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

Introduction

1 On 19 February 2016, the Secretary of the NSW Ministry of Health, Mary Foley announced an Inquiry under Section 122 of the Health Services Act 1997. The Inquiry related to prescribing of chemotherapy at St Vincent' s Hospital, Darlinghurst by Dr John Grygiel, a senior staff specialist in Medical Oncology, during the period from June 2012 to June 2015 ('the incident'). The Terms of Reference (ToR) of the Inquiry, finalised on 25 February 2016, are appended (Attachment A).

2 The Inquiry team (Professor David Currow, Chief Cancer Officer NSW, Chief Executive Officer, Cancer Institute NSW; Dr Paul Curtis, Director Clinical Governance, Clinical Excellence Commission; Mr Paul Gavel, Director Workforce, HealthShare NSW); and Dr Tina Chen, Medical and Scientific Advisor, Cancer Institute NSW) were asked to deliver an Interim report by 31 March, 2016 to the Secretary, NSW Ministry of Health.

3 There were five sources of information sought to inform the Inquiry for its interim report:

A **Documents** were sourced from St Vincent's Hospital related to the Terms of Reference for the Inquiry. The Inquiry has undertaken significant work to coherently assemble these documents and forensically assess their value. The Inquiry has relied on the provision of these documents, rather than conducting its own search for all documents and communications related to the incident.

B **Written questions** were provided to St Vincent's Hospital for their response.

C **Interviews** were conducted with key current and former staff.

D **Case note reviews** were conducted for the relevant patient cohort.

E **Expert input** is being sought from interstate experts in medical and radiation oncology, clinical pharmacology, pharmacy and a health consumer.

Patients and families have not yet been invited to participate in the Inquiry within the timeframe for provision of this interim report, given initial uncertainties about who was affected. The Inquiry intends this be done as a matter of priority in the next stage.

4 By way of interviews, it must be noted that neither the practitioner concerned nor the Head of the Department of Medical Oncology for the majority of the time concerned have not yet been available to interview. Both have indicated their availability for interview on return from overseas (19 and 4 April 2016, respectively) as part of the next stage of the Inquiry.

5 From data sources A to E, a timeline of events has been compiled. The Inquiry was advised in a timeline provided by St Vincent's and confirmed by several interviewees that conversations took place during June and July, at which concerns about off-protocol flat dose prescribing of carboplatin were raised. These discussions included a discussion and agreement amongst the Head and Neck cancer Multidisciplinary meeting in June 2015 that all new patients would be prescribed the eviQ protocol dosing regimen. Key events for which the Inquiry has seen documentary evidence are as follows:

Date	*Document/event*
7–12 August 2015	Matter for Information prepared by Medicine Clinical Stream Manager, Executive Sponsors Chief Operating Officer (COO); Director Clinical Governance and Chief Medical Officer (DCG and CMO). Refers to initial review group having briefed the COO and CMO on 7.8.2015. Initial review commenced: 5 patients with recent disease recurrence identified of a total group of 'over 70' patients. Agreed to review a larger subset. Further briefing was to be provided in the week beginning 17.8.2015
31 August 2015	DCG and Director of Cancer Services (DCS) meet with Dr Grygiel
6 October 2015	Findings of internal review presented. Decision taken to proceed to external review.
16 November 2015	Matter for Information regarding Final Internal Investigation was provided to the St Vincent's Executive
22 December 2015	External review commences
9 February 2016	External review report sent to St Vincent's
18 February 2016	A media report is aired
23 February 2016	Open Disclosure with most affected patients commences

6 A more complete timeline (Attachment B) outlines key steps in the process of defining the incident and quantifying its magnitude in terms of the health of the community. Of note, the initial review (5 patients with known recurrence), the internal review (47 patients) and the external review occurred over a period spanning from the beginning of August 2015 until early February, 2016. In that time, no comprehensive case note review occurred for people known to have been prescribed off-protocol carboplatin at a flat dose of 100 mg.

7 As a result of case note review against an audit tool that was endorsed by the interstate experts, there is a complete data tree available for the years 2012-2015 (Attachment C). (This will need to be expanded in full for the period 2009-2011 to gauge more accurately the impact of such prescribing).

