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

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## Introduction

1 On 19 February 2016, the then Secretary of the NSW Ministry of Health, Mary Foley AM, 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 (St Vincent's Hospital) by Dr John Grygiel, a senior staff specialist in Medical Oncology, from June 2012 to June 2015. The Terms of Reference (ToR) of the Inquiry were finalised on 25 February 2016.

2 The Inquiry (Professor David Currow, Chief Cancer Officer and 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) delivered their Interim Report on 31 March 2016 to the Secretary, NSW Ministry of Health. On 5 April 2016, the report was published on the NSW Health website at http://www.health.nsw.gov.au/Hospitals/Pages/cancer-patients-inquiry.aspx.

3 The Terms of Reference were expanded on 4 April 2016 to include: patients under the care of Dr Grygiel treated at Western NSW Local Health District (LHD), and its predecessor from January 2006, and the application of the eviQ protocols and any other standardised evidence-based protocols at Western NSW Local Health District and systems in place for monitoring application of those protocols.

4 The Terms of Reference were subsequently further amended to require:

- a Final Report on the matters relating to people with cancer who were treated at St Vincent's Hospital to be provided by 31 July 2016 (which was subsequently published on the NSW Health website address given in paragraph 2), and
- a report on the matters relating to people treated at Western NSW Local Health District to be provided by 16 September 2016.

The final consolidated Terms of Reference are at Appendix A.

5 The Final Report on St Vincent's Hospital was provided to the Secretary on 31 July 2016. The current Report deals with Dr Grygiel's practice at Western NSW LHD and the LHD's systems for monitoring the application of evidence-based treatment protocols.

6 Whereas at St Vincent's Hospital, Dr Grygiel's practice focused on subspecialty care, in Western NSW LHD, Dr Grygiel practised as a general medical oncologist.

7 At the time the Inquiry's Terms of Reference were expanded to incorporate patients treated by Dr Grygiel at Western NSW LHD, the Inquiry was aware of five patients treated at the LHD who received 100 mg carboplatin, none of whom was treated for a head and neck cancer. In June 2016, the Inquiry extended an invitation to those five patients and their families to participate in an interview. One person took up the invitation.

8 The Inquiry took a systematic approach to identifying patterns of care among people for whom Dr Grygiel prescribed chemotherapy.

9 The sources of information that informed the Inquiry in relation to this Report are:

**a** **Documents** provided by Western NSW LHD, including its *Clinical Services Framework 2015 — A coherent system of care for Western NSW Local Health District* and its *Non-Surgical Cancer Services Framework 2014–2016*.

**b** **Written responses t**o the Inquiry's written questions;

**c** **Interviews** conducted with current and former staff and contractors engaged by the LHD, including a further interview with Dr Grygiel. One person declined an invitation to meet members of the Inquiry. Fourteen interviews were conducted with 16 people. Most interviews were conducted during the Inquiry's two visits to Orange.

**d** **Reviews of clinical records** for three patient cohorts, with a view to identifying patterns of prescribing. The patient cohorts are described in paragraph 23. Paragraphs 21 and 70 to 75 describe the limitations of the clinical records to which the Inquiry had access.

**e** **Clinical input** from the medical oncologist members of the Expert Panel established by the Inquiry.

## Background

### WESTERN NSW LOCAL HEALTH DISTRICT

10 Western NSW Local Health District (Western NSW LHD) is a local health district comprising 39 health services stretching from Bathurst in the east to Bourke and up to the Queensland border in the north-west, Cobar in the west, and Grenfell and Cowra in the south. Western NSW LHD covers around 250,000 square kilometres in area. The LHD is diverse encompassing cities, inner regional, outer regional and remote communities, with a population of 270,775 (2011 Census).

### MEDICAL ONCOLOGY SERVICES AT WESTERN NSW LOCAL HEALTH DISTRICT

11 The Inquiry was advised that Dr Grygiel practised as a fly -in, fly-out (FIFO) medical oncologist from 1989 to March 2012. Dr Grygiel held weekly clinics alternating between Bathurst and Orange. The LHD advised that, in addition to Bathurst and Orange, patients were treated at Cowra, Parkes and Dubbo. Dr Grygiel was the only medical oncologist practising at Bathurst and Orange at that time. (There was also a FIFO haematologist and a locally-based radiation oncologist who commenced in Orange in March 2011.)

12 For the 12 months from March 2012 to March 2013, Dr Grygiel provided a telehealth follow-up service to Western NSW LHD clinic patients already known to him. During this time, new patients were generally seen at Nepean Hospital unless they were too unwell to travel, when they were seen by a clinician who provided a FIFO service fortnightly to Orange for that 12 months.

13 Dr Grygiel's appointment was variously as a Visiting Medical Officer and an Honorary Medical Officer. Western NSW LHD (and previous Area Health Services (AHS)) provided clinic space in Bathurst and Orange for Dr Grygiel to see patients; nursing assistance during the clinics and in the administration of intravenous chemotherapy; and clerical assistance with appointments.

The LHD/AHS did not receive a facility fee from Dr Grygiel. Dr Grygiel arranged typing for his clinical correspondence.

14 According to the LHD's advice on clinic numbers by year, between 2006 and 2011 the average number of new patients seen at Dr Grygiel's Bathurst clinic was about 125 patients per year and in at the Orange clinic it was about 140 patients per year.

15 The medical oncology pharmacy service was a contracted compounding service which was primarily concerned with providing injectable chemotherapeutic agents as prescribed.

16 Western NSW LHD advised the Inquiry that the Greater Western Area Health Service (the immediate predecessor of Western NSW LHD) contracted McBeaths as its chemotherapy provider from 2006 to October 2010 and Fresenius Kabi (Pharmatel) from October 2010.

17 The LHD advised the Inquiry that, in October 2007, the then Greater Western Area Health Service (GWAHS) adopted the Cancer Institute NSW Standard Cancer Treatment (CI-SCaT) protocols [GWAHS Policy Standards of Practice (SOP) 1.5.1, dated 11 October 2007]. This was updated in 2010 by GWAHS to replace CI-SCaT with eviQ [GWAHS Policy SOP 1.5.1 (2), dated 11 February 2010]. Western NSW LHD has indicated that these Standards of Practice were presented and discussed at the GWAHS Cancer and Palliative Care Services Management Group and Clinical Stream meetings, the Oncology and Palliative Care Clinical Area Meeting (OPACM), oncology staff meetings across the LHD, would have been emailed to oncology registered nurses (RNs) and provided to Dr Grygiel in hard copy. Dr Grygiel indicated to the Inquiry at interview that he was not aware of the GWAHS adopting these Standards of Practice. In 2015-2016, the LHD acquired the MOSAIQ Oncology Information Management System and loaded the relevant protocols into the new system.

