

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

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**ST VINCENT'S
HEALTH NETWORK**
SYDNEY

A SERVICE OF ST VINCENT'S HEALTH AUSTRALIA

SELECT COMMITTEE ON OFF-PROTOCOL PRESCRIBING OF CHEMOTHERAPY IN NSW

Submission

St Vincent's Hospital Sydney

October 2016

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1. Statement from the Group CEO and Hospital CEO

The past nine months have been some of the most testing in the 160-year history of St Vincent's Hospital, in Sydney.

Every year, the Hospital conducts close to a million patient treatments.

We are a centre of excellence in patient care and a global leader in many areas of medical research.

And yet, in responding to a doctor's off-protocol prescription of chemotherapy to a group of head and neck cancer patients, we failed to meet our own high expectations and those of our patients.

Of course, our own disappointment pales in comparison to the distress experienced by patients and their families: for them, it has delivered an extra and unnecessary source of anxiety and uncertainty.

To those patients and families, we once again say sorry.

We acknowledge that, from the outset, we failed to appreciate the seriousness of this situation – nor understand the distress it would cause patients – and this coloured our responses throughout.

For example, early questions about the doctor's dosage practice should have been raised formally. However, in the department where the problem occurred, we had a culture of acceptance, rather than a culture of challenge.

When we detected the problem, our investigations should have been more comprehensive and completed more quickly. Early on we made the decision not to contact patients until we had all the information so as not to cause unnecessary distress, but we now recognise this was a mistake. We should have communicated with our patients earlier.

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

Those of us in senior positions – at the Hospital and within the broader St Vincent's Health organisation – take responsibility for what happened. We also take responsibility for putting things right so that something like this never happens again.

We have participated openly with the Inquiry led by the NSW Cancer Institute and have fully accepted its criticisms and findings.

Since the NSW Cancer Institute's interim report was published in April, we have been focussed on implementing its recommendations for the Hospital. These included follow up with patients, reviewing our incident management processes, and providing extra education and training for staff.

Critically, we have redoubled our efforts at improving workplace culture, fostering a spirit of challenge and inquiry when it comes to clinical decisions.

We have also put in place a world-standard cancer electronic medical record and prescribing system pre-loaded with evidence-based protocols. Under such a system, if any clinician wants to prescribe medication outside the guidelines they must submit their request for peer review and provide the evidence to support it. There are regular clinical audits to ensure this is occurring.

The Hospital has embraced the opportunity to make improvements to our systems, processes and culture in the clinical areas involved in the issue.

The Hospital's process of implementation has been independently monitored by Professor Robert Thomas, Chief Advisor on Cancer to the Victorian Government and one of Australia's most respected cancer surgeons. Professor Thomas' guidance has helped the hospital immeasurably. As difficult as this process has been, we believe we come out of it stronger as a result.

We also believe that this issue has highlighted a broader cultural issue in the health sector. The fact that off-protocol prescribing was not confined to St Vincent's – or even to one doctor – suggests there is work to do across the sector. To that end, St Vincent's Hospital Sydney recognises the state-wide initiatives and reforms underway and we look forward to participating in them.

St Vincent's has a proud history when it comes to its commitment to clinical governance and patient outcomes. Unfortunately, this chapter represents a blemish on this legacy. We hope that this Inquiry will help reaffirm the actions we must pursue in order to ensure that such failings do not occur again – at St Vincent's or any other hospital.

Toby Hall
Group Chief Executive Officer
St Vincent's Health Australia
October 2016

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

2. Background

Cancer Care at St Vincent's Hospital Sydney

Each year, St Vincent's supports 1200 new cancer patients at our Darlinghurst campus. The St Vincent's Campus operates as a joint facility, with a range of services and facilities working together with shared management and clinical governance structures to provide cancer care, teaching, education and research. Campus-wide, St Vincent's provides a comprehensive range of cancer services across all facilities.

The team at St Vincent's includes: surgeons; oncologists; nurses; cancer care coordinators; radiation therapists; pathologists; radiologists; pharmacists; supportive and palliative care doctors; social workers; and clinical psychologists.

The off-protocol prescribing

Between January 2006 and June 2015, 129 people were treated by Dr John Grygiel at St Vincent's Hospital Sydney with an off-protocol flat dose of 100mg Carboplatin. Further information about the patient cohort and their treatment, head and neck cancer and protocols for chemotherapy prescribing can be found in the *Report of the Inquiry under section 122 of the Health Services Act 1997*.

The 'Section 122 Inquiry'

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.

As an affiliated health organisation under the *Health Services Act 1997*, St Vincent's Hospital Sydney is subject to the same administration and oversight requirements as Local Health Districts (LHDs) under Chapter 10 Part 1. As such, the Secretary of Health has the power to inquire into the administration, management and services of St Vincent's Hospital Sydney and has the same powers of entry and inspection and compelling of documents and records as for LHDs.

The Inquiry was led by Professor David Currow, Chief Cancer Officer, Cancer Institute NSW, supported by Dr Tina Chen also from the Cancer Institute NSW, Dr Paul Curtis, Director Clinical Governance, Clinical Excellence Commission and Mr Paul Gavel, Director Workforce, HealthShare NSW (the Inquiry Team).

The Inquiry's Interim Report was released on 4 April 2016; the Final Report on St Vincent's was released on 2 August 2016 and the report on patients treated at Western NSW Local Health District was released on 20 September 2016.

St Vincent's Hospital Sydney welcomed and participated fully in the Inquiry. The Hospital provided approximately 1500 separate documents to the review team. The Hospital encouraged staff to participate in the Inquiry and many staff were interviewed or provided statements.

The Hospital accepted the Inquiry's recommendations in full.

Implementation of Recommendations from the Inquiry

The below table outlines the progress of St Vincent's Hospital in implementing the 10 recommendations for the Hospital from the Interim Inquiry Report and the one additional recommendation from the Final Report. The table also provides information on St Vincent Hospital's progress in implementing the four state-wide recommendations for Local Health Districts and Speciality Networks.

The Interim Report provided an additional seven recommendations for other parties, with the Final Report bringing this number to eight. St Vincent's Hospital welcomed these recommendations and fully supported the Inquiry to deliver on its revised Terms of Reference.

