The Victorian Lung Cancer Registry Pilot: Improving the quality of lung cancer care through the use of a disease quality registry.

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RS conceived of the study, and participated in its design and coordination and drafted the manuscript.
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JM conceived of the study, and participated in its design and coordination.
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Background: Lung cancer remains a major disease burden in Victoria (Australia) and requires a complex and multidisciplinary approach to ensure optimal care and outcomes. To date, no uniform mechanism is available to capture standardized population based outcomes and thereby provide benchmarking. The establishment of such a data platform is therefore a primary requisite to enable description of process and outcome in lung cancer care and to drive improvement in the quality of care provided to individuals with lung cancer.

Materials and Methods: A disease quality registry pilot has been established to capture prospective data on all adult patients with clinical or tissue diagnoses of small cell (SCLC) and non-small cell lung cancer (NSCLC). Steering and management committees provide clinical governance and supervise quality indicator selection. Quality indicators were selected following extensive literature review and evaluation of established clinical practice guidelines. A minimum dataset has been established and training and data capture by data collectors is facilitated using a web based portal. Case ascertainment is established by regular institutional reporting of ICD-10 discharge coding. Recruitment is optimized by provision of opt-out consent.

Results: The collection of a standardized minimum data set optimizes capacity for harmonized population-based data capture. Data collection has commenced in a variety of settings reflecting metropolitan and rural, and public and private health care institutions. The data set provides scope for the construction of a risk-adjusted model for outcomes. A data access policy and a mechanism for escalation policy for outcome outliers has been established.

Conclusions: The Victorian Lung Cancer Registry provides a unique capacity to provide and confirm quality assessment in lung cancer and to drive improvement in quality of care across multidisciplinary stakeholders.

Background

Lung cancer remains a major disease burden in Australia, the fourth most common cancer, with 9563 new cases reported in 2006 comprising 9% of all cancer cases[1]. Survival continues to be poor and represents the leading cause of cancer death (7626 deaths 2007), where just 12% of patients survive 5 years from diagnosis.

The optimal management of lung cancer is complex and dependent on coordinated multidisciplinary evaluation, decision-making and access to a broad array of diagnostic and therapeutic resources. The availability, timeliness and effectiveness of each of these processes is likely to determine the quality of delivered care and hence impact outcome. Additionally, there is evidence of variation in care and prognosis in selected groups including rural and remote communities[2;3], lower socioeconomic areas[4;5] as well as higher disease incidence in indigenous Aboriginal and Torres Strait Islander communities[6;7].

Clinical disease quality registries enable the collection of defined minimum clinical datasets from patients which enable the description of indicators describing the quality of disease management, including safety, effectiveness, efficiency, timeliness, equity of access and patient-centredness in clinical care[8;9].

The description of indicators reflecting domains of quality enables benchmarking and the feedback of clinically credible information to clinicians to drive quality improvement to health services, hospitals, clinical units and clinicians[10].

Lung cancer management has a number of attributes which demand an urgent need to develop data systems to drive quality improvement at state and national levels. These attributes include a high burden of mortality, morbidity and cost; management processes which are sequential, multidisciplinary, interdependent and complex and concerns regarding equity of access and variation in practice of care. We describe the development of a scalable pilot clinical quality registry for non-small cell and small cell lung cancer with the objective of driving improvement in the quality of care delivered to patients in Victoria, Australia.

Methods/Design

METHODS/DESIGN

A pilot lung cancer quality registry was established in July 2011 with the objective of systematically collecting information on all newly diagnosed NSCLC and SCLC; to assess patterns of presentation, care, and outcomes; to enable assessment of quality measures, the evaluation of variation, and the potential causes of this variation.

Registry governance

The VLCR governance model was developed in accordance with the Operating Principles and Technical Standards for Australian Clinical Quality Registries[11] outlined in Figure 1.

Population and recruitment strategy

Site selection targeted centres providing substantial patient numbers with representation from metropolitan and regional hospitals in both private and public sectors. In total, the seven sites accounted for approximately 20.1% of newly diagnosed lung cancer cases in Victoria (Victorian Cancer Registry 2008).

