

AUDIT OF PUBLIC PATIENT CANCER CARE IN NSW FINAL REPORT



Health



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Contents

EXECUTIVE SUMMARY.....	4
1. Background.....	5
2. Methodology	5
2.1 Scope	5
2.2 Case Identification and Selection	6
2.3 LHD/SHN Clinical Review Teams.....	6
2.4 Clinical Information.....	7
2.5 Clinical Review Team Outcomes	8
3. Findings	8
3.1 Sample Demographics.....	8
3.2 Out of Scope Cases	9
3.3 Clinical Review Team Findings	9
3.3.1 Treatment outside expected / reasonable norms with rationale provided.....	10
4. Conclusion	10

EXECUTIVE SUMMARY

In August 2016 the then NSW Minister for Health announced that there would be a review undertaken to reassure NSW cancer patients that their treatment is sound. This was in response to an Inquiry under Section 122 of the Health Services Act 1997 that found a Senior Medical Oncologist at St Vincent's Hospital Sydney had been prescribing chemotherapy that was 'off-protocol', that is practising in a manner that is not consistent with standard protocols for cancer treatment in NSW. This audit was complemented by an 1800 Inquiry Line to allow people with concerns to call and seek further advice or assistance.

The Ministry established a steering committee to support the audit of public cancer patients. The committee is chaired by the Deputy Secretary System Purchasing and Performance (SPP) of the Ministry of Health and comprises a range of representatives from Local Health Districts (LHDs), NSW Health Pillar organisations (Clinical Excellence Commission and Cancer Institute NSW), the Australian Medical Association (NSW), the Clinical Oncological Society of Australia, the Medical Oncology Group of Australia, the College of Surgeons (NSW), the Faculty of Radiation Oncology within the College of Radiologists (NSW), as well as consumers.

The audit methodology was developed with the steering committee and LHD / Specialty Health Network (SHN) Directors of Cancer Services. The methodology called for a locally led process of review and as such each LHD and SHN convened a clinical review team to implement the audit.

The care of 1,802 patients was reviewed. The sample for each LHD/SHN was based on geographical cancer incidence levels. 1,800 cases represents a statistically valid sample designed to provide a starting point to identify any potential areas of concern that may need further sampling and investigation.

Of the 1,802 finalised cases, 1,795 found to have had treatment within expected and reasonable norms and 7 found to have had treatment outside expected norms. Further review of the records by the local clinical review team determined there was adequate documentation and explanation provided by the treating clinician for the treatment being outside the norm.

1. Background

In February 2016, an Inquiry under Section 122 of the Health Services Act 1997 (the section 122 Inquiry) was announced to investigate the prescribing of chemotherapy at St Vincent's Hospital by a senior staff specialist in Medical Oncology. The Inquiry team, led by the NSW Health Chief Cancer Officer, released a final report on 2 August 2016. The review found a number of patients under the care of a Senior Medical Oncologist were treated with off-protocol flat dosing of chemotherapy. Off-protocol was considered by the Inquiry as the use of a chemotherapy drug in a way that is not provided for in established treatment protocols, calculated as a personalised dose according to their protocol, or conducted with oversight of the Human Research Ethics Committee as set out by the Australian Code for the Responsible Conduct of Research.

In conjunction with the release of the section 122 Inquiry final report, and to reassure patient's that their cancer treatment was within expected norms, the then Minister for Health announced that a review would be undertaken of NSW cancer patients who had received treatment in a public facility between January 2012 and December 2016. The review took the form of a systematic audit process, sampling cases based on cancer incidence levels across the state. The approach was complemented by an 1800 Inquiry Line that allowed people with concerns to call and ask that their care be further investigated.

2. Methodology

The audit was designed to examine the treatment of cancer at the time it is newly diagnosed in people treated in NSW public hospitals, in the context of peer review.

In August 2016, a Steering Committee was established by the Ministry of Health to provide oversight of the audit process, including confirmation of the audit methodology. The Steering Committee is chaired by the Deputy Secretary, System Purchasing and Performance, NSW Ministry of Health. Members included representatives from the Australian Medical Association (NSW), the Clinical Oncological Society of Australia, the Medical Oncology Group of Australia, the College of Surgeons (NSW), the Faculty of Radiation Oncology within the College of Radiologists (NSW), Local Health District (LHD) Chief Executives and consumer representatives.

The audit methodology was developed with the steering committee and LHD / Specialty Health Network (SHN) Directors of Cancer Services. The methodology called for a locally led process of review and as such each LHD and SHN initiated a clinical review team to implement the audit. Audit procedures were also developed to supplement the methodology and provide implementation guidelines for the LHDs and SHNs.

2.1 Scope

The audit was designed to review cancer treatment for a sample of people with cancer, treated within a facility of NSW Health between January 2012 and December 2016.