Number	Recommendation	Status
Recommendation 1 (Interim Report)	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 (Interim Report)	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 (Interim Report)	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 (Final Report – Amended)	Reports on patient outcomes to the Hospital's Patient Safety and Quality Committee and Clinical Council on six monthly, and annually to the Deputy Secretary, NSW Ministry of Health.	COMPLETE
Recommendation 5 (Interim Report)	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.	SUPPORTED BY ST VINCENT'S
Recommendation 6 (Interim Report)	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 (Interim Report)	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 (Interim Report)	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 (Interim Report)	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 <i>(Interim Report)</i>	That St Vincent's Hospital ensure that Mortality and Morbidity meetings use data beyond individual patients to examine patterns of care and outcomes benchmarked with similar hospitals or health services or, at least, the most recent, relevant peer-reviewed literature.	IN PROGRESS
Recommendation 11 <i>(Final Report – Amended)</i>	Given the categorisation of 'unanticipated' would not have flagged any of the patients affected by this off-protocol prescribing for review by the hospital-wide Mortality Review Committee, it is recommended that the Committee consider reviewing a random selection of 'expected' deaths rather than relying on the subjective decision that the death was 'unanticipated'.	COMPLETE
Recommendation 12 <i>(Interim Report)</i>	That St Vincent's Hospital revisit mechanisms for escalation of clinical concerns to ensure that key line-managers are seen as crucial to the process of adequately addressing clinical concerns from junior nursing, pharmacy and medical staff	IN PROGRESS
Recommendation 13 <i>(Interim Report)</i>	Given clinicians should be able to override doses once entered into MOSAIQ where appropriate for an individual patient, Local Health Districts and Speciality Networks to ensure that the most senior oncology pharmacist and the head of medical oncology review such overrides regularly to identify any patterns that may suggest similar dosing issues	COMPLETED AT ST VINCENT'S
Recommendation 14 <i>(Interim Report)</i>	That Local Health Districts and Speciality Networks pre-load eviQ protocols into electronic chemotherapy prescribing systems.	COMPLETED AT ST VINCENT'S
Recommendation 15 <i>(Interim Report)</i>	That Local Health Districts and Speciality Networks ensure that minuted meetings of Multidisciplinary Cancer Care teams occur after relevant international or national meetings and on an ad-hoc basis as seminal new evidence emerges that should influence practice.	COMPLETED AT ST VINCENT'S
Recommendation 16 <i>(Interim Report)</i>	That the Cancer Institute NSW works with oncology groups to facilitate meetings occurring after major conferences to review new evidence and agree on which of the evidence should be adopted.	SUPPORTED BY ST VINCENT'S
Recommendation 17 <i>(Interim Report)</i>	That the Cancer Institute NSW prepares a new patient information sheet on dose adjustment of chemotherapy to allow patients and their caregivers to understand the rationale for it.	SUPPORTED BY ST VINCENT'S
Recommendation 18 <i>(Interim Report)</i>	That the Ministry of Health, with the Cancer Institute NSW, examine ways to ensure that all people diagnosed with notifiable cancer in NSW have their care overseen by a Multidisciplinary Cancer Care Team that includes all relevant medical, nursing, pharmacy and allied health staff.	SUPPORTED BY ST VINCENT'S
Recommendation 19 <i>(Interim Report)</i>	That the Secretary, NSW Ministry of Health, expand the terms of reference of this Inquiry to include: patients treated by Dr Grygiel in Western NSW Local Health District (or its predecessors) back to the beginning of 2006 (when CISCAT, the predecessor of eviQ first became available); and patients treated since 2006 by Dr Grygiel at St Vincent's Hospital Darlinghurst.	SUPPORTED BY ST VINCENT'S
Recommendation 20 <i>(Interim Report)</i>	Now that the magnitude of the systematic off-protocol prescribing is apparent, expand the Terms of Reference of this Inquiry to include information provided to the affected patients and their families in consenting to treatment by Dr Grygiel and the impact on them.	SUPPORTED BY ST VINCENT'S

Recommendation 21 <i>(Final Report)</i>	Ensure adequate informed consent for all medical interventions, including chemotherapy. If the clinician knows that his/her practice is outside accepted practice, there is a particular onus to draw this to the attention of patients in the process of providing informed consent, and to document this in the patient notes.	IN PROGRESS
Recommendation 22 <i>(Final Report)</i>	There are a number of outsourced providers in oncology across NSW in areas such as compounding pharmacy and radiotherapy. These providers should have the same responsibility to demonstrate the quality of their care and share clinical data as any other member of the multidisciplinary cancer care team. They should also have the same responsibilities to contribute to the fail-safe checks that are a hallmark of good multidisciplinary teams and evidence-based clinical care, including escalation where there are concerns about care that have not been adequately addressed. This should be properly reflected in relevant contracts as they are negotiated between Local Health Districts/ Specialty Health Networks and this party providers.	IN PROGRESS
Recommendation 23 <i>(Final Report)</i>	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.	IN PROGRESS

Full reports on the Hospital's implementation progress at three and six months are attached to this submission. These reports have been independently assessed (see further information below) and have been provided to the Secretary of Health. They are also publically available on the St Vincent's Hospital Sydney website. A further public report on progress will be made at 12 months.

Oversight and monitoring

St Vincent's Health Australia process

The Hospital engaged Professor Robert Thomas, Chief Cancer Advisor to the Victorian Government, to independently monitor and assess progress implementing the recommendations. Professor Thomas chairs a Steering Committee of Hospital senior leaders, key St Vincent's Health Australia executive including the Group CEO, and subject matter experts.

Ministry process

As an AHO under the *Health Services Act 1997*, St Vincent's Hospital Sydney is subject the NSW Health Performance Framework. Under this Framework, St Vincent's 'performance level' has been elevated to Level 2 in light of the findings of the s122 Inquiry. This involves regular monitoring by the Ministry.

The NSW Ministry of Health has appointed Ms Susan Pearce, Deputy Secretary, System Purchasing and Performance, to monitor the Hospital's implementation of the s122 Inquiry's recommendations. St Vincent's meets with the NSW Ministry of Health on a monthly basis to report on progress.

NSW Ministry of Health has advised that they are satisfied with the progress of the implementation of recommendations during these meetings.

3. This Submission

This submission outlines St Vincent's Hospital's response to the Legislative Council Select Committee on off-protocol prescribing of chemotherapy in New South Wales and aims to address the points as outlined within the Terms of Reference:

That a select committee be established to inquire into and report on off-protocol prescribing of chemotherapy in NSW including at St Vincent's Hospital, St George Hospital, Sutherland Hospital, Macquarie University Hospital and clinics at Orange and Bathurst, and in particular:

- (a) the efficacy of electronic prescribing systems, and their capacity to stop or limit off-protocol prescribing of chemotherapy,*
- (b) the value of a potential new patient information sheet on dose adjustment for patients and caregivers information,*
- (c) the process and systems around informed consent for all medical interventions, including chemotherapy,*
- (d) the capacity of the NSW Health system to have all notifiable cancer patients in New South Wales overseen by a Multidisciplinary Cancer Care Teams, and if this may prevent off-protocol prescribing,*
- (e) St Vincent's Hospital capability to comply with relevant NSW Health Policy Directives and Guidelines, particularly Open Disclosure Policy (PD2014_028) and Incident Management Policy (PD2014_004),*
- (f) the NSW Health Code of Conduct and specific programs within NSW Health and St Vincent's Hospital, in relation to staff raising concerns about the practice of clinicians, and other breaches of the Code of Conduct.*

4. Response to the Terms of Reference

A:

The efficacy of electronic prescribing systems, and their capacity to stop or limit off-protocol prescribing of chemotherapy

St Vincent's Hospital Sydney strongly supports electronic prescribing systems as important mechanisms to help deliver evidence-based, standardised cancer care. The Hospital considers that electronic prescribing systems, with pre-loaded evidence-based protocols, in conjunction with robust governance processes, significantly reduce the risk of off-protocol prescribing (such as that of Dr Grygiel between 2006 and 2015).

