dosing matter. ¹⁹² Disclosure by St Vincent's Hospital to some affected patients. ¹⁹³

¹⁸⁰ Evidence, Dr Gardiner, 29 November 2016, p 61.

¹⁸¹ Evidence, Dr Gardiner, 29 November 2016, p 61.

¹⁸² Evidence, Associate Professor Anthony Schembri, Chief Executive Officer, St Vincent's Health Network Sydney, 31 October 2016, p 52.

¹⁸³ Section 122 inquiry final report, p 5.

¹⁸⁴ Section 122 inquiry final report, p 5.

¹⁸⁵ Section 122 inquiry final report, p 5.

¹⁸⁶ Section 122 inquiry final report, p 5.

¹⁸⁷ Section 122 inquiry final report, p 5.

¹⁸⁸ Section 122 inquiry final report, p 5.

¹⁸⁹ Section 122 inquiry final report, p 5.

¹⁹⁰ Evidence, Associate Professor Schembri, 31 October 2016, p 47.

¹⁹¹ Evidence, Mr Hall, 29 November 2016, p 34.

¹⁹² 7.30, ABC, 'Up to seventy cancer patients under-dosed during treatment at Sydney hospital', Matt Peacock, 18 February 2016.

¹⁹³ Section 122 inquiry final report, p 5; evidence, Associate Professor Gallagher, 31 October 2016, p 35.

19 February 2016	Western NSW Local Health District and Macquarie University Hospital both notify Ministry of Health that Dr Grygiel worked at their institutions. ¹⁹⁴ The Secretary of NSW Health announces an inquiry under section 122 of the <i>Health Services Act 1997</i> relating to the prescribing of chemotherapy at St Vincent's Hospital by Dr John Grygiel from June 2012 – June 2015. ¹⁹⁵ St Vincent's Hospital lodges complaint about Dr Grygiel with NSW Health Care Complaints Commission. ¹⁹⁶
23 February 2016	St Vincent's Hospital commences open disclosure process with all affected patients. ¹⁹⁷
31 March 2016	Section 122 inquiry interim report on St Vincent's Hospital handed down. ¹⁹⁸
4 April 2016	Section 122 inquiry terms of reference expanded to include: <ul style="list-style-type: none"> • patients under the care of Dr Grygiel in Western NSW LHD from January 2006 • the application of eviQ protocols at Western NSW LHD and systems in place for monitoring application of the protocols.¹⁹⁹
22 April 2016	Medical Council of NSW imposes conditions on Dr Grygiel's practice. ²⁰⁰
31 July 2016	Section 122 inquiry final report on St Vincent's Hospital handed down. ²⁰¹
4 August 2016	Dr Grygiel dismissed by St Vincent's Hospital. ²⁰²
16 September 2016	Section 122 inquiry report on patients treated at Western NSW LHD handed down. ²⁰³

¹⁹⁴ Evidence, Mr Scott McLachlan, Chief Executive Officer, Western NSW Local Health District, 2 November 2016, p 3; evidence, Ms Carol Bryant, Chief Executive Officer, Macquarie University Hospital, 24 February 2017, p 18.

¹⁹⁵ NSW Ministry of Health, *Inquiry under Section 122 of the Health Service Act 1997*, <http://www.health.nsw.gov.au/patients/cancertreatment/pages/cancer-patients-inquiry.aspx>.

¹⁹⁶ Evidence, Ms Sue Dawson, Commissioner, Health Care Complaints Commission, 24 February 2017, p 9.

¹⁹⁷ Section 122 inquiry final report, p 5.

¹⁹⁸ NSW Ministry of Health, *Inquiry under Section 122 of the Health Service Act 1997*, <http://www.health.nsw.gov.au/patients/cancertreatment/pages/cancer-patients-inquiry.aspx>.

¹⁹⁹ NSW Ministry of Health, *Inquiry under Section 122 of the Health Service Act 1997*, <http://www.health.nsw.gov.au/patients/cancertreatment/pages/cancer-patients-inquiry.aspx>.

²⁰⁰ Correspondence from Ms Paula Ardino, Principal Monitoring Officer, Medical Council of New South Wales, to secretariat, 18 April 2017.

²⁰¹ NSW Ministry of Health, *Inquiry under Section 122 of the Health Service Act 1997*, <http://www.health.nsw.gov.au/patients/cancertreatment/pages/cancer-patients-inquiry.aspx>.

²⁰² Answers to supplementary questions, St Vincent's Hospital Sydney, received 29 November 2016, p 26. We note that in March 2017 Dr Grygiel and St Vincent's Hospital settled an unfair dismissal case initiated by Dr Grygiel prior to the matter being heard by the Fair Work Commission.

²⁰³ NSW Ministry of Health, *Inquiry under Section 122 of the Health Service Act 1997*, <http://www.health.nsw.gov.au/patients/cancertreatment/pages/cancer-patients-inquiry.aspx>.

The allegations are made

- 3.22** The section 122 inquiry final report states that in June and July 2015 concerns about off-protocol flat dose prescribing emerged in several ways.²⁰⁴
- 3.23** The committee heard that it was Dr Stephen Cooper, Radiation Oncologist, who first raised concerns about Dr Grygiel's prescribing. Having noted an increased number of recurrences among head and neck cancer patients, Dr Cooper questioned whether the two might be linked.²⁰⁵
- 3.24** Dr Cooper advised the committee that his recollection of the first time he became aware of concerns about Dr Grygiel's off-protocol prescribing was during a 'corridor conversation' with a head and neck cancer care coordinator, who pointed out to him that Dr Grygiel was using a flat dose of carboplatin. Up until that time, Dr Cooper stated that he had 'no idea that that was the case.'²⁰⁶ He further advised that he has no recollection of any discussion with Dr Grygiel regarding the prescribed dose of carboplatin, and does not believe that any such discussion occurred prior to the events in mid 2015. He did, however, recall discussions with Dr Grygiel about the latter's choice of cisplatin over carboplatin.²⁰⁷ (See chapter 1 for an explanation of these chemotherapies.)
- 3.25** Associate Professor Gallagher advised the committee that Dr Cooper first brought the matter to his attention in June 2015,²⁰⁸ in his role as campus Director of Cancer Services. He told the committee, 'The first time it was raised I said, "You need to be sure of what you are saying." ... I implied to him that he needed to provide more information so that I could realistically alert the Director of Clinical Governance.'²⁰⁹

Discussion in the multidisciplinary team

- 3.26** The section 122 inquiry final report states:

As to whether the issue was discussed at the Head and Neck Cancer Multidisciplinary meeting in June 2015, there are two different accounts: (i) that, following a challenge to the practice, there was an agreement that all new patients would be prescribed according to the eviQ protocol dosing regimen from then on; and (ii) no such discussion took place.²¹⁰

²⁰⁴ Section 122 inquiry final report, p 4.

²⁰⁵ Evidence, Associate Professor Gallagher, 31 October 2016, pp 38-39; evidence, Associate Professor Gallagher, 29 November 2016, p 48.

²⁰⁶ Evidence, Dr Cooper, 31 October 2016, p 56; see also answers to supplementary questions, Dr Cooper, received 25 November 2016, p 2.

²⁰⁷ Answers to supplementary questions, Dr Cooper, p 2.

²⁰⁸ Evidence, Associate Professor Gallagher, 31 October 2016, pp 38-39.

²⁰⁹ Evidence, Associate Professor Gallagher, 31 October 2016, p 39; answers to supplementary questions, St Vincent's Hospital Sydney, received 28 November 2016, p 74.

²¹⁰ Section 122 inquiry final report, p 4.

- 3.27** Dr Grygiel told the committee that he was not aware of his off-protocol dosing ever having been raised in a multidisciplinary team (MDT) meeting.²¹¹
- 3.28** Associate Professor Anthony Schembri, Chief Executive Officer, St Vincent's Health Network Sydney, advised that in June or July 2015 the matter of Dr Grygiel's off-protocol prescribing was discussed in the head and neck cancer MDT, comprised of up to 20 people, and the discussion there was that the practice would cease.²¹² Associate Professor Gallagher advised that he did not recall which of the weekly MDT meetings in June 2015 it was raised, but it was prior to 25 June 2015, when he went on leave. His recollection was that he, Dr Grygiel, Dr Cooper, and two other doctors were present for the discussion, in which Dr Cooper raised that he believed Dr Grygiel was not prescribing standard doses of carboplatin for head and neck cancer patients and challenged the practice.²¹³
- 3.29** Asked whether he ever questioned Dr Grygiel on his use of carboplatin rather than cisplatin, Professor Gallagher advised that this had been discussed at head and neck MDTs over the years.²¹⁴

The Director of Clinical Governance is alerted

- 3.30** The committee was informed that sometime prior to 25 June 2015, Associate Professor Gallagher raised the matter with Dr Brett Gardiner, the hospital's then Director of Clinical Governance and Chief Medical Officer.²¹⁵ Associate Professor Gallagher advised that, 'I brought it up with him on several different occasions. Then he made the decision that there would be an internal review.'²¹⁶
- 3.31** Associate Professor Schembri confirmed that both Dr Gardiner and Associate Professor Gallagher were responsible for supervising Dr Grygiel's work at that time.²¹⁷
- 3.32** Dr Gardiner confirmed that it was Associate Professor Gallagher, as Director of Cancer Services, who first raised the issue of chemotherapy prescribing with him, however, he could not recall the date.²¹⁸

Other senior hospital staff are alerted

- 3.33** Dr Gardiner sent an email on 5 August 2015 notifying the Chief Executive and others of the potential issue among head and neck cancer patients, and flagging the issue's discussion at a forthcoming meeting of senior staff. The email suggested a process of information gathering (the internal investigation) 'in order to scope what will form the need for a review that will

²¹¹ Evidence, Dr Grygiel, 1 November 2016, p 8.

²¹² Evidence, Associate Professor Schembri, 31 October 2016, p 38.

²¹³ Answers to supplementary questions, St Vincent's Hospital Sydney, p 79.

²¹⁴ Answers to supplementary questions, St Vincent's Hospital Sydney, p 93.

²¹⁵ Answers to supplementary questions, St Vincent's Hospital Sydney, p 76.

²¹⁶ Evidence, Associate Professor Gallagher, p 35; answers to supplementary questions, St Vincent's Hospital Sydney, p 77.

²¹⁷ Evidence, Associate Professor Schembri, 31 October 2016, p 34.

²¹⁸ Evidence, Dr Gardiner, 29 November 2016, p 61.

need to be externally conducted’, and noted the ramifications of the issue as ‘exceptionally serious’ if substantiated.²¹⁹

- 3.34** Associate Professor Schembri confirmed that he was informed of the issue on 5 August 2015,²²⁰ as did Ms Gabrielle Prest, Medicine Clinical Stream Manager, St Vincent’s Health Network Sydney, who confirmed that this occurred ahead of a meeting of senior staff to discuss the matter on the 7 August 2015.²²¹ According to Ms Prest, others who were informed at around the same time were the Manager for Safety and Quality, the Chief Operating Officer, the Director of Pharmacy Services and the Senior Oncology Pharmacist.²²²
- 3.35** Dr Gardiner advised that at the 7 August 2015 meeting attended by the Chief Operating Officer, the Director of Cancer Services, the Manager of Cancer Services, the Chief Pharmacist and two other oncology pharmacists, as well as one person from the Quality and Safety Unit, he was informed of a number of matters:
- Dr Grygiel had changed his prescribing practice to align with eviQ protocols
 - the MOSAIQ electronic system was shortly to be introduced (in August 2015), which included the eviQ protocols, and these would have the effect of controlling the chemotherapy prescribing
 - a new policy was being introduced to mandate a process to follow in the event someone wanted to prescribe outside guidelines
 - the pharmacy department could monitor the chemotherapy prescribing
 - Dr Grygiel’s prescribing was a radiosensitising dose and was not the primary treatment for the patient.²²³
- 3.36** In addition, Dr Gardiner told the committee that he was left with the impression that the prescribing had not had an adverse effect on patients. It was decided at the meeting that he and Associate Professor Gallagher would speak to Dr Grygiel, and that Associate Professor Gallagher would take steps to obtain patient information.²²⁴ Dr Gardiner was then on leave for two weeks, and when he returned he met with Dr Grygiel on 31 August 2015.²²⁵
- 3.37** Associate Professor Schembri briefed Mr David Factor, Director of Media and Communications, about the issue in August 2015 during a routine weekly catch up.²²⁶

²¹⁹ Email from Dr Brett Gardiner, 5 August 2015, attachment to answers to questions on notice, St Vincent’s Hospital Sydney, received 23 December 2016.

²²⁰ Evidence, Associate Professor Schembri, 31 October 2016, p 44.

²²¹ Answers to supplementary questions, St Vincent’s Hospital Sydney, p 101.

²²² Evidence, Ms Gabrielle Prest, Medicine Clinical Stream Manager, St Vincent’s Health Network Sydney, 31 October 2016, p 44.

²²³ Evidence, Dr Gardiner, 29 November 2016, p 61.

²²⁴ Evidence, Dr Gardiner, 29 November 2016, p 61.

²²⁵ Evidence, Dr Gardiner, 29 November 2016, p 64.

²²⁶ Answers to supplementary questions, St Vincent’s Hospital Sydney, pp 98-100.

Discussions with Dr Grygiel

3.38 Dr Cooper told the committee that in June 2015, after he had raised the issue of Dr Grygiel's dosing with Associate Professor Gallagher, he asked Dr Grygiel directly about it.²²⁷ However, Dr Grygiel disputed that this conversation took place.²²⁸

3.39 According to Dr Grygiel, at a meeting with Associate Professor Gallagher and Dr Gardiner on 31 August 2015, Associate Professor Gallagher advised him an internal investigation had been completed and that no patients had been harmed. He said he took this as having been exonerated, but also agreed to abide by the dosing guidelines, with some discretion based on monitoring of side effects:

What happened at the meeting was that the three of us met and Richard Gallagher explained the results of an internal investigation. The summary of those results was that I had been exonerated, I had no case to answer and no patients had been damaged or hurt by my treatment. They asked me at that stage, for the sake of any disgruntlement that may be held in the treatment team, would I mind adopting the area under the curve guideline. I said I had no problems with adopting the area under the curve guideline in the treatment of these patients provided I could retain the authority to down dose if side effects determined that.²²⁹

3.40 Asked whether the word 'exonerated' was used, Dr Grygiel asserted that it was, by Associate Professor Gallagher.²³⁰ Dr Grygiel further contended that his version of events, prepared by his legal team in order to respond to the initial 7.30 broadcast, was verified by Dr Gardiner in an email subsequently provided to the committee.²³¹

3.41 In that email, Dr Gardiner's account is as follows:

On 31 August 2015, a meeting was held between Dr Grygiel, Dr Gallagher, and Dr Gardiner concerning the allegation of 'under-dosing' of patients with Carboplatin. At this meeting, Dr Grygiel's reasons for prescribing the dose of carboplatin which were at variation to the EviQ protocol were discussed. The reasons outlined by Dr Grygiel included the toxicity of Carboplatin on patients and various evidence as to the effectiveness of various dosage regimes. The meeting was part of the internal process review and no criticisms were made of Dr Grygiel. It was noted at the meeting that recurrences in the small number of patients identified were outside the primary radiotherapy treatment zone, and were considered to be probably not related to the clinical dosing decision made by Dr Grygiel.²³²

3.42 According to Dr Grygiel, because he was 'exonerated' he was 'completely blindsided' by the allegations aired on 7.30 on 18 February 2016. He told the committee that he was aware that an external investigation report was being commissioned, but he 'had no inkling of that report until the day of the initial 7.30 report, when the new Head of Medical Oncology, Associate

²²⁷ Evidence, Dr Cooper, 31 October 2016, p 58; answers to supplementary questions, Dr Cooper, p 2.

²²⁸ Evidence, Dr Grygiel, 1 November 2016, p 11.

²²⁹ Evidence, Dr Grygiel, 1 November 2016, p 4.

²³⁰ Evidence, Dr Grygiel, 1 November 2016, p 13.

²³¹ Evidence, Dr Grygiel, 1 November 2016, p 13.

²³² Email from Dr Brett Gardiner to Mr Steven Blanks, 22 February 2016, attached to answers to questions on notice, Dr John Grygiel, Medical Oncologist, received 28 November 2016.

Professor Anthony Joshua shared it with him. He went on to insist that serious concerns about his practices were never expressed to him.²³³

- 3.43** The committee asked both Associate Professor Gallagher and Dr Gardiner for their recollections of these events. Professor Gallagher advised that the meeting was led by Dr Gardiner as Director of Clinical Governance; he himself had attended as Director of Cancer Services. Associate Professor Gallagher disputed that he had told Dr Grygiel he had been exonerated, noting that the internal investigation was not finished at the time of the meeting. He told the committee that the purpose of meeting was to alert Dr Grygiel to the fact that there was an investigation, and to have him agree to change his prescribing habit, which he did.²³⁴
- 3.44** Dr Gardiner's recollection of the 31 August 2015 meeting was that Dr Grygiel was asked to explain the basis for his prescribing, and that it was confirmed that the hospital was in the process of undertaking a review. According to Dr Gardiner, Dr Grygiel confirmed that he would change his practice and prescribe in accordance with the eviQ protocol.²³⁵ He advised the committee that the word 'exonerated' was not used, and nor was this the spirit of the meeting. He conceded that it was possible Dr Grygiel had misunderstood the tenor of the meeting, as there were no criticisms levelled at him because the seriousness of the issue was not known at the time. Nevertheless, according to Dr Gardiner, at that time it was not a matter of saying Dr Grygiel was right or wrong.²³⁶

The clinical governance response

- 3.45** Once the allegations of off-protocol prescribing were raised with the Director of Clinical Governance, and senior staff met to discuss the matter on 7 August 2015, a number of actions under the umbrella of 'clinical governance' were then set in train. These included consideration of whether this was 'an incident' of which hospital senior management and the Ministry of Health would be notified, and the conduct of an internal investigation, then an external review.
- 3.46** Following a summary of the section 122 inquiry's extensive criticisms of the clinical governance response, the evidence that the committee received in relation to each of these actions is discussed below.

Section 122 inquiry findings

- 3.47** The section 122 inquiry formed a number of highly critical conclusions in respect of St Vincent's Hospital's clinical governance response:

²³³ Evidence, Dr Grygiel, 1 November 2016, p 12.

²³⁴ Evidence, Associate Professor Gallagher, 29 November 2016, pp 39-40; see also answers to supplementary questions, St Vincent's Hospital Sydney, pp 80 and 85.

²³⁵ Evidence, Dr Gardiner, 29 November 2016, p 61.

²³⁶ Evidence, Dr Gardiner, 29 November 2016, p 64.

- Instead of acting in the best interests of patients, the hospital's response was inadequate, drawn out, internalised and defensive.²³⁷
- There appeared to be no effective sponsorship of the incident, no sense of urgency about the internal investigation or external review, nor any urgency to review affected patients. This could not be attributed to any point in time or individual; rather it appeared to come about because the matter was framed as an 'error', as 'underdosing' or as a protocol variation, rather than being recognised as a notifiable incident involving a clinician unilaterally prescribing off-protocol with flat dosing. This was a key reason why six months passed between the notification of senior management and the completion of the external review.²³⁸
- In that time, no comprehensive case note review occurred for people known to have been prescribed off-protocol flat dose 100 mg carboplatin.²³⁹
- The internal investigation that took place between August and October 2015 had no terms of reference and did not address the clinical concerns that precipitated the investigation in the first place.²⁴⁰ It failed to adequately determine the clinical impact on patients, and focused solely on the dose of carboplatin prescribed. It also failed to seek input from content experts in medical or radiation oncology. In turn, this meant that the impact of the prescribing was under-recognised, which in turn provided false reassurance to the hospital, which was passed on to the community via the media.²⁴¹
- The hospital failed to understand that the external review confirmed that there was a substantial issue to be addressed, and the serious implications for patients.²⁴²
- The hospital did not comply with a number of NSW Health policies for managing such incidents that is, the Incident Management Policy, the Open Disclosure Policy, and the Managing Concerns and Complaints about a Clinician (MCCC) policy.²⁴³
- Hospital management did not appropriately escalate the issue to the Ministry of Health through a reportable incident brief as required by the Ministry's Incident Management Policy Directive. There were two occasions when this would have been appropriate: when the 'lookback procedure'²⁴⁴ was contemplated in August 2015, and when the St Vincent's Health Australia CEO and board were notified in November 2015.²⁴⁵ Further, under the Ministry's Incident Management Policy, the hospital should have consulted with the Ministry when the hospital determined to go to external review, but it did not do so.²⁴⁶

²³⁷ Section 122 inquiry final report, p 31.

²³⁸ Section 122 inquiry final report, p 19.

²³⁹ Section 122 inquiry final report, p 5.

²⁴⁰ Section 122 inquiry final report, p 20.

²⁴¹ Section 122 inquiry final report, p 20.

²⁴² Section 122 inquiry final report, p 20.

²⁴³ Section 122 inquiry final report, pp 28-31.

²⁴⁴ Lookback is a process that is triggered when a notification of a clinical incident or concern from any source leads to the need for the notification, investigation and the management of a group of commonly affected patients. See NSW Health, *Lookback policy*, 28 September 2007.

²⁴⁵ Section 122 inquiry final report, p 28.

²⁴⁶ Section 122 inquiry final report, p 29.

- The hospital also failed to recognise that the scenario fitted the MCCC policy’s highest severity rating ‘one or more events involving potential serious morbidity and gaps in clinical performance or serious concerns by colleagues about the health and safety of patients’, which required immediate:
 - notification to the hospital CEO
 - determination of whether the Health Care Complaints Commission/Medical Council need to be involved
 - consideration of whether variations to privileges were required
 - management and investigation.²⁴⁷
- The clinical governance department had a ‘proactive responsibility’ to guide the hospital and clinical leaders on the best response to such incidents, on look back and open disclosure.²⁴⁸

3.48 The report further highlighted that the hospital’s senior staff bore a significant level of responsibility for the poor response:

The hospital and clinical leaders had a proactive responsibility to insightfully see the issue for what it was and to quickly obtain an accurate characterisation of the issue, identify all affected patients and to notify those patients in an empathetic, timely and informative manner, to notify the public of the practice and convey how it was managing Dr Grygiel. They also had a proactive responsibility to ensure the issue was being managed appropriately, that appropriate content expertise was being used to analyse the issue so as to understand its root cause, and that any conflicts of interest and internal conflicts were acknowledged and addressed.²⁴⁹

3.49 The inquiry’s recommendations in respect of clinical governance were as follows:

- That St Vincent’s Hospital provide education to key staff on key policies, including the Lookback Policy²⁵⁰
- That the hospital ‘manage any similar incidents with sufficient content-specific expertise and an explicit methodology for defining the magnitude and impact of the clinical incident and its likely consequences.’²⁵¹

Evidence before the committee

3.50 Noting both the extent and the severity of the deficiencies in the hospital’s clinical governance response, the committee explored a number of specific issues in detail with inquiry participants.

²⁴⁷ Section 122 inquiry final report, pp 30-31.

²⁴⁸ Section 122 inquiry final report, p 32.

²⁴⁹ Section 122 inquiry final report, p 32.

²⁵⁰ Section 122 inquiry final report, p 36.

²⁵¹ Section 122 inquiry final report, p 36.

Recognition of the seriousness of the issue

- 3.51** At several points in our inquiry, St Vincent’s Hospital representatives acknowledged that they had misjudged the seriousness of this matter from the start, and that this had impacted on all aspects of their response.²⁵² Associate Professor Schembri explained that had an external review with oncologist expertise been conducted earlier, the seriousness of the situation would have been recognised earlier:

Had we had an oncologist at the time provide that review, then it would have been a very different scenario because we would have realised the seriousness of the issue back in August [2015].²⁵³

- 3.52** Dr Kerry Chant, Chief Health Officer, NSW Ministry of Health, observed that even when the external review report was handed down, the issue was aired in the media, and the Ministry was formally notified, St Vincent’s Hospital failed to understand the seriousness of the issue:

[E]ven in the February when the formal notification to the Ministry came and the issue emerged. I believe that St Vincent’s did not understand the nature and seriousness of the issue, and therefore that factored into the way the incident was portrayed and the information provided. I think there was a fundamental failure to recognise that which then flowed through to all of the communication from that point.²⁵⁴

- 3.53** As evidence of this failure even at this stage of events, the committee learned that it was only after the 7.30 story was aired that the hospital lodged a complaint with the Health Care Complaints Commission about Dr Grygiel’s prescribing.²⁵⁵

Incident management and notification

- 3.54** Associate Professor Schembri further advised that one of the consequences of the hospital misunderstanding the seriousness of the issue was that there was no trigger to notify the matter to the Ministry of Health.²⁵⁶

- 3.55** The committee heard that the Ministry was only formally notified in February 2016, once the hospital had received the external report from the interstate oncologist and was preparing to inform patients.²⁵⁷ Despite surfacing in June 2015, the first time it was raised with the Ministry was in November 2015, when Associate Professor Schembri informally advised the Chief Health Officer.²⁵⁸ Dr Chant’s involvement at this point is discussed in detail in the final section of this chapter.

²⁵² Submission 59, St Vincent’s Hospital Sydney, p 3; evidence, Associate Professor Schembri, 31 October 2016, p 46; answers to supplementary questions, St Vincent’s Hospital Sydney, received 28 November 2016, p 3; evidence, Mr Hall, 29 November 2016, p 33.

²⁵³ Evidence, Associate Professor Schembri, 31 October 2016, p 46.

²⁵⁴ Evidence, Dr Kerry Chant, Chief Health Officer, NSW Ministry of Health, 29 November 2016, p 3.

²⁵⁵ Evidence, Ms Dawson, 24 February 2017, p 9.

²⁵⁶ Evidence, Associate Professor Schembri, 31 October 2016, pp 44 and 46.

²⁵⁷ Evidence, Associate Professor Schembri, 31 October 2016, p 47.

²⁵⁸ Evidence, Associate Professor Schembri, 31 October 2016, pp 52-53; answers to supplementary questions, St Vincent’s Hospital Sydney, pp 69-71.

3.56 The committee learned that a draft reportable incident brief by which the Ministry would have been notified was commenced on 7 August 2015, but never completed nor lodged.²⁵⁹

3.57 The committee sought more information from St Vincent’s Hospital about the decision that Dr Grygiel’s flat dosing was not a formal incident, and the hospital’s response included:

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.²⁶⁰

3.58 Associate Professor Schembri explained in his evidence that the decision not to characterise the matter as an incident at this time was a team one, further stating that it was not a conscious or direct decision, but rather, an omission. He also explained the rationale for the team’s view:

The view was 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.²⁶¹

3.59 Associate Professor Schembri also advised that the hospital has put in place systems to ensure that it does not happen again, and has clarified that it is the responsibility of the Director of Clinical Governance to make such an assessment.²⁶²

3.60 Dr Gardiner’s evidence was also that it was a collective view formed at the 7 August 2015 meeting that because the chemotherapy at issue was for the purpose of radiosensitisation it probably did not have any impact on patients, and that further information was required. The consequence was that the reportable incident brief commenced before the meeting was not completed and submitted.²⁶³ Dr Gardiner noted other actions agreed at the meeting, whilst acknowledging that avoidable delays then occurred:

I was left with the impression that such prescribing had not had an adverse effect on patients. At the conclusion of this meeting it was planned that the Director of Cancer Services and I were to arrange to speak to Dr Grygiel. It was also my understanding that the Manager of Cancer Services was taking steps to obtain patient information.

²⁵⁹ Return to order for papers, 23 February 2016, Underdosing of chemotherapy patients, St Vincent’s Health Australia, email from Associate Professor Anthony Schembri, Chief Executive Officer, St Vincent’s Hospital Sydney, to Ms Gabrielle Prest, Medicine Clinical Stream Manager, document no. 7(a) 92.2, document tabled by the Hon Jeremy Buckingham MLC, 29 November 2016.

²⁶⁰ Answers to supplementary questions, St Vincent’s Hospital Sydney, p 3; see also p 101.

²⁶¹ Evidence, Associate Professor Schembri, 31 October 2016, p 40.

²⁶² Evidence, Associate Professor Schembri, 31 October 2016, pp 39-40.

²⁶³ *In camera* evidence, Dr Gardiner, 29 November 2016, pp 2-3.

However, there was a significant delay in this process which I very much regret that I did not manage more closely.²⁶⁴

- 3.61** Asked why the hospital did not activate the guidelines for the management of complaints or concerns about a clinician (the ‘MCCC guidelines’) at that time, Associate Professor Schembri explained that this was because the hospital did not then have all the information necessary, but was still conducting its reviews. One of the aims of the external review by an expert in oncology was to assess the doctor’s practice.²⁶⁵
- 3.62** The hospital further advised that to the best of its knowledge, there was no contact between anyone at the hospital and NSW Health regarding this matter from the time of the phone call between Associate Professor Schembri and Dr Chant, up until the formal notification in February 2016.²⁶⁶

The internal investigation

- 3.63** St Vincent’s Hospital’s internal investigation commenced on 7 August 2015.²⁶⁷ It was conducted by a medical registrar from the clinical governance unit,²⁶⁸ with representatives from quality and safety, the clinical stream and pharmacy. The team reviewed the pattern of prescribing, clinical records and the eviQ guidelines²⁶⁹ for 47 head and neck cancer patients treated with carboplatin whose treating surgeon was Professor Gallagher.²⁷⁰ It covered the period January 2012 to April 2015. The internal investigation revealed that prescribing of chemotherapy outside the eviQ guidelines had occurred.²⁷¹
- 3.64** Mr Hall acknowledged that the internal investigation should have been handled by a more senior clinician than a registrar, noting that this was done at the direction of the then Director of Clinical Governance. He further conceded that this decision impacted on the hospital’s understanding of the seriousness of the situation.²⁷²
- 3.65** Mr Hall acknowledged that the decision to limit the cohort to patients of Associate Professor Gallagher was inadequate and explained that the rationale had been to enable ease of access to understand if there was a problem. Mr Hall also accepted that the initial investigation should have had greater depth and should have been assisted by an external person with medical oncology expertise.²⁷³ He further noted that while the internal investigation underestimated the seriousness of the problem at that point, it was sufficient to ensure the hospital conducted the external review, carried out by an external medical oncologist.²⁷⁴

²⁶⁴ Evidence, Dr Gardiner, 29 November 2016, p 61.

²⁶⁵ Evidence, Associate Professor Schembri, 31 October 2016, p 40.

²⁶⁶ Answers to questions on notice, St Vincent’s Hospital Sydney, received 23 December 2016, p 1.

²⁶⁷ Answers to questions on notice, St Vincent’s Hospital Sydney, p 8.

²⁶⁸ Evidence, Mr Hall, 29 November 2016, p 37; answers to questions on notice, St Vincent’s Hospital Sydney, p 4.

²⁶⁹ Evidence, Associate Professor Schembri, 31 October 2016, pp 50-51.

²⁷⁰ Evidence, Mr Hall, 29 November 2016, p 44.

²⁷¹ Evidence, Associate Professor Schembri, 31 October 2016, p 51.

²⁷² Evidence, Mr Hall, 29 November 2016, p 37.

²⁷³ Evidence, Mr Hall, 29 November 2016, p 44.

²⁷⁴ Evidence, Mr Hall, 29 November 2016, p 45.

3.66 Dr Cooper highlighted the absence of clinical expertise on the internal investigation as a critical issue, in that without this expertise, the internal investigation was not able to make a judgement as to whether Dr Grygiel's pattern of prescribing was within the spectrum of reasonable care:

I think that the hospital has conceded on multiple occasions that the rigour with which this issue was investigated was insufficient. A major component of that was a failure to get expert external advice in sooner that could say yes, there was an issue, or no, there was not. As I have said, anybody can see, yes, he has given you a dose lower than eviQ. So what? It is: Is the dose that has been given reasonable, or could it be construed to be within the spectrum of reasonable care? To answer that question, they required much earlier genuine subspecialty expertise input into the question, which they did not get. I think in retrospect they would have gotten it. By the time it was sought, it was initially slow to come back and it took some time before the true nature of the problem became apparent.²⁷⁵

The external review

3.67 St Vincent's Health Australia advised that following the completion of the internal investigation, the Director of Cancer Services and the Director of Clinical Governance decided on 6 October 2015 to proceed to external review.²⁷⁶ Asked whether communication with a reporter from 7.30 was a factor in this decision, the hospital denied that this was the case, noting that the decision was made well over a month before the reporter first approached the hospital in November 2015.²⁷⁷ The external review commenced on 22 December 2015 and its report was provided to St Vincent's Hospital on 9 February 2016.²⁷⁸

3.68 With regard to commissioning the external review, Dr Gardiner told the committee that Associate Professor Gallagher was tasked with making inquiries about a suitable reviewer, and that he, Dr Gardiner, followed the matter up from time to time until he went on extended leave from 19 November 2015 to 1 February 2016. The terms of reference for the external review were developed during his leave without his input. Upon returning from leave he made inquiries as to the external review report, which he did not see until 17 February 2017. He told the committee that it was only when he received it that he appreciated the degree of concern.²⁷⁹ Dr Gardiner acknowledged that 'there were a lot of delays', but denied that they were deliberate, saying, 'I really do not believe they were deliberate at all.'²⁸⁰ He identified a number of contributory factors:

- He did not prioritise the matter effectively
- Staff were absent when information was needed

²⁷⁵ Evidence, Dr Cooper, 31 October 2016, p 62.

²⁷⁶ Answers to questions on notice, St Vincent's Health Australia, pp 7-8; answers to supplementary questions, St Vincent's Hospital Sydney, p 7.

²⁷⁷ Answers to supplementary questions, St Vincent's Hospital Sydney, p 33.

²⁷⁸ Section 122 inquiry final report, p 5.

²⁷⁹ Evidence, Dr Gardiner, 29 November 2016, pp 61-62; *in camera* evidence, Dr Gardiner, 29 November 2016, p 1.

²⁸⁰ *In camera* evidence, Dr Gardiner, 29 November 2016, p 1.

- The initial external reviewer identified at the end of November declined the task, such that another reviewer needed to be sourced.²⁸¹

Disclosure to patients

3.69 A very significant issue of concern during both the section 122 inquiry and our own was St Vincent's Hospital's poor handling of the process of informing individual patients and family members that their chemotherapy was not provided in accordance with clinical protocols.

The section 122 inquiry

3.70 According to the section 122 inquiry final report, once St Vincent's Hospital did recognise it was dealing with a serious issue, it failed to demonstrate an understanding of the distress the issue was likely to cause to patients and their families, both those directly affected and others treated at the hospital.²⁸² The inquiry then made a number of other serious criticisms about the hospital's actions:

When there should have been open disclosure and action in accordance with NSW Health policy, there was avoidance of responsibility to act decisively in the interests of the patients. These were failures of clinical governance processes, clinical leadership and management.²⁸³

3.71 The report made a number of specific observations about the hospital's handling of the open disclosure process:

- While the Ministry of Health's Open Disclosure Policy requires that disclosure commence as soon as possible,²⁸⁴ the first disclosure to patients did not occur until 18 February 2016, and the formal open disclosure to remaining patients commenced on 23 February 2016.²⁸⁵
- While the Open Disclosure Handbook underscores that patients should be contacted directly before learning about an event from other sources, 'almost all' of the affected patients had their open disclosure only after the 7.30 story was broadcast on 18 February 2016.²⁸⁶
- Half of the patients and next of kin first became aware of the issue via the 7.30 broadcast. They were either watching the report themselves, or told about it by family and friends.²⁸⁷
- Some were first informed of the issue via a phone call from St Vincent's Hospital before the story aired; a few received a phone call afterwards.²⁸⁸

²⁸¹ *In camera* evidence, Dr Gardiner, 29 November 2016, p 1.

²⁸² Section 122 inquiry final report, p 30.

²⁸³ Section 122 inquiry final report, p 32.

²⁸⁴ Section 122 inquiry final report, p 29.

²⁸⁵ Section 122 inquiry final report, p 5.

²⁸⁶ Section 122 inquiry final report, pp 29-30.

²⁸⁷ Section 122 inquiry final report, p 25.

- Patients and family members reported that their initial reactions were shock and a lack of understanding of what the news meant for them, or of their options.²⁸⁹
- Some patients attending the hospital for treatment after the media report were still unclear whether they were in the off-protocol cohort.²⁹⁰
- Patients and family members expressed anger and dismay with St Vincent's Hospital when they realised it had been aware of the issue before the media report went to air.
- Some considered that the hospital's written communication was impersonal and focused on protecting the hospital rather than helping patients.
- Some next of kin expressed distress that the contact had caused, particularly with regard to the unanswered question as to whether the off-protocol dose had contributed to the death of their loved one.
- Most interviewees reported receiving a phone call from a senior doctor, during which they received an apology, but a number felt that the caller was unduly focused on themselves. Patients expressed frustration that no one had been able to advise them on how their chances of survival might be affected.²⁹¹
- While some patients said that St Vincent's Hospital had offered them support, others felt there was no follow through. Some reported feeling alienated or labelled as difficult patients when they returned for appointments. A few expressed anger that they felt the hospital left them to organise their own follow up care.²⁹²
- Some patients and family members had no concerns and believed that they or their loved one received the best possible care and that the hospital had done all it could.²⁹³

3.72 The inquiry's interim report recommended that St Vincent's Hospital ensure that every patient and/or their family be given the opportunity to participate fully in an open disclosure process.²⁹⁴

3.73 In addition, the report made three recommendations in respect of patient follow up and monitoring – that the hospital:

- support patients whose care has been affected to have ongoing follow up in another oncology unit if that is their choice
- offer more intensive follow up and to detect any loco-regional or distant disease at the earliest possible time, acknowledging that the peer reviewed literature provides no apparent guidance on what to do under these circumstances

²⁸⁸ Section 122 inquiry final report, p 25.

²⁸⁹ Section 122 inquiry final report, p 25.

²⁹⁰ Section 122 inquiry final report, p 26.

²⁹¹ Section 122 inquiry final report, p 26.

²⁹² Section 122 inquiry final report, pp 26-27.

²⁹³ Section 122 inquiry final report, p 27.

²⁹⁴ NSW Ministry of Health, *Inquiry under section 122 of the Health Services Act 1997: Off-protocol prescribing of chemotherapy for head and neck cancers*, Interim report, 31 March 2016 (hereafter section 122 inquiry interim report), p 16. The wording of the recommendation was modified in the final report.

- report on patient outcomes to the Hospital's Patient Safety and Quality Committee and Clinical Council six monthly, and annually to the Deputy Secretary, NSW Ministry of Health.²⁹⁵
- 3.74** It further recommended that the Cancer Registry managed by the Cancer Institute NSW 'Flag every patient identified ... so that outcomes for this group of people are systematically evaluated on a regular basis, and that survival analyses can be undertaken on this cohort of patients in relation to people with comparable disease.'²⁹⁶
- 3.75** The section 122 final report notes each of these four recommendations as actioned.²⁹⁷
- 3.76** A related issue concerned the hospital's public statements in the wake of the scandal that followed the 7.30 broadcasts. The section 122 inquiry report made a number of criticisms:
- Public statements by the hospital did not reflect the magnitude of the issue nor its consequences. The initial statements contained errors of fact and key omissions. They also failed to acknowledge the potential distress caused to the hospital's cancer patients and their families, whether or not they were prescribed the flat dose of carboplatin.²⁹⁸
 - The hospital's public statements were misleading. The statement that 'no patients appeared to have suffered any negative impact as a result of the dosage issue' was not accurate because neither the internal investigation nor external review examined any patient level outcome data. In addition, the statement that Dr Grygiel was 'immediately counselled and placed under strict supervision' was not true.²⁹⁹
- 3.77** The inquiry recommended that St Vincent's Hospital 'Review the process of preparing and verifying public statements within the Hospital to include relevant consultation, content expertise and sign-off.' This was noted in the final report as actioned.³⁰⁰

Evidence before the committee

- 3.78** Dr Kerry Chant, Chief Health Officer, emphasised to the committee how important it is in a public health approach to make sure that affected patients are informed about a matter before they hear it in the media.³⁰¹ She highlighted as extremely problematic the fact that St Vincent's Hospital patients first heard about this matter via the media, as well as the insufficient patient support built into the hospital's open disclosure process:

The fact that many patients heard about this for the first time in the media is just totally inappropriate ... The regret I have is that that was the way the information unfolded, and patients were presented with that and that there was not adequate support put in for patients in the disclosure process ... I think that St Vincent's did

²⁹⁵ Section 122 inquiry final report pp 35-36.

²⁹⁶ Section 122 inquiry final report, p 40.

²⁹⁷ Section 122 inquiry final report, pp 35 and 40.

²⁹⁸ Section 122 inquiry final report, pp 20-21.

²⁹⁹ Section 122 inquiry final report, p 21.

³⁰⁰ Section 122 inquiry final report, p 36.

³⁰¹ Evidence, Dr Chant, 29 November 2016, p 4.

not understand the seriousness of the issue and did not act with sufficient urgency or put in place sufficient supports to ensure that accurate information was provided to patients in a timely, supported way. That is what I am left with the greatest concern about.³⁰²

- 3.79** Dr Chant further noted that St Vincent's Hospital staff were inadequately briefed, so that when patients started to ask questions there was no ability to direct them to someone who answered their questions. She told the committee it would have been better to have brought the patients in and proactively advised them, rather than waiting for their next visit for them to be reviewed.³⁰³
- 3.80** Each of these deficiencies is reflected in the experience of Mr Ken and Ms Natalie Dugdale, set out in the case study below.

