

**INQUIRY INTO OFF-PROTOCOL PRESCRIBING OF
CHEMOTHERAPY IN NSW**

Organisation: NSW Health
Date received: 21 October 2016

Legislative Council Select Committee Inquiry into off-protocol prescribing of chemotherapy in New South Wales

NSW Health Submission

October 2016

Legislative Council Select Committee Inquiry into off-protocol prescribing of chemotherapy in New South Wales

Introduction

One in every two people in NSW will be diagnosed with cancer by the age of 85 years.¹

Treatment for the tens of thousands of people in NSW who are diagnosed with cancer every year is delivered through a healthcare system that has a range of robust and mature regulatory mechanisms and governance processes to ensure treatment is patient-centred, safe and of a high quality. Core elements include legal and professional responsibilities of individual registered health practitioners; governance and regulation of public and private health service providers, and oversight and training of specialist medical practitioners by specialist medical colleges and professional societies.

In 2016 a number of concerns were raised about prescribing of chemotherapy at St Vincent's Hospital, Darlinghurst and later by patients in western NSW. These concerns were investigated through an Inquiry established under section 122 of the *Health Services Act 1997* with all recommendations accepted by NSW Health for full implementation. To further assure the community, an audit is underway of the cancer treatment provided to patients in NSW public hospitals since January 2012. Patients or loved ones have been able to use a number of toll-free local and state information lines to register any concerns.

This submission outlines current cancer treatment practice across NSW. It explains the effect standardised treatment protocols have had on the practice of medical oncology since they were introduced in NSW in late 2005. The submission also details the significant actions being taken to strengthen the care of people with cancer in NSW in response to recommendations of the section 122 Inquiry.

1. Cancer outcomes and chemotherapy treatment in NSW

Cancer outcomes in NSW

- 1.1 Cancer outcomes for people in Australia and in NSW are among the best in the world. Survival following cancer treatment is considered a key index of the overall effectiveness of health services in the management of patients with these diseases.²
- 1.2 The International Cancer Benchmarking Partnership compared the five-year relative survival from four cancers (colorectal, lung, breast [in women] and ovarian cancers) in 12 jurisdictions with population-based cancer registries in six countries over a period of 12 years. The study found that overall survival from these cancers was consistently higher in Australia (NSW and Victoria), Canada and Sweden than in the other participating countries.²
- 1.3 There are more than 200 types of cancers, of which the most commonly diagnosed in NSW are prostate and breast cancers, melanoma, lung and colorectal (bowel) cancers. The Cancer Institute NSW has projected that there will be 48,600 new diagnoses of notifiable³ cancers in NSW in 2016⁴ rising from 42,079 new cases in 2012.¹

- 1.4 People treated for cancer in NSW Health facilities report high levels of satisfaction with the care they receive. Of the more than 3700 respondents to a Bureau of Health Information survey who visited a NSW public hospital outpatient cancer clinic, 99 per cent rated the care they received as very good or good with 92 per cent indicating they would speak highly of the clinic. Ninety-seven per cent of these patients said they were always treated with respect and dignity.⁵

The public health system in NSW

- 1.5 NSW Health is the largest public health care system in Australia, and one of the largest in the world. Each year, NSW Health cares for millions of people and oversees billions of dollars' worth of investment in patient care, building, equipment, technology and research. NSW Health employs around 108,000 staff and includes more than 230 public hospitals and health services.⁶
- 1.6 There has been significant government investment in cancer services across the state. In addition to metropolitan cancer centres, new regional cancer centres have been established in Port Macquarie, Lismore, Coffs Harbour, Tamworth, Nowra, Orange and Shoalhaven since 2007. Chemotherapy cancer care is supported in NSW by 149 medical oncologists⁷, medical specialists in training and a wide range of nursing and allied health specialists. As well as care in hospital, public outpatient areas provide for over 219,000 non-admitted patient service events for medical oncology treatment.⁸
- 1.7 The NSW Ministry of Health is a department of the NSW Government. The governance framework for NSW Health establishes the accountability systems and relationships between the NSW Ministry of Health, on behalf of the NSW Government and the public health system. The framework also recognises the specific purpose of each organisation and its legislative functions, as well as its workforce and employment responsibilities within the system.
- 1.8 Clinical services are provided by local health districts, which are responsible for providing services within defined geographical regions, and two specialty networks (the Sydney Children's Hospitals Network and the Justice and Forensic Mental Health Network), which provide specialist statewide services. NSW Health organisations may directly provide clinical services, either through NSW Health Service employees or individual contractors such as visiting medical practitioners, or may enter into contract arrangements with third party organisations to provide services to public patients on behalf of the public health system. As an example, the Chris O'Brien Lifehouse, a not-for-profit private hospital charity, provides cancer services for public patients under contract to Sydney Local Health District. Pathology, pharmacy and medical imaging services, among others, can also be provided by third party contractors. In some rural and remote areas, public health organisations may complement local services with fly-in/fly-out services by specialist medical practitioners.
- 1.9 The *Health Services Act 1997* also provides for the recognition and funding of affiliated health organisations, to enable designated non-profit, religious, charitable or other non-government organisations to be treated as part of the public health system where they control hospitals or services that contribute significantly to the

operation of the public health system. An example is St Vincent's Hospital Sydney Limited, which operates the St Vincent's Hospital, Darlinghurst (referred to throughout this submission as St Vincent's Hospital). The Minister for Health and the Secretary, NSW Health have a range of powers under the *Health Services Act* to direct and regulate the activities of such affiliated health organisations to ensure the safety and quality of the services they provide.

- 1.10 The Cancer Institute NSW was established under the *Cancer Institute (NSW) Act 2003* to lessen the impact of cancer on people in NSW, working across the health care system to promote better cancer prevention, early detection, diagnosis, treatment and care. The Cancer Institute NSW sponsors innovative programs within the public health system and works with the Ministry of Health and other NSW Health organisations to promote a patient-focused, seamless multidisciplinary approach to cancer care. Central to this approach is the principle that treatment is tailored to the characteristics and condition of each patient.

Cancer treatment in NSW

- 1.11 People with cancer may be treated in NSW in one or more of the following settings:
- in a NSW public hospital or community health service
 - in a private health facility licensed under the *Private Health Facilities Act 2007 (NSW)*
 - by a clinician or clinicians in private practice.
- 1.12 In all of these treatment settings, there is a range of legal and regulatory mechanisms designed to ensure health care that is safe, of a high quality, and respectful of individual patient autonomy in making decisions about their treatment.
- 1.13 Every health practitioner has a legal and professional responsibility to ensure that treatment is provided competently and in accordance with widely accepted peer professional practice, and that the patient gives informed consent to the treatment provided.
- 1.14 Health practitioners such as medical practitioners, pharmacists and nurses are required to be registered under the *Health Practitioner Regulation National Law (NSW)* (the National Law). Under the co-regulatory model in NSW, registration processes are managed at the national level by the Australian Health Practitioner Regulatory Authority and responsibility for ensuring protection of the public and maintenance of professional standards is managed at the state level by profession-specific Councils and the Health Care Complaints Commission.
- 1.15 The health profession Councils are established under the National Law and deal with the health, performance and conduct responsibilities of registered health practitioners, including managing complaints in conjunction with the Health Care Complaints Commission. The Councils are also responsible for taking urgent action to protect the public, where appropriate, including by way of action to suspend practitioners or through the imposition of conditions.

- 1.16 The Commission is established under the *Health Care Complaints Act 1993* and operates as an independent watchdog on the NSW Health system and NSW health service providers. It is established at arm's length from government to protect public health and safety by dealing with complaints about health service providers in NSW, with a particular emphasis on the investigation and prosecution of serious complaints. The HCCC works in consultation with the health profession Councils. No other Australian state or territory has an independent watchdog with the same level of investigatory and prosecutorial powers as the NSW Health Care Complaints Commission. Key features of the Commission include:
- A complaint to the Commission may be made by any person about a health service provider, including an individual health practitioner (whether registered or not) or an organisational health service provider such as a hospital or public health organisation
 - The Commission has broad investigative powers, including powers to require the provision of relevant information, records and evidence, to compel witnesses and to enter premises and search and seize material under search warrant
 - An independent Director of Proceedings is responsible for all decisions as to whether to prosecute complaints before a disciplinary body
 - A Joint Parliamentary Committee established under the Act oversees and reports on the Commission's carrying out of its functions
- 1.17 Treatment for cancer usually involves one or more medical specialties. Specialist medical practitioners are admitted to, and subject to the requirements of, specialist medical colleges. For example, medical oncologists undergo many years of training to qualify for admission to fellowship of the Royal Australasian College of Physicians. They then undergo continuing professional development through ongoing training and further education to ensure their skills and knowledge in respect of medical oncology are up-to-date and to support their meeting the standard of practice of their peers working within the discipline of medical oncology. Peak representative bodies or professional societies (which, in the case of medical oncology, is the Medical Oncology Group of Australia Incorporated) also work to improve and develop clinical practice, research and knowledge in their medical specialty.
- 1.18 Within NSW Health, these general oversight mechanisms are complemented by clinical governance frameworks and processes that are designed to reinforce safe, high quality health care. Public health organisations are responsible for having in place formal processes for the credentialing and appointment of all specialist medical practitioners who work in NSW public health facilities. The credentialing process involves assessing and verifying a practitioner's qualifications, knowledge, skills, clinical judgement, abilities, experience and other professional attributes. This is done to form a view about the competence, performance and professional suitability of that practitioner to deliver safe health care services within a given health facility. Practitioners are appointed to perform clinical services within a defined scope of practice. This process is supported by Medical and Dental Appointments Advisory Committees. These Committees are responsible for reviewing the qualifications and experience of medical practitioners, and advising the chief executive of the relevant public health organisation on the type of practice the medical practitioner may then undertake in that organisation.

- 1.19 Cancer treatment in NSW may also be provided in a private health facility licensed under the *Private Health Facilities Act 2007*. The NSW Ministry of Health has regulatory responsibility for licensed private health facilities. Any private premises at which chemotherapy (other than oral) is administered are required to be licensed as a private health facility under the *Private Health Facilities Act*. That Act and the *Private Health Facilities Regulation 2010* set out standards with which licensees must comply. It is a criminal offence to operate an unlicensed private health facility.
- 1.20 Many cancer-related services in NSW are provided by practitioners in private practice. For example, a visit to a general practitioner (GP) about a skin cancer may result in a pathology test and a referral to a surgeon who removes the lesion in a procedure performed in the surgeon's private rooms. Medical services involved in this common scenario (including the services provided by the GP, the pathologist and the surgeon) are primarily funded by the Commonwealth Government through the Medicare Benefits Schedule. NSW Health does not have a direct role in providing or overseeing cancer services in this scenario.

Chemotherapy treatment

- 1.21 Clinicians who treat people for cancer, usually working as part of a multidisciplinary team, are responsible for the development and implementation of an individualised treatment plan for each patient. The treatment plan sets out whether the treatment for that patient will include surgery, chemotherapy and radiation therapy, either alone or in combination. The treating clinicians are also responsible for reviewing the condition of the patient on an ongoing basis, to ensure they continue to receive the most appropriate care. While all members of the multi-disciplinary team have an important role to play, the specialist medical oncologist has ultimate responsibility for decisions on the prescribing and administration of chemotherapy.
- 1.22 From its relatively recent beginnings in treating leukaemias and other haematological cancers, chemotherapy is now used to treat many cancers. Sometimes it is the only treatment a patient receives, but it is often used in combination with other cancer treatments. Neoadjuvant chemotherapy is chemotherapy that is used to reduce a tumour before surgery. Neoadjuvant chemoradiation is radiotherapy administered concurrently with chemotherapy prior to surgery. Adjuvant chemotherapy follows other treatment to lower the risk of disease recurrence; adjuvant chemoradiation is radiotherapy administered concurrently with chemotherapy after surgery.
- 1.23 In NSW, chemotherapy by infusion can only occur through NSW public hospital cancer services or in chemotherapy class licensed private health facilities under the *Private Health Facilities Act 2007*. Oral chemotherapy can be taken by patients in the community after they have filled their prescription at a community or hospital pharmacy.

Evidence based treatment

- 1.24 NSW Health expects that clinicians will provide evidence-based and peer-reviewed best practice cancer treatment drawing on a range of state, national and international sources, including clinical guidelines and protocols.

- 1.25 The Clinical Practice Guidelines developed by the National Comprehensive Cancer Network (NCCN, a network of cancer centres in the United States) document evidence-based and consensus-driven approaches to decision-making about cancer treatment. The Guidelines include recommendations on prevention, diagnosis, treatment and supportive care that will optimise patient outcomes.
- 1.26 NSW has established evidence-based cancer treatment protocols that complement these Guidelines by providing information at the point-of-care about the optimal administration of chemotherapy and, more recently, radiotherapy once a treatment decision has been reached.
- 1.27 In 2004 the Cancer Institute NSW assumed responsibility for an intranet cancer treatment resource created by oncology teams based in the former South Eastern Sydney Area Health Service to reduce variations in cancer treatments and provide patients and general practitioners with information about cancer treatments. This became a state-wide resource under the first NSW Cancer Plan (2004–2006) and was launched as a website, the Cancer Institute NSW Standard Cancer Treatments (CI-SCaT), in late 2005. Unlike clinical guidelines such as the NCCN Clinical Practice Guidelines, CI-SCaT did not provide specific direction on which therapies to choose, but was a resource intended to provide information for treating clinicians and patients on the optimal prescribing and administration of a chosen therapy, as well as promote greater consistency in cancer treatment. CI-SCaT was designed to be updated in real time as new evidence emerged, with its protocols being revised and reviewed by a series of multidisciplinary clinical reference groups.
- 1.28 In 2005, a qualitative research study surveyed a sample of junior and senior doctors, nurses and pharmacists who treated adults with cancer in eight public hospitals in NSW about the information sources they used at the point of care.⁹ The study found there was no standardised approach to the pharmacological treatment of cancer patients by the surveyed clinicians, and envisaged that CI-SCaT would fill a gap in this respect.
- 1.29 In 2009, CI-SCaT was rebranded as eviQ Cancer Treatments Online. There are now more than 600 eviQ treatment protocols.
- 1.30 As use of eviQ increased, including by interstate clinicians, it became clear a national model would provide a wider pool of clinical experts to contribute to protocol development and review, ensuring the continued quality and currency of content. The national adoption of eviQ has been a key project of the National Cancer Work Plan, developed by the National Cancer Expert Reference Group and endorsed by the Council of Australian Governments in 2012. By the end of 2013, Memoranda of Understanding were in place with every state and territory in Australia. These agreements endorsed eviQ as a preferred source of evidence-based cancer treatment information in Australia and committed to allowing clinicians from interstate to participate in eviQ reference committee development and review of protocols. The first eviQ National Advisory Board meeting was held in March 2014. eviQ Reference Committees now have wide representation from all states and territories.

- 1.31 eviQ has had an increasing number of international users from almost 150 countries and is featured on the Union of International Cancer Control International Cancer Control Partnership portal. Ongoing update of the eviQ continues to be characterised by editorial independence, the engagement of many clinicians and strict governance processes. This includes reliance on the best, most recent and most comprehensive evidence available at the time protocols are developed, consistent with the National Health and Medical Research Council hierarchy of levels of evidence.
- 1.32 As well as providing patients and clinicians with current evidence-based and peer-reviewed best practice cancer treatment protocols, eviQ provides dose calculators to assist clinicians in deriving the appropriate dose of their chosen drug for each patient.
- 1.33 As part of the eviQ Education program, the Cancer Institute NSW also provides online learning resources for medical, nursing, allied health and general ward staff, to assist in standardising and promoting evidence-based care for people with cancer. Recognising the role community pharmacists have in supporting patients who have been prescribed oral chemotherapy, the eviQ education module for community pharmacists includes patient education and counselling.

Inquiry under s122 of the Health Services Act

- 1.34 Following concerns raised related to off-protocol prescribing of chemotherapy at St Vincent's Hospital, an Inquiry was established by the Secretary, NSW Health under section 122 of the *Health Services Act*. There were three reports arising from this Inquiry: Off-protocol prescribing of chemotherapy for head and neck cancers: Interim report, 31 March 2016 [Tab A]; Off-protocol prescribing of chemotherapy for head and neck cancers: Final report, 31 July 2016 [Tab B]; and Prescribing of chemotherapy: Report on patients treated at Western NSW Local Health District, 16 September 2016 [Tab C].
- 1.35 The section 122 Inquiry Reports outline the rigorous processes for obtaining and refining evidence about cancer treatments through several phases of clinical trials. The Reports explain the factors a medical oncologist takes into account in deciding the most appropriate treatment for an individual patient, including the patient's general health and ability to tolerate toxicities. As noted in the Report on Patients treated at Western NSW Local Health District:

"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." (par 40)

"[W]hen 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." (par 43)

- 1.36 The dosing disclaimer to the eviQ chemotherapy treatment protocols indicates that: *“There is limited evidence for dose modification. The recommendations made on eviQ regarding dose modification are intended as a guide and are generally conservative, placing a greater weight on safety compared to efficacy. It should be noted however, that dose modifications which are intended to improve the safety profile of a drug may compromise the efficacy of the regimen.”*¹⁰
- 1.37 The section 122 Inquiry identified some prescribing that was not in accordance with accepted practice, particularly in relation to full discussion with patients as part of the informed consent process; documenting the rationale for treatment decisions, and the ability of other health professionals to raise and escalate concerns about prescribing practices. The Inquiry made recommendations designed to strengthen the systems in place in local health districts and specialty networks to ensure robust clinical cultures and provide mechanisms for visibility of care. Details of St Vincent’s Hospital’s responses to the Inquiry recommendations are provided later in this submission (2.5, 2.6). Western NSW Local Health District is due to report on progress in December 2016.
- 1.38 The Inquiry Reports articulate the following principles for people diagnosed with cancer:
- their care should be provided by specialists who are active members of a multidisciplinary cancer care team
 - they should be provided with sufficient information to enable them to understand the risks and therapeutic benefits of the treatment proposed for them, so they can provide fully informed consent
 - their proposed treatment should be based on the best available evidence
 - they should receive a full explanation of the rationale for, and implications of, any proposed variations to the treatment protocol
 - they should be able to place full confidence and trust that the facilities where they are being treated have in place checks and balances to ensure safe and effective delivery of treatment, including chemotherapy; and that such checks and balances include the ability of other health professionals to question decisions made by treating clinicians, and to raise concerns; and regular, rigorous review and audit processes that monitor outcomes and identify and address variations from best practice.

2. Terms of reference

2.1 Efficacy of electronic prescribing systems

Overview

- 2.1.1 Oncology Management Information Systems (OMIS) are comprehensive information technology solutions that allow users in the hospital environment to oversee all aspects of oncology care for their patients, from diagnosis to follow-up.
- 2.1.2 When prescribing occurs in these systems, care plans to support the administration of chemotherapy are developed locally and approved by senior clinicians, in accordance with local governance processes. The care plan is based on the eviQ protocols and other evidence-based sources of information, and also contains local information about supportive therapy and any prerequisite tests and information. For each patient who is to receive chemotherapy, the treating clinician assigns a care plan. Taking into consideration the patient's clinical characteristics and the results of tests (for example, blood tests) the clinician tailors the care plan accordingly. This can include varying a dose of a chemotherapy drug. Regardless of the way the clinician varies a dose in an OMIS, a report can be developed that indicates the prescribed dose has been varied from the original dose indicated in the care plan.
- 2.1.3 When the pharmacist receives the electronic (or written) prescription, it is expected that he or she conducts a full assessment to ensure the prescription is correct (including the correct drugs, dose, route of administration, infusion times, diluents, volumes, frequency, cycles, previous treatment, current medications and the cumulative dose the patient should receive) before ordering the drugs. The pharmacist is expected to clarify any questions with the prescribing doctor, and document in the care plan any changes that are made to the prescription. The pharmacist then orders the drugs to be compounded and dispensed locally or orders them from an external provider. In both circumstances, a final check is expected to be done by the pharmacist before the drugs leave the pharmacy to be administered to the patient.
- 2.1.4 Before administering chemotherapy, nurses should assess the patient for previous toxicity and check that the treatment to be administered is correct against the care plan and the patient's test results. They check the doses are correct, according to the factors that personalise the dose such as the patient's weight, body surface area or kidney function. They have a responsibility to clarify any questions with the prescribing doctor or the pharmacist, and document any changes in the OMIS.
- 2.1.5 A fully implemented OMIS has the capacity to generate reports to support improvements in the quality of the cancer service delivery. Electronic prescribing is the computer-based electronic generation, transmission and filing of a medical prescription. Electronic prescribing modules are an additional functionality within an OMIS to support monitoring, evaluation and reporting on variances in treatment. Electronic prescribing can provide an audit trail for prescribing; alert a treating clinician to document a decision to vary a treatment protocol; streamline work processes, and provide a mechanism for formal and documented review of treatment doses prior to administration.

Current Approach

- 2.1.6 Local health districts are responsible for the formal governance processes to support safe OMIS use, including processes to ensure appropriate access and security of information. In NSW, OMIS for medical oncology commenced with facilities in Wollongong and Campbelltown and are now in the process of being purchased or implemented in every local health district. These OMIS will allow for electronic prescribing of chemotherapy.
- 2.1.7 Cancer services in NSW currently fall into three broad groups in terms of OMIS maturity: (i) there is a fully implemented OMIS including electronic prescribing; (ii) the OMIS has been implemented for documenting patient care information but not yet for electronic prescribing so prescribing is still paper-based; (iii) an OMIS is being commissioned.
- 2.1.8 The Interim Report of the section 122 Inquiry acknowledged that medical oncologists should be able to override doses entered into an OMIS but recommended that such overrides be reviewed regularly to identify any prescribing patterns of concern (Recommendation 13). The Final Report expanded that Recommendation to state that local health districts that do not yet have an Oncology Management Information System should accelerate efforts to install them.
- 2.1.9 St Vincent's Hospital implemented an OMIS (MOSAIQ) in 2015, with implementation of electronic prescribing completed by September 2015. Western NSW Local Health District has implemented MOSAIQ, including electronic prescribing.

Action in progress

- 2.1.10 Local health districts are reviewing their local governance arrangements for cancer services. This includes systems for reviewing the prescribing of chemotherapy drugs before they are ordered or compounded, systems for auditing prescribing practice, and those for implementing electronic prescribing (where it is not already in place).
- 2.1.11 By early 2018, all local health districts will have a functioning OMIS in place. The Cancer Institute NSW is supporting implementation in three local health districts that either do not have an OMIS, or have purchased an OMIS which is not yet implemented.
- 2.1.12 The Cancer Institute NSW is working with local health districts to standardise and optimise the use of OMIS across the state. The NSW government is investing \$6 million over three years to 2018-19 to enable local health district staff to make the best use of electronic systems to support improved clinical care, data analysis and reporting. This includes standardising processes for developing and approving care plans as well as processes for documenting the rationale for variations from protocols. Local health districts will develop standardised reports on protocol variation to be considered by relevant organisational quality and safety committees and morbidity and mortality committees as well as by board quality and safety sub committees. Each local health district will be responsible for reviewing and responding to any reported variances. Reporting will be done at a frequency that will enable variations from protocol to be identified between patient treatment cycles (which usually occur each three to four weeks). As part of its state-wide remit for

using its core datasets to report to local health districts on unwarranted clinical variations, the Cancer Institute NSW will also be developing indicators on variance from eviQ protocols.

2.2 Patient information sheet on dose adjustment

Overview

- 2.2.1 The NSW Health policy on informed patient consent (see Term of Reference 2.3) requires patients to be given sufficient information to have a genuine understanding of the nature of the proposed treatments or alternatives as well as any risks and benefits.
- 2.2.2 Since its inception in late 2005 (as CI-SCaT), the eviQ online resource has made information publicly available specifically for people who have been diagnosed with cancer. This includes information on each treatment protocol that outlines the treatment and its side effects, and frequently asked questions. Information about support and resources is included, as are links to a set of questions, in 20 different languages, that patients might ask their health professionals.
- 2.2.3 eviQ also publishes patient information sheets on chemotherapy safety at home, frequently occurring side effects and commonly asked questions about chemotherapy. These sheets are available in English, Arabic, Traditional Chinese, Simplified Chinese, French, Greek, Italian, Korean, Spanish and Vietnamese.
- 2.2.4 The Cancer Institute NSW publishes on its website details of the information and support resources provided by the Cancer Council Australia, Cancer Council NSW and other community organisations supporting people affected by cancer.

Current Approach

- 2.2.5 In addition to publicly available resources, it is common practice for patients to be actively provided with eviQ patient information sheets and a variety of material, including videos, from organisations such as the Cancer Council. This is provided by their treating team as part of the information and education before chemotherapy begins.
- 2.2.6 The section 122 Inquiry Interim Report recommended that the Cancer Institute NSW prepare a new information sheet with advice on dose adjustment of chemotherapy so that patients and their caregivers would be better able to understand the rationale for any changes in dose or timing of treatment (Recommendation 17).

Action in progress

- 2.2.7 In consultation with the Cancer Institute NSW Community and Consumer Advisory Panel, the eviQ team has developed and published a new information sheet, 'Understanding chemotherapy and treatment changes', to assist patients and clinicians in discussing chemotherapy treatment. The information sheet gives clear explanation of the many valid reasons, based on individual patient characteristics and condition, where a medical oncologist might recommend a variance in the dose of chemotherapy. The information sheet also suggests patients raise with their doctors any questions they have about the chemotherapy they are being prescribed.

- 2.2.8 The information sheet will be promoted by NSW Health through local health districts and specialty networks and through the Cancer Institute NSW clinical, community and consumer networks.

2.3 The process and systems around informed consent for all medical interventions, including chemotherapy

Overview

- 2.3.1 Obtaining a patient's informed consent to medical intervention or treatment such as chemotherapy is a fundamental legal and ethical responsibility of the treating medical practitioner.
- 2.3.2 What is required for informed consent will vary, to some extent, depending upon the complexity of the treatment or procedure involved, the risks and benefits of the treatment proposed, and other treatment options available. Obtaining informed consent from a patient to have blood taken for a routine blood test, for example, will generally be straightforward and will not require the patient's written consent. On the other hand, where complex medical treatment is recommended, informed consent will normally require a discussion of relevant matters with the patient (particularly where there are risks or other treatment options) as part of the consent process, including documentation of the patient's consent.

Current Approach

- 2.3.3 NSW Health has well established policies and systems in place to ensure that clinical staff working in NSW Health are aware of, and implement, the requirement for informed consent for medical interventions. This requirement has been included in state-wide policy documents for more than 25 years.
- 2.3.4 The current state wide policy directive is Consent to Medical Treatment – Patient Information PD2005_406. Compliance with this policy directive by local health districts, specialty networks and other public health organisations is mandatory.
- 2.3.5 The key principles that inform the NSW Health state wide policy are:
- Adult patients with capacity have a right to decide what happens to their own bodies. This means that, in general, medical treatment cannot be provided without consent
 - Adults with capacity have the right to refuse treatment, for any reason, even if refusal of treatment is likely to lead to serious injury or death
 - Medical practitioners should assume that adult patients have capacity to consent unless there is evidence to contradict this assumption
 - Patients (including adults, young people and children) must be provided with sufficient information about their condition, treatment options and prognosis in order to make or contribute to their own treatment decisions
 - Information provided to patients needs to be tailored to the individual's needs and circumstances

- Subject to accepted legal and ethical standards of medical care, patients without the capacity to consent have a right to a substitute decision-maker and to be provided with care consistent with valid advance care directives that they have made. This may include appointment of a guardian to make medical treatment decisions in accordance with the *Guardianship Act 1987*.

2.3.6 The implications of these principles for health care professionals and managers are that they must:

- understand the legal requirements for obtaining consent from patients and the consequent need to provide patients with sufficient information
- ensure that documented evidence of a patient's consent or refusal of treatment is recorded in the patient's health care record
- ensure that patient autonomy and decision-making is respected and that patients are provided with appropriate information relevant to their treatment; and
- understand their legal obligations with regard to providing medical treatment to patients who do not have capacity to consent.

2.3.7 In order to ensure compliance with legal requirements, consistency and simplicity of application, the general approach adopted in NSW Health is for a single model consent form to apply to all medical interventions. Specific consent forms are generally only used where there is a legal requirement to do so, such as substitute decision-making for children or adults lacking capacity to consent.

2.3.8 Local health districts and networks are permitted to develop local consent forms for use within their health service, based on the state wide model consent form, subject to endorsement of the form by a local forms committee.

2.3.9 Local health districts and networks are to comply with the NSW Health policy directive for obtaining informed consent from patients and this compliance is audited. Practice varies with regard to the format in which documents are stored (electronic format or paper records).

2.3.10 The Health Education and Training Institute include resources on informed consent in a range of their education programs such as Nursing, Midwifery and the Law.

Action in progress

2.3.11 The section 122 Inquiry's Final Report recommended that clinicians across NSW ensure adequate informed consent for all medical interventions, including chemotherapy. If the clinician knows that his or her practice is outside accepted practice, there is a particular onus to draw this to the attention of patients in the process of providing informed consent, and to document this in the patient notes (Recommendation 21). Local health districts and networks are currently reviewing how their processes specifically address this section 122 Inquiry recommendation.

2.3.12 The Ministry of Health is currently undertaking a comprehensive review of the Policy Directive, Consent to Medical Treatment – Patient Information PD2005_406. The review will include converting the Policy Directive into a manual, reflecting that the policy provides operational guidance and outlines procedures to support compliance.

It will also enable the document to be updated from time to time to reflect any changes in law, policy or practice around informed consent. The manual will include examples of frequently occurring scenarios, in order to support best practice in obtaining informed consent to health treatment.

- 2.3.13 The draft new manual contains a number of provisions dealing specifically with chemotherapy, including explicitly requiring written patient consent for chemotherapy and retaining the guidance in the current policy directive about managing informed consent in circumstances where chemotherapy involves the administration of medication over a period of time or over a series of patient visits.
- 2.3.14 As part of the consultation process on the revised draft informed consent manual, comment will be sought on whether there should be specific guidance in relation to several issues arising from the section 122 Inquiry. These questions include:
- whether any additional specific requirements should be included in the manual regarding informed consent for chemotherapy
 - whether the consent manual should include any specific guidance or discussion of the requirements for informed consent where a clinician knows his or her practice is outside accepted practice.

2.4 The capacity of the NSW Health system to have people diagnosed with cancer overseen by a multidisciplinary cancer care team

Overview

- 2.4.1 Multidisciplinary care has demonstrated a range of benefits for people with cancer including: improved treatment planning (such as adding neoadjuvant or adjuvant chemotherapy or chemoradiation to a treatment plan where the main treatment is surgery), increased opportunity to participate in clinical trials and better coordination of treatment.
- 2.4.2 Cancer Australia defines multidisciplinary care as “... an integrated team approach to health care in which medical and allied health care professionals consider all relevant treatment options and collaboratively develop an individual treatment and care plan for each patient”. Cancer Australia further suggests that “a central theme of meetings should be prospective treatment planning.”¹¹ Other important factors for the conduct of these multidisciplinary meetings are:
- the need for protocols that ensure patient preferences, concerns and circumstances are considered in developing the plan and that the outcomes of the meeting are discussed with the patient, who agrees to the final treatment plan and
 - the availability of information about the patient which will vary according to the type of cancer. With patient consent to this use of their information, this is likely to include relevant details of their medical history, pathology reports and slides, imaging films and scans, the results of diagnostic examinations, blood test results and any previous treatment plans.

- 2.4.3 The level of discussion of patients at any multidisciplinary cancer care team meeting reflects the complexity of patients' individual clinical and psychosocial characteristics. As an example the team will have well established and documented characteristics of the people for whom an in depth discussion is not required. For all other patients, discussion will be required to assist in developing the most appropriate treatment plan for them.
- 2.4.4 Each multidisciplinary cancer care team is responsible for documenting:
- its membership, including the core disciplines that are fundamental to treatment planning for the relevant tumour group
 - the team's role in treatment planning and ongoing care
 - local protocols to guide the decision-making process
 - the decisions that are made at each meeting.

Current Approach

- 2.4.5 All local health districts have established multidisciplinary cancer care teams or have access to them, including through telehealth arrangements.
- 2.4.6 The section 122 Inquiry Interim Report recommended that minuted meetings of multidisciplinary cancer care teams occur after relevant international or national meetings and on an *ad hoc* basis as new evidence emerges (Recommendation 15). The Inquiry Report on patients treated at Western NSW Local Health District recommended that, where multidisciplinary cancer care teams have a single member from a discipline, clinicians consider joint minuted meetings with another team after relevant national or international meetings (Recommendation 14).

Action in progress

- 2.4.7 Following the section 122 Inquiry, local health districts and networks are reviewing the terms of reference for their multidisciplinary cancer care teams consistent with Inquiry recommendations. Local health districts and networks are also reviewing the ways they can ensure emerging evidence is presented and discussed at meetings of multidisciplinary cancer care teams or other appropriate forums.
- 2.4.8 The Cancer Institute NSW now requires, as a condition of the funding it provides to local health districts and networks to support multidisciplinary cancer care teams, that they report on the number of patients overseen by each team.

2.5 St Vincent's Hospital's capability to comply with relevant NSW Health Policy Directives and Guidelines

Overview

- 2.5.1 St Vincent's Hospital Sydney Limited, which operates St Vincent's Hospital, is an affiliated health organisation under the *Health Services Act*. St Vincent's Hospital is required, as a condition of subsidy, to comply with all policy directives issued by the NSW Ministry of Health that apply to affiliated health organisations.

- 2.5.2 The NSW Health Performance Framework provides for performance reviews of public health organisations, including the potential escalation of performance levels. Performance levels are assigned to all local health districts and specialty networks in a range between zero and four. Zero means there are no performance concerns and four indicates the health service is Challenged and Failing, prompting actions such as commissioning an independent review or appointing an administrator.
- 2.5.3 Affiliated health organisations are subject to the NSW Health Performance Framework to the extent appropriate to their roles and functions. A failure by an affiliated health organisation to comply with the requirements of its performance agreement may result in the organisation being placed on escalated performance management.
- 2.5.4 In addition to the Secretary's power to enter into a performance agreement with an affiliated health organisation, the *Health Services Act* provides for the Minister for Health and the Secretary to exercise the following powers to direct and regulate the activities of affiliated health organisations :
- the Minister determines the level of funding to be provided to affiliated health organisations, including imposing conditions on that funding, such as a condition that the organisation complies with applicable policy directives issued by the Secretary
 - the Minister determines the role, functions and activities of any recognised establishment or recognised service of an affiliated health organisation
 - the Minister approves the affiliated health organisation's by-laws.

Current approach

- 2.5.5 The Service Agreement that applies to St Vincent's Hospital sets out the service and performance expectations and funding. Under this Agreement, St Vincent's Hospital is required to meet the service obligations and performance requirements, including meeting key performance indicators in several domains, such as safety and quality, service access and patient flow, and people and culture.

Action in progress

- 2.5.6 In response to the section 122 Inquiry Interim Report, on 14 April 2016 the performance level of the affiliated health organisation that includes St Vincent's Hospital was escalated to a performance level of two, indicating it was Under-Performing. Level two requires the service to undertake an in-depth assessment of the problem, identify options to address it, provide a detailed recovery plan and meet the Ministry of Health monthly to discuss progress. In this instance, the Inquiry Interim and Final Reports and their recommendations have served as the recovery plan. Updates on actions taken by St Vincent's Hospital to address Inquiry recommendations are provided at monthly meetings with the Ministry.
- 2.5.7 St Vincent's Hospital's three-month progress report of July 2016 on its implementation of the recommendations in the Inquiry Interim Report was included as an Appendix to the Inquiry Final Report. Actions that St Vincent's Hospital has taken on recommendations have included offering apologies, open disclosure and the provision of clinical and psychosocial support to patients and their families who were affected by the off-protocol prescribing of chemotherapy. There has also been

action on the provision of education on relevant NSW Health policies; a review of processes and practice in relation to incident management; the introduction of a communications campaign to drive cultural change in relation to escalating concerns about patient care, and the establishment of a MOSAIQ Care Plan Committee to oversee the process for approving care plans and monitoring protocol variations.

- 2.5.8 In its progress report of October 2016, St Vincent's Hospital has reported that it is implementing improvements to its procedures and practices for meetings of mortality and morbidity committees and for internal escalation of clinical concerns. St Vincent's Hospital is engaging the NSW Clinical Excellence Commission and the Health Education Training Institute in responding to the new recommendations for cultural change that the section 122 Inquiry made in its Final Report.
- 2.5.9 The section 122 Inquiry Recommendation Seven addressed the need for St Vincent's Hospital to provide education to key staff on relevant NSW Health policies, including the Lookback Policy, Incident Management Policy, Open Disclosure Policy, and Managing Complaints or Concerns About a Clinician.
- 2.5.10 At monthly meetings with the Ministry, St Vincent's Hospital has demonstrated a continuing focus on improving the education of its staff on NSW Health policies, specifically those related to critical incidents.
- 2.5.11 St Vincent's Hospital has also developed a new Incident Management Training program, designed to support the implementation of the NSW Health Incident Management, Lookback and Open Disclosure policies. The program was delivered in May 2016 to 150 staff including the St Vincent's Hospital Sydney executive, clinical stream directors, clinical stream managers, heads of department, department managers and senior managers. St Vincent's Hospital has indicated it will provide this training annually to ensure new staff receive the training. The program will also be delivered as a refresher for existing staff every two years.

2.6 NSW Health Code of Conduct and programs within NSW Health and St Vincent's Hospital in relation to staff raising concerns about the practice of clinicians

Overview

- 2.6.1 NSW Health has core values which seek to provide a workplace that is collaborative, open, respectful and empowering.
- 2.6.2 The NSW Health Code of Conduct defines standards of ethical and professional conduct required of everyone working in NSW Health, as well as behaviours which are unacceptable and will not be tolerated. The Code of Conduct applies to all NSW Health organisations, including affiliated health organisations.
- 2.6.3 The Code of Conduct assists with building a positive workplace culture based on NSW Health core values. The Code is intended to provide a framework to promote ethical day-to-day conduct and decision-making. A program called Core Chat, developed by the NSW Health Education and Training Institute, supports the implementation of the

NSW Health Code of Conduct and core values across the system, through conversations that provide mutually acceptable and forward focused conflict resolution, rather than being about blame, prejudice, conflict or anxiety.

- 2.6.4 NSW Health workplace relations policies are underpinned by the NSW Health Code of Conduct and relevant industrial and legislative requirements. These policies provide for employee and workplace management practices that enable the attraction, recruitment and retention of the right staff in the right positions and the management of these staff during the employment relationship to enable the provision of safe and effective patient care. The policies provide for the appropriate management of employee performance and conduct issues.
- 2.6.5 There are several NSW Health policies that apply where staff raise concerns about the practice of clinicians, and other breaches of the Code of Conduct, providing:
- principles for managing complaints or concerns about clinicians
 - guidance on roles and responsibilities, including the responsibility of all staff to be vigilant in identifying and raising concerns about colleagues whose health, conduct or performance is a risk to patient safety, to the organisation, or to others, and the responsibility of the organisation to actively manage complaints and concerns
 - key features to be reflected in all NSW Health organisation policies on performance management
 - assistance to managers to fulfil their obligations to eliminate or minimise the risk of bullying and managing complaints about bullying
 - encouragement and support to staff to resolve conflict and workplace grievances
 - requirements for the timely management of allegations of staff misconduct.
- 2.6.6 As an example, the Complaint or Concern about a Clinician Policy Directive 2006_007 establishes a set of principles to be used when managing a complaint or concern about a clinician. It applies to all clinicians working in the NSW health system, whether employed or contracted. The accompanying Complaint or Concern about a Clinician - Management Guidelines GL2006_002 describe how to address the complaint or concern, while ensuring that the interests of the organisation, the public and the needs of the professional are met. Chief executives of public health organisations have a primary obligation to ensure complaints and concerns are acted upon, by way of investigation and, where necessary, that appropriate action is taken to implement findings.

Current Approach

- 2.6.7 Strategy one of the NSW State Health Plan: Towards 2021 focuses on delivering a positive workforce culture in NSW Health. The Health Professionals Workforce Plan 2012-2022 was developed to set out the actions required to deliver a healthy workforce with the right people, with the right skills in the right place, ensuring the NSW Health core values are embedded across the spectrum of healthcare delivery. The NSW Health Workplace Culture Framework: Making a positive difference to workplace culture has been designed to embed cultural improvement strategies as part of core business in every facility.

- 2.6.8 NSW Health has been conducting workplace culture surveys with staff since 2011. The 2015 YourSay Workplace Culture Survey showed continued improvement in the Workplace Culture Index [54 per cent in 2015, an increase of eight percentage points since 2011] and the Employee Engagement Index [68 per cent in 2015, an increase of five percentage points since 2011] across the NSW Health system as a whole.
- 2.6.9 The Health Education and Training Institute provides courses and programs that support the implementation of a positive workplace culture through developing workforce capability in the application of core values and Core Chat as well as leadership, communication and conflict resolution competencies.
- 2.6.10 These actions are supported at a state level by NSW Health participation in the Public Service Commission People Matters staff survey. This survey supports system wide monitoring of culture while maintaining a focus on local implementation of workplace culture programs.

Action in progress

- 2.6.11 The section 122 Inquiry identified that pharmacists and nurses raising questions with a prescribing medical oncologist and escalating any unaddressed concerns was integral to the safe prescribing and administration of chemotherapy.
- 2.6.12 The Inquiry recommended that St Vincent's Hospital revisit mechanisms for escalating clinical concerns (Recommendation 12).
- 2.6.13 St Vincent's Hospital has advised the NSW Ministry of Health that it has launched a local communications campaign called 'It's OK to ask' which aims to ensure patient safety is an ongoing focus, through promoting a culture of open dialogue between all staff. The key message is that staff should feel empowered to ask questions of their peers and leaders particularly in relation to patient care. Staff are being reminded of the specific avenues available for escalation and support.
- 2.6.14 St Vincent's Hospital is also working with the Health Education and Training Institute to review the applicability of their NSW Health Leadership Program. This program broadly covers topics relating to achievement of outcomes, self-development and personal leadership capacity, engaging with people and building relationships, internal and external stakeholder management and addressing complex challenges to positively transform the system.

-
- ¹ Cancer Institute NSW. New South Wales Cancer Statistics [Internet]. Sydney: Cancer Institute NSW; 2016 [cited 13 October 2016.] <https://www.cancerinstitute.org.au/understanding-cancer/cancer-in-nsw/all-cancers-nsw-data>
- ² Coleman MP, Forman D, Bryant H, Butler J, Rachet B, Maringe C et al, Cancer survival in Australia, Canada, Denmark, Norway, Sweden, and the UK, 1995-2007 (the International Cancer Benchmarking Partnership): an analysis of population-based cancer registry data. *Lancet*. 2011;377: 127–38.
- ³ NSW Health Policy Directive PD2009_012, Cancer Registry — Notifying Cancer Cases to the NSW Central Cancer Registry, Appendix 1, 24–35
- ⁴ Cancer Institute NSW. New South Wales Cancer Statistics. [Unpublished]
- ⁵ Bureau of Health Information. Patient Perspectives – How do outpatient cancer clinics perform? Experiences and outcomes of care, February and March 2015. Sydney (NSW); BHI; 2016. Available from http://www.bhi.nsw.gov.au/BHI_reports/patient_perspectives/how_do_outpatient_cancer_clinics_perform
- ⁶ NSW Health Annual Report 2014-15. Sydney: NSW Ministry of Health; 2015; pp ii, 6.
- ⁷ Australian Institute of Health and Welfare. National Health Workforce Dataset 2015. [Internet]. [cited 18 October 2016] <http://www.aihw.gov.au/workforce/>
- ⁸ Australian Institute of Health and Welfare 2016. Non-admitted patient care 2014–15: Australian hospital statistics. Health Services series no.60. Cat. No. HSE 174. Canberra: AIHW. (Table 3.3). Refer <https://www.ihsa.gov.au/what-we-do/tier-2-non-admitted-care-services-classification> for the classification of Tier 2 non-admitted care services.
- ⁹ Tan EL, Stark H, Lowinger JS, Ringland C, Ward R, Pearson S-A, Information sources used by New South Wales cancer clinicians: a qualitative study. *Intern Med J*.2006;36;711-7
- ¹⁰ eviQ Cancer Treatments Online 2016 [Internet]. Sydney: Cancer Institute NSW; 2016 [cited 13 October 2016], <https://www.eviq.org.au>
- ¹¹ Cancer Australia. All about multidisciplinary care. [Internet] [cited 20 October 2016] <https://canceraustralia.gov.au/clinical-best-practice/multidisciplinary-care/all-about-multidisciplinary-care>.

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:

<i>Date</i>	<i>Document/event</i>
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 tumour site, N describes the regional lymph nodes, and M describes the presence or absence of distant metastasis. 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 overridden 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 suggest 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.

References

1. Currow DC, Thomson W, Lu H. Cancer in NSW: Incidence and Mortality Report 2010. Sydney: Cancer Institute NSW, October 2015. 2015.
2. AIHW. Head and neck cancers in Australia. Australian Institute of Health and Welfare Cancer Series Number 83 Cat no CAN 80 Canberra: AIHW. 2014.
3. ESMO. Head and Neck Cancer: A Guide for Patients. EUROPEAN SOCIETY FOR MEDICAL ONCOLOGY Information based on ESMO Clinical Practice Guidelines - v20151. 2015.
4. Pfister DG, Spencer S, Brizel DM, Burtneß B, Busse PM, Caudell JJ, et al. Head and Neck Cancers, Version 1.2015. Journal of the National Comprehensive Cancer Network : JNCCN. 2015;13(7):847-55; quiz 56.
5. NICE. Improving Outcomes in Head and Neck Cancers. . National Institute for Clinical Excellence, London November 2004 ISBN: 1-84257-812-X. 2004.
6. AIHW. Head and Neck Cancers. Australian Institute of Health and Welfare Available at <http://www.aihw.gov.au/cancer/head-and-neck/> accessed 29th March 2016. 2016.
7. Gregoire V, Lefebvre JL, Licitra L, Felip E. Squamous cell carcinoma of the head and neck: EHNS-ESMO-ESTRO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Annals of oncology : official journal of the European Society for Medical Oncology / ESMO. 2010;21 Suppl 5:v184-6.
8. Pignon JP, Bourhis J, Domenge C, Designe L. Chemotherapy added to locoregional treatment for head and neck squamous-cell carcinoma: three meta-analyses of updated individual data. MACH-NC Collaborative Group. Meta-Analysis of Chemotherapy on Head and Neck Cancer. Lancet (London, England). 2000;355(9208):949-55.
9. J. Bourhis CAJ-PPobotM-NCG. Update of MACH-NC (Meta-Analysis of Chemotherapy in Head & Neck Cancer) database focused on concomitant chemoradiotherapy. Journal of Clinical Oncology, 2004 ASCO Annual Meeting Proceedings (Post-Meeting Edition) Vol 22, No 14S (July 15 Supplement), 2004: 5505 Institut Gustave-Roussy, Villejuif, France. 2004.
10. SIGN. Diagnosis and Management of Head and Neck Cancer. Scottish Intercollegiate Guidelines Network SIGN 90 October 2006. 2006.
11. Fountzilas G, Ciuleanu E, Dafni U, Plataniotis G, Kalogera-Fountzila A, Samantas E, et al. Concomitant radiochemotherapy vs radiotherapy alone in patients with head and neck cancer: a Hellenic Cooperative Oncology Group Phase III Study. Medical oncology (Northwood, London, England). 2004;21(2):95-107.
12. Olmi P, Crispino S, Fallai C, Torri V, Rossi F, Bolner A, et al. Locoregionally advanced carcinoma of the oropharynx: conventional radiotherapy vs. accelerated hyperfractionated radiotherapy vs. concomitant radiotherapy and chemotherapy--a multicenter randomized trial. International journal of radiation oncology, biology, physics. 2003;55(1):78-92.
13. Jeremic B, Shibamoto Y, Stanisavljevic B, Milojevic L, Milicic B, Nikolic N. Radiation therapy alone or with concurrent low-dose daily either cisplatin or carboplatin in locally advanced unresectable squamous cell carcinoma of the head and neck: a prospective randomized trial. Radiotherapy and oncology : journal of the European Society for Therapeutic Radiology and Oncology. 1997;43(1):29-37.
14. Guan J, Li Q, Zhang Y, Xiao N, Chen M, Zhang Y, et al. A meta-analysis comparing cisplatin-based to carboplatin-based chemotherapy in moderate to advanced squamous cell carcinoma of head and neck (SCCHN). Oncotarget. 2016.
15. Bourhis J, Rivera F, Mesia R, Awada A, Geoffrois L, Borel C, et al. Phase I/II study of cetuximab in combination with cisplatin or carboplatin and fluorouracil in patients with recurrent or metastatic squamous cell carcinoma of the head and neck. Journal of clinical oncology : official journal of the American Society of Clinical Oncology. 2006;24(18):2866-72.
16. Forastiere AA, Metch B, Schuller DE, Ensley JF, Hutchins LF, Triozzi P, et al. Randomized comparison of cisplatin plus fluorouracil and carboplatin plus fluorouracil versus

methotrexate in advanced squamous-cell carcinoma of the head and neck: a Southwest Oncology Group study. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology*. 1992;10(8):1245-51.

17. De Andres L, Brunet J, Lopez-Pousa A, Burgues J, Vega M, Tabernero JM, et al. Randomized trial of neoadjuvant cisplatin and fluorouracil versus carboplatin and fluorouracil in patients with stage IV-M0 head and neck cancer. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology*. 1995;13(6):1493-500.
18. Bonner JA, Harari PM, Giralt J, Azarnia N, Shin DM, Cohen RB, et al. Radiotherapy plus cetuximab for squamous-cell carcinoma of the head and neck. *The New England journal of medicine*. 2006;354(6):567-78.

