**Does timely care matter to lung cancer patients? A sub-study of the Continuous Improvement in Care – Cancer (CIC-Cancer) Project.**

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| **1. Project Details** |

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| **Research Project Title:** | Does timely care matter to lung cancer patients? A sub-study of the Continuous Improvement in Care – Cancer (CIC-Cancer) Project.  |
| **Protocol Number (Version and Date):** | V1 30/04/2019 |
| **Amendment** **(Number and Date):** | Not applicable  |
| **Project Start Date:** | June 2019 | **Project Finish Date:** | June 2021  |
| **Coordinating Principal Investigator Name:** | Dr Phoebe Brownell  |
| **Coordinating Principal Investigator Contact Details:** | Phone: 0411 618 742 Email: phoebe.brownell@health.wa.gov.au  |
| **Sponsor Name (if applicable):** | Not applicable  |
| **Laboratory Name (if applicable):** | Not applicable  |

* 1. *Project Summary*

Lung cancer is the leading cause of cancer-related mortality and morbidity in Australia, with more than 8000 Australians predicted to die in 2018 alone.1 Due to the poor outcomes experiences by many lung cancer patients, clinicians attempt to provide rapid review, diagnosis and treatment and adhere to the timeframes suggested in the Cancer Council’s Optimal Care Pathway (OCP).2 Whilst scientific end points, such as progression free survival and overall survival are important , there is currently a move towards the measurement of patient reported outcomes (PROMs) and patient satisfaction as quality indicators in cancer care. This move is being championed in Western Australia by the Continuous Improvement in Care – Cancer (CIC-Cancer) Project.

 This study aims to establish if providing guideline-driven care, in terms of timeliness, improves patient satisfaction amongst people with suspected or proven lung cancer. Patients with primary lung cancer undergoing antineoplastic treatment will respond to the Patient Satisfaction with Cancer Care survey tool.3 This tool asks patients to respond to 18 statements on a five point Likert scale and assesses various healthcare domains, including access to appointments and communication from the treating physician. Statistical methods will then be used to establish if timely care is a predictor of patient satisfaction.

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| **2. Rationale / Background** |

* 1. *Summary of findings from previous projects, relevant to this proposed project*.

Lung cancer places a significant burden on the Australian health care system, both in terms of mortality and morbidity. It is the fifth most common cancer in Australia but the leading cause of cancer related death, with more than 9 000 people predicted to die from lung cancer in 2018 in Australia alone.1 Despite significant improvements in cancer survivorship over the last 30 years, there has been only minimal improvement in lung cancer outcomes, with the five year survival rate still sitting below 20%.1 Lung cancer is also the leading cause of cancer related morbidity, accounting for almost 20% of all cancer burden in our community, predominantly due to premature death.1

Given the poor outcomes for patients with lung cancer, both national and international guidelines have been created, to standardize patient care between sites and provide a framework for best clinical practice.These guidelines emphasise rapid review, diagnosis and treatment. The Optimal Care Pathway (OCP) used in Australia focusses on timely and pathway-driven care with patient-centric support provided alongside medical treatment at each stage of the lung cancer journey. In terms of timeliness, the OCP suggests that a patient in whom there is a suspicion of lung cancer on the basis of imaging, should be seen by a specialist within 14 days of referral and once a diagnosis of primary lung cancer is made, treatment should be commenced within 42 days of the original referral to a specialist.2

The Australian OCP recommends timeframes that are comparable for the most part with those suggested in international guidelines.4,5 The United Kingdom refers to the 2017 National Optimal Lung Cancer Pathway, which suggests maximum waiting times of 14 days from referral to diagnosis and 28 days from diagnosis to treatment.4 The American College of Chest Physicians’ guideline states that “for patients with known or suspected lung cancer, we suggest that the delivery of care be timely and efficient,” but does not specify a particular timeframe.5 The evidence that these timeframes is based on is mixed and many studies suggest that the ability of lung cancer services to comply with them is variable.6 This means that ongoing research into the impact of timeliness of lung cancer care is important in validating our current guidelines and defining new timeframes if needed.