Case study – Ken and Natalie Dugdale³⁰⁴

Mr Ken Dugdale was a patient of Dr Grygiel's. He and Natalie first heard about the underdosing matter on 7.30. They happened to have an appointment with Dr Grygiel the morning after the story was broadcast.

Dr Grygiel was not there and Ken and his wife Natalie were met by a registrar who proceeded with a lengthy consultation (in which the registrar disagreed with Natalie and Ken that the cancer was recurring) without any indication that Ken was among the patients who had received off-protocol chemotherapy, nor even that he might have been in this group.

As the consultation concluded, Natalie asked about the underdosing story, and the registrar replied that they only found out about it early that morning and didn't know much.

Natalie asked the registrar to find someone who could provide some information. After 20 minutes or so the registrar returned with a senior doctor who advised them that Ken was one of the affected patients and it appeared he only received a third of the dose that he should have. The senior doctor commented, 'Well as least you got some chemo, some is better than none.'

As the doctors were not forthcoming with more information, Natalie had to ask what this meant for Ken, and what would happen next. She and Ken were told to go home and get a routine check up in three months.

Natalie became very distressed. The doctors wished them all the best and showed them the door without asking if they could get her and Ken anything, nor arranging for a social worker to talk with them.

Soon afterwards, Ken's cancer was confirmed to have recurred.

³⁰² Evidence, Dr Chant, 29 November 2016, p 3.

³⁰³ Evidence, Dr Chant, 29 November 2016, p 4.

³⁰⁴ Submission 6, Mrs Natalie and Mr Ken Dugdale, p 4. This case study is based on the content of the submission; see also Mr and Mrs Dugdale's appearance on 7.30, ABC, 'Inquiry launched into St Vincent's Hospital chemotherapy dosage scandal, Matt Peacock, 23 February 2016, <http://www.abc.net.au/7.30/content/2015/s4412339.htm>.

3.81 St Vincent’s Hospital representatives acknowledged at several points in our inquiry how poorly the disclosure to patients had been handled, most particularly the delays, and apologised accordingly.³⁰⁵ For example, Associate Professor Schembri stated, ‘we now understand that that was an error and we are very, very sorry to the relatives and our patients. We are putting in place steps to make sure that our open disclosure process is more timely in the future.’³⁰⁶

3.82 Mr Hall emphasised that it was the hospital’s intention from early August 2015 to go to full disclosure with patients, the media and the Ministry of Health, noting that there is documentation to support this assertion. He explained that the delay occurred because the hospital sought to gain information for patients, whom they recognised as highly vulnerable:³⁰⁷

The heart of the thinking was that people did not want to cause further distress to a group of patients who were suffering very significant cancers and, as Associate Professor Gallagher has said, a number of whom were most likely to die. We did not want to give them more stress while they were undergoing treatment without fully understanding what had happened ... In hindsight, we should have talked to them earlier and taken them through the process. That was a failing on our part, which we have acknowledged a number of times.³⁰⁸

3.83 Mr Hall conceded that the hospital’s motivation to protect patients’ welfare ultimately ‘turned out to be against those interests’.³⁰⁹ Similarly, Associate Professor Gallagher acknowledged that on reflection, the delay in open disclosure itself caused harm.³¹⁰

3.84 In its submission to our inquiry, the hospital acknowledged its mistakes with respect to its public statements:

The Hospital’s public statements on this issue were made with the best of intentions, using the information we had on hand. But clearly, the processes we followed in preparing those statements were inadequate. We made mistakes and our statements contained inaccuracies. However, at no point did we intentionally set out to mislead the public or misrepresent the position.³¹¹

3.85 The committee asked St Vincent’s Hospital representatives about the accuracy of its media statement that, ‘No patients appear to have suffered any negative impact as a result of the dosage.’ Mr Hall acknowledged that these words should not have been used, stating:

I think that that was a poor phrase. We should not have used it. We have acknowledged that the media releases were not as good as they should have been. We should have said at that time, “We do not know what the impact is on patients.” In fact, we will not know the true impact on patients for several years to come. We have

³⁰⁵ Evidence, Mr Hall, 29 November 2016, p 50; evidence, Associate Professor Schembri, 31 October 2016, p 49; answers to supplementary questions, St Vincent’s Hospital Sydney, p 35.

³⁰⁶ Evidence, Associate Professor Schembri, 31 October 2016, p 49.

³⁰⁷ Evidence, Mr Hall, 29 November 2016, p 38.

³⁰⁸ Evidence, Mr Hall, 29 November 2016, p 49; see also answers to supplementary questions, St Vincent’s Hospital Sydney, p 6 and submission 59, St Vincent’s Hospital Sydney, p 3.

³⁰⁹ Evidence, Mr Hall, 29 November 2016, p 51.

³¹⁰ Evidence, Associate Professor Gallagher, 29 November 2016, p 52.

³¹¹ Submission 59, St Vincent’s Hospital Sydney, p 3.

committed to following up on those patients and see what happens in their particular circumstances. Absolutely, that statement should not have been used.³¹²

Continued treatment of patients by Dr Grygiel

- 3.86** A separate but related issue raised during our inquiry was that patients continued to be treated by and referred to Dr Grygiel after the allegations of his off-protocol prescribing were made, and as the internal and external reviews progressed. The committee received confidential evidence as to the dismay and distress of patients when they later realised that they had been referred to Dr Grygiel without any disclosure that his prescribing was under scrutiny.
- 3.87** Concerned about the ethical implications of this, the committee asked Associate Professor Gallagher about it. He acknowledged that he had continued to refer patients to Dr Grygiel after the matter had come to his attention, that is, from June 2015, through to November 2015.³¹³ He assured the committee that he was sure that Dr Grygiel had changed his practice.³¹⁴ Pressed as to why he continued to refer, he advised that there was no alternative but to refer patients to Dr Grygiel until the new head of medical oncology was appointed on the campus. He also suggested that it was for the good of patients to have each of the doctors looking after them in the same location.³¹⁵
- 3.88** Associate Professor Gallagher subsequently advised the committee that while he never followed up with Dr Grygiel to ask whether he had changed his practice, there was no need to do so as he was aware the practice had ceased. The Kinghorn Cancer Centre's pharmacist had advised that Dr Grygiel had started using the eviQ protocol.³¹⁶ In addition, the Director of Pharmacy and senior oncology pharmacists were aware of the concerns that had been raised, as were members of the team overseeing the internal investigation into Dr Grygiel's dosing practice, so Associate Professor Gallagher was confident that pharmacy would have notified either him or the Medicine Clinical Stream Manager of any irregularities in prescribing practices.³¹⁷ Asked if he had any concerns about the treatment provided between August 2015 and February 2016, Associate Professor Gallagher stated that he did not.³¹⁸
- 3.89** In addition, Associate Professor Gallagher clarified the referral pathway as being that all of the hospital's head and neck cancer patients are discussed at the Head and Neck MDT and a recommendation made for each patient's a treatment pathway:

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.³¹⁹

³¹² Evidence, Mr Hall, 31 October 2016, p 39.

³¹³ Evidence, Associate Professor Gallagher, 31 October 2016, pp 36 and 47.

³¹⁴ Evidence, Associate Professor Gallagher, 31 October 2016, pp 36 and 37.

³¹⁵ Evidence, Associate Professor Gallagher, 29 November 2016, p 46; see also 31 October 2016, p 37.

³¹⁶ Answers to supplementary questions, St Vincent's Hospital Sydney, p 84.

³¹⁷ Answers to supplementary questions, St Vincent's Hospital Sydney, p 86.

³¹⁸ Evidence, Associate Professor Gallagher, 29 November 2016, p 46.

³¹⁹ Answers to supplementary questions, St Vincent's Hospital Sydney, p 87.

- 3.90** The committee also questioned Dr Cooper about whether, upon becoming aware of Dr Grygiel's prescribing patterns, he changed his recommendations to patients. He responded that it was his understanding at the time that Dr Grygiel had changed his practices in July, shortly after he was confronted with the concerns, so that they were in accordance with eviQ.³²⁰ Asked whether he ever recommended that a patient seek a treatment regime different from what Dr Grygiel was recommending as a flat dose of carboplatin, Dr Cooper underscored that the drug and dose are 'entirely the responsibility of the medical oncologists'.³²¹ He went on to advise that, 'In the course of caring for patients, at about the time the concerns about the drug and dose were being raised, I did have cause to say to patients, "Push John on the question of which drug and what dose."'»³²²
- 3.91** As noted in the previous chapter, Dr Grygiel took leave from February 2016 and was dismissed in August 2016.³²³ The hospital confirmed that Dr Grygiel continued to treat eight patients in the affected cohort between June 2015 and February 2016,³²⁴ but that he had ceased flat dosing in June 2015, as evidenced by the hospital's pharmacy records, which indicated that Dr Grygiel's final pharmacy order for 100 mg carboplatin was on 5 June 2015. It further advised that the MOSAIQ e-prescribing system which prevents any doctor from prescribing off-protocol without approval, was introduced on 10 August 2015.³²⁵
- 3.92** The President of the Medical Council of New South Wales, Dr Greg Kesby, advised the committee that as an interim arrangement, on 22 April 2016 the Council placed conditions upon Dr Grygiel's registration: that he prescribe in accordance with eviQ guidelines and be subject to supervision and review. These conditions will fall away after the Health Care Complaints Commission's investigation concludes. If the matter proceeds to a prosecutorial level, they may or may not be replaced by other conditions.³²⁶
- 3.93** Asked what supervision was in place in respect of Dr Grygiel's prescribing while he continued to practice at St Vincent's Hospital, Mr Hall summarised the arrangements as follows:

To be clear, what happened with Dr Grygiel was that in June 2015 the issue was discovered. He agreed, as I understand it, at the [multidisciplinary team], to stop that treatment regime and to start prescribing in line with the eviQ protocol guidelines. Further to that, we implemented an electronic system in August to ensure that he practised within those guidelines. My understanding is that if Dr Grygiel wanted to go outside those guidelines he committed to talking to the MDT. Plus, the pharmacy team would have highlighted to the MDT and I think also Professor Gallagher, any attempt by Dr Grygiel to go outside those treatment regimes. His treatment regime from that point onwards was monitored by the system, by the MDT and also by the

³²⁰ Evidence, Dr Cooper, 31 October 2016, p 59.

³²¹ Evidence, Dr Cooper, 31 October 2016, p 59.

³²² Evidence, Dr Cooper, 31 October 2016, p 59.

³²³ Evidence, Mr Hall, 29 November 2016, pp 33-34.

³²⁴ Answers to supplementary questions, St Vincent's Hospital Sydney, p 53.

³²⁵ The hospital also advised that MOSAIQ was implemented independent of the issue of Dr Grygiel's dosing: answers to supplementary questions, St Vincent's Hospital Sydney, pp 37 and 43.

³²⁶ Evidence, Dr Greg Kesby, President, Medical Council of NSW, 24 February 2017, p 14; correspondence from Ms Paula Ardino, Principal Monitoring Officer, Medical Council of NSW, to secretariat, 18 April 2017.

pharmacy team. That regime was put in place for Dr Grygiel and for all the other doctors. His treatment regime was, though, monitored from that point onwards.³²⁷

- 3.94** The committee also pursued this issue with Professor Currow, who reported that based on its clinical review, the section 122 inquiry found that no patients received a flat dose of 100 mg carboplatin after June 2015.³²⁸ In respect of Dr Grygiel's colleagues' inability to refer to another medical oncologist, Professor Currow also advised that "The nature of sub-specialist clinical practice generally, not just in cancer, is that often there will only be one sub-specialist in a particular sub-specialty, even in a larger teaching hospital."³²⁹ Asked whether he was concerned that patients continued to be referred to Dr Grygiel, Professor Currow referred to these statements and further advised, "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."³³⁰

Was there a cover up?

- 3.95** The section 122 inquiry framed the many failures that occurred in St Vincent's Hospital's handling of this matter as systemic ones, arising largely from issues of organisational culture, as discussed in detail in the following chapter. The committee sought to test these conclusions by examining whether the hospital had actively covered up the matter, given that there were so many aspects to the hospital's failures, as well as the significance of those failures for the patients concerned and for the broader public's confidence in the hospital system.
- 3.96** Asked whether he thought it credible that there was no cover up, Professor Currow replied, "I do not have any evidence of a cover up."³³¹
- 3.97** Asked whether she believed that St Vincent's Hospital did not act to cover up the health scandal, Dr Chant pointed to the findings of the section 122 inquiry and underscored the systemic failures that had occurred:

I would say that St Vincent's failed to understand the seriousness of it; they failed to understand the need to progress things rapidly and to concurrently have good communication plans in place and they failed to organise systems to ensure that the patient disclosure process was done in a proper and appropriate way.³³²

- 3.98** Dr Gardiner told the committee that he accepted a significant level of responsibility for what transpired, although not full responsibility, noting that he was part of a team that determined the hospital's response and acted on it. Dr Gardiner explained that some of the delays were caused by his need to take leave for health reasons in 2015 and 2016, including a period of extended leave from November 2015 to February 2016.³³³ In addition, Associate Professor

³²⁷ Evidence, Mr Hall, 31 October 2016, p 39.

³²⁸ Answers to supplementary questions, Professor Currow, received 28 November 2016, p 2.

³²⁹ Answers to supplementary questions, Professor Currow, received 28 November 2016, p 5.

³³⁰ Answers to supplementary questions, Professor Currow, received 28 November 2016, p 5.

³³¹ Evidence, Professor Currow, 31 October 2016, p 7.

³³² Evidence, Dr Chant, 29 November 2016, p 5.

³³³ Evidence, Dr Gardiner, 29 November 2016, p 62.

Gallagher was on leave from the end of August until early October 2015.³³⁴ Dr Gardiner told the committee:

I do accept a lot of responsibility for this. There were a lot of us here and I do not know all the ins and outs of this. It concerns me that it has all come out in the media that there is a cover up and all those sorts of things. From my point of view, I never believed there was any sort of cover up.³³⁵

3.99 Dr Gardiner expressed regret about his handling of the broader clinical governance response, and offered an apology to patients and their loved ones:

I have reflected on my own role in this review and I regret that I did not manage the process in a more timely way. I wish that I had appreciated the seriousness of the issue earlier in time and had been more proactive in managing the review and implementing a disclosure process. I do accept my shortcomings in this process and I sincerely apologise for them. In particular, I want to apologise to the patients and their family and friends who have been left with uncertainty and all the stress that comes with that. I am sorry.³³⁶

3.100 Dr Gardiner went on to observe that many of the individuals involved must regret what happened, and he also pointed to the systemic factors at play:

I believe there would be many people at St Vincent's Hospital who have some regret about what they said or did not say or do. I think a lot of this weighs on people's hearts ... I always believed it was a systemic issue. We had a doctor prescribing in a particular way in a major hospital for a long time. We all bear some responsibility for that.³³⁷

3.101 The section 122 inquiry noted that, 'Several interviewees acknowledged that they wished they had managed the response differently.'³³⁸

3.102 Mr Hall strongly refuted any suggestion of concealment on the part of hospital staff, and once again acknowledged the hospital's failings:

There has been no evidence available to me, including from Profess Currow's inquiry, that the hospital intentionally misled the public, our patients or the government about this matter. The hospital's mistake was that they clearly did not appreciate the seriousness of this issue. We have said before—we have said it publicly on a number of occasions—and acknowledge absolutely that this was a failure on our part. This affected, pretty much from day one, how we responded to the issue, including how it was investigated and how it was internally reported, and, in turn, how it was broadened to the Ministry.

We have publicly admitted these mistakes and apologised, and we are working to make sure that they never happen again. We have participated in a number of inquiries—hopefully, with total openness. We are also committed to implementing all

³³⁴ Evidence, Dr Gardiner, 29 November 2016, p 64.

³³⁵ *In camera* evidence, Dr Gardiner, 29 November 2016, p 1.

³³⁶ Evidence, Dr Gardiner, 29 November 2016, p 62.

³³⁷ Evidence, Dr Gardiner, 29 November 2016, p 63.

³³⁸ Section 122 inquiry final report, p 19.

of the changes and recommendations of the inquiry. A number of those have already been implemented. Again, I would like to offer my apologies to patients and their families who were affected by this incident.³³⁹

- 3.103** Asked whether the Ministry of Health considered that St Vincent’s Hospital put its reputation before patient outcomes, Ms Karen Crawshaw, Deputy Secretary, Governance, Workforce and Corporate, NSW Ministry of Health, also pointed to the hospital’s failure to grasp the significance of a clinician not acting in accordance with guidelines, and that this in turn affected its subsequent actions:

I think it goes back to what Professor Currow was talking about a minute ago, that in the organisation’s mind they had not correctly characterised the issue in the first place; they had characterised it as a variation from normal practice but not a variation that constituted an inappropriate departure. As we know, doctors make clinical judgements to vary from a protocol. But this was an issue, and as a consequence of their characterisation of that incident I think a lot of things flowed from that, including the issue of reputation and how they managed the incident.³⁴⁰

Chief Health Officer’s involvement

- 3.104** When the committee learned that the Chief Health Officer was informed on 16 November 2015 of the issue of underdosing of chemotherapy patients at St Vincent’s Hospital,³⁴¹ it questioned her extensively on how that occurred and her response.
- 3.105** Dr Chant advised the committee that Associate Professor Schembri advised her informally, in a phone call, in which he stated that there was potential for a media story in relation to concerns about a doctor’s prescribing of a chemotherapy drug. He indicated that the hospital was engaging an external consultant to review the issue. Dr Chant told the committee that she did not have a strong recollection of the phone call as it is not unusual for her to take calls of this nature from chief executives or other senior health service staff. Nevertheless, she was confident that in keeping with her standard approach to such matters she would have sought to ascertain a number of things in the interests of managing public health and safety:

[I]n any call, even where the purpose may be to advise me of a potential media story, my standard practice is to explore the issue to ascertain whether immediate steps are needed to protect public health and safety; whether individual patients are at risk, whether those patients at risk have been advised, and to satisfy myself whether appropriate action is in hand. In this case I was assured that St Vincent’s had reviewed the matter and there was no issue of patient harm.³⁴²

- 3.106** Dr Chant further advised the committee that because external reviews commonly occur, she did not see this action as indicative of an issue of concern, particularly in light of Associate Professor Schembri’s assurance that the internal investigation had concluded that no patients

³³⁹ Evidence, Mr Hall, 29 November 2016, p 32.

³⁴⁰ Evidence, Ms Karen Crawshaw, Deputy Secretary, Governance, Workforce and Corporate, NSW Ministry of Health, 31 October 2016, p 26.

³⁴¹ Answers to supplementary questions, St Vincent’s Hospital Sydney, p 69.

³⁴² Evidence, Dr Chant, 29 November 2016, p 2; see also correspondence from Dr Kerry Chant, Chief Health Officer, NSW Health, to Committee Chair, 1 November 2016, p 1.

were negatively affected. She stated, ‘Based on the information I was provided by Professor Schembri, I ended the conversation confident there was no ongoing risk to patients requiring action by me.’³⁴³ She recalled suggesting that Professor Currow, as Chief Cancer Officer, may be able to provide useful suggestions on external experts. She then rang Professor Currow to advise him of Associate Professor Schembri’s call, then followed up with Professor Schembri to confirm she had contacted Professor Currow, who was happy to assist in the identification of external experts.³⁴⁴ Dr Chant told the committee:

I ended the call with Professor Schembri with the clear impression that the matter was in hand, and that there was no significant public health or safety issue that warranted further action by me ... and I received no further communication or information about this matter until February 2016.³⁴⁵

3.107 Questioned as to whether it was appropriate for her to have taken Associate Professor Schembri’s advice at face value, Dr Chant responded that she did not pick up any concerns:

If there are any concerns that I had picked up in the conversation, and that would have brought into question the assertion from the chief executive in these circumstances, I certainly would have made further inquiries ... I felt that [it] was prudent and appropriate to urge Associate Professor Schembri to make contact with Professor Currow. As I said, I would have seen the steps of engaging an external expert as a very positive step in getting to the bottom and confirming the internal investigation findings.³⁴⁶

3.108 On further questioning about whether she had any ‘alarm bells’ from the phone call, or had thought to follow it up further, Dr Chant responded:

I really would have expected that ... [because] the issue was being raised with me by a chief executive of a network, that I should be able to rely on them recontacting me. My actions would have been very different if I had had an inkling of patient harm or the seriousness of it. So I think it is very important to understand the construct of the mindset that I had formed in that November 2015 conversation, which then really influenced my degree of follow-up. I certainly aggressively follow up anything where there is a concern about patient harm. It is not uncommon that I am dealing with many issues. I would not want to overstate the seriousness of all of them but there are a number of things that at one time I am following up and I think I should be able to rely on the chief executive of the local district, including the policies and procedures we have in place, including the role that the Clinical Governance Unit provides and others, in terms of managing these incidents.

As I said, the November call to me was very much a heads-up call: “Just letting you know this might turn out to be a potential media story. It’s all in hand. No patient harm. We are going to get an external review”, and I would have been very affirming of external reviews because in my practice I use external experts as an important component of adding transparency and veracity to internal findings.³⁴⁷

³⁴³ Evidence, Dr Chant, 29 November 2016, p 2.

³⁴⁴ Evidence, Dr Chant, 29 November 2016, p 2.

³⁴⁵ Evidence, Dr Chant, 29 November 2016, p 2.

³⁴⁶ Evidence, Dr Chant, 29 November 2016, p 3.

³⁴⁷ Evidence, Dr Chant, 29 November 2016, p 8.

- 3.109** Dr Chant told the committee that she did not advise any other senior executives nor the Minister's office of Associate Professor Schembri's call.³⁴⁸ In addition, she stated that while she did not have a clear recollection of informing the media unit, she may have done so, given that the context of the call was media related.³⁴⁹ Dr Chant subsequently advised that further enquiries within NSW Health indicated that the Ministry's Director Public Affairs recalled that Dr Chant did mention the matter as a 'heads up' for possible media inquiries, and that the Director Public Affairs did not inform anyone else.³⁵⁰
- 3.110** Dr Chant told the committee that once the seriousness and scope of the issue became apparent in February, culminating in the establishment of the section 122 inquiry on 19 February 2016, she informed the senior executive team of Associate Professor Schembri's November call.³⁵¹ Dr Chant explained the context:
- It was in the general context of the discussion around St Vincent's Hospital's management. Obviously we were very concerned that things were put in place to support the response to the patients. There were many discussions going on around how the disclosure process could be supported for St Vincent's Hospital. I would also like to say that at that point in time the focus quickly moved. My fundamental focus shifted to western New South Wales, where it became evident that [Dr Grygiel] had been practising for a period of time ... My focus was on supporting western New South Wales.³⁵²
- 3.111** Professor Currow confirmed that Associate Professor Schembri contacted him in November 2015, with the content being 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.'³⁵³ He further advised that he told no one in the Ministry about the conversation before February 2016,³⁵⁴ nor did he at any time inform the then Minister for Health or anyone in her office.³⁵⁵ Asked whether he told the Ministry he was aware of the issue at St Vincent's Hospital in November 2015, before agreeing to complete the section 122 inquiry, Professor Currow stated that he was not given sufficient information in November 2015 to enable him to realise that the incidents were connected.³⁵⁶

Committee view

- 3.112** It is abundantly clear to the committee that the failures of St Vincent's Hospital in identifying the issue and responding to the allegations of off-protocol prescribing of chemotherapy were substantial, multifaceted and prolonged. The hospital's key failures were that it did not escalate numerous concerns raised by staff for more than a decade; it did not understand the

³⁴⁸ Evidence, Dr Chant, 29 November 2016, pp 2 and 4-5

³⁴⁹ Evidence, Dr Chant, 29 November 2016, p 7.

³⁵⁰ Answers to questions on notice, Dr Kerry Chant, received 23 December 2016, p 1.

³⁵¹ Evidence, Dr Chant, 29 November 2016, p 7.

³⁵² Evidence, Dr Chant, 29 November 2016, pp 7-8.

³⁵³ Answers to supplementary questions, Professor Currow, received 28 November 2016, p 8.

³⁵⁴ Answers to supplementary questions, Professor Currow, received 28 November 2016, p 8.

³⁵⁵ Answers to supplementary questions, Professor Currow, received 22 December 2016, p 9.

³⁵⁶ Answers to supplementary questions, Professor Currow, received 28 November 2016, p 9.

seriousness of the issue; it failed to grasp the imperative to act quickly; it failed to communicate with patients effectively, and to support them appropriately. The failure to engage external expertise to illuminate the clinical significance of the problem at an early stage was pivotal. And as the hospital has recognised, its actions actually served to compound patients' distress.

- 3.113** The evidence that we have received from patients has served to highlight the human dimension to this scandal, and has set in sharp relief the profound trust that patients place not only in their treating doctors, but also in the hospital in which their treatment occurs. In this matter St Vincent's Hospital did not live up to the trust that its patients placed in it.
- 3.114** There were many deficiencies in the clinical governance response, despite the policies that were in place to support this: the hospital did not recognise the matter as a clinical incident; the internal investigation was not undertaken by a senior doctor and was limited in scope, and thus not as informative as it should have been; the external review was plagued by delays.
- 3.115** Patients and their families should have been told in August 2015 that allegations had been made and were being investigated. Instead, more than half learned about it no less than six months later – via the media. The case study on page 51 indicates just how ham-fisted and insensitive the disclosure process was, even for patients then in the care of the hospital's clinicians. How is it possible that when the hospital had the external review report for nine days before the story broke on 18 February 2016, it had still told very few patients and had planned so poorly the disclosure process? The unacceptable disclosure process exacerbated an already incredibly difficult time for patients who had been diagnosed with cancer.
- 3.116** While the hospital was confident that Dr Grygiel had ceased prescribing off-protocol from June 2015, patients were understandably mortified to realise that they were referred to him for cancer treatment without any acknowledgement that his practice was under investigation. While the clinicians referring patients had grounds to consider his practice had changed and was being monitored, surely patients had a right to be informed of the situation. Again, this points to a systemic insensitivity to patients' perspectives.
- 3.117** It is clear to the committee that the hospital's senior management put their public standing ahead of the best interests of their patients as the matter unfolded and quickly became a full blown scandal. The committee agrees with the conclusion of the section 122 inquiry that 'there was avoidance of responsibility to act decisively in the interests of the patients' and that there were 'failures of clinical governance processes, clinical leadership and management.'³⁵⁷
- 3.118** In our view it is not credible that, despite widespread knowledge among junior nursing, pharmacy and medical staff who raised concerns about Dr Grygiel's practice on numerous occasions for over a decade, no-one at a senior level in either the oncology department or management was aware of the issue. While there were certainly elements of individual and collective human error, as well as systemic failures, that contributed over time to the crisis that unfolded, the committee is not able to discount the possibility of a cover-up on the part of St Vincent's Hospital. While the crisis was precipitated by the 7.30 broadcast, it was clearly the result of the hospital's actions over time.

³⁵⁷ Section 122 inquiry final report, p 32.

- 3.119** The fact that things were handled very differently by Western NSW LHD (discussed in chapter 5 of this report) serves to highlight that St Vincent's Hospital's response could have been so much better, with far less distress for patients and families, and far less damage to the hospital's reputation.
- 3.120** Unfortunate as St Vincent's Hospital's mistakes are, the committee accepts its leaders' assurances that the hospital is now fully aware of those mistakes, and regrets them sincerely.
- 3.121** Significantly, St Vincent's Hospital has acknowledged its many failures and has publicly apologised for them. The hospital also welcomed and participated fully in the section 122 inquiry, then accepted its recommendations in full. We explore its responses in detail in the following chapter, along with the various actions that the hospital has taken in response to individual recommendations.
- 3.122** Finally, the committee accepts the Chief Health Officer's evidence that she responded appropriately when St Vincent's Health Network's CEO informally advised her in November 2015 that: an issue had emerged with regard to chemotherapy dosing; the matter was proceeding to external review; it was in hand; and at that stage, no further action was necessary on her part.

Chapter 4 St Vincent's Hospital's actions in response to the section 122 inquiry

A key issue for this inquiry, for the section 122 inquiry and for St Vincent's Hospital itself is how the events that transpired at the hospital could have happened, despite all the systems and policies in place and its highly qualified professional staff. How could a doctor be systematically dosing outside of accepted, evidence based practice without others becoming aware, and how could the hospital respond to the matter so poorly? The answer to these questions necessarily informs the actions that the hospital must take to address its failures and ensure that they do not happen again. In this chapter the committee considers the steps that St Vincent's Hospital has taken in response to the section 122 inquiry and its recommendations.

First, the chapter documents the performance monitoring arrangements for the hospital put in place by the NSW Ministry of Health from April 2016. Next, it explores key contributors to the failures in St Vincent's Hospital's response, the primary contributor being organisational culture. The committee then examines the hospital's major actions in response to the section 122 inquiry recommendations: its public apology; strategies aimed at bringing about cultural change; staffing changes; measures to address incident management and open disclosure; systems for electronic prescribing; and strategies to enhance informed consent. Notably, these key actions correspond to key areas of criticism documented in the previous chapter.

Acceptance of the section 122 inquiry recommendations

- 4.1 Each of the section 122 inquiry recommendations made specifically to St Vincent's Hospital was noted at the relevant point in the previous chapter. A table setting out each of the inquiry's recommendations is set out in appendix 3.³⁵⁸
- 4.2 The hospital advised the committee that it 'welcomed and participated fully' in the section 122 inquiry, providing approximately 1,500 documents to the review team and actively encouraging its staff to participate. It accepted the inquiry's recommendations in full.³⁵⁹
- 4.3 In addition, the hospital has engaged Professor Robert Thomas, Chief Cancer Adviser to the Victorian Government, to independently oversee and report on the hospital's progress in implementing the inquiry recommendations at three, six and twelve months. Professor Thomas chairs a steering committee comprised of the hospital Chief Executive Officer and other senior hospital leaders, key St Vincent's Health Australia executive including the group CEO, and subject matter experts. The hospital CEO chairs the hospital's implementation working group.³⁶⁰

³⁵⁸ Also, an overview of the scope, findings and recommendations of the section 122 inquiry is provided in chapter 1.

³⁵⁹ Submission 59, St Vincent's Hospital Sydney, p 5.

³⁶⁰ Submission 59, St Vincent's Hospital Sydney, p 8; answers to supplementary questions, St Vincent's Hospital, received 28 November 2016, p 20.

Consequences for the hospital

- 4.4 The Ministry of Health advised the committee that on 14 April 2016, in light of the findings in the section 122 inquiry interim report about St Vincent's hospital's handling of the off-protocol prescribing incident, the hospital was escalated to a performance level of two under the NSW Health Performance Agreement Framework. This performance level indicates that the network was underperforming.³⁶¹ As a result of that rating, St Vincent's Health Network was required to:
- undertake an in depth assessment of the relevant problem
 - identify options to address it
 - provide a detailed recovery plan
 - meet the Ministry of Health monthly to discuss progress.³⁶²
- 4.5 NSW Health advised that the section 122 inquiry interim and final reports and their recommendations served as the recovery plan. Updates on actions taken by St Vincent's Hospital to address the inquiry recommendations have been provided at monthly meetings with the Ministry.³⁶³ In addition, the hospital has submitted to the Secretary for Health detailed three, six and 12 month progress reports on the implementation of the recommendations. Each was independently assessed by Professor Thomas and published on the hospital's website.³⁶⁴
- 4.6 NSW Health advised the committee that the chief executive of St Vincent's Health Network had agreed to an external review in April 2017 of the network's progress and resolution of the inquiry's recommendations, and that this review will assist the Ministry to assess any change in performance level.³⁶⁵
- 4.7 Noting that the Ministry's monitoring amounted to St Vincent's Hospital being on 'significant and serious performance watch', Ms Karen Crawshaw, Deputy Secretary, Governance, Workforce and Corporate, NSW Health, assured the committee that the Ministry was taking

³⁶¹ Answers to supplementary questions, NSW Ministry of Health, received 28 November 2016, pp 1-2 and 4. The Ministry's submission notes that under the performance framework, all local health districts and specialty networks are assigned a level between zero and four, with zero indicating there are no performance concerns and four indicating the health service is 'challenged and failing': submission 49, NSW Ministry of Health, p 16.

³⁶² Submission 49, NSW Ministry of Health, p 16; answers to questions on notice, NSW Ministry of Health, received 28 November 2016, p 2; answers to supplementary questions, NSW Ministry of Health, received 28 November 2016, pp 1-2 and 4.

³⁶³ Answers to questions on notice, NSW Ministry of Health, received 28 November 2016, p 2; answers to supplementary questions, NSW Ministry of Health, received 28 November 2016, pp 1-2 and 4.

³⁶⁴ Submission 59, St Vincent's Hospital Sydney, p 8; St Vincent's Hospital Sydney, *Inquiry under section 122 of the Health Services Act 1997: Off-protocol prescribing of chemotherapy for head and neck cancers*, final implementation report, April 2017, (hereafter St Vincent's Hospital Sydney, section 122 inquiry final implementation report).

³⁶⁵ Answers to supplementary questions, NSW Ministry of Health, received 28 November 2016, p 4.

the matter extremely seriously,³⁶⁶ and will be formally scrutinising the hospital's implementation of each of the recommendations into the future:

But it is something that the Ministry, in relation to every aspect of the implementation by St Vincent's of the recommendations that they have supported, will be monitoring over the course of time ... there is absolutely no question about active monitoring of St Vincent's for the foreseeable future.³⁶⁷

Factors behind the hospital's poor response to the allegations

4.8 Before examining St Vincent's Hospital's key actions in respect of the section 122 inquiry recommendations, the committee first explores a major factor behind the hospital's many failings in its response to the allegations of off-protocol prescribing of chemotherapy: organisational culture. Next it explores whether the multidisciplinary team context in which Dr Grygiel's prescribing took place was a contributing factor.

4.9 At this point the committee notes again that the primary issues identified in respect of the hospital by the section 122 inquiry were systemic ones, rather than individual. In addition, we make the observation that the Health Care Complaints Commission's (HCCC's) investigations, whilst necessarily examining the individual actions of Dr Grygiel (and those of Dr Kiran Phadke at Sutherland and St George Hospitals, as discussed in chapter 7), are also concerned with a number of systemic issues that resonate with both the section 122 inquiry findings and the evidence that this committee received. Ms Sue Dawson, Commissioner, HCCC, set out these systemic issues:

The investigations that are on foot raise a range of different issues. They stem beyond the clinical actions of Dr Grygiel and Dr Phadke. They touch on some more systemic issues, as you would imagine, such as mandatory reporting, informed consent, the operation of multidisciplinary teams, education and training and culture.³⁶⁸

Organisational culture

4.10 The section 122 inquiry final report, and its leaders in their evidence to the committee, highlighted organisational culture within St Vincent's Hospital as a very significant contributor to the failure to recognise and respond effectively to the issue of off-protocol prescribing of chemotherapy. It identified culture as the 'overriding reason' for the poor handling of the matter:

³⁶⁶ Evidence, Ms Karen Crawshaw, Deputy Secretary, Governance, Workforce and Corporate, NSW Ministry of Health, 31 October 2016, p 32.

³⁶⁷ Evidence, Ms Crawshaw, 31 October 2016, p 31.

³⁶⁸ Evidence, Ms Susan Dawson, Commissioner, NSW Health Care Complaints Commission, 24 February 2016, p 6.

The inquiry team is left with a view that these cultural characteristics prevented the organisation from responding effectively to the incident, resulting in the need for an inquiry to examine the patients' treatment, experiences and outcomes.³⁶⁹

- 4.11** As noted in the previous chapter, the section 122 inquiry recognised as a cultural issue the long history of staff raising concerns about Dr Grygiel but not formalising or escalating them.³⁷⁰
- 4.12** The final report drew particular attention to the cultural problems within the hospital's Cancer Services stream, where there were 'tensions, unresolved grievances and conflicts' and mistrust arising from the failure to resolve longstanding conflicts constructively and sensitively. According to the report, "This meant that when the incident was identified, the organisation was not able to see and characterise the issue clearly, support people who raised it, understand and analyse what had occurred in a timely way, and develop a patient-centred, empathetic response."³⁷¹
- 4.13** The final report stated that in a cultural context, it found that the hospital lacked a number of characteristics:
- leadership that provided insight, direction and urgency;
 - a patient-centred approach;
 - analytical rigour, or the necessary questioning scepticism for an accurate characterisation of the issue;
 - training for clinical leaders in leadership and in policy and process; and
 - demonstration of adherence to values at a time when they were most needed.³⁷²
- 4.14** The solution, the report stated, is cultural transformation 'to build a constructive, inclusive, people focused clinical culture', to be achieved through:
- a clear understanding of mission;
 - living the organisation's values;
 - knowing what a high performing team looks like and relentlessly building it; and
 - exceptional leadership that is visible, collaborative, people focused, with a strong sense of mission and values.³⁷³
- 4.15** To this end, the inquiry recommended that 'St Vincent's Hospital initiate, and oversee, a program that will build within cancer services a constructive, people-focused culture for patients and staff. This should include a facilitated restorative program to rebuild relationships and trust within the senior clinical community in cancer services, and between cancer services and hospital management.'³⁷⁴

³⁶⁹ NSW Ministry of Health, *Inquiry under section 122 of the Health Services Act 1997: Off-protocol prescribing of chemotherapy for head and neck cancers*, Final report, 31 July 2016 (hereafter section 122 inquiry final report), pp 33-34.

³⁷⁰ Evidence, Professor David Currow, Chief Cancer Officer, NSW, and Chief Executive Officer, Cancer Institute NSW, 31 October 2016, pp 16 and 17.

³⁷¹ Section 122 inquiry final report, p 32.

³⁷² Section 122 inquiry final report, p 31.

³⁷³ Section 122 inquiry final report, p 33.

³⁷⁴ Section 122 inquiry final report, p 41.

- 4.16** The committee sought more information from the section 122 inquiry team about the nature of the cultural problems, in order to better understand the issues at play. Mr Paul Gavel, Director Workforce, HealthShare NSW, advised that the ‘tensions, unresolved grievances and conflicts’ within cancer services were generally ‘about how services should be deployed, the process for filling leadership positions, behaviour and allegations of bullying.’³⁷⁵ He advised that the matters did not involve bullying of junior staff by senior clinicians;³⁷⁶ nor did they involve Dr Grygiel. According to Mr Gavel, the impact of these cultural issues was that when the hospital became aware of the off-protocol prescribing, ‘there should have been open disclosure and action in accordance with NSW Health policy, there was avoidance to act decisively in the interests of patients.’³⁷⁷
- 4.17** St Vincent’s Hospital acknowledged that prior to 2015, ‘there were a small number of allegations of bullying in the Radiation Oncology Department which were investigated and appropriate action taken’,³⁷⁸ and confirmed that no staff had raised issues of bullying in relation to Dr Grygiel’s dosing practices.³⁷⁹
- 4.18** Asked whether the section 122 inquiry leaders were confident that St Vincent’s Hospital is able to rebuild a culture to prevent these events from happening in the future, Mr Gavel observed that St Vincent’s Hospital had committed itself to this task, and that effective leadership will be central to the transformation.³⁸⁰ He also stated that the process will take a number of years:

We wrote [the recommendation addressing culture] in a deliberately constructive manner, talking about needing to build a constructive culture, needing to be inclusive of the people involved at St Vincent’s and cancer services, needing for it to be people centred, the importance of leadership in that, and the recommendation was around needing to do that through a facilitated arrangement that involves all of the people. It will take a number of years. We did not say that in the report, but if you want to read any of the literature on culture, cultures are not built in one moment.³⁸¹

- 4.19** Asked whether St Vincent’s Hospital’s position as a private, contracted hospital rather than a public one was a significant factor, Ms Crawshaw stated that she did not consider this to be the case. Pointing out that as the same policies and procedures apply equally to St Vincent’s Hospital as other hospitals, she recognised the issue as primarily about organisational culture. Echoing the section 122 inquiry’s perspective that the events at St Vincent’s Hospital occurred in the context of poor organisational culture, Ms Crawshaw observed that sound regulations and policies are dependent upon a positive culture to work effectively:

But, like anywhere, what you put in terms of regulation and compliance regimes and policy has to be dealt with in a way that a good culture engenders that and makes sure

³⁷⁵ Answers to questions on notice, Mr Paul Gavel, Director Workforce, HealthShare NSW, received 28 November 2016, p 1.

³⁷⁶ Answers to questions on notice, Mr Gavel, p 1.

³⁷⁷ Answers to questions on notice, Mr Gavel, p 1.

³⁷⁸ Answers to supplementary questions, St Vincent’s Hospital Sydney, p 57.

³⁷⁹ Answers to supplementary questions, St Vincent’s Hospital Sydney, p 59.

³⁸⁰ Evidence, Dr Gavel, Director Workforce, HealthShare NSW, 31 October 2016, p 18.

