

What does it cost to include an economic evaluation in a trial?

One of the questions we are often asked here at CREST, particularly around NHMRC trial time is “what does it cost to include an economic evaluation in a trial”? While there is no single answer to this question, we explored this issue in a recent CREST

Factsheet: http://www.chere.uts.edu.au/crest/pdfs/Factsheet_CostingAnEconEval_FINAL.pdf

Briefly, the resources needed to conduct an economic evaluation will vary between trials, and depend on whether it is conducted prospectively or retrospectively, and the extent of modeling and additional data analysis required to translate the trial outcomes to a meaningful incremental cost per unit of health gain. In general the budget required for the data collection and analysis of economic outcomes can be estimated by considering the following issues when planning a clinical trial:

- ◆ Trial design: consider whether the trial design aligns with the economic

question. Is a specific economic sub-study required, for example to collect local resource use data or to facilitate the estimation of quality adjusted life years?

- ◆ Data collection: Are there additional data required for the economic evaluation that are not planned for collection within the trial? Are new data collection methods/tools required? Is access to administrative or secondary datasets (such as Medicare data for pharmaceutical and medical service use, or hospital records) required to provide additional data?

- ◆ Data analysis: Is additional analysis required to estimate and cost the resource use for each trial group? Is additional analysis required to translate trial outcomes to outcomes that

are meaningful for decision makers (such as the relationship between progression free survival and overall survival, or quality of life). Is additional modeling required?

Within each step, specific health economics expertise might be required, although other members of the clinical trial team (such as the trial statistician or CRAs for data collection) might perform some activities. This has implications for the trial budget. Similarly, access to secondary databases or specialised software will also impact on the trial budget. For further discussion of these points and estimates of the resource requirements associated with health economics input for a trial please visit the CREST Factsheet (as above).

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CREST Workshops: 2013 and beyond.

During 2013, CREST held two in-house workshops *Understanding Health Economics in Cancer Research* (May and October) attended by 47 participants, ranging from cancer clinicians, to trial group Executive officers, clinical trial researchers and members of NGOs. Following feedback from participants in the May workshop, the October workshop followed a new more interactive format. Participants had the chance to apply what they were learning to three cases: brachytherapy for prostate cancer; telemedicine for lung disorders; and immunotherapy for melanoma. Through these three cases, in three interactive sessions through the day, participants were able to engage with each other as well as the course facilitators to see how the health economic concepts applied

in real world cases.

The *Understanding Health Economics in Cancer Research* workshops will continue in 2014. In addition, CREST is planning to hold a next phase workshop on economic modelling. This will build on the introductory workshops and give participants hands on experience in developing economic models (using TREEAGE), and in the interpretation of economic models. This workshop is to be held in early March 2014.

CREST is also planning to hold two consumer workshops in 2014. These workshops will be aimed at the consumer members of the clinical trial groups, or relevant cancer groups affiliated with the trial groups. Through the workshops (to

be held in Sydney and Melbourne), participants will be given an insight into the role health economics plays in making health care available, in particular pharmaceuticals and medical services. This will introduce participants to concepts in health economics, to the processes of the Pharmaceutical Benefits Advisory Committee and the Medical Services Advisory Committee, and to the role consumers play in providing data and shaping how evidence is viewed through the reimbursement process. These workshops will be held in late March and April.

Look out for flyers announcing the timing for these workshops early in the New Year.

Grant Funding Successes for CREST Members.

We'd like to congratulate a number of our team at CREST who were recently successful in being awarded the following NHMRC and ARC grants:

NHMRC Project Grant

Prof Jon Emery, Prof Danielle Mazza, Dr Neil Campbell, Dr Peter Murchie, Dr Andrew Martin, Dr Fiona WalterA/ Prof David Barnes, A/Prof Stephen Goodall: CHEST Australia: reducing time to consult in primary care with symptoms of lung cancer.

Prof Rosalie Viney, Dr Richard

Norman, Prof John Brazier, A/ Prof Paula Lorgelly, A/Prof Emily Lancsar: Developing an Australian valuation for the EQ-5D-5L Quality of Life Instrument.

NHMRC Early Career Fellowship

Dr Richard Norman: New approaches to describing and valuing quality of life: application and implications for economic evaluation.

ARC Discovery Grant

A/Prof Stephen Goodall, Prof Rosalie Viney, Dr Richard Nor-

man: Nanny State or good public policy: Do the benefits of mandatory health programs justify the loss of consumer choice?

Prof Anita Bundy, Dr Shirley Wyver, Prof Geraldine Naughton, A/Prof Paul Tranter, Prof Judy Simpson, Dr Richard Norman, Prof Louise Baur: Leveling the playing field: starting with the school playground.

Congratulations to Rosalie, Stephen and Richard and all your fellow collaborators – a fantastic outcome!!!

NHMRC is coming!

It hardly seems as though one NHMRC funding round has closed, and another round is about to open. As always, the team at CREST is here to assist with your grant applications and to provide comment and advice on the protocols being prepared for submission to the NHMRC. CREST can provide assistance in a number of ways:

- ◆ Prepare a CREST audit (a written review) of your protocol, focusing on whether it is amenable for an economic evaluation, and making suggestions as appropriate.
- ◆ Provide ad-hoc advice (either via phone or e-mail).
- ◆ Participate in protocol development discussions/

workshops.