However, there is currently a move towards the collection of patient reported health-related quality of life (HR-QOL) outcomes to guide service delivery and the measurement of patient satisfaction as a quality indicator in cancer care. This movement is being championed in Western Australia by the Continuous Improvement in Care – Cancer (CIC-Cancer) Project, which aims to establish clinical quality registries for five cancer types and assess the routine use of patient reported outcome measures (PROMs) to improve the patient experience. This emphasis on patient-centric care is of special importance in lung cancer, where the survival outcomes remain poor and enhancing quality of life and satisfaction with healthcare is paramount. Several studies suggest that delays in cancer diagnosis and treatment increase patient psychological distress but it is yet to be established whether achieving the recommended review and treatment intervals suggested in the OCP improves patient satisfaction with cancer care.7 The CIC-Cancer Project is well placed to investigate this question in a local cohort of patients.

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| **3. Project Aims / Objectives / Hypotheses** |

* 1. *Detailed description of the specific primary and secondary objectives and the purpose of the project. Describe any hypotheses that will be tested.*

The aim of this project is to establish if providing review and treatment within the OCP recommended timeframes improves patient satisfaction with cancer-related healthcare. We hypothesise that those patients reviewed and treated quickly will report higher levels of satisfaction.

 The primary objective is patient satisfaction, as measured by the PSCC survey tool.3 Secondary objectives or outcomes are patient responses to two additional questions. Firstly, “How would you rate overall the cancer care you have received to date?” with response options of 1 = Excellent, 2 = Good, 3 = Fair, 4 = Poor, 5 = Don’t know. Secondly, “Do you feel the time from your initial referral to starting treatment has been 1 = Much too quick, 2 = A bit too quick, 3 = Just right, 4 = A bit too slow, 5 = Much too slow.”

The purpose of this project is to validate the use of the Cancer Council OCP. In lung cancer care, we strive to provide timely care on the assumption that it will improve survival but the evidence supporting that is mixed.6 However, another reason for providing timely care would be to increase patient satisfaction with cancer-related health care and this is a very pertinent topic in the current climate of patient-centric care. If this project proves that providing guideline-driven timely care enhances patient satisfaction, it will help to validate our existing guidelines and approach to diagnosis and treatment in lung cancer patients.

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| **4. Project Design** |

* 1. *Type (e.g. pilot, qualitative, quantitative) and design (e.g. observational, intervention) of the project to be conducted, including how the objectives (listed in 3.1) will be measured.*

This is a prospective observational project where the primary outcome is measured on a quantitative scale.

The primary objective (patient satisfaction) will be measured using the PSCC survey tool.3 This is an 18 point survey that was developed and validated in an 891 American patient cohort in 2011 and covers several domains of patient satisfaction including access to and co-ordination of care and relationships and communication with health professionals. Each statement is responded to on a 5-point Likert scale where 1 = Strongly agree, 2 = Agree, 3 = Neutral, 4 = Disagree, 5 = Strongly disagree. The total score is obtained by adding each score, thus giving a result out of 90, where lower scores indicate better satisfaction with care.

 Secondary objectives will be measured on 5-point Likert scales as well, as outlined above.

* 1. *Source of participants, datasets or collections - research population, sample size, source, and sampling frame.*

All patients reviewed by the Royal Perth Hospital (RPH) respiratory service with suspected lung cancer will be offered participation in the CIC-Cancer Project. From this cohort, those with confirmed primary lung cancer and receiving active antineoplastic treatment will be eligible to take part in our patient satisfaction project. The project will also be running at St John of God Healthcare Midland Campus (SJOG Midland).

Based on a pilot of 40 Western Australian lung cancer patients, 80% of patients scored ≤36 on the PSCC (ie. responses of Strongly agree or Agree to all statements). In order to achieve a 6% absolute margin of error of the true proportion with a 95% confidence interval, the minimum sample size to adequately power this project is 171 patients.