Independent of this issue, St Vincent's implemented the MOSAIQ™ system into clinical practice in March/April 2015 as a booking and electronic clinical records system for cancer ambulatory care areas, with further final implementation of electronic prescribing of chemotherapy in August/September 2015.

A key benefit of electronic prescribing systems is that they allow for approved drug treatment protocols to be pre-loaded and prescribing restricted accordingly. Drug treatment protocols reflect extensive clinical trial evidence and are regularly updated when new evidence emerges.

At St Vincent's the NSW Cancer Institute's eviQ protocols are pre-loaded into MOSAIQ™. In coming months, St Vincent's will implement the recently upgraded version of MOSAIQ™ (version 2.62) which will automatically upload updates or new eviQ protocols as they are released.

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.

MOSAIQ™ allows for dose adjustments for the clinical needs of a patient within certain ranges set by the protocols. However, if a doctor wishes to prescribe off-protocol (outside of the normal variations for dose adjustments set by pre-loaded protocols), they must first submit their request – with appropriate evidence – to peer review through the MOSAIQ Care Plan Review Committee. The MOSAIQ Care Plan Committee commenced in January 2016 under the stewardship of the new Head of Department of Medical Oncology, together with the Haematology Head of Department.

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.

For any off-protocol prescribing, the pharmacist is required to verify that the care plan has been approved by the MOSAIQ Care Plan Review Committee before dispensing.

This Committee monitors 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).

The NSW Health Policy Directive (PD2016_033) *Approval Process of Medicines for Use in NSW Public Hospitals* guides the Committee through their evaluation process. This Committee reports to the St

Vincent's Drug and Therapeutics Committee, as well as to the Cancer Services Clinical Governance Committee.

B:

The value of a potential new patient information sheet on dose adjustment for patients and caregivers information

St Vincent's acknowledges that many of Dr Grygiel's patients felt they did not have appropriate information about their treatment.

Dose adjustments or variations in cancer care can be required depending on a patient's condition, response to therapy and the drugs used. The Hospital fully supports the recommendation of the Inquiry for a new patient information sheet on dose adjustment.

St Vincent's Hospital has changed a number of processes to improve the information provided to patients including to formally document information provided in patient consent processes.

The existing practice at St Vincent's is that all patients are provided with a copy of the NSW Cancer Institute's eviQ chemotherapy protocol at education sessions ahead of their first treatment and when consent is obtained. Drug doses and frequency of doses, including the likelihood of variations that may need to be made, are also discussed at this time.

St Vincent's is now trialling an additional process to improve the information available for patients for whom a non-eviQ care plan is recommended.

These patients are now provided with information in writing about their proposed protocol, including the clinical rationale for proposing an approved non-eviQ protocol. (As noted in response to ToR A, only eviQ or *approved* non-eviQ protocols can be prescribed through MOSAIQ™.) This document is then scanned into the patient information system as an accompanying document to formally record their consent to the variation.

C:

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

Informed consent for all medical interventions

The NSW Health Policy (PD_2005_406) Consent to Medical Treatment – Patient Information was adopted by St Vincent's when it was developed. St Vincent's also has a local protocol in place for Informed Consent (the Informed Consent Protocol).

The protocol specifies the requirements and delegations for informed consent specific to St Vincent's and outlines the principles for informed consent that must be applied for any patient that is undergoing an operation, procedure, invasive investigation or treatment.

This policy and protocol applies to all medical treatment at St Vincent's, including chemotherapy. All patients receiving chemotherapy at St Vincent's require a signed consent form which outlines the nature of the chemotherapy to be prescribed as well as the material risks associated with the proposed chemotherapy that was discussed with the patient or person responsible.

A valid informed consent requires four key elements (*NSW Health Policy PD_2005_406*):

- (a) The patient must have capacity to give consent; and
- (b) The consent must be freely given; and
- (c) The information about the treatment is provided in a way the patient can understand (which includes the use of a qualified interpreter for culturally and linguistically diverse patients); and
- (d) The consent must be specific to the treatment the patient was informed of and agreed to.

In addition a Time-Out Check-Listing procedure is used to ensure the availability of signed valid consent form prior to the commencement of any operation, procedure or treatment including chemotherapy. Where a valid consent form is not present, the proposed treatment will not proceed.

Where a patient's condition changes significantly, then it is the responsibility of the Medical Officer to ensure that the new assessment of risk is made clear to the patient, or person responsible to ensure that the consent given remains valid, responsive and appropriate. St Vincent's respects the decision of any patient who refuses to provide consent for medical treatment.

Any patient that is unable to provide valid informed consent is managed in accordance with the provisions for substitute decision making as outlined in either the *Guardianship Act 1987 (NSW)* or the *Mental Health Act 2007 (NSW)* as applicable.

Training on informed consent is provided to all clinical staff at St Vincent's during orientation. Furthermore, our senior medical officer orientation program is being reviewed and will include education regarding St Vincent's expectations for valid informed consent.

Informed consent for non- eviQ protocol chemotherapy

As noted in response to ToR B, St Vincent's have now introduced additional processes for patients that are recommended to receive a non-eviQ protocol. This will improve the information provided to these patients about the proposed treatment, and formally record their consent to the variation. Treatment cannot commence without this formal consent being recorded.

D:

The capacity of the NSW Health system to have all notifiable cancer patients in New South Wales overseen by a Multidisciplinary Cancer Care Teams, and if this may prevent off-protocol prescribing

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.

St Vincent's considers there is strong value in Multidisciplinary Cancer Care Teams ('MDTs') – particularly in coordinating care across a range of disciplines and addressing both the physical and psychological needs of a person diagnosed with cancer.

At MDT case conferences, a patient case is presented, treatment options are reviewed, recommended and agreed by the team. However, MDTs do not generally discuss the exact doses of chemotherapy drugs if being used. Dosing is the decision of the treating medical oncologist who is expected to adhere to an evidence-based practice.

However, MDTs do encourage a culture of challenge and discussion, and as such, are part of a suite of mechanisms that can help prevent off-protocol prescribing.

Further information on St Vincent's cancer services MDTs can be found in our three-month implementation progress report at Attachment A.

E:

St Vincent's Hospital capability to comply with relevant NSW Health Policy Directives and Guidelines, particularly Open Disclosure Policy (PD2014_028) and Incident Management Policy (PD2014_004)

As an AHO under the *Health Services Act 1997*, St Vincent's Hospital Sydney is required to comply with applicable NSW Health Policy Directives as a condition of funding.