A systematic random sampling technique was employed. This method involved selecting 1,800 cases over the stated five year period with cases in the period January 2016 to June 2016 sampled at a higher rate. The sample size is statistically valid and provides an accurate assessment of the care and treatment of cancer patients in NSW. 'Statistically

valid' means that the sample size yields a high level of confidence in the result. The sample size was a starting point, and more cases were to be reviewed if there were any instances of care identified as outside expected norms with no valid rationale provided.

The methodology also allowed for review of cancer treatment for people who contacted a state-wide 1800 phone number or the LHD or SHN directly to express specific concerns about their cancer treatment and who meet the same criteria above.

Patient's on clinical trials, being treated with palliative intent or notifications received with no further care provided were all excluded from the audit scope. As out of scope cases were identified, the LHD or SHN was provided with replacement cases sourced through the same sampling methodology utilized to generate the original sample in order to ensure a full 1800 eligible cases were reviewed.

2.2. Case Identification and Selection

To ensure objectivity and consistency, the Ministry of Health with support from the Cancer Institute NSW, determined the sample size for each LHD and SHN. This was based on a process which accounted for population estimates of cancer incidence that have been notified to the NSW Cancer Registry. The sample included care offered across the spectrum of cancer disciplines, including oncology outpatient clinics, chemotherapy units, radiation oncology departments, haematology and surgical services. The sample was weighted towards people who had completed treatment in the last six months.

Cases for the audit were assigned to the LHDs and SHNs from the Ministry of Health. Lists were sourced from the NSW Cancer Registry and contained information for the LHD or SHN to identify the patient and some basic information on the diagnosis and locations of treatment. The list also contained a 'Patient Folder ID' which is a unique identifier that was used for communication between with the Ministry, LHD/SHN and Cancer Institute NSW. Case lists were shared using a secure file sharing mechanism and only utilised the unique identifier.

2.3 LHD/SHN Clinical Review Teams

Each LHD and SHN put in place a clinical review team, consisting of the following members at a minimum:

The Heads of (or delegates for):

- a) Medical Oncology / Haematology
- b) Radiation Oncology
- c) Surgery
- d) Pharmacy (or Oncology Pharmacy)
- e) Oncology Nursing

The LHD/SHN audit process was overseen by the respective Director of Cancer Services with overall executive sponsorship by the LHD or SHN Chief Executive.

Treating clinicians did not review their own cases. Members of the clinical review team were required to deputise for other specialists within the LHD or SHN in cases where one of their patients was subject to the clinical review process.

If an LHD or SHN had limited access to a practitioner in a discipline, arrangements were made with another LHD or SHN for the review to be done by another specialist or team of specialists, as appropriate.

2.4 Clinical Information

For each patient included in the audit, the clinical review team collated relevant clinical information from their records. To assist, the Ministry of Health distributed a structured template based on the version utilised by the Cancer Institute NSW during the Inquiry into off-protocol prescribing of chemotherapy.

The LHD/SHN clinical review team examined the collated information for each patient with a view to determining whether or not the cancer treatment provided was 'within norms' for cancer care in the particular patient's circumstances. These determinations took into account a number of factors including adherence to treatment protocols for cancer. It also took into account after selecting a treatment protocol, that clinicians may individualise treatment by adjusting the dosage according to a patient's age, health, height, weight and other factors such as gender and ethnicity. In addition, after treatment has commenced clinicians may further modify subsequent doses if, for example, a patient has an adverse reaction to the drug.

Individualised chemotherapy treatments may vary from published treatment protocols. This variation may be clinically appropriate and necessary to personalise the treatment for each individual person. It is noted however, variation from treatment protocols and reasons for this should always be discussed with the patient and recorded in the patient's medical records.

Care provided to a patient may be considered outside reasonable norms when treatment varies significantly from published treatment protocols and is not supported by evidence, when doses are not personalised to an individual patient, or when the justification for a dose variation is not clearly documented or communicated to patients.

The methodology of the audit accepted there is no "one-size-fits-all" set of defined parameters that would be equally applicable to all cases. The process of review required the application of clinical judgment by highly skilled clinical review teams, a process that took many thousands of hours. It was suggested that, at a minimum, the clinical review team should specifically consider the following clinical aspects of each patient's initial treatment.

For cases involving surgical treatment:

- choice of treatment and procedure (including the decision of no treatment)
- resection margins (the edge or border of tissue removed in cancer surgery)
- post-operative complications
- histopathology reviewed (the study of diseased tissue removed because of suspected cancer)

For cases involving chemotherapy/radiotherapy:

- choice of treatment and protocol (including the decision of no treatment)

2.5 Clinical Review Team Outcomes

Each case reviewed classified the care the patient received into one of the following three groups with the accompanying actions:

- i. Within expected / reasonable norms – no further action.
- ii. Outside expected / reasonable norms; valid rationale for decision and discussion with the patient/informed consent documented in clinical records – no further action.
- iii. Outside expected / reasonable norms; no rationale for decision provided – refer to a state-wide independent expert panel for an additional detailed review (feedback to the patient / the patient's next-of-kin).