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

Off-protocol prescribing of chemotherapy for head and neck cancers

Final report

31 July 2016

Table of Contents

Introduction

Background

Findings

Recommendations

References

Appendix A Final Consolidated Terms of Reference

Appendix B Clinical Review and Findings

B.1 Methodology for the clinical review

B.2 Fields in the clinical audit tool

B.3 Data tree

B.4 Table comparing baseline characteristics of patients with head and neck cancers treated with three different chemotherapy regimens

B.5 Number of patients treated with flat dose 100 mg carboplatin over time

Appendix C Timeline for the development of CI-SCaT and eviQ and their adoption as policy

C.1 South Eastern Sydney and Illawarra Area Health Service Policy PD233: Cancer Services — use of eviQ cancer Treatments Online

Appendix D External advice provided to the Inquiry

Appendix E List of journal articles provided to the Clinical Expert Panel

Appendix F Flow diagram of standard chemotherapy prescribing and administration process

Appendix G Interim Report: St Vincent's Hospital's three month progress report on implementation of recommendations

Appendix H NSW Health Policy Directives and Guidelines

H.1 Incident Management Policy (PD2014_004)

H.2 Lookback Policy (PD2007_075)

H.3 Complaint or Concern about a Clinician — Principles for Action (PD2006_007)

H.4 Complaint or Concern about a Clinician — Management Guidelines (GL2006_002)

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 incident'). The Terms of Reference (ToR) of the Inquiry were finalised on 25 February 2016 (see Appendix A).
- 2 The Terms of Reference for this Inquiry are built around the hospital's response to Dr Grygiel's prescribing of off-protocol flat dose 100 mg carboplatin. There are separate ongoing inquiries by the Health Care Complaints Commission (HCCC) and the Medical Council of New South Wales, into the clinical practice and professional conduct of Dr Grygiel.
- 3 The Inquiry team (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>.
- 4 The Terms of Reference were expanded on 4 April 2016 to include: patients of Dr Grygiel's treated in the Western NSW Local Health District; consideration of the information provided to patients directly affected by the incident (and their families) and patients with cancer treated by Dr Grygiel from January 2006 to June 2015. The Final Report was to be provided to the Secretary by 31 July 2016.
- 5 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 Sydney to be provided by 31 July 2016, 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.
- 6 There were seven sources of information, detailed below, that informed the Inquiry for its Interim Report and this Final Report in relation to St Vincent's Hospital.
 - A Documents** were sourced from St Vincent's Hospital relating to the Terms of Reference for the Inquiry. 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 of St Vincent’s Hospital and other relevant people who agreed to be interviewed. Several people declined an invitation to meet members of the Inquiry team. The number of people interviewed was 30; the number of interviews held was 34.
 - D Reviews of clinical records** were conducted for the relevant patient cohort from St Vincent’s Hospital. Radiation oncology records were sourced from the third party radiation oncology provider following protracted negotiations.
 - E Expert clinical input** was provided by clinicians and academics in medical and radiation oncology, clinical pharmacology and pharmacy, who were predominantly from interstate.
 - F Patients and families** whose care was affected by the off-protocol flat dosing of carboplatin chemotherapy, and who accepted an invitation to participate in the Inquiry, were interviewed. The interview process and questions were developed in consultation with a health consumer advisor.
 - G Submissions** were received from several people. Some were responses to the Inquiry’s Interim Report. The submissions generally related to views on clinical issues relevant to the Inquiry.
- 7 From these data sources, the following timeline of events has been compiled. The Inquiry was provided with key dates by St Vincent’s Hospital. The Inquiry was advised that, in June and July 2015, concerns about off-protocol flat dose prescribing of carboplatin were raised in several ways. As to whether the issue was discussed at the Head and Neck cancer Multidisciplinary meeting in June 2015, there are two different accounts: (i) that, following a challenge to the practice, there was an agreement that all new patients would be prescribed according to the eviQ protocol dosing regimen from then on; and (ii) no such discussion took place. Subsequent key events for which the Inquiry has seen documentary evidence or has been advised by more than one person are as follows:

<i>Date</i>	<i>Document/event</i>
7–12 August 2015	<p>Several meetings held. It was also considered whether the Lookback Policy should be invoked.</p> <p>Matter for Information prepared by Medicine Clinical Stream Manager, Executive Sponsors Chief Operating Officer (COO); Director Clinical Governance (DCG) and Chief Medical Officer (CMO; one person occupying both these roles).</p>

Initial review group of pharmacy, nursing and medical staff briefed the COO and CMO on 7.8.2015.

Initial internal investigation commenced: 5 patients with recent disease recurrence identified of a total group of 'over 70' patients.

Agreed to review a larger subset of the original list of approximately 70 patients.

A further briefing to the CMO and COO was to be provided in the week beginning 17.8.2015

10 August 2015	MOSAIQ oncology information system implemented at St Vincent's Hospital.
31 August 2015	DCG and Director of Cancer Services (DCS) met Dr Grygiel. No contemporaneous written record of this meeting exists.
16 November 2015	Matter for Information attaching Final Internal Investigation was provided to the St Vincent's Hospital Executive.
24 November 2015	Formal invitation issued to the first external reviewer who was approached
26 November 2015	First external reviewer declines invitation
10 December 2015	Meeting of the St Vincent's Health Australia Board included a brief regarding this matter, under the heading "Emerging Risks"
11 December 2015	Second external reviewer approached informally
22 December 2015	External review commences
9 February 2016	External review report sent to St Vincent's Hospital
18 February 2016	Disclosure to some affected patients First media report is aired
22 February 2016	Further email to St Vincent's Hospital from the external reviewer
23 February 2016	Open Disclosure processes with other affected patients commence

- 8 The initial investigation (5* patients with known recurrence), the internal investigation (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 flat dose 100 mg carboplatin.

* Of note, 1 person with known cancer recurrence, who was initially thought to have been treated with an off-protocol flat dose 100 mg carboplatin, was later confirmed to have had treatment using a standard protocol.

- 9 The Inquiry has conducted detailed reviews of the clinical records of people treated with this off-protocol dose and their outcomes to date, using an audit tool (see Appendix B.2) that was endorsed by the Clinical Expert Panel. The results are summarised in a complete data tree (see Appendix B.3).

Background

- 10 To deliver the best cancer care, emerging treatments are rigorously compared to standard treatments. This usually requires several phases of clinical trials, culminating in at least one large, international clinical trial that quantifies the comparative net effect of the emerging treatment for that patient population. If the overall benefit of the emerging treatment is sufficiently greater, it then becomes the new standard treatment. Such comparisons require carefully designed and executed clinical studies to be ethically justified and clinically sound.
- 11 There are areas of clinical practice where new evidence is required in order to refine practice, even for medications that have been used for decades. Using a chemotherapy drug in a way that is not provided for in established treatment protocols is problematic. Benefits and harms in the short and long term will be uncertain and almost impossible to quantify. Instead, new knowledge needs to be collected in a systematic way, with clear research protocols set out before such work begins, with clear processes of informed consent for people being treated on such a protocol under the oversight of Human Research Ethics Committee as set out by the Australian Code for the Responsible Conduct of Research. Without such a framework, it will be difficult to define the net effects of such prescribing and such prescribing would need to be considered 'off protocol'. If a clinician is going to move away from the available evidence, at a minimum there is an onus on that clinician to frame a hypothesis prospectively and collect data to test, with the explicit oversight of a Human Research Ethics Committee, whether the different clinical approach is at least as effective in treating the cancer and has other demonstrable benefits.
- 12 Administering chemotherapy requires a careful balance between the anti-cancer effect that is sought (in this case radiosensitisation) and side effects. Studies to determine the optimal dose and dose frequency are complex, require objective measures in order to determine the net effect and are unlikely to be robust unless there is a comparator group to establish superiority to current therapy (greater anti-cancer effect, less toxicity with equivalent effect on cancer, greater anti-cancer effect and less toxicity).

- 13 Treatment protocols for chemotherapy are based on the best available published evidence from clinical trials. Each describes:
- the treatment schedule: drug names; drug doses and the way these doses are to be calculated; the number and frequency of doses; and how the drugs are administered;
 - any tests required before, during or after treatment;
 - possible side-effects;
 - situations when it may be appropriate to change doses, dose intervals or choose another chemotherapy protocol altogether.
- 14 With any treatment, the treating clinician needs to make a judgement about the expected outcomes, the likelihood and magnitude of benefits and harms, in both the short and the long term. Much of this clinical judgement is because of the co-morbidities which are so frequently encountered in cancer care, particularly as the population ages. The particular challenge for medical oncology is that many chemotherapies have a relatively narrow therapeutic window: maximising the effect on the cancer while minimising the effect on the rest of the person's body is key to optimising the use of chemotherapy. This includes minimising acute toxicities so that therapy can, ideally, be completed in the timeframe originally sought at the dose originally proposed in order to maximise the net benefits of the therapy.
- 15 In most cases, a medical oncologist first considers the standard protocol for the particular cancer and the stage of the cancer. Depending on the patient's personal characteristics (such as age, general health, kidney function and body habitus), the medical oncologist may choose to modify the application of the protocol. For example, when prescribing a drug that is cleared through the kidneys, the medical oncologist will take the patient's kidney function into account. Such changes, and the reasons for them, should be discussed with the patient and documented by the medical oncologist in the patient's medical records.
- 16 Most of the advances in cancer survival in the last 30 years have been due to incremental improvements on previous treatment protocols, including improved patient selection — they are many small step-wise advances in treatment.

HEAD AND NECK CANCERS

- 17 Head and neck cancers refer to a heterogeneous group of cancers that usually form in the squamous cells lining the mucosal surfaces 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 2012, there were 1,118 new cases of head and neck cancers and 365 deaths from head and neck cancers (1-3).

- 18 Risk factors for mucosal head and neck cancers include tobacco and alcohol consumption, and infection with human papillomavirus (HPV). The latter has only been recently recognised as the cause for a major shift to younger, non-smokers being diagnosed with these cancers. Across Australia, the younger age group who have evidence of human papilloma virus contribute to an increasing proportion of people diagnosed with head and neck cancer. This contrasts with the typical patient population of three decades ago, who were predominantly older, with high smoking rates and alcohol intake.

ANATOMY

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

STAGING

- 20 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. Head and neck cancers are 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 tumour, N describes the presence of cancer in regional lymph nodes, and M describes the presence or absence of distant metastases. The TNM combination can be summarised, for head and neck cancers, into a stage group between I (localised disease) and IV (either locally advanced disease or disease that has spread to other parts of the body).

OVERALL 1 AND 5 YEAR SURVIVAL

- 21 In NSW, for all people diagnosed with head and neck cancer in 2005-2009, 1-year and 5-year relative survival rates (across all disease stages) were 80.8% and 59.6%, respectively. These figures continue to improve over time: for people diagnosed in 1995-1999, 1-year and 5-year relative survival was 78.4% and 52.9% respectively. (Of note, expected survival rates will be lower in the patient cohort considered in this report as, by definition, they had more advanced disease than everyone diagnosed with these cancers which would include people with early stage disease at the time of diagnosis.)
- 22 The sub-group of patients who are younger, non-smokers and non-drinkers, and are HPV positive, has a more favourable prognosis.

TREATMENT

- 23 All patients who are diagnosed with a head and neck cancer should have their care overseen by a multidisciplinary cancer care team (MDT). The MDT comprises various health professionals, including: surgical, medical and radiation oncologists, pathologists, radiologists, dietitians, speech pathologists, nurses, pharmacists, physiotherapists, dentists and social workers. Its initial objective is to determine the type of cancer and its extent of disease for each patient. From that, taking account of the patient's general health and expressed preferences, the MDT should then discuss and agree on the most appropriate recommended treatment strategy. The MDT has ongoing oversight of the patient's progress in his or her treatment, particularly if the cancer does not respond to therapy or if it recurs (6).
- 24 Surgery and radiotherapy are methods of local treatment for head and neck cancers. In early (stage I and II) disease, surgery and radiotherapy give 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. The population covered in this Inquiry had locally advanced disease, treatment options for which are clearly outlined in the National Comprehensive Cancer Network (NCCN) guidelines and in the eviQ Cancer Treatments Online information on how to administer the chemotherapy chosen.
- 25 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, advanced or metastatic disease, and where systemic therapy is indicated, chemotherapy is the standard option and may be augmented for some patients with radiotherapy to specific sites of disease and, in a highly selected sub-group, surgery. Supportive care interventions are recommended for managing the nutritional, psychological, social and physical needs that may arise with treatment or from the disease itself (7).

Chemoradiation versus radiotherapy alone for head and neck cancers

- 26 In both resectable and unresectable cancers, concurrent chemoradiation (chemotherapy and radiotherapy administered over the same period of time) has shown an absolute overall survival benefit of up to 8 percentage points at five years, compared with radiotherapy alone, based almost entirely on studies of cisplatin (8–10). Control of the cancer locally (loco-regional control) is also improved with chemoradiation when compared with radiotherapy alone. However, there is increased acute toxicity when chemotherapy is used concurrently with radiotherapy (11–13). Chemotherapy in this setting is termed a radiosensitiser.

- 27 Supportive care has also improved markedly in the last decade. It is important to anticipate likely treatment toxicities and to treat them actively in order to optimise the ability to tolerate the anti-cancer therapies and to deliver these therapies on dose and on time. In the use of carboplatin or cisplatin chemotherapies, this particularly includes nausea, which can limit the ability to tolerate chemotherapy.

Chemotherapeutic agents in chemoradiation for head and neck cancers

- 28 Cisplatin is the first-line chemotherapeutic agent because there is most evidence available in terms of its efficacy, when used in combination with radiotherapy for people with head and neck cancers. More recently, the targeted agent cetuximab (which has been subsidised in Australia since 2007) is indicated for patients who are not candidates for cisplatin in combination with radiotherapy (14). Carboplatin is the third-line choice and can be used for patients who have previously been treated with cisplatin, or are known not to be able to tolerate cisplatin. The studies that have been reported generally suggest there is a benefit using carboplatin concurrently with radiotherapy but the magnitude of benefit over radiotherapy alone is difficult to quantify. It should be noted that all controlled studies published used a higher dosage of carboplatin than an off-protocol flat dose 100 mg carboplatin. 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 (12). In general, cisplatin is associated with more toxicity for kidneys, nerves and hearing than carboplatin, although carboplatin is more toxic to bone marrow. Compared to cisplatin in this clinical setting, there are relatively few clinical trials of carboplatin, and none published comparing carboplatin directly with cisplatin. All protocols for cisplatin or carboplatin would adjust dose to the characteristics of each patient.
- 29 Induction chemotherapy is chemotherapy given as initial treatment prior to other treatment. In head and neck cancers, induction chemotherapy usually involves cisplatin. When cisplatin is used in induction chemotherapy, carboplatin could be the appropriate agent for the subsequent chemoradiation because of the risk of the cumulative effects from prior cisplatin use.

Chemotherapy dosing in chemoradiation

- 30 The dose of chemotherapy drugs is most often personalised to an individual by calculating the dose for the person's body surface area (BSA), using height and weight variables.
- 31 Cisplatin is administered every three weeks in the setting of radiotherapy for head and neck cancers with the aim of giving three doses (cycles) at the same time as radiotherapy. The dose is personalised for each person depending on their body surface area (BSA) and kidney function. Not everyone completes the chemotherapy

but there will still be an overall benefit if a person receives at least two cycles (a cumulative dose of $\geq 200 \text{ mg/m}^2$) (15). Other options could include weekly cisplatin at a dose of 40 mg/m^2 . Likewise, a cumulative dose of 200 mg/m^2 of cisplatin is the minimum effective radiosensitisation dose in concurrent chemoradiation (15–18).

- 32 For carboplatin, dosing by body surface area (BSA) does not correlate well with toxicity. In 1989, Calvert *et al* (19) developed a dosing formula that still achieves the desirable concentration of the drug in the blood (referred to as the area under the curve or AUC) but accounts for the patient's kidney function, and therefore reduces toxicity. This area under the curve-based dosing is recommended for carboplatin nationally and internationally. Such a formula is an estimate, and although other calculations for dosing exist, this is the most widely used approach currently to personalise the dose for each patient.
- 33 A less-used alternative to area under the curve-based dosing is one based on normative population data for carboplatin clearance. This approach, however, would still adjust for poor kidney function.
- 34 The Clinical Expert Panel (Appendix D; see paragraph 46) reached a consensus that an initial dosing of $\pm 25\%$ of area under the curve (AUC) dose would be within the acceptable clinical range depending on the patient's specific clinical circumstances. After the initial dosing, doses may vary even more, but will still be clinically appropriate, because more clinical factors (such as the patient's experience of toxicities, changes in organ function or other complications of treatment) need to be considered. On some occasions, people will be prescribed 100 mg carboplatin because that is the calculated personalised dose according to their protocol.
- 35 Flat dosing (prescribing the same dose regardless of patients' personal characteristics) of carboplatin is off-protocol and not supported by evidence, while failing to personalise the dose. Deviation from the evidence available requires the prescribing medical oncologist to provide evidence or to do a prospective study overseen by a Human Research Ethics Committee. The onus is on the practitioner who is not using the best available evidence to demonstrate that they are not causing any more harm and their outcomes are at least as good.
- 36 At a population level, the effect of area under the curve (AUC) dosing of carboplatin lies between radiotherapy alone and cisplatin dosed by body surface area (BSA) (best available evidence for drug of choice and dose). It is unknown where off-protocol flat dose 100 mg carboplatin lies on the spectrum of response.

eviQ AND NATIONAL COMPREHENSIVE CANCER NETWORK (NCCN) GUIDELINES

- 37 eviQ is the nationally endorsed provider of evidence-based cancer treatment information at the point-of-care for the optimal administration of chemotherapy. 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. A timeline detailing the development of eviQ's predecessor, CI-SCaT (Cancer Institute NSW Standard Cancer Treatments), its replacement with eviQ (<https://www.eviq.org.au>), and the adoption of eviQ as policy by the then South Eastern Sydney Area Health Service in 2009 (when St Vincent's Hospital was part of the Area Health Service) is at Appendix C.
- 38 eviQ treatment protocols are intended to provide guidance on the optimal prescribing (including dosing for a particular patient) and administration of a chosen therapy. They are distinct from clinical guidelines, which provide specific direction on which therapies to choose.
- 39 There are 26 head and neck chemotherapy protocols on eviQ, with 7 of them containing carboplatin. The recommended dose of single agent carboplatin with radiotherapy across these protocols ranges from area under the curve (AUC) 1.5 to 2. None recommends flat dosing.
- 40 Electronic prescribing in accordance with eviQ protocols is aided by the use of Oncology Medical Information Systems such as MOSAIQ, which was implemented in August 2015 at St Vincent's Hospital. MOSAIQ and similar software tools are pre-loaded with eviQ protocols to aid in optimal prescribing of chemotherapy.
- 41 The NCCN Clinical Practice Guidelines (https://www.nccn.org/professionals/physician_gls/f_guidelines.asp) document evidence-based and consensus-driven approaches to cancer treatment decision-making. They include recommendations on prevention, diagnosis, treatment, and supportive care that will optimise patient outcomes. eviQ complements the NCCN Clinical Practice Guidelines.
- 42 None of the NCCN Guidelines for the treatment of head and neck cancers refers to flat dosing.
- 43 The eviQ protocols (and the protocols of eviQ's predecessor Ci-SCaT) and the National Comprehensive Cancer Network (NCCN, USA) protocols for head and neck cancer with loco-regional spread have been in place for at least one decade.

MULTIDISCIPLINARY CLINICAL EXPERT PANEL

- 44 Patients who were treated with carboplatin and cisplatin during the period 2006-2015 by Dr Grygiel were identified through St Vincent's Hospital's pharmacy records. There were three groups of patients having chemoradiation: those who were treated with off-protocol flat dose 100 mg carboplatin; those who were treated with carboplatin at higher doses; and those who were treated with cisplatin.
- 45 Relevant clinical details were collected directly from the patients' medical records. For details see Appendix B.
- 46 The Inquiry empanelled an independent group of national experts in medical and radiation oncology, clinical pharmacology and oncology pharmacy (Appendix D), which included one face-to-face meeting. This group was provided with relevant journal articles generated through a systematic literature search and other journal articles provided to the Inquiry (see Appendix E). They were also provided with a clinically detailed summary, including stage of disease at diagnosis, co-morbidities, current disease or vital status.

Findings

THE PEOPLE AFFECTED AND THEIR TREATMENT

- 47 Most people treated with off-protocol flat dose 100 mg carboplatin were treated in the years 2012-2015. A much smaller number were treated in 2006-2010 (see Appendix B.5), as Dr Grygiel was not the predominant medical oncologist treating people with head and neck cancers at St Vincent's Hospital in those earlier years. Dr Grygiel was absent from St Vincent's Hospital between these two periods.
- 48 In the period from January 2006 to February 2016, 129 people were treated by Dr John Grygiel with off-protocol flat dose 100 mg carboplatin. One hundred and three of those people were treated for a head and neck cancer. The other 26 people were treated with a range of cancers: see Appendix B.3.
- 49 In the same period, the total number of people with head and neck cancers treated by Dr Grygiel with platinum-based chemotherapy (cisplatin or carboplatin at either off-protocol flat dose 100 mg or calculated according to area under the curve) was 195. As indicated above, 103 of these people received an off-protocol flat dose of 100 mg carboplatin:
- 87 with primary loco-regional disease at diagnosis,
 - 1 with primary metastatic disease at diagnosis and
 - 4 with primary disease of unspecified extent at diagnosis. Additionally,
 - 8 were having treatment for recurrent loco-regional disease,
 - 1 for recurrent metastatic disease and
 - 2 recurrent disease of unspecified extent (see Appendix B.3).
- The last patients to receive an off-protocol flat dose 100 mg carboplatin were treated in June 2015. (ToR 1a)
- 50 Additionally in that period, 54 patients were treated with a carboplatin dose of greater than 100 mg and 38 were treated with cisplatin.
- 51 One half of the patients treated with off-protocol, flat dose 100 mg carboplatin were ≤60 years of age (mean age was also 60). Eighty percent were males and 51% had co-morbidities. For people treated with >100 mg carboplatin, the median and mean ages were also 60 but 71% had co-morbidities. For those treated with cisplatin calculated according to body surface area (BSA), median and median age were 55. For those treated with carboplatin (both 100 mg and >100 mg), approximately half were treated post-operatively with chemoradiation and the other half were treated with chemoradiation without surgery. Only two patients in the 100 mg group had their treatment documented as being given with palliative intent, also confirmed by the radiotherapy data.

- 52 There are no discernable differences in the baseline personal, clinical or tumour characteristics between patients who were prescribed 100 mg carboplatin, those who were prescribed a higher dose of carboplatin, and those who were prescribed cisplatin (see Appendix B.4). The Inquiry was not able to identify a clear approach to patient selection. Although it was suggested to the Inquiry that frailty was the differentiating factor, this is not supported by the clinical data.
- 53 Given the period of time in which the majority of people were treated with off-protocol flat dosing carboplatin (2012-2015, see Appendix B.5), it is too early to determine any trends in survival or cancer recurrence and how these may differ from people treated with cisplatin dosed according to body surface area (BSA) (standard cisplatin).
- 54 Completion rates for both chemotherapy and radiotherapy were high for the cohort of patients treated with carboplatin, both the patients with the off-protocol flat dose 100 mg carboplatin and those who received a dose calculated according to the area under the curve (AUC). Other measures of toxicity may include hospital admissions; these rates are also low, even in people treated with cisplatin. Given such low rates, it is unlikely that any differential rates of hospitalisation would be seen in the group treated with off-protocol flat dose 100 mg carboplatin.
- 55 The effect of off-protocol flat dose 100 mg carboplatin for head and neck cancers has not been quantified in clinical trials or prospective data collections. As such, it is not possible to determine what outcomes patients will experience.
- 56 For people who have head and neck cancers (including HPV related), if cancer recurrence occurs, it is usually in the first three years following treatment. The risk of recurrence is low for patients who completed their treatment more than three years ago and currently have no known disease. This pattern is reflected in the proposed enhanced follow-up algorithm by St Vincent's Hospital in response to the Interim Report for people who received off-protocol flat dose 100 mg carboplatin (see Appendix G).
- 57 Establishing a causal link between having received the off-protocol flat dose prescribing of 100 mg carboplatin 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 off-protocol treatment and yet not have the cancer recur. If a patient received off-protocol treatment, it is impossible to tell what the outcomes would have been had he or she received a dosage according to a currently available protocol. (ToR 1a)

- 58 It would be expected that, on a population basis, a failure to adhere to protocols puts every person treated at risk of higher rates of cancer recurrence and higher overall mortality. This does not translate to a quantifiable change in an individual's risk for recurrence or death. In the context of this Inquiry, one cannot quantify the extent of any harm to an individual. (ToR 1a)
- 59 Furthermore, a proportion of people with head and neck cancers are frail, with widespread disease, where death is a likely outcome from the time of diagnosis. Particular risk factors for these cancers mean the same people have many co-morbidities. The population served by St Vincent's Hospital, in general, has head and neck cancers with poorer prognosis due to underlying risk factors and co-morbidities. (ToR 1a)
- 60 To date, of the 103 people treated with the off-protocol flat dose of 100 mg carboplatin, 37 have died of the cancer, 5 have died of non-cancer causes and 4 have died with an unspecified cause of death. Two of these people were identified in the medical record as having treatment with palliative intent. Of the 57 people who are still alive, 42 are disease-free, 10 have local disease and 5 have distant disease. At this point in time, the Inquiry is unable to quantify the impact of this prescribing on cancer recurrence or mortality rates (see Appendix B.3). (ToR 1a)
- 61 The Inquiry was told by several interviewees 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 and radiosensitising chemotherapy. No evidence has been presented by Dr Grygiel, or found in the international peer-reviewed literature to support this contention. (As discussed above, all cancer therapy is a careful balance of maximising the effect on cancer cells 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)
- 62 Dr Grygiel was interviewed by the Inquiry. At the interview, Dr Grygiel was asked whether he was "aware of any published protocols or guidelines for 100 mg flat dose" to which he replied "no". Further, the practice was not overseen by a Human Research Ethics Committee and no data were collected prospectively nor retrospectively to establish the net effect of this practice on patients' outcomes (benefits and harms).

CLINICAL CARE

- 63 In the last decade, the protocols for platinum-based chemotherapy in treating people with head and neck cancers have remained unchanged. The best available evidence throughout that time was, and is, standard cisplatin. By contrast, this group of patients was treated with carboplatin (the third-line choice, for which there is less evidence of its efficacy in this clinical setting) at a flat dose, rather than a dose according to available protocols. There is no perfect way of dosing platinum-based chemotherapy, but the standard remains until a better way is established in accordance with the evidence-generation process described above. (ToR 2)

MEDICAL ONCOLOGY DEPARTMENT

- 64 Fail-safe mechanisms that should have alerted senior staff to this practice include checking by pharmacy staff dispensing the medication and nursing staff administering the medication. (Appendix F)
- 65 Pharmacists dispensing the chemotherapy, nurses administering it and doctors who were working under the supervision of specialist medical oncologists 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 should have known it was occurring and escalated their concerns about the practice. (ToR 2)
- 66 Dr Grygiel stated that there were others who were aware of the practice but the Inquiry was unable to corroborate the statement.

HEAD AND NECK MULTIDISCIPLINARY TEAM (MDT)

- 67 The Head and Neck MDT's individual patient assessment and documentation records were comprehensive and well presented. (ToR 3)
- 68 There was conflicting evidence presented to the Inquiry during interviews regarding whether there had been a discussion about choice of drug and dosing with other clinicians at St Vincent's Hospital. Since the Inquiry completed the Interim Report, it has seen clinical correspondence from 2014 on one patient from Dr Grygiel to two other members of the Head and Neck MDT, outlining both the choice of drug (carboplatin) and a flat dose. The onus was on Dr Grygiel to contextualise this decision to use carboplatin and to use a flat dose with his colleagues. There are conflicting accounts of whether or not this happened. (ToR 3)
- 69 There is no evidence of the Head and Neck MDT conducting meetings, separate from discussions about patient care, to consider their current therapies or treatment protocols, nor new and emerging evidence. (ToR 3)

CANCER SERVICES STREAM

- 70 There were no processes to review non-standard protocols in cancer services. (ToR **3**)
- 71 Due to the benefits and risks of chemotherapy, clinicians need to be able to adjust drugs and dosages appropriately to patients' needs. Although there are mechanisms in place to reduce the risk of such variations in prescribing in the future, the MOSAIQ® oncology medical chemotherapy ordering 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, including independent clinical review, of such prescribing is required. (ToR **1b**, ToR **4**)
- 72 At the time of the Inquiry's Interim Report, St Vincent's Hospital had put in place for its cancer services actions to 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), as well as the appointment of new medical oncologists; (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 from this time; (ToR **3**)
 - eviQ being reiterated as the evidence-based resource for electronic prescribing of all chemotherapy across the campus, and pre-loaded into the MOSAIQ® electronic prescribing program, which was implemented in August 2015 for medical oncology (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

- 73 As a staff specialist, Dr Grygiel should have had an annual performance review. Only one performance review has been provided (2014). (ToR 3)
- 74 There appeared to be no effective executive sponsorship of the incident. There was no sense of urgency about the internal investigation or external review 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 to these people, 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. The problem 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)
- 75 Several interviewees acknowledged that they wished they had managed the response differently.
- 76 Campus-wide actions that St Vincent’s Hospital had put in place at the time of the Inquiry’s Interim Report and that will reduce, but not preclude, the recurrence of such prescribing 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 campus cancer plan. (ToR 1b)
- 77 Since the publication of the Interim Report, St Vincent’s Hospital has indicated to the Inquiry that several campus-wide initiatives are in train:
- completion of a staff engagement survey, “You’re the Voice”, with executive oversight and analysis to develop action plans to drive cultural change;
 - implementing an “It’s OK to ask” campaign aimed at empowering all staff and encouraging a culture of open dialogue and mutual respect; and
 - providing staff with education about the requirement to escalate clinical concerns.

THE INTERNAL INVESTIGATION

- 78 The internal investigation, carried out by St Vincent's Hospital between August and October 2015 to examine the pattern of off-protocol prescribing had no terms of reference and failed to define the scope or approach to the issue with a methodology that covered the clinical concerns that had contributed to the investigation in the first place. (ToR 1a)
- 79 The internal investigation failed to determine adequately the clinical impact on patients as it failed to examine any clinical outcomes such as survival or cancer recurrence. Given that the investigation 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 investigation failed to define relevant clinical and patient factors such as the extent of disease and treatment intent before patients started therapy, and rates of recurrence and death. Instead, the investigation focused solely on the dose of carboplatin prescribed. The internal investigation 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 (flat dose in comparison with area under the curve). (ToR 1a)
- 80 The internal investigation failed to seek input from content experts in medical or radiation oncology to the detriment of the investigation and the timeliness in defining the nature, extent and impact of this pattern of off-protocol prescribing. This underplayed the impact of this prescribing and provided false reassurance to St Vincent's Hospital, which was passed on to the community through its media channels. (ToR 1a)
- 81 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

- 82 The external review report should have been understood to confirm that there was a substantial issue to be addressed and alert the Hospital to the serious implications that this had for patients. (ToR 1a)
- 83 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 (cancer 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, whether or not they had been prescribed the off-protocol flat dose of carboplatin. (ToR **1a**)

- 84 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 investigation and external review did not examine any patient-level outcome data from this off-protocol prescribing. Reference to cancer recurrence rates, particularly, should not have been made given that neither the internal investigation nor external review quantified these rates. As such, St Vincent's Hospital'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 the findings in his report were being used. (ToR **1b**)
- 85 The hospital's public statement also indicated Dr Grygiel was "*immediately counselled and placed under strict supervision*". Interviewees have corroborated that this did not occur. It should be noted that Dr Grygiel continued as Acting Head of Department for several months after the hospital became aware of the off-protocol prescribing. (ToR **3**)

INTERVIEWS WITH PATIENTS, FAMILIES AND NEXT-OF-KIN

- 86 Patients who had been treated since 2012 with off-protocol flat dosing of 100 mg carboplatin, and family members, and next-of-kin of people who had died were offered an interview to ensure that the Inquiry was informed by their experiences.
- 87 This section of the report summarises the interviews conducted with patients treated for head and neck cancers by Dr Grygiel at St Vincent's Hospital. The interviews were conducted by the Clinical Excellence Commission.
- 88 It should be noted that the information contained in this section of the report is based on interviews with 26 patients or next-of-kin and is not intended to represent the views of all patients with head and neck cancer treated by Dr Grygiel.

Invitation Process

- 89 At the time of the Interim Report, the Inquiry identified 78 patients with head and neck cancer who had received at least one course of 100 mg carboplatin under the care of Dr Grygiel at St Vincent's Hospital between June 2012 and June 2015.
- 90 On 6 May 2016, letters were sent to 66 of these patients or their next-of-kin, inviting them to participate in an interview. (For 11 of the other 12 patients, no current address was available. The twelfth patient had recently died and details of the next-of-kin were not immediately available; a letter of invitation was subsequently sent to the next-of-kin on 2 June 2016.)
- 91 Twenty-seven patients or next-of-kin accepted the invitation to participate in an interview. During June and July 2016, 26 interviews were conducted. Three

unsuccessful attempts were made to re-contact the 27th respondent. Interviews were offered either face-to-face in the patient's or family's home, at the Clinical Excellence Commission or by telephone depending on the patient's or family's preference.

92 Of the 26 interviews conducted:

- 7 were with an unaccompanied patient;
- 9 were with the patient and their partner and/or family members;
- 9 were with next-of-kin of a deceased patient; and
- 1 was conducted with the patient's partner alone as the patient was too sick to speak.

Conduct of Interviews

- 93 The interviewer was accompanied by a note-taker, who typed the patients' and families' responses directly into a computer. Interview length ranged from 45 minutes to 1 hour. Interview questions were developed by the Inquiry Team with input from a health consumer advisor appointed by the Inquiry. A series of questions was asked, focusing on informed consent to treatment, open disclosure by St Vincent's Hospital and the patient's experience.
- 94 Interviewees were advised that they could bring a support person to the interview and further advised during the interview of the support services made available to patients and families by St Vincent's Hospital including a dedicated 1800 telephone number. Interviewees were also informed that they could stop the interview at any time.

Summary of Interviews

- 95 The interview notes were analysed by the Clinical Excellence Commission to determine common themes. Some patients and next-of-kin also provided the Inquiry with copies of their own notes, correspondence and other information regarding their treatment which was then reviewed by the interviewers.

General

- 96 Patients and next-of-kin expressed appreciation for being offered the opportunity to participate and to provide their information directly to the Inquiry. Most interviewees expressed a keen interest in being kept informed about the availability of the Inquiry's Final Report.

Treatment planning

- 97 Some patients mentioned that they were aware that their care had been discussed by the multidisciplinary cancer care team when they had attended the clinic and some recalled attending a meeting themselves involving a number of specialists. Interviewees reported being informed of their cancer treatment plan and not being given much opportunity to ask questions.

- 98 One interviewee reported a dispute relating to treatment planning between Dr Grygiel and another specialist doctor regarding the order of treatment received.

"There was conflict between what Dr XXXX had told them and the treatment that Dr Grygiel was providing. When questioned, Dr XXXX's information was discarded by Dr Grygiel and his course of treatment and opinion governed <the patient's> care as he was the oncologist."

Information provision

- 99 Some patients and next-of-kin mentioned information about chemotherapy and treatment that they had received from St Vincent's Hospital. Some patients had received eviQ website print-outs of patient information about chemotherapy and provided copies to the Interviewers. Some other patients stated that they had not received information and instead sought their own information on the internet.
- 100 A few interviewees reported receiving 'patchy' information regarding treatment. One family mentioned that information provision was not tailored to suit patients with head and neck cancers experiencing impairments as a consequence of their cancer.

Discussion of chemotherapy treatment options

- 101 Almost all of the patients and next-of-kin reported that they did not recall Dr Grygiel discussing chemotherapy drug options with them but rather that they were told by Dr Grygiel which chemotherapy drug was being recommended. Typically, Dr Grygiel was perceived as 'the expert who knows best' and the recommended treatment was not questioned. Interviewees indicated that they 'trusted the advice of the expert'. Some family respondents indicated that they did not feel included in decision-making; nor did they feel comfortable questioning doctors, stating "if the doctor says it has to be done, then that's OK". Respondents reflected that they did not know 'the right questions to ask anyway' and had 'complete faith and trust' in Dr Grygiel as the doctor and professor. In reference to treatment recommendations, some patients mentioned that, in discussion with other doctors in the head and neck cancer multidisciplinary team, doctors other than Dr Grygiel informed them that "this is what the team said, this is what the team thinks is best".

"<The patient> was going to get carboplatin. Dr Grygiel said "This is the drug we are using.""

"You put your life in their hands...You feel secure, don't you."

- 102 One patient did recall discussing the choice of recommended chemotherapy drug with Dr Grygiel and reported that Dr Grygiel stated that the recommended carboplatin was the "best option" for the patient.

"I did a Google search prior to my meeting with Dr Grygiel. I knew about the drugs carboplatin and cisplatin - so I was aware of the drug - but I did not focus on dosages or frequency and treatment of either. I was aware of cisplatin. But Dr Grygiel made his recommendation which was carboplatin 100 mg - I have this noted in my clinical notes."

- 103 One next-of-kin could not recall at all whether options for chemotherapy treatment had been discussed.

Dosage level

- 104 Most of the patients and next-of-kin responded that they were not aware of the carboplatin dosage level used for their chemotherapy treatment while under the care of Dr Grygiel.

- 105 Some interviewees reported that there had been a discussion with Dr Grygiel about the chemotherapy dose level:

- One patient reported that they were aware that they were to receive a dose of 100 mg carboplatin. The patient reported that they had queried at the time if this was "the best option?" and Dr Grygiel responded that it was the "best option for you".
- One patient recalled being told by Dr Grygiel that the chemotherapy was a "low dose" in the context of side effects but not in the context of treatment protocols.

"I felt relieved that I only needed a low dose of treatment as the side effects would not be as bad, but I would have accepted the need for stronger doses if that was what was needed to treat my cancer".

- One patient noted that Dr Grygiel had told them that they were to receive a "small dose" as a higher dose was not necessary

"The main discussion regarding the chemotherapy was that it was a small dose that was being used to help the radiotherapy have full effect."

- 106 One next-of-kin stated that they were informed that "low dose" chemotherapy plus radiation was being offered and that Dr Grygiel said that "this was proving to be very successful amongst head and neck patients" and that "he <Dr Grygiel> had great success with this treatment". The patient is reported as having said to Dr Grygiel at this time: "that he wanted the strongest dose....'I want to live'."

"Dr Grygiel explained that in his view higher doses did not assist. With the lower dose there is an ability to cope - so using a higher dose was not seen by him < Dr Grygiel> to have any significant improvements to survival rate."

Discussion about risks and benefits of chemotherapy treatment

- 107 Half of the patients and next-of-kin interviewed did not recall discussions with Dr Grygiel about the 'risks and benefits' of the chemotherapy he recommended.

"Left it to him. You put your life in their hands."

- 108 Some interviewees stated that Dr Grygiel had talked generally about "toxicity and side effects".

"<The patient> will be given carboplatin and toxicity will be bearable and not too many side effects"

- 109 Some interviewees reported that Dr Grygiel and other staff had talked with them about nausea, loss of appetite and hair loss.

"He <Dr Grygiel> also said that with the lower dose it won't make you sick or lose your hair. He <Dr Grygiel> also told him that the chemotherapy was to help the radiotherapy 'do its job'."

- 110 A few patients noted that Dr Grygiel had mentioned a risk of the chemotherapy potentially causing cancers in the future.

"Dr Grygiel said - 'Hit it with the big guns, as it is a very aggressive cancer and you may not survive without the treatment.' He also said the chemo 'may cause some other cancers in 40 years.'"

Open disclosure

- 111 Half of the patients and next-of-kin first became aware of the off-protocol dosing issue relating to Dr Grygiel's care of head and neck patients at St Vincent's Hospital through a media report that aired on TV on 18 February 2016. Either the patients or next-of-kin were watching the TV themselves or they were phoned by family and friends about the TV media report.

- 112 Some interviewees reported first becoming aware of the issue when they received a call from St Vincent's Hospital before the TV media report aired while a few did not become aware until they received a phone call from St Vincent's Hospital after the TV media report.

- 113 A few interviewees first became aware of the issue when they heard a radio news report or read a newspaper article on the day after the TV program aired. One patient became aware when a friend telephoned (who was also receiving treatment with Dr Grygiel) to say they had arrived at the St Vincent's Hospital clinic for an appointment to be informed Dr Grygiel was not there. Another patient was travelling overseas during February and heard a phone voice message on return saying "to ring St Vincent's Hospital if they needed help."

- 114 Initial reactions from patients and next-of-kin were shock and lack of understanding of what this news meant for them or their loved ones. Interviewees reported that they didn't know 'what the issue was' and that they didn't understand the implications nor what their options were.

"<The patient> first heard about this when he listened to a phone message from St Vincent's Hospital. <The patient> felt the caller assumed that he had seen media reports about the issue, and didn't really tell him very much.... <The patient> was initially quite confused about the issue but was able to contact a close friend who was also involved and got more information from him. He then went and investigated previous media reports for a sense of how he may have been affected. <The patient> described feeling 'floored' by these events."

"<The patient> received a letter about 2 weeks after the report he heard on the radio, he noted the letter was dated the 1st of March (after he heard the TV show). Soon after receiving the letter from St Vincent's Hospital, he received a phone call from them. They asked him if he had any issues since hearing the news and told him that he could contact them if he needed assistance in any way. He was also offered an earlier appointment for his follow up if he wished.... <The patient> received a second call from St Vincent's Hospital and was asked how he was. At this point <the patient> describes feeling increasingly stressed and anxious about the situation and his future health."

115 Some patients coming into St Vincent's Hospital for further treatment after the media story were still unclear about whether they were indeed a patient who had received at least one course of 100 mg carboplatin. One patient noted meeting with another doctor in the team and asking the doctor if they were an affected patient. The patient was shocked that the specialist didn't know, said they would find out and then replied to the patient "Yes — you are in the cohort".

116 Interviewees expressed that they were angry and dismayed with St Vincent's Hospital when they realised that St Vincent's Hospital had been aware of the issue prior to the media report that aired on 18 February 2016. Some interviewees were also annoyed at St Vincent's Hospital for saying in the media that 'there is no impact for patients'.

"<The patient> and his family are also aware that St Vincent's Hospital were aware that < Dr Grygiel> was under-dosing his patients for some time prior to the media release and even more concerning to the family was that they knew about his alternative practice at the time when <the patient> was referred back to Dr Grygiel for treatment when he had a recurrence of the tumour."

117 Poor communication by St Vincent's Hospital was noted by some next-of-kin as causing great distress particularly when they received phone calls from St Vincent's Hospital asking to speak to the deceased.

"The first phone call asked for <'the deceased patient'>. A lady rang from St Vincent's Hospital. Then the letter from the CEO was addressed to the patient (deceased)."

118 Some next-of-kin interviewed expressed that they were most concerned about the distress that the contact caused particularly regarding the unanswered question of whether the off-protocol dose may have contributed to the death of their loved one.

119 Some interviewees reported an overall sense that that written communication from St Vincent's Hospital was impersonal and focussed on protecting St Vincent's Hospital rather than helping patients.

"The letter felt formulaic, and <the patient> still wasn't sure what was going on."

"<The patient> noted that 2-3 weeks after the phone conversation with St Vincent's Hospital, he received a letter from St Vincent's Hospital. <The patient> felt this was 'scripted' and 'political' and didn't really provide him with any real information. He was told that someone would be in further contact with him, but this didn't happen. He eventually contacted them and requested one of the specialists call him.<The patient> was very concerned about the way he was contacted and felt there was too much emphasis on 'fixing' the problem, rather than ensuring the patients were OK and adequately supported."

120 Interviewees reported talking with senior specialist doctors at St Vincent's Hospital to obtain further information about the impact on their care and outcomes. Most interviewees reported receiving a phone call from a senior doctor during which an apology was received. However, this apology was sometimes also accompanied by an expression of anger by the doctor that the doctor personally had not been advised by Dr Grygiel that he was departing from standard protocol care or that the doctor's own personal reputation was being tarnished by the media. This focus on the 'impact on

the clinician' was not appreciated by the next-of-kin in light of their own distress nor by the patients given their own uncertainty about the impact on their survival. Patients expressed feeling very frustrated that no one had been able to advise them about how this issue may affect their own chances of recurrence. A few interviewees said that they found the media reports more informative than the communication from St Vincent's Hospital.

- 121 Some patients mentioned that St Vincent's Hospital had offered them support and access to an 1800 phone number. A few interviewees noted, however, that they felt there was no 'follow through' by St Vincent's Hospital.

"We were offered half an hour of counselling support only – why so limited a time?"

- 122 Some patients reported feeling 'alienated' and 'labelled' at St Vincent's Hospital as 'difficult patients' when they came back to St Vincent's Hospital for care and clinic appointments. A few patients also reported being angry that they felt that their follow-up care was 'left up to them' to organise. One next-of-kin reported having contacted St Vincent's Hospital repeatedly to request a check-up appointment for the patient, after becoming aware of the incident when it was raised by the media in February 2016. When the follow-up appointment occurred, scans revealed that the cancer had spread.

"Dr XXXX said, 'Why didn't you contact us earlier?' I said, 'We did!' Dr XXXX said, 'Why didn't you speak to my registrar?' I said, 'We did call and speak to the registrars.' ... They only found that the cancer had spread because I asked that they do the scans. Why didn't they get <the patient> back in straight away to have a check-up when they knew there was a problem with the chemotherapy?"

- 123 Some interview respondents had no concerns and believed that they or their loved ones received the best possible care and 'everything possible had been done'.

- 124 A few interviewees mentioned experiencing a disconnect between the St Vincent's Hospital core mission and values and the way in which St Vincent's Hospital had interacted with them or their family.

"St Vincent's four core values – compassion, justice, integrity and excellence – unfortunately all four of these have been seriously lacking in the way our family has been dealt with by that hospital"

Organisational issues

- 125 A few interviewees noted that given it was a chemotherapy dosage issue that they would have expected the hospital pharmacy to detect such an issue.

"We thought the worst had been over. Why did the pharmacy not say anything?"

- 126 Some interviewees expressed dismay that issues with chemotherapy dosage didn't appear to have been addressed by the head and neck cancer multidisciplinary cancer care team.

"It's not just Dr Grygiel – there was a whole team - why didn't anyone else raise the issue?"

"How could this have happened?"

STATE LEVEL – NSW HEALTH POLICIES

- 127 St Vincent's Hospital management did not appropriately escalate the issue to the Ministry of Health through a Reportable Incident Brief (RIB) as required by the Incident Management Policy Directive 2014_004 (see Appendix H.1). 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 and Board were notified in late 2015. (ToR 1c)
- 128 The Lookback Policy (PD2007_075; see Appendix H.2) was correctly considered in August 2015; however, the internal investigation 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. (ToR 3)

Incident Management Policy PD2014_004 (ToR 1c)

- 129 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 and recurrence rates in mid-2015.
- 130 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 address the flat dosing as an 'incident' even though it was not in accordance with protocol and no evidence supporting the practice was provided to the staff nor subsequently to the Inquiry.
- 131 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 carboplatin to many head and neck cancer patients remained unknown to senior hospital management until mid-2015.
- 132 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

- 133 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.

- 134 In regard to conflict of interest, this was an incident that should not have been investigated internally, and there should have been arm's length delineation between clinicians who were part of the Head and Neck MDT and any investigations or reviews.
- 135 Advice from a medical and a radiation oncologist is likely to have framed relevant Terms of Reference for, and the data made available to, the investigation and reviews 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)

- 136 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 patients should have had open disclosure quickly if they received off-protocol flat dose 100 mg carboplatin.

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 flat dose carboplatin for head and neck cancers had open disclosure only after a media report aired on 18 February 2016.

- 137 A review team convened in August 2015. Disclosure commenced more than six months later. The information provided by St Vincent's Hospital states that there was a risk of greater harm if the incident was disclosed without knowing the effects of the off-protocol flat dose prescribing of 100 mg carboplatin. The decision as to when to disclose is difficult, particularly if patients are frail and unwell but those factors do not work against disclosing in a timely way (Open Disclosure Handbook, page 65).
- 138 Under this policy, serious incidents require submission of a Reportable Incident Brief.
- 139 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.
- 140 The response by St Vincent's Hospital, 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 who had been treated at St Vincent's Hospital, regardless of whether they were directly affected. (ToR 1c) During patient and family interviews some families indicated that they were not satisfied with the information they received during open disclosure and that their concerns were not addressed. A few people even indicated they obtained more information from the media than they received from the hospital's open disclosure. (ToR 1c)

Managing Complaints or Concerns About a Clinician (MCCC) PD 2006_007 (see Appendix H.3) and Guideline GL2006_002 (ToR 1c) (see Appendix H.4)

- 141 The decision not to activate the MCCC policy was incorrect.
- 142 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.*
- 143 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.

144 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 issue was referred to the HCCC and the Medical Council in February 2016.)

ST VINCENT'S HOSPITAL WORKPLACE CULTURE

145 Culture is about how things are done. A constructive clinical culture is built upon visible, people-focused leadership which emphasises patient-centred care.

146 This issue and the response to it has highlighted a range of cultural issues that the senior clinical leadership, hospital administration and Board will need to manage with purpose and clarity. This response will need to focus the future of the St Vincent's Hospital cancer service on excellence in care and a constructive, people-focused workplace culture.

147 This section of the report makes some observations on the culture in the workplace and offers some insights into how to proceed to build a constructive culture within cancer services.

148 In a cultural context, what the Inquiry has found lacking is:

- leadership that provided insight, direction and urgency;
- a patient-centred approach;
- analytical rigour, or the necessary questioning scepticism for an accurate characterisation of the issue;
- training for clinical leaders in leadership and in policy and process; and
- demonstration of adherence to values at a time when they were most needed.