St Vincent's Hospital generally performs well in how we respond to incidents including open disclosure in accordance with NSW Health policies and the values of St Vincent's Health Australia.

In 2015, the NSW Ministry of Health undertook a Service Capacity Assessment Project to review Hospital governance processes throughout NSW following government reforms in 2011, which included the establishment of Local Health Districts and Speciality Health Networks with Governing Boards, new Activity-based Funding agreements and individual service agreements.

In its report, the NSW Ministry of Health reported that St Vincent's had considerable strengths in Network governance and stewardship, legislative compliance systems, risk management, internal audit, clinical governance framework, managing clinical incidents, open disclosure, partnerships with organisations and the community.

The report also outlined that St Vincent's had rigorous processes in place to manage, monitor and report clinical incidents. All incidents were reviewed within 24 hours and open disclosure was initiated early. The Root Cause Analysis (RCA) process is well accepted and the implementation of recommendations is monitored until closure. RCA findings are discussed at formal governance committees, ward meetings, within stream levels and used for training purposes. St Vincent's was noted as having a Network approach to reviewing RCA findings and recommendations and undertaking clinical reviews where trends in non-serious incidents are noted.

However, we recognise that in the case of Dr Grygiel's off-protocol prescribing we failed to define the seriousness of the incident and this impacted on all aspects of our response, including how the NSW Health policy directives were applied.

We have provided information below about the systems we have in place to manage incidents in accordance with NSW Health policies, and what we have done in response to the findings of the NSW Cancer Institute Inquiry into off-protocol prescribing to strengthen how we apply these policies.

Incident Management

St Vincent's has two local procedures; *St Vincent's Hospital - Critical Incident: Initial Management Meeting Protocol* and *Managing RCA Recommendations Protocol* that facilitate our compliance with NSW Health Incident Management Policy (PD 2014_004).

Key systems in place at St Vincent's to support the Policy are outlined below.

Riskman™

- Implemented in July 2006 as the incident reporting system.
- Enhancements have continued to be made to the system since implementation to support effective management.
- Since 2010, data has been submitted on a six monthly basis to the Clinical Excellence Commission for inclusion into the NSW Ministry of Health incident data portal.
- Staff are informed at orientation of their roles and responsibilities for reporting in the Riskman™ system. Further detailed education is provided to nursing and medical staff with case studies and lessons learnt from investigations undertaken at St Vincent's.

- In 2013, a Riskman™ e-learning pathway was introduced and includes a module on human factors to facilitate understanding of how and why incidents occur and prevention strategies. Face-to-face sessions have also been held with managers on the capabilities and practicalities of reviewing and extracting aggregated incident data from Riskman™ for use at team or department meetings.
- Since 2013, St Vincent's has seen an 18.7% increase in incident notifications.

Root Cause Analysis (RCA)

- A RCA Toolkit is available and contains various documents to support the RCA teams with investigation methodology.
- A two-day RCA training program is conducted annually at St Vincent's with over 220 staff trained in the RCA methodology since 2007.
- St Vincent's uses the NSW Severity Assessment Code (SAC) as per *PD2014_004 Incident Management* and RiskMan™ to notify and apply an initial SAC score upon identification that an incident has occurred.
- Staff at the time of the incident are required to immediately take action to mitigate any possible harmful consequences.
- Depending upon the SAC rating allocated, an escalation process will trigger an email notification to the manager responsible for the area where the incident occurred.
- The manager is then required to review the incident and confirm the SAC rating.
- RCA Team Leaders must complete the two day RCA training prior to undertaking a RCA. Support is provided by the Patient Safety and Quality Unit to RCA teams and provides critical review of RCA reports prior to final submission and endorsement by the Network Executive.
- 47 SAC1 RCAs have been conducted since February 2013 and during this time, 97.6% of the final RCA reports have been submitted to the NSW Ministry of Health within the 70 day timeframe.
- All RCA reports from 2013 are published on the Hospital's Intranet for use by staff as learning opportunities and SVHA has recently summarised all RCA's reports with key findings over the prior two years. Incident data is analysed by primary incident type for the various clinical committees and regular analysis of all incident data is presented to the St Vincent's Patient Safety and Quality Committee and Clinical Council. Collated series of contributing factors as to why the incidents occurred have been used to help inform activities for the St Vincent's Health Network Sydney Patient Safety and Quality Plan 2016-2020.
- RCA recommendations are entered into the RiskMan™ system and can be tracked by location and are allocated to a person responsible for implementing the recommendations.

SAC 1 and 2

- An email alert to senior managers and the Network Executive is triggered.
- An alert is also sent to the St Vincent's Health Australia Director of Clinical Governance and Group Manager Quality and Safety.
- A critical incident meeting is scheduled within 24 hours of notification of SAC 1 and 2 incidents to plan how the incident will be investigated with a protocol used to guide this process.
- For SAC 1 incidents a Reportable Incident Brief is prepared, reviewed by the Director of Clinical Governance, signed by the Chief Executive Officer and submitted to the NSW Ministry of Health.
- SAC 1 incidents undergo an RCA and RCA teams are commissioned as per the NSW Health Policy.
- A member of the Patient Safety and Quality Unit team is included as an RCA member to maintain consistency in RCA methodology and to support staff to develop skills in investigating serious clinical events.
- External members are enrolled for all incidents involving suspected suicide of mental health patients as per the NSW Health policy.

- RCA reports and SAC 2 incident investigations are discussed at Stream Level Clinical Governance meetings and at various content specific hospital level committees.

SAC 3 and 4

- For incidents rated SAC 3 or 4, the unit / ward manager investigates the incident, implements corrective action and it is discussed at ward / unit meetings.

St Vincent's Hospital acknowledges that NSW Health incident management policies were not appropriately applied in response to this incident. The Hospital has made a number of changes as part of our improvement process in response to this issue which we have detailed below.

Review of incident management practices and policies

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 should be anticipated.
- 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 from other health services or providers.
- 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 to be 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.

Education and training

Improving the education of our staff is a key part of the improvement process for the Hospital. 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 Health Education Training Institute (HETI) online, which St Vincent's Hospital gained access to in January 2016.

This training program was delivered May to July 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 training is continuing to be rolled out to capture these staff. 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.

The Hospital's Incident Management Training program for managers is in addition to the mandatory training prescribed by NSW Health for all staff on state-wide incident management systems.

Open Disclosure

To ensure ongoing compliance with the *Open Disclosure Policy PD_2014_028*, the following takes place at St Vincent's:

- Open disclosure training is mandatory for all staff on HETI online.
- Open disclosure is presented at clinical staff orientation.
- Open disclosure is recorded in Riskman™ as a mandatory category. The information must include names of staff who completed the open disclosure. Initial and final open disclosure must be recorded.
- The Clinical Governance Support Officer reviews all SAC 1 and 2 incidents to ensure compliance with Open Disclosure Policy.
- The Clinical Governance Support Officer provides assistance with open disclosure including supporting staff, liaising with families, arranging meetings, contacting relevant staff members and family members.
- The Clinical Governance Support Officer holds informal mini-sessions with nurse unit managers and clinical stream managers upon request.

