Issue Panel 18

How to dead with model uncertainty at the planning stage of costeffectiveness?: Tips from Global Experience

Presentation for

ISPOR Asia Pacific Conference 2018, Tokyo Japan

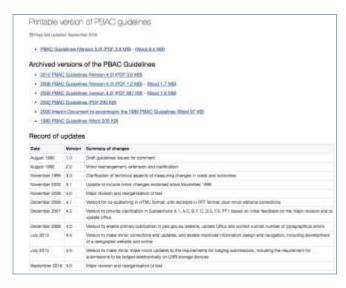
George Papadopoulos Director and Partner Lucid Health Consulting Pty Ltd Australia www.lucidhealthcon.com

Agenda

- · Australian Cost Effectiveness Analysis Guidelines
- · Uncertainty in the "Guidelines"
- · Sources of Uncertainty
- · Tips on handling uncertainty
- Conclusion
- Questions......

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Australia's CEA Guidelines - a short history



- Draft guidelines issued in August 1990 – that's 28 years ago
- CEA mandatory in 1993, but v3.0 in Nov 1995 were first clear set of guidelines
- Version 5.0 Sept 2016
- Public Summary Documents in July 2005

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Source: Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (PBAC) https://pbac.pbs.gov.au/

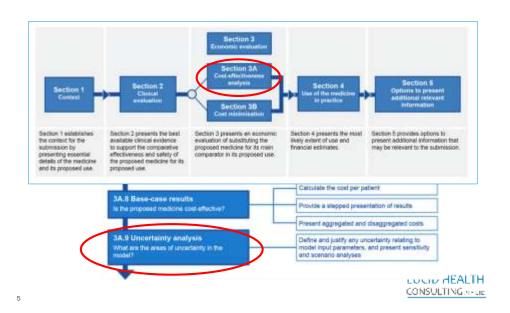
Australia's CEA Guidelines – uncertainty issues

 60 pages • 15 mentions on uncertainty 1995 • 109 pages 2002 • 6 mentions on uncertainty 298 pages 120 mentions on uncertainty 2006 • 300 pages • 100 mentions on uncertainty 2008 350 pages • 100 mentions on uncertainty • 216 pages • 110 mentions on uncertainty 2016

Source: Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (PBAC 4 https://pbac.pbs.gov.au/ Commercial in Confidence

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Where is "uncertainty" dealt with?



Section 3A.9 Uncertainty Analysis (Analyses)



- Models and Supporting
 Document are provided in
 the submission but are not
 publically available
- Review of Public Summary Documents and PBAC Outcomes
- 3A.9.1 Identifying and defining uncertainty in the model
 - Parameter uncertainty
 - · Translational uncertainty
 - · Structural uncertainty
- 3A.9.2 Presentation of univariate sensitivity and scenario analyses
- 3A.9.3 Presentation of multivariate and probabilistic sensitivity analyses
- · 3A.9.4 Summary of the uncertainty analysis

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Sources of Uncertainty

- Time horizon
- · Extrapolation method
- Duration of treatment effect
- Inclusion/exclusion of AEs
- Health states included
- How parameters change over time
- · Link between surrogate and final outcomes
- Model specific structural parameters

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Tips

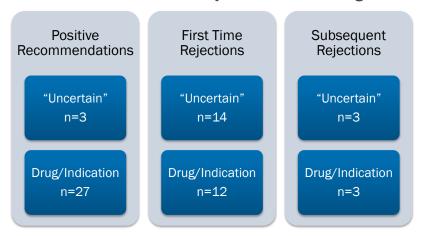
- Currently no standard approach to assessing uncertainty
- It is difficult and time consuming
- Does have an impact on the ICER
- Conduct sensitivity analyses to assess assumptions
- Identify potential sources of structural uncertainty when developing model
- Compare model with published models
 - Review Published Summary Documents and PBAC Outcomes
- Consider what's likely to be important or of interest

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Why does it matter?

Outcomes from the July 2018 PBAC Meeting



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But, remember......

"Essentially, all models are wrong, but some are useful"

George E P Box (1919-2013)

George Edward Pelham Box FRS (18 October 1919 - 28 March 2013) was a British statistician, who worked in the areas of quality control, time-series analysis, design of experiments, and Bayesian inference.



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