149 As a result, the attempts to characterise the issue and follow policy, were unsuccessful: instead of acting in the best interests of the patients, the organisation's response to the issue was inadequate, drawn out, internalised and defensive. (ToR 3)

150 In the medical oncology unit, when treatment was challenged, it seems there was always acceptance of the explanation provided by Dr Grygiel instead of escalation to an appropriate clinical expert.

- 151 Pharmacy had a proactive responsibility to more diligently monitor prescribing with a view to detecting patterns in the prescribing and to escalate concerns through to hospital management.
- 152 Dr Grygiel had a proactive responsibility to let the MDT know he was prescribing off-protocol and familiarise them with the implications of what he was doing so they were empowered to endorse it as a team, or seek further information or expert input.
- 153 When there should have been open disclosure and action in accordance with NSW Health policy, there was avoidance of responsibility to act decisively in the interests of the patients. These were failures of clinical governance processes, clinical leadership and management. (ToR 3, ToR 5)
- 154 There was a trusting casualness amongst the people who should have been more enquiring about this prescribing, when the hospital became aware of it.
- 155 There were tensions, unresolved grievances and conflicts within cancer services. Failure to resolve long-standing conflicts constructively and with understanding has contributed to mistrust within parts of the clinical community. This meant that when the incident was identified, the organisation was not able to see and characterise the issue clearly, support people who raised it, understand and analyse what had occurred in a timely way, and develop a patient-centred, empathetic response.
- 156 Clinical governance had a proactive responsibility to coach and guide the hospital and clinical leadership on the best response to such situations and the best approach to look back and open disclosure. Such processes should be necessary only rarely, but have to be able to swing into place urgently when needed.
- 157 The hospital and clinical leaders had a proactive responsibility to insightfully see the issue for what it was and to quickly obtain an accurate characterisation of the issue, identify all affected patients and to notify those patients in an empathetic, timely and informative manner, to notify the public of the practice and convey how it was managing Dr Grygiel. They also had a proactive responsibility to ensure the issue was being managed appropriately, that appropriate content expertise was being used to analyse the issue so as to understand its root cause, and that any conflicts of interest and internal conflicts were acknowledged and addressed. Concerns about patient outcomes were the catalyst for the issue being raised in the first place, but patient outcomes were not at the centre of the organisational investigation and response. This mismatch lies at the heart of many of the problems outlined in this report.
- 158 Given media statements on issues of this nature are cleared through the national office, there was a proactive responsibility to ensure that those statements were entirely accurate and that all affected patients, or their families, had been appropriately informed before the issue was aired publicly.

- 159 No medical oncologist was providing input to the hospital's executive team to inform and prepare the public statements, nor check their accuracy.
- 160 That the issue was inaccurately characterised in the first place and the response to it was internalised, without sufficient inquiry as to the extent and nature of the off-protocol dosing, meant that inaccurate and incomplete communications were more than likely. Perhaps this is nowhere better shown than in the hurried and poorly conceived attempts to contact some patients on the day it was clear the issue was going to be aired in the media.
- 161 The overriding reason for all of this is cultural; remembering that, in its purest sense, culture is about how things are done.
- 162 The solution is to build a constructive, inclusive, people-focused clinical culture. This is achieved through:
- a clear understanding of mission;
 - living the organisation's values;
 - knowing what a high performing team looks like and relentlessly building it; and
 - exceptional leadership that is visible, collaborative, people focused, with a strong sense of mission and values.
- 163 The senior leaders within cancer services, across all of the clinical disciplines (surgery, radiation and medical oncology), and all the professions (medical, dentistry, nursing, pharmacy, allied health), need to work cohesively and purposefully to lead this cultural transformation. They need to be supported and enabled by executive and management, who will need to oversee and guide this transformation and the rebuilding of confidence and morale among staff members in cancer services.
- 164 Relationships and trust within cancer services, and between some senior clinicians and St Vincent's Hospital management, will need to be rebuilt and this will require facilitated intervention with a restorative program. This will need to aim to build trust, understanding, respect and collaboration. The people within the service will need to approach this with commitment, purpose, truthfulness, empathy, patience and willingness.
- 165 More broadly, the Inquiry team is of the view that there are effective policies in NSW which, if followed, provide a patient-centred and timely response to clinical issues of this nature. They offer a clear guidance and framework on responsibilities, timelines and processes for investigation and resolution. These are rare events but the system needs to be able to swing into place a full response, with clarity and purpose, urgently when they arise. There is a preparedness required at an organisational level, to be able to recognise such events and respond appropriately. As with any rare but

significant event, the emergency response largely determines the outcomes. In general, other organisations in the health system approach problems with clinical practice or outcomes by using the policies in a way that is consistent with their intention.

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

Recommendations

The numbering of the Recommendations builds on the Inquiry's Interim Report so that they can be cross-referenced directly.

All of the recommendations in the Interim Report stand. They have been grouped below, into the organisations to which responsibility falls (Recommendations 1–18).

Recommendations 19 and 20 related only to the extended Terms of Reference (see Appendix A).

Four recommendations from the Interim Report have been amended, in order to further progress them (Recommendations 2 amended, 4 amended, 11 amended and 13 amended).

There are 3 entirely new recommendations (Recommendations 21–23).

Interim Report Recommendations

Responsible organisation: St Vincent's Hospital

The responses below are based on advice provided to the Inquiry by St Vincent's Hospital (see Appendix H).

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

Response —actioned

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

Response —actioned

St Vincent's Hospital has contacted all identified patients and/or their families.

- 2 amended **Ensure that every patient or his or her family identified by the Inquiry as having received flat dose carboplatin between 2006 and 2011 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;

Response —actioned

- 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;

Response —actioned

4 amended Reports on patient outcomes to the Hospital's Patient Safety and Quality Committee and Clinical Council six monthly, and annually to the Deputy Secretary, NSW Ministry of Health.

- 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 [the Interim Report and paragraphs 127-144 of this Final Report];

Response —actioned

- 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;

Response — policies updated and other management action taken

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

Response — actioned

- 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;

Response — in progress/ongoing.

- 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';

Response — in progress/ongoing

The Cancer Institute is exploring the feasibility of whether death notifications can be made available to hospitals close to real time. In the interim, the recommendation has been amended.

- 11 amended Given the categorisation of 'unanticipated' would not have flagged any of the patients affected by this off-protocol prescribing for review by the hospital-wide Mortality Review Committee, it is recommended that the Committee consider reviewing a random selection of 'expected' deaths rather than relying on the subjective decision that the death was 'unanticipated';**

- 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;

Response — actioned/ongoing

Responsible organisation: NSW Health

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 suggest similar dosing issues;

Response —in progress

Across the state, this is mostly in place. The areas where this is not immediately possible are the Local Health Districts which have not yet installed Oncology Medical Information Systems (OMIS) for electronic prescribing. In areas where this has not been immediately possible for the aforementioned reason interim measures are in place and will continue to be monitored by the System Purchasing and Performance Division at the Ministry of Health.

That Local Health Districts and Specialty Networks:

- 13 amended** **Ensure those LHDs that do not have an oncology management information system accelerate efforts to install them, as a matter of priority**

It is noted that all but two LHDs have an OMIS and those that don't have funding to commission one.

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

Response —in progress

Where electronic Oncology Medical Information Systems are in place, there is a combination of automated and manual uploading. Those that are still manual are working toward being electronic.

That Local Health Districts and Specialty Networks:

- 14 amended** **To avoid transcription errors, LHDs should move to automated uploading of eviQ protocols onto Oncology Medical Information Systems**

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.

Response —in progress/ongoing

Although many MDTs have updates after international meetings, the evidence needs to be translated into an agreed local response by the MDT and a plan of action for implementation.

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.

Response —ongoing

There is excellent coverage of MDTs available in NSW through Canrefer. The MDTs can be identified by people with cancer and their general practitioners through canrefer.org.au. Use of an MDT when people are referred to cancer services is high. This recommendation requires ongoing work to increase the number of people diagnosed with cancer who are referred to MDTs in the first place.

Recommendation 5 was actioned as dealt with in this report.

Responsible organisation: Cancer Institute NSW

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.

Response — actioned

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;

Response — actioned

The Cancer Institute is scoping the running of these meetings.

This is on the eviQ website at eviq.org.au

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

Response — actioned

This is on the eviQ website at eviq.org.au

New Recommendations

That clinicians across NSW

- 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 patient notes.

Recommendation to Local Health Districts and Speciality Health Networks

- 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 hallmark of good multidisciplinary teams and evidence-based clinical care, including escalation where there are concerns about care that have not been adequately addressed. This should be properly reflected in relevant contracts as they are negotiated between Local Health Districts/Speciality Health Networks and third party providers.

Recommendation to St Vincent's Hospital

- 23** That St Vincent's Hospital initiate, and oversee, a program that will build within cancer services a constructive, people-focused culture for patients and staff. This should include a facilitated restorative program to rebuild relationships and trust within the senior clinical community in cancer services, and between cancer services and hospital management.

References

1. Cancer Institute NSW. New South Wales Cancer Statistics [Internet]. Sydney: Cancer Institute NSW; 2016 [cited 2016 Jul 31]. Available from: <http://www.statistics.cancerinstitute.org.au/>
2. Australian Institute of Health and Welfare (AIHW). Head and neck cancers in Australia. Australian Institute of Health and Welfare Cancer Series Number 83 Cat no CAN 80 Canberra: AIHW. 2014.
3. European Society for Medical Oncology (ESMO). Head and neck cancer: A guide for patients — information based on ESMO Clinical Practice Guidelines. European Society for Medical Oncology. v. 2015.1. 2015.
4. National Comprehensive Cancer Network. Head and neck cancers: NCCN Clinical Practice Guidelines in Oncology. NCCN; 2015.
5. National Institute for Health and Care Excellence (NICE). Improving outcomes in head and neck cancers [Internet]. London: NICE; 2004 [cited 2016 Jul 31]. Available from: <https://www.nice.org.uk/guidance/csg6>
6. Westin T, Stalfors J. Tumour boards/multidisciplinary head and neck cancer meetings: are they of value to patients, treating staff or a political additional drain on healthcare resources? Current opinion in otolaryngology & head and neck surgery. 2008;16(2):103-7.
7. Grégoire V, Lefebvre JL, Licitra L, Felip E. Squamous cell carcinoma of the head and neck: EHNS-ESMO-ESTRO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Annals of oncology. 2010;21(Suppl 5):v184-6.
8. Pignon JP, Bourhis J, Domenge C, Designé L. Chemotherapy added to locoregional treatment for head and neck squamous-cell carcinoma: three meta-analyses of updated individual data. MACH-NC Collaborative Group. Meta-Analysis of Chemotherapy on Head and Neck Cancer. Lancet. 2000;355(9208):949-55.
9. Pignon JP, le Maître A, Maillard E, Bourhis J, MACH-NC Collaborative Group. Meta-analysis of chemotherapy in head and neck cancer (MACH-NC): an update on 93 randomised trials and 17,346 patients. Radiotherapy and oncology. 2009;92(1):4-14.
10. Bourhis J, Amand C, Pignon JP, MACH-NC Collaborative Group. Update of MACH-NC (Meta-Analysis of Chemotherapy in Head & Neck Cancer) database focused on concomitant chemoradiotherapy. Journal of clinical oncology. 2004;22(14S,July 15 Supplement):2004: 5505.
11. Scottish Intercollegiate Guidelines Network (SIGN). Diagnosis and management of head and neck cancer: A national clinical guideline. Edinburgh: SIGN; 2006 [cited 2016 Jul 31]. Available from: <http://sign.ac.uk/guidelines/fulltext/90/index.html>
12. Fountzilas G, Ciuleanu E, Dafni U, Plataniotis G, Kalogera-Fountzila A, Samantas E, et al. Concomitant radiochemotherapy vs radiotherapy alone in patients with head and neck cancer: a Hellenic Cooperative Oncology Group Phase III Study. Medical oncology. 2004;21(2):95-107.

13. Olmi P, Crispino S, Fallai C, Torri V, Rossi F, Bolner A, et al. Locoregionally advanced carcinoma of the oropharynx: conventional radiotherapy vs. accelerated hyperfractionated radiotherapy vs. concomitant radiotherapy and chemotherapy--a multicenter randomized trial. *International journal of radiation oncology, biology, physics*. 2003;55(1):78-92.
14. Bonner JA, Harari PM, Giralt J, Azarnia N, Shin DM, Cohen RB, et al. Radiotherapy plus cetuximab for squamous-cell carcinoma of the head and neck. *The New England journal of medicine*. 2006;354(6):567-78.
15. Loong HH, Ma BB, Leung SF, Mo F, Hui EP, Kam MK, et al. Prognostic significance of the total dose of cisplatin administered during concurrent chemoradiotherapy in patients with locoregionally advanced nasopharyngeal carcinoma. *Radiotherapy and oncology*. 2012;104(3):300-4.
16. Ang KK. Concurrent radiation chemotherapy for locally advanced head and neck carcinoma: are we addressing burning subjects? *Journal of clinical oncology*. 2004;22(23):4657-9.
17. Ghi MG, Paccagnella A, Floriani I, Garavaglia D. Concomitant chemoradiation in locally advanced head and neck squamous cell carcinoma: A literature-based meta-analysis on the platinum concomitant chemotherapy. *Journal of clinical oncology*. 2011;29(Suppl): abstr 5534.
18. Nwizu T, Adelstein DJ. In squamous cell head and neck cancer: which platinum, how much and how often? *Expert review of anticancer therapy*. 2014;14(9):1033-9.
19. Calvert AH, Newell DR, Gumbrell LA, O'Reilly S, Burnell M, Boxall FE, et al. Carboplatin dosage: prospective evaluation of a simple formula based on renal function. *Journal of clinical oncology*. 1989;7(11):1748-56.

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

Off-protocol prescribing of chemotherapy for head and neck cancers — Final report

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*

Off-protocol prescribing of chemotherapy for head and neck cancers — Final report

Appendix B

Clinical Review and Findings

- B.1 Methodology for the clinical review
- B.2 Fields in the clinical audit tool
- B.3 Data tree
- B.4 Table comparing baseline characteristics of patients with head and neck cancers treated with three different chemotherapy regimens
- B.5 Number of patients treated with flat dose 100 mg carboplatin over time

Appendix B.1 Methodology for the Clinical Review

Identification of patients

Patients who were treated with platinum-based chemotherapy (either carboplatin or cisplatin) at St Vincent's during the period between January 2006 and February 2016 by Dr Grygiel were identified through St Vincent's Hospital pharmacy records. The majority of these patients received the chemotherapy as part of chemoradiation (i.e. concurrently with radiotherapy).

An extensive review of the relevant literature was undertaken: see the References and Appendix E. Of note, controlled clinical studies published on carboplatin-based chemoradiation for head and neck cancers all used a higher dose of carboplatin than 100 mg. Accordingly, the identified patients were categorised into three groups:

- 1 those who were treated with carboplatin at 100 mg flat dose;
- 2 those who were treated with carboplatin at higher doses; and
- 3 those who were treated with cisplatin.

Some patients had more than one course of chemotherapy, not always using the same chemotherapeutic agent. To avoid double-counting:

- a patient who was treated with flat dose 100 mg carboplatin, even if he or she was also treated with cisplatin, would be placed in group 1;
- a patient who received both a higher dose of carboplatin and cisplatin would be placed in the group that corresponded with the main treatment he or she was given.

All patients in group 1 (129 patients) were included in the clinical review. Of these, 103 were treated for head and neck cancers (see Appendix B.3 for the tumour types of the other 26 people).

Matching

To enable comparisons on an appropriate basis (like with like), patients in group 1 were matched to patients in groups 2 and 3 according to tumour type (including the site of the cancer) and the year in which the patient was treated. The Inquiry was then able to compare demographic and clinical characteristics and the stage of the tumour at the time of treatment (baseline characteristics) appropriately. The purpose of these comparisons was to understand the basis on which the population who were treated with off-protocol flat dose 100 mg carboplatin were selected.

All patients in group 3 were matched to patients in group 1. All but three patients in group 2 were matched to patients in group 1.

Data collection

For all patients in group 1, and the matched patients from groups 2 and 3, detailed clinical information (see Appendix B.2 for the audit tool) was collected from:

- paper-based medical records, including chemotherapy charts, held by St Vincent's;
- St Vincent's electronic medical information systems;
- radiotherapy data extracts provided by St Vincent's third party radiation oncology provider; and
- the NSW Cancer Registry.

Analysis

For the people in group 1 who had head and neck cancers:

- information about their vital and disease status is summarised in the data tree at Appendix B.3;
- their baseline characteristics, and the baseline characteristics of the matched patients from groups 2 and 3 are summarised in the table at Appendix B.4.

The number of patients in group 1 by year of treatment is shown in the graph at Appendix B.5.

Appendix B.2 Fields in the Clinical Audit Tool

- Background patient information
 - Medical record number (MRN)
 - Surname
 - First name
 - Gender
 - Date of birth
 - Aboriginal status
 - Torres Strait Islander status
 - Clinical summary
 - Comorbidities
 - Alcohol history
 - Smoking history
 - ECOG status
 - Social support
 - Pre-treatment nutritional status
 - Allergies
 - Lung cancer
 - Pulmonary function test date and result
- Pathology
 - Tumour stream
 - Site
 - Histology / morphology
 - Head and neck cancer
 - HPV status
 - P16 status
 - Lung cancer
 - Gene mutation status
 - Breast cancer
 - Hormone and HER2 receptor status
 - Oesophageal cancer
 - HER2-neu status
 - Bowel cancer
 - Mutation testing status
 - MMR / MSI status
 - Endometrial cancer
 - Hormone receptor status
 - Oligodendroglioma
 - 1p19q deletion status
 - Date of multidisciplinary team assessment

- Stage
 - T
 - N
 - M
 - Summary
- Current treatment setting
 - Intent (curative, palliative, not specified)
 - Setting (neoadjuvant, postoperative, definitive)
 - Line of treatment (non head and neck cancer)
- Previous treatments
 - Neoadjuvant
 - Date (last dose)
 - Agent / regimen
 - Planned number of cycles
 - Actual number of cycles
 - Reasons for difference between planned and actual
 - Surgery
 - Date
 - Procedure
 - Resection margins (including R classification)
 - Number of lymph nodes harvested
 - Number of involved lymph nodes
 - Size of largest lymph node
 - Extranodal extension
 - Lymphovascular invasion
 - Perineural invasion
 - pT
 - pN
 - pM
 - p summary stage
 - Postoperative chemotherapy
 - Date (last dose)
 - Agent / regimen
 - Planned number of cycles
 - Actual number of cycles
 - Reasons for difference between planned and actual
 - Postoperative radiotherapy
 - Date completed
 - Dose
 - Number of fractions
 - Definitive chemotherapy
 - Date (last dose)
 - Agent / regimen
 - Planned number of cycles

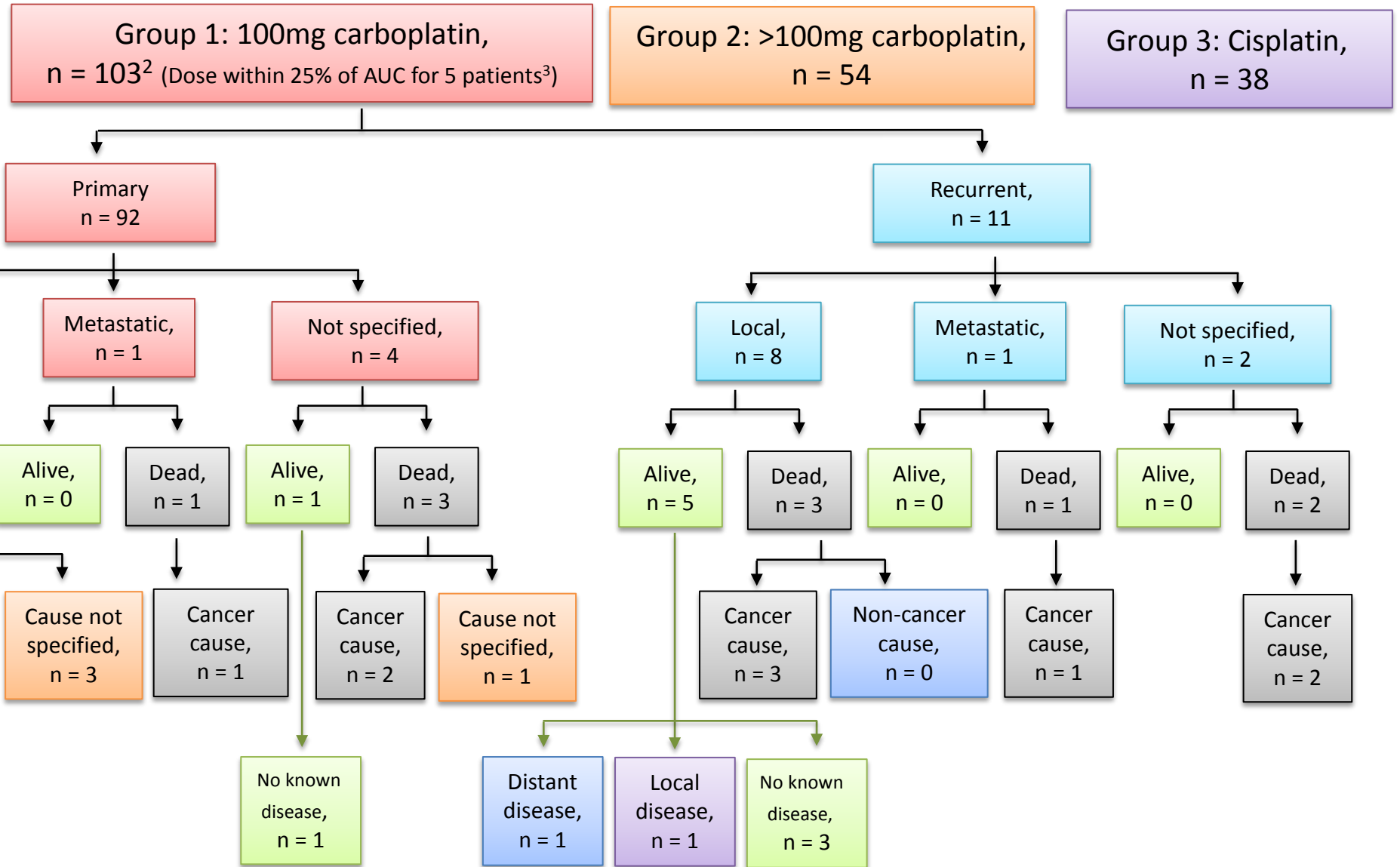
- Actual number of cycles
 - Reasons for differences between planned and actual
 - Definitive radiotherapy
 - Date completed
 - Dose
 - Number of fractions
- Current chemotherapy
 - Baseline patient information
 - Height
 - Weight
 - Intentional dose modifications and rationale
 - Serum creatinine
 - eGFR
 - EDTA GFR
 - Creatinine clearance (calculated by pharmacist)
 - Prescription
 - Agent / regimen
 - Prescriber surname
 - Prescriber signature on order
 - Date of order
 - Prescribed dose
 - Calculated dose
 - Administered dose
 - Pharmacist or nurse comments in patient notes and details
 - Intended frequency
 - Intended number of cycles
 - Consent form documented
 - eviQ protocol
 - protocol included in patient notes
 - protocol ID
 - protocol referenced in patient notes
 - Detailed information for each cycle received
 - Date
 - Dose
 - Reason for changes if different to prescribed
 - Different prescriber to original
 - Supportive care medications prescribed and rationale
 - Clinical trial or experimental treatment
- Current radiotherapy
 - Prescription
 - Prescriber surname
 - Prescriber signature on order
 - Date of order
 - Areas treated

- Total dose to gross disease
 - Number of fractions
 - Dose per fraction
 - Nodal dose
 - Prescribed dose matches protocol
 - Planned dose
- Radiotherapy received
 - Actual dose delivered
 - Start date
 - End date
 - Treatment interruptions (dates and reasons)
- Nutritional support during treatment (Yes / No)
 - PEG tube (insertion and removal dates)
 - NG tube (insertion and removal dates)
 - TPN (details)
- Subsequent events
 - Emergency department presentations (Yes / No)
 - Date
 - Details of presentation
 - Admissions (Yes / No)
 - Date
 - Details of admission
 - Supportive care required for significant episodes of care (Yes / No)
 - Date
 - Details of required care
- Outcomes
 - Last follow-up
 - Date
 - Discipline
 - Locoregional recurrence (Yes / No)
 - Date
 - Site of recurrence
 - Details of recurrence
 - Treatment for recurrence
 - Distant recurrence (Yes / No)
 - Date
 - Site of recurrence
 - Details of recurrence
 - Treatment for recurrence
 - Death (Yes / No)
 - Date
 - Cause of death

Patients under the care of Dr Grygiel treated with chemoradiation¹ involving 100 mg carboplatin for cancers other than head and neck cancers at St Vincent's Hospital January 2006 – February 2016, n = 26

Site	n
Lung	14
Musculoskeletal	1
Skin	1
Thymus	1
Upper GI	4
Urogenital	5

Patients under the care of Dr Grygiel treated with chemoradiation¹ for head and neck cancers at St Vincent's Hospital January 2006 – February 2016, n = 195



¹ Some patients did not have records of radiotherapy treatment.

² AUC could not be calculated for one patient who had no serum creatinine results.

³ For 5 patients, 100mg was within 25% of the AUC dose, but this was charted without dose calculation.

Table 1: Disease spread at baseline for patients treated for head and neck cancers with 100mg carboplatin

Disease spread at baseline	Number of patients
Local	95
Metastatic	2
Not specified	6

Table 2: Outcomes for patients treated for head and neck cancers with 100mg carboplatin

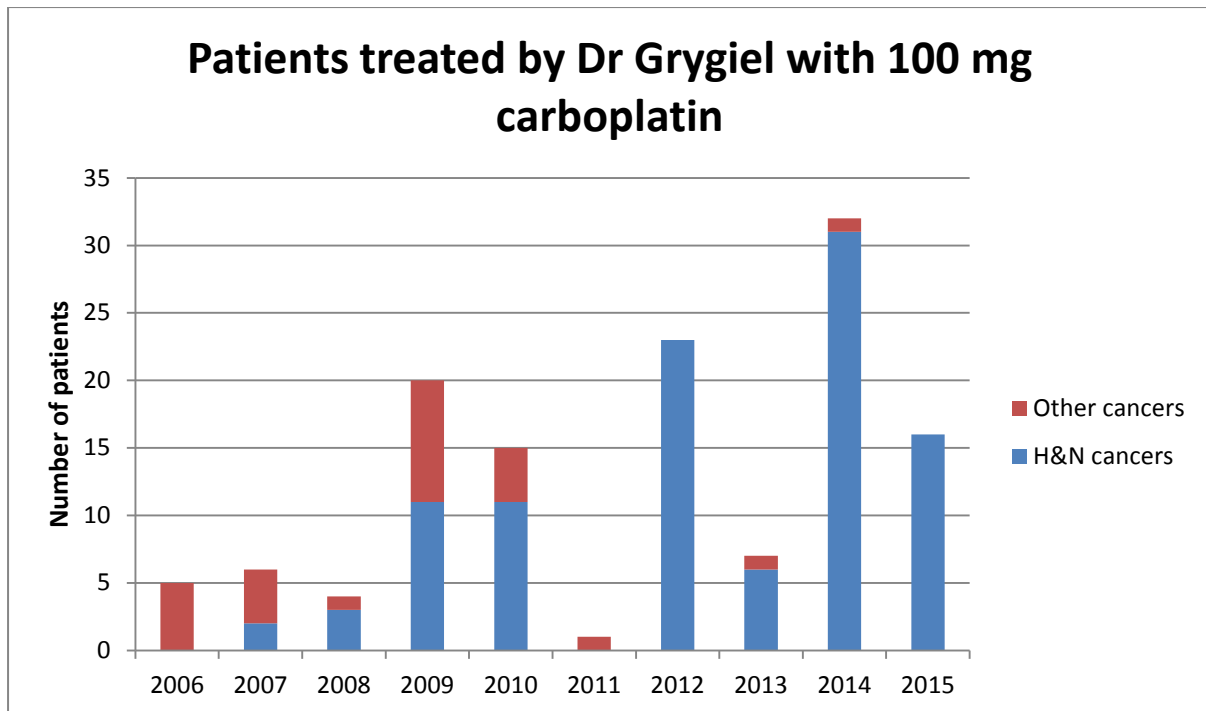
Vital status	Local disease	Distant disease	Suspected disease	No known disease	Total
Dead	11	17	11	7	46
Alive	10	5	0	42	57

Table comparing baseline characteristics of patients treated by Dr Grygiel for head and neck cancers with three different chemotherapy regimens January 2006 - February 2016 Appendix B.4

		Number of patients					
		Group 1: off-protocol flat dose 100 mg carboplatin		Group 2: carboplatin > 100 mg		Group 3: cisplatin	
Baseline characteristics		103		51		38	
Age	Median	60		59		54.5	
	Mean	60.3		60.7		56.3	
		n	%	n	%	n	%
Gender	Male	82	79.6	47	92.2	28	73.7
	Female	21	20.4	4	7.8	10	26.3
Co-morbidities	Yes	52	50.5	36	70.6	13	34.2
	No	51	49.5	15	29.4	25	65.8
Smoking	Yes	74	71.8	34	66.7	26	68.4
	No	27	26.2	15	29.4	11	28.9
	Not specified	2	1.9	2	3.9	1	2.6
Alcohol	Yes	83	80.6	40	78.4	27	71.1
	No	15	14.6	8	15.7	8	21.1
	Not specified	5	4.9	3	5.9	3	7.9
Human papilloma virus status	Positive	40	38.8	16	31.4	9	23.7
	Negative	22	21.4	14	27.5	5	13.2
	Not specified	41	39.8	21	41.2	24	63.2
Treatment context	Induction (neoadjuvant)	0	0.0	0	0.0	5	13.2
	Postoperative	55	53.4	22	43.1	12	31.6
	Definitive	48	46.6	29	56.9	21	55.3
Primary or recurrent disease	Primary	92	89.3	46	90.2	35	92.1
	Recurrent	11	10.7	5	9.8	3	7.9
Disease spread	Local disease	95	92.2	50	98.0	36	94.7
	Metastatic disease	2	1.9	1	2.0	1	2.6
	Not specified	6	5.8	0	0.0	1	2.6
Treatment intent	Curative/disease control	26	25.2	42	82.4	15	39.5
	Palliative	2	1.9	3	5.9	4	10.5
	Not specified	75	72.8	6	11.8	19	50.0

		Number of patients					
		Group 1: off-protocol flat dose 100 mg carboplatin		Group 2: carboplatin > 100 mg		Group 3: cisplatin	
Baseline characteristics		103		51		38	
		n	%	n	%	n	%
Summary stage of tumour	1	2	1.9	0	0.0	0	0.0
	2A	0	0.0	0	0.0	0	0.0
	2B	0	0.0	0	0.0	0	0.0
	2 (exact stage not specified)	2	1.9	1	2.0	3	7.9
	3A	0	0.0	0	0.0	0	0.0
	3B	0	0.0	0	0.0	1	2.6
	3 (exact stage not specified)	21	20.4	11	21.6	6	15.8
	4A	60	58.3	35	68.6	26	68.4
	4B	3	2.9	3	5.9	0	0.0
	4C	2	1.9	1	2.0	1	2.6
	4 (exact stage not specified)	0	0.0	0	0.0	0	0.0
	Not specified	13	12.6	0	0.0	1	2.6

*Detailed clinical information was collected for 51 of the 54 patients in group 2, who were matched to patients in group 1 (see Appendix B.1)
For other relevant details, see Appendix B.3



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

Off-protocol prescribing of chemotherapy for head and neck cancers — Final report

Appendix C

Timeline for the development of CI-SCaT and eviQ, and their adoption as policy

- Standard Cancer Treatment Guidelines was an application containing information on cancer types, drugs, chemotherapy protocols, symptoms and symptom management created by oncology teams based in the South Eastern Sydney Area Health Service, led by Professor Robyn Ward at St Vincent's Hospital, Sydney.
- In October 2004 the Cancer Institute NSW assumed responsibility for the protocols application, renamed Cancer Institute NSW Standard Cancer Treatments (CI-SCaT), with the intention that it would become a state-wide resource under the first NSW Cancer Plan. The CI-SCaT website was launched in October 2005.
- The take-up of the website and its protocols led to the need for greater functionality. CI-SCaT was rebranded as eviQ Cancer Treatments Online, launched in October 2009.
- In March 2012, eviQ began working towards endorsement as a national Program. Memoranda of Understanding were in place with every state and territory by the end of 2013. eviQ is used in more than 90% of Australian cancer centres.
- The South Eastern Sydney and Illawarra Area Health Service (SESIAHS), which included St Vincent's Hospital, adopted the Cancer Services — use of eviQ Cancer Treatments online on 27 July 2009 (PD233, Appendix C.1 attached). The policy provided for eviQ protocols to be adopted and accepted within SESIAHS; where there was a need to vary an eviQ policy or procedure for local use, the local service would develop an exception business rule for use within that unit; and the business rule would comply with the standards and formats defined in the SESIAHS Framework for Policies, Procedures and Guidelines.
- eviQ provides evidence-based cancer treatment protocols at the point-of-care for the optimal administration of chemotherapy. The eviQ protocols are intended to provide guidance on the optimal prescribing (including dosing for a particular patient) and administration of a chosen therapy. They are distinct from clinical guidelines, which provide specific direction on which therapies to choose.

INTERNAL ONLY

SESAHS POLICY

COVER SHEET

NAME OF DOCUMENT	Cancer Services – use of eviQ Cancer Treatments online
TYPE OF DOCUMENT	Policy
DOCUMENT NUMBER	PD 233
DATE OF PUBLICATION	27 July 2009
RISK RATING	Low
REVIEW DATE	July 2014
FORMER REFERENCE(S)	Nil
EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	Director Cancer Services Clinical Stream
AUTHOR	Clinical Stream Manager Cancer Services Clinical Stream
KEY TERMS	Cancer, Oncology, eviQ, policy, procedure
SUMMARY	<p>This policy provides a framework for SESAHS Cancer Services to ensure evidence of efficacy, safety and effective resource utilisation to safely comply with cancer treatment protocols.</p> <p>It ensures optimal treatment to cancer patients by complying with and maintaining Policies and Procedures that are based on and reference, legislative requirements, NSW Health Directives, Australian Standards, best practice, specific industry requirements, regulatory and professional body requirements.</p>

COMPLIANCE WITH THIS DOCUMENT IS MANDATORY

Feedback about this document can be sent to areapolicy@sesiahs.health.nsw.gov.au

INTERNAL ONLY
SESIAHS POLICY**Cancer Services– use of eviQ cancer treatments online****PD 233****1. POLICY STATEMENT**

South Eastern Sydney Illawarra Area Health Service (SESIAHS) supports the delivery of best practice treatment to cancer patients and the provision of up-to-date information on cancer treatment protocols to Cancer Centres and ward staff within SESIAHS. To ensure this level of care and support is provided, the following principles will apply:

- 1.1 All policies and procedures approved by the Cancer Institute NSW and displayed on the eviQ website will be adopted and accepted as the standard within SESIAHS.
- 1.2 The eviQ website will be accessed via the Cancer Institute NSW website or directly via <http://www.eviq.org.au/>.
- 1.3 When there is a need to vary an eviQ policy or procedure for local use, the local service will develop an exception business rule for use within that unit. The local service business rule shall comply with the standards and formats defined in the [SESIAHS Framework for Policies, Procedures and Guidelines](#) and abide by principles of document control detailed in [SESIAHS PD 006 Document Control](#).
- 1.4 All new Cancer treatments or amendments are to be sent to eviQ Cancer Treatment online to be considered for inclusion in eviQ. Requests for consideration of a new treatment or amendments to treatments/protocols are to be [emailed](mailto:feedback@eviq.org.au) to feedback@eviq.org.au
- 1.5 eviQ is not intended to replicate or replace the knowledge, skills, experience, or clinical judgement of experienced health professionals.

2. AIMS

The purpose of this policy is to ensure clinical practice in SESIAHS Adult Cancer Services is evidence-based and research driven in accordance with the NSW Cancer Plan 2007-2010.

The eviQ Cancer Treatments online (previously known as CI - SCaT) website provides clinicians with cancer treatment protocols and allows them to have the full understanding of contemporary literature, key evidence and international standards necessary to deliver optimal treatment to cancer patients.

This policy provides an over arching framework to support the use of EviQ within SESIAHS and defines the process for meeting the Australian Council on Healthcare Standards EQulP 4; Standard 1.4, Criterion 1.4.1 and Standard 3.1, Criterion 3.1.5.

INTERNAL ONLY
SESIAHS POLICY**Cancer Services– use of eviQ cancer treatments online****PD 233****3. TARGET AUDIENCE**

All SESIAHS Cancer Services related staff providing cancer treatment including:

- Medical Officers
- Allied Health
- Clinical Nurse Consultants
- Cancer Nurse Coordinators
- Registered Nurses and Enrolled Nurses

4. INFORMATION ABOUT eviQ

eviQ Cancer Treatments online [previously known as Cancer Institute - Standard Cancer treatments (CI-Scat)] is a comprehensive information repository containing evidence-based cancer treatments that includes:

- Chemotherapy Drug Protocols
- Radiotherapy Protocols
- Standard Drug Protocols
- Nurse Procedures
- Special Clinical Instructions
- Supportive Care instructions

The protocols and information are reviewed annually. A password is currently necessary to access this site, to access the online application form: <http://www.eviq.org.au/>.

eviQ website calculations function is integrated into the display of Chemotherapy Drug Protocols. The Calculations function includes BMI, BSA, ideal body weight, creatinine clearance, opioid and corrected calcium, and is intended to be used as an adjunct to prescribing.

eviQ is relevant to Medical Oncology, Haematology, Palliative Care, Cancer Genetics, Bone Marrow Transplantation, Primary Health care and Radiation Oncology services.

5. DOCUMENTATION

None required

7. REFERENCES

[Australian Council on Healthcare Standards Equip 4](#)
[eviQ Cancer Treatments online](#)
[Correct Patient, Correct Procedure, Correct Site Policy Directive \(PD2007_079\)](#)
[NSW Cancer Plan 2007-2010](#)
[NSW Health PD2005_406 Consent to Medical Treatment – Patient Information](#)
[SESIAHS Framework for Policies, Procedures and Guidelines](#)
[SESIAHS PD 006 Document Control](#)

INTERNAL ONLY
SESIAHS POLICY**Cancer Services– use of eviQ cancer treatments
online****PD 233****8. REVISION & APPROVAL HISTORY**

Date	Revision No.	Author and Approval
July 2008	Draft Document	Elizabeth Browne – Clinical Stream Manager Cancer Services. Approved June 2009 Cancer Services Committee and Director Cancer Stream. Approved by Chief Executive at Clinical Council 22.7.2009

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

Off-protocol prescribing of chemotherapy for head and neck cancers — Final report

Appendix D

External advice provided to the Inquiry

Members of the Clinical Expert Panel

Dr Christine Carrington, Senior Consultant Pharmacist, Cancer Services and Assistant Director, Pharmacy, Princess Alexandra Hospital, Queensland

Dr Joanna Dewar, Medical Oncologist, Sir Charles Gairdner Hospital and Clinical Professor, University of Western Australia

Dr Graeme Dickie, Director of Radiation Oncology, Royal Brisbane & Women's Hospital, Queensland

Dr Brett Hughes, Clinical Director Oncology, The Prince Charles Hospital
Senior Staff Specialist Medical Oncology, Royal Brisbane Hospital
Associate Professor, University of Queensland

Dr Lizbeth Kenny, Senior Radiation Oncologist, Royal Brisbane & Women's Hospital,
Medical Director, Central Integrated Regional Cancer Service (CIRCS)
Medical Director, Herston Imaging Research Facility
Adjunct Professor, School of Medicine, University of Queensland
Chair, Statewide Cancer Clinical Network, Department of Health, Queensland

Dr Ganessan Kichenadasse, Staff Specialist Medical Oncologist, Flinders Medical Centre;
Lecturer, Department of Medicine, Flinders University and
PhD candidate in Clinical Pharmacology, Flinders University, South Australia

Professor Jennifer Martin, Chair of Clinical Pharmacology and Toxicology, University of Newcastle/Calvary Mater Hospital, Newcastle

Professor Lester Peters AM, Radiation Oncologist, Peter MacCallum Cancer Centre, Victoria

Health Consumer Advisor

Mr Tony Lawson, Chair, Consumers Health Forum of Australia

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

Off-protocol prescribing of chemotherapy for head and neck cancers — Final report

Appendix E

Journal articles and other literature provided to the Clinical Expert Panel

Abola MV, Prasad V, Jena AB. Association between treatment toxicity and outcomes in oncology clinical trials. *Annals of oncology*. 2014;25(11):2284-9.

Accord Healthcare Inc. Carboplatin Injection BP: Product Monograph. Canada. 2008.

Accord Healthcare Limited. Carboplatin: Summary of Product Characteristics. United Kingdom. 2012.

Accord Healthcare Pty Ltd. CARBACCORD (Carboplatin) Solution for Injection: Product Information. Australia. 2013.

Accord Healthcare Pty Ltd. CARBOPLATIN INTAS (Carboplatin) Solution for Injection: Product Information. Australia. 2014.

Actavis New Zealand Limited. CARBACCORD 10mg/mL: Data Sheet. Version 1.2. New Zealand. 2013.

Ainsworth NL, Marshall A, Hatcher H, Whitehead L, Whitfield GA, Earl HM. Evaluation of glomerular filtration rate estimation by Cockcroft-Gault, Jelliffe, Wright and Modification of Diet in Renal Disease (MDRD) formulae in oncology patients. *Annals of oncology*. 2012;23(7):1845-53.

Al-Sarraf M, Metch B, Kish J, Ensley J, Rinehart JJ, Schuller DE, et al. Platinum analogs in recurrent and advanced head and neck cancer: A Southwest Oncology Group and Wayne State University Study. *Cancer treatment reports*. 1987;71(7-8):723-6.

Anderson P, Aguilera D, Pearson M, Woo S. Outpatient chemotherapy plus radiotherapy in sarcomas: improving cancer control with radiosensitizing agents. *Cancer control*. 2008;15(1):38-46.

Ang KK. Concurrent radiation chemotherapy for locally advanced head and neck carcinoma: Are we addressing burning subjects? *Journal of clinical oncology*. 2004;22(23):4657-9.

Ang KK, Zhang Q, Rosenthal DI, Nguyen-Tan PF, Sherman EJ, Weber RS, et al. Randomized phase III trial of concurrent accelerated radiation plus cisplatin with or without cetuximab for stage III to IV head and neck carcinoma: RTOG 0522. *Journal of clinical oncology*. 2014;32(27):2940-50.

Banning M. A review of clinical decision making: Models and current research. *Journal of clinical nursing*. 2008;17(2):187-95.

Baxter Healthcare Pty Ltd. Baxter Carboplatin: Consumer Medicine Information. Australia. 2008.

Baxter Healthcare Pty Ltd. Baxter Carboplatin: Product Information. Australia. 2008.

BC Cancer Agency. BC Cancer Agency Drug Manual: Carboplatin. Canada: BC Cancer Agency; 2014.

Bölke E, Peiper M, Gripp S. Chemotherapy in unresectable head and neck cancer. *New England journal of medicine*. 2008;358(10):1075;author reply

Bonner JA, Harari PM, Giralt J, Azarnia N, Shin DM, Cohen RB, et al. Radiotherapy plus cetuximab for squamous-cell carcinoma of the head and neck. *New England journal of medicine*. 2006;354(6):567-78.

Bonner JA, Harari PM, Giralt J, Cohen RB, Jones CU, Sur RK, et al. Radiotherapy plus cetuximab for locoregionally advanced head and neck cancer: 5-year survival data from a phase 3 randomised trial, and relation between cetuximab-induced rash and survival. *The lancet oncology*. 2010;11(1):21-8.

Bouaud J, Seroussi B. Revisiting the EBM decision model to formalize non-compliance with computerized CPGs: Results in the management of breast cancer with OncoDoc2. *AMIA annual symposium proceedings*. 2011:125-34.

Bourhis J, Rivera F, Mesia R, Awada A, Geoffrois L, Borel C, et al. Phase I/II study of cetuximab in combination with cisplatin or carboplatin and fluorouracil in patients with recurrent or metastatic squamous cell carcinoma of the head and neck. *Journal of clinical oncology*. 2006;24(18):2866-72.

Budach W, Bölke E, Kammers K, Gerber PA, Orth K, Gripp S, et al. Induction chemotherapy followed by concurrent radio-chemotherapy versus concurrent radio-chemotherapy alone as treatment of locally advanced squamous cell carcinoma of the head and neck (HNSCC): A meta-analysis of randomized trials. *Radiotherapy and oncology*. 2016;118(2):238-43.

Burtneß B, Goldwasser MA, Flood W, Mattar B, Forastiere AA, Eastern Cooperative Oncology Group. Phase III randomized trial of cisplatin plus placebo compared with cisplatin plus cetuximab in metastatic/recurrent head and neck cancer: An Eastern Cooperative Oncology Group study. *Journal of clinical oncology*. 2005;23(34):8646-54.

Calais G, Alfonsi M, Bardet E, Sire C, Germain T, Bergerot P, et al. Randomized trial of radiation therapy versus concomitant chemotherapy and radiation therapy for advanced-stage oropharynx carcinoma. *Journal of the National Cancer Institute*. 1999;91(24):2081-6.

Calvert AH, Newell DR, Gumbrell LA, O'Reilly S, Burnell M, Boxall FE, et al. Carboplatin dosage: Prospective evaluation of a simple formula based on renal function. *Journal of clinical oncology*. 1989;7(11):1748-56.

Candelaria M, Garcia-Arias A, Cetina L, Dueñas-Gonzalez A. Radiosensitizers in cervical cancer. Cisplatin and beyond. *Radiation oncology*. 2006;1:15.

Carless P. Proposal for the inclusion of carboplatin (as a representative of the antineoplastic - cytotoxic drug class) in the WHO model list of essential medicines. Switzerland: 17th Expert Committee on the Selection and Use of Essential Medicines; 2009.

Chan AT, Grégoire V, Lefebvre JL, Licitra L, Hui EP, Leung SF, et al. Nasopharyngeal cancer: EHS-ESMO-ESTRO clinical practice guidelines for diagnosis, treatment and follow-up. *Annals of oncology*. 2012;23(Suppl 7):vii83-5.

Chew-Harris JS, Chin PK, Florkowski CM, George P, Endre Z. Removal of body surface area normalisation improves raw-measured glomerular filtration rate estimation by the Chronic Kidney Disease Epidemiology Collaboration equation and drug dosing in the obese. *Internal medicine journal*. 2015;45(7):766-73.

Chew-Harris JS, Florkowski CM, George PM, Endre ZH. Comparative performances of the new chronic kidney disease epidemiology equations incorporating cystatin C for use in cancer patients. *Asia-Pacific journal of clinical oncology*. 2015;11(2):142-51.

Chitapanarux I, Lorvidhaya V, Kamnerdsupaphon P, Sumitsawan Y, Tharavichitkul E, Sukthomya V, et al. Chemoradiation comparing cisplatin versus carboplatin in locally advanced nasopharyngeal cancer: Randomised, non-inferiority, open trial. *European journal of cancer*. 2007;43(9):1399-406.

Cohen EE, Halpern AB, Kasza K, Kocherginsky M, Williams R, Vokes EE. Factors associated with clinical benefit from epidermal growth factor receptor inhibitors in recurrent and metastatic squamous cell carcinoma of the head and neck. *Oral oncology*. 2009;45(10):e155-60.

Cooper JS, Forastiere A, Jacobs J. Treatment of advanced head and neck cancer. *New England journal of medicine*. 2004;351(8):830.

Cooper JS, Pajak TF, Forastiere AA, Jacobs J, Campbell BH, Saxman SB, et al. Postoperative concurrent radiotherapy and chemotherapy for high-risk squamous-cell carcinoma of the head and neck. *New England journal of medicine*. 2004;350(19):1937-44.

Craig AJ, Samol J, Heenan SD, Irwin AG, Britten A. Overestimation of carboplatin doses is avoided by radionuclide GFR measurement. *British journal of cancer*. 2012;107(8):1310-6.

Curt GA, Grygiel JJ, Corden BJ, Ozols RF, Weiss RB, Tell DT, et al. A phase I and pharmacokinetic study of diamminecyclobutane-dicarboxylatoplatinum (NSC 241240). *Cancer research*. 1983;43(9):4470-3.

De Andrés L, Brunet J, López-Pousa A, Burgués J, Vega M, Tabernero JM, et al. Randomized trial of neoadjuvant cisplatin and fluorouracil versus carboplatin and fluorouracil in patients with stage IV-M0 head and neck cancer. *Journal of clinical oncology*. 1995;13(6):1493-500.

Denis F, Garaud P, Bardet E, Alfonsi M, Sire C, Germain T, et al. Final results of the 94-01 French Head and Neck Oncology and Radiotherapy Group randomized trial comparing radiotherapy alone with concomitant radiochemotherapy in advanced-stage oropharynx carcinoma. *Journal of clinical oncology*. 2004;22(1):69-76.

Dienstmann R, Braña I, Rodon J, Tabernero J. Toxicity as a biomarker of efficacy of molecular targeted therapies: Focus on EGFR and VEGF inhibiting anticancer drugs. *Oncologist*. 2011;16(12):1729-40.

Dooley MJ, Poole SG, Rischin D. Dosing of cytotoxic chemotherapy: Impact of renal function estimates on dose. *Annals of oncology*. 2013;24(11):2746-52.

Ekhart C, de Jonge ME, Huitema AD, Schellens JH, Rodenhuis S, Beijnen JH. Flat dosing of carboplatin is justified in adult patients with normal renal function. *Clinical cancer research*. 2006;12(21):6502-8.