³⁸¹ Evidence, Dr Gavel, 31 October 2016, p 18.

it works effectively. What was found here was a culture that mitigated against those policies and regulations working effectively.³⁸²

Multidisciplinary team

- 4.20** As a separate but related issue to culture, during its hearings, the committee sought to understand whether the functioning of the multidisciplinary head and neck cancer team (hereafter the MDT) had been a contributing factor to the hospital's poor handling of the off-protocol prescribing matter. Specifically, the committee wished to understand why the head and neck MDT team of which he was a member had not identified that Dr Grygiel was systematically underdosing his patients. As noted in chapters 2 and 3, the head and neck surgeon and radiation oncologist with whom Dr Grygiel worked both denied any knowledge of his dosing practices prior to June 2015.
- 4.21** The section 122 inquiry report stated that 'Dr Grygiel had a proactive responsibility to let the MDT know he was prescribing off protocol and familiarise them with the implications of what he was doing so they were empowered to endorse it as a team, or seek further information or expert input.'³⁸³
- 4.22** It also noted that there was no evidence that the MDT met, separate to discussions about patient care, to consider their current therapies nor new and emerging evidence.³⁸⁴ To address this, the inquiry recommended that local health districts and specialty networks ensure that minuted meetings of multidisciplinary cancer care teams occur after relevant international or national meetings and on an ad hoc basis as seminal new evidence emerges that should influence practice.³⁸⁵
- 4.23** Asked about whether the MDT has a one-off or ongoing role with regard to sharing information and decisions about patients, Professor David Currow, Chief Cancer Officer, NSW, Chief Executive Officer of the Cancer Institute NSW, and Co-leader of the section 122 inquiry, explained that the role of an MDT is to (1) agree that the disease of a particular patient is cancer and (2) contextualise the findings to the individual patient:

The inquiry's report is very careful in its wording here. It talks about the care of people being overseen by a multidisciplinary team. Much of that depends on the maturity of that multidisciplinary team, on how rapidly the evidence in that particular tumour stream is changing and how it adapts to that. Importantly, there are two processes for a multidisciplinary cancer care team. The first of those processes is to determine what is the cancer and what is its extent of disease. That is, in some language in the literature, referred to as a multi-specialist meeting, which is really to make sure that the radiologist and imaging specialists, the pathologist, the surgeon and the medical and radiation oncologist have agreed about the label of cancer ... The second, broader discussion is really to contextualise those findings in the light of this

³⁸² Evidence, Ms Crawshaw, 31 October 2016, pp 26-27.

³⁸³ Section 122 inquiry final report, p 32.

³⁸⁴ Section 122 inquiry final report, p 17.

³⁸⁵ Section 122 inquiry final report, p 38.

patient, their comorbidities, their preferences and the other issues that they face in life.³⁸⁶

4.24 Asked whether it was reasonable to expect that the MDT would notice routine flat dosing and be a forum to challenge or question the practice, Professor Currow indicated that with only one medical oncologist on such a team, the ability to identify issues in prescribing is limited. He explained that the recommendation above was crafted to address this, with a view to promoting cross fertilisation and the application of new evidence in the clinical context.³⁸⁷

4.25 Associate Professor Richard Gallagher, Head and Neck Surgeon and Director of Cancer Services, explained how St Vincent's Hospital's head and neck MDT works to enable a holistic approach to a patient, with each clinician bringing their own expertise to the table.³⁸⁸ He advised that, prior to mid 2015, the dosage of chemotherapy was never discussed at the head and neck MDT, consistent with the operating principle that while the drug and the treatment regime are discussed, dosage is not.³⁸⁹ Associate Professor Gallagher noted that that team differs to many other MDTs in that the patient is discussed prior to their surgery and other treatment:

A lot of other MDTs—say, for breast or colorectal cancer— those patients have had operations done by surgeons who are then bringing the results of that surgery to the MDT to then discuss treatment. That is never what happens with head and neck cancer. We bring our patients along, make a decision about their treatment which will not include the exact dosages of chemotherapeutic agents ... they may go down a surgical pathway and then once we have got some results after surgery we would proceed down the adjuvant treatment with radiotherapy with or without chemotherapy.³⁹⁰

4.26 In a similar vein, Dr Stephen Cooper, Radiation Oncologist and Chair of the hospital's head and neck unit, confirmed that dosage is not considered by the MDT and explained that this is because the discussion occurs well in advance of the medical oncologist's dosage decision, which must wait until other actions take place:

[Dosage] is not discussed at the MDT, and the reason why it is not discussed is that a new patient will come to the clinic, or a patient requiring care, and a program will be plotted out—they need these tests, they need to follow through this thing, we need to organise these things, we will go down this route—and it is likely that they will need these treatments in due course, full stop. Some months later they may get to the stage of getting their chemotherapy, but we have not attempted to specify a dose predicated on everything that is going to happen over the coming weeks and months ... We do not know [at that point] what is going to happen.³⁹¹

³⁸⁶ Evidence, Professor Currow, Chief Cancer Officer, NSW, Chief Executive Officer of the Cancer Institute NSW, and Co-leader of the section 122 inquiry, 31 October 2016, p 10.

³⁸⁷ Evidence, Professor Currow, 31 October 2016, p 11.

³⁸⁸ Evidence, Associate Professor Richard Gallagher, Head and Neck Surgeon and Director of Cancer Services, St Vincent's Health Network Sydney, 31 October 2016, pp 41-42.

³⁸⁹ Evidence, Associate Professor Gallagher, 31 October 2016, pp 46-47.

³⁹⁰ Evidence, Associate Professor Gallagher, 31 October 2016, p 42.

³⁹¹ Evidence, Dr Stephen Cooper, Radiation Oncologist, Genesis Cancer Care NSW, 31 October 2016, pp 57-58.

4.27 In addition, Ms Gabrielle Prest, Medicine Clinical Stream Manager, St Vincent's Health Network Sydney and Mr Toby Hall, Group Chief Executive Officer, St Vincent's Health Australia, advised that as each clinician in the MDT is considered an expert in their field, the specifics of their treatment is not discussed by the MDT.³⁹² Dr David Dalley, Medical Oncologist and Dr Grygiel's former supervisor concurred, stating, 'I would not comment about the dose of radiotherapy to the radiotherapists and I would not expect them to comment about the dose of chemotherapy.'³⁹³

4.28 The committee challenged St Vincent's representatives as to how a multidisciplinary team can truly provide optimal care when they do not know the dosage. Ms Prest further explained why it is in the context of an individual consultation with a medical oncologist that the decision about dosing occurs:

At the multidisciplinary team the medical oncologist might agree to take care of the patient. The patient will subsequently attend in the rooms to see the doctor. At that point in time some other parameters are needed to make a decision about what treatment will occur, for example the pathology reports will be looked at, recent blood counts, they will take weight and height to look at body surface area ... It is when the patient is presenting before the doctor and having the one-on-one conversation where they get to confirm at that point and then the prescription process starts. That is when the checking processes proceed with the pharmacist checking and so on.³⁹⁴

4.29 Ms Prest also noted that prescribing decisions at St Vincent's Hospital (as of August 2015 – subsequent to Dr Grygiel ceasing off protocol dosing, as noted in the previous chapter) occur via the MOSAIQ system, becoming part of the patient's electronic record, and subject to monitoring and approval.³⁹⁵ Mr Hall explained that MOSAIQ operates such that if a clinician wants to dose outside the protocol, he or she must discuss it with their colleagues and obtain approval (although not necessarily via the MDT).³⁹⁶ The capacity of MOSAIQ, and the eviQ protocols loaded into it, to prevent off-protocol prescribing of chemotherapy is discussed briefly in the following section, and then in greater detail in chapter 8.

Key actions in response to the section 122 inquiry recommendations

4.30 It is not the role of the committee to examine St Vincent's Hospital's actions in response to each specific recommendation from the section 122 inquiry; this responsibility lies with the Ministry of Health. For a detailed account of the hospital's actions we refer readers to:

- the hospital's submission to our inquiry, which contains the hospital's detailed three and six month reports on implementation to the Ministry of Health

³⁹² Evidence, Ms Gabrielle Prest, Medicine Clinical Stream Manager, St Vincent's Health Network Sydney, 29 November 2016, p 42; Evidence, Mr Toby Hall, Group Chief Executive Officer, St Vincent's Health Australia, 29 November 2016, p 43.

³⁹³ Evidence, Dr David Dalley, Former Head of Medical Oncology, St Vincent's Health Network Sydney, 29 November 2016, p 54.

³⁹⁴ Evidence, Ms Prest, 29 November 2016, p 43.

³⁹⁵ Evidence, Ms Prest, 29 November 2016, p 42.

³⁹⁶ Evidence, Mr Hall, 29 November 2016, p 43.

- the hospital's final implementation report, submitted to the Ministry in April 2017, published on the hospital's website and also the committee's website.

4.31 The remainder of this chapter takes a thematic approach, focusing on the hospital's actions in respect of key aspects of the section 122 report. First it documents the hospital's apology to patients and the broader community; then it considers the hospital's key actions with regard to more systemic issues in respect of cultural change, staffing, incident management, open disclosure, electronic prescribing and informed consent. A number of these issues are discussed again in a statewide context in chapter 8.

Apologies to patients

4.32 The first recommendation in the section 122 inquiry's interim report, released in April 2016, was that St Vincent's Hospital '[a]s a priority, apologise to patients and their families for any distress that this off-protocol prescribing or its reporting has caused'.³⁹⁷

4.33 The hospital subsequently apologised directly to each of the affected patients and families via telephone and also in writing. In these communications the hospital:

- apologised for the distress that the matter caused
- advised patients and/or families of the release of the section 122 interim report
- offered further support including follow up appointments for ongoing treatment and opportunity to discuss the report's findings
- offered to bring forward the patient's next scheduled review (where relevant).³⁹⁸

Public apology

4.34 The hospital also issued a public apology soon after the report's release, its statement reading in part:

The hospital apologises deeply and unreservedly to the patients and families affected by this matter. We are sorry you've had to go through this; and we are sorry for letting you down in this way.

In fact, we apologise to all our cancer patients at the Sydney hospital – including those not directly affected or involved in the dosage issue – because many would still have found this matter a source of anxiety and concern.

Finally, we apologise to the public, who rightfully have high expectations of the hospitals that care for them and their loved ones.³⁹⁹

³⁹⁷ NSW Ministry of Health, *Inquiry under section 122 of the Health Services Act 1997: Off-protocol prescribing of chemotherapy for head and neck cancers*, interim report, 31 March 2016 (hereafter section 122 inquiry interim report), p 16; section 122 inquiry final report, p 35.

³⁹⁸ St Vincent's Hospital Sydney, section 122 inquiry final implementation report, p 2. The report notes that there was a small number of the affected patient group who did not have next of kin or for whom the hospital did not have contact details.

4.35 The hospital again publicly apologised in August 2016, after the section 122 inquiry's final report handed down.⁴⁰⁰

4.36 At the committee's first hearing, Mr Hall reiterated the hospital's regret, its full acceptance of the section 122 inquiry's criticisms, and its pledge to address each of the inquiry recommendations:

The last nine months have been some of the most testing in a long and proud history for St Vincent's Hospital in Sydney and indeed the entire St Vincent's Health organisation. Our hospitals are recognised nationally and internationally as centres of excellence, but in this case across a range of measures we absolutely failed to live up to the high standards we set ourselves. Of course our challenges absolutely pale in comparison to the distress that has been experienced by patients and their families. To them I say again that we are deeply sorry. We are sorry for what we put you through. We are sorry for the pain and distress caused to you and your families ...

We are determined to put things right and we do so in the knowledge that there is a deep well of goodwill towards St Vincent's Hospital. However, again we reiterate that we absolutely apologise to the patients and their families who were affected by this terrible situation. It is now up to us to prove that the goodwill that has been placed in us is not misplaced.⁴⁰¹

4.37 Mr Hall emphasised to the committee that, 'Those of us in senior positions take responsibility for what has happened and equally we are taking responsibility for putting things right for the future'. He further assured the committee that the hospital's work to address each of the inquiry recommendations is the beginning of a long term effort to make amends and to restore public confidence and trust.⁴⁰²

Cultural change

4.38 No doubt recognising the significance of the section 122 inquiry's focus on culture – especially for the Cancer Services stream – St Vincent's Hospital advised the committee, 'Critically, we have redoubled our efforts at improving workplace culture, fostering a spirit of challenge and inquiry when it comes to clinical decisions.'⁴⁰³

Actions targeting the Cancer Services stream

4.39 The hospital advised that its program of work to address cultural change in the Cancer Services stream involves:

³⁹⁹ St Vincent's Hospital Sydney, *Statement regarding off-protocol dosing of Carboplatin*, April 2016, <https://svhs.org.au/home/newsroom/announcements/statement-off-protocol-dosing-carboplatin>.

⁴⁰⁰ St Vincent's Hospital Sydney, *St Vincent's Hospital Response to final report on off-protocol prescribing inquiry*, August 2016, <https://svhs.org.au/home/newsroom/announcements/final-report-off-protocol-prescribing-inquiry> (accessed 28 March 2016)

⁴⁰¹ Evidence, Mr Hall, 31 October 2016, p 33.

⁴⁰² Evidence, Mr Hall, 31 October 2016, p 33; see also submission 59, St Vincent's Hospital Sydney, p 3.

⁴⁰³ Submission 59, St Vincent's Hospital Sydney, p 3.

- new leadership and changes in key personnel – including the appointment of a new head of medical oncology, new medical oncologists, and a new Director of Cancer Services
- measuring staff engagement and satisfaction via an annual survey
- a facilitated restorative process as recommended by the section 122 inquiry that explores the events surrounding the off-protocol prescribing of chemotherapy and what is needed to rebuild confidence and trust within the service and in the community
- education and training including statewide Health Education and Training Institute (HETI) programs such as on clinician disclosure and building a safe workplace culture.⁴⁰⁴

4.40 In respect of the facilitated restorative process, the hospital advised that it has engaged a consultant group to assist in facilitating focus groups with Cancer Services staff and hospital executive and senior leaders to explore the events that occurred, along with what is needed to rebuild confidence and trust within the service and with the community. The focus will be on ways to:

- Re-establish the effectiveness of the team after a period of instability, triggered by events relating to clinical practice.
- Create a culture of engaging and empowering individuals in taking personal and professional responsibility for their behaviour and for their practice.
- Enhance the level of collegiality, and sense of trust and respect among team members; and, between the team and the organisation, enabling a culture where everyone's voice is valued and listened to.
- Support the team in developing comfort, skill and confidence in the giving and receiving of feedback, across a continuum of challenge, and to recognise and respond to the need to escalate relevant issues.
- Challenge and support the team to establish ways of working that enable a safe, positive and appreciative team culture.⁴⁰⁵

4.41 Further, the hospital advised that its new Head of Medical Oncology, Professor Anthony Joshua, has undertaken a special project on increasing medical engagement in incident management as part of his participation in the Clinical Excellence Commission's Executive Clinical Leadership Program.⁴⁰⁶

'It's OK to ask' campaign

4.42 Beyond Cancer Services, in order to encourage a broader 'culture of challenge', the hospital advised that it is implementing new programs across St Vincent's Sydney Hospital and the entire St Vincent's Health Australia Group.

4.43 First, a new campaign, *'It's OK to ask'* was launched in July 2016 to drive cultural change across St Vincent's Hospital Sydney. The campaign aims to ensure patient safety is paramount through encouraging a culture of open dialogue between all staff, based on mutual respect.

⁴⁰⁴ Submission 59, St Vincent's Hospital Sydney, p 20; answers to supplementary questions, St Vincent's Hospital, p 22.

⁴⁰⁵ St Vincent's Hospital Sydney, Section 122 inquiry final implementation report, pp 14-15.

⁴⁰⁶ St Vincent's Hospital Sydney, Section 122 inquiry final implementation report, p 14.

The program is sponsored by and reports to the hospital Chief Executive Officer, Associate Professor Anthony Schembri, and features the following messages:

- St Vincent’s fosters a culture of open dialogue between all staff, based on mutual respect.
- Staff should not be afraid to ask questions of their peers, or raise concerns.
- Specific avenues are available to staff to escalate a concern.⁴⁰⁷

4.44 Associate Professor Schembri advised the committee that alongside this peer focused program, the hospital has established a system that enables staff to voice concerns directly with senior management:

What we have also put in place is a system whereby staff can escalate outside of their department to members of the executive, to our clinical leaders, to myself, to Mr Hall, and so we have made it very clear to our staff that there is not just the culture of challenge and peer review that we are wanting to develop at St Vincent’s, but that staff feel comfortable to raise concerns with me and with other senior leaders ... We have an email address where staff can bring any concerns they have to our attention, and so they can do it anonymously or, if they feel comfortable, to raise it directly with us. We will certainly listen to their concerns.⁴⁰⁸

4.45 Phase two of the campaign, implemented in late 2016, focused on patients and their families, with the message that anyone under the hospital’s care, including their carer or loved-one, has a right to respectfully seek more information or clarification about their treatment.⁴⁰⁹

Ethos – Inspired to shine

4.46 In addition, the national St Vincent’s Health Australia *Ethos – Inspired to shine* as a long term program driving change in workforce culture across the entire organisation. It aims to foster a culture that encourages feedback, addresses behaviour that undermines patient or staff wellbeing and embeds safe, respectful and professional behaviour as norms. Built on the principle that all staff should feel welcome, valued and safe, the program includes:

- an accountability pathway
- a peer driven early intervention process
- a reporting system that allows safe voicing of concerns and provides reliable data
- a package of capability building and training to equip leaders and staff with skills to role model and teach safe behaviour
- the development of relationships across the health sector, ‘recognising that change of this magnitude cannot be undertaken in isolation.’⁴¹⁰

⁴⁰⁷ Submission 59, St Vincent’s Hospital Sydney, p 21; answers to supplementary questions, St Vincent’s Hospital Sydney, p 22.

⁴⁰⁸ Evidence, Associate Professor Anthony Schembri, Chief Executive Officer, St Vincent’s Health Network Sydney, 31 October 2016, pp 45-46.

⁴⁰⁹ Submission 59, St Vincent’s Hospital Sydney, p 21; answers to supplementary questions, St Vincent’s Hospital Sydney, p 22.

- 4.47 The hospital's submission made the link between this program, cultural change, structural improvements, skills training and improved health care delivery:

Better management of, and responses to, inappropriate behaviour, early intervention and improved accountability will support a culture of safety and the delivery of safer, more reliable healthcare. This requires a redesign of the current structures and processes for dealing with inappropriate behaviour, as well as training for leaders, managers and staff in the skills they need to prevent and respond to inappropriate behaviour.⁴¹¹

Staff feedback

- 4.48 The hospital has also established a new program, *You said; We did*, to provide new avenues for staff feedback and to communicate actions taken in response.⁴¹²

Staffing

- 4.49 As noted in chapter 2, Dr Grygiel was dismissed from the hospital in August 2016.⁴¹³
- 4.50 In addition to the personnel changes in Cancer Services noted above, the hospital advised that it has established two new clinical leadership roles: a new Director of Medical Services, who leads the hospital's medical workforce, and a new Director of Clinical Governance, who is in charge of medical standards.⁴¹⁴
- 4.51 The committee is aware that Dr Brett Gardiner resigned as Director of Clinical Governance and Chief Medical Officer in June 2016. Dr Gardiner advised us that he resigned chiefly to look after his health, owing to issues that predated but were not helped by the crisis that unfolded at the hospital. He told the committee, 'I had a number of reasons for resigning. Principally for me is that it affected me quite greatly. I had to look after my mental and physical health ... I had considered where I was and I essentially wanted to resign. I needed to do something for myself.'⁴¹⁵
- 4.52 St Vincent's Hospital advised that following the completion of the section 122 inquiry, it engaged an external expert to assess the performance of relevant hospital staff in relation to this matter, with a view to taking any necessary disciplinary action and/or reporting to the HCCC.⁴¹⁶ It subsequently informed the committee that the independent review team

⁴¹⁰ Submission 59, St Vincent's Hospital Sydney, p 22; answers to supplementary questions, St Vincent's Hospital Sydney, p 22; St Vincent's Hospital Sydney, Section 122 inquiry final implementation report, p 15.

⁴¹¹ Submission 59, St Vincent's Hospital Sydney, p 21.

⁴¹² St Vincent's Hospital Sydney, Section 122 inquiry final implementation report, p 13.

⁴¹³ Answers to supplementary questions, St Vincent's Hospital Sydney, p 26. As noted in chapter 2, Dr Grygiel and St Vincent's Hospital subsequently settled an unfair dismissal case initiated by Dr Grygiel.

⁴¹⁴ Answers to supplementary questions, St Vincent's Hospital Sydney, p 27.

⁴¹⁵ Evidence, Dr Brett Gardiner, Former Director, Clinical Governance, St Vincent's Health Network Sydney, 29 November 2016, pp 62–63.

⁴¹⁶ Answers to supplementary questions, St Vincent's Hospital, pp 27 and 29.

‘concluded that overall, there was not a particular person, other than Dr Grygiel himself, that had allowed his practice to commence and continue.’ In addition, the review made a number of recommendations on culture which are feeding into the hospital’s actions, noted above:

Consistent with the [section 122 inquiry], the review found that not all staff were aware of requirements under the health department’s policies and should have been better prepared to raise concerns and challenge practice. As such, the review made some recommendations in relation to training, developing clearer guidelines for raising concerns, and culture which are being actioned.⁴¹⁷

Incident management

4.53 The committee documented in chapter 3 the section 122 inquiry’s findings as to the serious failings in St Vincent’s Hospital’s incident management system when concerns were raised about Dr Grygiel’s prescribing practices.

4.54 In its submission to our inquiry, and in its three month and six month reports on implementation of the section 122 inquiry recommendations, the hospital acknowledged that NSW Health’s incident management policies, including the lookback policy, were not appropriately applied in response to the off-protocol prescribing incident. It advised that the hospital has implemented a number of changes to address this.⁴¹⁸

Review of incident management practices and policies

4.55 The hospital reviewed its incident management practices, with the key objective of ensuring 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, who is now required to ensure the immediate input of a subject matter expert to ascertain the magnitude and impact of the incident and potential consequences.
- The clinical subject matter expert, to be included in any future incident reviews, will ideally be from outside the hospital.
- The Director of Clinical Governance will review and formally appoint all investigation team members.
- Relevant 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 this
 - the requirement for a reportable incident brief

⁴¹⁷ St Vincent’s Hospital Sydney, further response to supplementary question, received 24 March 2017, p 1. See also submission 59, St Vincent’s Hospital Sydney, p 17.

⁴¹⁸ Submission 59, St Vincent’s Hospital Sydney, p 17.

- the type of investigation to be completed in accordance with policy
- the proposed membership of the review team
- management of any immediate clinical risks.⁴¹⁹

4.56 In addition, since the off-protocol prescribing incident, the hospital has established a dedicated quality manager for each clinical stream, and regular clinical governance meetings now occur to monitor incident data and other key performance measures.⁴²⁰

4.57 The hospital has also strengthened responsibility and accountability via stream clinical governance meetings for incident management at the local level, which is then monitored at the hospital level via the Patient Safety and Quality Committee.⁴²¹

Education and training

4.58 The hospital has also developed a staff training program to complement these changes and improve the management of corporate and clinical incidents through better knowledge of the relevant systems. The program was delivered in mid 2016 to the hospital executive clinical stream directors, clinical stream managers, heads of department, department managers and senior managers. It will be provided annually for new staff and delivered as a refresher every two years.⁴²² Associate Professor Schembri explained the training program to the committee:

One of the things that we have done to ensure that it does not happen again, is over 150 of our senior managers have undergone a comprehensive training program around the Ministry's incident management policy and protocols, as well as how you recognise an incident, the open disclosure process, and we will repeat that on an ongoing basis to ensure that all of our staff are familiar with the expectations around incident management.⁴²³

Open disclosure

4.59 The section 122 inquiry's many criticisms of the hospital's handling of the open disclosure process for patients affected by Dr Grygiel's off protocol prescribing were documented in the previous chapter.

4.60 St Vincent's Hospital's submission to our inquiry accepted that the hospital should have commenced the open disclosure process much earlier, and acknowledged that some patients found the initial open disclosure process in February 2016 upsetting and frustrating.

4.61 The hospital advised the committee that:

⁴¹⁹ Submission 59, St Vincent's Hospital Sydney, p 17; answers to supplementary questions, St Vincent's Hospital Sydney, p 2; St Vincent's Hospital Sydney, Section 122 inquiry final implementation report, p 7.

⁴²⁰ Submission 59, St Vincent's Hospital Sydney, p 17.

⁴²¹ St Vincent's Hospital Sydney, Section 122 inquiry final implementation report, p 7.

⁴²² Submission 59, St Vincent's Hospital Sydney, pp 17-18.

⁴²³ Evidence, Associate Professor Schembri, 31 October 2016, pp 44-45; see also St Vincent's Hospital Sydney, Section 122 inquiry final implementation report, p 6.

- In April 2016 it recontacted all affected patients and/or families (who were able to be contacted) to apologise, and to provide ongoing disclosure, support and transparency around the findings of the section 122 inquiry interim report.
- Patients and families were again contacted in July 2016 when the inquiry's final report was handed down.
- All those able to be contacted were offered:
 - meetings to discuss any concerns they may wish to raise
 - counselling
 - a dedicated point of contact at the hospital for any subsequent issues or questions.
- A 24 hour 1800 phone number was established for any patients, family or loved ones with questions, which has now been replaced by a statewide 1800 number, established by NSW Health.
- The hospital facilitated independent case reviews for those patients and family members that requested it and offered additional follow up to patients that requested an earlier review. It subsequently tracked all relevant patients to ensure they are receiving appropriate follow up.
- It also provided additional training and education on open disclosure via the incident management training noted above and the Clinical Excellence Commission.⁴²⁴

Electronic prescribing

4.62 As noted in chapter 3, in August 2015, shortly after concerns about Dr Grygiel's prescribing were escalated, St Vincent's Hospital coincidentally implemented the MOSAIQ electronic prescribing system, with preloaded evidence based (eviQ) protocols for chemotherapy patients. While this initiative was not put in place in response to the off-protocol prescribing matter, the hospital highlighted its relevance to the committee stating, 'The hospital considers that electronic prescribing systems ... in conjunction with robust governance processes, significantly reduce the risk of off-protocol prescribing'.⁴²⁵

4.63 All pharmacy orders prescribed in MOSAIQ are verified and approved by the senior oncology pharmacist. While individualised dose adjustments are allowed within certain set ranges, a clinician wishing to make any significant variation to eviQ care plans must submit their proposal with evidence for peer review through the MOSAIQ care plan review committee. The committee's approval must be verified by the pharmacist before dispensing.⁴²⁶

Informed consent

4.64 As noted in chapter 2, Dr Grygiel's practices in respect of informed consent, as well as his off-protocol prescribing, were of concern for the section 122 inquiry. The inquiry recommended that the hospital ensure adequate informed consent for all medical interventions, including

⁴²⁴ Submission 59, St Vincent's Hospital Sydney, pp 18-19. In addition, the hospital documented the numerous ways in which it ensures ongoing compliance with NSW Health's open disclosure policy.

⁴²⁵ Submission 59, St Vincent's Hospital Sydney, p 10.

⁴²⁶ Submission 59, St Vincent's Hospital Sydney, p 10.

chemotherapy, asserting that ‘If the clinician knows that his/her practice is outside accepted practice, there is a particular onus to draw this to the attention of patients in the process of providing informed consent and to document this in the patient notes.’⁴²⁷

- 4.65** The hospital acknowledged in its submission to our inquiry that ‘many of Dr Grygiel’s patients felt they did not have appropriate information about their treatment.’⁴²⁸ It further stated that while it expects all clinicians to comply with its informed consent policy, it accepts the section 122 inquiry findings and recommendation about informed consent, and that it has subsequently changed a number of processes to improve the information provided to patients including to formally document the information provided in the process of obtaining consent.
- 4.66** The hospital advised that the existing practice 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.
- 4.67** For those patients for whom a non-eviQ care plan is recommended, as of late 2016, the hospital was trialling an additional process, whereby patients are provided with written information about their proposed protocol, including the clinical rationale for it. The document is then scanned into the patient information system to formally record their consent.⁴²⁹
- 4.68** St Vincent’s Hospital further advised that all clinical staff receive training on informed consent during orientation, and that its senior medical officer orientation program is being reviewed and will include education regarding expectations for valid informed consent.⁴³⁰

Multidisciplinary team meetings to consider emerging evidence

- 4.69** In respect of the section 122 inquiry’s recommendation (noted in paragraph 4.22 above) that all local health districts and health networks ensure that minuted meetings of multidisciplinary cancer care teams occur to consider seminal new evidence as it emerges, St Vincent’s Hospital advised that it has taken the following actions:
- Every MDT meeting has discussion of significant new evidence that may influence practice as an agenda item. The minutes are signed off by the MDT chair and recorded in MOSAIQ.
 - The Director of Cancer Service’s quarterly meetings with the MDT chairs also involve a formal review of new evidence.

⁴²⁷ Section 122 inquiry final report, p 41.

⁴²⁸ Submission 59, St Vincent’s Hospital Sydney, p 12.

⁴²⁹ Submission 59, St Vincent’s Hospital Sydney, p 10 and St Vincent’s Hospital Sydney, Section 122 inquiry final implementation report, p 22. The hospital also advised the committee of its broader framework and requirements in respect of informed consent on p 13 of the submission and in answers to supplementary questions, St Vincent’s Hospital Sydney, p 11.

⁴³⁰ Answers to supplementary questions, St Vincent’s Hospital Sydney, p 11.

- Beyond MDT meetings, the Cancer Services stream has implemented signoff sheets across clinical trials, units and research, or journal club monthly meetings, to foster quicker adoption of clinical practice changes for new and compelling evidence.⁴³¹

Monitoring patient outcomes

- 4.70** In respect of monitoring the health outcomes of patients in the affected cohort, the section 122 inquiry recommended that St Vincent's Hospital report on patient outcomes to the hospital's Patient Safety and Quality Committee and Clinical Council six monthly, and annually to the Deputy Secretary, Ministry of Health.⁴³²
- 4.71** The hospital's 12 month implementation report notes that the first report on patient outcomes, which outlined the process for review and follow up for affected patients and the structure of future reports, was provided to the St Vincent's Health Network Sydney Clinical Council in February 2016. In addition, a regular report to the Patient Safety and Quality Committee has occurred since December 2016. The item is a standing agenda item on the respective committees. As of April 2017, the hospital was preparing its first report to the Ministry of Health.
- 4.72** According to the hospital, its Director of Cancer Services has formal responsibility for reviewing the full patient cohort on a monthly basis until all patients have been followed for five years. A function has been built into the hospital's MOSAIQ system to enable regular reports to be generated and reviewed.⁴³³

Review of contracts with third party oncology providers

- 4.73** The section 122 inquiry made the following recommendation to all LHDs and specialty networks:

There are a number of outsourced providers in oncology across NSW in areas such as compounding pharmacy and radiotherapy. These providers should have the same responsibility to demonstrate the quality of their care and share clinical data as any other member of the multidisciplinary cancer care team. They should also have the same responsibilities to contribute to the fail-safe checks that are a hallmark of good multidisciplinary teams and evidence-based clinical care, including escalation where there are concerns about care that have not been adequately addressed. This should be properly reflected in relevant contracts as they are negotiated between Local Health Districts/ Specialty Health Networks and third party providers.⁴³⁴

- 4.74** St Vincent's Health Network advised the committee that it supports this recommendation, and as of April 2017 was in the process of ensuring that all outsourced providers of cancer services have equal responsibility to demonstrate the quality of their care and share clinical data. In addition, the hospital has undertaken a review of its contracts with third party providers in cancer services to ensure the recommendation is met, with potential

⁴³¹ St Vincent's Hospital Sydney, Section 122 inquiry final implementation report, p 19.

⁴³² Section 122 inquiry final report, p 36.

⁴³³ St Vincent's Hospital Sydney, Section 122 inquiry final implementation report, p 4.

⁴³⁴ Section 122 inquiry final report, p 41.

improvements identified for negotiation at the expiry of current contracts. This will be incorporated into the tendering process.⁴³⁵

Other key actions

- 4.75** Two further actions on the part of the hospital are noted here.
- 4.76** First, the hospital advised that as of November 2016, it had commenced a complete review of the treatment of all of Dr Grygiel's identifiable patients since 2006, when the eviQ guidelines were introduced.⁴³⁶
- 4.77** Second, clinical staff have been advised that any off-protocol prescribing is subject to strict obligations on their behalf. Mr Hall advised the committee that he personally had made these requirements clear to staff:

I have spoken to senior clinicians at St Vincent's Hospital and also across our group to say very clearly that any clinician who wants to go outside standard treatment protocols has to do so in a research-based project and they have to tell their peers and they have to tell the MDT. That did not happen in this case. The senior clinicians in the hospitals have had that discussion to ensure they are following through, and I believe they have a good understanding of that.⁴³⁷

Committee view

- 4.78** From the committee's perspective, it is heartening that St Vincent's Hospital has taken responsibility for the very serious failures in the hospital's response to off-protocol prescribing of chemotherapy, and is systematically addressing them.
- 4.79** Without doubt, accountability has been very important to this process. The consequences to St Vincent's Hospital flowing from the section 122 inquiry have been extremely serious. The committee considers that the substantial accountability requirements put in place by the Ministry of Health are appropriate. The regime of reporting required of the hospital appears to be helping to facilitate both the insights and the changes necessary to ensure that such events do not occur again at that hospital.
- 4.80** As noted earlier in this chapter, it is not the role of this committee to assess the hospital's actions in detail, nor to scrutinise its response to every specific recommendation of the section 122 inquiry. Our observations here are thus general, picking up on key issues highlighted in the previous chapter.
- 4.81** The actions that the hospital has set in place since the section 122 inquiry commenced have been necessarily ambitious and multifaceted. Notably, St Vincent's Hospital has recognised that these actions will require long term effort and must be led by senior management. Mr Hall's assurance that those in senior positions at St Vincent's take responsibility for what occurred and for setting things right is welcome and absolutely necessary under the

⁴³⁵ St Vincent's Hospital Sydney, Section 122 inquiry final implementation report, p 20.

⁴³⁶ Answers to supplementary questions, St Vincent's Hospital Sydney, p 52.

⁴³⁷ Evidence, Mr Hall, 31 October 2016, p 45.

circumstances. As committee members commented during our hearings, leadership comes from the top and organisational change will only occur with a genuine commitment among leaders to bring about that change.

- 4.82** The section 122 inquiry's findings about organisational culture as the primary contributor to what occurred were very troubling. It is thus pleasing that St Vincent's is implementing multiple strategies to address culture in its Cancer Services stream, as well as across the broader hospital and St Vincent's Australia Group. Cultural change will take time but is essential if the hospital and its individual staff are to move forward from past events. Improving culture will mean that the hospital's policies and regulatory systems work more effectively. Better working environments will surely also enable better clinical care, and help to rebuild trust with patients and the community.
- 4.83** The committee is also encouraged by the actions that St Vincent's Hospital has put into place with regard to staffing, incident management, open disclosure, electronic prescribing, and informed consent. We trust that each of these actions will enable the hospital to demonstrate its progress in achieving necessary change, again with the ultimate goals of improving patient care and rebuilding the trust of patients and the public. Tracking the health outcomes of the affected cohort is also critically important, and we take this issue up in further detail in chapter 6.
- 4.84** In sum, the committee finds that St Vincent's Hospital Sydney failed to prevent and to respond effectively to the off-protocol prescribing of chemotherapy. However, in the year that has passed since the handing down of the section 122 inquiry's interim report, St Vincent's Hospital has demonstrated that it has taken responsibility for these serious, manifold failures and appears to be addressing them appropriately. The committee is not in a position to judge the appropriateness of each and every action, whether individually or in their entirety. However we trust that these judgements have been exercised by the hospital's independent advisor and by senior officers of the Ministry of Health during the process of the hospital's three, six and 12 monthly reports on its actions, along with its monthly meetings with the Ministry.

Finding

That St Vincent's Hospital Sydney failed to prevent and to respond effectively to the off-protocol prescribing of chemotherapy that occurred in the hospital. However, it has since taken responsibility for these failures and is addressing them appropriately.

- 4.85** The committee spent some time in hearings endeavouring to understand the workings of the multidisciplinary team, so as to appreciate how, in the context of holistic patient care, Dr Grygiel's colleagues were not aware of his dosing practices for many years. We take up this issue, as well as the improvements to electronic prescribing, incident management and informed consent, in the final chapter of this report. Many of the problems highlighted at St Vincent's Hospital surely exist in other local health districts, and lessons learned so painfully there can inform others too.

Chapter 5 Other institutions

Earlier chapters in this report focussed on Dr Grygiel's treatment of patients and the subsequent response of St Vincent's Hospital. This chapter considers other institutions in which Dr Grygiel's prescribing of off-protocol chemotherapy was found to have occurred, namely the Western NSW Local Health District and Macquarie University Hospital.

The chapter first considers the Western NSW Local Health District. It notes the findings and recommendations of the section 122 investigation and the district's implementation of those recommendations. The chapter then discusses Dr Grygiel's prescribing practices at Macquarie University Hospital and the response of the hospital once it became aware of his off-protocol dosing of chemotherapy.

Western NSW Local Health District

- 5.1** Dr John Grygiel practiced as a fly-in fly-out medical oncologist⁴³⁸ in the Western NSW Local Health District (LHD) for 23 years between 1989 and March 2012, holding weekly clinics alternating between Bathurst and Orange. Dr Grygiel was the only medical oncologist practicing in Bathurst and Orange in this period. Western NSW LHD provided Dr Grygiel with clinic space to consult with patients, clerical assistance with appointments, and nursing assistance during the clinics and administration of chemotherapy.⁴³⁹
- 5.2** Following the ending of his fly-in fly-out role, Dr Grygiel provided a telehealth⁴⁴⁰ follow-up service for his existing patients between March 2012 and March 2013.⁴⁴¹
- 5.3** Western NSW LHD first became aware of Dr Grygiel's off-protocol prescribing practices as a result of the ABC 7.30 program, aired on 18 February 2016.⁴⁴² The district's Chief Executive Officer, Mr Scott McLachlan, informed the committee that following the broadcast, the district took immediate steps to advise the relevant authorities that Dr Grygiel had also worked as an oncologist in the Western NSW LHD, and to provide advice and support to Dr Grygiel's patients and their families:

Immediately the day after we gathered a team comprising some of the most senior clinicians and management people to help understand the potential scale of the issue in western New South Wales. On that day, we contacted the Clinical Excellence

⁴³⁸ Fly-in fly-out medical specialists are appointed by the Western NSW Local Health District to visit regional centres including Bathurst and Orange on a regular basis to provide patient care. The provision of fly-in fly-out medical care allows patients to receive specialist medical care in their region rather than travelling long distances to access treatment.

⁴³⁹ NSW Ministry of Health, *Inquiry under section 122 of the Health Services Act 1997: Prescribing of chemotherapy, Report on patients treated at Western NSW Local Health District*, (hereafter section 122 inquiry Western NSW Local Health District report), pp 4-5.

⁴⁴⁰ Telehealth uses information and communications technology to allow a patient to have an appointment with a specialist remotely and can be held at a doctor's clinic, local hospital or in a patient's home.

⁴⁴¹ Section 122 inquiry Western NSW Local Health District report, p 4.

⁴⁴² Evidence, Mr Scott McLachlan, Chief Executive Officer, Western NSW Local Health District, 2 November 2016, p 3.

Commission, the Cancer Institute, the Health Care Complaints Commission, and a range of other people to try to understand the scale of the issue, and to understand Dr Grygiel's visits over some years and the type of patients he treated. First we needed to help patients through what we knew would be a very concerning series of events. We took steps very early to set up a cancer inquiry line. The director of clinical governance and some of our most senior clinical governance people manned that line from day one.⁴⁴³

- 5.4** The Western NSW LHD then began the process of reviewing the impact of Dr Grygiel's prescribing practices on patients in the district:

We took steps within the next week to understand the group of patients who might have been affected. We undertook an initial review and started to understand the issue facing us. All of our considerations revolved around the patients in our region, knowing the fear and concern that cancer brings to patients and their family. Throughout that week we started much more dialogue with NSW Health, the Cancer Institute, and the Clinical Excellence Commission. They were our guiding partners in understanding the steps we needed to take. We started to document all of the concerns that we were becoming aware of, and took steps to address them.⁴⁴⁴

The section 122 inquiry

- 5.5** Dr Grygiel's dosing of cancer patients in Western NSW LHD was taken up for investigation by the section 122 inquiry, which subsequently found that the district acted 'promptly and proactively, in the best interests of its patients'⁴⁴⁵ when it became aware of Dr Grygiel's prescribing practices.
- 5.6** As noted in chapter 1, the section 122 inquiry was initially charged with investigating Dr Grygiel's prescribing practices at St Vincent's Hospital, however, in April 2016 the inquiry terms of reference were extended to review:
- the dosing of cancer patients under the care of Dr Grygiel in Western NSW LHD (and its predecessor) from January 2006
 - the application of eviQ and other treatment protocols in the Western NSW LHD and systems in place for monitoring the protocols.⁴⁴⁶
- 5.7** The section 122 inquiry team reported the findings of their review of patients treated at Western NSW LHD in a specific report in September 2016. The inquiry repeated a number of recommendations made in earlier reports; it also made two recommendations specifically to the Western NSW LHD, two new recommendations to the NSW Ministry of Health and one new recommendation to the Cancer Institute NSW.⁴⁴⁷ These findings and recommendations are discussed below in respect of several key issues:

⁴⁴³ Evidence, Mr McLachlan, 2 November 2016, p 3.

⁴⁴⁴ Evidence, Mr McLachlan, 2 November 2016, p 3.

⁴⁴⁵ Section 122 inquiry Western NSW Local Health District report, p 13.

⁴⁴⁶ Section 122 inquiry Western NSW Local Health District report, appendix A, Final consolidated terms of reference.

⁴⁴⁷ The full list of recommendations can be found in Section 122 inquiry Western NSW Local Health District report, pp 16-17.

- Dr Grygiel's dosing of cancer patients
- record keeping
- the application of eviQ and other treatment protocols
- clinical governance for visiting specialists
- informed consent.

Dr Grygiel's dosing of cancer patients

5.8 Where Dr Grygiel's practice at St Vincent's Hospital was primarily focussed on treating patients with head and neck cancers, in Western NSW LHD Dr Grygiel practiced as a general medical oncologist treating a broad range of cancers. In addition to treating patients with carboplatin and cisplatin, Dr Grygiel also prescribed capecitabine. The section 122 inquiry examined Dr Grygiel's prescribing practices in respect of all these chemotherapy drugs.