**ADMINISTRATION OF CHEMOTHERAPY DRUGS**

18 Chemotherapy can be given in different ways, including: by injection/infusion or orally, as either tablets or capsules. Most intravenous chemotherapy is administered by an oncology nurse in an outpatient chemotherapy unit. Oral chemotherapy is taken by patients in the community, having filled their prescription at a community or hospital pharmacy.

19 There are three roles that ensure the safe delivery of chemotherapy: the prescriber (the doctor or nurse practitioner); the compounder/dispenser (pharmacist); and the oncology nurse administering the treatment. For oral chemotherapy, the last checking mechanism does not exist.

20 When chemotherapy is administered in the hospital setting, the prescription is kept as part of the patient's medical records (either a paper-based medication chart or an electronic prescription in the medical oncology information system). Other details of treatment are also usually captured in the patient's records, such as: the treatment schedule (name of the drug, dose and number of doses, frequency of administration, periods of time not taking chemotherapy), results of relevant blood tests and the patient's height and current body weight.

21 Oral chemotherapy is prescribed by the medical oncologist. For the time covered by the Inquiry, this was on a hand-written prescription given to the patient to be filled at either the hospital pharmacy or a community pharmacy. Copies of these prescriptions are often not kept by the hospital, and the patient's record contains only the medical oncologist's record of the clinical consultation. Consequently, there is often less information in a hospital's medical records about prescriptions of oral chemotherapy than chemotherapy administered within the hospital setting. Separately, for oral medication, there is no record that can confirm that the patient has taken the full course of treatment as prescribed. If this is a subsidised chemotherapy, under the Pharmaceutical Benefits Scheme (PBS), there will be a record of the medication dispensed held by the Commonwealth Government. Under the National Health (Pharmaceutical Benefits) Regulations 1960, retail pharmacies are required to retain PBS prescriptions for a minimum of 2 years.

**PATIENT REVIEW**

22 The Inquiry was asked to "review the dosing of cancer patients under the care of Dr John Grygiel at Western NSW Local Health District (and its predecessor) from January 2006, and the application of the *Cancer Institute eviQ Protocols* and any other standardised, evidence- based protocols at Western NSW Local Health District and systems in place for monitoring application of those Protocols" (Inquiry Term of Reference 7(c)).

23 The Inquiry considered patients under the care of Dr Grygiel in Western NSW LHD. There are three sub-groups of patients the Inquiry identified from his practice, reflecting his patterns of care:

(i) a random sample of patients seen by Dr Grygiel in the oncology outpatient clinics at Bathurst (n = 56) and Orange hospitals (n = 61; see paragraph 27)
(ii) people treated with carboplatin or cisplatin (n = 41; see paragraphs 28–30)
(iii) people treated with the oral chemotherapy drug capecitabine (n = 97; see paragraph 31)

24 In addition, 16 patients or their families contacted the LHD after the media reports in February 2016 and queried the dose of chemotherapy they received. The LHD advised the Inquiry in June 2016 that one of its medical oncologists had reviewed one of the patients; and that the medical records for a second patient could not be located. The Inquiry conducted an assessment of the chemotherapy prescribed to the other 14 patients against the relevant eviQ protocols and advised the LHD accordingly, noting that 4 of these patients were first treated before 2006 (the commencement date of the period covered by the Inquiry).

25 The LHD also provided the Inquiry with a basic summary of the treatment details of a further three patients who had contacted the LHD. One patient did not wish to be contacted; two patients did not want the matter to be taken further.

26 Finally, two of the LHD's current medical oncologists had indicated to the LHD there were another three patients they were treating and about whose previous treatment they had concerns. The LHD provided details to the Inquiry, which included these three patients in the assessment discussed in paragraph 24.

27 The Inquiry asked the LHD to provide records of Dr Grygiel's oncology outpatient clinic appointments at Bathurst and Orange for the period 2006-2013. Patients who had only one appointment at the clinic were assumed not to have proceeded to have treatment; the population from which the sample was derived therefore included only patients who had at least one follow-up appointment. A random sample of 10% of the number of patients treated in each year was derived from the population, where each person treated was equally likely to have his or her treatment reviewed. This was group (i) (see paragraph 23).

28 The LHD advised the Inquiry that, based on information provided by the LHD's current pharmacy provider and a review conducted by one of its medical oncologists, a total of 41 patients under the care of Dr Grygiel were treated with either carboplatin or cisplatin between late 2010 and March 2013 (see paragraph 44). This was group (ii) (see paragraph 23 and Appendix B.1).

29 Twenty-one of the patients in group (ii) were treated with carboplatin. The LHD's medical oncologist did not identify any dosing issues in relation to 12 of these patients. Of the other 9 patients, 5 received 100 mg carboplatin as part of concurrent chemoradiation for three different tumour groups (urological, gynaecological and neurological). This treatment was similar to the pattern of treatment of the patients for whom Dr Grygiel prescribed off-protocol flat dose 100 mg carboplatin at St Vincent's Hospital (the link to the Inquiry's report is provided in paragraph 2). Of the remaining 4 patients, the medical oncologist questioned the choice of carboplatin in relation to 3 of them. The fourth received a higher than usual dose of carboplatin.

30 No dosing issues were identified in relation to the patients who were treated with cisplatin.

31 Dosing anomalies with capecitabine were identified to the Inquiry. To better understand and characterise any pattern of prescribing, the Inquiry identified patients for whom capecitabine was prescribed by Dr Grygiel. A total of 97 patients (group (iii)) was identified from three information sources:

- dispensing records held by the LHD's current pharmacy provider (n = 74);
- the list of patients in group (i) (paragraph 27) (n = 24, including 6 who were also in the dispensing records); and
- the lists of patients forwarded by the LHD to the Inquiry, about whose treatment questions had been raised by the patient, their family or one of the LHD's medical oncologists (paragraphs 24–26) (n = 5).

The majority of the 97 patients (n = 78) were being treated for colorectal cancer.