* 1. *Participant inclusion criteria.*

1) Diagnosis of primary lung cancer

2) Receiving active antineoplastic therapy

3) Reviewed by the Respiratory Service during the study period of 2019 – 2021.

* 1. *Participant exclusion criteria.*

1) Patients under the age of 18

2) Patients unable to answer survey questions

3) Patients with mesothelioma.

* 1. *Participant withdrawal criteria and procedures specifying (if applicable):*

*(a) when and how to withdraw participants from the project;*

*(b) the type and timing of the data to be collected for withdrawn participant(s);*

*(c) whether and how participants are to be replaced; and*

*(d) the follow-up for participants withdrawn from the project.*

Patients are free to withdraw from the project at any point between recruitment and survey administration. They will be provided with contact details for the Co-ordinating Principle Investigator to this end. Patients are also free to withdraw from the CIC-Cancer Project at any point and this would imply withdrawal from the patient satisfaction study as well, given access to CIC-Cancer data is required.

 Patients who withdraw from the study will not be committed to any follow up. None of their stored data will be used. They will be replaced by other lung cancer patients identified by the RPH respiratory service.

* 1. *Measures taken to minimise/avoid bias, including randomisation and blinding.*

The PSCC survey will be administered by a clinician who is not involved in the patient’s care to avoid reporting bias.

* 1. *Maintenance of any blinding records or randomisation codes and procedures for breaking codes.*

Not applicable

* 1. *Methods to be used for the project, including justifications for interventions, procedures, measurements, observations, laboratory investigations.*

Suitable patients will be contacted via email, postal mail or telephone by the study investigators within one week before or after commencing cancer treatment. No response will prompt a second contact before the patient is deemed to have declined participation in the study.

The Patient Satisfaction with Cancer Care (PSCC) survey tool will be administered.3 In addition, each patient will be asked two further questions. Firstly, “How would you rate overall the cancer care you have received to date?” with response options of 1 = Excellent, 2 = Good, 3 = Fair, 4 = Poor, 5 = Don’t know. Secondly, “Do you feel the time from your initial referral to starting treatment has been 1 = Much too quick, 2 = A bit too quick, 3 = Just right, 4 = A bit too slow, 5 = Much too slow.” The total score is obtained by adding the individual scores to give a total out of 90 points, where lower scores equate to higher levels of satisfaction.

 Demographic and clinical data, such as age, gender, health insurance status, medical comorbidities and performance status will also be extracted from the CIC-Cancer database for each patient to be analysed as possible confounding factors in patient satisfaction. The CIC-Cancer Project has ethics approval at RPH and is awaiting final HREC approval at SJOG Midland at the time of writing.

* 1. *Expected duration of the project, and a description of the sequence and duration of all techniques or assessments to be performed, including follow-up (if applicable).*

Based on the current number of lung cancer patients being seen at both RPH and SJOG Midland, it is anticipated that it will take two years to recruit the required 171 patients. There will be simultaneous patient recruitment, survey administration, interrogation of the CIC-Cancer database and data entry. Statistical analysis will occur at the end of the study period. Patients are not required for any follow up.

* 1. *Criteria for the termination of the project (if applicable).*

The project will end when the sample size of 171 patients has been reached.

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| **5. Treatment of Participants** |

* 1. *The treatments, interventions or methods to be utilised and the follow-up period for participants for each treatment group/arm of the project.*

See above for project methodology. No intervention is involved in this study. Patients are not committed to any follow up after survey administration.

* 1. *The medications/treatments permitted (including rescue medication) and not permitted before and/or during the project.*

There are no restrictions on patient choice of treatment, provided they are receiving active lung cancer therapy.

* 1. *The procedures for monitoring participant compliance (if applicable).*

Not applicable.

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| **6. Assessment of Efficacy** |

* 1. *Specification of the efficacy parameters (if applicable).*

Not applicable – the study does not involve an intervention.