Section 122 inquiry findings and recommendations

- 5.9** The section 122 inquiry team did not identify any dosing anomalies in relation to Dr Grygiel's prescribing of cisplatin in the Western NSW LHD.⁴⁴⁸
- 5.10** In relation to Dr Grygiel's prescribing of carboplatin, it found that of a group of 21 patients prescribed carboplatin, five received a flat dose of carboplatin as a chemoradiation agent, similar to the treatment of patients at St Vincent's Hospital.⁴⁴⁹ As noted in chapter 1, flat dosing of carboplatin is considered off-protocol as carboplatin doses are calculated using Area Under the Curve (AUC), taking into account an individual's age, gender, body weight and renal function.⁴⁵⁰
- 5.11** The section 122 inquiry found that 23 patients in Western NSW LHD were prescribed the chemotherapy drug capecitabine at a 'substantially reduced dose' by Dr Grygiel.⁴⁵¹
- 5.12** The inquiry report noted that, unlike cisplatin and carboplatin which are delivered intravenously in hospital, capecitabine is an oral chemotherapy drug taken in tablet form. Patients requiring oral chemotherapy receive a prescription for their medication from their oncologist which they fill at a pharmacy; chemotherapy dispensing records will be held by the pharmacy. Copies of the prescription are often not kept by the hospital and the patient's medical record may only contain the oncologist's record of the clinical consultation.⁴⁵²

⁴⁴⁸ Section 122 inquiry Western NSW Local Health District report, pp 7, 12.

⁴⁴⁹ Section 122 inquiry Western NSW Local Health District report, p 7.

⁴⁵⁰ NSW Ministry of Health, *Inquiry under section 122 of the Health Services Act 1997: Off-protocol prescribing of chemotherapy for head and neck cancers*, Final report, 31 July 2016, (hereafter section 122 inquiry final report) p 11.

⁴⁵¹ Section 122 inquiry Western NSW Local Health District report, p 11.

⁴⁵² Section 122 inquiry Western NSW Local Health District report, p 5.

5.13 Because chemotherapy dispensing records for capecitabine were not held by the LHD, the section 122 inquiry team sought assistance from the Commonwealth Pharmaceutical Benefits Scheme (PBS) to obtain dispensing records of capecitabine in the Western NSW LHD.⁴⁵³

5.14 At the time of publication of the section 122 inquiry report on Western NSW LHD, the PBS had agreed to the release relevant capecitabine data, however, the data had not yet been received by the section 122 inquiry team. The inquiry team noted, however, that when the PBS data was received it would not be able to compare the dose prescribed for some patients with the treatment protocol (that is, the evidence based dose), because of inadequate chemotherapy record keeping on the part of Western NSW LHD:

The Pharmaceutical Benefits Scheme (PBS) has agreed to release the data for capecitabine prescribed by Dr Grygiel for patients in Western NSW LHD. Despite the availability of these PBS records, it will not be possible to compare the evidence-based dose with the dose that was actually prescribed for some patients, given that adequate chemotherapy record-keeping (for example, height and weight) was not in place in the LHD. There is an onus on each practitioner to adequately record in patients' medical records all prescriptions for oral chemotherapy and the reasons for it.⁴⁵⁴

5.15 The committee learned that an increasing proportion of chemotherapy prescribed to cancer patients is for oral delivery. Professor David Currow, Co-leader of the section 122 inquiry, advised that this has implications for the way in which health districts maintain accurate records for their patients:

... an increasing proportion of chemotherapy is now administered by tablet or capsule. That is a very big change over the last decade. It means that line of sight to that kind of clinical care is now through different lenses—through the Pharmaceutical Benefit Scheme rather than through hospital dispensing records, for example. What we are seeing is a rapid and continuing change in chemotherapy and how it is considered, and how it will be taken forward into the future.⁴⁵⁵

5.16 In light of this significant shift, the section 122 inquiry recommended that the Ministry of Health consider mechanisms to capture systematically the prescribing of oral chemotherapy across New South Wales.⁴⁵⁶ The section 122 inquiry further recommended that the Western NSW LHD continue to identify people who were prescribed reduced dose capecitabine as data becomes available.⁴⁵⁷

Western NSW Local Health District's response

5.17 Western NSW LHD's six month response to the section 122 inquiry report advised that the PBS provided capecitabine dispensing records in November 2016. An independent locum oncologist engaged by the LHD was undertaking a systematic review of the medical records of patients prescribed capecitabine.

⁴⁵³ Section 122 inquiry Western NSW Local Health District report, pp 6, 15.

⁴⁵⁴ Section 122 inquiry Western NSW Local Health District report, p 15.

⁴⁵⁵ Evidence, Professor David Currow, Chief Executive Officer, Cancer Institute NSW, Chief Cancer Officer NSW, Chairman of Section 122 Inquiry, 31 October 2016, p 11.

⁴⁵⁶ Section 122 inquiry Western NSW Local Health District report, p 17.

⁴⁵⁷ Section 122 inquiry Western NSW Local Health District report, p 15.

- 5.18 The LHD advised that affected patients and/or their families had been provided with a written apology and offered a face to face meeting and ongoing support. Where patient contact details were out of date, the LHD informed the committee that multiple contact attempts were made and other sources of contact information were utilised.⁴⁵⁸

Record keeping

- 5.19 All clinicians involved in providing care for a patient have a statutory obligation to keep comprehensive clinical records.⁴⁵⁹ For those patients treated by Dr Grygiel in Western NSW, the pharmacist, medical oncologist and the LHD each had a responsibility to maintain accurate clinical records.⁴⁶⁰

Section 122 inquiry findings and recommendations

- 5.20 The section 122 inquiry noted that Dr Grygiel's record keeping for patients in the Western NSW LHD was by way of letters to referring doctors, copied to the oncology clinic. The letters did not always record the prescribed dose of chemotherapy.⁴⁶¹ Additionally, oncology nurses attended Dr Grygiel's clinics and their notes were incorporated into patients' medical records.⁴⁶²
- 5.21 The section 122 inquiry found that the quality of the Western NSW LHD's record keeping was 'poor'. Fundamental elements such as identifying information or a patient's weight (a vital requirement for determining chemotherapy dosage) were often missing from patient records. Additionally, records for some patients could not be located at all.⁴⁶³
- 5.22 The section 122 inquiry commented that accurate and comprehensive records are of vital importance for ensuring continuity of care, particularly in circumstances where patients receive treatment from fly-in fly-out medical specialists. Comprehensive clinical records also enable the conduct of clinical audits to ensure the quality and safety of patient care.⁴⁶⁴
- 5.23 To improve record keeping by the Western NSW LHD, the section 122 inquiry recommended that the district 'Maintain clinical records for all patients treated in a public hospital or clinic that are comprehensive enough to ensure that the care can be offered safely and that the quality of that care is capable of objective evaluation. This includes where patients are being treated on behalf of the LHD by a third party provider.'⁴⁶⁵

⁴⁵⁸ Western NSW Local Health District, *Section 122 inquiry of the Health Service Act 1997, Prescribing of chemotherapy: Report on patients treated at Western NSW Local Health District, Implementation of Recommendations – Six Month Report*, March 2017 (hereafter Western NSW Local Health District six month implementation report), p 7.

⁴⁵⁹ In New South Wales, the Health Practitioner Regulation 2016 sets out the legal requirements for medical record keeping.

⁴⁶⁰ Section 122 inquiry Western NSW Local Health District report, p 14.

⁴⁶¹ Section 122 inquiry Western NSW Local Health District report, p 14.

⁴⁶² Section 122 inquiry Western NSW Local Health District report, p 14.

⁴⁶³ Section 122 inquiry Western NSW Local Health District report, p 14.

⁴⁶⁴ Section 122 inquiry Western NSW Local Health District report, p 14.

⁴⁶⁵ Section 122 inquiry Western NSW Local Health District report, p 16.

Western NSW Local Health District's response

- 5.24** Western NSW LHD has conceded that its past record keeping practices were ‘unacceptable’.⁴⁶⁶
- 5.25** Dr Rob Zielinski, a medical oncologist in Orange, informed the committee that while the district had an electronic medical records system for general inpatients and the emergency department for a number of years, electronic medical records systems were not in place across the district for every hospital or facility.⁴⁶⁷ However, Mr Scott McLachlan, Chief Executive Office of Western NSW LHD, informed the committee that in 2015 the district commenced the staged implementation of the medical record keeping system MOSAIQ, and was the first rural region in New South Wales to do so.⁴⁶⁸
- 5.26** Mr McLachlan explained that MOSAIQ had transformed the district’s ability to put in place safeguards and have good document and record keeping.⁴⁶⁹
- 5.27** The district advised that complete medical records for all people with cancer who visit outpatient clinics are now stored in MOSAIQ (for medical oncology and haematology) and ARIA (for radiation oncology).⁴⁷⁰
- 5.28** In terms of ensuring the accountability of third party providers (including fly-in fly-out medical oncologists) to maintain comprehensive clinical records, Mr McLachlan told the committee that the district still had ‘a lot of work to do’ to ensure that contracts for third party providers included ‘strong approaches around record keeping’.⁴⁷¹

The application of eviQ and other treatment protocols

- 5.29** As discussed in chapter 1 of this report, chemotherapy treatment protocols accepted for use in New South Wales are provided on eviQ, an internet based cancer treatment resource. EviQ and its predecessor CI-SCaT were adopted by the Western NSW Greater Area Health Service (the forerunner of the Western NSW LHD) in 2007. The section 122 inquiry was charged with examining the application of the eviQ and other standardised treatment protocols and systems in place for monitoring application of those protocols.

Section 122 inquiry findings and recommendations

- 5.30** Dr Grygiel began working in the Western NSW LHD prior to the introduction of CI-SCaT and eviQ, and he indicated to the section 122 inquiry team that he was not aware of the

⁴⁶⁶ Evidence, Mr McLachlan, 2 November 2016, p 2.

⁴⁶⁷ Evidence, Dr Rob Zielinski, Medical Oncologist, Central West Cancer Care Centre, Orange Health Service, 2 November 2016, p 18.

⁴⁶⁸ Evidence, Mr McLachlan, 2 November 2016, p 2.

⁴⁶⁹ Evidence, Mr McLachlan, 2 November 2016, p 15.

⁴⁷⁰ Western NSW Local Health District, *Section 122 inquiry of the Health Service Act 1997, Prescribing of chemotherapy: Report on patients treated at Western NSW Local Health District, Implementation of Recommendations – Three Month Report*, December 2016 (hereafter Western NSW Local Health District three month implementation report), p 10.

⁴⁷¹ Evidence, Mr McLachlan, 2 November 2016, p 10.

adoption by the district of the treatment protocols.⁴⁷² However, Western NSW LHD informed the section 122 inquiry team that treatment protocols were presented and discussed at various staff meetings and meetings of clinicians, emailed to registered nurses and provided to Dr Grygiel in hard copy.⁴⁷³

5.31 The section 122 inquiry team found that although treatment protocols were adopted by Western NSW LHD in 2007, no governance systems were put in place to ensure that clinicians adhered to the protocols.⁴⁷⁴

5.32 The section 122 inquiry therefore recommended that the district put in place systems to ensure that the oncology pharmacist and the head of medical oncology review any overrides in the electronic prescribing system that may suggest patterns of off-protocol prescribing.⁴⁷⁵

Western NSW Local Health District's response

5.33 The district has introduced the following changes to ensure adherence to treatment protocols:

- In 2015, shortly before Dr Grygiel's prescribing practices came to light, Western NSW LHD began the staged implementation of the electronic medical records system MOSAIQ. MOSAIQ may be preloaded with treatment protocols and an electronic prescribing module.⁴⁷⁶
- Dedicated oncology pharmacists have been appointed at Orange, Dubbo and Bathurst to review all MOSAIQ chemotherapy prescriptions.
- All chemotherapy prescriptions entered into MOSAIQ which are less than 80 per cent of the expected calculated dose are reviewed.
- A specialist medical clinician will identify any prescribing patterns which may indicate variations from treatment protocols.
- A specialist medical clinician will identify the reason for any dosage variation including requiring physicians to specify and document the reason in the electronic medical record.
- The specialist medical clinician will rotate on a three monthly basis to maintain transparency and reduce bias.
- Monthly audits are being undertaken and reports are provided to the cancer clinical stream regarding prescribing variations from protocols.
- Comprehensive guidelines for chemotherapy prescribing have been published.⁴⁷⁷

5.34 Western NSW LHD further advised that it is monitoring the implementation of this recommendation on an ongoing basis.⁴⁷⁸

⁴⁷² Section 122 inquiry Western NSW Local Health District report, p 5.

⁴⁷³ Section 122 inquiry Western NSW Local Health District report, p 17.

⁴⁷⁴ Section 122 inquiry Western NSW Local Health District report, p 13.

⁴⁷⁵ Section 122 inquiry Western NSW Local Health District report, p 16.

⁴⁷⁶ Evidence, Mr McLachlan, 2 November 2016, p 2.

⁴⁷⁷ Western NSW Local Health District three month implementation report, p 9.

⁴⁷⁸ Western NSW Local Health District three month implementation report, p 9.

Clinical governance for visiting specialists

- 5.35** Dr Grygiel was employed variously as a Visiting Medical Officer (VMO) and as an Honorary Medical Officer (HMO) in the Western NSW LHD.⁴⁷⁹ While treating patients in his capacity as an HMO, Dr Grygiel acted as a private practitioner, billed Medicare and prepared correspondence on his St Vincent's Hospital letterhead.⁴⁸⁰
- 5.36** Model VMO and HMO service contracts specify that clinicians engaged under these contracts shall comply with the NSW Health Code of Conduct and any other policies that are expressed to apply to the clinician.⁴⁸¹
- 5.37** In terms of his working relationship with fellow clinicians in that LHD, Western NSW representatives advised the committee that Dr Grygiel was known to be 'difficult to get on with', 'abrupt' and 'not comfortable being challenged'.⁴⁸²

Section 122 inquiry findings and recommendations

- 5.38** The section 122 inquiry noted that Dr Grygiel did not respond co-operatively to other clinicians when questions were asked about his choice of dosage:

The Inquiry is aware of one instance where in an email to a clinic nurse, when a pharmacist queried a dose, Dr Grygiel said 'tell them to mind their own business'. The effect of this manner of response could be that health professionals may not raise issues in the future, when raising concerns is a checking mechanism for optimal patient care.⁴⁸³

- 5.39** It further observed that while concerns were raised by staff about Dr Grygiel's attitude on more than one occasion, no complaint was ever subject to formal escalation procedures.⁴⁸⁴
- 5.40** The section 122 inquiry found that concerns about Dr Grygiel's behaviour were not effectively escalated by the district and this raised questions around the workplace culture and clinical governance processes in place in the Western NSW LHD, particularly clinical governance relating to visiting medical officers.⁴⁸⁵

⁴⁷⁹ Section 122 inquiry Western NSW Local Health District report, p 15. Visiting medical officers are employed under service contracts and receive remuneration to provide services for the local health district. Honorary medical officers are appointed under service contracts to provide services for or on behalf of a local health district but are not remunerated for those services by the district.

⁴⁸⁰ Evidence, Mr McLachlan, 2 November 2016, p 9.

⁴⁸¹ NSW Health, *Model service contracts – VMO and HMO* (31 March 2014), http://www1.health.nsw.gov.au/PDS/pages/doc.aspx?dn=PD2014_008. The NSW Health Code of Conduct defines standards of ethical and professional conduct required of everyone working within NSW Health, including behaviours that are unacceptable and will not be tolerated.

⁴⁸² Evidence, Mr McLachlan, Ms Ruth Jones, Director, Cancer Services Innovation, and Ms Sue Patterson, General Manager, Bathurst Health Service, Western NSW Local Health District, 2 November 2016, p 5.

⁴⁸³ Section 122 inquiry Western NSW Local Health District report, p 15.

⁴⁸⁴ Evidence, Ms Jones, 2 November 2016, p 6.

⁴⁸⁵ Section 122 inquiry Western NSW Local Health District report, pp 13-14.

- 5.41** The section 122 inquiry team made two recommendations to ensure staff escalated concerns and communicated effectively:
- That the LHD put in place strategies to ensure all clinical staff and third party providers understand their professional responsibility to use escalation processes for issues of clinical concern or professional conduct
 - To ensure the structure of cancer services enables building of relationships and mutual trust and respect between clinicians and managers through the establishment of facilitated programs.⁴⁸⁶
- 5.42** At the time of Dr Grygiel's employment in the Western NSW LHD, visiting fly-in fly-out medical specialists worked 'side by side' district cancer services, but did not work together to 'plan and build cancer services'. The section 122 inquiry found that this approach and associated lack of cohesion created clinical governance issues, although the district did not recognise the problem as one of clinical governance.⁴⁸⁷
- 5.43** The section 122 inquiry team recommended that all health districts and specialty networks, including Western NSW LHD, review clinical service arrangements in place for fly-in fly-out practitioners to ensure clarity about the relationship between those practitioners and locally-based services including:
- clinical record-keeping/sharing
 - clinical care in the absence of the fly-in fly-out practitioner
 - clinical governance
 - quality improvement initiatives
 - service planning.⁴⁸⁸

Western NSW Local Health District's response

- 5.44** In relation to communication issues and concerns about the escalation of complaints, including complaints about fly-in fly-out medical specialists, Mr McLachlan told the committee there had been a change in culture in recent years; the district had no tolerance for any clinician whose performance was outside the code of conduct, and this was articulated clearly to all members of staff. Mr McLachlan considered that the changes in training provided to younger clinicians encouraged them to speak up and escalate concerns:

We have a code of conduct with a set of values that we hold dear and part of that is respect between all clinicians. We have asked every single one of our teams to outline both their above-the-line and their below-the-line behaviours right across the whole of the organisation. In those below-the-line behaviours quite a few staff often articulate some of the behaviours that make them uncomfortable. That allows each staff member to call that in their team. It also allows the manager to step in and help manage those once they are better defined.

⁴⁸⁶ Section 122 inquiry Western NSW Local Health District report, p 1

⁴⁸⁷ Section 122 inquiry Western NSW Local Health District report, p 15.

⁴⁸⁸ Section 122 inquiry Western NSW Local Health District report, p 17.

I think what we are seeing is a dramatic change in the training of young clinicians in helping them to speak up and in helping to provide a culture in our environment that is much more open and inviting for younger clinicians to raise issues and escalate concerns. I think we are a long way from some of the days that we are talking about.⁴⁸⁹

- 5.45** To strengthen the capacity of staff to escalate clinical or professional concerns, the LHD advised that all staff would be trained in the *Speaking up for Safety* program, which equips staff to raise safety concerns with colleagues in a structured, respectful and supported way. The LHD informed the committee that by March 2017 over 600 staff had completed the *Speaking up for Safety* program and training was continuing across the district.⁴⁹⁰
- 5.46** To build relationships and mutual trust between cancer clinicians and those managing cancer services, the district has relaunched the cancer clinical stream. The stream is currently developing a new cancer plan for the district.⁴⁹¹
- 5.47** Mr McLachlan told the committee that the district was now less reliant on the services of fly-in fly-out practitioners to provide specialist care to residents in the region, owing to extensive investment in the provision of locally based facilities.

The past decade has seen unprecedented investment in infrastructure, services, and facilities, allowing us to transition from being reliant on fly-in fly-out services. There has been provision of locally based cancer services with only those patients with rare or complex cancers needing to be referred to a metropolitan facility.⁴⁹²

- 5.48** While the district was moving towards more locally-based cancer care, Mr McLachlan commented that there would always be a role for fly-in fly-out specialists in the region, and it was important for the district to strengthen clinical governance for fly-in fly-out specialists:

I think fly in, fly out services have been a core part of rural health service delivery for a lot of years and it will be into the future. We have got a lot of fly in, fly out clinicians that come into our region and they are some of the best specialists in Australia and we welcome them to part of our teams. I think that it is something that we need to strengthen some of the governance around where we put together a task force to focus on that.⁴⁹³

- 5.49** Western NSW LHD completed a review of its rural area health service in June 2016. The review included a stocktake of services that visit the district's north-western region on a fly-in fly-out basis.⁴⁹⁴
- 5.50** As of September 2016, Western NSW LHD had commenced a review of medical specialist outreach services to the north-western region of the district.⁴⁹⁵ The district has consulted with other specialist outreach service providers including the Rural Doctors Network, Royal Flying

⁴⁸⁹ Evidence, Mr McLachlan, 2 November 2016, p 6.

⁴⁹⁰ Western NSW Local Health District six month implementation report, p 8.

⁴⁹¹ Western NSW Local Health District six month implementation report, p 9.

⁴⁹² Evidence, Mr McLachlan, 2 November 2016, p 2.

⁴⁹³ Evidence, Mr McLachlan, 2 November 2016, p 8.

⁴⁹⁴ Western NSW Local Health District six month implementation report, p 12.

⁴⁹⁵ Section 122 inquiry Western NSW Local Health District report, appendix D.

Doctors Services and the Primary Health Network as part of the review. As of March 2017, a dedicated project officer had been appointed and working groups had been established to advance the review. The LHD advised that reviews of the rural aerial health service and medical specialist outreach services to north-western communities would culminate in a framework to assess the current situation for fly-in fly-out services, particularly in the north-west region of the district.⁴⁹⁶

Informed consent

- 5.51** As outlined in chapter 1, informed consent is a process whereby a patient gives consent to receive medical treatment, having been provided with sufficient information about their condition, including investigation options, treatment options, benefits, possible adverse effects or complications, and the likely result if treatment is not undertaken.

Section 122 inquiry findings and recommendations

- 5.52** Dr Grygiel informed the section 122 inquiry that every patient he treated in Western NSW LHD signed a consent form for chemotherapy treatment. However, the inquiry found no consent forms in the medical records.⁴⁹⁷ Further, while Dr Grygiel prescribed a significantly reduced dose of capecitabine for a number of patients, the inquiry could find no evidence of a ‘documented rationale to the clinical decision for dose reduction’ for any of these patients.⁴⁹⁸
- 5.53** The absence of signed consent forms or documentation of the reason for prescribing a reduced dose in any of Dr Grygiel’s patient’s medical records implies that affected patients were unaware that the dose of chemotherapy they received was off-protocol. The section 122 inquiry noted that where a clinician decides to change a treatment protocol, the clinician has a responsibility to discuss this decision with the patient and document the decision in the patient’s medical records:

... when a decision is made to change the treatment protocol, the clinician has a responsibility to document the rationale for the clinical decision in the patient’s medical record. The clinician also has a responsibility to thoroughly discuss with the patient, as part of the informed consent process, the implications of the decision, including less certainty of therapeutic benefit, as well as other treatment options.⁴⁹⁹

- 5.54** The section 122 inquiry did not make a recommendation specifically to Western NSW LHD in relation to informed consent, however, in the final report on its investigation into St Vincent’s Hospital, the section 122 inquiry recommended that clinicians across New South Wales ensure adequately informed consent for all medical interventions including chemotherapy. The recommendation further noted that there is a particular onus on clinicians who know their practice is outside accepted practice to draw this to the attention of their patients and to document this in patient notes.⁵⁰⁰ NSW Health’s work at the state level to

⁴⁹⁶ Western NSW Local Health District six month implementation report, pp 12-13.

⁴⁹⁷ Section 122 inquiry Western NSW Local Health District report, p 12.

⁴⁹⁸ Section 122 inquiry Western NSW Local Health District report, p 11.

⁴⁹⁹ Section 122 inquiry Western NSW Local Health District report, pp 9-10.

⁵⁰⁰ Section 122 inquiry final report, 31 July 2016, p 41.

address the section 122 inquiry recommendation in respect of informed consent is discussed in chapter 8.

- 5.55** Western NSW LHD informed the committee that it ensures it complies with informed consent policies of NSW Health, and is currently developing a specific consent form for chemotherapy and immunotherapy patients. The form will be signed by patients prior to commencing treatment and stored on the district's electronic record keeping system, MOSAIQ.⁵⁰¹

Committee view

- 5.56** When Western NSW LHD became aware that Dr Grygiel had prescribed off-protocol doses of chemotherapy to patients at St Vincent's Hospital the district took immediate steps to inform Dr Grygiel's patients and launched an investigation into whether Dr Grygiel's prescribing practices in Western NSW LHD were off-protocol. The committee commends the district for its swift response and for its focus on the wellbeing of patients.
- 5.57** The trust that patients place in their doctor and hospital when they undergo cancer treatment is no less when that doctor is providing services on a fly-in fly-out basis. At the same time, these contract arrangements pose additional challenges for clinical governance that must be addressed.
- 5.58** The committee wholeheartedly agrees that provision of locally based care is preferable from a patient's perspective, as well as enabling greater oversight of clinical decision making. But, as Western NSW LHD has acknowledged, fly-in fly-out doctors will always be a necessary component of health care in rural areas.
- 5.59** Local health districts have a fundamental responsibility to ensure that those clinicians are subject to effective clinical governance in order to ensure quality of care. This means ensuring that record keeping and systems in place, such as treatment protocols, are used by all clinicians, irrespective of their employment status.
- 5.60** Accurate record keeping is central to the provision of safe and appropriate patient care. Comprehensive records allow for the seamless handover of patient care between clinicians – this is particularly important in those circumstances where patients receive care from fly-in fly-out medical specialists who are not in the district on a full time basis. Further, accurate record keeping provides assurance to all clinicians responsible for the care of a patient that the patient understands and has consented to the chemotherapy treatment they have received.
- 5.61** The committee is encouraged that the district has responded comprehensively to the section 122 inquiry recommendations in relation to record keeping and treatment protocols and has established an electronic record keeping system and introduced extensive changes to ensure all clinicians prescribe chemotherapy in accordance with treatment protocols.
- 5.62** The committee notes that the district's review of medical specialist outreach service arrangements to the north-western region is ongoing. The committee therefore urges the

⁵⁰¹ Answers to questions on notice, Western NSW Local Health District, received 1 December 2016, p 1.

district to ensure that the review encompasses all of the Western NSW LHD, with a strong focus on fly-in fly-out medical specialists and that proper governance structures are established for these specialists. A comprehensive clinical governance framework will ensure that fly-in fly-out medical specialists are subject to the same safeguards as clinicians who work in the district on a permanent basis and reassure patients in regional and remote areas that they will receive appropriate specialist care regardless of the way they access treatment.

Recommendation 1

That the Western NSW Local Health District:

- ensure that its review of medical specialist outreach service arrangements encompasses all of the Western NSW Local Health District, with a strong focus on fly-in fly-out medical specialists
 - establish proper governance structures to ensure fly-in fly-out medical specialists are subject to the same safeguards as locally based clinicians.
-

Macquarie University Hospital

5.63 Macquarie University Hospital is a private teaching hospital, established in 2010. Dr Grygiel was employed by the hospital as an accredited practitioner, working as a specialist oncologist from June 2010 until his resignation in October 2012.⁵⁰² As noted in chapter 1, the section 122 inquiry did not include Macquarie University Hospital because it is a private facility.

5.64 The committee heard that like Western NSW LHD, Macquarie University Hospital first became aware of Dr Grygiel's prescribing through the ABC 7.30 program.⁵⁰³

5.65 The hospital's Chief Executive Officer, Ms Carol Bryant, informed the committee that following the broadcast, the hospital conducted an internal investigation to ascertain whether Dr Grygiel had prescribed off-protocol doses of chemotherapy to Macquarie University Hospital patients. It found that 21 patients had been prescribed flat doses of carboplatin by Dr Grygiel and NSW Health was immediately informed of the Hospital's preliminary and subsequent findings,⁵⁰⁴ in accordance with legislation:

Private Health Facilities are required under the Private Health Facility legislation to have an incident management system in place that includes identification and reporting of "adverse events" to the NSW Ministry of Health. An adverse event is "an unintended injury to a patient, or a complication caused by the health care management of a patient, that results in disability, death of the patient or a prolonged hospital stay by the patient".

⁵⁰² Evidence, Ms Carol Bryant, Chief Executive Officer, Macquarie University Hospital, 24 February 2017, p 18, p 23.

⁵⁰³ Evidence, Ms Bryant, 24 February 2017, p 18.

⁵⁰⁴ Evidence, Ms Bryant, 24 February 2017, pp 18-19.

There are also obligations imposed on Private Health Facilities under the Health Practitioner National Law to report notifiable conduct of employees and/or contractors who are registered health professionals to the registration authorities.⁵⁰⁵

- 5.66** Ms Bryant advised the committee that, following the internal investigation's finding that Dr Grygiel had prescribed flat dosing to 21 patients, the hospital formally notified the NSW Ministry of Health, and began the process of informing affected patients and offering follow up support: 'Our focus has been talking to the patients, making sure they are informed, apologising, offering them an oncologist review.'⁵⁰⁶
- 5.67** The hospital also referred the 21 affected patients to the Health Care Complaints Commission and those patients are part of the Commission's current investigation.⁵⁰⁷
- 5.68** Ms Bryant informed the committee that, prior to the 7.30 broadcast and the hospital's own internal investigation, no concerns were ever raised by fellow clinicians, including pharmacists and oncology nurses that the chemotherapy doses Dr Grygiel prescribed may have been incorrect or off-protocol.⁵⁰⁸
- 5.69** Ms Bryant did advise that Dr Grygiel had a reputation for being 'abrupt and abrasive', rude to nurses and non-compliant when it came to responding to requests to sign off on certain documents.⁵⁰⁹
- 5.70** Indeed, formal complaints in relation to Dr Grygiel's conduct were raised with hospital management in January 2012 and these were acted on shortly afterward.⁵¹⁰ Ms Bryant emphasised that concerns relating to Dr Grygiel's communication style were general and not specifically related to his dosage of chemotherapy for patients at Macquarie University Hospital.⁵¹¹
- 5.71** In respect of off-protocol prescribing, the hospital's internal investigation found that oncology nurses checked the dose of the chemotherapy drug against Dr Grygiel's prescription and then administered the dose, however, there was no checking at that time by any clinician of the prescription against eviQ guidelines. Ms Bryant told the committee that this was because eviQ guidelines at the hospital 'were in their infancy and really only came into prominence in 2012.'⁵¹²
- 5.72** Macquarie University Hospital advised that procedures at the hospital have changed as a consequence of the internal review. EviQ guidelines are now widely available and referred to by pharmacists and nurses before administering chemotherapy:

⁵⁰⁵ Answers to supplementary questions, Ms Karen Crawshaw, Deputy Secretary, Governance, Workforce and Corporate, NSW Ministry of Health, 28 November 2016, p 1.

⁵⁰⁶ Evidence, Ms Bryant, 24 February 2017, p 22.

⁵⁰⁷ Evidence, Ms Crawshaw, 31 October 2016, p 21 and Evidence, Ms Sue Dawson, Commissioner, NSW Health Care Complaints Commission, 24 February 2017, p 2.

⁵⁰⁸ Evidence, Ms Bryant, 24 February 2017, p 22.

⁵⁰⁹ Evidence, Ms Bryant, 24 February 2017, p 19.

⁵¹⁰ Evidence, Ms Bryant, 24 February 2017, p 18.

⁵¹¹ Evidence, Ms Crawshaw, 31 October 2016, p 18.

⁵¹² Evidence, Ms Bryant, 24 February 2017, p 22.

EviQ guidelines are available on an app, they are available on a shortcut on the computer top, they are available within the record, so there are multiple checks by the nurses, by the pharmacists as that prescription comes in before it is ever administered, so things have changed.⁵¹³

- 5.73** In addition, the hospital's electronic medical records (EMR) system is in the process of being upgraded to ensure clinicians responsible for prescribing and administering chemotherapy drugs will do so within the eviQ guidelines:

At present MUH [Macquarie University Hospital] has requested our software provider to assist in the development of a chemotherapy module in its EMR and plans to test this function over the next 12 months. MUH intends to duplicate the alert system that exists for Schedule 8 drugs and introduce a new alert for chemotherapy drugs. It is anticipated that the alerts will incorporate references to the EviQ guidelines, and prompt EMR users to calculate the chemotherapy dose in accordance with those guidelines.⁵¹⁴

- 5.74** Further to the introduction of checks in the EMR and a change in procedures for the prescribing of chemotherapy drugs, Ms Bryant advised that work is underway to bring about a change in culture at the hospital. Following a review of quality and safety the hospital has established an IT governance and a patient safety and quality governance committee and has appointed a director of patient safety and quality, a director of nursing and a director of medical services.⁵¹⁵

Committee view

- 5.75** The committee took limited evidence in respect of Dr Grygiel's prescribing of chemotherapy at Macquarie University Hospital and, without the benefit of a section 122 inquiry investigation, has been unable to explore issues at Macquarie University Hospital in depth.
- 5.76** Furthermore, the committee has no wish to undermine the current investigations of the Health Care Complaints Commission and will therefore not comment specifically on Dr Grygiel's actions at Macquarie University Hospital.
- 5.77** However, it is clear to the committee that a common failing of all affected institutions in this inquiry has not been a lack of guidelines or policies but the lack of checking mechanisms to ensure that guidelines are adhered to. As we noted in chapter 4 in respect of St Vincent's Hospital, policies and regulations are dependent upon positive organisational culture to work effectively.
- 5.78** The committee is reassured that Macquarie University Hospital has taken steps to ensure that off-protocol prescribing of chemotherapy will not happen in the future, with the introduction of a patient and safety quality committee, an upgrade to the hospital's electronic medical records system to prompt physicians to prescribe chemotherapy treatment within eviQ guidelines and a commitment to bringing about a change in workplace culture.

⁵¹³ Evidence, Ms Bryant, 24 February 2017, p 22.

⁵¹⁴ Submission 100, Macquarie University Hospital, p 1.

⁵¹⁵ Evidence, Ms Bryant, 24 February 2017, pp 23-24.

Chapter 6 The section 122 inquiry

In chapter 1, the committee set out the terms of reference for the section 122 inquiry, its team and process. Subsequent chapters documented those findings and recommendations as the background to the committee's own examination of Dr John Gryiel's prescribing, St Vincent's Hospital's response to the allegations and its later actions, based on the evidence gathered during our own inquiry.

This chapter canvasses a number of issues raised by our inquiry participants about the section 122 inquiry itself. These concerned the scope of the inquiry, the expertise it utilised, the participation of key individuals, ongoing monitoring of the patients affected by off-protocol dosing of chemotherapy and the subsequent review of cancer patients across New South Wales.

Inquiry scope

- 6.1 As noted in chapter 1, the section 122 inquiry examined Dr Gryiel's prescribing of chemotherapy between 2006 and 2015, with a focus on off-protocol flat dose prescribing of the drug carboplatin. Professor David Currow, Chief Cancer Officer, NSW, Chief Executive Officer of the Cancer Institute NSW, and Co-leader of the inquiry, explained to our committee the role of chemotherapy protocols and the section 122 inquiry's working definition of off-protocol prescribing:

Chemotherapy protocols provide guidance on dosing, formed by clinical consensus based on the best available evidence. Appropriate variation in prescribing is not only expected but essential. This means the dose is personalised, supported by the best available evidence where it exists. The justification for the dose variation is clearly documented and patients give informed consent, having understood the risks and benefits of the treatment. There comes a point where variation from the protocol is so great that treatment is no longer based on evidence. This is what the inquiry describes as "off-protocol".⁵¹⁶

- 6.2 The patients captured by this clinical 'incident' were defined as those treated with the 'off-protocol flat dose 100 mg carboplatin'.⁵¹⁷ At St Vincent's Hospital, 129 people were found to be in this group;⁵¹⁸ at Western NSW Local Health District (LHD), five were found to be in this group, while another 23 received a significantly reduced dose of another drug, capecitabine.⁵¹⁹ Additional patients of Western NSW LHD receiving a reduced dose of capecitabine were subsequently identified via Pharmaceutical Benefits Scheme records.⁵²⁰

⁵¹⁶ Professor David Currow, Chief Cancer Officer NSW and Chief Executive Officer, Cancer Institute NSW, 31 October 2016, p 2.

⁵¹⁷ NSW Ministry of Health, *Inquiry under section 122 of the Health Services Act 1997: Off-protocol prescribing of chemotherapy for head and neck cancers*, Final report, 31 July 2016 (hereafter section 122 inquiry final report), p 14.

⁵¹⁸ Section 122 inquiry final report, p 14.

⁵¹⁹ NSW Ministry of Health, *Inquiry under section 122 of the Health Services Act 1997: Prescribing of chemotherapy*, Report on patients treated at Western NSW Local Health District, 16 September 2016, (hereafter section 122 inquiry Western NSW Local Health District report) p 12.

⁵²⁰ See Western NSW Local Health District, *Section 122 inquiry of the Health Service Act 1997, Prescribing of chemotherapy: Report on patients treated at Western NSW Local Health District, Implementation of Recommendations – Six Month Report*, March 2017, p 7.

- 6.3** The committee became aware of a family with concerns that patients prescribed the drug temozolomide⁵²¹ by Dr Grygiel were not addressed by the section 122 inquiry. The family had had two meetings with St Vincent's Hospital, and the hospital had apologised to them. Committee members questioned Professor Currow as to why the inquiry had not included these patients, and the number of cases involved.
- 6.4** Professor Currow advised that 11 people treated at St Vincent's Hospital prescribed the oral chemotherapy temozolomide came to the attention of the section 122 inquiry.⁵²² Asked whether the inquiry had ignored this group, he strongly denied that this was the case and advised that their cases had been considered.⁵²³
- 6.5** Professor Currow explained that the decision not to include the group was on the advice of the inquiry's panel of experts that it is very difficult, based on the available evidence, to draw a line around what is on- and off-protocol in the palliative setting.⁵²⁴ He noted that the section 122 inquiry terms of reference placed the focus on 'first dose of treatment with curative or adjuvant intent', and emphasised that in the palliative setting, where the primary aim is not to cure but to control symptoms and optimise functioning in the face of advanced cancer, the extent to which individual clinical judgement is exercised means that the boundaries of off-protocol are much more difficult to determine.⁵²⁵
- 6.6** Professor Currow further explained the rationale for the decision not to include this group, based on the absence of available evidence:

Very few of those studies, if any, are done in the patient population about whom we are talking. These are people with multiple comorbidities as their bodies close down, often with kidney and liver dysfunction, and the evidence base is simply not there to inform it. As such, these people were not, as you suggest, ignored because they were dying, the evidence was not there to draw an absolute line and say that that was either on-protocol, a variation of the protocol or off-protocol. There is no single standard against which we can judge that. The committee, therefore, I believe quite rightly on the advice of the expert panel, said that it is unable to determine the breadth of that prescribing because the evidence base is simply not there. It is not that we have not looked for it; it does not exist.⁵²⁶

The expert panel

- 6.7** One inquiry participant, Dr David Dalley, the former Head of Medical Oncology at St Vincent's Health Network, told the committee he was disappointed that the section 122

⁵²¹ Temozolomide is used primarily for the treatment of brain cancers.

⁵²² Answers to questions on notice, Professor David Currow, Chief Cancer Officer NSW and Chief Executive Officer, Cancer Institute NSW, received 28 November 2016, p 1.

⁵²³ Evidence, Professor Currow, 31 October 2016, pp 4-5.

⁵²⁴ Evidence, Professor Currow, 31 October 2016, pp 3-5.

⁵²⁵ Evidence, Professor Currow, 31 October 2016, pp 4-5 and 8.

⁵²⁶ Evidence, Professor Currow, 31 October 2016, p 14.

inquiry did not make greater use of medical oncologist expertise.⁵²⁷ Asked about this, Professor Currow advised:

As stated in its Final Report on St Vincent's Hospital, the section 122 Inquiry empanelled and received expert advice from an independent group of national experts in medical and radiation oncology, clinical pharmacology and oncology pharmacy. Three of the eight members of the Clinical Expert Panel are medical oncologists.⁵²⁸

Participants

6.8 The section 122 inquiry final report on St Vincent's Hospital notes that the inquiry drew on seven sources of information:

- documents sources from the hospital
- written questions to and answers from the hospital
- interviews with key current and former staff
- reviews of clinical records for the relevant patient cohort
- the expert clinical panel
- interviews with patients and families
- submissions from several individuals.⁵²⁹

6.9 In respect of the interviews with key current and former staff, the final report indicated that, 'Several people declined an invitation to meet members of the inquiry team.'⁵³⁰

6.10 The committee sought to illuminate this issue, in light of strong concerns about a potential gap in evidence raised by inquiry participants such as Dr Laurence J Denholm:

Prof. Currow and his Inquiry team would not have issued invitations to particular people unless the Inquiry team believed these people had information relevant to their Inquiry. The fact that these people declined to meet with members of the Inquiry team indicates that critical forensic information which should have been available to the Currow Inquiry was not available, potentially compromising the findings of the Currow Inquiry.⁵³¹

6.11 Professor Currow advised the committee that four individuals declined to participate, three of whom were junior medical staff who had moved to other roles. The other was a senior clinician.⁵³² Of these four, three formally declined, and the other, who initially agreed to be

⁵²⁷ Evidence, Dr David Dalley, Former Head of Medical Oncology, St Vincent's Health Network Sydney, 29 November 2016, pp 53 and 54.

⁵²⁸ Answers to supplementary questions, Professor David Currow, Chief Cancer Officer NSW and Chief Executive Officer, Cancer Institute NSW, received 22 December 2016, p 1.

⁵²⁹ Section 122 inquiry final report, pp 3-4.

⁵³⁰ Section 122 inquiry final report, p 4.

⁵³¹ Submission 95, Dr Laurence J Denholm, p 1.