The Inquiry obtained detailed clinical information from medical records held by Western NSW LHD; and vital status and confirmation of disease recurrence from the NSW Cancer Registry. (See Appendix B.2 to the Inquiry's Final Report on St Vincent's Hospital for the audit tool.)

**ADJUVANT CHEMOTHERAPY FOR COLORECTAL CANCER**

32 Bowel (colorectal) cancer is the second most common cancer in NSW (1, 2). In NSW, for people diagnosed with colorectal cancer between 2005 and 2009, the five-year survival rate was 67.5% (1). Stage at diagnosis (the extent of spread of the cancer from the primary site in which it arose) guides management and predicts survival rates for patients. Colorectal cancer is staged using the Union for International Cancer Control (UICC): TNM (Tumour, Nodes, Metastases) Classification of Malignant Tumours or the American Joint Committee on Cancer (AJCC) Cancer Staging Manual. T describes the primary **t**umour, N describes the presence of cancer in regional lymph **n**odes, and M describes the presence or absence of distant **m**etastases. The TNM combination can be summarised, for colorectal cancer, into a stage group between I (localised disease) and IV (disease that has spread to one or more other parts of the body).

33 Surgery is the mainstay of treatment for colorectal cancer, particularly for stages I–III. Adjuvant chemotherapy (cancer treatment after treating the primary disease to lower the risk of disease recurrence) is recommended for patients with stage III and a sub-group of patients with high-risk stage II disease. For stage IV disease, on the rare occasions when the primary and metastatic tumours are both considered resectable, initial chemotherapy followed by surgery is an option. In locally advanced rectal cancer, neoadjuvant radiotherapy (radiotherapy before surgery) or neoadjuvant chemoradiation (radiotherapy administered concurrently with chemotherapy before surgery) is recommended.

34 The treatment plan for each patient will depend on the stage of disease, the purpose of the treatment (to cure the cancer or to relieve its symptoms) and other patient characteristics (for example, general health and informed patient preference).

35 5-Fluorouracil (5-FU) is the key drug in adjuvant chemotherapy for colorectal cancer, and most clinical trials in this area were conducted in the 1990s (3–5). Compared with surgery alone, 5-FU-based adjuvant chemotherapy has been shown to be associated with an overall five-year absolute survival benefit of 7 percentage points (5). For individual patients, this benefit would vary, depending on the stage of disease, the location of the tumour (colon or rectum) and other patient, tumour and treatment factors.

36 Capecitabine is an oral form of 5-FU, and has been shown to have at least equivalent efficacy to 5-FU when used as adjuvant chemotherapy for colorectal cancer (6). More recently, it has been shown that there is also further survival benefit associated with adding oxaliplatin to 5-FU or capecitabine, particularly for younger patients (7). For locally advanced rectal cancer, neoadjuvant chemoradiation that includes 5-FU or capecitabine-based chemotherapy reduces the risk of local recurrence but does not improve five-year overall survival (8,9). There is also evidence supporting the use of capecitabine in metastatic (stage IV) colorectal and breast cancers. Capecitabine has a narrow therapeutic index (a small difference in dose between causing toxicity and not getting sufficient therapeutic effect).

37 The clinical trial that demonstrated the equivalence of capecitabine to 5-FU/leucovorin as adjuvant chemotherapy for colorectal cancer used a capecitabine dosing protocol of 1250 mg/$m^2$ twice a day (6). Due to the capecitabine-associated toxicity, a large proportion of

patients in the trial required a dose reduction or a dose delay. Nevertheless, therapeutic effectiveness was still demonstrated. The Inquiry's clinical Expert Panel indicated that many medical oncologists, when using capecitabine alone, would probably commence treatment with a dose between 1000 mg/$m^2$ and 1250 mg/$m^2$ twice a day and, if tolerated, increase up to 1250 mg/$m^2$ twice a day (dose escalation). With the average body surface area (BSA) being 1.8, this means an average person would usually commence treatment with a dose around 2000 mg twice a day. The dosing protocol on eviQ (approved in February 2006) was 2000 mg twice a day as a fixed dose. As the interpretation of evidence by the eviQ expert group evolved, this was changed in July 2012 to 1250 mg/$m^2$ twice a day.

38 There are two common options for neoadjuvant treatment for locally advanced rectal cancer: a shorter course of radiotherapy alone and a longer course of 5-FU/capecitabine-based chemoradiation (8–12). There is no significant difference in local recurrence, overall survival or long-term toxicity between the two treatment options (13–15). There is evidence that the longer course chemoradiation is somewhat more effective in reducing the tumour size by the time surgery takes place (13,14). Based on clinical trial evidence, the recommended dose of capecitabine in neoadjuvant chemoradiation is 825 mg/$m^2$ twice a day (16,17). The dosing protocol for capecitabine on eviQ (approved in August 2005) was 1500 mg twice a day as a fixed dose. As the interpretation of evidence by the eviQ expert group evolved, this was changed in January 2012 to 825 mg/$m^2$ twice a day (giving an approximate dose of 1500mg twice each day for the average sized person).

39 Determining the optimal dose for a chemotherapy drug is a complex, costly and time-consuming process that requires a series of carefully designed clinical trials, followed by post-marketing pharmacovigiliance.

40 In deciding the most appropriate treatment for the patient, clinicians balance a number of factors, including the patient's general health and their ability to tolerate toxicities. A medical oncologist may choose to modify the application of the relevant treatment protocol (derived from the clinical trials), especially if the patient would not have met the eligibility criteria for the trials on which the protocol is based. If a medical oncologist is particularly concerned about the patient's ability to tolerate the chemotherapy, it is accepted practice to start the patient at a lower dose of the drug and, if tolerated, subsequently escalate the dose.

41 The ability of the clinician to critically appraise research evidence and its applicability to the individual patient is key to providing high quality, patient-centred care. Evidence from clinical trials and expert clinical judgement in applying the evidence are both necessary to best practice.

42 When an evidence-based treatment protocol is changed (for example, using a lower dose of a chemotherapy drug that has not been rigorously studied), evidence to inform the outcomes cannot be inferred.

43 For these reasons, when the 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. Many clinicians would also discuss their decisions to modify treatment protocols with colleagues who specialise in the same discipline.