* 1. *The methods and timing for assessing, recording, and analysing efficacy parameters (if applicable).*

Not applicable.

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| **7. Assessment of Safety** |

* 1. *Summary of known and potential risks and benefits (including emotional trauma), if any, to research participants.*

The only foreseeable risk from this project is emotional discomfort or inconvenience at having to provide survey answers.

The potential benefit to individual patients is opening channels of open dialogue about aspects of patient satisfaction (provision of information, shared decision making, communication with their clinician etc) with their treating clinician and empowering patients to seek improvement in the facets of care that make them more satisfied.

* 1. *The procedures for assessing and responding to potential participant safety events*.

Not applicable.

* 1. *The procedures for eliciting reports of and for recording and reporting adverse events. Include definitions of adverse events.*

Patients will be made aware during recruitment that they are free to contact the Co-ordinating Principle Investigator if survey administration causes emotional distress and withdraw from the project. Adverse events will not be elicited in any other way.

* 1. *The type and duration of the follow-up of participants after adverse events.*

There will be no follow up.

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| **8. Data Management, Statistical Analysis and Record Keeping** |

* 1. *Description of the statistical methods to be employed, including timing of any planned interim analysis.*

Data will be summarised using means (standard deviations) or medians (interquartile ranges) for continuous variables (as appropriate for the distribution) and frequency (percentages) for categorical variables.  The relationship between the PSCC and timeliness of care will be considered using appropriate generalised linear models.  These relationships will be estimated in isolation and following adjustment for potential confounding factors, including age, medical co-morbidities and performance status.

 There will be no interim analysis.

* 1. *If applicable, the number of participants planned to be enrolled (if possible, including number at each site). Document the reason for choice of sample size, including reflections on (or calculations of) the power of the project and clinical justification.*

As described above, based on a pilot of 40 Western Australian lung cancer patients, 80% of patients scored ≤36 on the PSCC (ie. responses of Strongly agree or Agree to all statements). In order to achieve a 6% absolute margin of error of the true proportion with a 95% confidence interval, the minimum sample size to adequately power this project is 171 patients. It is anticipated that 120 patients will be recruited from RPH and 51 patients from SJOG Midland.

* 1. *The level of significance to be used.*

A p value of <0.05 will be used as the level of significance during data analysis.

* 1. *Procedures for reporting any deviation(s) from the original statistical plan (any deviation(s) from the original statistical plan should be described and justified in the protocol and/or in the final report, as appropriate).*

Deviations from protocol will be reported to the relevant HRECs at the time of data analysis.

* 1. *If applicable, the selection of participants to be included in the analyses (e.g. all randomised participants, all eligible participants, or all evaluable participants).*

All patients with completed surveys will be included in the data analysis.

* 1. *Information on how data will be managed, including coding for computer analysis and data handling (collection, storage, maintenance, security and archiving). Include details regarding these processes if the data is sent off-site (e.g. encryption).*

Demographic and clinical data that is collected as part of the CIC-Cancer Project will ultimately be stored on a secure online platform but this is still under construction. In the interim, it is stored on a password protected spreadsheet and uploaded to the Respiratory server at each hospital (which requires authority access).

Hard copies of patient survey responses will be kept in a secure location at each hospital site, as per individual hospital confidentiality arrangements. Electronic copies will be stored in a password protected file on the Respiratory server. In the longer term, survey responses will also be uploaded and stored on the CIC-Cancer online platform.

 Data will be destroyed after the minimum retention period, in keeping with the Information Storage and Disposal Policy, published by the Department of Health in 2014.

* 1. *Procedure for accounting for missing, unused, and spurious (false) data.*

Missing data will be accounted for using data imputation methods. If the amount of missing data falls beyond these methods (ie. more than 20% of data is missing), it will be discounted from the project and destroyed. Unused and spurious data will also be destroyed.