Background to head and neck cancers

HEAD AND NECK CANCER

8 Head and neck cancers refer to a heterogeneous group of cancers that usually form in the squamous cells in the head and neck. Worldwide, head and neck cancers account for 4% of all cancers. Incidence rates have increased significantly over the last ten years, and are considerably higher in males and people aged 60 years and over. In NSW in 2010, there were 1,110 new cases of head and neck cancers and 363 deaths from head and neck cancers (1-3).

9 Risk factors for head and neck cancers include tobacco and alcohol consumption, and infection with human papillomavirus (HPV).

ANATOMY

10 Head and neck cancers are categorised by the area in which it begins, including the oral cavity, throat (pharynx and larynx), sinuses, nasal cavity and salivary glands. Squamous cell carcinoma is the most common histologic type that make up more than 90% of all head and neck cancers (3-5).

STAGING

11 Stage at diagnosis guides management and predicts survival rates for patients. Head and neck cancers are staged using the Union for International Cancer Control (UICC): TNM Classification of Malignant Tumours or the American Joint Committee on Cancer (AJCC) Cancer staging manual. T describes the primary **t**umour site, N describes the regional lymph **n**odes, and M describes the presence or absence of distant **m**etastasis. The TNM combination can be summarised into a stage group between I (localised disease) and IV (has spread to other parts of the body).

OVERALL 1 AND 5 YEAR SURVIVAL

12 In Australia, for people diagnosed with head and neck cancers in 2007-2011, the 5-year relative survival was 68%. This figure has improved over time: for people diagnosed in 1982-1986, the 5-year relative survival was 62% (6). (Of note, mortality will be higher in the patients affected by this incident, as they had more advanced disease at the time treatment commenced.)

13 In NSW, for all people diagnosed with head and neck cancer in 2005-2009, 1-year and 5-year relative survival (across all disease stages) was 80.8% and 59.6%, respectively. Similar to the national trend, this figure has improved over time: for people diagnosed in 1995-1999, 1-year and 5-year relative survival was 78.4% and 52.9% respectively.

14 The subgroup of patients who are younger, non-smokers and non-drinkers, and are HPV positive, tends to have a more favourable prognosis.

TREATMENT

15 All patients with a diagnosis of head and neck cancer should be overseen by a multidisciplinary team.

16 In early (stage I and II) disease, surgery or radiotherapy gives similar loco-regional control (7). In patients with locally advanced (stage III and some stage IV) disease, surgery to remove the tumour followed by reconstructive surgery and radiotherapy is generally proposed if the tumour is considered resectable. Chemoradiation, which has been shown to be more effective than radiotherapy alone, is recommended post-operatively for people with positive tumour margins or when the cancer has spread beyond the external lining of the lymph nodes. In people whose disease cannot be surgically removed, chemoradiation is the preferred definitive treatment. In patients with recurrent, very advanced or metastatic disease, and where systemic therapy is indicated, palliative chemotherapy is the standard option and may be augmented for some patients with radiotherapy and, in a highly selected subgroup, surgery. Supportive care interventions are recommended for managing the psychological, social and physical needs that may arise with treatment (7).

Chemoradiation versus radiotherapy alone

17 In both resectable and non-resectable disease, concurrent chemoradiation (chemotherapy and radiotherapy administered over the same period of time) has shown an absolute overall survival benefit of 8% at five years (8, 9). The largest benefit is in people ≤60 years. Loco-regional control is also improved with chemoradiation when compared with radiotherapy alone. However, there is increased acute toxicity when radiotherapy is used with chemotherapy (10-13).

Chemotherapeutic agent in chemoradiation

18 Cisplatin is the chemotherapeutic agent that has the greatest efficacy in chemoradiation for head and neck cancers (14). Carboplatin is used for patients who could not tolerate cisplatin. Patients treated with radiotherapy in combination with cisplatin achieve higher overall and disease-free survival, as well as longer time to progression than those treated in combination with carboplatin (11, 13, 15-17). In general, cisplatin is associated with more side-effects than carboplatin.

19 Induction chemotherapy is chemotherapy given prior to surgery or definitive chemoradiation. In head and neck cancers, induction chemotherapy usually involves cisplatin. While induction chemotherapy is not considered standard treatment for these cancers at present, when it is used with cisplatin, carboplatin would be the appropriate agent for the subsequent chemoradiation because of the risk of the cumulative effects from prior cisplatin use.

20 Recently, the targeted agent cetuximab is indicated for patients who are not candidates for cisplatin in combination with radiotherapy (18).

