



*QALY assessments for
PBAC submissions:*

A consultant's perspective

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Imagine...

A new client requests work on a cost-utility model for their product tacufloxamib to prevent post-prandial somnolence...

? But from where to source the utility values for use in the model?

Easy – just look them up in the utilities database....

.....RIGHT!

The reality...

- QALY analysis may not always be relevant or informative.
 - *Does the treatment and the condition imply that there will be QoL implications?*
 - *Are those implications likely to be meaningful?*
 - *Will attempts to assess QALYs provide the PBAC with the evidence it needs to make a decision?*

- Utility values are not readily available.
 - *How do we go about finding relevant utility values?*
 - *How do we choose which values to include in a QALY analysis?*

*Is a QALY analysis warranted
and will it add to the decision
making process?*

Appropriateness/relevance of QALY analysis

- Assess whether a QALY analysis is an appropriate means of quantifying the incremental benefit:
 - *May be minimal disutility associated with the condition (or its sequelae) - either in an absolute sense, or relative to overall survival (eg. for event based analyses).*
 - *May be minimal disutility associated with the treatment (or its comparator), including adverse events.*
- Will attempts to estimate QALYs generate more uncertainty than not?

Will it assist decision making?

- Consider precedents within that indication (or similar areas):
 - *Has the value of other outcomes (such as LYG, responders, fractures avoided) already been established within that indication?*
 - *Are there examples where the PBAC has made a positive recommendation in the absence of a cost-per QALYG?*
- Clearly, advice of the PEB should be sought.

The search for utility values....

Utility values from clinical studies

- Randomised controlled trials (either direct or indirect):
 - *Rarely available.*
 - *Utility data from the trials may be incomplete or not reported.*
 - *Important to separate HRQoL data from utility data.*

Direct preference elicitation

- Use of TTO, SG or DC studies to elicit utility values.
- Design of health state descriptors is key to ensure they:
 - *Reflect the indication.*
 - *Reflect clinical practice.*
 - *Reflect the respective treatments (impact on patients, adverse events etc).*
 - *Can be readily interpreted – can the factors driving the resulting utilities be readily understood or are there too many interacting factors?*

Direct preference elicitation

- Studies can be tailored to investigate hypothesised sources of QoL difference.
- Provides local valuations of differences in QoL.
- The challenges:
 - *There is often insufficient time to conduct such studies – lead times for study development and implementation do not match desired submission timeframes (or budgets).*
 - *Who should be surveyed (patients, carers, general population etc).*
 - *Are the results realistic?*

Published literature

- Are there issues of applicability eg. right indication, wrong setting (population) or vice versa.
- There may be numerous studies, each using different instruments to assess utility within the same setting, or for different health states within an indication.
 - *Is it appropriate to combine (or average) utility values derived from different instruments?*
 - *Can utility weights for different health states be sourced from different studies?*
 - *Present multiple possibilities – how would this be interpreted?*

Published literature

- Develop a filter for consideration of evidence:
 - *Are the published “utility” weights preference based?*
 - *Are there issues of applicability*
 - *population and indication?*
 - *for the intended use in the economic model?*
 - *What might the PBAC consider most relevant eg. preference based values from health ratings by a relevant patient group, valued using societal preferences?*

Other sources of information

- Online databases
 - *Typically limited to data published in the literature.*
 - *May offer little in the way of new information.*

- Mapping from HRQoL in studies to preference based measures:
 - *Are there validated mapping tools available? If not, who would complete the mapping?*
 - *May be considered low level of evidence.*

Other sources of information

- Physician rated QoL.
 - *How many physicians would represent a reliable sample?*
 - *What would they be valuing (what are the relevant health states etc)?*
 - *How would it be interpreted?*

An “indicative” value?

- In some cases, appropriate values cannot be found, but it is clear that there are likely to be QoL implications.
- Use of “indicative” values may be considered:
 - *May introduce more uncertainty than not.*
 - *How close are they a match to what would normally be required.*
 - *Could the case be made in a qualitative sense (or using a threshold analysis) rather than attempting to estimate a QALY?*

Growing use of QALYs in decision making increases the need for better sources of acceptable/ validated utility values....