## Findings

### PATIENT REVIEW — DOSING ANOMALIES

44 The Inquiry was provided by Western NSW LHD with a series of documents that comprised several lists of patients under the care of Dr Grygiel who were prescribed carboplatin or cisplatin between late 2010 and March 2013, based on information provided by the current pharmacy provider and the review conducted by the LHD's medical oncologist (see paragraph 28) . In accordance with its Terms of Reference, the Inquiry had requested details of patients who received carboplatin or cisplatin between January 2006 and February 2016. Dr Grygiel's practice at Western NSW LHD ceased in March 2013 (see paragraphs 11 and 12). The LHD advised that pharmacy records prior to late 2010 no longer existed (see paragraph 21). In relation to the prescribing of off-protocol flat dose 100 mg carboplatin, therefore, the Inquiry was able to consider only patients treated between the end of 2010 and March 2013.

45 As outlined in paragraph 29, the LHD advised the Inquiry of 5 patients at Western NSW LHD who received 100 mg carboplatin as part of concurrent chemoradiation. The Inquiry could not identify any single agent flat dose carboplatin protocols for these cancers. The Inquiry has not identified any other patients who received this dose from the groups of patients described in paragraphs 24 to 27 and 31. This treatment was similar to the pattern of treatment of the patients for whom Dr Grygiel prescribed off-protocol 100 mg flat dose carboplatin at St Vincent's Hospital. As explained in the Inquiry's Final Report on St Vincent's Hospital, this prescribing practice is not supported by evidence. The Inquiry cannot, however, quantify the effect of this practice on any individual patient.

46 As indicated in paragraph 31, the Inquiry identified 97 patients as having been treated by Dr Grygiel with capecitabine. Treatment occurred between January 2006 and March 2013 (with the exception that 1 was treated in 2004 and included because they had contacted the LHD). Of these 97 patients, 58 had, at the time of initial presentation, metastatic disease or were patients for whom the stated goal of treatment was to relieve symptoms rather than to cure the cancer (palliative treatment intent).

47 It is recognised that there is a greater scope for decreasing the intensity of treatment in the setting of metastatic disease or treatment with palliative intent, given the progressive frailty of this population. Consequently, the Inquiry focused on reviewing the dosing of chemotherapy for the 39 patients who were treated with capecitabine as neoadjuvant or adjuvant therapy.

48 As explained in paragraph 37, the Inquiry's clinical experts indicated that, due to associated toxicity, many medical oncologists would commence capecitabine treatment at a dose 20-25% lower than the dose used in the defining clinical trial. Following discussions with the clinical Expert Panel, it was suggested that in most instances of curative treatment, an initial dose of

capecitabine could be expected to be within 25% of this commonly used starting point, unless there are particular factors that would support further dose reduction, which should be clearly documented in the patient's medical record. The protocols that applied across this time, which were used in the clinical review of the 39 patients are as follows:

| Dose (twice a day) | Adjuvant chemotherapy (for stage II and stage III colorectal cancer) | | | Neoadjuvant capecitabine chemoradiation (for locally advanced rectal cancer) | |
|---|---|---|---|---|---|
| | Capecitabine alone | | Capecitabine in conjunction with other drugs | | |
| | Fixed | BSA‡ | BSA‡ | Fixed | BSA‡ |
| Trial/eviQ† | 2000 mg | 1250 mg/$m^2$ | 1000 mg/$m^2$ | 1500 mg | 825 mg/$m^2$ |
| Commonly used starting point | 1500 mg | 1000 mg/$m^2$ | 750 mg/$m^2$ | 1150 mg* | 620 mg/$m^2$ |

* As capecitabine tablets only come in the strengths of 150 mg and 500 mg, the value is rounded to the closest possible combination of these strengths.

† See paragraph 37.

‡ BSA, body surface area.

49 Of these 39 patients prescribed capecitabine by Dr Grygiel, 4 did not have capecitabine prescribed as initial chemotherapy. The parameters above were applied to the first dose of the initial neoadjuvant or adjuvant chemotherapy prescribed for the other 35 patients. These parameters cannot be applied to subsequent doses given variation in response to treatment.

50 Of the 35 patients, 23 were found to have the first dose of the initial neoadjuvant or adjuvant chemotherapy prescribed at a dose that appears to be substantially lower than expected norms (more than 25% lower than the already 20-25% reduced commonly used starting point), of both the fixed (where appropriate) and the body surface area dosing.

51 For the group of 23 patients, 4 were prescribed neoadjuvant capecitabine chemoradiation for locally advanced rectal cancer; 17 patients were prescribed adjuvant capecitabine alone for stage III colorectal cancer; and 2 patients were prescribed both treatments. See Appendix B.2.

52 For the 19 patients (17 + 2, see paragraph 51) prescribed adjuvant capecitabine at a substantially reduced dose, 18 were prescribed 1000 mg twice a day as a fixed dose and 1 was prescribed 1000 mg in the morning and 500 mg in the evening as a fixed dose. For the 6 patients (4 + 2, see paragraph 51) prescribed neoadjuvant capecitabine chemoradiation at a substantially reduced dose, 2 were prescribed 500 mg twice a day as a fixed dose and 4 were prescribed 500 mg once a day as a fixed dose.

53 For the whole group of 23 patients who had a substantially reduced dose of capecitabine, there was no evidence, from the records that were available to the Inquiry, of a documented rationale to the clinical decision for dose reduction by the treating oncologist. In addition, there was no evidence of subsequent dose escalation, based on available records. At interview, Dr Grygiel indicated that he sought to minimise toxicity in the patient population

and chose a lower dose for people who were more frail. The Inquiry noted that people treated with these substantially reduced doses were in general older and have more co-morbidities when compared to the other patients.

54 The 23 patients were characterised by the following criteria:

- neoadjuvant or adjuvant chemotherapy with curative treatment intent;
- evaluation of the first dose of first line chemotherapy;
- the first dose is a more than 25% reduction of the commonly used starting dose in the table in paragraph 48;
- absence of a documented reason for the dose reduction; and
- no evidence of dose escalation.

Applying these criteria, these 23 patients therefore were prescribed substantially reduced doses for which there is no rigorous evidence, either from clinical trials or documented clinical rationale.

55 In summary, in relation to prescribing by Dr Grygiel, the Inquiry found:

- carboplatin and cisplatin – prescribing of flat dose 100 mg carboplatin for 5 people;
- capecitabine — significantly reduced dose for 23 patients;
- other prescribing — no anomalous patterns were identified.