Carboplatin dosing

21 The clinical efficacy and toxicity of carboplatin correlate closely with the clearance of the drug, which occurs through the kidneys. While body surface area (BSA)-based dosing is used for many chemotherapeutic agents, carboplatin dosing by BSA does not take into account the patient's kidney function, which may result in overdosing (in patients with poor kidney function) or underdosing (in patients with above average kidney function). Area under the (plasma concentration/time) curve (AUC)-based dosing, with consideration of kidney function, is recommended for carboplatin. A less-used alternative is based on normative population data for carboplatin clearance, but even these doses would be adjusted in the presence of very poor kidney function.

EVIQ AND NATIONAL COMPREHENSIVE CANCER NETWORK (NCCN) GUIDELINES

22 eviQ is the nationally endorsed provider of evidence-based cancer treatment information at the point of care. It provides health professionals with current evidence-based and peer-reviewed best practice cancer treatment protocols and patient information. All eviQ treatment protocols are reviewed regularly to ensure content is updated with the latest available evidence. There are 26 head and neck chemotherapy protocols on eviQ, with 7 of them containing carboplatin. The recommended dose of single agent carboplatin across these protocols ranges from AUC 1.5 to 2.

23 The NCCN Clinical Practice Guidelines document evidence-based and consensus-driven approaches to cancer management. They include recommendations on prevention, diagnosis, treatment, and supportive care that will optimise patient outcomes. Guidelines dated 2015 are available for head and neck cancer management. In these guidelines, the recommended dose of single agent carboplatin is not specified, however the individual studies referenced in the guidelines dose according to AUC or BSA. None of the NCCN Guidelines use flat dosing.

Findings

THE PEOPLE AFFECTED AND THEIR TREATMENT

24 In the period 2012 to 2015, 138 people with head and neck cancers were treated by Dr John Grygiel at St Vincent's Hospital, Darlinghurst with platinum-based chemoradiation. Of these people, 78 received an off-protocol flat dosage of 100 mg carboplatin: 64 with primary loco-regional disease, 1 with primary metastatic disease and 3 with primary disease of unspecified extent. Additionally, 7 were having treatment for recurrent loco-regional disease, 1 for recurrent metastatic disease and 2 not specified. (ToR **1a**)

25 Additionally, 35 patients were treated with a carboplatin dose of greater than 100 mg in that time period and 25 with cisplatin.

26 To date, of the 78 treated with the off-protocol flat dose of 100 mg carboplatin 23 have died of cancer, 3 have died of non-cancer causes and 4 have died with an unspecified cause of death. (ToR **1a**) At this point in time, the Inquiry is unable to quantify the impact of this prescribing. A proportion of these people are frail, with widespread disease, with death as the expected outcome from the time of diagnosis.

27 The Inquiry was consistently told that off-protocol flat dose prescribing of carboplatin for head and neck cancer was justified by Dr Grygiel because it was believed that it could reduce toxicity and increase the rate of people completing radiotherapy. No evidence has been presented from data at St Vincent's Hospital or from the peer-reviewed literature internationally to support this contention. Dr Grygiel will be offered an opportunity to provide such evidence when interviewed. (It should be appreciated that all cancer therapy is a careful balance of maximising the effect on cancer while minimising side effects, not simply focusing on the latter. Such considerations are part of the informed consent process in discussion with patients and their families.) (ToR **1a**)

PATIENTS AND THEIR CLINICAL OUTCOMES

28 Protocols are based on the best evidence to get the best outcomes. Consequently, it would be expected that on a population basis, a failure to adhere to protocols is likely to result in higher rates of local recurrence and higher overall mortality. The Inquiry cannot quantify this risk for individual patients. (ToR **1a**)

29 There was a significant delay in effecting open disclosure. Almost all of the people affected or their families only received disclosure after a media report going to air. This is not consistent with the NSW Health Open Disclosure Policy Directive or the principles underlying it. (ToR **1b**)

30 The response by St Vincent's, when it realised there was an issue, failed to demonstrate an understanding of the distress this issue was likely to cause to patients and their families. (ToR **1c**)