However, St Vincent's accepts that in response to Dr Grygiel's off-protocol prescribing we should have started the open disclosure process much earlier. Early on, the Hospital made the decision not to contact patients until we had all the information so as not to cause unnecessary distress from fractured or incomplete advice, but we now recognise this was a mistake.

St Vincent's also acknowledges that some patients found our initial open disclosure process in February upsetting and frustrating. We sincerely apologise for that.

In April 2016, St Vincent's Hospital re-contacted all affected patients and/or families (where able to be contacted) to apologise, provide ongoing disclosure, support and transparency around the findings of the NSW Cancer Institute Inquiry Interim Report. 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. The patient / family group were again contacted in July when the Final Report was released.

Those patients and family that the Hospital has been able to contact have been offered meetings to discuss any concerns they may wish to raise. Both patients and family are offered any counselling support they may require and have also been offered a dedicated point of contact at St Vincent's for any subsequent issues or questions they may want to raise. In addition, St Vincent's established a 24/7, 1800 phone number for any patients, family or loved-ones who may have any questions related to this issue (which has now been replaced by a statewide 1800 number, established by NSW Health).

St Vincent's has facilitated independent case reviews for those patients and family of Dr Grygiel's who request it and has also offered additional follow-up to patients if they request an earlier review. The Hospital is currently tracking all relevant patients to ensure they are receiving appropriate follow-up.

We are also increasing training and education on open disclosure in response to this issue:

- **The new Incident Management Training outlined above – which over 150 staff have now completed – includes dedicated modules on open disclosure.**
- **Further, in 2016 clinical stream managers have commenced attending the Clinical Excellence Commission's open disclosure training.**

F:

The NSW Health Code of Conduct and specific programs within NSW Health and St Vincent's Hospital, in relation to staff raising concerns about the practice of clinicians, and other breaches of the Code of Conduct

St Vincent's Health Australia has a long legacy as a values-based organisation and has prided itself on living these values through its professional practices. St Vincent's Hospital has in place policies and guidelines to ensure that all staff are aware of, and adhere to the St Vincent's Health Australia Code of Conduct and the mission and values of the organisation (available on the St Vincent's Health Australia website). Orientation and other training and education is provided to staff in relation to these policies, guidelines and the St Vincent's Health Australia Code of Conduct. This is consistent with our obligations under our service level agreement with NSW Health.

St Vincent's Hospital utilises HETI online for all mandatory and local training requirements. This ensures consistency with NSW Health policies as well as meeting St Vincent's Health Australia requirements.

St Vincent's Hospital Sydney wants any and all staff to be empowered to raise and escalate concerns about the practice of clinicians. However, we recognise that this did not happen in the case of Dr Grygiel's off-protocol prescribing.

St Vincent's Hospital acknowledges there were cultural issues in the Medical Oncology Department that prevented staff from raising concerns. Rather than a culture of challenge we instead had a culture of acceptance: junior staff accepted the doctor's dosage practices and senior staff were not made aware of it.

We are implementing a cultural change program in our Cancer Services to build a constructive culture of challenge. This program of work involves:

- **New leadership and changes in key personnel** – In December 2015, we appointed a new Head of Medical Oncology and new medical oncologists. We also have a new Director of Cancer Services.
- **Measuring staff engagement and satisfaction** – St Vincent's staff recently participated in a staff engagement survey run by Gallup. This survey is internationally recognised and validated and will provide baseline data on staff engagement and satisfaction. The results can be broken down by teams and Cancer Services will develop a specific action plan for their Department. The survey will be repeated annually to allow for tracking of results over time.
- **A facilitated restorative process** – St Vincent's is implementing the recommendation of the s122 Inquiry for a facilitated restorative process in Cancer Services. We plan to engage an agency to assist in facilitating focus groups with Cancer Services staff and the Executive and Senior Leaders of St Vincent's to explore the events and how/what is needed to rebuild confidence and trust within the service and with the community. This will encourage ongoing open dialogue and establish team charters.
- **Education and Training** – The Hospital is working with HETI to explore linking into state-wide education programs such as *Clinician Disclosure* and *Building a Safe Workplace Culture*. In addition, the Hospital is reviewing the applicability of the NSW Health Leadership Program to St Vincent's. We plan to roll out these education programs – starting with Cancer Services and then across St Vincent's Hospital – further aligning with the training programs in other LHDs.

St Vincent's also believes there is work to do to encourage a culture of challenge across our health services, and across the health sector more generally. There is now a well-established link between clinician behaviour and patient safety outcomes such as surgical complications (Catron, Guillaumondegui et al. *Am J Med Qual*. 2015 Apr 27); adherence to patient safety processes such as handwashing (Talbot, Johnson, Fergus et al. *Infect Control Hosp Epidemiol* 2013; 34(11): 1129-1136) and medical team performance (Riskin, Erez, Foulk et al. *Amer. Acad Paediatrics* 2015; June).

Cultural change across the health sector, including equipping staff with the skills to speak up and creating a culture of feedback will take time. At St Vincent's, we are committed to this change process in accordance with our values. We are implementing a number of new programs in Sydney and across the St Vincent's Health Australia Group.

It's OK to Ask (St Vincent's Hospital Sydney)

In July 2016, St Vincent's launched a new campaign for staff *'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 program is sponsored by, and reports to, the Hospital CEO.

'It's OK to Ask' features the following messages:

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

The *'It's OK to Ask'* campaign aims at empowering staff – all of whom have something to contribute – no matter how senior or junior and regardless of speciality or role. The campaign makes clear that all staff should feel comfortable about escalating any patient care queries they may have with their peers or leaders.

In establishing *'It's OK to Ask'*, St Vincent's has put in place a variety of mechanisms to support all staff. If staff feel that they have a clinical question, or feel they need to escalate a matter on behalf of a patient, contact should be made with the clinical stream director or manager or any of the relevant Hospital Executive members.

The impact the *'It's OK to Ask'* campaign is having on staff attitudes and behaviours will be periodically measured and tracked through staff surveys. The first results will be available shortly and will be used to continue to drive the campaign and make change.

Later in 2016, St Vincent's will roll out phase two of the *'It's OK to Ask'* campaign which will focus on patients and their families. Similar to the staff campaign, the message will be that anyone under St Vincent's care, including their carer or loved-one has a right to respectfully seek more information or clarification about their treatment. The campaign will align with the Clinical Excellence Commission's REACH program.

Ethos – Inspired to Shine program (St Vincent's Health Australia – National)

The Ethos program aims to foster a culture that encourages feedback, addresses behaviour that undermines patient or staff wellbeing and embeds safe, respectful and professional behaviour so it is what we do every day. This program has St Vincent's Health Australia Board approval and is a priority program across the St Vincent's Group.