56 When the Inquiry identified the substantially reduced doses of capecitabine that had been prescribed for patients at Western NSW LHD, it informed St Vincent's Hospital. St Vincent's Hospital has taken immediate action to identify, and is actively reviewing, patients for whom Dr Grygiel prescribed capecitabine in the light of these findings.

**PATIENT REVIEW — IMPACT ON PATIENT OUTCOMES**

57 Establishing a causal link between having received a substantially reduced dose of capecitabine and subsequent outcomes (disease recurrence, death) is not possible for individual patients. There are many factors that contribute to outcomes after cancer treatment, and the cancer can recur even with optimal treatment. Conversely, a patient could receive a lower dose and yet not have the cancer recur. If a patient received a lower dose, it is impossible to tell what the outcomes would have been had he or she received a dosage according to a currently available protocol.

58 A fully informed, shared treatment decision requires the medical oncologist to discuss with the patient the implications for both the therapeutic benefit and the toxicity and before modifying the treatment protocol, especially when the treatment intent is curative.

59 At interview, Dr Grygiel indicated that every patient in Western NSW LHD signed a consent form for chemotherapy. The Inquiry found none of these forms in the medical records.

60 The clinical experts have advised that enhancements to routine follow-up would not confer additional clinical benefits for the patients who received the substantially reduced dose of capecitabine.

**WESTERN NSW LOCAL HEALTH DISTRICT**

61 The Inquiry has found that there were governance issues in how the cancer services were managed, such as: the lack of escalation processes had one of the checking mechanisms (see paragraph 19) questioned Dr Grygiel's dosing; or the LHD's failure to engage effectively with Dr Grygiel in relation to their mutual responsibilities, including for quality assurance. The Inquiry found no evidence of systems in place to ensure adherence to the protocols that were adopted by the LHD in 2007 (CI-SCaT) and 2010 (eviQ).

62 Checking mechanisms work when the clinicians concerned are able to question practices in the secure knowledge they will be received in a professional manner. If this is not the case, LHD processes need to be adequate to ensure such concerns can be escalated and dealt with appropriately. It was reported to the Inquiry that Dr Grygiel was not always receptive to questions being raised about issues such as chemotherapy dosing. 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.

63 The Inquiry has seen no evidence that this issue was effectively escalated, raising questions about the culture and the clinical governance processes in how this behaviour was dealt with by the LHD.

64 The Inquiry understands that there was a general MDT attended by Dr Grygiel. The LHD advised that, more recently, the MDTs in the LHD have actively sought links to specialist MDTs in other centres in order to strengthen discussions about patient care.

65 The LHD management responded promptly and proactively, in the best interests of its patients, when it became aware of issues relating to Dr Grygiel's flat dose prescribing of 100 mg carboplatin, following the airing of a media report on 18 February 2016. The LHD opened an inquiry line for concerned patients and families, and maintained contact with the patients and families who used it.

66 Notwithstanding the Inquiry's comments in relation to some aspects of Dr Grygiel's prescribing practices, at both St Vincent's Hospital and at Western NSWLHD, the issue should not be characterised only as an issue about an individual clinician's prescribing. It is clear to the Inquiry that there are issues relevant to the LHD. The most notable LHD issues have been in the area of clinical governance relating to visiting medical officers, how clinical concerns are escalated and record-keeping.

67 The model by which a cancer service and a FIFO medical oncologist operated side by side but without working together to plan and build cancer services, appears to the Inquiry to be a major reason this has not been seen as a clinical governance issue. In the process of interviewing staff, it became apparent to the Inquiry that this dichotomy, although better than

it was, exists to this day despite local staff specialists having being appointed in medical oncology. Several people told the Inquiry that, while the first attempt to establish a cancer stream was unsuccessful, they were hopeful the recent second attempt would be an effective means by which the clinicians and the LHD administration could work cohesively in pursuit of common objectives for cancer patients' care.

**DOCUMENTATION AND RECORD-KEEPING**

68 The nature of the practice arrangement in this instance placed a record-keeping onus on the LHD, Dr Grygiel and the pharmacy provider.

69 There is an onus on LHDs to have record systems in place and to ensure that individual practitioners' records are integrated into a comprehensive clinical record for each of their patients, especially for continuity of care when a FIFO practitioner is not present locally for the majority of the time.

70 The quality of the LHD's clinical record-keeping was poor. Some fundamental requirements were lacking. For example, patients' body weight was often not recorded; yet this information is crucial in determining the appropriate chemotherapy dose. The Inquiry found, on multiple occasions, pages of clinical records that contained no identifying information of the patient. The LHD was unable to locate the records of some patients. The Inquiry was not provided with any clinical records from the clinic at Cowra.

71 The LHD's record-keeping rendered the Inquiry's clinical review more difficult and more time-consuming than it need have been. While the Inquiry was exhaustive in compiling the information provided in a way that would enable proper and consistent assessment, it was constrained by the quality and comprehensiveness of the patient records.

72 The LHD must have access to adequate clinical records to provide clinical care and to conduct clinical audit to ensure quality and safety of the care patients receive. Systems should be in place for the routine capture, use and reporting of these clinical data. This requirement must be reflected in all contractual relationships between third party providers and any NSW Health entity.

73 Dr Grygiel's record-keeping was through letters to the referring doctor, copied to the oncology clinic. Oncology nurses attended Dr Grygiel's clinics so that they could take their own notes and then be aware, prior to the receipt of Dr Grygiel's letters, of what needed to be done for the ongoing care of the patients. The Inquiry has seen that notes made by the nurses were incorporated in patients' medical records. Most of the clinical information the Inquiry compiled and relied on for the clinical review was derived from Dr Grygiel's clinic letters. This includes the prescribed dose of oral chemotherapy when it was recorded.

74 As explained previously (paragraph 15), there have been a number of pharmacy providers contracted by the LHD since 2006. The current provider was responsive to the Inquiry's requests and able to provide records of 74 people for whom its predecessors dispensed the oral chemotherapy drug, capecitabine.

75 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.