Ekhart C, Rodenhuis S, Schellens JH, Beijnen JH, Huitema AD. Carboplatin dosing in overweight and obese patients with normal renal function, does weight matter? *Cancer chemotherapy and pharmacology*. 2009;64(1):115-22.

Etienne MC, Leger F, Pivot X, Chatelut E, Bensadoun RJ, Guardiola E, et al. Pharmacokinetics of low-dose carboplatin and applicability of a method of calculation for estimating individual drug clearance. *Annals of oncology*. 2003;14(4):643-7.

Fava GA, Guidi J, Rafanelli C, Sonino N. The clinical inadequacy of evidence-based medicine and the need for a conceptual framework based on clinical judgment. *Psychotherapy and psychosomatics*. 2015;84(1):1-3.

Fernandez A, Sturmberg J, Lukersmith S, Madden R, Torkfar G, Colagiuri R, et al. Evidence-based medicine: Is it a bridge too far? *Health research policy and systems*. 2015;13:66.

Forastiere A, Weber R, Ang K. Treatment of head and neck cancer. *New England journal of medicine*. 2008;358(10):1076;author reply 1077-8.

Forastiere AA, Metch B, Schuller DE, Ensley JF, Hutchins LF, Triozzi P, et al. Randomized comparison of cisplatin plus fluorouracil and carboplatin plus fluorouracil versus methotrexate in advanced squamous-cell carcinoma of the head and neck: A Southwest Oncology Group study. *Journal of clinical oncology*. 1992;10(8):1245-51.

Fortin A, Audet N, Caouette R. Treatment of advanced head and neck cancer. *New England journal of medicine*. 2004;351(8):829-31;author reply 831.

Fountzilas G, Ciuleanu E, Dafni U, Plataniotis G, Kalogera-Fountzila A, Samantas E, et al. Concomitant radiochemotherapy vs radiotherapy alone in patients with head and neck cancer: A Hellenic Cooperative Oncology Group Phase III Study. *Medical oncology*. 2004;21(2):95-107.

Fresenius Kabi Australia Pty Ltd. Carboplatin Kabi Injection: Consumer Medicine Information. Australia. 2011.

Fresenius Kabi Australia Pty Ltd. Carboplatin Kabi: Product Information. Australia. 2011.

Fresenius Kabi Oncology PLC. Carboplatin: Summary of Product Characteristics. United Kingdom. 2013.

Galsky MD, Hahn NM, Rosenberg J, Sonpavde G, Hutson T, Oh WK, et al. A consensus definition of patients with metastatic urothelial carcinoma who are unfit for cisplatin-based chemotherapy. *The lancet oncology*. 2011;12(3):211-4.

Galsky MD, Hahn NM, Rosenberg J, Sonpavde G, Hutson T, Oh WK, et al. Treatment of patients with metastatic urothelial cancer "unfit" for Cisplatin-based chemotherapy. *Journal of clinical oncology*. 2011;29(17):2432-8.

Grégoire V, Lefebvre JL, Licitra L, Felip E, EHNS-ESMO-ESTRO Guidelines Working Group. Squamous cell carcinoma of the head and neck: EHNS-ESMO-ESTRO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Annals of oncology*. 2010;21(Suppl 5):v184-6.

Guan J, Li Q, Zhang Y, Xiao N, Chen M, Zhang Y, et al. A meta-analysis comparing cisplatin-based to carboplatin-based chemotherapy in moderate to advanced squamous cell carcinoma of head and neck (SCCHN). *Oncotarget*. 2016;7(6):7110-9.

Harbison J. Clinical judgement in the interpretation of evidence: A Bayesian approach. *Journal of clinical nursing*. 2006;15(12):1489-97.

Head and Neck Cancer Working Group. South Australian Head and Neck Cancer Pathway. Australia: Department of Health and Ageing, Government of South Australia; 2013.

Hempel G, Boos J. Flat-fixed dosing versus body surface area based dosing of anticancer drugs: There is a difference. *Oncologist*. 2007;12(8):924-6.

Ho K, Slevin N. A comparison of cisplatin and fluorouracil alone or with docetaxel in squamous cell carcinoma of the head and neck. *Nature clinical practice oncology*. 2008;5(6):306-7.

Homma A, Shirato H, Furuta Y, Nishioka T, Oridate N, Tsuchiya K, et al. Randomized phase II trial of concomitant chemoradiotherapy using weekly carboplatin or daily low-dose cisplatin for squamous cell carcinoma of the head and neck. *Cancer journal*. 2004;10(5):326-32.

Hospira Australia Pty Ltd. DBL Carboplatin Injection: Product Information. Australia. 2015.

Hospira Healthcare Corporation. Carboplatin Injection BP: Product Monograph. Canada. 2014.

Hospira New Zealand Limited. DBL Carboplatin Injection: Data Sheet. New Zealand. 2015.

Hospira United Kingdom Limited. Carboplatin: Summary of Product Characteristics. United Kingdom. 2015.

Hospira Worldwide Inc. CARBOplatin Injection. United States. 2015.

Ivy SP, Zwiebel J, Mooney M. Follow-up for information letter regarding AUC-based dosing of carboplatin. United States: National Institutes of Health, National Cancer Institute; 2010.

Jereczek-Fossa B, Jassem J, Karnicka-Mlodkowska H, Badzio A, Moś-Antkowiak R, Krawczyk K, et al. Does chemotherapy-induced leukopenia predict a response in small-cell lung cancer? *Journal of cancer research and clinical oncology*. 1998;124(2):106-12.

Jeremic B, Shibamoto Y, Stanisavljevic B, Milojevic L, Milicic B, Nikolic N. Radiation therapy alone or with concurrent low-dose daily either cisplatin or carboplatin in locally advanced unresectable squamous cell carcinoma of the head and neck: A prospective randomized trial. *Radiotherapy and oncology*. 1997;43(1):29-37.

Jeremic B, Zivic L, Jevremovic S. Radiotherapy and cisplatin in metastatic squamous cell carcinoma of an unknown primary tumor localized to the neck. A phase II study. *Journal of chemotherapy*. 1992;4(6):399-402.

Karthikeyan G, Pais P. Clinical judgement and evidence-based medicine: Time for reconciliation. *Indian journal of medical research*. 2010;132:623-6.

Kaur P, Chauhan A, Singh G. Concurrent low dose carboplatin with radiotherapy versus radiotherapy alone in management of locally advanced head and neck cancer patients. *Indian medical gazette*. 2012(July):274-8.

Kim R, Hahn S, Shin J, Ock CY, Kim M, Keam B, et al. The effect of induction chemotherapy using docetaxel, cisplatin, and fluorouracil on survival in locally advanced head and neck squamous cell carcinoma: A meta-analysis. *Cancer research and treatment*. 2016;48(3):907-16.

Koukourakis MI, Stefanaki I, Giatromanolaki A, Frangiadaki C, Armenaki A, Georgoulas V, et al. Fractionated carboplatin radiosensitization: A phase I dose-escalation study. *American journal of clinical oncology*. 1998;21(6):595-601.

Kudelka AP, Siddik ZM, Balat O, Kavanagh JJ. Carboplatin dosimetry in renal failure. *Journal of clinical oncology*. 1995;13(8):2147-8.

Kumagai S, Sugiyama T, Shoji T, Michimae H, Katsumata N, Aoki D, et al. Does severe anemia caused by dose-dense paclitaxel-carboplatin combination therapy have an effect on the survival of patients with epithelial ovarian cancer? Retrospective analysis of the Japanese Gynecologic Oncology Group 3016 trial. *International journal of gynaecological cancer*. 2011;21(9):1585-91.

Lauritsen J, Gundgaard MG, Mortensen MS, Oturai PS, Feldt-Rasmussen B, Daugaard G. Reliability of estimated glomerular filtration rate in patients treated with platinum containing therapy. *International journal of cancer*. 2014;135(7):1733-9.

Lawrence TS. Radiation sensitizers and targeted therapies. *Oncology*. 2003;17(12 Suppl 13):23-8.

Lawrence YR, Vikram B, Dignam JJ, Chakravarti A, Machtay M, Freidlin B, et al. NCI-RTOG translational program strategic guidelines for the early-stage development of radiosensitizers. *Journal of the National Cancer Institute*. 2013;105(1):11-24.

Lee CK, Gurney H, Brown C, Sorio R, Donadello N, Tulunay G, et al. Carboplatin-paclitaxel-induced leukopenia and neuropathy predict progression-free survival in recurrent ovarian cancer. *British journal of cancer*. 2011;105(3):360-5.

Lindauer A, Eickhoff C, Kloft C, Jaehde U. Population pharmacokinetics of high-dose carboplatin in children and adults. *Therapeutic drug monitoring*. 2010;32(2):159-68.

Loong HH, Ma BB, Leung SF, Mo F, Hui EP, Kam MK, et al. Prognostic significance of the total dose of cisplatin administered during concurrent chemoradiotherapy in patients with locoregionally advanced nasopharyngeal carcinoma. *Radiotherapy and oncology*. 2012;104(3):300-4.

Mathijssen RH, de Jong FA, Loos WJ, van der Bol JM, Verweij J, Sparreboom A. Flat-fixed dosing versus body surface area based dosing of anticancer drugs in adults: Does it make a difference? *Oncologist*. 2007;12(8):913-23.

Mayne Pharma International Pty Ltd. Carboplatin MYX Solution for Injection: Product Information. Australia. 2011.

McTiernan A, Jinks RC, Sydes MR, Uscinska B, Hook JM, van Glabbeke M, et al. Presence of chemotherapy-induced toxicity predicts improved survival in patients with localised extremity osteosarcoma treated with doxorubicin and cisplatin: A report from the European Osteosarcoma Intergroup. *European journal of cancer*. 2012;48(5):703-12.

Mellis C. Evidence-based medicine: What has happened in the past 50 years? *Journal of paediatrics and child health*. 2015;51(1):65-8.

Merck Serono Australia Pty Ltd. Erbitux 5mg/mL: Product Information. Australia. 2015.

Moding EJ, Kastan MB, Kirsch DG. Strategies for optimizing the response of cancer and normal tissues to radiation. *Nature reviews drug discovery*. 2013;12(7):526-42.

Murray B, Bates J, Buie L. Impact of a new assay for measuring serum creatinine levels on carboplatin dosing. *American journal of health-system pharmacy*. 2012;69(13):1136-41.

Mylan Institutional LLC. Carboplatin Injection. United States. 2014.

National Comprehensive Cancer Network (NCCN). Head and Neck Cancers: NCCN Clinical Practice Guidelines in Oncology. United States: NCCN; 2015.

National Institute for Clinical Excellence (NICE). Cetuximab for the treatment of locally advanced squamous cell cancer of the head and neck. United Kingdom: NICE; 2008.

National Institute for Clinical Excellence (NICE). Cetuximab for the treatment of recurrent and/or metastatic squamous cell cancer of the head and neck. United Kingdom: NICE; 2009.

National Institute for Clinical Excellence (NICE). Improving Outcomes in Head and Neck Cancers: The Manual. United Kingdom: NICE; 2004.

Nieder C, Pawinski A, Andratschke NH. Combined radio- and chemotherapy for non-small cell lung cancer: Systematic review of landmark studies based on acquired citations. *Frontiers in oncology*. 2013;3:176.

Novartis New Zealand Ltd. Carboplatin Ebewe: Data Sheet. New Zealand. 2014.

Novotech (Australia) Pty Ltd. Carboplatin Injection: Product Information. Australia. 2009.

Nutting CM, Bhide SA, Harrington KJ. Treatment of head and neck cancer. *New England journal of medicine*. 2008;358(10):1076-7;author reply 1077-8.

Olmi P, Crispino S, Fallai C, Torri V, Rossi F, Bolner A, et al. Locoregionally advanced carcinoma of the oropharynx: Conventional radiotherapy vs. accelerated hyperfractionated radiotherapy vs. concomitant radiotherapy and chemotherapy—a multicenter randomized trial. *International journal of radiation oncology, biology, physics*. 2003;55(1):78-92.

Omega Laboratories Ltd. Carboplatin Injection: Product Monograph. Canada. 2011.

O'Rourke N, Roqué IFM, Farré Bernadó N, Macbeth F. Concurrent chemoradiotherapy in non-small cell lung cancer. *Cochrane database of systematic reviews*. 2010(6):CD002140.

Petrelli F, Coinu A, Riboldi V, Borgonovo K, Ghilardi M, Cabiddu M, et al. Concomitant platinum-based chemotherapy or cetuximab with radiotherapy for locally advanced head and neck cancer: A systematic review and meta-analysis of published studies. *Oral oncology*. 2014;50(11):1041-8.

Pfizer Australia Pty Ltd. Carboplatin Injection: Product Information. Australia. 2009.

Pfizer New Zealand Ltd. Carboplatin Injection: Data Sheet. New Zealand. 2010.

Pignon JP, Bourhis J, Dumenil C, Designé L. Chemotherapy added to locoregional treatment for head and neck squamous-cell carcinoma: Three meta-analyses of updated individual data. MACH-NC Collaborative Group. Meta-Analysis of Chemotherapy on Head and Neck Cancer. *Lancet*. 2000;355(9208):949-55.

Pignon JP, le Maître A, Maillard E, Bourhis J, MACH-NC Collaborative Group. Meta-analysis of chemotherapy in head and neck cancer (MACH-NC): An update on 93 randomised trials and 17,346 patients. *Radiotherapy and oncology*. 2009;92(1):4-14.

Porceddu SV, Campbell B, Rischin D, Corry J, Weih L, Guerrieri M, et al. Postoperative chemoradiotherapy for high-risk head-and-neck squamous cell carcinoma. *International journal of radiation oncology, biology, physics*. 2004;60(2):365-73.

Posner MR, Herschock DM, Blajman CR, Mickiewicz E, Winkquist E, Gorbounova V, et al. Cisplatin and fluorouracil alone or with docetaxel in head and neck cancer. *New England journal of medicine*. 2007;357(17):1705-15.

Provincial Head and Neck Tumour Team. Nasopharyngeal Cancer Treatment. Version 1. Canada: Alberta Health Services; 2013.

Racadot S, Mercier M, Dussart S, Dessard-Diana B, Bensadoun RJ, Martin M, et al. Randomized clinical trial of post-operative radiotherapy versus concomitant carboplatin and radiotherapy for head and neck cancers with lymph node involvement. *Radiotherapy and oncology*. 2008;87(2):164-72.

Rankin EM, Mill L, Kaye SB, Atkinson R, Cassidy L, Cordiner J, et al. A randomised study comparing standard dose carboplatin with chlorambucil and carboplatin in advanced ovarian cancer. *British journal of cancer*. 1992;65(2):275-81.

Reeves TD, Hill EG, Armeson KE, Gillespie MB. Cetuximab therapy for head and neck squamous cell carcinoma: A systematic review of the data. *Otolaryngology—head and neck surgery*. 2011;144(5):676-84.

Ruo Redda MG, Ragona R, Ricardi U, Beltramo G, Rampino M, Gabriele P, et al. Radiotherapy alone or with concomitant daily low-dose carboplatin in locally advanced, unresectable head and neck cancer: Definitive results of a phase III study with a follow-up period of up to ten years. *Tumori*. 2010;96(2):246-53.

Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. Evidence based medicine: What it is and what it isn't. *British medical journal*. 1996;312(7023):71-2.

Saghir F, Feldman LE. Treatment of head and neck cancer. *New England journal of medicine*. 2008;358(10):1076;author reply 1077-8.

Saunders MI, Rojas AM. Management of cancer of the head and neck--a cocktail with your PORT? *New England journal of medicine*. 2004;350(19):1997-9.

Schuell B, Gruenberger T, Kornek GV, Dworan N, Depisch D, Lang F, et al. Side effects during chemotherapy predict tumour response in advanced colorectal cancer. *British journal of cancer*. 2005;93(7):744-8.

Scottish Intercollegiate Guidelines Network (SIGN). Diagnosis and management of head and neck cancer: A national clinical guideline. Scotland: SIGN; 2006.

Seiwert TY, Salama JK, Vokes EE. The chemoradiation paradigm in head and neck cancer. *Nature clinical practice oncology*. 2007;4(3):156-71.

Sonpavde G. Treatment of advanced head and neck cancer. *New England journal of medicine*. 2004;351(8):829-31;author reply -31.

Soulieres D, Senzer NN, Vokes EE, Hidalgo M, Agarwala SS, Siu LL. Multicenter phase II study of erlotinib, an oral epidermal growth factor receptor tyrosine kinase inhibitor, in patients with recurrent or metastatic squamous cell cancer of the head and neck. *Journal of clinical oncology*. 2004;22(1):77-85.

Specenier P, Vermorken JB. Cetuximab: Its unique place in head and neck cancer treatment. *Biologics*. 2013;7:77-90.

Straus SE, McAlister FA. Evidence-based medicine: A commentary on common criticisms. *Canadian Medical Association journal*. 2000;163(7):837-41.

Sun Pharma Global FZE. Carboplatin Injection. United States. 2014.

Swanson JA, Schmitz D, Chung KC. How to practice evidence-based medicine. *Plastics and reconstructive surgery*. 2010;126(1):286-94.

Swedish Council on Health Technology Assessment. Methods to Estimate and Measure Renal Function (Glomerular Filtration Rate): A systematic review. Sweden: 2013.

Teva Canada Limited. Carboplatin Injection: Product Monograph. Canada. 2013.

Trotti A, 3rd, Pajak TF, Ridge JA. Treatment of head and neck cancer. New England journal of medicine. 2008;358(10):1076;author reply 1077-8.

U.S. Food and Drug Administration. Carboplatin dosing United States. 2015 [updated 27 November 2015;23 August 2016]. Available from:
<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm228974.htm>.

Ugarte A. Squamous cell carcinoma of the head and neck: A guide for patients - Information based on ESMO Clinical Practice Guidelines. 2015.

Vanderveken OM, Szturz P, Specenier P, Merlano MC, Benasso M, Van Gestel D, et al. Gemcitabine-Based Chemoradiation in the Treatment of Locally Advanced Head and Neck Cancer: Systematic Review of Literature and Meta-Analysis. Oncologist. 2016;21(1):59-71.

Vermorken JB, Mesia R, Rivera F, Remenar E, Kawecki A, Rottey S, et al. Platinum-based chemotherapy plus cetuximab in head and neck cancer. New England journal of medicine. 2008;359(11):1116-27.

Vermorken JB, Specenier P. Optimal treatment for recurrent/metastatic head and neck cancer. Annals of oncology. 2010;21(Suppl 7):vii252-61.

Victorian Department of Health and Human Services. Optimal care pathway for people with head and neck cancers. Australia: Victorian Government; 2015.

Watanabe N, Kaneko T, Fujitani S, Umeyama M, Nomura Y, Zusho H, et al. [A combination of low-dose carboplatin (CBDCA) and radiation therapy in head and neck cancer patients--response and hematologic toxicity]. Gan To Kagaku Ryoho. 1999;26(1):101-6 [abstract only].

Whittle J, Graham J, Ismail H, Hicks R, Lichtenstein M, Rischin D, et al. Comparison of glomerular filtration rate calculated using IDMS creatinine in the Cockcroft Gault equation with glomerular filtration rate measured using 51Cr-EDTA. 2015 ASCO Annual Meeting. 2015.

Woolever DR. The art and science of clinical decision making. Family practice manager. 2008;15(5):31-6.

Yalcyn B, Buyukcelik A, Utkan G. Treatment of advanced head and neck cancer. New England journal of medicine. 2004;351(8):829-31;author reply -31.

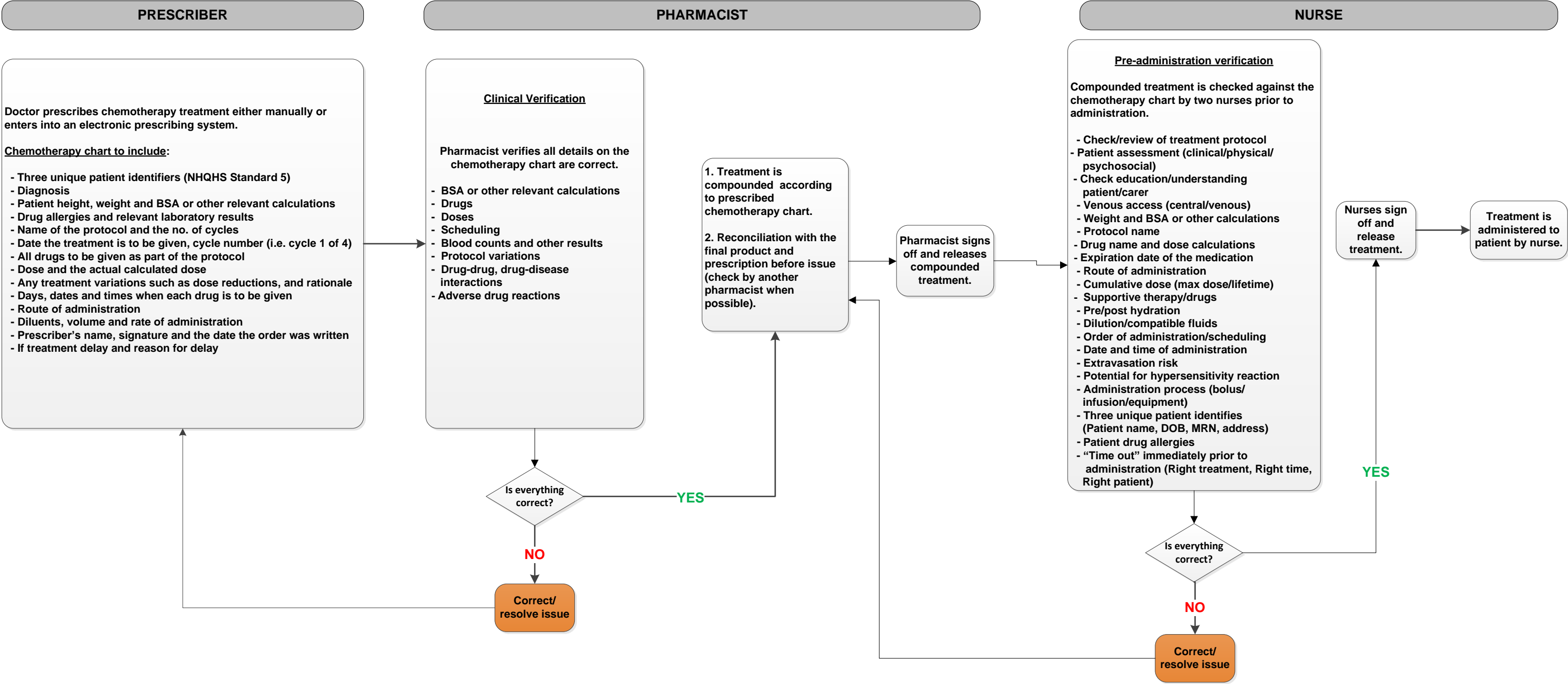
Inquiry under section 122 of the *Health Services Act 1997*

Off-protocol prescribing of chemotherapy for head and neck cancers — Final report

Appendix F

Flow diagram of standard chemotherapy prescribing and administration process

Flow diagram of standard chemotherapy prescribing and administration process



Adpated from:

1. COSA Clinical Oncological Society of Australia (2008) – Guidelines for the Safe Prescribing, Dispensing and Administration of Cancer Chemotherapy (page 17, table 5 Suggested content of treatment plan and pg 18, table 6 Information to be included on a chemotherapy order
2. Neuss MN, Polovich M, McNiff K et al. 2013 updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards including Standards for the Safe Administration and Management of Oral Chemotherapy. J Oncol Pract. 2013 Mar;9(2 Suppl):5s-13s

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

Off-protocol prescribing of chemotherapy for head and neck cancers — Final Report

Appendix G

Interim Report: St Vincent's Hospital's three month progress report on implementation of recommendations



INQUIRY UNDER SECTION 122 OF THE HEALTH SERVICES ACT 1997

Off-protocol Prescribing of Chemotherapy for Head & Neck Cancers

Implementation of recommendations – three month progress report

St Vincent's Hospital Sydney

July 2016

Statement from Hospital

St Vincent's Hospital Sydney accepts the findings of the Interim Report and is fully committed to introducing all recommendations related to the Hospital – including any that are made in the final report.

St Vincent's apologises – deeply and unreservedly – to the patients and families affected by this matter and to all our cancer patients.

The implementation of the Inquiry's recommendations address the Hospital's two main priorities: to support the patients affected and their families, and to make sure an event of this nature does not happen again.

The process of implementation so far has been valuable to St Vincent's and we are working hard to make improvements to our systems, processes and culture. An overview of progress as at July 2016 is below.

We would like to thank Professor Robert Thomas for his support and guidance throughout this period.



Associate Professor Anthony Schembri
Chief Executive Officer
St Vincent's Health Network Sydney
July 2016



Associate Professor Richard Gallagher
Director Cancer Services
St Vincent's Health Network Sydney
July 2016

Note from Independent assessor

Since April, I have been working with St Vincent's Hospital Sydney as they implement the recommendations of the Interim Report. My role is to provide independent oversight of the implementation and provide public reports on progress at three, six and 12 month milestones.

I believe the Hospital has made significant progress in addressing the recommendations of the Inquiry's Interim Report and restoring public confidence in its cancer treatment services.



Professor Robert Thomas OAM
Chief Cancer Advisor to the Victorian Government
July 2016

Table of Contents

Statement from Hospital	2
Note from Independent assessor	2
1. Introduction	1
Background	1
This report.....	1
Overview of progress against recommendations	1
2. Recommendations for St Vincent's Hospital Sydney	4
Recommendation 1:.....	4
Recommendation 2:.....	5
Recommendation 3:.....	6
Recommendation 4:.....	7
Recommendation 7:.....	8
Recommendation 8:.....	9
Recommendation 9:.....	10
Recommendation 10:.....	11
Recommendation 11.....	12
Recommendation 12:.....	13
3. Recommendations for Local Health Districts and Speciality Networks – state-wide	14
Recommendation 13:.....	14
Recommendation 14:.....	15
Recommendation 15:.....	16
4. Recommendations for other parties.....	17

1. Introduction

Background

On 19 February 2016, the Secretary of the NSW Ministry of Health (the Secretary of Health) initiated an Inquiry under Section 122 of the *Health Services Act 1997* in relation to the prescribing of chemotherapy at St Vincent's Hospital by Dr John Grygiel during the period June 2012 to June 2015.

The Inquiry's terms of reference were expanded in April 2016 to also include patients treated by Dr Grygiel in the Western NSW Local Health District, and any patients treated by Dr Grygiel at St Vincent's Hospital Sydney since 2006.

The Inquiry is being conducted by: Professor David Currow, Chief Cancer Officer, Cancer Institute NSW; Dr Paul Curtis, Director Clinical Governance, Clinical Excellence Commission; and Mr Paul Gavel, Director Workforce, HealthShare NSW (the Inquiry Team). The Interim Report of the Inquiry was released by the Secretary of Health on 4 April 2016.

This report

This report provides an update on the progress of St Vincent's Hospital in implementing the ten recommendations for the Hospital from the Interim Inquiry Report (Section 2). This report also provides information on St Vincent Hospital's progress in implementing the three state-wide recommendations for Local Health Districts and Speciality Networks (Section 3).

The Interim Report provided an additional seven recommendations for other parties, which are addressed in Section 4 of this report. A number of these recommendations relate to next stage of the Inquiry and its expanded scope. St Vincent's Hospital welcomed these recommendations and has fully supported the Inquiry to deliver on its revised Terms of Reference.

This report is an initial three month progress report on implementation. St Vincent's Hospital Sydney will provide further public reports on progress six and 12 months following the release of the Interim Report (October 2016 and April 2017).

This report has been endorsed by Professor Robert Thomas OAM, Chief Cancer Advisor to the Victorian Government. Professor Thomas was engaged by St Vincent's Health Australia to provide independent oversight of the Hospital's implementation of the Inquiry's recommendations.

Overview of progress against recommendations

Number	Recommendation	Status
Recommendation 1	That St Vincent's Hospital as a priority, apologise to patients and their families for any distress that this off-protocol prescribing or its reporting has caused.	COMPLETE
Recommendation 2	That St Vincent's Hospital ensure that every patient or his/her family is given the opportunity to participate fully in an Open Disclosure process.	COMPLETE
Recommendation 3	That St Vincent's Hospital supports patients whose care has been affected to have ongoing follow-up in another oncology unit if that's their choice.	COMPLETE
Recommendation 4	That St Vincent's Hospital offer more intensive follow-up to detect any loco-regional disease, at the earliest possible time, acknowledging that the peer-reviewed literature provides no apparent guidance on what to do under these circumstances.	ONGOING
Recommendation 5	That the Inquiry provide patients and their families with the opportunity to provide information to the Inquiry, now that the	SUPPORTED BY ST VINCENT'S

	magnitude and likely effects of this off-protocol prescribing have started to be quantified.	
Recommendation 6	That the NSW Cancer Registry, managed by the Cancer Institute NSW, flag every patient identified by this Inquiry who has had an off-protocol flat dose of 100mg carboplatin prescribed for the treatment of cancer so that outcomes for this group of people are systematically evaluated on a regular basis, and that survival analyses can be undertaken on this cohort of patients in relation to people with comparable disease.	SUPPORTED BY ST VINCENT'S
Recommendation 7	That St Vincent's Hospital provide education to key staff on those key policies, including the Lookback Policy, given the findings in relation to the policies.	COMPLETE
Recommendation 8	That St Vincent's Hospital manage any similar incidents with sufficient content-specific expertise and an explicit methodology for defining the magnitude and impact of the clinical incident and its likely consequences.	COMPLETE
Recommendation 9	That St Vincent's Hospital review the process of preparing and verifying public statements within the Hospital to include relevant consultation, content expertise and sign-off.	COMPLETE
Recommendation 10	That St Vincent's Hospital ensure that Mortality and Morbidity meetings use data beyond individual patients to examine patterns of care and outcomes benchmarked with similar hospitals or health services or, at least, the most recent, relevant peer-reviewed literature.	IN PROGRESS
Recommendation 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'.	COMPLETE
Recommendation 12	That St Vincent's Hospital revisit mechanisms for escalation of clinical concerns to ensure that key line-managers are seen as crucial to the process of adequately addressing clinical concerns from junior nursing, pharmacy and medical staff	IN PROGRESS
Recommendation 13	Given clinicians should be able to override doses once entered into MOSAIQ where appropriate for an individual patient, Local Health Districts and Speciality Networks to ensure that the most senior oncology pharmacist and the head of medical oncology review such overrides regularly to identify any patterns that may suggest similar dosing issues	COMPLETED AT ST VINCENT'S
Recommendation 14	That Local Health Districts and Speciality Networks pre-load eviQ protocols into electronic chemotherapy prescribing systems.	COMPLETED AT ST VINCENT'S
Recommendation 15	That Local Health Districts and Speciality Networks ensure that minuted meetings of Multidisciplinary Cancer Care teams occur after relevant international or national meetings and on an ad-hoc basis as seminal new evidence emerges that should influence practice.	COMPLETED AT ST VINCENT'S
Recommendation 16	That the Cancer Institute NSW works with oncology groups to facilitate meetings occurring after major conferences to review new evidence and agree on which of the evidence should be adopted.	SUPPORTED BY ST VINCENT'S
Recommendation 17	That the Cancer Institute NSW prepares a new patient information	SUPPORTED BY

	sheet on dose adjustment of chemotherapy to allow patients and their caregivers to understand the rationale for it.	ST VINCENT'S
Recommendation 18	That the Ministry of Health, with the Cancer Institute NSW, examine ways to ensure that all people diagnosed with notifiable cancer in NSW have their care overseen by a Multidisciplinary Cancer Care Team that includes all relevant medical, nursing, pharmacy and allied health staff.	SUPPORTED BY ST VINCENT'S
Recommendation 19	That the Secretary, NSW Ministry of Health, expand the terms of reference of this Inquiry to include: patients treated by Dr Grygiel in Western NSW Local Health District (or its predecessors) back to the beginning of 2006 (when CiSCAT, the predecessor of eviQ first became available); and patients treated since 2006 by Dr Grygiel at St Vincent's Hospital Darlinghurst.	SUPPORTED BY ST VINCENT'S
Recommendation 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.	SUPPORTED BY ST VINCENT'S

2. Recommendations for St Vincent's Hospital Sydney

Recommendation 1:

That St Vincent's Hospital as a priority, apologise to patients and their families for any distress that this off-protocol prescribing or its reporting has caused.

Status: COMPLETE

Summary of progress (at 3 months):

St Vincent's Hospital apologises deeply and unreservedly to the patients and families affected by this matter for the distress it has caused.

All attempts have been made by the Hospital to contact the affected patient group and/or their families to provide this apology directly.

Commencing 4 April, the Hospital made phone calls to the patients and/or families (where contact details are available) to make this apology. Up to three calls have been made to each patient to attempt contact. The Hospital followed up by sending letters to all of the affected patients and/or their families (where contact details were available) to provide a written apology. There are a small number of the affected patient group who do not have a next of kin or for whom the Hospital does not have contact details.

In these phone calls and letters, St Vincent's Hospital:

- apologised for the distress this matter has caused;
- advised patients and /or families of the release of the Interim Report;
- offered further support including additional follow-up appointments for ongoing treatment and opportunity to discuss the finding of the report;
- offered the opportunity to bring forward their next scheduled review (where relevant).

In addition, a letter was also sent to the patient's GP, informing them of the patient's inclusion in this issue and outlining follow up care plans. An offer was made for them to contact the Hospital if they wished to discuss any aspect of their patients care.

St Vincent's Hospital also issued a public apology to the affected patients and families, as well as to all our cancer patients including those not directly affected by the off-protocol dosing. Further, the Hospital established a dedicated 1-800 phone number for any patients, family members or community members that may have concerns. The public apology and the 1-800 number are available on the Hospital's website, under Cancer Services.

For patients and families experiencing distress, the Hospital offered a referral for social work or psychology support.

Future actions:

The 1800 number remains available for any patients and family members with concerns. We continue to apologise to any cancer patient experiencing distress as a result of this issue and make appropriate supports available.

Recommendation 2:

That St Vincent's Hospital ensure that every patient or his/her family is given the opportunity to participate fully in an Open Disclosure process.

Status: COMPLETE**Summary of progress (at 3 months):**

St Vincent's Hospital is fully committed to the Open Disclosure process in accordance with NSW Health policy, and our values and service philosophy. In response to the Interim Report's findings, the Hospital acknowledges that some patients and families would have preferred earlier disclosure than was originally provided when the issue was identified. We apologise for any additional distress our actions caused.

In response to the findings of the Interim Report, supporting our patients and their families – including through timely open disclosure – is the Hospital's key priority.

As outlined in response to Recommendation 1, St Vincent's Hospital has re-contacted all affected patients and/or families (where able to be contacted) to provide ongoing disclosure, support, access and transparency around the findings in the Interim Report and the next steps in the Inquiry.

The follow-up for this cohort has been tailored in accordance with their wishes. Some patients and/or families have participated in face to face family meetings or additional appointments with their specialist, others have had regular phone contact with the Hospital's dedicated Clinical Governance Support Manager, and others have requested no further review or updates.

St Vincent's Hospital has also been contacted by a number of other cancer patients and/or families not affected by the off-protocol prescribing of Carboplatin. We recognise that this issue may have caused distress and anxiety for many patients and are committed to supporting any patient with concerns. Any cancer patient and/or family with concerns has been offered a review of their chemotherapy dosing and the opportunity to participate in an Open Disclosure process.

For these patients, the Hospital has implemented a standardised review protocol where the review is approved and signed by the Head of Oncology prior to discussion with the patient or their next of kin. One external review has been requested. The Hospital respects this request and has organised for this to be conducted by another health service, including the provision of clinical records.

Future actions:

Open disclosure will continue to be offered and provided to the affected cohort as the Final Report is released and St Vincent's Hospital continues to make system improvements to address the Inquiry's recommendations. Prior to the release of the Final Report, St Vincent's Hospital Sydney will again contact the affected patient/family group (where contact details are available) to:

- advise them of the release of the Final Report;
- update on the Hospital's progress implementing recommendations from the Interim Report;
- reiterate our apology for the distress caused; and
- offer additional support and follow-up.

The Hospital will continue to offer to review the chemotherapy dosing of any patient or family with concerns.

Recommendation 3:

That St Vincent's Hospital supports patients whose care has been affected to have ongoing follow-up in another oncology unit if that's their choice.

Status: COMPLETE

Summary of progress (at 3 months):

St Vincent's Hospital Sydney respects the choice of any patient to have ongoing follow-up in another oncology unit and will fully support any such request.

At this time, one patient has requested to receive their follow-up care in another oncology unit. St Vincent's Hospital Sydney has facilitated the transfer of this patient's care to another hospital.

Future actions:

St Vincent's Hospital Sydney will support and facilitate any future patient requests to transfer care.

Recommendation 4:

That St Vincent's Hospital offer more intensive follow-up to detect any loco-regional disease, at the earliest possible time, acknowledging that the peer-reviewed literature provides no apparent guidance on what to do under these circumstances.

Status: ONGOING**Summary of progress (at 3 months):**

St Vincent's Hospital is committed to providing all additional follow-up that is clinically appropriate.

In each case, the treating specialist has determined a follow-up plan tailored to the individual patient condition and progress along their treatment pathway. Where clinically indicated or requested by a patient, follow-up appointments have been facilitated at an earlier date.

Routine follow-up of head and neck patients after the completion of treatment follows a predictable pattern:

- Every three months in years one and two.
- Every four months in year three.
- Every six months in years four and five.

This follow-up is usually performed by the treating surgeon and/or radiation oncologist. It is rare for medical oncologists to follow these patients unless part of a trial.

For this cohort of patients, the Hospital has put in place a more intensive follow-up program for the affected patient group:

- All patients to be followed three-monthly for three years.
- All patients will have PET-CT performed at one, two and three years, where clinically appropriate
- During the five year follow-up post treatment, all treating / reviewing doctors will be requested to send copies of their letters to the Director of Cancer Services so these can be compiled into follow-up matrix to capture patients' progress and survival (i.e. alive and well; alive with diseases; deceased from disease; deceased from other causes). The matrix will be forwarded to the Hospital CEO quarterly.

The Director of Cancer Services has formal responsibility for reviewing the full patient cohort on a monthly basis until all patients have been followed to five years. This review will assess if further follow-up may be appropriate. To support this, the Hospital has established new processes in MOSAIQ to track the affected patient group.

Future actions:

Follow-up is an ongoing process.

Recommendation 7:

That St Vincent's Hospital provide education to key staff on those key policies, including the Lookback Policy, given the findings in relation to the policies.

Status: COMPLETE

Summary of progress (at 3 months):

St Vincent's Hospital accepts the findings of the Interim Report about failures in the application of NSW Health policies in response to the incident. Improving the education of our staff is a key part of the improvement process for the Hospital. Our expectation is that all senior staff can effectively respond to critical incidents in accordance with NSW Health policies and our values.

St Vincent's Hospital has developed a new Incident Management Training program to address the findings and recommendations of the Inquiry. The program has been designed to support the implementation of the NSW Health Incident Management and Lookback policies. It aims to improve the management of corporate and clinical incidents through effective understanding and practical knowledge of the systems in place for managing them.

The program ensures all mandatory training requirements on governance, openness, learning, obligation, accountability, just culture, appropriate prioritisation, cooperation, collaboration and communication are met. The learning pathway includes mandatory training requirements to be completed through HETI online, which St Vincent's Hospital gained access to in January 2016.

This training program was delivered in May 2016 to the St Vincent's Hospital Sydney Executive, Clinical Stream Directors, Clinical Stream Managers, Heads of Department, Department Managers and Senior Managers (over 150 staff). A small number of relevant staff were unable to attend one of these sessions due to clinical duties and/or leave and will receive the training as soon as possible.

The Hospital's Incident Management Training program for managers is in addition to the mandatory training prescribed by NSW Health for all staff on the relevant incident management system, for St Vincent's this is the RiskMan user training.

Future actions:

This program will be provided annually to capture new staff. In addition, it will be delivered as a refresher for existing staff every two years.

Recommendation 8:

That St Vincent's Hospital manage any similar incidents with sufficient content-specific expertise and an explicit methodology for defining the magnitude and impact of the clinical incident and its likely consequences.

Status: Incident management process review COMPLETE**Summary of progress (at 3 months):**

St Vincent's Hospital recognises that our systems and processes failed to define the seriousness of the incident which impacted on all aspects of our response.

The Hospital has reviewed its practices and policies in relation to incident management as a result of the Inquiry. A key objective of the review has been to ensure the inclusion of content-specific expertise to determine the magnitude and impact of clinical incidents.

As a result of this review, a number of key changes have been made which are reflected in the revised Incident Management Policy and Lookback Policies:

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

Further, the Hospital now has a dedicated quality manager for each clinical stream and regular clinical governance meetings occur where incident data and trends, and other key clinical performance measures are monitored. These structures were not in place at the time of the incident.

Future actions:

The Hospital is strengthening responsibility and accountability through Stream Clinical Governance Meetings for incident management at the local level. This will be monitored at the Hospital level through the Patient Safety and Quality Committee.

Recommendation 9:

That St Vincent's Hospital review the process of preparing and verifying public statements within the Hospital to include relevant consultation, content expertise and sign-off.

Status: COMPLETE

Summary of progress (at 3 months):

St Vincent's Hospital Sydney has reviewed processes for preparing and clearing media statements and responses. The objective of the review was to strengthen the processes for assuring accuracy of public statements in light of the Interim Report's findings.

Under the new processes, input and written sign-off from the relevant expert / clinical authority in addition to the Hospital CEO is required for all public statements on non-routine and critical issues.

Recommendation 10:

That St Vincent's Hospital ensure that Mortality and Morbidity meetings use data beyond individual patients to examine patterns of care and outcomes benchmarked with similar hospitals or health services or, at least, the most recent, relevant peer-reviewed literature.

Status: IN PROGRESS**Summary of progress (at 3 months):**

St Vincent's Health Australia expects the conduct of Mortality and Morbidity meetings as a routine mechanism for monitoring patterns of care and outcomes.

The Hospital's Mortality and Morbidity meetings are being strengthened by access to the best available data to allow for benchmarking where possible. This includes:

- data from other health services – state-wide or national (where available); and/or
- peer-reviewed literature.

The Stream's Clinical Governance Committees and the Hospital-wide Mortality Review Committee provide oversight of the Hospital's Mortality and Morbidity Meetings to ensure trend analysis and benchmarking occurs.

Future actions:

On an annual basis, the Oncology Unit will now activate a tumour stream audit for peer consideration and review. Summary Mortality and Morbidity Rate data will be audited by the Director of Cancer Services annually, and benchmarked against best practice, incorporating literature review.

The Hospital will continue to investigate possible data sources for benchmarking, including state-level data from the Cancer Institute NSW through the NSW Clinical Cancer Registry, and provide a further update on progress against this recommendation in our next progress report.

Recommendation 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'.

Status: COMPLETE

Summary of progress (at 3 months):

St Vincent's Hospital Sydney routinely reviews all deaths through mortality review system. In response to this recommendation, St Vincent's Hospital Sydney has made the following changes to the Terms of Reference of the hospital-wide Mortality Review Committee:

1. The Committee will now routinely include a random selection of 'expected' deaths for review. Unit Mortality & Morbidity Committees will also review a selection of 'expected' deaths.
2. The Committee will now consider deaths outside the Hospital where patients had previously been treated at St Vincent's.
 - This will only be possible where advice is received of such deaths *and* information surrounding the death is available for review.
 - The Hospital is not aware of a State-based process or system that would systematically enable the sharing of this information, but the Committee will conduct these reviews where the information is available.

Future actions:

The Hospital has been unable to access information on deaths outside of St Vincent's from the NSW deaths data register. We would welcome access to this or another data source to support these reviews.

Recommendation 12:

That St Vincent's Hospital revisit mechanisms for escalation of clinical concerns to ensure that key line-managers are seen as crucial to the process of adequately addressing clinical concerns from junior nursing, pharmacy and medical staff

Status: IN PROGRESS**Summary of progress (at 3 months):**

St Vincent's Hospital Sydney expects that line managers and clinical staff should escalate clinical concerns. In light of the findings of the Interim Report, the Hospital is taking action in a number of areas to ensure that line managers and clinical staff are supported to meet these expectations.

Processes and education

The Hospital has reviewed the Incident Management and Lookback processes to identify improvements – see response to recommendation 8. These policies articulate responsibilities for all staff, managers and executives.

Further, the Hospital has developed and implemented new Incident Management Training for all Executive, Clinical Stream Directors, Clinical Stream Managers, Heads of Department, Department Managers and Senior Managers – see response to recommendation 7. This training included responsibilities for managers in escalating concerns.

Cultural change

The Hospital is implementing a communications campaign called "It's OK to ask" to drive cultural change. The campaign aims to ensure patient safety is paramount through encouraging a culture of open dialogue between all staff which is based on mutual respect.

The key message is that staff should feel empowered to ask questions of their peers or leaders, and feel comfortable to raise concerns that they may have in their work environment or in relation to patient care.

A key component of the strategy is to highlight to staff that the Hospital has specific avenues available to escalate an issue as well as to provide staff with support. For those staff wishing to escalate an issue, they are directed towards their stream / department manager, or any member of the St Vincent's Hospital Executive. Managers are supported on how to manage any concerns that are raised with them.

Future actions:

The Hospital considers that ongoing cultural change is critical to implementing this recommendation. We are committed to an ongoing program of communication and education for all staff on their responsibilities and the ways the Hospital will support them to raise concerns. The Hospital intends to develop a program to measure and track staff engagement with this program.

3. Recommendations for Local Health Districts and Speciality Networks – state-wide

Recommendation 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 suggest similar dosing issues

Status: COMPLETE**Summary of progress (at 3 months):**

St Vincent's Hospital Sydney has implemented these changes.

All orders prescribed in MOSAIQ for EviQ and approved non-EviQ care plans or protocols are verified and approved by the senior oncology pharmacist in the ambulatory care setting. This process is overseen by the MOSAIQ Care Plan Committee, which commenced in January 2016 under the stewardship of the new Head of Department of Medical Oncology, together with the Haematology Head of Department.

All variations to approved care plan dosing are able to be monitored through MOSAIQ.

Hospital process for new requests for protocols/care plans:

1. Non-Urgent/Standard: Non-urgent requests are tabled for consideration at the monthly MOSAIQ Care Plan Review committee.
2. Urgent: For urgent requests, the protocol request together with appropriate evidence-based literature is submitted on an application form and is emailed by the pharmacist to the Head of Department (Medical Oncology or Haematology) for review and approval 'out of session'. The request and decision are then tabled at the next MOSAIQ Care Plan Review Committee. If this protocol is likely to be used more frequently, it is loaded into MOSAIQ as a routine approved protocol/care plan.

This committee will monitor all significant protocol variations (i.e. those made that are not in line with reasonable variations according to the unique clinical adjustments often necessary in cytotoxic prescribing – e.g. dose reductions due to myelosuppression).

Recommendation 14:
Pre-load eviQ protocols into electronic chemotherapy prescribing systems.

Status: COMPLETE

Summary of progress (at 3 months):

St Vincent's Hospital implemented MOSAIQ (and subsequently loaded all current eviQ protocols) into clinical practice in March/April 2015 as a booking and EMR (clinical records) system for cancer ambulatory care areas. Final implementation of e-prescribing was completed in August/September 2015.

Future actions:

The recently upgraded version of MOSAIQ (V 2.6) will allow St Vincent's Hospital to automatically receive recently updated or approved EviQ protocols/care plans from the Cancer Institute of NSW. This will be implemented in coming months.

Recommendation 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.

Status: COMPLETE**Summary of progress (at 3 months):**

St Vincent's Hospital Sydney have implemented this recommendation.

At every meeting of the Multidisciplinary Cancer Care Teams (MDTs at St Vincent's), any discussion had of significant new evidence that may influence practice, will be captured as part of the MDT. The Chair of the MDT signs off on that meeting and that is captured in that cancer stream module in MOSAIQ. Cancer specific MDTs are held according to the volume of presenting cases (e.g. weekly, fortnightly or monthly).

In addition, at St Vincent's quarterly meetings are held by the Director of Cancer Services with the MDT Chairs. These meetings also involve a formal review of new evidence, including from peak North American and European meetings (e.g. American Society of Clinical Oncologists).

Beyond the MDTs meetings, the Cancer Services Stream has also implemented sign-off sheets across clinical trials, units and research or journal club monthly meetings to foster quicker adoption of clinical practice changes for new and compelling evidence. These records are also considered in Department or Stream clinical governance meetings.

Future action:

The MDT review process is being built into all MOSAIQ MDT modules which will be implemented from June 2016.

4. Recommendations for other parties

The remaining recommendations of the Interim Report were directed to other parties. This section provides a brief overview of the actions St Vincent's Hospital Sydney has taken to support the implementation of these recommendations.