The provision of CREST advice does not presume in any way that our team members would be involved in the trial. That is a matter for the trial team, and further on-going involvement by CREST may or may not be appropriate. Our aim is to provide you with timely and meaningful advice when preparing your NHMRC applications.

If you would like to use CREST for health economics input to your protocol prior to submitting an application to the NHMRC, either contact your trial group Executive Officers, or contact Richard De Abreu Lourenço at CREST directly at Richard.deabreulourenco@chere.uts.edu.au.

The key is to get in early!!

The Sources of QALY Weights in Economic Evaluations in Cancer

In a recently completed review of economic evaluations in cancer published in the years 1995, 2000, 2005 and 2010, we sought to understand how quality of life weights were sourced for use in estimating quality adjusted life years (QALYs). This is important, not only in terms of cataloguing the use and change in QALY valuation methods but also to highlight the potential uncertainties that exist in the methods that are used to source QALY weights. Full details and results of this review are forthcoming in a CREST Factsheet, but can be summarised as:

- ◆ Multi-attribute utility instruments (MAUIs) used within clinical trials are arguably the gold standard for determining QALY weights. Despite this they were not commonly used in the 112 cancer studies reviewed; only 16 of the 112 studies used QALY weights derived directly within the corresponding clinical study, of which only nine included a MAUI.
 - ◆ There is no clear preference for which MAUI should be used. Within the studies reviewed, the EQ-5D was used most commonly (in 28% of all studies that used MAUIs).
 - ◆ It is likely that the valuations obtained from different MAUIs (such as the EQ-5D, the HUI-3, the SF-6D) are not comparable. This is of concern
- given the number of papers that rely on QALY weights from secondary references (96 of 112 papers used a secondary source study) that may have employed multiple methods that are not comparable.
- ◆ If MAUIs elicited within a trial are not available, a health state valuation experiment (such as a time-trade-off or standard gamble) is preferable to a non-preference-based approach. 48% of the studies reviewed used a health state valuation experiment. Where health state valuations are used, these should be valued by the general public or patients rather than medical professionals.
 - ◆ If QALY weights are obtained from the literature, information on how they have been derived should be provided. In general, the preferred sources for QALY weights are economic research articles (reporting on the results from MAUIs or health state valuation experiments) or databases, rather than other cost-effectiveness analyses (which might have relied on secondary sources themselves).

Clinical and epidemiological data registries - what else can you consider?

Clinical studies provide critical data on the efficacy and safety of health care interventions within a trial setting. Clinical and epidemiological data registries have the potential to provide an important, real-world adjunct to that information by providing evidence on the treatment and outcomes associated with health care in Australia. In particular, the information available through registries can be vital to inform decisions about the introduction of new treatment procedures, equipment, support systems or medications that have an impact on how health care resources are allocated.

So if you are establishing a clinical or epidemiological data registry, what types of information might you consider collecting that would assist in decisions about resource allocation? Some examples of information that are particularly important from the

perspective of resource allocation and patient care are:

- ◆ Ongoing outcomes such as treatment response (including adverse effects) and survival;
- ◆ Treatment utilisation, including pharmaceutical therapies, medical services, diagnostic and imaging services and surgical care; and
- ◆ Quality of life, assessed in a manner that can be quantified for the purposes of an economic evaluation (such as using a multi-attribute utility instrument).

Collecting this type of information does not necessarily mean expanding the scope of the registry. For example, information on the use of pharmaceutical therapies and medical services can be accessed for patients in the registry by collecting

participant consent to access Medicare data. In this way, ongoing data collection for the registry is minimised, but the scope for a more expansive analysis (including pharmaceutical and medical service use) is retained.

As always, if you are thinking of establishing a clinical/epidemiological database and would like advice on its use for later economic analysis, please contact the team at CREST.

Do you have a trials group newsletter?

CREST can provide articles which introduce CREST services, or which provide commentary on a health economics topic of interest to your members.

Please contact us if you would like to discuss the possibilities.

What has CREST been up to?

The CREST team had a productive second half of the year:

Trial Group Collaborations:

- ◆ Commencement of the first structured training opportunity with the ALLG. Working with the team on the RATHL trial, this is assessing response adapted therapy using FDG-PET in patients with Hodgkin's lymphoma.
- ◆ Conduct of trial protocol reviews/audits, and provision of advice on the use of health economic data (quality of life and cost information) for forthcoming trials.
- ◆ Participation in the PC4 CDW (September 2013).
- ◆ Presentation to the ANZMTG ASM (November 2013).
- ◆ Participation at the PoCoG CDW and SAC (December 2013).

Health Economics Workshops:

- ◆ One day workshop held in Sydney (Understanding Health Economics), October 2013.

Website Updates:

- ◆ Ongoing updates of the CREST website: <http://www.chere.uts.edu.au/CREST>, including new Factsheets and publications of interest.

Other Activities:

- ◆ Meetings with the Clinical Trial Group Executive Officers.
- ◆ Attendance at the Genomic Cancer Clinical Trials Initiative Workshop (November 2013).