⁵³² Evidence, Professor Currow, 31 October 2016, pp 7 and 13.

interviewed, subsequently indicated they were seeking legal advice. None of the four were currently employed at St Vincent's Hospital. All three junior medical staff were registrars who had worked with Dr Grygiel at some time on rotation.⁵³³

- 6.12** Professor Currow defended the integrity of his inquiry, emphasising to the committee the high level of cooperation from current and former staff with his inquiry and his confidence that the various sources of information enabled the inquiry to fulfil its terms of reference.⁵³⁴ He noted that a very clear and consistent picture of the problems at St Vincent's had been revealed by participants:

Four doctors declined to participate in the inquiry, that is correct. However, as I have indicated, when we look at the evidence that has been provided to the inquiry through documents from St Vincent's Hospital, through written responses to questions provided to St Vincent's Hospital, through clinical case note audit, through interviews of St Vincent's staff, the picture is absolutely consistent ... [W]e have found problems which have consistently been reflected through those documents, through the clinical case note reviews and through the interviews. As such, further interviews are not going to change the findings that there are problems in culture, in systems and in clinical governance that need to be addressed.⁵³⁵

- 6.13** Dr Stephen Cooper, Radiation Oncologist and Chair of the Head and Neck Unit at St Vincent's Hospital, advised the committee that he was the senior clinician who had declined to participate. As noted in chapter 3, Dr Cooper is employed by Genesis Cancer Care, which is contracted to provide radiation oncology at the hospital. Dr Cooper explained his reason for declining and shed light on his communications with the section 122 inquiry:

I declined the initial invitation to appear at Dr Currow's inquiry on the basis that at the time the invitation was extended there had been considerable media attention about the matter and I was concerned that I may be misrepresented in the media and further, if I was misrepresented and I or what I said was not fairly reported, there were no protections available to me under the provisions of the *Health Services Act 1997* (NSW).

I was extended a further invitation to appear at a later stage during the inquiry process. I offered to reconsider my position if Dr Currow would agree to provide me with notice of the issues and I or questions he wished to canvass with me. Dr Currow did not agree to provide questions on notice as he had not done so for others who had attended the inquiry. On that basis, I did not provide any evidence to Dr Currow's inquiry.⁵³⁶

- 6.14** Committee members pursued the matter of interested parties who did not participate in the section 122 inquiry in a second hearing with Professor Currow, with the aim of examining the veracity of the inquiry. The committee was particularly concerned that the inquiry did not

⁵³³ Answers to supplementary questions, Professor Currow, received 28 November 2016, p 4. As noted below, the senior clinician was employed by an organisation contracted to provide services at St Vincent's Hospital.

⁵³⁴ Evidence, Professor Currow, 31 October 2016, p 7.

⁵³⁵ Evidence, Professor Currow, 31 October 2016, p 13; see also answers to supplementary questions, Professor Currow, received 28 November 2016, p 5.

⁵³⁶ Answers to questions on notice, Dr Stephen Cooper, Radiation Oncologist, Genesis Cancer Care NSW, received 25 November 2016, p 1.

benefit from the participation of Dr Cooper, who was a central figure in the matter as it unfolded.

- 6.15** Professor Currow conceded that the section 122 inquiry could not know what it has not been told, but emphasised that its findings at no time relied on a single participant or document; rather, they were triangulated across the various sources of evidence. He further noted that, ‘importantly, we have both St Vincent’s and NSW Health accepting the recommendations in their entirety across these programs. The findings of this inquiry stand.’⁵³⁷ He underscored that the inquiry had found substantial problems at St Vincent’s Hospital, and went on to assert the value of the inquiry for the health system as a whole:

But what I am saying is that this inquiry has found very clearly that there are problems of culture, of systems, of clinical governance, that require remediation, and the recommendations, if enacted, are going to improve the health in this State as a direct consequence of the inquiry.⁵³⁸

- 6.16** Dr Paul Curtis, Director of Governance and Assurance at the NSW Clinical Excellence Commission, and Co-leader of the section 122 inquiry, also addressed this matter. He emphasised the breadth of evidence utilised by the inquiry, in terms of its interviews and large volume of documentation, to arrive at ‘the substantive issues of concern’. Dr Curtis noted that the inquiry was not charged with looking at individuals’ actions, but with identifying these substantive issues, with a view to improving the system of cancer care. Like Professor Currow, he underscored that the inquiry had achieved that goal.⁵³⁹

Other matters

- 6.17** In a statement provided for Avant Law, representing Dr Grygiel, Dr Ian E Haines made a number of criticisms of the section 122 inquiry final report, based on his review of the chemotherapy treatment literature. The committee received the statement in the final two weeks of the inquiry and was thus unable to explore the veracity of its contents with any other inquiry participants.⁵⁴⁰

Actions following the section 122 inquiry

- 6.18** The committee also considered two actions that were not part of the section 122 inquiry, but rather, followed on from it: the Cancer Institute NSW’s monitoring of the patients found to have been subject to off-protocol prescribing of chemotherapy; and the Ministry of Health’s audit of cancer patients across the state.

⁵³⁷ Evidence, Professor Currow, 29 November 2016, p 26.

⁵³⁸ Evidence, Professor Currow, 29 November 2016, p 27.

⁵³⁹ Evidence, Dr Paul Curtis, Director, Governance and Assurance, NSW Clinical Excellence Commission, 29 November 2016, p 27.

⁵⁴⁰ Statement of Dr Ian E Haines MBBS FRACP FACHPM, 4 May 2017, enclosed in correspondence from Ms Helen Turnbull, Special Counsel Professional Conduct, Avant Law Pty Ltd, to Chair, 5 May 2017.

Ongoing monitoring of the patients who received off-protocol dosing

6.19 In chapter 4 we noted St Vincent’s Hospital’s actions in respect of the section 122 inquiry recommendation that the hospital report on patient outcomes to the health network’s Clinical Council on a six monthly basis, and to the Deputy Secretary of the Ministry of Health annually. The hospital has committed to reviewing the full patient cohort on a monthly basis for five years.⁵⁴¹

6.20 In addition, the section 122 inquiry recommended that patient outcomes be tracked by the NSW Cancer Registry, managed by the Cancer Institute NSW:

Flag every patient identified by this inquiry who has had an off-protocol flat dose of 100 mg carboplatin prescribed for the treatment of cancer so that outcomes for this group of people are systematically evaluated on a regular basis, and that survival analyses can be undertaken on this cohort of patients in relation to people with comparable disease.⁵⁴²

6.21 The inquiry final report notes this recommendation as actioned.⁵⁴³ Further, as noted in chapter 4, St Vincent’s Hospital has built into its MOSAIQ system a function enabling it to generate and review reports on the patient cohort.⁵⁴⁴

6.22 Dr Laurence J Denholm suggested that there has been a lack of transparency in the published data on the patient cohort to date, and made an impassioned plea on behalf of patients and family members subjected to the off-protocol dosing that their health outcomes be independently monitored into the future, with due transparency as a mark of respect:

The most important question in the minds of patients and their families since this off-protocol chemotherapy prescribing issue emerged in the media is really quite simple. “Did concurrent radiochemotherapy with a flat 100 mg initial dose of carboplatin harm patients by increasing their risk of tumour progression and death?” This is not a question that will go away. Regular monitoring of the surviving patients in the [St Vincent’s Hospital] patient dataset, with transparent disclosure of the monitoring and data analysis methodologies and the results, will remain a matter of critical interest to surviving patients and families until this question is answered. Clear communication to patients and families about future monitoring of affected patients and their pair matched controls, the data analysis methodology and how results will be disclosed is critical ... Patients and families must have confidence that a rigorous, ongoing, comprehensive and independent process of patient monitoring and data analysis is being pursued.⁵⁴⁵

6.23 Dr Denholm asserted that if St Vincent’s Hospital’s dataset does not have sufficient power to detect the maximum variation in tumour progression and patient survival that could be expected, then patients and families should be advised of this as soon as possible and not left

⁵⁴¹ St Vincent’s Hospital Sydney, *Inquiry under section 122 of the Health Services Act 1997: Off-protocol prescribing of chemotherapy for head and neck cancers*, final implementation report, April 2017 (hereafter St Vincent’s Hospital Sydney, section 122 inquiry final implementation report), p 5.

⁵⁴² Section 122 inquiry final report, p 40.

⁵⁴³ Section 122 inquiry final report, p 40.

⁵⁴⁴ St Vincent’s Hospital Sydney, Section 122 inquiry final implementation report, p 4.

⁵⁴⁵ Submission 95a, Dr Laurence J Denholm, pp 2-3.

waiting for an anticipated answer. He also warned against the use of any such failure of the dataset to infer that there was no effect on survival.⁵⁴⁶

Statewide audit of cancer patients

- 6.24** In a media release issued on 2 August 2016, the then Minister for Health, the Hon Jillian Skinner MP, made a commitment to reviewing all cancer patients in the public system in the last five years. This commitment was made in the context of an announcement of the investigation into the care provided by Dr Kiran Phadke at Sutherland and St George Hospitals (discussed in the following chapter), which followed several months after the 7.30 story on St Vincent's Hospital. The media release stated:

All public cancer patients who have received treatment over the past five years will be reviewed. Chief Executives of Local Health Districts and Specialty Networks will be required to confirm in writing that patients are being treated in accordance with the appropriate protocols. Chief Executives will also be asked to confirm in writing that all patients are being provided with sufficient information to make informed decisions about their cancer therapies, which would entail their written informed consent. The Cancer Institute NSW will independently review these reports.⁵⁴⁷

- 6.25** The Ministry of Health's submission to our inquiry indicated that the initiative is intended to provide further assurance to the community about the delivery of cancer care.⁵⁴⁸

- 6.26** The committee subsequently learned from Ms Susan Pearce, Deputy Secretary, System Purchasing and Performance with the Ministry of Health, that this review was proceeding as an audit of public cancer patients, utilising a randomised sample of a minimum of 1,800 patients, rather than a review of all cancer patients.⁵⁴⁹ Professor Currow assured the committee that, 'this is a systematic approach to look at the patterns of care.'⁵⁵⁰ Similarly, Ms Pearce emphasised the statistical validity of the audit and explained the approach to be followed in respect of any patient found to receive less than reasonable care:

I repeat that the sample size is statistically valid and will provide an accurate assessment of treatment. We also have a secondary process by which, during the course of the audit, if it is found that the care is outside of expected or reasonable norms—and there is no valid reason for that and no consent from the patient—there is a requirement for a further five cases from that clinician and within that modality, to be examined. That will be referred to the statewide expert panel. The other major issue is that there will then be a formal look-back process, which would involve a much larger group of patients. We are combining the process of the audit with policy

⁵⁴⁶ Submission 95a, Dr Laurence J Denholm, p2.

⁵⁴⁷ Media release, Hon Jillian Skinner MP, Minister for Health, 'Incorrect treatment of Southern Sydney cancer patients', 2 August 2016. The media release concerned Dr Kiran Phadke's treatment of haematology patients at Sutherland and St George Hospitals, as discussed in chapter 7.

⁵⁴⁸ Submission 49, NSW Ministry of Health, p 1.

⁵⁴⁹ Evidence, Ms Susan Pearce, Deputy Secretary, System Purchasing and Performance, NSW Ministry of Health, 31 October 2016, pp 23-24.

⁵⁵⁰ Evidence, Professor Currow, 31 October 2016, p 24.

instruments that we have around formal look-back, open disclosure and so on, all of which will be applied.⁵⁵¹

6.27 Ms Pearce advised the committee on progress of the audit, as of 31 October 2016, since the then Minister's announcement:

- A steering committee comprised of the Australian Medical Association, medical professional groups and consumer groups and a number of LHD chief executives, had been convened.
- A statewide expert panel was to be established.
- Regular discussions were taking place with LHD directors of cancer services.
- A methodology had been developed in consultation with stakeholders, then finalised and issued to local health districts.
- As part of the process, a 1800 number had been established, providing an additional avenue for participants to seek a review.
- Local health districts were tasked with establishing local audit teams.⁵⁵²

6.28 Ms Pearce further advised that once the audit commenced, the audit teams would review the relevant patient files. An algorithm would guide the process of audit, such that care is assessed with regard to what the clinical record shows.⁵⁵³

Committee view

6.29 The section 122 inquiry made a very substantial contribution to the understanding of the government and the public about what transpired at St Vincent's Hospital and Western NSW Local Health District, both in terms of the off-protocol prescribing that occurred and also the hospitals' responses to it. Nevertheless, while the committee acknowledges that the section 122 inquiry only had the power to invite participants and not to compel them, the fact that one key individual declined to participate does leave the inquiry open to some level of criticism.

6.30 We take Professor Currow's point that the otherwise comprehensive evidence from a range of sources furnished a very clear and consistent picture of the problems at St Vincent's Hospital in respect of organisational culture, clinical governance and systems. However, as a parliamentary committee we consider it in the public interest that as much as possible about what transpired at the hospital be brought to light. Our own inquiry has helped to fill that gap in evidence and we anticipate that the Health Care Complaints Commission's investigation will do so as well.

6.31 We accept Professor Currow's explanation as to why the section 122 inquiry's expert panel considered that people treated with temozolomide should not be included in the section 122 inquiry's patient cohorts, notwithstanding that St Vincent's Hospital apologised to at least one

⁵⁵¹ Evidence, Ms Pearce, 31 October 2016, p 23.

⁵⁵² Ms Pearce, 31 October 2016, p 23.

⁵⁵³ Ms Pearce, 31 October 2016, p 23.

family prescribed that treatment. The committee has pursued this issue because it highlights again the profoundly distressing experience of patients and their families to learn that they did not receive – or even that they may not have received – recommended doses of chemotherapy. We trust that the section 122 inquiry was cognisant of this distress and dealt with the patients as sensitively and constructively as it was able.

- 6.32** The distress of patients and families was also highlighted in the evidence we received. They are very concerned with whether their off-protocol dosing has or will increase their risk of tumour progression or death. The section 122 inquiry's recommendations for ongoing monitoring of this group is surely built on a recognition of this concern, and on the obligation of the health system to track and understand the outcomes for this patient group. The committee agrees with stakeholders that it is essential that this data be independently evaluated and transparent, and that patients and families be kept informed as to the power of the dataset to answer their questions. The Cancer Institute should also continue to monitor and assess the morbidity and mortality rates of the affected patient cohort, comparing and contrasting those rates with expected ranges, until at least 2022.

Recommendation 2

That the Cancer Institute NSW:

- ensure that, in the interests of transparency, all evaluations of the outcomes for patients who received an off-protocol flat dose of 100 mg carboplatin or reduced dose capecitabine be independently evaluated and published, subject to patient confidentiality
- keep the affected cohort of patients informed as to the capacity of the evaluation dataset to shed light on their health outcomes
- continue to monitor and assess the morbidity and mortality rates of the affected patient cohort and compare and contrast with expected ranges until at least 2022.

-
- 6.33** It is self evident that following the scandal that engulfed St Vincent's Hospital, spread out to Western NSW LHD, then arose again in relation to Sutherland and St George Hospitals, the Ministry of Health needed to take steps to investigate the quality of cancer care provided across the state, both in terms of treatment being in accordance with evidence based protocols and in terms of informed consent. For this reason, the committee saw significant value in the commitment to conduct a statewide review of all cancer patients. The subsequent audit of a randomised sample with a minimum of 1,800 patients is somewhat less than initially proposed, however, we accept the Ministry's assurances that the sample will be statistically valid and will deliver an accurate assessment of treatment. We are also assured by the secondary process put in place for when cases are found to be outside of accepted or reasonable care. In the interest of patients' and the broader community's trust in our health system, we await the audit's results with great interest, and recommend that the results of the audit be published in detail, subject to patient confidentiality.

Recommendation 3

That the NSW Ministry of Health, in the interests of transparency and building the community's trust in the health system, publish the results in detail of its audit of public cancer patients, subject to patient confidentiality.

Chapter 7 **The investigation of Dr Kiran Phadke's practice at Sutherland and St George Hospitals**

As noted in chapter 1, Dr Kiran Phadke, a haematologist and oncologist practicing at St George and Sutherland Hospitals, became a focus for the committee's inquiry after the then Minister for Health, the Hon Jillian Skinner MP, linked Dr Phadke's treatment of patients with the prescribing practices of Dr John Grygiel in a statement to the media on 2 August 2016.⁵⁵⁴

The committee received a large number of submissions from patients and colleagues of Dr Phadke expressing strong support for him. It also heard evidence from Dr Phadke and the South Eastern Sydney Local Health District (LHD), who carried out an investigation into his practice.

This chapter briefly documents the investigation process and findings in respect of Dr Phadke, then his response to them.

The South Eastern Sydney Local Health District investigation

- 7.1** The committee heard that allegations about Dr Phadke's clinical practice were raised by a nurse in April 2016. The South Eastern Sydney LHD immediately referred the matter to the Health Care Complaints Commission (HCCC) and commenced an internal investigation. A review of patients was conducted as part of the investigation and on 30 August 2016 the Medical Council of NSW imposed interim conditions upon his clinical practice.⁵⁵⁵ Dr Phadke was suspended from duty on full pay by the LHD and his clinical privileges suspended.⁵⁵⁶ The HCCC's investigation of Dr Phadke is, at the time of writing, on foot.⁵⁵⁷
- 7.2** Mr Gerry Marr, Chief Executive of the LHD, advised the committee that 27 cases were reviewed as part of the investigation.⁵⁵⁸ The concerns raised by nursing staff were assessed and substantiated by the internal review, which also found additional areas of concern. An external review was then conducted, in accordance with NSW Health policies.⁵⁵⁹ Mr Marr explained that there were two elements to the external investigation:

⁵⁵⁴ The Hon Jillian Skinner MP, Minister for Health, 'Incorrect treatment of Southern Sydney cancer patients', *Media Release*, 2 August 2016. <http://www.health.nsw.gov.au/news/Documents/20160802_02.pdf>

⁵⁵⁵ Evidence, Mr Gerry Marr, Chief Executive, South Eastern Sydney Local Health District, 1 November 2016, p 16; correspondence from Ms Paula Ardino, Principal Monitoring Officer, Medical Council of NSW, to secretariat, 18 April 2017.

⁵⁵⁶ Evidence, Mr Marr, 1 November 2016, p 17.

⁵⁵⁷ Evidence, Ms Susan Dawson, Commissioner, NSW Health Care Complaints Commission, 24 February 2017, p 4.

⁵⁵⁸ Evidence, Mr Marr, 1 November 2016, p 17.

⁵⁵⁹ Evidence, Mr Marr, 31 March 2017, pp 16 and 18.

- A clinical review of the specific patients about whom concerns were raised, along with a five year lookback.⁵⁶⁰ These were reviewed by a practicing haematologist independent of St George and Sutherland Hospitals.
- A review of the clinical governance matters surrounding the cases, presided over by an independent chair with a background at the NSW Clinical Excellence Commission.⁵⁶¹

7.3 At the committee's request, the South Eastern Sydney LHD provided us with a confidential copy of the investigation reports sent to Dr Phadke. Owing to its detail in respect of individual patients, and because the HCCC investigation is still underway, it is not appropriate to refer directly to the contents of the investigation report here. However, the committee is able to refer to information published in the media and evidence taken at the inquiry's public hearings. In brief, the findings of the investigation were as follows:

- Of the 27 patients reviewed, six patients were found to have been harmed as a result of inappropriate care by Dr Phadke.
- Eight patients may be at risk of future harm as a result of inappropriate care.
- Six patients were not harmed but there was criticism of the care provided.
- Seven patients received appropriate care.
- There were serious departures from accepted standards in all areas of Dr Phadke's clinical practice, in terms of diagnosis, staging, providing advice to patients, treatment choices, documentation, and engagement with peers.⁵⁶²

7.4 Dr Phadke was provided with a copy of the investigation report in February 2017 and invited to submit his response. He was advised that the LHD would carefully consider the submissions and seek independent advice if necessary. Mr Marr advised Dr Phadke that if, following consideration of Dr Phadke's submission, he accepted the findings of the investigation report, he 'would be minded to terminate' Dr Phadke's employment.⁵⁶³

7.5 The committee learned during its second hearing with South Eastern Sydney LHD representatives that the then Minister for Health had named Dr Phadke in the media, against the LHD's advice. Mr Marr told the committee:

On 27 July 2016 I provided written advice to the Ministry to go to the Minister to say that I thought it was inadvisable to name Dr Phadke in public because it may compromise our ability to sustain natural justice and confidentiality in the ongoing inquiry. The Minister then announced Dr Phadke's name on 2 August. I do have to say that my advice was in the narrow definition of the inquiry. The Minister must have

⁵⁶⁰ As noted in chapter 3, lookback is a process triggered when a notification of a clinical incident or concern from any source leads to the need for the notification, investigation and management of a group of commonly affected patients.

⁵⁶¹ Evidence, Mr Marr, 1 November 2016, p 18.

⁵⁶² Murray Trembath, 'Doctor Kiran Phadke faces sack from St George and Sutherland Hospitals', *St George and Sutherland Shire Leader*, 1 February 2017.

⁵⁶³ Murray Trembath, 'Doctor Kiran Phadke faces sack from St George and Sutherland Hospitals', *St George and Sutherland Shire Leader*, 1 February 2017.

other considerations that I have no privilege to and she took that decision based on a whole number of factors.⁵⁶⁴

Dr Phadke's perspective

- 7.6** At the time of Dr Phadke's hearing on 31 March 2017, he had provided a written response to the LHD investigation report and was awaiting the LHD's decision. Dr Phadke told the committee that he practices across both haematology and oncology, but in recent times had practiced predominantly with colorectal cancer and lymphomas. Overall, he had practiced for over 40 years, 35 of those at St George and Sutherland Hospitals. He had been Director of Medical Oncology for almost 25 years until he voluntarily stepped down from that role in 2015.⁵⁶⁵
- 7.7** Dr Phadke apologised for the distress caused to his patients and their families as a result of the LHD's investigation.⁵⁶⁶
- 7.8** Dr Phadke's response to the report's findings were as follows:
- The welfare of his patients has always been his paramount concern. Often there are several treatment options available to patients with different risks, side effects and success rates. He has always considered each of those factors, along with treatment regime that accords with the most recent protocols and guidelines.⁵⁶⁷
 - Guidelines are helpful but 'not the be all and end all.' Clinical judgment must be exercised with regard to the patient's wishes, mental health, physical health conditions, comorbidities and tolerance to previous treatments, such that the guidelines are used as a base, and an 'individual recipe' determined for the patient. Any departures from the guidelines that did occur only did so in the sense that he tailored the treatments to the individual patients. His practice has always been to consider all these factors and to discuss the advantages and disadvantages of treatment options with patients, in order to obtain their informed consent for the particular course of treatment.⁵⁶⁸
 - Of the small number of his cases identified by the LHD as falling outside the guidelines, these were among the most difficult cases in his career, due to patient-specific issues. He has responded to all the issues raised in respect of these cases and is satisfied he provided appropriate care in each case; he also considers no patient was harmed.⁵⁶⁹
 - In these cases, his treatment often extended over a number of years and involved extremely ill people whose outlook was not positive.⁵⁷⁰
 - Issues with respect to process, 'which made it absolutely difficult for a mere individual like [him] to combat this kind of machinery' included:

⁵⁶⁴ Evidence, Dr Marr, 31 March 2016, pp 20-21.

⁵⁶⁵ Evidence, Dr Kiran Phadke, Medical Oncologist, 31 March 2016, p 2.

⁵⁶⁶ Evidence, Dr Phadke, 31 March 2016, p 2.

⁵⁶⁷ Evidence, Dr Phadke, 31 March 2017, p 2.

⁵⁶⁸ Evidence, Dr Phadke, 31 March 2017, pp 2, 3 and 7.

⁵⁶⁹ Evidence, Dr Phadke, 31 March 2017, pp 3 and 5.

⁵⁷⁰ Evidence, Dr Phadke, 31 March 2017, p 3.

- The Director of Cancer Services who initiated the complaint, sat on the open disclosure process and participated in the reviews is not a haematologist.⁵⁷¹
 - No haematologist from St George appears in any of the reports on Dr Phadke, despite the complaints being in that speciality.⁵⁷²
 - The LHD’s CEO is married to the CEO of the Clinical Excellence Commission, and this situation engenders a greater pressure within the LHD to follow clinical guidelines.⁵⁷³
 - Two of the internal reviewers and the first external had previously worked with Dr Phadke.⁵⁷⁴
 - When Dr Jo Karnaghan, the LHD’s Director of Medical Services, informed Dr Phadke of his suspension, she advised that the threshold for examining complaints was now going to be low, given the events at St Vincent’s Hospital.⁵⁷⁵
 - Senior officers of the Ministry of Health were evidently involved in the matter.⁵⁷⁶
 - The LHD had not previously raised any concerns about his practice prior to the complaints being categorised as severity assessment code 1; nor did they allow him an opportunity to respond to the matters raised before he was suspended.⁵⁷⁷
- In respect of the 14 patients that the LHD concluded Dr Phadke had caused harm or placed at risk of harm, he considers that their personalised treatment was successful, and that the patients were happy and comfortable with the treatment programs given them. None of the complaints were initiated by patients.⁵⁷⁸

7.9 Dr Phadke further asserted that the Medical Council’s decision to impose interim conditions on his practice had not been informed by two favourable review reports, as these had not been forwarded by the LHD.⁵⁷⁹

7.10 Dr Phadke noted that he had a history of speaking his mind about hospital administration matters. Asked whether it was possible that given this history, the emergence of the off-protocol dosing scandal in oncology at St Vincent’s Hospital provided an opportunity to ‘throw him under the bus’, Dr Phadke responded that he believed this was the case.⁵⁸⁰

⁵⁷¹ Evidence, Dr Phadke, 31 March 2017, p 3.

⁵⁷² Evidence, Dr Phadke, 31 March 2017, p 3.

⁵⁷³ Evidence, Dr Phadke, 31 March 2017, pp 3 and 6.

⁵⁷⁴ Evidence, Dr Phadke, 31 March 2017, pp 5 and 11.

⁵⁷⁵ Evidence, Dr Phadke, 31 March 2017, p 3.

⁵⁷⁶ Evidence, Dr Phadke, 31 March 2017, p 3.

⁵⁷⁷ Evidence, Dr Phadke, 31 March 2017, pp 3 and 10.

⁵⁷⁸ Evidence, Dr Phadke, 31 March 2017, p 10.

⁵⁷⁹ Evidence, Dr Phadke, 31 March 2017, p 14. In his evidence, Mr Marr responded that there would have been no reason to submit the reports on two cases where no adverse findings were made. Only cases where there has been a question of poor care or adverse events would be forwarded to the decision making body. See evidence, Mr Marr, 31 March 2016, p 25.

⁵⁸⁰ Evidence, Dr Phadke, 31 March 2017, p 11.

The local health district's decision

7.11 On 13 April 2017 the LHD announced that as there were no adverse findings in his oncology practice, Dr Phadke's suspension with respect to oncology practice was lifted with immediate effect. Dr Phadke was able to return to Sutherland and St George Hospitals subject to the conditions imposed by the Medical Council. As part of the decision, Dr Phadke agreed not to practice haematology.⁵⁸¹

Committee view

7.12 The committee notes that South Eastern Sydney LHD representatives responded to Dr Phadke's assertions in paragraphs 7.8-7.10 at their hearing on 31 March 2017.⁵⁸²

7.13 As in respect of Dr John Grygiel (see chapter 2), the committee has chosen not to comment in respect of Dr Phadke's actions as we cannot in any way undermine the Health Care Complaints Commission investigation currently underway, nor any future legal proceedings that might arise from that investigation.

⁵⁸¹ Media statement, South Eastern Sydney Local Health District, 'Dr Kiran Phadke', 13 April 2017.

⁵⁸² Evidence, Mr Marr, Dr Jo Karnaghan, Director, Medical Services, Ms Margaret Savage, Director, Professional Practice Unit, and Dr James Mackie, Medical Executive Director, South Eastern Sydney Local Health District, 31 March 2017, pp 16-27.

Chapter 8 Safeguards for the future

Every health practitioner has a legal and professional responsibility to ensure that treatment is provided competently and in accordance with widely accepted peer professional practice, and that the patient gives informed consent to the treatment provided.⁵⁸³

Informed by the systemic problems that contributed to the events that transpired at St Vincent's Hospital and Western NSW Local Health District, the section 122 inquiry made a number of recommendations to NSW Health for statewide implementation, which NSW Health accepted in full.⁵⁸⁴

This chapter concludes the committee's report by examining statewide actions to better safeguard against off-protocol prescribing. First it explores the issue that many participants spoke up for: that treatment guidelines and protocols are necessary, but they must allow for flexibility according to the characteristics of the individual patient, if they are to support optimal care.

The committee then considers several areas of statewide action broadly consistent with our terms of reference: electronic prescribing; coordinated cancer care via multidisciplinary teams; informed consent; reporting and managing incidents; and organisational culture. In each section we set out participants' views on how action in the specific area can strengthen the health system and facilitate better care, then the relevant section 122 findings and recommendations. We then document current actions, as advised by the NSW Ministry of Health. The chapter concludes with a number of recommendations to strengthen systems and build safeguards to prevent what occurred at St Vincent's Hospital from happening elsewhere.

Section 122 inquiry recommendations

- 8.1** As noted in chapter 4, the primary issues identified in respect of St Vincent's Hospital by the section 122 inquiry were systemic ones, rather than individual. In that context, the inquiry made recommendations to improve systems across New South Wales.
- 8.2** Each of the statewide recommendations is reflected in the full table of section 122 inquiry recommendations in appendix 3. According to NSW Health, together, the recommendations were 'designed to strengthen the systems in place in local health districts and specialty networks to ensure robust clinical cultures and provide mechanisms for visibility of care.'⁵⁸⁵ The NSW Health submission to our inquiry set out the principles underpinning the section 122 recommendations:

The Inquiry Reports articulate the following principles for people diagnosed with cancer:

- their care should be provided by specialists who are active members of a multidisciplinary cancer care team
- they should be provided with sufficient information to enable them to understand the risks and therapeutic benefits of the treatment proposed for them, so they can provide fully informed consent

⁵⁸³ Submission 49, NSW Ministry of Health, p 3.

⁵⁸⁴ Submission 49, NSW Ministry of Health, p 1.

⁵⁸⁵ Submission 49, NSW Ministry of Health, p 8.

- their proposed treatment should be based on the best available evidence
- they should receive a full explanation of the rationale for, and implications of, any proposed variations to the treatment protocol
- they should be able to place full confidence and trust that the facilities where they are being treated have in place checks and balances to ensure safe and effective delivery of treatment, including chemotherapy; and that such checks and balances include the ability of other health professionals to question decisions made by treating clinicians, and to raise concerns; and regular, rigorous review and audit processes that monitor outcomes and identify and address variations from best practice.⁵⁸⁶

- 8.3** Professor David Currow, Chief Cancer Officer, NSW, Chief Executive Officer of the Cancer Institute NSW, and Co-leader of the section 122 inquiry, explained that the statewide recommendations were aimed at providing a stronger framework around the individual clinician: while all doctors have a professional responsibility for the care that they offer wherever they are in the health system, the recommended initiatives aimed ‘to strengthen the processes that surround them, that support them, and particularly in team-based care.’⁵⁸⁷
- 8.4** Ms Susan Pearce, Deputy Secretary, System Purchasing and Performance, NSW Ministry of Health, advised that implementation of these recommendations has been facilitated via correspondence to all LHDs, performance meetings with chief executives and their teams, and other processes of follow up.⁵⁸⁸

Flexibility in chemotherapy prescribing protocols

- 8.5** Before examining each of the key areas of action statewide that are flowing from the section 122 inquiry, the committee now considers an issue that came up at many points during this inquiry: the flexibility built into chemotherapy prescribing protocols. There was a consensus among inquiry participants that guidelines are necessary, but that they must allow for flexibility according to the individual patient if they are to support quality care.
- 8.6** The Medical Oncology Group of Australia (MOGA), the peak representative body for medical oncologists, articulated the difference between off-protocol prescribing and personalised dose adjustment:

We would like to clarify the situation by noting the difference between systematic alteration of a protocol and individual adjustment of a protocol to adjust the dose for an individual patient. We regard the former when it is not based on scientific data as being incommensurate with good practice, but the latter is an intrinsic part of good practice as it seeks to match the dose to particular characteristics or toxicities experienced by a particular patient.

Decisions to vary chemotherapy doses are carried out to personalise therapy for each individual patient. Factors that influence this decision include overall health and

⁵⁸⁶ Submission 49, NSW Ministry of Health, p 8.

⁵⁸⁷ Evidence, Professor David Currow, Chief Cancer Officer, NSW, Chief Executive Officer, Cancer Institute NSW, and Co-leader of the section 122 inquiry, 31 October 2016, p 29.

⁵⁸⁸ Evidence, Ms Susan Pearce, Deputy Secretary, System Purchasing and Performance, NSW Ministry of Health, 31 October 2016, pp 29-30.

performance status, associated co-morbidities and cancer disease burden at the time of each assessment. The ultimate aim of care is to achieve meaningful benefit without overwhelming adverse events that may worsen a patient's quality of life.⁵⁸⁹

- 8.7** In a submission on behalf of CCA Health Care, Mr Tony Noun, Director and Chairman, also underscored an individualised approach as essential:

Accepting that all regimens in eviQ are evidence-based, it must be remembered that they were written as guidelines and not absolutes. Patients are unique and a “one-size fits all” approach cannot be applied, otherwise, why do we need doctors? Dosage is customised to the individual patient by the doctor.⁵⁹⁰

- 8.8** Dr David Bell, Senior Medical Oncologist at the Northern Cancer Institute, echoed this position, emphasising the role of the clinician in individualising treatment according to the patient's characteristics such as age, weight, comorbidities and so on, with the informed consent of the patient:

We tailor treatment to the individual. This is an important concept. This is not recipe book medicine ... This [protocol] is a guideline as to what would be an appropriate dose for a fit patient who fits the criteria for the trial entry that led to that protocol being on eviQ in the first place. So there are a lot of judgement calls that have to be made ... Most of us, particularly if we have been in the business for a while, start to learn how we can modify the doses and we explain that to the patient. They need to know. It is their life, it is their body and they are receiving these toxic substances.⁵⁹¹

- 8.9** Dr Bell referred to ‘the rarefied experience of a clean clinical trial to prove a point about the efficacy of a protocol, which may be driven by the pharmaceutical company, may be investor driven.’⁵⁹² He gave an example of one drug for whom only one out of three patients could be treated according to the protocol in eviQ, and explained that the remaining patients would be treated with a modified dose. Dr Bell further explained to the committee:

Quite often in these trials they are looking for, if you like, very clean patients to prove a point about the efficacy. These patients tend to be younger, on average. They rarely have any significant comorbidities. They tend to have fairly limited metastatic disease, so their prognosis, even without treatment, is likely to be longer than perhaps the average patient we see. They are important studies to do because they do prove efficacy, but the toxicity may be very different because of the type of patient selected from, if you like, the real-world patient.⁵⁹³

- 8.10** Professor Jennifer Martin, Chair of Clinical Pharmacology at the University of Newcastle and Professor Stephen Ackland, Director of the Hunter Cancer Research Alliance, University of Newcastle, identified a number of issues in respect of protocols or guidelines:

- It is important to be cognisant of who writes guidelines, who badges them and who supports them.

⁵⁸⁹ Submission 55a, Medical Oncology Group of Australia, p 1.

⁵⁹⁰ Submission 115, CCA Health Care, p 1.

⁵⁹¹ *In camera* evidence, Dr David Bell, Senior Medical Oncologist, Northern Cancer Institute, 31 October 2016, p 10. Evidence published by resolution of the committee.

⁵⁹² *In camera* evidence, Dr Bell, 31 October 2016, p 9.

⁵⁹³ *In camera* evidence, Dr Bell, 31 October 2016, p 9.

- Evidence and guidelines are two different things. Guidelines vary as to who writes them, how often they are updated, and if they are in eviQ, whether they come with dosing support software updated by the local oncologist, pharmacologist or pharmacist.
- Too great a focus on compliance with guidelines can detract from the uniqueness of an individual patient with specific health needs.⁵⁹⁴
- There is a need for better quality evidence that facilitates more precise decisions about dosing anti-cancer drugs, both older and newer.⁵⁹⁵

8.11 Professor Currow of the Cancer Institute, which produces the eviQ protocols, confirmed that personalised dosing is fundamental to quality care:

That variation in dose is absolutely crucial to personalising care ... we cannot in any way proscribe that or we will be compromising care. It is not only valid; it is essential that such variation is in place and is allowed to continue.⁵⁹⁶

Possible model for administering deviations from protocol in medical oncology

8.12 The NSW Health submission explained its procedural requirements for chemotherapy prescriptions that are outside protocol:

When the pharmacist receives the electronic (or written) prescription, it is expected that he or she conducts a full assessment to ensure the prescription is correct (including the correct drugs, dose, route of administration, infusion times, diluents, volumes, frequency, cycles, previous treatment, current medications and the cumulative dose the patient should receive) before ordering the drugs. The pharmacist is expected to clarify any questions with the prescribing doctor, and document in the care plan any changes that are made to the prescription. The pharmacist then orders the drugs to be compounded and dispensed locally or orders them from an external provider. In both circumstances, a final check is expected to be done by the pharmacist before the drugs leave the pharmacy to be administered to the patient.

Before administering chemotherapy, nurses should assess the patient for previous toxicity and check that the treatment to be administered is correct against the care plan and the patient's test results. They check the doses are correct, according to the factors that personalise the dose such as the patient's weight, body surface area or kidney function. They have a responsibility to clarify any questions with the prescribing doctor or the pharmacist, and document any changes in the [oncology management information system].⁵⁹⁷

8.13 In paragraph 8.18 below (and in chapter 4) we note the process for oversight of off-protocol dosing decisions now in place at St Vincent's Hospital, and in paragraph 5.33 we documented the oversight procedures that have been adopted in Western NSW Local Health District. Both

⁵⁹⁴ Evidence, Professor Jennifer Martin, Chair, Clinical Pharmacology, University of Newcastle, 1 November 2016, p 28.

⁵⁹⁵ Evidence, Professor Stephen Ackland, Director, Hunter Cancer Research Alliance, University of Newcastle, 1 November 2016, p 28.

⁵⁹⁶ Evidence, Professor Currow, 31 October 2016, p 12.

⁵⁹⁷ Submission 49, NSW Ministry of Health, p 9.

of these are operationalised via the electronic prescribing system MOSAIQ discussed in the following section.

8.14 CCA Healthcare offered a potential model procedure for administering deviations from protocol in medical oncology:

It is a registered nurse's responsibility to check all medication to be administered to ensure that:

- The patient is suitable to receive this medication;
- Before administration the mode of action of the medication is understood by the registered nurse;
- The order is clearly written and signed by the prescribing doctor;
- Consent has been given by the patient and is also signed by the prescribing/treating doctor;
- The patient is reviewed and is well enough in accord with base-line data required for the prescribed therapy / medication. If not, then the doctor is to be contacted and medication is either reduced to enable administration in line with protocol or is deferred or ceased altogether. This is a process that must be undertaken in consultation with the doctor and documented by the nurse;
- The dose is appropriate (within acceptable range) in accord with the regimen ordered, [Cancer Institute NSW] guidelines and the patient's [body surface area] – Essential that this is checked prior to each and every administration;
- Before administration the route of administration of the medication is understood by the registered nurse and administered accordingly; and
- The medication is checked by 2 Registered nurses and signed off.

If there is ever any doubt about a medication, dose ordered, route of administration or patient's condition, then this should be addressed with the doctor ordering the medication. Discussion should take place between the doctor and nurse and there should be detailed documentation as to why a dose ordered varies from the regimen be it dose-reduced, dose-increased or dose-omitted. This **MUST** be communicated clearly to the patient and their significant others. This communication and the outcome **MUST** be comprehensively documented ...

If the dose varies from the standard protocol, the most important thing ... is for the doctor to document why there is a deviation and to explain that to the nursing staff, before administering the medication. There must be clear and evidence-based rationale for the deviation.

The key is **DOCUMENTATION**. However, irrespective, when a dose significantly varies from eviQ, it **MUST** be discussed with the [Director of Clinical Services] and taken up at the next [quality assurance] and [medication advisory committee] meetings. The [Director of Clinical Services] may discuss the matter with other clinicians and if appropriate discuss with [the Cancer Institute NSW] and the attending physician.⁵⁹⁸

⁵⁹⁸ Submission 115, CCA Healthcare, pp 1-2.