Recommendation	St Vincent's actions to support implementation
<p>Recommendation 5</p> <p>That the Inquiry provide patients and their families with the opportunity to provide information to the Inquiry, now that the magnitude and likely effects of this off-protocol prescribing have started to be quantified.</p>	<p>St Vincent's Hospital has fully supported this recommendation. The Hospital has provided patient details to the Inquiry Team for the purposes of patients and families being provided with the opportunity to provide information to the Inquiry.</p> <p>St Vincent's Hospital has provided a dedicated patient liaison contact for affected patients and families.</p>
<p>Recommendation 6</p> <p>That the NSW Cancer Registry, managed by the Cancer Institute NSW, flag every patient identified by this Inquiry who has had an off-protocol flat dose of 100mg carboplatin prescribed for the treatment of cancer so that outcomes for this group of people are systematically evaluated on a regular basis, and that survival analyses can be undertaken on this cohort of patients in relation to people with comparable disease.</p>	<p>St Vincent's Hospital have developed the capacity to generate a specialised report in MOSAIQ that flags all the affected patients identified by the Inquiry.</p>
<p>Recommendation 16</p> <p>That the Cancer Institute NSW works with oncology groups to facilitate meetings occurring after major conferences to review new evidence and agree on which of the evidence should be adopted.</p>	<p>St Vincent's have implemented such reviews internally. We support, and will participate in, Cancer Institute NSW processes.</p>
<p>Recommendation 17</p> <p>That the Cancer Institute NSW prepares a new patient information sheet on dose adjustment of chemotherapy to allow patients and their caregivers to understand the rationale for it.</p>	<p>St Vincent's supports this initiative and will adopt new resources developed by the Cancer Institute NSW when available.</p> <p>In the interim, St Vincent's Hospital Sydney has developed a patient information sheet in line with this recommendation which will be introduced shortly.</p>
<p>Recommendation 18</p> <p>That the Ministry of Health, with the Cancer Institute NSW, examine ways to ensure that all people diagnosed with notifiable cancer in NSW have their care overseen by a Multidisciplinary Cancer Care Team that includes all relevant medical, nursing, pharmacy and allied health</p>	<p>This is a key component of the St Vincent's Campus Cancer Plan and we will support and adopt any state-wide approaches developed by the Ministry of Health and the Cancer Institute NSW.</p>

staff.	
Recommendation 19 That the Secretary, NSW Ministry of Health, expand the terms of reference of this Inquiry to include: patients treated by Dr Grygiel in Western NSW Local Health District (or its predecessors) back to the beginning of 2006 (when CiSCAT, the predecessor of eviQ first became available); and patients treated since 2006 by Dr Grygiel at St Vincent's Hospital Darlinghurst.	St Vincent's has continued to provide evidence and participate fully in the Inquiry, including providing all patient information and medical records available to us as requested by the Inquiry.
Recommendation 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.	St Vincent's has continued to provide evidence and participate fully in the Inquiry.

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

Off-protocol prescribing of chemotherapy for head and neck cancers — Final report

Appendix H

NSW Health Policy Directives and Guidelines

- H.1 Incident Management Policy (PD2014_004)
- H.2 Lookback Policy (PD2007_075)
- H.3 Complaint or Concern about a Clinician — Principles for Action (PD2006_007)
- H.4 Complaint or Concern about a Clinician — Management Guidelines (GL2006_002)

Policy Directive



Ministry of Health, NSW
 73 Miller Street North Sydney NSW 2060
 Locked Mail Bag 961 North Sydney NSW 2059
 Telephone (02) 9391 9000 Fax (02) 9391 9101
<http://www.health.nsw.gov.au/policies/>

Incident Management Policy

Document Number PD2014_004

Publication date 10-Feb-2014

Functional Sub group Clinical/ Patient Services - Incident management
 Clinical/ Patient Services - Governance and Service Delivery

Summary Provides direction for a consistent approach to managing and investigating clinical incidents and ensures processes comply with the requirements of the Health Administration Act 1982.

This policy directive has been co-authored by the Clinical Excellence Commission and the Legal and Regulatory Services Branch in the Ministry of Health.

Replaces Doc. No. Incident Management [PD2007_061]
 Reportable Incident Definition under section 20L of the Health Administration Act [PD2005_634]

Author Branch Clinical Excellence Commission

Branch contact Clinical Excellence Commission 92695565

Applies to Local Health Districts, Board Governed Statutory Health Corporations, Chief Executive Governed Statutory Health Corporations, Specialty Network Governed Statutory Health Corporations, Affiliated Health Organisations, Public Health System Support Division, Community Health Centres, NSW Ambulance Service, Public Health Units, Public Hospitals, NSW Health Pathology

Audience All staff including clinicians, managers and contractors

Distributed to Public Health System, Community Health Centres, Divisions of General Practice, Government Medical Officers, NSW Ambulance Service, Ministry of Health, Public Health Units, Public Hospitals, Private Hospitals and Day Procedure Centres

Review date 10-Feb-2019

Policy Manual Patient Matters

File No. D13/21700

Director-General

Status Active

This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is **mandatory** for NSW Health and is a condition of subsidy for public health organisations.

INCIDENT MANAGEMENT POLICY

PURPOSE

The purpose of this policy is to provide direction to health services regarding the management of both clinical and corporate incidents, including the provision of appropriate feedback to patients, families/support persons and clinicians, and the sharing of lessons learned to prevent patient harm. This policy describes a statewide system for managing clinical and corporate incidents in order that health practitioners, managers and staff respond effectively to them.

MANDATORY REQUIREMENTS

Each NSW Health entity is required to have in place a system to manage incidents based on the following principles:

Openness about failures – incidents are reported and the incident acknowledged without fear of inappropriate blame. Patients and their families/support persons are offered an apology and told what went wrong and why

Emphasis on learning – the system is oriented towards learning from mistakes and consistently employs improvement methods for achieving this

Obligation to act – the obligation to take action to remedy problems is clearly accepted and the allocation of this responsibility is unambiguous and explicit

Accountability – the limits of individual accountability are clear, individuals understand when they may be held accountable for their actions

Just culture – individuals are treated fairly

Appropriate prioritisation of action – action to address problems is prioritised and resources directed to those areas where the greatest improvements are possible

Cooperation, collaboration and communication – teamwork is recognised as the best defence of system failures and is explicitly encouraged and fostered within a culture of trust and mutual respect.

IMPLEMENTATION

All Staff are responsible for:

- Notifying all incidents identified using the Incident Information Management System (IIMS)
- Commencing and/or participating in the open disclosure process as appropriate
- participating in the investigation of incidents as required
- Participating in the implementation of recommendations arising from the investigation of incidents
- Encouraging colleagues to notify incidents that have been identified.

Local Health Districts and Special Health Networks are responsible for

- Ensuring staff are trained in incident management (including IIMS) and able to investigate incidents and action recommendations
- Ensuring an effective incident management system is in place for investigating and actioning recommendations for all incidents
- Ensuring that there is timely notification of incidents to the Minister's office, Director-General, Deputy Director-General and the Strategic Relations and Communications Branch of the MoH by submitting a Reportable Incident Brief (RIB) as required and notifying by telephone if urgent attention is required

- Ensuring that there is timely notification to NSW Treasury Managed Fund (TMF) of all incidents that have the potential to become claims
- Ensuring the monitoring and rating of all risks identified from incident investigation and analysis as per the NSW Health Risk Management - Enterprise-Wide Policy and Framework (PD2009_039)
- Reporting all Severity Assessment Code (SAC) 1 incidents to the MoH within 24 hours or the next business day
- Ensuring processes are in place to manage clinical RIBs in accordance with this policy to protect statutory privilege under *Section 23 of the Health Administration Act 1982*
- Conducting privileged Root Cause Analysis (RCA) on clinical SAC1 incidents, and other incidents when deemed appropriate, in accordance with *Part 2, Division 6C of the Health Administration Act 1982*
- Conducting a detailed investigation of all corporate SAC 1 incidents
- Where a privileged RCA has been conducted, providing RCA reports to the MoH within 70 calendar days of notification of the incident in IIMS
- Providing a report on key findings from corporate SAC 1 investigations to the MoH within 70 calendar days
- Taking local action to ensure appropriate incident management and preventing recurrence of incidents
- Reporting of trended incident data and outcomes of RCAs and Corporate SAC 1 investigations to relevant groups within health services
- Ensuring appropriate resources are available for effective incident management and patient safety initiatives
- Implementing policies and local practices that support staff and encouraging an environment where incident notification and active management of incidents is fostered
- Contributing to statewide improvements as required.

Clinical Excellence Commission (CEC) is responsible for

- Reviewing clinical incidents and investigation reports
- Providing advice to the system in response to specific queries about clinical incident management, and in response to analysis of clinical incidents
- Providing advice and regular reports to the MoH on clinical quality, patient safety issues and trends and lessons learned from the clinical incident management process
- Disseminating lessons learned from clinical incident management
- Providing advice to the MoH on strategies to minimise clinical system errors across the state
- Developing State-wide policies and strategies in relation to patient safety and health care quality
- Identifying education needs emerging from clinical incident management.

NSW Ministry of Health (MoH) is responsible for

- Ensuring health services have systems in place to report, investigate and implement the actions necessary to prevent clinical and corporate incidents, protect patient safety and improve clinical quality
- Establishing and maintaining systems to monitor and manage incidents reported to the MoH
- Receiving and viewing notifications about clinical and corporate SAC1 health care incidents
- Reviewing advice and reports provided by the CEC on analysis of trends from RCAs and issues arising from all clinical incident (SAC) categories
- Providing advice to the Minister for Health on issues of public concern and media or public attention
- Providing an appropriate statewide response to new risks as they are identified.

REVISION HISTORY

Version	Approved by	Amendment notes
February 2014 (PD2014_004)	Director General	This amended policy contains changes to the national sentinel event definitions and replaces PD2007_061 and PD2005_634
July 2007 (PD2007_061)	Director General	Replaces PD2006_030
May 2006 (PD2006_030)	Director General	Replaces PD2005_604 and PD2005_404
November 2005 (PD2005_634)	Director General	Reportable Incident Definition under section 20L of the Health Administration

ATTACHMENTS

1. Incident Management Policy: Procedures

Incident Management Policy



Issue date: February-2014

PD2014_004

CONTENTS

1	INTRODUCTION.....	1
1.1	Aim.....	1
1.2	Scope.....	1
1.3	Associated Documents.....	1
1.4	Key Definitions	2
1.5	Acronyms	5
2	THE INCIDENT MANAGEMENT PROCESS	5
2.1	Step 1 – Identification.....	7
2.2	Step 2 – Immediate action.....	7
2.3	Step 3 – Notification	7
2.3.1	Documentation of the clinical incident in the health record.....	7
2.3.2	Incident notification in the incident management system – by the Notifier.....	7
2.3.3	Incident notification – Management responsibility	8
2.3.4	Notification to Patient – Open Disclosure	8
2.3.5	Notification to NSW Treasury Managed Fund (TMF).....	8
2.3.6	Notifications for Corporate Incidents	8
2.4	Step 4 – Prioritisation	9
2.4.1	Severity Assessment Code Scoring Steps	9
2.5	Step 5 – Investigation.....	10
2.5.1	Levels of Investigation.....	10
2.5.2	Investigations and conduct/impairment/performance issues with individual clinicians	12
2.5.3	Decommissioning RCAs	14
2.5.4	The management of SAC1/Privileged clinical incident investigations across Health Service boundaries	14
2.5.5	Investigation of clinical incidents across sectors.....	15
2.5.6	Director General Inquiries under the <i>Health Services Act 1997</i>	17
2.6	Step 6 – Classification	17
2.7	Step 7 – Analysis.....	17
2.8	Step 8 – Action.....	18
2.9	Step 9 – Feedback following investigation.....	18
2.9.1	Feedback to Patients and/or Support Person - Open Disclosure.....	18
2.9.2	Feedback to Staff.....	18
3	REPORTABLE INCIDENT BRIEFS.....	19
3.1	RIB reporting requirements	19
3.2	RIB reporting process.....	22
3.3	Information required in the RIB report.....	23
4	PRIVILEGED ROOT CAUSE ANALYSIS UNDER THE <i>HEALTH ADMINISTRATION ACT 1982</i>.....	24
4.1	Statutory Privilege	24
4.1.1	What the Privilege covers	24
4.1.2	Internal Working Documents of the Privileged RCA team	25

4.1.3	What the privilege does not cover	26
4.1.4	Disclosure of information.....	26
4.2	The Privileged RCA Process	26
4.2.1	Task 1 – Appointment and membership of the RCA Team.....	26
4.2.2	Task 2 – Notification to staff involved in the incident	28
4.2.3	Task 3 – The RCA Investigation.....	28
4.2.4	Task 4 – Reporting.....	29
4.2.4.1	Signing off the final report	29
4.2.5	Variation in RCA Process.....	30
4.2.6	Timeframes for RCA Process.....	30
4.2.7	Incidents involving the Coroner or Police	30
4.3	The Corporate RCA Process.....	30
4.4	Steps in the Investigation	31
4.5	Timeframes for Corporate Investigation Process.....	31
4.6	The Final RCA or Detailed Investigation Report	31
4.7	Signing off the final report.....	32
5	EVALUATION AND REVIEW	32
5.1	Performance Indicators	32
5.1.1	Clinical Incidents.....	32
5.2	Corporate Incidents	33
6	APPENDICES.....	34
6.1	Appendix A – Relevant NSW Health legislation, Policy Directives, Guidelines, Information Bulletins and other resources	34
6.1.1	Relevant NSW Health legislation	34
6.1.2	Relevant NSW Health Policy Directives and Guidelines.....	34
6.1.3	Other Resources.....	36
6.2	Appendix B – Severity Assessment Code (SAC) May 2011	37
6.3	Appendix C – Sample letter informing CE of issues that may involve individual performance	39
6.4	Appendix D – Reportable Incident Definition under <i>Section 20L of the Health Administration Act 1982</i>	40
6.5	Appendix E – Statutory health corporations and Affiliated health organisations.....	42
6.6	Appendix F – Appointment of RCA Team.....	44
6.7	Appendix G – Letter to RCA Team Member	45
6.8	Appendix H – Appointment of Core RCA Team Members	47
6.9	Appendix I – Appointment of Additional Member to RCA Team.....	48
6.10	Appendix J – Notification of staff involved in incident.....	49
6.11	Appendix K – The Five Rules of Causation	51
6.12	Appendix L – Final RCA Report.....	53

1 INTRODUCTION

1.1 Aim

The aim of the Incident Management Policy Directive is to:

- a. Ensure a consistent and coordinated approach to incident management including the identification, notification, investigation and analysis of incidents resulting in appropriate action
- b. Allow the lessons learned to be shared across the whole health system
- c. Ensure Health Services establish processes that comply with the legal aspects of both clinical and corporate incident management
- d. Establish standard approaches to both clinical and corporate incident management including the establishment of performance indicators to monitor compliance.

1.2 Scope

This Policy Directive

- a. Applies to all incidents that occur in the health system
- b. Provides guidance on the difference between clinical and corporate incidents and the key elements of the different approaches required
- c. Is applicable to clinical staff and non-clinical staff
- d. Describes roles and responsibilities in the incident management process
- e. Articulates mandated reporting requirements from legal and policy perspectives
- f. Defines the timeframes within which incidents, and the results of the investigation of these incidents, are to be reported
- g. Identifies the state-level processes for aggregation, analysis, learning and action on incidents
- h. Outlines other policy and legislated incident reporting requirements.

For the purposes of this policy, the term “Health Services” refers to Public Health Organisations including Statutory Health Corporations and Affiliated Health Organisations, and the Ambulance Service of NSW.

Compliance with this Policy Directive is mandatory for all Health Service staff.

1.3 Associated Documents

This Policy Directive is to be read in conjunction with the Incident Management Policy Statement and other policies relating to incident management (*Appendix A*).

1.4 Key Definitions

The following terms are used in this document

Ambulance Service of NSW	The Ambulance Service of NSW as defined in the <i>Health Services Act 1997</i> .
Actual SAC	The rating applied to each incident when it is reviewed by a manager. Further management of the incident is based on this confirmed rating.
Apology	A key aspect of open disclosure is saying sorry or offering an apology to the patient and their family/carer following an incident. An apology is an expression of sympathy or regret, or of a general sense of benevolence or compassion, in connection with any matter, whether or not the apology admits or implies an admission of fault in connection with the matter.
Classification	The process for capturing relevant information about an incident to ensure the complete nature of the incident, including causative and contributory factors from a range of perspectives, is documented and understood.
Clinical Excellence Commission (CEC)	A Board governed statutory health corporation established under the <i>Health Services Act (section 41)</i> . It builds on the foundation work carried out by the Institute of Clinical Excellence established in 2001. Under the Act, a statutory health corporation is established to enable certain Health Services and support services to be provided within the State other than on an area/local health district basis.
Clinical Governance Unit	The Clinical Governance Unit (CGU) has the role of support, performance and conformance to develop and monitor policies and procedures for improving systems of care. The CGU will contribute to the Patient Safety and Clinical Quality program by ensuring it is uniformly implemented across the state and for overseeing the risk management of patient safety and clinical quality by building upon existing incident management and investigation.
Clinical Risk Action Group (formerly Clinical Risk Review Committee/Reportable Incident Review Committee)	<p>The NSW Health Clinical Review Action Group (CRAG) is responsible for examining and monitoring serious clinical adverse events reported to the MoH via Reportable Incident Briefs and ensuring that appropriate action is taken. The Committee analyses information reported to it on specific incidents, identifies issues relating to morbidity and mortality that may have statewide implications and provides strategic direction and advice on policy development to effect health care system improvement.</p> <p>The workings of this Committee are subject to special statutory privilege under section 23 of the <i>Health Administration Act 1982</i>.</p>
Clinician	A health practitioner or Health Service provider of any profession regardless of whether the person is a registered health practitioner.
Complaint	<p>A complaint is</p> <ol style="list-style-type: none"> 1. An expression of dissatisfaction that may have one or more associated issues 2. A concern that provides feedback regarding any aspect of service that identifies issues requiring a response. <p>A complaint may, for example be about policies, procedures, employee conduct, provision of information, quality of communication or treatment, or</p>

	<p>quality, access to or promptness of service. Complaints do not include requests for services or information or explanation of policies or procedures or industrial matters between Health Services and unions.</p> <p>Complaints may be made, for example, in person, by telephone, letter, survey and in some cases through the media.</p>
Hazard	A source or situation with a potential for harm in terms of human injury or ill health, damage to property, damage to the environment or a combination of these.
Health Service	Refers to Public Health Organisations including Statutory Health Corporations and Affiliated Health Organisations, and the Ambulance Service of NSW.
IIMS	The NSW Health Incident Information Management System ¹ .
Incident	Any unplanned event resulting in, or with the potential for, injury, damage or other loss. This includes a near miss.
Incident category	Grouping of incidents in the incident management system, for example clinical, staff, visitor/contractor incidents, property, security, hazard incidents and complaints.
Incident Investigation	The management process by which underlying causes of undesirable events are uncovered ² .
Incident Management	A systematic process for identifying, notifying, prioritising, investigating and managing the outcomes of an incident and steps are taken to prevent similar occurrences.
Incident type	The core issues of the incident such as a fall or medication error. There can be more than one type of incident associated with each registered incident.
Local Health Districts (LHDs)	Bodies corporate constituted under section 17 <i>Health Services Act 1997</i> that are principally concerned with the conduct of public hospitals and health institutions and the provision of Health Services to residents within a designated geographic area.
Minimum Dataset	The minimum amount of information to be captured for the incident notification to be considered completed in the incident management system. It refers to the datasets associated with the incident type selected.
Near miss	Any event that could have had adverse consequences but did not. An arrested or interrupted sequence where the incident was intercepted before causing harm e.g. an incorrect medication added to an infusion but not administered.
Notifier	Any member of staff of the NSW health system who enters information into the incident management system of an incident or near miss, for any incident category. Consumers may notify an incident via the complaints process.

¹ The Incident Information Management System (IIMS) incorporates the Advanced Incident Management System (AIMS®) software application as its underlying database.

² Woloshnowych M, Rogers S, Taylor-Adams S, Vincent C. "The investigation and analysis of critical incidents and adverse events in healthcare." Health Technology Assessment, 2005 9 (9): vii.

Notification	The process of entering or documenting data about an incident or near miss for any of the incident categories into the incident management system.
Open Disclosure	The process of communicating with a patient and/or their support person about a patient related incident.
Registered user	An authorised person nominated by the health district/ network/ service with registered access to the incident management system.
Reportable Incident	An incident requiring a RIB. This includes both clinical and corporate SAC 1 incidents and also any matter that requires direct notification to the MoH under existing legislative reporting requirements or policy directive. See section 3 of this policy.
Reportable Incident Brief (RIB)	The method for reporting defined health care incidents to the MoH. The RIB process encompasses clinical and corporate incidents. Clinical RIBs are created for the purpose of authorised investigation and research and are privileged under the <i>Health Administration Act 1982</i> .
Root Cause Analysis (RCA)	A method used to investigate and analyse incidents to identify the root causes and factors that contributed to the incident. The process yields recommended actions directed at the prevention of a similar occurrence.
SAC 1 Reportable Incident	An incident occurring in the health system that must be reported to the MoH. All clinical SAC 1 incidents require an RCA.
Severity Assessment Code (SAC)	A numerical score applied to an incident based predominantly on its consequence. Its prime purpose is to direct the level of investigation required for a particular event (<i>Appendix A</i>).
Significant Patient Risk	A significant risk is one where there is a high probability of a substantial and demonstrable adverse impact. In each case a significant risk will be sufficiently serious to warrant an immediate response to reduce the risks to patients. This may include interventions or changes to systems, clinical care or clinical practice. http://www.safetyandquality.gov.au/publications/advisory-a1301-notification-of-significant-risk/
Specialty Health Networks	Statutory health corporations constituted under section 41 Health Services Act that are specialty network governed pursuant to section 52F <i>Health Services Act 1997</i> .
Support Person	An individual identified by the patient as a nominated recipient of the information regarding their care. This may include the patient's family members, partner, carer or friends. In cases of dispute between the patient's family members, partner or carer and /or friends about who should receive information the patient's wishes should be paramount. Where a patient is unable to give consent, the next person responsible under the <i>Guardianship Act 1987</i> should be approached.

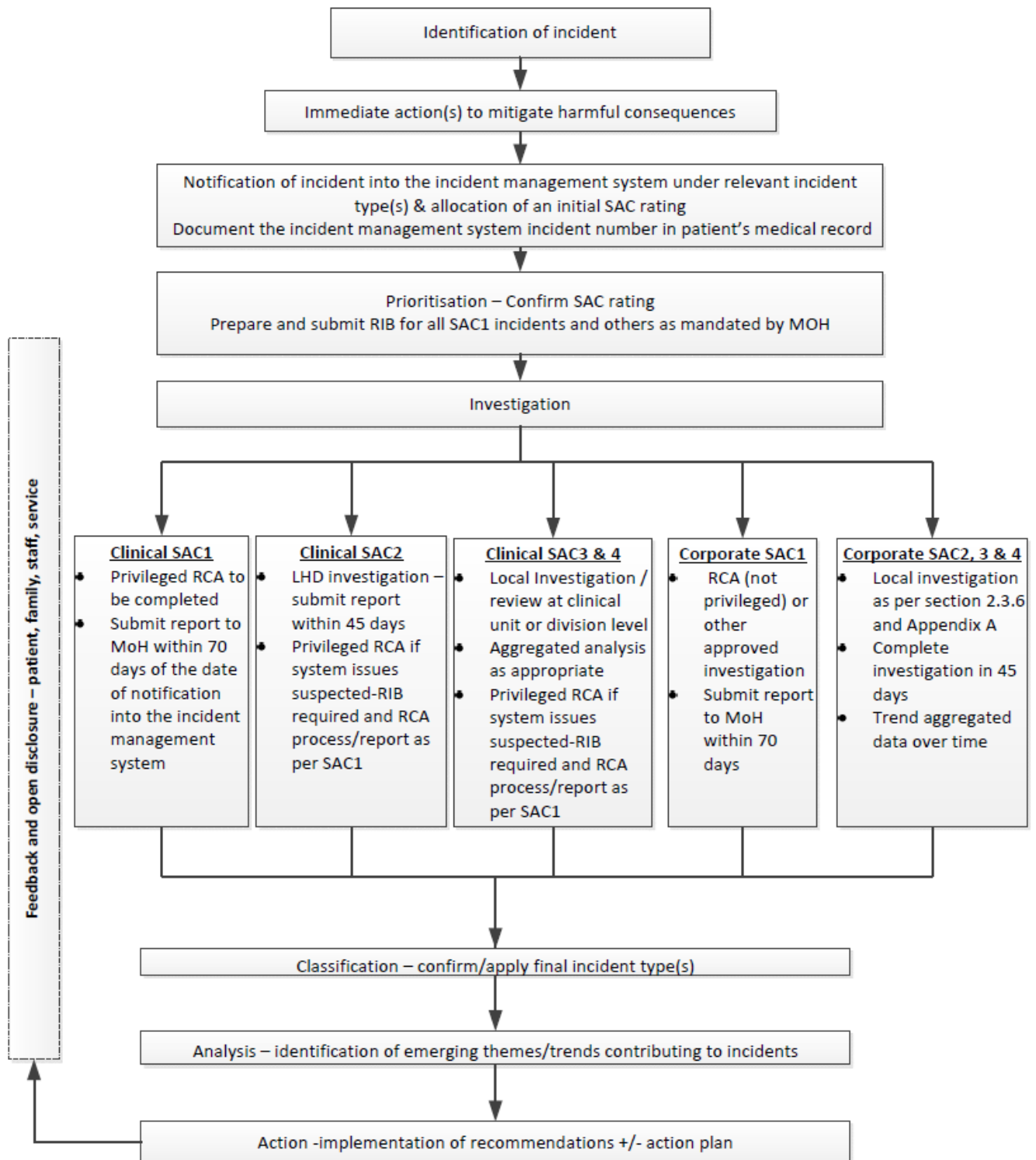
1.5 Acronyms

CE	Chief Executive
CEC	Clinical Excellence Commission
CGU	Clinical Governance Unit
CHASM	Collaborating Hospitals Audit of Surgical Mortality Committee
CRAG	Clinical Risk Action Group
DCG	Director of Clinical Governance
MoH	Ministry of Health
ID	Identification (number)
IIMS	Incident Information Management System
LHD	Local Health District
MDS	Minimum Data Set
PD	Policy Directive
RCA	Root Cause Analysis
RIB	Reportable Incident Brief
SAC	Severity Assessment Code
SCIDUA	Special Committee for Investigating Deaths Under Anaesthesia
SHN	Specialty Health Network
GIPA	Government Information (Public Access) Act 2009
QSA	Quality Systems Assessment
WH&S	Work Health and Safety

2 THE INCIDENT MANAGEMENT PROCESS

When an incident occurs in a Health Service a series of actions must follow. The importance of identifying these as separate steps is to ensure that all appropriate action is taken. The incident management process is represented diagrammatically below.

Diagram 1: The NSW Health Incident Management Process



2.1 Step 1 – Identification

Incidents may be identified through a number of methods. These may include: direct observation, team discussion, Coroner's reports, mortality and morbidity review meetings, death review processes, staff meeting discussions, complaints, audits and/or chart reviews.

Incidents may be identified at the time they occur or at any time after the event. Health Services need to implement processes which facilitate the identification and reporting of all incidents in a timely manner.

2.2 Step 2 – Immediate action

Following identification of an incident, it may be necessary to take immediate actions to mitigate the harmful consequences of the incident. These actions may include:

- a. Providing immediate care to individuals involved in the event (patient, staff or visitors) to prevent the harm from becoming worse
- b. Making the situation/scene safe to prevent immediate recurrence of the event
- c. Removing malfunctioning equipment or supplies, isolating these items and preserving them intact
- d. Gathering basic information from staff while the details are still fresh in the minds of the involved clinicians. Further direction on how facilities might ensure this is done in a manner which maintains privilege in SAC 1 and other events requiring a privileged RCA (see 4.2.3). Information will not attract privilege unless it is prepared for the dominant purpose of assisting an appointed RCA team in the conduct of its investigation
- e. Notifying police and security.

2.3 Step 3 – Notification

Staff members are required to notify all identified incidents (both clinical and corporate), near misses and complaints in the incident management system.

2.3.1 Documentation of the clinical incident in the health record

- All actual clinical incidents must be documented in the patient's health record.
- Care must be taken to ensure only clinically relevant information is included in the health record.
- Staff must document the incident management system ID number in the health record with the information about the incident.
- If the incident has been identified via a complaint, the complaint details should not be recorded in the health record.

2.3.2 Incident notification in the incident management system – by the Notifier

All incidents, both clinical and corporate, once identified, need to be recorded in the incident management system. The notifier undertakes an initial assessment of severity of the incident using the SAC (see *Appendix B*) and gives their

opinion of how the incident may have been prevented. The notifier may choose to remain anonymous, or include identifying information.

This step:

- a. Must occur as soon as practicable and preferably by the end of the notifier's work day
- b. Must not include identifiable details such as staff names.

There are several mandatory fields that must be entered into the system for each incident. The minimum dataset (MDS) that guides further review, management and classification for each incident is determined by the incident category.

Health Services should have in place a mechanism for patients and/or their family members or carer to report an incident. The use of the complaints management process may be appropriate in some instances, but the patient/family member or carer should be able to notify that the incident has occurred, without the need to register a complaint. In this instance it may be appropriate for a clinician or manager to record the incident in the incident management system.

2.3.3 Incident notification – Management responsibility

The manager reviews the incident notification, completes the incident management screen and either allocates or confirms the SAC according to the details of the incident or near miss. The actual SAC must be applied and incident status changed from the original classification of 'new' within 5 days of the incident being notified in incident management system.

If it has been necessary to use a paper-based notification form, the incident form is not to be retained once entered into the incident management system.

2.3.4 Notification to Patient – Open Disclosure

As early as possible after the event, the provider should share with the patient and/or their family or carer what is known about the event and what actions have been taken to immediately mitigate or remediate the harm to the patient. An expression of apology or regret can be extended at that time.

Refer to NSW Health policy and guidelines on open disclosure for further guidance (*Appendix A*).

2.3.5 Notification to NSW Treasury Managed Fund (TMF)

Incidents with the potential for a medico legal claim must be reported to TMF as soon as possible.

2.3.6 Notifications for Corporate Incidents

The following policies outlining notification responsibilities may be relevant depending on the nature of the corporate incident (the list is not exhaustive- further relevant policies are listed at *Appendix A*):

- Workplace Health & Safety: Policy and Better Practice Guide PD 2013-005– notifications to WorkCover
- Legal Matters of Significance To Government PD2006-009 –notification to the General Counsel, MoH
- Corrupt Conduct - Reporting to the Independent Commission
- Against Corruption (ICAC) PD 2011-070-notification to ICAC
- Public Interest Disclosures PD 2011-061-may involve notification to ICAC or NSW Police
- Child related Allegations, Charges and Convictions against Employees PD 2006_025 – notification to NSW Ombudsman, Police, Family and Community Services
- Criminal Allegations, Charges or Convictions against employees PD2006_026 notification to NSW Police.

2.4 Step 4 – Prioritisation

The purpose of prioritisation is to ensure that a standardised, objective measure of severity is allocated to each incident or near miss. The SAC must be used to prioritise all notifications. The key purpose of the SAC is to determine the level of investigation and action required. Therefore the degree of harm suffered should be the key consideration. Experience has demonstrated that predicting the likelihood of recurrence is not helpful as it can be unreliable. In some situations it has led to inappropriate downgrading of incidents and inadequate analysis and management. Caution is therefore recommended when applying the “frequency” component.

The SAC guides the level of investigation and the need for additional notification. The Chief Executive of the organisation must be advised of all SAC 1 (clinical and corporate) incidents.

2.4.1 Severity Assessment Code Scoring Steps

A SAC is to be applied to all incidents. Details about the SAC process can be found at *Appendix B*. There are two steps required:

Step 1: Determine the consequence or outcome of the incident by assessing the actual outcome of the incident based on the definitions provided in the consequence table. The matrix also provides for the calculation of likelihood of recurrence. This can be difficult to assess, and adds little value in the context of deciding the level of investigation for an incident that has already occurred.

Step 2: Implement appropriate action

Each incident is assessed for the actual consequence and the potential consequence. The potential consequence is the worst-case scenario for the incident being assessed. There is a great deal of benefit in investigating near miss incidents especially if the potential consequence of the near miss could have been a SAC 1 or SAC 2 event.

Wherever possible, and as early as practicable, the patient and/or the family/carer and other relevant persons should be given the opportunity to provide information (verbal or written), as part of the investigation process.

The collection of evidence and basic facts about the incident should commence at the earliest possible time, preferably when the event is first recognised. For clinical SAC 1 incidents, direction is provided at 4.2.3 about the process for appointing core personnel of the RCA team, as soon as possible after the event so that statutory privilege under the *Health Administration Act 1997* attaches to the information obtained.

2.5 Step 5 – Investigation

All notified incidents require review at an appropriate level. The SAC applied in the prioritisation stage guides the level of investigation. If additional input is needed before an accurate SAC score can be applied, steps should be taken to address this immediately so that legislated requirements can be met without delay. It may be necessary to make a “judgement call” in relation to the SAC based on the best evidence available, where the gathering of further evidence will amount to an unacceptable delay.

All Health Services should:

- a. assign appropriate levels of responsibility for investigation and action on all incidents
- b. have procedures in place for the investigation of incidents
- c. provide access to training programs for the investigation of incidents
- d. have appropriately trained staff to support staff involved in investigations
- e. assign appropriate levels of resourcing to enable effective investigations to be undertaken
- f. ensure that the Clinical Governance Unit and/or Corporate Governance Unit (or equivalent) provides appropriate oversight of the quality of investigation processes and outcomes

2.5.1 Levels of Investigation

As a general guideline, the following levels of investigation are considered appropriate.

CLINICAL INCIDENTS

Clinical SAC 1 incidents

- a. All clinical SAC 1 incidents require a privileged RCA investigation. This is a legislative requirement of the Health Administration Act 1982 and Regulations. See section 4 of this policy for detailed information about the requirements for a privileged RCA investigation of clinical SAC 1 incidents. The methodology taught and promoted by the Clinical Excellence Commission should not be deviated from without prior agreement with that organisation. This is to ensure that important considerations of investigation such as privilege and fairness are adhered to.
- b. All clinical SAC1 incidents must have the final RCA report completed and submitted to the MoH within 70 calendar days from the notification of the incident in the incident management system.

Clinical SAC 2 Incidents

The following are the key components of management of SAC 2 incidents.

- a. Senior management is to be notified and management responsibility must be specified.
- b. An investigation is to be undertaken. This may be in the form of an RCA or any other investigation methodology which enables drilling down to the causative factors of the event. Each organisation is to have policies and procedures in place for the investigation of incidents and training programs in place for staff to investigate incidents.
- c. It should be noted that under the legislation a privileged RCA may be conducted for SAC 2, 3 or 4 incidents, if the Chief Executive is of the opinion that the incident may be the result of a serious systemic problem that justifies the appointment of an RCA team. The commissioning of the RCA must be in accordance with this Policy, as outlined at 4.2, to attract the statutory privilege. Clinical SAC 2 Reports of investigations conducted by RCA must be submitted to the MoH within the required 70 day time frame.
- d. If there is disagreement in relation to the type of investigation to be undertaken on a clinical SAC 2 incident, the Director of Clinical Governance (DCG) is to make the final determination. Ongoing monitoring and analysis by the organisation of aggregated incident data must occur.
- e. Organisational level improvement activities are to be developed and implemented.
- f. Investigation should be completed, where possible, within 45 days of being notified in the incident management system or a progress report outlining the management plan with a revised completion date should be submitted to the appropriate senior manager.
- g. Where available, State-wide or LHD tools and templates should be utilised for SAC2 investigation reports

Clinical SAC 3 & 4 Incidents

- a. All SAC 3 and 4 incidents need to be reviewed. Such reviews will be undertaken at the local level, but management responsibility for the review process must be assigned.
- b. It may be considered appropriate to aggregate a number of similar SAC 3 or 4 incidents and to perform a review of the aggregated incidents
- c. As well as investigation or review at the local level, monitoring of trended aggregated incident data may also identify and prioritise issues requiring a practice improvement project.
- d. Investigation should be completed, where possible, within 45 days of being notified in the incident management system or a progress report outlining the management plan with a revised completion date should be submitted to the appropriate senior manager
- e. As with SAC 2 incidents, a privileged RCA may be conducted for clinical SAC 3 and 4 incidents in the circumstances where the Chief Executive considers the incident may be the result of a serious systemic problem. In these

circumstances the RCA report must be submitted to the MOH within the required timeframe of 70 days.

CORPORATE INCIDENTS

Corporate SAC 1 Incidents

- a. Investigations of SAC1 corporate incidents will be determined by the nature of the incident. They may be in the form of an RCA or any other investigation methodology which involves ascertaining the causative factors of the event. Relevant MoH and Health Service policy documents should inform the level and nature of the investigation (Appendix A)
- b. All Corporate SAC 1 incidents must have a detailed investigation completed and a report submitted to the MoH within 70 days from the notification of the incident in the incident management system

Corporate SAC 2, 3 and 4 Incidents

- a. All SAC 2,3 and 4 incidents need to be reviewed.
- b. The nature and the level of the investigations will be determined by the incident and its severity. Relevant MoH and Health Service policy documents should be referred to inform the level and nature of the investigation (Appendix A).
- c. Ongoing monitoring of trended aggregated incident data may identify and prioritise issues requiring a practice improvement project
- d. Investigation should be completed within 45 days of being notified in the incident management system or a progress report outlining the management plan with a revised completion date being submitted to the appropriate manager

An aggregated de-identified report on all corporate SAC1,2,3 and 4 incidents is to be provided by each LHD and SHN to its Internal Audit Committee. Similarly, an aggregated report on all Workplace Health and Safety (WHS) incidents is to be provided to the Director, Workforce Development and any relevant OH&S Committee.

2.5.2 Investigations and conduct/impairment/performance issues with individual clinicians

Investigations conducted under this policy should not attempt to assess the adequacy of an individual's performance or competence. Where a question of individual performance or competence arises, it is to be managed via the organisation's performance management system and/or PD2006 007 Directive Complaint or Concern about a Clinician – Principles for Action and GL2006 002 Complaint or Concern about a Clinician – Management Guidelines.

Investigators are, however, expected to explore **why** staff involved in incidents acted as they did, and should be encouraged to pose appropriate questions to

explore the human factors aspects of the event in question. Typical issues might include fatigue, training and communication. In this way, the team is not endeavouring to judge the competence or adequacy of performance of any individual.

Professional Misconduct, Unsatisfactory Professional Conduct and Impairment

Under section 200(1) of the *Health Administration Act 1982*, where the RCA team forms the opinion that an incident may involve professional misconduct, unsatisfactory professional conduct or impairment by an individual clinician/s, the RCA team **must** notify the CE in writing. In relation to the meaning of “professional misconduct” and “unsatisfactory professional conduct”, see Part 8, Division 1 of the *Health Practitioner Regulation National Law (NSW)*. In relation to the meaning of “impairment”, see S5 of the *Health Practitioner Regulation National Law (NSW)*.

Unsatisfactory Professional Performance

Under Section 200(2) of the *Health Administration Act 1982* where the RCA team forms the opinion that an incident may involve unsatisfactory professional performance by a clinician, the RCA team **may** notify the CE in writing. Although the RCA team holds discretion to report in these circumstances, it should err on the side of caution and notify the concerns to the CE. “Unsatisfactory professional performance” means professional performance that is unsatisfactory within the meaning of Division 5 of Part 8 of the [Health Practitioner Regulation National Law \(NSW\)](#).

Content of Notification of Conduct, Performance or Impairment issues

The RCA team’s notification is to disclose the identity of the person to whom the notification relates, regardless of whether the person consents to the disclosure. The notification is also to specify whether the concern relates to professional misconduct, unsatisfactory professional conduct or unsatisfactory professional performance or whether the person is or may be suffering from impairment together with a brief description of the nature of the concern. No other information obtained during the privileged RCA should be provided.

See *Appendix C* for a template letter that may be used by the RCA Team Leader to inform the CE of an incident involving suspected individual conduct, performance or impairment issues.

The CE will determine appropriate action which will be in accordance with *PD2006_007 Complaint or Concern about a Clinician – Principles for Action* and *GL2006_002 Complaint or Concern about a Clinician – Management Guidelines*.

The RCA Team will take no further action on the matter that relates to the individual.

The RCA Team may continue to investigate the systems issues in the incident.

2.5.3 Decommissioning RCAs

The only reason for decommissioning an RCA is where the RCA team identifies individual clinician conduct, impairment or performance issues that may be responsible for the incident and there are no readily identifiable systems issues to consider.

The Health Service notifies the MoH following the decommissioning of the RCA and provides the reason for the decommissioning of the RCA by completing the front page of the RCA template and submitting this to the MoH – email address quality@doh.health.nsw.gov.au

This is also the email address for submission of completed RCAs.

2.5.4 The management of SAC1/Privileged clinical incident investigations across Health Service boundaries

Clinical incidents may occur in one Health Service but be notified through another e.g. when there has been a patient transfer or services provided across organisational boundaries. It is the responsibility of each DCG to oversee the management of cross-boundary incidents.

The management process is:

- a. The incident is notified through the incident management system and a RIB is completed
- b. The authority for transfer of a clinical incident from one Health Service to another and acceptance of that transfer resides with the DCGs of each organisation
- c. If responsibility for managing the clinical incident is transferred to another Health Service this is to be reassigned in the incident management system. A request is to be provided to NSW Health Share helpdesk to arrange incident relocation in the incident management system
- d. The MoH is informed of action taken in regard to liaison with the other Health Service via the RIB
- e. The DCG of the Health Service with agreed primary responsibility for managing the clinical incident is responsible for overseeing management of the incident including the RCA and informing the notifying Health Service of their staff's involvement in the RCA process.

On occasion, both organisations may need to be involved in the clinical incident management when there are issues relevant to both parties, for example by participating in an RCA and accepting responsibility for implementation of recommendations. In that case, the incident should be copied and linked in the incident management system. Both parties may also need to be involved in the open disclosure process.

RCA teams seeking to access patient health information for the purpose of an investigation across two or more Health Services are able to share the information for this purpose without patient consent under the *Health Records and Information Privacy Act 2002* and *Health Records and Information Privacy Regulation 2012*.

2.5.5 Investigation of clinical incidents across sectors

Some incidents may occur across more than one sector, for example in primary and in secondary care settings or between the public and the private or non government organisation sectors. It is the responsibility of each DCG to ensure appropriate management of cross-boundary incidents. Depending on the severity of the incident, the DCG may need to involve personnel from the other sector(s) in the incident reporting and investigation processes.

The incident management process should be discussed and agreed with an appropriate senior representative of the other entity and the process progressed in a manner that meets the legislated/licensing requirements of each and every entity.

Where a clinical incident involves both an LHD/SHN and a private health facility licensed under the *Private Health Facilities Act 2007*, then both entities may be required or permitted to carry out a privileged RCA under legislation (under the *Private Health Facilities Act 2007* licensed private health facilities are required to carry out an RCA in relation to clinical SAC 1 incidents, and are also permitted to carry out an RCA in respect of other clinical incidents where the incident indicates there may be a serious systemic problem).

In that event, it is possible for the LHD/SHN and licensed private health facility to elect to carry out a “joint” RCA investigation as follows:

- a. Each entity would separately appoint the same RCA team members and each team is then able to carry out the statutory functions, on behalf of each entity, concurrently.
- b. The RCA team members conduct meetings, interviews and other investigations acting in the capacity of both RCA teams, effectively at the same time. It is important that documentation of these processes makes it explicit that the RCA team is acting in two different statutory capacities simultaneously in carrying out these activities.
- c. Team members need to ensure that they address the notification requirements of both the *Health Administration Act 1982* and the *Private Health Facilities Act 2007* e.g. in relation to concerns about possible misconduct or unsatisfactory professional performance.
- d. A separate RCA report is required in respect of each Act, although, depending upon the team’s findings and recommendations, the content of these Reports could be the same.

Such a joint RCA process is only appropriate where there may be common factual issues or issues relating to the interaction of the two service providers,

for example issues relating to communication between the services or to transfer processes.

Incidents Involving Multiple States/Territories

There are several ways in which other jurisdictions may be engaged in an investigation by an RCA team appointed by an LHD or SHN.

- a. Representatives from the involved service or facility can be invited to participate actively as an RCA team member.
- b. The team can request a copy of the relevant medical records and related documentation from the other jurisdiction, to inform the analysis.
- c. RCA team members can include involved parties from the other jurisdiction in the interviewing and fact finding process.

Formal correspondence from the CE to his or her equivalent in the other State or Territory would assist the team in achieving its objectives. This should state clearly what the team is seeking and remind the recipient that participation on the team and provision of information to the team during interviews will be covered by privilege.

Access to relevant medical records held by another jurisdiction for the purposes of the RCA team's investigation will generally be governed by applicable privacy legislation in that jurisdiction. Further advice may be sought from the CEC.

Management of Corporate Incidents across Health Service Boundaries

The responsibility for managing cross boundary corporate incidents rests with the most appropriate Health Service CE.

The management process is:

- a. The incident is notified through the incident management system and a RIB is completed
- b. The authority for transfer of an incident from one Health Service to another and acceptance of that transfer resides with the CE of each Health Service.
- c. If responsibility for managing the incident is transferred to another Health Service this is to be reassigned in the incident management system. A request is to be provided to NSW Health Share helpdesk to arrange incident relocation in the incident management system
- d. The MoH is informed of action taken in regard to liaison with the other Health Service via the RIB
- e. The CE of the Health Service with agreed primary responsibility for managing the clinical incident is responsible for overseeing management of the incident including the RCA and informing the notifying Health Service of their staff's involvement in the RCA process.

On occasion, both organisations may need to be involved in the corporate incident management when there are issues relevant to both parties, for example by participating in an RCA and accepting responsibility for implementation of recommendations. In that case, the incident should be copied and linked in the incident management system. Both parties may also need to be involved in the open disclosure process.

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.

2.6 Step 6 – Classification

This is the process of capturing relevant information from a range of perspectives about an incident to ensure that the complete nature of the incident, including causative and contributory factors, is documented and understood. Classification of all incidents involving patients, staff, visitors, volunteers, contractors or corporate systems can be made in the incident management system.

Classification is undertaken by nominated personnel according to the service delivery model of each Health Service and may include local managers, patient safety managers, Workplace Health & Safety managers and staff of Clinical Governance Units (CGU).

The SAC will determine the amount of information required in order to classify the incident. SAC 1 events require advanced classification. SAC 2 events require the basic classification. SAC 3 and 4 events only require completion of the minimum dataset.

2.7 Step 7 – Analysis

The purpose of analysis is to understand how and why the incident occurred, to identify ways of improving the systems of care and prevent recurrence. Analysis must take place at a number of levels in the system: at the level at which the incident occurred (for example the ward or the patient interface in a primary care setting); at the organisational level and at the State and National level. Different data are analysed and different action is expected at these various levels. Groups of incidents may be analysed to identify trends or emerging themes.

Health Services are responsible for analysis and action at the health organisation level; the MoH and the CEC are responsible for analysis and action at the State level.

2.8 Step 8 – Action

Action is the implementation of recommendations from the investigations and reviews and the development of better systems to ensure improved practice.

A suitable timeframe for the implementation of recommendations must be documented in action plans and the incident management system. Information should also include who will be accountable for the actions.

Where an RCA is involved, the CE is responsible for deciding whether recommendations are accepted and approved and for ensuring implementation of the approved recommendations. The CE must be able to justify in writing at the time of submitting the RCA Report why a particular recommendation is not supported or actioned and what alternative actions might occur. The CE may consult with other staff about the RCA team's recommendations and provide feedback to the RCA team prior to sign-off (see 4.1.4) OK.

Ongoing monitoring is required to ensure recommendations are addressed in a timely manner and to evaluate the success of any action taken to achieve improvement.

2.9 Step 9 – Feedback following investigation

Feedback is an important component of a successful incident management program.

2.9.1 Feedback to Patients and/or Support Person - Open Disclosure

Information about SAC 1 and SAC 2 clinical incidents should be offered to the patient and/or their support person and/or family as it comes to hand. Feedback should be provided in accordance with NSW Health policy on Open Disclosure (see Appendix A).

- a. Disclosures should be made to the individual patient and any family/key support person the patient would like to be present
- b. In circumstances where discussion with the patient is not possible or appropriate, his or her next of kin, designated contact person, or representative should be informed
- c. Consideration must be given to the patient's cultural and ethnic identity and first language and the support needed.

The information provided to the patient and/or their support person and/or family can be based on a variety of sources. The final report from a RCA is one of those sources. A copy of the RCA report may be given to the patient/support person/family. Ideally, the report should be discussed with the patient/support person/family in person. This will allow for questions to be addressed and to ensure that the often impersonal and clinical nature of the report can be explained.

2.9.2 Feedback to Staff

The success of incident management is dependent on feedback to all staff on the results/outcomes of investigations in a timely manner.

Feedback must be provided to staff involved in the incident and should occur as soon as possible, including after the completion of the RCA. The information to be provided is limited to that which is included in the final RCA report. This way staff involved in the incident will be informed of the conclusions reached by the team and of the recommendations arising from any investigation.

Feedback should also be given to the broader group of clinical providers and managers within the organisation. This feedback will focus on the lessons to be learned by the organisation and system amendments that will provide a greater chance that the incident will not happen again. Such feedback and discussion could take place at; for example, ward meetings, mortality and morbidity review meetings and Grand Rounds.

Regular reports on trended aggregated data and outcomes of RCAs are to be provided to the executive team and board of management, peak quality committee (or other relevant committee) and staff. Feedback should include updates as the changes are made and improvements achieved as a result of these changes. This will also provide a level of accountability for implementation of the recommendations that come from the RCA or other investigation.

3 REPORTABLE INCIDENT BRIEFS

The Reportable Incident Brief (RIB) system is designed for the reporting of specific health care incidents to the MoH. The RIB process is used for reporting both clinical and corporate incidents.

Clinical incidents: all clinical incidents reported in RIBs are referred to the NSW Health Clinical Risk Action Group (CRAG). CRAG is responsible for examining and monitoring serious clinical incidents via a number of mechanisms, including RIBs. The clinical incident RIBs and the work of this Group are subject to special statutory privilege under *Section 23 of the Health Administration Act 1982*.

Corporate incidents: Corporate incidents occurring in the health care setting are those involving staff, visitor, contractors, property, security and hazards.

3.1 RIB reporting requirements

All actual SAC 1 incidents, both clinical and corporate, must be notified to the MoH via a RIB, within 24 hours of notification of the incident in the incident management system (The RIB does not replace the requirement for early notification of an incident to the appropriate Deputy Director-General and the Strategic Relations and Communications Branch of the MoH).

