Using Observational Data for Economic Analyses... A Case Study from the Literature

Economic analyses of cancer treatments often rely on data from randomised controlled trials (RCTs). Sometimes, these data may not fully reflect real world treatment practices or patient characteristics. In such situations, observational data might be useful. This has been highlighted in a recent study by Wang et al (2018) on the use of observational data to develop an economic analysis of treatments for follicular lymphoma (FL). The study predicted medical costs (associated with diagnosis, monitoring, treatment and end-of-life care), life expectancy, and quality-adjusted-life years (QALYs) for FL patients using population-based observational data from the United Kingdom’s Haematological Malignancy Research Network. Data from 1,860 individuals from this database were used to develop a discrete event simulation (DES) model to reflect real world treatment strategies for FL. The model incorporated the capacity to investigate multiple treatment strategies at the same time, including treatment options for symptomatic and asymptomatic patients, while capturing the heterogeneity of patients’ characteristics.

The authors demonstrate that using observation data it is possible to estimate treatment costs and outcomes for patients with FL; the estimated average lifetime costs of treatment of FL ranged from US$7,709 to US$63,864 per patient, and average life expectancy from 75 days to 17.56 years. Other studies have used similar modelling techniques to explore optimal treatment strategies in economic evaluation for cancers; Blommestein et al (2016) used real-world data to estimate the cost-effectiveness of treatment strategies in multiple myeloma, while Groot et al (2017) investigate the cost-effectiveness analysis of sequential first and second-line treatments for metastatic renal cell carcinoma.

The use of observational data within economic evaluations is not without its concerns. Generally, observational data has selection bias in that they reflect treatment allocations that were not randomly assigned. This can reduce our confidence in comparisons of the effect of different treatment strategies, potentially resulting in uncertainty in the results of economic evaluations that use those comparisons. Nonetheless, Wang et al (2018), note that using observed data to build flexible, adaptable models that allow the costs and effects of multiple treatment strategies to be captured at the same time, better reflects clinical practice and may facilitate more informed decision making.

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The advent of immunotherapy is changing the historically poor survival rate of patients with advanced melanoma, and has now become standard of care. However, the costs of immunotherapy agents are substantial to both patients and the Australian healthcare system. As the optimal length of treatment in stable or responding patients is currently unknown, demonstrating non-inferiority in interrupted compared to continuous immunotherapy treatment could have major financial implications.

In collaboration with the Canadian Cancer Trials Group (CCTG), the Australia and New Zealand Melanoma Trials Group (ANZMTG) will shortly be opening a trial in Australia and New Zealand – ANZMTG 01.17 STOP-GAP – an international, investigator-led, multicentre, randomised phase III trial investigating continuous versus interrupted anti-PD-1 therapy for patients with unresectable or metastatic melanoma. The study is led by ANZMTG Executive Member, Associate Professor Victoria Atkinson of Princess Alexandra Hospital, who was awarded an NHMRC Project Grant to conduct the trial. Professor Rosalie Viney, Professor of Health Economics and Director of the Centre for Health Economics Research and Evaluation (CHERE), is a Chief Investigator on the successful grant.

In addition to the study’s co-primary endpoints of overall and progression-free survival, ANZMTG are collaborating with investigators at CHERE to investigate how the duration of anti-PD-1 therapy impacts on the quality of life of patients, as well as health system and out-of-pocket costs. The aim of the economic evaluation is to quantify the difference in the costs and outcomes (quality-adjusted life years, QALYs) between the use of continuous versus interrupted therapy. This will highlight the potential trade-offs of the different treatment durations. Cost-effectiveness and cost-utility analyses will be conducted to compare the overall cost per life-year and per QALY between the treatment arms.

STOP-GAP will be the first trial to quantify healthcare and out-of-pocket costs for use of immunotherapy in Australian melanoma patients. Compared to continuous treatment, interrupted immunotherapy is likely to substantially reduce healthcare costs. It is also likely to decrease costs of hospital visits for treatment administration, treatment for adverse events, and patient travel costs. If survival outcomes are similar between the treatment arms, there would be strong evidence to change practice in support of interrupted treatment for all patients responding to immunotherapy.

ANZMTG collaborates with CHERE via CREST to design studies which incorporate robust collection of health economic data, which can be translated into practical and useful information for Australian healthcare providers. ANZMTG is excited to continue working with CHERE, and to answer key health economic questions on the STOP-GAP trial.

Associate Professor Victoria Atkinson

Professor Rosalie Viney

For more information on ANZMTG 01.17 STOP-GAP, please contact: anzmtg01.17@melanoma.org.au.

Contributed by: Evan Buck, ANZMTG
Late last year the Australasian Leukaemia & Lymphoma Group (ALLG) welcomed the release of the Select Committee report into Funding for Research into Cancers with Low Survival Rates, calling on the Federal Government to make research into low-survival cancers a national health priority.