76 The Inquiry also sought from the LHD all the relevant documentation associated with the engagement and appointment of Dr Grygiel, from his first appointment to his last. The LHD was able to locate:

- a letter from the Director of Clinical Services, dated 8 September 2003, informing Dr Grygiel that the Board of Directors of the Mid Western Area Health Service had appointed him as a Visiting Medical Officer, Medical Oncologist to Bathurst, Orange and Parkes Hospitals for the quinquennial appointment period ending 30 September 2008;
- the contract between the Greater Western Area Health Service and Dr Grygiel for an appointment to Bathurst Orange Health Service as a Honorary Medical Officer in the specialty of medical oncology for the period from 1 February 2009 to 31 January 2014; and
- the contract between Western NSW Local Health District for the provision of services as an Honorary Medical Officer between 26 March 2012 and 26 March 2013.

## Recommendations

Note: the references in parentheses are to corresponding recommendations in the Inquiry's Final Report on St Vincent's Hospital.

## Responsible organisation: Western NSW Local Health District

1. (1) People whose care has involved reduced doses of chemotherapy (off-protocol 100 mg flat dose carboplatin, reduced dose capecitabine in the setting of the neoadjuvant or adjuvant treatment of bowel (colorectal) cancer) are contacted by the LHD in order to receive an apology for the added uncertainty regarding the likely effect of their treatment on their clinical outcomes. To date, the LHD has contacted the majority of people.

2. (2) Ensure that every patient or his / her family in the group described in Recommendation 1 is given the opportunity to participate fully in an Open Disclosure process as outlined in NSW Health Policy Directive PD2014_028 and is provided with relevant support.

3. (3) Establish a process for patients and families who are concerned their treatment may have involved a reduced dose of chemotherapy to contact the Local Health District.

4. (4) In the view of the Expert Panel, there is no need for change to clinical follow-up for the cohort of people identified who have had dose reductions.

5. Continue to identify people who potentially were prescribed reduced dose capecitabine as data become available from the Commonwealth Government Pharmaceutical Benefits Scheme.

6. (12) Put in place a communications strategy to ensure clinical staff at all levels and third party providers understand their professional responsibility to use the LHD's escalation processes for issues of clinical concern or professional conduct.

7. (23) Ensure the current structure of cancer services in the LHD enables the building of relationships and mutual trust and respect between cancer clinicians and those managing cancer services. This should include a facilitated program to build relationships and trust within the senior clinical community in cancer services and cancer administration. The new cancer clinical stream should take a leadership role in developing and implementing this program.

8. (13) The LHD must 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.

9. 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.

## Responsible organisation: Ministry of Health

10. (22) Consider developing standard clauses for inclusion in contracts between Local Health Districts/Specialty Networks and third party providers to require comprehensive and timely access to clinical information from the third party providers to ensure quality of care for patients treated on behalf of Local Health Districts or Specialty Networks.

11. Consider mechanisms to capture systematically the prescribing of oral chemotherapy across NSW, including the prescription of oral chemotherapy in a medical oncology information system.

12. The Ministry of Health oversee the implementation of the recommendations in the Western NSW LHD.

## Responsible organisation: All Local Health Districts and Specialty Networks

13. Review fly-in / fly-out (FIFO) clinical service arrangements to ensure clarity about the relationship between FIFO practitioners and locally-based services including: clinical record-keeping / sharing; clinical care in the absence of the FIFO practitioner; clinical governance; quality improvement initiatives and service planning.

14.(15) Where multidisciplinary cancer care teams (MDTs) have a single member from a discipline, clinicians consider joint minuted meetings with at least one other MDT after relevant national or international meetings as seminal new evidence emerges that could influence practice.

## Responsible organisation: Cancer Institute NSW

15. (6) Flag every patient on the population-based NSW Cancer Registry identified by this Inquiry who has had an off-protocol flat dose of 100 mg carboplatin or reduced dose capecitabine prescribed for the treatment of cancer so that outcomes for this group of people are systematically evaluated on a regular basis.

16. Continue to disseminate the chemotherapy community pharmacy module. Actively promote community pharmacies that ensure their pharmacists have completed this learning module.

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# Inquiry under section 122 of the *Health Services Act 1997*

Prescribing of chemotherapy — Report on patients treated at Western NSW Local Health District

Appendix A

Final Consolidated Terms of Reference (21 July 2016)

# INQUIRY UNDER SECTION 122
# of the
# HEALTH SERVICES ACT 1997

## TERMS OF REFERENCE – DOSING OF CANCER PATIENTS

I, Mary Foley, Secretary of the NSW Ministry of Health do hereby initiate an inquiry under section 122 of the Health Services Act 1997. The inquiry is into issues arising from the dosing of cancer patients under the care of Dr John Grygiel which were not in accordance with the *eviQ Protocols*, at the Kinghorn Cancer Centre, St Vincent's Hospital, Darlinghurst, from June 2012 to June 2015 ["the incident"].

**The Inquiry is to be undertaken by**:

- Professor David Currow, Chief Cancer Officer and Chief Executive of the NSW Cancer Institute; and
- Dr Paul Curtis, Director Clinical Governance, Clinical Excellence Commission;
- Supported by Dr Tina Chen, Medical and Scientific Advisor, Cancer Information Analysis, NSW Cancer Institute and Mr Paul Gavel, Director Workforce HealthShare NSW.

**The inquiry shall**:

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* PD2014_004;
      - *Open Disclosure Policy* PD2014_028;
      - *Complaint or Concern about a Clinician – Principles for Action* PD2006_007;
      - *Complaint or Concern about a Clinician – Management Guidelines* GL2006_002.

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 as outlined at paragraph 1 above.

4. Identify any systemic learnings arising from the inquiries 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 to the Secretary on a further date, as directed by the Secretary.

In order to progress action under paragraphs 1, 2 and 3, the Inquiry may:

(a) consider the independent expert review conducted by Dr Brian Stein, Medical Oncologist;
(b) access the medical records of cancer patients of St Vincent's Hospital from 2009 to the present.

**AS AMENDED 4 April 2016**

7. The inquiry is extended:

(a) to include consideration of the information provided to patients directly affected by the incident (and their families) in consenting to treatment by Dr Grygiel, and to consider the impact on those affected patients and their families;

(b) to include cancer patients treated by Dr John Grygiel at St Vincent's Hospital, Darlinghurst from January 2006;

(c) to review the dosing of cancer patients under the care of Dr John Grygiel at Western NSW Local Health District (and its predecessor) from January 2006, and the application of the *Cancer Institute eviQ Protocols* and any other standardised evidence based protocols at the Western NSW Local Health District and systems in place for monitoring application of those Protocols;

(d) In relation to 7 (b) (and (c) above, to include consideration of the CiSCat (prior to the availability of the eviQ Protocols).