The Chief Executive or his/her delegate is responsible for notifying the Minister's Office, the Director-General, the Deputy Director-General and the MoH's Media Unit when there are incidents which have the potential to become matters of public interest.

Where there is a need to notify the MoH outside of business hours, the relevant Deputy Director-General is to be notified, as well as the on-call Media Unit officer, on pager 9962 9980.

Clinical RIBs are privileged in accordance with Section 23, *Health Administration Act 1982*, and should be maintained securely and not used for any other purpose.

An incident that has both clinical and corporate components will be covered by statutory privilege. Such incidents should be marked as “clinical” on the RIB.

A RIB is to be submitted within 24 hours of the SAC being allocated. There are instances where it is not possible to allocate a SAC to an incident (particularly a SAC 1 incident) until additional information is available. In such instances, the Health Service is required to act immediately to obtain such information or advice so that legislated requirements are met.

The following types of incidents require prompt advice to the MoH as a RIB.

3.1.1 Clinical Incidents

- Death of a patient unrelated to the natural course of illness
- Suspected suicide of a person (including a patient or community patient) who has received care or treatment for a mental illness from the relevant Health Services organisation where the death occurs within 7 days of the person’s last contact with the organisation or where there are reasonable clinical grounds to suspect a connection between the death and the care or treatment provided by the organisation
- Suspected homicide committed by a person who has received care or treatment for mental illness from the relevant Health Services organisation within six months of the person’s last contact with the organisation or where there are reasonable clinical grounds to suspect a connection between the death and the care or treatment provided by the organisation
- Unexpected intra-partum stillbirth
- Procedures involving the wrong patient / body part regardless of the outcome (SAC1-SAC4).

OR

- The Sentinel Events, those being:
 - Procedures involving the wrong patient or body part resulting in death or major permanent loss of function
 - Suspected suicide of a patient in an inpatient unit
 - Retained instruments or other material after surgery requiring re-operation or further surgical procedure
 - Medication error leading to the death of a patient reasonably believed to be due to incorrect administration of drugs
 - Intravascular gas embolism resulting in death or neurological damage
 - Haemolytic blood transfusion reaction resulting from ABO (blood group) incompatibility

- Maternal death or serious morbidity associated with labour or delivery
- Infant discharged to wrong family.

“Major Clinical Consequences”

An incident with “major clinical consequences” is one which involves a patient:

- Suffering a major permanent loss of function (sensory, motor, physiologic or psychological) unrelated to the natural course of the illness and differing from the expected outcome of patient management
- Suffering significant disfigurement as a result of the incident
- At significant risk due to being absent against medical advice/absconding
- Subjected to threatened or actual physical or verbal assault requiring external or police intervention.

Probability of Recurrence

- (i) Frequent expectation that the incident will recur immediately or within weeks or months
- (ii) Likely probability incident will recur more than once within 12 months
- (iii) Possible possibility incident may recur at some time every 1 to 2 years
- (iv) Unlikely possibility incident may recur at some time in 2 to 5 years.

When Health Services are reporting incidents involving patient on patient or patient on staff assaults resulting in injury or death of a patient or staff member and there are reasonable clinical grounds to suspect a connection between the assault/death and care provided by the organisation these are to be reported as a clinical RIB.

3.1.2 Corporate Incidents

- Unexplained death of a staff member
- Suspected suicide or attempted suicides by a staff member where the staff member was not a client of mental Health Services
- Fire, bomb or other threatening activities in the health facility
- Critical equipment breakdown or failure
- Serious threats affecting the facility’s operation
- Complete loss of service i.e. power or water failure
- Criminal activity in or related to the workplace
- Non-accreditation of service provider
- Violence or threats of assaults on patients, staff or other persons in the Health Service. This includes incidents involving:
 - assaults on, and or abuse of, patients (including children) and other vulnerable patients by staff or other persons and incidents involving abuse of staff by patients or other persons
 - staff members assaulting other staff members
- Incidents for which reporting is mandated – (see 3.1.3 below).

3.1.3 Mandated reporting - Legal and Policy Requirements

There are matters that require mandatory notification via a RIB to the MoH regardless of the SAC.

These include but are not limited to:

- a. Deaths or other incidents reportable to the Mental Health and Drug & Alcohol Office
- b. When methadone or buprenorphine is associated with or potentially associated with a child's presentation or admission to hospital
- c. Deaths in custody
- d. Significant legal action initiated by or against a Health Service. See PD2006_009 *Legal matters of significance to government*, for further information concerning the notification of significant legal matters
- e. Industrial disputes, particularly where an interruption may be marked
- f. The commencement of a Work Cover prosecution
- g. All incidents that involve the incorrect patient, procedure or site
- h. Radiation incidents reportable to the Radiation Advisory Council (RAC) under the Radiation Control Act (2003)
- 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
- j. Child related allegations, charges and convictions against staff which are notifiable to the Child Protection Helpline or Child Wellbeing Unit (where appropriate), NSW Police and/or Ombudsman and require investigation by the Health Service. These allegations may be work or non-work related
- k. Criminal charges against a staff member related to the workplace or that are outside of work but impact on the workplace in terms of risks, e.g. sexual assault criminal charges
- l. Accreditation agency notification to a health service of the detection of one or more significant risks to patient harm.³

See *Appendix A* for policy directives and legislation outlining existing reporting requirements.

3.2 RIB reporting process

The RIB reporting process is as follows:

- a. RIBs are to be completed in the incident management system or its approved equivalent
- b. A SAC is to be applied to all incidents reported via the RIB system
- c. The Chief Executive (CE) is responsible for authorising the RIB

³ The Australian Health Service Safety and Quality Accreditation (AHSSQA) Scheme also requires approved accrediting agencies to notify regulators if a significant patient risk is identified during an onsite visit to a health service organisation.

- d. The RIB is then submitted to the MoH (RIBs@doh.health.nsw.gov.au) within 24 hours of the incident being notified in IIMS.⁴ RIBs must be forwarded under the signature of the CE or nominated delegate and dated. Where IIMS is in use, this will be by a system generated email
- e. If the issue requires urgent State-level response and/or involvement, the Health Service is to provide telephone advice that a RIB has been emailed. This information should be relayed to the Chief Executive at CEC and to the MoH's Strategic Relations and Communications Branch during business hours. After hours the on call media officer for the Ministry of Health should be notified
- f. If there is a requirement for the SAC to be altered after a RIB has been submitted, the CE is responsible for authorising any change to the SAC documented in the RIB. Once the CE authorises the change to the SAC, the RIB is resubmitted to the MoH. When the RIB is resubmitted the text of the RIB must clearly indicate that this is an update of a previously submitted RIB, quote the previous MoH TRIM number and provide a reason for the update
- g. All RIBs involving suspected suicide or suspected homicide by patients of mental Health Services must be referred to the local Director of Mental Health Services for review of the SAC prior to submission of the RIB to the DCG
- h. Clinical RIBs are privileged documents. There are restrictions on their distribution. They should not be used for purposes other than providing information to CRAG in accordance with the *Health Administration Act 1982*
- i. Health Districts/ Networks/Services should have processes in place to ensure security of RIBs.

3.3 Information required in the RIB report

- a. RIBs must provide a succinct description which clearly outlines the key issues and the circumstances of the event
- b. RIBs must state the incident type (clinical or corporate), the actual SAC and the reason for reporting the incident to the MoH
- c. Patient information contained in the RIB must be de-identified
- d. The RIB is to contain facts, initial analysis and future actions to be undertaken, opinion and subjective comment are to be avoided
- e. The RIB is to indicate if initial open disclosure has occurred
- f. Do **not** send attachments such as health care records, pathology or autopsy reports and other patient identifying reports with the RIB
- g. As identifying details are required on the Client Death Report Form that is completed for notification of deaths of mental health patients, this form should be sent directly to the Mental Health and Drug & Alcohol office at the NSW Ministry of Health.

⁴ Or later if it is not possible to determine that the incident rates a SAC 1 at this time. See Section 3.1 for further explanation.

4 PRIVILEGED ROOT CAUSE ANALYSIS UNDER THE *HEALTH ADMINISTRATION ACT 1982*

All clinical SAC 1 incidents under Division 6C of the *Health Administration Act 1982* require the appointment of an RCA team, and the RCA process is afforded statutory privilege (see *Appendix D*). The provisions under the *Health Administration Act 1982* apply to all LHDs, the statutory health corporations and the affiliated health organisations, as provided under the *Health Services Act 1997*, as listed in *Appendix E*.

Further, the CE has discretion to appoint a RCA team to investigate any clinical incident of a lesser severity than SAC 1, if the CE is of the opinion that the incident may be the result of a serious systemic problem that justifies the appointment of such a team. In that event, the RCA process will also enjoy statutory privilege. Health Services should implement processes to allow local quality assurance committees and mortality and morbidity committees to recommend to the CE that an RCA team be appointed to review incidents or issues that may be indicative of serious systemic problems.

The legislation does not provide privilege for the investigation of corporate SAC 1 incidents.

4.1 Statutory Privilege

4.1.1 What the Privilege covers

The privilege provided under Division 6C of the *Health Administration Act 1982*, applies to:

- a. Any document prepared
- b. Any communications, whether written or verbal, between RCA team members and any other person (e.g. clinicians involved in the incident).

Where the document is prepared, or the communications are made, for the dominant purpose of the conduct of the investigation by the RCA team.

Privilege will not apply to documents or communication created before a RCA team has been commissioned.

This means that:

- a. RCA team members cannot be compelled to produce or give evidence of any document created by or on behalf of, at the request of, the RCA Team, where the document was for the dominant purpose of the conduct of the investigation by the RCA team
- b. Any person who is not a member of the RCA team who creates a document or makes communications (written or verbal) that is for the dominant purpose of assisting with the conduct of the investigation by the RCA team (this may include administrative assistants to the RCA team, clinicians involved in the incident investigated by the team, or experts engaged by the RCA team to assist it with the investigation) cannot be compelled to produce or give evidence of the document or communication

- c. The final RCA report prepared by the RCA team cannot be adduced or admitted as evidence in any proceedings (including coronial proceedings, or any proceedings in which it is claimed a procedure or practice was careless or inadequate)
- d. RCA team members acting in good faith for the purposes of the exercise of the RCA team's function are also protected from personal liability, including actions for defamation.

The legislation also establishes tight confidentiality requirements, making it an offence for a team member to disclose any information obtained during the investigation, unless it is for a purpose that is part of the RCA process.

4.1.2 Internal Working Documents of the Privileged RCA team

During the RCA process, the team will generate documents, including preliminary notes, records of interviews with staff/clinicians, minutes of meetings and records of discussions with various people either involved in the incident or with fundamental knowledge of the incident or processes involved. During the RCA process some of these items may need to be transferred to other team members or, in limited circumstances, to the CE e.g. in relation to proposed recommendations. **All this material is privileged.**

a. Storage and transfer of privileged RCA material

To protect the privilege, these records are to be maintained in a separate RCA team file marked "privileged" and stored securely in a location nominated by the Director of Clinical Governance to ensure the privilege is upheld in the event of a subpoena or application for access under GIPA.

Privileged material is not to be sent in the general post but should be sent by secure internal transport processes. Health Services need to have appropriate policies and procedures in place to manage the transfer of such materials.

b. Retention of RCA documents related to clinical incidents

Records relating to RCAs are required to be retained under the same rules applying to "legal matters and incident management" under clause 1.14 of the General Retention and Disposal Authority — Public Health Services: Patient/Client Records (GDA 17). Under this requirement, the RCA records must be retained for a minimum of 7 years after the last action. As the records are not admissible in court or other proceedings, and can only be accessed by members of the RCA team, the 7 year period applies whether or not legal proceedings have been commenced.

4.1.3 What the privilege does not cover

Statutory privilege does not cover:

- a. Pre-existing documents, such as clinical incident summaries, medical records or other records created in the course of providing general care of patients or management of the Health Service, and not as part of the RCA
- b. Notifications made by the RCA team under section 200 of the *Health Administration Act 1982*, which relates to the responsibility of the RCA team to notify the CE where the RCA team forms the opinion that the incident raises matters that may involve professional misconduct, unsatisfactory professional conduct, impairment or unsatisfactory professional performance of an individual clinician
- c. Information entered into the incident management system
- d. The final RCA report
- e. Any communication that is not for the dominant purpose of the RCA process.

4.1.4 Disclosure of information

The privilege does not prevent information being given by a RCA team to another privileged committee (for example a RCA team is entitled to give information to The Special Committee for Investigating Deaths Under Anaesthesia (SCIDUA), The Collaborating Hospitals Audit of Surgical Mortality Committee (CHASM); and the NSW Clinical Risk Action Group (CRAG)). Information provided in this way will retain privilege through the protections granted to those committees under Section 23 of the *Health Administration Act 1982*.

Further, a RCA team may disclose information about recommendation(s) proposed by the team to the CE of the Health Service that appointed the RCA team; for the purposes of informing the CE about the proposed recommendation(s) and enabling the CE to consult with other staff members of the Health Service about the proposed recommendation(s), and provide feedback to the RCA team regarding the proposed recommendation(s). All such communication between the CE and the RCA team about the proposed recommendation(s) will remain privileged, and should be done formally in writing.

4.2 The Privileged RCA Process

There are four key tasks involved in the root cause analysis process

4.2.1 Task 1 – Appointment and membership of the RCA Team

The CE is responsible for appointing and signing off the membership of the RCA team.

At least some of the members of the team should have fundamental knowledge of the care processes in the area where the incident occurred. No member of

the RCA team should have been directly involved in the incident or in the care of the patient. Where possible and practical, the RCA team should include at least one member who is external to the LHD or Health Service. Further, RCA team members should not have any personal or non-professional connection with any clinician who has been involved in the incident. A direct line manager should not be a member of a RCA team which is investigating an incident involving his or her department or unit. All persons involved in overseeing the quality of the RCA process itself should be appointed members of the RCA Team. This will ensure they are covered by statutory privilege.

A RCA team investigating suspected suicide should in its membership include a senior mental health clinician who is independent of the facility involved in care. A RCA team investigating suspected homicides or other serious crimes should in its membership include a senior mental health clinician who is independent of the service involved in care.

Team members are to receive a letter of appointment. See *Appendix F* for a template.

a. Informing team members of their roles and responsibilities

Those appointed to a RCA team are to be informed of their role and responsibilities as members of a RCA Team. *Appendix G* provides a template letter outlining the role and responsibilities of team members.

b. Record of RCA Team appointment

The statutory privilege will only apply if it can be shown that the RCA team was properly constituted under the *Health Administration Act 1982*. As such, it is critical that comprehensive records are prepared and retained relating to the appointment of the RCA team.

Records will include:

- An original copy of the letters of appointment of the RCA team members
- The date of appointment
- Clear identification of the incident in relation to which the RCA is to be conducted
- The names of the RCA team members.

c. Process for appointment of RCA Team

The identification of appropriate personnel for appointment to a RCA team can delay the appointment of the RCA team. Best practice in conducting RCA investigations globally recognises the advantages of the immediate collection of evidence and facts pertaining to the event, particularly in the first 48 hours following a serious clinical incident. Health Services should have in place a process that enables the immediate appointment by the CE of core personnel to a RCA team as soon as a clinical SAC 1 incident is notified to the CE. This process would involve a standing instrument of appointment for certain experienced and trained personnel, who can facilitate the early collection of such information and material for the RCA investigation e.g. the

DCG and/or Patient Safety Manager. A template for the immediate appointment of a “core” RCA team member is provided at *Appendix H*.

Once the remaining proposed RCA team members are identified, a further instrument of appointment should be executed by the CE that refers to the earlier instrument of appointment, and appoints the balance of the members of the RCA team. A template for the later appointment of additional members after appropriately qualified and/or expert individuals have been identified, is provided at *Appendix I*.

This process will ensure that statutory privilege attaches to all documents and communications prepared for the purposes of the RCA team in the initial period immediately following the incident, and prior to the appointment of the full RCA team.

4.2.2 Task 2 – Notification to staff involved in the incident

The RCA team will contact staff involved to discuss the incident and gather information as part of the investigation. A template that can be used to inform staff of the RCA process and to explain the staff members’ legal rights and responsibilities is provided at *Appendix J*.

4.2.3 Task 3 – The RCA Investigation

There are six key steps in undertaking an RCA investigation:

1. Interviews and gathering information– interviews of people relevant to the incident are undertaken. This must include clinicians who were involved in the incident as well as the patient and/or the family or carers. It may also include people relevant to current policy and process e.g. the pharmacist, the biomedical engineer or the hospital architect
2. Simple flow charting – a process to help determine what the team knows about the sequence of events, what they do not know and what they need to find out
3. Detailed flow charting – to enable the identification of the most significant problems where barriers might interrupt the flow of events for future prevention of similar events. Further causal analysis will centre on these issues to determine the underlying root causes
4. Causal factor charting – by asking what changed, what conditions were present and what was not done at each of the key potential barrier points, the team identifies the underlying causal issues and depicts them in a causal sequence. These causal factors are then analysed to determine root causes. A complex healthcare case will typically identify between 3 and 5 root causes, although this number can vary
5. Causation statements – a written description of each of the causal sequences presented in a statement linking the root causes to the outcome
6. Recommendations – the team nominates actions to causation that would most likely prevent or mitigate the root causes.

4.2.4 Task 4 – Reporting

All privileged RCA Teams must prepare a final report. Once this final report is signed off by the CE it is not protected by statutory privilege. The report must contain:

- a. A de-identified description of the reportable incident
- b. A clear written description of the findings of the analysis of the information gathered about the reportable incident
- c. The incident ID from the incident management system and MoH RIB number
- d. Causation statement/s that indicate the reasons the RCA Team considers the incident occurred (assuming that causation has been established). These should be written in accordance with the rules of causation established by NSW Health (see *Appendix K*)
- e. Recommendations for system changes to improve procedures or practices to minimise recurrence of the incident if root causes have been determined and such recommendations can be made.

The final RCA report must not include the name or address of an individual patient or service provider involved in the incident, unless that person has consented, in writing, to that information being disclosed. The final report must also not disclose, as far as is practicable, any other material that identifies or may lead to the identification of such an individual. It should not contain details about the membership of the RCA team.

The final RCA report may contain recommendations about system improvement opportunities that have been identified during the investigation, but have not contributed to the adverse outcome.

See *Appendix L* for the final report template. Organisations should use this template to ensure the final report meets legislative and policy requirements.

4.2.4.1 Signing off the final report

- a. Prior to final sign-off, the RCA team may seek a formal written opinion from the CE about any proposed recommendations, in accordance with 4.1.4
- b. At the conclusion of the RCA, the RCA team must submit a copy of its signed report (but no other documentation) to the CE
- c. The CE is to review the RCA report and endorse the report prior to submission to the MoH
- d. Any disagreement that the CE may have with any of the recommendations in the final report is to be documented separately and submitted with the final report. It should outline the reason/s for the disagreement and any proposed alternative action. The original RCA team report is to be submitted unchanged accompanied by this additional documentation.

The CE may delegate the responsibility for endorsing the final report prior to submission to the MoH, but remains ultimately accountable for its content.

4.2.5 Variation in RCA Process

There are instances when a variation to the RCA process is acceptable. These instances include:

- a. Assigning more than one incident to an RCA team where incidents are of the same classification
- b. Resolution of the RCA process in a shorter timeframe due to early completion of the investigation.

Any variation to the RCA process is to be documented in the final Report for sign off by the CE or nominated delegate.

4.2.6 Timeframes for RCA Process

The maximum time allowed for an RCA to be completed and the report to be submitted to the MoH is 70 calendar days from when the incident was notified in the incident management system. This time frame and requirement for submission applies to all privileged RCAs regardless of the incident's SAC.

4.2.7 Incidents involving the Coroner or Police

A referral for investigation of a death to the Coroner or the Police does not affect the requirement to undertake an investigation of an incident, including, where appropriate, an RCA.

If the Coroner requests a copy of the final RCA report, the LHD should provide it so that the Coroner is aware of any system changes that are occurring since the incident. The RCA report cannot, however, be tendered in evidence. If lawyers have been engaged to represent the LHD/SHN, the panel firm should forward the RCA report to the Coroner using a standard pro-forma letter which alerts the Coroner to S20R of the *Health Administration Act 1982*. If lawyers are not engaged, the CE should provide a covering letter with the report noting that the RCA has been provided for information only and that pursuant to S20R of the *Health Administration Act 1982*, it cannot be adduced or admitted in any proceedings.

A police or coronial investigation **should not** delay the commencement of an RCA.

4.3 The Corporate RCA Process

4.3.1 Detailed investigation for Corporate SAC 1 incidents

All corporate SAC 1 incidents require either a root cause analysis or a detailed investigation to be undertaken. The RCA Report or Detailed Investigation

Report must be provided to the Ministry of Health within 70 calendar days after the incident is notified in the incident management system. RCAs of corporate SAC 1 incidents do not attract the statutory privilege outlined in section 4 that applies to RCAs conducted in respect of clinical SAC 1 incidents.

Nevertheless, it is important that any serious or major corporate incident that receives a SAC 1 rating be properly investigated, so that the cause of the incident can be identified, and any appropriate remedial action is implemented to mitigate against a similar incident occurring again.

4.3.2 Membership of the Corporate Investigation Team

The RCA or Detailed Investigation Team should generally consist of 3 to 5 members. The members should have fundamental knowledge about the corporate processes in the area where the incident occurred, but not have been directly involved in the incident.

4.4 Steps in the Investigation

There are six key steps in undertaking the detailed investigation.

1. Assessment of the incident to determine whether the issues, e.g. negligence, criminal, corruption and make initial reports if appropriate e.g. police, ICAC
2. Planning the investigation – identify scope, potential sources of information and resources required
3. Conduct interviews and collect detailed information about the incident
4. Assessing the results – once all information has been gathered, analyse the findings
5. Barriers and recommendations – identify the barriers that would most likely prevent or mitigate the problem – then determine appropriate recommendations
6. Reporting to the CE and the Ministry of Health.

4.5 Timeframes for Corporate Investigation Process

Detailed Investigation Reports must be submitted to the Ministry of Health within 70 calendar days of the incident being notified in the incident management system.

4.6 The Final RCA or Detailed Investigation Report

All RCA Teams or Detailed Investigation Teams must prepare a final Report.

The Report must contain:

- A description of the reportable incident
- The Incident ID from the incident management system
- A causation statement/s that indicates the reasons why the Investigation Team consider the incident occurred
- Recommendations for system changes to improve procedures or practices to minimise recurrence of the incident.

4.7 Signing off the final report

- At the end of the investigation, the Investigation Team is to provide a copy of their Report to the CE.
- The CE reviews the recommendations for consideration and endorsement before the Report is submitted to the Ministry.
- The CE is able to seek clarification from the Investigation Team if the rationale for any recommendation is unclear.
- The CE is also able to add recommendations to the final report but this must be clearly documented.
- If the CE does not agree with any of the recommendations then this is documented in the final report with the reason/s why and the proposed alternative action.
- The CE is to ensure that any relevant final internal and external notification requirements as outlined in legislation and relevant policies is attended to including the NSW Health Service Check Register.

5 EVALUATION AND REVIEW

Clinical Incidents

The DCG is responsible for monitoring and evaluating notifications in the incident management system at the local level to ensure:

- a. The effective management of incidents that occur within health facilities
- b. The effectiveness of risk mitigation strategies.

The DCGs are to provide a report to their peak quality committee on the management of risks identified through incident management on a regular basis. This report includes a suite of performance indicators relevant to the LHD or SHN including those listed in Section 6.1.

5.1 Performance Indicators

5.1.1 Clinical Incidents

The key performance indicator in this policy is:

- Submission of final RCA Report to the MoH within 70 calendar days of incident notification in incident management system.

The following performance indicators should be included in the quarterly reports to the peak LHD/SHN quality committee:

- a. Submission of a RIB to the MoH, concerning all SAC 1 incidents, both clinical and corporate, within 24 hours of notification in the incident management system

- b. Proportion of obligatory external notifications made within required time frames
- c. Proportion of SAC 2 incident investigations completed within 45 days as monitored in the incident management system or have a progress report outlining the management plan with a revised completion date being submitted to the appropriate senior manager
- d. Proportion of SAC 3 and 4 investigations completed within 45 days as monitored in the incident management system or have a progress report outlining the management plan with a revised completion date being submitted to the appropriate senior manager
- e. Proportion of SAC 1 incidents notified where incident status = new in ≤ 24 hrs of incident occurring
- f. Proportion of SAC 2, 3 and 4 incidents notified where incident status = new in ≤ 5 days of incident occurring
- g. Proportion of all actual SAC 2, 3 and 4 incidents where incident status = complete in ≤ 45 days of incident occurring
- h. Proportion of RCA recommendations completed within stated timeframe
- i. Proportion of incidents notified which have recommendations for action
- j. Proportion of incidents notified where recommendations have been completed.

5.2 Corporate Incidents

The key performance indicator in this policy is:

- Submission of final RCA Report (where relevant) to the MoH within 70 calendar days of incident notification in the incident management system.

The following performance indicators should be included in the incident management framework at a Health Service level for corporate incidents:

- a. Submission of a Reportable Incident Brief to the MoH, concerning all SAC 1 corporate incidents within 24 hours of notification in the incident management system
- b. Proportion of obligatory external notifications made within required timeframes
- c. Proportion of SAC 2 incident investigations completed within 45 days as monitored in the incident management system or have a progress report outlining the management plan with a revised completion date being submitted to the appropriate senior manager
- d. Proportion of SAC 3 and 4 investigations completed within 45 days as monitored in the incident management system or have a progress report outlining the management plan with a revised completion date being submitted to the appropriate senior manager
- e. Proportion of SAC 1 incidents notified where incident status = new in ≤ 24 hrs of incident occurring
- f. Proportion of SAC 2, 3 and 4 incidents notified where incident status = new in ≤ 5 days of incident occurring
- g. Proportion of all actual SAC 2, 3 and 4 incidents where incident status = complete in ≤ 45 days of incident occurring
- h. Proportion of RCA recommendations completed within stated timeframe

- i. Proportion of incidents notified which have recommendations for action
- j. Proportion of incidents notified where recommendations have been completed.

6 APPENDICES

6.1 Appendix A – Relevant NSW Health legislation, Policy Directives, Guidelines, Information Bulletins and other resources

6.1.1 Relevant NSW Health legislation

NSW Health Legislation can be accessed at:

<http://www0.health.nsw.gov.au/aboutus/legal/legal.asp>

- 1) *Health Administration Act 1982*
- 2) *Health Administration Regulation 2010*
- 3) *Health Care Complaints Act 1993 (NSW)*
- 4) *Health Records and Information Privacy Act 2002*
- 5) *Health Records and Information Privacy Regulation 2012*
- 6) *Health Services Act 1997*
- 7) *Privacy and Personal Information Protection Act 1998*
- 8) *Private Health Facilities Act 2007*
- 9) *Private Health Facilities Regulation 2010*

6.1.2 Relevant NSW Health Policy Directives and Guidelines

NSW Health Policy Directive, Guidelines and Information Bulletin can be accessed at:

<http://www.health.nsw.gov.au/policies/pages/default.aspx>

Policies, Guidelines and Information Bulletin	Document No.
Child Related Allegations, Charges and Convictions Against Employees	PD2006_025
Codes of Conduct – NSW Health	PD2012_018
Complaint or Concern about a Clinician – Management – Management Guidelines	GL2006_002
Complaint or Concern about a Clinician – Management – Principles for Action	PD2006_007
Complaint Management Policy	PD2006_073
Complaint Management Guidelines	GL2006_023
Corrupt Conduct – Reporting to the Independent Commission Against Corruption (ICAC)	PD2011_070

Correct Patient, Correct Procedure and Correct Site	PD2007_079
Coroners Cases and the Coroner's Act 2009	PD2010_054
Criminal Allegations, Charges and Convictions Against Employees	PD2006_026
Data collections – Disclosure of unit record data held for research or management of Health Services.	PD2012_051
Deaths – Perinatal- Hospital procedures for review and reporting of perinatal deaths	PD2011_076
Effective Incident Response Framework for Prevention & Management in the Health Workplace	PD2005_234
Electronic Information Security Policy – NSW Health	PD2013_033
Employment Checks - Criminal Record Checks and Working with Children Checks	PD2013_028
Legal matters of significance to government	PD2006_009
Lookback Policy	PD2007_075
Management of Reportable Infection Control Incidents	PD2005_203
Management of a Sudden Unexpected Death in Infancy	PD2008_070
Medication Handling in NSW Public Health Facilities	PD2013_043
NSW HEALTHPLAN	PD2009_008
Injury Management and Return to Work	PD2013_006
NSW Health Privacy Manual (Version 2) 2005	PD2005_593
Open Disclosure Guidelines	GL2007_007
Open Disclosure Policy	PD2007_040
Protecting People and Property: NSW Health Policy and Standards for Security Risk Management	IB2013_024
Incident Management Policy	PD2014_004
Reporting of Thefts and Losses	PD2005_026
Reporting of Maternal Deaths to the NSW Department of Health	PD2005_219
Risk Management – Enterprise-Wide Policy and Framework – NSW Health	PD2009_039
Workplace Health and Safety: Policy and Better Practice Guide	PD2013_050

6.1.3 Other Resources

- 1) Easy Guide to Clinical Practice Improvement: A Guide for Healthcare Professionals. 2002
http://www0.health.nsw.gov.au/resources/quality/pdf/cpi_easyguide.pdf
- 2) IIMS Training Coordinator Guide
- 3) NSW Health Patient Matters Manual at
<http://www.health.nsw.gov.au/policies/manuals/Pages/patient-matters-manual.aspx>
- 4) Documentation Retention and Disposal
- 5) NSW Ombudsman, Child Protection in the Workplace – Responding to Allegations against Employees

Policies, Guidelines and Information Bulletin

- 6) General Retention & Disposal Authority – Public Health Services: Administrative Records – GDA 21 – IB2005_027
- 7) General Retention and Disposal Authority – Public Health Services: Patient/Client Records (GDA 17) – IB2004_20
- 8) NSW Health Patient Matters Manual: Chapter 9 Health Records and information
- 9) Investigation Resources - (Contact the Internal Audit Unit of your organisation for further information).

Resource Name

ICAC Fact Finder, A 20-step guide to conducting an inquiry in your organisation, Nov 2003

NSW Ombudsman, Investigating Complaints – A manual for Investigators

NSW Ombudsman, Natural justice/Procedural fairness, Fact Sheet 2004

NSW Ombudsman, Reasons for Decisions Fact Sheet, June 2005

Woloshynowych, M. Rogers S, Taylor-Adams S and Vincent C, The investigation and analysis of critical incidents and adverse events in healthcare. Health Technology Assessment 2005; Vol 9: number 19

6.2 Appendix B – Severity Assessment Code (SAC) May 2011

STEP 1 Consequences Table (For notification, consider the actual consequence or outcome using this table as a guide. The examples listed here are not exhaustive.)

		Action Required				
		Serious	Major	Moderate	Minor	Minimum
CLINICAL CONSEQUENCE	Patient	<p>Patients with Death unrelated to the natural course of the illness and differing from the immediate expected outcome of the patient management or:</p> <ul style="list-style-type: none"> ■ Suspected suicide⁵ ■ Suspected homicide⁶ ■ Unexpected intra-partum stillbirth <p>or any of the following:</p> <p>The Sentinel Events</p> <ul style="list-style-type: none"> ■ Procedures involving the incorrect patient or body part resulting in death or major permanent loss of function ■ Suspected suicide of a patient in an inpatient unit ■ Retained instruments or other material after surgery requiring re-operation or further surgical procedure ■ Medication error leading to the death of a patient reasonably believed to be due to incorrect administration of drugs ■ Intravascular gas embolism resulting in death or neurological damage ■ Haemolytic blood transfusion reaction resulting from ABO incompatibility ■ Maternal death or serious morbidity associated with labour and delivery ■ Infant discharged to the incorrect family 	<p>Patients suffering a Major permanent loss of function (sensory, motor, physiologic or psychological) unrelated to the natural course of the illness and differing from the expected outcome of patient management or any of the following:</p> <ul style="list-style-type: none"> ■ Suffering significant disfigurement as a result of the incident ■ Patient at significant risk due to being absent against medical advice ■ Threatened or actual physical or verbal assault of patient requiring external or police intervention 	<p>Patients with Permanent reduction in bodily functioning (sensory, motor, physiologic, or psychological) unrelated to the natural course of the illness and differing from the expected outcome of patient management or any of the following:</p> <ul style="list-style-type: none"> ■ Increased length of stay as a result of the incident ■ Surgical intervention required as a result of the incident 	<p>Patients requiring Increased level of care including:</p> <ul style="list-style-type: none"> ■ Review and evaluation ■ Additional investigations ■ Referral to another clinician 	<p>Patients with No injury or increased level of care or length of stay</p>
	Staff	Death of staff member related to work incident or suicide, or hospitalisation of 3 or more staff	Permanent injury to staff member, hospitalisation of 2 staff, or lost time or restricted duty or illness for 2 or more staff or pending or actual WorkCover prosecution, or threatened or actual physical or verbal assault of staff requiring external or police intervention	Medical expenses, lost time or restricted duties or injury / illness for 1 or more staff	First aid treatment only with no lost time or restricted duties	No injury or review required
	Visitors	Death of visitor or hospitalisation of 3 or more visitors	Hospitalisation of up to 2 visitors related to the incident / injury or pending or actual WorkCover prosecution	Medical expenses incurred or treatment of up to 2 visitors not requiring hospitalisation	Evaluation and treatment with no expenses	No treatment required or refused treatment
	Services	Complete loss of service or output	Major loss of agency / service to users	Disruption to users due to agency problems	Reduced efficiency or disruption to agency working	Services: No loss of service
	Financial	Loss of assets replacement value due to damage, fire etc > \$1M, loss of cash/investments/assets due to fraud, overpayment or theft >\$100K or WorkCover claims > \$100K	Loss of assets replacement value due to damage, fire etc \$100K-\$1M, loss of cash/investments/assets due to fraud, overpayment or theft \$10K-\$100K or WorkCover claims \$50K-\$100K	Loss of assets replacement value due to damage, fire etc \$50K to \$100K or loss of cash/investments/assets due to fraud, overpayment or theft to \$10K	Loss of assets replacement value due to damage, fire etc to \$50K	No financial loss
CORPORATE CONSEQUENCE	Environment	<i>Toxic release off-site with detrimental effect. Fire requiring evacuation</i>	Off-site release with no detrimental effects or fire that grows larger than an incipient stage	Off-site release contained with outside assistance or fire incipient stage or less	Off-site release contained without outside assistance	Nuisance releases

STEP 2 Likelihood Table

Probability	Definition
-------------	------------

STEP 4 Action Required Table

Action Required

⁵ Suspected suicide of a person (including a patient or community patient) who has received care or treatment for a mental illness from a Health Service or other PHO where the death occurs within 7 days of the person's last contact with the organisation or where there are reasonable clinical grounds to suspect a connection between the death and the care or treatment provided by the organisation.

⁶ Suspected homicide committed by a person who has received care or treatment for mental illness from a Health Service or other PHO within 6 months of the person's last contact with the organisation or where there are reasonable clinical grounds to suspect a connection between the death and the care or treatment provided by the organisation

Categories	
Frequent	Is expected to occur again either immediately or within a short period of time (likely to occur most weeks or months)
Likely	Will probably occur in most circumstances (several times a year)
Possible	Possibly will recur – might occur at some time (may happen every 1 to 2 years)
Unlikely	Possibly will recur – could occur at some time in 2 to 5 years
Rare	Unlikely to recur – may occur only in exceptional circumstances (may happen every 5 to 30 years)

1	Extreme risk – immediate action required – Reportable Incident Brief (RIB) for all SAC 1 incidents must be forwarded to the MoH within 24 hours. A Privileged Root Cause Analysis (RCA) investigation must be undertaken for all Clinical SAC 1 incidents with a report being submitted to the MoH.
2	High risk – need to notify senior management. Detailed investigation required. Ongoing monitoring of trended aggregated incident data may also identify and prioritise issues requiring a practice improvement project.
3	Medium risk – management responsibility must be specified – Aggregate data then undertake a practice improvement project. Exception – all financial losses must be reported to senior management.
4	Low risks – manage by routine procedures – Aggregate data then undertake a practice improvement project.
NB – An incident that rates a SAC 2, 3 or 4 should only be reported to the MoH if there is the potential for media interest or requires direct notification under existing MoH legislative reporting requirements or NSW MoH Policy Directive.	

STEP 3 SAC Matrix

		CONSEQUENCE				
		Serious	Major	Moderate	Minor	Minimum
LIKELIHOOD	Frequent	1	1	2	3	3
	Likely	1	1	2	3	4
	Possible	1	2	2	3	4
	Unlikely	1	2	3	4	4
	Rare	2	3	3	4	4
Every incident assessed against the Severity Assessment Code Matrix should be scored separately for both their actual and potential consequence or outcome						

6.3 Appendix C – Sample letter informing CE of issues that may involve individual performance

DATE

INSERT NAME

INSERT FACILITY

INSERT ADDRESS

Dear [Insert Name]

I am writing to advise you that the RCA Team appointed on *[Insert date]* to investigate the Clinical incident *[insert the incident management system ID]*, has identified that the incident raises issues that may relate to individual conduct.

The RCA Team is of the opinion that the incident raises matters that may involve *(Please delete which ever of the following is not relevant)*.

- professional misconduct or unsatisfactory professional conduct
(mandatory reporting requirement)

or

- a person suffering from an impairment
(mandatory reporting requirement)

or

- unsatisfactory professional performance
(discretionary reporting)

The above concerns of the RCA Team relate to *[insert name of the staff member who is of concern]*. In brief the matter of concern is *[Insert a brief outline of the matter of concern]*.

The matter is referred to you in accordance with the terms of section 200 of the *Health Administration Act 1982* for appropriate action.

The RCA Team will continue to investigate the systems issues related to the incident. /
The RCA Team will now conclude its investigation of this incident. *(Please delete whichever is not relevant)*.

Yours Sincerely

Signature

Name

Designation

RCA Team Leader

6.4 Appendix D – Reportable Incident Definition under *Section 20L of the Health Administration Act 1982*

Under the provisions of Division 6C of Part 2 of the *Health Administration Act 1982* when a “reportable incident” involving a relevant Health Services organisation is reported to the Chief Executive of the organisation, the organisation is to appoint a root cause analysis team in relation to the reportable incident.

The Ministry of Health and *Health Administration Regulation 2005* has determined that “Reportable Incident” is defined as follows.

A “Reportable Incident” involves:

- (1) The incident must have had “serious clinical consequences” (as defined below) and the probability of recurrence must fall into one of categories (i) to (iv) listed below; OR
- (2) The incident must have had “major clinical consequences” (as defined below) and the probability of recurrence must fall into one of categories (i) to (ii) listed below.

Under section 20M of the Act, an RCA is required to be conducted once the incident has been reported to the Chief Executive.

The Chief Executive should be notified via a Reportable Incident Brief in accordance with this Policy.

“Serious Clinical Consequence”

An incident with “serious clinical consequence” is one that involves:

- The death of a patient unrelated to the natural course of the illness and differing from the immediate expected outcome of the patient management
- Suspected suicide of a person (including an inpatient or community patient) who has received care or treatment for a mental illness from the relevant Health Services organisation where the death occurs within 7 days of the person’s last contact with the organisation or where there are reasonable clinical grounds to suspect a connection between the death and the care or treatment provided by the organisation
- Suspected homicide committed by a person who has received care or treatment for mental illness from the relevant Health Services organisation within six months of the person’s last contact with the organisation or where there are reasonable clinical grounds to suspect a connection between the death and the care or treatment provided by the organisation
- Unexpected intra-partum stillbirth

OR

- The Sentinel Events those being:

- Procedures involving the wrong patient or body part resulting in death or major permanent loss of function
- Suspected suicide of a patient in an inpatient unit
- Retained instruments or other material after surgery requiring re-operation or further surgical procedure
- Medication error leading to the death of a patient reasonably believed to be due to incorrect administration of drugs
- Intravascular gas embolism resulting in death or neurological damage
- Haemolytic blood transfusion reaction resulting from ABO (blood group) incompatibility
- Maternal death or serious morbidity associated with labour or delivery
- Infant discharged to wrong family.

“Major Clinical Consequences”

An incident with “major clinical consequences” is one which involves a patient:

- Suffering a major permanent loss of function (sensory, motor, physiologic or psychological) unrelated to the natural course of the illness and differing from the expected outcome of patient management
- Suffering significant disfigurement as a result of the incident
- At significant risk due to being absent against medical advice/absconding
- Subjected to threatened or actual physical or verbal assault requiring external or police intervention.

Probability of Recurrence

- (i) Frequent - expectation that the incident will recur immediately or within weeks or months
- (ii) Likely - probability incident will recur more than once within 12 months
- (iii) Possible - possibility incident may recur at some time every 1 to 2 years
- (iv) Unlikely - possibility incident may recur at some time in 2 to 5 years.

6.5 Appendix E – Statutory health corporations and Affiliated health organisations

In addition to Local Health Districts the following facilities are defined as “relevant health Services organisations” subject to the RCA privilege provisions under the *Health Administration Act 1982*:

Statutory health corporations¹

- The Agency for Clinical Innovation
- Bureau of Health Information
- Clinical Excellence Commission
- Health Education and Training Institute
- The Justice Health and Forensic Mental Health Network
- NSW Kids and Families
- The Sydney Children’s Hospitals Network (Randwick and Westmead) (incorporating The Royal Alexandra Hospital for Children)

Affiliated Health Organisations

<i>Name of organisation</i>	<i>Recognised establishment or recognised service</i>
<i>Benevolent Society of New South Wales</i>	<ul style="list-style-type: none"> • Central Sydney Scarba Services • Early Intervention Program • Eastern Sydney Scarba Services • South West Sydney Scarba Services
<i>Calvary Health Care (Newcastle) Limited</i>	<ul style="list-style-type: none"> • Calvary Mater Newcastle
<i>Calvary Health Care Sydney Limited</i>	<ul style="list-style-type: none"> • Calvary Health Care Sydney
<i>Carrington Centennial Care Ltd</i>	<ul style="list-style-type: none"> • Carrington Centennial Nursing Home
<i>Catholic Healthcare Limited</i>	<ul style="list-style-type: none"> • St Vincent’s Health Service, Bathurst • Lourdes Hospital and Community Health Service (other than Holy Spirit Dubbo)
<i>Hammondcare Health and Hospitals Limited</i>	<ul style="list-style-type: none"> • Braeside Hospital, Prairiewood • Greenwich Hospital, Greenwich • Neringah Hospital, Wahroonga • Northern Beaches Palliative Care Service
<i>Karitane</i>	<ul style="list-style-type: none"> • Child and Family Health Services at Carramar, Fairfield, Liverpool and Randwick

¹Current as the date this Policy Directive was issued

<i>Mercy Care Centre, Young</i>	<ul style="list-style-type: none">• Mercy Care Centre: Young, excluding Mount St Joseph's Nursing Home
<i>Mercy Health Service Albury Limited</i>	<ul style="list-style-type: none">• Mercy Health: Albury
<i>NSW Service for the Treatment and Rehabilitation of Torture and Trauma Survivors (STARTTS)</i>	<ul style="list-style-type: none">• NSW Service for the Treatment and Rehabilitation of Torture and Trauma Survivors (STARTTS)
<i>Royal Rehabilitation Centre Sydney</i>	<ul style="list-style-type: none">• Royal Rehabilitation Centre Sydney
<i>Royal Society for the Welfare of Mothers and Babies</i>	<ul style="list-style-type: none">• Tresillian Family Care Centres at Belmore, Penrith, Willoughby and Wollstonecraft
<i>St Vincent's Hospital Sydney Limited</i>	<ul style="list-style-type: none">• Sacred Heart Health Service• St Joseph's Hospital (Auburn)• St Vincent's Hospital, Darlinghurst
<i>Stewart House</i>	<ul style="list-style-type: none">• Child health screening services at Stewart House Preventorium, Curl Curl
<i>The College of Nursing</i>	<ul style="list-style-type: none">• Nursing Education Programs conducted under agreement with the NSW Department of Health
<i>The Uniting Church in Australia</i>	<ul style="list-style-type: none">• Lottie Stewart Hospital• War Memorial Hospital (Waverley)

6.6 Appendix F – Appointment of RCA Team

In accordance with *Part 2, Division 6C of the Health Administration Act 1982*

I, (insert name of Chief Executive) in accordance with section 20M of the *Health Administration Act 1982*, do hereby appoint the following persons to a Root Cause Analysis Team:

Insert name, title, background, employing organisation (team leader)

Insert name, title, background, employing organisation (team member)

Insert name, title, background, employing organisation (team member)

Insert name, title, background, employing organisation (team member)

Insert name, title, background, employing organisation (team member)

to consider and determine the root causes and contributing factors for the Clinical incident
(*insert the incident management system incident ID*)

[insert summary of incident (include date)]

and to prepare a report of the root cause analysis in accordance with section 20O of the *Health Administration Act 1982*.

A root cause analysis conducted in accordance with this appointment shall be privileged in accordance with the terms of Part 2, Division 6C of the *Health Administration Act 1982*.

(signed)

(name of CE)

(date)

6.7 Appendix G – Letter to RCA Team Member

DATE

INSERT NAME
INSERT FACILITY
INSERT ADDRESS

Dear (Insert Name)

I am writing to you to advise that in accordance with Division 6C of the *Health Administration Act 1982* and the *NSW Health Incident Management Policy*, you have been appointed to an RCA team to determine the root cause and contributing factors for the Clinical SAC 1 reportable incident (*insert the incident management system ID*), as set out in the attached appointment document.

You have been selected as a member of this team because your expertise and experience is essential to the review of this incident.

The work of the RCA team will be privileged in accordance with the *Health Administration Act*. This has a number of implications, of which you should be aware:

1. Restrictions on disclosure of information

You are required to maintain confidentiality in relation to your work as a member of this team, and you must not make your own record or discuss the investigation with anyone who is not part of the team, except for the purposes of exercising the function or any recommendation of an RCA team or for the purposes of preparing a report on the RCA.

2. Statutory Privilege

The internal workings of RCA Teams appointed under the *Health Administration Act* are *privileged*. This means:

- Members of the team cannot be compelled to give evidence about information obtained by them as part of their work on the RCA Team
- Members of the team cannot be compelled to produce to court, papers created or communications (written or verbal) made for the dominant purpose of the RCA Team carrying out its functions
- The final RCA report prepared by the RCA Team cannot be adduced or admitted as evidence in any proceedings (including coronial proceedings, or any proceedings in which it is claimed a procedure or practice was careless or inadequate)
- Members of the team are protected from personal liability, including actions for defamation, provided they act in good faith as a part of the RCA Team function.

Team members should be aware there are limits to the privilege:

- The privilege will **not** apply to pre-existing documents such as a notification in the incident management system, or medical records or other records created for general care or management reasons
- The privilege does not prevent release of the final report outside the organisation, to the patient or family of the patient.

3. Concerns or complaints about an individual clinician not to be investigated

The RCA Team does not have any authority to investigate concerns or complaints about an individual clinician. Under the terms of the *Health Administration Act*, where the RCA Team considers the reportable incident *may* involve professional misconduct or unsatisfactory professional performance or possible impairment issues the team **must** notify the CE in writing.

The RCA Team may, at its discretion, notify the CE if an incident may involve unsatisfactory professional performance.

Following notification to the CE the team will take no further action on the individual matter.

4. Requirements for the Final RCA Report

The final report must contain:

- the incident management system incident number
- the MoH RIB number
- a description of the incident
- causation statements outlining root causes, where root causes have been determined
- recommendations for change and improvement where appropriate and
- monitoring processes for follow-up of recommended actions.

The final report is to be submitted to the CE on the (*insert date*)

Thank you for your participation in this important patient safety activity.

Yours sincerely

Signature

Name

Designation

6.8 Appendix H – Appointment of Core RCA Team Members

In accordance with Part 2, Division 6C of the *Health Administration Act 1982*

I, (insert name of Chief Executive) in accordance with section 20M of the *Health Administration Act 1982*, do hereby appoint the following person/s to a Root Cause Analysis Team:

Insert name, title, background, employing organisation (Team leader)

Insert name, title, background, employing organisation (Team member)

to consider and determine the root causes and contributing factors for the Clinical incident
(*insert the incident management system incident ID*)

[insert summary of incident (include date)]

and to prepare a report of the root cause analysis in accordance with section 20O of the *Health Administration Act 1982*.

The Root Cause Analysis Team member/s listed above shall form the core personnel of the team, and may commence work immediately gathering material relevant to the discharge of the RCA Team's statutory functions under the *Health Administration Act*. I intend to appoint additional members to the RCA Team to assist it in its work as soon as further individuals with appropriate expertise and/or experience have been identified.

A root cause analysis conducted in accordance with this appointment, including any activities carried out by the core RCA Team members appointed by this instrument in carrying out their statutory functions, shall be privileged in accordance with the terms of Part 2, Division 6C of the *Health Administration Act 1982*.

(signed)

(name of CE)

(date)

6.9 Appendix I – Appointment of Additional Member to RCA Team

On [insert date] in accordance with Part 2, Division 6C of the *Health Administration Act 1982*, I appointed core members of an RCA Team to consider and determine the root causes and contributing factors for the Clinical incident [insert the incident management system incident ID].

A copy of the original instrument of appointment is **attached** and marked “A”.

Having regard to the nature of the incident and the appropriate expertise and/or experience required by the RCA Team in order to properly carry out its statutory functions, in accordance with section 20M of the *Health Administration Act 1982*. I have determined to appoint the following additional members to that RCA Team:

Insert name, title, background, employing organisation (team member)

Insert name, title, background, employing organisation (team member)

Insert name, title, background, employing organisation (team member)

Insert name, title, background, employing organisation (team member)

and to prepare a report of the root cause analysis in accordance with section 20O of the *Health Administration Act 1982*.