Inclusion and exclusion criteria

INCLUSION CRITERIA

Lung cancer patients over 18 years with institutional discharge ICD-10 lung cancer coding (C34.0 – C34.9, Z85.1, Z85.2) including:

1) Clinical *or* pathological diagnostic basis.

2) Diagnosis date falls after institution enrolment and commencement of data capture (*incident cases*).

3) Patients with previous lung cancer (>5 years previous) but with no identifiable intervening disease included as second primary disease.

EXCLUSION CRITERIA

Exclusion criteria include:

1) Diagnosis prior to data capture commencement (*prevalent cases*).

2) Patients decline participation and opt off consent.

3) Secondary lung cancer (metastases to the lung from alternate primary)

4) Mesothelioma

5) Unable to comply with registry requirements

Recruitment

Participating hospitals provide by secure file transfer, a subject list coded within sequential 2-4 week recruitment frames. Living subjects are mailed a patient information booklet detailing the objectives and requirements of patient participation and invited to opt off by phone call to the registry via a freephone number. Data collection commences two weeks following mail-out if a consent opt-off has not been received.

Ethics and consent

The registry has been assessed and approved by Monash University (CF11/1693 - 2011000940 - approved to June 2016) and participating hospital's ethics committees.

Determining the minimum dataset and quality indicators

In the absence of broadly accepted Quality Indicators (QI) for lung cancer care a comprehensive evidence review was undertaken. The strategy involved: 1. Review of Australian clinical practice guidelines (CPG) for management of NSCLC and

SCLC (NHMRC)[12]. 2. Review of International CPG for the management of NSCLC and SCLC (USA ASCO, Europe ESMO, UK NICE)[13-39]. 3. Review of literature available since publication of clinical practice guidelines[40-69]. 4. Literature review of existing QI in the diagnosis and management of lung cancer. 5. Call for expert review and proposal of novel indicators for lung cancer care. CPG were considered for inclusion on the basis of established selection criteria including a need to be epidemiologically robust, evidence-based, clearly defined, feasibly collected and practically collectable with reasonable effort, and providing scope for leverage by a CPG to improve efficiency of the measure. A list of clinical practice guidelines captured by the VLCR is provided in Table 1. Quality indicators were derived from literature and clinical practice guidelines review following a process of expert consideration and negotiation and are listed in Table 2.

Follow up

At six, twelve and twenty four months after diagnosis, vital status checks are made and living participants contacted by telephone to verify management details and to measure general health and disease-specific quality of life. The general health quality of life (QoL) tool selected was the SF12v2[28]

Reporting framework

It is anticipated that the feedback of institutional performance will recruit competitive engagement by participating stakeholders following a feedback loop. Reporting and feedback of results is to be performed using three mechanisms. First, online reports of quality indicators will be available via the VLCR portal in which the stakeholder's institutional performance will be available to individual stakeholders while the performance of other institutions will be available in blinded format. Second, prepared annual reports of quality indicators will be returned to institutional

stakeholder groups in which the home institution will be able to compare their performance with the blinded performance of other institutional stakeholders. Finally, the VLCR will publish an annual report of VLCR quality indicator outcomes.

The reporting framework has been established in compliance with National Operating Principles for Clinical Quality Registries.[41] An escalation policy has been developed in consultation with clinicians and health services to flag outliers in relation to risk adjusted mortality. Aggregate reports will be made available to hospital executives and identifiable case information will be accessible by the clinician and the head of unit.

Discussion

Benchmarking in cancer care has demonstrable benefit in improving quality in clinically relevant outcomes[70;71], and there is now established evidence of benefit in cancer attributable to the development and institution of cancer registries[72]. While clinical benefit remains a primary objective, additional benefits have been identified and include the development of platforms to support longitudinal research[73], a capacity to coordinate provincial funding opportunities[74] and a possible role in cancer prevention[75].

Key to the interpretation of quality measures in lung cancer care is definition of the population under review. The pursuit of quality at individual, institutional and regional levels are meritorious yet the denominators for each description remain distinct. Descriptions emanating from multidisciplinary meetings[76] and regional group practices[42] have been reported, however, such reports may self select organisations with established desire and process for quality improvement. The total population of individuals with NSCLC/SCLC is therefore of primary interest whether they be clinically or pathologically ascertained, treated or untreated with definitive therapy, covered or uncovered by health insurance and independent of presentation to specific institutions such as hospital multidisciplinary care meetings.