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

The Ethos program is built on three principles; that all staff and patients should feel welcome, valued and safe. The program includes:

- a validated, tiered accountability pathway (based on the principles of the Vanderbilt Promoting Professional Accountability model) and a peer driven early intervention process to provide a consistent and transparent approach to addressing unnecessary variation in behaviour;
- a reporting system to allow a safe voice and capture reliable data; and
- a package of capability building and training to equip leaders and staff with the skills they need to role model and teach safe behaviour.

The Ethos program also includes the development of relationships across the health sector, recognising that culture change of this magnitude cannot be undertaken in isolation.

Additionally, St Vincent's, through the Ethos program, seeks to reward and empower staff that demonstrate the highest standards of professionalism as this group represents our cultural strength and will lead the way for others. Project Ethos is a long-term program which strives to enable change in workforce culture across St Vincent's Health Australia.



**ST VINCENT'S
HEALTH NETWORK**
SYDNEY

A SERVICE OF ST VINCENT'S HEALTH AUSTRALIA

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

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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 complied 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.



**ST VINCENT'S
HEALTH NETWORK**
SYDNEY

A SERVICE OF ST VINCENT'S HEALTH AUSTRALIA

INQUIRY UNDER SECTION 122 OF THE HEALTH SERVICES ACT 1997

Off-protocol Prescribing of Chemotherapy for Head & Neck Cancers

Implementation of recommendations – six month progress report

St Vincent's Hospital Sydney

October 2016

Statement from Hospital

St Vincent's Hospital Sydney accepts the findings of the Interim and Final Reports and continues to work towards introducing all recommendations related to the Hospital and Speciality Health Networks.

St Vincent's has continued to learn from the implementation of the recommendations which will lead to overall improvements within our healthcare system – not only on our campus – but State-wide.

St Vincent's is committed to restoring confidence within cancer services and treatment on campus with a continued drive for a people focussed culture for patients and staff.

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

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

Associate Professor Richard Gallagher
Director Cancer Services
St Vincent's Health Network Sydney
October 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
Special Medical Advisor to the Victorian Government
October 2016

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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 was 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 and Final Report on 2 August 2016.

This report

This report provides an update on the progress of St Vincent's Hospital in implementing the recommendations for the Hospital from the Interim Inquiry Report and one additional recommendation from the Final Report (Section 2).

This report also provides information on St Vincent Hospital's progress in implementing the four state-wide recommendations for Local Health Districts and Speciality Networks (Section 3).

The Interim Report provided an additional seven recommendations for other parties, with the Final Report bringing this number to eight. These are addressed in Section 4 of this report. St Vincent's Hospital welcomed these new recommendations and has continued to work towards implementing the outstanding recommendations.

This report is a follow up report to the three month implementation progress report released in July 2016. As such, it reports on those recommendations from the Interim Report which were 'in progress' at the time of the three month report and for new recommendations and/or amended recommendations. Recommendations that are unchanged and where the implementation was complete at the time of the three month report are not covered in this report.

St Vincent's Hospital Sydney will provide a further public report at the 12 month point (April 2017).

This report has been endorsed by Professor Robert Thomas OAM, Special 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 (Interim Report)	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 (Final Report – Amended)	That St Vincent's Hospital ensure that every patient or his or her family identified by the Inquiry as having received a flat dose of carboplatin between 2006 and 2011 is given the opportunity to participate fully in an Open Disclosure process.	COMPLETE
Recommendation 3 (Interim Report)	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 (Final Report – Amended)	Reports on patient outcomes to the Hospital's Patient Safety and Quality Committee and Clinical Council on six monthly, and annually to the Deputy Secretary, NSW Ministry of Health.	COMPLETE
Recommendation 5 (Interim Report)	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.	SUPPORTED BY ST VINCENT'S
Recommendation 6 (Interim Report)	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 (Interim Report)	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 (Interim Report)	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 (Interim Report)	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 (Interim Report)	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 <i>(Final Report – Amended)</i>	Given the categorisation of 'unanticipated' would not have flagged any of the patients affected by this off-protocol prescribing for review by the hospital-wide Mortality Review Committee, it is recommended that the committee consider that Committee consider reviewing a random selection of 'expected' deaths rather than relying on the subjective decision that the death was 'unanticipated'.	COMPLETE
Recommendation 12 <i>(Interim Report)</i>	That St Vincent's Hospital revisit mechanisms for escalation of clinical concerns to ensure that key line-managers are seen as crucial to the process of adequately addressing clinical concerns from junior nursing, pharmacy and medical staff	IN PROGRESS
Recommendation 13 <i>(Interim Report)</i>	Given clinicians should be able to override doses once entered into MOSAIQ where appropriate for an individual patient, Local Health Districts and Speciality Networks to ensure that the most senior oncology pharmacist and the head of medical oncology review such overrides regularly to identify any patterns that may suggest similar dosing issues	COMPLETED AT ST VINCENT'S
Recommendation 14 <i>(Interim Report)</i>	That Local Health Districts and Speciality Networks pre-load eviQ protocols into electronic chemotherapy prescribing systems.	COMPLETED AT ST VINCENT'S
Recommendation 15 <i>(Interim Report)</i>	That Local Health Districts and Speciality Networks ensure that minuted meetings of Multidisciplinary Cancer Care teams occur after relevant international or national meetings and on an ad-hoc basis as seminal new evidence emerges that should influence practice.	COMPLETED AT ST VINCENT'S
Recommendation 16 <i>(Interim Report)</i>	That the Cancer Institute NSW works with oncology groups to facilitate meetings occurring after major conferences to review new evidence and agree on which of the evidence should be adopted.	SUPPORTED BY ST VINCENT'S
Recommendation 17 <i>(Interim Report)</i>	That the Cancer Institute NSW prepares a new patient information sheet on dose adjustment of chemotherapy to allow patients and their caregivers to understand the rationale for it.	SUPPORTED BY ST VINCENT'S
Recommendation 18 <i>(Interim Report)</i>	That the Ministry of Health, with the Cancer Institute NSW, examine ways to ensure that all people diagnosed with notifiable cancer in NSW have their care overseen by a Multidisciplinary Cancer Care Team that includes all relevant medical, nursing, pharmacy and allied health staff.	SUPPORTED BY ST VINCENT'S
Recommendation 19 <i>(Interim Report)</i>	That the Secretary, NSW Ministry of Health, expand the terms of reference of this Inquiry to include: patients treated by Dr Grygiel in Western NSW Local Health District (or its predecessors) back to the beginning of 2006 (when CiSCAT, the predecessor of eviQ first became available); and patients treated since 2006 by Dr Grygiel at St Vincent's Hospital Darlinghurst.	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	SUPPORTED BY

<i>(Interim Report)</i>	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
Recommendation 21 <i>(Final Report)</i>	That clinicians 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.	SUPPORTED BY ST VINCENT'S
Recommendation 22 <i>(Final Report)</i>	There are a number of outsourced providers in oncology across NSW in areas such as compounding pharmacy and radiotherapy. These providers should have the same responsibility to demonstrate the quality of their care and share clinical data as any other member of the multidisciplinary cancer care team. They should also have the same responsibilities to contribute to the fail-safe checks that are a hallmark of good multidisciplinary teams and evidence-based clinical care, including escalation where there are concerns about care that have not been adequately addressed. This should be properly reflected in relevant contracts as they are negotiated between Local Health Districts / Specialty Health Networks and third party providers.	IN PROGRESS AT ST VINCENT'S
Recommendation 23 <i>(Final Report)</i>	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.	IN PROGRESS

2. Recommendations for St Vincent's Hospital Sydney

Recommendation 2:

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

AMENDED TO

St Vincent's 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.