A root cause analysis conducted in accordance with this appointment shall be privileged in accordance with the terms of Part 2, Division 6C of the *Health Administration Act 1982*.

(signed)

(name of CE)

(date)

6.10 Appendix J – Notification of staff involved in incident

DATE

INSERT NAME
INSERT FACILITY
INSERT ADDRESS

Dear [insert name]

Following the recent reporting of incident number xxx in the Incident Information Management System and in accordance with the *Health Administration Act 1982* and the NSW Health Incident Management Policy, the [insert name] Local Health District Chief Executive has appointed a Root Cause Analysis (RCA) Team. The team will review systems and processes surrounding the incident to determine the root cause and factors contributing to the clinical incident [provide a brief description of the incident]. Because of your knowledge of this incident, a member of the RCA Team may contact you to arrange a suitable time to discuss the circumstances of the incident from your perspective. You are entitled to have a support person with you during the interview should you so wish.

The *Health Administration Act 1982* outlines specific restrictions on and responsibilities of RCA Teams. These include

1. Restrictions on disclosure of information

Members of the Root Cause Analysis Team are required to maintain confidentiality in relation to this investigation. They must not make their own records or discuss the investigation with anyone who is not part of the team, except for the purposes of the RCA Team or for the purposes of preparing a report on the RCA.

2. Statutory Privilege

The internal workings of RCA Teams appointed under the *Health Administration Act* are *privileged*. This means:

- RCA Team members cannot be compelled to produce or give evidence of any document created by or on behalf of, at the request of, the RCA Team, where the document was for the dominant purpose of the conduct of the investigation by the RCA Team
- Any document that you prepare, or any communication (written or verbal) that you make, that is for the dominant purpose of assisting with the conduct of the investigation by the RCA Team cannot be produced before any court, tribunal or other person

- The final RCA report prepared by the RCA Team cannot be adduced or admitted as evidence in any proceedings (including coronial proceedings, or any proceedings in which it is claimed a procedure or practice was careless or inadequate)
- RCA Team members acting in good faith for the purposes of the exercise of the RCA Team's function are also protected from personal liability, including actions for defamation.

There are limits to the privilege:

- The privilege will **not** apply to pre-existing documents such incident management system notification classification, or medical records or other records created for general care or management reasons
- The privilege does not prevent release of the final Report outside the organisation, to the patient or family of the patient.

For further information, refer to the provisions of Part 2, Division 6C of the *Health Administration Act* 1982 at <http://www0.health.nsw.gov.au/aboutus/legal/legal.asp>

3. Concerns or complaints about an individual clinician not to be investigated

The RCA Team does not have any authority to investigate concerns or complaints about an individual clinician. Under the terms of the *Health Administration Act*, where the RCA Team considers the reportable incident *may* involve professional misconduct or unsatisfactory professional conduct or possible impairment issues the team **must** notify the Chief Executive in writing.

The RCA Team may, at its discretion, notify the Chief Executive in writing if an incident may involve an unsatisfactory professional performance.

Once the CE has been notified the team will take no further action on the individual matter.

If you wish to discuss this matter, further please feel free to contact

insert name, title and contact number

Thank you for your participation in this important patient safety activity.

Yours sincerely

Signature
Name
Designation

6.11 Appendix K – The Five Rules of Causation

*Adapted from David Marx and the Veterans Affairs National Center for Patient Safety

The five rules of causation are designed to improve the analysis and documentation of causal issues within the RCA process

- **Rule 1 - Causal Statements must clearly show the "cause and effect" relationship.**

When describing why an event has occurred, you should show the link between your root cause and the bad outcome. Focus on showing the link from your root cause to the undesirable patient outcome you are investigating.

Example:

- **Incorrect:** The established rostering practices in the surgical unit were inappropriate
 - **Correct:** The established rostering practices in the surgical unit led to the resident's fatigue which increased the likelihood that he submitted a test request for the incorrect patient via the electronic system.
- **Rule 2 – Use specific and accurate descriptors for what occurred, avoiding negative or vague words**

To force clear cause and effect expressions (and avoid inflammatory statements), avoid the use of vague or negative words that can be replaced by a more accurate, clear description. Even words like "carelessness" and "complacency" are bad choices because they are broad, negative judgments that do little to describe the actual conditions or behaviours that led to the mishap.

Example:

- **Incorrect:** Poorly trained nurse
 - **Correct:** The level of the nurse's training increased the likelihood that she misunderstood the IV pump controls which led to missing steps in the programming of the dose and rate. This resulted in the patient receiving a rapid infusion of the drug and his cardiac arrest.
- **Rule 3 – Identify the preceding cause(s), not the human error**

Most of our mishaps involve at least one human error. Unfortunately, the discovery that a human has erred does little to aid the prevention process. You must investigate to determine WHY the human error occurred. It can be a system-induced error (e.g., step not included in medical procedure) or an at-risk behaviour (doing task by memory, instead of a checklist). **For every human error in your causal chain, you must have a corresponding cause.** It is the cause of the error, not the error itself, which leads us to productive prevention strategies.

Example

- **Incorrect:** The registrar did not review the discharge summary
- **Correct:** The absence of replacement medical staff to cover registrars on sick leave led to the registrar being rushed and taking short cuts resulting in the patient being discharged with the wrong discharge summary. This resulted in the GP continuing the wrong dose of anticoagulant therapy and the patient's gastro-intestinal bleed.

- **Rule 4 - Each procedural deviation must have a preceding cause.**

Procedural violations are like errors in that they are not directly manageable. Instead, it is the cause of the procedural violation that we can manage. If a clinician is violating a procedure because it is the local norm, we will have to address the incentives that created the norm.

Example

- **Incorrect:** The pharmacy technician did not follow the correct dispensing procedure
- **Correct:** The absence of an orientation programme led to the pharmacy technician being unaware of the practice of routine checking by two persons which resulted in the incorrect dispensing of the medication. This led to the provision of the wrong strength of solution resulting in the respiratory arrest of the child.

- **Rule 5 - Failure to act is only causal when there was a pre-existing duty to act.**

The duty to act may arise from standards and guidelines for practice; or other duties to provide patient care. We need to find out why this mishap occurred in our system as it is designed today. For instance, a doctor's failure to prescribe a cardiac medication after an infarct can only be causal if he was required by established guidelines to do so.

Example

- **Incorrect:** The Visiting Medical Officer (VMO) did not review the patient after surgery
- **Correct:** The absence of a requirement for VMOs to review patient's after they have undergone a surgical procedure led to the patient not being attended by a specialist for 10 days which contributed to the delay in recognition of the patient's deterioration and her subsequent death.

6.12 Appendix L – Final RCA Report

Health District / Network			
Final RCA Report			
Reference Numbers (where applicable)			
MoH RIB No:		IIMS No:	
LHD TRIM No:		LHD File No:	
RCA No:		LHD RIB No:	
Incident Details			
Date of Incident:		__ / __ / __	
Date of Incident Notification in IIMS:		__ / __ / __	
Reporting Details			
Staff member/s responsible for feedback to staff (include position)			
Staff member/s responsible for feedback to patient/support person (include position)			
By when?			
Final RCA report signed off by RCA Team on:		__ / __ / __	
Date report due to CE:		__ / __ / __	
Date signed by CE:		__ / __ / __	
Date due to be submitted to NSW Ministry of Health:		__ / __ / __	
Date submitted to NSW Ministry of Health		__ / __ / __	
Date submitted to NSW Ministry of Health:		__ / __ / __	
Notification of decommissioning of RCA			
RCA decommissioned:		YES / NO (please select)	
Reason for decommissioning:			
If the RCA has been decommissioned has an investigation been undertaken on the systems issues:		YES / NO (please select)	
Comments			
Referral to other committees/agencies			
Health Care Complaints Commission	<input type="checkbox"/>	Coroner	<input type="checkbox"/>
Other	<input type="checkbox"/>		
If 'Other' please specify:			
Contact Details			
LHD / SHN			
Contact Person:			
Telephone Number:			
Email Address:			

Final RCA Report

Description of incident that was investigated

(this is a concise chronological account of what happened to the patient)

Summary of RCA Team findings and recommendations

The following summary provides an analysis of the event, any contributing factors and what the team is recommending to prevent a similar occurrence in the future.

On investigation, the RCA Team found...

Following the investigation, the RCA team (Please select the appropriate box/boxes)

☐ was unable to identify any root causes or contributory factors

☐ was unable to identify any gaps in service delivery

☐ identified systems improvement opportunities unrelated to the root causes / contributing factors.

For Internal use only:

<input type="text"/>	Attached in TRIM	<input type="text"/>	Date
<input type="text"/>	Copied to the CEC	<input type="text"/>	Date
<input type="text"/>	Filed	<input type="text"/>	File No.

Table 1 – Root Cause / Contributing Factors Table (a requirement when causes have been identified)

Documentation of causation statements is a legislative requirement. All causation statements must comply with the Rules of Causation. Each root cause displayed must be addressed in the action plan.

Describe the root cause and categorise the cause or contributing factor according to the triage cards and flip chart definitions.

Item No.	Description (of Root Cause / Contributory factor)	Category (described in the Checklist Flip Chart for Root cause Analysis Teams)						
		Communication	Knowledge, skills and competence	Work environment / scheduling	Patient factors	Equipment	Policies / procedures	Safety Mechanisms
1								
2								
3								
4								
5								

Table 2 – RCA Team Recommendations (a requirement when causes have been identified)

Causation statement number ¹	Recommendation/s Description of action to be taken	Risk Classification. Eliminate, Control Accept ²	Position of person responsible for implementation Recommendation/s	Outcome measure	Completion date e.g. 3 months = 22/02/06	Management Concurrent Y/N
1						
2						
3						
4						
5						

¹ The number here relates to the numbered causation statement in **Table 1 ROOT CAUSE / CONTRIBUTING FACTORS TABLE**

² Actions can be classified as eliminating, controlling or accepting the risk. If accepting the risk, risk minimisation strategies need to be in place. Weaker actions are those that accept the risk and include redundancy/double checks, warnings and labels, new procedures and policies, new memorandums, training in absence of knowledge deficit and additional study/ analysis. Medium actions are those taken to control the risk and include checklists and cognitive aids, increased staffing, decreased workload, use of read backs, eliminating look-alikes and sound alike and eliminating or reducing distractions. Stronger actions are those taken to eliminate the risk and include simplified processes that remove unnecessary steps, standardise equipment, processes or care plans.

Table 3 – Systems improvement opportunities unrelated to root causes or contributing factors (modification of these issues would not have helped to prevent the event)

Item No	Description	Recommendation	Position of person responsible for implementation Recommendation/s	Outcome measure	Completion date e.g. 3 months = 22/02/06	Management Concurrence Y/N
1						
2						
3						
4						
5						

RCA Report Final Sign Off

The recommendation/s from the Root Cause Analysis of the incident are endorsed/not endorsed.

Name	Title	Signature	Date
[CE / Service Director]			
Name			
Name			
Name			

I, _____ from _____

endorse /endorse with the following provisions/ do not endorse¹⁰ the recommendations of this RCA.

(Signature)

Chief Executive / Service Director

Date

¹⁰ If not endorsed, please provide reasons and document revised action.

Policy Directive



Ministry of Health, NSW
 73 Miller Street North Sydney NSW 2060
 Locked Mail Bag 961 North Sydney NSW 2059
 Telephone (02) 9391 9000 Fax (02) 9391 9101
<http://www.health.nsw.gov.au/policies/>

Lookback Policy

Document Number PD2007_075

Publication date 28-Sep-2007

Functional Sub group Clinical/ Patient Services - Governance and Service Delivery
 Clinical/ Patient Services - Incident management
 Population Health - Infection Control

Summary The policy is to ensure a consistent, coordinated and timely approach for notification and management of potentially/affected patients when necessary.

Replaces Doc. No. Lookback [PD2006_070]

Author Branch Clinical Excellence Commission

Branch contact Clinical Excellence Commission

Applies to Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations, Affiliated Health Organisations - Declared, Public Health System Support Division, Community Health Centres, Dental Schools and Clinics, Government Medical Officers, NSW Ambulance Service, Public Health Units, Public Hospitals

Audience All staff, including managers, clinicians

Distributed to Public Health System, Community Health Centres, Dental Schools and Clinics, Divisions of General Practice, Environmental Health Officers of Local Councils, Government Medical Officers, Health Associations Unions, Health Professional Associations and Related Organisations, NSW Ambulance Service, Ministry of Health, Public Health Units, Public Hospitals, Private Hospitals and Day Procedure Centres, Private Nursing Homes, Tertiary Education Institutes

Review date 30-Dec-2016

Policy Manual Not applicable

File No. 06/3861

Status Active

Director-General

This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is **mandatory** for NSW Health and is a condition of subsidy for public health organisations.

Lookback Policy

Document Number PD2007_075

Publication date 28-Sep-2007

Functional Sub group Clinical/ Patient Services - Governance and Service Delivery
Clinical/ Patient Services - Incident management
Population Health - Infection Control

Summary The policy is to ensure a consistent, coordinated and timely approach for notification and management of potentially/affected patients when necessary.

Replaces Doc. No. Lookback [PD2006_070]

Author Branch Clinical Excellence Commission

Branch contact Clinical Excellence Commission

Applies to Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations, Affiliated Health Organisations - Declared, Public Health System Support Division, Community Health Centres, Dental Schools and Clinics, Government Medical Officers, NSW Ambulance Service, Public Health Units, Public Hospitals

Audience All staff, including managers, clinicians

Distributed to Public Health System, Community Health Centres, Dental Schools and Clinics, Divisions of General Practice, Environmental Health Officers of Local Councils, Government Medical Officers, Health Associations Unions, Health Professional Associations and Related Organisations, NSW Ambulance Service, Ministry of Health, Public Health Units, Public Hospitals, Private Hospitals and Day Procedure Centres, Private Nursing Homes, Tertiary Education Institutes

Review date 28-Sep-2012

Policy Manual Not applicable

File No. 06/3861

Status Active

Director-General

This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is **mandatory** for NSW Health and is a condition of subsidy for public health organisations.

LOOKBACK

POLICY

TABLE OF CONTENTS

1) INTRODUCTION	3
2) OBJECTIVES	3
3) ROLES AND RESPONSIBILITIES	4
3.1 THE DEPARTMENT IS RESPONSIBLE FOR:	4
3.2 CHIEF EXECUTIVE IS RESPONSIBLE FOR:	4
3.3 DIRECTOR OF CLINICAL GOVERNANCE IS RESPONSIBLE FOR:	4
3.4 CLINICIANS ARE RESPONSIBLE FOR:	4
4) STEPS	5
4.1 STEP 1-IMMEDIATE ACTION	5
4.2 STEP 2- EXPERT ADVISORY GROUP	6
4.3 STEP 3-ACTION PLAN AND IMPLEMENTATION	6
4.4 STEP 4-EVALUATION OR REVIEW OF LOOKBACK:	8
4.5 SUMMARY DIAGRAM OF STEPS	9
5) PERFORMANCE MEASURES	9
6) DEFINITIONS	10
7) FURTHER READING	11

1) Introduction

Lookback is a process that is triggered when a notification of a clinical incident or concern from any source leads to the need for the notification, investigation and the management of a group of commonly affected patients. The clinical incident may arise from complications or errors relating to diagnostics, treatment or products that patients have received.

For the management of a lookback process concerning communicable/infectious diseases, refer to PD2005_203: Infection Control Management of Reportable Incidents and/or PD2005_162: HIV, Hepatitis B or Hepatitis C - Health Care Workers Infected. The NSW Health Notifiable Diseases Manual provides guidance to Public Health Units to respond to notifications of the diagnosis of Scheduled Medical Conditions as prescribed by the Public Health Act 1991. Such conditions are therefore outside the scope of this policy.

The purpose of this policy is to ensure a consistent, coordinated and timely approach for notification and management of potentially/affected patients when necessary.

For the purpose of this policy, the term “health services” refers to Public Health Organisations and the Ambulance Service of NSW.

This policy documents the steps, including the communication strategy, that are to be undertaken by the health services when a lookback is initiated.

Health services are required to develop their own local policies and procedures, consistent with this policy, to address any potential lookback exercise.

What is a lookback?

The lookback process is triggered when a group of patients are affected by a common clinical incident that may be related to time, place, and treatment. The group of patients may have been recipients of a faulty medical device or equipment and/or inappropriate/inadequate treatment or diagnostics. The process involves:

- Identifying, tracing, communicating, and providing appropriate ongoing advice to, and/or management of, the group of patients.
- Notification to appropriate bodies involving the Department and formation of a communication strategy.
- Notification to the wider public.

2) Objectives

The objectives of this policy are to:

1. Assist the health services with the timely management of appropriate and relevant care for affected groups of patients.
2. Establish a standard approach to notification of patients, families/carers, health administrators and the public of clinical incidents involving potential injury, damage, loss or other harm to groups of patients.

Title: Lookback Policy

3. Ensure that communication with, and support for, all affected and potentially affected patients, their families and/or carers occurs in a timely manner.
4. Ensure that communication with the Minister for Health, the Director-General and the public occurs in a consistent and timely manner.
5. Ensure that the health services have established and consistent processes in place when a lookback exercise is undertaken.

3) Roles and Responsibilities

3.1 The Department is responsible for:

- Dissemination of information and notification to health services of the clinical incident or concern.
- Assisting the health services with the lookback process and coordinating communications where more than one health service is involved.
- Assisting the health services with the development and management of communication strategies.
- Allocating an executive to work with the health services at all stages of managing the lookback.

3.2 Chief Executive is responsible for:

- Initiation of the lookback process.
- Coordination with any other involved health services.
- Decisions on public notification, media management and advising the Director-General and the Minister.

3.3 Director of Clinical Governance is responsible for:

- Development and documentation of local lookback policy and procedures.
- Actioning and management of the lookback process.
- Conducting an evaluation and review as required when a lookback has been completed and reporting the results to the Health Care Quality Committee.
- To liaise with clinicians involved in the lookback.

3.4 Clinicians are responsible for:

- Liaise and act in accordance with the Director of Clinical Governance and expert group throughout the lookback.
- Apply Open Disclosure principles (Open Disclosure Policy Directive PD2007_040) when communicating with patients, families and/or carers.

Title: Lookback Policy

- Maintain records of the confirmation that the discussions of a lookback event with their affected patients have taken place.

4) Steps

The following steps are to be included in any local lookback process.

4.1 Step 1 - Immediate Action

Identify the members of an Area Team to form a steering group; lead by a member of the Area Executive that includes the Director of Clinical Governance, and the local public relations/media unit. A relevant Director, or delegate from the Department will be allocated to work with the Area Team at all stages of the lookback.

Within 24 hours of recognition of the triggering event, the steering group is to decide on the immediate responses that include:

- Undertaking a risk assessment to determine the immediate facts and nature of the risk to patients /carers.
- Addressing and managing issues of notification to the Department via a RIB in accordance with PD2007_061 Incident Management Policy and recorded in the IIMS.

This information contained within the RIB is to include:

- 1) Urgency
 - 2) Need for Department notification
 - 3) Determining who has been affected
 - 4) Process for determining risks
- Agree on the formation of an Expert Advisory Group comprising experts in the area of concern, relevant clinicians, and department/directorate heads to devise and implement a detailed patient action plan.
 - Agree on a media and patient communications management plan. The aim is to be proactive in public disclosure whilst managing the manner in which affected patients receive the information and how media questions will be answered.

Communications management

Full public disclosure following the principles outlined in PD2007_040 Open Disclosure Policy should be the guiding principle for communications management throughout the lookback process and should ideally occur as soon as possible following the discovery of the triggering event and include:

- Being open with information as it arises from the lookback.
- Ongoing liaison with the media throughout the lookback process.

Title: Lookback Policy

- Preliminary notification being made public where a situation requires additional time for the discovery of accurate information to be provided to patients and the wider public.

Media management

The health service media unit is the primary point of contact for news organisations and requests for interviews or information should be directed through the unit.

The lead member of the Area Team should ensure that the health service media unit advises the Department Media Unit at the earliest possible time. The health service and Department Media Unit are to develop and collaborate on a communication strategy for the media and the general public at all stages of managing the lookback.

The health service media staff will:

- Nominate a spokesperson for public and media communications.
- Determine key messages.
- Minimise the delay in response to the public and the media
- Develop questions and answers in advance
- Work with the Area Team to develop a strategy for notification of external organisations such as appropriate medical colleges and any other affected organisations. It is appropriate that the Area Team in accordance with advice from the Department and health service media units conduct such notification.

4.2 Step 2 - Expert Advisory Group

An expert advisory group is to be convened as soon as possible and at the latest within 5 calendar days of the triggering event to advise on a detailed action plan with timeframes. Close communication with the Director of Clinical Governance must be maintained until all action is complete.

If there is no risk to patients, the lookback process is complete. The expert advisory group will communicate this to the Director of Clinical Governance. In these circumstances, the near miss should prompt the organisation to review and investigate issues associated with the event to ensure future patient safety.

4.3 Step 3 - Action Plan and Implementation

Identifying and tracing affected patients, families and/or carers

The health services are responsible for the identification and tracing of the affected patients and must allocate appropriate resources to ensure that this is undertaken.

Patient communication and support

The expert advisory group should provide advice to the Director of Clinical Governance in determining the person/s best suited to communicating sensitive news with affected

Title: Lookback Policy

patients their families and/or carers. The health service should document the details of actions according to local policy and procedure.

Strategies in communication and support for patients should include:

- Identifying immediate and ongoing management needs of patients their families and/or carers.
- Ensuring that patients understand the processes for ongoing management and have written advice/fact sheets concerning this.
- Ensure that relevant fact sheets containing information on the lookback are published on the health service inter/intranet website.
- Ensuring adequate resources are in place to provide the level of service required.

All information should be given in accordance with the PD2007_040 Open Disclosure Policy and privacy principles PD2005_593 Privacy Manual (Version 2) – NSW Health. Initial communication should be direct, either face-to-face or via telephone, where the patient must be given the opportunity to ask questions.

The following should be included in the patient communication and support plan:

- A designated point of contact for patients their families and/or carers.
- Regular and ongoing information updates provided to patients their families and/or carers.
- Affected patients are offered a written apology by the health service.
- Establishment of a toll free telephone hotline for patients and families/carers to ask any questions and to obtain information.
- Affected patients who need additional consultation have these appointments expedited to allay any anxieties or concerns that they may have.

Patients their families and/or carers should not incur any cost from any additional consultations required:

- Provision of follow-up at no cost to patients their families and/or carers.
- The health services offer to pay for any additional consultation (eg General Practitioners or Specialists Medical Practitioners) for affected patients, arising out of the lookback.
- Affected patients who have had to pay for additional consultations are reimbursed for these expenses.

Group meetings should not be undertaken for reasons of confidentiality of patient information and protection to the privacy of those involved. Every attempt should be made to inform all patients involved at approximately the same time and, where possible, in advance of any media attention of the issue.

Title: Lookback Policy

The health service is to form teams consisting of counsellors and mental health clinicians to offer/provide counselling and psychological support to all affected patients their families and/or carers. Appointing an independent body to conduct counselling services during the lookback process should be considered.

Staff communication and support

A communication and support plan should be devised for staff. This should include communication and support for:

- All staff who are managing the lookback process.
- All staff working in the area of concern.
- All other staff that may be affected.

Record keeping

The health service is to maintain records of the confirmation by treating clinicians that the discussion of a lookback event with their affected patients has taken place.

4.4 Step 4 - Evaluation or Review of Lookback:

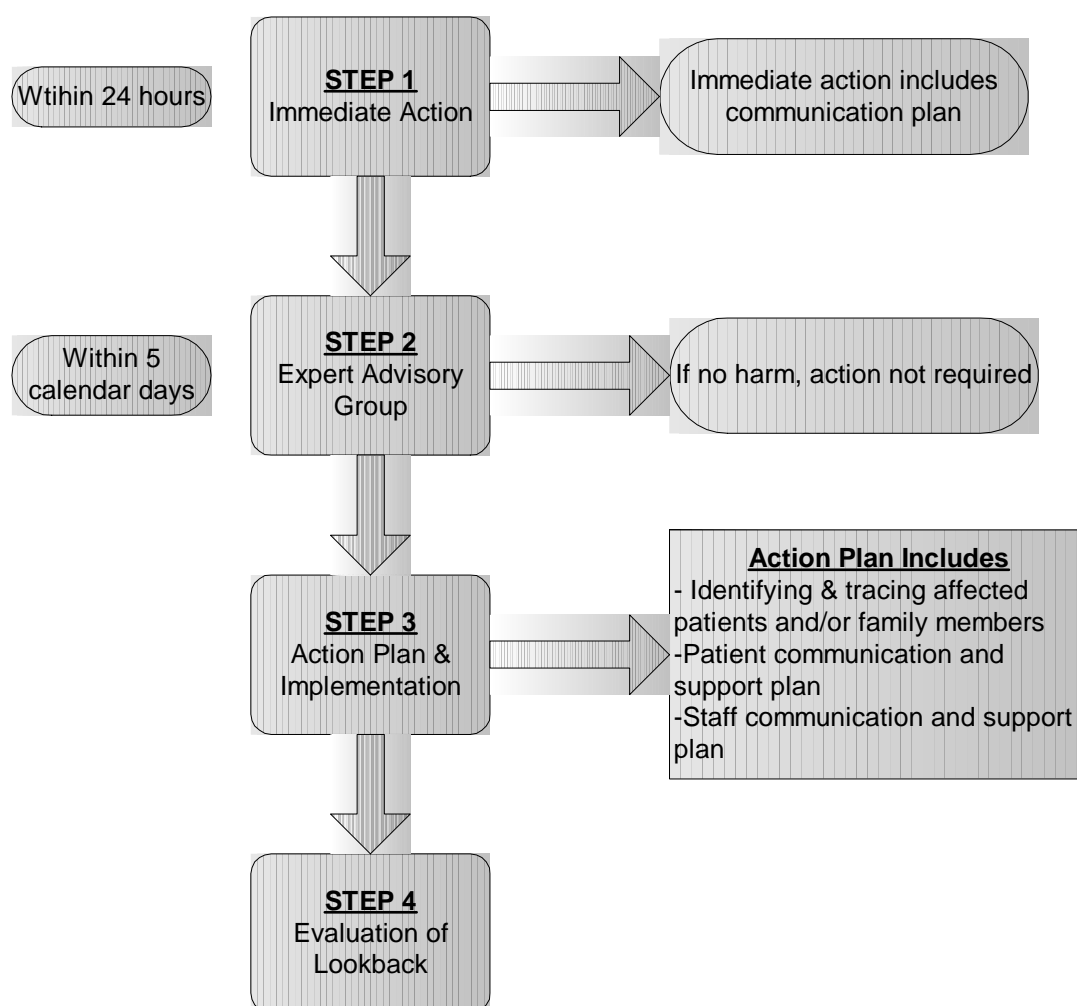
Directors of Clinical Governance are required to evaluate the management of the lookback to assess the efficiency and effectiveness of the process. Key measures should be assessed and strategies for further improvement should be implemented and reported to the Chief Executive as required.

Directors of Clinical Governance are to:

- Implement strategies to prevent this or similar events from recurring.
- Communicate lessons learned from the lookback process to the Department and other health services.

Evaluation reports, including performance measures, are to be reported to the Health Care Quality Committee.

4.5 Summary Diagram of Steps:



5) Performance Measures

The following process performance measure is to be developed and reported to the Chief Executive by the health service.

- Documented local policies and procedures consistent with this policy are in place in each health service.

Key measures showing compliance with this policy must be reported as part of the lookback evaluation.

- All patients who are of immediate risk to be contacted within 2 weeks
- Patients are to be contacted within 2 months of the triggering event, in the event that further information/investigations are required to evaluate risk to patients and such risk is eventually detected.

6) Definitions

Ambulance Service of NSW

The Ambulance Service of NSW as defined in the Health Services Act 1997.

Area Health Services

Organisations constituted under the Health Services Act 1997 that are principally concerned with the provision of health services to residents within a designated geographic area.

Clinician

A health practitioner or health service provider regardless of whether the person is registered under a health registration act.

Department

NSW Department of Health.

Health Services

For the purposes of this policy the term "health services" refers to Public Health Organisations including Area Health Services and the Ambulance Service of NSW.

IIMS

The NSW Health Incident Information Management System (IIMS). This system incorporates the Advanced Incident Management System (AIMS) software application as its underlying database.

Lookback Process

The lookback process is triggered when a group of patients are affected by a common clinical incident that may be related to time, place, and treatment. The group of patients may have been recipients of a faulty medical device or equipment and/or inappropriate/inadequate treatment or diagnostics. The process involves:

- Identifying, tracing, communicating, and providing appropriate ongoing advice to, and/or management of, the group of patients.
- Notification to appropriate bodies involving the Department and formation of a communication strategy.
- Notification to the wider public.

Near Miss

Any event that could have had adverse consequences but did not and is indistinguishable from an actual incident in all but outcome. A near miss is further categorised as:

- Actual harm with no adverse outcome: an incident occurred and ran to completion but resulted in no harm.
- Arrested or interrupted sequence: the incident was intercepted prior to causing harm.

Title: Lookback Policy

- Hazardous event or circumstances: the incident involved a dangerous state or the possibility of harm occurring.

Open Disclosure

The process of providing an open, consistent approach to communicating with the patient and their support person following a patient related incident. This includes expressing regret for what has happened, keeping the patient informed, and providing feedback on investigations, including the steps taken to prevent a similar incident occurring in the future. It is also about providing any information arising from the incident or its investigation relevant to changing systems of care in order to improve patient safety.

Public Health Organisations (PHO)

This term refers to an area health service, statutory health corporation or an affiliated health organisation in respect of its recognised establishments and recognised services as defined in the Health Services Act 1997.

For the purposes of this policy, the relevant statutory health corporations and affiliated health organisations are set out in Appendix B of PD2007_061 Incident Management Policy.

Reportable Incident

An incident identified according to PD2007_061 Incident Management Policy that requires direct notification to the Department under existing legislative reporting requirements or Departmental policy directive.

7) Further Reading

GL2007_007: Open Disclosure Guideline

http://www.health.nsw.gov.au/policies/gl/2007/pdf/GL2007_007.pdf

PD2005_162: HIV, Hepatitis B or Hepatitis C- Health Care Workers Infected

http://www.health.nsw.gov.au/policies/PD/2005/pdf/PD2005_162.pdf

PD2005_203: Infection Control Management of Reportable Incidents

http://www.health.nsw.gov.au/policies/PD/2005/pdf/PD2005_203.pdf

PD2005_593: Privacy Manual (Version 2) – NSW Health

http://www.health.nsw.gov.au/policies/pd/2005/pdf/PD2005_593.pdf

PD2006_007: Complaints or Concern about a Clinician

http://www.health.nsw.gov.au/policies/pd/2006/pdf/PD2006_007.pdf

PD2006_014: Notification of Infectious Diseases under the Public Health Act 1991

http://www.health.nsw.gov.au/policies/pd/2006/pdf/PD2006_014.pdf

PD2007_061: Incident Management Policy

http://www.health.nsw.gov.au/policies/pd/2007/PD2007_061.html

PD2007_036: Infection Control Policy

http://www.health.nsw.gov.au/policies/pd/2007/pdf/PD2007_036.pdf

Title: Lookback Policy

PD2007_040: Open Disclosure Policy

http://www.health.nsw.gov.au/policies/pd/2007/pdf/PD2007_040.pdf

NSW Clinical Governance Directions Statement

<http://www.health.nsw.gov.au/quality/clingov/pdf/cgudirstat.pdf>

NSW Notifiable Diseases Manual

<http://www.health.nsw.gov.au/infect/diseases.html>

Professor Debora Picone AM
Director-General

Policy Directive



Ministry of Health, NSW
 73 Miller Street North Sydney NSW 2060
 Locked Mail Bag 961 North Sydney NSW 2059
 Telephone (02) 9391 9000 Fax (02) 9391 9101
<http://www.health.nsw.gov.au/policies/>

Complaint or Concern about a Clinician - Principles for Action

Document Number PD2006_007

Publication date 30-Jan-2006

Functional Sub group Clinical/ Patient Services - Incident management
 Clinical/ Patient Services - Governance and Service Delivery
 Personnel/Workforce - Conduct and ethics
 Personnel/Workforce - Occupational Health & Safety

Summary The policy describes the principles for managing complaints or concern regarding all clinicians and outlines the roles and responsibilities for ensuring all complaints or concerns are managed by the PHO, and outlines the legislative responsibility for doing so.

Replaces Doc. No. Complaint or Concern About a Clinician - Management [PD2005_610]

Author Branch Workplace Relations

Branch contact Workplace Relations 9391 9360

Applies to Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations, Community Health Centres, Dental Schools and Clinics, Government Medical Officers, NSW Ambulance Service, Ministry of Health, Public Hospitals

Audience Administration, all clinical staff

Distributed to Public Health System, Community Health Centres, Dental Schools and Clinics, Divisions of General Practice, Government Medical Officers, Health Associations Unions, Health Professional Associations and Related Organisations, NSW Ambulance Service, Ministry of Health, Public Health Units, Public Hospitals, Tertiary Education Institutes

Review date 30-Jun-2016

Policy Manual Not applicable

File No. 05/4484-1

Status Active

Director-General

This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is **mandatory** for NSW Health and is a condition of subsidy for public health organisations.

Complaint or Concern about a Clinician - Principles for Action

Document Number PD2006_007

Publication date 30-Jan-2006

Functional Sub group Clinical/ Patient Services - Incident management
Clinical/ Patient Services - Governance and Service Delivery
Personnel/Workforce - Conduct and ethics
Personnel/Workforce - Occupational Health & Safety

Summary The policy describes the principles for managing complaints or concern regarding all clinicians and outlines the roles and responsibilities for ensuring all complaints or concerns are managed by the PHO, and outlines the legislative responsibility for doing so.

Replaces Doc. No. Complaint or Concern About a Clinician - Management [PD2005_610]

Author Branch Workplace Relations

Branch contact Workplace Relations 9391 9360

Applies to Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations, Community Health Centres, Dental Schools and Clinics, Government Medical Officers, NSW Ambulance Service, Ministry of Health, Public Hospitals

Audience Administration, all clinical staff

Distributed to Public Health System, Community Health Centres, Dental Schools and Clinics, Divisions of General Practice, Government Medical Officers, Health Associations Unions, Health Professional Associations and Related Organisations, NSW Ambulance Service, Ministry of Health, Public Health Units, Public Hospitals, Tertiary Education Institutes

Review date 30-Jan-2011

Policy Manual Not applicable

File No. 05/4484-1

Status Active

Director-General

This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is **mandatory** for NSW Health and is a condition of subsidy for public health organisations.

**COMPLAINT OR CONCERN ABOUT A CLINICIAN
PRINCIPLES FOR ACTION**

CONTENTS

1	INTRODUCTION	3
1.1	Purpose	3
1.2	Rationale	3
1.3	Scope	3
1.4	Background	4
2	Coverage of this Policy	4
3	ROLES AND RESPONSIBILITIES	5
3.1	The Responsibility of the Chief Executive	5
3.2	The Responsibility of the Director of Clinical Governance	5
4	Legislative Requirement to Act on Clinician Performance Issues	6
5	The Role of Codes of Conduct	6
6	General Principles	7
7	Definitions	10

1. INTRODUCTION

1.1 Purpose

The purpose of this Policy Directive is to establish a set of principles, which must be addressed when managing a complaint or concern about a clinician. A **clinician is defined** as a health practitioner or health service provider (whether or not the person is registered under a Health Registration Act).

This Policy Directive and any associated policies are applicable to all clinicians working in the NSW health system, whether employed or contracted.

The Policy Directive should be read in conjunction with the *Complaint or Concern about a Clinician - Management Guidelines GL2006_002*, which set out a framework that Public Health Organisations can adopt and adapt at a local level. The Guidelines describe how to address the complaint or concern, while ensuring that the interests of the organisation, the public and the needs of the professional are met.

The Policy Directive and Guidelines are part of a suite of documents relating to Complaints Handling across the NSW health system. Section 2 provides guidance on the appropriate policy to pursue, depending on the nature of complaint or concern.

Compliance with this policy is mandatory.

1.2 Rationale

Management of complaints or concerns about clinicians is an important component of improving patient safety and clinical quality within a health service.

Management of a complaint or concern includes a number of steps to ensure that any immediate risks identified are managed appropriately, and effective action is taken to provide safe and appropriate care and maintain community confidence.

1.3 Scope

This Policy Directive applies to all concerns or complaints about a clinician that occur within the NSW Public Health System while recognising that other policies may be relevant to the particular complaint (see section 2). The Directive:

- Establishes the Principles which must be complied with when dealing with a complaint or concern and;
- Describes when a matter must be reported to a health registration board under the Health Services Act (1997).

1.4 Background

The NSW Department of Health produced a Guideline on The Management of a Complaint or Concern about a Clinician in 2001. The guideline was developed in collaboration with the NSW Medical Board, the NSW Department of Health, the Health Care Complaints Commission (HCCC), the NSW Council on Quality in Health Care, the Wentworth Area Health Service and the Hunter Area Health Service Clinical Governance Unit.

The guideline has been reviewed, revised and updated into two documents, A Policy Directive establishing **mandatory Principles for Action** and a Guideline establishing a *Framework for Management*, to recognise and support the following initiatives:

1. Amendments to the Health Services Act (1997), which require Chief Executives (CE) to report professional misconduct or unsatisfactory professional conduct of visiting practitioners and employees to their relevant registration board;
2. The *NSW Patient Safety and Clinical Quality Program* (PD2005_608), establishment of Clinical Governance Units in Area Health Services (AHS) and other Public Health Organisations (PHO), and the Incident Management System and,
3. Policies relating to the Appointment of Visiting Practitioners and Staff Specialists, (PD2005_496 & PD2005_500), Delineation of Privileges for Visiting Practitioners and Staff Specialists (PD2005_497) and the Performance Review of Visiting Practitioners (PD2005_498).

2. Coverage of this Policy

As noted above, this Policy Directive and the Framework form part of a suite of complaints and accountability policies operating in NSW Health. When a complaint or concern arises, managers must consider whether action is required in accordance with this and/or other policies, as follows:

- If the complaint involves system related incidents it should be managed in accordance with the Incident Management Policy (PD2005_604);
- Disciplinary matters should be managed in accordance with A Framework for Managing the Disciplinary Process in NSW Health (PD2005_225);
- Grievances should be managed in accordance with Effective Grievance Resolution: Policy & Better Practice (PD2005_584);
- Child related complaints should be managed in accordance with Part 3A of the Ombudsman's Act 1974, Policy and Guidelines for the Development of Protected Disclosures Procedures in Health Services (PD2005_135), and Protecting Children and Young People (PD2005_299), noting the specific reporting and investigation requirements outlined in these policies;

- Harassment matters should be managed in accordance with Joint management and Employee Association Policy Statement on Bullying, Harassment and Discrimination (PD2005_223)
- Possible corrupt conduct should be managed in accordance with Reporting Possible Corrupt Conduct to the Independent Commission Against Corruption (PD2005_173).

In regard to criminal matters, health services are required to review all complaints or allegations against employees as to whether a criminal offence is involved.

3. ROLES AND RESPONSIBILITIES

3.1 The Responsibility of the Chief Executive

The Chief Executive (CE) of the Area Health Service (AHS) or other Public Health Organisation (PHO) has a primary obligation to ensure complaints and concerns are acted upon, by way of investigation and, where necessary, appropriate action to implement findings.

The CE is responsible for reporting to registration boards in accordance with the provisions of the Health Services Act (1997) any conduct of a visiting practitioner (or employee) that the CE suspects on reasonable grounds may constitute professional misconduct or unsatisfactory professional conduct under the Health Registration Act by which the registration authority is constituted.

The CE is also responsible for ensuring that recommendations resulting from the management of complaints or concerns are considered by the appropriate forum, and acted upon where appropriate.

The CE is responsible for notifying the Director-General and relevant external agencies where a complaint against a clinician concerns a serious criminal matter, professional misconduct, unsatisfactory professional conduct or inappropriate child related conduct.

3.2 The Responsibility of the Director of Clinical Governance

The Area Health Service Directors of Clinical Governance (DCG) takes the overarching responsibility to ensure the system for managing complaints about clinicians is in place, and functions effectively.

The DCG should be notified of all complaints via appropriate organisational reporting structures, and agree on the proposed steps to manage the complaint.

All Clinical Governance Units are required to have an identified Designated Senior Complaints Officer. The Designated Senior Complaints Officer or their delegate must be contactable 24 hours a day, 7 days a week.

The Director of Clinical Governance is responsible for ensuring the appropriate process for managing complaints or concerns is understood, and followed by the organisation.

4. Legislative Requirement to Act on Clinician Performance Issues

The CE is responsible for reporting to registration boards in accordance with the provisions of the Health Services Act (1997) any conduct of a visiting practitioner (or employee) that the CE suspects on reasonable grounds may constitute professional misconduct or unsatisfactory professional conduct under the Health Registration Act by which the registration authority is constituted.

Refer to the list of Acts included in Section 7 Definitions of this Policy Directive.¹

5. The Role of Codes of Conduct

All Area Health Service and other PHO staff and contractors are expected to behave and practise in a manner consistent with the NSW Health Code of Conduct (PD2005-626).

A number of professional groups have Codes of Conduct that set out minimum standards of behaviour and practice for that professional group. All clinicians are expected to behave and practise in a manner consistent with their respective Codes of Conduct.

For professional groups where there is no registration board (such as for Occupational Therapists and Social Workers), the NSW Health Code of Conduct serves as a reference to expected standards of behaviour and is important in managing complaints or concerns regarding those professional groups.

The following **NSW Health Professional Registration Boards have binding codes** of Professional Conduct made pursuant to health professional legislation:

- NSW Medical Board: Code of Professional Conduct, Good Medical Practice – Duties of a Doctor Registered with the NSW Medical Board 2005;
- NSW Podiatrists Registration Board: Code of Professional Conduct 2000;
- NSW Psychologists Registration Board: Code of Professional Conduct 2004;
- NSW Chiropractors Registration Board: Code of Professional Conduct 2004;

¹ Health Services Act 1997 at <http://www.legislation.nsw.gov.au> (accessed 12/12/2005)

- NSW Optometrists Registration Board: Code of Professional Conduct 2005;
- NSW Osteopaths Registration Board: Code of Professional Conduct 2004

Although **the following are non-binding codes** of professional conduct under the legislation, these codes are instructive of expected standards of practice and behaviour in the professions to which they relate.

- NSW Dental Technicians Board: Guidelines for Professional Practice;
- NSW Nurses and Midwives Board endorse the Australian Nursing Council: Code of Professional Conduct for Nurses in Australia 2003 (Applicable to all Nurses and Midwives);
- Australian Physiotherapy Association: Code of Conduct 2001 (Applicable to all Physiotherapists who are members of the APA);
- The Society of Hospital Pharmacists of Australia: Code of Ethics 1996 (applicable to all Pharmacists who are members of the SHPA);
- Pharmaceutical Society of Australia: Code of Professional Conduct;
- OT Australia: Code of Ethics 2001 (A guide for all Occupational Therapists);
- Australian Association of Social Workers: AASW Code of Ethics, 2nd Edition, 2002 (Applicable to all members of the AASW);
- Australian institute of Radiography: Code of Ethics 2002;
- Dietitians Association of Australia's (DAA) Code of Professional Conduct and Code of Ethics 2001.

6. General Principles

Certain general principles apply to the management of a complaint or concern about a clinician regardless of the severity or nature of action to be taken. The nature of the complaint or issue may dictate how these principles are given effect and so a degree of flexibility in the approach taken to manage the complaint/concern may be required.

These general principles are:

- **Notification.** Notification of the complaint or concern may initially be verbal or written. Anyone can notify a complaint or concern. All verbal complaints must subsequently be documented, either by the person making the notification or by the person receiving the complaint. Any

matter (whether notified as a complaint or not) involving patient harm (or a near miss) will be entered into the Incident Information Management System (IIMS);

- **Reporting.** Anyone who has a concern or receives a complaint must report this to a supervisor, or the Area Designated Senior Complaints Officer. It is the responsibility of all staff to be vigilant in identifying and raising a complaint or concern about colleagues whose health, conduct or performance is a risk patient safety, to the organisation, or others;
- **Health and safety of patients.** The primary concern in managing complaints or concerns about a clinician is the health and safety of patients. Any risk to the safety of patients must be removed or managed as the first step in the management of a complaint or concern about a clinician.
- **Responsibility for action. It is the responsibility of management to act on complaints or concerns about clinicians.** The AHS or other PHO must actively manage the complaint or concern, and cannot defer this obligation to a registration board or the Health Care Complaints Commission. If a registration board takes emergency suspension action, or uses its emergency powers to place conditions on the clinicians' practice, then the AHS or other PHO will need to respond to address the external restrictions.
- **The decision to immediately suspend , to alter clinical privileges, or provide alternative non-clinical duties,** is at the discretion of the CE in consultation with the clinician's clinical director. The reasons for taking action, or for electing not to take action should be clearly documented; A decision to take administrative action in relation to a clinician as a result of an initial risk assessment should in no way be an indication of the guilt or misconduct of an employee.
- **Appropriate investigation** of all complaints (including apparently frivolous, vexatious and trivial complaints) must be undertaken;
- **Risk management.** Complaints and concerns should be investigated at the earliest stages, to reduce the risk of adverse outcomes;
- **Fairness.** Investigations are to be conducted in a fair, impartial and appropriate manner, having regard to the circumstances of the complaint or concern including;
 - providing the clinician with information about the issues under review or investigation at the appropriate time;
 - giving the clinician a fair hearing and an opportunity to respond to all allegations;
 - ensuring decisions are made by an unbiased or impartial decision maker; and,

- ensuring decisions are based on material that is relevant to the case;
- know who the complainant is unless the complaint is made under Protected disclosures.

The complainant has:

- the right to have their complaint taken seriously;
 - the right to have their complaint properly investigated;
 - the right to be given feedback on the outcome of the investigation.
- **Standards.** The standards against which judgments are to be made, or are being made, must be made explicit. In general, this will be the standard reasonably expected of a clinician of an equivalent level of training and experience, at the time of service. Standards to be applied may be legislative, professional or sources in NSW Health policy obligations;
 - **Privacy and Confidentiality.** Details of the matter should be disclosed only on a “need to know” basis, recognising any obligation to report information to other bodies, for example professional registration boards; Privacy legislation and Department privacy requirements need to be considered in the management of a complaint or concern about a clinician. All information in respect of complaints is to be treated as private and confidential
 - **Independence and Impartiality.** Conflicts of interest should be avoided wherever possible, and where unavoidable, must be disclosed. There should be no relationship between the investigator and the clinician being investigated or other significant party, which could reasonably be perceived to bias the investigation. For example, a competing clinician in the same small town or specialty, or a peer in the same clinical unit, or a friend of the clinician, or anyone who may gain a pecuniary or other benefit from a decision;
 - **Support person.** If the investigation of the matter involves an interview with the clinician, he or she is entitled to be accompanied by a support person (for example, a professional association representative). The support person does not have input into the investigation interview and must sign a confidentiality agreement.
 - **Impairment of a clinician where there is a registration board.** At any level of investigation, inquiries may uncover impairment as a major contributor to performance concerns. If this is the case the matter should also be referred to the appropriate registration board for action under their procedures for dealing with impaired registrants;
 - **Impairment of clinician where there is no registration board.** Where there is no relevant registration board, eg for social workers and

occupational therapists, the relevant professional association may still be able to assist in a review or investigation, or may wish to revoke professional membership, and should therefore be informed in lieu of a registration body;

- **Statutory obligations.** These principles do not negate any statutory obligations in relation to reporting, investigating or otherwise dealing with a matter;
- **External agency involvement.** Where the matter has required the notification and /or involvement of an external body, for example Police, appropriate ongoing liaison with that body should occur to ensure that both the PHO and the external body's requirements and obligations are satisfactorily met and the management of the complaint or concern by either party is not compromised.
- **Provision of information.** All relevant parties in the process should be informed of the outcome;
- **Complaints or concerns that are withdrawn** should still be investigated, and managed according to the findings;
- **Referral of issues to the relevant body for consideration.** For example where following an investigation, it is considered that a medical practitioner's clinical privileges should be reviewed, a recommendation should be made to the Medical and Dental Appointments Advisory Committee for such a review;
- **Appropriate outcomes.** Outcomes must be supported by the findings of the review or investigation and be proportionate with any identified areas of poor practice or conduct;
- **Records** are to be kept and the outcome documented. The **Director of Clinical Governance** is to report individual and/or trend information to the Chief Executive of the organisation. Where a decision is made not to take action in response to a complaint or concern, this decision, and the rationale for not proceeding must be documented.

7. Definitions

Area Health Services (AHS) - provide the operational framework for the provision of public health services in NSW. They are constituted under the Health Services Act 1997 and are principally concerned with the provision of health services to residents within the geographic area covered by that health service.

Clinician – a health practitioner or health service provider regardless of whether the person is registered under a Health Registration Act.

Clinical Governance Unit (CGU) - Established within each Area Health Service to oversee the implementation of the NSW Patient Safety and Clinical Quality Program.

Complaint - includes any expression of dissatisfaction by a complainant that may have one or more associated issues.

Concern – feedback regarding any aspect of service where the person does not make a complaint, but that identifies issues requiring investigation².