Electronic prescribing

- 8.15** The first area of statewide action to help safeguard against off-protocol prescribing considered in this chapter concerns electronic prescribing. The terms of reference for our inquiry asked the committee to consider the efficacy of electronic prescribing systems and their capacity to limit off-protocol prescribing of chemotherapy.
- 8.16** The NSW Health submission explained that oncology management information system (OMIS), such as MOSAIQ ‘are comprehensive information technology solutions that allow users in the hospital environment to oversee all aspects of oncology care for their patients, from diagnosis to follow up.’⁵⁹⁹ According to NSW Health, ‘A fully implemented OMIS has the capacity to generate reports to support improvements in the quality of the cancer service delivery. Electronic prescribing is the computer-based electronic generation, transmission and filing of a medical prescription.’⁶⁰⁰
- 8.17** Inquiry participants who affirmed the value of electronic prescribing systems with built in eviQ guidelines as a way of preventing flat dosing included Professor Ackland,⁶⁰¹ MOGA,⁶⁰² St Vincent’s Hospital⁶⁰³ and NSW Health.⁶⁰⁴
- 8.18** As noted in chapter 4, St Vincent’s Hospital commenced implementing MOSAIQ in March/April 2015, independent of the off-protocol prescribing incident, and expressed strong support for electronic prescribing systems as mechanisms to help deliver evidence-based, standardised cancer care and to significantly reduce the risk of off-protocol prescribing.⁶⁰⁵ In terms of how MOSAIQ enables immediate oversight of dosing decisions, in chapter 4 we also noted St Vincent’s Hospital’s advice that all pharmacy orders prescribed in MOSAIQ are verified and approved by a senior oncology pharmacist. Beyond allowable individualised dose adjustments, a clinician wishing to make a significant variation to an eviQ care plan must submit their proposal with evidence for peer review through the MOSAIQ care plan review committee. The committee’s approval must be verified by the pharmacist before dispensing.⁶⁰⁶ This process reflects that expected by NSW Health, as set out above in paragraph 8.12.
- 8.19** MOGA advised that it sees electronic prescribing systems as ‘fundamental to improving cancer patient care by contributing to the safe and effective prescribing and dispensing of oncology drugs and treatments including chemotherapy’.⁶⁰⁷ It suggested that they can assist in reducing errors during the dispensing process and serve as a recording system for monitoring prescription records, as well as other aspects of patients’ medical histories. MOGA further noted, however, that such systems need to be integrated into a comprehensive electronic

⁵⁹⁹ Submission 49, NSW Ministry of Health, p 9. The submission also sets out the process that it expects pharmacists and nurses to follow when they respectively assess and check the dosing of the prescribing doctor.

⁶⁰⁰ Submission 49, NSW Ministry of Health p 9.

⁶⁰¹ Evidence, Professor Ackland, 1 November 2016, p 29.

⁶⁰² Submission 55, Medical Oncology Group of Australia, p 3.

⁶⁰³ Submission 59, St Vincent’s Hospital Sydney, p 10.

⁶⁰⁴ Submission 49, NSW Ministry of Health, p 9.

⁶⁰⁵ Submission 59, St Vincent’s Hospital Sydney, p 10.

⁶⁰⁶ Submission 59, St Vincent’s Hospital Sydney, p 10.

⁶⁰⁷ Submission 55, Medical Oncology Group of Australia, p 3.

patient health record system and supported by appropriate management infrastructure, and that this requires extensive resourcing and staffing support.⁶⁰⁸

Section 122 inquiry

- 8.20** The section 122 inquiry made three recommendations with regard to OMIS and electronic prescribing at the statewide level.
- 8.21** First, it recommended that given clinicians should be able to override doses once entered into MOSAIQ for an individual patient, local health districts and specialty networks should ensure that the most senior oncology pharmacist and the head of medical oncology review such overrides regularly to identify any patterns that may suggest similar dosing issues.⁶⁰⁹
- 8.22** As of July 2016, when the section 122 inquiry final report was released, action on the recommendation was ‘in progress’, with the review mechanisms ‘mostly in place’. The LHDs where it had not yet been implemented were those that had not yet installed their OMIS for electronic prescribing, and interim measures were in place for these LHDs.⁶¹⁰
- 8.23** The second recommendation was that those LHDs and specialty networks which have not yet installed OMIS ‘accelerate efforts to install them, as a matter of priority’. As at July 2016, all but two LHDs had an OMIS and those that did not had been funded to commission one.⁶¹¹
- 8.24** Third, the section 122 inquiry recommended that to avoid transcription errors, LHDs move to automated uploading of eviQ protocols onto OMIS. Again as of July 2016, this was in progress. Where electronic OMIS were in place, there was a combination of automated and manual uploading, and those still manual were working towards being electronic.⁶¹²

Current actions

- 8.25** Professor Currow confirmed to the committee that the electronic prescribing systems being implemented across the state necessarily provide for variation in doses.⁶¹³
- 8.26** In terms of actions in progress, in October 2016 NSW Health advised that by early 2018 all LHDs will have a functioning OMIS in place, and that the NSW Cancer Institute is supporting implementation in the remaining three LHDs that either do not yet have their OMIS in place, or who have purchased but not yet implemented it.⁶¹⁴

⁶⁰⁸ Submission 55, Medical Oncology Group of Australia, p 3.

⁶⁰⁹ NSW Ministry of Health, *Inquiry under section 122 of the Health Services Act 1997: Off-protocol prescribing of chemotherapy for head and neck cancers*, Final report, 31 July 2016 (hereafter section 122 inquiry final report), p 38.

⁶¹⁰ Section 122 inquiry final report, p 38.

⁶¹¹ Section 122 inquiry final report, p 38.

⁶¹² Section 122 inquiry final report, p 38.

⁶¹³ Evidence, Professor Currow, 31 October 2016, p 12.

⁶¹⁴ Submission 49, NSW Ministry of Health, p 10.

- 8.27** In addition, the Cancer Institute NSW is working with LHDs to ‘standardise and optimise’ the use of OMIS across the state, with funding of \$6 million over three years to 2018-19 to enable LHD staff to utilise electronic systems to support improved clinical care, data analysis and reporting. NSW Health provided further information on its work here:

This includes standardising processes for developing and approving care plans as well as processes for documenting the rationale for variations from protocols. Local health districts will develop standardised reports on protocol variation to be considered by relevant organisational quality and safety committees and morbidity and mortality committees as well as by board quality and safety sub committees. Each local health district will be responsible for reviewing and responding to any reported variances ... As part of its state-wide remit for using its core datasets to report to local health districts on unwarranted clinical variations, the Cancer Institute NSW will also be developing indicators on variance from eviQ protocols.⁶¹⁵

- 8.28** From an LHD perspective, as noted in chapter 5, Mr Scott McLachlan, Chief Executive of the Western NSW LHD, attested that MOSAIQ had transformed that district’s ability to provide safeguards and good record keeping. He also reported that by providing data on prescribing, it facilitates clinicians getting together on a regular basis and having a conversation about their practice, reflecting on the way that they prescribe and coordinate patient care, including across multiple sites.⁶¹⁶ Dr Rob Zielinski, Medical Oncologist at Orange, underscored the value of now having an oncology pharmacist in each site, while also attesting to the transparency and team approach that MOSAIQ is facilitating in his locality.⁶¹⁷

- 8.29** The consumer group Cancer Voices NSW told the committee that it supports the introduction of common electronic prescribing systems across the NSW cancer care sector, with capability linked directly to the MyHealth Record so that it is viewable by the patient as well as their advising clinicians.⁶¹⁸

- 8.30** MOGA called for a unified electronic oncology medical information and prescribing system across the state, suggesting that the existing information technology infrastructure has not been implemented uniformly to date. It further proposed that:

[A] unified electronic oncology medical information and prescribing system (OMIS) across the state (or nationally) will provide real time reporting of cancer data to enable clinicians and administrators to monitor treatment results and identify “outlying” management decisions that may require further investigation and peer-review.⁶¹⁹

- 8.31** Professor Currow responded to MOGA’s assertion by writing to the committee, stating:

The ability to identify, monitor, evaluate and report on off-protocol treatment variances does not depend on all cancer services using the same OMIS. Indeed,

⁶¹⁵ Submission 49, NSW Ministry of Health, pp 10-11; see also evidence, Professor Currow, 31 October 2016, p 12.

⁶¹⁶ Evidence, Mr Scott McLachlan, Chief Executive Officer, Western NSW Local Health District, 2 November 2016, p 15.

⁶¹⁷ Evidence, Dr Rob Zielinski, Medical Oncologist, Central West Cancer Care Centre, Orange Health Service, 2 November 2016, p 16.

⁶¹⁸ Submission 108, Cancer Voices NSW, p 2.

⁶¹⁹ Submission 55a, Medical Oncology Group of Australia, pp 1-2.

recognising the importance of competition, NSW Health made a policy decision not to choose a single state-wide vendor for an OMIS. All OMIS in NSW, regardless of the vendor, are compliant with Health Level-7 (HL7) international standards for inter-system and inter-organisation messaging.⁶²⁰

- 8.32** Professor Currow noted that every LHD either has an OMIS or has been funded to implement one, and that the Cancer Institute is working closely with all of them to support implementation and thus enable them to optimise the ability to electronically prescribe, using eviQ treatment protocols as a baseline. He advised that once e-prescribing has been established in all cancer services, the LHDs will be able to identify, monitor, evaluate, and report on off-protocol treatment variance in real time.⁶²¹
- 8.33** Professor Currow further addressed MOGA's suggestion that the NSW Cancer Registry does not provide real-time monitoring of outcome data in New South Wales, stating, 'No population-based cancer registry in Australia provides real-time monitoring of clinical data, nor were they ever designed to do so. Rather, they enable reporting on long-term trends in cancer incidence and mortality.'⁶²² He went on to outline the Cancer Registry's achievements and requirements in respect of data collection and reporting on cancer system performance and cancer outcomes.⁶²³

Coordinated cancer care via multidisciplinary care teams

- 8.34** The second area for statewide action across the health system to provide better safeguards against off-protocol prescribing is in respect of multidisciplinary cancer care teams. The capacity of multidisciplinary teams (MDTs) to prevent off-protocol prescribing was a prominent issue during our inquiry. The committee's terms of reference charged us with examining this issue, as well as the capacity of the NSW Health system to have all notifiable cancer patients overseen by a multidisciplinary cancer care team.
- 8.35** In chapter 1 the committee noted that clinicians treating people with cancer usually work as part of a multidisciplinary team to devise an individual treatment plan for each patient. The plan specifies whether a patient receives surgery, chemotherapy, radiation treatment or a combination of these. Medical oncologists within the multidisciplinary team make treatment decisions in relation to the prescribing and administration of chemotherapy.⁶²⁴ NSW Health advised that, 'While all members of the multidisciplinary team have an important role to play, the specialist medical oncologist has ultimate responsibility for decisions on the prescribing and administration of chemotherapy.'⁶²⁵
- 8.36** In chapter 4 the committee examined whether the functioning of the head and neck MDT at St Vincent's Hospital had been a contributing factor in the hospital's poor handling of the off-protocol prescribing matter, and particularly why that team had not identified that Dr Grygiel

⁶²⁰ Correspondence from Professor David Currow, Chief Cancer Officer and Chief Executive, Cancer Institute NSW, to Chair, 20 December 2016, p 1.

⁶²¹ Correspondence from Professor Currow to Chair, 20 December 2016, p 1.

⁶²² Correspondence from Professor Currow to Chair, 20 December 2016, p 2.

⁶²³ Correspondence from Professor Currow to Chair, 20 December 2016, p 2.

⁶²⁴ Submission 49, NSW Ministry of Health, p 5.

⁶²⁵ Submission 49, NSW Ministry of Health, p 5.

was systematically underdosing his patients. There we explored at length the specific issue of whether the MDT should consider the chemotherapy dosage of individual patients (see paragraphs 4.20 to 4.29).

8.37 Offering a patient and family member perspective, Mrs Natalie Dugdale and Mr Ken Dugdale called for senior medical practitioners on MDTs to be held more accountable for their actions.⁶²⁶

8.38 Dr Laurence J Denholm noted the research evidence describing problems of poor communication and coordination between specialists from different disciplines in cancer care. He noted that MDTs and grand rounds are important strategies to minimise the problems in treatment planning and monitoring. He did, however, suggest that MDTs may not address the day-to-day issues for patients, because for any patient, 'the MDT is a daunting environment in which to question a treatment decision or raise concern about supportive care.'⁶²⁷

8.39 Cancer Voices NSW expressed strong support for all cancer patients being overseen by an MDT wherever practically possible, noting that distance barriers are being overcome for this purpose, using teleconsultation.⁶²⁸

8.40 Professor Stephen Ackland attested to the benefits of a well functioning MDT in terms of challenging individual views and reaching consensus, whilst noting that this depends upon effective communication and team work:

There needs to be good communication between people who should be working together. It is important for them to work together well ... One of the real advantages of multidisciplinary team meetings is the capacity to question each other's views and reach a consensus on the best way to deliver multidisciplinary care.⁶²⁹

8.41 MOGA expressed its support for all cancer patients to be overseen by an MDT. Noting that making this a reality requires resources and facilities, it proposed that this goal 'could form part of an extensive quality improvement initiative for NSW Health'. MOGA identified a number of advantages to the oversight of MDTs by suggesting that they can:

- assist in ensuring that patients receive best practice care
- enhance the quality of a cancer patient's treatment and experience
- facilitate the contribution of each of the team members
- help address any issues that may arise in relation to off-protocol prescribing, such as adverse effects.⁶³⁰

8.42 Similarly, NSW Health noted that MDTs have demonstrated benefit in terms of improved treatment planning (such as adding neoadjuvant or adjuvant chemotherapy or chemoradiation

⁶²⁶ Submission 6, Mrs Natalie and Mr Ken Dugdale, p 3.

⁶²⁷ Submission 95a, Dr Laurence J Denholm, p 4.

⁶²⁸ Submission 108, Cancer Voices NSW, p 2.

⁶²⁹ Evidence, Professor Ackland, 1 November 2016, p 30.

⁶³⁰ Submission 55, Medical Oncology Group of Australia, p 4.

to a treatment plan where the main treatment is surgery), better coordination of treatment, and increased opportunity to participate in clinical trials.⁶³¹

Section 122 inquiry

- 8.43** In his evidence to the committee, Professor Currow agreed with the imperative to improve coordination of cancer care.⁶³² In addition, as noted earlier in this chapter, he highlighted the aim of that inquiry's recommendations to support clinicians through systemic improvements, particularly in relation to team based care.⁶³³
- 8.44** The section 122 inquiry recommended that the Ministry of Health, with the Cancer Institute NSW examine ways to ensure that all people diagnosed with notifiable cancer in New South Wales have their care overseen by a multidisciplinary cancer care team that includes all relevant medical, nursing, pharmacy and allied health staff.⁶³⁴
- 8.45** In addition, as noted in chapter 4, in order to promote discussion of emerging evidence and cross-fertilisation of practice, the inquiry recommended that LHDs and specialty networks ensure that minuted meetings of multidisciplinary cancer care teams occur after relevant international or national meetings and on an ad hoc basis as seminal new evidence emerges that should influence practice.⁶³⁵
- 8.46** In respect of the first recommendation, as of July 2016, the Ministry advised that implementation was ongoing, and stated:
- There is excellent coverage of MDTs available in New South Wales through Canrefer. The MDTs can be identified by people with cancer and their general practitioners through canrefer.org.au. Use of an MDT when people are referred to cancer services is high. This recommendation requires ongoing work to increase the number of people diagnosed with cancer who are referred to MDTs in the first place.⁶³⁶
- 8.47** NSW Health also noted that action on the second recommendation was 'in progress/ongoing'. It stated that 'Although many MDTs have updates after international meetings, the evidence needs to be translated into an agreed local response by the MDT and a plan of action for implementation.'⁶³⁷
- 8.48** In addition, the section 122 inquiry report on Western NSW LHD recommended that where multidisciplinary cancer care teams have a single member from a discipline, clinicians consider

⁶³¹ Submission 49, NSW Ministry of Health, p 14.

⁶³² Evidence, Professor Currow, 31 October 2016, p 12.

⁶³³ Evidence, Professor Currow, 31 October 2016, p 29.

⁶³⁴ Section 122 inquiry final report, p 39.

⁶³⁵ Section 122 inquiry final report, p 38.

⁶³⁶ Section 122 inquiry final report, p 39. Canrefer, administered by the Cancer Institute NSW, is an online cancer services directory for residents of New South Wales and the Australian Capital Territory. It lists specialists, hospitals and services that provide diagnosis and treatment for people suspected of or diagnosed with cancer.

⁶³⁷ Section 122 inquiry final report, p 38.

joint minuted meetings with another team after relevant national or international meetings.⁶³⁸ That report does not provide comment on the progress of that recommendation.

Current actions

- 8.49** The NSW Health submission to our inquiry advised that following the section 122 inquiry, LHDs and specialty networks are reviewing the terms of reference for their multidisciplinary cancer care teams, consistent with the above recommendations. They are also reviewing mechanisms to ensure emerging evidence is presented and discussed at meetings of MDTs and other appropriate forums.
- 8.50** It further noted that the Cancer Institute now requires, as a condition of the funding it provides to LHDs and specialty networks, that they report on the number of patients overseen by each team.⁶³⁹

Informed consent

- 8.51** The third key area of statewide action to provide better safeguards against off-protocol prescribing concerns informed patient consent. As noted in chapter 1, informed consent refers to a person's voluntary decision about medical care, made with knowledge and understanding of the benefits and risks involved.⁶⁴⁰
- 8.52** The inquiry terms of reference charged our committee with considering:
- the processes and systems around informed consent for all medical interventions including chemotherapy
 - the value of a potential new information sheet on dose adjustment for patients and caregivers.
- 8.53** The Ministry observed that 'Obtaining a patient's informed consent to medical intervention or treatment is a fundamental legal and ethical responsibility of the treating medical practitioner.'⁶⁴¹ It advised that NSW Health has well established policies and systems in place to ensure that clinical staff working in the health system are aware of, and implement, the informed consent requirements. Compliance with the current statewide policy directive *Consent to Medical Treatment – Patient Information* is compulsory for all LHDs, specialty networks and other public health organisations, and the compliance of LHDs and networks is audited.⁶⁴²

⁶³⁸ NSW Ministry of Health, *Inquiry under section 122 of the Health Services Act 1997: Off-protocol prescribing of chemotherapy for head and neck cancers*, Western NSW Local Health District report, 16 September 2016, p 17.

⁶³⁹ Submission 49, NSW Ministry of Health, p 15.

⁶⁴⁰ Medical Board of Australia, *Good Medical Practice*, March 2014, p 9.

⁶⁴¹ Submission 49, NSW Ministry of Health, p 12.

⁶⁴² Submission 49, NSW Ministry of Health, p 12; see also evidence, Ms Karen Crawshaw, Deputy Secretary, Governance, Workforce and Corporate, NSW Ministry of Health, 31 October 2016, p 30.

- 8.54** In accordance with the principles underpinning the policy, health care professionals and managers must:
- understand the legal requirements for obtaining consent from patients and the consequent need to provide patients with sufficient information
 - ensure that documented evidence of a patient’s consent or refusal of treatment is recorded in the patient’s health care record
 - ensure that patient autonomy and decision-making is respected and that patients are provided with appropriate information relevant to their treatment and
 - understand their legal obligations with regard to providing medical treatment to patients who do not have capacity to consent.⁶⁴³
- 8.55** In order to ensure compliance, consistency and simplicity of application, the general approach adopted in NSW Health is for a single model consent form to apply to all medical interventions.⁶⁴⁴ While the use of the model consent form is mandatory for public hospitals, the general legal requirement for obtaining patient consent applies to all doctors.⁶⁴⁵
- 8.56** In respect of auditing of doctors’ compliance with obtaining informed consent from patients, NSW Health advised that patient consent is monitored via the national accreditation scheme that assesses hospitals against ten National Health and Safety Quality Health Service Standards. In addition, consent may be considered as part of a local health district audit or review of an issue or process where specific concerns have been raised.⁶⁴⁶
- 8.57** NSW Health noted that its policy on informed consent ‘requires patients to be given sufficient information to have a genuine understanding of the nature of the proposed treatments or alternatives and any risks and benefits.’⁶⁴⁷ It advised that since the commencement of the eviQ online resource, information sheets for patients have been available for those diagnosed with cancer via the Cancer Institute NSW’s eviQ website. This includes information on each treatment protocol outlining the treatment and its side effects, frequently asked questions, support and resources. Links to a set of questions that patients can ask their health professionals are also available in 20 different languages.⁶⁴⁸
- 8.58** Mr Ken and Mrs Natalie Dugdale offered a patient and caregiver perspective on informed consent, observing that ‘Patients are vulnerable, scared and they trust their medical practitioners.’⁶⁴⁹ They also highlighted how clinicians’ time demands play out in their interactions with patients:

Medical practitioners forget they are dealing with people’s lives and do not allow enough time for appointments, therefore patient/carers do not have enough time to ask questions most doctors rush you in and tell you what they are going to do.

⁶⁴³ Submission 49, NSW Ministry of Health, p 13.

⁶⁴⁴ Submission 49, NSW Ministry of Health, p 12.

⁶⁴⁵ Answers to supplementary questions, NSW Ministry of Health, received 28 November 2016, p 2.

⁶⁴⁶ Answers to supplementary questions, NSW Ministry of Health, p 3.

⁶⁴⁷ Submission 49, NSW Ministry of Health, p 11.

⁶⁴⁸ Submission 49, NSW Ministry of Health, p 11.

⁶⁴⁹ Submission 6, Mrs Natalie and Mr Ken Dugdale, p 2.

If you question the doctor and become very upset [they] let you know that they are the expert and to trust them. This is not always the fault of the medical practitioner, they are under extreme pressure due to an aging population and other community related health issues. Also some medical practitioners at a senior level have dual roles and their time is used in multiple capacities.⁶⁵⁰

8.59 MOGA observed that informed consent for chemotherapy administration is a standard component of Australian medical oncology practice, and that international best practice dictates that consent conversations be well documented. It also noted the ethical and practical aspects to consent:

Ethically, consent conversations allow medical oncologists to fulfil their obligations to assist cancer patients to make independent choices about their medical care. Accordingly, informed consent is not limited to a single discussion or a form; rather, it is an ongoing communication process that is central to the medical oncologist - cancer patient relationship. Consent conversations can be documented through a written consent form that is reviewed with the cancer patient, signed, and stored in their medical record. Making a detailed note in a patient's medical record to document that all of the required elements of a consent conversation took place is equally appropriate because written consent forms are not always required by law or facility policies. At this time international practice in medical oncology is that either a note in the patient's medical record or the use of a consent form are taken as an indication that a consent conversation took place.⁶⁵¹

8.60 MOGA also noted that while consent forms cannot replace direct communication between a medical oncologist and their patient, they serve a number of functions in that they can:

- enhance the consent process and the quality of the patient experience
- serve as a guide for clinicians during consent conversations to ensure all required elements are covered
- provide a reference for patients about their treatment plan
- (when signed) serve as instant, standardised documentation should litigation arise, providing strong evidence that the doctor engaged the patient in an appropriate discussion.⁶⁵²

8.61 Like MOGA, Dr Zielinski of the Orange Health Service emphasised that in practice, consent is a complex and often protracted process because patients need time to receive and absorb information:

You have got to prove to the patient, I believe, they understand what they are signing up for, and [passing] them a consent form the first time you meet them when you have delivered an immense amount of complex information maybe is not the best time to get consent. Nurses also go through a checklist. eviQ has got a very neat checklist, which does talk about fertility, vascular access, all those other things, and

⁶⁵⁰ Submission 6, Mrs Natalie and Mr Ken Dugdale, pp 1-2.

⁶⁵¹ Submission 55, Medical Oncology Group of Australia, pp 3-4.

⁶⁵² Submission 55, Medical Oncology Group of Australia, p 4.

that maybe is a much more appropriate time. So consent is a protracted process, I think.⁶⁵³

8.62 Cancer Voices offered a number of comments in respect of informed consent:

Accepted processes and systems for informed consent are essential, both in relation to the treatment and side effects, as well as the cost (if private). Consent forms should be developed in consultation with health consumer organisations to ensure they are clear and cover any areas of concern to the patient. They should also be discussed before signing. Copies should be held by both clinician and patient. Preferably the consent form will become part of a cancer treatment and care plan to be held by the patient.⁶⁵⁴

8.63 Alongside strategies targeting doctors and other health care practitioners, Professor Currow noted the imperative for our health system to empower patients in their decision making, particularly through the provision of information and facilitating better interactions between patients and doctors:

I think the other aspect of this ... is the issue of empowering patients more effectively and ensuring that they have information at their disposal that can help them to ask informed questions, and providing question prompt lists, which have a good evidence base for improving the interaction between patients and clinicians and between families and clinicians. Again, as with all the issues we have discussed today, there is no single, simple solution ... A multimodal system that includes patient empowerment is absolutely crucial if we are going to ensure that people are making fully informed decisions.⁶⁵⁵

Section 122 inquiry

8.64 The committee noted in chapter 2 that the section 122 inquiry found Dr Grygiel's practice wanting not only in terms of his prescribing in accordance with the relevant protocol, but also his discussions with patients and their families and his documentation of their consent (see paragraphs 2.6 to 2.9).

8.65 The section 122 inquiry made the following recommendations:

- That clinicians across New South Wales ensure adequate informed consent for all medical interventions, including chemotherapy. If the clinician knows that his/her practice is outside accepted practice, there is a particular onus to draw this to the attention of patients in the process of providing informed consent, and to document this in the patient notes.
- That the Cancer Institute NSW prepare a new patient information sheet on dose adjustment of chemotherapy to allow patients and their caregivers to understand the rationale for it.

⁶⁵³ Evidence, Dr Zielinski, 2 November 2016, p 7.

⁶⁵⁴ Submission 108, Cancer Voices NSW, p 2.

⁶⁵⁵ Evidence, Professor Currow, 31 October 2016, p 30.

8.66 At the time of the report's release, the new patient information sheet was published and available on the eviQ website.⁶⁵⁶

Current actions

8.67 NSW Health advised the committee that, as of October 2016, it was undertaking a comprehensive review of its informed consent procedures. This will include converting the *Consent to Medical Treatment* policy into a consent manual to contain a number of provisions specifically related to chemotherapy, including explicitly requiring written patient consent. The manual will:

- provide operational guidance to health care practitioners
- outline procedures to support compliance
- be able to be updated from time to time to reflect legal, policy or practice developments
- include examples of frequently occurring scenarios, in order to support best practice in obtaining consent.⁶⁵⁷

8.68 A final draft of the new manual to accompany the model consent form was to be issued for consultation before the end of 2016, with the final version expected to be issued in the first quarter of 2017.⁶⁵⁸

8.69 NSW Health further advised that the new information sheet for patients, 'Understanding chemotherapy and treatment changes', includes clear explanation of the many valid reasons, based on individual patient characteristics and conditions, where a medical oncologist might recommend a variance in the dose of chemotherapy. The information sheet suggests patients raise with their doctors any questions they have about the chemotherapy they are being prescribed. It will be promoted by NSW Health through LHDs, specialty networks, and the Cancer Institute NSW clinical, community and consumer networks.⁶⁵⁹

Reporting and managing incidents

8.70 The next area of statewide action to better safeguard against off-protocol prescribing of chemotherapy concerns strategies to improve the reporting and management of incidents. As documented in chapter 2, at St Vincent's Hospital there was a history of staff not reporting concerns about Dr Grygiel's prescribing, and then when concerns were raised by a senior clinician, the hospital failed to recognise the matter as a notifiable incident and to manage it accordingly.

8.71 As noted in chapter 1, a clinical incident is any unplanned event which causes, or has the potential to cause, harm to a patient. Incident management is governed by the NSW Health

⁶⁵⁶ Section 122 inquiry final report, pp 40-41.

⁶⁵⁷ Submission 49, NSW Ministry of Health, pp 13-14; see also Ms Crawshaw, 31 October 2016, p 30.

⁶⁵⁸ Answers to supplementary questions, NSW Ministry of Health, p 2.

⁶⁵⁹ Submission 49, NSW Ministry of Health, pp 11-12.

Incident management policy, which sets out the steps that must be taken in response to any incident including identification, notification, investigation and analysis.⁶⁶⁰

- 8.72 Also relevant are the NSW Health *Complaints and concerns about a clinician* policy directive, which establishes a set of principles that apply, and the accompanying *Complaints and concerns about a clinician* management guidelines, which provide the process to be followed to ensure that the interests of the organisation, the public and the practitioner are met, and to ensure that appropriate action is taken to implement findings.⁶⁶¹
- 8.73 The committee learned that mandatory reporting is in place for ‘reportable conduct’ under the *Health Practitioner Regulation National Law Act 2009* (which is applied, with modifications, as a law of NSW by the *Health Practitioner Regulation (Adoption of National Law) Act 2009* (NSW)).⁶⁶²
- 8.74 According to NSW Health, ‘Health care practitioners have a legal, ethical and professional responsibility to raise any concern they have about the practice of another professional. Health care managers equally have a responsibility to act on any concerns raised in a timely and effective way.’⁶⁶³ The Ministry advised the committee of current mechanisms available to ensure staff can raise concerns without fear of victimisation or adverse consequences.⁶⁶⁴
- 8.75 By way of example, Mr Gerry Marr, Chief Executive Officer of the South Eastern Sydney Local Health District noted that he views the 1,820 notifications of incidents in a year within his LHD as positive, in that together they indicate staff feel safe and supported to report incidents. He also noted that the NSW Health Code of Conduct governs staff responsibility in these matters, and that there is also ‘a great deal of training’ in this area.⁶⁶⁵

Section 122 inquiry

- 8.76 While the section 122 inquiry made a number of recommendations to improve reporting and managing incidents specifically at St Vincent’s Hospital, it did not make any such recommendations for statewide implementation.⁶⁶⁶

Current actions

- 8.77 Regardless, NSW Health representatives advised the committee that it is currently putting in place a new incident management system, ims+, which will:
- be easier to use

⁶⁶⁰ NSW Health, *Incident Management Policy*, 10 February 2014.

⁶⁶¹ Submission 49, NSW Ministry of Health, p 18. Other relevant documents include the NSW Health *Code of conduct*.

⁶⁶² Answers to supplementary questions, Professor Currow, received 28 November 2016, p 7.

⁶⁶³ Answers to supplementary questions, NSW Health, p 4.

⁶⁶⁴ Answers to supplementary questions, NSW Health, pp 4-5.

⁶⁶⁵ Evidence, Mr Gerry Marr, Chief Executive, South Eastern Sydney Local Health District, 1 November 2016, p 22.

⁶⁶⁶ Refer to chapters 3 and 4 and Section 122 inquiry final report, pp 36-37 for the relevant recommendations.

- provide quality data and reporting
- enable feedback to the notifiers of incidents
- improve the ability to effectively record, track, manage and report on clinical, corporate and work health and safety incidents, including actions taken to address issues and mitigate existing risks
- provide for patients and consumers to log their concerns directly into the system online.⁶⁶⁷

8.78 The Ministry advised that implementation will commence mid 2017, and be completed by the end of 2017.⁶⁶⁸

Organisational culture

8.79 The final area of statewide action to help safeguard against off-protocol prescribing of chemotherapy concerns organisational culture. As the section 122 inquiry observed, ‘Culture is about how things are done. A constructive clinical culture is built upon visible, people-focused leadership which emphasises patient-centred care.’⁶⁶⁹

8.80 Dr Laurence J Denholm observed some of the cultural forces at work in hospitals, and the challenges to address them:

Rigid and formal hierarchical organisational structures where status depends on position, and status is critical to financial success, facilitate a culture in which any question is a challenge to authority and any challenge is a personal threat. But long-standing organisational culture problems cannot be resolved simply by more externally imposed rules. Some external compliance monitoring is also needed. But most of all there must be changes at the top to drive down a more inclusive culture.⁶⁷⁰

8.81 In chapter 4 the committee noted that the section 122 inquiry report highlighted organisational culture within St Vincent’s Hospital and especially within the cancer services stream, as ‘the overriding reason’ for the failure to recognise and respond effectively to off-protocol prescribing of chemotherapy. There we documented the numerous actions that the hospital is taking to address the recommendation that it initiate and oversee a program that will build within cancer services a constructive, people focused culture for patients and staff.

8.82 Looking statewide, NSW Health advised the committee that it ‘has core values which seek to provide a workplace that is collaborative, open, respectful and empowering.’⁶⁷¹ The Ministry’s current approach in this area is driven by the *NSW Health State Plan: Towards 2021*, the first strategy of which focuses on delivering a positive workforce culture in NSW Health. Underneath this, the *NSW Health workplace culture framework: Making a positive difference to*

⁶⁶⁷ Answers to supplementary questions, NSW Ministry of Health, pp 2 and 5; evidence, Ms Crawshaw, 31 October 2016, p 29.

⁶⁶⁸ Answers to supplementary questions, NSW Health, p 2.

⁶⁶⁹ Section 122 inquiry final report, p 31.

⁶⁷⁰ Submission 95a, Dr Laurence J Denholm, p 4.

⁶⁷¹ Submission 49, NSW Ministry of Health, p 17.

workplace culture was designed to embed cultural improvement strategies as core business in every facility.⁶⁷²

8.83 The NSW Health submission further noted that the Health Education and Training Institute provides courses and programs that support the development of a positive workplace culture through building workforce capability in applying core values as well as leadership, communication, and conflict resolution competencies.

8.84 It further identified workplace culture surveys such as the Yoursay Workplace Culture Survey and the People Matter Survey as elements of its current approach to organisational culture.⁶⁷³

Patient advisor-advocates

8.85 Dr Denholm offered the committee a detailed proposal for a formal system of independent ‘patient advisor-advocates’ at hospitals around the state as a means of empowering patients and addressing the cultural characteristics of hospitals that can actually work against patients’ interests.⁶⁷⁴

8.86 Dr Denholm noted that patients are often very unwell, confused by the organisational complexity of the modern hospital system, and even when they have good family support, would benefit from an advocate. He argued that independent advice and advocacy is most important to the patient when the system is failing them, as it did at St Vincent’s Hospital.⁶⁷⁵

8.87 To address this, Dr Denholm proposed the establishment of a system of independent ‘patient advisor-advocates’ similar to the official visitor system in mental health services, with the following elements:

- Individuals would be appointed by an agency outside the hospital system, appropriately qualified and properly resourced.
- They would have appropriate legal status and powers including access and inquiry powers within the hospital, equivalent to those of official visitors.
- They would be completely independent of the hospital and LHD, and act for the patient with the patient’s agreement.
- They would have a broad oversight role but only as necessary to inform their advisory and advocacy roles on behalf of patients.
- Each hospital would require at least one standing patient advisor-advocate, but that person should be able to call in additional ones for a period if there is evidence of systems failure or significant culture problems at the hospital.

⁶⁷² Submission 49, NSW Ministry of Health, p 18.

⁶⁷³ Submission 49, NSW Ministry of Health, p 19.

⁶⁷⁴ Submission 95a, Dr Laurence J Denholm, pp 4-6.

⁶⁷⁵ Submission 95a, Dr Laurence J Denholm, p 4.

- The patient advisor-advocate would establish a secure system in the hospital for any patient or staff member to disclose their concern about the treatment of a particular patient, on a confidential basis.⁶⁷⁶

8.88 Dr Denholm suggested that the nature of the role would mean that the advisor-advocates could play a significant part in ensuring properly informed consent, would help address the power imbalance and ‘information asymmetry’ inherent in the doctor-patient relationship in cancer services, and would significantly improve public confidence in the system.⁶⁷⁷

Committee view

8.89 In addition to the numerous strategies now being implemented at St Vincent’s Hospital, Western NSW Local Health District and Macquarie Hospital, to prevent further off-protocol prescribing of chemotherapy, there is also significant work progressing to enhance statewide safeguards that will help to ensure that similar problems do not occur in other parts of the hospital system in the future.

8.90 Like many inquiry participants, the committee recognises that chemotherapy prescribing protocols must have inbuilt flexibility to allow clinicians to personalise dosing according to the unique needs of individual patients. We are pleased that the electronic prescribing systems being implemented across the state necessarily provide for variation in doses, and we note the capacity of these systems to facilitate monitoring and oversight of dosing decisions and thus help safeguard against off-protocol chemotherapy prescribing. These systems can also facilitate evidence based care, informed discussions between clinicians, and generate reports to support quality improvements to cancer care.

8.91 The committee notes that detailed procedures are now in place at St Vincent’s Hospital and Western NSW LHD to provide oversight of chemotherapy dosing decisions, and we also see value in the model offered by CCA Health Care presented earlier in this chapter. Each of these adds operational detail to the broader procedures currently expected by NSW Health (set out in paragraph 8.12). The committee does not possess the expertise to assess the relative merits of each approach, nor to determine whether there is an ideal model for statewide implementation. Perhaps a standardised approach has merit; on the other hand, a localised approach may be more appropriate. We recommend that the Cancer Institute NSW examine whether, beyond allowable individualised dose adjustments, a model for oversight of significant variations to chemotherapy protocols should be adopted statewide. In doing so, it should consider the various models documented in this report and operating elsewhere.

Recommendation 4

That the Cancer Institute NSW examine whether, beyond allowable individualised dose adjustments, a model for oversight of significant variations to chemotherapy protocols should be adopted statewide.

⁶⁷⁶ Submission 95a, Dr Laurence J Denholm, pp 4-6.

⁶⁷⁷ Submission 95a, Dr Laurence J Denholm, p 6.

- 8.92** The committee acknowledges the significant progress that LHDs and specialty networks have made in establishing oncology management information systems that enable e-prescribing, as well as the support that the Cancer Institute NSW is providing to the remaining LHDs to achieve implementation. NSW Health has indicated that all LHDs will have a functioning OMIS in place by early 2018. We affirm the value of this work by recommending that the Cancer Institute NSW ensure that all LHDs and specialty networks meet this goal.

Recommendation 5

That the Cancer Institute NSW ensure that all local health districts and specialty health networks have a functioning oncology management information system in place by early 2018.

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- 8.93** Multidisciplinary teams also have an important role to play in prevention, in that a well functioning team can enhance treatment planning and act as a check and balance on individual clinician decisions.
- 8.94** In respect of multidisciplinary teams, the committee notes the Ministry's advice that implementation of the section 122 inquiry recommendation that NSW Health and the Cancer Institute examine ways to ensure that all people diagnosed with notifiable cancer in New South Wales have their care overseen by a multidisciplinary cancer care team is ongoing, and that it requires continuing work to increase the number of people referred to an MDT in the first place.
- 8.95** We acknowledge as a valuable strategy the Cancer Institute's requirement as a funding condition for LHDs and specialty networks, that they report on the number of patients overseen by each MDT. Unfortunately, the committee has no further information on what else NSW Health and the Cancer Institute are doing to improve the number of such referrals, but presumably the efforts are targeted towards general practitioners and patients.
- 8.96** For the committee, patients' access to these teams is of critical importance, given the evidence we have received about the many advantages of multidisciplinary care, not just in preventing off-protocol chemotherapy prescribing but more fundamentally in ensuring quality care. We believe that the time has come to move beyond 'examining ways to ensure' patients are overseen by an MDT, towards making this happen. We recommend that the Ministry and Cancer Institute develop and implement an action plan to this end.

Recommendation 6

That the NSW Ministry of Health and Cancer Institute NSW develop and implement an action plan to ensure that all people diagnosed with notifiable cancer in New South Wales have their care overseen by a multidisciplinary cancer care team that includes all relevant medical, nursing, pharmacy and allied health staff.

- 8.97** As a separate but related issue, the question of whether MDTs can better prevent off-protocol prescribing informed the committee's questioning of St Vincent's Hospital representatives about why the hospital's head and neck MDT had not been aware of Dr Grygiel's dosing practices (see paragraphs 4.24 to 4.29). We were advised that the MDT discusses the patient prior to their surgery and other treatment, and, at that point, it is too early for decisions about chemotherapy dosage. Rather, dosage decisions are subsequently made in a one-on-one consultation with the medical oncologist, taking account of pathology reports and other information.
- 8.98** For the committee, this raised the issue of whether an MDT has a one-off or ongoing role in respect of individual patients. The overview of multidisciplinary care set out in the NSW Health submission emphasises prospective treatment planning for individual patients but does not shed further light on the issue. Notably, the Canrefer website administered by the Cancer Institute NSW indicates an ongoing role for these teams by defining an MDT as 'a team of doctors, nurses and allied health professionals who meet regularly to plan treatment for people with newly diagnosed cancer and to review the treatment plans of existing patients during or after their treatment.'⁶⁷⁸
- 8.99** Based on the evidence we received, it appears that the relevant MDT at St Vincent's Hospital only had a one-off role with respect to individual patients, with those patients not discussed again by the team. If this is the case, it raises questions about how other MDTs across the state, for any cancer type, are functioning in terms of ongoing oversight of individual patient treatment. The reason why this is important is that an ongoing review role may have provided greater oversight of Dr Grygiel's prescribing and helped to identify his off-protocol dosing. It is also important because surely an ongoing role goes hand in hand with holistic, quality patient care.
- 8.100** The committee recognises that an ongoing role for MDTs demands additional time from clinicians and others, and implies additional resourcing more broadly, but if it results in better oversight of patients and higher quality, holistic care, then an ongoing role should be standard practice.
- 8.101** In addition to the key issue of whether dosage itself is discussed by an MDT, during our inquiry issues have been raised with respect to the composition of MDTs and whether attendance should be compulsory. Obviously there are many complex issues here. Clinicians are already time poor, the broader health system is already very stretched, and individual clinicians possess expertise in their respective fields.
- 8.102** Nevertheless, the committee considers that all of these issues should be examined by NSW Health and the NSW Cancer Institute via a review of best practice in multidisciplinary cancer care teams. The review should consider the benefits of ongoing team oversight of individual patients, the role of the team with respect to oversight of dosing decisions, team membership and whether attendance should be compulsory.

⁶⁷⁸ Canrefer, NSW Cancer Institute, <https://www.canrefer.org.au/about-canrefer/about-canrefer>.

Recommendation 7

That the NSW Ministry of Health and the Cancer Institute NSW undertake and publish a review of best practice in multidisciplinary cancer care teams that considers the evidence about:

- the benefits of ongoing team oversight of individual patients
- the role of the team with respect to oversight of chemotherapy dosing decisions
- team membership
- whether clinician attendance should be compulsory.

The review should then form the basis for NSW Health policy in respect of multidisciplinary cancer care teams across New South Wales.