In the event that a case was confirmed as being outside expected/reasonable norms without valid rationale, the LHD or SHN was to notify the patient or the patient's next-of-kin through normal LHD/SHN policies and procedures (including Open Disclosure – NSW Health PD 2014_028), and refer the case to a state-wide expert panel. The LHD or SHN was also to inform the clinician of the outcomes of the review and that further reviews would be conducted.

The audit was designed so if a case was confirmed by the state-wide expert panel to be outside expected/reasonable norms, the local review teams would analyse an additional five cases. The five cases would have been treated by the same clinician, within the timeframe of the audit. If one or more of these additional cases are identified as 'outside expected/reasonable norms; no rationale for decision provided' by the local review team, all additional cases will need to be referred back to the State-wide Expert Panel and the NSW Health Lookback Policy (PD 2007_075) would need to be initiated.

3. Findings

A total of 1,802 cases were finalised by the LHD and SHNs via a local level review process.

Five calls from the state-wide 1800 phone line were referred to the appropriate LHD or SHN as they related to the care of a patient. While these calls did not meet the criteria of the audit and were not included in the final audit count, a local review was conducted, and consultation occurred with the caller to provide reassurance and the opportunity for any further questions.

3.1 Sample Demographics

The finalised cases were not limited by type of cancer or cancer treatment. Cases reviewed represented multiple tumour groups (including breast, colorectal, gastrointestinal, lung, haematology, neurological, head and neck, genitourinary, gynaecologic, cutaneous, and sarcoma).

Cases were assessed across the spectrum of cancer disciplines including chemotherapy, radiation oncology, haematology and surgical services. There were a number of cases returned that had treatment across multiple cancer disciplines (i.e. surgery and chemotherapy). For these cases, all treatment occurrences were reviewed and a holistic approach was applied when determining the clinical review team outcome. The finalised

sample was made up of 51 per cent males and 49 per cent female. Age ranges are represented in Table 1.

Table 1. Audit sample age range

Age range (yrs)	Percentage of sample
0 - 49	11
50 - 59	12
60 - 69	22
70 - 79	27
80+	28
Total	100

3.2 Out of Scope Cases

If the LHD/SHN clinical review teams assessed that a case did not meet the scope of the audit as outlined in section 2.1, this case was referred back to the Ministry. A total of 565 out-of-scope cases were submitted to the Ministry from across the state. To maintain the integrity of the sample, a 'like' replacement case was provided by the NSW Cancer Registry based on area of residence, location of treatment and year of first treatment.

Cases returned to the Ministry as out-of-scope were for reasons including:

- patient did not receive cancer treatment in the LHD/SHN it was originally allocated (these cases were returned to the NSW Cancer Registry reserve pool, and utilised for the appropriate LHD/SHN if required)
- patient received palliative management for symptomatic treatment only with no intention to cure the cancer or otherwise change the clinical course
- initial cancer diagnosis was outside the timeframe for the audit
- patient was treated in a private facility with no element of public treatment within the scope timeframe
- patient was on a clinical trial for cancer treatment
- no definitive cancer diagnosis in the LHD/SHN it was allocated
- skin cancer managed by a local general practitioner

3.3 Clinical Review Team Findings

The local clinical review teams classified each case into one of three groups (as described in 2.5). The review team outcomes are displayed in Table 2 by Metropolitan and Rural and Regional LHD/SHNs to reflect the population estimates of cancer incidence of which the audit sample size was based on.

Table 2. Clinical review team outcomes

NSW Health Districts and Specialty Networks	Total reviewed (no. cases)	Treatment within expected/reasonable norms (no. cases)	Treatment outside expected/reasonable norms with valid rationale provided (no. cases)	Treatment outside expected/reasonable norms with no rationale provided (no. cases)
Metropolitan	1259	1257	2	0
Rural and regional	543	538	5	0
Total	1802	1795	7	0

3.3.1 Treatment outside expected/reasonable norms with rationale provided

The audit methodology acknowledged that determining the appropriateness of care is highly complex and context dependent.

For the 7 cases in this category, the local clinical review teams were able to establish, and accepted, that there was valid rationale for the treatment provided.

Reasons included;

- altered treatment due to the presence of comorbidities not reflected in the standard treatment for the patient's age and tumour group
- treatment options limited by the patient's specific requests (including fertility preservation)
- patients who chose not to return for treatment

4. Conclusion

The audit provided an opportunity for insight into the care provided to cancer patients across the state. It included a diverse range of cancers, across a number of age ranges and was representative of care delivered in metropolitan and regional locations.

After a review by a team of specialists, the audit found that none of the 1,802 cases were assessed to have treatment outside expected and reasonable norms without valid rationale having been provided. A number of elements were taken into account in establishing 'reasonable' norms including adherence to treatment protocols and the individual circumstances of the patient.

Going forward there is still a number of opportunities to lead process improvement relating to cancer care in NSW. The NSW Ministry of Health continues to work with the LHDs and SHNs to implement initiatives relating to the management and monitoring of care consistent with the recommendations of the s. 122 Inquiry.