Department – The NSW Department of Health

Health Registration Act – includes any of the Acts listed below

- Chiropractors Act 2001
- Dental Technicians Registration Act (1975)
- Dental Practice Act (2001)
- Medical Practice Act (1992)
- Nurses and Midwives Act (1991)
- Optical Dispensers Act (1963)
- Optometrists Act (2002)
- Osteopaths Act (2001)
- Pharmacy Act (1964)
- Physiotherapists Act (2001)
- Podiatrists Act (1989) & Podiatrists Act (2003) uncommenced
- Psychologists Act (2001) No 69

Health Service – includes:

- Medical, hospital and nursing services
- Dental services
- Psychiatric and psychological services
- Pharmaceutical services
- Ambulance services
- Community health services

² Based on Western Australian Complaint Management Policy, Information Series No.6, Western Australia Department of Health, 2001

- Health education services
- Services provided by podiatrists, chiropractors, osteopaths, optometrists, physiotherapists, acupuncturists, occupational therapists, speech pathologists, audiologists, audiometrists, radiographers, social workers, nutritionists and dieticians, orthoptists, environmental and public health professionals, prosthetists and therapeutic counsellors
- Services provided in other allied or alternative health care fields
- Welfare services necessary to implement any services referred to above

Impairment means a person suffers from any physical or mental impairment, disability, condition or disorder, which detrimentally affects or is likely to detrimentally affect the person's physical or mental capacity to practise.

Line manager – the manager to whom an individual reports.

Performance – refers to the knowledge and skill possessed and applied by the clinician in the course of their duties. Performance is also influenced by experience, application and attitude.

Public Health Organisation (PHO) - refers to a statutory health corporation or an affiliated health organisation in respect of its recognised establishments and recognised services as defined in the Health Services Act (1997) and the Ambulance Service of NSW.

Guideline



Department of Health, NSW
 73 Miller Street North Sydney NSW 2060
 Locked Mail Bag 961 North Sydney NSW 2059
 Telephone (02) 9391 9000 Fax (02) 9391 9101
<http://www.health.nsw.gov.au/policies/>

Complaint or Concern about a Clinician - Management Guidelines

Document Number GL2006_002

Publication date 30-Jan-2006

Functional Sub group Clinical/ Patient Services - Governance and Service Delivery
 Clinical/ Patient Services - Incident management
 Personnel/Workforce - Conduct and ethics
 Personnel/Workforce - Industrial and Employee Relations

Summary The guideline sets out an operational framework for the use of public health organisations when dealing with a complaint or concern about an individual clinician and guides for the process for implementing the NSW Health Policy Directive Complaint or Concern about a Clinician - Principles for Action (PD2006_007).

Replaces Doc. No. Complaint or Concern About a Clinician - Management [PD2005_610]

Author Branch Clinical Safety, Quality and Governance

Branch contact Quality and Safety Branch 9391 9200

Applies to Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations, Community Health Centres, Dental Schools and Clinics, NSW Ambulance Service, NSW Dept of Health, Public Hospitals

Audience Administration, all clinical staff

Distributed to Public Health System, Community Health Centres, Dental Schools and Clinics, Divisions of General Practice, Government Medical Officers, Health Associations Unions, Health Professional Associations and Related Organisations, NSW Ambulance Service, NSW Department of Health, Public Health Units, Public Hospitals, Tertiary Education Institutes

Review date 30-Sep-2011

Policy Manual Not applicable

File No. 05/4484-1

Status Active

COMPLAINT OR CONCERN ABOUT A CLINICIAN – MANAGEMENT GUIDELINES

CONTENTS

1	PURPOSE	3
2	STEPS IN MANAGING A COMPLAINT OR CONCERN.....	3
2.1	Identification.....	3
2.2	Notification	3
2.3	Investigation	4
2.3.1	Skills required to investigate a Complaint or Concern	6
2.3.2	Possible Findings of the Investigation.....	7
2.4	ACTIONS	8
2.4.1	Action in response to identified performance issues	8
2.4.2	Action on other issues (such as conduct, corrupt behaviour).....	9
2.4.3	Systems issues	9
2.4.4	No further action	9
3	REPORTING REQUIREMENTS	9
3.1	Area Health Service requirements.....	9
3.2	Reporting to other external bodies.....	10
3.2.1	Obligation to report to Police.....	10
4	DEFINITIONS	10
APPENDIX 1: MANAGING THE COMPLAINT OR CONCERN PROCESS		12
APPENDIX 2: SEVERITY RATINGS AND SUMMARY OF ACTIONS AND RESPONSIBILITIES		13
APPENDIX 3: EXAMPLES OF SEVERITY OF COMPLAINTS OR CONCERNS.....		14
APPENDIX 4: LEGISLATION AND OTHER DOCUMENTS RELEVANT TO THIS GUIDELINE		16
APPENDIX 5 NSW DEPARTMENT OF HEALTH DOCUMENTS AND POLICY DIRECTIVES		17
APPENDIX 6 USEFUL WEBSITES FOR PROFESSIONAL STANDARDS AND CODES OF CONDUCT		18
APPENDIX 7 OTHER RESOURCE MATERIALS		19

COMPLAINT OR CONCERN ABOUT A CLINICIAN –MANAGEMENT GUIDELINES

1. PURPOSE

These Guidelines set out an operational framework when dealing with a complaint or concern about an individual clinician and guide the process for implementing the NSW Health Complaint or Concern about a Clinician Policy Directive – Principles for Action (PD2006_007)

All Area Health Services and other Public Health Organisations are required to have appropriate local policies in place to ensure consistency with these guidelines.

2. STEPS IN MANAGING A COMPLAINT OR CONCERN

2.1 Identification

Complaints or Concerns regarding clinicians may be identified via a number of mechanisms including:

- receipt of a complaint from a patient, family member, or person external to the NSW health system;
- complaints or concerns raised by other clinicians or staff within the NSW health system;
- Coronial Inquiries or Health Care Complaints Commission (HCCC) investigations;
- during normal performance review processes in accordance with NSW Health policy directives;
- during the investigation of an incident (under the Incident Management Policy PD2005_604); and,
- during routine peer reviews.

At any stage during the process of managing a complaint or concern, it may be possible to identify cases of suspected professional misconduct or suspected unsatisfactory professional conduct (see definition of unsatisfactory professional conduct and professional misconduct under section 3.1) or cases of impairment, poor performance or behaviour or systems issues.

2.2 Notification

All complaints or concerns regarding individuals should be notified in the first instance to the relevant line manager.

The **line manager** is responsible for gathering sufficient information to ensure that an informed judgement can be made regarding the severity of the complaint. Where the complaint or concern relates to the line manager, or where there is a perceived lack of impartiality by the line manager, the next senior manager should be informed and undertake this role.

Title: Complaint Or Concern About A Clinician – Management Guidelines

Where possible, **senior management** of the organisation (for example the **Director of Nursing** or the **Director of Clinical Services**) are responsible for the management of complaints or concerns about a clinician.

The senior management then notifies the **Director of Clinical Operations** (DCO) who in turn informs the Chief Executive (CE) and the Director of Clinical Governance (DCG) of the complaint or concern.

If the complainant prefers not to approach local management or perceives a response to be unsatisfactory, the **Designated Senior Complaints Officer** is also available for receiving complaints.

Part 3A of the Ombudsman Act 1974 requires certain allegations involving children to be reported to the Ombudsman irrespective of whether an investigation reveals inappropriate conduct. Where a complaint involves conduct regarding a Child that is under the age of 18 at the time of the incident, the NSW Health Policy Directive concerning the management of criminal and child related allegations should be consulted.

The Director-General is to be notified via a Reportable Incident Brief where a complaint relates to a matter of suspected professional misconduct or suspected unsatisfactory professional conduct.

2.3 Investigation

When managing complaints or concerns, local health facilities should have regard to both the NSW Health Code of Conduct and the relevant professional Code of Conduct. The behaviour of all clinicians must be assessed against the NSW Health Code of Conduct (PD2005_626) where applicable to the complaint being managed.

The following sequence of events is a model for the development of local procedures:

1. All complaints and concerns are graded according to their severity to assist in determining appropriate action. Refer to Appendix 2 for a summary of required actions.
2. Undertake a risk assessment to determine immediate actions to minimise risk to patients and/or staff and others.
3. Assess the complaint to determine the nature of the complaint or concern in order to decide how to proceed, including the appropriate process to be followed (ie child protection, grievance policy, disciplinary matter, protected disclosure, etc as referred to in the Policy Directive Complaint or Concern about a Clinician – Principles for action PD2006_007).
4. The AHS or other Public Health Organisation must identify who is responsible for ensuring appropriate communication occurs with the clinician at all stages of the process. Meetings with the clinician should occur as necessary and appropriate throughout the investigation process, to gather information, provide information on findings and to allow the clinician the opportunity to discuss and respond to findings.

Title: Complaint Or Concern About A Clinician – Management Guidelines

5. The AHS or other Public Health Organisation should liaise with the relevant registration board and/or HCCC to ensure the organisation's investigation does not impact adversely on registration board / HCCC investigations.
6. Assign responsibility for investigation of the complaint or concern. To ensure an investigation is free from any actual or perceived bias and any conclusions drawn are based on an objective analysis of the evidence, it may be necessary to obtain an independent expert opinion on the issues under investigation, or to have the investigation conducted by an independent third party. This may be particularly important in rural or highly specialised clinical areas. The independent expert opinion needs to be free of conflict of interest, and not be a colleague of the clinician under investigation.
7. Advise clinician of the complaint, including the nature of the complaint, and the process of investigation. Assess whether the situation warrants standing down the clinician pending the investigation. If the clinician is stood down the relevant registration board or other authority is to be advised at this time.
8. Advise the complainant (if any) of the proposed process for managing the complaint.
9. Obtain information relevant to the complaint or concern from all appropriate sources including other clinicians or staff members and the notifier/complainant to clarify scope of complaint. Information collected will vary depending on the nature of the concern raised and according to the nature and severity of the complaint. Information collected may include: statements from, or interviews with, relevant parties including people receiving a health service and their relatives; site inspection; record review; clinical practice or indicator data; variation reports; clinical reviews; relevant policy / clinical standards, physical evidence and other relevant material.
10. Identify and analyse the issues arising from the complaint/initial notification or from information collected.
11. Advise the clinician when all of the relevant information has been collected and analysed. The AHS or other PHO should provide the clinician with enough information to allow the clinician to fully respond to the allegation/s. The clinician is offered the opportunity to make a submission on the proposed action.
12. Recommendations provided to the CE must be based on the findings, and be consistent with Patient Expectations as outlined in the NSW Patient Safety and Clinical Quality Program, principles of clinical and corporate governance and professional standards.
13. The CE reviews the appropriateness of the recommendations and authorises their implementation.
14. The clinician is informed of the outcome.
15. The complainant (if any) must be informed of the outcome of the investigation.

Title: Complaint Or Concern About A Clinician – Management Guidelines

16. The investigation should be concluded expeditiously. It is recommended that all investigations be completed within 60 days. Where it is anticipated that the investigation is likely to take more than 60 days to complete, the DCG should be provided with an investigation plan including setting out investigation milestones, action required and timeframes, to allow the DCG to follow up and monitor the investigation process. The complainant should also be advised of the revised timeframe.

2.3.1 Skills required to investigate a Complaint or Concern

Investigation of complaints requires special skills. A person allocated by the AHS or other PHO to undertake an investigation of a complaint or concern needs to:

- be impartial. The investigation should not be undertaken by anyone who stands to benefit by finding fault, or by not finding fault;
- have demonstrated skills in gathering information, managing timelines and negotiating with people;
- be ethical when eliciting information from any person involved in a complaint;
- ensure fair participation of all parties involved in a complaint;
- maintain confidentiality;
- be able to identify and acknowledge concerns;
- have good knowledge and understanding of relevant NSW Health Policy Directives;
- show understanding through listening and questioning skills;
- use appropriate language and terminology;
- be able to use conflict resolution strategies;
- be accessible, well organised and consistent;²
- have good analytical skills.

AHS and other PHOs should have sufficient people trained to undertake investigations. Resource documents for undertaking investigations are listed in Appendix 7.

² Complaints Management Handbook for Health Care Services 2004, Department of Health & Ageing, Commonwealth of Australia, 2004

2.3.2 Possible Findings of the Investigation

The investigation of the complaint or concern will lead to one or more of the following findings:

1. **Identification that professional misconduct or unsatisfactory professional conduct may have occurred.** These cases **must** be reported by the CE to the relevant registration board in accordance with the Health Services Act (1997); they should also be notified to the Director of Clinical Operations and any other relevant member of the Senior Executive: the Director-General must be notified via a Reportable Incident Brief (RIB)

Unsatisfactory professional conduct is defined in broadly similar terms in all Health Registration Acts, and may include the following:

- any conduct that demonstrates a significant lack of knowledge, skill, judgment or care, by the practitioner in the practice (of their profession);
- contravention of the relevant Act or Regulations;
- contravention of conditions of registration;
- criminal convictions and criminal findings;
- accepting a benefit for a recommendation of a health product;
- offering a benefit for a referral or recommendation;
- accepting a benefit for a referral or recommendation to a health service provider;
- failure to disclose a pecuniary interest in giving a referral or recommendation;
- engaging in overservicing;
- permitting an assistant to attend, treat, or perform operations on patients in matters requiring professional discretion or skill;
- assisting unregistered practitioners;
- failing to render urgent attention;
- other improper or unethical conduct.

Professional misconduct is defined in similar terms in the Health Registration Acts as unsatisfactory professional conduct of a sufficiently serious nature to justify suspension of the practitioner from practising (their profession) or the removal of the clinician's name from the register.¹

¹ NSW Medical Board Professional Conduct at www.nswmb.org.au; Nurses and Midwives Board at <http://www.nmb.nsw.gov.au>

Title: Complaint Or Concern About A Clinician – Management Guidelines

2. **identification of performance issues, but not sufficiently serious** to warrant reporting to a health professional registration board. In such cases, further action may be required eg skills development, referral to the registration board for management under performance assessment provisions, or local performance monitoring or review;
3. **identification of behaviour issues**, such as not turning up for scheduled work, or not being available while on call, these cases should be managed through performance review and ongoing monitoring;
4. **impairment**, in such cases the matter should be referred to the appropriate registration board for action under their procedures for dealing with impaired registrants. Where there is no relevant registration board, eg for social workers and occupational therapists, the relevant professional association may still be able to assist in a review or investigation, or may wish to revoke professional membership, and should therefore be informed in lieu of a registration body;
5. **identification of systems issues**, these should be managed in accordance with the incident management process
6. **no identification of individual performance or system issues**, findings need to be documented.

2.4 ACTIONS

All cases where there are reasonable grounds to suspect the conduct of a particular health professional may involve professional misconduct or unsatisfactory professional conduct **must** be notified to the CE of the AHS or other Public Health Organisation as soon as they are identified.

Sections 99A and 117A of the Health Services Act (1997) **requires the CE to notify the relevant registration board** of “any conduct of a visiting practitioner (or employee) that the chief executive officer suspects on reasonable grounds may constitute professional misconduct or unsatisfactory professional conduct under the Health Registration Act by which the registration authority is constituted.”

2.4.1 Action in response to identified performance issues

Where performance issues are identified, the organisation has an obligation to act in accordance with routine performance management processes. Appropriate actions may include:

- counselling;
- reskilling or limiting practice;
- requiring the clinician to attend courses (eg on anger management or communication);
- ensuring the clinician adheres to their employment contract, and taking appropriate action in accordance with AHS or other PHO Human Resource Management processes if the clinician refuses to comply.

Title: Complaint Or Concern About A Clinician – Management Guidelines

The relevant industrial award, relevant registration board requirements where applicable, and the appropriate NSW Department of Health Policy Directives and Guidelines guide the performance management of all clinicians. A list of these is included in Appendix 4 and 5.

2.4.2 Action on other issues (such as conduct, corrupt behaviour)

Other issues of significance that may be identified should be managed in accordance with other relevant NSW Health Policy Directives and Guidelines, as follows:

- disciplinary matters should be managed in accordance with A Framework for Managing the Disciplinary Process in NSW Health (PD2005_225);
- grievances should be managed in accordance with Effective Grievance Resolution: Policy & Better Practice (PD2005_584);
- child related complaints should be managed in accordance with Part 3A of the Ombudsman Act 1974 and relevant NSW Health policies, Policy and Guidelines for the Development of Protected Disclosures Procedures in Health Services (PD2005_135), and Protecting Children and Young People (PD2005_299), noting the specific reporting and investigation requirements outlined in these policies;
- harassment matters should be managed in accordance with Joint Management and Employee Association Policy Statement on Bullying, Harassment and Discrimination (PD2005_223);
- possible corrupt conduct should be managed in accordance with Reporting Possible Corrupt Conduct to the Independent Commission Against Corruption (PD2005_173).

Relevant NSW Department of Health Policy Directives and Guidelines are listed in Appendix 5.

2.4.3 Systems issues

If the investigation reveals that systems issues rather than individual performance issues are the basis for the complaint or concern then the issue is managed in accordance with the Incident Management Policy (PD2005_604).

2.4.4 No further action

This needs to be appropriately documented.

3. REPORTING REQUIREMENTS

3.1 Area Health Service requirements

The DCG should be advised of the findings and outcome of the investigation, and how, if required, the clinical risk will be managed (for example, whether the matter is to be referred to the credentialing subcommittee, or any other remedial action).

The DCG needs to develop systems for the reporting of the outcomes of all complaints or concerns periodically to the senior executive.

Title: Complaint Or Concern About A Clinician – Management Guidelines

3.2 Reporting to other external bodies

The complaint or concern may identify issues that require mandatory reporting under existing legislative reporting requirements or departmental policy directives. Please see the Incident Management Policy (PD2005_604).

Where a complaint or concern is also reported to an external body, appropriate liaison with that external body should occur to ensure that both agencies' requirements and obligations are satisfactorily met and each other's management of the complaint or concern is not compromised.

The AHS or other Public Health Organisation must still satisfactorily act, in accordance with this guideline, upon complaints or concerns referred to an external body.

3.2.1 Obligation to report to Police

Consideration must be given to whether a criminal offence may have occurred. All suspected criminal acts must be reported to the NSW Police Service as soon as they are identified and investigated by the health service in accordance with the NSW Health Policy Directive concerning the allegation of criminal and child related conduct.. The Department of Health Employment Screening and Review Branch is available to provide advice on any matters that may require notification to NSW police and can be contacted on (02) 9215 4777.

4. DEFINITIONS

Area Health Services (AHS) - provide the operational framework for the provision of public health services in NSW. They are constituted under the Health Services Act 1997 and are principally concerned with the provision of health services to residents within the geographic area covered by that health service.

Clinician – a health practitioner or health service provider regardless of whether the person is registered under a health registration act.

Clinical Governance Unit - Established within each Area Health Service to oversee the implementation of the NSW Patient Safety and Clinical Quality Program.

Complaint - includes any expression of dissatisfaction by a complainant that may have one or more associated issues.

Concern – feedback regarding any aspect of service where the person does not make a complaint, but that identifies issues requiring investigation²

Health Registration Act – means any of the Acts listed in Appendix 4

Health Service – includes:

- Medical, hospital and nursing services
- Dental services
- Psychiatric and psychological services

² Based on Western Australian Complaint Management Policy, Information Series No.6, Western Australia Department of Health, 2001

Title: Complaint Or Concern About A Clinician – Management Guidelines

- Pharmaceutical services
- Ambulance services
- Community health services
- Health education services
- Services provided by podiatrists, chiropractors, osteopaths, optometrists, physiotherapists, acupuncturists, occupational therapists, speech therapists, audiologists, audiometrists, radiographers, social workers, nutritionists and dieticians, orthoptists, environmental and public health professionals, prosthetists and therapeutic counsellors
- Services provided in other allied or alternative health care fields
- Welfare services necessary to implement any services referred to above

Impairment means a person suffers from any physical or mental impairment, disability, condition or disorder, which detrimentally affects or is likely to detrimentally affect the person's physical or mental capacity to practise.

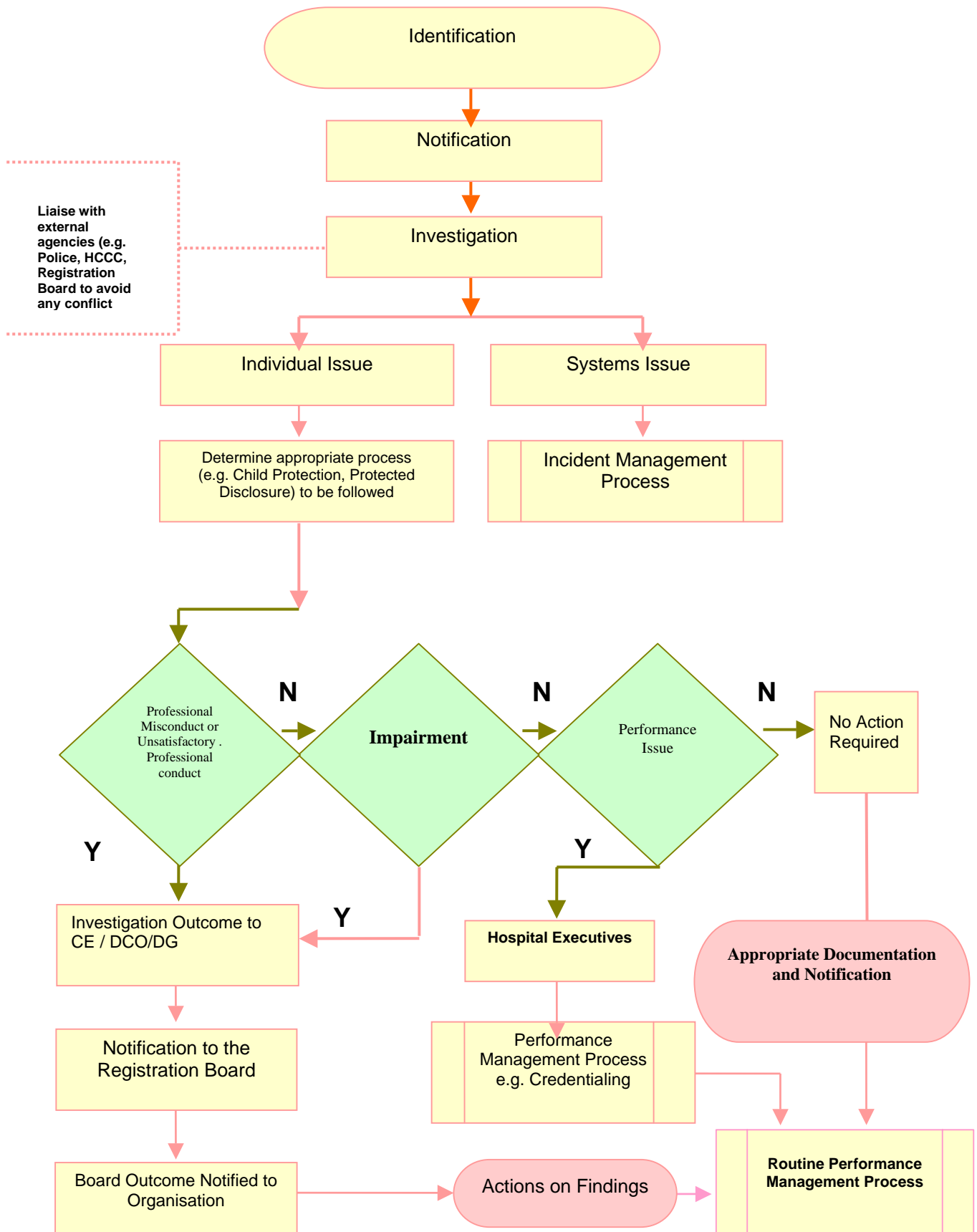
Line Manager – the manager to whom an individual reports.

Performance – refers to the knowledge and skill possessed and applied by the clinician in the course of their duties. Performance is also influenced by experience, application and attitude.

Public Health Organisation (PHO)- refers to a statutory health corporation or an affiliated health organisation in respect of its recognised establishments and recognised services as defined in the Health Services Act (1997) and the Ambulance Service of NSW as defined in the Health Services Act (1997).

APPENDIX 1: MANAGING THE COMPLAINT OR CONCERN PROCESS

Investigation of Complaint or Concern about a Clinician



APPENDIX 2: SEVERITY RATINGS AND SUMMARY OF ACTIONS AND RESPONSIBILITIES

This table guides the action of the senior person managing the complaint. The actions documented here are in addition to the suggested sequence in the Guideline see section 2. Steps in managing complaints or concerns about a clinician. A risk assessment of the issues raised in the complaint or concern should be undertaken to ensure patient safety.

Severity Rating	Severity description used to assess a complaint or concern	Actions required following risk assessment of the Complaint or Concern.
1	Very serious complaint or concern arising from one or more events involving unexpected mortality or serious morbidity, gaps in clinical performance, an external event relevant to performance (such as a criminal conviction or termination of employment in another facility) or serious concerns by colleagues about the health and safety of patients.	<ol style="list-style-type: none"> 1. Notify CE/DCG immediately. 2. Determine whether requires notification to registration board, and any other relevant authority (eg Coroner, police). 3. Consider immediate suspension of clinical privileges in cases of suspected professional misconduct 4. Consider whether variations to clinical privileges are required.
2	Significant complaint or concern, where there may be one or more events involving unexpected mortality or increasingly serious morbidity (SAC 1 or 2), and there may be a pattern of suboptimal performance or variation in clinical outcomes over a period of time.	<ol style="list-style-type: none"> 1. Notify DCG. 2. Consider whether variations to clinical privileges are required. 3. Investigate
3	Complaint or concern that the performance, practice or clinical outcome achieved by an individual clinician varies from peers or from expectations, but where there has not been any event involving unexpected mortality or serious morbidity.	<ol style="list-style-type: none"> 1. Notify DCG. 2. Management and Investigation as per AHS policy/procedure. 3. Manage outcomes in accordance with relevant policy or Award.
4	Complaint or concern appears frivolous, vexatious or trivial.	<ol style="list-style-type: none"> 1. Management and investigation as per AHS policy/procedure. 2. Continue standard performance monitoring and management. 3. Notify DCG of findings and actions

Where there are reasonable grounds to suspect the conduct of a health professional may involve professional misconduct or unsatisfactory professional conduct the CE of the AHS or other Public Health Organisation must be notified as soon as they are identified.

Sections 99A and 117A of the Health Services Act (1997) **requires the CE to notify the relevant registration board** of “any conduct of a visiting practitioner (or employee) that the chief executive officer suspects on reasonable grounds may constitute professional misconduct or unsatisfactory professional conduct under the Health Registration Act by which the registration authority is constituted.”

APPENDIX 3: EXAMPLES OF SEVERITY OF COMPLAINTS OR CONCERNS

EXAMPLES – LEVEL 1

- A surgeon operates on a patient to perform a lumpectomy, and decides to perform a mastectomy without consent. The patient complains to hospital. The CE of the organisation is informed and the NSW Medical Board is notified.
- A patient complains that she has been coerced by the hospital's Clinical Psychologist to engage in sex. The CE is informed and the NSW Psychologists Registration Board is notified. NSW Police also informed. The Psychologist is removed from a patient contact role.
- A nurse expresses concern to a supervisor that an anaesthetist has been observed leaving the operating theatre on a number of occasions during surgery, drugs have been missing from the drug cabinet and the anaesthetist is displaying erratic behaviours. The anaesthetist denies any substance abuse problem. The NSW Medical Board is notified.

EXAMPLES – LEVEL 2

- The Director of Physiotherapy becomes concerned at the high number of cases of Erb's Palsy in babies delivered by a particular obstetrician. (Erb's Palsy is caused by an injury to the nerves of the shoulder, resulting in varying degrees of paralysis. Poor management of the shoulders during the birth may cause this problem.) An investigation of the obstetrician's cases is commenced, and includes review of practice and outcomes compared with colleagues.
- The Nursing Unit Manager receives a complaint that a nurse almost gave a patient a transfusion of the wrong blood type. The complainant, a colleague, overheard the family objecting. The nurse dismisses the concerns of the family. The colleague intervened before the transfusion took place.

EXAMPLE – LEVEL 3

- A Registrar complains to the Head of Surgery that a Surgeon is performing unnecessary surgical operations, when more up-to-date techniques, such as laparoscopic techniques are available. A review of the Surgeon's cases over the preceding month is conducted.

EXAMPLE – LEVEL 4

- A patient complains that the Resident and Registrar looking after her are too young to be doctors. No complaint is made about the manner of the doctors or the care they have provided.

APPENDIX 4: LEGISLATION AND OTHER DOCUMENTS RELEVANT TO THIS GUIDELINE

Legislation: http://www.legislation.nsw.gov.au
Health Services Act (1997)
Health Care Complaints Act (1993)
Health Administration Act (1982)
Independent Commission Against Corruption Act (1988)
Protected Disclosures Act (1994)
Ombudsman Act (1974)
Privacy and Personal Information Protection Act (1998)
Health Records and Information Privacy Act (2002)
Health Profession Registration Acts:
Chiropractors Act 2001
Dental Technicians Registration Act (1975)
Dental Practice Act (2001)
Medical Practice Act (1992)
Nurses and Midwives Act (1991)
Optical Dispensers Act (1963)
Optometrists Act (2002)
Osteopaths Act (2001)
Pharmacy Act (1964)
Physiotherapists Act (2001)
Podiatrists Act (1989) & Podiatrists Act (2003) uncommenced
Psychologists Act (2001) No 69

APPENDIX 5 NSW Department of Health Documents and Policy Directives

PD2005_610	Complaint or Concern about a Clinician – Principles for Action.
GL2005_061	NSW Health Better Practice Guidelines for Frontline Complaints Handling, 1998.
PD2005_585	A Framework for Managing the Quality of Health Services in NSW, NSW Health, 1999.
GL2005_062	The Clinician's Toolkit for Improving Patient Care, NSW Health 2002
PD2005_608	NSW Patient Safety & Clinical Quality Program, 2005
PD2005_609	NSW Patient Safety & Clinical Quality Program Implementation
SHPN (QSB) 050105	NSW Clinical Governance Directions Statement, NSW Health, 2005.
PD2005_333	Model Policy for the Safe Introduction of New Interventions, 2003.
PD2005_380	Correct Patient, Correct Site, Correct Procedure Model Policy, 2004.
PD2005_500	Appointment of staff specialists, 2005.
PD2005_496	Appointment of visiting practitioners, 2005.
PD2005_497	Delineation of clinical privileges for visiting practitioners and staff specialists, 2005.
PD2005_498	Performance review of visiting practitioners, 2005.
PD2005_604	Incident Management Policy, 2005.
PD2005_225	A Framework for Managing the Disciplinary Process in NSW Health.
PD2005_568	Employee Assistance Programs: NSW Health Policy & Better Practice.
PD2005_584	Effective Workplace Grievance Resolution: Policy & Better Practice.
PD2005_574	Child Abuse Allegations – Ombudsman Amendment (Child Protection and Community Services) Act 1998.
PD2005_167	Employees Conducting Financial Transactions and/or Dealing with Money/Property for Patients/Clients.
PD2005_223	Joint management and Employee Association Policy Statement on Bullying, Harassment and Discrimination.
PD2005_469	Personnel Conduct – Managing Conflicts of Interest in the Public Health System.
PD2005_135	Policy and Guidelines for the Development of Protected Disclosures Procedures in Health Services
PD2005_593	Privacy Manual (Version 2)
PD2005_086	Recommendations of Service Providers to Patients by Staff of Health Organisations
PD2005_173	Reporting Possible Corrupt Conduct to the Independent Commission Against Corruption.
PD2005_299	Protecting Children & Young People.
PD2005_109	Procedures for Recruitment/Employment of Staff and Other Persons – Improper Conduct.
PD2005_626	Code of Conduct - NSW Health

APPENDIX 6 Useful Websites for Professional Standards and Codes of Conduct

NSW Chiropractors Registration Board	http://www.health.nsw.gov.au/hprb/chiro_web/
NSW Medical Board	www.nswmb.org.au
NSW Nurses and Midwives Registration Board	http://www.nmb.nsw.gov.au/
NSW Optical Dispensers Licensing Board	http://www.health.nsw.gov.au/hprb/optical_web/opt_cont.html
NSW Osteopaths Registration Board	http://www.health.nsw.gov.au/hprb/osteo_web/
NSW Psychologists Registration Board	http://www.health.nsw.gov.au/hprb/psych_web/psy_cont.htm
NSW Optometrists Registration Board	http://www.health.nsw.gov.au/hprb/optom_web/
NSW Physiotherapists Registration Board	http://www.health.nsw.gov.au/hprb/physio_web/
NSW Podiatrists Registration Board	http://www.health.nsw.gov.au/hprb/pod_web/
Australian Association of Social Workers	www.aasw.ans.au
Society of Hospital Pharmacists	www.shpa.org.au/docs/practicestandards.html
OT Australia	www.otnsw.com.au
Pharmaceutical Society of Australia	www.psa.org.au/ecms
Australian Physiotherapy Association	www.physiotherapy.asn.au
Dietitians Association of Australia	http://www.daa.asn.au/
Australian Institute of Radiography	http://www.a-i-r.com.au

APPENDIX 7 Other Resource Materials

Australian Council for Safety and Quality in Health Care Commonwealth of Australia, Complaints Management Handbook for Health Care Services, July 2005

<http://www.safetyandquality.org/complntmgmthbk.pdf>

Australian Council for Safety and Quality in Health Care Commonwealth of Australia, Better Practice guidelines on complaints management for health care services

<http://www.safetyandquality.org/guidecomplnts.pdf>

ICAC Fact Finder. A 20-step guide to conducting an inquiry in your organisation, Nov 2003.

http://www.icac.nsw.gov.au/files/pdf/pub2_74cp.pdf

NSW Ombudsman, The complaint handlers toolkit, Sydney, June 2004.

NSW Ombudsman, Handling complaints, Fact Sheet, Sydney, March 2004.

<http://www.nswombudsman.nsw.gov.au/publication/PDF/factsheets/Handling%20complaints.pdf>

NSW Ombudsman, Investigating complaints: A manual for investigators, Sydney, June 2004.

NSW Ombudsman, Investigation of complaints, Fact Sheet, Sydney, 2004.

http://www.nswombudsman.nsw.gov.au/publication/PDF/factsheets/Investigation_of_Complaints.pdf

NSW Ombudsman, Natural justice / Procedural fairness, Fact Sheet, Sydney, 2004.

http://www.nswombudsman.nsw.gov.au/publication/PDF/factsheets/FS_PublicSector_14_Natural_Justice.pdf

NSW Ombudsman, Protected Disclosures, Fact Sheet, Sydney, June 2005

<http://www.nswombudsman.nsw.gov.au/publication/PDF/factsheets/Protected%20Disclosure%20Fact%20Sheet%20CEOs%20Senior%20Managers5.pdf>

NSW Ombudsman, Protection of Whistleblowers Fact Sheet, Sydney, September 2005

http://www.nswombudsman.nsw.gov.au/publication/PDF/factsheets/infosheet_prot_whistleblowers.pdf

NSW Ombudsman, Reasons for Decisions Fact Sheet, Sydney, June 2005

http://www.nswombudsman.nsw.gov.au/publication/PDF/factsheets/FS_PublicSector_18_Reasons_Decisions.pdf

Australian Council for Safety and Quality in Health Care National Patient Safety Education Framework ,Canberra, July 2005.

<http://www.safetyandquality.org/framework0705.pdf>

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

Table of Contents

Introduction

Background

Findings

Recommendations

References

Appendix A Final Consolidated Terms of Reference

Appendix B Clinical Review and Findings

B.1 Data tree — off-protocol flat dose 100 mg carboplatin

B.2 Data tree — capecitabine

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

Appendix D Summary of material provided by the Western NSW Local Health District outlining current and proposed services

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** to 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 tumour, N describes the presence of cancer in regional lymph nodes, and M describes the presence or absence of distant metastases. 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/m² 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/m² and 1250 mg/m² twice a day and, if tolerated, increase up to 1250 mg/m² 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/m² 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/m² 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/m² 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 pharmacovigilance.
- 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 NSW LHD, 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.

References

1. Cancer Institute NSW. Bowel cancer. 2016 [Internet]. Alexandria NSW: Cancer Institute NSW; 2016 Sep [cited 2016 Sep 5]. Available from: <https://www.cancerinstitute.org.au/understanding-cancer/cancer-in-nsw/bowel-cancer>
2. Cancer Institute NSW. All cancers data NSW [Internet]. Alexandria NSW: Cancer Institute NSW; 2016 June [cited 2016 Sep 5]. Available from: <https://www.cancerinstitute.org.au/understanding-cancer/cancer-in-nsw/all-cancers-nsw-data>
3. Efficacy of adjuvant fluorouracil and folinic acid in colon cancer. International Multicentre Pooled Analysis of Colon Cancer Trials (IMPACT) investigators. *Lancet* 1995;345(8955):939-44.
4. Glimelius B, Dahl O, Cedermark B, Jakobsen A, Bentzen SM, Starkhammar H, et al. Adjuvant chemotherapy in colorectal cancer: a joint analysis of randomised trials by the Nordic Gastrointestinal Tumour Adjuvant Therapy Group. *Acta Oncol* 2005;44(8):904-12.
5. Gill S, Loprinzi CL, Sargent DJ, Thome SD, Alberts SR, Haller DG, et al. Pooled analysis of fluorouracil-based adjuvant therapy for stage II and III colon cancer: who benefits and by how much? *J Clin Oncol* 2004;22(10):1797-806.
6. Twelves C, Scheithauer W, McKendrick J, Seitz JF, Van Hazel G, Wong A, et al. Capecitabine versus 5-fluorouracil/folinic acid as adjuvant therapy for stage III colon cancer: final results from the X-ACT trial with analysis by age and preliminary evidence of a pharmacodynamic marker of efficacy. *Ann Oncol* 2012;23(5):1190-7.
7. Schmoll HJ, Tabernero J, Maroun J, de Braud F, Price T, Van Cutsem E, et al. Capecitabine Plus Oxaliplatin Compared With Fluorouracil/Folinic Acid As Adjuvant Therapy for Stage III Colon Cancer: Final Results of the NO16968 Randomized Controlled Phase III Trial. *J Clin Oncol* 2015;33(32):3733-40.
8. Sauer R, Becker H, Hohenberger W, Rodel C, Wittekind C, Fietkau R, et al. Preoperative versus postoperative chemoradiotherapy for rectal cancer. *N Eng J Med* 2004;351(17):1731-40.
9. Sauer R, Liersch T, Merkel S, Fietkau R, Hohenberger W, Hess C, et al. Preoperative versus postoperative chemoradiotherapy for locally advanced rectal cancer: results of the German CAO/ARO/AIO-94 randomized phase III trial after a median follow-up of 11 years. *J Clin Oncol* 2012;30(16):1926-33.
10. Kapiteijn E, Marijnen CA, Nagtegaal ID, Putter H, Steup WH, Wiggers T, et al. Preoperative radiotherapy combined with total mesorectal excision for resectable rectal cancer. *N Eng J Med* 2001;345(9):638-46.
11. Peeters KC, Marijnen CA, Nagtegaal ID, Kranenbarg EK, Putter H, Wiggers T, et al. The TME trial after a median follow-up of 6 years: increased local control but no survival benefit in irradiated patients with resectable rectal carcinoma. *Ann Surg* 2007;246(5):693-701.
12. van Gijn W, Marijnen CA, Nagtegaal ID, Kranenbarg EM, Putter H, Wiggers T, et al. Preoperative radiotherapy combined with total mesorectal excision for resectable rectal cancer: 12-year follow-up of the multicentre, randomised controlled TME trial. *Lancet Oncol* 2011;12(6):575-82.

13. Bujko K, Nasierowska-Guttmejer A, Wyrwicz L, Malinowska M, Krynski J, Kosakowska E, et al. Neoadjuvant treatment for unresectable rectal cancer: an interim analysis of a multicentre randomized study. *Radiother Oncol* 2013;107(2):171-7.
14. Bujko K, Nowacki MP, Nasierowska-Guttmejer A, Michalski W, Bebenek M, Kryj M. Long-term results of a randomized trial comparing preoperative short-course radiotherapy with preoperative conventionally fractionated chemoradiation for rectal cancer. *Br J Surg* 2006;93(10):1215-23.
15. Bujko K on behalf of the Polish Colorectal Study Group. Neoadjuvant chemoradiation for fixed cT3 or cT4 rectal cancer: Results of a Polish II multicentre phase III study. Proceedings of the 2016 Gastrointestinal Cancers Symposium; 2016: San Francisco, CA 94103: *J Clin Oncol* 2016; 34(suppl 4S; abstr 489).
16. Roh, M, Yothers GA, O'Connell MJ, Beart RW, Pitot HC, Shields AF, et al. The impact of capecitabine and oxaliplatin in the preoperative multimodality treatment in patients with carcinoma of the rectum: NSABP R-04. *J Clin Oncol* 2011;29(18 Suppl):3503.
17. Hofheinz, R D, Wenz F, Post DS, Matzdorff A, Laechelt S, Hartmann JT, et al. Chemoradiotherapy with capecitabine versus fluorouracil for locally advanced rectal cancer: a randomised, multicentre, non-inferiority, phase 3 trial. *Lancet Oncol* 2012;13(6):579-588.

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*

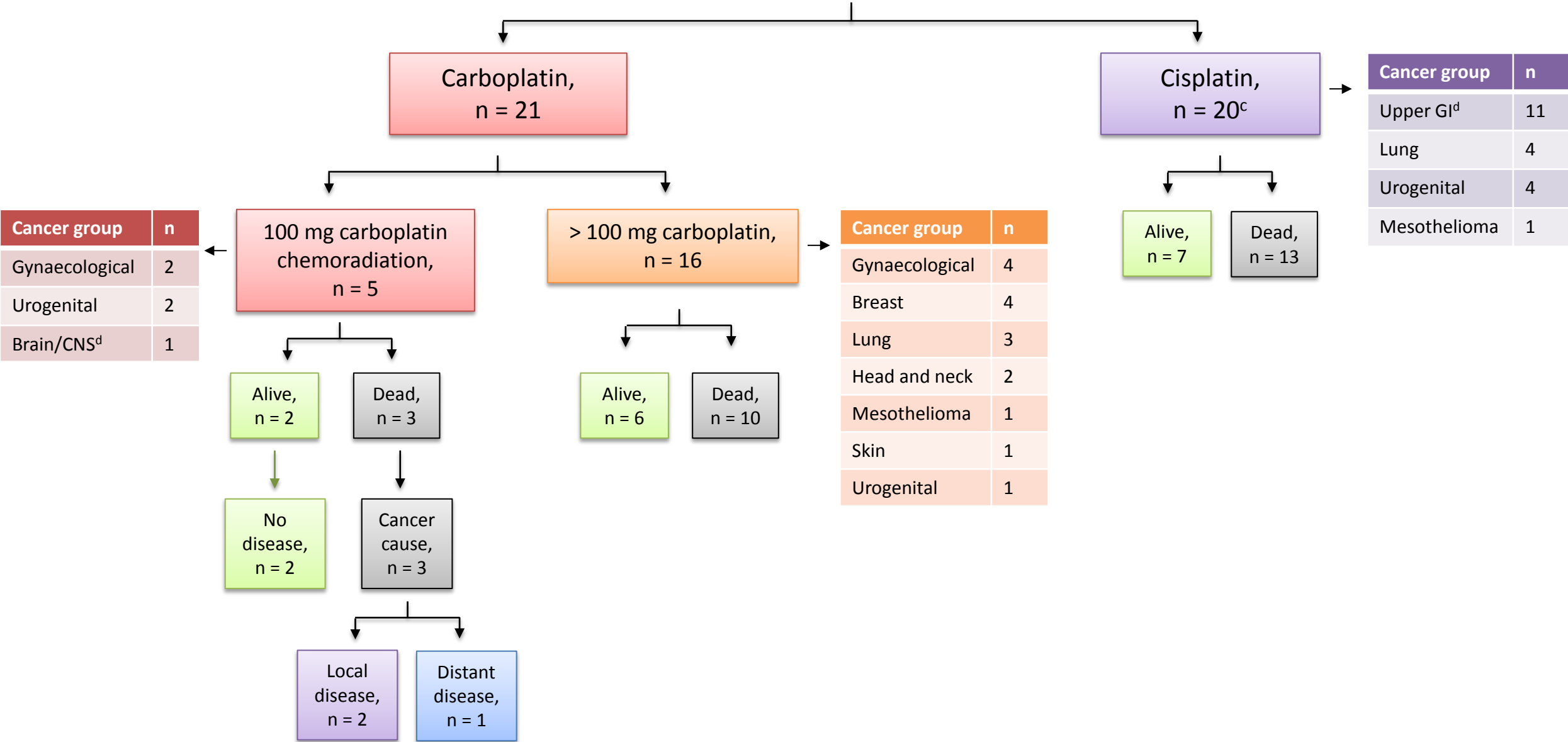
Prescribing of chemotherapy — Report on patients treated at Western NSW Local Health District

Appendix B

B.1 Data tree — off-protocol flat dose 100 mg carboplatin

B.2 Data tree — capecitabine

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

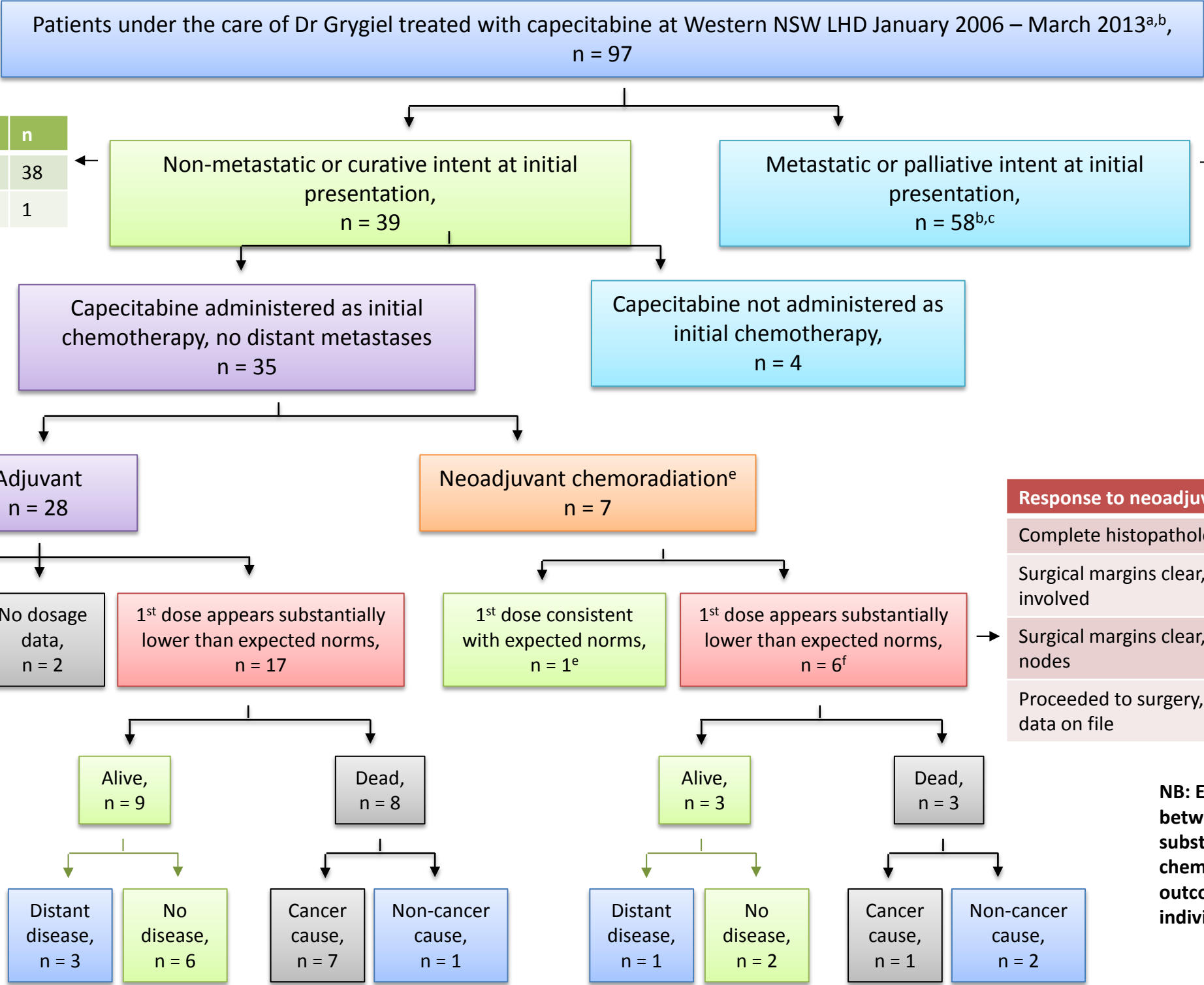


^a Dr Grygiel listed as prescriber or name of prescriber not specified

^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



^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

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
<p>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</p>	<p>In 2015 WNSW LHD commenced the staged implementation of MOSAIQ®, with the latest upgrade available in April 2016.</p> <p>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.</p> <p>WNSW LHD has developed and implemented a Chemotherapy Prescription Review process guided by Terms of Reference (TOR) and a monthly reporting template, to:</p> <ul style="list-style-type: none"> • 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. • Identify any prescription patterns which may indicate variations from protocol causing under dosing. • 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. <p>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).</p> <p>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.</p>

RECOMMENDATION	WNSW LHD ACTION
<p>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</p>	<p>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.</p>
<p>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</p>	<p>There are a number of Multidisciplinary Cancer Care Team meetings in WNSW LHD to discuss patient diagnosis and treatment plans including:</p> <ul style="list-style-type: none"> ▪ General Cancer MDT in Dubbo ▪ Dubbo links into Lifehouse Thoracic MDT ▪ Breast and General Cancer MDT at Orange with Bathurst linking in ▪ Gastrointestinal Cancer MDT at Orange ▪ Prostate Cancer MDT at Orange ▪ Minimally invasive palliative care at Orange with Dubbo linking in ▪ Orange links into Upper Gastrointestinal MDT at Nepean ▪ Orange links into Lung MDT at Nepean ▪ 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	<p>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.</p> <p>This consent form will provide formal acknowledgement that informed consent for treatment has been obtained by the treating clinician.</p>

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.	<p>The WNSW LHD has an external compounding chemotherapy provider following a tender process undertaken in 2014/15.</p> <p>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.</p> <p>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.</p>

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.