

The Case for QALY's: US Decision-Making for Pharmaceuticals

Disadvantages?

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What's wrong with QALYs, they seem so nice?



savethekoala.com

Apologies to R. Townsend
& Koala Bears

What's Wrong with QALY's - Common Criticisms

- Historically cost-utility analysis was used to value programs with widely different outcomes – often mis-applied
- Whose preferences should be used?
- Can the stages of disease be adequately depicted so utilities can be determined? Measurement is problematic
- May not ethically distribute healthcare – often left with discussing appropriate thresholds
- Methods...Others...

Leibman Applied CUA: Evaluation of Applied QALY's

- **Credible**
- **Understandable**
- **Actionable**

Evaluation of Applied QALY's Credible?

- US – “social values” – multiple perspectives
- There is more to decision making than just the value of a C/E ratio, including among others, considerations of distribution
- However, use of QALYs ignores such considerations by:
 - Treating all QALYs equally
 - Maximizing the total quantity of QALYs regardless of their distribution

Evaluation of Applied QALY's Credible?

- Not all QALYs are created equal
- Example: Alzheimer's Disease (AD)
 - Health state classification instruments to address the dynamics of elderly patients (Alzheimer's patient and their caregivers)
 - Is the role of proxies for measuring and valuing AD patients health sufficiently understood
 - Methods needed to properly account and aggregate the health benefits derived by caregivers and families of the AD
- Instead of valuing all QALYs equally, we may want to weight QALYs for different groups / interventions differently

Evaluation of Applied QALY's Understandable?

- Many interventions are funded despite higher than “traditionally acceptable” C/E ratios, for instance:
 - The *minimum* CER of enzyme replacement therapy for Gaucher’s disease range between \$49,000/QALY and \$147,000/QALY (Whittington and Goa, *Pharmacoeconomics* 1995;7:63-90)
 - Median CER of commonly performed blood safety interventions is \$355,000/QALY (Yeh J. et al *Infus Ther Transfus Med* 2002;29:218-25)
 - CER of pediatric pneumococcal vaccine is \$80,000/QALY (societal perspective) and \$176,000/QALY (health care payer perspective) (Ray TG. *Expert Rev Vaccines* 2002;(1):65-74)

Evaluation of Applied QALY's Understandable?

- Medicare technology coverage looks similar:
 - Left-ventricular assist devices: \$500,000-\$1.4 million/QALY
 - Lung-volume reduction surgery: \$98,000-\$330,000/QALY
 - Implantable cardioverter defibrillators: \$30,000-\$85,000/QALY
 - PET for Alzheimer's disease: Over \$500,000/QALY

Evaluation of Applied QALY's Understandable?

- Example - Alzheimer's Disease (Mis-application?)