8. In order to address the additional matters listed in paragraph 7 above, the Inquiry may access the medical records of the relevant cancer patients of St Vincent's Hospital and the Western NSW Local Health District as required.

**AS AMENDED 21 July 2016**

9. The Inquiry is to report to the Secretary as follows:

(a) a final report on the matters relating to the dosing of cancer patients treated at the Kinghorn Cancer Centre, St Vincent's Hospital to be provided by 31 July 2016;

(b) a report on the matters relating to the dosing of cancer patients at Western NSW Local Health District to be provided by 16 September 2016.

# Inquiry under section 122 of the *Health Services Act 1997*

## Prescribing of chemotherapy — Report on patients treated at Western NSW Local Health District

## Appendix B

Patients under the care of Dr Grygiel[a] treated with carboplatin or cisplatin at Western NSW LHD October 2010 – March 2013[b], n = 41

- Carboplatin, n = 21
  - 100 mg carboplatin chemoradiation, n = 5
    - Alive, n = 2
      - No disease, n = 2
    - Dead, n = 3
      - Cancer cause, n = 3
        - Local disease, n = 2
        - Distant disease, n = 1

| Cancer group | n |
|---|---|
| Gynaecological | 2 |
| Urogenital | 2 |
| Brain/CNS[d] | 1 |

  - > 100 mg carboplatin, n = 16
    - Alive, n = 6
    - Dead, n = 10

| Cancer group | n |
|---|---|
| Gynaecological | 4 |
| Breast | 4 |
| Lung | 3 |
| Head and neck | 2 |
| Mesothelioma | 1 |
| Skin | 1 |
| Urogenital | 1 |

- Cisplatin, n = 20[c]
  - Alive, n = 7
  - Dead, n = 13

| Cancer group | n |
|---|---|
| Upper GI[d] | 11 |
| Lung | 4 |
| Urogenital | 4 |
| Mesothelioma | 1 |

[a] Dr Grygiel listed as prescriber or name of prescriber not specified
[b] Based on information provided by the pharmacy provider
[c] 1 patient also received carboplatin at a dose of > 100 mg
[d] Upper GI = upper gastrointestinal; CNS = central nervous system

Data presented are based on available records as at 1 September 2016

Patients under the care of Dr Grygiel treated with capecitabine at Western NSW LHD January 2006 – March 2013[a,b], n = 97

Non-metastatic or curative intent at initial presentation, n = 39

| Cancer group | n |
|---|---|
| Colorectal | 38 |
| Upper GI[d] | 1 |

Metastatic or palliative intent at initial presentation, n = 58[b,c]

| Cancer group | n |
|---|---|
| Colorectal | 40 |
| Breast | 10 |
| Upper GI[d] | 8 |

Capecitabine administered as initial chemotherapy, no distant metastases n = 35

Capecitabine not administered as initial chemotherapy, n = 4

Adjuvant n = 28

Neoadjuvant chemoradiation[e] n = 7

1st dose consistent with expected norms, n = 9

No dosage data, n = 2

1st dose appears substantially lower than expected norms, n = 17

1st dose consistent with expected norms, n = 1[e]

1st dose appears substantially lower than expected norms, n = 6[f]

Alive, n = 9

Dead, n = 8

Distant disease, n = 3

No disease, n = 6

Cancer cause, n = 7

Non-cancer cause, n = 1

Alive, n = 3

Dead, n = 3

Distant disease, n = 1

No disease, n = 2

Cancer cause, n = 1

Non-cancer cause, n = 2

| Response to neoadjuvant chemoradiation | n |
|---|---|
| Complete histopathological response | 1 |
| Surgical margins clear, lymph nodes not involved | 1 |
| Surgical margins clear, involved lymph nodes | 3 |
| Proceeded to surgery, no histopathology data on file | 1 |

**NB: Establlishing a causal link between having received a substantially reduced dose of chemotherapy and subsequent outcomes is not possible for individual patients.**

[a] This is not an exhaustive list, and more patients may be identified as data from the Pharmaceutical Benefits Scheme (PBS) become available
[b] 1 patient was treated in 2004 - this patient contacted the LHD
[c] Includes patients with suspected/probable metastatic disease
[d] Upper GI = upper gastrointestinal
[e] 1 patient with upper gastrointestinal tract cancer received chemotherapy alone
[f] 2 patients also received adjuvant doses that appear to be substantially lower than expected norms

Table 1: Outcomes for patients whose first dose of initial neoadjuvant or adjuvant capecitabine appeared to be substantially lower than expected norms

| Vital status | Local disease | Distant disease | Suspected disease | No known disease | Total |
|---|---|---|---|---|---|
| Dead | 2 | 6 | 1 | 2 | **11** |
| Alive | 0 | 4 | 0 | 8 | **12** |

Data presented are based on available records as at 1 September 2016

# Inquiry under section 122 of the *Health Services Act 1997*

## Prescribing of chemotherapy — Report on patients treated at Western NSW Local Health District

## Appendix C

Advice from Western NSW Local Health District on implementation of the recommendations in the Inquiry's Report on off-protocol flat dosing of chemotherapy for head and neck cancers that were addressed to Local Health Districts

Western NSW Local Health District (WNSW LHD) response to recommendations identified in the Inquiry under Section 122 – *Off-protocol prescribing of chemotherapy for head and neck cancers*: Final Report