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| **9. Monitoring / Audit** |

* 1. *Statement that the project investigators/institutions will permit project-related monitoring, audits, and regulatory inspections, providing direct access to source data/documents. This may include, but not limited to, review by external sponsors, Human Research Ethics Committees and institutional governance review bodies.*

We will permit project-related monitoring, auditing and inspection by the bodies outlined above.

* 1. *Description of the procedures for monitoring and auditing. The sponsor may nominate the form of monitoring and auditing and will indicate the times of audit visits.*

Project staff will submit annual progress reports and a final report at study completion to the relevant HRECs, as per Research Governance Service protocols.

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| **10. Quality Control and Quality Assurance** |

* 1. *Statement that the project will be conducted in compliance with the protocol, Good Clinical Practice and the application regulatory requirements.*

This project will be conducted in compliance with the study protocol, Good Clinical Practice and relevant regulatory requirements.

* 1. *Quality control & quality assurance measures to ensure quality of data.*

Data quality will be ensured by routine checks and quality control measures at each stage of the project. Each survey will be administered with the same wording to ensure consistency in reporting. Each survey will be checked for completeness by the project team members at the time of administration, so that missing data can be collected immediately. The online platform will be checked weekly for missing entries. Data analysis will be performed by two CIC-Cancer statisticians with cross-checking to avoid errors.

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| **11. Ethics** |

* 1. *Description of ethical considerations related to the project with particular reference to participant consent (including Participant Information and Consent Forms or waiver of consent, where relevant).*

All patients taking part in the CIC-Cancer Project are required to provide written consent, stating that they agree to their clinical information being accessed and used in associated research. Patients will not be required to provide further written consent for this sub-study. Consent will be implied if the patient responds to the satisfaction survey.

Patients will be free to decline the offer of participation in the study at any time between recruitment and survey administration.

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| **12. Budget, Financing, Indemnity and Insurance** |

* 1. *Budget, financing, indemnity and insurance, if not addressed in a separate agreement.*

The project will be funded by in-kind support from the Respiratory Departments at RPH and SJOG Midland. Any shortfall in funding will be met by the CIC-Cancer Project.

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| **13. Publication**  |

* 1. *Publication and dissemination of project results (including any limitations), if not addressed in a separate agreement.*

This study will form a chapter in Dr Brownell's thesis during her Master of Clinical Research. We also hope to present our findings at the Australian Lung Cancer Conference in 2022 and will submit the paper for publication in the Internal Medicine Journal.

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| **14. References** |

1. Cancer Australia. Lung Cancer [Internet]. Cancer Australia [cited 2019 March 25]. Available from: https://lung-cancer.canceraustralia.gov.au/home.
2. Cancer Council Australia. Optimal care pathway for people with lung cancer [Internet]. Cancer Council Australia [cited 2019 March 6]. Available from: http://www.cancer.org.au/health-professionals/optimal-cancer-care-pathways.html.
3. Jean-Pierre P, Fiscella K, Freund K et al. Structural and reliability analysis of a patient satisfaction with cancer-related care measure: A multi-site patient navigation research program study. Cancer. 2011; 117(4):854-861.
4. Lung Clinical Expert Group. National Optimal Lung Cancer Pathway and Implementation Guide [Internet]. Lung Clinical Expert Group [cited 2019 April 5]. Available from: https://www.cancerresearchuk.org/sites/default/files/national\_optimal\_lung\_pathway\_aug\_2017.pdf
5. Ost DE, Yeung SJ, Tanoue LT. Clinical and organizational factors in the initial evaluation of patients with lung cancer. Chest. 2013;143(5):e121S-e141S.
6. Olsson JK, Schultz EM, Gould MK. Timeliness of care in patients with lung cancer: a systematic review. Thorax. 2009;64:749-756.
7. Risberg R, Sorbye S, Norum J, Wist EA. Diagnostic delay causes more psychological distress in female than male cancer patients. Anticancer Res. 1996;16(2):995-999.