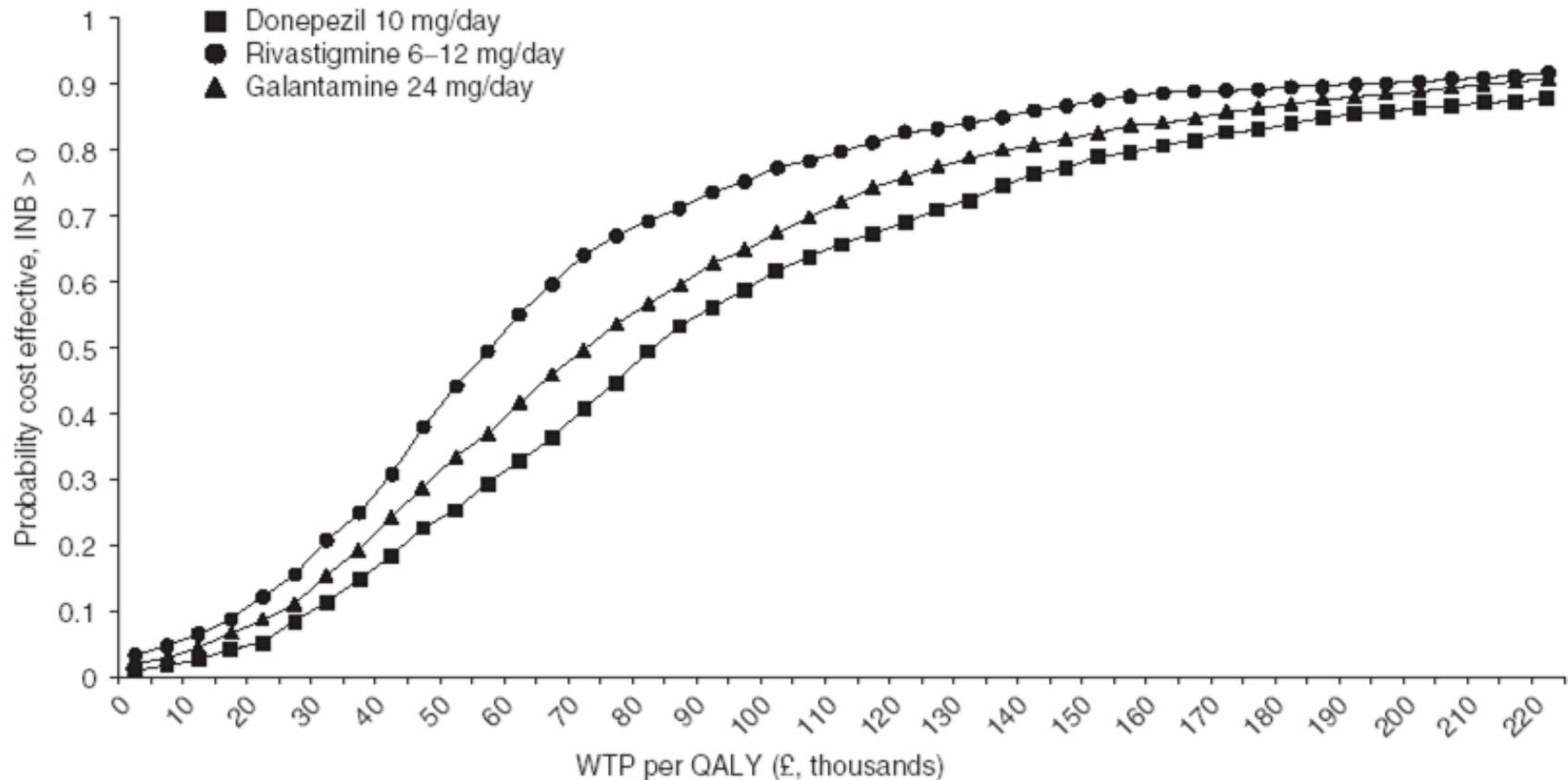


Fig. 2. Cost-effectiveness acceptability curve for cholinesterase inhibitors (donepezil, rivastigmine, galantamine) compared with usual care. Drug costs are in 2005 values, willingness to pay (WTP) figures are in 2003 values. **INB** = incremental net benefit; **QALY** = quality-adjusted life-year. Green, et al, 2005.

Evaluation of Applied QALY's Understandable Action?

- 3 AChEI's – Recommended as options
- AD of moderate severity (MMSE 10-20)
 - Diagnosis of AD
 - Specialist clinic assessment of cognitive, global, and behavioral functioning, ADLs, and QoL – CG input
 - Judgement on likelihood of compliance
 - If GPs take over care, there should be a shared care protocol
 - Review every 6 months (MMSE, global, functional, behavioral)
- Memantine not recommended

Evaluation of Applied QALY's Actionable?

- What is the objective?
 - What question(s) are we trying to answer and who wants the answer?
 - What decision will be made?

Evaluation of Applied QALY's Actionable?

- Common Payer Questions/Focus:
 - Unmet need within the therapeutic area

 - Comparing treatments within same class of medications or within same disease state (NOT disparate disease states with different outcomes)

 - Determining budget impact of interventions
 - QALYs do not address budget impact

Recent Legislation as a guide?

- MMA - Section 1013
- ...AHRQ to conduct and support research with a focus on outcomes, comparative clinical effectiveness, and appropriateness of pharmaceuticals, devices, and health care services.
 - Priority conditions
 -reducing variations in prevention, diagnosis, treatment or management of a disease...improving health outcomes and/or reducing costs
- Focus on ‘comparative effectiveness’

AHRQ Focus

- Mark McClellan – December 2005:
- AHRQ Effective Healthcare Program and ‘Comparative Effectiveness’:
 - “It will help beneficiaries in Medicare and Medicaid and their providers make more informed decisions about the costs and benefits of treatment for a common health problem with a number of treatment alternatives available.”

DERP-ization of Drug Review

- Drug Effectiveness Review Project (DERP)
 - collaboration of organizations that have joined together to obtain the best available evidence on effectiveness and safety comparisons between drugs in the same class, and to apply the information to public policy and decision making in local settings.