CLINICAL CARE

31 The eviQ protocols (and the protocols of eviQ's predecessor CiSCaT) and the National Cancer Clinical Network (NCCN, USA) protocols for head and neck cancer with loco-regional spread have been in place for at least one decade. In that time, the protocols for platinum-based chemotherapy have not been modified. The evidence would support first line use of cisplatin chemotherapy with the dose adjusted to body surface area (BSA) for each patient. By contrast, what happened for this group of patients was that they were treated with carboplatin (a less efficacious choice than cisplatin and, latterly, cetuximab) and the dose was not adjusted for key factors such as kidney function or body habitus. Although there is no perfect way of dosing platinum-based chemotherapy, even fixed dose protocols would use population norms (a higher dose than that given in this off-protocol dosing) and adjust that fixed dose for poor kidney function on a patient-by-patient basis. (ToR **2**)

MEDICAL ONCOLOGY DEPARTMENT

32 Junior pharmacists, nurses and doctors who have practised in medical oncology at St Vincent's Hospital during these years have either challenged the practice or sought an explanation for it. The practice was widely known, and senior pharmacy and nursing staff either knew, or should have known, it was occurring. (ToR **3**)

33 As a staff specialist, Dr Grygiel should have had an annual performance review. Only one performance review has been provided (2014). (ToR **3**)

HEAD AND NECK MULTIDISCIPLINARY TEAM (MDT)

34 The Head and Neck MDT individual patient assessment and documentation records were comprehensive and well presented. (ToR **3**)

35 There is no evidence to suggest this off-protocol flat dose prescribing of carboplatin for head and neck cancers had been discussed with or was known by other disciplines working in the multidisciplinary team.

36 When the prescribing was challenged in the MDT in June 2015, Dr Grygiel changed his prescribing of carboplatin by using the eviQ protocol from that time.

37 There is no evidence of the Head and Neck MDT conducting meetings, separate from discussions about patient care, to consider new and emerging evidence. (ToR **3**)

CANCER SERVICES STREAM

38 There were no processes to review non-standard protocols. (ToR **3**)

39 Due to the benefits and risks of chemotherapy, clinicians need to be able to adjust dosages appropriate to patients' needs and wishes. There are times when off-protocol prescribing can be appropriate. Although there are mechanisms in place to reduce the risk of such off-protocol prescribing in the future, the MOSAIQ® system can still be over-ridden on a patient-by-patient, drug-by-drug basis (and such functionality is crucial to personalising medication doses). Wherever this happens, careful ongoing monitoring of such prescribing is required. (ToR **1b,** ToR 4)

40 Across time, St Vincent's Hospital has put in place for its cancer services actions that will reduce, but not preclude, the recurrence of such prescribing, including:

- appointing a new Head of Medical Oncology (which interviewees reflected was already positively influencing the culture of the organisation); (ToR **3**)
- ensuring every patient referred will have his/her care overseen by a multidisciplinary cancer care team; (ToR **3**)
- ensuring multidisciplinary cancer care team meetings will include nursing, pharmacy and other allied health staff in future; (ToR **3**)
- eviQ being adopted as the evidence-based resource for electronic prescribing of all chemotherapy across the campus, pre-loaded into the MOSAIQ® electronic prescribing program (ToR **2**); and
- the formation of a committee to consider any application from a clinician for off-protocol prescribing. (ToR **1b**)

ST VINCENT'S HOSPITAL

41 Given the commitment to quality patient care, it is appreciated that this incident has been traumatic for clinical staff, hospital administration and St Vincent's more broadly.

42 There appeared to be no effective executive sponsorship of the incident. There was no sense of urgency about the internal or external reviews that were undertaken. It was assumed that because an early decision (although not clear by whom) was made that there was no further treatment that could be offered and the practice had ceased, there was no urgency to review affected patients. There is no single time point or person who is responsible for the lack of urgency: it appears to have come about from the way the incident was framed – an 'error', 'under-dosing' or as a 'protocol variation' by a senior clinician rather than characterising it as someone unilaterally prescribing 'off-protocol' with flat dosing. This is a key reason that the time taken from escalating the prescribing to senior members of the leadership team (beginning of August 2015) until the external review was completed (early February 2016) was six months. This delay was compounded by the absence of content experts and even the external reviewer's engagement was not framed with medical oncology content knowledge. (ToR **1a**, ToR **3**)

THE INTERNAL REVIEW

43 The internal review carried out by St Vincent's Hospital to examine the pattern of off-protocol prescribing failed to define the extent of the review through setting any terms of reference and failed to define the approach to the issue with a methodology that covered the clinical concerns that had contributed to the review in the first place. (ToR **1a**)