- 8.103** In relation to informed consent, the committee is mindful that signed consent is very different to informed consent, in which a patient fully understands their treatment and the benefits and risks involved. We acknowledge the perspective of patients and caregivers, that doctors are time poor and often authoritative in their manner, and of doctors, that the process is complex and necessarily occurs over a period of time.
- 8.104** The committee recognises that in the context of cancer, informed consent raises particular challenges. The patient and their family have just had their world blown apart by their diagnosis. In addition, chemotherapy, radiation treatment and surgery are all complex procedures carrying substantial risks, all of which require careful explanation. Hence, it is very often the case that only after a patient returns for a second or perhaps even a third visit, that they can absorb the information required for their consent to be truly informed. The committee heard that consent to chemotherapy cannot take a standardised approach, but must respond to the unique needs of the patient.
- 8.105** While we received evidence that many clinicians fully appreciate their obligations here, the experience at St Vincent's Hospital, Macquarie Hospital and the Western NSW Local Health District highlights the substantial risks – both to patient's safety and to the integrity of the health system – when clinicians do not fulfil their obligations.
- 8.106** The committee acknowledges the work that NSW Health is doing to provide additional, practical guidance to medical and other health practitioners about informed consent procedures, and to enhance compliance. We agree with the requirement that written patient consent be obtained for chemotherapy. In addition, we support Professor Currow's view on the additional imperative to empower patients more effectively through the provision of material that both informs them and enhances their interactions with doctors. We recommend that NSW Health and the Cancer Institute NSW continue to address both dimensions of this very important work.

Recommendation 8

That NSW Ministry of Health:

- continue to build the capacity of all health professionals to fulfil their ethical and legal obligations with regard to informed consent
 - with the Cancer Institute NSW, implement further strategies to empower patients to fully exercise informed consent.
-

- 8.107** Consistent with this, the committee recommends that NSW Ministry of Health implement improved patient consent procedures, including two particular measures. First, all patients must be provided with a copy of the NSW Cancer Institute's eviQ chemotherapy protocol at education sessions ahead of their first treatment. Second, when consent is obtained after a non-eviQ plan is recommended, patients must be provided with information about the proposed protocol, including the clinical rationale for it, and a completed patient consent form be scanned into the patient information system. The committee further recommends that NSW Ministry of Health ensure that all key clinical staff are educated in expectations regarding valid informed consent.
-

Recommendation 9

That the NSW Ministry of Health implement improved patient consent procedures which include 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
- when consent is obtained after a non-eviQ plan is recommended, patients are provided with information about the proposed protocol, including the clinical rationale for it, and a completed patient consent form is scanned into the patient information system.

Recommendation 10

That the NSW Ministry of Health ensure that all key clinical staff are educated in expectations regarding valid informed consent.

- 8.108** The events at St Vincent's Hospital highlight the ongoing need to support the reporting and management of clinical incidents, in order to ensure that health staff report inappropriate clinical practices and that such reports are managed and investigated effectively.

- 8.109** The committee acknowledges the work that is progressing to establish the new ims+ incident management system across the state. We would be interested to know more about the supports (other than policies and guidelines) available to LHDs, health network and hospital staff charged with responding to these incidents. The unique St Vincent's Hospital scenario suggests that the hospital would have benefited from outside assistance at a much earlier stage of events. We have not taken evidence on the centralised clinical governance supports that are available to LHDs and specialty networks, but a 'one stop shop' that provides advice and guidance may have some value.
-

- 8.110** A fundamental message from the section 122 inquiry was that robust regulatory systems and policies will fall down when an organisation's culture is poor. The highly problematic culture that existed at the time in St Vincent's Hospital's cancer services may also exist in other parts of the state's hospital system. In the committee's view, all parts of our health system across the state must continually build a culture that is constructive, inclusive, and both people and patient focused. As we emphasised in chapter 4, this requires highly effective leadership and a genuine commitment to cultural excellence. Culture is also everybody's responsibility, and training at every level of the organisation can be a valuable way of engendering change.
- 8.111** Finally, the committee sees value in the model of patient advisor-advocate proposed to us as a means of empowering patients and families during their health crisis. We recommend that NSW Health consider establishing such positions, informed by the official visitor model.

Recommendation 11

That the NSW Ministry of Health consider establishing a system of independent patient advisor-advocates in hospital cancer services, based on the official visitor model, as a means of empowering patients.

Appendix 1 Submissions

No	Author
1	Name suppressed
2	Professor David L Morris
3	Ms Debra Smith
4	Confidential
5	Dr Leong-Fook Ng (Partially confidential)
5a	Dr Leong-Fook Ng
6	Mrs Natalie & Mr Ken Dugdale (Partially confidential)
6a	Confidential
7	Ms Cheryl Mae Hingerty (Partially confidential)
8	Dr Kevin Hanel
9	Mrs Alice & Prof. Sever Sternhell (Partially confidential)
10	Dr Tanya Phillips
11	Ms Linda Patterson
12	Confidential
13	Name suppressed
14	Mr Michael Douglas
15	Mr Richard Newburg
16	Professor Barry J Allen PhD Dsc AO
16a	Professor Barry J Allen PhD Dsc AO
17	Name suppressed (Partially confidential)
18	Mr James Dyson
19	Mr John Ayliffe (Partially confidential)
20	Name suppressed
21	Mr Stuart Hills
22	Mr Barry Bradshaw
23	Mrs Corinne Stolzenhein
24	Mrs Joy Packer
25	Confidential
26	Name suppressed (Partially confidential)
27	Mr Jeff Puckeridge (Partially confidential)
28	Mr Fred Hanssens (Partially confidential)
29	Mr Kevin Moran

No	Author
30	Mr Francis Mawby JP
31	Mr Cornelis Snel
32	Mrs Pat Jesson (Partially confidential)
33	Confidential
34	Sister Vianney Hatton
35	Name suppressed
36	Name suppressed
37	Mr Ron Backhouse
38	Mr Neville Hatton (Partially confidential)
39	Mr Brian Bown
40	Ms Ruth Irwin (Partially confidential)
40a	Ms Ruth Irwin
41	Mr James Lees
42	Mr John A Masterson
43	Mr Anthony Ainsworth (Partially confidential)
44	Name suppressed
45	Name suppressed (Partially confidential)
46	Confidential
47	Confidential
48	Mr Dennis King
49	NSW Health
50	Professor Stephen Ackland & Professor Jennifer Martin, University of Newcastle
51	Name suppressed (Partially confidential)
52	Confidential
53	Ms Kim Dunn
54	Mr Gary Challinor
55	Medical Oncology Group of Australia
55a	Medical Oncology Group of Australia
56	Name suppressed
57	Name suppressed
58	Mr Themis Theo
59	St Vincent's Hospital Sydney
60	Name suppressed (Partially confidential)
61	Mr Matthew Fitzgerald

No	Author
62	Confidential
63	Name suppressed (Partially confidential)
64	Dr Jodi Lynch
65	Name suppressed (Partially confidential)
66	Mr Brian Nobbs (Partially confidential)
67	Mr Arthur Harris
68	Mrs Daphne Patterson
69	Mr William (Bill) Peters
70	Mr Andrew Finney
71	Ms Doreen Monti
72	Mr Garry Clarke
73	Mrs Lois Aspin (Partially confidential)
74	Mrs Margaret Cantrell
75	Name suppressed (Partially confidential)
76	Name suppressed (Partially confidential)
77	Mr Ray Butcher
78	Confidential
79	Confidential
80	Mr Trevor & Mrs Kim McGuire (Partially confidential)
80a	Mr Trevor & Mrs Kim McGuire
81	Ms Jill Newth
82	Ms Sharon Drake
83	Mrs Kay and Mr Gary Osmond
84	Name suppressed (Partially confidential)
85	Confidential
86	Group of General Practitioners in the Sutherland area
87	Mr Stephen Thornley
88	Name suppressed (Partially confidential)
89	Ms Eileen Draper
90	Mr Alan Brett (Partially confidential)
91	Ms Sandra Greck
92	Name suppressed (Partially confidential)
93	Mr Alan Branch
94	Name suppressed (Partially confidential)

No	Author
95	Dr Laurence J Denholm
95a	Dr Laurence J Denholm
95b	Confidential
96	Ms Barbara Krickl
97	Dr Louis McGuigan
98	Confidential
99	Name suppressed (Partially confidential)
100	Macquarie University Hospital (Partially confidential)
101	Mr Jeffrey Saunders (Partially confidential)
102	Mrs Judy Hills & Mr Adam & Mr Brad Hills (Partially confidential)
103	Name suppressed
103a	Confidential
104	Name suppressed (Partially confidential)
105	Mr Josef Ressler (Partially confidential)
106	Mrs Susan Green (Partially confidential)
107	Name suppressed
108	Cancer Voices NSW
109	Confidential
110	Confidential
111	Name suppressed (Partially confidential)
112	Mr Keith Winstanley
113	Dr Jim Sternhell BDS (Partially confidential)
114	Ms Ann Schiller
115	CCA Healthcare

Appendix 2 Witnesses

Date	Name	Position and Organisation
Monday 31 October 2016 Macquarie Room, Parliament House, Sydney	Professor David Currow	Chief Cancer Officer, NSW, Chief Executive Officer, Cancer Institute NSW and Co-leader, section 122 inquiry
	Dr Paul Curtis	Director, Governance and Assurance, NSW Clinical Excellence Commission, and Co-leader, section 122 inquiry
	Mr Paul Gavel	Director, Workforce, HealthShare NSW, and member, section 122 inquiry
	Ms Susan Pearce	Deputy Secretary, System Purchasing and Performance, NSW Ministry of Health
	Ms Karen Crawshaw	Deputy Secretary, Governance, Workforce and Corporate, NSW Ministry of Health
	Mr Toby Hall	Group Chief Executive Officer, St Vincent's Health Australia
	Associate Professor Anthony Schembri	Chief Executive Officer, St Vincent's Health Network, Sydney
	Associate Professor Richard Gallagher	Director of Cancer Services, St Vincent's Health Network Sydney
	Mr David Faktor	Director of Media and Communications, St Vincent's Health Network Sydney
	Dr Stephen Cooper	Radiation Oncologist, Genesis Cancer Care NSW, and Chair, Head and Neck Multi-disciplinary Committee, St Vincent's Hospital
Dr David Bell	Senior Medical Oncologist, Northern Cancer Institute	
Tuesday 1 November 2016 Macquarie Room, Parliament House, Sydney	Dr John Grygiel	Medical Oncologist
	Mr Gerry Marr	Chief Executive, South Eastern Sydney Local Health District
	Dr James Mackie	Medical Executive, Director, South Eastern Sydney Local Health District
	Dr Jo Karnaghan	District Director of Medical Services, South Eastern Sydney Local Health District

Date	Name	Position and Organisation
	Ms Margaret Savage	Director of Professional Practice Unit, South Eastern Sydney Local Health District
	Professor Jennifer Martin	Chair of Clinical Pharmacology, University of Newcastle
	Professor Stephen Ackland	Director, Hunter Cancer Research Alliance, University of Newcastle
Wednesday 2 November 2016 Coral Sea Room, Ex-Services' Club, Orange	Mr Scott McLachlan	Chief Executive Officer, Western NSW Local Health District
	Dr Rob Zielinski	Medical Oncologist, Central West Cancer Care Centre, Orange Health Service
	Ms Ruth Jones	Director, Cancer Services Innovation, Western NSW Local Health District
	Ms Di Wykes	Director, Cancer Services Innovation, Western NSW Local Health District
	Ms Sue Patterson	General Manager, Bathurst Health Service
	Ms Catherine Nowlan	General Manager, Orange Health Service
Tuesday 29 November 2016 Jubilee Room, Parliament House, Sydney	Dr Kerry Chant	Chief Health Officer, NSW Ministry of Health
	Professor David Currow	Chief Cancer Officer, NSW, Chief Executive, Cancer Institute NSW, and Co-leader, section 122 inquiry
	Dr Paul Curtis	Director, Governance and Assurance, NSW Clinical Excellence Commission, and Co-leader, section 122 inquiry
	Mr Paul Gavel	Director Workforce, HealthShareNSW, and Member, section 122 inquiry
	Dr Tina Chen	Medical and Scientific Advisor, Cancer Institute NSW, and Member, section 122 inquiry
	Mr Toby Hall	Group Chief Executive Officer, St Vincent's Health Australia
	Ms Gabrielle Prest	Medicine Clinical Stream Manager, St Vincent's Health Network Sydney

Date	Name	Position and Organisation
	Mr David Faktor	Director of Media and Communications, St Vincent's Health Network Sydney
	Associate Professor Richard Gallagher	Director of Cancer Services, St Vincent's Health Network Sydney
	Mr David Dalley	Former head of Medical Oncology, St Vincent's Health Network, Sydney
	Dr Brett Gardiner	Former Director, Clinical Governance and former Chief Medical Officer, St Vincent's Health Network, Sydney
Friday 24 February 2017 Jubilee Room, Parliament House, Sydney	Ms Sue Dawson	Commissioner, NSW Health Care Complaints Commission
	Mr Tony Kofkin	Director of Investigations, NSW Health Care Complaints Commission
	Dr Greg Kesby	President, Medical Council of New South Wales
	Ms Carol Bryant	Chief Executive Officer Macquarie University Hospital
Friday 31 March 2017 Macquarie Room, Parliament House, Sydney	Dr Kiran Phadke	Medical Oncologist and Haematologist
	Mr Gerry Marr	Chief Executive, South Eastern Sydney Local Health District
	Dr James Mackie (<i>via teleconference</i>)	Medical Executive, Director, South Eastern Sydney Local Health District
	Dr Jo Karnaghan	District Director of Medical Services, South Eastern Sydney Local Health District
	Ms Margaret Savage	Director of Professional Practice Unit, South Eastern Sydney Local Health District

Appendix 3 Section 122 inquiry recommendations⁶⁷⁹

Number	Recommendation
Recommendation 1 <i>(Interim report)</i>	That St Vincent's Hospital as a priority, apologise to patients and their families for any distress that this off-protocol prescribing or its reporting has caused.
Recommendation 2 <i>(Interim report)</i>	That St Vincent's Hospital ensure that every patient or his/her family is given the opportunity to participate fully in an Open Disclosure process.
Recommendation 3 <i>(Interim report)</i>	That St Vincent's Hospital supports patients whose care has been affected to have ongoing follow-up in another oncology unit if that's their choice.
Recommendation 4 <i>(Final report – amended)</i>	Reports on patient outcomes to the Hospital's Patient Safety and Quality Committee and Clinical Council on six monthly, and annually to the Deputy Secretary, NSW Ministry of Health.
Recommendation 5 <i>(Interim report)</i>	That the Inquiry provide patients and their families with the opportunity to provide information to the Inquiry, now that the magnitude and likely effects of this off-protocol prescribing have started to be quantified.
Recommendation 6 <i>(Interim report)</i>	That the NSW Cancer Registry, managed by the Cancer Institute NSW, flag every patient identified by this Inquiry who has had an off-protocol flat dose of 100mg carboplatin prescribed for the treatment of cancer so that outcomes for this group of people are systematically evaluated on a regular basis, and that survival analyses can be undertaken on this cohort of patients in relation to people with comparable disease.
Recommendation 7 <i>(Interim report)</i>	That St Vincent's Hospital provide education to key staff on those key policies, including the Lookback Policy, given the findings in relation to the policies.
Recommendation 8 <i>(Interim report)</i>	That St Vincent's Hospital manage any similar incidents with sufficient content-specific expertise and an explicit methodology for defining the magnitude and impact of the clinical incident and its likely consequences.
Recommendation 9 <i>(Interim report)</i>	That St Vincent's Hospital review the process of preparing and verifying public statements within the Hospital to include relevant consultation, content expertise and sign-off.
Recommendation 10 <i>(Interim report)</i>	That St Vincent's Hospital ensure that Mortality and Morbidity meetings use data beyond individual patients to examine patterns of care and outcomes benchmarked with similar hospitals or health services or, at least, the most recent, relevant peer-reviewed literature.

⁶⁷⁹ This table sets out the recommendations in the interim and final reports of the section 122 inquiry. It does not include those in the Western NSW report.

Recommendation 11 <i>(Final report - amended)</i>	Given the categorisation of ‘unanticipated’ would not have flagged any of the patients affected by this off-protocol prescribing for review by the hospital-wide Mortality Review Committee, it is recommended that the Committee consider reviewing a random selection of ‘expected’ deaths rather than relying on the subjective decision that the death was ‘unanticipated’.
Recommendation 12 <i>(Interim report)</i>	That St Vincent’s Hospital revisit mechanisms for escalation of clinical concerns to ensure that key line-managers are seen as crucial to the process of adequately addressing clinical concerns from junior nursing, pharmacy and medical staff
Recommendation 13 <i>(Interim report)</i>	Given clinicians should be able to override doses once entered into MOSAIQ where appropriate for an individual patient, Local Health Districts and Speciality Networks to ensure that the most senior oncology pharmacist and the head of medical oncology review such overrides regularly to identify any patterns that may suggest similar dosing issues
Recommendation 14 <i>(Interim report)</i>	That Local Health Districts and Speciality Networks pre-load eviQ protocols into electronic chemotherapy prescribing systems.
Recommendation 15 <i>(Interim report)</i>	That Local Health Districts and Speciality Networks ensure that minuted meetings of Multidisciplinary Cancer Care teams occur after relevant international or national meetings and on an ad-hoc basis as seminal new evidence emerges that should influence practice.
Recommendation 16 <i>(Interim report)</i>	That the Cancer Institute NSW works with oncology groups to facilitate meetings occurring after major conferences to review new evidence and agree on which of the evidence should be adopted.
Recommendation 17 <i>(Interim report)</i>	That the Cancer Institute NSW prepares a new patient information sheet on dose adjustment of chemotherapy to allow patients and their caregivers to understand the rationale for it.
Recommendation 18 <i>(Interim report)</i>	That the Ministry of Health, with the Cancer Institute NSW, examine ways to ensure that all people diagnosed with notifiable cancer in NSW have their care overseen by a Multidisciplinary Cancer Care Team that includes all relevant medical, nursing, pharmacy and allied health staff.
Recommendation 19 <i>(Interim report)</i>	That the Secretary, NSW Ministry of Health, expand the terms of reference of this Inquiry to include: patients treated by Dr Grygiel in Western NSW Local Health District (or its predecessors) back to the beginning of 2006 (when CiSCAT, the predecessor of eviQ first became available); and patients treated since 2006 by Dr Grygiel at St Vincent’s Hospital Darlinghurst.
Recommendation 20 <i>(Interim report)</i>	Now that the magnitude of the systematic off-protocol prescribing is apparent, expand the Terms of Reference of this Inquiry to include information provided to the affected patients and their families in consenting to treatment by Dr Grygiel and the impact on them.
Recommendation 21 <i>(Final report)</i>	Ensure adequate informed consent for all medical interventions, including chemotherapy. If the clinician knows that his/her practice is outside accepted practice, there is a particular onus to draw this to the attention of patients in the process of providing informed consent, and to document this in the patient notes.

<p>Recommendation 22 <i>(Final report)</i></p>	<p>There are a number of outsourced providers in oncology across NSW in areas such as compounding pharmacy and radiotherapy. These providers should have the same responsibility to demonstrate the quality of their care and share clinical data as any other member of the multidisciplinary cancer care team. They should also have the same responsibilities to contribute to the fail-safe checks that are a hallmark of good multidisciplinary teams and evidence-based clinical care, including escalation where there are concerns about care that have not been adequately addressed. This should be properly reflected in relevant contracts as they are negotiated between Local Health Districts/Specialty Health Networks and third party providers.</p>
<p>Recommendation 23 <i>(Final report)</i></p>	<p>That St Vincent's Hospital initiate, and oversee, a program that will build within cancer services a constructive, people-focused culture for patients and staff. This should include a facilitated restorative program to rebuild relationships and trust within the senior clinical community in cancer services, and between cancer services and hospital management.</p>

Appendix 4 Minutes

Minutes no. 1

Tuesday 23 August 2016

Select Committee on Off-Protocol Prescribing of Chemotherapy in NSW

Room 1136, Parliament House at 1.00 pm

1. Members present

Mr Green (*Chair*)

Mrs Taylor (*Deputy Chair*)

Mr Buckingham

Mrs Houssos

Mr Khan

Mrs Maclaren-Jones

Mr Secord

2. Tabling of resolution establishing the committee

The Chair tabled the resolution of the House establishing the committee, which reads as follows:

1. That a select committee be established to inquire into and report on off-protocol prescribing of chemotherapy in NSW including at St Vincent's Hospital, St George Hospital, Sutherland Hospital, Macquarie University Hospital and clinics at Orange and Bathurst, and in particular:
 - (a) the efficacy of electronic prescribing systems, and their capacity to stop or limit off-protocol prescribing of chemotherapy,
 - (b) the value of a potential new patient information sheet on dose adjustment for patients and caregivers information,
 - (c) the process and systems around informed consent for all medical interventions, including chemotherapy,
 - (d) the capacity of the NSW Health system to have all notifiable cancer patients in New South Wales overseen by a Multidisciplinary Cancer Care Teams, and if this may prevent off-protocol prescribing,
 - (e) St Vincent's Hospital capability to comply with relevant NSW Health Policy Directives and Guidelines, particularly Open Disclosure Policy (PD2014_028) and Incident Management Policy (PD2014_004),
 - (f) the NSW Health Code of Conduct and specific programmes within NSW Health and St Vincent's Hospital, in relation to staff raising concerns about the practice of clinicians, and other breaches of the Code of Conduct.
2. That, notwithstanding anything to the contrary in the standing orders, the committee consist of seven members comprising:
 - (a) three government members, being Mrs Taylor, Mrs Maclaren-Jones and Mr Khan,
 - (b) two opposition members, being Mr Secord and a member nominated by the Leader of the Opposition, and
 - (c) two crossbench members, being Mr Green and Mr Buckingham.
3. That the Chair of the committee be Mr Green and the Deputy Chair be Mrs Taylor.

4. That members may be appointed to the committee as substitute members for any matter before the committee by providing notice in writing to the Committee Clerk, with nominations made as follows:
 - (a) nominations for substitute government or opposition members are to be made by the Leader of the Government, Leader of the Opposition, Government or Opposition Whip or Deputy Whip, as applicable, and
 - (b) nominations for substitute crossbench members are to be made by the substantive member or another crossbench member.
5. That a committee member who is unable to attend a deliberative meeting in person may participate by electronic communication and may move any motion and be counted for the purpose of any quorum or division, provided that:
 - (a) the Chair is present in the meeting room,
 - (b) all members are able to speak and hear each other at all times, and
 - (c) members may not participate by electronic communication in a meeting to consider a draft report.
6. That, unless the committee decides otherwise:
 - (a) submissions to inquiries are to be published, subject to the Committee Clerk checking for confidentiality and adverse mention and, where those issues arise, bringing them to the attention of the committee for consideration,
 - (b) the Chair's proposed witness list is to be circulated to provide members with an opportunity to amend the list, with the witness list agreed to by email, unless a member requests the Chair to convene a meeting to resolve any disagreement,
 - (c) the sequence of questions to be asked at hearings alternate between opposition, crossbench and government members, in that order, with equal time allocated to each,
 - (d) transcripts of evidence taken at public hearings are to be published,
 - (e) supplementary questions are to be lodged with the Committee Clerk within two days, excluding Saturday and Sunday, following the receipt of the hearing transcript, with witnesses requested to return answers to questions on notice and supplementary questions within 21 calendar days of the date on which questions are forwarded to the witness, and
 - (f) answers to questions on notice and supplementary questions are to be published, subject to the Committee Clerk checking for confidentiality and adverse mention and, where those issues arise, bringing them to the attention of the committee for consideration.
7. That the committee:
 - (a) commence its inquiry after the inquiry under Section 122 of the Health Service Act 1997 releases its findings in relation to the dosing of cancer patients at Western NSW Local Health District, due to occur on 16 September 2016, and
 - (b) report by March 2017.

3. Correspondence

The committee noted the following item of correspondence.

Received:

- 17 August 2016 – letter from the Hon Walt Secord to the Chair, regarding the conduct of the committee's inquiry.

4. Conduct of the inquiry into off-protocol prescribing of chemotherapy in NSW

4.1 Inquiry timeline

The committee noted that under the resolution of the House, the committee is not authorised to commence its inquiry until after the inquiry under section 122 of the *Health Service Act 1997* releases its findings in relation to dosing of cancer patients at the Western NSW Local Health District, due to occur on 16 September 2016.

Resolved, on the motion of Mr Khan: That the committee meet on a date after the 16 September 2016 to discuss the future conduct of the inquiry.

Resolved, on the motion of Mr Buckingham: That the secretariat commence preparing a draft list of stakeholders to be invited to make written submissions, which would include Mr Secord's preliminary list of witnesses identified in his correspondence of 17 August, and that the list be provided to members before the next meeting.

4.2 Briefing from the Clerk

The Clerk of the Parliaments provided a briefing on possible procedural issues relating to the inquiry.

5. Adjournment

The committee adjourned at 1.35 pm, *sine die*.

Teresa McMichael

Clerk to the Committee

Minutes no. 2

Tuesday 20 September 2016

Select Committee on Off-Protocol Prescribing of Chemotherapy in NSW

Room 1043, Parliament House at 1.02 pm

1. Members present

Mr Green (*Chair*)

Mrs Taylor (*Deputy Chair*)

Mr Buckingham (from 1.03 pm)

Mrs Houssos

Mr Khan

Mrs Maclaren-Jones

Mr Secord (via teleconference)

2. Draft minutes

Resolved, on the motion of Mr Khan: That draft minutes no. 1 be confirmed.

3. Conduct of committee proceedings - media

Resolved, on the motion of Mr Khan: That unless the committee decides otherwise, the following procedures are to apply for the life of the committee:

- the committee authorise the filming, broadcasting, webcasting and still photography of its public proceedings, in accordance with the resolution of the Legislative Council of 18 October 2007
- the committee webcast its public proceedings via the Parliament's website, where technically possible
- the committee adopt the interim guidelines on the use of social media and electronic devices for committee proceedings, as developed by the Chair's Committee in May 2013
- media statements on behalf of the committee be made only by the Chair.

Mr Buckingham arrived at 1.03 pm.

4. **Inquiry timeline**

The committee noted that the following dates had been set aside for inquiry activities: 31 October, 1 November, 2 November and 29 November 2016.

Resolved, on the motion of Mrs Maclaren-Jones: That the committee receive a private briefing regarding best practice chemotherapy treatment on 31 October 2016 from 9am-11am, and that the briefing be recorded by Hansard.

Resolved, on the motion of Mrs Houssos: That the committee conduct hearings in Sydney on 31 October, 1 November and 29 November, and in Orange on 2 November 2016.

5. **Closing date for submissions**

Resolved, on the motion of Mrs Maclaren-Jones: That the closing date for submissions be Sunday 23 October 2016.

6. **Stakeholder list**

Resolved, on the motion of Mr Khan: That members have until 12pm Wednesday 21 September 2016 to nominate additional stakeholders to the stakeholder list.

7. **Advertising**

Resolved, on the motion of Mr Buckingham: That the committee advertise the inquiry in the Early General News sections of the Sydney Morning Herald, Daily Telegraph, Bathurst Western Advocate, Central Western Daily and Dubbo Daily Liberal on Wednesday 28 September 2016.

Resolved, on the motion of Mrs Maclaren-Jones: That the total costs of advertising be tabled with the committee.

8. **Adjournment**

The committee adjourned at 1.24 pm until Monday 31 October 2016 (private briefing and public hearing).

Teresa McMichael

Clerk to the Committee

Minutes no. 3

Monday 31 October 2016

Select Committee on Off-Protocol Prescribing of Chemotherapy in New South Wales
Macquarie Room, Parliament House at 8.45 am

1. **Members present**

Mr Green (*Chair*)
Mrs Taylor (*Deputy Chair*)
Mr Buckingham (from 8.50 am)
Mrs Houssos
Mr Khan
Mrs Maclaren-Jones
Mr Secord

2. **Draft minutes**

Resolved, on the motion of Mrs Houssos: That draft minutes no. 2 be confirmed.

3. Correspondence

The committee noted the following item of correspondence:

Received:

- 17 October 2016 – Email exchange between Associate Professor Anthony Schembri, Chief Executive Officer, St Vincent’s Health Network, and secretariat, regarding invited witnesses
- 19 October 2016 – Email from Ms Kathy Chapman, Director, Cancer Programs Division, Cancer Council NSW, to secretariat, indicating that the Cancer Council NSW does not wish to appear at a hearing
- 20 October 2016 – Letter from Moray & Agnew Lawyers on behalf of Dr Phadke to the Chair regarding the committee’s media release and his participation in the inquiry
- 24 October 2016 – Email from Dr Stephen Cooper, Radiation Oncologist, Genesis Cancer Care, and Chair, multi-disciplinary head and neck unit, St Vincent’s Hospital, to secretariat, requesting to be accompanied to his hearing by a support person and that confidential patient information not be canvassed during the public hearing
- 27 October 2016 – Email from Ms Helen Turnbull, Special Counsel, Professional Conduct, Avant Mutual Group Ltd, requesting that Dr John Grygiel be accompanied by two legal advisers
- 28 October 2016 – Letter from Mr Gerry Marr, Chief Executive, South Eastern Sydney Local Health District to secretariat, requesting to give certain evidence in camera at the 1 November 2016 hearing
- 31 October 2016 – Email exchange with NSW Health officers regarding Western NSW Local Health District representatives to give evidence on 2 November 2016.

Sent:

- 26 October 2016 – Letter from Chair to Moray & Agnew Lawyers representing Dr Phadke regarding the committee’s media release and his participation in the inquiry
- 31 October 2016 – Letter from Chair to Ms Deborah Hyland, Director, Strategic Relations and Communications, NSW Health, encouraging the requested representatives from Western NSW Local Health District to accept the committee’s invitation to give evidence on 2 November 2016.

4. Correspondence from Moray & Agnew on behalf of Dr Phadke

Resolved, on the motion of Mrs Houssos: That the committee authorise the publication of correspondence from Moray & Agnew Lawyers on behalf of Dr Phadke to the Chair regarding the committee’s media release and his participation in the inquiry, dated 20 October 2016 and the committee’s response to this letter, dated 26 October 2016.

Resolved, on the motion of Mr Khan: That the committee permanently keep its media release off the website and advise Dr Phadke’s lawyers accordingly.

Mrs Taylor moved: That the committee write to the South Eastern Sydney Local Health District, with a copy to the Minister, to seek assurances that employees can freely participate in the inquiry, and that this correspondence be published.

Question put.

The committee divided.

Ayes: Mr Green, Mr Khan, Mrs Maclaren-Jones, Mrs Taylor.

Noes: Mr Buckingham, Mrs Houssos, Mr Secord.

Question resolved in the affirmative.

5. Requested St Vincent’s Hospital witness: Professor Brett Gardiner

The committee noted that the secretariat has been unable to make contact with Professor Brett Gardiner, Former Director of Clinical Governance at St Vincent’s Hospital, as he no longer works for the hospital and the contact details held by St Vincent’s are no longer current. Internet searches have provided no further assistance in locating Professor Gardiner.

6. Support person for Dr Stephen Cooper

Resolved, on the motion of Mr Buckingham: That the committee agree to allow Dr Cooper to be accompanied by a support person during his appearance at the hearing, subject to the support person sitting next to the witness and not taking an active role during proceedings.

7. Legal advisors for Dr Grygiel

Resolved, on the motion of Mr Khan: That the committee agree to allow Dr Grygiel to be accompanied by his legal advisors during his appearance at the hearing, subject to the legal advisor sitting next to the witness to assist in an advisory capacity only and not taking an active role during proceedings.

8. Western NSW Local Health District representatives to appear at the 2 November 2016 public hearing

Resolved, on the motion of Mrs Taylor: That the committee write to NSW Health encouraging the requested representatives from Western NSW Local Health District to accept the committee's invitation to give evidence on 2 November 2016.

9. Approach regarding naming of individual patients during the public hearings

The Chair briefed the committee on the proposed approach to discussion of patients and other individuals during the public hearing.

10. Requests for *in camera* hearings

Resolved, on the motion of Mr Khan: That the committee agree to requests from patients or their family members who are appearing as a witness to give evidence *in camera*, on the understanding that their transcript may be published with identifying information redacted.

Resolved, on the motion of Mrs Maclaren-Jones: That the committee take evidence from representatives of the South Eastern Sydney Local Health District in public, and then take evidence *in camera* specifically in relation to the investigation concerning Dr Kiran Phadke.

11. Public submissions

The committee noted that the following submissions were published by the committee clerk under the authorisation of the resolution appointing the committee: submission nos. 2, 3, 10, 11, 14-16a, 18, 21-24, 29-31, 39, 40a, 41, 42, 48-50, 55, 58, 59, 64, 67, 69-71, 77 and 8, 53, 54, 74, 83, 87, 89, 91, 95, 97.

12. Partially confidential submissions

Resolved, on the motion of Mr Khan:

- That the committee authorise the publication of submission nos. 1, 13, 20, 35, 36, 44, 45, 56, 57, 60, 79, 92, 94 with the exception of potential adverse mention, identifying and/or sensitive information which are to remain confidential, as per the request of the author
- That the committee authorise the publication of submission nos. 5, 7, 19, 27, 28, 32, 38, 40, 65, 66, 80, with the exception of potential adverse mention, identifying and/or sensitive information which are to remain confidential, as per the recommendation of the secretariat.

13. Confidential submissions

Resolved, on the motion of Dr Khan:

- That the committee keep submission nos 6, 12, 46, 47, 52, 62, 78, 85 confidential, as per the request of the author as they contain identifying and/or sensitive information or they contain potential adverse mention.
- That the committee keep submission no 4 confidential, as per the recommendation of the secretariat, as they contain identifying and/or sensitive information.

14. Private briefing with Dr David Bell, Senior Medical Oncologist, Northern Cancer Institute

Dr Bell briefed the committee on best practice chemotherapy treatment.

Dr Bell tendered the following document:

- Janette Vardy, Ryan Dadasovich, Philip Beale, Michael Boyer and Stephen J Clarke, 'Eligibility of patients with advanced non-small cell lung cancer for phase III chemotherapy trials' (2009) *BMC Cancer*.

15. Public hearing

Witnesses, the public and the media were admitted.

The Chair made an opening statement regarding the broadcasting of proceedings and other matters.

The following witnesses were sworn and examined:

- Professor David Currow, Chief Executive, Cancer Institute of NSW
- Dr Paul Curtis, Director, Governance and Assurance, NSW Clinical Excellence Commission
- Mr Paul Gavel, Director, Workforce, HealthShareNSW.

The evidence concluded and Dr Curtis and Dr Gavel withdrew.

The Chair reminded Professor Currow that he did not need to be sworn, as he had been sworn at an earlier hearing.

The following witnesses were sworn and examined:

- Ms Susan Pearce, Deputy Secretary, System Purchasing and Performance, NSW Ministry of Health
- Ms Karen Crawshaw, Deputy Secretary, Governance, Workforce and Corporate, NSW Ministry of Health.

The evidence concluded and the witnesses withdrew.

The following witnesses were sworn and examined:

- Mr Toby Hall, Group CEO, St Vincent's Health Australia
- Associate Professor Anthony Schembri, CEO, St Vincent's Health Network, Sydney
- Associate Professor Richard Gallagher, Director of Cancer Services, St Vincent's Health Network Sydney
- Ms Gabrielle Prest, Medicine Clinical Stream Manager, St Vincent's Health Network Sydney
- Mr David Faktor, Director of Media and Communications, St Vincent's Health Network Sydney.

The evidence concluded and the witnesses withdrew.

The following witness was sworn and examined:

- Dr Stephen Cooper, Radiation oncologist, Genesis Cancer Care NSW, and Chair, head and neck multi-disciplinary committee, St Vincent's Hospital.

The evidence concluded and the witness withdrew.

16. Tendered documents

Resolved, on the motion of Mr Buckingham: That the committee accept the following document tendered during the private briefing:

- Janette Vardy, Ryan Dadasovich, Philip Beale, Michael Boyer and Stephen J Clarke, 'Eligibility of patients with advanced non-small cell lung cancer for phase III chemotherapy trials' (2009) *BMC Cancer*, tendered by Dr Bell.

17. Submissions

Resolved, on the motion of Mr Buckingham: That the revised submission 94 replace the author's original submission, published as partially confidential, at the request of the submission author.

Resolved, on the motion of Mr Buckingham: That the committee authorise the publication of submission 103, with the exception of potential adverse mention, identifying and/or sensitive information, which is to remain confidential, as per the recommendation of the secretariat.

18. Public hearing – 29 November 2016

Resolved, on the motion of Mr Secord: That Dr Kerry Chant, Chief Health Officer, NSW Health, be invited to give evidence at the public hearing on 19 November 2016.

19. Adjournment

The committee adjourned at 5.20 pm until Tuesday 1 November 2016 (*public hearing*).

Rebecca Main

Committee Clerk

Minutes no. 4

Tuesday 1 November 2016

Select Committee on Off-Protocol Prescribing of Chemotherapy in New South Wales

Macquarie Room, Parliament House at 9.00 am

1. Members present

Mr Green (*Chair*)

Mrs Taylor (*Deputy Chair*)

Mr Buckingham

Mrs Houssos

Mr Khan

Mrs Maclaren-Jones

Mr Secord

2. Public hearing

Witnesses, the public and the media were admitted.

The Chair made an opening statement regarding the broadcasting of proceedings and other matters.

The following witness was sworn and examined:

- Dr John Grygiel, Medical oncologist.

The evidence concluded and the witness withdrew.

The following witnesses were sworn and examined:

- Ms Margaret Savage, Director, Professional Practice Unit, South Eastern Sydney Local Health District
- Mr Gerry Marr, Chief Executive, South Eastern Sydney Local Health District
- Dr James Mackie, Medical Executive Director, South Eastern Sydney Local Health District
- Dr Jo Karnaghan, District Director, Medical Services, South Eastern Sydney Local Health District.

The public evidence concluded.

The public and the media withdrew.

3. In camera hearing

According to previous resolution of the committee, the committee proceeded to take evidence *in camera*.

The committee proceeded to take evidence *in camera* from the following witnesses:

- Ms Margaret Savage, Director, Professional Practice Unit, South Eastern Sydney Local Health District
- Mr Gerry Marr, Chief Executive, South Eastern Sydney Local Health District
- Dr James Mackie, Medical Executive Director, South Eastern Sydney Local Health District
- Dr Jo Karnaghan, District Director, Medical Services, South Eastern Sydney Local Health District.

Persons present other than the committee: Angeline Chung, Rebecca Main, Merrin Thompson, Jenny Whight and Hansard reporters.

The *in camera* evidence concluded and the witnesses withdrew.

4. **Public hearing**

The public and media were readmitted.

The following witnesses were sworn and examined:

- Professor Jennifer Martin, Chair of Clinical Pharmacology, University of Newcastle
- Professor Stephen Ackland, Director, Hunter Cancer Research Alliance, University of Newcastle.

The evidence concluded and the witnesses withdrew.

The public and the media withdrew.

5. ***In camera* hearing**

According to previous resolution of the committee, the committee proceeded to take evidence *in camera*.

The following witnesses were sworn and examined:

- Witnesses A and B.

The committee proceeded to take evidence *in camera*.

Witness B tendered the following document:

- Aaron Lewis, Robert Kang, Alexandra Levine and Ellie Maghami, 'The new face of head and neck cancer: The HPV epidemic' (2015) September *Oncology*, pp 616-626.

Persons present other than the committee: Angeline Chung, Rebecca Main, Merrin Thompson, Beverly Duffy, Jenny Whight and Hansard reporters.

The *in camera* evidence concluded and the witnesses withdrew.

6. **Correspondence**

The committee noted the following items of correspondence:

Sent

- 31 October 2016 – Letter from Chair to Mr Gerry Marr, Chief Executive, South Eastern Sydney Local Health District (SESLHD), regarding submissions from SESLHD employees to the inquiry.

Received

- 31 October 2016 – Letter from Mr Gerry Marr, Chief Executive, South Eastern Sydney Local Health District (SESLHD) to Chair, regarding submissions from SESLHD employees to the inquiry
- 1 November 2016 – from Dr Kerry Chant, Chief Health Officer and Deputy Secretary, Population and Public Health, NSW Health, to the Chair, regarding communication with St Vincent's Hospital in November 2015.

Resolved, on the motion of Mrs Taylor: That the correspondence from Mr Marr and Dr Chant be published.

7. **Witnesses**

Resolved, on the motion of Mr Buckingham: That the following witnesses be called or recalled to appear at a date to be confirmed in 2017:

- Professor David Currow, Chief Executive, Cancer Institute of NSW
- Professor Brett Gardiner, former Director of Clinical Governance at St Vincent's Health Network
- Associate Professor Richard Gallagher, Director of Cancer Services, St Vincent's Health Network Sydney
- Dr David Dalley, former Head of Medical Oncology, St Vincent's Health Network.

8. Adjournment

The committee adjourned at 1.26 pm until Wednesday 2 November 2016 (*public hearing*).

Rebecca Main

Committee Clerk

Minutes no. 5

Wednesday 2 November 2016

Select Committee on Off-Protocol Prescribing of Chemotherapy in New South Wales

Coral Sea Room, Orange Ex-Services' Club at 9.02 am

1. Members present

Mr Green (*Chair*)

Mrs Taylor (*Deputy Chair*)

Mr Buckingham

Mrs Houssos

Mr Khan

Mrs Maclaren-Jones

Mr Secord

2. Public hearing

Witnesses, the public and the media were admitted.

The Chair made an opening statement regarding the broadcasting of proceedings and other matters.