Status: COMPLETE

Summary of progress (at 6 months):

With the release of the final report in August 2016, this recommendation was amended to ensure that all patients identified by the extended Terms of Reference who had received a flat dose of carboplatin between 2006 and 2011 were provided with an opportunity to participate in an Open Disclosure process.

St Vincent's supports this amendment and contact was made with all patients or families for the affected group.

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.

AMENDED TO

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

Status: COMPLETE**Summary of progress (at 6 months):**

With the release of the final report in August 2016, this recommendation was amended so that reports on patient outcomes be made to the Hospital's Patient Safety and Quality Committee and Clinical Council every six months and annually to the NSW Ministry of Health.

St Vincent's supports this amendment and a report will be provided, where possible, on this cohort of patients. This item will become a standing agenda item on the respective committees and no further action at this stage is required.

As reported within the three month progress report, 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. St Vincent's is building into MOSAIQ functioning so that regular reports can be generated and reviewed, including patients seen by other ENT and Head and Neck surgeons.

All patients that have contacted St Vincent's and requested further information have had their records updated in MOSAIQ with the data manager responsible for checking back through other patient information systems on campus for any evidence of activity for these patients.

Future actions:

Reports to be provided, where possible, on this cohort of patients.

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 6 months):

St Vincent's Health Australia requires the conduct of Morbidity and Mortality meetings as a routine mechanism for monitoring patterns of care and outcomes through a peer review process. Work has been undertaken to strengthen the consistency and standardisation of the Morbidity and Mortality meetings at St Vincent's. This includes the appointment of a project officer and development of an action plan to reconfirm expectations and accountability, review and implement standardised templates in line with the Clinical Excellence Commission's guidelines for Morbidity and Mortality review, and guidance and support to ensure appropriate trend analysis of data and benchmarking occurs so that monitoring reflects a more comprehensive scope than just patient level data review.

Following consultation and endorsement with Senior Clinicians in the Hospital Wide Mortality Review Committee, the following actions have been completed:

1. Establishing the current baseline through the review of all Terms of Reference for Departmental Morbidity and Mortality meetings and articulating the benchmarking data currently used by each Department
2. Established a process for obtaining bench mark data when not available for some tumour stream
3. Reviewing the current policy and procedure, including the current template for Morbidity and Mortality meeting minutes to ensure a standardised approach at the Department level (including a minimum frequency of meetings)
4. Establishing accountability for monitoring the appropriate conduct and participation in Morbidity and Mortality meetings at the Clinical Stream level through the requirement to report all Departmental Morbidity and Mortality meetings to the monthly Stream Clinical Governance meetings and through a four monthly quality report of Morbidity and Mortality outcomes by Stream to the Hospital Wide Mortality Review Committee and the Patients Safety and Quality Committee
5. Review of the past 12 months of Morbidity and Mortality meeting minutes through a quality audit with recommendations being fed back to Department and Clinical Streams
6. Support to Departments and Clinical Streams to ensure appropriate benchmarking and trend data is made available to conduct Morbidity and Mortality meetings
7. Communication Strategy to encourage referral of recommendations to ensure organisation wide learning's are captured and shared
8. Obtaining all benchmarking data currently used to establish the current data set for use in Morbidity and Mortality meetings

Future actions:

A further quality audit will be conducted in 2017 to confirm sustainability of the improvement initiatives undertaken to strengthen the Morbidity and Mortality review system and ensure accountability across the organisation.

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'.

AMENDED TO

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'

Status: COMPLETE**Summary of progress (at 6 months):**

As noted within the three month report, St Vincent's has been unable to access information on deaths outside of the Hospital from the NSW deaths data register.

St Vincent's Hospital Sydney routinely reviews all deaths through mortality review system and changes were made to the Terms of Reference of the hospital-wide Mortality Review Committee to reflect this recommendation. 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.

Future actions:

St Vincent's will continue to review a random selection of 'expected' deaths as per this recommendation.

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: ONGOING**Summary of progress (at 6 months):**

St Vincent's Hospital Sydney expects that line managers and clinical staff should escalate clinical concerns. In light of the findings of the Inquiry, 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

Since the three-month report, St Vincent's has continued to ensure the new Incident Management Training for all Executive, Clinical Stream Directors, Clinical Stream Managers, Heads of Department, Department Managers and Senior Managers (which included the Incident Identification and Management, Open Disclosure and the Root Cause Analysis review process) is rolled out. The Patient Safety and Quality Unit has continued to deliver this training to staff who were unable to attend the scheduled sessions in May 2016.

Cultural change

St Vincent's is continuing to engage staff through the 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.

'It's OK to Ask' features the following messages:

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

The *'It's OK to Ask'* campaign aims at empowering staff – all of whom have something to contribute – no matter how senior or junior and regardless of speciality or role. The campaign makes clear that all staff should feel comfortable about escalating any patient care queries they may have with their peers or leaders.

In establishing *'It's OK to Ask'*, St Vincent's has put in place a variety of mechanisms to support all staff. If staff feel that they have a clinical question, or feel they need to escalate a matter on behalf of a patient, contact should be made with the clinical stream director or manager or any of the relevant Hospital Executive members.

St Vincent's is currently conducting a staff survey to gauge the impact the *'It's OK to Ask'* campaign is having throughout the organisation. The results will be used to continue to drive the campaign and make change.

Future actions:

Later in 2016, St Vincent's will roll out phase two of the *'It's OK to Ask'* campaign which will focus on patients and their families. Similar to the staff campaign, the message will be that anyone under

St Vincent's care, including their carer or loved-one has a right to respectfully seek more information or clarification about their treatment. The campaign will align itself with the Clinical Excellence Commission's (CEC) REACH program.

Recommendation 23 (NEW):

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.

Status: IN PROGRESS

Summary of progress (at 6 months):

St Vincent's supports this new recommendation that sees a specific program within cancer services developed to build a constructive, people focussed culture for patients and staff, whilst also building restoring relationships with the clinical community in cancer services and senior management.