44 The internal review failed to determine adequately the clinical risks to patients as it failed to examine any clinical outcomes such as survival or cancer recurrence. Given that the review was generated in part by concerns about the rate of recurrence of people with head and neck cancers, it is not clear why the internal review failed to define relevant clinical and patient factors such as extent of disease and treatment intent before patients started therapy, and rates of recurrence and death. Instead, the review focused solely on the dose of carboplatin prescribed. The internal review did not assess the management of these patients, compared to other ways of treating them, with the exception of the dose differences from currently available protocols that covered the time period of the Inquiry. (ToR **1a**)

45 The internal review consisted of a very limited review of cases: the initial numbers of patients affected were unknown as no methodology was devised to identify the extent of this prescribing; only a subset of those identified were reviewed; and the review only addressed a comparison of the flat dosing against the area under the curve (AUC) dosing with no reference to patient outcomes. (ToR **1a**)

46 The internal review failed to seek input from content experts in medical or radiation oncology to the detriment of the review and the timeliness in defining the nature, extent and impact of this pattern of off-protocol prescribing. (ToR **1a**)

47 There appears to have been an acceptance of Dr Grygiel's explanation for using a flat dose of carboplatin without appropriate provision by the clinician of peer-reviewed literature or other documentation such as consensus statements from national or international clinical bodies to support the practice. (ToR **2**)

48 Committee oversight (multidisciplinary team meetings, Cancer Services Clinical Governance meetings, Patient Safety and Quality Committee meetings) of this off-protocol prescribing for head and neck cancers appears to be mentioned in passing in some late 2015 meeting minutes without any substantive discussion of the issues being minuted. (ToR **3**)

PUBLIC STATEMENTS BY ST VINCENT'S HOSPITAL

49 The external review should have been understood to confirm that there was a substantial issue to be addressed and alert the Hospital to the implications for patients. (ToR **1a**)

50 Public statements by St Vincent's Hospital about Dr Grygiel's prescribing practices did not fully reflect the magnitude of the issue or its consequences. The initial statements contained important factual errors (reference to the prescribing being taken from an outdated eviQ protocol) as well as key omissions (recurrence or death rates). Further, there was a lack of acknowledgement of the potential distress caused to St Vincent's cancer patients and their families. (ToR **1a**)

51 The hospital's public statement that "*no patients appeared to have suffered any negative impact as a result of the dosage issue*" is not accurate because the internal and external reviews did not examine any patient-level outcome data from this off-protocol prescribing. Reference to recurrence rates particularly should not have been made given that neither the internal nor external review quantified these rates. As such, St Vincent's public statements were misleading. This motivated the external reviewer to send a further email of clarification to St Vincent's Hospital indicating his concerns about how his response was being used. (ToR **1b**)

52 The hospital's public statement also indicated Dr Grygiel was "*immediately counselled and placed under supervision*". The review team has been advised that, in fact, this did not occur. (ToR **3**)

53 Campus-wide actions that will reduce but not preclude the recurrence of such prescribing that St Vincent's Hospital has put in place include:

- improved benchmarking and reporting across the whole organisation; (ToR **4**)
- setting up a Clinical Council; (ToR **4**)
- creating a campus-wide Mortality Review Committee to which anyone can refer; and
- the release of a new cancer plan. (ToR **1b**)

STATE LEVEL – NSW HEALTH POLICIES

54 Management did not appropriately escalate the issue to the Ministry of Health through a Reportable Incident Brief (RIB) as required by the Policy Directive 2014_004. There were at least two occasions when a RIB was appropriate: when a Lookback procedure was correctly contemplated in August 2015, and when the St Vincent's Health Australia CEO was notified in November 2015. (ToR **1c**)

55 The Lookback Policy (PD2007_075) was correctly considered in August 2015; however, the internal review undertaken by St Vincent's did not meet the criteria of a Lookback under PD2007_075. The Policy requires both an entry into the incident management

system and the notification of patients and their families within 2 months. This timeline was not met and there is still no entry in the local incident management system (RiskMan®). (ToR **3**)

Incident Management Policy PD2014_004 (ToR 1c)

56 The off-protocol flat dose prescribing of carboplatin does not seem to have been recognised as an 'incident' at St Vincent's Hospital despite concerns that were expressed by clinicians about the dosing, recurrence rates in mid-2015 and the internal review report.