The VLCR pilot aims at expansion to the whole Victorian population but commences by sampling from institutions that differ in size, geography (urban vs rural), population composition, patient volume, resource availability and administrative structure (public vs private). The proposed hypothesis is that process and outcome measures are likely to vary between centres due to organisational differences and may result in inequities in both access to care and in process of care provision

between centres. The sampling strategy chosen therefore is to attempt to identify variation which may be potentially amenable to feedback improvement rather than to create a representative sample of the Victorian population.

Domains of quality assessment describe the structure, process and outcome of lung cancer care[41;77]. Structural quality reflects the suitability of the setting to provide lung cancer care and considers the availability of facilities, material and human resources, and organizational structure to provide a capacity for care delivery[78]. Structural quality measures have potential to identify gaps in care due to unavailability of resources such as access to EBUS, PET scanning or experienced thoracic surgeons.

Process quality reflects the actual delivery of care, including consultation, communication, diagnostic tests, procedures, and the type of care a patient receives for a given situation (such as radiation vs surgery), and may be assessed by comparison of delivered care with recommended standard of care. The use of process measures has the distinct benefit of providing local institutions (departments) direct capacity for audit and review with the identification of actionable outcomes. Surgical examples may include reduced pneumonectomy and exploratory thoracotomy rates[79] and the increased use of VATS surgical access.

Outcome describes the consequence of care and may be assessed by measures including quality of life, mortality or survival. Outcome measures are broadly regarded but are subject to multiple confounders and degraded by problems with data completeness.

The selection of individual measures and the breadth and range of measures of lung cancer quality remains somewhat contentious given a varying range of evidence in

support of such measures. Evolving patterns of care will also insist that panels of quality measures will need to evolve as investigation and management approaches evolve.

Data completeness is a key challenge to the collection of data sets across a range of institutions where data capture systems may provide some variation. A review of data completeness is therefore proposed by the VLCR after a period of data capture with a view to censoring data elements that fail to meet capture standards.

Previous attempts at aggregation of disparate data sets for the purpose of quality improvement has been fraught with difficulty and the potential for degeneracy[80-82] and so the capacity to populate such registries is clearly dependent on the prospective development of a standardised and unified data system across a population.

In Australia, cancer is a notifiable disease with a mandate to collect data on cancer incidence and mortality. Despite legislative responsibility to notify cancer registries of new diagnoses, as many as 12% remain unreported, raising doubt about the completeness of governmental registry data sets[83-85]. Previous studies also reveal that case ascertainment may be influenced by institutional data systems and that inadequacies therein may mask variations in care[86]. Incomplete ascertainment by registries may also significantly bias estimates of survival[873], therefore prompting the need for review of ascertainment strategies. The use of opt-out consent provides a major advance by enabling rapid optimal recruitment with minimal opt outs and minimised distress to participants.

The Danish Lung Cancer Registry (DLCR) established in 2000, collects data on lung cancer patients, with ascertainment provided by positive diagnostic procedures or

specific NSCLC related treatment completion[79]. The population recruited therefore potentially excluded individuals who did not achieve a tissue diagnosis and those who may not have had a specific treatment for lung cancer. Feedback to participating surgeons was provided through direct daily reporting from the database as well as annual reports which were evaluated by a steering committee inviting feedback through a series of local, regional and national audits to help identify problems and barriers and to propose specific strategies in order to improve specific results.

The DLCR has reported impressive statistical and clinical improvement in 1 and 2-year postoperative survival, 30-day postoperative mortality, agreement between clinical TNM stage (cTNM) and pathological TNM stage (pTNM), operation types (lobectomy vs pneumonectomy) and waiting times.

Indicators reported by the DLCR were restricted to thoracic surgery but a clear model and proof of concept is provided for other lung cancer diagnostic, management and therapeutic skill groups. Indeed little evidence has been reported in the areas of quality improvement in medical and radiation oncology, palliative care and respiratory medicine and even less in the area of patient related outcomes in NSCLC. This paucity of information identifies a clear unmet need in describing quality across the entire multidisciplinary process of care and the importance of the development of indicators to reflect patient related outcomes in NSCLC.

