CARE: Developing a <u>C</u>linical Composite Score for mNSCLC <u>A</u>nd co-design solutions to bridge Metropolitan vs <u>Re</u>gional gap

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INTRODUCTION

- Lung cancer is the **fifth** most common cancer in Australia[1]

- Despite its prevalence it has the highest mortality rate with a 5-year survival of only **24%**[1]

- There is also an absolute difference of **6%** in 5-year survival between patients in metropolitan areas versus those in regional/rural areas[2]

- The **CARE** CCS (clinical composite score) aims to bridge this gap for patients with mNSCLC

1. https://www.canceraustralia.gov.au/cancer-types/lung-cancer/statistics
2. https://ncci.canceraustralia.gov.au/outcomes/relative-survival-rate/5-year-relative-survival-diagnosis

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INTRODUCTION

- **Challenges for patients living in regional/rural areas include:**

- Increased distance to treating centre

- Delayed referral and/or diagnosis

- Reduced availability of optimal imaging e.g. FDG-PET

- Poor compliance to treatment

- Paucity of clinical trials

INTRODUCTION

- **mNSCLC also demonstrates multiple biological differences unique to each patient's cancer. These include**:

- Well-differentiated versus poorly differentiated disease

- Histological heterogeneity e.g. TTF-1 positive/negative

- PD-L1 expression percentage variation

- Metabolic activity rate variation

- Presence of visceral/CNS metastases at diagnosis

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INTRODUCTION

- The **CARE** CCS will encapsulate these biological variations as well as patient and health service factor differences

- This composite score will aid prognostication and guide the optimal treatment plan for each patient

- Identifying these more at-risk patients will aim to lead to optimization of resource allocation and changes at a systemic level

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CARE AIMS

1. Develop a Clinical Composite Score for patients with mNSCLC, incorporating tumour factors, patient factors and health service-related service-factors, to identify at-risk patients of a poorer outcome

2. Co-design a solution (with consumer representatives) in the regional setting, to address issues identified through the CCS, to propose system-level change

3. Propose a validation study and methodology for CCS in a larger, prospective, multi-centre study

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METHODOLOGY

- Retrospective analysis of over 300 patients treated for lung cancer at Grampians Health, starting from July 2017

- This analysis will aim to identify predictors of lung cancer outcomes across three main areas

1. Clinical factors

2. Patient factors

3. Health service factors

METHODOLOGY

- Measurements will include:

- **Clinical independent variables** e.g.PDL1 (negative, >1% and >50%), TTF1 (positive/negative)

- **Non-clinical independent variables** e.g. distance from health service, socio-economic index for area (SEIFA), Aboriginal or Torres Strait Islander (yes/no)

- **Dependent variables** e.g. adherence/receipt of guideline-concordant treatment, timeliness to care, progression free survival (PFS), overall survival (OS)

- **Covariates** e.g. age, sex, smoking status, visceral metastasis, central nervous system metastasis, tumour differentiation, mean SUV on FDG-PET scan.

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METHODOLOGY

- *a priori* power analysis was conducted revealing a total sample of n=293 participants required to achieve a power of 0.95

- To describe clinical and non-clinical variables, means and standard deviations will be reported. T-tests and chi-square will be used to report differences between groups

- To explore the association between independent and dependent variables, univariate and multivariate regression models with significant variables in univariate analysis will be conducted

- All regression models will be adjusted for covariates a priori

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METHODOLOGY

- Variables which remain significant ($p < 0.05$) after multivariate analysis will be used to create a composite score to predict lung cancer outcomes

- The score will use variables identified as significantly associated with PFS or OS, allocating weighted points based on size of regression coefficients as required

- This will lead to the creation of a developed tool to derive a clinical composite score

METHODOLOGY

- Any issues identified from this analysis will be discussed in consultation with regional consumers

- Consumers include lung cancer patients, their families and consumer awareness groups

- This will facilitate co-design of any required solutions

- The completed methodology and protocol could then be trialled in a larger multi-centre study

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SUMMARY

- The **CARE** clinical composite score aims to address the negative imbalance towards patients living in regional/rural Australia

- This score will readily identify patients at risk of poorer outcome for treatment of their lung cancer and deliver optimal personalised healthcare

- With the input of patients, their families, and local healthcare providers, this will hopefully lead to positive systemic changes for patients with lung cancer both at a regional and ultimately national level

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