ALLG featured strongly in the report and was instrumental in a number of the 25 recommendations the Committee presented to Government. In response, the ALLG put out a media release welcoming the report and highlighting its support in the implementation of the recommendations.

As a result, the Federal Government announced the release of an additional $78 million for research projects as part of the landmark Medical Research Future Fund (MRFF).

The increased funding to the MRFF is a demonstration of the Government’s commitment to research, and was a significant boost to the $13 million that was originally flagged prior to the Select Committee hearing and subsequent report.

The MRFF program includes more than $56 million for clinical trial research projects for devastating conditions like acute myeloid leukaemia and Lymphoma and will be made available for clinical trials during 2018-19.

**Vale Professor Michael Pfreundschuh**

Professor Michael Pfreundschuh, one of the leading experts in the world of lymphoma research and treatment, sadly passed away on March 5th 2018.

ALLG CEO, Delaine Smith said the news of his passing came as a shock to many members of the ALLG.

Professor Mark Hertzberg noted, “No words can adequately express our sadness at his passing, and our gratitude to Professor Pfreundschuh’s inexhaustible energy and creative power. He will be sadly missed.”

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**Scientific Meeting, May 2018**

The ALLG held its May 2018 Scientific Meeting at the Park Hyatt, Melbourne.

A key objective of the Scientific Meetings was to promote engagement among our members. Along with the normal activities such as ‘Meet the Chief’ and social networking events, this year we included a fundraising area. It was lovely to see the members engaged and enjoying their time between sessions.

Chair of the Scientific Advisory Committee (SAC), A/Prof Peter Mollee introduced the new 2018 SAC and called on the membership to support the ALLG and each other by opening new trials and recruiting patients to achieve research objectives. He also congratulated the ALLG on achieving 8 ALLG trials publications in peer reviewed journals during 2017.

The next Scientific Meeting will be held 13th – 16th November, 2018 at the Brisbane Hilton.

For further information about the ALLG, its trial portfolio and other activities, please visit the ALLG website ([www.allg.org.au](http://www.allg.org.au)).

*Contributed by: Bernadette Marr, ALLG*
CREST has been providing health economics support and advice to the Cancer Australia Cooperative Clinical Trial Groups (CTGs) and their members since 2010.

As we near the end of this current phase of our service, we would like your feedback on our services to date, the current levels of awareness about health economics within your CTG, the need for health economics services in the future and what sorts of services you might be interested in receiving.

If you would like to provide your feedback, you can do so via a short, online survey. There are only eight questions in this survey, so it should take only a few minutes to complete. All your responses will be treated in confidence. Information from the survey will be reported to Cancer Australia in aggregate form only, and a summary will be provided in a future issue of the CREST Newsletter.

If you would like to complete the survey it can be accessed via the following link:
https://utsbusiness.az1.qualtrics.com/jfe/form/SV_et9SzNyTuxf7C29

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### Call for Submissions Regarding Multiple Tumour (pan-tumour) Indications for PD-1 and PD-L1 Checkpoint Inhibitor Immunotherapies

The Hon. Minister Hunt, Minister for Health has requested that the Pharmaceutical Benefits Advisory Committee (PBAC) provides advice regarding options for subsidy via the Pharmaceutical Benefits Scheme (PBS) of checkpoint inhibitors for the programmed death receptor 1 (PD-1) and its ligand (PD-L1) for the treatment of multiple cancers.

The PBS currently provides subsidised access to checkpoint inhibitors for eligible patients with advanced or metastatic melanoma, kidney cancer, classical Hodgkin lymphoma and lung cancer. The PBAC is now considering whether to subsidise more PD-1 and PD-L1 checkpoint inhibitors, expand the patient eligibility criteria and expand the list of cancer types indicated.

The PBAC will hold a special meeting in August 2018 to discuss the future evaluation of PD-1 and PD-L1 checkpoint inhibitors for multiple cancer types and is seeking input from clinical trial groups as well as industry, researchers and consumer organisations ahead of the August meeting.

There is a specific pro-forma for the provision of input, which includes questions like:

- In what indications has your organisation completed clinical trials with a PD-1 and PDL1 inhibitor? Please include both positive and negative studies.
- In what indications is your organisation currently conducting or planning to conduct clinical trials with PD-1 or PD-L1 inhibitors? If usual PBAC processes were to be followed, when would you expect to make an application for subsidy for these indications?

- How does your organisation decide which indications to study and which to prioritise for registration or subsidy?

For those who may be interested in contributing to this meeting of the PBAC, the background paper and submission template are located at:


Submissions are due 29th June 2018.
Over the past decade, ANZUP has grown from a small organisation of 150 members to a network of well over 1,350 members across Australia, New Zealand and internationally. In this time ANZUP has undertaken clinical trials involving thousands of patients and is recognised on the international stage. Thanks to the dedication of ANZUP’s members and supporters, the group continues to lead the way in improving outcomes for people affected by genitourinary cancers.