57 Staff interviewed indicated that the flat dosing of carboplatin was raised with Dr Grygiel on many occasions from at least 2005. In each case, clinicians accepted the explanation of Dr Grygiel. They therefore did not understand the flat dosing as an 'incident' even though it was not in accordance with protocol and no evidence supporting the practice was provided.

58 Failure by staff to recognise this prescribing as a clinical incident resulted in no incidents being reported in the St Vincent's Hospital RiskMan® system. Therefore Dr Grygiel's practice of prescribing an off-protocol flat dose of carboplatin to many head and neck cancer patients remained unknown to senior hospital management until August 2015.

59 The Incident Management Policy also mandates reporting to the Ministry of Health using a Reportable Incident Brief (RIB). The policy states:

> ***3.1.3 Mandated reporting - Legal and Policy Requirements***
>
> *There are matters that require mandatory notification via a RIB to the MoH (after being entered in to the incident management system) regardless of the SAC.*
>
> *(i) Other matters either raising issues likely to have a major impact on the Health Service or have State-wide implications such as assault or violence against a patient/client by an employee*

60 Under clause 2.5.6 of the Incident Management Policy, St Vincent's Hospital should have consulted the Ministry of Health when they determined to go to external review:

> ***2.5.6 Director General Inquiries under the Health Services Act 1997***
>
> *Clinical and corporate incidents can raise issues which may require a more formal inquiry that is independent of the Health Service. This may arise where a clinical or corporate incident raises broad State-wide or general clinical practice issues, serious public interest matters or matters where there is a potential conflict of interest in the organisation overseeing its own investigation. Where the CE considers an independent external inquiry may be required, he/she should contact the MoH's Legal and Regulatory Services Branch. In the event that the matter being investigated is clinically focused, the CEC will also have a role in determining further action.*

There is no evidence of this occurring.

61 Internal or external advice from a medical and radiation oncologist would have improved the Terms of Reference for the external review commissioned by St Vincent's and provided a more timely opportunity for a better assessment of the risks to patients who had been exposed to this off-protocol prescribing.

Open Disclosure Policy PD2014_028 (ToR 1c)

62 With patient safety incidents, there is a requirement to start the disclosure process as soon as possible. The cases involved are not 'near miss incidents' so all patients should have had open disclosure quickly if they received off-protocol carboplatin at the flat dose of 100 mg.

Definitions:
***Patient safety incident** – harmful or no harm incident – Any unplanned or unintended event or circumstance which could have resulted, or did result in harm to a patient. This includes harm from an outcome of an illness or its treatment that did not meet the patient's or the clinician's expectation for improvement or cure.*

***Harmful incident**: a patient safety incident that resulted in harm to the patient, including harm resulting when a patient did not receive their planned/expected treatment (replaces 'adverse event' and 'sentinel event').*

***No harm incident**: a patient safety incident which reached a patient but no discernible harm resulted.*

Further guidance is provided in the Open Disclosure Handbook (http://www.cec.health.nsw.gov.au/programs/open-disclosure#handbook): "*Where appropriate, the timing of the disclosure to individuals who may have been affected needs to be considered **so that a person is contacted before learning about the event from other sources**"*. Almost all of the people who experienced off-protocol prescribing of off-protocol flat dose carboplatin for head and neck cancers had open disclosure only after a media report aired on 18 February 2016.

63 A review team convened in August 2015. Disclosure commenced six months later. It is stated in the information provided by St Vincent's Hospital that there was a risk of greater harm if the incident was disclosed without knowing the effects of the off-protocol flat dose prescribing. The decision as to when to disclose is difficult, particularly if patients are frail and unwell but those factors do not work against disclosing (Open Disclosure Handbook, page 65).

64 Under this policy, serious incidents require submission of a RIB.

65 The principles of Open Disclosure for conversations with the affected patient should include:

- acknowledgment of the incident to the patient as soon as possible;
- communications which are truthful, timely and clear;
- an apology offered; and
- ongoing care and support as required.

Managing Complaints or Concerns About a Clinician (MCCC) PD 2006_007 and Guideline GL2006_002 (ToR 1c)

66 The decision not to activate the MCCC policy was incorrect.

67 The scenario fits severity rating 1: *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*.

68 Rating 1 requires immediate:

- notification to the Chief Executive Officer (CEO);
- determination of whether the Health Care Complaints Commission (HCCC)/Medical Council need to be involved;
- consideration of whether variations to privileges are required (in conjunction with the clinician's clinical director); and
- management and investigation.