- 14 States and Canada were participants in 2006

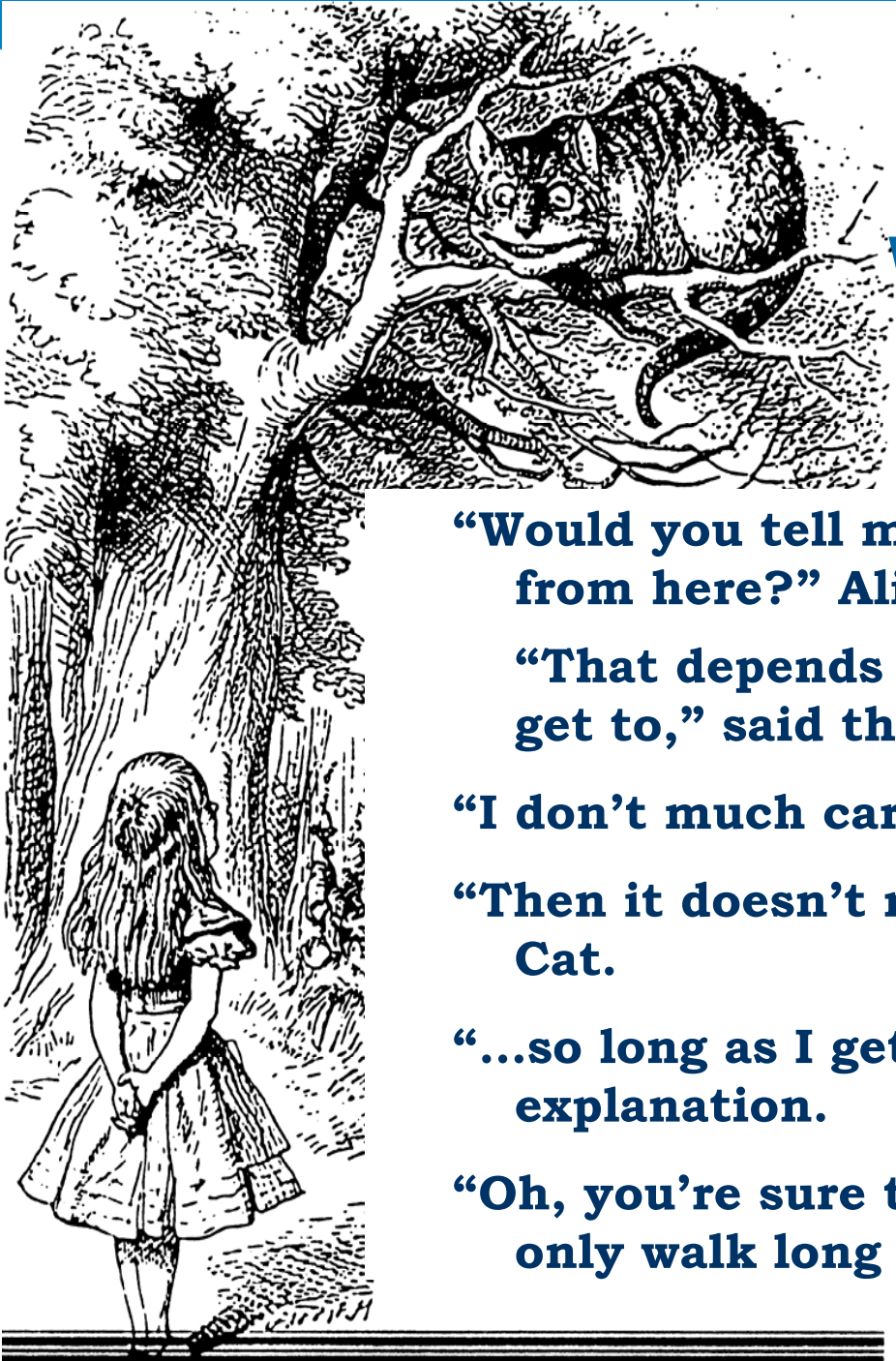
Opportunity for QALY's

Thought-provoking comments

- QALY's as descriptive rather than prescriptive tool
 - An important piece of information among others
 - “Cost-consequence” approach to decision making
- QALY Thresholds need to be created by perspective (and perhaps by disease state)
- Move to cost-effectiveness within treatment
 - DERPs with CEA (and common denominator)

If not handled carefully QALYs can hurt and embarrass you





Where do we go from here?

“Would you tell me, please, which way I should go from here?” Alice asked the Cheshire Cat.

“That depends a good deal on where you want to get to,” said the Cat.

“I don’t much care where...” said Alice.

“Then it doesn’t matter which way you go”, said the Cat.

“...so long as I get somewhere”, Alice added as an explanation.

“Oh, you’re sure to do that,” said the Cat, “if you only walk long enough”.