The following witnesses were sworn and examined:

- Mr Scott McLachlan, Chief Executive, Western NSW Local Health District
- Dr Rob Zielinski, Medical Oncologist, Central West Cancer Care Centre, Orange Health Service
- Ms Ruth Jones, Director, Cancer Services, Western NSW Local Health District
- Ms Di Wykes, Director, Clinical Governance, Western NSW Local Health District
- Ms Sue Patterson, General Manager, Bathurst Health Service
- Ms Catherine Nowlan, General Manager, Orange Health Service

The evidence concluded and the witnesses withdrew.

The public and the media withdrew.

3. *In camera* hearing

According to previous resolution of the committee, the committee proceeded to take evidence *in camera*.

Persons present other than the committee: Angeline Chung, Beverly Duffy, Merrin Thompson, Jenny Whight and Hansard reporters.

Witness C was sworn and examined.

Witness C tendered the following document:

- 'Adjuvant CE (Cyclophosphamide and Epirubicin)', patient information sheet, Daffodil Cottage, Bathurst Base Hospital.

The witness withdrew.

Witnesses D and E were sworn and examined *in camera*.

The witnesses withdrew.

Witness F was sworn and examined *in camera*.

Person present other than the committee: Ms Gaye Walker.

The *in camera* evidence concluded and the witness withdrew.

4. Witnesses

The committee agreed that witnesses proposed to appear at a hearing in the new year be invited instead to appear on 29 November 2016, and that the secretariat circulate a proposed hearing schedule for members' consideration.

5. Adjournment

The committee adjourned at 12.25 pm until Tuesday 29 November 2016 (*public hearing*).

Merrin Thompson
Committee Clerk

Minutes no. 6

Tuesday 29 November 2016

Select Committee on Off-Protocol Prescribing of Chemotherapy in New South Wales
Jubilee Room, Parliament House, Sydney at 9.45 am

1. Members present

Mr Green (*Chair*)

Mrs Taylor (*Deputy Chair*)

Mr Buckingham

Mr Farlow (substituting for Mr Khan from 1.45 pm)

Mrs Houssos

Mrs Maclaren-Jones

Mr Pearce (substituting for Mr Khan from 9.45 am until 12.45 pm)

Mr Secord

2. Apologies

Mr Khan

3. Previous minutes

Resolved, on the motion of Mr Buckingham: That draft minutes nos. 3, 4 and 5 be confirmed.

4. Correspondence

The committee noted the following items of correspondence:

Received:

- 3 November 2016 – Email from Mr Garry Clarke to Chair, responding to evidence of Professor Jenny Martin, University of Newcastle, on 1 November 2016
- 11 November 2016 – Letter from Moray & Agnew Lawyers to Chair, declining the committee's invitation to Dr Kiran Phadke to give evidence on 29 November 2016
- 15 November 2016 – Email exchange between Associate Professor Anthony Schembri, CEO, St Vincent's Health Network Sydney and the secretariat concerning attendance of witnesses at 29 November 2016 hearing
- 20 November 2016 – Letter from Witness B to Chair, clarifying evidence given *in camera* on 1 November 2016
- 22 November 2016 – Email from Ms Caroline Lamb, Executive Officer, Medical Council of NSW, to secretariat, advising that the President of the Medical Council of NSW is not able to attend on 29 November 2016

- 28 November 2016 – Email from Dr David Dalley, former Director of Medical Oncology, St Vincent’s Health Network Sydney, to secretariat, requesting that he be accompanied by his legal adviser during his hearing on 29 November 2016
- 28 November 2016 – Email from Dr Brett Gardiner, former Director, Clinical Governance, and former Chief Medical Officer, St Vincent’s Health Network Sydney, to secretariat, requesting that he be accompanied by his legal advisers during his hearing on 29 November 2016
- 28 November 2016 – Letter from Professor David Currow, Chief Cancer Officer and Chief Executive, Cancer Institute NSW, to secretariat, clarifying evidence given by Ms Ruth Jones, Director Cancer Services, Western NSW Local Health District, on 2 November 2016
- 28 November 2016 – Letter from Ms Deborah Hyland, Director, Strategic Relations and Communications, NSW Health, to secretariat, advising that the South Eastern Sydney Local Health District report of the investigation into Dr Kiran Phadke is expected to be completed later in December.

Sent:

- 14 November 2016 – Letter from Chair to Ms Suzanne Wallace, Partner, Moray & Agnew, providing an interim response to the letter dated 11 November 2016, regarding the committee’s invitation to Dr Kiran Phadke to give evidence on 29 November 2016
- 15 November 2016 – Letter to Dr Brett Gardiner, former Director of Clinical Governance and former Chief Medical Officer, St Vincent’s Hospital Sydney, inviting him to give evidence at the hearing on 29 November 2016
- 15 November 2016 – Letter to Dr David Dalley, former Head of Medical Oncology, St Vincent’s Hospital Sydney, inviting him to give evidence at the hearing on 29 November 2016
- 29 November 2016 – Letter from Chair to Ms Suzanne Wallace, Partner, Moray & Agnew, advising that the committee will consider the matter of Dr Phadke’s appearance in February when the South Eastern Sydney Local Health District investigation has progressed.

Resolved, on the motion of Mr Secord: That the committee keep confidential the letter from Witness B to Chair, received 20 November 2016.

Resolved, on the motion of Mrs Maclaren-Jones: That the committee agree to Dr Dalley and Dr Gardiner’s requests to be accompanied by their legal advisers during their hearings, subject to the legal advisers sitting next to the witnesses and not taking an active role during proceedings.

Resolved, on the motion of Mr Buckingham: That the correspondence from Professor Currow, Chief Cancer Officer and Chief Executive, Cancer Institute NSW, be published.

Resolved, on the motion of Mrs Houssos: That the letter from Ms Suzanne Wallace, Partner, Moray & Agnew related to Dr Phadke, dated 11 November 2016, and the committee response dated 14 November 2014, be published.

Resolved, on the motion of Mrs Maclaren-Jones:

- That the committee meet in early February 2017 to consider the South East Sydney Local Health District report on the investigation of Dr Kiran Phadke
- That the committee write to Ms Suzanne Wallace, Partner, Moray & Agnew, to advise that the committee will consider the matter of Dr Phadke’s appearance in February when the South Eastern Sydney Local Health District investigation has progressed
- That the committee authorise the publication of the letter from the Chair to Ms Suzanne Wallace, Partner, Moray & Agnew, dated 29 November 2016.

5. Public submissions

The committee noted that the following submissions were published by the committee clerk under the authorisation of the resolution appointing the committee: submission nos. 34, 37, 43, 61, 68, 72, 81, 82, 86, 93, 95a, 96, 108, 112.

6. Partially confidential submissions

Resolved, on the motion of Mrs Houssos:

- That the committee authorise the publication of submission nos. 17, 26, 51, 63, 75, 76, 84, 88, 99, 104, 111 with the exception of potential adverse mention, identifying and/or sensitive information which are to remain confidential, as per the request of the author
- That the committee authorise the publication of submission nos. 9, 73, 90, 101, 102, 105, 106 with the exception of potential adverse mention, identifying and/or sensitive information which are to remain confidential, as per the request of the secretariat.

7. Confidential submissions

Resolved, on the motion of Mrs Taylor: that the committee keep submission nos. 6, 33, 95b, 103a, 107, 110 confidential, as per the request of the author as they contain identifying and/or sensitive information or they contain potential adverse mention.

8. Answers to questions on notice and supplementary questions

Resolved, on the motion of Mrs Taylor: That the committee keep confidential the answers to questions on notice received from:

- Witness A (1 November 2016) – received 19 November 2016
- Witness B (1 November 2016) – received 20 November 2016
- Witnesses D and E (2 November 2016) – received 3 November 2016.

Resolved, on the motion of Mr Secord: That the committee authorise the publication of the following answers to questions on notice and supplementary questions:

- Answers to supplementary questions – Dr Stephen Cooper, Radiation Oncologist, Genesis Cancer Care – received 25 November 2016
- Answers to questions on notice – Professor David Currow, Chief Executive, Cancer Institute of NSW and s122 inquiry co-leader – received 28 November 2016
- Answers to supplementary questions – Professor David Currow, Chief Executive, Cancer Institute of NSW and s122 inquiry co-leader – received 28 November 2016
- Answers to supplementary questions – Dr Paul Curtis, Director, Governance and Assurance, NSW Clinical Excellence Commission and s122 inquiry co-leader – received 28 November 2016
- Answers to supplementary questions – Mr Paul Gavel, Director Workforce, HealthShare NSW and s122 inquiry co-leader – received 28 November 2016
- Answers to questions on notice – Ms Karen Crawshaw, Deputy Secretary, Governance, Workforce and Corporate, NSW Ministry of Health – received 28 November 2016
- Answers to supplementary questions – Ms Karen Crawshaw, Deputy Secretary, Governance, Workforce and Corporate, NSW Ministry of Health – received 28 November 2016
- Answers to supplementary questions – Ms Susan Pearce, Deputy Secretary, System Purchasing and Performance, NSW Ministry of Health – received 28 November 2016
- Answers to questions on notice – Associate Professor Anthony Schembri, CEO, St Vincent's Health Network Sydney – received 28 November 2016
- Answers to questions on notice – Associate Professor Richard Gallagher, Director of Cancer Services, St Vincent's Health Network Sydney – received 28 November 2016
- Answers to supplementary questions from St Vincent's Health Australia received 28 November 2016, including answers from:
 - Associate Professor Richard Gallagher, Director of Cancer Services, St Vincent's Health Network Sydney
 - Mr David Faktor, Director of Media and Communications, St Vincent's Health Network Sydney
 - Ms Gabrielle Prest, Medicine Clinical Stream Manager, St Vincent's Health Network Sydney
- Answers to questions on notice – Mr Gerry Marr, Chief Executive, South Eastern Sydney Local Health District – received 28 November 2016.

The committee noted that Mr Secord had concerns about the answers to questions on notice and supplementary questions being received late in the day on the day prior to the public hearing, and requested that the timing of when answers are due be considered for future witnesses.

9. Publication of Dr David Bell's transcript and slides

Resolved, on the motion of Mrs Taylor: That the committee authorise the publication of the transcript of evidence, PowerPoint slides of Dr David Bell Senior Medical Oncologist, Northern Cancer Institute, on 31 October 2016 and the following research article tendered by Dr Bell:

- Janette Vardy, Ryan Dadasovich, Philip Beale, Michael Boyer and Stephen J Clarke, 'Eligibility of patients with advanced non-small cell lung cancer for phase III chemotherapy trials', *BMC Cancer* (2009) April.

10. In camera transcript

Resolved, on the motion of Mr Secord: That the committee keep confidential the transcript of evidence of Witnesses A and B on 1 November 2016, at the request of the witnesses.

11. Tendered documents – 2 November 2016

Resolved, on the motion of Mr Buckingham: That the committee accept and publish the following document tendered during the *in camera* hearing on 2 November 2016:

- Adjuvant CE (Cyclophosphamide and Epirubicin), patient information sheet, Daffodil Cottage, Bathurst Base Hospital.

12. Public hearing

Witnesses, the public and the media were admitted.

The Chair made an opening statement regarding the broadcasting of proceedings and other matters.

The following witness was sworn and examined:

- Dr Kerry Chant, Chief Health Officer, NSW Ministry of Health.

The evidence concluded and the witness withdrew.

The following witnesses were sworn and examined on their former oaths:

- Professor David Currow, Chief Executive, Cancer Institute NSW and co-leader of s122 inquiry
- Dr Paul Curtis, Director, Governance and Assurance, NSW Clinical Excellence Commission and co-leader of s122 inquiry
- Mr Paul Gavel, Director Workforce, HealthShareNSW and co-leader of s122 inquiry.

The following witness was sworn and examined:

- Dr Tina Chen, Medical and Scientific Advisor, Cancer Institute NSW and co-leader of s122 inquiry.

The evidence concluded and the witnesses withdrew.

The public and media withdrew.

13. Answers to questions on notice and supplementary questions

Resolved, on the motion of Mr Pearce: that the committee authorise the publication of the following answers to questions on notice and supplementary questions:

- Answers to questions on notice – Dr John Grygiel, Medical oncologist – received 29 November 2016
- Answers to supplementary questions and attachments – Dr John Grygiel, Medical oncologist – received 29 November 2016.

14. Summons

Resolved, on the motion of Mr Secord: That, under the authority of s 4(2) of the *Parliamentary Evidence Act 1901*, and at his request, the committee issue a summons to Dr Brett Gardiner, former Director of

Clinical Governance and former Chief Medical Officer, St Vincent's Health Network Sydney, to attend to give evidence before the committee on 29 November 2016 at 4.30 pm.

15. **Public hearing**

Witnesses, the public and the media were readmitted.

The following witnesses were sworn and examined on their former oaths:

- Mr Toby Hall, Group CEO, St Vincent's Health Australia
- Ms Gabrielle Prest, Medicine Clinical Stream Manager, St Vincent's Health Network Sydney
- Mr David Faktor, Director of Media and Communications, St Vincent's Health Network Sydney
- Associate Professor Richard Gallagher, Director of Cancer Services, St Vincent's Health Network Sydney.

Mr Buckingham tabled documents from St Vincent's Hospital obtained under an order of the House for the production of documents under standing order 52, relating to under-dosing of chemotherapy patients.

The evidence concluded and the witnesses withdrew.

The following witness was sworn and examined:

- Dr David Dalley, former Head of Medical Oncology, St Vincent's Health Network Sydney.

The evidence concluded and the witness withdrew.

The following witness was sworn and examined:

- Dr Brett Gardiner, former Director, Clinical Governance, St Vincent's Health Network, Sydney.

The public evidence concluded.

The public and the media withdrew.

16. ***In camera* hearing**

Resolved, on the motion of Mrs Houssos: That the committee proceed to take evidence from Dr Gardiner *in camera*.

Persons present other than the committee: Angeline Chung, Beverly Duffy, Rebecca Main, Merrin Thompson, Jenny Whight, Hansard reporters, Ms Leonie Beyers, legal adviser to Mr Gardiner and Ms Naomi Sharp, legal adviser to Mr Gardiner.

The *in camera* evidence concluded and the witness withdrew.

17. **Tabled documents**

Resolved, on the motion of Mr Buckingham: That the committee authorise the publication of certain tabled documents from St Vincent's Hospital obtained under an order of the House for the production of documents under standing order 52, relating to under-dosing of chemotherapy patients:

- Report on investigation findings in regards to dosing of Carboplatin in head and neck cancer patients, by Dr P Savage, Medical governance/administration trainee, undated
- Cancer and Immunology Program Clinical Governance Committee, Minutes, 4 July 2015
- H&N Chemotherapy Critical Incident Action Register, August – November 2015, undated
- Unposted incident – Edit 1, St Vincent's Mater Health, undated.

18. **Request for document from St Vincent's Health Network Sydney**

Resolved, on the motion of Mrs Houssos: That the committee seek from St Vincent's Health Network Sydney a copy of the email dated 5 August 2015 from Dr Brett Gardiner to senior staff that the committee was advised identified the potential issue relating to under-dosing of head and neck patients.

19. **Additional witness**

Resolved, on the motion of Ms Houssos: That Witness G be invited to give *in camera* evidence at the hearing on 24 February 2017.

20. Adjournment

The committee adjourned at 5.20 pm, *sine die*.

Merrin Thompson
Committee Clerk

Minutes no. 7

Friday 10 February 2017

Select Committee on Off-Protocol Prescribing of Chemotherapy in New South Wales

Room 1254, Parliament House, Sydney at 11.03 am

1. Members present

Mr Green (*Chair*)

Mrs Taylor (*Deputy Chair*) (*by teleconference*)

Mrs Maclaren-Jones

Mr Mookhey (substituting for Mrs Houssos for the duration of the inquiry)

Dr Phelps (substituting for Mr Khan)

Mr Secord

2. Apologies

Mr Buckingham

3. Previous minutes

Resolved, on the motion of Mrs Maclaren-Jones: That draft minutes no 6 be confirmed.

4. Correspondence

The committee noted the following items of correspondence:

Received:

- 27 November 2016 – Email from Dr Laurence Denholm to secretariat, forwarding journal extract on patient preferences in head and neck cancer treatment
- 27 November 2016 – Email from Dr Laurence Denholm to secretariat, forwarding journal extract on de-escalating treatment for HPV-positive tumours
- 5 December 2016 – Letter from a former patient of Dr Grygiel's to the Commissioner, Health Care Complaints Commission, copied to the committee
- 6 December 2016 – Email from Dr Leong Ng to committee, forwarding letter published in British Medical Journal coauthored by Dr Ng referring to dosing of chemotherapy patients
- 18 December 2016 – Email from Dr Laurence Denholm attaching an article on head and neck tumours
- 20 December 2016 – Letter from Professor David Currow, Chief Cancer Officer NSW and Chief Executive Officer, Cancer Institute NSW, responding to supplementary submission 55a from the Medical Oncology Group of Australia
- 9 January 2016 – Email from Mr Brendan Stone, Director, Cabinet and Inquiries, Strategic Relations and Communications, NSW Health, to secretariat, advising South Eastern Sydney Local Health District attendees at the hearing on 24 February 2017, the progress of the investigation into Dr Phadke and attaching the Western NSW Local Health District progress report on implementation of s122 inquiry recommendations
- 10 January 2017 – Letter from Ms Carol Bryant, Chief Executive Officer, Macquarie University Hospital, requesting that she be accompanied by a legal adviser to the hearing on 24 February 2016 and that certain information in submission 100 remain confidential
- 20 January 2017 – Email from Dr Brett Gardiner to secretariat, noting no objection to the publication of his *in camera* transcript of 29 November 2016

- 3 February 2017 – Email from Ms Deb Hyland, Strategic Relations and Communications, NSW Health – advising that the South Eastern Sydney Local Health District will not be providing the committee with a copy of its investigation report on Dr Kiran Phadke until after 20 February 2016
- 6 February 2017 – Letter from Ms Caroline Lamb, Executive Officer, Medical Council of NSW, to secretariat, requesting that Dr Greg Kesby, President, Medical Council of NSW, be summoned to attend the hearing on 24 February 2017, and that Ms Lamb attend as his support person
- 7 February 2017 – Email from Mr Paul Spink, Executive Officer, NSW Health Care Complaints Commission, requesting that Ms Sue Dawson, Commissioner, and Mr Tony Kofkin, Director of Investigations, NSW Health Care Complaints Commission, be summoned to attend the hearing on 24 February 2017
- 9 February 2017 – Email from the Hon Trevor Khan MLC to the Chair, disclosing that he received medical treatment at St Vincent’s Hospital in November 2016
- 9 February 2017 – Email from the Opposition Whip to secretariat, advising that the Hon Daniel Mookhey MLC will be substituting for the Hon Courtney Houssos MLC for the duration of the inquiry
- 10 February 2017 – Email from the Government Whip to secretariat, advising that the Hon Dr Peter Phelps MLC will be substituting for the Hon Trevor Khan MLC at the meeting on 10 February 2016.

The committee noted that the following items of correspondence were published by the committee clerk, following authorisation via email:

- 20 December 2016 – Letter from Professor David Currow, Chief Cancer Officer NSW and Chief Executive Officer, Cancer Institute NSW, responding to supplementary submission 55a from the Medical Oncology Group of Australia
- 9 January 2016 – Email from Mr Brendan Stone, Director, Cabinet and Inquiries, Strategic Relations and Communications, NSW Health, to secretariat, advising South Eastern Sydney Local Health District attendees at the hearing on 24 February 2017, the progress of the investigation into Dr Phadke and attaching the Western NSW Local Health District progress report on implementation of s122 inquiry recommendations.

Resolved, on the motion of Dr Phelps:

- That the committee keep confidential the correspondence from a former patient of Dr Grygiel to the Commissioner, NSW Health Care Complaints Commission, copied to the committee, dated 5 December 2016, as per the recommendation of the secretariat, as it contains identifying and/or sensitive information and potential adverse mention.
- That the committee agree to the request of Ms Carol Bryant, Chief Executive Officer, Macquarie University Hospital, to be accompanied by a legal adviser during her hearing, subject to the legal adviser sitting next to the witness and not taking an active role during proceedings.
- That, under the authority of s 4(2) of the *Parliamentary Evidence Act 1901*, and at his request, the committee issue a summons to Dr Greg Kesby, President, Medical Council of NSW, to attend to give evidence before the committee on 24 February 2017 at 11.30 am.
- That the committee agree to the request of Ms Caroline Lamb, Executive Officer, Medical Council, to accompany Dr Greg Kesby, President, Medical Council of NSW as a support person during his hearing, subject to her sitting next to the witness and not taking an active role in proceedings.
- That, under the authority of s 4(2) of the *Parliamentary Evidence Act 1901*, and at their request, the committee issue a summons to Ms Sue Dawson, Commissioner, NSW Health Care Complaints Commission and Mr Tony Kofkin, Director of Investigations, NSW Health Care Complaints Commission, to attend to give evidence before the committee on 24 February 2017 at 10.30 am.

5. Investigation report on Dr Kiran Phadke

Resolved, on the motion of Dr Phelps: That the committee write to the South Eastern Sydney Local Health District to request copies of:

- the investigation report on Dr Phadke
- Dr Phadke’s response to the investigation report

- the final report outlining actions to be taken.

Resolved, on the motion of Dr Phelps: That the committee wait until it receives the investigation report on Dr Phadke then consider whether or not to invite Dr Phadke and representatives of the South Eastern Sydney Local Health District to appear at a short hearing on a date to be determined in March.

Mr Secord tabled a media statement made by him regarding Dr Kiran Phadke's participation in the inquiry.

Resolved, on the motion of Mr Mookhey: That the committee publish Mr Secord's media statement.

6. Answers to questions on notice and supplementary questions

The committee noted that the following answers to questions on notice and supplementary questions were published by the committee clerk under the authorisation of the resolution appointing the committee:

- Answers to questions on notice – Western NSW Local Health District - received 1 December 2016
- Answers to supplementary questions – Professor David Currow, co-leader, s122 inquiry - received 22 December 2016
- Answer to question on notice – Dr Kerry Chant, Chief Health Officer, NSW Ministry of Health – received 23 December 2016
- Further response to question on notice – Ms Karen Crawshaw, Deputy Secretary, Governance, Workforce and Corporate, NSW Ministry of Health – received 23 December 2016
- Answers to questions on notice – Mr Toby Hall, Group Chief Executive Officer, St Vincent's Health Australia – received 23 December 2016.

Resolved, on the motion of Dr Phelps: That the answer to question 6 of St Vincent's Health Australia's answers to questions on notice received 23 December 2016 be kept confidential.

7. Public submissions

The committee noted that the following submissions were published by the committee clerk under the authorisation of the resolution appointing the committee: submission nos. 5a and 55a.

8. Partially confidential submissions

Resolved, on the motion of Mrs Maclaren-Jones: That the committee authorise the publication of submission 100 from Macquarie University Hospital, with the exception of identifying and/or sensitive information which is to remain confidential, as per the request of the author.

9. *In camera* transcript – 29 November 2016

Resolved, on the motion of Mrs Maclaren-Jones: That the committee authorise the publication of Dr Brett Gardiner's *in camera* transcript of 29 November 2016.

10. Reporting date

Resolved, on the motion of Mrs Taylor: That the Chair seek the approval of the House to extend the reporting date until Friday 19 May 2017 and that the committee table its report by Friday 19 May 2017.

11. Adjournment

The committee adjourned at 11.17 am, until Friday 24 February 2017 (*public bearing*).

Merrin Thompson
Committee Clerk

Minutes no. 8

Friday 24 February 2017

Select Committee on Off-Protocol Prescribing of Chemotherapy in New South Wales

Jubilee Room, Parliament House, Sydney at 9.05 am

1. Members presentMr Green, *Chair*Mrs Taylor, *Deputy Chair*

Mr Buckingham

Mr Mookhey (substituting for Mrs Houssos)

Mr Khan

Mrs Maclaren-Jones

Mr Secord

2. Draft minutes

Resolved, on the motion of Mrs Taylor: That draft minutes no. 7 be confirmed.

3. Correspondence

The Committee noted the following items of correspondence:

Received:

15 February 2017 – Letter from Ms Gabrielle Prest, Medicine Clinical Stream Manager, St Vincent's Health Network Sydney, to Chair, requesting a correction to transcript of 31 October 2015

- 20 February 2016 – Email from Ms Margaret Savage, Director, Professional Practice Unit, South Eastern Sydney Local Health District – forwarding letter from Mr Gerry Marr, Chief Executive and redacted investigation reports on Dr Kiran Phadke, and requesting confidentiality.

Sent:

- 13 February 2017 – Letter from Chair to Mr Gerry Marr, Chief Executive, South Eastern Sydney Local Health District, concerning investigation into Dr Kiran Phadke (*attached*)

Resolved, on the motion of Mr Buckingham:

- That the committee authorise the publication of correspondence from Ms Gabrielle Prest, Medicine Clinical Stream Manager, St Vincent's Health Network Sydney, requesting a correction to the transcript of 31 October 2015, dated 15 February 2017, and that the correction be footnoted in the transcript.
- That the committee keep the following documents confidential, as per the request of the author, as they contain sensitive information and potential adverse mention:
 - Email from Ms Margaret Savage, Director, Professional Practice Unit, South Eastern Sydney Local Health District to Chair, dated 20 February 2017
 - Letter from Mr Gerry Marr, Chief Executive, dated 20 February 2017
 - Redacted investigation reports on Dr Kiran Phadke.

4. Partially confidential submission

Resolved, on the motion of Mrs Taylor: That the committee authorise the publication of submission no 113, with the exception of sensitive information and potential adverse mention, as per the recommendation of the secretariat,

5. Confidential submission 6a and its attachments

Resolved, on the motion of Mr Khan: That the committee keep submission no 6a confidential, as per the recommendation of the secretariat, as it contains identifying and/or sensitive information, and potential adverse mention.

Resolved, on the motion of Mr Khan: That the committee consider the attachments to submission 6a.

Resolved, on the motion of Mr Khan: That the attachments to submission 6a be accepted and kept confidential.

6. Investigation reports on Dr Phadke

Resolved, on the motion of Mr Secord: That the committee invite

- Dr Kiran Phadke to appear at a hearing on a date to be determined in March and, in the event he declines to attend, the committee is to consider whether to issue a summons
- representatives of South Eastern Sydney Local Health District to appear at the same hearing.

7. *In camera* hearing

Resolved, on the motion of Dr Mookhey: That the committee proceed to take evidence from Witness G *in camera*.

Persons present other than the committee: Rebecca Main, Merrin Thompson, Jenny Whight, Angeline Chung and Hansard reporters.

The *in camera* evidence concluded and the witness withdrew.

8. Public hearing

Witnesses, the public and the media were admitted.

The following witnesses were sworn and examined:

- Ms Sue Dawson, Commissioner, NSW Health Care Complaints Commission
- Mr Tony Kofkin, Director of Investigations, NSW Health Care Complaints Commission.

The evidence concluded and the witnesses withdrew.

The following witness was sworn and examined:

- Dr Greg Kesby, President, Medical Council of NSW

The evidence concluded and the witnesses withdrew.

Mr Buckingham left the room at 11.50 am.

The following witness was sworn and examined:

- Ms Carol Bryant, Chief Executive Officer, Macquarie University Hospital

The evidence concluded and the witnesses withdrew.

9. Adjournment

The committee adjourned at 1.00 pm, *sine die*.

Merrin Thompson
Committee Clerk

Minutes no. 9

Friday 31 March 2017

Select Committee on Off-Protocol Prescribing of Chemotherapy in New South Wales

Macquarie Room, Parliament House, Sydney at 9.12 am

1. Members presentMr Green, *Chair*Mrs Taylor, *Deputy Chair*

Mr Buckingham

Mr Mookhey

Mr Khan

Mrs Maclaren-Jones

Mr Secord

2. Draft minutes

Resolved, on the motion of Mrs Maclaren-Jones: That draft minutes no. 8 be confirmed.

3. Correspondence

The Committee noted the following items of correspondence:

Sent

- 6 March 2017 – Letter from Chair to Ms Suzanne Wallace, Moray & Agnew Lawyer, requesting to reconsider the invitation to appear before the committee.

Received

- 14 March 2017 – email from Dr Leong Ng to the committee, enclosing links to media articles
- 16 March 2017 – email from Dr Leong Ng to the committee, enclosing link to medical journal
- 16 March 2017 – email from Ms Suzanne Wallace, Moray & Agnew Lawyers to the secretariat, advising that she will attend the hearing on 31 March 2017 as Dr Phadke's support person
- 22 March 2017 – letter from Moray & Agnew Lawyers to the chair, attaching redacted response from Dr Kiran Phadke to the South Eastern Sydney Local Health District investigation report and requesting that the response remain confidential
- 24 March 2017 – email from Mr Brendan Stone, NSW Ministry of Health, to the secretariat, advising that the preference of the South Eastern Sydney Local Health District and Ministry of Health is that the committee see Dr Phadke's response to the South Eastern Sydney Local Health District investigation report directly from Dr Phadke
- 24 March 2017 – email from Mr Paul Andrews, St Vincent's Health Australia, to the secretariat, attaching an updated response to supplementary question number 29 from the public hearing held on 31 October 2016.

Resolved, on the motion of Mr Khan:

- That the committee agree to allow Dr Kiran Phadke to be accompanied by his legal adviser, Ms Suzanne Wallace, during his hearing, subject to the legal adviser sitting next to the witness and not taking an active role during proceedings.
- That the committee keep the following documents confidential, as per the request of the author, as they contain sensitive information:
 - Letter from Moray & Agnew Lawyers, dated 22 March 2017
 - Redacted response of Dr Kiran Phadke to the South Eastern Sydney Local Health District investigation report
- That the committee publish the updated response of St Vincent's Health Australia to supplementary question number 29 from the public hearing held on 31 October 2016.

4. Submission

The following submission was published by the committee clerk under the authorisation of the resolution appointing the committee: submission no. 114.

5. Answers to questions on notice

Resolved, on the motion of Mr Buckingham: That the committee authorise the publication of:

- Answer to question on notice – NSW Health Care Complaints Commission – received 23 March 2017
- Answers to questions on notice – Macquarie University Hospital- received 27 March 2017
- Answers to questions on notice – Medical Council of New South Wales – received 27 March 2017.

6. Public hearing

Resolved, on the motion of Mrs Taylor: that witnesses appearing at today's hearing be requested to return answers to questions on notice and supplementary questions within 14 calendar days of the date on which questions are forwarded to them.

Witnesses, the public and the media were admitted.

The following witness was sworn and examined:

- Dr Kiran Phadke, medical oncologist and haematologist

The evidence concluded and the witness withdrew.

The following witnesses were examined on their former oaths:

- Ms Margaret Savage, Director, Professional Practice Unit, South Eastern Sydney Local Health District
- Dr Jo Karnaghan, District Director, Medical Services, South Eastern Sydney Local Health District
- Mr Gerry Marr, Chief Executive, South Eastern Sydney Local Health District
- Dr James Mackie, Medical Executive Director, South Eastern Sydney Local Health District (*via teleconference*).

The evidence concluded and the witnesses withdrew.

7. Adjournment

The committee adjourned at 11.54 am, *sine die*.

Merrin Thompson

Clerk to the Committee

Draft minutes no. 10

Thursday 11 May 2017

Select Committee on Off-Protocol Prescribing of Chemotherapy in New South Wales

Room 1136, Parliament House, Sydney at 4.40 pm

1. Members present

Mr Green, *Chair*

Mrs Taylor, *Deputy Chair*

Mr Buckingham

Mr Mookhey

Mr Khan

Mrs Maclaren-Jones

Mr Secord

2. Previous minutes

Resolved, on the motion of Mr Khan: That draft minutes no. 9 be confirmed.

3. Correspondence

The Committee noted the following items of correspondence:

Received

- 1 April 2017 – Email from Mr Erik Horwich to secretariat, regarding the conduct of the section 122 inquiry into off-protocol prescribing of chemotherapy
- 18 April 2017 – Email from Ms Paula Ardino, Principal Monitoring Officer, Medical Council of NSW, to secretariat, advising the dates that practice conditions were imposed upon Dr John Grygiel and Dr Kiran Phadke
- 20 April 2017 – Email from Dr Leong Ng to committee, regarding clinical practice guidelines
- 26 April 2017 – St Vincent's Health Network, Section 122 inquiry final implementation report, April 2017
- 27 April 2017 – Western NSW Local Health District, Section 122 inquiry six month implementation report, March 2017
- 5 May 2017 – Letter from Ms Helen Turnbull, Special Counsel, Avant, providing a statement by Dr Ian E Haines on off-protocol prescribing of chemotherapy, on behalf of Dr Grygiel
- 9 May 2017 – Email from Mr Matthew Flattery, NSW Health, to secretariat, attaching media statement from South Eastern Sydney Local Health District regarding the investigation of Dr Phadke and requesting that appendices to answers to questions on notice be kept confidential because they contain identifying information.

Resolved, on the motion of Mr Buckingham:

- That the committee authorise the publication of:
 - St Vincent's Health Network, Section 122 inquiry final implementation report
 - Western NSW Local Health District, Section 122 inquiry six month implementation report
 - Correspondence from Mr Erik Horwich to secretariat, regarding the conduct of the section 122 inquiry into off-protocol prescribing of chemotherapy
 - Correspondence from Ms Paula Ardino, Principal Monitoring Officer, Medical Council of NSW, to secretariat, advising the dates that practice conditions were imposed upon Dr John Grygiel and Dr Kiran Phadke
 - Correspondence from Ms Helen Turnbull, Special Counsel, Avant, providing a statement by Dr Ian E Haines on off-protocol prescribing of chemotherapy, on behalf of Dr Grygiel
 - Media statement from South Eastern Sydney Local Health District.
- That the committee keep the correspondence from Dr Leong Ng to committee, regarding clinical practice guidelines, confidential as per the request of the author.

4. Public submissions

The committee noted that the following submissions were published by the committee clerk under the authorisation of the resolution appointing the committee: submission nos. 80a, 115.

5. Confidential submissions

Resolved, on the motion of Mrs Maclaren-Jones: That the committee keep submission nos 98 and 109 confidential, as per the recommendation of the secretariat, as they contain identifying and/or sensitive information.

6. Answers to questions on notice

The committee noted that the following answer to question on notice was published by the committee clerk under the authorisation of the resolution appointing the committee:

- Answer to question on notice – Dr Kiran Phadke – received 19 April 2017.

Resolved, on the motion of Mrs Taylor: That, in respect of the answers to questions on notice from South Eastern Sydney Local Health District, received 27 April 2017, the committee:

- authorise the publication of the answers
- keep the appendices confidential, as per the request of the author, as they contain identifying and/or sensitive information.

7. *In camera* transcripts

Resolved, on the motion of Mr Buckingham: That the committee keep the following *in camera* transcripts confidential, as per the recommendation of the secretariat.

- 1 November 2016 (South Eastern Sydney Local Health District)
- 2 November 2016 (Witnesses C, D, E, F)
- 24 February 2017 (Witness G)

8. Consideration of the Chair's draft report

The Chair submitted his draft report entitled *Off-protocol prescribing of chemotherapy in New South Wales*, which, having been previously circulated, was taken as being read.

Resolved, on the motion of Mr Buckingham: That paragraph 3.112 be amended by omitting:

‘It is abundantly clear to the committee that the failures of St Vincent’s Hospital in responding to the allegation of off-protocol prescribing of chemotherapy were substantial, multifaceted and prolonged. As the Chief Health Officer observed, the hospital’s key failures were that it did not understand the seriousness of the issue; it failed to grasp the imperative to act quickly;’

and inserting instead:

‘It is abundantly clear to the committee that the failures of St Vincent’s Hospital in identifying the issue and responding to the allegations of off-protocol prescribing of chemotherapy were substantial, multifaceted and prolonged. The hospital’s key failures were that it did not escalate numerous concerns raised by staff for more than a decade; it did not understand the seriousness of the issue; it failed to grasp the imperative to act quickly;’

Resolved, on the motion of Mr Buckingham: That paragraph 3.114 be amended by inserting ‘not undertaken by a senior doctor and was’ after ‘the internal investigation was’.

Resolved, on the motion of Mr Secord: That paragraph 3.115 be amended by inserting at the end, ‘The unacceptable disclosure process exacerbated an already incredibly difficult time for patients who had been diagnosed with cancer.’

Resolved, on the motion of Mr Buckingham: That paragraph 3.117 be omitted:

‘It seems to the committee that there was some element of self-preservation on the hospital’s part as the matter unfolded and quickly became a full blown scandal, with staff seeking to manage a very difficult situation with an eye to the hospital’s public standing. However, we cannot conclude that there was any cover up. In our view there were elements of individual and collective human error, as well as systemic failures, that contributed over time to the crisis that unfolded. While the crisis was precipitated by the 7.30 broadcast, it was clearly the result of the hospital’s actions over time.’

and the following new paragraphs inserted instead:

‘It is clear to the committee that the hospital’s senior management put their public standing ahead of the best interests of their patients as the matter unfolded and quickly became a full blown scandal. The committee agrees with the conclusion of the section 122 inquiry that “there was avoidance of responsibility to act decisively in the interests of the patients” and that there were “failures of clinical governance processes, clinical leadership and management.”

In our view it is not credible that, despite widespread knowledge among junior nursing, pharmacy and medical staff who raised concerns about Dr Grygiel’s practice on numerous occasions for over a decade, no-one at a senior level in either the oncology department or management was aware of the issue. While

there were certainly elements of individual and collective human error, as well as systemic failures, that contributed over time to the crisis that unfolded, the committee is not able to discount the possibility of a cover-up on the part of St Vincent's Hospital. While the crisis was precipitated by the 7.30 broadcast, it was clearly the result of the hospital's actions over time.'

Mr Secord moved: That a new recommendation be inserted after paragraph 4.79:

'Recommendation X:

That the NSW Government consider legislation or measures to bring St Vincent's Health Network under closer scrutiny of NSW Health, especially in regard to medical and corporate governance, to ensure openness and transparency for patients and their families.'

Question put.

The committee divided.

Ayes: Mr Buckingham, Mr Mookhey, Mr Secord.

Noes: Mr Green, Mr Khan, Mrs Maclaren-Jones, Mrs Taylor.

Question resolved in the negative.

Mr Secord moved: That the finding after paragraph 4.84 be amended by inserting 'Initially, St Vincent's and senior doctors as well as senior management sought to cover up the matter.' after 'that occurred in the hospital.'

Question put.

The committee divided.

Ayes: Mr Buckingham, Mr Mookhey, Mr Secord.

Noes: Mr Green, Mr Khan, Mrs Maclaren-Jones, Mrs Taylor.

Question resolved in the negative.

Mr Secord moved: That the following new paragraph be inserted before paragraph 6.31:

'The committee found that the section 122 inquiry conducted by the Chief Cancer Officer and Chief Executive of the Cancer Institute NSW, Professor David Currow, for NSW Health, was inadequate as it did not compel witnesses to appear and failed to properly investigate the off-protocol chemotherapy treatment at NSW hospitals.'

Question put.

The committee divided.

Ayes: Mr Buckingham, Mr Mookhey, Mr Secord.

Noes: Mr Green, Mr Khan, Mrs Maclaren-Jones, Mrs Taylor.

Question resolved in the negative.

Resolved, on the motion of Mr Secord: That a new dot point be inserted at the end of recommendation 2: 'continue to monitor and assess the morbidity and mortality rates of the affected patient cohort and compare and contrast with expected ranges until at least 2022.'

Resolved, on the motion of Mr Secord: That a new recommendation be inserted after recommendation 8:

'Recommendation X:

That the NSW Ministry of Health implement improved patient consent procedures which include 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

- when consent is obtained after a non-eviQ plan is recommended, patients are provided with information about the proposed protocol, including the clinical rationale for it, and a completed patient consent form is scanned into the patient information system.’

Resolved, on the motion of Mr Secord: That another new recommendation be inserted after recommendation 8:

‘Recommendation X:

That the NSW Ministry of Health ensure that all key clinical staff are educated in expectations regarding valid informed consent.’

Mr Secord moved: That a new recommendation be inserted after recommendation 9:

‘Recommendation X:

That the NSW Government set up a special commission of inquiry led by a retired or serving judge with the powers of a royal commission to subpoena documents and compel witnesses to appear, and it would include an examination of the off-protocol chemotherapy dosing at St Vincent’s Hospital, Western NSW Local Health District and Macquarie University Hospital.’

Question put.

The committee divided.

Ayes: Mr Buckingham, Mr Mookhey, Mr Secord.

Noes: Mr Green, Mr Khan, Mrs Maclaren-Jones, Mrs Taylor.

Question resolved in the negative.

Resolved, on the motion of Mr Secord: That:

- The draft report, as amended, be the report of the committee and that the committee present the report to the House;
- The transcripts of evidence, submissions, tabled documents, answers to questions on notice and supplementary questions, and correspondence relating to the inquiry be tabled in the House with the report;
- Upon tabling, all unpublished attachments to submissions be kept confidential by the committee;
- Upon tabling, all unpublished transcripts of evidence, submissions, tabled documents, answers to questions on notice and supplementary questions, and correspondence relating to the inquiry, be published by the committee, except for those documents kept confidential by resolution of the committee;
- The committee secretariat correct any typographical, grammatical and formatting errors prior to tabling;
- The committee secretariat be authorised to update any committee comments where necessary to reflect changes to recommendations or new recommendations resolved by the committee;
- Dissenting statements be provided to the secretariat within 24 hours after receipt of the draft minutes of the meeting;
- The report be tabled at 12 noon, Thursday 18 May 2017.

9. Adjournment

The committee adjourned at 5.04 pm *sine die*.

Merrin Thompson
Committee Clerk