This year’s Annual Scientific Meeting (ASM) at the Hyatt Regency Sydney will celebrate ANZUP’s milestone 10th anniversary with an exceptional program. Moving away from the current trend of big data, the theme ‘Putting People First’ will focus on the management of GU cancers from a holistic, people-centric perspective. Delegates will have the opportunity to interact with and learn from an outstanding international faculty (including Laurence Albiges, Tamim Niazi, Sumanta (Monty) Kumar Pal, Angie Smith, Chris Sweeney, Bertrand Tombal and Viktor Grunwald) and numerous national GU experts.

As a truly multidisciplinary meeting, the ASM has sessions to suit everyone working in GU cancers. The main program will be complemented by the Translational Research Symposium, the popular and interactive MDT Masterclass and the PCFA/ANZUP Nurses Symposium. To register and view the complete ASM program, go to https://www.anzup.org.au/content.aspx?page=asm-home.

Providing a clear pathway for ideas and concepts remains a key focus of ANZUP’s activities. A total of 29 concepts were presented for multidisciplinary discussion at the 2018 disease-specific Concept Development Workshops (held in April and May). The workshops were well attended by clinicians at all stages of their career, highlighting the importance of brainstorming ideas, but also in developing and educating the next generation.

ANZUP’s other activities include the production of the Below the Belt Pedalthon cycling fundraiser. Following four successful years in Sydney, the inaugural Melbourne Pedalthon was held in March adding $80,000 to the $1 million already raised since 2014. 100% of funds from the Pedalthon are directed into the Below the Belt Research Fund for reinvestment into investigator-led research projects intended to lead to future ANZUP trials. Despite some challenging Melbourne weather, 30 teams demonstrated their dedication to the cause by completing 2,120 laps or 6,572km. The Pedalthon spirit will continue at the 5th Sydney Pedalthon at Eastern Creek on 18 September, visit www.belowthebelt.org.au for more details.

Contributed by: Michelle Bowers, ANZUP Cancer Trials Group
The Australia New Zealand Gynaecological Oncology Group (ANZGOG) aims to improve outcomes and quality of life for women with gynaecological cancer through conducting and promoting cooperative clinical trials and undertaking multidisciplinary research into the causes, prevention and treatments of gynaecological cancer.

Annual Scientific Meeting

The Annual Scientific Meeting (ASM) of ANZGOG was held in Brisbane from 4th to 7th April, with the theme “Challenges in Precision Gynaecological Cancer in a Molecular Era”.

One of the main outcomes of the Meeting will hopefully be more Australia and New Zealand centres becoming recruiting sites, which will lead to an increase in the number of women enrolled in clinical trials, and improved survival and wellbeing for women with gynaecological cancers.

Next year’s meeting will be in Sydney from 20th – 23rd March with a theme of “Radical treatments for gynaecological cancers: hope or hype?”

Trials in recruitment

For the complete list of ANZGOG trials currently in recruitment, please visit https://www.anzgog.org.au/research/trials/

PHAEDRA – A Phase II trial of durvalumab (Medi 4736) in advanced endometrial cancer.

The primary purpose of this trial is to evaluate the safety and efficacy of durvalumab for the treatment of advanced endometrial cancer. It is hoped that this trial will provide information on whether durvalumab is safe and effective for the treatment of advanced endometrial cancer.

The trial is seeking participation from women who have DNA MMR-deficient endometrial cancer.

EMBRACE - Phase II clinical trial of the PARP inhibitor, olaparib, in HR-deficient metastatic breast and relapsed ovarian cancer in patients without germline mutations in BRCA1 and BRCA2

The purpose of this study is to assess whether olaparib is effective in treating advanced ovarian and breast cancer in women who do not have inherited changes in their BRCA genes, but whose cancers have HR deficiency.

VIP - A Phase II trial of oral vinorelbine in patients with relapsed platinum resistant or platinum refractory high-grade serous ovarian cancer of the C5 molecular subtype.

Vinorelbine is a chemotherapeutic agent that is currently used for the treatment of lung and breast cancer. This clinical study is being carried out to find out if treatment with vinorelbine will have beneficial effects in patients with ovarian/fallopian tube or peritoneal cancer belonging to the C5 subgroup. In addition, we will also study how specific changes and molecular markers in blood and tumour specimens from women enrolled on the trial may be used to predict the chance of benefiting from study treatment.

Contributed by: Ruth Gordon, ANZGOG
CREST Presents!

It has been a busy last few months with CREST members presenting and participating in a number of trial group events. In March, Richard De Abreu Lourenco attended the Trans-Tasman Radiation Oncology Group (TROG) ASM in Hobart and presented a session on the role of health economics in the changing face of radiotherapy.