The development of a lung cancer quality indicator data platform providing prompt and accurate data to healthcare providers is a likely crucial prelude to quality improvement in lung cancer care. The key to success of the process however will lie in the capacity of the registry to recruit critical appraisal and response to data

outcomes by both hospital clinicians and by the governance, management and administration of health authorities.

The Victorian Lung Cancer Registry pilot is a scalable initiative with the capacity to become a population-based registry with the objective of improving knowledge of patterns and quality of care; reduction in variation of treatment and outcome; to improve compliance with best practice guidelines and to improve the understanding of factors that predict favorable and unfavourable treatment outcomes in lung cancer care.

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Table 1. VLCR Clinical Practice Guidelines

Clinical Practice Guidelines captured in VLCR
NSCLC **Diagnosis and staging**
1. TNM stage, performance status and weight loss are independent prognostic factors in patients with non-small cell lung cancer, and should be documented at diagnosis in all patients. IV
2. Due to the therapeutic implications, it is important to classify the histologic subtype of NSCLC on diagnostic specimens as accurately as possible, particularly to enable accurate distinction between the key histologic subtypes: adenocarcinoma and squamous cell carcinoma.
3. Patients with mediastinal nodes larger than 1cm in transverse diameter

on CT who otherwise have resectable lung disease should undergo further staging evaluation.

4. PET has been found to be more accurate than CT in mediastinal nodal staging for non-small cell lung cancer. A negative PET is highly specific, but positive PET nodes are not always malignant and histological confirmation may be required before advancing to definitive management. I-O

5. PET is more accurate in overall M staging than conventional staging methods.

Treatment

1. Surgical resection is recommended for early stage non-small cell lung cancer, as this gives the best results of any form of treatment.

2. Lobectomy is preferred to limited resection in patients with operable T1 N0 NSCLC. II

3. Regional lymph node assessment should be performed with all lung resections for NSCLC. Radical mediastinal lymph node dissection whilst more accurately staging the patient provides no significant survival advantage over appropriate mediastinal lymph node sampling. II

4. In patients who have had complete resection of stage I NSCLC, postoperative radiotherapy is not recommended.

5. In patients who have had complete resection of stage II NSCLC, postoperative radiotherapy is not recommended.

6. Patients with completely resected stage II NSCLC should be offered 3-4 cycles of adjuvant cisplatin based chemotherapy.

7. Patients who have a good performance status (WHO 1, 2) and completely resected stage III non-small cell lung cancer should be offered adjuvant cisplatin-based chemotherapy.

8. In patients with inoperable stage I NSCLC and good performance status, high dose radiotherapy is an appropriate treatment option.

9. Chemotherapy is appropriate treatment for patients with advanced NSCLC who have good performance status (ECOG ≤ 2) and are otherwise medically fit as it has been shown to improve survival.

10. Concomitant cisplatin and radiotherapy are associated with a better survival than if the two treatments are given sequentially. II

11. Patients fit for chemotherapy should be offered 3G platinum-based combination chemotherapy (vinorelbine, paclitaxel, docetaxel, irinotecan or gemcitabine) in preference to 3G agent monotherapy, as it is more effective.

12. For patients with good performance status and inoperable stage III NSCLC, the concurrent administration of chemotherapy and radiotherapy is recommended.

13. The combination of cisplatin-based chemotherapy and radical radiotherapy in patients with good performance status is associated with a small but significant survival advantage compared with radiotherapy alone in NSCLC. I

14. In patients with inoperable NSCLC and who have no evidence of distant metastases, radiotherapy is recommended to loco-regional disease because it may be associated with a survival advantage compared with placebo. II

SCLC
Diagnosis and staging

1. In patients with small cell lung cancer, stage (limited versus extensive) and performance status are essential prognostic factors, and should be documented at diagnosis in every case.

Treatment

1. Platinum-etoposide regimens are considered the standard systemic chemotherapy in the treatment of limited stage small cell lung cancer.