That Local Health Districts and Specialty Networks:

| RECOMMENDATION | WNSW LHD ACTION |
|---|---|
| 13. given clinicians would 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 suggest similar dosing issues | In 2015 WNSW LHD commenced the staged implementation of MOSAIQ®, with the latest upgrade available in April 2016.<br><br>WNSW LHD have appointed 3 dedicated oncology pharmacists (3 year contract position based at Orange, Dubbo and Bathurst) to review all chemotherapy orders in MOSAIQ.<br><br>WNSW LHD has developed and implemented a Chemotherapy Prescription Review process guided by Terms of Reference (TOR) and a monthly reporting template, to:<br><br>• Review all chemotherapy prescriptions (both intravenous and oral) entered into electronic prescribing software (i.e. MOSAIQ®) which are less than 80% of the expected calculated dose. The calculated dose is based on agreed standardised chemotherapy prescriptions (as defined by eviQ and/or entered on prescribing software) and patient characteristics.<br>• Identify any prescription patterns which may indicate variations from protocol causing under dosing.<br>• Identify reasons for using a varied dose in each affected patient including contacting physicians who have not documented a reason for reducing a dose and asking them to specify a reason either verbally or written to the chair and document this reason in the electronic medical record.<br><br>As part of the TOR, the chair will rotate on a three monthly basis in order to maintain transparency and reduce bias with decisions related to chemotherapy dose variations against published protocols (Appendix 1).<br><br>WNSW LHD Cancer Services have also commenced the process of reviewing chemotherapy prescribing guidelines. Once these guidelines have been finalised and endorsed by the Cancer Clinical Stream, implementation will occur. |

| RECOMMENDATION | WNSW LHD ACTION |
|---|---|
| 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 | Multidisciplinary Team (MDT) Meetings TOR have been updated to ensure a 'standing agenda item' that allows new evidence/ practice/ clinical trials to be presented. This standing agenda item will also be included at specific tumour stream MDT meetings. This TOR has been reviewed and will be submitted to the Cancer Clinical Stream for endorsement with implementation to follow. |
| 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 | There are a number of Multidisciplinary Cancer Care Team meetings in WNSW LHD to discuss patient diagnosis and treatment plans including:<br>▪ General Cancer MDT in Dubbo<br>▪ Dubbo links into Lifehouse Thoracic MDT<br>▪ Breast and General Cancer MDT at Orange with Bathurst linking in<br>▪ Gastrointestinal Cancer MDT at Orange<br>▪ Prostate Cancer MDT at Orange<br>▪ Minimally invasive palliative care at Orange with Dubbo linking in<br>▪ Orange links into Upper Gastrointestinal MDT at Nepean<br>▪ Orange links into Lung MDT at Nepean<br>▪ Bathurst and Orange link into Lymphoma MDT at Westmead |

New Recommendations

That clinicians across NSW:

| RECOMMENDATION | WNSW LHD ACTION |
|---|---|
| 21. 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 patients notes | WNSW LHD has developed a 'chemotherapy / immunotherapy consent form' for all patients to sign prior to commencing treatment. This form has been forwarded to the Legal Department at the Ministry of Health (MOH) seeking feedback. Endorsement by the LHD forms committee will be sought and followed by implementation across the WNSW LHD.<br><br>This consent form will provide formal acknowledgement that informed consent for treatment has been obtained by the treating clinician. |

That Local Health Districts and Specialty Networks:

| RECOMMENDATION | WNSW LHD ACTION |
|---|---|
| 22. 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 hall mark 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 contract as they are negotiate between Local Health Districts/ Speciality Health Networks and third party providers. | The WNSW LHD has an external compounding chemotherapy provider following a tender process undertaken in 2014/15.<br><br>A component of the contractual relationship involves the reporting of clinical data relating to chemotherapy provision and pathways for escalation of any concerns. Regular meetings to review performance and address any concerns by either party are also included within the contractual relationship.<br><br>The provider offers an additional level of fail-safe checks with their willingness to remotely connect to MOSAIQ® over the locally-based oncology pharmacist reviews/checking of chemotherapy drugs and doses. |

# Inquiry under section 122 of the *Health Services Act 1997*

## Prescribing of chemotherapy — Report on patients treated at Western NSW Local Health District

## Appendix D

## Summary of material provided by the Local Health District outlining current and proposed services

**CANCER SERVICES AT WESTERN NSW LOCAL HEALTH DISTRICT IN 2016**

The LHD's preferred model of care moving forward for specialist cancer services is "hub" services at Bathurst, Orange and Dubbo, supporting satellite chemotherapy services and providing increased outreach consultation services to smaller centres:

- The Central West Cancer Care Centre in Orange offers a comprehensive range of locally-based services, including surgical, radiation and medical oncology, haematology and palliative care.
- In Bathurst, cancer services are provided at Daffodil Cottage, a purpose-built facility. The service is coordinated by locally-based oncology nurses and supported by regular clinics conducted by visiting medical oncologists, radiation oncologists and a haematologist from Orange.
- A clinical trials unit was established in 2014 in Orange.
- In Dubbo, cancer services are provided at the Alan Coates Cancer Centre, a purpose-built facility within the grounds of Dubbo Hospital. The service is now coordinated by a locally-based medical oncologist and haematologist, supported by visiting medical oncologists from the Chris O'Brien Lifehouse in Camperdown, radiation oncologists in Orange and haematologists from the Royal Prince Alfred Hospital.
- Outreach chemotherapy clinics are held in Mudgee, Parkes and Cowra district hospitals, where oncology nurses administer chemotherapy and supportive treatments. Nurses from these clinics engage in a rotation program at Bathurst, Dubbo and Orange to provide on-the-job training, education and other professional development.

**REVIEWS OF SERVICES UNDERWAY IN THE LHD**

The LHD has advised that its planning to meet increasing demand for cancer services, associated with a forecast 33% increase in cancer incidence between 2008 and 2021, includes consideration of the model for cancer services, the location and degree of centralisation of services and increasing access to services where appropriate "close to home". Workforce planning involves the progressive appointment of locally-based staff specialists in medical oncology, radiation oncology and haematology in Orange and Dubbo, reducing the dependence on fly-in fly-out services. Greater use of telehealth is proposed, with support provided from metropolitan tertiary centres and rural referral hospitals, for clinicians working in district and rural hospitals and community settings. The LHD has advised that it plans to develop, and monitor compliance with, clinical pathways for each major tumour group.

The Inquiry was informed by the LHD of several projects underway that would assess fly-in fly-out services, the status of visiting medical practitioners, the service needs of the community and the LHD and a governance structure for the development of services. These projects included a review of the efficiency and efficacy of the Rural Aerial Health Service, which provided a stocktake of services visiting the north-west sector of the LHD on a fly-in fly-out basis.

Western NSW LHD also advised the Inquiry that it had commenced the planning of a project to review Honorary Medical Officer (HMO) appointments in the LHD. Phase I of the project will include a stocktake of current HMO appointments, ensuring all HMOs have contracts and/or licence agreements, and a review of governance. Phase II of the project will include the development of service level agreements with metropolitan hospitals where appropriate, the establishment of house rules at the LHD's facilities and an escalation process for any clinical or other performance concerns.