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CRITIQUE

Oxford
Outcomes
An ICON plc Company

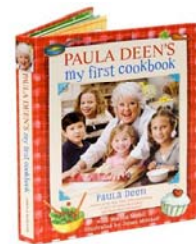
2008 Methods Guide

- Aimed to standardise submissions
 - Strong emphasis on EQ-5D
 - May not be the best measure but all on level playing field
 - For binary decisions (Yes/ No) it may be sufficiently accurate/ sensitive
 - Possibility of pleading special case for use of other instruments

The perceived problem

- Confusion regarding NICE submissions
 - Despite availability methods guide, NICE conference, Scientific Advice Programme and huge volume of publications from NICE
 - Disconnect between UK and Global groups?
- Companies unsure about
 - Suitability of HRQL methods
 - Suitability of sources of information

Technical Support Documents



Approaches to NICE submissions

- Adversarial approach
 - Attempt to exploit loopholes or weaknesses in guidance
 - “EQ-5D is not valid in this condition”
 - Marked out by a degree of (deliberate) misunderstanding
 - TSDs arguably provide far greater scope for this
- Alternatively they may hit the desks of regulatory affairs
 - If they do then the content will impact pharma

Status

- But what is the status of these TSDs?
 - NICE approved?
 - The views of Uni of Sheffield/ Brunel?
 - Will they be updated?
 - How will they be affected by the forthcoming revised NICE methods guide?

Comments - mapping

- Mapping not helpful when no conceptual overlap
 - How is this established *a priori*?
- Should we consider the range of values that the mapping algorithm can predict?
 - Is this an issue?
- The mapping guidance says nothing about the SF-6D type of approach where utilities are derived from existing methods

Comments – other sources of utilities

- Addressing content validity of EQ-5D
 - No details regarding how this is done
 - Commonly assessed with qualitative methods
- Responsiveness
 - Often benchmarked against a clinical measure such as FEV1. Obvious flaw in this argument

Comments – cont.

- Discussion of where EQ-5D is insensitive is quite weak
 - Insensitive to general population?
- *Consider use of bolt-on dimensions*
 - Dependent on many issues (IP, technical issues etc)
 - This is an unproven technology

Comments: Using values in models

- Problems of joint states
 - Is this just restricted to 2 states?
 - If >2 then multiplicative may look very odd
 - Could be a common problem in diabetes for example
 - Is this also a recommendation regarding inclusion of adverse events?

Main points for clarification

- Status of TSDs
- Where recommendations are made in a TSD does that mean appraisal committees will not go against such recommendations
- TSDs are based upon expert opinion largely
 - Should evidence base be more formalised
- What scope is there for new methods or innovation?