69 It is the role of the CEO to ensure complaints or concerns are acted upon, by way of investigation and, where necessary, appropriate actions. The CEO is also responsible for reporting to registration boards any conduct that may constitute unsatisfactory professional conduct or professional misconduct. (The Ministry of Health has referred this incident to the HCCC and the Medical Council.)

ST VINCENT'S HOSPITAL WORKPLACE CULTURE

70 Culture is about how things are done. There are actions around this incident that give cause for concern. In particular, the institutional action and response has been cautious, and initially all internalised, when there should have been an accurate characterisation of the issue, decisive and timely action, and more immediate openness with patients. The decision to internalise the knowledge and the response to this knowledge, appears to have contributed to a slowness in identifying the extent and impact of the incident. Thinking lacked clarity. No-one took overall responsibility for addressing the incident. This delayed advising and supporting patients and their families. Not seeking expert input into framing the internal or external reviews is another consequence of this culture. (ToR **3**)

71 In the medical oncology unit, when treatment was challenged, it seems there was always acceptance of the explanation provided by Dr Grygiel. When people acted, the action went only so far. 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. These conclusions are based on initial observations and evidence, and further work will be necessary to establish the full impact of these actions on the people connected to this incident. (ToR **3,** ToR **5**)

72 As part of the performance review process for senior medical officers, there should be a review of medical officers' practice in accordance with accepted guidelines and best available evidence. Any deviation from these accepted guidelines or best practice should be reviewed by peers. (ToR **1c**)

TERMS OF REFERENCE FOR THIS INQUIRY

73 The full extent of this prescribing has not yet been defined. Further work needs to be undertaken to define the extent and impact of this off-protocol prescribing. (ToR **5**)

74 There is evidence to date of off-protocol flat dose prescribing for a small number of people with cancers other than head and neck cancers. The extent of this is yet to be determined. (ToR **5**)

Recommendations

PATIENTS

That St Vincent's Hospital:

1 as a priority, apologise to patients and their families for any distress that this off-protocol prescribing or its reporting has caused;

2 ensure that every patient or his / her family is given the opportunity to participate fully in an Open Disclosure process;

3 supports patients whose care has been affected to have ongoing follow-up in another oncology unit if that is their choice;

4 offer more intensive follow-up 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;

That the Inquiry:

5 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. Particular questions arise for the Inquiry around the information provided to patients in order for them to have had sufficient and adequate information in consenting to their treatment.

That the NSW Cancer Registry, managed by the Cancer Institute NSW:

6 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.

ST VINCENT'S HOSPITAL

That St Vincent's:

7 provide education to key staff on those key policies, including the Lookback policy, given the findings in relation to the policies discussed in paragraphs 54–69 of this report;

8 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;

9 review the process of preparing and verifying public statements within the Hospital to include relevant consultation, content expertise and sign-off;

10 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;

11 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, request that Committee consider deaths of patients treated at St Vincent's Hospital, not simply those who die in St Vincent's Hospital, and also consider reviewing a random selection of 'expected' deaths rather than relying on the subjective decision that the death was 'unanticipated';

12 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;

STATE-WIDE MEDICAL ONCOLOGY

That Local Health Districts and Specialty Networks:

13 given clinicians should be able to override doses once entered into MOSAIQ® where appropriate for an individual patient, ensure that the most senior oncology pharmacist and the head of medical oncology review such overrides regularly to identify any patterns that may suggests similar dosing issues;

14 pre-load eviQ protocols into electronic chemotherapy prescribing systems;

STATE-WIDE CANCER SERVICES

That Local Health Districts and Specialty Networks:

15 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.

That the Cancer Institute NSW:

16 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;

17 prepares a new patient information sheet on dose adjustment of chemotherapy to allow patients and their caregivers to understand the rationale for it;

That the Ministry of Health, with the Cancer Institute NSW:

18 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.

SCOPE OF THE INQUIRY TERMS OF REFERENCE

That the Secretary, NSW Ministry of Health:

19 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)
- patients treated since 2006 by Dr Grygiel at St Vincent's Hospital, Darlinghurst

20 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.

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