St Vincent's Hospital acknowledges there were cultural issues in the Medical Oncology Department that prevented staff from raising concerns. Rather than a culture of challenge we instead had a culture of acceptance: junior staff accepted the doctor's dosage practices and senior staff were not made aware of it.

We are implementing a cultural change program in our Cancer Services to build a constructive culture of challenge. This program of work involves:

- **New leadership and changes in key personnel** – In December 2015, we appointed a new Head of Medical Oncology and new medical oncologists. We also have a new Director of Cancer Services.
- **Measuring staff engagement and satisfaction** – St Vincent's staff recently participated in a staff engagement survey run by Gallup. This survey is internationally recognised and validated and will provide baseline data on staff engagement and satisfaction. The results can be broken down by teams and Cancer Services will develop a specific action plan for their Department. The survey will be repeated annually to allow for tracking of results over time.
- **A facilitated restorative process** – St Vincent's is implementing the recommendation of the s122 for a facilitated restorative process in Cancer Services. We plan to engage an agency to assist in facilitating focus groups with Cancer Services staff and the Executive and Senior Leaders of St Vincent's to explore the events and how/what is needed to rebuild confidence and trust within the service and with the community. This will encourage ongoing open dialogue and establish team charters.
- **Education and Training** – The Chief Executive Officer has met with the Chief Executive of the Health Education Training Institute (HETI) to explore options of linking into state-wide education programs such as *Clinician Disclosure* and *Building a Safe Workplace Culture*. The plan will be to roll out these state-wide education programs – starting with Cancer Services and then across St Vincent's Hospital – further aligning with the training programs in other Local Health Districts.

St Vincent's also believes there is work to do to encourage a culture of challenge across our health services, and across the health sector more generally. There is now a well-established link between clinician behaviour and patient safety outcomes such as surgical complications (Catron, Guillaumondegui et al. Am J Med Qual. 2015 Apr 27); adherence to patient safety processes such

handwashing (Talbot, Johnson, Fergus et al. Infect Control Hosp Epidemiol 2013; 34(11); 1129-1136) and medical team performance (Riskin, Erez, Foulk et al. Amer. Acad Paediatrics 2015; June).

Cultural change across the health sector, including equipping staff with the skills to speak up and creating a culture of feedback will take time. At St Vincent's, we are committed to this change process in accordance with our values. We are implementing a number of new programs in Sydney and across the St Vincent's Health Australia Group.

It's OK to ask (St Vincent's Hospital Sydney)

In July 2016, St Vincent's launched a new campaign for staff *'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 program is sponsored by, and reports to, the Hospital CEO.

'It's OK to Ask' features the following messages:

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

The *'It's OK to Ask'* campaign aims at empowering staff – all of whom have something to contribute – no matter how senior or junior and regardless of speciality or role. The campaign makes clear that all staff should feel comfortable about escalating any patient care queries they may have with their peers or leaders.

In establishing *'It's OK to Ask'*, St Vincent's has put in place a variety of mechanisms to support all staff. If staff feel that they have a clinical question, or feel they need to escalate a matter on behalf of a patient, contact should be made with the clinical stream director or manager or any of the relevant Hospital Executive members.

The impact the *'It's OK to Ask'* campaign is having on staff attitudes and behaviours will be periodically measured and tracked through staff surveys. The results will be used to continue to drive the campaign and make change.

Later in 2016, St Vincent's will roll out phase two of the *'It's OK to Ask'* campaign which will focus on patients and their families. Similar to the staff campaign, the message will be that anyone under St Vincent's care, including their carer or loved-one has a right to respectfully seek more information or clarification about their treatment. The campaign will align with the Clinical Excellence Commission's REACH program.

Ethos – Inspired to Shine program (St Vincent's Health Australia – National)

The Ethos program aims to foster a culture that encourages feedback, addresses behaviour that undermines patient or staff wellbeing and embeds safe, respectful and professional behaviour so it is what we do every day. This program has St Vincent's Health Australia Board approval and is a priority program across the St Vincent's Group.

Better management of and responses to inappropriate behaviour, early intervention and improved accountability will support a culture of safety and the delivery of safer, more reliable healthcare. This

requires a redesign of the current structures and processes for dealing with inappropriate behaviour, as well as training for leaders, managers and staff in the skills they need to prevent and respond to inappropriate behaviour.

The Ethos program is built on three principles; that all staff and patient should feel welcome, valued and safe. The program includes:

- a validated, tiered accountability pathway (based on the principles of the Vanderbilt Promoting Professional Accountability model) and a peer driven early intervention process to provide a consistent and transparent approach to addressing unnecessary variation in behaviour;
- a reporting system to allow a safe voice and capture reliable data; and
- a package of capability building and training to equip leaders and staff with the skills they need to role model and teach safe behaviour.

The Ethos program also includes the development of relationships across the health sector, recognising that culture change of this magnitude cannot be undertaken in isolation.

Additionally, St Vincent's, through the Ethos program, seeks to reward and empower staff that demonstrate the highest standards of professionalism as this group represents our cultural strength and will lead the way for others. Project Ethos is a long-term program which strives to enable change in workforce culture across St Vincent's Health Australia.

Future actions:

St Vincent's will continue to work with the multiple initiatives as outlined above, both strategies that are developed at a local level as well as National priorities.

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

Recommendation 22 (NEW):

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

Status: IN PROGRESS**Summary of progress (at 6 months):**

St Vincent's supports this recommendation and is in the process of ensuring that all outsourced groups for Cancer Services have the same responsibility to demonstrate the quality of their care and share clinical data outlined within their contracts.

Future actions:

St Vincent's will continue to undertake a review of contracts with third party providers in cancer services to ensure that this recommendation is achieved.

4. Recommendations for other parties

The remaining recommendations of the Interim Report were directed to other parties and supported by St Vincent's. Actions taken to assist with the implementation of these recommendations were outlined in the three month progress report.

This section provides a brief overview of the actions St Vincent's Hospital Sydney has taken to support the implementation of the new recommendation for clinicians across NSW.

Recommendation	St Vincent's actions to support implementation
<p>Recommendation 21 <i>The clinicians across NSW:</i> Ensure adequate informed for all medical interventions, including chemotherapy. If the clinician knows that his/her practice is outside accepted practice, there is a particular onus to draw this to the attention of patients in the process of providing informed consent, and to document this in the patient notes.</p>	<p>St Vincent's Hospital fully supports this recommendation.</p> <p>St Vincent's Hospital have changed a number of processes to improve the information provided to patients including to formally document information provided in patient consent processes.</p> <p>At St Vincent's, all patients are provided with a copy of the NSW Cancer Institute's eviQ chemotherapy protocol at education sessions ahead of their first treatment and when consent is gained.</p> <p>We are now trialling an additional process for those patients that are recommended to receive a non-eviQ protocol to formally record their consent to the variation. These patients are now provided with information in writing about their proposed protocol, including the clinical rationale for proposing an approved non-eviQ protocol. This document is then scanned into the patient information system as an accompanying document.</p>