April and May saw CREST members attend a number of concept development workshops. This included the ANZUP concept development workshops for renal cell carcinoma (RCC), germ-cell cancer and prostate cancer. In a presentation at the RCC workshop, participants were reminded of the potential value of thinking about assessing costs and outcomes early in the development of a new trial concept. In May, Phil Haywood, participated in the COGNO Ideas Generation Workshop and presented on key elements of health economics to think about when developing new studies. With a similar theme, Richard and Oona Reardon attended the PoCoG fear of cancer recurrence focused concept development workshop, highlighting different ways to think about intervention value, as well as participating in a productive and lively research discussion.

Finally, Richard presented at the Breast Cancer Trials IMPACT Workshop in Melbourne, providing participants with an overview of not only health economics, but how it is used in cancer research, its role in the funding of health care services in Australia and New Zealand, and take-aways for consumers involved in clinical trials.

Breast Cancer Trials: 40th Annual Scientific Meeting

The Breast Cancer Trials (formerly the ANZBCTG) 40th Annual Scientific Meeting (ASM) will be held from 25th – 27th July 2018 at The Westin Sydney. This is a very special milestone for the largest, independent, oncology clinical trials research group in Australia and New Zealand.

The conference will include a full day for the Trials Coordination Forum and two days of Scientific Sessions, covering timely reviews of breast cancer clinical trials, discussion of new protocols, future clinical trials research and other research developments.

The ASM is an opportunity for breast cancer researchers throughout Australia and New Zealand to learn of recent advances in breast cancer research worldwide; to share knowledge and research outcomes; and to collaborate and plan for new research projects.

To register for the ASM, please visit www.bct2018.org.

Contributed by: Anna Fitzgerald, BCT
Call for Applications!

COGNO is pleased to call for applications for the MSD Hubert Stuerzrl Memorial Educational Award 2018.

The purpose of this award is to encourage education and training in the field of Neuro-Oncology and will provide up to $15,000 for the successful recipient to:
- Attend an international Neuro-Oncology scientific meeting
- Undertake a Neuro-Oncology Preceptorship during 2018-2019

The Award is open to applications from individuals with a clear interest in the field of Neuro-Oncology and includes:
- Advanced Trainees in Medical Oncology, Neurology, Radiation Oncology, Neurosurgery, Pathology or Radiology
- Medical Oncologists, Neurologists, Radiation Oncologists, Neurosurgeons, Pathologists or Radiologists of no more than 5 years standing who are enrolled in full-time or part-time post-graduate research (PhD or MD)

The successful recipient will be required to provide a report on their meeting attendance and their Preceptorship to the COGNO Management Committee and in a suitable form for the COGNO newsletter. The successful recipient will also be invited to be a member of the COGNO Scientific Advisory Committee for a 12 month period.

Applications will be assessed on merit by a committee established by COGNO including senior specialists representing Medical Oncology, Radiation Oncology, Neurosurgery, Neuropathology and Neuroradiology.

Closing Date for Applications: Friday 29 June 2018. Applications should be sent by email to cogno@cogno.org.au.

Eligibility Criteria
- Advanced Trainees in Medical Oncology, Neurology, Radiation Oncology, Neurosurgery, Pathology or Radiology who are Australian or New Zealand Residents and financial or registered members of their relevant Australian and New Zealand Academic College
- Medical Oncologists, Neurologists, Radiation Oncologists, Neurosurgeons, Pathologists or Radiologists of no more than 5 years standing who are Australian or New Zealand Residents and are enrolled in full-time or part-time post-graduate research (PhD or MD)

Application Requirements
- Full curriculum vitae including details of training, awards and prizes, publications and meeting presentations
- Covering letter addressing the selection criteria and advising the international conference the applicant intends to attend
- Letters of support from three professional referees. Please ensure that you include only originals or certified copies of all letters of support. These need to be presented with the signature of the supporter or referee on their organisational letterhead.

Selection Criteria
- Academic record and recommendations of referees
- Evidence of commitment to a long term career and research experience in the field of Neuro-Oncology
- The benefit for the applicant in attending an international meeting and undertaking a Preceptorship
What has CREST been up to?

Trial Group Collaborations:

- Presented at the TROG ASM in Hobart, March 2018.
- Participated in the Breast Cancer Trials IMPACT workshop held in Melbourne, May 2018.
- Participated in the ANZUP CDWs, PoCoG CDW and COGNO Ideas Generation Workshop.
- Clinical trial audits, and ongoing advice on the development of trial protocols and data collection forms.
- Membership of scientific advisory/steering committees.

Other Activities:

- Ongoing correspondence with Clinical Trial Groups
- Continuation of the Structured Training Opportunities program.