2. The platinum etoposide regimen is recommended as the first-line therapy for patients with extensive stage small cell lung cancer. Irinotecan-platinum may be an alternative in selected patients.

3. Platinum plus etoposide is recommended as the chemotherapy backbone for concurrent chemoradiotherapy in patients with limited stage small cell lung cancer.

4. Fit patients with limited stage small cell lung cancer should receive thoracic radiotherapy concurrently with the first cycle of chemotherapy or as soon as possible thereafter.

5. Patients with limited stage and a complete response to initial therapy, and patients with extensive stage and any response to initial therapy should be offered prophylactic cranial irradiation.

6. For patients who have achieved a complete response after induction therapy, prophylactic cranial irradiation is associated with a reduction in

rate of brain metastases and prolongation of survival.

PALLIATIVE AND SUPPORTIVE CARE

1. Psychological interventions and early referral to psycho-oncology and palliative care services improves quality of life in patients with cancer.

2. It is recommended to refer patients with stage IV inoperable NSCLC to palliative care at the time of diagnosis of metastatic disease.

3. Radiotherapy is an effective modality for the management of certain symptoms caused by uncontrolled intrathoracic disease, and short courses of radiotherapy are as effective as more fractionated regimens.

4. When surgery is not considered appropriate, radiotherapy should be started immediately. Radiotherapy is considered as effective as surgery in achieving symptomatic relief.

5. Specialist palliative care services should be used to improve outcomes in the care of patients with cancer.

Table 2. VLCR Quality Indicators

Process and diagnostic indicators

1. Proportion of patients diagnosed ≤ 28 days from referral
2. Proportion of patients initiating definitive treatment ≤ 14 days from diagnosis
3. Proportion of patients initiating definitive treatment ≤ 42 days from referral
4. Proportion of patients with documented screening for supportive care needs
5. Proportion of patients with documented ECOG status at diagnosis
6. Proportion of patients with documented LOW at diagnosis
7. Proportion of patients with documented clinical TNM prior to definitive treatment
8. Proportion of patients with documented pathological TNM post curative resection
9. Highest level of staging prior to curative resection
10. Proportion of patients with pathological diagnosis

Surgical Indicators:

1. Proportion of patients with clinical stage I and II non-small cell lung cancer (NSCLC) and no medical contraindications to operative intervention undergoing surgical resection

2. Proportion of surgical resection patients with clinical stage I and II non-small cell lung cancer (NSCLC) and no medical contraindications to operative intervention undergoing lobectomy
3. Proportion of patients with clinical stage I and II non-small cell lung cancer (NSCLC) and no medical contraindications to operative intervention undergoing surgical resection by VATS approach
4. Proportion of patients with clinical stage I and II non-small cell lung cancer (NSCLC) and no medical contraindications to operative intervention undergoing surgical resection with lymph node dissection
5. 30 day postoperative mortality for patients with clinical stage I and II non-small cell lung cancer (NSCLC) and no medical contraindications to operative intervention undergoing surgical resection

Chemotherapy Indicators:

1. Proportion of patients with infiltrative stage III (N2,3) NSCLC and performance status 0-1 considered for curative-intent treatment receiving concurrent combination platinum-based chemotherapy and radiotherapy
2. Proportion of patients with completely resected pathologic stage IIA,B(N0-1) NSCLC and good performance status receiving postoperative platinum-based chemotherapy
3. Proportion of patients with known epidermal growth factor receptor (EGFR) mutations and stage IV NSCLC receiving first-line therapy with an EGFR tyrosine kinase inhibitor (gefitinib, erlotinib).

Radiotherapy Indicators:

1. Proportion of patients with infiltrative stage III (N2,3) NSCLC and performance status 0-1, considered for curative-intent treatment receiving combination platinum-based chemotherapy and radiotherapy .

Palliative care Indicators:

1. Proportion of patients with stage IV NSCLC referred for palliative care within 8 weeks of diagnosis/staging.
2. Proportion of patients receiving chemotherapy within 30 days of death
3. Proportion of patients receiving no active anti-cancer treatment

Survival

1. 6 months
2. 1 year
3. 2 years
4. 5 years

Quality of Life

1. SF12 at 6 months
2. SF12 at 1 year

Figure 1. VLCR Governance structure